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Marriage Patterns and Childbearing: Results From a Quantitative Study in North of Iran

Ziba Taghizadeh[1], Fereshteh Behmanesh[2] & Abbas Ebadi[3]

[1] Department of Midwifery and Reproductive Health, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran

[2] Reproductive Health, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran

[3] Behavioral Sciences Research Center and Nursing Faculty of Baqiyatallah University of Medical Sciences, Tehran, Iran

Correspondence: Fereshteh Behmanesh, PhD Candidate in Reproductive Health, School of Nursing and Midwifery, Tehran University of Medical Sciences, Tehran, Iran. Tel: 98-11-3219-9595. E-mail: f.behmanesh2015@gmail.com

Abstract

Social changes have rapidly removed arranged marriages and it seems the change in marriage pattern has played a role in childbearing. On the other hand, there is a great reduction in population in many countries which requires a comprehensive policy to manage the considerable drop in population. To achieve this goal, initially, the factors affecting fertility must be precisely identified. This study aims to examine the role of marriage patterns in childbearing. In this cross-sectional quantitative study, 880 married women 15-49 years old, living in the north of Iran were studied using a cluster sampling strategy. The results showed that there are no significant differences in reproductive behaviors of three patterns of marriage in Bobol city of Iran. It seems there is a convergence in childbearing due to the different patterns of marriage and Policymakers should pay attention to other determinants of reproductive behaviors in demographic planning.

Kewords: traditional marriage, modern marriage, intergrated marriage, marriage patterns, reproductive behaviors, childbearing

1. Introduction

Marriage is amongst the most important social, cultural and biological aspects of human life that is affected by the changes in communities and can also affect the family and reproductive changes. Marriage and the family formation process changes when the social system is modified or, in other words, adapting to socio-economic conditions. As G. Good asserted, the macro-global processes such as modernization, industrialization and urbanization have changed the traditional structure of families (Abbasi-Shavazi et al., 2009). In the past, due to the influence of kinship networks and strengthening ethnical solidarity, the process of marriage was arranged by more significant others including parents who attempted to choose spouses for their children based mainly on the interests and considerations of the family. However, it seems that the role and autonomy of individual in marriage has increased and the pattern of marriage has changed from a traditional one, planned and selected by parents, to a modern one (Retherford et al., 1996; Choe et al., 2005; Mensch et al., 2005; Moultrie et al., 2012; Ghimire & Axinn, 2013; Abbassi Shovazi & Sadeghi, 2006; Entezari, 2011).

The results of a study by Ogawa in 2003 showed that traditional marriage in Japan between 1955 and 1998 dropped from 63 percent to 7 percent. Likewise, Xiaowei's study (2004) revealed the decrease of traditional pattern of marriage and increase of the romantic relationship and marriage (with furture autonomy in starting and stabilizing the relationship) in different ethnical groups in China since 1949. The results of a survey in Iran in 2005 also showed that 38 percent of marriages took place by the couples' own selection abbasi (Abbasi-Shavazi & Sadeghi, 2006).

The sociocultural context of marriage and family plays a key role in shaping reproductive behaviors and attitudes abbasi (Abbasi-Shavazi & Asgari Nodoshan, 2005). That is, childbearing, as one of the most important decisions and practices in the life and the main topic of research in the field of demography, should be socio-culturally

contextualized (Balbo et al., 2013).

Reproduction, besides the biomedical aspects, also has a socio-cultural form which changes based on various factors in different societies. Opportunities and incentives for childbearing in women are different across populations and subgroups and from society to society. All of these create the differences in the average number of children in women with ethno-culturally diverse background (Weeks, 2010). Morover, human behaviors, including reproductive behavior, is dependent on the social and cultural environment (Morita et al., 2012) and individual and cultural differences that exist in communities lead to different reproductive behaviors (Morgan & Bachrach, 2011).

1.1 Literature Review

Review of literature reveals that a number of factors have effects on the reproductive behaviors. These factors are: age, religion, education, mother's employment, maternal age, number of children, age at first pregnancy, access to birth control and contraception methods, healthy lifestyles, family income, type of dating and marriage patterns (traditional, modern and post-modern), ethnicity, having ealier relativeness of couple before marriage (e.g. cousin marriage), women's autonomy, place of birth and urban and rural roots, degree of industrialization, social development, ethnic and cultural beliefs and traditions, the society's regard for the number of family members (McDonald, 2000; Weeks, 2010; Ogawa, 2003; Erfani, 2012; Adhikari, 2010; Dauletova et al., 2012; Morita et al., 2012; Ghimire & Axinn, 2013; Abbassi Shovazi & Asgari Nodoshan, 2005; Abbassi Shovazi & Sadeghi, 2006; Hossein Zadeh et al., 2010).

According to the existing studies, there have been five steps of demographic transition in Iran:

First: decline of fertility in the early 1970s after a long period of high fertility experience in the country;

Second: increased fertility in the period 1976-1980;

Third: the relatively constant progress from 1980 to 1984;

Fourth: slow decline in fertility from 1985 to 1988;

Fifth: the dramatic decline in fertility from 1989 onwards (Abbasi-Shavazi et al., 2009).

Careful study of the document of the first national development program in Iran reveals that, the objective of the family planning program in the late 1980s was to reduce the total fertility rate of 2.3 children per mother by 2010 (Abbasi-Shavazi et al., 2003; Hosseini & Begi, 2012; Abbasi-Shavazi et al., 2004; Abbasi-Shavazi & McDonald, 2006; Hosseini, 2012; Mirzaie, 2005; Mohammad et al., 2002). Indeed, this objective for the family planning program was achieved a decade earlier, so that in 2009, Iran was very close to the replacement level fertility, namely 1.8 children per woman (Salehi−Isfahani et al., 2010).

Since 2009, in which the revision of the official population policy agenda was suggested, two opposite approaches, in connection with Iran's population policy have been discussed: The first approach belongs to the advocates of increase in birth rate and the second approach belongs to the advocates of the management window of opportunity and family planning. The first group believes that in future, the country will suffer from the aging population and decreased workforce. The second group called for a comprehensive population policy for the management window of opportunity and sustaining natural family planning in order to prevent unwanted pregnancy and induced abortion and, finally, to become ready to face the inevitable consequences of the transition in age structure and aging population (Hosseini & Begi, 2012; Hosseini, 2012).

The experience of fertility transition in Iran indicates that although family planning programs are effective in rapidly fertility decrease and its continuation from the second half of the 1980s onwards, the changes in people's reproductive behaviors are influenced by other factors. In fact, the process of fertility transition in Iran is considered proportionate to the changes occurred in various economic, social and some traditional family aspects, leading to the related changes in patterns of marriage and, ultimately, changes in behavior, ideals and aspirations of the people for childbearing. The advocates of the management window of opportunity believe thatany practical application in the field of fertility should be based on economic, social, cultural and demographic realities of Iranian society, and the causes of low fertility should be examined before implementing any program (Calwell et al., 2002; Hosseini, 2012; Hosseini & Begi, 2012; Abbasi-Shavazi & Hosseini, 2009).

As mentioned in previous studies, one of the factors affecting fertility has been the changes in marriage patterns. Researchers believe that changes in the pattern of mate selection from traditional to modern, and the increased role of women in family decisions that increased decision-making power has reduced their childbearing (Abbassi Shovazi & Asgari Nodoshan, 2005). In another study, women who had registered marriage (traditional) were compared to women with civil marriage; they tend to have more children (Akinyoade, 2007; Dauletova et al.,

2012). The results of Rashid's study (Rashid, 2006) vary from the previous studies which have shown that women who have had a love marriage want to have children, and more children right after their marriage, for the duration and strength of this relationship.

Since the pattern of mate selection may affect reproductive behaviors and reproductive behaviors have an important role in sexual and reproductive health and women's health and also Preserving women's health is not only a basic human right, but it is also essential for the health of all nations and Women's health affects long-term health of theirs, their family members, and community (Baheiraei et al., 2014), knowing reproductive behaviors of women in modern and traditional mate selection patterns is considered very important in health, demographic, economic, political and educational strategic planning. On the other hand, as the reproductive behaviors are influenced by culture and vary from society to society, studying the behaviours and the factors influencing such behaviours in each city and province of the country in order to adopt appropriate health policies seems necessary.

The city of Babol was chosen as the researcher was familiar with the language and the culture of its people, and this familiarity with the dialect of Babol city made it possible to access real data collection; on the other hand, until the start of the study, no study has been done on the reproductive behaviors of women in mate selection patterns. Also, since the city of Babol is geographically located at the center of Mazandaran province, it can be culturally representative of the whole culture of people in this province and the results can be generalized to this province as a whole. Hence, the present investigation studied the childbearing women in reproductive age, according to their type of mate selection pattern.

2. Methods

2.1 Research Design

This study began in April 2013 and was completed in January 2014. In this cross-sectional study, after getting a letter from the University Ethics Committee with the number of: 92-130-1297, a questionnaire was used to examine "reproductive behaviors of women" in the north of Iran. The questionnaire was developed using an existing questionnaire, namely "the fertility transition questionnaire in Iran," originally developed by M. J. Abbasi -Shavazi (Abbasi-Shavazi et al., 2009).Then, a panel of experts comprising professionals with diverse academic backgrounds was selected to identify items relevant to the marriage patterns and reproductive behaviors and to improve and perfect the questionnaire.The final questionnaire was done based on the design and evaluation of psychometric study. The psychometric properties assessment of instruments includes the determination of quantitative and qualitative formal validity and the determination of quantitative and qualitative content validity Duval (Duval et al., 2006). For the qualitative content validity, 15 experts suggested to add or remove items, observe proper grammar and use proper words, and for the quantitative content validity, two ratios of content validity ratio (CVR) and the content validity index (CVI) were used. To check the reliability, the questionnaire was completed in two stages, within two weeks by the 20 married women of reproductive age, and the scores obtained in the test and re-test were compared with each other by the Spearman correlation coefficients. Finally, the questionnaire was used to obtain a sample. Required sample size was determined using data from a pilot study with 85 subjects.

2.2 Sampling and Procedure

The samples were 880 married women between 15-49 years old, lived in rural and urban areas in four geographic areas of six districts of Babol city using a multi-stage cluster sampling method. So the first cluster was designated (villages or towns) in these areas and the number of households in each clusterwas divided into the total number of households in four regions; the resulting number was multiplied by the total number of samples (880). After determining the number of samples in each village and town, interviewers attended in the clinics and received the informed consent from eligible clients and questionnaires were completed. Inclusion criteria for participating in this study were being married women of reproductive age (15-49 years), having at least one child and with no diseases or deficiencies such as the primary and secondary infertility, a kind of disease that can cause interference in their fertility, severe mental disability and psychiatric disorders which may cause inability to respond to the questionnaire. The exclusion criteria of this study was the lack of response to the maximum 10% of the questions. Subjects were free to refuse to fill out the questionnaire at any stage of the proceeding. After completing the questionnaires, data were analyzed using IBM SPSS software (version 21).

2.3 Data Analysis

To manage and analyze data, a number of descriptive and inferential methods of statistics including ANOVA, Chi-square, Kruskal-Wallis and Factorial Analysis of variance were applied.

3. Results

In this study, total information including the socio-demographic characterstics was collected from about 880 married women in the reproductive age (15-49 years) from the city of Babol in the north of Iran (Table 1).

Table 1. Socio-demographic characterstics of married women (15-49 years) in Babol, in the north of Iran

Socio-demographic profile	Frequency	%	Socio-demographic profile	Frequency	%
Age			**The economic situation**		
15-25	111	12.6	Low	184	20.8
26-35	371	42.2	Medium	534	60.7
36-45	293	33.3	High	160	18.2
46-49	105	11.9			
Level of education			**Current employment status**		
Illiterate	38	4.3	Unemployed	625	71.022
Primary school	149	16.9	Laborer	37	4.2
Guidance school	152	17.3	Employee	103	11.7
High School/Diploma	323	36.7	Freelance	91	10.34
Bachelor and higher	221	25.1	Student	24	2.727
Place of Birth			**Current place of living**		
City	349	39.7	City	485	55.1
Rural	531	60.3	Rural	395	44.9
Employment status before the first pregnancy			**Age of marriage**		
Unemployed	677	76.9	<15	114	13.0
Laborer	29	3.3	15-19	424	48.2
Employee	85	9.7	20-25	275	31.2
Freelance	56	6.4	26-30	55	6.2
Student	33	3.8	>30	12	1.3
Family connections before marriage			**Living with family (first 2 years of marriage)**		
Relative	153	17.4	With at least one of my own family members	22	2.5
Unrelated (with pre-familiarity)	225	25.6	With at least one of my husband's family members	409	46.5
Unrelated(without pre-familiarity)	502	57.0	None	445	50.6

Following a review by the research team and modern and traditional definitions of marriage from various works (Xiaohe & Whyte, 1990; Ghimire et al., 2006), marriage patterns classified into 8 clusters or categories based on the initial classification of the panel of experts, and integrated with 3 traditional, modern and integrated patterns based on three items (selecting mate by parents, romantic relationship and relations before marriage and satisfaction in the time of marriage). According to the results of this study, the integrated marriage patterns had the highest frequency (77.2%) and the pattern of modern marriage (10.9%) had the lowest frequency with very little difference in the pattern of traditional marriage (7.11%) (Table 2).

Table 2. Marriage patterns of the participated married women (15-49 years) in Babol, Iran (first division)

Pattern of Marriage	Frequency	%
1. Traditional	103	11.7
• I did not know my husband before marriage, we met each other through matchmaking and I was not really satisfied and I was somehow forced to marry him.	79	9
• I knew my husband before marriage and through matchmaking and somehow with no satisfaction I was really forced to marry him.	21	2.4
• Our marriage was a sort of arranged marriage (marriage with parental consent like uncle and a cousin marriage, marriage agreement, etc.).	3	0.3
2. Integrated	**679**	**77.2**
• I knew my husband before marriage and I was married through matchmaking and and with the approval and satisfaction of myself and my family.	212	24.1
• We did not know each other before marriage. I met him through matchmaking and we married with my consent and my family's approval.	467	53.1
3. Modern	**98**	**11.1**
• We were intrigued and wanted each other before marriage and married with our family's approval.	72	8.2
• We were intrigued and wanted each other before marriage and married despite the objections of our families.	24	2.7
• Even though we were friends before our marriage, I was not going to marry him and I was actually kind forced to marry him.	2	0.2
4. Please note other patterns …	**0**	**0**
Total	**880**	**100**

In this study, a number of bivariate statistical methods including ANOVA, Chi-square test and Kruskal-Wallis test was used to examine the difference among the three patterns of marriage in terms of socio-demographic characteristics. Plus, the Factorial Analysis of Variance was applied to examine the main effect of marriage patterns on the average number of children in married women. The results of these tests showed that these three patterns of marriage are not statistically significant in terms of socio-demographic variables such as education, place of birth, current place of life, employment status of woman before the first pregnancy, current employment status, independent living place during the first two years of marriage and marriage age. However, age of samples in modern marriage patterns (32.33±84.8) was significantly lower than traditional marriage patterns (23.36±84.8) (p <0.05). Morover, there is no statistically significant difference among the three groups of marriage pattern in the number of gravid, pregnancy or no current pregnancy, experiencing child mortality, the number of sons and daughters, experiencing abortion and unwanted pregnancy.

Table 3. The main effect of the marriage patterns on the average number of children in Bobol, Iran

Variables	Mean Square	F	P-value
Age	53.16	157.59	**0.000**
Education	1.21	3.59	0.058
Place of birth	0.84	2.51	0.11
Residence	0.42	1.26	0.26
Job before pregnancy	0.011	0.03	0.85
Current Job	0.69	2.06	0.15
Age of husband	0.98	2.92	0.08
Husband's education	0.69	2.05	0.15

Occupation of husband	0.43	1.29	0.25
Relationship with husband	0.21	0.63	0.42
Number of marriages	0.88	2.61	0.10
Age at current marriage	0.02	0.05	0.81
Living with relatives in the first two years of marriage	0.61	1.81	0.17
Socio-Economic Status (SES)	0.09	0.26	0.60
The Marriage pattern	0.34	1.01	0.36

Difference in the number of children among the three patterns of marriage, as one of the reproductive behaviors was the main aim of this study. One-way ANOVA test revealed that there are no statistically significant differences between three patterns of marriage in the number of children. To remove the effect of demographic variables on child number from marriage patterns, Factorial Analysis of Variance was used. However , this test showed no significant deference in marriage patterns on child number (Table 3).

4. Disscussion

In this study, the role of marriage pattern on the most important reproductive behaviors like the number of children was examined. Researchers believe that reproduction varies according to the pattern of marriage and this difference is mainly created by the characteristics of socioeconomic diversity which is associated with the differences in the type of mate selection (Ogunjuyigbe & Adeyemi, 2003).

Nowadays, it seems that the role of families in marriage of their offspring is declining and people's attitudes are changing in this regard. Social changes have rapidly removed arranged marriages by parents' selection, which also occurred in Asia, Africa and Latin America nearly three decades ago. It seems that the change in the type of marriage has played an important role in childbearing (Ghimire & Axinn, 2013).

Women whose their husbands are chosen by families or relatives marry earlier, have children earlier, and have higher fertility levels as they are more prone to fertility from the marriage until menopause. In this type of marriage, girls are more likely to drop out of school due to early marriage. Thus, lower education levels, which reduce the awareness of family planning methods, may be another factor in the high fertility levels. The age difference between spouses in traditional marriages is usually higher, which results in less interaction between couples regarding a suitable and more desirable number of children, as well as the use of contraceptives, thereby increasing the level of fertility. In contrast, women who participate in choosing their husbands typically have a higher education level (Smith et al., 2009; Ogunjuyigbe & Adeyemi, 2003) and, because of greater awareness and increased use of contraceptives, increased decision-making power in the household, especially in the case of fertility, providing job opportunities and greater interaction between couples before and after marriage (because of lowerage difference), have lower fertility levels (Ogunjuyigbe & Adeyemi, 2003).

In the present study, the pattern of marriage of women of childbearing age had no effect on the average number of children, which is different from the results of some studies which showed fertility is higher in traditional pattern of marriage than in modern marriages (Feyisetan & Bankole, 1991; Ghimire & Axinn, 2013) and studies with entirely diverse results (Ogunjuyigbe & Adeyemi, 2003; Rashid, 2006; Akinyoade, 2007; Dauletova et al., 2012) are also different. In a study conducted in the rural areas of Nepal, researchers showed that despite the decline of the family involvement in pattern of marriage and changes in people's attitude towards the pattern of marriage issue, the fertility levels of the women are still high. In this study, the average number of children in the modern marriage was higher than the traditional pattern of marriage and it was perhaps due to the high level of family control on the couples life (Ogunjuyigbe & Adeyemi, 2003).

This study on the main effect of the marriage patterns on reproductive behavior has encountered some limitations as follows: First, many of the macro changes or transitions in socio-cultural, political and economic fieldswhich result in differences in patterns of marriage can also affect the reproductive behaviors in the society (Fricke & Teachman, 1993; Reddy & Modell, 1995; Pallitto & O'Campo, 2004; Abbassi Shovazi & Sadeghi, 2006). Hence, the study of the main effect of marriage patterns on the reproductive behaviors including the number of children requires careful consideration of all socio-cultural, economic, and political underlying factors that may form reproductive behaviors, schemas and attitudes. Second, the marriage pattern cannot be considered independent from the marriage timing. As recognized in the literature, the marriage timing is an important factor

in explaining reproductive behavior (Haddad, 2012; Smock & Greenland, 2010; Schuler et al., 2006; Rashid, 2006; Mensch et al., 2005; Choe et al., 2005; Wong & Yeoh, 2003; Ogawa, 2003; Makoto, 2001; Retherford et al., 1996; Bongaarts, 1994; Bankipour Fard et al., 2011).

As a result, marriage timing must be considered at the same time of the investigation on the role of marriage patterns on childbearing. In the present study, these factors were also studied. Due to the differences between the findings of this study and some of the existing studies, it seems that today, there is a convergence in reproductive behaviors due to the marriage selection patterns and different socioeconomic backgrounds. This finding of our study is similar to a previous enquiry   by Abbasi *et al* (Abbasi-Shavazi et al., 2004) in Iran. Their observation showed that reproductive behaviors and attitudes in all age groups are similar, and there are no significant differences among different social groups including rural and urban, literate and illiterate women. Likewise, Ogawa (Ogawa, 2003) in a study in Japan did not observe any relationship between the type of marriage (traditional or modern) and interval between marriage and first pregnancy, which is one of the most important variables in women's fertility.

5. Conclution

In summary, the evidence in this study indicated that changes in marriage process and the marriage patterns like the transition from traditional to modern or integrated models, cannot make significant changes in the reproductive behaviors in the contemporary Iran. So, according to the new demographic polices of Iran to increase the population, it seems that policy makers should pay more attention to the Macrolevel determinants of fertility such as socio-economic status. We think the convergence in reproductive behaviors there are in other province of Iran too and the researcher should study this phenomen to policy-makers can have proper planning in the field of reproductive behaviors of Iranian people.

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Conflict of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Dysfunctional Metacognitive Beliefs in Body Dysmorphic Disorder

Zahra Zeinodini[1], Sahar Sedighi[1], Mandana Baghertork Rahimi[1],
Simasadat Noorbakhsh[1] & Sepideh Rajezi Esfahani[1]

[1] Behavioral Sciences Research Center of Shahid Beheshti University of Medical Sciences, Tehran, Iran

Correspondence: Zahra Zeinidini, Behavioral Sciences Research Center of Shahid Beheshti University of Medical Sciences, Psychiatry ward of Imam Hossein Hospital, Shahid Madani St, Tehran, Iran. Tel/Fax: 98-217-755-3047. E-mail: zahra.zeinodini@yahoo.com

Abstract

The present study aims to examine the correlation of body dysmorphic disorder, with metacognitive subscales, metaworry and thought-fusion. The study was conducted in a correlation framework. Sample included 155 high school students in Isfahan, Iran in 2013-2014, gathered through convenience sampling. To gather data about BDD, Yale-Brown Obsessive Compulsive Scale Modified for BDD was applied. Then, Meta Cognitive Questionnaire, Metaworry Questionnaire, and Thought-Fusion Inventory were used to assess metacognitive subscales, metaworry and thought-fusion. Data obtained from this study were analyzed using Pearson correlation and multiple regressions in SPSS 18. Result indicated YBOCS-BDD scores had a significant correlation with scores from MCQ ($P<0.05$), MWG ($P<0.05$), and TFI ($P<0.05$). Also, multiple regressions were run to predict YBOCS from TFI, MWQ, and MCQ-30. These variables significantly predicted YBOCS [$F_{(3,151)} =32.393$, $R^2=0.57$]. Findings indicated that body dysmorphic disorder was significantly related to metacognitive subscales, metaworry, and thought fusion in high school students in Isfahan, which is in line with previous studies. A deeper understanding of these processes can broaden theory and treatment of BDD, thereby improve the lives of sufferers and potentially protect others from developing this devastating disorder.

Keywords: body dysmorphic disorder, cognitive therapy, cognition, adolescent, metacognitive beliefs

1. Introduction

Known as dysmorphophobia, Body Dysmorphic Disorder (BDD) is a mental health problem which is chronic and disabling, known by a preoccupation with an imagined deformity in appearance. BDD is characterized by problematic disruptions in self-esteem, time-consuming repetitive actions and avoidance (e.g., of social interactions, mirrors, lights), which typically starts in adolescence and has a mean age of onset at 16 years and mode of 13 years (Phillips, Menard, Fay, & Weisberg, 2005). The overall point prevalence in general population, equal in both genders, is 0.7-2.4% (Gupta, Huynh, & Ginsburg, 2013), moreover its rates were higher in patients with social phobia and obsessive-compulsive disorder (Wells, 2010).

One route to a deeper understanding of the processes underlying the psychopathology of BDD is examining the cognitive mechanisms involved in the knowledge, interpretation, and regulation of thinking itself. These mechanisms comprise the domain of 'metacognition' or thinking about thinking (Wells, 2011). The dominant theory regarding the role of metacognition in psychopathology is self-regulatory executive function (S-REF) theory (Wells, 2011), which identifies two basic components of metacognition: knowledge and regulation. According to the theory, metacognitive knowledge consists of the beliefs an individual holds about the course and consequences of cognitive enterprises. This knowledge may be accurate or inaccurate, explicit or implicit, and can be triggered unintentionally by retrieval cues (Wells, 2013). Metacognitive regulation involves executive functions such as planning, resource allocation, monitoring, and correcting of cognitive events. In S-REF theory, psychological disorder is associated with dysfunction of this system, in a way that the regulation and knowledge processes become maladaptive (Wells, 2010, 2011).

One of the fundamental concepts of metacognitive model is thought-fusion in which metacognitive beliefs eliminate the borders between thought, incidents and acts (Gladstone et al., 2005). On the other hand, worry as a key part of distress has been described as a chain of thoughts and images and relatively automatic thoughts related to possible threatening outcomes and their potential consequences (Cooper & Osman, 2007). Worry is

widespread both in people with disorders or those without, which varies in degree existing among people rather than the quality of its existence. Uncontrollability of worry might cause drastic interference and distress in daily life; in addition, metaworries are considered as problematic components of metacognition. Also, worry can become the focus of anxious apprehension. Studies by Cooper and Osman (Cooper & Osman, 2007) showed that people with BDD had completely different metacognitive thought that they were unattractive, ugly, inferior, and worthless. Metacognitive control strategies, defined as those strategies used to control the cognitive system, are not only likely to strengthen or suppress mental strategies but to increase monitoring processes as well.

Cross-sectional and directional relationships between maladaptive metacognition and a wide range of psychological dysfunctions have been extensively demonstrated. These include depression (Wells, 2011), GAD (Wells, 2010), PTSD (Wells, Walton, Lovell, & Proctor, 2014), obsessive-compulsive disorder (Barahmand & Shahbazi, 2013), eating disorders (McDermott & Rushford, 2011), and psychosis (Hutton, Morrison, Wardle, & Wells, 2014). If S-REF theory is correct in identifying dysfunctional metacognition as a generic vulnerability factor underlying psychopathology, this should be also held true for BDD. If metacognitive factors were proved important in BDD, this would invite the application of MCT to its treatment.

The present research aims to investigate the relationships between dysfunctional metacognition and body dysmorphic disorder.

2. Method

The present research, which was conducted within a correlation framework, examined the relationships between dysfunctional metacognitive variables and body dysmorphic disorder. Population included all male and female students who studied in high school in 2010-2011 in Isfahan, Iran.

2.1 Participants

Current study is a correlation study. To determine the sample size, the Cochran's sample size formula for correlation study was used:

$$n = \frac{T^2 pq}{d^2}$$

in which T=1.96, p=0.5, q=0.5, and d=0.11. The minimum sample size needed to obtain statistically valid results was 79, and we reduplicated samples to obtain higher validity.

Research sample included 155 adolescent students aged between 12 and 17 years who were selected through convenient sampling from three high schools, which are governmental educational center in Isfahan (2013-2014). Individuals above the age of 17 years or below the age of 12 years were not considered, as their prevalence in the BDD population is small to allow meaningful statistical analysis. Students who were too medically or psychologically too compromised to give informed consent were not considered. Since less information is available about rates of body dysmorphic disorder in addition to the fact that such patients are more linked to dermatologists and plastic surgeons rather than psychiatrists or psychologists (Gupta et al., 2013), the current research focused mainly on students in high school. Inclusion and Exclusion criteria are presented in Table 1. According to exclusion criteria, 28 participants excluded.

Table 1. Inclusion and Exclusion criteria

Inclusion Criteria	Exclusion Criteria
Having an age range of 12-17	Receiving pharmacotherapy or psychotherapy
Satisfaction to participate	Having psychosis or schizophrenia
Written informed consent form	Having personality disorders
	Not willingness to participate

2.2 Procedure

Participants were approached by the researchers, who explained the project, providing plain language statements (PLS), and answered queries. Students were assured that their decision regarding participation would not affect anything at school. Those who agreed to participate signed a consent form and were given a questionnaire set to return later in a sealed envelope to the researchers. To protect anonymity, the researchers did not view questionnaires completed by their own acquaintances. All participants received an ID enabling them to withdraw

their information should they change their mind about participating. Completion of the questionnaire set required approximately 40 minutes. All of the tests were conducted by two school psychologists in an office one by one.

2.3 Measures

All participants were assessed by Yale Brown Obsessive Compulsive Scale Modified for BDD to find out whether they have BDD. Thought-Fusion Instrument and Short Form of the Metacognition Questionnaire have also been used to investigate their dysfunctional metacognition.

Yale Brown Obsessive Compulsive Scale Modified for BDD: YBOCS-BDD is a 12-item questionnaire, rated by a clinician. It has questions on preoccupations (5), compulsive behaviors (5), insight (1), and avoidance (1). Mostly, it was developed as a measure of severity of BDD symptoms. Each item is scored in 5-point Likert's scale from 0 (totally agree) to 4 (totally disagree). Philips et al (Phillips, Hollander, Rasmussen, & Aronowitz, 1997) have confirmed the reliability of YBOCS-BDD through interrater and test-retest. YBOCS-BDD was reported to have positive correlation (r=0.51) with Global Assessment of Functioning in DSM. Rabiei et al. (Rabiei, Khormdel, Kalantari, & Molavi, 2010) examined the factor structure, validity and reliability of the Modified Yale-Brown Obsessive-Compulsive Scale in a sample of Iranian students. They found that YBOCS-BDD had satisfactory reliability and validity in the sample of Iranian students, and could therefore be used for diagnostic and therapeutic purposes (Rabiei et al., 2010).

Thought-Fusion Instrument (TFI): TFI consists of 14 items rated on a 0 to 100 scale which assess metacognitive beliefs about the meaning, importance, and peril of intrusive thoughts. It was designed to measure the three types of thought fusions: Thought-Action Fusion, Thought-Event Fusion and Thought-Object Fusion. Gwilliam et al (Gwilliam, Wells, & Cartwright-Hatton, 2004) obtained acceptable reliability and preliminary evidence supports its convergent and discriminate validity. Also, other studies have showed the correlation from 0.4 to 0.7 between TFI and metacognitive beliefs instrument and thought action fusion (Rachman, Thordarson, Shafran, & Woody, 1995). Khoramdel et al have reported satisfactory reliability and validity in Iranian students population which can be used for diagnosis and treatment (Khoramdel, Rabiee, Molavi, & Neshatdoost, 2010).

A Short Form of the Metacognition Questionnaire (MCQ-30): it has 30 multiple choice items which are in ranges of totally disagree (1 point), partially agree (2 points), mildly agree (3 points) and totally agree (4 points). MCQ measures five components including 1) cognitive confidence, 2) positive beliefs about worry, 3) cognitive self-consciousness, 4) negative beliefs about thoughts and danger which are out of control, and 5) beliefs about demand to control thoughts (Wells & Cartwright-Hatton, 2004). The Cronbach's alpha coefficient for all questions was reported in a range of 0.72 to 0.93, and the test-retest reliability coefficient of the Short From of the Metacognition Questionnaire was reported 0.73 (Wells & Cartwright-Hatton, 2004). It also demonstrated acceptable psychometric properties in Iranian population (Shirinzadeh, Goudarzi, Ghanizadeh, & Taghavi, 2008).

Metaworry Questionnaire (MWQ): The questionnaire has 7 items which measure worry and metacognition. There are two scales for each item. One to assess the frequency of meta-worry which is a Likert's scale ranging from 1 to 4 with each point labeled as follows: Never; sometimes; often; almost always. The other is used to rate the belief in each meta-worry at its time of occurrence and ranges from 0 to 100 with anchor points labeled at each extreme as follows: I do not believe this thought at all, and I am completely convinced this thought is true (Wells, 2005). It has very good internal reliability, and the scales correlated meaningfully with existing measures. Cronbach's alpha coefficients of the MWQ were 0.88 for the frequency scale and 0.95 for the belief scale. The meritorious and marvelous criteria were respectively satisfying the MWQ frequency subscale (0.87), and the belief subscale (0.93). The variables were inter-correlated because Bartlett's test statistic (p<.0005) was highly significant for both the frequency and belief variables. MWQ scales were positively correlated with AnTI metaworry subscale, negative beliefs about worry measured with the MCQ social worry, health worry, and positive worry beliefs. Males and females were found not to differ significantly on each of the subscales (Wells, 2005).

2.4 Ethical Aspects

The Study was approved by the Ethical Review Board of the Behavioral Sciences Research Center of Shahid Beheshti University of Medical Sciences, Tehran, Iran (1393-1-102-1356-1, 10. Feb. 2013). Informed consent forms were obtained from all participants. Before starting the study, in a formal session in school, the participants and their parents were provided with a general overview of the goals and aspects of the study. They were also informed that they were participating voluntarily, and that they could leave the study at any time without any negative consequences. The results were used anonymously and all of the data were kept secret in this study.

2.5 Statistical Analyses

Analyses were performed using the Statistical Package for Social Sciences (SPSS) version 18. Both descriptive and inferential statistics had been used to find the possible correlation between BDD and dysfunctional metacognition. Data obtained from this study were analyzed using Pearson correlation and multiple regressions.

3. Results

In Table 2, demographic information of participants is presented.

Table 2. Demographic characteristics of participants

Variables	Levels of variables	frequency	percentage
Gender	Male	77	49.5
	Female	78	50.5
History of hospitalization	Yes	17	10.96
	No	138	89.4
History of academic failure	Yes	12	7.74
	No	143	92.26
Father's education	Diploma	36	23.22
	undergrad	93	60
	Post grad	26	16.78
Mother's education	Diploma	89	57.41
	undergrad	46	29.67
	Post grad	20	12.92

Table 3 shows the Pearson correlation matrix of YBOCS-BDD with MCQ-30, MWQ, and TFI.

Table 3. Correlation matrix among metacognitive components, thought confusion, metaworry and body dysmorphic disorder

	YBOCS-BDD	MCQ	MWQ	TFI
YBOCS-BDD	1			
MCQ	0.39[*]	1		
MWQ	0.42[*]	0.33	1	
TFI	0.35[*]	0.32	0.44	1

[*] $p < 0.05$.

As shown in Table 3, the students' scores in all dysfunctional metacognition components are related to the body dysmorphic disorder significantly. In other words, YBOCS-BDD scores demonstrated a significant relationship with MCQ (r=0.39, P<0.05), MWQ (r=0.42, P<0.05), and TFI (r=0.35, P<0.05).

Tables 4 and 5 present the results of multiple regressions to predict YBOCS from TFI, MWQ and MCQ-30 scores.

Table 4. The results of multiple regressions for TFI, MWQ, and MCQ-30 in high school students

Model		Sum of Squares	df	Mean Square	F	P value
1	Regression	270.032	3	90.011	32.393	.000[b]
	Residual	2282.608	151	108.696		
	Total	2552.640	154			

a. Dependent Variable: YBOCS;

b. Predictors: (Constant), TFI, MWQ, MCQ-30.

Table 5. The results of multiple regressions for TFI, MWQ, and MCQ-30 in high school students

Model		Unstandardized Coefficients		Standardized Coefficients	t	P value	95.0% Confidence Interval for B	
		B	Std. Error	Beta			U	L
1	(Constant)	35.439	13.334		2.658	.000	7.710	63.168
	TFI	-.411	.478	-.178	-.859	.010	-1.406	.584
	MWQ	.248	.468	.110	.530	.047	-.726	1.222
	MCQ-30	-.438	.417	-.220	-1.050	.006	-1.304	.429

a. Dependent Variable: YBOCS; p<.05.

As shown in Table 5, a multiple regression was run to predict YBOCS from TFI, MWQ, and MCQ-30. These variables statistically significantly predicted YBOCS [F (3,151) =32.393, p< 0.0005, R^2=0.577]. All variables added statistically significantly to the prediction (p<0.05).

4. Conclusions

The present research aimed to examine the relationship between dysfunctional metacognition with body dysmorphic disorder (BDD). Findings show that BDD has a significant positive relationship with thought fusion, metaworry, and dysfunctional metacognition, which is consistent with previous studies (Cooper & Osman, 2007; Fairfax, 2008; Holmes, Arntz, & Smucker, 2007; McDermott & Rushford, 2011; Toh, Rossell, & Castle, 2009; Veale et al., 2014).

BDD patients are engaged in dysfunctional metacognition about their body appearance (Cooper & Osman, 2007). The metacognition components of body dysmorphic disorder include the strategies for metacognitive controlling such as suppressing thoughts about being ugly, worries about dysmorphic, rumination avoiding, reassurance seeking or excessive grooming (Cooper & Osman, 2007). According to Veale (Veale et al., 2014), in BDDs, metacognition is a noticeable issue in information processing, and it possibly aids maintenance of symptoms. Considering the relationships between metacognitive components and body dysmorphic disorder, it is worth of notice that the scores of components could successfully predict the disorder (Arbel, Koren, Klein, & Latzer, 2013; McDermott & Rushford, 2011; Wells, 2013).

The demonstrated importance of dysfunctional metacognition in BDD illuminates a possible mechanism for the inefficacy of CBT in its treatment (Toh et al., 2009). By focusing exclusively on the content of thoughts, CBT neglects the crucial role played by cognitive processes underlying these thoughts. S-REF theory contends that these metacognitions generate the problematic thought content challenged in CBT; therefore, merely modifying that content without addressing its underlying source is unlikely to prove effective in the long term. To overcome this limitation, Wells (Wells, 2011) developed metacognitive therapy, which aims to decrease dysfunctional metacognitive beliefs and strategies and teach the individual new ways of consciously experiencing cognitive events.

Given its demonstrated effectiveness in several psychological disorders (Wells, 2011), the present results suggest that metacognitive therapy may hold great therapeutic potential for BDD. The positive correlation between metacognitive beliefs and scores of body dysmorphic disorder in high school student could have implication for practice. According to wells (Wells, 2010), psychiatric disorders are caused by metacognitive thoughts which can be controlled or changed. Thus, recognizing thoughts of BDD patients can be the initial step to design and practice metacognitive therapeutic method for those patients.

The current study is one of the first to demonstrate that metacognitive dysfunction may play a key role in BDD. This study had some limitations including the fact that the groups were not homogeneous, the age and education level of applicants were not various enough and interview, due to expensive implementation costs, was not employed as an instrument in selecting applicants. It is suggested that a parallel study should be conducted for the applicants with different age and education level in homogenous groups. The findings should be interpreted in the context of certain methodological limitations which should be addressed in future research. First, the cross-sectional design precludes causal conclusions. Longitudinal studies of the relationships between metacognition and BDD symptoms, as well as experimental manipulations of these variables, and studies on clinical and nonclinical populations may provide evidence of causality. Second, the relatively small sample limits generalizability; therefore a large, multi-site study should be established to determine if these findings are replicable. To substantiate the specificity of the results to BDD, a control group from patients with body dysmorphic disorder should be included. Furthermore, as self-report measures are intrinsically prone to idiosyncratic interpretation and demand characteristics, response authenticity should be strengthened by use of implicit measures and interviews. Finally, future studies should consider depression, anxiety and other psychological disorders as confounding variables.

In conclusion, findings indicated that body dysmorphic disorder was significantly related to metacognitive subscales, metaworry, and thought fusion in high school students in Isfahan, which is in line with previous studies.

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Conflict of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Characteristics of Inpatient Falls not Reported in an Incident Reporting System

Shin-ichi Toyabe [1]

[1] Niigata University Crisis Management Office, Niigata University Hospital, Niigata, Japan

Correspondence: Shin-ichi Toyabe, Niigata University Crisis Management Office, Niigata University Hospital, Asahimachi-Dori 1-754, Chuo-Ku, Niigata City 951-8520, Japan. Tel: 81-25-227-0375. E-mail: toaybe@med.niigata-u.ac.jp

Abstract

An incident reporting system is the most commonly used method to identify patient safety incidents in a hospital. However, non-reporting of incidents for various reasons is a serious problem. We studied the rate of inpatient falls that were not reported in an incident reporting system but were recorded in medical charts and we evaluated characteristics of those falls by comparing with the falls reported in incident reports in a Japanese acute care hospital setting. Falls recorded in medical charts were detected by using a text mining method followed by a manual chart review. About 25% of the recorded falls were not reported in incident reports. Male patients, first fall, long lag time until recording, no witness at the time of the fall and physician profession were shown to be significant factors associated with non-reporting. Our results show that the rate of non-reporting of inpatient falls in a Japanese acute care hospital is compable to that shown in previous studies in other conutries and that the same barriers to incident reporting as those found in previous studies exist in the medical staff.

Keywords: falls, adverse events, incident reports, text mining, natural language processing

1. Introduction

An incident reporting system is commonly used to identify patient safety incidents or adverse events in a hospital (Aspden et al., 2004). However, non-reporting is an inevitable problem in this method because the method relies on voluntary willingness of medical staff (Cullen et al., 1995; Oliver et al., 2007). In addition, a significant lag time between incidents and submission of incident reports impairs quick detection of incidents (Hirose et al., 2007). The non-reporting of incidents is especially problematic when the incidents result in serious or fatal injuries. In addition, this problem might affect the results of epidemiological studies on incidents, planning of effective countermeasures to reduce the incidents, and evaluation of the countermeasures taken against the incidents.

Inpatient falls are the most common incidents that occur in a hospital. Since about 3 to 10% of inpatient falls in a hospital result in physical injuries including bone fracture and intracranial hemorrhage, it is necessary to identify injurious falls quickly (Toyabe, 2010, 2012a, 2012b). One strategy to prevent inpatient falls is a targeted intervention that focuses on patients at high risk for falls (Gates, Fisher, Cooke, Carter, & Lamb, 2008). Therefore, accurate epidemiology of falls in a hospital is necessary to determine whether the intervention for high-risk patients is effective. The non-reporting problem might prevent quick detection of severe cases and hinder evaluation of the effectiveness of intervention against inpatient falls.

It has been suggested in previous reports that there are various barriers to incident reporting that lead to non-reporting (Evans, Cameron, Myles, Stoelwinder, & McNeil, 2005; Waring, 2005). However, there are only few reports about factors that affect non-reporting of inpatient falls (Hill et al., 2010) and there is no report of this problem in a Japanese acute care hospital setting. The aim of this study was to clarify the rate of inpatient falls that are not reported by an incident reporting system and what factors affect the non-reporting of inpatient falls in a Japanese acute care hospital setting. To answer the questions, we analyzed significant characteristics of falls that were not reported in incident reports but were recorded in medical charts, as compared with falls that were reported in incident reports. We performed a two-step procedure of the first screening with a text mining method and then confirmed the results of the first screening by a manual chart review.

2. Methods

2.1 Setting

This study was conducted at Niigata University Hospital, an 825-bed academic teaching hospital in the city of Niigata. There are 23 clinical departments and the service area of the hospital as a tertiary care hospital covers all districts in Niigata Prefecture, which has a population of 2 400 000. All patients who had been admitted to the hospital during the period from June 2011 and August 2011 were studied. During the period, 4439 patients (52 551 patient-days) were admitted to the hospital.

2.2 Data Collection

Information on patients' background including age, gender, cognitive status, major diagnostic category of the patient's principal diagnosis, admission ward, admission day and discharge day was obtained from the hospital information system (HIS). Information on falls recorded by incident reports was obtained from online incident reporting system. Incident reports contained information on degree of injury of the patient, type of event and essential information on the event such as the name of the patient, the name of the medical staff involved, the exact time and place that the event occurred, detailed information on the course of the incident, action taken by medical staff and outcome of the event. In addition to the data on falls obtained from incident reports, data on falls were also obtained from progress notes of the electronic medical record (EMR) by using a text mining method (Toyabe, 2012a). Briefly, the text data of progress notes of the EMR were obtained from the HIS electronically. One unit of record corresponds to text data written at a time in progress notes by medical staff. The progress notes were written by various types of staff including physicians, nurses, and other medical staff. The text data were then applied to morphological analysis, which is a process of segmenting a sentence into a row of morphemes. The row of morphemes was applied to syntactic analysis to determine the grammatical structure of the sentence and the dependency relationship between the morphemes. These pretreated data were then analyzed to determine whether they contained sets of morphemes and their dependency relationship that were specific for the text data in which the occurrence of the fall events was described. Text mining analyses were performed using the software Text Mining Studio (NTT DATA Mathematical Systems Inc., Tokyo, Japan). The sensitivity of the text mining analysis to detect fall events from the progress notes was as high as 100%, but the positive predictive value was as low as 6% (Toyabe, 2012a). Therefore, the sentences detected by text mining analysis were checked by a manual chart review to determine whether they really contained information on the occurrence of fall events.

2.3 Statistical Analyses and Ethical Consideration

Fall events detected from incident reports and progress notes of the EMR were divided into three groups in terms of where the falls events were recorded: falls recorded only in incident reports, falls recorded only in progress notes, and falls recorded in both incident reports and progress notes. These three categories of fall events were compared in terms of factors that could influence the recording or reporting of fall events such as patient background and fall-related information. Comparison of discrete variables between the groups was performed using the chi-square test and Fisher's exact test. Continuous variables such as lag time between falls and data submission were expressed as medians (25th-percentile, 75th-percentile), and comparison of unpaired continuous variables between groups was performed by Kruskal-Wallis' test and Wilcoxon's rank sum test. A paired comparison of groups was performed by using Friedman's test or Wilcoxon's signed rank test. Multivariate logistic analysis was performed to find factors that were associated with non-reporting among the above-mentioned various factors. A stepwise selection method was used to determine the most significant factors. In all statistical analyses, a p-value less than 0.05 was considered significant. All statistical analyses except text mining analysis were performed by using SPSS Statistics 22 (IBM Japan Ltd., Tokyo, Japan). This study was approved by the Ethics Committee of Niigata University School of Medicine.

3. Results

3.1 Falls Detected From Medical Records

From progress notes of the EMR for the patients, we electronically obtained 640 434 records. These data were subjected to text mining analysis, and records suspected to have fall-related information were obtained (Table 1). A total of 10 200 records (1.59%) were suspected to have fall-related information among the 640 434 records. The fall-related information could be divided into five categories which consisted of fall motion (slipping or tripping), losing balance of the body, injuries suffered by falls, falling from the bed, and use of a fall-detecting sensor for patients at risk for falls. The most frequent category was losing balance of the body (5567, 54.58%), followed by fall motion (4297, 42.13%). The 10,200 records obtained by text mining were then checked by a

manual chart review. As a result, 635 records (6.23%) out of the 10 200 records actually contained information on falls. The other 9565 records that were initially suspected to have fall-related information were finally found to have no information on actual falls. They contained information related to risk assessment of falls, falls that could be avoided before they happened, or falls that occurred before the patients were admitted to our hospital. Among the five categories of fall-related information, the category that contained the largest number of records was that related to fall motion (555 out of 635, 87.40%). On the other hand, the category related to injuries suffered from falls contained information on actual falls most frequently (89 out of 320, 27.81%). Eventually, 635 records (0.10%) related to 164 actual fall events were obtained from 640 434 records from 52 551 patient-days. Therefore, the rate of recorded falls in our hospital was calculated to be 3.12 per 1,000 patient-days.

3.2 Types of Record of Falls

Among the 164 fall events, 123 falls (75.0%) were reported in incident reports. The other 41 falls (25.0%) were recorded in progress notes of the EMR but were not reported in incident reports. There were no falls that were reported in incident reports but were not recorded in the EMR (Fig. 1). We initially planned to focus on three groups for comparison, but the comparison was made between two groups: falls that were recorded both in the EMR and incident reports and falls that were recorded in the EMR but were not reported in incident reports.

3.3 Characteristics of Falls not Reported in the Incident Reporting System

Various characteristics of falls reported in incident reports and falls not reported in incident reports were compared (Table 2). Falls not reported in incident reports were more likely to include falls of male patients (p<0.001), first falls (p=0.001), falls that occurred on a holiday (p=0.024), falls that occurred without a witness (p<0.001) and falls recorded by physicians (p<0.001). On the other hand, falls not recorded in incident reports were less likely to include falls of patients with a cognitive disorder (p=0.002), falls that occurred during the night shift (p=0.019), injurious falls (p=0.041) and falls recorded by nurses (p<0.001). Lag time between falls occurring and submission of the data into the EMR was significantly longer for falls not reported by incident reports than for falls reported by incident reports (p=0.002). When the lag time was analyzed for falls that were recorded in both incident reports and progress notes of the EMR, the lag time in incident reports was significantly longer than the lag time in progress notes of the EMR (p<0.001). Multivariate logistic analysis with a stepwise selection method was performed to determine factors that were most significantly associated with falls not reported by incident reports (Table 3). Male gender, first fall, long lag time between occurrence of the fall and submission of data, no witness at the time of the fall and falls recorded by physicians were significantly associated with falls not recorded in incident reports.

Table 1. Results of text mining and subsequent chart review of progress notes of the EMR to detect inpatient falls

Fall-related information	Number of records suspected to have fall-related information	Number of records that contained information on true fall events	Rate of true fall events
Fall motion (slips or trips)	4297	555	12.92%
Losing balance of the body	5567	66	1.19%
Injury suffered from falls	320	89	27.81%
Drop from bed	381	48	12.60%
Use of fall-detecting sensor	342	6	1.75%
Total	10 200	635	6.23%

A total of 640,434 records obtained from progress notes of the EMR were subjected to text mining analysis, and 10,200 records (1.59%) were suspected to have fall-related information. The fall-related information could be divided into five categories. The records that were captured by text mining analysis were subsequently examined by a manual chart review. Eventually, 635 true fall events were identified (0.10% of total records). Since a record suspected to have fall events and a record that has information on true fall events could belong to more than one of the categories of fall-related information, the sum of number of records belonging to each category was not

equal to the total number of records.

Table 2. Comparison of the characteristics of falls reported in incident reports and those of falls not reported in incident reports

	Total falls	Falls recorded in incident reports	Falls not recorded in incident reports	Sig.
N	164	123	41	
Age	66.5 (51.0, 78.0)	67.0 (51.0, 79.0)	62.0 (49.0, 74.0)	0.163
Male	42 (25.6%)	14 (11.4%)	28 (68.3%)	<0.001
Cognitive disorder	28 (17.1%)	27 (22.0%)	1 (2.4%)	0.002
Major diagnostic category				0.156
Nervous system	22 (13.4%)	20 (16.3%)	2 (4.9%)	
Ear, nose, mouth and throat	12 (7.3%)	5 (4.1%)	7 (17.1%)	
Respiratory system	15 (9.1%)	9 (7.3%)	6 (14.6%)	
Circulatory system	10 (6.1%)	6 (4.9%)	4 (9.8%)	
Digestive system	27 (16.5%)	19 (15.4%)	8 (19.5%)	
Hepatobiliary system and pancreas	15 (9.1%)	11 (8.9%)	4 (9.8%)	
Kidney and urinary tract	16 (9.8%)	12 (9.8%)	4 (9.8%)	
Male reproductive system	14 (8.5%)	13 (10.6%)	1 (2.4%)	
Myeloproliverative diseases	14 (8.5%)	11 (8.9%)	3 (7.3%)	
Others	19 (11.6%)	17 (13.8%)	2 (4.9%)	
Ward				0.088
A	12 (7.3%)	6 (4.9%)	6 (14.6%)	
B	18 (11.0%)	17 (13.8%)	1 (2.4%)	
C	12 (7.3%)	8 (6.5%)	4 (9.8%)	
D	14 (8.5%)	11 (8.9%)	3 (7.3%)	
E	13 (7.9%)	10 (8.1%)	3 (7.3%)	
F	12 (7.3%)	8 (6.5%)	4 (9.8%)	
G	17 (10.4%)	10 (8.1%)	7 (17.1%)	
Others	66 (40.2%)	52 (42.3%)	11 (26.8%)	

Table 2. (continue)

	Total falls	Falls recorded in incident reports	Falls not recorded in incident reports	Sig.
First fall	107 (65.2%)	72 (58.5%)	35 (85.4%)	0.001
Falls that occurred on a holiday	39 (23.8%)	24 (19.5%)	15 (36.6%)	0.024
Time of falls (shift)				0.037
8:30 to 16:30 (day)	69 (42.1%)	47 (38.2%)	22 (53.7%)	0.123
16:30 to 24:00 (twilight)	45 (27.4%)	32 (26.0%)	13 (31.7%)	0.613
0:00 to 8:30 (night)	50 (30.5%)	44 (35.8%)	6 (14.6%)	0.019
No witness at the time of a fall	53 (32.3%)	21 (17.1%)	32 (78.0%)	<0.001

Location of fall				0.557
Out of room	42 (25.6%)	29 (23.6%)	13 (31.7%)	
Bedside	62 (37.8%)	47 (38.2%)	15 (36.6%)	
Diagnostic imaging	19 (11.6%)	17 (13.8%)	2 (4.9%)	0.097
Injurious falls	32 (19.5%)	29 (23.6%)	3 (7.3%)	0.041
Mild	26 (15.9%)	24 (19.5%)	2 (4.9%)	0.048
Moderate to severe	6 (3.7%)	5 (4.1%)	1 (2.4%)	1.000
Person who recorded fall				<0.001
Physician	16 (9.8%)	2 (1.6%)	14 (34.1%)	<0.001
Nurses	142 (86.6%)	116 (94.3%)	26 (63.4%)	<0.001
Others	6 (3.7%)	5 (4.1%)	1 (2.4%)	1.000
Lag time between episode and record	2.0 (0.0, 4.0)	1.0 (0.0, 4.0)	4.0 (1.0, 8.0)	0.002

Various characteristics of falls reported in incident reports and falls not reported in incident reports were compared.

Table 3. Characteristics of falls not reported in incident reports

	B	S.E.	p-value	Exp (B)	95% C.I. for Exp (B)	
					Lower	Upper
Male gender	3.302	0.765	<0.001	27.167	6.070	121.584
First fall	2.154	0.931	0.021	8.617	1.390	53.438
Lag time	0.226	0.085	0.008	1.254	1.061	1.482
Witness	-2.709	0.694	<0.001	0.067	0.017	0.260
Person who found fall (vs nurses)			0.002			
Physicians	4.487	1.270	<0.001	88.869	7.379	1070.238
Others	-17.076	18 590.892	0.999	0.000	0.000	
Constant	-3.785	1.066	<0.001	0.023		

Multivariate logistic analysis with a stepwise variable selection method was used to find factors that were significantly associated with non-reporting.
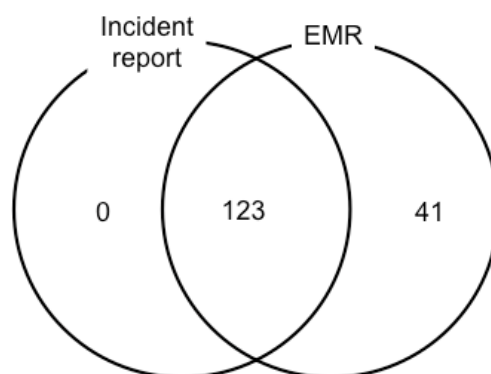
Figure 1. Fall events captured from incident reports and progress notes of the EMR

4. Discussion

Our results showed that 25% of recorded falls were not reported in the incident reporting system. It is well known that a voluntary incident reporting system can detect only a part of the incidents occurring in a hospital (Sari, Sheldon, Cracknell, & Turnbull, 2007). This situation is the same for inpatient falls. Healey et al. reported that the rate of falls in acute hospitals varied remarkably between hospitals from 0.2 to 11.5 (average 4.8) falls per 1,000 bed days based on incident reports and that this variability in the rate of falls was mainly due to reporting bias of medical staff (Healey et al., 2008). Hill et al. reported that hospital incident reporting systems captured only 75.5% of fall events (Hill et al., 2010), and Grenier-Sennelier et al. reported that 20.4% of inpatient falls were not reported in incident reports (Grenier-Sennelier, Lombard, Jeny-Loeper, Maillet-Gouret & Minvielle, 2002). These figures of non-reporting of inpatient falls are comparable to our results. Our results show that the non-reporting problem in inpatient falls is also the same in a Japanese acute care hospital setting.

The non-reporting problem is especially important when the precise incidence and detailed information on incidents are required. Examples of such situations include epidemiological study of inpatient falls, validation of countermeasures against falls, and development of risk assessment systems for inpatient falls. In reality, fall incidence in our hospital was estimated to be 2.34 per 1,000 bed days based only on information from incident reports, but it was calculated to be 3.12 per 1,000 bed days based on the results of a chart review. There is a remarkable difference, which might lead to an incorrect conclusion that the present countermeasures against inpatient falls are effective.

This non-reporting problem occurs with the background of various barriers to incident reporting. Previous studies showed that uncertainness of which incidents and why the incidents should be reported, cumbersome procedure to report, lack of feedback to reporters, and culture of blame in the organization were inhibiting factors for incident reporting (Evans et al., 2005). We tried to clarify the barriers to incident reporting in inpatient falls. Our results showed that male patients, initial falls, falls that were not found immediately by medical staff, falls found by physicians, and falls that took a long time until medical staff knew the events were significant factors for medical staff not reporting the events in the incident reporting system. The reason why falls of male patients were less likely to be reported in the incident reporting system is unknown. One possible reason is that male patients might be less likely to sustain an injury from falling (Hitcho et al., 2004), and medical staff were shown to be more likely to report injurious falls (Hill et al., 2010). In accordance with this speculation regarding the reason, we observed that injurious falls were more likely to be reported in the incident reporting system in our study. Falls that were not noticed immediately by medical staff or falls that took a long time until medical staff became aware of them were less likely to be reported in the incident reporting system. Patients who experience falls often do not inform medical staff about their falls, and medical staff often become aware that a patient has fallen by chance from conversation with the patient. Since these falls are apparently not injurious, they seem less likely to be reported in the incident reporting system. Other factors that were found to influnece non-reporting in this study were in accordance with the results of the previous studies. The first fall was less likely to be reported in the incident reporting system as was shown in previous studies (Hill et al., 2010). Falls found by physicians were less likely to be reported in the incident reporting system. It is well known that physicians report incident reports less frequently than do nurses (Evans et al., 2005). The attitude towards incidents and participation in the incident reporting system varied between physicians and other medical professionals (Waring, 2004).

In order to deal with the non-reporting problem, use of more than one method to detect medical incidents is recommended (Olsen et al., 2007; Naessens et al., 2009). Since incidents identified by one method were not identified using another method (Naessens et al., 2009), combination use of several methods to detect incidents instead of the use of a single method is important. At present, information on medical incidents mainly originates from a retrospective chart review (Olsen et al., 2007) and voluntary reports from health care professionals (Medicine 2004). However, several other methods have been used to identify these events. Hospital patients' reports revealed a number of incidents that were not recorded in medical records (Davis, Sevdalis, Neale, Massey, & Vincent, 2012). A full-time fall evaluation service consisting of trained nurses could remarkably increase the capture of fall events (Shorr et al., 2008). The Agency for Healthcare Research and Quality (AHRQ)-defined patient safety indicators (PSI) using International Classification of Diseases (ICD) - diagnosis codes from discharge abstracts can detect a larger number of incidents than an incident reporting system can (Naessens et al., 2009). Recently, medical record reviewing by using the Institute for Healthcare Improvement (IHI) Global Trigger Tool has become increasingly popular because it could identify a much larger extent than that detected by an incident reporting system (Classen et al., 2011; Rutberg et al., 2014). The Global Trigger Tool uses specific methods for reviewing medical charts by several staff that are trained to review the charts in a systemic manner

(Classen et al., 2011). Although the methods can detect a greater amount of incidents, staff education and the chart reviewing process could be time-consuming and costly.

In the present study, we used an information technology-assisted retrospective chart review. We used a text mining method in the first screening process of the chart review, and the screened records were manually confirmed to actually contain information on falls. By using this method, we could reduce candidates for manual chart review to 1.6% of the original text data. As medical information becomes increasingly computerized, automated methods to detect incidents using information technology have been developed (Govindan, Van Citters, Nelson, Kelly-Cummings, & Suresh, 2010). Detection of incidents using computerized methods to scan medical charts requires less time and personnel resources than those used in traditional methods. On the other hand, the text-mining method or natural language processing method has a number of limitations and shortcomings for daily use. First, the method cannot detect adverse events that were not recorded in any fields of medical charts and can only find adverse events recorded in an object data field. For example, radiology reports have been used for detection of patient falls in previous studies (Bates et al., 2003). However, we found that the efficiency for detection of fall events from radiology reports or image order entries was very low compared with that from progress notes (Toyabe, 2012a). Diagnostic imaging is not often performed in patients who seem not to have suffered injuries after falls. Second, false-positive results are difficult to avoid in the method. Our method was not simple keyword searching but was a method for capturing context corresponding to inpatient falls from sentences. Nevertheless, the positive predictive value of our method was quite low in some of the fall-related information categories. The development of a more sophisticated algorithm in those categories is needed for improvement of the false positive rate and for practical use of the method.

5. Conclusion

Our results showed that 25% of recorded falls were not reported in the incident reporting system and that the rate of non-reporting of inpatient falls in a Japanese acute care hospital is compable to that found in previous studies in other conutries. Non-reporting of fall events was significantly associated with several factors including male patients, first fall, long lag time until recording, no witness at the time of the fall and physician profession. The results suggest that the barriers to incident reporting that exist in the medical staff of a Japanese acute care hospital are the same as those found in previous studies in other countries.

Conflict of Interest

Authors have declared that no conflict interests.

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Comparing Intelligence Quotient (IQ) Among 3 to 7-Year-Old Strabismic and Nonstrabismic Children in an Iranian Population

Mahboubeh Ghaderpanah[1], Feraidoon Farrahi[1], Gholamreza Khataminia[1], Ahmad Jahanbakhshi[1], Leila Rezaei[2], Ashraf Tashakori[3] & Mohammad Mahboubi[2,4]

[1] Department of Ophthalmology, Ophthalmology Research Center, Jundishapur University of Medical Sciences, Ahvaz, Iran

[2] Department of Ophthalmology, Kermanshah University of Medical Science, Kermanshah, Iran

[3] Psychiatric Ward of Golestan Hospital, Jundishapur University of Medical Sciences, Ahvaz, Iran

[4] Abadan School of Medical Sciences, Abadan, Iran

Correspondence: Ahmad Jahanbakhshi, Resident of Ophthalmology, Department of Ophthalmology, Ophthalmology Research Center, Jundishapur University, Ahvaz, Iran. Tel: 98-613-222-8076. E-mail: Ahmadjahanbakhshi52@yahoo.com

Abstract

This study was designed to compare the Intelligence Quotient (IQ) among 3 to 7-year-old strabismic and nonstrabismic children in an Iranian population.

In this cross-sectional study, 108 preschool children with equal numbers of strabismic/non-strabismic disorder (age 3–7 years) were randomly selected from exceptional strabismus clinics of Ahvaz and were evaluated with the preschool and primary scale of intelligence versions of Wechsler (WPPSI).

In the current study, 108 children were evaluated. In strabismic patients the mean performance, verbal and total IQ were 89.46±19.79, 89.57±21.57 and 91.54±22.08 respectively.These mean scores in normal children were 91.89±47.53, 87.56±15.6 and 89.96±17.62consecuently. The results showed that these three different IQ subscales were not significantly different among 3 to 7 years old strabismic and nonstrabismic children ((P>0.05 for all comparisons). There was no significant difference in IQ between two sexes (P>0.05) while Persian tribe children had greater IQ score compared to other tribes (P<0.05). Also, higher paternal educational status of children related to higher IQ score. IQ score was better in combined deviations and was higher in exotropes than esotropes; however, these differences were not statistically significant (P>0.05).

In this evaluation, we did not found a significant negative interference of strabismus on IQ score of preschool children. It can be concluded that paternal educational level and tribe have a significant effect on intelligent quotient, while this is not the case on sex and ocular deviation.

Keywords: intelligence quotient, strabismus, deviation

1. Introduction

Strabismus (ocular misalignment) is one of the ophthalmological problems that can affect the quality of life of individuals. Patient with strabismus fail to achieve proper binocular vision because they are unable to simultaneously direct each eye to the same point in space. In addition, the appearance of misaligned eyes might result in social prejudice by associating strabismus with personality defects and below average intelligence (Olitsky, Sudesh, Graziano, Hamblen, Brooks, & Shaha, 1999). Prejudice relating to strabismus can extend beyond social relationships. Adult with strabismus are likely to develop mannerisms to camouflage their dysfunction and avoid eye contact during social interactions (Nelson, Gunton, Lasker, Nelson, & Drohan, 2008; Durnian, Owen, Baddon, Noonan, & Marsh, 2010). They also perceive that strabismus has a negative impact on secure employment and opportunities for career advancement (Durnian et al., 2010).

The main purpose of strabismus treatment is the alignment of the visual axes in order to achieve single binocular vision with good image fusion. Other advantages of strabismus correction include the improvement of any abnormal head posture, expansion of the visual field, restoration of stereoscopic acuity, centralization of the

visual field, elimination of diplopia, improvement in ocular motility, improvement in psychomotor development, and restoration of normal appearance (Olitsky et al., 1999; Nelson et al., 2008). Most aspects of development are dependent or guided by visual system. So, identifying the effective factors on intelligence and early treatment of them in children can prevent learning disorders and secondary problems in children.

Within the past few years, psychological issues of children have received a lot of attention. Egeland et al obtained a great correlation between childhood behavioral disorders and behavioral disorders of adulthood (Egeland, Pianta, & Ogawa, 2004). Different plans have been designed in order to identify risk factors which are specific to each disorder and selecting population which is prone to danger in order to conduct interventions. However, such plans are expensive and involve specialized screening (Do Zois & Dobson, 2006). Behavioral disorders in children bring many problems for society because children behavior influences on their family, teachers and everyone who has close relationship with children. The final losers of such effects are children themselves. On the other hand, behaviors of such children have negative influence on their education process and insignificant advancement in academic area is the immediate resultant of such behaviors (Egeland et al., 2004; Do Zois & Dobson, 2006).

Previous studies on the intelligence and psychosocial negative effects of strabismus in adults were published (6). However, to our knowledge only one no controlled study have investigated the Intelligence Quotient (IQ) (without attention to age differences) among strabismic patients in Iran. The aims of this study were to compare the IQ properties in 3 to 7-year-old preschool children with or without strabismus in the another portion of Iranian population.

2. Methods

2.1 Study Design

Cross sectional, case control, prospective study.

2.2 Ethical Consideration

All study procedures were conducted in accordance with the Declaration of Helsinki. A participant information sheet and verbal explanation were given. This is an anonymous questionnaire, so no personally identifiable information of patients and parents was recorded. The consent to participate in this study was assumed upon the completion of this questionnaire (i.e., completing the questionnaires implies giving consent to participate). The institutional ethics committee approved the study, and all patients provided written informed consent.

2.3 Participants

A consecutive sample of 54 child patients with strabismus was visited at strabismus clinic of Emam khomeini eye hospital (Ahvaz, Khuzestan, Iran). They were attending the hospital in connection with their strabismus, possibly with a view to having strabismus surgery. At the time of the study, the patients were interviewed in the strabismus outpatient department. After examination by ophthalmologist; patients who met surgical indications were added to a waiting list for a strabismus surgery.

In this study, inclusion criteria for strabismus patients were: aged between 3-7 years; no history of any eye related surgery before participation or any diagnosed emotional   or anxiety disorders; no other facial or ocular abnormalities or metabolic or neurologic diseases; good cooperation of children for IQ test and the angle of deviation was no less than 15 prism diopters (PD).

A control group of 54 children without any visual defect were recruited. To ensure similar baseline conditions, subjects were all from the family of strabismic patients. Visually normal child were companions or family members of the patients in the eye clinic.

2.4 Questionnaires

The preschool and primary scale of intelligence versions of Wechsler (WPPSI) have been developed following standard processes of translation to Persian (Razavieh & Shahim, 2008). Questionnaires include items that are designed to be relevant to a particular group of ages, and are therefore more sensitive to small but clinically significant changes in IQ in either group.

Khuzestanian population include three peculiar peoples: Persian, Arab, and Bakhtyari tribe, so, this test performed by three different psychologists (Persian speaking, Arabic speaking, Bakhtyari speaking).Specifically, either psychologists who were predominate to first language of patients performed their IQ test. All of the test portions were discussed by an expert pediatric psychologist.

This test included two portions: performance and verbal intelligence:

1). The performance subscale contained 6 items: animal house (with 1-3 time repetition), picture completion (23 pictures), geometric design, block design, picture arrangement, object assembly coding.

2). The verbal subscale contained 7 different items: information, vocabulary (22 words), arithmetic, similarities (16 items), comprehension (15 items), sentences and digit span.

Answers for each item was recorded in a rating scale. From these crude scales, a verbal intelligence score, performance intelligence score and total intelligence score was calculated and recorded in special form.

The average or normal, range of IQ is 90 to110; IQ scores of at least 120 are considered superior. Mental retardation is defined as an IQ below 70, which corresponds to the lowest 2.2 percent of the population (B. J. Sadock & V. A. Sadock, 2007).

2.5 Data Collection

All data were collected among strabismus patients prior to any strabismus-related surgery. Researchers emphasized that participation was entirely voluntary and the choice to participate or not had no impact on their surgery or treatment.

For the purpose of standardization, the questionnaires were bound in a fixed order.

A subgroup of 54 nonstrabismic children was randomly selected from the strabismic patient's family who matched in sex and age. Demographic information such as age, sex, and special first language, educational level of the parents, their domicile, the type of deviation, angle of deviation in prism diopter (PD) and refractive error (hyperopic and myopic) was recorded.

2.6 Statistical Analysis

Statistical analysis was performed using SPSS software (version 18, SPSS Inc). Data is expressed as mean ± SD. A p -value of less than 0.05 is considered to be statistically significant. We compared the mean score in strabismic patients, with that in visually normal children using t-test, Pearson correlation coefficient and ANOVA test.

3. Results

3.1 Demographic and Baseline Characteristics

A total of 108 questionnaires were fully or correctly completed. Thus 108 valid demographic and Wechsler questionnaires were available for statistical analysis.

In strabismic group: 25 patients (46.3%) were female and 29 patients (53.7%) were male.

In nonstrabismic or normal group: 31 children (57.4%) were female and 23 children (42.6%) were male.

The mean age of strabismic and normal children were 5.1 ± 1.12 and 5.1±1.09 years, respectively; range, 3.9-6.6 years. No statistically significant differences were found between the study groups (strabismic patients, visually normal children) in terms of age, gender, and socioeconomic status (Table 1).

Table 1. The frequency and percentage of children in both groups based on sex (n=108)

Sex	Strabismic group		Normal group	
	Frequency	Percentage%	Frequency	Percentage%
Female	25	46.3	31	57.4
Male	29	53.7	23	42.6
Total	54	100	54	100

In strabismic group 46 children (85%) were hyperopic and 8 children (15%) were myopic. The mean refractive error in hyperopic eyes were+3.46±2.65 dpt (ranging from+1.75 to +5.25 dpt). The mean refractive error in myopic eyes were-3.68±2.01 dpt (ranging from-1.00 to −8.25 dpt).

From 54 families that their strabismic and nonstrabismic children participated in this study only 15 mothers (27.7%) and 16 fathers (29.7%) of them hold a university certificate and above, while about 70% reported an education level below high school diploma. All children of present study had both father and mother and financial and emotional support of them.

Table 2. Frequency and percentage of educational level of parents

Educational level	Maternal educational level		Paternal educational level	
	Frequency	Percentage%	Frequency	Percentage%
Illiterate	9	16.7	5	9.2
Elementary	9	16.7	10	18.5
High school diploma	21	38.9	23	42.6
Associated degree	5	9.2	5	9.2
Graduate and more	10	18.5	11	20.5
Total	54	100	54	100

In this study twenty six of families (48.1%) were Bakhtiyari tribe, 15 families (27.8) were Arabic tribe and 13 other families (24.1%) were Persian tribe.

3.2 Relationship Between Intelligence Quotient (IQ) Scores of Study Groups Compared to Normal Population

Intelligence quotient (IQ) scores of two study groups compared to normal Iranian population are showed in Tables 3 and 4.

Table 3. Iranian population standard of Wechsler intelligence Quotient (IQ) (Razavieh & Shahim, 2008; B. J. Sadock & V. A. Sadock, 2007)

Level of IQ	Intelligence Quotient	Theoretical percentage	Real percentage
Very superior	>130	2.2	2.4
Superior	120-129	6.7	8.1
Bright	110-119	16.1	17.1
Normal or Average	90-109	50	47.1
Dull or Subnormal	80-89	16.1	15.3
Borderline	70-79	6.7	7.5
Mental retard	<70	2.2	2.2
Total	-	100	100

Table 4. Intelligence quotient (IQ) scores in the study population compared to a normal Iranian population

IQ level	Expected percentage in Iranian population (%)	Observed frequency and percentage in patients (%)	Difference (=Observed –Expected percentage percentage).
Superior elite	2.2	2 (3.7)	+1.5
Elite	6.7	7 (13)	+6.3
Bright	16.1	7 (13)	-3.1
Average or Normal	50	8 (14.8)	-35.2
Dull or Subnormal	16.1	12 (22.2)	+6.1
Borderline mental retard	6.7	10 (18.5)	+11.8
Mental retard	2.2	8 (14.8)	+12.6

According to histogram 1, 2 total IQ score distribuation in strabismic children do not have significant different from normal distribution. (Histogram 1, 2)
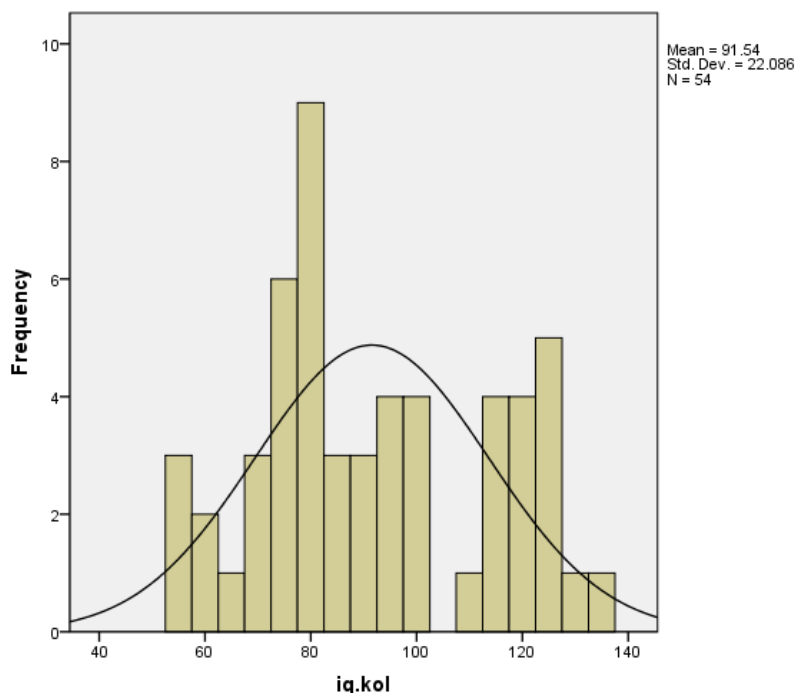
Histogram 1. Distribution of total intelligence quotient (IQ) scores in the strabismic group compared to the normal population
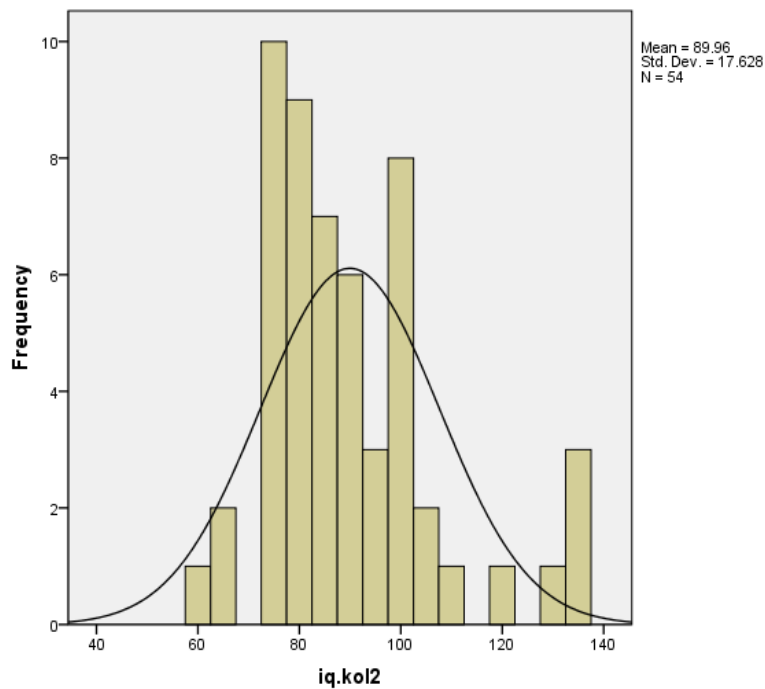
Histogram 2. Distribution of total intelligence quotient (IQ) scores in the nonstrabismic (normal) group compared to the normal population

In strabismic patients the mean verbal IQ were 89.46±19.79 and the mean performance IQ were 89.57±21.57. There was no significant difference between two IQ scores in strabismic patients (P-value =0.95).

In normal children the mean performance IQ and verbal IQ were 91.89±47.53 and 87.56±15.6 respectively that did not have significant difference (P-value=0.49).

We did not found statistical different in IQ scores of both strabismic and normal groups (all p-value>0.05) (Table 5).

Table 5. Mean and SD of intelligence quotient (IQ) in two study groups based on three different IQ subscales

Groups	Verbal IQ	Performance IQ	Total IQ
Strabismic	89.46±19.79	89.57±21.57	91.54±22.08
Normal	87.56±15.6	91.89±47.53	89.96±17.62
t-test (P-value)	0.55 (0.5)	0.32 (0.74)	0.68 (0.49)

3.3 Relationship between Intelligence Quotient (IQ) and Sex

In 54 strabismic children (25 female and 29 male) the mean IQ scores of female were higher than male, however this difference were not statistical significant (P-value >0.05) (Table 6).

Table 6. Mean and SD of intelligence quotient (IQ) in different IQ category based on different sex

Groups	Verbal IQ	Performance IQ	Total IQ
Female	90.19±16.69	96.61±60.33	91.77±15.88
Male	84.00±13.55	85.52±20.11	87.52±19.84
t-test (P value)	1.47(0.15)	0.84 (0.4)	0.87 (0.38)

3.4 Relationship between Intelligence Quotient (IQ) and Tribe

In 54 strabismic patients (26 Bakhtiyari, 15 Arab, 13 Persian) the verbal IQ in Bakhtiyari, Arab, Persian were 90.69±16.93, 75.73±21.04 and 102.85±13.56 respectively and this difference were statistically significant (P=0.001). Other performance and total IQ of these three tribes were different statistically (P value=<0.05) (Table 7).

Table 7. Mean and SD of intelligence quotient (IQ) in different IQ category based on different tribes

Tribes	Frequency (Percentage %)	Verbal IQ	Performance IQ	Total IQ
Bakhtiyari	26(48.1)	90.69±16.93	84.88±16.15	92.50±19.76
Arab	15(27.8)	75.73±21.04	82.40±21.09	77.80±19.14
Persian	13(24.1)	102.85±13.56	107.23±23.32	105.46±21.55
ANOVA)P-value)	-	8.5 (0.001)	7.13 (0.002)	6.69 (0.003)

3.5 Relationship Between Intelligence Quotient (IQ) and Paternal Educational Level and Child Age

Furthermore, Pearson momentum correlation coefficient investigated to study the relation between paternal educational level and IQ subscales. The correlation between paternal and maternal educational level and three different subscale of IQ was significant. Moreover, there was significant correlation between children age and IQ score (P= 0.01 for all comparisons) (Table 8).

Table 8. Pearson correlation coefficient to show the relation between paternal educational level and child age and three different intelligence quotient (IQ) subscales

Variable	Verbal IQ	Performance IQ	Total IQ
Maternal education	0.58 (0.01)	0.49 (0.01)	0.63 (0.01)
Paternal education	0.53 (0.01)	0.37 (0.01)	0.53 (0.01)
Children age	0.65 (0.01)	0.45 (0.01)	0.58 (0.01)

3.6 Relationship between Intelligence Quotient (IQ) and Ocular Deviation Types

With regard to the type of strabismus, 94% of patients had horisontal deviation (74% esotropia, 20% exotropia) and 6% combined deviation (vertival and horizontal). The patients with exotropia recorded better IQ scores than patients with esotropia in the performance IQ, the verbal subscale and in the total subscale of IQ. Although patients with combined deviation have better performance and total IQ, but these difference were not statistically significant (p-value >0.05 for all comparisons) (Table 9)

Table 9. Mean and SD of different intelligence quotient (IQ) category based on different ocular deviation types

Type of deviation	Frequency (Percentage%)	Verbal IQ	Performance IQ	Total IQ
Esotropia	40(74)	87.43±20.44	85.5±19.68	88.63±21.87
Exotropia	11(20)	95.50±16.13	99.40±22.37	98.70±18.30
Combined	3(6)	94.75±22.23	105.75±28.24	102.75±30.71
ANOVA(P-value)	-	0.81 (0.44)	3.1 (0.06)	1.41 (0.25)

The patients with constant deviation recorded better IQ scores than patients with alternate in all of IQ subscales, but these difference were not statistically significant(p-value >0.05 for all comparisons) (Table 10).

Table 10. Mean and SD of different intelligence quotient (IQ) score in constant and alternate strabismus

Deviation	Frequency (Percentage%)	Verbal IQ	Performance IQ	Total IQ
Constant	12(22)	96.25±17.43	92.92±24.05	96.33±22.49
Alternate	42(78)	87.52±20.18	88.62±21.03	90.17±22.04
t-test (P-value)	-	1.35 (0.18)	0.60 (0.54)	0.85 (0.39)

3.6 Relationship between Intelligence Quotient (IQ) and Amblyopia

Among of 54 strabismic patients, 30 patients (55.5%) had amblyopia, of whom 10 had unilateral (18.5%) and 20 had bilateral (37%) amblyopia. Mean IQ score in relation to amblyopia is presented in Table 12. Even though amblyopic patients had higher IQ levels than non-amblyopic counterparts, there was no significant difference in this regard (P>0.05). (Table 11)

Table 11. Frequency of different types of amblyopia and relation between amblyopia and intelligence quotient (IQ) scores

Amblyopia	Frequency (Percentage%)	Verbal IQ	Performance IQ	Total IQ
Unilateral amblyopia	10(18.5)	92.3±19.58	89.00±22.14	92.5±23.06
Bilateral amblyopia	20(37)	89.55±16.56	94.1±20.49	90.4±21.17
No amblyopia	24(44.5)	88.21±22.82	86.04±22.43	92.08±23.31
ANOVA, P-value	-	0.14 (0.86)	0.75 (0.47)	0.04 (0.95)

4. Discussion

Intelligence can be defined as the ability to assimilate factual knowledge, to recall either recent or remote events, to reason logically, to manipulate concepts, to translate the abstract to the literal and the literal to abstract, to analyze and synthesize forms, and to deal meaningfully and accurately with problems and priorities deemed important in a particular setting. The most useful intelligence test must measure a variety of skills and abilities including verbal and performance, early learned and recently learned, timed and none timed (Razavieh & Shahim, 2008). Finally, the comparison of the findings of many studies for investigation of reliability and validity of intelligence tests and cognitive abilities indicates that the Wechsler is the best standardized and most widely used intelligence test in our clinical practice today (B. J. Sadock & V. A. Sadock, 2007; Ebrahim & Kamkari, n.d.; Sadeghi, Rabiee, & Abedi, 2011).

The main purpose of this study was to compare intelligence quotient (IQ) of strabismic children and healthy non strabismic preschool children in a Khuzestanian population.

Akinci A et al found that the children with intellectual disability had significantly more nystagmus, strabismus, astigmatism, and hypermetropia than controls. Children with syndromic intellectual disability had significantly more nystagmus, strabismus, astigmatism, and hypermetropia than subjects with nonsyndromic intellectual disability. Increasing severity of intellectual disability was related to higher prevalence of nystagmus, strabismus, astigmatism, hypermetropia, and anisometropia (Akinci, Oner, Bozkurt, Guven, Degerliyurt, & Munir, 2008).

A pleiotropic relationship between intelligence and myopia has been shown to exist. Large eyes (as measured by axial length) have been shown to lead to myopia, and large brains have been shown to be more intelligent. Many authors showed that the myopia/intelligence relationship could arise because a single genetically controlled mechanism affects both brain size and eye size (Tay, Au Eong, Ng, & Lim, 1992; Miller, 1992; Teasdale, Fuchs, & Goldschmidt, 1988).

Sayyadi S et al compared visual perceptual skills among 8 to 10-year-old strabismic and nonstrabismic cerebral palsy (CP) children. They found that non-strabismic CP children had greater visual perceptual quotient compared to strabismic one. They concluded that age and strabismus have a significant effect on visual perceptual quotient (Sayyadi, Lajevardi, Aliabadi, Keihani, & Abbasi, 2011).

Rosner M et al conducted a nationwide study of the relationship among refractive error, intelligence scores, and years of schooling in 157,748 males aged 17 to 19 years, they found a strong association of myopia with both intelligence and years of school attendance (Rosner & Belkin, 1987).

Reports of the psychosocial negative effects of strabismus in adults were published in litrature; the patients said that every aspect of their lives was affected by strabismus, such as self-esteem, employment prospects, interpersonal relationships, education, and playing sports. A study determined that 41.3% patients with strabismus developed mental health problems compared with 30.7% from the control group (Mohney, B. G., McKenzie, Capo, Nusz, Mrazek, & Diehl, 2008; Chua & Mitchell, 2004).

We found only one article in literature that determined IQ score in strabismic patients objectively. Bagheri et al carried out a study in Tehran, Iran on patients with age range of 4-63 years, it was reported that the total IQ score was significantly lower in comparison to the normal population. (6) However, they did not evaluate IQ score of children and adult separately and we did not observed a significant impact of strabismus on the IQ score of the interviewed children.

The results of our study indicate that no significant differences in any of IQ score are evident between males and females, however males in the Chinese sample obtained significantly higher IQ scores than females. These observations were not present in the Japan and United States samples (Liu & Lynn, 2011).

Analysis of the effect of parents' education level on the three different subscale of IQ showed that the correlation between paternal and maternal educational level and IQ were significant. Like Bagheri et al study it was observed that about70% of parents have the education level below high school diploma, but their results were completely different with those obtained in the current study. They showed that a positive correlation between educational level of the patients and their IQ with no correlation between the level of parents' education and patients' IQ score (Bagheri et al., 2013). With regard to the difference in the age range of the two studies participants, his results were different with those obtained in our study and suggested that the effects may be due to an effect of genetic factors and parents financial support on memory of children (B. J. Sadock & V. A. Sadock, 2007). Moreover, there was significant correlation between children age and IQ score in the present study (Table 8).

There were statistically significant differences between tribes and IQ scores in our study groups. In this study, it

was found that all performance, verbal and total IQ were significantly higher in Persian tribe, we know the predominant language in kindergarten, cinema and other public spaces of Ahvaz is Persian. So Arabic or Bakhtyari tribe preschool children may showed some difficulty in the test answering.

We found that the effect of the tribe and paternal educational level was greater than the ocular misalignment.

Previous studies reported that strabismic patients with vertical deviations were more intelligent than patients with horizontal deviations; this may be due to compensatory mechanisms such as abnormal head posture (Bagheri et al., 2013). Our results support this concept, partly. In this present study, it has been shown that a minimal, non significant, effect of combined vertical and horizontal ocular deviation in IQ score compared with horizontal deviation alone were found among strabismic children.

Consistent with previous studies, our results indicated that patients with esotropia would more often show lower IQ score compared to exotropic patients. Olitsky SE and colleagues for example, found a negative association between psychosocial characteristics and strabismus and children with esotropia were rated more negatively than those with exotropia on most of these characteristics (Olitsky, Sudesh, Graziano, Hamblen, Brooks, & Shaha, 1999). In contrast, Bagheri et al. found low levels of intelligence in strabismic patients with esotropia (Bagheri et al., 2013).

The present research had some restrictions like similar studies. The current study could not evaluated diplopia in children. Adult patients with diplopia often complain about difficulties to concentrate and to orientation. They have to close one eye to see things better, but this behavior can result in feelings of eye strain (Hatt, Leske, Bradley, Cole, & Holmes, 2009).

This may explain why diplopic adult patients also report psychosocial concerns since double vision may make them feeling tired, stressed and worried. It may be more important factor to affect the test passing. Moss TP has reviewed the literature relating to the visibility and severity of a disfigurement and psychological distress in adult. He concluded that there is no clear relation between the objective severity of a ''visible difference'' and adjustment (Moss, 2005).

In regards to strabisimic patients, ophthalmologist should observe not only the evidence of difficulties with daily visual functions but also related psychosocial concerns. We believe that improving attitude of society in relation to these children remains the most practical approach to decreasing psychological distress in future. With respect to the results obtained better support of parents and other care providers of children, particularly at home and, play an important role in decreasing the rate of the adulthood behavior disorder and intelligence deficiency.

5. Conclusion

In the present research, members of study and control groups had same socio-economic status. Therefore, it seems possible to face random homogeneity in respondents (which is one of the enhancing validity factors of statistical conclusion of studies). However, this study failed to show the effect of ocular misalignment on IQ and suggested that it is not a sufficient stimulus for eliciting IQ and any other factors such as tribes and paternal educational level may be more important factors.

This study demonstrated the importance of paternal educational level and tribe, regardless of ocular misalignment, because it cannot interfere with the functional well-being of the children. The complexity of the relationships between IQ, and strabismus warrant additional studies to clarify any cause-effect relationship.

In order to establish the longer term impact of ocular deviation and ocular surgery follow up questionnaires and interviews 2 years later are planned.

Authors Contribution

This work was carried out in collaboration between all authors and assistants.

Conflict of Interest

Authors have declared that no conflict interests exist.

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Predictors of Mortality in Patients Undergoing Mitral Valve Replacement

Muhammad Farhan Khan[1], Muhammad Shahzeb Khan[2], Faizan Imran Bawany[2], Mudassir Iqbal Dar[1], Mehwish Hussain[2], Saima Farhan[1], Kaneez Fatima[2], Khizar Hamid[2], Mohammad Hussham Arshad[3], Maira Aziz[4], Uswah Siddiqi[4], Nashit Irfan Aziz[4], Muhammad Bazil Musharraf[5] & Abdul Bari Khan[1]

[1] Civil Hospital, Karachi, Pakistan

[2] Dow Medical College, Dow University of Health Sciences, Karachi, Pakistan

[3] Aga Khan University Hospital, Karachi, Pakistan

[4] Department of Biological Sciences, The Lyceum

[5] Karachi Grammar School, Karachi, Pakistan

Correspondence: Muhammad Shahzeb Khan, Dow Medical College, Dow University of Health Sciences, Karachi, Pakistan. Tel: 92-321-206-6743. E-mail: Shahzebkhan@gmail.com

Abstract

Objective: Although mitral valve replacement is frequently performed in patients of all age groups, there are few studies available which determine the causes of operative mortality in mitral valve replacement especially in our region. Therefore, the objective of this study was to identify factors that are significantly associated with operative mortality in mitral valve replacement.

Methods: From August 2012 to March 2013, 80 consecutive patients undergoing mitral valve replacement in a single tertiary hospital were included. Patients with a history of previous coronary artery bypass graft surgery or congenital heart problems were excluded from the sample. The included patients were observed for a period of 30 days. Pre and post-operative variables were used to identify significant predictors of mortality.

Results: The overall hospital mortality (30 days) was 15%. High post-perative creatinine (P =0.05), high ASO titre (P=0.03), young age (P=0.011), low cardiac output (P=0.0001), small mitral valve size (P=0.002) and new onset of atrial fibrillation (P=0.007) were the significant independent predictors of operative morality.

Conclusion: Mitral valve replacement can be performed in third world countries with limited resources with low mortality. However, optimal selection of mitral valve size can help to improve operative mortality.

Keywords: mitral valve replacement, mortality, Pakistan, predictors

1. Introduction

Mitral valve pathology is the most common disorder amongst all valvular heart diseases. Though symptomatic improvement may be attained through medical treatment, many patients require minimally invasive procedures or replacement of the diseased valve for improvement of their condition (Turi, 2004). Sudden- onset (acute) cases of mitral regurgitation usually arise due to infection of mitral valve or abrupt disruption of valves that may be due to rupture of one of the supporting muscles following ischemic damage due to myocardial infarction. Many acute mitral regurgitation patients are in a critical condition and should be indicated for emergent mitral valve replacement.

The main idea behind surgical valve replacement in valvular heart disease is that the prosthesis selected to substitute for a stenotic or regurgitant valve will result in improvement in cardiac function, keeping in mind the complications associated with surgery and mechanical prosthetic valves (Bolman, 2007). Although not universal, it is a well-known fact that replacement of mitral valve is associated with greater short term and long term mortality as compared to mitral valve repair (Suri et al., 2006). Therefore, mitral valve repair is a more common surgical modality opted for, followed by mitral valve replacement (Turi, 2004). As a result, it is important to determine which preoperative and operative variables are associated with increased operative 30 day mortality following mitral valve replacement. We hypothesize that certain variables such as gender, age, Left Ventricular

End Systolic Dimension (LVESD), low cardiac output and size of the prosthetic mitral valve may have a significant impact on operative mortality.

Therefore, the purpose of our study was to identify variables that are significantly associated with 30 day operative mortality in mitral valve replacement.

2. Methodology

In this prospective study, 80 consecutive patients undergoing mitral valve replacement in a single tertiary hospital were included. The data was collected during the time period of 7 months from August 2012 to March 2013. All patients with mitral valve disease such as stenosis or regurgitation were a part of our study. However, patients with a history of previous coronary artery bypass graft surgery or congenital heart problems were excluded from the sample. Similarly, patients who were undergoing concomitant surgical procedures such as aortic valve replacement or coronary artery bypass graft surgery were also excluded from the study. The included patients were observed for a period of 30 days. Pre-operative profile and operative and post-operative variables were gathered for the sample. Pre-operative profile included variables such as age, gender, blood group, Anti Streptolysin O (ASO) titre and New York Heart Association (NYHA) classification. Moreover, left ventricular function details and mitral valve areas were noted after the echocardiogram. The operative variables such as cross clamp and bypass time were jotted down by the surgeon himself.

All mortalities that occurred during the hospital stay and those that occurred after discharge but within 30 days of the valve replacement were defined as operative mortality. However, deaths which had no association with the operation were not included in operative mortalities. The pre and post-operativevariables were used to identify significant predictors ofoperative mortality in mitral valve replacement. Informed written consent was taken from each patient. For entering and analysis of data, SPSS version 21 was used. Mean ± standard deviation was computed for continuous variables. Frequency and percentages were calculated for categorical variables. Mann-whitney U test and chi-square with Fisher's exact test were run to compare outputs in expired and alive patients. P value less than 0.05 was considered as significant.

3. Results

The incidence of 30 days mortality in mitral valve replacement was found to be 15% (n=12). The mean age of the patients was 30 ± 11 years. More than of the patients were male (n = 46, 57.5%). O +ve (n = 34, 42.5%) and B +ve (n = 27, 33.8%) blood groups were more common among the patients. Only one (1.3%) patient had a previous history of myocardial infarction while 2 (2.5%) patients were obese. Fifty five (68.8%) patients were classified as NYHA class 1 and 2 whereas the remaining patients (31.3%) were classified as class 3 and 4. Hepatitis profile of 10 (12.5%) patients was positive (Table 1).

Table 1. Showing the baseline variables of the patients

Mean Age (years)		30 ± 11
Gender	male	34 (42.5%)
	female	46 (57.5%)
Blood group	A+ve	9 (11.3%)
	A-ve	2 (2.5%)
	B+ve	27 (33.8%)
	B-ve	1 (1.3%)
	O+ve	34 (42.5%)
	O-ve	1 (1.3%)
	AB+ve	5 (6.3%)
	AB-ve	1 (1.3%)
History of myocardial infarction	yes	1 (1.3%)
	no	79 (98.8%)
Obesity	yes	2 (2.5%)
	no	78 (97.5%)

NYHA classification	class 1, class 2	55 (68.8%)
	class 3, class 4	25 (31.3%)
Hepatitis profile	negative	70 (87.5%)
	positive	10 (12.5%)

The patients who expired were significantly younger than those who survived (P = 0.011). The NYHA classification was similar in both expired and alive patients (Table 2). The Anti Streptolysin O (ASO) titre of the patients was divided into groups, values less than 200 and more than 200. Fourteen patients had ASO titre greater than 200 and out of them 5 (35.7%) expired. Out of 66 patients who had ASO titre less than 200, 59 (89.4%) did not have operative mortality. This difference was statistically significant (P = 0.03). Atrial fibrillation was significantly more common in patients who expired as compared to those who survived (P = 0.007). Moreover, out of the 12 patients who died, 9 had low cardiac output (P < 0.0001). The postoperative creatinine value was on average two times higher in expired patients as compared to those who survived (P = 0.05) (Table 3).

Table 2. Comparison of baseline variables with operative mortality

		Expired	Alive	P Value
Mean Age (years)		24 ± 17	31 ± 10	0.011
Gender	male	6 (17.65)	28 (82.4%)	0.569
	female	6 (13%)	40 (87%)	
History of myocardial infarction	yes	0 (0%)	1 (100%)	>0.999
	no	12 (15.8%)	67 (84.8%)	
Obesity	yes	0 (0%)	2 (100%)	>0.999
	no	12 (15.4%)	66 (84.6%)	
NYHA classification	class 1, class 2	7 (12.7%)	48 (87.3%)	0.502
	class 3, class 4	5 (20%)	20 (80%)	

Table 3. Showing the predictors of mortality

		Expired	Alive	P Value
ASO titre	<200	7 (10.6%)	59 (89.4%)	0.03
	>200	5 (35.7%)	9 (64.3%)	
Atrial fibrillation	yes	8 (32%)	17 (68%)	0.007
	no	4 (7.3%)	51 (92.7%)	
Need for synchronized shock	yes	8 (61.5%)	5 (38.5%)	<0.0001
	no	4 (6%)	63 (94%)	
Low cardiac output	yes	9 (64.3%)	5 (35.7%)	<0.0001
	no	3 (4.5%)	63 (95.5%)	
Post op creatinine		2.18 ± 2.07	0.94 ± 0.23	0.05

The mean size of the prosthetic mitral valve used was significantly smaller in expired patients as compared to those who did not suffer death (P = 0.002). However, mitral valve area and type of mitral valve disease (stenosis or regurgitation) were not significantly different in expired and alive patients. Intra aortic balloon pump was used in 4 patients and all of these 4 expired. Moreover, all the patients who survived did not require intra aortic balloon pump (P < 0.0001) (Table 4).

Table 4. Effect of operative variables on operative mortality

		Expired	Alive	P Value
left ventricular function	good	3 (8.8%)	31 (91.2%)	0.215*
	moderate	9 (20%)	36 (80%)	
	poor	0 (0%)	1 (100%)	
Mitral regurgitation	absent	5 (12.5%)	35 (87.5%)	0.755
	present	7 (17.5%)	33 (82.5%)	
Mitral stenosis	absent	5 (17.2%)	24 (82.8%)	0.749
	present	7 (15.6%)	44 (86.27%)	
Intra-aortic balloon pump	yes	4 (100%)	0 (0%)	<0.0001
	no	8 (10.5%)	68 (89.5%)	
Reopened	yes	4 (66.7%)	2 (33.3%)	0.004
	no	8 (10.8%)	66 (89.2%)	
Wound infection	yes	0 (0%)	2 (100%)	>0.999
	no	12 (15.4%)	66 (84.6%)	
Mitral valve area		1.2 ± 0.5	1.1 ± 0.5	0.978
Pulmonary artery pressure		60 ± 14	63 ± 18	0.62
Systolic dimension (mm)		37 ± 12	36 ± 11	0.822
Diastolic dimension (mm)		52 ± 16	51 ± 12	0.736
Cross clamp time (minutes)		65 ± 39	57 ± 37	0.438
Bypass time (minutes)		98 ± 51	75 ± 47	0.088
Mitral valve size (mm)		27 ± 3	30 ± 2	0.002

*The p-value obtained by Mann-Whitney U test.

4. Discussion

The most serious consequence of rheumatic fever is rheumatic heart disease that occurs in roughly 30% of patients. Patients with sudden onset rheumatic fever may present with pancarditis along with valvular pathology, heart failure and pericarditis (Zakkar, Amirak, Chan, & Punjabi, 2009). Incidence of rheumatic heart disease has dropped during the last 40 years in western world. However, it is still remains a major health challenge in developing countries. It is estimated that 16 million individuals are affected by rheumatic heart disease around the globe, with roughly 281,000 new cases and 234,000 deaths every year (Carapetis, Steer, Mulholland, & Weber, 2005). One of the most common valvular complications of rheumatic heart disease is mitral stenosis and/or regurgitation. In majority of cases, mitral valve replacement is typically essential, however in few cases mitral valve repair can also be performed (Zakkar et al., 2009). Previous studies have shown that mitral valve replacement is associated with greater incidence of operative mortality (Suri et al., 2006). Therefore, our study highlights important pre and postoperative variables that could have a significant impact on operative mortality in mitral valve replacement.

Magnanti et al. (2010) and his colleagues have showed in their study that low cardiac output syndrome, after mitral valve surgery, significantly increases mortality and morbidity. The syndrome is characterized by the need of a post-operative intra-aortic balloon pump or inotropic support for longer than thirty minutes in intensive care unit. Therefore, mechanical circulatory support is required especially in high risk patients, in whom mitral valve surgery is becoming increasingly popular. Increased mortality due to low cardiac output after mitral valve surgery is also evident from the results of our study that show a significant association between the two (p<0.0001). However, the prevalence (17.5%) of low cardiac output syndrome was relatively greater in our study as compared to the prevalence of 7% reported by a previous study (Maganti et al., 2010).

The results of our study also indicate that small size of mitral valve was significantly associated with higher rates of mortality. This could be explained by patient prosthesis mismatch (PPM) after mitral valve replacement. It is

believed that this mismatch can result in elevated transvalvular gradients mimicking those with mitral stenosis (Suri et al., 2006). Furthermore, these high transvalvular gradients can result in left atrium dilation which can subsequently cause atrial fibrillation. Magne et al. (2007) hypothesized that PPM might have significant impact on mortality after MVR. Our data also indicates that almost 25% of the patients had atrial fibrillation. The mechanism hypothesized above may be a crucial mechanism by which atrial fibrillation occurs after MVR. Hence optimal selection of prosthetic mitral valve size is essential. Optimal selection of prosthetic valve would lower down the chances of PPM greatly and consequently reduce mortality rates. Great implantability of the prosthetic valve can only be achieved be choosing an appropriate size of the valve being implanted.

One of the most common ways to assess kidney function is to measure serum creatinine levels. Serum creatinine levels remain mostly constant in patients with normal kidney function, with a daily fluctuation of roughly 7% (Traynor, Mactier, Geddes, & Fox, 2006). Our results show that post-operative creatinine had a significant impact on operative mortality in mitral valve replacement (P value=0.05). Magnanti et al. (2010) has also shown that decreased renal function is an independent predictor of mortality (odds ratio=4.3). Therefore, it can easily be inferred from these findings that proper renal function with adequate creatinine clearance can significantly lower mortality after mitral valve surgery. The association of increased mortality with elevated creatinine and NYHA class IV is further emphasized by the results of Nowicki et al and his colleagues (2004). Their results were supported by a high sensitivity and specificity index as measured through the area under receiver operating characteristic (ROC) curve (0.79, 95% CI, 0.76-0.81). In contrast, our results did not show a significant effect of NHYA class on 30 day mortality.

Moreover, the results of our study show that LVESD was not significantly different between expired and non-expired patients. In fact, the mean value of LVESD was almost identical in alive and expired patients. This is in contrast with a study that showed LVESD was a significant independent predictor of mortality in mitral valve replacement (Tribouilloy et al., 2009). However, they had only taken mitral regurgitation patients due to fail leaflets. In that study it was concluded that all patients should be operated before LVESD reaches 40 mm to reduce mortality. Our study did not show any such association and most of the patients who died had LVESD less than 40 mm.

Although our study has provided some interesting findings, there are a few limitations to that should be considered. Firstly, the small sample size of 80 patients makes it difficult to generalize all the findings obtained by the study. Secondly, we did not determine the predictors associated with mid or long term mortality. Studies in the future should focus on the significant predictors of long term mortality after mitral valve replacement by doing a long follow up. Additionally, health related quality of life should also be accessed after mitral valve replacement. Nevertheless, this study has listed down some of the significant predictors of mortality after mitral valve replacement in developing countries. It has also enlightened on the crucial issue of the selecting optimum size of the valve for which the researchers could also design new studies focusing on factors affecting the size of prosthetic mitral valve. These studies will help to lower down the PPM mismatch.

5. Conclusion

The results of our study indicate that young age, ASO titre greater than 200, postoperative atrial fibrillation, high post-operative creatinine levels, small prosthetic mitral valve size implanted and low cardiac output were significant predictors of mortality. We also conclude that small mitral valve size can lead to severe PPM and subsequently atrial fibrillation. This can be easily prevented by choosing prosthesis with a larger orifice area. However, more long term clinical studies with larger samples should be conducted to determine predictors of mortality after mitral valve replacement in developing countries.

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Conflict of Interest

Authors have declared that no conflict interests exist.

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Survey of Nursery Errors in Healthcare Centers, Isfahan, Iran

Ali Ayoubian[1], Mansooreh Habibi[2], Pouria Yazdian[3], Hossein Bagherian-Mahmoodabadi[4], Peyman Arasteh[5, 6], Tannaz Eghbali[6] & Tohid Emami Meybodi[7]

[1] Health Research Center, Baqiyatallah University of Medical Sciences, Tehran, Iran

[2] Mazandaran University of Medical Sciences, Sari, Iran

[3] Student Research Committee, Shahid Sadughi University of Medical Sciences, Yazd, Iran

[4] Department of Health Services Management, Isfahan University of Medical Sciences, Isfahan, Iran

[5] Non Communicable Diseases Research Center, Fasa University of Medical Sciences, Fasa, Iran

[6] Student Research Committee, Shiraz University of Medical Sciences, Shiraz, Iran

[7] Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Correspondence: Mansooreh Habibi, Mazandaran University of Medical Sciences, Sari, Iran. Tel: 98-91-1127-4723. E-mail: mansoore.habibi@yahoo.com

Abstract

Background & Aim: Nurse's mistakes usually have a strong effect on the patients trust and satisfaction in the health services systems, and it can also lead to stress and moral contradicts among nurses. This study has aimed to survey the rate of nurses' mistakes, according to documents in the Isfahan Province during 2007-2012.

Methods: The study was a descriptive cross-sectional study. The sample population consisted of all complaints concerning nursing services provided in hospitals, private clinics and other health service centers between 2007 and 2012, submitted to the Forensic Medicine Commission Office, in Isfahan. The data were collected by a cheklist and analyzed using SPSS version 16.0 software.

Results: Out of 708 complaints, 70 (9.8%) cases were related to nurses. Twenty-four cases led to awards. The age range of nurses was 35-40 (25.7%). Out of 70 nurses with a record, 75% (53 people) were female and the rest were male. Sixty four nurses (91.4%) were working in hospitals. Negligence was the first basis of the court rulings (16 cases out of 24). Nurses' recklessness in providing services was due to their convictions among 66.7% of the cases

Conclusion: Although efforts to reduce and control nurses' faults and mistakes depends on using a system for studying and removing the factors which lead to faults, human error is inevitable in every occupation and a 100% accurate operation is unreachable.

Keywords: nursery mistakes, nurse, delivery of health care

1. Background

Human beings always make mistakes. This is also true for the health care staff and authorities. Regardless of their skills, experiences, and commitments, the nurses may and will make mistakes. There are thousands of cases of injuries or even deaths recorded in the USA as a result of physicians and nurses' faults and mistakes. More than 2000 deaths are recorded due to nursing mistakes in the USA each decade. Nursing mistakes may bring dire consequences to the patients (Anderson & Webster, 2001).

The international council of nurses declared that developing the quality of services by nurses is necessary to improve the patients' health and all nurses are responsible to preserve the patients' security in all aspects. This includes making the patients and personnel informed about the possibility of faults, methods for reducing the rate of mistakes, supporting patients' security and reporting any cases to the authorities (Johnstone & Kanitsaki, 2006).

The performance of the nurses is usually questioned more than any other staff in health services (Cho et al., 2009) -particularly by physicians- concerning the role of nurse as the most important member of developing the quality

of health services. Similar to the management of the medication, nurses also have the responsibility for the patients' security, consequently, they might be accused of wide ranges of issues (Joolaee, Hajibabaee, Peyrovi, Haghani, & Bahrani, 2011).

Balas et al. showed that 30% of the nurses participating in their study had made a mistake at least once (Balas, Scott, & Rogers, 2004). Several studies have been carried out on estimating the nursing and medical mistakes. A study on physicians' activity in Harvard University showed that more than 70% of the unwanted incidents had been due to the poor performance of the medical staff and more than 90% of them were preventable (Burroughs et al., 2005).

In accordance with the studies by the American Medical Association, at least 100 patients die because of the faults in the health services and 92% of the staff believe that nurses are largely to blame (Frith, 2013).

Medical mistakes are usually brought to the court under the titles of 1- Skill-based errors; 2- Rule-based errors; and 3- Knowledge-based errors. However, the errors by nature are usually unintentional. Studies in the European countries showed that nursing mistakes are sustained by 18-28% of the patients (Reason, 2000). It is notable that informing the public about patients' bill of right draws the patients' attention to the health services in hospitals. In this case many patients will take legal action against health staff neglecting health care standards (Ayoubian, Mahmoodabadi, & Dehaghi, 2013).

The medical faults in Iran are proposed under the topic of medical faults and refer to the responsibility of the providers of services for the damages and losses occurred during treatment (Zeraatchi, Talebian, Nejati, & Dashti-Khavidaki, 2013). The complaints about medical faults usually fall into 4 groups: carelessness, incautious, lack of proficiency, and lack of observance of governmental derivatives. However, the faults generally are unintentional. On one hand, there are no categorized data and information regarding the reasons of the faults and types of them and the available information are about the occurrence of the faults in Iran.

This is not because of low rates of faults in Iran, but because of lack of accurate recording and registration systems and research studies in this field. On the other hand, the increase of referred files and the patients' complaints against physicians and nurses to medical system administrations and courts depicts the existence and the increase of faults in this group of people (Joolaee et al., 2011).

2. Objective

The occurrence of such faults leads to destroy trust and, consequently, the dissatisfaction of patients. In this case it can be said that health services can bring about stress and moral conflicts for the nurses and health service staff. Therefore, this study has aimed to demonstrate the rate of mistakes committed by nurses between the years 2007-2012.

3. Methods

The study is a descriptive cross sectional work. The study population was comprised of all the submitted complaints to Isfahan Province Forensic Medicine Commission Office regarding nursing services provided in hospitals, private clinics and other health services centers between 2007 and 2012. The complaints had been made from April 2007 to March 2012 (n=708). Owing to the paucity of the sample size, census sampling was used. Totally, there were 70 complaints regarding the nursing services (9.8%) and all these cases were examined in this work.

The participation criteria were i) the complaints must be about poor nursing services provided in hospitals, clinics, and other health service centers; ii) the complaints must be submitted between April 2005 and March 2010; and iii) the complaints must be examined and finalized by the commission. The exclusion criterion was that the complaint was not about poor services by the nursing staff.

Data were collected using a cheklist which was designed based on age, gender, education level, subject of complaint, result of the case, and place of service. The validity of the check list was confirmed by the experts and scholars. The study was carried out in the archive department of Isfahan Province Forensic Medicine Organization in spring 2012. During this study, all data collection processes were done after securing the required permissions, the researchers made their best not to interrupt the normal work process of the department; and the confidentiality of the information was observed.

Manual work procedure in the department (no computerized system was available) and limited time to examine the files and confidentiality of the information were some of the limitations of the study. Data analysis was carried by using SPSS version 16.0 software.

4. Results

As listed in Table 1, the largest group of cases was filed against staff in the age ranges of 35 to 40 (25.7%). Next in line were the age groups of 30 to 35 and 20 to30 with 15 and 17 files respectively.

Table 1. Frequency of complaints against nurses, by the age of nurses

Age	N	%
20-25	6	8.6
25-30	15	21.4
30-35	17	24.3
35-40	18	25.7
40-45	7	10
45-50	4	5.7
50-55	3	4.3
Total	**70**	**100**

Women constituted 75.7% (53 out of 70) of the sample group. Out of the 70 nurses in the study, 24 cases led to conviction and 46 to acquittal ruling.

Table 2 lists the frequency of place service provision. Among nurses studied on, 64 (91.4%) worked in hospitals. None of the cases occurred in private clinics.

Table 2. Frequency of complaints against nurses by nurses' work place

Location of Service	N	%
Hospital	64	91.5
Private Clinic	1	1.4
Home Care	4	5.7
Other	1	1.4
Total	**70**	**100**

Incautiousness was one of the most important bases of conviction of nurses in 66.7% (16 out of 24 cases). Lack of observation and governmental instruction 16.7%, carelessness 12.5%, and low proficiency 4.1% were next on the line.

The faults had occurred because of reasons such as carelessness, administrating without the permission of the supervisor, loss of the count of gauzes and leaving one in the patient's stomach, immature child delivery, failing to take care of mental patients, using wrong gauzes, failing to inform physicians about patients' conditions, providing services out of professional competency, unpermitted hospitalization and default in the attendance of the patient.

The findings show that on average the court ruling was one adult blood-money in 23% of the cases, half of adult blood-money was the most common ruling and 1.5% of the adult blood-money was the minimum conviction. Also among 70 complaints against the nurses that have been studied, 24 cases of them (34.3%) led to convictions and 46 cases (65.7%) have led to exoneration.

Table 3 suggests that in 50% of the cases (12 out 24) conviction was 1-10% of an adult blood money. None of the cases resulted in more than 50% of the adult blood-money.

Table 3. Frequency of convicted nurses by an adult blood money

Penalty Fee	N	%
1-10	12	50
11-20	1	4.2
21-30	3	12.5
31-40	1	4.2
41-50	7	29.1
Total	24	100

Table 4 shows that nurses' recklessness in providing services was due to their convictions among 66.7% of the cases.

Table 4. Frequency of the cause of nurses' conviction

Cause	N	%
Imprudence	3	12.5
Recklessness	16	66.7
Lack of Skill	1	4.1
Lack of Comply with Government System	4	16.7
Total	24	100

5. Discussion

Results show that out of the 708 complaint cases 70 cases (9.8%) were against nurses. In a study by Frouzesh, the figure was reported 2%, which is a considerable difference in compared to our findings (Foruzesh, Ghorbani, Vosugh, & Mohammadi, 2011). Concerning the 70 cases against nurses, 24 (34.3%) leaded to conviction (44.3%) and 46 (65.7%) to acquittal. Negligence, breach of instructions, remiss, and lack of enough skill were the main bases of the rulings.

Prohibited activities in provision of medical services are a common case in Iranian hospitals. It is a common case where the nurse provides medical service out of their competency, which ends up with negative side effects on the patients and file of complaints. Regarding other ranks of nursing such health staff and health assistants, there are many cases where they are instructed by nurses to provide services that they do not have the competency for. There are many cases in courts filled by those sustained unwanted side effects by such services (Iyer, 2002).

Nelson et al. reported that handing over non-health care services such as preparing specimens, computer stuff, secretary services, over works and tiredness, assignment of physicians' tasks, bad penmanship of physicians, lack of pharmacological knowledge, pressure for more services, and employment of students instead of qualified personnel, improper physician shifts, lack of access to pharmacologists for consultation are of the main causes of faults of nursing services (Nelson, Evans, Samore, & Gardner, 2005).

On the other hand, reports by studies in other countries showed that human factors are effective in nursing services (Nelson et al., 2005). Consistently, our results showed that negligence is the main cause of faults in nursing services. However, this is inconsistent with the results obtained by Nelson.

Furthermore, the results showed that nurses in hospitals under the supervision of the University of Medical Sciences and Social Security Organization had the maximum number of complaints. This is not surprising taking into account the extension of the services provided by these two groups of hospitals. Therefore, this unconfirmed result seems reasonable enough.

The majority of the nurses were women, which is expectable concerning the fact that the majority of the nurses are women. The results showed that there are several factors to blame as to preparing the ground of making nursing mistakes. The first way to cut these mistakes is to spot the causes (Kingston, Evans, Smith, & Berry, 2004).

In addition, creating an environment where all nursing staff declare their mistakes to their colleagues, managers, and medical team and creating opportunities to compensate the mistakes is another way to deal with medical mistakes and faults. The authorities need to collect information of the types of mistakes, circumstances (work shift, staffing, personal characteristics, and soon) and use the information to deal with the causes of mistakes (Johnstone & Kanitsaki, 2006).

It is expectable that nurses are the first group of staff who are blamed for bad services, however, what may help the staff under hard working condition is to inform them about the rules and regulations (Green, 2004).

6. Conclusion

Human mistakes are intrinsic to any profession and having a system which is free of fault is not achievable. However, the implementation of a systematic approach to deal with the causes of faults and removing them are the keys to control the rate of staff faults.

The results showed that the main cause of the faults done by nurses is negligence. To deal with this issue and mainly negligence-based mistakes, it is recommended to hold periodical recalling courses for the nurses, to supply required qualified nursing staff for health centers and to implement an effective system to distribute patients to the capacity of the health services. New approaches to keep the nurses' update (based on recent publications, books, journals, etc.) must be developed. Work mistakes take place either due to lack of skills or negligence.

Acknowledgements

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Quality of Life for Saudi Patients With Heart Failure: A Cross-Sectional Correlational Study

Mohannad Eid AbuRuz[1,2], Fawwaz Alaloul[3], Ahmed Saifan[1], Rami Masa'Deh[1] & Said Abusalem[3]

[1] College of Nursing, Applied Science University, Amman, Jordan

[2] King Fahad Specialist Hospital, Dammam, KSA

[3] School of Nursing, University of Louisville, Louisville, Kentucky, USA

Correspondence: Mohannad Eid AbuRuz, Assistant Professor, Po Box 142 Shafa Badran, Amman 11934, Jordan. Tel: 96-279-862-1580; Fax: 96-265-232-899. E-mail: mohannadeid@yahoo.com, m_aburz@asu.edu.jo

Abstract

Introduction: Heart failure is a major public health issue and a growing concern in developing countries, including Saudi Arabia. Most related research was conducted in Western cultures and may have limited applicability for individuals in Saudi Arabia. Thus, this study assesses the quality of life of Saudi patients with heart failure.

Materials and Methods: A cross-sectional correlational design was used on a convenient sample of 103 patients with heart failure. Data were collected using the Short Form-36 and the Medical Outcomes Study-Social Support Survey.

Results: Overall, the patients' scores were low for all domains of Quality of Life. The Physical Component Summary and Mental Component Summary mean scores and SDs were (36.7±12.4, 48.8±6.5) respectively, indicating poor Quality of Life. Left ventricular ejection fraction was the strongest predictor of both physical and mental summaries.

Conclusion: Identifying factors that impact quality of life for Saudi heart failure patients is important in identifying and meeting their physical and psychosocial needs.

Keywords: Arab world, ejection fraction, GCC, heart failure, Medical Outcomes Study-Social Support Survey, Middle East, quality of life, Saudi Arabia, Short Form-36, social support

1. Introduction

Heart failure (HF) is a chronic syndrome characterized by significant physical, psychological and social burdens, resulting in poor quality of life (QoL) (Demir & Unsar, 2011). It is a chronic and progressive clinical syndrome associated with increased neuro-hormonal activity and multiple organ dysfunction (Fotos et al., 2013). HF is a major public health issue, with 23 million cases worldwide, and rising (Liu & Eisen, 2014). Projections show that by 2030 the prevalence of HF will increase by 25% from 2013 estimates in the US (Heidenreich et al., 2011). The American Heart Association (AHA) estimates that 5.7 million Americans older than 20 years have HF based upon 2007-2010 data (Roger et al., 2012), representing an annual cost of $34.4 billion annually (Heidenreich et al., 2011). The incidence of HF ranges between 1% and 19.3 per 1,000 person-years in older adults ≥65 years (Bui, Horwich, & Fonarow, 2011; Roger et al., 2012).

Approximately 6.5 million patients in Europe and 2.5 million patients in Japan suffer from HF (Fotos et al., 2013). In the UK, HF affects an estimated 3% of people aged between 65 and 74 years; this prevalence increases with age and affects approximately 15% of the population aged over 74 (Riley, 2014). Similar to the global picture, HF is also a growing concern in developing countries (Pelegrino, Dantas, & Clark, 2011). The extrapolated prevalence of HF in Saudi Arabia is 455,222 cases and the estimated incidence is 32,200 cases annually (Health Grades Inc., 2012). A recent study by Albackr et al. (2013) showed that 20% of the patients who were admitted to Saudi hospitals with acute coronary syndrome (ACS) had HF.

HF has negative impacts on all aspects of patients' physical, social, psychological, emotional and spiritual well-being (Heo et al., 2009; Chen et al., 2010). HF patients have difficulties in performing activities of daily

living; suffer from economic, sexual and psychosocial problems; and encounter troubles in social and professional relationships (Demir & Unsar, 2011; Pelegrino et al., 2011). These negative consequences are frequently due to secondary symptoms associated with HF such as fatigue, shortness of breath, insomnia, drowsiness and anxiety (Heo et al., 2008, 2009). Therefore, nursing interventions to improve QoL for patients with HF is warranted. The objectives of HF treatment are to maximize life expectancy, improve QoL, and prevent disease progression and hospital admissions.

In order to identify effective interventions to improve QoL, it is imperative to identify factors associated with changes in QoL among patients with HF, including age, gender, social support and marital status (Pelegrino et al., 2011), functional class, duration of HF, left ventricular ejection fraction (LVEF), other comorbidities and psychosocial status (Chung et al., 2012; Son et al., 2012).

Culture plays an important role in defining health, sickness, and shapes individuals' QoL (Padilla, Kagawa-Singer, & Ashing-Giwa, 2012). Therefore, the World Health Organization (WHO, 1995) emphasized the role of culture in shaping QoL and defined it as the "Individual's perception of his/her position in life in the context of the culture and value systems in which he/she lives, and in relation to his/her goals, expectations, standards and concerns" (p.1405). Huang et al. (2010) found that QoL among Taiwanese patients was better than among American patients with HF due to cultural differences.

There are differences between Arab-Islamic and Western cultures in terms of customs, relationships and values. Saudi Arabia is a Middle Eastern, Arabic, Islamic country characterized by a collectivist society with strong family and community ties, abiding Islamic faith, restraint in disclosing personal matters, including health-related issues (Wehbe-Alamah, 2008), and a male-dominated culture (Al-Krenawi & Graham, 2000). Arab patients may prefer not to express their physical and mental complaints that consequently impact their health and QoL. They may rely on their faith in relieving their discomfort. Hence, outcomes of research conducted in Western culture may be or may be not applicable to individuals residing in Saudi Arabia. Therefore, this study was conducted to determine if research outcomes from Western culture can be applied to Saudi Arabian patients with HF.

Social support has positive outcomes on different aspects of patients' health. Social support was found to reduce mortality, enhance healthy lifestyles, provide a buffer against adverse life events (Staniute, Brozaitiene, & Bunevicius, 2013) and improve QoL (Sammarco & Konecny, 2010; Wang, Lau, Chow, Thompson, & He, 2014). Muslim and Arabic cultures are known to provide social support to the individuals when they are sick or in need for help. However, the association of perceived social support with QoL among Saudi Arab and Muslim patients with HF has not been explored. So far, QoL for patients with HF has been studied mostly in the US (Heo et al., 2009; Pelegrino et al., 2011), Canada (Ducharme et al., 2005) and Europe (Fotos et al., 2013).

1.1 Aim

Given the massive negative effects of HF and its progressive nature, in addition to the lack of knowledge about QoL of HF patients in Saudi Arab patients, the purposes of this study were to: 1) identify demographic characteristics (age, sex, income, and marital status) and medical variables (LVEF, HF duration, presence of diabetes mellitus, and hypertension) associated with QoL; (2) examine the relationships of social support dimensions with QoL in patients with HF; and (3) identify variables that explain the greatest amount of variance in physical component summary (PCS) and mental component summary (MCS) of QoL.

2. Methods

2.1 Design, Sample and Setting

A cross-sectional correlational design was used. A convenient sample of 103 patients with HF was adequate to detect statistical significant results based on 80% power, a Cronbach's alpha of 0.05, 12 independent variables, and an estimated effect size of 0.2 (Soper, 2013). The inclusion criteria were patients diagnosed with HF able to read and write in Arabic. Patients were excluded from the study if they had cancer or major psychiatric problems that could affect the completion of the questionnaires or their QoL. The sample was recruited from a tertiary care hospital in the Eastern province of the Kingdom of Saudi Arabia. This tertiary care hospital is the largest hospital in the Eastern province, with a capacity of 1500 beds. Moreover, it is specialized in cardiac and oncology care, and receives referral cases from all other hospitals in the Eastern province, which has a population of approximately seven million. All other hospitals in that area are smaller hospitals. Based on this information, the patients included in this study were from all the cities of the Eastern province.

2.2 Measurement of Variables

QoL was measured using the Short Form-36 version 2 (SF36). This generic instrument to measure QoL has been

widely used for patients with HF (Coelho et al., 2005). This tool is a 36-item multiple-response option questionnaire with eight scales: physical functioning (10 items), role physical functioning (four items), role emotional functioning (three items), vitality (four items), mental health (five items), social functioning (two items), body pain (two items), general health (five items), and one item comparing current patient's health with the last year (Ware & Sherbourne, 1992). Scales are measured on a 0-100 score. Higher scores indicate higher levels of QoL in each domain. Two major summaries can be calculated: Physical Component Summary (PCS), which consists of physical functioning, role physical functioning, body pain, general health, and Mental Component Summary (MCS), which consists of: role emotional functioning, vitality, mental health, and social functioning.

The psychometric properties of this instrument were evaluated for 1,980 patients aged16-74 years. The results showed that the instrument had satisfactory to excellent alpha reliability coefficients (Brazier et al., 1992), with Cronbach's alpha greater than 0.75 for all scales except social functioning ($\alpha = 0.73$) (Brazier et al., 1992). The SF-36 also has an evidence of construct validity by a strong correlation with Nottingham Health Profile (Brazier et al., 1992). This instrument was translated into Arabic and has shown satisfactory psychometric results (Coons et al., 1998). The minimum Cronbach's alpha for general health was 0.71, and the highest was for physical functioning (0.94).

Medical Outcomes Study-Social Support Survey (MOS-SSS): To assess perceived functional support, the MOS-SSS was used. The MOS-SSS survey consists of 19 self-reported questions (Sherbourne & Stewart, 1991). The first 18 items are divided into four subscales: emotional/informational support (eight items), affectionate support (three items), tangible support (four items) and positive social interaction (three items). These subscales have a five-point Likert scale ranging from 1 (none of the time) to 5 (all of the time). All raw scale scores are standardized by transforming them into a 0-100 scale. Item number 19 measures the availability of people to support respondents and keep their minds at peace. Higher scores for the subscales and for the overall support index indicate a higher level of support (Sherbourne & Stewart, 1991).

The internal consistency reliability for this instrument was evaluated using a sample of 2,987 patients with chronic conditions. The scale with lowest alpha score was positive social interaction ($\alpha = 0.91$) and the highest alpha score scale was emotional/informational support scale ($\alpha = 0.96$). The alpha for the overall support index was 0.97 (Sherbourne & Stewart, 1991). This questionnaire had strong convergent and discriminate validity. This instrument was translated into Arabic and had good internal consistency in a sample of 63 Arab stem cell transplant survivors. Cronbach's alphas ranged from 0.79 to 0.87(Alaloul, 2007).

Demographic and medical characteristics: A demographic form was developed by the researchers and by trained research assistants to collect data on participants' age, sex, marital status, educational level, employment status and annual income. Additionally, medical variables including time since diagnosis with HF, LVEF, history of diabetes, or hypertension were included in the demographic form.

2.3 Procedure

Institutional review board (IRB) approval was obtained from King Fahd Specialist Hospital (Dammam) IRB Committee. The principal investigator met with administrators, physicians and the nursing director and explained the purposes and nature of the study. HF patients who met the inclusion criteria were contacted during their visit to the outpatient clinic. The study was explained and informed consent was obtained from patients who agreed to participate. Participants completed the questionnaire in a quiet, private place in the hospital. Each participant completed the SF-36, the MOS-SSS and the demographic data form. Two trained nurse research assistants obtained patients' demographic characteristics and medical variable data from patients' medical records.

2.4 Data Analysis

Data were analyzed using the Statistical Package for the Social Sciences for Windows 21.0 (SPSS, Inc., Chicago, Illinois). An alpha of < 0.05 was used to determine the statistical significance of analyses. Descriptive statistics (mean, standard deviation or frequency, and range) were used to assess participant's demographic and medical characteristics, the SF-36, and the MOS-SSS scores.

To identify factors associated with QoL, a series of bivariate correlations were conducted to test for associations between the two summary subscales of the SF-36 (physical and mental) and demographic variables (i.e., age, educational level, yearly income, marital status, and employment status), medical variables (LVEF, duration of HF, and the presence of hypertension or diabetes). Pearson r for interval measures, the Spearman ρ for ordinal measures, and the χ^2 test for categorical measures. Predictor variables with significant correlation (p-value <0.1) were selected for further analysis. Next, stepwise regression analysis was used to evaluate the strength of

association of demographic characteristics, medical variables, and perceived social support with two summary subscales of the SF-36 (physical and mental). For multivariate analyses, multicollinearity was assessed using bivariate correlations among predictor variables, tolerance indices, and variance inflation factors; no serious multicollinearity was found among predictor variables.

3. Results

3.1 Descriptive Statistics

The mean age of the participants was 50.3 years (SD = 16.3, rang: 19-90). The duration patients' had HF ranged from 1-15 years, with a mean of 5.4 years. Their mean ejection fraction was 37.9% (SD = 5.7, range: 30-55). Approximately three-quarters (73%) of the sample had hypertension, and half had diabetes. Other participants' demographic characteristics are presented in Table 1. Medical Outcomes Study-Social Support Survey Scores are presented in Table 2. The emotional/informational support dimension had the lowest mean score and tangible support had the highest mean score. The mean scores for the QoL domains, the PCS and the MCS are presented in Table 3. Overall, the patients' scores were low for all domains indicating poor QoL. The PCS and MCS mean results were low, indicating poor QoL as well. The lowest mean score was for General Health (General perception about health), which meant that the patients felt poor QoL, whereas mental health had the highest mean score.

Age, ejection fraction, and tangible support were significantly correlated with both PCS and MCS (Table 4). Therefore, these variables were included in stepwise regression. These three variables explained 39% of total PCS subscale variation. Age, and LVEF explained 27% of total MCS subscale variation (Table 5).

Table 1. Demographic Characteristics of Patients with Heart Failure (N = 103)

Characteristics	n (%)
Gender	
Male	60 (58.3)
Female	43 (41.7)
Marital status	
Single	15(14.5)
Married	63 (61.2)
Divorced	8 (7.8)
Widowed	17 (16.5)
Employment	
Employed	74 (71.9)
Educational level	
Less than high school/High School	18 (17.5)
Diploma	24 (23.3)
Holding Bsc	61 (59.2)
Income	
Less than 3000 SR	29 (28.2)
From 3001-5000SR	18 (17.5)
5001-10000SR	31 (30.1)
More than 10000 SR	25 (24.3)

SR: Saudi Riyals.

Table 2. Medical Outcomes Study-Social Support Survey Scores of the Saudi Patients with Heart Failure (N = 103)

Scale/Subscale	Mean	SD	Possible Range	Actual Range
Emotional/Information Support	60.6	13.9	0-100	25-100
Tangible Support	84.7	12.1	0-100	25-100
Affectionate Support	74.0	12.7	0-100	25-75
Positive Social Interaction	63.8	12.5	0-100	25-75
Total score	65.6	12.7	0-100	25-80

Table 3. Scores for the SF-36 Quality of Life Domains, PCS, and MCS of the Participants (N = 103)

Subscale	Mean	SD	Possible Range	Actual Range
Physical Functioning (Level of limitation in physical activities)	42.9	14.1	0-100	0-80.0
Role Physical (Problems with usual role related to physical health)	43.2	11.5	0-100	25-75.0
Social Functioning (Interference with social activities)	45.0	10.7	0-100	12.5-62.5
Role Emotional (Problems with usual role related to emotional health)	45.2	9.6	0-100	25.0-75.0
Bodily Pain (Level of pain)	33.9	11.5	0-100	22.5-67.5
General Health (General perception about health)	26.8	12.5	0-100	0-55.0
Vitality (Energy and fatigue)	51.6	6.8	0-100	31.3-68.8
Mental Health (Level of psychological status)	53.4	8.3	0-100	35.0-75.0
Physical component summary	*36.7*	*12.4*	*0-100*	*13.3-61.6*
Mental Component summary	*48.8*	*6.5*	*0-100*	*30.3-63.0*

Table 4. Correlations between physical and mental component summaries and Selected Significant Demographic, Medical Variables and Social Support Subscales (N = 103)

Variables	Age	LVEF	History of HTN	History of DM	Emotional Support	Tangible Support	Affectionate Support	Positive Social Interaction
Physical component summary	-.457**	.613**	-.352**	-.201*	.360**	.454**	.319**	.386**
Mental component summary	.516**	.451**	-.320**	-.238*	.469**	.324**	NS	.343**

LVEF: Left ventricular ejection fraction; HTN: hypertension; DM: Diabetes Mellitus; ** significant, P<.001; * significant at P<.05; NS: Not significant.

Table 5. Regression Analyses: Predictors of the PCS and MCS of the SF-36 (N = 103)

Outcomes/Predictors	Standardized β	t	Model Statistics
Physical component summary			
Ejection Fraction	0.61	7.8	
Tangible Support	0.29	3.8	$R^2 = 0.39$; $F(3,99) = 60.7$, $p < .001$
Age	-0.25	-3.4	
Mental component summary			
Ejection Fraction	0.37	3.8	
Age	-0.21	-4.9	

4. Discussion

In this study, Saudi patients reported poor QoL in all domains, PCS, and MCS of the SF36. Moreover, the general perceptions of health and pain domains had the lowest scores respectively, which indicate that they know that their heath is poor and affecting their QoL. We drew this conclusion when we compared the results of this study with the mean norms SF-36v2 of Maglinte, Hays, and Kaplan (2012), which was conducted in a developed country. Inconsistent with our findings, Peters-Klimm et al. (2010) found that social functioning and role emotional were slightly impaired. In Turkey, which has similar cultural characteristics, similar findings were found (Demir & Unsar, 2011)

Culture, knowledge, attitudes, beliefs or health care system issues are potential explanations for these differences (Huang et al., 2010). Saudis prefer not to disclose their emotions during illness to the public and may avoid seeking emotional and social help from healthcare providers (Al-Busaidi, 2010), although they ask for assistance to meet their physical needs, which are impossible to hide. Patients received tangible support from their first-degree family members and the personal attendants who are always around sick people in Saudi Arabia for socio-cultural and religious reasons. Our findings showed that tangible support has the highest mean among all support subscales. Further studies are paramount to explore differences in QoL among different cultures.

The findings of this study are comparable to those of Hoekstra et al. (2011) who found that mental health QoL domain was slightly compromised among patients with HF from the Netherlands. In our study, mental health domain had the highest score (53.4, SD= 8.3), which is still slightly below the mean found by Maglinte et al. (2012) of 54.27 (SD = 13.28), which indicates that it is slightly compromised. Maglinte et al. (2012) found that the mental component domain was the highest among all domains consistent with our study findings. We found that the mental health domain has the highest score that contributes to the improvement of QoL; however, it was not statistically significant in the regression models. Also, consistent with our study, several studies reported impaired pain domain scores (Rustoen et al., 2008; Nesvold et al., 2011). Different reasons need to make the health care providers pay more attention to pain assessment and management among Saudi patients. For Saudi participating patients, pain is part of their chronic illness and may be seen as a way to purify (expiate) their sins (Al-Busaidi, 2010; Van denBranden, 2010).

When examining the relationship between demographic and medical variables associated with QoL in Saudi patients with HF, LVEF had the strongest correlation with QoL among Saudi patients followed by age. These two variables were significant in predicting all QoL domains. Other variables that have a significant relation with the QoL were the Tangible Support, history of HTN, and DM. However, only Tangible Support remained a significant predictor of QoL.

Low LVEF, which is an objective clinical measurement of HF, leads to pulmonary edema resulting in fatigue and dyspnea. Different studies showed that LVEF is a strong predictor of mortality (Rizzello et al., 2009; Banovic et al., 2011) and hospital admissions (Chaudhry et al., 2013) for patients with HF. Two studies (Heo et al., 2008; Pelegrino et al., 2011) showed that there is a relationship between LVEF and QoL. They also found that there is a significant positive correlation between LVEF and QoL. In this study, high levels of LVEF were associated with better QoL. Therefore, effective management of LVEF might improve patients' overall signs and symptoms, reduce mortality rate, hospitalization, fatigue and enhanced QoL.

The results of this study showed that younger people had better PCS and MCS scores, which are associated with better QoL. Consistent with previous studies (Fotos et al., 2013; Iqbal et al., 2010; Lewis et al., 2007), younger age was significantly correlated with higher PCS score, higher physical functioningand higher role physical

domain scores of the SF-36. On the other hand, being older was associated with better mental component and mental health domain SF-36 scores.

Heo et al. (2008) found that age independently predicted QoL and physical symptoms at one and three months' follow-up; younger patients had better QoL and better PCS activities. Younger patients reported performing more activities of daily living and had better QoL in a study in Turkey (Demir & Unsar, 2011). Age remained significant in all regression models for all domains of QoL when it was checked among overweight or obese adults (Wang et al., 2013). When Pelegrino et al. (2011) checked health-related QoL determinants in outpatients with HF, they found a negative significant relationship between age and QoL. Patients aged ≥ 65 years had poorer QoL compared to those aged < 65 years, which is consistent with our study findings.

One of our aims in this study was to describe the association of perceived social support with QoL among participating patients with HF. Patients with HF received a moderate to high level of social support. Previous studies (Bennett et al., 2001; Barutcu & Mert, 2013) showed nearly the same results. Barutcu & Mert (2013) found that Turkish HF patients, who are mostly Sunni Muslims (and thus sharing many socio-cultural traits with patients in Saudi Arabia), received extensive social support from their families (Tangible Support). Tangible Support had the highest scores among all types of support and remained significant in all regression models in both MCS and PCS. This is not surprising since patients with these compromised summaries due to the disease process and treatment complexity were more in need of tangible support (Tajvar et al., 2013).

Moreover, all support subscales had a positive correlation with the PCS and MCS subscales indicting that this support will improve the QoL for HF patients, including participating patients in this study. Fotos et al. (2013) found that unmarried patients with HF have poorer QoL than married patients, which supports the relationship of the Tangible Support provided by the family members and other people with the improvement of QoL. Therefore, establishing support groups and encouraging patients to seek support from friends, the community, and healthcare providers in addition to their families might improve their perceived social support in all dimensions.

5. Conclusion

Participating Saudi patients with HF reported poor QoL in all domains, PCS and MCS. They had moderate to high support scores indicating a positive affect on their QoL but their general QoL scores were still low. Older adult patients with acutely low LVEF had the lowest QoL scores, indicating a need for further attention and management. The holistic care for patients with HF by a multidisciplinary team of healthcare professionals and families could improve their QoL.

Conflict of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Detection of Hydroxychloroquine Retinal Toxicity by Automated Perimetry in 60 Rheumatoid Arthritis Patients With Normal Fundoscopic Findings

Qader Motarjemizadeh[1], Naser Samadi Aidenloo[1] & Mohammad Abbaszadeh[1]

[1] Department of Ophthalmology, Urmia University of Medical Sciences, Urmia, Iran

Correspondence: Naser Samadi Aidenloo, Department of Ophthalmology, Urmia University of Medical Sciences, Urmia 57147-83734, Iran. Tel: 98-914-340-7326. E-mail: dr.nasersamadi@yahoo.com

Abstract

Hydroxychloroquine (HCQ) is an antimalarial drug used extensively in treatment of autoimmune diseases such as rheumatoid arthritis. Retinal toxicity is the most important side effects of this drug. Even after the drug is discontinued, retinal degeneration from HCQ can continue to progress. Consequently, multiple ophthalmic screening tests have been developed to detect early retinopathy. The aim of the current study was to evaluate the value of central 2-10 perimetry method in early detection of retinal toxicity. This prospective cross-sectional investigation was carried out on 60 rheumatoid arthritis patients, who had been receiving HCQ for at least 6 months and still were on their medication (HCQ intake) at the time of enrollment. An ophthalmologist examined participants using direct and indirect ophthalmoscopy. Visual field testing with automated perimetry technique (central 2-10 perimetry with red target) was performed on all included subjects twice in 6 months interval: The first one at the time of enrollment and the second one 6 months later. Males and females did not show any significant difference in terms of age, duration of therapy, daily and cumulative HCQ dose, anterior or posterior segment abnormalities, hypertension, body mass index, and best corrected visual acuity. Anterior segment was abnormal in 9 individuals including 3 subjects with macular pigmentary changes, 4 individuals with cataract and 2 cases with dry eyes. Moreover, 12 subjects had retinal pigmented epithelium (RPE) in their posterior segments. After 6 months, depressive changes appeared in 12 subjects. Additionally, HCQ therapy worsened significantly the perimetric results of 5 (55.6%) patients with abnormal anterior segment. A same trend was observed in perimetric results of 6 (50.0%) subjects with abnormal posterior segments (P=0.009). The daily dose of HCQ (P=0.035) as well as the cumulative dose of hydroxychloroquine (P=0.021) displayed statistically significant associations with perimetric results. Central 2-10 perimetry is a useful method for early detection of HCQ retinal toxicity, but more comprehensive studies, with larger sample size, longer-term follow-up and more precise techniques are mandatory to confirm HCQ retinal toxicity.

Keywords: hydroxychloroquine, rheumatoid arthritis, perimetry, retinal toxicity

1. Introduction

1.1 Introduce the Problem

Hydroxychloroquine (HCQ) is an anti-malarial drug that has been used for the treatment of rheumatoid arthritis, systemic lupus erythematosus and some other connective tissue diseases. It has been reported that HCQ administration is associated with toxic side effects on the retinal pigment epithelium (RPE) as well as on the outer retina (Finbloom, Silver, Newsome, & Gunkel, 1985; Mavrikakis et al., 2003; Shearer & Dubois, 1967; Weiner, Sandberg, Gaudio, Kini, & Berson, 1991). Early signs of functional disturbances include pigmentary abnormalities of the PRE, paracentral visual field defects, color vision deficiencies and reading difficulties. If these early signs are overlooked, a severe retinal toxicity with irreversible visual loss may develop.

Retinal toxicity from HCQ is of serious ophthalmologic concern. Because even after the drug is discontinued, there is little if any visual recovery. Additionally, it has been shown that the retinal degeneration caused by HCQ can continue to progress (Marmor, Carr, Easterbrook, Farjo, & Mieler, 2002). For this reason, regular screening for retinal toxicity is recommended to detect early retinopathy and discontinue the therapy. Several different techniques have been proposed so far as screening methods for the early detection of HCQ retinopathy

(Browning, 2002; Marmor et al., 2002; Warner, 2001). However, most of these methods are not sensitive enough. Consequently, there is no consensus regarding the screening routine for early detection of retinopathy (Alarcon, 2002; American College of Rheumatology Ad Hoc Committee on Clinical Guidelines, 1996; Bishara & Matamoros, 1989; Easterbrook, 1999; Semmer, Lee, Harrison, & Olsen, 2008).

The purpose of the current investigation was to assess the value of central 2-10 perimetry in early detection of retinal toxicity.

2. Method

2.1 Patients

All participants gave written informed consent to participating in this investigation, which was approved by the Ethics Committee of Urmia University of Medical Sciences. Moreover, the procedures complied with the tenets of the Declaration of Helsinki and subsequent revisions. A total of 60 individuals who had normal fundoscopy were included in this cross-sectional, prospective study. The investigation was conducted on patients with rheumatoid arthritis who had been receiving HCQ for at least 6 months. All included individuals were on their medication (HCQ intake) at the time of enrollment as well. On the other hand, the exclusion criteria were: i) a history of renal or liver dysfunction, ii) use of tricyclic antidepressants, iii) a history of eye trauma, iv) amblyopia, v) a history of diseases that could alter the fundus perimetry such as gross ametropia, glaucoma, macular drusen, and other maculopathies, vi) a history of hydroxychloroquine or chloroquine intake, and vii) abnormal fundoscopic signs at the time of study.

2.2 Ophthalmologic Examination

All patients underwent an ophthalmologic examination including perimetry, visual acuity, and fundoscopy. An ophthalmologist examined participants using direct and indirect ophthalmoscopy and central 2-10 perimetry technique. Demographic and clinical characteristics such as age, gender, blood pressure, medical history, and dose of HCQ intake, were all retrieved from participants' medical files. Visual field testing with automated perimetry was performed on all included subjects twice in a 6 months interval: The first perimetry was achieved at the time of enrollment whereas the second one was carried out 6 months later. All perimetric examinations were interpreted by the same ophthalmologist. The central visual field was examined with a 10-2 visual program on the Humphrey Visual Field Analyzer (Humphrey Instruments Inc, Dublin, California, USA) using red target. Individuals with systolic/diastolic blood pressures higher than 140/90 mmHg or subjects who were using antihypertensive medications were considered as hypertensives.

2.3 Statistical Analysis

Statistical analyses were performed by Statistical Package for the Social Sciences (SPSS ver. 19; SPSS Inc, Chicago, USA). Fisher's exact test was utilized to compare qualitative variables whereas Mann-Whitney U-test was used to compare intergroup continuous parameters. Two-sided P values less than 0.05 was considered statistically significant for all analyses.

3. Results

We evaluated a total of 11 men (aged 32-66 years; mean=42.73) and 49 women (aged 38-66 years; mean=40.22) in the current study. Table 1 displays the baseline characteristics in the investigated population according to the gender. None of these parameters showed a significant difference between males and females. The average duration of HCQ therapy was 5.22 years (min=8 months, max=84 months) in males and 6.31 years (min=6 months, max=120 months) in females. Anterior segment was abnormal in 9 individuals including 3 subjects with macular pigmentary changes, 4 individuals with cataract and 2 cases with dry eyes. On the other hand, 2 men and 10 women had retinal pigmented epithelium (RPE) in their posterior segments. The minimum and maximum daily HCQ doses were 45 mg and 450 mg in our population, respectively.

Table 1. Comparison of demographic characteristics and clinical parameters between males and females

Variable	Male (N=11)	Female (N=49)	Total (N=60)
Age [year], Mean (SD)	42.73 (7.93)	40.22 (8.14)	40.94 (7.64)
Duration of therapy [month], Mean (SD)	5.22 (2.43)	6.31 (2.86)	6.08 (2.54)
Anterior segment, N (%)			
Normal	9 (81.8)	42 (85.7)	51 (85)
Abnormal	2 (18.2)	7 (14.3)	9 (15)
Posterior segment, N (%)			
Normal	9 (81.8)	39 (79.6)	48 (80)
Abnormal (with RPE)	2 (18.2)	10 (20.4)	12 (20)
Hypertension, N (%)	3 (27.3)	15 (30.6)	18 (30)
BMI [Kg/m^2], Mean (SD)	26.25 (4.09)	24.43 (3.11)	25.11 (3.64)
BCVA [logMAR], Mean (SD)	0.17 (0.26)	0.16 (0.31)	0.16 (0.28)
Daily HCQ dose [mg], Mean (SD)	161.8 (107.3)	172.2 (95.3)	168.6 (102.4)
Cumulative HCQ dose [g], Mean (SD)	235.4 (175.4)	241.5 (190.6)	239.4 (182.1)

BCVA: best corrected visual acuity; HCQ: hydroxychloroquine; logMAR: logarithm of the minimum angle of resolution scale; RPE: Retinal pigmented epithelium; mg: milligram; g: gram.

Among 60 patients who were assessed by perimetry, 48 cases (80.0%) had normal results whereas 12 subjects (28.6%) showed depressive changes after 6 months. Table 2 has summarized the results of the second visual field testing in the total population, in those who had normal fundus and in patients with normal/abnormal anterior and posterior segments. After 6 months, HCQ therapy deteriorated significantly the perimetric results of 5 (55.6%) patients (P=0.013) with abnormal anterior segment. A same trend was observed in perimetric results of 6 (50.0%) subjects with abnormal posterior segments (P=0.009). In addition, depressive changes also developed in 7 (14.6%) out of 48 patients who had normal fundus at the beginning of the study (Table 2).

Table 2. Results of visual field testing 6 months after the first perimetric examination.

	Perimetry		Total	P value
	Normal	Depressive		
Total population, N (%)	48 (80.0)	12 (20.0)	60	-
Patients with normal fundus, N (%)	41 (85.4)	7 (14.6)	48	-
Anterior segment, N (%)				
Normal	42(83.4)	7 (16.6)	51	0.013
Abnormal	4 (44.4)	5 (55.6)	9	
Posterior segment, N (%)				
Normal	42(87.5)	6 (12.5)	48	0.009
Abnormal	6 (50.0)	6 (50.0)	12	

Table 3 compares the mean levels of daily and cumulative HCQ doses between different perimetric results of the investigated population. The daily dose of HCQ as well as the cumulative dose of hydroxychloroquine displayed statistically significant associations with perimetric results (P=0.035 and P=0.021, respectively).

Table 3. The mean levels of daily and cumulative HCQ doses according to perimetric results.

	Perimetry	N (%)	Mean (SD)	P value
Daily HCQ dose [mg], Mean (SD)	Depressive	12 (20)	185.7 (105.2)	0.035
	Normal	48 (80)	166.5 (93.2)	
Cumulative HCQ dose [gr], Mean (SD)	Depressive	12 (20)	257.5 (189.2)	0.021
	Normal	48 (80)	235.2 (164.8)	

HCQ: hydroxychloroquine.

4. Discussion

Toxic retinopathy is one of the serious side effects associated with the use of chloroquine and hydroxychloroquine. Risk factors proposed for the development of HCQ retinopathy include long duration of treatment (>5 years), high daily drug dosage (>6.5 mg/kg of lean body weight), concomitant renal or liver disease, high level of body fat, and age of older than 60 years (Bernstein, 1991; Browning, 2002; Marmor et al., 2002). Regular screening examinations are critical in early diagnosis as well as in prevention of HCQ toxicity. Nowadays, drug discontinuation is the only way to prevent ocular side effects (Marmor et al., 2002). Making the decision to cease the drug is based on diagnostic and screening examinations. However, for the most majority of patients, taking chloroquine or HCQ is the most effective way to control the underlying systemic disease. Moreover, drug cessation can lead to deteriorating of underlying disorder. In some occasions, it may also be necessary to substitute other medications such as steroids which are associated with serious systemic side effects (Yam & Kwok, 2006). Ocular screening tests have a fundamental role in early diagnosis of HCQ toxicity, and therefore should be chosen with great precision. It has been reported that central 10-2 perimetry is more sensitive than fundoscopy and color vision testing (Elder, Rahman, & McLay, 2006). In the present investigation, we aimed to evaluate the value of central 2-10 perimetry in early detection of retinal toxicity in 60 rheumatoid arthritis patients with normal fundoscopic findings.

There is a controversy about whether the dosing regimen and the total dose of Chloroquine or HCQ are associated with the risk of retinopathy (Puavilai et al., 1999). Indeed, Chloroquine retinopathy was initially observed in subjects receiving an overdose of this drug (Francois, de Rouck, Cambie, & de Laey, 1972; Grierson, 1997; M. J. Vedy, 1975). Additionally, further cases of maculopathy were described in subjects who used chloroquine prophylaxis at 100 mg daily for more than 10 years, with cumulative doses ranging around 300 g (Chovet, Vedy, Fauxpoint, & Vingtain, 1979; Metge, Rodor, Chovet, Montabone, & Llavador, 1979; Trojan, 1975; J. Vedy, Fauxpoint, Labat, Carrica, & Rivaut, 1978). It has also been shown that a cumulative dose of >700 g might be toxic, corresponding to a prophylaxis of 100 mg per day for 20 years (Chovet et al., 1979; J. Vedy, Graveline, Carrica, Rivaud, & Chanut, 1979). There are also some investigations in the literature that have shown that a cumulative dose of 185 g (Balo, Mensah, & Mihluedo, 1996) or even 140 g (Ducousso et al., 1995) should be considered as the threshold dose to avoid retinopathy. This is compatible with our findings. Hence, we suggest that, in any case, patients should be systematically screened before this cumulative dose is reached.

There is no general consensus on the definition of true hydroxychloroquine retinopathy. In the current study, those who had normal fundus and perimetric results at the beginning of the study but developed depressive changes during the follow up period were considered as HCQ retinopathic patients. According to this criterion, 21 subjects who had abnormal anterior or posterior segments were found in our population. All of these subjects were recognized using automated perimetry with red target methods. Interestingly, the mean concentration of cumulative HCQ dose was significantly higher in participants with abnormal anterior (P=0.041) and posterior (P=0.032) segments compared with subjects who had normal segments. A similar trend – with borderline P values – was also observed for the daily HCQ doses (P=0.052 for subjects with abnormal anterior segment and P=0.043 for subjects with abnormal posterior segment compared with cases with normal anterior/ posterior segments).

After combining the data of 9 prospective studies, Yam and Kwok (Yam & Kwok, 2006) reported that, out of a total of 2404 patients who received HCQ therapy, only 9 patients developed retinopathy (0.4%). Moreover, in a prospective study of 526 patients, the overall incidence of irreversible hydroxychloroquine retinopathy was 0.38% (Mavrikakis et al., 2003), whereas the highest incidence of 4% occurred in a prospective study of 99 patients (Rynes, 1983). On the other hand, the incidence rate in our population was 20%. However, it seems that the majority of these patients actually are reversible premaculopathy rather than true retinopathy, when the

Bernstein's (Bernstein, 1991) or Easterbrook's definitions (Easterbrook, 1993) of HCQ retinopathy were considered. Thus, more comprehensive studies, with larger sample size, longer-term follow-up and more precise techniques are mandatory to confirm HCQ retinal toxicity.

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The Relationship Between the Customer Relationship Management and Patients' Loyalty to Hospitals

Shadi Hajikhani[1], Seyed Jamaledin Tabibi[1] & Leila Riahi[1]

[1] Department of Health care Services Management, Faculty of Medical Sciences, Science and Research Branch of Tehran, Islamic Azad University, Tehran, Iran

Correspondence: Seyed Jamaledin Tabibi, Professor, Department of Health care Services Management, Faculty of Medical Sciences, Science and Research Branch of Tehran, Islamic Azad University, Hesarak, Tehran, Iran. Tel: 98-91-21-303-567. E-mail: sjtabibi@yahoo.com

Abstract

Background and Aim: Customer Relationship Management (CRM) with its various components has been considered as a tool causing customers' loyalty. The present study aims to investigate the relationship between the various components of customer relationship management and patients' loyalty to the place of their treatment.

Methods: This cross sectional and descriptive-analytical study was conducted among nurses and hospitalized patients in inpatient wards in selected hospitals in 2014. Using the stratified random sampling method, 224 valid and reliable researcher-drafted questionnaires were completed for CRM by nurses and 359 questionnaires were completed by patients for patients' loyalty in the studied wards. Data were analyzed using the $SPSS_{20}$ software.

Results: There was no statistically significant relationship between the level of patients' loyalty and organizational indicators, information technology and knowledge management (P Value>0.05). However, there was a statistically significant relationship between loyalty and the dimensions of the service process (P Value=0.04), human resources (P Value=0.002) and CRM (P Value=0.038). The strength of these relationships were 34, 40 and 36 percent, respectively all of which were positive.

Conclusion: Customer Relationship Management is a tool for improving influencing factors on patients' satisfaction and loyalty. Therefore, attempts to implement customer relationship management as a process for improving hospitals performance and improving communication between service providers in hospitals and customers leading to enhance patients' loyalty should be taken into account by managers and policy makers in the health sectors.

Keywords: CRM, organization and management, patients, hospitals

1. Background

Attracting and maintaining customers have long been believed to be of main aspects of activities in every organization. New forms of competition and structural changes in transactional processes have led to the creation of patterns for long term communication between stakeholders in market (Šebjan, Bobek, & Tominc, 2014). However, the competition has increased in various businesses due to the diversification of customers' demands. Indeed, many businesses try to build effective communication with customers in order to consider their needs. In addition, they found out that maintaining current customers is cheaper than attracting new ones. To do so, Customer Relationship Management (CRM) systems have been implemented in many cases (Choi et al., 2013; Lee, 2012; Tohidi & Jabbari, 2012). Thus, attracting and maintaining customers and creating loyalty among them in organizations are considered as aims of the establishment of the CRM (Ngai, 2005).

Is said that CRM, as a new term, was widespread since the mid-1990s (Choi et al., 2013; Ngai, 2005). This system is a marketing technique and an investment approach through which an organization can understand customers and influence customers' behavior. All this is done through providing customized services for each group of customers and a significant relationship in order to acquire more customers, retain customer, increase customers' loyalty and improve customers' profitability (Choi et al., 2013; King & Burgess, 2008; Kostojohn, Johnson, Paulen, & McKinnie, 2011; Lee, 2012).

There are several factors influencing customers' loyalty such as employee satisfaction, employee loyalty and the quality of services (Arab, Tabatabaei, Rashidian, Forushani, & Zarei, 2012; Caruana, 2002; Tabibi, Kakhani, Gohari, & Shahri, 2009).

Nowadays, the number of health care centers has increased along with the increased competition in the health care industry. This has resulted in establishing the customer relationship management system in order to meet diverse demands of customers. Due to the intensifying competition among health care centers, services tailored to customers are provided through analyzing their needs by the centers (Choi et al., 2013; Trepper, 2000).

The CRM for health care service providers is an approach through which they learn whatever related to their patients, their viewpoints and expectations in order to make relationship with them, provide timely information and follow up their related results so that they can carry out corrective measures, increase customer loyalty and gain more profit (S.-Y. Hung, W.-H. Hung, Tsai, & Jiang, 2010). Also, CRM is a way to maximize patients' satisfaction through identifying patients' needs and providing high quality health care services based on patients' preferences (Choi et al., 2013).

A favorable relationship between health care providers and patients not only enhances patients' satisfaction but also improves the quality of health (Almunawar & Anshari, 2012; Beak, 2008). The importance of this issue is to the extent that issues related to CRM such as the provision of care to uninsured individuals, medical/ hospital interactions and customers' satisfaction have been categorized among 9 high priority factors in hospitals (Hung et al., 2010).

2. Objective

Most of the past attempts by hospitals related to the implementation of the CRM have been wrongly directed and supported (Young, 2007). It is therefore necessary to investigate and prioritize affairs required for establishing and implementing CRM. This study aims to investigate the relationship between the dimensions of CRM in hospital wards and patients' loyalty in order to help managers identify influential dimensions of this technique on patients and their loyalty.

3. Methods

This cross sectional and descriptive-analytical study conducted in 2014 aimed to investigate the relationship between customer relationship management and patients' loyalty. The study was conducted in 34 inpatient wards in selected hospitals affiliated to Tehran University of medical sciences. Nurses (N=429) and patients (N=4127) in inpatient wards in the studied hospitals were the population of this study. In order to determine the sample size, at first the Morgan's table and stratified random sampling method were used and the total number of sample for all hospitals were calculated (S=583) (S $_{Nurse}$= 224 & S $_{Patients}$=359). In each hospital, the number of nurses and patients were determined in terms of wards and this number of sample size proportional to the number of nurses and patients was distributed.

Two questionnaires including the CRM questionnaire and the patient loyalty questionnaire were used to gather data. The CRM questionnaire was a researcher-drafted one consisting of two parts. The first part included demographic information of participants and the second part was consisted of 42 questions in 5 areas - organizational indicators (9 questions), service-providing process (9 questions), human resources (12 questions), information technology (6 questions) and knowledge management (6 questions). This questionnaire was designed based on the 5-point Likert scale consisting of very high (5 point), high (4 point), moderately (3 point), low (2 point) and very low (1 point). The validity of the questionnaire which was based on the collective judgment of scholars and experts and by using the content validity index (CVI) was calculated to be 84%. Also, in order to assess the reliability of the questionnaire, the Cronbach's alpha was calculated to be 96%. As to measure patients' loyalty, the questionnaire used by Tabibi et al. (Tabibi et al., 2009) was used which consisted of 5 questions; that validity and reliability   the Cronbach's alpha was calculated to be 86%.

The researcher distributed the CRM questionnaire among nurses working in morning, evening and night shifts in 34 inpatient wards in the studied hospitals. Also, the patients' loyalty questionnaire was distributed among the hospitalized patients at the point of discharge in these 34 wards.

The SPSS 20 software and descriptive and inferential statistical methods were used to analyze data. Descriptive statistics were used to draw the frequency distribution tables and inferential statistics were used to determine differences and the relationship between variables. The Kolmogorov-Smirnov test (KS-test) was used to assess the normality of the scores distribution. Also, Pearson's and Spearman's correlation test were performed to assess the correlation between variables. To address ethical and legal issues, a letter of permission was issued by the relevant university. Also, the participants were given sufficient explanations and they were assured that the

questionnaires information will be kept confidential.

4. Results

Among the nurses, 96% were female, 50% were married and 96% had a Bachelor of Science degree in nursing; 88% were nursing experts and 9% were head nurses. The average age of the nurses was 30.54±5.1 years and the average years of work experience among them was 6.8±4.8 years. Among the patients, 52% were female, 85% were married, 18% had college degrees, 43% were housewives, 41% were salaried employees in the public and private sectors, 62% were over the age of 40. Among the 93% of those covered by the health insurance, 73% had basic health insurance and 27% of them were covered by complementary health insurance, besides the basic health insurance.

Among the 34 studied wards, the mean score of loyalty was 3.43; the mean score of organizational indicators was 3.39; the mean score of service process was 3.48; the mean score of human resources was 3.77; the mean score of information technology was 3.44; the mean score of the knowledge management was 3.34 and the mean score of CRM was 3.52. The highest attainable score was 5.

The Kolmogorov-Smirnov test showed that all the scores of loyalty, organizational indicators, service- providing process, human resources, information technology, knowledge management and the customer relationship management were normally distributed.

Table 1. Results of Kolmogorov-Smirnov normality test for the variables of loyalty and CRM and its 5 areas in the studied hospitals

Variable	Kolmogorov- Smirnov			Mean
	Statistics	Df	Sig.	
Loyalty	0.07	34	0.2	3.43
Organizational indicators	0.08	34	0.2	3.39
Service providing process	0.09	34	0.2	3.48
Human resources	0.10	34	0.2	3.77
Information technology	0.09	34	0.2	3.44
Knowledge management	0.10	34	0.2	3.34
CRM	0.10	34	0.2	3.52

Table 2. The correlation between the customer relationship management and its components and patients' loyalty in the studied hospitals

		Loyalty	Organizational Indicators	Service-Providing Process	Human Resources	Information Technology	Knowledge Management	CRM
Loyalty	Pearson's correlation	1	0.3	0.34*	0.40*	0.2	0.3	0.36*
	decision criterion (2-tailed)		0.1	0.04	0.002	0.2	0.1	0.038
Organizational indicators	Pearson's correlation		1	0.81**	0.6	0.7	0.8	0.9
	decision criterion (2-tailed)			0.001	0.006	0.001	0.008	0.003
Service-providing process	Pearson's correlation			1	0.81**	0.6	0.7	0.9
	decision criterion (2-tailed)				0.004	0.003	0.001	0.001

Human resources	Pearson's correlation	1	0.84**	0.63**	0.86**
	decision criterion (2-tailed)		0.003	0.002	0.001
Information technology	Pearson's correlation		1	0.776**	0.877**
	decision criterion (2-tailed)			0.004	0.002
Knowledge management	Pearson's correlation			1	0.889**
	decision criterion (2-tailed)				0.001
CRM	Pearson's correlation				1
	decision criterion (2-tailed)				-

* Correlation is significant at the 0.05 level (2-tailed);

** Correlation is significant at the 0.01 level (2-tailed).

The findings of Table 2 indicates that there was no statistically significant relationship between the level of patients' loyalty and organizational indicators, information technology and knowledge management (P Value>0.05). However, there was a statistically significant relationship between loyalty and the dimensions of the service-providing process (P Value=0.04), human resources (P Value=0.002) and the CRM (P Value=0.038).

The assessment of the correlation between the CRM components with each other and with CRM also indicates that there is also a significant relationship between all these components. This is while the dimensions of organizational indicators and the service-providing process showed the highest correlation with CRM (90 percent) and the dimension of human resources showed the lowest correlation with CRM (86 percent).

5. Discussion

The results of the study showed that there is a statistically significant difference between the level of loyalty among male and female in the studied population (P Value=0.02). However, there is no statistically significant correlation between demographic features including marital status, age, the status of insurance and the type of insurance, the level of education and the status of employment with patients' loyalty. This issue indicates that the perception among patients in various groups in the studied population is nearly the same.

There is no statistically significant relationship between the level of patients' loyalty and organizational indicators, information technology and knowledge management. However, there is a statistically significant and positive relationship between loyalty and the dimensions of the service-providing process, human resources and the CRM. There is also significant relationship between CRM and all its components; while the dimensions of organizational indicators and the service-providing process showed the highest correlation with the CRM. In other words, there is a significant relationship between customer relationship management and patients' loyalty, however, no relationship was observed in the areas of organizational indicators, information technology and knowledge management. It may be concluded that patients can well understand the two areas of human resources and service-providing process and express their opinion in this regard. However, the areas of organizational indicators, information technology and knowledge management are not observable and understandable for patients.

There are strong correlations between customer relationship management and its dimensions (organizational indicators, the service-providing process, human resources, information technology and knowledge management).

Consistent with these results, Foss also regarded the cooperation among various sections, as one of the

components of organizational indicators, as a necessary approach for customer relationship management (Foss, Stone, & Ekinci, 2008). Dewhurst et al. stated in their study that information technology has facilitated and increased the relationship with customers in various ways and has enabled organizations for personalization (Dewhurst, Martínez Lorente, & Dale, 1999). In a study on success factors in customer relationship management in hospitals conducted by Hung et al. considered the existence of knowledge management in hospitals as a necessary component for the success of CRM (Hung et al., 2010). In this regard, Hussain et al. also acknowledged the importance of human resources and the way of providing services (Hussain et al., 2014).

The results of the Pearson's correlation test show that there is a significant correlation between customer relationship management and patients' loyalty to the medical ward.

Cobelas et al. concluded that when a hospital meets a patient's needs at a higher level than he/she expects, then this patient will not change the hospital (Cobelas et al., 2001). Adeleke (Adeleke & Aminu, 2012) introduced three factors of 'the quality of services', 'customer satisfaction' and 'the perception of participation' as three main factors of customer loyalty. The customer relationship management is a tool creating these three factors, so these findings are consistent with those of this study.

Also, Galbreath and Rogers have considered 'customization', 'customized communication' (personalization for the individual customer) and 'providing after sales support services' as the three main goals of customer relationship management (Galbreath & Rogers, 1999). Paazine stated that the improvement in customer services, cost reduction as well as customer retention and loyalty are the basic aims of implementing CRM in hospitals (Paazine, 2011). The results of this study are also consistent with those of the current study. Furthermore, in a study conducted by Gbadeyan, stated that CRM has had a significant impact on the quality of hospital services in Nigeria which in turn creates patient satisfaction and loyalty (Gbadeyan, 2010).

A significant relationship between the component of service-providing processes and loyalty was observed. Arab et al. have reported the process quality as one of the dimensions influencing loyalty (Arab et al., 2012). Kessler and Mylod (Kessler & Mylod, 2011) also stated that the process of service provision plays an important role in the patients' perception of the quality of services which is consistent with the results of the current study.

Also, a significant relationship was observed between the components of human resources and loyalty. Ayimbillah Atinga et al. (Ayimbillah Atinga, Abekah-Nkrumah, & Ameyaw Domfeh, 2011) considered the lack of opportunity to ask personal questions, limited time spent with physician and the behavior of physician as the main reasons for patient dissatisfaction with hospitals. Arab et al. (Arab et al., 2012) also proved that a strong positive relationship exists between the score of patient loyalty and the dimension of interactive quality (the quality of interaction between staff and patients). The results of these two studies are also consistent with those of the current study.

Despite the significant relationship between CRM and patient loyalty, there is no significant relationship between three components (KM, OI, IT) with patient loyalty. The cause should be sought in objectives and functions of these three components in hospitals. These three components, unlike the other two components (HR, SP), are not tangible and understandable for hospitalized patients, but patients have a direct and understandable relationship with human resources and service-providing processes. Hussain et al. (Hussain et al., 2014) also acknowledged the influence of human resources and the way of providing health services on patients. These three components can be considered as factors supporting and strengthening two components (HR, SP). Also, Kaufman in a report on the impact of internet and information technology on diabetes treatment stated that they can be applied as effective tools for better treatment of more number of patients (Kaufman, 2010). Choi et al. in their study mentioned that there is a significant relationship between the quality of information and the quality of services with consumers' perceived benefit and satisfaction; Consequently the perceived benefit and satisfaction have considerable impact on individual and organizational performance (Choi et al., 2013). Bahadori et al. also emphasized the importance of organizational structures on the improvement of quality and services for patients' satisfaction (Bahadori, Yaghoubi, Javadi, & Rahimi, 2015). Indeed, these three components are considered as tools for human resources in hospitals.

6. Conclusion

Customer relationship management can be applied to enhance patients' loyalty; while, two areas of human resources and service-providing process can directly affect patient loyalty, three areas including organizational indicators, information technology and knowledge management are considered as factors influencing patient loyalty to medical wards indirectly.

In order to improve customer relationship management, all its areas should go further in the same direction. In

addition, human resources and their functions are considered as the most important dimensions of patient satisfaction and loyalty. It can therefore be concluded that in order to implement CRM, firstly managers should focus on human resources and service-providing processes. However, in long terms, they should know that improvements in these two dimensions requires strong support by knowledge management, information technology and appropriate organizational structures.

Limitations

The lack of a hospital in which the CRM has been completely implemented is a limitation of this study, so that each hospital had taken steps in achieving the CRM, so inpatient wards in participating hospitals were selected for the setting of the study.

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Histological Stains: A Literature Review and Case Study

Hani A Alturkistani[1], Faris M Tashkandi[1] & Zuhair M Mohammedsaleh[2]

[1] Faculty of Medicine, King Abdulaziz University, Jeddah, Saudi Arabia

[2] Faculty of Applied Medical Sciences, University of Tabuk, Tabuk, Saudi Arabia

Correspondence: Zuhair Mohammedsaleh, Faculty of Applied Medical Sciences , University of Tabuk, Tabuk, Saudi Arabia. E-mail: zuhair.saleh966@gmail.com

Abstract

The history of histology indicates that there have been significant changes in the techniques used for histological staining through chemical, molecular biology assays and immunological techniques, collectively referred to as histochemistry. Early histologists used the readily available chemicals to prepare tissues for microscopic studies; these laboratory chemicals were potassium dichromate, alcohol and the mercuric chloride to harden cellular tissues. Staining techniques used were carmine, silver nitrate, Giemsa, Trichrome Stains, Gram Stain and Hematoxylin among others.

The purpose of this research was to assess past and current literature reviews, as well as case studies, with the aim of informing ways in which histological stains have been improved in the modern age. Results from the literature review has indicated that there has been an improvement in histopathology and histotechnology in stains used. There has been a rising need for efficient, accurate and less complex staining procedures. Many stain procedures are still in use today, and many others have been replaced with new immunostaining, molecular, non-culture and other advanced staining techniques. Some staining methods have been abandoned because the chemicals required have been medically proven to be toxic. The case studies indicated that in modern histology a combination of different stain techniques are used to enhance the effectiveness of the staining process. Currently, improved histological stains, have been modified and combined with other stains to improve their effectiveness.

Keywords: histological staining, histology, histopathology, histochemistry

1. Introduction

Histology is the microscopic study of animal and plant cell and tissues through staining and sectioning and examining them under a microscope (electron or light microscope). There are various methods used to study tissue characteristics and microscopic structures of the cells. Histological studies are used in forensic investigations, autopsy, diagnosis and in education. In addition, histology is used extensively in medicine especially in the study of diseased tissues to aid treatment (Black, 2012).

Histological staining is a series of technique processes undertaken in the preparation of sample tissues by staining using histological stains to aid in the microscope study (Anderson, 2011). The process of histological staining takes five key stages which involve; fixation, processing, embedding, sectioning and staining (Titford, 2009). Great changes have been done on techniques used for histological staining through chemical, molecular biology assays and immunological techniques collectively and have facilitated greatly in the study of organs and tissues (Shostak, 2013).

2. Specific Aspects of Histopathology

2.1 Staining

Staining is used to highlight important features of the tissue as well as to enhance the tissue contrast. Hematoxylin is a basic dye that is commonly used in this process and stains the nuclei giving it a bluish color while eosin (another stain dye used in histology) stains the cell's nucleus giving it a pinkish stain. However, there are other several staining technicques used for particular cells and components (Black, 2012). Staining is a commonly used medical process in the medical diagnosis of tumors in which a dye color is applied on the posterior and anterior border of the sample tissues to locate the diseased or tumorous cells or other pathological cells (Musumeci, 2014). In biological studies staining is used to mark cells and to flag nucleic acids, proteins or

the gel electrophoresis to aid in the microscopic examination (Jackson & Blythe, 2013). In some cases, various multiple staining methods are used such as differential staining, double staining or the multiple staining (Iyiola & Avwioro, 2011).

2.2 Fixation

In histology, fixation refers to the use of chemicals to preserve the natural tissue structure and maintain the cell structure from degradation. Mostly, neutral buffered formalin is used in this case when a light microscope is to be used to conduct the study. Fixatives enhance the preservation of tissues and cells through an irreversible process through cross-linking proteins. However, while the process serves to preserve the structure of the cell for the purpose of histological studies, it has been found to destroy and denature proteins rendering them dysfunctional (Young, O'Dowd, & Stewart, 2010). Formalin fixation denatures the DNA, miRNA and the mRNA tissues and extraction of these components for the purpose of histology may lead to flawed results (Anderson, 2011).

The fixation phase retains the chemical composition of the tissues, hardens the cells or tissues for sectioning and delays degradation (Titford, 2009). In addition, fixatives changes tissue penetration and influence antigen exposures which may be productive or detrimental (Iyiola & Avwioro, 2011). These fixatives are administered in two ways: through perfusion and immersion of the prepared tissue. These fixatives are infused in the animals' body through diffusion. Perfusion is a slower process, require more time and only one fixative can be used at a time (Shostak, 2013). There are a number of fixatives in use, but the formaldehyde fixatives are the most commonly used (Black, 2012). The neutral buffered formalin (NBF) stabilizes amino acids in proteins and offers good tissues and cell structure preservation. The paraffin-formalin (paraformaldehyde- PFA) is effective in immunostaining but requires it to be freshly prepared to enhance its effectiveness (Iyiola & Avwioro, 2011). The Bouin fixative has been found to be effective in delicate and soft tissues such as small tissues, embryo and brain tissues (Musumeci, 2014). Bouin fixative offers good preservation of nuclei and the glycogen, but its penetrations are slow and distorts mitochondria and the kidney tissues (Weiss, Delcour, Meyer, & Klopfleisch, 2010).

Dehydration: In this step, the aim is to remove water from the selected tissues to solidify them and facilitate the cutting of thin sections of slides, more thinly for use in light microscopes and thick for the electron microscope. Water is removed from the tissues through the dehydration method through ethanol (Shostak, 2013). The process is repeated through a hydrophobic clearing substance such as xylene to remove the alcohol and paraffin wax and the infiltrated agent. Resins are used to enhance cutting of thin sections of the tissues (Titford, 2009).

Embedding: In staining, the process of embedding is done using paraffin wax to enhance easier extraction of cellular structures. In complex cellular tissues, plastic resin or wax is used, or combinations of fixatives are used to produce good morphology (Musumeci, 2014). However, these fixatives may lead to degradation of the cell and tissue structures due to prolonged heating, and this may lead to problems when conducting the hybridization process arising from the unstable RNA. In the same line, the infiltration of paraffin wax leads to inhibition of the penetration of antibody, chemical other fixatives. In order to alleviate this problem, freezing of tissues after the embedding, removing wax after staining and the use of PFA fixatives offers a reliable solution to improved morphology (Titford, 2009).

Sectioning: In histology sectioning refers to the preparation of 'ribbon' like microtomes of a tissue for the purpose of mounting it on a microscope slide for examination (Cai, Caswell, & Prescott, 2014). In this case, a series of thin sections of tissues of required thickness are cut and prepared through the paraffin method.

Antigens Retrieval: This is the next process after fixation and embedding and focuses on retrieving antigens that have been masked. When formalin fixatives are used as well as other aldehyde fixations the cross-linking of proteins leads to masking of the antigen sites, and this leads to weaker immunohistochemical staining. The antigen retrieval process serves to break protein cross-links and unmask the epitopes and the antigens that were fixed and embedded using formalin and paraffin (Titford, 2009). The overall strategy is to improve on the staining intensity of the antibodies (Cai, Caswell, & Prescott, 2014).

The commonly used antigen retrieval techniques are through heat-induced and proteolytic retrieval methods. The proteolysis digestion process should take the minimal dosage and time possible to avoid over digestion that may denature the tissue structures and the epitopes (Musumeci, 2014). The heat method leads to protein denaturalization and in some cases antigens are lost (Black, 2012). Similarly, heating may lead to the reversal of the chemical modifications induced during the fixation period. Heating from such devices as microwaves leads to chemical reactions of the protein structure (Shostak, 2013). However, a combination of enzymatic and heat retrieval methods lead to effective staining intensity (Godwin, 2011).

2.3 Gross and Microscopic Examination

The gross examination is a laboratory procedure in which pathological and medical examination is done through visible aspects of the eye. In microscopic examinations, pathological changes are done using a microscope (light or electronic microscope) (Musumeci, 2014). In most aspects, gross examination precedes microscopic examination in the identification of samples for microscopic examination. For instance, gross examination helps the pathologist identify the cells or tissues that have lumps (possibly cancer) but microscopic examination is used to confirm.

2.4 Some Advanced Histological Techniques

In the modern age of histology there have been significant improvements in histological stains and techniques. Advanced histological techniques are immunohistochemistry, antibody binding and electron microscopy (Titford, 2009). In the same line, advanced stains include: immunohistochemical (IHC), routine hematoxylin eosin (H&E) and the *in situ* hybridization (Musumeci, 2014). Modern stains used are;

- Masson's Stain used in connective tissues
- Golgi Stain used in neuronal fibres
- Toluidine Blue
- Immunological labeling that have fluorescent or enzymatic stains
- Kluver-Barrera Stain used in Lipofuscin
- Mallory's CT Stain
- Periodic Acid-Schiff (PAS) Stain used in carbohydrates.

2.5 Regulations of Histologic in Different Countries

Most countries have standards and organizations that collaborate with national and international groups involved in the control and standardization of biological staining methods. Standardization is important in setting uniform criteria, methods and technical specifications of the stains used. The objective is to enhance establishment of procedures that produce stain substances that produce microscopic results capable of been reproducible in different countries in areas of cytology, bacteriology, histopathology and hematology (Lyon & Horobin, 2010) .

Formal regulatory bodies that standardize stains and are independent of manufacturers are: International Organization for Standardization (ISO), European Committee for Standardization (CEN) and the American National Standards Institute (ANSI). Other bodies involved in the standardization of staining substances are: the USA Clinical Laboratory Standards Institute (CLSI), the World Health Organization (WHO) and the European Diagnostic Manufacturers Association (EDMA) among others. These regulatory bodies accredit, evaluate and approve manufacture and the use of staining dyes, antibodies, fluorochromes and the nucleic acid probes (Lyon & Horobin, 2010).

2.6 Objectives of the Study

A background study on commonly used histological staining techniques and stains indicate that some fixatives and techniques used in the histological processes are effective. However, some stains and processes are ineffective, and this leads to denaturalizationof tissues and cells which inhibit effective histological studies. The objective of this research was to assess past and current literature reviews and cases in the aim of informing ways in which histological stains have been improved in the modern histopathology. As a result, this study focuses on conducting an extensive and qualitative case study of past and present histological processes with the aim of understanding how histological strains could be improved.

3. Methodology

The research used an extensive exploration and review of historical, recent and current medical research studies and case studies in order to collect quantitative and qualitative data in regard to histological stains used in the past and recent cases (Silverman, 2011). In this case, a database of clinical pathology journals involving past and recent usage of histological stains was made. The identified pathological journals, articles, and case studies were reviewed, analyzed, and important trends in the use of histological stains were made. As such, through integrative and intensive literature and case study reviews rich, data were collected in regard to stains used in the past and present to consider how histological stains should be improved. This triangulation helps to gather and assess in-depth data on past, present and future stain and staining techniques (Silverman, 2011).

4. Literature Review

4.1 Historical Histological Staining Techniques in Medicine and Biological Studies

The history of staining indicates that the application of histological techniques is a relatively new area of diseases diagnosis (Rodrigues et al., 2009). Historical staining techniques by early pathologists and surgeons were borrowed from a seventeen scientist Leeuwenhoek, who was instrumental in histology using substances such as Madder, indigo and saffron to stain tissues and using rudimentary microscopes to study them (Titford, 2009). These categories of early researchers used the microanatomy to draw a relationship among differences in cells as well as delineating a normal plant cell structure from that of the animal (Bancroft & Layton, 2013).

Later, newer techniques were devised to enhance the study of cell structure in detail using various laboratory chemicals to preserve tissues in their natural form before staining (Titford & Bowman, 2012). Joseph Von Gerlach was viewed as the pioneer of microscopical staining in 1858 when he used ammoniacal carmine successfully to stain cerebellum cells (Costa, Brito, Gomes, & Caliari, 2010).

The early histologists used the readily available chemicals to prepare tissues for microscopic studies; these laboratory chemicals were potassium dichromate, alcohol and the mercuric chloride to hard cellular tissues (Iyiola & Avwioro, 2011). These fixatives and staining agents were ingenious and after a period colored staining agents were developed which are still applicable in current laboratory staining techniques (Black, 2012). Examples of these ingenious colored stains still in use include the trichrome that is used in the liver and renal biopsies as well as the silver nitrate that is used in other organisms (Musumeci, 2014).

Great development in histologic stains was shaped by the improved technologic development of microscopes and the establishment of the histologic stains (aniline dye) in 1856 in Germany which manufacture a variety of new histological stains (Shostak, 2013). At the same time, research and knowledge relating to anatomy and tissues of the human body increased, and this knowledge was used to further research into new-histological techniques for the study of diseased tissue (Titford, 2009).

In the wake of the nineteenth century, many medical centers hired physicians, pathologists and surgeons to handle surgical issues (Titford & Bowman, 2012). It is this crop of pathologists who devised intraoperative staining techniques for frozen tissues sections by adapting a special staining technique in histopathology. It is during this time that the paraffin infiltration staining technique was devised (Shostak, 2013). Owing to this achievement, the non-malignant and the malignant tumors were studied, and a bacterium was identified as the causal organism of the disease in the nineteenth century (Godwin, 2011).

The Gram staining method was named after a Danish inventor Hans Christian Gram, who invented it as an approach to differentiating bacteria species in 1875 (Anderson, 2011). It is while working at the city morgue with his colleagues that Gram devised the technique of staining for the purpose of distinguishing the type of bacterium infection and also as a way of making the bacteria visible on selected and stained lung tissues during examination (Black, 2012). Although this technique was found unsuitable for certain bacterium organisms, it is still used today and competes fairly with modern molecular techniques of histology (Shostak, 2013).

4.2 Important Histological Stains Used in the Past and Present

Carmine

It is a commonly used stain in histology used by early botanists such as John Hill in their studies in 1770s (Jackson & Blythe, 2013). The stain was used to study microscopic tissue structures when in ammoniacal solution form and it is still used today in histologic studies. In particular, the stain was used widely by Rudolph Virchow (1821–1902) in microscopic studies; Virchow is considered as the 'father of pathology' (Musumeci, 2014).

Hematin and Hematoxylin

These are naturally occurring substances that have been in use in the history of histopathology (Titford, 2009). The stain was developed by Wilhelm von Waldeyer in 1863 and was obtained from a log tree found in Central America. Hematoxylin is a weak stain and is used with a combination of other solutions in oxidized form (Shostak, 2013).

In particular, the stain is combined with an oxidizer mordant to enhance its differentiating capacity of cell components; these solutions are called Hematoxylin. The versatility of the stain has enhanced the development of various Hematoxylin methods (Titford & Bowman, 2012). Historically, Hematoxylin was made into a nuclear stain that had shorter staining time and was resistant to acidic solutions; this made it suitable for histologic stain techniques requiring several steps (Anderson, 2011).

Silver Nitrate

Silver Nitrate has had a long usage in historical staining techniques and is still used in modern pathology. Initially, early researchers used silver nitrate to enhance the visibility of the tissue structure while studying it; this was done by applying solid silver nitrate on a tissue and then studying it (Titford & Bowman, 2012). The stain substance has been developed for many compounds, and confirmatory tests are needed when silver nitrate is used (Shostak, 2013). Silver nitrate stain has also been found to be reduced by argentaffin cells found in the epithelial linings of lungs, intestines, melanin and others (Musumeci, 2014).

However, methods have been devised to 'tailor' these tissues to avoid argyrophilic reactions when silver nitrate is used during staining process (Titford, 2009). In particular, methods such as the Gomori reticulin methods and the Grocott-Gomori method were devised to assess missing tissues and diseases in the liver and the rectum (Nadworny, Wang, Tredget, & Robert, 2010).

Other Staining Procedures That Were Developed Recently

The Hematoxylin and Eosin Procedures

Although historically used, there have been great laboratory changes in Hematoxylin stains; nearly all tissue specimens are treated with Hematoxylin and Eosin today (Bancroft & Layton, 2013). In addition, various Hematoxylin methods have been developed but all follow the same approach of staining tissue specimens in a hematoxylin, alcohol and tap or alkaline water to clear argentaffin agents. It has been found that most histopathological processes could be studied using the Hematoxylin and Eosin procedures (Titford & Bowman, 2012). In the same line, the method is quick to execute, cheap and can be altered. However, the Hematoxylin and Eosin are inefficient in that not all features of a substance can be received and special stains must be used (Musumeci, 2014).

Romanowsky Stains–Giemsa Stains

They were developed in the 1891 by Dimitri Romanowsky and popular for its multicolor in identifying blood parasites. The Giemsa Stains procedure is still used today. There has been great improvement in the stains, and its various methods make it applicable in paraffin-embedded, formalin-fixed and bone marrow biopsies (Musumeci, 2014).

Gram Stain

The Gram staining method was named after a Danish inventor Hans Christian Gram, who invented it as an approach to differentiating bacteria species in 1875 (Musumeci, 2014) . Gram devised the technique of staining for the purpose of distinguishing the type of bacterium infection and also as a way of making the bacteria visible on selected and stained lung tissues during examination (Shostak, 2013). Although this technique was found unsuitable for certain bacterium organisms, it is still used today and competes fairly with modern molecular techniques of histology (Rudijanto, 2007). However, Gram technique is infallibly limited in the application on matters of environmental microbiology (Titford, 2009). That aside, Gram techniques had had success when performed on biopsy of infected parts and produced results quickly especially when there is a significant difference in prognosis and treatment. The method is often used in modern histology especially in paraffin fixatives for tissue sectioning (Titford & Bowman, 2012). In a recent case in Kuwait, the Gram staining technique was particularly effective in the diagnosis of Gonorrhea giving 99.4% effective results (Iyiola & Avwioro, 2011). The method is still used today especially with paraffin sections and has been modified to suit different substances.

Trichrome Stains

Historical assessment on the use of various stains in histology indicates that most pathologists were attracted by stains that gave multicolored results on the tissue specimens. As such, trichrome stains were developed from this need (Shostak, 2013). There have been various multiple stains such as blue–eosin, "triacid stain" by Ehrlich's (1888) and Masson's trichrome stain that has been popular in the modern histology. Trichrome stains show how complex the staining methods have become in the search of an efficient and consistent stain that would show fine, differentiated tissues (Musumeci, 2014).

4.3 Case Study Reviews

Case Study 1

This study was done in order to compare different staining methods and assess their effectiveness. The specific aim was to assess if the newly developed staining methods, the *Helicobacter pylori* silver stain HpSS methods and the modified McMullen's methods in the identification of H pylori organism. The method involved selecting

tissue sections of gastric biopsies of 63 patients diagnosed with dyspepsia. The section tissues were stained using the four staining methods. In all the 63 cases, 30 sections tested positive for Helicobacter pylori while 30 tested negative for all cases of pylori infection while the remaining were tested using a combination of five histological tests (Anderson, 2011) . The results indicated that, the interobserver stain method was the best for antibodies at 98%, followed by Giemsa at 87%, then the HpSS at 85%. At gold standard level, it was found that the Giemsa stain method was the best followed by McMullen's method (Rotimi, Cairns, Gray, Moayyedi, & Dixon, 2000). The study conclusions were that in all cases of staining, the *H pylori* infection was revealed; however, the modified Giemsa stain was the most effective for its sensitivity, ease of use, reproducibility and cost-effectiveness.

Case Study 2

The aim was to investigate the difference in capacity among different stains: Hematoxylin and Eosin, toluidine blue Stain, neuron-specific enolase (NSE) immunostaining and the S 100 protein. These stains were applied to assess the presence of neurons and mast cells in acute appendices Specimens were collected from clinically acute appendices categorized as histologically positive and negative. In the study all the 50 appendix specimens sections were subjected to Hematoxylin and Eosin, toluidine blue Stain, neuron-specific enolase (NSE) immunostaining and the S 100 protein. Hematoxylin and Eosin were applied as a routine stain for general study of the tissues while Toluidine blue stain was applied to enhance the easier study of mast cells. In addition, neuron-specific enolase (NSE) immunostaining was used as a marker and as well as the S 100 protein.

The results indicated that when comparing Hematoxylin and Eosin stain with S 100 they? showed 100% accuracy in identifying the denatured mucosal cells. However, the combination of these different staining methods resulted in a supplementary technique effective than the conventional staining method in observing changes and the pattern of diseased cells as well as the morphological shape of nerve fibers in the inflamed appendices (Russell & Gordon, 2009). In addition, the use of the several staining methods aided in confirming results of earlier stain diagnosis.

5. Results and Discussion

The literature review on staining techniques indicates that there has been great improvement in the histopathology and histotechnology. Historically, staining techniques used were carmine, silver nitrate, Giemsa, Trichrome Stains, Gram Stain and Hematoxylin among others (Titford & Bowman, 2012). These staining techniques are still in use although several modifications have been made to improve their efficiency. In other cases, some stain methods used earlier have been abandoned as they were toxic. Several staining techniques have been established to improve the staining methods.

There has been a rising need for efficient, accurate and less complex staining procedures (Harris & McCormick, 2010). The histopathology lab today is laden with a great work load and different types of histological assignments (Musumeci, 2014). As such, most histologists are more trained on special stains for particular works to give efficient results (Morelli, Porazzi, Ruspini, Restelli, & Banfi, 2013). In the history of histology, a great shift and development in histologic stains were shaped by improved technologic development of microscopes and the establishment of the histologic stains factory (aniline dye) in 1856 in Germany which manufactured variety of new-histological stains (Godwin, 2011) .

These pathologists devised intraoperative staining techniques for frozen tissues sections by adapting a special staining technique in histopathology (Loreto, Leonardi, Musumeci, Pannone, & Castorina, 2013). It is during this time that the paraffin infiltration staining technique was devised (Titford, 2009). While these changes have taken place, there are old stain procedures that are still in use today and many others have been replaced with new immunal or staining techniques.

Additionally, the complexity of stains has been enhanced for the purpose of efficient and consistent staining processes that show fine and differentiated tissues (Ntziachristos, 2010).

6. Summary

Histological staining is a commonly used medical process in pathological diagnosis and forensic studies. The process of histological staining takes five key stages, and they include fixation, processing, embedding, sectioning and staining. Early histologists used the readily available chemicals to prepare tissues for microscopic studies; these laboratory chemicals were potassium dichromate, alcohol and the mercuric chloride to hard cellular tissues. These fixatives and staining agents were ingenious and after a period colored staining agents were developed which are still applicable in the laboratory staining techniques today.

Staining techniques used were; carmine, silver nitrate, Giemsa, Trichrome Stains, Gram Stain and Hematoxylin

among others. There have been great changes in the techniques used for histological staining through chemical, molecular biology assays and immunological techniques collectively referred to us histochemistry and have facilitated greatly in the study of organs and tissues. Hematoxylin is a basic dye that is commonly used in this process and stains the nuclei giving it a bluish color while eosin (another stain dye used in histology) stains the cell's nucleus giving it a pinkish stain (Victor, 2013). While these changes have taken place, there are old stain procedures that are still in use today and many others have been replaced with new immunalstaining or staining techniques (Sine, 2014).

Some staining methods have been abandoned because the chemicals required have been medically proven to be toxic. Similarly, there have been great changes in workload requiring more advanced technics of staining. The case studies indicate that, in the modern histology a combination of different stain techniques are used to enhance the effectiveness of the staining process. In the modern histologic as a way of improving histological stains, several stains have been modified and combined with other stains to improve their effectiveness.

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Clinical Factors Influencing the Efficacy of Systemic Moxifloxacin in the Therapy of Patients With Generalized Aggressive Periodontitis: A Multilevel Analysis From a Clinical Trial

Carlos M. Ardila[1] & Isabel C. Guzmán[1]

[1] Biomedical Stomatology Research Group, Department of Periodontology, School of Dentistry, Universidad de Antioquia U de A, Medellín, Colombia

Correspondence: Carlos Martín Ardila, Universidad de Antioquia U de A, Medellín, Colombia, Calle 70 No. 52-21, Medellín 057, Colombia. Tel: 57-42-196-700. E-mail: martin.ardila@udea.edu.co

Abstract

Background: It has been reported that clinical results of mechanical periodontal treatment could differ between subjects and among different sites of the tooth in the patient. The objective of this multilevel analysis is to investigate clinical factors at subject and sites of the tooth that influence variations in clinical attachment (CAL) increase and probing depth (PD) diminution of adjunctive moxifloxacin (MOX) at six months post-treatment in generalized aggressive periodontitis.

Methods: This clinical trial included 40 patients randomly distributed to two therapy protocols: scaling and root planing alone or combined with MOX. Multilevel linear models for continuous variables were formulated to evaluate the clinical impact of the hierarchical configuration of periodontal data.

Results: Six months following therapy, the divergences between both protocols were statistically significant in PD diminution and CAL increase, favouring the MOX therapy (p<0.001). Besides, the multilevel analysis revealed that adjunctive MOX at the subject level, non-molar and the interaction non-molar x MOX at the tooth level, interproximal sites and the interaction interproximal sites x MOX at the site level, were statistically significant factors in determining CAL increase and PD diminution.

Conclusions: The main cause of variability in CAL gain and PD reduction following adjunctive MOX was attributable to the tooth level. Adjunctive MOX and their interactions with non-molar and interproximal sites showed higher clinical benefits at the tooth and site levels which could be essential for PD reduction and CAL gain in generalized aggressive periodontitis subjects.

Keywords: clinical trial, generalized aggressive periodontitis, moxifloxacin; multilevel analysis

1. Introduction

Aggressive periodontitis shows a rapid attachment loss related to compromised host immune reaction and greatly pathogenic microorganisms (Teughels, Dhondt, Dekeyser, & Quirynen, 2014). A recent systematic review and meta-analysis indicated that for the management of aggressive periodontitis subjects, adjunctive antibiotics plus mechanical therapy occasioned a considerable supplementary benefit than mechanical treatment alone; a tendency presented that amoxicillin plus metronidazole (AMOX+METRO) is the most effective antimicrobial protocol (Keestra, Grosjean, Coucke, Quirynen, & Teughels, 2014). Also, a clinical study documented that systemic moxifloxacin (MOX) leads to better advantages than scaling and root planing (SRP) in subjects with aggressive periodontitis (GAgP) (Ardila et al., 2015). Adjunctive AMOX+METRO (Keestra et al., 2014; Guerrero et al., 2005) and MOX (Ardila et al., 2015) have showed higher benefits in clinical attachment level (CAL) increase and probing depth (PD) diminution in comparison to SRP alone in aggressive periodontitis.

Nevertheless, it has been reported that clinical results of mechanical therapy could differ not simply among subjects but likewise among different sites of the tooth in the patient (Van der Weijden & Timmerman, 2002). This concern has been elucidated by various researchers in periodontitis patients treated with SRP, adjunctive antibiotics, surgical therapy and combinations of these therapies (D'Aiuto, Ready, Parkar, & Tonetti, 2005; Tomasi, Koutouzis, & Wennström, 2007; Mdala et al., 2012; Kim, Schenk, Lungeanu, Reitmeir, & Eickholz,

2007; Mombelli et al., 2013). Most of these clinical studies have contemplated chronic periodontitis patients, but almost nothing is known in aggressive periodontitis subjects. Also, a meta-analysis (Keestra et al., 2014) indicated that the efficacy of AMOX+MET in aggressive periodontitis subjects is lower after 3 months than the efficacy in chronic periodontitis subjects; nevertheless, the efficacy of AMOX+MET was advanced at six and twelve months in aggressive periodontitis than in chronic periodontitis subjects. Besides, systematic reviews (Herrera et al., 2002; Haffajee et al., 2003) have recommended that the additional advantage estimated from antimicrobial treatment could be better in subjects with aggressive periodontitis. These results could indicate that adjunctive antibiotics have not the same effect in chronic than in aggressive periodontitis patients.

Considering some particularities of aggressive periodontitis, namely, age of beginning, periods of advance, forms of damage and clinical evidence of swelling (Armitage & Cullinan, 2010), among others, the influence of the fundamentally ordered configuration of periodontal figures in the treatment of aggressive periodontitis must be explored. It is coherent to contemplate that based on these particularities periodontal treatment could diverge not simply between individuals but also among tooth sites in aggressive periodontitis patients.

To our understanding, no investigations have assessed the influence of the hierarchical organization of periodontal information in determining the variability of the clinical outcomes after adjunctive MOX in aggressive periodontitis. Also, adjunctive MOX has been scarcely studied in clinical trials, particularly in aggressive periodontitis. Thus, the aim of this multilevel analysis was to investigate clinical factors that influence variations in clinical attachment increase and probing depth diminution of adjunctive MOX compared to SRP alone at six months post-treatment in GAgP patients.

2. Method

Comprehensive descriptions of the clinical trial design containing patients' selection, randomization, allocation, therapy, adherence and clinical evaluation have been previously published (Ardila et al., 2015). A concise description is given here.

2.1 Subjects

The subjects had at minimum twenty teeth, excepting third molars and teeth designated for removal. The study protocol was permitted by the Ethics Board on the Faculty of Dentistry of the Universidad de Antioquia agreeing to the Declaration of Helsinki. All individuals were informed independently concerning the purposes, possible dangers and advantages of the therapies and signed the informed agreement.

The diagnosis of GAgP was made following the recommendations of the American Academy of Periodontology (Armitage, 1999).

2.2 Investigational Scheme and Therapy

Both therapies included mechanical therapy plus adjunctive MOX (400 mg one per day for seven days) or SRP plus placebo (control group) one per day for seven days. An equalized chance block system was accomplished to organize the randomization sequence to evade unequal equilibrium between both therapies. The randomization list was referred to a clinical director no involved in the investigation, which applied the distribution. Consequently, therapy allocations were distributed to numbered obscure packets.

2.3 Clinical Evaluation

Patients were examined at baseline and at six months after treatment. At each checking appointment, detectable plaque, bleeding on probing (BOP), PD and CAL were determined at six sites of each tooth (excepting third molars). The PD and CAL lengths were documented to the closest millimeter by a standardized probe (UNC-15, Hu-Friedy, Chicago, IL).

The same blinded, qualified and standardized clinician completed the evaluation at all appointments for selected patients. The examiner dentist did not execute the treatment on the patients. The intra-examiner concordance was calculated before and through the experimental phase. The intra-class concordance for average CAL and PD were 0.91 and 0.92, correspondingly.

2.4 Primary and Secondary Outcome Variables

In the present multilevel analysis, a change in CAL regarding baseline and six months (ΔCAL) was measured as the primary outcome characteristic. Secondary result variable contained changes for the average variations of PD. Consequently, a difference in PD concerning baseline and six months (ΔPD) was considered as a dependent variable.

The sample size to guarantee sufficient power was estimated contemplating changes of one mm for CAL and a

standard deviation of 1 mm between treatments (Varela et al., 2011). Considering these estimates, it was established that ≥12 patients per protocol would be required to supply 80% power with an α of 0.05. To compensate drop-out proportion, 20 subjects were enlisted per therapy protocol.

2.5 Statistical Analysis

Changes in quantitative and qualitative parameters were assessed by independent t-test (data were distributed normally) and X^2 test, respectively. Independent t-test was executed to define the changes between treatments concerning differences in clinical parameters (CAL and PD). A repeated-measures ANOVA was performed to identify intra-group changes in clinical factors. These analyses were implemented operating a statistical software (Statistical Package for the Social Sciences, version 18, Chicago, IL). The alpha was established to 5%.

Three levels of variability were demarcated: the subject, the tooth, and the site. Patient factors incorporated age (years), gender, plaque and BOP scores and treatments (Adjunctive MOX versus SRP+placebo). Tooth parameters included one categorical variable: molars/non-molars. Site characteristics considered location (interproximal versus buccal/lingual). Variance models (empty models) were created calculating differences in CAL (ΔCAL) and PD (ΔPD) regarding baseline and six months as dependent variables without incorporating explanatory variables. The empty models were computing considering the complete variation of ΔCAL and ΔPD and to assign it to the subject, tooth, and site levels. A sequence of explicatory factors was formerly analysed (multivariate models) in order to calculate the association between each explicatory variable and the dependent variable. When the explanatory variable was statistically significant, the interaction with MOX was also included in the multivariate model.

Consequently, multilevel linear models for continuous variables were analysed, incorporating examinations for the normality of the residuals at the diverse levels. Multicollinearity examination was executed for each independent variable. Regression coefficients were calculated operating iterative general least squares. Nested models were examined for significant advances in model fitting by relating the diminution in -2 log likelihood (-2LL) with a X^2 allocation. All multilevel analyses were completed executing a statistical package (MLwin 2.02, London, UK). The alpha was established to 5%.

3. Results

This experimental study had six months of development. A total of 40 subjects who joined the dental clinics of the Universidad de Antioquia, Medellín, Colombia, were enrolled between February 2012 and August 2013.

Of the 40 patients enrolled, 36 patients had all the information for all examinations while four patients had one absent appointment. Intent-to-treat analyses were executed in the 4 patients with absent information; consequently the final examination was passed forward, offering a total of 40 patients with full information that were involved in the analyses. Flow chart of the trial design was explained earlier (Ardila et al., 2015).

Patients enlisted in the clinical trial described complete adherence to the recommended sequence of MOX and placebo and nobody informed unfavorable episode related with the treatment.

The baseline features of the patients have been formerly presented (Ardila et al., 2015); there were no observed dissimilarities between protocols for socio-demographic characteristics.

The factors related with the three levels that were investigated are specified in Table 1.

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Table 1. Age, gender and baseline parameters associated with patient, tooth and site levels

Parameter	Value
Patients	$N = 40$
Age (mean±SD)	27.4±1
Gender (male/female)	17/23
Treatment (Moxifloxacin/mechanical therapy)	20/20
Plaque score (mean±SD)	44±13
Bleeding on Probing score (mean±SD)	46±13
Tooth	$N = 1079$
Site	$N = 6474$
Probing Depth (mean±SD)	4.3±0.4
Clinical Attachment Level (mean±SD)	4.9±0.5
Position (db/b/mb/dl/l/ml)	1079 each one

SD: standard deviation; db: distobuccal; b: buccal; mb: mesiobuccal; dl: distolingual; l: lingual; ml: mesiolingual.

The data involved 6474 tooth sites at 1079 teeth in 40 patients. Variations in CAL and PD in the two groups through the trial phase are observed in Table 2. In both treatments protocols a significant diminution of PD and CAL increase was observed ($p < 0.0001$), and this change was preserved after six months. The changes between therapies were significant after treatment, favouring the MOX group ($p < 0.001$).

Table 2. Changes in the clinical parameters in the two protocols during the trial phase

Parameter	Moxifloxacin		Control group	
	Baseline	6 months	Baseline	6 months
Clinical Attachment Level (mean±SD)	4.92±0.5*	3.14±0.6**	4.93±0.4*	3.77±0.4**
Probing Depth (mean±SD)	4.27±0.4*	3.08±0.6**	4.34±0.5*	3.5±0.4**

SD: standard deviation;

*Changes were detected among the two time evaluations (repeated-measures ANOVA $p < 0.001$);

** Changes were perceived between the treatments (t-test $p < 0.001$).

Results from the empty multilevel models with ΔCAL and ΔPD as the dependent variables are presented in Tables 3 and 4.

The empty model for ΔCAL provided a total unexplained variance of 1.96, the majority attributed to variation between teeth (60%), followed by between sites (24%) and between subjects (16%). The addition of the explanatory variables occasioned a 35% diminution of the entirely inexplicable variability: 25%, 38% and 33% at the subject, tooth and site levels, respectively. Appreciably superior fit was reached introducing the clinical explicatory variables at the three levels (P<0.05) (Table 3).

Table 3. Hierarchical regression analysis assessing the influence of subject, tooth and site characteristics in the variability of clinical attachment level (CAL) gain

Intercept	ΔCAL Baseline-6months	
	Empty model	Multivariate model
	β±SE	β±SE
	2.974±0.095	3.743±0.225
Patient (Level 3)	0.317±0.081 (16) ‡	0.237±0.059 (-25%)†
Tooth (Level 2)	1.183±0.054 (60) ‡	0.732±0.034 (-38%)†
Site (Level 1)	0.461±0.009 (24) ‡	0.308±0.006 (-33%)†
Total variance	1.961	1.277
-2 LL	17083.055	12305.077*

‡ Proportion of variability in ΔCAL provided by the multilevel analysis at the subject, tooth, and site levels.

† Change in the proportion of variability in ΔCAL at the subject, tooth, and site levels when explicatory factors were incorporated in the analysis.

*Variation in -2 LL was significant ($P<0.001$).

The empty model for ΔPD presented a total unexplained variance of 1.46, the majority accredited to variation between teeth (61%), followed by between sites (22%) and between subjects (17%). The insertion of the explanatory variables conducted to a 17% diminution of the absolutely inexplicable variability: 17%, 20% and 9% at the subject, tooth and site levels, respectively. Meaningfully improved fit was accomplished including the clinical explanatory variables at the three levels (P<0.05) (Table 4).

Table 4. Hierarchical regression analysis assessing the influence of subject, tooth and site characteristics in the variability of probing depth (PD) reduction

Intercept	ΔPDBaseline-6months	
	Empty model	Multivariate model
	β±SE	β±SE
	2.816±0.084	3.622±0.264
Patient (Level 3)	0.246±0.063 (17)‡	0.203±0.051 (-17%)†
Tooth (Level 2)	0.885±0.040 (61)‡	0.711±0.033 (-20%)†
Site (Level 1)	0.325±0.006 (22)‡	0.304±0.006 (-9%)†
Total variance	1.456	1.218
-2 LL	14790.139	10193.559*

‡ Proportion of variability in ΔPD provided by the multilevel analysis at the subject, tooth, and site levels.

† Change in the proportion of variability in ΔCAL at the subject, tooth, and site levels when explicatory factors were incorporated in the analysis

* Variation in -2 LL was significant ($P<0.001$)

Table 5 depicts the multilevel multivariate model studying the explicatory variables analysing ΔCAL as the outcome variable. At the subject level, adjunctive MOX showed a significantly more positive response in terms of CAL gain (P=0.02). At the tooth level, the analysis demonstrated that non-molars presented the best significant gains in CAL than molars (P<0.0001). Furthermore, the interaction non-molar x MOX was significantly associated with CAL gain at six months (P<0.0001). Finally, at the site level, interproximal locations were the zones where CAL gains were superior to at the buccal/lingual sites (P=0.02). Also, the interaction interproximal sites x MOX was significantly associated with CAL gain at six months (P<0.0001).

Table 5. Hierarchical regression analysis assessing the influence of subject, tooth and site factors, describing the variance in clinical attachment level (CAL) gains

Parameters	ΔCAL Baseline-6months (β±SE)	*P* value
Subject Level		
Adjunctive MOX/SRP+placebo	0.620±0.309	0.02
Tooth Level		
Tooth position (non-molar/molar)	0.845±0.069	<0.0001
Non-molar x MOX	-0.311±0053	<0.0001
Site Level		
(db-mb-dl-ml/b-l)	0.055±0.028	0.02
(db-mb-dl-ml) x MOX	-0.295±0.026	<0.0001

db: distobuccal; b: buccal; mb: mesiobuccal; dl:distolingual; l: lingual; ml: mesiolingual.

A similar tendency shows the multilevel multivariate model investigating the explanatory variables influencing ΔPD as the dependent variable (Table 6). At the patient level, adjunctive MOX showed a significantly more advantageous response in terms of PD reduction (P=0.04). At the tooth level, the analysis demonstrated that non-molars presented the best reductions in PD than molars (P<0.0001). Moreover, the interaction non-molar x MOX was significantly associated with PD reduction at six months (P<0.0001). Also, at the site level, interproximal positions were the parts where PD reductions were superior to at the buccal/lingual sites (P=0.01). Besides, the interaction interproximal sites x MOX was significantly associated with PD reduction at six months (P=0.02).

Table 6. Hierarchical regression analysis assessing the influence of subject, tooth and site factors, describing the variance in probing depth (PD) reduction

Parameters	ΔPD Baseline-6months (β±SE)	*P* value
Subject Level		
Adjunctive MOX/SRP+placebo	0.781±0.454	0.04
Tooth Level		
Tooth position (non-molar/molar)	0.817±0.058	<0.0001
Non-molar x MOX	-0.914±0.185	<0.0001
Site Level		
(db-mb-dl-ml/b-l)	0.045±0.020	0.01
(db-mb-dl-ml) x MOX	-0.130±0.064	0.02

db: distobuccal; b: buccal; mb: mesiobuccal; dl:distolingual; l: lingual; ml: mesiolingual.

4. Discussion

The application of surrogate parameters such as PD and CAL to estimate the clinical success of several therapies is a usual method (Greenstein, 2005). In this report, variations in CAL and PD between baseline and 6 months after adjunctive MOX to one-stage full-mouth SRP compared to SRP alone were evaluated using a multilevel approach. Consequently, the main cause of variability in CAL gain and PD reduction following adjunctive MOX was referable to the tooth level, followed by the site and the subject levels. Comparable effects were documented in a previous multilevel analysis relating nonsurgical and surgical therapy in subjects with aggressive and chronic periodontitis (Kim et al., 2007). Also, merely elements at the tooth position level were recognized by a multilevel model as significant for the management result of adjunctive doxycycline for the re-instrumentation of pathologic sites in subjects with chronic periodontitis (Tomasi et al., 2008).

In the present research, the final model for ΔCAL, including all of the significant factors conducted to a 35% diminution of the entirely inexplicable variability. Besides, the final model for ΔPD conducted to a 17% decrease

of the total inexplicable variation being higher at the tooth level. These conclusions focus the significance of considering factors related with the tooth level in order to elect periodontal therapy properly. In line, the observations reported by Tomasi et al. (2007) recommend focusing on factors at the tooth level in order to explore for supplementary elements that may impact the projection of the result of pathologic pockets in patients with chronic periodontitis. A similar recommendation could apply in aggressive periodontitis.

In the current study, the multilevel models associated CAL gain and PD reduction with adjunctive MOX (at the patient level); non-molar and the interaction non-molar x MOX (at the tooth level); and interproximal sites and the interaction interproximal sites x MOX (at the site level). The significant interactions between MOX with non-molar and interproximal sites show that MOX could be a crucial factor for PD reduction and CAL gain in GAgP.

To the best knowledge of the authors, this is the initial experimental study that evaluates the influence of different factors at the subject, tooth and site levels in the adjunctive MOX treatment of patients diagnosed with GAgP. Previous investigations have studied subjects with chronic and aggressive periodontitis managed with various forms of therapies (D'Aiuto et al., 2005; Tomasi et al., 2007; Mdala et al., 2012; Kim et al., 2007; Mombelli et al., 2013). Curiously, the efficacy of systemic MOX in chronic periodontitis using a multilevel approach has not been evaluated previously. However, the efficacy of adjunctive MOX regarding PD diminution and CAL increase has been also perceived in chronic periodontitis patients (Guentsch et al., 2008). Also, using multilevel models, Mdala et al. (2012) showed that adjunctive AMOX+MET presented more clinical advantages than others therapies. Overall, our results corroborate the published information presented earlier showing that treatment results in dissimilar positions and teeth in the identical subject are not independent (Tomasi et al., 2007; Mdala et al., 2012; Kim et al., 2007).

In this report, worst results were detected in molars, which is in agreement with conclusions informed by others researchers who applied hierarchical approaches in the evaluation of the therapy effect (D'Aiuto et al., 2005; Tomasi et al., 2007; Mdala et al., 2012); this observation may be related to difficult accessibility for subgingival SRP in molars (Tomasi et al., 2007). Kim et al. (2007) in a multilevel analysis reported more pronounced PD diminution and CAL increase in single-rooted teeth. In line, Mombelli et al. (2013) indicated that in non-molar that were treated with AMOX+MET fewer sites remained with PD>4mm and BOP. Also here, the interaction non-molar and MOX was associated with greater PD reduction and CAL gain.

This multilevel analysis showed that at the site level more diminutions in PD were detected for interdental positions than in buccal/lingual sites. This is in conformity with preceding information (D'Aiuto et al. 2005; Tomasi et al., 2007) and coherent with the predominant situation of profounder pockets in the interdental spaces (D'Aiuto et al., 2005). In this report, the interaction interproximal sites and MOX was associated with higher PD diminution and CAL increase. In accordance, a recent meta-analysis indicated that systemic antibiotics showed a significant additional PD diminution and CAL increase for modest and profound pockets (Keestra et al., 2014). Also in this investigation, the use of adjunctive MOX resulted in CAL increase and PD diminution with data comparable with previous studies that used AMOX+METRO in GAgP (Aimetti, Romano, Guzzi, & Carnevale, 2012; Mestnik et al., 2012).

The current report did not observe any influence of age, gender, plaque and BOP at the patient level on CAL gain and PD reduction. Comparable inferences have been informed in multilevel studies (Tomasi et al., 2007; D'Aiuto et al., 2005; Kim et al., 2007; Tomasi et al., 2008). As was reported here, a relatively modest influence of patient's parameters in multilevel analysis has been generally documented (D'Aiuto et al., 2005); D'Aiuto et al. (2005) suggest that patients with significant systemic conditions may cause more variability. In concordance with a previous multilevel studied where mechanical and surgical periodontal treatments were compared in aggressive and chronic periodontitis patients, more factors related with tooth level affecting therapy results than subject related features (Kim et al., 2007).

Although in the present report smokers were excluded, multilevel studies revealed that smoking revealed a adverse influence on the magnitude of PD reduction (Tomasi et al., 2007) and CAL gain (Kim et al., 2007) in patients treated with nonsurgical (Tomasi et al., 2007; Kim et al., 2007) and surgical therapies (Kim et al., 2007).

One weakness of this multilevel analysis is the six-month estimation phase. Categorically, a longer prospective observation of these patients will be indispensable to conclude if this adjunctive treatment would generate determined satisfactory modifications in the periodontal clinical parameters over time.

In conclusion, adjunctive MOX, non-molar and the interaction non-molar x MOX, interproximal sites and the interaction interproximal sites x MOX were factors in determining CAL increase and PD diminution in GAgP. The main cause of variability in CAL increase and PD diminution following adjunctive MOX was attributable to

the tooth level. Finally, adjunctive MOX and their interactions showed higher clinical benefits at the tooth and site levels.

Acknowledgments

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Decomposing Cost Efficiency in Regional Long-term Care Provision in Japan

Yasuhiro Yamauchi[1]

[1] Faculty of Economics, Tezukayama University, Nara, Japan

Correspondence: Yasuhiro Yamauchi, Faculty of Economics, Tezukayama University, 7-1-1 Tezukayama, Nara 631-8501, Japan. Tel/Fax: 81-742-88-6037. E-mail: yamauchi@tezukayama-u.ac.jp

Abstract

Many developed countries face a growing need for long-term care provision because of population ageing. Japan is one such example, given its population's longevity and low birth rate. In this study, we examine the efficiency of Japan's regional long-term care system in FY2010 by performing a data envelopment analysis, a non-parametric frontier approach, on prefectural data and separating cost efficiency into technical, allocative, and price efficiencies under different average unit costs across regions. In doing so, we elucidate the structure of cost inefficiency by incorporating a method for restricting weight flexibility to avoid unrealistic concerns arising from zero optimal weight. The results indicate that technical inefficiency accounts for the highest share of losses, followed by price inefficiency and allocation inefficiency. Moreover, the majority of technical inefficiency losses stem from labor costs, particularly those for professional caregivers providing institutional services. We show that the largest share of allocative inefficiency losses can also be traced to labor costs for professional caregivers providing institutional services, while the labor provision of in-home care services shows an efficiency gain. However, although none of the prefectures gains efficiency by increasing the number of professional caregivers for institutional services, quite a few prefectures would gain allocative efficiency by increasing capital inputs for institutional services. These results indicate that preferred policies for promoting efficiency might vary from region to region, and thus, policy implications should be drawn with care.

Keywords: cost efficiency, data envelopment analysis, non-parametric frontier approach, long-term care, Japan

1. Introduction

Many developed countries face a growing need for long-term care provision because of population ageing. Japan is one such example, given its population's longevity and low birth rate. As Aboagye et al. (2014) contend, social security to the elderly may be improved and extended by ensuring that the traditional in-kind social security system arranged by the extended family go hand-in-hand with the formal social security structure. Considering this, in 2000, the Japanese government initiated a mandatory social long-term care insurance (LTCI) system, which is operated by both the central and the local governments (Ikegami, 1997; Campbell & Ikegami, 2000). Based on the physical and mental status of the individual, irrespective of his/her income or family situation, this system makes long-term care a universal entitlement for every Japanese citizen aged 65 years and above. LTCI basically operates on social insurance principles: recipients receive services and choose providers, but cash allowances are not provided. Out-of-pocket expenses for elderly beneficiaries amount to 10% of the expenses for services received. The remaining revenues from premiums, national taxes, prefectures, and municipalities are 50%, 25%, 12.5%, and 12.5%, respectively.

As this system has proven to be popular among the general public, who have widely accepted it as a normal feature of social policy, demand for LTCI services has significantly increased, giving rise to the problem of runaway expenditures. Over the program's 12 years of operation since FY 2000, in which LTCI was established, the number of persons certified by all Japanese local governments to be in need of long-term care increased by 144%, to 5.33 million, far exceeding the growth (38%) of the population aged 65 years and above during the same time. Public expenditure for long-term care in FY 2012 amounted to 8.9 trillion yen (= 98 billion U.S. dollars), 1.88% of Japan's nominal GDP, which is higher than median value of OECD countries (OECD, 2013).

Furthermore, an ageing population, declining birth rates, and prolonged economic problems have forced Japan's policymakers to consider containing the costs of providing long-term care. Over the next decade, the proportion of Japan's elderly people who are at least 75 years old and prone to needing long-term care is expected to increase by 50%, to approximately 22 million. In recent years, the Japanese government implemented major LTCI reforms to restrict costs by assigning room fees and board expenses for institutional care, proactively promoting in-home services, and increasing emphasis on preventive services for those with lower needs and those at risk of needing future care.

This study examines the efficiency of Japan's regional LTCI services. We perform a data envelopment analysis (DEA) on 47 regions by prefecture, Japan's subnational jurisdiction. Numerous recent studies have measured the efficiency of long-term care using DEA, a linear programming technique developed by Charnes et al. (1978) based on earlier works (Farrell, 1957) and related methods. According to Hollingsworth (2008), who presents a review of published papers on frontier efficiency measurement in healthcare, after hospitals, nursing homes constitute the second-most common application for this method.

In terms of efficiency of long-term care, previously studied subjects include nursing homes, group homes, visiting nurse service agencies, municipalities, long-term care wards, geographically defined community care access centers, and similar institutions. The most common subject for study is nursing homes. Studies on nursing homes in the U.S., the Netherlands, and Italy include those by Sexton et al. (1989) and Nyman et al. (1990); Kooreman (1994); and Garavaglia et al. (2011), respectively. Although many studies have investigated efficiency in long-term care provision, there are relatively few studies on a regional long-term care system managed by a local public entity, which is the focus of this study. The latter include literature on municipalities (e.g., Erlandsen & Førsund, 2002; Hougaard et al., 2004; Laine et al., 2005; Borge et al., 2009). To elucidate the structure of cost inefficiency, we apply the formula used by Thanassoulis et al. (2012), which is a modification of the method suggested by Tone (2002) and Tone and Tsutsui (2007), and we deconstruct cost efficiency into technical, allocative, and price efficiencies. This study is unique in that it is the first to decompose cost efficiency into various efficiencies including price efficiency in the regional long-term care context.

This study is structured as follows. Section 2 provides the methodology and data used for estimating the efficiency of long-term care. Section 3 presents the estimation results and is followed by the discussion and concluding remarks in Section 4.

2. Methods and Data

2.1 Methods

We perform a DEA using the data of Japan's 47 prefectures. DEA is a non-parametric frontier approach based on linear programming that converts multiple input and output measures of a decision-making unit (DMU) into a single comprehensive measure of its productive efficiency by comparing related DMUs (Charnes et al., 1978). An advantage of DEA is that it does not assume frontiers to possess a particular functional form, unlike in the estimation of stochastic frontier models (Crivelli et al., 2002). DEA also differs from ordinary least squares estimation, which is based on comparisons relative to an average unit. We measure the monetary values of inefficiency, which are then separated into several components by input factor (Thanassoulis et al., 2012).

This paper considers n DMUs and m inputs for producing s outputs. We denote the input and output vectors as $\mathbf{x}_j \in R^m$ and $\mathbf{y}_j \in R^s$, respectively, for each DMU_j $(j = 1, ..., n)$. We define the input and output matrices as $\mathbf{X} = (\mathbf{x}_1, ..., \mathbf{x}_n) \in R^{m \times n}$ and $\mathbf{Y} = (\mathbf{y}_1, ..., \mathbf{y}_n) \in R^{s \times n}$, respectively. We assume that $\mathbf{X} > 0$ and $\mathbf{Y} > 0$. For each DMU_j $(j = 1, ..., n)$, we denote the input factor price vector for input $\mathbf{x}_j$ by $\mathbf{w}_j \in R^m$ and the input factor price matrix as $\mathbf{W} = (\mathbf{w}_1, ..., \mathbf{w}_n) \in R^{m \times n}$. For DMU_j, the actual total input cost C_j is calculated as follows:

$$C_j = \sum_{i=1}^{m} W_{ij} x_{ij}, \tag{1}$$

where x_{ij} is the amount of the ith input used by DMU_j, and w_{ij} is the input factor price. We assume that elements $w_{ij} x_{ij}, ..., w_{mj} x_{mj}$ are denominated in homogenous units, that is, in Japanese yen, such that the summation is measurable.

First, we calculate the technical efficiency of Japan's long-term care provision. The production possibility set P is defined as

$$P = \left\{ (\mathbf{x}, \mathbf{y}) \mid \mathbf{x} \geq \mathbf{X}\lambda, \ \mathbf{y} \leq \mathbf{Y}\lambda, \ \lambda \geq \mathbf{0} \right\}. \tag{2}$$

The technical efficiency θ^* of DMU_j is measured using the input-oriented variable returns to scale (VRS) model (Banker et al., 1984):

$$\theta^* = \min_{\theta, \lambda, s^-, s^+} \theta \,,$$

subject to

$$\theta \mathbf{x}_j = \mathbf{X}\lambda + \mathbf{s}^- \,, \tag{3}$$

$$\mathbf{y}_j = \mathbf{Y}\lambda - \mathbf{s}^+ \,,$$

$$\mathbf{e}\lambda = 1 \,,$$

$$\lambda \geq \mathbf{0}, \ \mathbf{s}^- \geq \mathbf{0}, \ \mathbf{s} \geq \mathbf{0} \,.$$

Since we use cross-sectional data of 47 regions with uncontrollable heterogeneity in population size, we employ the VRS model. In addition, we incorporate a method for restricting weight flexibility to avoid unrealistic concerns arising from zero optimal weight. The method by Wong and Beasley (1990) for restricting weight flexibility uses the following proportions:

$$0 \leq a_i \leq \frac{v_i x_{ij}}{T_j} \leq b_i \leq 1 \,, \tag{4}$$

where a_i and b_i are regarded as suitable lower and upper limits, respectively; $T_j = \sum_{i=1}^m v_i x_{ij}$ is the total input; and v_i indicates the weight to be attached to the input measure.

The specification of the limit $[a_i, b_i]$ is a value judgment (Wong & Beasley, 1990). However, we have no consensus on the relative importance of each input for Japan's long-term care provision. Hence, we specify the limit as follows:

$$a_i = \min \frac{v_{ij} x_{ij}}{T_j} > 0 \quad (j = 1, \ldots, n) \quad \text{and} \quad b_i = \max \frac{v_{ij} x_{ij}}{T_j} < 1 \quad (j = 1, \ldots, n) \,, \tag{5}$$

where v_{ij} is estimated by the basic VRS model without restricting its weight flexibility.

Let $(\theta^*, \lambda^*, \mathbf{s}^{-*}, \mathbf{s}^{+*})$ be the optimal solution for model (3) after adding weight restrictions. The projection of the efficiency frontier can then be given by

$$\mathbf{x}_j^* = \theta^* \mathbf{x}_j - \mathbf{s}^{-*} \,, \ \mathbf{y}_j^* = \mathbf{y}_j + \mathbf{s}^{+*} \,, \tag{6}$$

Where $\mathbf{x}_j^*$ indicates the vector of the technically efficient inputs for DMU_j for producing $\mathbf{y}_j^*$.

The corresponding technically efficient total input cost for DMU_j can be expressed as follows:

$$C_j^* = \sum_{i=1}^m w_{ij} x_{ij}^* = \sum_{i=1}^m w_{ij} (\theta^* x_{ij} - s_i^{-*}) \,. \tag{7}$$

Loss due to this technical inefficiency is calculated as follows:

$$L_j^T = C_j - C_j^* (\geq 0). \tag{8}$$

The technical efficiency TE of DMU_j is defined as follows:

$$\mathrm{TE} = \frac{C^*}{C} \,. \tag{9}$$

Next, we calculate the cost efficiency of Japan's long-term care provision. Traditional cost efficiency is defined as follows:

$$\gamma = \frac{\mathbf{w}_j \mathbf{x}^*}{\mathbf{w}_j \mathbf{x}_j} \,, \tag{10}$$

where $\mathbf{x}^*$ is the vector obtained as the optimal solution to the following linear program:

$$C^{**} = \min_{x, \lambda} \mathbf{w}_j \mathbf{x} \,,$$

subject to

$$\mathbf{x} \leq \mathbf{X}\lambda \,,$$

$$\mathbf{y}_j \leq \mathbf{Y}\lambda \,, \tag{11}$$

$$\mathbf{e}\lambda = 1 \,,$$

$$\lambda \geq \mathbf{0} \,.$$

The optimal solution from this model yields the minimum cost C^* at which DMU_j could secure its outputs, given the unit costs.

Losses due to this cost inefficiency are calculated as follows:

$$L_j^C = C_j - C_j^{**} (\geq 0) \cdot \tag{12}$$

As cost efficiency is the product of technical and allocative efficiencies, the allocative efficiency AE of DMU$_j$ is defined as follows:

$$\text{AE} = \frac{C^{**}}{C^*} . \tag{13}$$

AE reflects the adjustment to the optimal input mixture based on the given input price ratio. Loss due to this allocative inefficiency is calculated as follows:

$$L_j^A = C_j^* - C_j^{**} (\geq 0) \cdot \tag{14}$$

Next, we calculate the price efficiency of Japan's long-term care provision. Considering the input price differences caused by unit price variations between DMUs, costs can be reduced by altering input factor prices (Tone & Tsutsui, 2007). We use Thanassoulis et al.'s (2012) approach, wherein price efficiency is estimated using the traditional cost model, which identifies the input volumes that will minimize costs given a DMU's price. Then, using the optimal input volumes from the traditional cost model (x_{ij}^{**}), we compute the corresponding cost vectors for each DMU$_j$: $\overline{\mathbf{X}} = (\overline{\mathbf{x}}_1, ..., \overline{\mathbf{x}}_n)$ with $\overline{\mathbf{x}}_j = (w_{1j} x_{1j}^{**}, ..., w_{mj} x_{mj}^{**})^T$. Next, we use these cost vectors in the model as follows:

$$\mathbf{e}\overline{\mathbf{x}}_o^* = \min_{\overline{x},\lambda} \mathbf{e}\overline{\mathbf{x}} ,$$
$$\text{subject to} \quad \overline{\mathbf{x}} \leq \mathbf{X}\lambda ,$$
$$\mathbf{y}_o \leq \mathbf{Y}\lambda , \tag{15}$$
$$\mathbf{e}\lambda = 1 ,$$
$$\lambda \geq \mathbf{0} .$$

This model seeks to minimize a DMU's aggregate costs, controlling for output levels. It identifies cost savings by altering unit prices and input mix simultaneously (Thanassoulis et al., 2014).

Let the optimal (minimum) cost estimated for DMU$_j$ by the price efficiency model be denoted as C^{***}.

Loss due to this price inefficiency is calculated as follows:

$$L_j^P = C_j^{**} - C_j^{***} (\geq 0) \cdot \tag{16}$$

As the overall cost efficiency including price efficiency (PE) is $C^{***}/C_j = (C^{**}/C_j) \times (C^{***}/C^{**})$, the PE of DMU$_j$ is defined as follows:

$$\text{PE} = \frac{C^{***}}{C^{**}} . \tag{17}$$

In accordance with Thanassoulis et al.'s (2012) method, our methodology assumes that volumes change first, and prices change residually.

2.2 Data

We use data of 47 regions by prefecture. This level of analysis was chosen because although municipalities serve as LTCI insurers and administer LTCI based on the national government's guidelines, prefectures provide municipalities with technical and administrative support and have the authority to decide on the number of LTC providers. In addition, as pointed out by Kawase and Nakazawa (2009), there can be significant elderly migration at the municipality level depending on the availability of institutional services. The current study's sample size is limited to, but comparable with, those used in other DEA studies on long-term care. The data are obtained from Japan's Ministry of Health, Labour and Welfare (MHLW) and other relevant entities and cover FY2010. The datasets are obtained from several sources. Input data are obtained from the Survey of Institutions and Establishments for Long-term Care (MHLW). Capital cost data are gathered from the Briefing Survey on Economic Conditions in Long-term Care (MHLW). The Survey on Employment in Long-term Care (Care Work Foundation, 2011) provides the labor unit cost data, and the Report on Condition of Long-term Care Projects (MHLW) provides the output data. Although DEA has a limitation in terms of measurement errors, they are considered to be small as the survey forms were completed by public officers or administrative staff of long-term care providers, all of whom are assumed to be familiar with the actual situation. These data include the most recent LTCI reports before the Great East Japan Earthquake.

The model comprises six inputs with unit costs and one united output. The number of variables is chosen to balance the trade-off between the model's descriptive and discriminatory powers. Capital input variables include

the following: (a) the admission capacity of institutional services and (b) number of providers for in-home services. Labor input variables are numbers of (c) professional caregivers for institutional services, (d) professional caregivers for in-home services, (e) medical nurses, and (f) other staff (allied health professionals and office workers). The admission capacity of institutional services excludes that of day services, the number of providers for in-home services and professional caregivers for institutional services contains those for day services, and the number of professional caregivers for in-home services excludes those for day services. The differences in the above-mentioned inclusions/exclusions depend on the definitions and ranges of data in input factor prices (unit costs). Medical nurses include regular nurses, assistant nurses, healthcare nurses, and maternity nurses. "Other staff" refers to care managers, pharmacists, nutritionists, physiotherapists, occupational therapists, speech–language–hearing therapists, psychiatric social workers, care counselors, life counselors, cooks, dental hygienists, and welfare equipment counselors. Labor input variables [(c)–(f)] are calculated to yield their full-time equivalents.

Input factor prices (unit costs), using input variables for capital costs, are weighted average depreciation and interest on borrowing for (g) institutional services (per bed) and (h) in-home services (per office). The availability of factor price data for capital costs is extremely limited. As a result, we necessarily use unit cost data categorized by five levels of urbanization. Meanwhile, labor costs include per-person scheduled salaries and wages of (i) professional caregivers for institutional services, (j) professional caregivers for in-home services, (d) medical nurses, and (e) other staff.

For outputs, we calculate the weighted number of persons requiring care based on the certification of long-term care as (m) requirement of care. This factor is selected for the following reasons. A problem with analyzing the efficiency of providing care is the difficulty in measuring its conceptual output, namely, improved health status, or more generally, improved quality of life (Kooreman, 1994). DEA and related efficiency analyses frequently employ the concept of case mix—the type of disorder and its severity in patients treated by a unit; however, to the best of our knowledge, Japan's government does not collect outcome data or process performance systematically. This limits the possibility of employing outcome-related measures for determining quality of care. Therefore, our choice for this variable depends on the particulars of Japan's long-term care system. The provision of some services requires a Care-Needs Certification in the Long-Term Care Insurance System. Under Japan's Long-Term Care Insurance Act, "An insured person that intends to receive long-term care benefit shall obtain certification by a municipality pertaining to the fact that the said insured person qualifies as a person requiring long-term care and as to the category of condition of need for long-term care for which said insured person qualifies." Therefore, this analysis employs the weighted number of persons certified as requiring care for the annual workload weighted by the degree of the seriousness of the disorder. We use "estimated total care minutes per day" (ETCM) as the weighting index for disorder seriousness (Table 1). ETCM is the official criterion for Japan's LTC Insurance Care Needs Levels and shows the estimated times needed for daily long-term care (Tsutsui & Muramatsu, 2005). For example, for 2012, Tokyo recorded the following number of people dependent on healthcare: 61,205 needed "support 1" care; 55,969 needed "support 2" care; 75,410 needed "level 1" care; 79,411 needed "level 2" care; 60,833 needed "level 3" care; 56,732 needed "level 4" care; and 54,926 needed "level 5" care. Accordingly, we can show the index for requirement of care $= 25 \times 61{,}205 + 32 \times 55{,}969 + 32 \times 75{,}410 + 50 \times 79{,}411 + 70 \times 60{,}833 + 90 \times 56{,}732 + 110 \times 54{,}926 = 25{,}110{,}853$.

Table 1. Criteria for LTC insurance care needs levels

Level of care needed	Estimated Total Care Minutes per Day
Not eligible	< 25
Support 1	25 ≤
Support 2 and Level 1	32 ≤
Level 2	50 ≤
Level 3	70 ≤
Level 4	90 ≤
Level 5	110 ≤

* As of 2010.

** We calculated the number of persons requiring care using "Estimated Total Care Minutes per Day" as the weighting index for seriousness.

The summary statistics for the input and output values are described in Table 2. The maximum values of input and output exceed the minimum numbers of input and output by more than 10 times. The maximum values of input and output belong to either Tokyo Metropolis [(a), (c), (e), (f), and (m)] or Osaka Prefecture [(b) and (d)], both of which have high populations. The minimum values belong to either Tottori Prefecture [(b), (d), (e), (f), and (m)] or Yamanashi Prefecture [(a) and (c)], both of which have low populations. We use DEA-solver Professional Version 9.0 to calculate the efficiency estimates (Cooper et al., 2007).

Table 2. Major dataset statistics

n = 47	Average	S.D.	Max	Min
Input data				
Capital				
(a) Admission capacity of institutional services	20,478	16,416	79,129	6,417
(b) Offices for in-home services	2,532	1,799	8,392	763
Labor				
(c) Professional caregivers for institutional services	15,577	11,042	50,528	4,991
(d) Professional caregivers for in-home services	3,584	3,638	18,286	745
(e) Medical nurses	3,614	2,402	11,667	1,199
(f) Other staff	8,581	6,073	29,724	2,725
Input factor prices (thousand yen*)				
Depreciation cost and interest on borrowing				
(g) Institutional services (per bed)	424	14.5	451	400
(h) In-home services (per office)	3,009	568	4,148	2,267
Scheduled salaries and wages (per capita)				
(i) Professional caregivers for institutional services	2,323	163.9	2,729	2,015
(j) Professional caregivers for in-home services	2,257	209.9	2,763	1,783
(k) Medical nurses	3,065	331.2	3,967	2,480
(l) Other staff	2,870	207.0	3,392	2,499
Output data				
(m) Requirement of care	60,24,084	48,71,280	2,51,10,853	17,48,422

Sources: The datasets for this study are obtained from (1) the Survey of Institutions and Establishments for Long-term Care (MHLW) for (a) to (f), (2) the Briefing Survey on Economic Conditions in Long-term Care (MHLW) for (g) to (h), (3) the Survey on Employment in Long-term Care (Care Work Foundation, 2011) for (i) to (l), and (4) the Report on Condition of Long-term Care Projects (MHLW) for (m). * One thousand yen was equivalent to about 11 U.S. dollars in 2010.

3. Empirical Results

Table 3 presents a summary of estimated capital and labor costs ($\mathbf{w}_j\mathbf{x}_j$) from our data for each prefecture. We note that these calculated costs differ from actual costs and do not contain operating costs except capital and labor costs. According to our data for 2010, the total estimated capital and labor costs for all prefectures were approximately 4.6 trillion yen (= 51 billion U.S. dollars). This table demonstrates that labor costs are significantly greater than capital costs. The labor costs of professional caregivers for institutional services (average: 37.9%) comprise the largest proportion of each area's long-term care costs. On the other hand, the labor costs of professional caregivers for in-home services (average: 7.6%) comprise the smallest proportion of each area's long-term care costs. This might mean that there is more potential to contain long-term care costs by promoting the labor productivity of professional caregivers in institutional services.

Table 3. Estimated costs according to the raw data

n = 47	Average	S.D.	Max	Min
Capital cost (million yen*)				
Institutional services	8,782	7,258	34,557	2,674
(%)	8.8%	0.7%	10.6%	7.1%
In-home services	7,616	5,302	22,546	2,078
(%)	8.1%	1.7%	12.6%	4.9%
Labor cost (million yen*)				
Professional caregivers for institutional services	36,971	28,564	1,37,886	12,632
(%)	37.9%	2.1%	42.3%	34.2%
Professional caregivers for in-home services	8,268	8,888	43,655	1,641
(%)	7.6%	1.9%	14.2%	4.8%
Medical nurses	11,525	8,991	46,281	3,575
(%)	11.8%	1.1%	14.1%	9.5%
Other staff	25,259	19,751	1,00,817	8,011
(%)	25.9%	1.3%	28.4%	23.1%

* One million yen was equivalent to about 11 thousand U.S. dollars in 2010.

Table 4 summarizes the results of technical efficiency (*TE*), allocative efficiency (*AE*), price efficiency (*PE*), and overall efficiency (*OE*). *OE* was calculated as follows:

$$OE = TE \times AE \times PE . \qquad (18)$$

The average *OE* index is 0.794, with a minimum of 0.695. The average *TE* index is 0.914, which is lower than the average *AE* index (0.938) and the average *PE* index (0.929).

Table 4. Summary of estimated efficiency indexes

n = 47	Average	S.D.	Max	Min
Technical efficiency (TE)	0.914	0.067	1.000	0.786
Allocative efficiency (AE)	0.938	0.047	1.000	0.814
Price efficiency (PE)	0.929	0.049	1.000	0.794
Overall efficiency (OE)	0.794	0.065	1.000	0.695

Table 5 presents overall inefficiency losses and the factor-oriented decomposition of each estimated inefficiency loss. Inefficiency losses are derived by totaling the differences between the costs given by the raw data and the estimated optimum costs for each prefecture. As seen in the table, overall inefficiency losses amount to 922 billion yen (approximately 9 billion U.S. dollars), their ratio to the total cost being 19.9%. This result indicates substantial variations in efficiency across prefectures and reveals that the national-level efficiency potential is approximately 20%. Overall inefficiency losses by labor cost amount to 786 billion yen (85% of overall inefficiency losses), which is greater than overall inefficiency losses by capital costs (136 billion yen, which comprise 15% of overall inefficiency losses). This result shows that promoting labor productivity, rather than capital productivity, has more potential to contain long-term care costs.

Table 5. Overall inefficiency losses and factor-oriented decomposition

Inefficiency	Overall		Technical		Allocative		Price	
Capital cost (million yen*)								
Institutional services	45,313	4.9%	32,510	7.8%	4,667	1.9%	8,137	3.2%
In-home services	90,195	9.8%	43,692	10.5%	30,710	12.2%	15,793	6.2%
Labor cost (million yen*)								
Professional caregivers for institutional services	3,85,016	41.8%	1,65,274	39.5%	1,30,322	51.9%	89,420	35.4%
Professional caregivers for in-home services	36,553	4.0%	20,439	4.9%	-4,694	-1.9%	20,808	8.2%
Nurses	1,18,017	12.8%	50,739	12.1%	11,316	4.5%	55,962	22.1%
Other staff	2,46,809	26.8%	1,05,288	25.2%	78,871	31.4%	62,651	24.8%
Total loss (million yen*)	9,21,904	100.0%	4,17,942	100.0%	2,51,192	100.0%	2,52,770	100.0%
(Ratio of overall inefficiency loss)				(45.3%)		(27.2%)		(27.4%)
(Ratio of total cost)		(19.9%)		(9.0%)		(5.4%)		(5.5%)

* One million yen was equivalent to about 11 thousand U.S. dollars in 2010.

Table 6. Various cases of factor-oriented allocative inefficiency loss

	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6	Case 7	Case 8	Case 9
Capital cost									
Institutional services	L	G	G	L	G	L	L	G	L
In-home services	L	L	L	G	L	L	L	G	G
Labor cost									
Professional caregivers for institutional services	L	L	L	L	L	L	L	L	L
Professional caregivers for in-home services	G	L	G	G	G	L	G	G	G
Nurses	L	G	L	L	G	G	G	L	G
Other staff	L	L	L	L	L	L	L	G	G
Number of prefectures	20	11	5	3	2	1	1	1	1

* Two prefectures have no allocative inefficiency loss.

* The Ls indicate allocative inefficiency losses. The Gs indicate allocative efficiency gains.

Technical inefficiency losses amount to 418 billion yen (9.0% of estimated total costs), which is greater than both allocative inefficiency losses (251 billion yen; 5.4% of estimated total costs) and price inefficiency losses (253 billion yen; 5.5% of estimated total costs). These results show that approximately half (45.3%) of overall inefficiency losses stem from technical inefficiency losses. Most technical inefficiency losses can be traced to labor costs for professional caregivers in institutional services (39.5% of technical inefficiency losses).

Allocative inefficiency losses amount to 251 billion yen (5.4% of estimated total costs), and the majority of allocative inefficiency losses can be traced to labor costs for professional caregivers in institutional services (51.9% of net allocative inefficiency losses). Furthermore, we find that few allocative inefficiency losses arise from labor costs associated with professional caregivers providing in-home care services. Instead, providing in-home care services shows an efficiency gain. Table 6 shows the various cases (patterns) of factor-oriented allocative inefficiency losses. The Ls indicate the existence of allocative inefficiency losses. The Gs show the presence of allocative efficiency gains. For example, in Case 1, 20 prefectures would gain allocative efficiency by increasing labor inputs for professional caregivers for in-home services and decreasing other inputs. In Case 3, 5 prefectures would gain allocative efficiency by increasing capital inputs and labor inputs for professional

caregivers for in-home services and decreasing other inputs. These results support government policy, which proactively promotes in-home services to make long-term care provision more efficient. But, although there is no prefecture that gains allocative efficiency by increasing the number of professional caregivers in institutional services, 18 prefectures would gain allocative efficiency by increasing capital inputs for institutional services. For example, in Case 2, 11 prefectures would gain allocative efficiency by increasing capital inputs for institutional services and labor inputs for nurses and decreasing other inputs. As illustrated in this example, preferred policies for promoting allocation efficiency vary from region to region.

Price inefficiency losses amount to 253 billion yen (5.5% of estimated total costs). When we decompose inefficiency losses by factor, we see that losses from labor costs for professional caregivers in institutional services exceed those from other factors. From this estimated result, we can conclude that lowering the labor rate of institutional services will significantly improve efficiency. However, such a strategy might incur the difficulty of securing sufficient employee numbers.

4. Discussion and Conclusion

In this study, we examined the efficiency of Japan's regional long-term care for 2010. We performed a DEA on 47 regions by prefecture, Japan's subnational jurisdiction. To elucidate the structure of cost inefficiencies in Japan's provision of long-term care, we applied the formula used by Thanassoulis et al. (2012), which is a modification of the methods proposed by Tone (2002) and Tone and Tsutsui (2007), for separating cost efficiency into technical, allocative, and price efficiencies.

The results of this study are as follows: (a) technical inefficiency accounts for the highest share of losses, followed by price inefficiency and allocation inefficiency; (b) the majority of technical inefficiency losses stem from labor costs, particularly those for professional caregivers providing institutional services; (c) the largest share of allocative inefficiency losses can also be traced to labor costs for professional caregivers providing institutional services; instead, the labor provision of in-home care services shows an efficiency gain; (d) however, a number of prefectures would gain allocative efficiency by increasing capital inputs for institutional services.

These results reveal substantial efficiency variations across prefectures and show national-level efficiency potential to be approximately 20%. This finding suggests that regional long-term care efficiency could be improved through better services and resource provision management. Thus, the first policy implication drawn from this study concerns reforming institutional service provision, which could help improve the efficiency of Japan's long-term care system. Despite structural changes to the LTCI system in 2000, the new program had minimal impact on institutional care providers (Ikegami et al., 2003). One could argue that institutional services show scope for improvement through higher labor productivity, especially via technical efficiency. As Japan's prefectures regulate the market entry of institutional services in each region, thus preventing private for-profit providers from entering the market freely, the principle of market competition may not work as intended, and institutional service providers may have less incentive to increase efficiency. With regard to charter status, most studies in U.S. context show that for-profit firms run nursing homes more efficiently than nonprofit or government-owned ones (Nyman & Bricker, 1989; Nyman et al., 1990; Fizel & Nunnikhoven, 1992; Chattopadhyay & Heffley, 1994; Rosko et al., 1995; Ozcan et al. 1998; Anderson et al., 2003), except for those with no statistically significant effect (Sexton et al., 1989; Fizel & Nunnikhoven, 1993; Zhang et al, 2008). However, a more detailed examination is necessary, because there are numerous viewpoints regarding the effect of ownership in the healthcare sector (Herr, 2008; Schwierz, 2011; Tiemann & Schreyögg, 2012); for example, in Germany context, Schwierz (2011) shows that the privatization of the hospital sector may slow down the reduction of excess capacities and be therefore socially wasteful. Furthermore, as pointed out by Tamiya et al. (2011), two-fifths of those certified would not have been eligible if German enrolment criteria had been applied. Therefore, we can say that, thus far, Japan has been over reliant on institutions that are not only expensive but that also endanger the elderly's dignity while offering them poor quality of life. Institutional services have significant potential to increase their efficiency, especially labor efficiency, by reducing services for those needing only minimal nursing care, focusing instead on providing services for those requiring more intensive nursing care.

Another policy implication for efficiency improvements that can be drawn from this study concerns promoting a shift to in-home services, as they can help reduce expenses incurred by Japan's long-term care system. In addition, beyond efficiency considerations, in-home and community-based services can contribute to the goal of the LTCI system, namely, encouraging individuals certified eligible for LTCI benefits to live independently at home as long as possible (Tomita et al., 2010).

Promotion of in-home services requires improving round-the-clock care and respite care. In addition, such a shift

requires fostering superior human resources. For instance, Kuwahara et al. (2013) focus on a slightly different topic and conduct a DEA on visiting nurse (VN) service agencies in Japan. They find that relatively efficient VN agencies filled at least 30% of their staff positions with experienced workers.

However, although none of the prefectures show efficiency gains from increasing the number of professional caregivers for institutional services, quite a few prefectures would gain allocative efficiency by increasing capital inputs for institutional services. As this means that preferred policies for promoting efficiency might vary from region to region, scrupulous attention must be paid while drawing possible policy implications from these results. Despite the useful insights obtained, this study has a limitation. To conduct an improved empirical analysis of long-term care performance, we need comprehensive data, especially on operating costs and quality of care (Laine et al., 2005). This goal can be pursued in a future study.

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Looking for a Taste of Home: A Qualitative Study of the Health Implications of the Diets of Australian - Based Southeast Asian Students

Jodie H. Leu[1] & Cathy Banwell[2]

[1] ANU Medical School, The Australian National University, Canberra, Australian Capital Territory, Australia

[2] National Centre for Epidemiology and Population Health, The Australian National University, Canberra, Australian Capital Territory, Australia

Correspondence: Jodie H. Leu, National Centre for Epidemiology and Population Health, The Australian National University, Canberra, Australian Capital Territory, Australia. Tel: 61-416-967-688. E-mail: jodie.leu@anu.edu.au

Abstract

Purpose: To investigate potential dietary changes among Southeast Asian international students living in self-catered accommodation while studying abroad and to consider implications for their health.

Design: Participants were interviewed about their food preferences and behaviours in their home countries and during their undergraduate studies at the Australian National University.

Setting: A university in Australia

Participants: Study participants were full-time undergraduate students over 18 years of age from Southeast Asian countries studying at the Australian National University for at least one year, and living at self-catered accommodation.

Methods: Thirty-one, in-depth, face-to-face qualitative interviews concerning usual diets were collected over a three month period in 2013. Interviews were coded and analysed with the aid of a computer program Atlas.ti.

Results: The macro-nutrient content of Southeast Asian international students' diets did not change a great deal when they moved to Australia. Most students replaced some preferred foods on occasions because they either could not afford them, they were not available or they lacked time to prepare them. These dietary changes were not necessarily reflected in changes to students' weights and most students considered that they were as healthy as when they lived at home.

Conclusion: As students' adapt to a new food environment they reflexively manage potential health risks. Strong student networks and an accessible and healthy food environment would support students to make healthy dietary choices although additional information about healthy diets could facilitate this further.

Keywords: Southeast Asia, ethnography, health and well-being, health promotion, semi-structured interviews, qualitative

1. Introduction

Each year an increasing number of students leave home to pursue higher education. In 2011, approximately 3.5 million students mainly from Asian countries such as China, India and Korea (Altbach et al., 2009; Coughlan, 2011) went abroad to study. In Australia, international students make up to 22% of the university population (Australian Government Department of Education and Training, 2014). These students face challenges due to their youth and inexperience in self-care. They are required to rapidly learn how to juggle their studies, cope with acculturation, form new friendship groups, and adapt to a new lifestyle. While challenging, these experiences encourage students to develop an adult and independent identity. Meanwhile, the habits and preferences formed during this period may have a lasting influence on their diets and health (Steptoe et al., 2002; Cluskey & Grobe, 2009; Ansari et al., 2012; Fyler et al., 2014).

Studying overseas has been implicated in increased health risks. Students from countries such as China and India

reduced their vegetable and meat intake when studying in the US and UK (Pan et al., 1999; Reeves & Henry, 2000; Papadaki & Scott, 2002; Satia-Abouta et al., 2002; Danquah et al., 2009; Almohanna, 2010; Trapp et al., 2011). Additionally, students are known to often turn to junk and processed foods (Racette et al., 2008; Strong et al., 2008). These dietary changes are similar to a shift to the modern western diet that is energy-dense, high in fat, sugars and low in vitamins, minerals and other valuable micronutrients (World Health Organisation, 2013). It is associated with overweight and obesity, poor physical and mental health and other non-communicable diseases (Hill & Weaver, 1991; Stoppani, 2007; Challem, 2008; Luntz, 2009; Smith, 2011). Furthermore, as students spend much time studying, they tend to have sedentary lifestyles that may exacerbate weight gain or result in poorer health (Schmidt, 2012).

Many factors have been identified that influence the type of food students are familiar with and which subsequently guide their tastes when they study abroad. These factors include their home food culture and domestic diets which are usually developed over childhood (Messer, 1984; Kittler & Sucher, 2008; National Consumers League, 2009; Amos & Lordly, 2014) and are deeply associated with identity making (Mead, 2007). In a new environment, factors such as affordability, accessibility and palatability of foods may also influence their dietary practices. For example, students are likely to have limited finances and they may find that preferred and familiar foods are either not available or too expensive (White & Kokotsaki, 2004; Certeau, 2007). Finally, as food preparation is often time consuming, students may resort to eating fast foods, instant meals or eat out particularly when under time pressures such as during exam and assessment periods. Ultimately all these factors can contribute to dietary changes with potential health impacts.

Until now, international student populations have been largely neglected in research into the health of young adults despite the growing numbers of students worldwide (Altbach et al., 2009; Coughlan, 2011). Most existing studies have been conducted in the US and UK and focus on Chinese and Indian students while other student nationalities are often overlooked. However, at Australian universities Southeast Asian students are an increasingly large and important group, making up the majority of remaining international student nationalities (The Australian National University, 2011). This paper investigates the significance and consequences of, and these students' responses to, factors that may influence their diets in an Australian university environment. Our aim is to develop an understanding of these students' perspectives on dietary changes to identify and emphasize areas to assist them in managing their lives and health in a new environment.

2. Method

2.1 Participant Characteristics and Sampling Procedures

Research participants were full-time undergraduate students from Southeast Asian countries aged 18 and over studying at the Australian National University for at least one year, and residing in self-catered accommodation. Initially, participants were purposely selected via the author's (JL's) access to several Southeast Asian student organisations and at events throughout the campus. Subsequent participants were recruited by snowball sampling. In addition, Facebook was used as a media platform where details of the study were posted onto two Facebook groups (as shown in Figure 1). Singaporean and Malaysian Chinese students were among the first to participate in the study followed by students from other Southeast Asian countries.
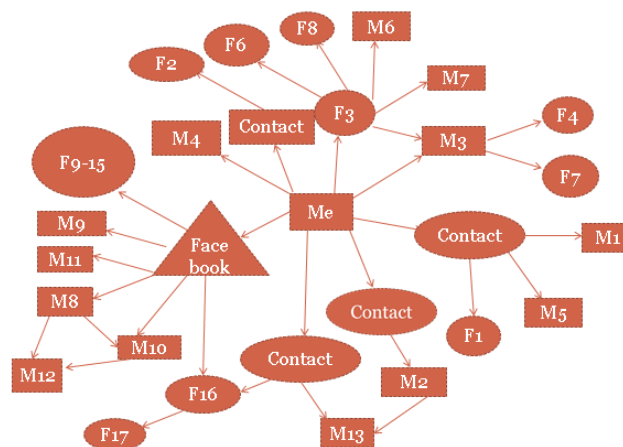
Figure 1. Diagram showing how participants were recruited through convenience and snowball sampling

2.2 Data Collection and Analysis

This study aimed to investigate the question: 'How do the diets of the international student population change after commencing study at the Australian National University?' with a specific focus on issues of affordability, accessibility, palatability, time constaints and weight and health implications. A semi-structured interview guide was developed based on relevant work by Eckermann (1997) and Hubert (2004). Open-ended questions were used to explore students' understandings and perceptions of their food preferences and behaviours both in their home countries and in Australia; their awareness of health campaigns in both settings; and their current exercise patterns and satisfaction with their weight. In addition, basic socio-demographic and health-related information such as perceived weight change, and self-rated health status was also collected (Miilunpalo et al., 1997; Mikolajczyk et al., 2008). Changes in macro nutrient intake were collected by asking students to illustrate the macro-composition of their old and new diets on pie charts (see Figure 2 for an example).
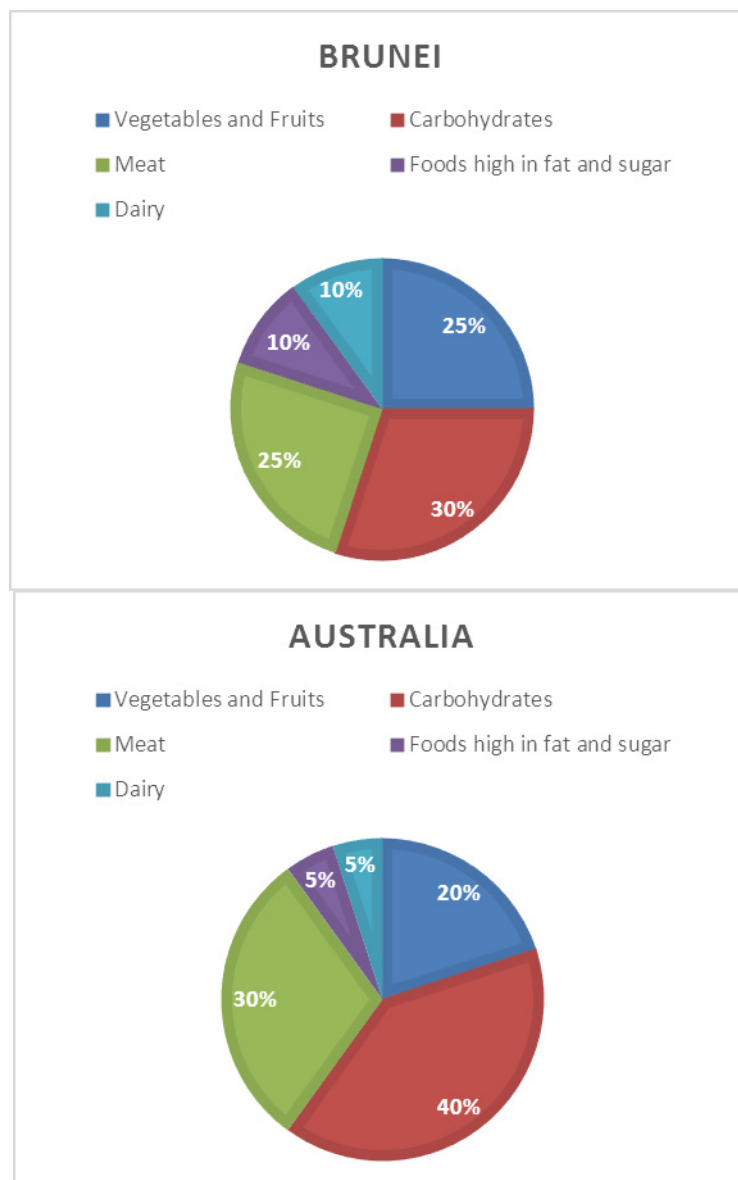
Figure 2. An example of a student's perception of the macro-composition of their dietary changes

The lead author (JL) conducted thirty-one interviews in English which were collected over a three month period in 2013 at a time and place convenient to the participant. Interviewing stopped once saturation of the main topic was achieved meaning that very little new information was gained in later interviews (Ulin et al., 2005;

Denscombe, 2010). Interviews were professionally transcribed and uploaded to Atlas.ti, a computer program that facilitates the coding process. The lead author read and re-read the transcripts to identify key concepts and codes related to food preferences, food practices, and dietary changes (Ulin, Robinson et al., 2005) and discussed the coding framework with the second author. Emergent themes were checked against existing literature and new themes were identified using a modified grounded theory approach (Pope & Mays, 2006).

2.3 Ethics and Informed Consent

Ethics clearance for the study was gained from ANU Human Research Ethics Committee (ANU HREC). Before participating in the interview, participants were fully informed about the study, their right to refuse to answer any questions and to withdraw from the study at any time. Each participant was also given a pseudonym to maintain confidentiality.

3. Results

3.1 Sample

The participants included more female than male students with most identifying Singapore as their country of origin followed by Malaysia and Vietnam. This mirrors the composition of international students at the university with 35.38% of international students coming from Southeast Asia (The Australian National University, 2011).

Table 1. Participants' Country of origin

Country of Origin	Participants	
	Male	Female
Indonesia	2	0
Malaysia	1	4
Singapore	7	7
Thailand	1	1
Vietnam	0	4
Other SE Asian countries	2	2
Total	13	18

NB: Participants were studying 19 different degrees with the largest number (9) doing a Bachelor of Commerce.

3.2 Affordability

Despite similarities in geographical location, each Southeast Asian country has its own culinary culture (Yen-Ho, 1995; Tan, 2011). While home culinary cultures formed an important part of students' food choices, this paper concentrates on issues that are relevant to most Southeast Asian students.

In this study, most participants had not lived away from home previously and had to learn for the first time how to manage their everyday living costs. Their budgets ranged from $20-200 per week. Their average expenditure on food per week was AUD81.54 for males and AUD85.42 for females. Students said they experienced 'price shock' because Australian food prices were several times higher than those they were used to or had expected.

Oh my gosh, like, why do I need to spend this much for… daily? So like... So I don't like to cook... [I] start cooking every day which I never did when I was in Malaysia. I never cooked at all when I was in Malaysia so I started cooking. And I didn't do that immediately so it was like a forced change that I had to do, like immediately. And then I guess like buying stuff I guess was like, oh my god. But just prices in general. - (Nila)

However, they developed strategies to manage. Students took time to compare prices between the major supermarket chains in Canberra. Mia explained that her and her friends tried to save money when buying food and said *"we actually take pictures of the products to see..."* Regardless of their socioeconomic backgrounds most students' searched for cheap and fresh items when shopping for food. Nevertheless, some participants would weigh up the benefits of paying a little more for items that taste better or have more nutritional value.

Um, I usually pick the cheapest one but it depends on the quality as well. Like, if it's cheap but very bad quality, I don't use it. Sometime the beef is on a special price, like $5 a kilogram but it's already black. I just don't use

that. - (Will)

Imported ethnic or cultural foods tend to be sold in lower quantities at higher prices (White & Kokotsaki, 2004). Thus, students often reserved 'cultural foods' for special occasions such as potlucks and group gatherings due to the cost and seasonality of ingredients and the amount of time needed to make the foods. Participants' also switched to other foods when the item they preferred was too expensive for their budget. For instance, Kaylee had come from a seaside town and was used to eating seafood daily but in Canberra she switched to meat as a source of protein instead. There were also participants who bought frozen vegetables and meats as these items could be stored for longer and cost less; though this was affected by accessible fridge space at their accommodation.

Many reasonably priced Asian restaurants are located close to the Australian National University to cater for the large number of Asian students. The frequency of eating out at restaurants varied greatly between participants and depended on factors such as the occasion, and whether they had additional money to spend. Most participants went to restaurants for birthdays or large gatherings of friends where the main course cost between AUD$15-30. In general, these shared meals, while more expensive than eating at their accommodation, were important as they allowed participants' to bond with others over food, thereby creating their own support systems that not only aided the process of acculturation but helped form friendships during their studies in Canberra (Amos & Lordly, 2014). Tran said it was also considered impolite to refuse invitations to eat out with friends due to the lack of funds.

I don't usually eat outside, I just buy food like once or twice a week, but when friends tried to gather round, it wouldn't be nice to say, "Oh I'm not gonna go out it's too expensive" so I just go - (Tran)

Students also had an opportunity to eat interesting food if they obtained part-time employment at restaurants to supplement their incomes or contribute to the cost of their studies.

I used to work at Thai restaurants so I get free Thai food all the time, really spicy food - (Jenny)

Regardless of their socioeconomic backgrounds, students tended to shop economically but were reluctant to sacrifice the quality of goods while doing so. However, it was unclear how much students relied on cheap foods such as instant noodles and other junk foods, as this depended on their moods and personal preferences which fluctuated and at times correlated with time scarcity and intensity of studies.

3.3 Accessibility and Availability

As globalization and migration patterns develop, Southeast Asian food cultures have been growing and evolving (Yen-Ho, 1995; Tan, 2011). Southeast Asian restaurants are common in Australia to cater to numerous Southeast Asian immigrants wanting to make and eat their own cultural foods as a connection with their home country (Duruz, 2007; Amos & Lordly, 2014). This growth has also promoted a trend in fusion foods (Tan, 2011), although this was not always viewed positively by participants.

When I miss Thai food like in my hometown, I can't really find like a good Thai food around… they are more Western Thai? You know what I mean? – (Will)

That just looks like some kind of bastardized fusion of different things and they're not really right. – (Brendan)

In the past, eating foreign foods in Australia was a luxury since most of the ingredients were imported thereby making these foods more expensive (White & Kokotsaki, 2004). However, foreign ingredients have become more accessible and somewhat more affordable recently due to higher demands. For instance, there are now aisles in mainstream Australian supermarkets devoted to condiments, ingredients, and prepacked or instant meals from overseas. Along with an influx of Asian grocery stores, this has allowed students to find ingredients to make their own cultural foods. However, a young woman suggested that locally bought foreign ingredients does not always taste authentic and can lead students to be disappointed in dishes they have prepared themselves.

Throwing away food is fine for me but food that you cook it's like "oh shit". I've been spending an hour or two doing that and now I'm throwing it away. It's kind of sad but you know. – (Tan)

Nevertheless, many students have adapted their diets to Australian conditions. They bought more salads, cereals and ingredients to make western foods that they enjoy as they are more easily available and easily prepared. Others however, still preferred to get some items from Asian grocery stores and these choices reflect how strongly participants adhere to their cultural identity and cultural foods (Anderson, 2005; Amos & Lordly, 2014).

I try to look for Halal, like in [supermarket] where we can get Halal chicken. But I'm not really a fan of chicken…'cause I really like beef, and the only one you can get beef from is in I think [a far suburb]...I went though, with [Friend] once, and it's usually expensive, probably 'cause it's the only place who sells it, and that

was the only time I went... – (Putri)

Canberra is renowned as a car-dependent city but most students cannot afford their own cars. It has a comparatively poor public bus service (to other major Australian cities) which students are forced to use to get to grocery stores in the city centre or elsewhere. Some students also walk about 20 minutes' from the University to the city centre whilst others ride their bikes.

I ride a lot, and my bike is my baby, seriously… with a bike, the trick is to fill up the basket [with food] and hang the rest of the stuff on the handles and then push it because if you ride it you'll definitely fall, and that way you can actually put more stuff and do more work – (Jenny)

As participants did not always have large amounts of free time, some of the cheaper markets and some speciality items outside the city centre were inaccessible for those who had no convenient and reliable transport. Nonetheless, participants' were willing to take the time to travel the extra distance by bus or car to seek out a particular ingredient. Women did not like to shop alone at night for safety reasons despite the short distance from the student accommodations to the city. They preferred to be accompanied by other friends or to shop during the day. Nevertheless, despite these limitations, most managed to access culturally valued foods.

3.4 Palatability

Many participants remarked that their home dietary culture strongly influenced their adult dietary preferences and behaviours. They preferred to eat the kinds of food they ate at home. For instance, many participants ate rice with most meals as it has been a part of their diets since they were very young. However, they also tried to be receptive to new foods which they could incorporate into their dietary repertoire (Anderson, 2005). Although taste or palatability has been identified as an important factor influencing the purchasing and making of foods, (Franciscy et al., 2004), this was not found to be the case in this study to the same extent. Students considered it a luxury to have the time and money to make or buy good tasting foods. Participants said they were sometimes in 'survival mode' when they ate food for sustenance and to relieve hunger rather than worrying about its taste. Consequently, the taste of food was important but less so that than other factors.

3.5 Time Scarcity

It takes time and practice for inexperienced students to learn to cook for themselves. Tan, a second year student, explained how she learnt:

Okay first year I can't cook at all. Like first time I came here I don't really know how to use a knife. I don't really know how to use knives and people are like, 'Oh no I cook for you…' My friend has been cooking for me for a while since first year… So first semester, people cook for me and then I tried to learn, they tried to teach me and like in that period of time and then second year I improved and now I can cook. - (Tan)

Participants, like Tan, with no prior cooking experiences struggled at first while others had been taught the basics like boiling water, cutting techniques and some simple recipes by their parents or housekeepers before commencing their studies. Often, participants would call their mothers or friends to ask how to cook certain foods or consult the internet. Both male and female students became better cooks over time. However, this did not always mean that they cooked healthy meals as time was also a crucial factor. Most students made simple stir-fries, pan-fried meats, soups, rice and noodles with various types of seasoning with the time taken ranging from 20 minutes to one hour, including eating and cleaning.

At first, most participants' juggled their daily living requirements with university demands whilst coping with homesickness. Over time, many developed strategies to improve their time management use. These included using familiar easy recipes, eating out if they were pressed for time particularly during exams and assessment times, cooking in bulk and storing food, and sharing cooking with friends. While cooking with friends was usually seen as a social activity (Amos & Lordly, 2014), some participants' also did this to provide more nutritionally balanced meals through the inclusion of a greater range of dishes and reduced costs (Ball & Brown, 2012); around AUD5 per person per meal was considered reasonable. However, this required complex scheduling to include a number of people as well as the need to accommodate the varying tastes and dietary requirements. Hence, some participants found that it was easier to cook by themselves. Overall, most participants' found cooking to be therapeutic and they enjoyed planning and cooking their meals, provided it did not take too long.

3.6 Health

According to an analysis of their pie chart diagrams, the macro-nutrient content of participants' diets did not appear to change greatly. Only 8 (26%) of participants indicated that they ate fewer vegetables and fruits and

increased their meat and carbohydrate intake. Other participants (11; 35.5%) said they made minimal or no changes in their diets and others thought that their diets were healthier (12, 38.7%), meaning that they had increased their fruit and vegetable intake and consumed less meat and carbohydrates. Women's diets were usually healthier while males tended to have similar or less healthy diets compared to their home diets. Most participants still thought that they could improve their diets by eating more fruits and vegetables although they also acknowledged that this would be more costly.

Healthier foods are actually more expensive...Natural foods are actually more expensive – Leny

Because processed foods are cheaper than fresh foods, we expected that students who spent less on food would have less healthy diets and lower self-rated health. However, (Table 2) men who had lower self-rated health spent more on food than those with higher self-rated health. In contrast, women who rated their health poorly spent less. Overall, most participants' assessed their self-rated health positively (Table 2). In a small, cross-sectional study such as this it is difficult to draw any conclusions although this finding suggests that men and women responded to budgetary constraints differently.

In comparison to European counterparts, fewer participants' felt that their health was very good (12.9% vs. 35.8%) and more felt that their health was only fair (25.8% vs. 8.9%) (Miilunpalo, Vuori, Oja, Pasanen, & Urponen, 1997). In the interviews participants who rated their health highly attributed this to frequent exercise rather than diet. Those who thought that their diets were healthier did not necessarily have better self-rated health.

Table 2. Participants' Self-rated health and average food expenditure per week

Self-Rated Health	Poor and Fair (N=9 29%)	Good (N = 14 45.2%)	Very Good & Excellent (N= 8 25.8%)
Males	5	3	5
Females	4	11	3
Males' Average Food Expenditure/Week (AUD)	97.00	78.33	72.50
Females' Average Food Expenditure/Week (AUD)	53.34	65.68	142.5

Male participants' BMIs ranged between 20.5 to 28.4 and females ranged between 17.8 to 28.9 (BMI = Weight (kg)/Height^2 (m)). Male and female students within a healthy BMI range generally spent comparatively modestly on food. However, a heavier BMI category was linked with greater expenditure on food among men and a lower expenditure by women suggesting once again gendered behaviours around food purchasing.

Table 3. Participants' BMI and average food expenditure per week

BMI Classification	Underweight <18.5 (N = 2, 6.5%)	Healthy Weight 18.5 - 23.9 (N = 20, 64.5%)	Overweight 24-26.9 (N = 5, 16.1%)	Obese >27 (N = 4, 12.9%)
Males	0	7	4	2
Females	2	13	1	2
Males' Average Food Expenditure/Week	n/a	72.86	85.00	105.00
Females' Average Food Expenditure/Week	92.5	78.27	75.00	55.00

NB: The ranges are based on Asian BMI cut-offs (Kanazawa, Yoshiike et al. 2002, Joslin Diabetes Center 2010).

4. Discussion

This study illustrates the way in which Southeast Asian students at the Australian National University have adapted to their new food environment. Despite initial difficulties, they have learned to manage issues of food affordability, accessibility and palatability and over time develop a reasonably healthy diet. A proportion of them thought that their diet was healthier than it had been in their home countries. Most existing studies find that

international student diets are less healthy than their home diets (Pan et al., 1999; Reeves & Henry, 2000; Papadaki & Scott, 2002; Satia-Abouta et al., 2002; Danquah et al., 2009; Almohanna, 2010; Ansari et al., 2012).

Existing literature shows that many international students (not in Australia) have unhealthy dietary practices including reduced intakes of vegetables, decreased or increased meat consumption in relation to affordability, and eating less due to budgetary constraints. They also skip breakfast due to class timetables meaning they eat only two meals a day. This is often associated with cost as the over-riding factor in influencing food preferences and choices along with availability and palatability (Pan et al., 1999; Reeves & Henry, 2000; Papadaki & Scott, 2002; Certeau, 2007; Danquah et al., 2009; Almohanna, 2010; Peltzer & Pengpid, 2015). Additionally, securing food has been identified as one of the factors that students worry about along with finances and loneliness (Gu et al., 2010). Other factors such as home cultures and time scarcity are also influential. Our participants were able to manage issues of affordability and availability and still purchase the kinds foods that they wanted to eat or make. These food choices were guided by familiar flavours from their home countries; though many were also willing to try and integrate other cuisines that they are not familiar with into their diets.

While palatability is thought to be a large factor affecting diets (Franciscy et al., 2004; Anderson, 2005), it was not always a determining factor for these students as there were times when food was thought to be only necessary for survival. The palatability of foods was sometimes less important than the time available to cook and eat. Students tended to eat premade meals and fast food when pressed for time during exam periods.

Our participants mainly rated themselves healthy although half the males were overweight or obese. Overall, their expenditure on food per week demonstrated that maintaining good self-rated health did not necessarily entail a high budget. Most participants felt that they could achieve an adequate diet on their budgets.

Weekly food expenditures pointed to differences in how men and women managed their diets within a tight budget. Women who were overweight or obese spent less on food than women of a normal BMI. Men who were overweight or obese spent considerably more than men with a normal BMI. This could be due to a variety of reasons such as: men eating much larger quantities to satisfy their hunger, buying more premade foods and being more likely to eat out than females (National Consumers League, 2009; de Saint Pol, 2014) while women on a low budget may be eating cheaper, less healthy and more energy dense foods or snacking more on cheap junk foods. It is possible that women who were concerned about their weight were spending less on food by buying smaller quantities. Women in the study with high self-rated health spent more on food than other women. Men with high self-rated health spent less than other men. Research (de Saint Pol, 2014), suggests that women may have more time or delegate more time to cook or shop often for healthier food options. In addition, men are more likely to over-estimate their health status than women (Wardle et al., 2006). These differences could also be due to personal physiological traits such as metabolism rates and family health history (Magkos & Mittendorfer, 2009). Additionally, while men and women with higher educational backgrounds tend to be more self-conscious and knowledgeable about their diets, differences in expenditure could also be due to the fact that women are more likely to be affected by sociocultural needs to be slimmer. Personal economic resources may also be a factor in food expenditure differences and health outcomes as those who have more money to spend are more likely to have access to better quality products (Cheung et al., 2011; Joh et al., 2013).

Based on data collected through their pie charts, it appears that participants mostly managed to maintain or even improve their diets by consuming more fruit and vegetables and fruit and minimizing carbohydrates, compared to when they were living in their home countries. However, this does not imply that their home diets were unhealthy. Indeed, traditional Southeast Asian diets are generally considered healthy and it is has only been since the widespread adoption of a more westernised and energy dense diet in these countries that there has been concern about diet-related health (Bengoa, 2001; Popkin & Gordon-Larsen, 2004; Popkin, 2004; Satia, 2010). Additionally, some participants also mentioned that obesity prevalence was not an issue in their home countries. For instance, in Vietnam, the prevalence of obesity was 1.6% for the population aged 20 and above (World Health Organisation, 2011).

Due to time and resource limitations in this study we were unable to measure caloric intakes, procure detailed food diaries, or measure food quantities and types accurately to obtain a clearer analysis on their cross-country dietary changes. Our findings related to food budgets, weight and health suggest that further qualitative and quantitative research would be useful. As this was a small qualitative study, the findings are not generalizable to the student population as a whole. It does provide however, an in-depth understanding of the factors related to dietary changes and health related outcomes that occur when Southeast Asian students move to Australia.

While there is an abundance of information on healthy diets and behaviours available through Australian media, there are no active campaigns or support for international students. However some students in this study sought

information because of their desire to be healthy suggesting that provision of diet and exercise information targeting overseas student groups at universities could be helpful.

5. Conclusion

Overall, this research found that most Southeast Asian students considered that their diets in Australia were as healthy as or healthier than in their home countries in terms of macro nutrients and food groups consumed. Due to issues of affordability, availability of cooking materials, and lack of food preparation time, most students found alternatives for some home foods. These Southeast Asian international students seemed to have better diets than those reported for other international student populations. BMI and self-rated health did not worsen due to dietary changes as suggested in previous literature. This may be because our student participants lived in self-catered accommodation, and could control their diets, cooking methods, and lifestyle. This dietary control was supported by relatively easy access to imported Asian foods and a range of fruit and vegetables available in nearby local supermarkets and shops. Another contributing factor to students' physical and mental well-being was the relationships they formed with other students with whom they cooked, shared chores and meals, and support. While catered accommodation frees time for students to study it may not provide as healthy an environment due to limited food choices and repetitive menus (Pliner & Saunders, 2008; Cluskey & Grobe, 2009). This perception was supported by some participants who had previously lived in catered accommodation. This study has implications not only for students' health but also for their ability to study and make the most of their opportunities while engaging in studies overseas.

As the factors of affordability, accessibility, availability, time scarcity, and palatability have been identified as potential barriers to achieving healthier diets, future studies could be done on how university facilities and related food provision services can help students achieve better diets and health in general. For instance, experimenting with trial cooking workshops, free exercise classes and information on how to prepare healthy meals targeted at the student population could help in finding solutions to promote better health and well-being. Without any interventions, long term unhealthy diets could affect students later on in life due to the association between unhealthy diets and the onset of non-communicable diseases.

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Rabies Epidemiology and Control in Ecuador

Esteban Ortiz-Prado[1,2], Jorge Ponce-Zea[2], Dario Ramirez[2], Anna M. Stewart-Ibarra[3,4], Luciana Armijos[5], Jaime Yockteng[6] & Washington B. Cárdenas[6,7]

[1] Universidad de las Americas, Quito, Ecuador

[2] Research and Development Department ENFARMA EP, Quito, Ecuador

[3] Department of Medicine and Center for Global Health and Translational Science, State University of New York Upstate Medical University, Syracuse, NY, USA

[4] Prometeo Program, SENESCYT, Quito, Ecuador

[5] Minister of Public Health, Quito, Ecuador

[6] Laboratorio de Biomedicina, Escuela Superior Politécnica del Litoral, ESPOL, Guayaquil, Ecuador

[7] Instituto Nacional de Investigacion en Salud Publica INSPI, Guayaquil, Ecuador

Correspondence: Esteban Ortiz-Prado, Associate Professor Faculty of Medicine, Department of Physiology, Universidad de las Américas, Calle de los Colimes y Avenida De los Granados, Quito 170137, Ecuador. E-mail: e.ortizprado@gmail.com

Abstract

Objective: Describe the epidemiology and the control effort for rabies in Ecuador.

Methods: This observational study included data from the Ecuadorian National Institute of Census and Statistics (INEC), and mortality and morbidity data reported by the Ministry of Public Health and the National Institute for Social Security. We conducted a phylogeny analyses to compare the N gene from the Challenge Virus Standard (CVS) vaccine strain used in Ecuador with published Cosmopolitan, Asian and Sylvatic strains. Descriptive and inferential statistics were used to determine the significance of the data.

Results: In 1996 Ecuador suffered the highest rate of rabies per capita in the Americas, with an incidence rate of 0.56 cases per 100 000 people per year. Human and canine rabies showed a sharp decline until 2012. Between 1994 and 2014, we found a correlation of 0.925 ($p < 0.01$) between annual cases of dog and human rabies. In 2011, there was an epidemic of sylvatic rabies transmitted to people by vampire bats (*Desmodus rotundus*) in the Amazon region, specifically in Morona Santiago, leading to 11 fatalities. Phylogenetic analyses of the CVS vaccine N gene showed an association with urban canine rabies strains (the Cosmopolitan lineage and Asian strains), whereas sylvatic rabies, like those reported in the Amazon region, were found to be grouped in a different clade represented mainly by bat-derived strains.

Conclusions: This study presents the first compilation of epidemiological data on rabies in Ecuador. The incidence of human and canine rabies, also known as urban rabies, has clearly decreased due to massive canine vaccination campaigns. Phylogenetic analysis of the prevailing vaccine used in the country showed a clear separation from bat-derived rabies, the source of recent rabies outbreaks. Efforts are ongoing to develop rabies vaccines that are highly specific to the rabies virus genotype circulating in the region, including sylvatic rabies. These efforts include the implementation of reverse genetics to generate recombinant virus coding for the prevailing glycoprotein gene.

Keywords: Rabies, Rabies vaccine, zoonotic disease, Ecuador, epidemiology

1. Introduction

Rabies is a preventable viral disease, typically transmitted through the bite of a rabid animal. The first detailed description of the rabies syndrome, including the long incubation period, is found in Fracastoro's writings during the Dark Ages. Louis Pasteur and Émile Roux, developed the first rabies vaccine in 1885 (Baer, 1991). The causative agent is a ~12 Kb, single-stranded, non-segmented negative sense RNA genome virus that belongs to the Mononegavirales order, Rhabdoviridae family and Lyssavirus genus. The rabies genome encodes five

proteins: nucleoprotein (N), phosphoprotein (P), matrix protein (M), glycoprotein (G) and polymerase (L). *Lyssavirus* show a broad antigenic cross reactivity at the nucleocapsid level due to a high sequence conservation of the N gene.

Virus entries are through wounds or by direct contact with mucosal surfaces. The virus replicates on nervous tissues or directly enters into peripheral nerves. Then the rabies virus travels by retrograde axoplasmic flow to the central nervous system, causing ultimately brain disease and death (Archer & Houldcroft, 2014). Rabies is almost inevitably fatal, and death occurs within a few days after symptoms onset. Early signs and symptoms of rabies include fever, headache, weakness anxiety, confusion, paralysis, excitation, hallucinations, agitation, hypersalivation, odynophagia and hydrophobia (Brass, 1994; Susilawathi et al., 2012; Udow, Marrie, & Jackson, 2013). Rabies has the highest case-fatality rate of any currently recognized infectious disease.

Diagnosis of rabies by clinical symptoms is difficult, except when specific disease signs appear as hydrophobia and aerophobia. Laboratory diagnosis can be done *post mortem* and *in vitam*; the main techniques are based on antibodies antigen detection, virus isolation and nucleic acid sequences amplification (PCR). Rapid fluorescence focus inhibition test (RFFIT) is the current gold standard serological assay, recommended by the World Health Organization (WHO). Nowadays, rabies affects more than 150 countries worldwide. More than 3.3 billion people live in endemic or enzoonotic regions where approximately 60 000 people die from rabies each year, especially in Asia and Africa (DeMaria, 2014).

The situation in regions like the United States differs considerably, where 1-2 cases per year are reported in the whole population, mainly transmitted by infected bats (Blanton, Palmer, Dyer, & Rupprecht, 2011). Nevertheless, more than 39 000 cases per year of suspicious animal bites that require post-exposure prophylaxis are reported in the United States (Brass, 1994; Fuenzalida, 1972). Post-exposure immunization is vital during the hours following contact with rabies, since it can prevent the disease that would otherwise cause the death of the patient (DeMaria, 2014; Mclean & WHO, 2011; Udow et al., 2013).

The estimated cost of this disease in Asia and Africa is $500 million dollars per year in direct costs, and more than $6 billion dollars in related costs, including loss of productivity, and the costs of vaccination and immunization (Knobel et al., 2005; Mclean & WHO, 2011). Currently, there is no effective treatment for rabies. For this reason, preventing the disease through vaccinations before and after exposure to the disease is a critical public health concern. In Ecuador, rabies vaccines continue to be produced using nerve tissue from suckling mice, principally for use in domestic animals. In other countries, these vaccines have been discontinued for human use because they are reactogenic and some are of low immunogenicity; instead of it, the use of the VERO cell rabies vaccine has been popularized.

In 1983 the first Meeting of the Directors of National Rabies Control Programs (in Spanish: Reunión de los Directores de los Programas Nacionales de Control de Rabia – REDIPRA) was held in Guayaquil, Ecuador, in response to recommendations by the 21st Session of the Pan American Health Organization's (PAHO). As a result of the meeting, the strategies and the action plan for eliminating urban rabies from Latin America were approved, and since then the number of cases of urban rabies have declined by 95% ("Rabia," 2014).

The aim of this study is to present the first synthesis of the epidemiology of rabies and its control efforts in Ecuador, in order to contribute to the public health management strategies in the country, given the lack of official national guidelines. We reviewed national and regional available data to describe the epidemiology of rabies in Ecuador, and present the current state of the rabies control efforts.

2. Methods

This observational study includes data from the Ecuadorian National Institute of Census and Statistics (INEC), mortality and morbidity data reported by the Ministry of Health and the National Institute for Social Security. The data of human rabies and dog rabies were analyzed using Pearson correlation in SPSS version 19.0 for Windows, and the maps were made using ArcMap version 10.1 for Windows.

Additionally, the study includes data collected from the production line of the different rabies vaccines of the National Institute of Public Health Research of Ecuador. Genetic diagnosis by RT-PCR and phylogenetic comparison of N genes from Challenge Virus Standard (CVS) vaccine strain used in Ecuador has been described previously (Nadin-Davis, Sheen, & Wandeler, 2009; Yockteng Melgar, 2014).

3. Results and Discussion

3.1 Human and Canine Rabies

In 1942 and 1943 the first documented outbreak of rabies was reported from the northern highland province of

Carchi. The disease spread throughout the country over the next ten years, from Carchi to Imbabura provinces, followed by Cotopaxi, Manabí, Tungurahua (1945), Chimborazo and Bolivar (1947), Los Rios (1948), and Guayas provinces (1949). The southern provinces of the country, such as Loja, began reporting cases in 1954. There is no record of the first outbreak in the Amazon region (Ministerio de Salud Pública, 2014).

From 1994 to 2014, the overall change in human rabies cases can be attributable to dog rabies cases (Figure 1 and 2). This inference was supported by a Pearson correlation index of 0.925 (p<0.01). Data from 2011 was not included because that outbreak was attributed to vampire bats bites. In 1996 Ecuador suffered one of the worst rabies outbreaks in the last fifty years, due to the lack of effective rabies-control policies. Sixty-five human deaths caused by rabies were notified and 1175 cases of canine rabies reported in the same year. This was the highest rate of rabies per capita in the Americas in that year, resulting in 0.56 cases per 100 000 people per year (INEC, 2011).
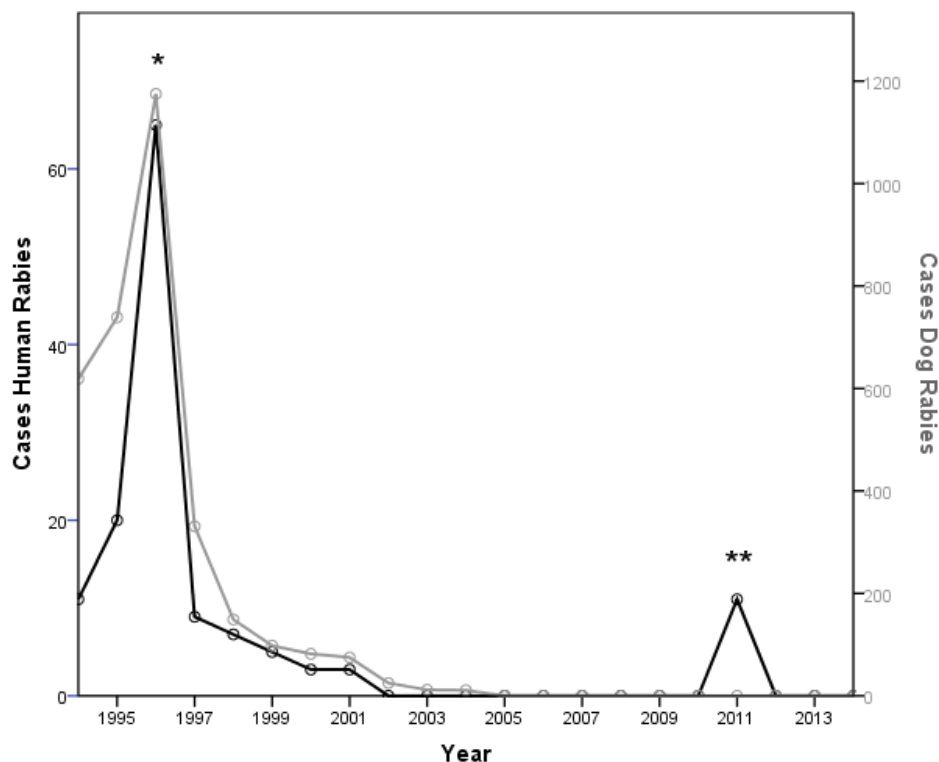
Figure 1. Annual reported cases of canine rabies (grey line) and human rabies cases (black line). *Start of national animal vaccination camping (1996). **Outbreak of sylvatic rabies due to transition by vampire bats (*Desmodus rotundus*) caused 11 human cases (2011). (Since 1994 to 2014, excluding 2011: Pearson correlation coefficient: r = 0.925, p<0.01)
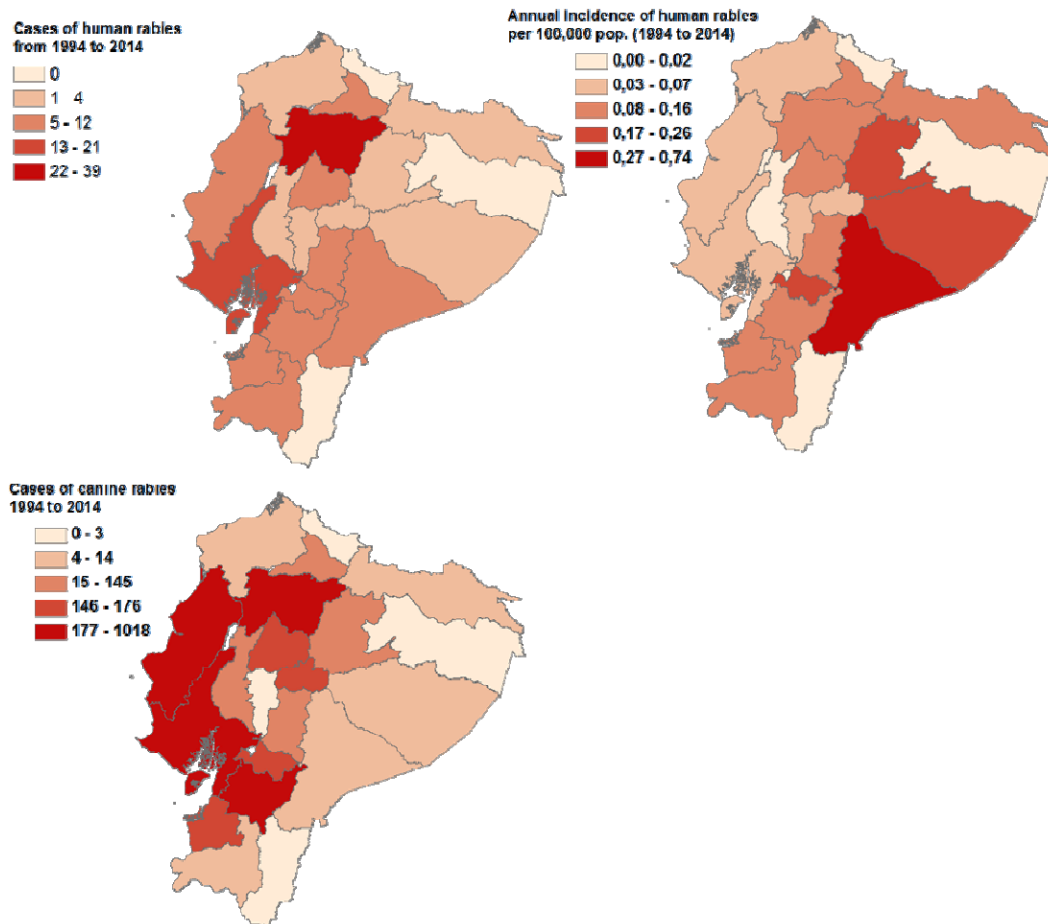
Figure 2. The spatial distribution of rabies by provinces in Ecuador. Top, clockwise: (1) total number of human rabies cases from 1994 to 2014, (2) the incidence of human rabies cases per 100 000 people per year from 1994 to 2014, and (3) the total number of canine rabies cases from 1994 to 2014

Following the outbreak, the Ministry of Health intervened and effectively cut rabies transmission, leading to only 5 cases of human rabies and 98 cases of canine rabies by 1999. Interventions included mass vaccination campaigns of dogs, leading to over 80% of canine vaccine coverage, as well as the implementation of a public neutering program to control urban fauna. By 2001, rabies reports had reduced to three cases of human rabies and 75 cases of canine rabies (Figure 1). In 2004, the last cases of canine rabies were reported in the country and in 2009 the last cases of urban rabies in humans were reported in Esmeraldas province. Human rabies transmitted by dogs is close to being eradicated in Ecuador primarily due to dog vaccination campaigns, which provide an immune barrier to viral circulation.

In Latin America and the Caribbean, they have implemented similar plans that include: 80% coverage of vaccination; care 100% of people exposed; surveillance; and education about risk of rabies. This led to the entire region to a reduction of 25,000 cases in 1980 to fewer than 300 in 2010. Since 2004, sylvatic rabies has been the main concern in the region, since there are more cases of bat transmitted rabies than dog transmitted rabies. However, there are not effective methods to control rabies in this type of populations (Vigilato et al., 2013).

3.2 Sylvatic Rabies

There have been three important sylvatic rabies breakouts in the last 15 years. The first one occurred in 1997, when eight human deaths by rabies were confirmed in the Numbat-kaime and Kunkuki communities, located in Morona Santiago province. The second outbreak caused four deaths in 2005 in the Jatun Molino, Pastaza province. The last breakout of sylvatic rabies occurred in 2011 in Morona Santiago, within Wampuik, Tarimiat and Tsurik Nuevo communities resulting in 11 deaths, including 9 children under the age of 15. The transmission was alluded to vampire bats (*Desmodus rotundus*).

The Ministry of Health and the Ministry of Agriculture, Livestock and Fisheries joined efforts immediately to take control of the outbreak. The Ministry of Health provided 56 000 doses of prophylaxis rabies vaccines for people in the communities under risk. The Ministry of Agriculture, Livestock and Fisheries reduced vampire bat populations in rural areas through the use of diphenadione, an anticoagulant given to cattle, despite the ecological costs of killing bats (Ministerio de Salud Pública, 2014).

Apart from experiences during the recent outbreak, we have limited information on prevalence of vampire bat bites, the ecology and transmission dynamics of sylvatic rabies in Ecuador. A study of the community perception of bat bites in the Ecuadorian Amazon showed that over 20% of households heads reported being bitten within the last year, indicating a high risk of exposure (Romero-Sandoval, Escobar, Utzet, Feijoo-Cid, & Martin, 2014). Additional research is needed in this area.

3.3 Rabies Surveillance and Diagnostics

In Ecuador there is an epidemiologic surveillance system for rabies connected to the Regional Rabies Surveillance System in the Americas (SIRVERA), coordinated by PAHO. Local health units send a weekly report of positive cases of human and animal rabies cases. The cases must be confirm by a lab test. These reports are consolidated at national level and then sent to SIRVERA.

Rabies weekly reports include information on cases, treatment, laboratory diagnosis results, vaccination, and suspected animal cases. However, surveillance systems need to be strengthened to inform control interventions at the sub-country level, especially since most rabies cases are reported from rural areas, where underreporting is likely.

The Ministry of Health has incorporated recently, with the help of Academia, a conventional RT-PCR method for rabies diagnostics, allowing for massive and independent processing of suspected samples (Yockteng Melgar, 2014). This was implemented by amplifying conserved regions of the nucleoprotein gene (Nadin-Davis et al., 2009) (Figure 3). Several reports have shown that genetic diagnosis is equal to or more sensitive and specific than the gold standard fluorescent antibody test (FAT) and mouse inoculation test (MIT) recommended by the WHO (Robardet, Picard-Meyer, Servat, & Cliquet, n.d.; Suin et al., 2014; Yang et al., 2012). Genetic methods can supplement diagnostic information generated by FAT and MIT tests to identify false negatives that result due to poor sample preservation, especially samples brought from remote communities (25). Several studies have shown that RT-PCR can detect genetic material even in decomposed or samples stored over long periods of time (Biswal, Ratho, & Mishra, 2007; Lopes, Venditti, & Queiroz, 2010).
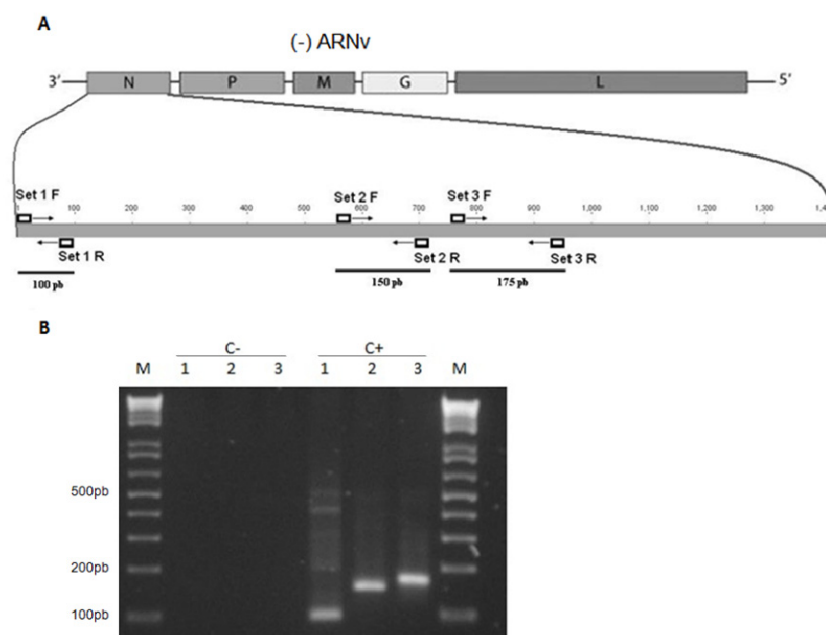
Figure 3. A) Schematic of the genetic organization of the rabies genome. The location of conserved regions for RT-PCR diagnosis is depicted. B) Agarose Gel resolving the RT-PCR diagnosis amplicons from three set of primers: 1, 2 and 3. Challenge Virus Standard (CVS) strain was use as the positive (C +) control and water as the negative (C-) control for RT-PCR. M is the DNA marker

The implementation of the genetic diagnosis has led to a better characterization of rabies molecular epidemiology in Ecuador. The phylogenetic relationship of the N gene from the Challenge Virus Standard (CVS) rabies virus strain, used in Ecuador for vaccine production, aligned with the Cosmopolitan lineage and Asian strains, the latter being the source of most urban (canine) rabies (Figure 4). However, all reported recent rabies outbreak have been associated with Chiroptera (bats) which segregated to a different clade, indicating genetic drift from the vaccine and a probable impairment in immunologic protection.
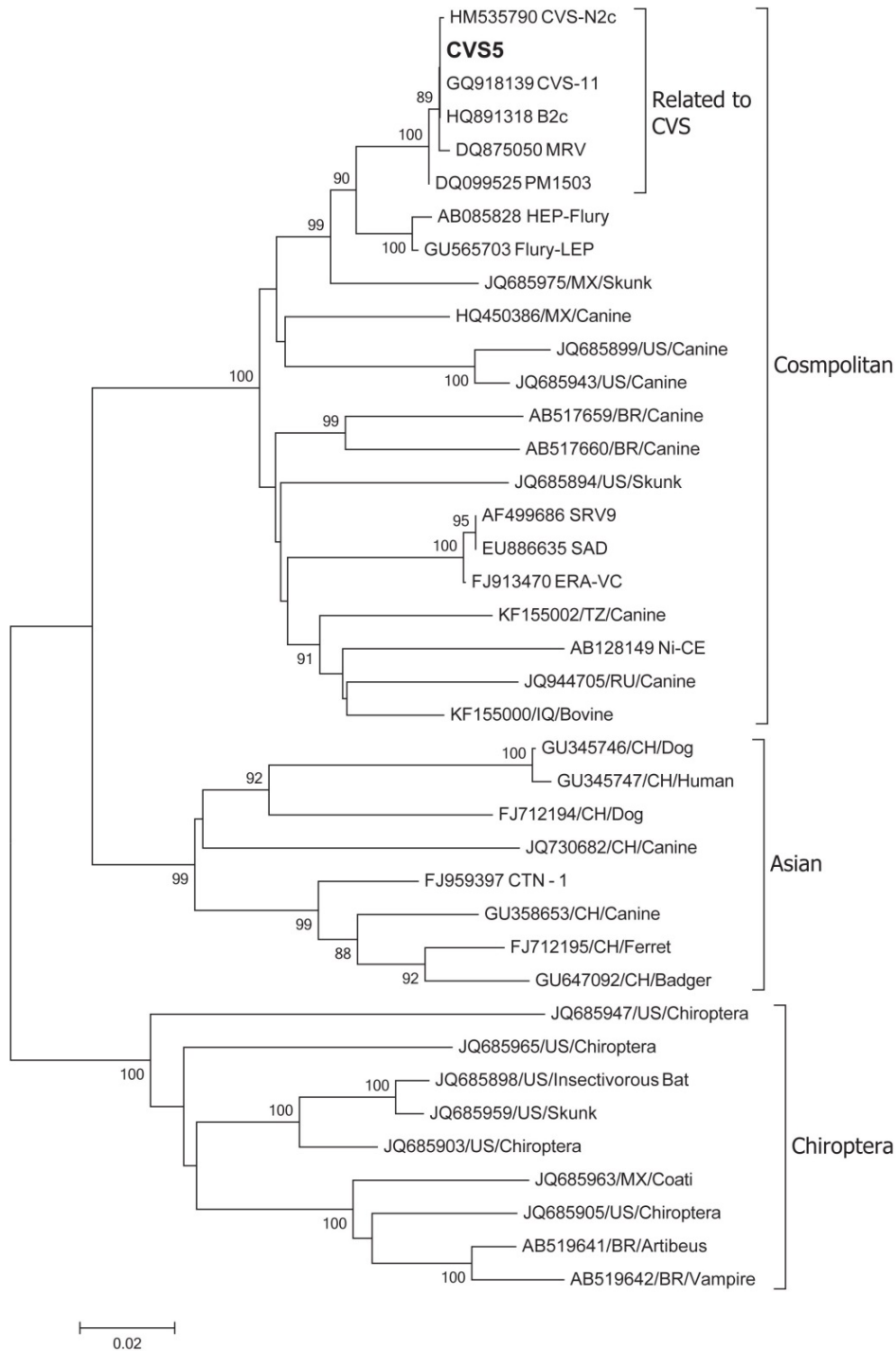
Figure 4. Phylogenetic comparison of N genes from Challenge Virus Standard (CVS) vaccine strain used in Ecuador (bold) with other rabies strains worldwide. The analysis was performed using Neighbour-Joining method based on the coding region of the N genes. Sequences were obtained from the GenBank. Bootstrap value >80% are shown next to the nodes

3.4 Rabies Vaccine Manufactured in Ecuador

In Ecuador, the current vaccine manufacturing process is based on the Fuenzalida-Palacios technique, which uses baby mouse brain infected with the rabies virus. Vaccines produced by this process are characterized by a high antigenic potency and an induced quick-lasting serologic response (Rosario Z. de Dávila et al., 1988). Human-use rabies vaccines are formulated using a UV-treated 2% baby mouse brain suspension from 24-hour-old mice that are previously inoculated with CVS 51 and 91 rabies virus strains. This vaccine has a 24-month shelf life when maintained at 2 to 8 °C without light exposure. All manufacturing process, procedures and techniques are in accordance with standards set by WHO/PAHO (Horowitz et al., 2003; "WHO | Rabies," n.d.).

Vaccine quality is ascertained through official release of each production batch, after all quality controls have been passed, with normalized procedures described in the Manual: Rabies-Lab techniques of the WHO (Meslin, Kaplan, Koprowski, Organization, & others, 1996). The vaccine potency test of the National Institute of Health (NIH test) is also performed, as described in the US Code of Federal Regulations (9CFR 113.209) (U.S. Government, 2014).

Over the last 20 years in Ecuador, 2 214 800 doses of nationally produced rabies vaccine were administered to people. In 2012, Ecuador discontinued domestic production of human rabies vaccines due to the implementation of a new administrative structure at the Ministry of Health, and began importing inactivated rabies vaccine grown in Vero cells. Canine vaccine is the only animal rabies vaccine still manufactured in Ecuador.

The effectiveness of the human and canine rabies vaccine made in Ecuador has never been assessed; however, the decline in the incidence of rabies in the country following mass campaigns is indicative of its effectiveness (Figure 1). Whilst in Ecuador there have not been reported severe adverse events, it is necessary to implement an adequate post-commercial control system. However, as an indicator of vaccine safety, a study of Ecuadorian manufactured vaccine was performed by the Ecuadorian NIH and found that adverse events in people exposed to the Ecuadorian rabies vaccine did not exceed international standards established for this product (Rosario Z. de Dávila et al., 1988). Consistency of manufacturing quality has been judged by the fact that almost all batches (99%) of vaccine that were produced were released to the public for human use.

In 2009, by presidential decree, the pharmaceutical state company (ENFARMA) was created, and it assumed the vaccine production competencies that were performed previously by the Ecuadorian NIH. This public company has the task of providing medicine to the National Health system. ENFARMA established a plan to implement a relative new technology (VERO cell cultures) for rabies vaccine production in new manufacturing facilities in the country. The company anticipates an annual production of 100 000 of human-use and 30 000 of veterinary-use doses. The re-establishment of local production will be important to control rabies outbreaks; however, vaccine production has been delayed until the construction of new manufacturing plants is completed in 2016.

4. Conclusion

This study provides the first compilation of the epidemiological data on rabies in Ecuador and a review of control efforts to date. Human and canine rabies, also known as urban rabies, have clearly decreased and are near eradication as the result of massive canine vaccination campaigns. High rates of canine vaccine coverage; as well as the implementation of sanitary measures for controlling urban fauna, have achieved the reduction of transmission from urban fauna to humans in Ecuador. These measures were implemented mainly after the epidemic in 1996. These strategies have decreased human rabies in many countries in South America (INEC, 2011; Paredes Cecilia, 2010), resulting in complete eradication in other countries (Smith, Orciari, Yager, Seidel, & Warner, 1992).

Sylvatic rabies remains a prevalent public health threat in Ecuador and other countries in the Amazon region. Our phylogenetic study (13) revealed that the local vaccine strain differs from the clade of sylvatic rabies, implying a different amino acid sequence that might affect the effectiveness of the vaccine. However, further antigenicity and immunogenicity studies must be done to assess the effectiveness of the local vaccine against sylvatic rabies strains. Additionally, we suggest the implementation of molecular surveillance of sylvatic rabies to better understand the virus evolution in Ecuador.

The public health sector should focus its efforts to educate people such as rural health workers and farmers, who may be in risk of rabies exposure. Multi-country collaborations for sylvatic rabies control are especially important in the Amazon region, where there is a high risk of cross-border disease propagation (Blanton et al., 2011; Takayama, 2008).

Acknowledgements

Conflict of Interest

The authors declare no conflict of interest of any kind.

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Concept of Educational Assistance to Health Protection of the Individual

Elena Aleksandrovna Levanova[1] , Olga Rafailovna Kokorina[2], Yuriy Vladimirovich Nikitin[2], Tatiyna Vladislavovna Perepelkina[2] & Polina Anatolievna Segodina[2]

[1] Moscow state pedagogical university, M. Pirogovskaya str., 1, Moscow, Russia

[2] Sakhalin state university, Lenin str., 290, Yuzhno-Sakhalinsk, Russia

Correspondence: Olga Rafailovna Kokorina, Sakhalin state university, Lenin str., 290, Yuzhno-Sakhalinsk 693000, Russia. Tel: 7-914-759-2953. E-mail: kokorinaolga@mail.ru

Abstract

The article describes the theoretical and practical need for the development of the concept of assistance to health protection of the individual in order to address the problem of health protection of students and teachers in the conditions of a higher pedagogical education. The problem of studying human health, its entirety, systemacity and connection with the environment attracts particular attention in recent years. This was one of the reasons to study the problem of "healthy lifestyle" as the qualitative characteristic of a human life aimed at health, due to the fact that a healthy lifestyle is one of the determinants of health. This is made possible with the use of specific health-protecting technologies aimed at searching for ways and means of protection and conservation of health of students and teachers in the conditions of the educational process and using educational tools, which is currently included into the priorities of education.

Keywords: concept, educational assistance, health-protecting technologies, health protection; individual, health, healthy lifestyle, professional education

1. Introduction

The strategic aims of education outlined in the "National Doctrine of Education in the Russian Federation through to 2025" are closely linked with the problems of Russian society, including "the creation of a framework for sustainable social, economic and intellectual development of Russia, ensuring a high quality of life of the people and national security". Main goals and objectives of education in the Doctrine include "fostering healthy lifestyle, development of children and youth sports", and the main objectives of the state in education include a comprehensive care for "the protection of life, health and physical education in the development of children, pupils and students".

Scientific and practical need to develop special health-protecting technologies, which mobilize resource potential of the participants in the educational process to achieve the objectives of the new educational paradigm, is increasing. In this regard, assistance to the protection of health as a process aimed at self-regulation of an individual and finding the meaning of a healthy lifestyle becomes the strategy of development of health-protecting technologies in an educational institution (Serikov, 2002).

Analysis of the practice of educational institutions revealed the importance of assistance to health protection in the following aspects: relevance of subjects of educational process that have health protection competence; need for technological support of the formation of the axiological attitude to health as a factor of personal development and its implementation in the process of interaction between the subjects of the educational process (Balsevich, 1990).

Currently, there are significant, unreasonably high overloads of the participants in the educational process in the system of basic and vocational education in Russia. Mechanisms of self-regulation of the individual begin to function at extreme values of life potentials of human health, creating a threat of its deterioration. Fatigue affects the health of participants in the educational process (Pasyukov & Kokorina, 2003). In addition, too severe regional climatic conditions that are characteristic of, for example, the Far North and equivalent areas divert the natural forces of the body to opposing them in terms of physical survival. This can also be a threat to health

safety of the participants in educational process (Pasyukov, 2004).

There is a social and educational need to study the values of health protection as a strategic part of educational activities of the educational institution that seeks not only to fully satisfy, but also create a need for a healthy lifestyle in the context of axiology of the health protection.

With all the real-life opportunities for educational assistance to health protection of the individual, today its potential as a pedagogical phenomenon is poorly understood and therefore not realized. Thus, the need arises for theoretical basis for constructing educational concept of assistance to health protection of the individual in terms of higher pedagogical education.

The emergence of the problem and the relevance of its research are determined by aggravation in educational theory and practice of a number of contradictions between:

a) society's need for a high level of health of the younger generation as a condition for the further development of the society and the lack of effectiveness of existing educational concepts and pedagogical tools aimed at protecting and improving the health of participants in the educational process;

b) the increasing demand for scientific (educational) feasibility of health protection of the individual in the conditions of higher pedagogical education and the lack of a holistic concept of self-educational activity of students of the higher education institution;

c) the ever-increasing potential of educational technologies aimed at optimizing the health protection of the individual and the lack of their relevance in the system of higher pedagogical education;

d) objective requirement to have a healthy lifestyle to ensure the health of the individual and insufficient development of its pedagogical foundations: the content of educational technologies that ensure its effectiveness in the conditions of higher pedagogical education.

2. Methodology

Given these theoretical positions, the experimental part of the study was conceived and implemented as experience of the development and empirical validation of the conceptual model to assist health protection of the individual in the conditions of pedagogical education, in order to determine the conditions and factors of development and integration of the structural components, their systematic interconnection and interdependent aggregate.

The following tasks have been put forward in the pedagogical experiment:

- practical implementation of the concept of educational assistance to health protection of the individual;

- experimental verification of pedagogical conditions of the concept;

- experimental approbation of the developed stages of the study;

- determination of the effectiveness of the introduction of the concept of education assistance to health protection of the individual.

Experimental work was carried out in three stages.

During the first stage (preliminary stating), the organization of educational process in higher education institution has been comprehensively studied, and the initial state of the health-protecting activities was defined; selection of specific techniques for the study of the initial state of the experimental object; definition of the features by which we can judge about the changes in the experimental object under the influence of appropriate educational assistance.

During the second stage (substantive and procedural), the formative experiment was conducted, during which the probation was determined: selection of the content of the experimental work; carrying out the experiment on determination and validation of pedagogical conditions; formation of the experimental method performance criteria for health-protecting training of students; recording of data on the course of the experiment based on the intermediate sections describing the object changes under the influence of the experimental system of measures.

The third stage (control and adjustment) included: analysis of the obtained experimental data; verification of the analytical material with the purpose, objectives and hypothesis of the study; processing of the results of the experiment, control diagnostics of level of assistance to health protection of the individual; description of the features of the subjects of the experimental treatment (students and teachers); comprehension and analytical presentation of the material and findings.

To achieve the objectives and verify the initial assumptions, set of the research methods was used: methods of

theoretical analysis (historiographical, retrospective); prognostic methods (modeling the educational process, summarizing the independent characteristics, expert assessments); diagnostic methods (questionnaires, interviews, discussions, evaluation, ranking, tests); archival methods (analysis of the products of work of teachers and students: creative individual assignments, essays, term papers and dissertations of students, reflection of the results of diagnostic and self-diagnostic); observational methods (direct and indirect observation); study and generalization of mass and excellence experience; experimental work; methods of statistical data processing (Guilford, 1991).

3. Results

Adoption of healthy lifestyle of young people in general and students in particular is regarded today as one of the priorities of the development of Russian education system. Significance of the formation of values of a healthy lifestyle is due to the need to maintain and increase the health of students and improve their physical, mental and social wellbeing. Good health and physical performance are a condition and a basis for unlocking the creativity potential of the individual, their professional self-realization (Kokorina, 2008).

The main goal of health-protecting education is to equip a person with scientific and theoretical knowledge about the formation, preservation and strengthening of health and practical knowledge of healing the body.

Understanding the philosophical, psychological and educational nature of the assistance to health protection of the individual in the conditions of the pedagogical education makes it possible to consider this process as a pedagogical concept, which defines the methodological approaches to assist the health protection of the individual in the conditions of the pedagogical education; main pedagogical trends and principles, a set of pedagogical conditions that increase the effectiveness of the assistance to health protection of the individual.

Study of methodological approaches, as well as the analysis of existing practices, allowed to define the concept of assistance to health protection of the individual in the conditions of the pedagogical education as a system of modern scientific and pedagogical views, ideas, target settings, priority areas, forms, methods of joint activity of participants in the educational process in forming a healthy lifestyle, readiness for professional health-protecting activity (Belikov, 2004).

Methodological basis of our concept is the methodology of the systematic, pragmatist, person-centered and axiological approaches to the study of nature and mechanism of interaction between the individual and the environment, the role of a healthy lifestyle in the development of the individual (Aizman, 2008), as well as the link between the qualities of a human as an individual and the same qualities as a subject of educational activities, philosophical, social, psychological and pedagogical theories, ideas, concepts providing an understanding of various aspects of health protection of the individual and realization of the implementation of assistance to health protection in the educational process of the high school.

The content of the pedagogical concept is defined by its key provisions that make up the original theoretical basis or a core–a system of initial assumptions that determine the features of construction of scientific theory and characterize its specificity. Based on this understanding, the core of the pedagogical concept should include laws and principles of assistance to health protection of the individual that allow to explain its nature and ensure the ability of theoretical and logic conclusion of all provisions of the pedagogical concept (Yakovlev &Yakovleva, 2006).

The main regularities in the study are identified as follows: effectiveness of assistance to health protection of the individual in the conditions of the pedagogical education is determined by taking into account dependencies such as the dynamics of the psycho-emotional state and health of students and the subsequent development and use of programs of correction of these states on the basis of the organization of humanistic interaction between students and teachers and the support of appropriate pedagogical principles.

Implementation of the above regularities is based on the following principles of humanistic pedagogy that determine educational assistance to health protection of the individual in the system of pedagogical education: the principle of the integrity of the individual, their psychosomatic, social and cultural unity, integrative exposure to health-protecting activities. At that, the priority components in the process of health-protecting activities should be self-realization, self-development and creativity that are in harmony with the inner nature of a human; principle of motivation of students to self-knowledge and self-actualization as unlocking their self, inner activity, initiative, where the teacher plays the role of an assistant, has found a certain reflection in the theoretical and practical exercises of Komensky, Pestalozzi, Diesterweg, Tolstoy, Ushinsky, Sukhomlinsky; the principle of joint action, based on the communicative exchange, enrichment of the student's personality, acquiring the experience of communication – according to the strategy of cooperation, the identity of the student is in the center of

education, the purpose of education should be in harmony with both the purpose of life of the individual and society; principle of health protection of the individual in the educational process involves the purposeful combination of energy-intensive labor of the education participants with energy savings of each of them, which is achieved through the creation of knowledge and the needs of a healthy lifestyle.

Fundamentally important position in the concept is that both teachers and students are a subjective basis. This means that the goal of assistance to health protection of the individual can be achieved at the simultaneous protection and formation of health of the educators and students (Pasyukov et al., 2006).

Theory and practice of pedagogical education rightly asserts that any pedagogical problem can only be solved with the help of adequate technology implemented by a qualified professional educator.

"Educational technology is an ordered and task-structured set of activities, operations and procedures to ensure correctly measured result in a changing environment" (Levanova et al., 2008). This definition most accurately reflects the dynamic process of educational assistance to health protection of the individual in the system of the higher pedagogical education.

In implementing the concept of assistance to health protection of the individual, we adhere to the following phases of educational technology: organization of the process; diagnostics; content of the implementation process; evaluation and analysis of results.

In the context of assistance to health protection of the individual, teachers and students communicate on the basis of "partnership, collaboration and cooperation". Such activities form the norms of cooperation, adjust behaviors, ways of interacting, which subsequently, in other educational systems (school) will express as acts of health protection. Communicative and technological skills are a form of intellectual and practical knowledge, and, consequently, their acquisition is related not only to the methodological aspects, but also to didactic (Pasyukov, 1999).

In the course of experimental work in the experiment was attended by 976 people, including 469 of 507 students and teachers. To ensure reliability and reproducibility of the research results the experimental work was conducted in four streams, repeated in different conditions and with different co-stav members.

Ascertaining stage of the experiment showed that the students of experimental and control groups was approximately at the same level of motivation of choice of profession, health status, readiness to the health improvement activities. At the end of the forming experiment in the control phase we conducted (according to the same method as that used for summative stage) final measurements of the level of adaptation of students to the conditions of professional education on the list of leading pedagogically driven ka quality.

Without changes in the control group remained an indicator of being able to organize their training activities, whereas students in the experimental group during the experiment, the figure took I took 1,2 times. This is due to the implementation of the pilot program of activity of the College for creating an environment of students ' adaptation to the conditions of professional education, transition to teaching in the "College-University" overall, which ranks independent work of students.

The observed increase in the values of the rate of formation of the desire to get a profession span of dagogo and work in this area the students of the experimental group in 1,5 times in comparison with the outcome strength indicator that indicates, in General, positive adaptation to the conditions of the these same indicators in the control group, the number of students showing sustained a genuine interest to the profession, increased only 1,7 times.

To determine the dynamics of relations second-year students to the conditions of professional training during the pedagogical experiment was conducted a second survey, which displays ruzhil: if in the first year leading motive of learning the teaching profession was the interest to a subject, in the second year of such a motive was the opportunity to train and educate children (68,9 per cent), i.e. there is a change in orientation of the individual towards teaching. Because of the changes undergone other motives for learning.

On indicators of development of academic skills in the course of the experiment was noted chen positive dynamics in the formation of such skills as the ability to write lectures, organized to activity and the ability to analyze the results. So the success of educational activity of students of the experimental group indicates increase academic achievement in core subjects, which was measured by the average score. So in the first year average score of students was 3,6, while the students of the second course – 4,2 points. Similar performance of the students in the control group was composed of respectively 3,7 and 3,9 points.

Experimental work in these areas showed the effectiveness of pedagogical co-operation in the educational

process of students in the experimental group, which is confirmed by the positive dynamics of the level of adaptability of the individual.

It was observed a decrease in the level of trait anxiety of the students of the experimental group. This facilitated the development of interpersonal communication in the process of joint activity of students and teachers, development of communicative skills in the study of psychological and pedagogical disciplines. The level of trait anxiety of the students of the experimental group, the reduction declined by 1,4 times, which is an indicator of adaptability of the individual to the learning environment, while students in the control group the decrease in personal anxiety occurred slightly and this collection rate at the time of the study continued to remain close to high.

The criteria for evaluating the effectiveness of promoting the health of students to the conditions of professional education in the experimental group were marked differences in the health status of students at different stages of adaptation. So, if in the initial stages of adaptation is a decrease in the level of physical health of freshmen, the analysis condition before the health of the students of the second course gives grounds to draw a conclusion about the positive dynamics of the studied parameters. At the same time, in terms of health index, an increase in the number of second year students of experimental group who did not apply to the doctor during the experiment, whereas in the control group among the students - sophomores an increase in this indicator slightly.

The reasons for the poor health status of students of the control group in contrast to the experimental, in our opinion, was the lack of teaching of health saving space, which is one of the conditions for promoting a healthy lifestyle students tov in the period of adaptation to the conditions of professional education.

Positive dynamics of health status of students of the experimental group comes amid increasing their awareness in the field of healthy lifestyles, the growing use of the developed tools and methods of health preservation in the educational process. This helps the students as quickly as possible to "slip" the initial phase of adaptation, allows to obtain the profession of teach-the determinant with the lowest energy demands (physical, mental, spiritual).

To determine the dynamics in orthobiosis students, we conducted repeated measurements and compared indicators obtained on the basis of the same methodologies as in the control phase.

Speculative enough students actively recognize all 13 factors orthobiosis and recognition is higher among students of the experimental group is 80,6% (compared to control group 74,2 per cent). Increase in perfect view of it from the students of the experimental group was 7,1%. The students of the control group and 1,3%. Real respect for students orthobiosis continues to be below the ideal representation of it (the experimental group -66,8%, control 52,3%). The increase in the performance of the experimental group were significant and amounted to 15,7%, in control group the increase was only 1,5%. Students realized the need to take care of their health and in the experimental group the increase in this factor was 20%, rationally organized his nutrition and sleep – an increase of 12%. Increased performance for the factors of "self-control" and "optimistic mood". Increase, respectively, 16% and 32%.

These results indicate that students recognized the role of self-control and optimization to statistical sentiment to preserve and strengthen their health. Much has changed for the better indicators for the factor "avoiding alcohol and quitting Smoking. Quit Smoking and/or throw 36% and restricted the use of alcohol 12%. Significant dynamics of spacecraft in the indicators for the factor "dedication to work/school" – 36% .These students appreciated the role of commitment in work/school as the basis of optimism, professional with insolvency and background to creative self. In the control group also noted changes in the real observance of orthobiosis, but the trend is insignificant. The increase occurred for the factor "observance sleep" 8% "optimistic mood" 4% "abstinence from alcohol" 4% and "dedication to work/school 4%. Unfortunately increased by one the number of Smoking students in con-control group. This is all the more negative as students majoring pedagogy and methods of primary and pre-school education are mostly girls. The growth indicators in the control group, we can explain the fact that students learn the discipline of the natural Sciences, psychology and pedagogy, as well as the course "human Ecology", which get some knowledge in the field of healthy lifestyle.

Factor analysis at the final stage of the research allowed us to determine the levels SFOR-valuations of orthobiosis students of both groups in the dynamics.

The number of students with a high level of orthobiosis in the experimental group increased by 24%, with the average level decreased by 4%, with a low level cut-elk 20%. In the control group, the situation has changed slightly: the number of students with a high level of orthobiosis increased by 4%, the number of students with a medium level of orthobiosis decreased by 4% and the number of students with a low level of orthobiosis remained unchanged.

The obtained results allow to conclude that students are prepared for a healthy moviesparade activities in the school system.

To determine the change in the value of students ' attitudes towards their health, we conducted repeated measurements and compared the performance obtained using the same techniques.

The data showed the dynamics of awareness of the value of health during the experiment. The growth of health indicators, placed first in a number of securities of power the students of the experimental group was +60%. The students of the control group it was only +12%. Positive growth rates in the pilot Noah group allows us to conclude that the training of students of pedagogical higher education institution to the health improvement activities in the school system is successful.

The measurement results of the final experiment (control) phase of study by means of drawing up the structural systemic criterion showed that the experimental group on these indicators is far ahead of the control group. Positive pedagogical effect is achieved. The effectiveness of the promotion of health protection of the person in 1,6 times higher.

The findings suggest that the experimental work resulted in creation of the effective system to assist health protection of the individual in the conditions of higher pedagogical education implemented in the period of study at the higher educational institution, in the course of professional activities. It was based on the developed and tested conceptual model, and the proposed health-protecting technologies allowed to ensure the unity and interrelation of units of this model to assist health protection of the individual in the conditions of higher pedagogical education.

4. Discussion

Problems of our study on the substantive and procedural levels are solved by the implementation of the identified set of principles of assistance to health protection of the individual in the conditions of higher pedagogical education, which are:

- scientific principle that defines the scientific knowledge as knowledge of basic ideas, concepts, laws, regularities of assistance to health protection of the individual, knowledge of leading pedagogical theories, basic categories and concepts of health-protecting pedagogy, mastery of systemic knowledge about the laws of human's connection with nature and society, processes of formation of a healthy personality in the real socio-cultural and educational space; development of creative potential of each teacher, formation of internal setting for self-education, self-education and self-development, formation of scientific knowledge about health through the development of set of disciplines aimed at student mastering theoretical and methodological foundations necessary for teachers in the future health-protecting activity (Smirnov, 2005);

- systemacity principle that considers the theory, system of concepts, trends, contradictions, laws and regularities in the relationship and interdependence, dynamics of development of all components of assistance to health protection of the individual, depending on the effectiveness of their implementation at every level; content of the professional activity of the teacher aimed at health protection in accordance with the objectives of pedagogical education that involve continuous social and moral common cultural and professional development and ability to choose pedagogical tools that enable the development of motivational value systems to strengthen and protect health;

- regionalization principle considering social and economic conditions of the region, climatic and geographical conditions, local and national peculiarities of functioning not only of the institutions of pedagogic education, but also the functioning of the regional educational system as a whole; according to some scientists, this principle emphasizes the tying of conditions in which a human develops to the place of residence, population in the geographical, social, economic terms (Nesterov, 1998);

- variability principle suggesting at various levels of assistance to health protection the provision of substantial, pragmatist and organizational abilities to meet the professional and personal needs;

- principle of focus of the educational process on the subject development and self-development, involving the design and implementation of training programs and health-protecting technologies contributing to the development of mechanisms to facilitate assistance to health protection of the individual;

- adaptability principle: manifestations of the individual's health depend on the specific adaptive situation, in this regard, this principle contributes to the ability of the individual to adapt to the conditions of professional education through the creation of an environment for the adaptation of the individual in the educational space of the higher education institution, which is one of the ways to assist health protection, because the human health is

based on adaptive mechanisms (Melinda et al., 1993);

- pedagogical appropriateness that allows students to differentiate values at the level of analytical, evaluative and predictive skills, build pedagogically reasonable relationships, regulate the inside and outside team relationships, and predict the outcome of interaction;

Implementation of these principles, justification of the essence and content of assistance to health protection of the individual in the conditions of pedagogical education, analysis of the basic contradictions in the educational environment, variety of positions of the modern paradigm of education and modern concepts of assistance to health protection of the individual allowed to establish dependence manifested in the form of the leading trends.

We single out a humanistic focus of health-protecting education as one of the leading trends in assistance to health protection of the individual in the conditions of pedagogical education.

Humanization of pedagogical education is inextricably linked with the creation of conditions for creative self-identity, choice of the area of activity, circle of meaningful communication and place of force. It is this area of human relationships in an educational institution that is today an area of anxiety and concern, because it is largely determined by the measure of human maturity of the graduate and their professionalism (Kulikova, 2001).

Humanization is one of the priorities of innovation in the field of multi-level professional education. This problem has always been the focus of scientists-philosophers, sociologists, psychologists and educators.

Humanization of vocational education provides the proper formation of the humanistic in a human. Teach something and make socially useful are technical means for the main function of humanization. It is important that an individual has found their identity and could realize it. It is important what image of an individual develops and how it is practically embodied in their life interval. It is an extremely global function of humanization of professional education (Nain, 2003).

Therefore, it is important to establish the humanistic nature of interaction between the participants in the educational process.

Interaction can be either formal, defined by the scope of "teacher - student" and the respective chain of command, or have a nature of substantial, creative union, where a teacher and a student become colleagues, peers, advancing in their self-development. Humanistic character of interaction between the participants in the educational process is an important condition for maintaining their mental health. As is well known, physical and mental health are interrelated and interdependent.

The trend of value-based health protection of the individual. Based on these traits of the individual, in our view, creation of the environment for students to adapt to the conditions of professional education will be successful with the implementation of professional focus of the content and organization of the educational process, and when bearing in mind that any kind of human activity, including skills development, is based on physiological phenomenon, the development of frameworks and norms of a healthy lifestyle becomes necessary in order to protect and strengthen the health of the individual. Implementation of the factor of health-protecting focus of the individual becomes possible with the creation of the educational health-protecting space.

Students' knowledge of means and methods of forming a healthy lifestyle and ways to improve and maintain their health is required for the formation and integrated development of pedagogical health-protecting space in pedagogical education institution. This work includes the development of special training programs (blocks, modules) to inform students about the rules and regulations of a healthy lifestyle.

In accordance with the standard of secondary and higher professional education, students study such subjects in the block of disciplines of biomedical training in the first year of pedagogical college as "Developmental anatomy, physiology and school hygiene" and "Basics of a healthy lifestyle". Their goal is to form a representation by students of children's bodies and their functional features in different ages, of the hygienic requirements for the educational process, and of the basics of a healthy lifestyle factors. However, these disciplines are not focused on the personality of the student as a future teacher, they do not contain any specific recommendations for health protection in the process of teaching and professional activities.

In this regard, the development of the problem of protecting and strengthening the health of students is of paramount importance for professional schools not only in theory but also in practical terms: the establishment of a harmonic connection between education and health provides quantitative and qualitative changes in the development of the student. In this work, the unity of action of pedagogy and hygiene is important (Anderson, 1984).

The trend of technologizing of the assistance to health protection of the individual in the conditions of

pedagogical education is a leading trend of formation of readiness of the future teachers to use health-protecting technologies in practice.

Our research and experimental work was focused on finding health-protecting technologies as a means of assistance to health protection of the individual in the context of a holistic pedagogical process based on the indissoluble unity of theoretical and practical training, various directions of teaching activities. We consider the educational process in the logic of the main components of practical readiness and stages of teaching. So, at the first stage – adaptation – the target setting for interaction based on the proposed meanings and values of the upcoming activities involves solving problems of formation of motivational and axiological attitude to joint work, creating emotional state for acquisition of specific practical skills that will help in mastering the profession, establishing contact, overcoming the stereotype of the object-subject relations, establishing a positive psychological climate.

The specified trends and principles are logically interrelated. Their implementation determines the psycho-pedagogical conditions of the effective assistance to health protection of the individual.

Such conditions are: creation of the environment for adaptation of the individual in the educational space of the higher education institution; establishment of humanistic interaction between the participants of the educational process in the joint curricular and extra-curricular activities; creation of pedagogical health-protecting space for maximum efficiency of physiological, psychological functions and behavioral reactions of the individual in the educational process; provision of adequate training of pedagogical staff to organize health protection of the individual.

5. Conclusion

The concept of assistance to health protection of the individual can be effectively implemented in the system of pedagogical education at the high organizational culture of the pedagogical education institution, qualification of the teacher (teaching staff) in this work, sufficient scientific and methodological support and application of performance criteria to activities of the students that are adequate to the task.

Educational technology of assistance to health protection of the individual in pedagogical education is aimed at consistent and continuous movement of interconnected components and stages, states of the educational process and actions of its participants. Each stage of the health-protecting activity corresponds to its own objectives, content, methods and results.

The developed conceptual framework of health protection of the individual in the conditions of higher pedagogical education opens a new direction of scientific and pedagogical research, which requires solving a number of undeveloped significant aspects of this problem. The promising direction of its solution is systematization of methods and technologies of health protection; development and testing of tools to optimize health-protecting environment in the context of higher pedagogical education. Scientific development of these and other problems in the pedagogical aspect will contribute to health protection of future teachers in the process of study at the higher education institution.

Solution of this problem should ensure not only a healthy lifestyle, comfort in the classrooms, teaching students skills to outline lectures and organize independent work, widespread introduction of computer technology, balanced diet, optimal mode of work and rest, treatment and preventive care, medical examinations, etc. but also the proper organization of the learning process.

This requires the researching teachers to develop appropriate recommendations aimed at strengthening and maintaining the health of students of pedagogical vocational education institutions, and as a consequence, improvement of the quality of education. Convergence of training and education about hygiene and prevention improves health and health promotion students. This is possible by combining the efforts of the team of the vocational education institutions and health care. Developing a holistic approach to the problem of health of students is directly related not only to the requirements of today, but also to the prospects of development of vocational education system, which in turn causes the consideration of it as a systematic and holistic education that models the activity and behavior of a human in the conceptual space of the subject-subject and subject-object relations.

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Effectiveness of Acceptance and Commitment Therapy on Interpersonal Problemsand Psychological Flexibility in Female High School Students With Social Anxiety Disorder

Sayedeh Monireh Azadeh[1], Hamid Kazemi-Zahrani[2] & Mohammad Ali Besharat[3]

[1] Department of Psychology, Faculty of Humanities, Najafabad Branch, Islamic Azad University, Najafabad, Isfahan, Iran

[2] Department of Psychology, Payame Noor University, Tehran, Iran

[3] Department of Psychology, University of Tehran, Tehran, Iran

Correspondence: Sayedeh Monireh Azadeh, Department of Psychology, Faculty of Humanities, Najafabad Branch, Islamic Azad University, Najafabad, Isfahan, Iran. E-mail: m_azadeh20@yahoo.com

Abstract

Social anxiety is a psychological disorder which has devastative and pernicious effects on interpersonal relationships and one's psychological flexibility. The aim of this research was to determine the effectiveness of Acceptance and Commitment Therapy on interpersonal problems and psychological flexibility in female high school students with social anxiety disorder. With a semi-experimental design, the subjects were assessed using the Social Anxiety Scale and clinical interview. The statistical population of the research was high school female students studying in 5 areas of Isfahan. 30 individuals were purposively selected as the sample. The subjects of the research were randomly assigned to the experimental and control groups. Acceptance and Commitment Therapy was given in 10 sessions of 90 minutes in the experimental group and the control group did not receive any treatment. Pre-test and post-test scores of Inventory of Interpersonal Problems, and Acceptance and Action Questionnaire were analyzed using multivariate analysis of variance & the results showed that after the intervention, there was a significant difference between the scores of the subjects in the experimental and control groups. This means that Acceptance and Commitment Therapy can influence interpersonal problems and their six dimensions and psychological flexibility as well.

Keywords: acceptance and commitment therapy, interpersonal problems, psychological flexibility, social anxiety disorder

1. Introduction

Social anxiety disorder is characterized by the main symptom of a given and persistent fear or anxiety in certain situations in which a person may be scrutinized by others precisely such as being in a group or community, being observed, or giving a speech in front of others (APA, 2013). It is one of the most common disorders among chronic psychological disorders (Andrews, Henderson, & Hall, 2001; McEvoy, Grove, & Slade, 2011) that is seen in almost 13% of people living in the community (Kessler, Petukhova, Sampson, Zaslavsky, & Wittchen, 2012) and has many devastating effects on one's job, education, interpersonal functioning or performance (Hofmann & Otto, 2008), body and personal life (Ruscio et al., 2008; Furmark, 2002) and uniquely predicted by anxiety sensitivity social concerns (Carter, Sbrocco, & Avati, 2009; Thibodeau, Gomez-Perez, & Asmundson, 2012; Olthuis, Watt, & Stewart, 2014). Social anxiety disorder is one of the early or premature anxiety disorders (Andrews, Henderson, & Hall, 2001; McEvoy, Grove, & Slade, 2011). Its onset is of adolescence and women are more susceptible to it than men (Ledley & Heimberg, 2006).

One of the important aspects of a person's life that is strongly associated with psychological distressesis interpersonal problems (Olivares, Piqueras, & Rosa, 2006). Interpersonal problems are defined as problems that are repeated in one's life and an individual experiences them in relation to others (Leary, 1957; Horowitz, 1994). They can be briefly divided into six areas including assertiveness, sociability, submissiveness, intimacy, taking responsibility, and controlling (Horowitz, Rosenberg, Ureno, & Villasenor, 1988). Interpersonal relationships are so important that a special share or contribution is considered for their role in the constitution and persistence of

psychological disorders in valid pathological and diagnostic classifications (APA, 2000). People with social anxiety experience limited and damaged interpersonal relationships (Wittchen, Stein, & Kessler, 1999). Therefore, the symptoms of social anxiety can be considered as part of a general interpersonal trauma (Tavali, Allahyary, & Azad Fallah, 2012).

On the other hand, what is considered as a key factor in social anxiety disorder (Biglan, Hayes, & Pistorello, 2008) and leads to the continuation or persistence and intensification of the disorder is lack of psychological flexibility which is described as dominance in verbal judgments and adjustable feelings and coping strategies (eg. avoidance and suppression) which are the cores of human suffering (Masuda et al., 2011). Psychological flexibility is in fact numerous behavioral patterns obtained by an individual's experiences which allow him to act or behave based on what is important to him in life and increase his behavioral flexibility (Bluett, Homan, Morrison, Levin, & Twohig, 2014). Lack of psychological flexibility can be observed in disorders such as depression (Bond & Bunce, 2006; Bohlmeijer, Fledderus, Rokx, & Pieterse, 2011; Forman et al., 2012) and the continuum or spectrum of anxiety disorders (Kashdan, Barrios, Forsyth, & Steger, 2006; Dalrymple & Herbert, 2007).

Among treatments for anxiety disorders, cognitive behavioral therapy (Goldin et al., 2014; McAleavey, Castonguay, & Goldfried, 2014; Boswell et al., 2013), interpersonal therapy (Borge et al., 2008), and exposure (Dixon, Kemp, Farrell, Blakey, & Deacon, 2015; Price, Mehta, Tone, & Anderson, 2011) can be mentioned. Another treatment that has been applied for this disorder is ACT (Dindo, 2015; Roemer, Orsillo, & Salters-Pedneault, 2008; Twohig, Hayes, & Masuda, 2006; Eifert & Forsyth, 2005). ACT is one of the third wave treatments and is considered as a form of cognitive behavioral therapy (Hayes, 2004) which has its roots in the new theory of cognition and language, which is known as the theory of the framework of mental relations (Twohig, Woidneck, & Crosby, 2013). One of the key features of ACT is its pragmatic philosophical structure which focuses on psychological behavior and is presented as pragmatic contextualization (Hayes, Strosahl, & Wilson, 2012). In this therapy, it is presumed that humans find a lot of their feelings, emotions, and internal thoughts annoying and always try to change these internal experiences or to get rid of them (Hayes, Villatte, Levin, & Hildebrandt, 2011). This effort to control is ineffective and in contrast leads to the intensification of feelings, emotions and thoughts that the person at first tried to avoid them (Hayes, Orsillo, & Roemer, 2010). ACT is a treatment approach including six specific psychological processes: acceptance, defusion, self as context, contact with present moment, values, and committed action (Luoma, Hayes, & Walser, 2007). All of these six processes are used with metaphor, experiential exercises and logical contradiction to escape from the literal or verbal content of the language and to communicate more with the continuous flow of experience at the present moment (Twohig, 2012). In fact, this therapy aims to draw the person with social anxiety disorder who is strictly trapped and stuck in experiential avoidance and cognitive fusion into acceptance and defusion.

Considering the use of this new approach for social anxiety disorder and the early onset of the disorder in adolescence, and on the other hand considering the point that the issue of interpersonal problems and psychological flexibility in social anxiety disorder have not been dealt with thoroughly, for better prognosis, and lower health care costs in case of treatment in this period of life, the main goal of the present research was to determine the effectiveness of ACT on interpersonal problems and psychological flexibility of girls with social anxiety disorder.

2. Materials and Method

2.1 Research Design

This research is quasi-experimental in which the pretest-posttest control group design was used. The treatment is the independent variable and the levels of the treatment are based on acceptance and commitment. Interpersonal problems and psychological flexibility are considered as dependent variables.

Research Subjects

The population of this research consisted of all high school girls in Isfahan city in 2014. The sampling was done in two stages: in the first stage, 170 students were selected by convenience method. Students who got high scores in Social Anxiety Scale for Adolescents were identified and were clinically interviewed (according to the criteria of the Diagnostic Statistical Manual, Fifth Edition). In the second stage, 30 students with social anxiety disorder were randomly assigned to two groups as follows: 15 individuals were put in the experimental group with ACT and 15 were assigned in the control group. The criteria for entry to the experimental group were: studying in high school, not taking psychiatric drugs, not having other psychological and personality disorders (determined with clinical interview), not participating simultaneously in other therapy programs and not receiving individual or personal counseling.

Instruments

Social Anxiety Scale for Adolescents: It includes 28 questions which measures adolescents' worries, fears, and avoidance behaviors in social situations such as interactions with friends and interaction at school. This scale includes 2 subscales of perception and fear from negative evaluations (15 questions) and tension and inhibition about social contact (13 questions). Each question is answered based on a 5-degree scale.

Alpha coefficients for the subscales of perception and fear from negative evaluations and tension and inhibitionabout social contact and the total score of social anxiety were obtained to be between 0.84 to 0.68 which show high levels of internal consistency SASA (Khodaee, Shekary, Paklk, Buttercream, & Toulabi, 2010). Correlation coefficients obtained from pretest-posttest for the subscales of this questionnaire and the total score of SASA were 0/77, 0/71, 0/60 respectively which were acceptable.

Inventory of Interpersonal Problems (IIP-60): This scale includes 60 items which is obtained from and is based on the results 0f 127-item version of this scale in a sample of students (Besharat, 2005). In the exploratory factor analysis, the research by Besharat (2010) confirmed six factors for the Inventory of Interpersonal Problems in addition to the general factor of interpersonal problems. These six factors are assertiveness, sociability, submissiveness, intimacy, taking responsibility, and controlling. Convergence and differential validity of Inventory of Interpersonal Problems were confirmed according to the research by Besharat based on correlation coefficients of the means of subjects' scores in Inventory of Interpersonal Problems with the indexes of psychological well-being, psychological helplessness, self-respect, and emotional intelligence. The internal consistency of the scale was calculated by Cronbach's alpha coefficients and was approved by correlation coefficients from 0/82 to 0/93. Test-retest reliability of the scale was approved based on the results of the retest by the coefficients from 0/65 to 0/81.

Acceptance and Action Questionnaire – II (AAQ-II): The main mechanism in ACT, which includes the aforementioned six processes,is psychological flexibility. Acceptance and Action Questionnaire evaluates whether ACT achieves the goal of psychological flexibility or not. In fact, this questionnaire is a self-assessment tool to measure psychological flexibility (Hayes, 2004). AAQ-II is a 10-item instrument with a good internal stability (α= 0/87) and test-retest reliability(r=0/80). AAQ-II includes positive and negative questions and is correlated with variables that are theoretically related to it. The high AAQ-II scores predicted mental health (Bond, Hayes, Baer, Carpenter, Guenole, Orcutt, & Zettle, 2011).

ACT based on the work by McKey, Lev, & Skeen (2012) was planned for a period of two and a half months (10 sessions of 90 minutes). Patients were trained once a week in a group session receiving ACT in accordance with the following content: In the first session, the preliminary test related to ten ineffective schemes in relationships was administered and after its completion and scoring, schemes and coping behaviors were explained and discussed and mindfulness exercises were given to clients. In the second session, schemes' stimulants were explored and individuals were drawn into creative hopelessness which is part of the acceptance process. In the third session, the consequences of coping behaviors were explained. In the fourth session, values in interpersonal relations were stated and identification of barriers while acting based on values was considered as the agenda or instruction. In the fifth session, individuals were trained in and exercised defusion skills. The sixth session focused on describing in place of judgment in interpersonal relationships. In the seventh session, anger was discussed as one of the most common coping behaviors. In the eighth session, emotions and the incompetency and inefficiency of controlling techniques were taught. In the ninth session, the issue of effective interpersonal communication was discussed. In the last session, all the stated discussions in the sessions were summarized and ways to expand action in the scope or realm of values were dealt with.

2.2 Research Procedure

After identifying female students with social anxiety disorder and getting their volunteer satisfaction for participating in the therapy, among subjects, 15 individuals were assigned to the experimental group and 15 individuals were assigned to the control group. Then, both groups completed Inventory of Interpersonal Problems and Acceptance and Action Questionnaire in the pretest stage. The subjects in the experimental group received ACT in 10 90-minute sessions once a week, but the control group did not receive any intervention. At the end of treatment, the subjects in both groups completed the questionnaires again in the post-test stage and finally the obtained data was analyzed by covariance analysis method.

3. Research Results

The mean and standard deviation of age was 15.43 and 0.78 with the range of 15 to 16 years old. There was no significant difference between the experimental and control group regarding age and grade variables. In Table 1,

the mean and standard deviation of the scores of variables in post-test and pre-test in the experimental and control groups are presented.

Table 1. Mean and standard deviation of the experimental and control groups in the studied variables in pre-test and post-test

Situation	The control group				The experimental group			
	Post-test		Pre-test		Post-test		Pre-test	
Variables	SD	$\bar{x}$	SD	$\bar{x}$	SD	$\bar{x}$	SD	$\bar{x}$
Problem with Assertiveness	0.56	1.76	0.61	1.82	0.44	1.17	0.76	1.80
Problem with sociability	0.51	1.76	0.48	2.03	0.75	1.56	0.60	2.28
Problem with Submissiveness	0.77	2.19	0.90	2.38	0.70	1.75	0.79	2.53
Problem with intimacy	0.62	1.77	0.66	1.57	0.92	1.49	0.75	1.73
Problem with taking responsibility	0.44	2.39	0.48	2.53	0.51	1.98	0.43	2.60
Problem with controlling	0.63	1.69	0.71	1.72	0.47	0.01	0.69	1.68
Interpersonal problems	2.14	11.44	2.04	12	2.55	8.98	2.43	12.84
Psychological flexibility	7.51	48.50	6.46	50.66	6.05	42.80	7	50.60

To see if the data is normal, Kolmogorov-Smirov test and to see the equality of variances, Leven test, and for studying the equality of correlation between variables, box's M test was administered. For assessing the degree of effectiveness of the intervention on all the dependent variables, Wilk's Lambda test was used. The results of Leven test for the equality of variances showed that in all the studied variables, there was equality of variances. The results of multivariate analysis of covariance showed that the linear combination of the studied variables had a significant difference regarding the two groups (P<0/001, F=26.49, and Wilk's Lambda=0.22). For determining the difference between the two groups regarding each variable, multivariate analysis of covariance was done whose results are presented in Table 2.

Table 2. The results of the multivariate analysis of covariance of interpersonal problems and its components and psychological flexibility

Source/Index	SS	df	F	P	Effect Size	Statistical Power
Problem with Assertiveness	1.208	1	9.17	0.006	0.29	0.82
Problem with sociability	0.82	1	5.90	0.02	0.21	0.64
Problem with Submissiveness	1.64	1	12.01	0.002	0.35	0.91
Problem with intimacy	2.66	1	9.23	0.006	0.29	0.82
Problem with taking responsibility	1.24	1	11.29	0.003	0.33	0.89
Problem with controlling	2.88	1	9.14	0.006	0.30	0.83
Interpersonal problems	76.19	1	68.76	0.0001	0.71	0.99
Psychological flexibility	91.81	1	39.71	0.0001	0.61	0.99

Regarding Table 2, the results of multivariate analysis of covariance showed that there is a significant difference between individuals with social anxiety disorder in the experimental and control groups. In other words, ACT reduced interpersonal problems and their components and increased psychological flexibility in the experimental group in comparison to the control group in the post-test stage. The effect of this intervention therapy on the decrease of interpersonal problems was 71% i.e. 71% of the total scores of the residual variance is related to the effectiveness of the intervention therapy. The statistical power of 100% indicates high statistical precision. Furthermore, the results of multivariate analysis of covariance revealed that there is a difference between female students with social anxiety disorder in the experimental and control groups regarding psychological flexibility (P<0/0001, F=39.71). Therefore, ACT was effective on the increase of psychological flexibility in the

experimental group in the post-test. The effect size in the post-test was 0/61.

4. Discussion and Conclusion

The present study aimed to assess the effectiveness of ACT on the interpersonal problems and psychological flexibility in girls with social anxiety. The findings of this research showed that ACT reduces interpersonal problems of the subjects in the experimental group in comparison to the control group. Although no researches have been found on the effectiveness of ACT on interpersonal problems, the researches done on this variable in other therapies are in line with the results of this research (Borge, Hoffart, Sexton, Clark, Markowitz, & McManus, 2008; McEvoy, Burgess, & Nathan, 2013). It can be explained that ACT teaches identification of judgments, evaluations, predictions, and introducing them as the internal mind and world and defusion and lack of fusion with them and draws individuals into values, and valuable goals in life. On the other hand, teaching effective interpersonal communication and assertiveness methods in the therapy protocol helps individuals with solving problems resulting from not learning how to make relationships and communicate and indecisiveness.

The findings of the research also indicated that there is a significant difference between the scores of the experimental group and the control group regarding psychological flexibility. In other words, ACT increases psychological flexibility in the subjects of the experimental group than in the control group. This result is consistent with other researches (Hayes & Strosahl, 2010). The explanation for this finding could be that although in this therapy exposure inside the session was not used, the exercises of behavioral commitment necessarily involves exposure to social situations outside the session. Defusion techniques and acceptance reduce the rate of irritation and annoyance of these situations for the patients. Although this therapy does not directly target the frequency and content of the mind of a person with social anxiety, the reduction of anxiety in social situations as a result of defusion and acceptance techniques, detailed discussions about individuals' values in social relations, individuals' goals, and explanation, clarification, and stipulation of values will all lead to the reduction of thoughts and the reduction of avoidance of the person from social situations.

In this therapy, instead of focusing on exposure, increasing the individual's tendency to experience an inner event as it is highlighted. The aim here is to help the individual to experience a thought which is due to schemes just as a thought and instead of responding to it which is generally avoiding social situations and friends, the person learns to do what is important to him in life and what is in line with his values i.e. a thought about what people will think in their relations with me or other thoughts in relations with others is not a problem but the main problem is the person's effort to respond to these thoughts and eventually avoiding the situations in which the person feels uncomfortable in and feels unrest or has thoughts about his schemes about making relationships and communicating with others.

In fact, the aim of this therapy was to increase one's behavioral repertoire when facing terrifying events which are stressful and annoying situations that he experiences in making relationships and communicating with others and this is called psychological flexibility.

With respect to the background and previous researches, the results of the present research show that this therapy, in comparison to other therapies, can be considered as the desirable therapeutic choice and it can provide a significant improvement by its processes. More research is needed to determine whether the processes that underpin ACT are different from available supported therapies. If ACT is something different, more research is needed to identify its final effect. Any research is inevitably faced with restrictions that note to change findings with regard to those limitations. Gender (using female subjects), no follow up to evaluate the effectiveness of the therapy in the long-term and convenience sampling were the limitations of this research. Thus, the generalization of the results should be cautious. It is suggested that future studies increase the generalizability of the results using both genders of boys and girls, and follow-up stage. Furthermore, using ACT to increase individuals' repertoire of behaviors and to movie in line with valuable life routes and increase the quality of people's lives is recommended.

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Health Promotion Behaviors and Chronic Diseases of Aging in the Elderly People of Iranshahr*- IR Iran

Zahra Pishkar Mofrad[1], Mozhgan Jahantigh[1] & Azizollah Arbabisarjou[1]

[1] Pregnancy Health Research Center, Zahedan University of Medical Sciences, Zahedan, IR Iran

Correspondence: Azizollah Arbabisarjou, Pregnancy Health Research Center, Zahedan University of Medical Sciences, Zahedan, IR Iran. E-mail: derranneh2005@yahoo.mail.com

Abstract

Introduction and Aim: Aging is considered as the phenomenon of the day in the health arena of the world and Iran. It is anticipated that there will be an explosion of aging population in Iran in about 2031 and 20-25% of the population will be aged over 60 years. With aging, chronic diseases also increase and diminish the functional ability of older people. On the other hand, increased healthcare costs should be also added to this issue. Health promotion is a concept of process that continues throughout life. As much as health promotion is important in children and adults, it is equally important in older people. In fact, the elderlies, as a group, also acquire many benefits from health promotion behaviors. Due to the increasing elderly population, geriatric health promotion and enhancing the health level of older people is proposed as a health priority that should be properly planned. Hence, the present study has been conducted in this regard and aims to identify behaviors of health promotion and chronic diseases of aging in the elderly people of Iranshahr-Iran.

Materials and Methods: The present research is a cross-sectional descriptive study whose population consists of 425 elderly people aged 60 years and over, who lived in the city of Iranshahr*, IR Iran. The random cluster sampling method has been used to select the research samples. The required information was collected using a questionnaire which was distributed among the older people through visiting their homes; then, the collected data was statistically analyzed using the statistical software of SPSS version 13.

Findings: The research findings show that the mean age of older people is 66.33 ± 7.7 and the highest frequency belongs to the age group of 60 years and the maximum age is 92 years. 69.5% of the older people were in the age group of the young elderly (60-69 years) and 44% of them lived with their married children; also 55.8%, 81.9%, 70.5%, and 74.4% of them were respectively female, illiterate, married, and unemployed. The mean score of geriatric health promotion behaviors was 6.1 ± 1.87 in the range of 0-11 and 54.9% of them got the score of the inappropriate health promotion behavior. The most frequent chronic diseases of older people were respectively joint problems (78.9%), sensory problems (64.1%), and hypertension (56.6%). No significant relationship was observed between the score of health promotion behaviors and "the gender, lifestyle and marital status of the older people", but there was statistically a significant relationship between the score of health promotion behaviors and "the age, education, and job of the older people".

Conclusion: Providing training programs for health promotion behaviors in elderly people can improve these behaviors and enhance their health and quality of life and reduce the incidence of chronic diseases in them. The goal of health promotion behaviors is to maintain performance, independence and quality of life; and many studies have demonstrated that the elderly people who aged 60 years and over benefit from health promotion behaviors more than middle-aged people.

Keywords: health promotion behaviors, chronic diseases, aging

1. Introduction

Aging is a critical period of human life and attention to the problems and needs of this stage is a social necessity. Aging is a natural, physiological, and time-dependent process, which begins at birth and continues until the end of life. In fact, aging is the last stage of the successive stages of life (Memarian, 1999; Timby & Smith, 2013). Terms such as elderly, aging, old, aged, and so on are usually used for those who have passed the age of 60 years or more (Tajvar, 2003). Life expectancy is the average number of years a person is expected to live, and has

significantly increased in the last hundred years (Brunner et al., 2010). The fact is that life expectancy has increased globally and this issue has been followed by the elderly phenomena in communities (Franceschi & La Vecchia, 2001). The number of elderly people is rapidly increasing worldwide. The world population is currently 6.3 billion people and will reach almost 8.7 billion people by 2050, from which 2 billion people will be aged 60 years and older Population (Salar, Alireza, & Fazlollah, 2004).

In Iran, the Geriatric Health Department of the Ministry of Health and Medical Education has announced that the acceleration of aging has been significant in the country. Currently, Iran is in the transition from young population to an aging one and soon it will be also among the countries with aging populations. At present, elderly people constitute 6.8% of the Iranian population and this rate will increase to 9 to10 million of the total population of the country (namely 10% of it) by 2030 (Teymoori et al., 2006). Iran will be place at superior ageing phase in thirty years in future. The highest pick of ageing is allocated to Iran in the world. Due to decreasing the children in the Iran, Iran has entered in to ageing phase with % 2.8 of geriatric population. Now, Iran has entered into the firat of ageing phase means %7-14 of geriatric population. It is predicted that Iran will entered into superior-ageing phase in next thirty years (more than 21% aged population) (Iran-newspaper, 2012). According to the censuses, the population of Sistan and Baluchestan Province has been 1,722,579 and 2,405,742 people in October 1996 and October 2006, respectively; from which 84,467 (in 1996) and 105,106 (in 2006) people were the adult population aged 60 years and older. Iranshahr is the oldest and largest city of Sistan and Baluchestan Province and its inhabitants are mostly indigenous and Balouch. According to the census taken in 2006, the population of the county and city of Iranshahr has been respectively 268,400 and 117,476 people, from which 11,473 and 3037 people were respectively the adult population aged 60 years and older in the county and city of Iranshahr. As the statistics of the country show, the city of Iranshahr has the youngest population among the cities of Iran (Housing, 1996).

According to the Pender's theory, health promotion behaviors include any action that is performed to increase or maintain the individual or group health and self-actualization (Richter et al., 1987). Health promotion behaviors are considered as one of the main criteria for determining health and preventing from being affected by many known diseases. In fact, health promotion and the prevention of disease are directly related to these behaviors (Loeb, 2003). Health promotion is a concept of process that continues throughout life. According to studies, a child's health can be positively or negatively affected by the mother's health habits during prenatal period; therefore, health promotion begins before birth and continues throughout childhood, youth, middle age, and old age (Brunner et al., 2010). Among the behaviors that must be encouraged and confirmed to reduce the loss of life due to premature mortality and ensure more and better quality of the remaining years of life, it can be pointed to regular exercise, adequate sleep, avoiding alcohol and tobacco use, proper nutrition, avoidance of obesity, age-appropriate vaccinations, medical care, and avoidance of stresses. As life expectancy increases, the importance of health promotion behaviors, with regard to maintaining functionality and independence of individuals and improving their quality of life, increasingly becomes apparent. Health promotion behaviors in elderly people have a potential impact on promoting their health and quality of life and equally reduce costs related to health care (Rocha et al., 2002).

One reason for the upward trend of chronic diseases in the world is the increase of life expectancy (Park, 2000). Aging is associated with a significant and higher prevalence of acute and chronic diseases as well as an increase in practical dependence on others. The results of the study conducted by Barry (2009) showed that 80% of elderly people have at least one chronic disease such as arthritis, blood pressure, respiratory diseases, cardio-vascular and sensory disorders (Barry, 2000). The majority of deaths (75%) in the United States occur in people aged 65 years and older, and more than half of the deaths are due to chronic diseases such as heart diseases and cancers (Brunner et al., 2010).

The increasing number of elderly people in the society increases the need for disease prevention and health promotion services, because the increase in the elderly population rises the risk of chronic diseases such as diabetes, cardiovascular, joint and bone diseases. These services help to maintain the maximum ability of an elderly person to be independence and get involved in the society as an active member and have the best quality of life (Salar et al., 2004). Also, elderly people are at the highest risk for lifestyle-related diseases such as heart diseases; hence, they will benefit more from health promotion behaviors (Levy et al., 2006). Due to the increasing elderly population, geriatric health promotion and enhancing the health level of older people is proposed as a health priority that should be properly planned, because many problems of old age are caused by the unhealthy lifestyle in this period (Saffari & Fariba, 2006).

Since the population structure of Iran is still young, the aging problem has not become severe yet; however, it is expected that in the coming years, the country is heavily involved with the problem; therefore, from now on, it is

necessary to take a comprehensive plan for teaching the healthy lifestyle in old age. To achieve this goal, it is necessary to know the exact situation and needs of this population group. Now considering the fact that in the next few years, elderly adults will constitute a great proportion of Iran, if these people are healthy, they will not be only a consumer. In fact, the lower their physical problems and chronic diseases are, the lower their costs will be. In this way, the two goals including the reduction of treatment costs and improving the quality of life of elderly people will be achieved. Accordingly, the present study attempts to investigate the health promotion behaviors of the elderly people of Iranshahr-Iran. Hence, the findings of this research can provide useful guidance for health policy makers of the region to develop appropriate plans for the population group of this Province. Thus, the present study is aimed at identifying health promotion behaviors and common chronic diseases of the elderly people of Iranshahr-Iran.

2. Materials and Methods

The present research is a cross-sectional descriptive study aimed at investigating behaviors of health promotion and chronic diseases of aging in the elderly people of Iranshahr-Iran. The research population consisted of all elderly people aged 60 years and over, who were mentally healthy and lived in the city of Iranshahr at the time of data collection. After a pilot study on a limited number of research units and using statistical formulas based on the calculated standard deviation, they were 425 elderly aged people, from which the samples were selected using the random cluster sampling method; in this way that two clusters were selected from each health center in the city of Iranshahr. Since there are seven health centers in this city, 14 clusters were totally selected. From each cluster, thirty families with elderly members were chosen. All elderly members of these families were enrolled and it made no difference how many of them lived in each selected family. Numbers of clusters were selected randomly and far apart. The required information was collected using a questionnaire which was distributed among the elderly people through visiting their homes. In addition of the questionnaire, a researcher-made checklist was also used as data collection instrument. The tools were developed using similar articles and authoritative sources and included three parts: 1- demographic data (age, gender, education, lifestyle, marital status, employment, etc.), 2- a list of chronic diseases, and 3- health promotion behaviors.

The items of the questionnaire were scored in this way that the elderly person received a score for performing each health promotion behavior. The maximum score that a person can obtain eleven. In the case of receiving more than half of the score, health promotion behaviors are considered for the elderly person. After random selection of clusters and visiting the subjects, all females and males whose birth date, according to their national ID card, was before September 1947, namely, they were 60 years and over, entered the research population. Then, the reason of visiting them was briefly explained to them; and after getting their consent and ensuring the confidentiality of information, the questionnaire was delivered to the person for being completed. In the case of illiteracy or visual problems of subjects, the items of the questionnaire were read by the researcher and their answers were inserted in the questionnaire. All females and males who were 60 years old and over and enjoyed alertness and mental health and were able to hear and talk, were included in the statistical population, but the people with psychological disorders, deafness or speech disabilities were excluded from the population.

The statistical software of SPSS (version 13) along with the statistical tests including correlation test, Tukey test, Chi-square, t-test, analysis of variance at the confidence interval of 95% were used to analyze the research data.

Ethics Committee of Zahedan University of Medical Sciences has approved this research.

3. Findings

According to findings, the mean age of elderly people was 66.33 ± 7.7 and the highest frequency belonged to the age group of 60 years and the maximum age is 92 years. Majority of the elderly people (69.5%) included in the age group of the young elderly (60-69 years) and 44% of them lived with their married children. Also 55.8%, 81.9%, 70.5%, and 74.4% of them were respectively female, illiterate, married, and unemployed. In this study, the frequency of health promotion behaviors of elderly people for behaviors of non-smoking, suitable exercise, low-salt diet, low-fat diet, eating at least three meals of fish per week, eating up to 5 meals of red meat per week, blood pressure control, control of the health status, and the flu vaccine injection in the past year are respectively 70.4%, 69.7%, 48.5%, 46.7%, 40.6%, 59.1%, 60.9%, 47.5%, and 8.6%. The mean score of geriatric health promotion behaviors was 6.1 ± 1.87 in the range of 0-11 and 54.9% of them got the score of the inappropriate health promotion behavior. The most frequent chronic diseases of elderly people were respectively joint problems (78.9%), sensory disabilities (64.1%), and hypertension (56.6%). No significant relationship was observed between the score of health promotion behaviors and "the gender, lifestyle and marital status of the elderly people", While there was statistically a significant relationship between the score of health promotion behaviors and "the age, education, and job of the elderly people".

Table 1. The comparison of the mean score of health promotion behaviors in elderly age groups of Iranshahr

Variable		Health Promotion Behavior Score			
		Number	Mean	Standard Deviation	Statistical Analysis
Age Groups	Young Elderly	294	6.30	1.87	F= 5.912
	Elderly	91	5.75	1.81	Df=420
	Older Elderly	38	5.42	1.74	P=0.003 ANOVA

The analysis of variance was used to compare the scores of health promotion behavior of elderly age groups. The findings showed that there was statistically a significant difference (P=0.003) between elderly age groups in terms of the mean of health promotion behaviors (Table 1). The results of Tukey's post hoc test showed that the mean score of the young elderly group was higher than the elderly and older elderly groups, but there was no significant difference between the elderly and older elderly groups in this regard.

Table 2. The comparison of the mean score of health promotion behaviors in elderly people with chronic diseases

Variable		Health Promotion Behavior Score			
		Number	Mean	Standard Deviation	Statistical Analysis
Hypertension	Disease History	212	6.58	1.83	F= 5.516
	Not Affected	206	5.6	1.79	Df=416 P<0.0001
Cardiovascular Disease	Disease History	132	6.37	1.91	T= 3.963
	Not affected	291	5.94	1.84	Df=412 P=0.031
Hyperlipidemia	Disease History	130	6.94	1.66	T= 6.642
	Not affected	293	5.69	1.82	Df=421 P<0.0001
Diabetes	Disease History	57	7	1.76	T= 2.158
	Not affected	357	5.95	1.85	Df=421 P<0.0001

Using the independent t-test and comparing the scores of health promotion behaviors based on the history of chronic diseases showed statically a significant difference (P<0.0001) (Table 2). In other words, the elderly people with chronic diseases had higher scores of health promotion behaviors.

4. Discussion

According to the results, 55.8% of elderly people were female and 69.5% of them were in the age group of young elderly (60-69). In a study conducted on Korean elderlies, researchers have reported the frequency of female elderlies 70.2%. Also, according to this report 56.7% of elderlies were in the age group of 65-74 (Lee et al., 2006). Orfila et al., (2006) found similar results: a frequency of 65.4% for female elderlies. In developed countries, on average, women live six to eight years longer than men. This issue can lead to an increase in the gap between the gender and age. It should be noted that according to the censuses taken in 2006, in Sistan and Baluchestan province and most of its counties, especially in Iranshahr, the number of male elderlies are higher than females. The reasons may be related to the high number of pregnancies and high mortality rate of women due to the complications of pregnancy. Also, the results showed that 29.5% of elderly people have lost their spouse. In a research, 28.8% of elderly people in villages of Ardebil-Iran have lost their spouse (Satari, 2007). In this regard, Lee et al. (2006) have reported the frequency of such elderlies to be 47.8%. The difference between results of the studies conducted by Sattari and Lee et al. is resulted from the difference between Korean and Iranian societies in terms of culture and religious beliefs about the second marriage and life expectancy in the

elderly population. It should be noted that the second marriage and multiplicity of wives may be one of the main reasons for such differences between Iranian and foreign studies in this regard.

In this study, 82% of elderly people were illiterate. Ahmadi et al. (2004) in a study conducted on the elderly people of Zahedan-Iran have reported the percentage of illiteracy to be 80.5%. The reason for the similarity of results is that the both regions under study, namely Iranshahr and Zahedan are two cities of Sistan and Baluchestan province which is a poor province and the majority of its elderly population has been illiterate or poorly educated in the past decades. 7.3% of elderly people live alone or with their relatives and the rest live with their spouse or married or single children; in other words, 92.7% of elderly people somehow live with their families. This can have origin in cultural, traditional context, their commitment to the values and norms of society, honoring and supporting the elderlies. In the study conducted by Saffari et al., 2006) the percentage of elder people living alone has been reported to be 8.6% while Lee et al.(2006) have reported the percentage of such elderlies to be 32.8% (Lee et al., 2006; Satari, 2007; Saffari et al., 2006). Again, the reason for the difference between the results of these two studies is the difference between the culture and religious beliefs of the two societies.

In the study of Lee et al. (2006) the mean score of health promotion behaviors has been reported equal to 3.97 ± 1.34 (ranging from 0 to 7). The findings show that the frequency of health promotion behaviors of non-smoking, low-salt diet, low-fat diet, eating up to 5 meals of red meat per week, and control of blood pressure, sugar and lipids was higher in female elderlies. Orfila et al. (2006) showed in their study that 23.47% of men and 93.8% of women had never been smoked. The reason for the difference between the frequency of men and women in terms of the behavior of smoking is that the women of this region mostly smoke hookah.

 It has reported the frequency of chronic diseases in the elderly population studied by them as 62.3%, 33.8%, 20.2%, 15.6%, 37.7%, and 41.7% for arthritis, blood pressure, heart diseases, diabetes, cataracts, and hearing loss, respectively (Orfila et al., 2006). Smeltzer has reported the frequency of most common chronic diseases in the population studied by her as 58.5%, 52.6%, and 42.7% for high blood pressure, arthritis, and high blood lipids and cholesterol, respectively (Brunner et al., 2010).

1.4% of the elderly people under study have reported no history of chronic disease. According to Barry, 80% of elderly people have at least one sensory chronic disease such as arthritis, high blood pressure, cardiovascular diseases, or sensory disorders (Barry, 2000). In this study, 78.4% of elderlies have reported four or more chronic diseases. At least 75% of elderlies are aged 65 years and older had a chronic disease. Approximately 50% of them were suffering from at least two chronic diseases (Kass-Bartelmes, 2002).

The incidence of diseases such as hypertension, cardiovascular diseases, hyperlipidemia, and diabetes are closely related to the lifestyle of people. The results of studies show that the majority of elderly patients with chronic diseases perform most health promoting behaviors such as non-smoking, physical activity, low salt and low fat diet, and annual check of blood pressure, blood glucose and lipids; or in other words, the elderly patients with these diseases perform more health promotion behaviors in comparison with other elderly people. Since this study only investigates health promotion behaviors of elderly people at the present time and does not deal with the behaviors throughout their life, the high frequency of these behaviors in this study can be due to incidence of the diseases and doctors' recommended treatment that have made the elderlies to perform health behaviors. The study conducted by McPhee et al. show that elderly adults who had reported higher health problems follow higher healthy lifestyle habits compared to adults without problems and diseases. Usually, people start a larger number of health habits when they notice the presence of specific and serious health problems (Brunner et al., 2010).

The results show that the mean score of health promotion behaviors in elderly females is higher than males; however, the difference between the two genders was not statistically significant. Lee et al. (2006) have reported a significant difference between the score of health promotion behaviors and gender.

Also, the results show that the highest frequency of performing health promotion behaviors is related to the age group of young elderlies. In the study conducted by Lee et al., 56.7% of subjects were in the age group of 65-74 and reported the highest frequency of health promotion behaviors. In addition, the mean score of health promotion behaviors was higher in young elderlies and the difference between young elderlies and older ones was significant in this regard. In other words, there is statistically a significant difference between the mean score of health promotion behaviors and the age group of elderlies (Lee et al., 2006). The reason for higher score of health promotion behaviors in the younger age group is that the younger people generally have greater life expectancy, higher functional ability, and lower chronic diseases.

Regarding the relationship between health promotion behaviors and literacy, the results showed that the

frequency of these behaviors is higher in literate elderlies and there is statistically a significant difference between the education and the score of health promotion behaviors, so that the mean score of health promotion behaviors in educated elderlies is higher than the illiterate ones. These results are consistent with results of the study conducted by Lee et al. (2006).

5. The Conclusion

Providing training programs to promote health behaviors in elderly people can improve these behaviors and increase their health and quality of life and reduce the incidence of chronic diseases in them. The goal of health promotion behaviors is to maintain performance, independence and quality of life; and many studies have demonstrated thial the elderly people who aged 60 years and over benefit from health promotion behaviors more than middle-aged people.

Acknowledgements

Iranshahr: Iranshahr County is a county in Sistan and Baluchestan Province, located in southeast of Iran. The capital of the county is Iranshahr. At the 2006 census, the county's population (including those portions of the county later split off to form Dalgan County and Bampur County) was 264,226, in 49,443 families; excluding those portions, the population was 164,447, in 30,501 families (Census of the Islamic Republic of Iran, 2006).

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Incidence Trend and Epidemiology of Common Cancers in the Center of Iran

Hosein Rafiemanesh[1], Narjes Rajaei-Behbahani[2], Yousef Khani[3], Sayedehafagh Hosseini[4], Zahra pournamdar[5], Abdollah Mohammadian-Hafshejani[6,7], Shahin Soltani[8], Seyedeh Akram Hosseini[9], Salman Khazaei[10] & Hamid Salehiniya[11,12]

[1] School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

[2] Department of Epidemiology and Biostatistics, Shahid Beheshti University of Medical Sciences, Tehran, Iran

[3] Alborz University of Medical Sciences, Karaj, Iran

[4] Endometriosis Research Center, Iran University of Medical Sciences, Tehran, Iran

[5] Pregnancy Health Research Center, Zahedan University of Medical Sciences, Zahedan, Iran

[6] Epidemiologist, School of Medicine, Rafsanjan University of Medical Sciences, Rafsanjan, Iran

[7] Department of Epidemiology and Biostatistics, School of Public Health, Isfahan University of Medical Sciences, Isfahan, Iran

[8] Department of Health Management and Economics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

[9] Mashhad University of Medical Sciences, Nursing Collage of Quchan, Quchan, Iran

[10] Department of Epidemiology & Biostatistics, School of Public Health, Hamadan University of Medical Sciences, Hamadan, Iran

[11] Minimally Invasive Surgery Research Center, Iran University of Medical Sciences, Tehran, Iran

[12] Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

Correspondence: Hamid Salehiniya, Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran. Tel: 98-935-775-0428. E-mail: alesaleh70@yahoo.com

Abstract

Introduction: Cancer is a major public health problem in Iran and many other parts of the world. The cancer incidence is different in various countries and in country provinces. Geographical differences in the cancer incidence lead to be important to conduct an epidemiological study of the disease. This study aimed to investigate cancer epidemiology and trend in the province of Qom, located in center of Iran.

Method: This is an analytical cross-sectional study carried out based on re-analysis cancer registry report and the disease management center of health ministry from 2004 to 2008 in the province of Qom. To describe incidence time trends, we carried out join point regression analysis using the software Join point Regression Program, Version 4.1.1.1.

Results: There were 3,029 registered cases of cancer during 5 years studied. Sex ratio was 1.32 (male to female). Considering the frequency and mean standardized incidence, the most common cancer in women were breast, skin, colorectal, stomach, and esophagus, respectively while in men the most common cancers included skin, stomach, colorectal, bladder, and prostate, respectively. There was an increasing and significant trend, according to the annual percentage change (APC) equal to 8.08% (CI: 5.1-11.1) for all site cancer in women.

Conclusion: The incidence trend of all cancers was increasing in this area. Hence, planning for identifying risk factors and performing programs for dealing with the disease are essential.

Keywords: incidence, cancer, trend, epidemiology, Iran

1. Introduction

Cancer is a major public health problem in Iran (Keyghobadi et al., 2015) and many other parts of the world. Approximately 14 million new cases of cancer and 8.2 million cancer deaths occurred worldwide. Based on GLOBOCAN in 2011, the Age-Standardized incidence Rate (ASR) of all cancers were105 and 165 per 100,000 person-years in men and women, respectively. Nearly 57% of new cancer cases and 65% of cancer deaths occurred in less developed regions (http://www.who.int/mediacentre/factsheets/fs297/en/, de Martel, 2012; Globocan, 2012; Malcolm, 2014; Negar Sadat Taheri et al., 2014).

The incidence of cancer is different in various countries. Ten common cancers in men in the world included lung, prostate, pancreas, lymph nodes, hematopoietic system, esophagus, stomach, bladder, kidney, and throat, but in women were lung, breast, pancreas, lymph nodes, hematopoietic system, stomach, cervix, kidney, rectum, and bladder (Joyce, 2007). According to the national report of cancer registry in 2009, 55.58% and 44.41% of cancer cases took place in Iran in men and women, respectively. Sex ratio was 1.25. As well, ten common cancers in Iranian men consisted of skin, stomach, prostate, bladder, colorectal, hematopoietic system, lung, esophagus, non-Hodgkin lymphoma, and brain and in women breast, skin, colorectal, stomach, esophagus, thyroid, hematopoietic system, ovary, brain, urinary tract (Iran Summer, 2011). Geographical differences in the cancer incidence lead to be important to conduct an epidemiological study of the disease. It is possible to find significant differences between developed and developing countries according to prevalence of cancers.

Iran is an ancient and developing countries country located in the Middle East, a region between Asia, Europe, and Africa. Iran is located in a special geostrategic situation by connecting the eastern and western parts of the world (Map 1).This country in recent years experiment the rapid development of modernity and industrialization, and changes in the environment and people's lifestyles, that this change may affect epidemiological patterns of different types of cancers (Elsayed et al., 2009; Abdolhassan Talaiezadeh et al., 2013; Marzieh et al., 2013; Almasi et al., 2015).

The area of Iran is 1,648,195 Km^2 that makes it the 17th largest country in the world. Iran divided into 30 provinces and 336 districts. Iran with a population of almost 70 million, of which more than 65% are urban dwellers, Iran's population is young; almost one third of the population is less than 15 years old and only almost 5% is over 60 years. The population annual growth rate in 2006 was 1.2%. According to official data, more than 90% of Iranian people are under the coverage of at least one kind of health insurance. Cardiovascular diseases are the first cause of mortality in Iran with more than 45% of deaths; the second cause of mortality is accidents, with almost 18% of all deaths. The third causes of mortality were cancer with 14% of total deaths; so that 98 cases daily die from cancer in Iran (Iavari et al., 2006; Negar Sadat et al., 2014).

Qom is one of the provinces of Iran with 11,237 km², it is in the north of the country, and its provincial capital is the city of Qom. In 2011, this province had a population of 1,151,672 out of which 95.2% resided in urban areas and 4.8% in rural vicinities. The province contains 1 city, 4 counties, 9 rural districts, and 256 villages. There was a little information about the trend of cancer incidence in this provinces. Since the first step to dealing with the diseases and planning for the prevention, having knowledge of conditions and trends of cancer in any society, this study aimed to investigate cancer incidence in Qom between 2004 and 2008.

2. Methods

2.1 Study Design

This was an analytical cross-sectional study carried out based on re-analysis Cancer Registry Center report of health deputy which is based on Iran ministry of health guidelines, from 2004 to 2008 in the province of Qom in Iran.

Map 1. Iran location in the word

2.2 Cancer Registry System in Iran

This analytic study was done based on longitudinal program in Iran that Similar to many countries in the world that have national registry of cancer (NCR) is trying to identify all cases of cancer occurring in Iran from 2004 to 2008. Data used in this study was obtained from a national registry of cancer (NCR), and Disease Control and Prevention (CDC) of ministry of Health and Medical Education in Iran for 2004 to 2008 (16). In 2008 in Iran, there are 30 provinces and 41 Medical Universities. Deputy for health of each university is responsible for health issues of the population and all health activities are managed by these deputies. All deputies for health have been included in the NCR. Registrar would apply the national registration software which was developed by CDC. For pathologic centers, without software, the cancer records were gathered manually. The Cancer Office of CDC should provide techniques and funding supports. The data are transmitted every 3 months, by electronic file and also hard copy of 'Cancer Registry Data Collection Form'; this form is comprised of three parts: part I, regarding patient's identity characteristics in addition to the name of biopsy-taker physician, name of hospital, location of which the biopsy is taken, clinical diagnosis and date of biopsy sent to histological laboratory and demographic information of the patients includes race and residence. Part II includes the most important findings of patient's clinical history. Part III includes preclinical findings. The information includes primary location of tumor, date of cancer diagnosis, morphology and histology and its behavior and diagnosis method. Physicians fill the form of clinical data and the official personnel fill the identity and demographic information. Quality control has been coordinated in five main areas by Cancer Office of CDC: (i) regarding completeness of coverage; (ii) completeness of details; (iii) accuracy of data; (iv) accuracy of reports; (v) accuracy of interpretation and (vi) repeated cases are deleted from national data. Surveillance of pathology is based on the cancer record in several selected provinces to compare it with the present pathology cancer record for a general and complete evaluation and also for the accuracy of the collected data. IARC software provides a way to identify inaccuracies in data coding. Accordance of The International Classification of Diseases for Oncology (ICD-OC: topography with ICD-OM: morphology) is done manually and also by considering age and sex groups (pathology file of fatal error has been revised by the Scientific Society of Pathology of Iran and also by two masters in pathology).

Method for deleting repeated cases: for the lack of any classified National Identification Numbers, the process for deleting the repeated cases was completed by a manual review of the record. After editing data of each province and considering in mind that for deleting of repeated cases, similar cases should also be the same as morphology, topography, identity and demographic information; deletion of the repeated cases would be done separately in each province and finally in all over country by experienced manual reviewers.

2.3 Statistical Methods

The average annual age-standardized incidence rate (ASR) per 100 000 person-years was calculated by the direct method using the World Standard Population. To describe incidence time trends, we carried out join point regression analysis using the software Join point Regression Program, Version 4.1.1.1 October 2014. The analysis included logarithmic transformation of the rates, standard error, maximum number of one join points, and minimum of four years between zero join points. Like the least squares regression method, the joinpoint program is used to find the best-fit line through several years of data. However, the joinpoint program uses an algorithm that tests whether a multi-segmented line is a significantly better fit then a straight or less-segmented line. The test of significance uses a Monte Carlo Permutation method (i.e., it finds "the best fit" line). Like the least squares regression method, the joinpoint program is used to find the best-fit line through several years of

data. Joinpoint regression analysis involves fitting a series of joined straight lines on a log scale to the trends. The aim of the approach is to identify possible joinpoints where a significant change in the trend occurs. In this study 0 joinpiont (Full model) was a significant model. All other program parameters were set to default values. All statistical tests were two sided. The significance level was considered as 0.05. Common cancers were defined as the number of reported cases and standardized incidence rates.

Center   University

Receive the information file from the University and Reading the data in software (provisional data)

Start

Information received from the lab and entering the soft

Final repetition and transfer in permanent information

Repetition of data and marking

Send to center

Preparing and sending the files of update permanent

Receive the update data file permanent and enter in

End process

Diagram 1. Process of data collection of cancer cause in Iran

3. Results

Overall, there was 3,029 registered cancer cases, of which 1383 case (43.1%) were women and 1826 cases (56.9%) men. Sex ratio was 1.32 (male to female). ASR was high in men than women. ASR was obtained about 70.09 per 100,000 people in women and 89.87 per 100,000 people in men. Considering mean standardized incidence, the most common cancer in women were breast, skin, colorectal, stomach and esophagus, while in men the most common cancers included skin, stomach, colorectal, bladder, and prostate. Five common cancers in men and women constituted 58.53% and 59.44%, respectively, from all cancers attributed to both sexes (Table 1).

Table 1. Frequency and standardized incidence of all sites and five common cancers by sex, during the years 2004 to 2008

Sex	Cancer			2004		2005		2006		2007		2008		Mean ASR	Total Count
				N	ASR	N	ASR	N	ASR	N	ASR	N	ASR	2004-2008	2004-2008
Female			All Site	212	66.69	256	67.74	279	74.84	298	81.53	338	89.67	76.09	1383
	Five Common Cancer	1	Breast	57	17.07	57	14.15	76	20.41	93	24.36	98	24.8	20.16	381
		2	Skin	30	11.34	34	9.63	26	8.08	35	10.63	34	9.07	9.75	159
		3	Colorectal	15	5.75	15	4.35	13	3.71	26	7.34	32	8.86	6.00	101
		4	Stomach	13	3.99	18	4.87	22	6.24	17	4.79	26	7.96	5.57	96
		5	Esophagus	15	4.94	18	4.99	15	4.29	20	6.28	17	4.49	5.00	85
	Total Five Cancer			130	43.09	142	37.99	152	42.73	191	53.4	207	55.18	46.48	822
Male			All Site	343	94.4	323	75.35	379	92.61	371	89.87	410	96.66	89.78	1826
	Five Common Cancer	1	Skin	62	17.79	57	14.43	57	14.32	49	13.01	61	14.19	14.75	286
		2	Stomach	42	12.30	58	13.64	63	15.86	59	14.36	58	13.87	14.01	280
		3	Colorectal	28	7.62	29	6.97	34	8.40	46	10.79	42	10.12	8.78	179
		4	Bladder	39	10.46	34	7.30	28	6.82	35	9.49	38	9.80	8.77	174
		5	Prostate	24	6.60	22	4.78	24	5.69	35	8.00	39	8.85	6.78	144
	Total Five Cancer			195	54.77	200	47.12	206	51.09	224	55.65	238	56.83	53.09	1063

4. Cancers in Women

There was an increasing and significant trend, according to the annual percentage change (APC) equal to 8.08% (CI: 5.1-11.1). The trend of five common cancers was 8.7% in women, which was not significant. Of five common cancers in women, breast, colorectal, and stomach increased, with APC of 13.8%, 1.3%, and 11.6%, respectively. Skin cancer (APC equal to -3.4%) had decreasing trend, while a constant trend was seen for esophagus cancer with APC of 0.4%). In above cancers, none of the trends in women showed significant changes. (p>0.05) (Table 2).

Table 2. Join point analysis for incidence of all site and five common cancer by sex in Qom, Iran, 2004-2008; ASR– age-standardized rate per 100 000 (using world standard population)

Sex	Cancer			2004 - 2008	
				APC	95% CI
Female			All Site	8.1^	5.1 to 11.1
	Five Common Cancer	1	Breast	13.8	-1.7 to 31.6
		2	Skin	-3.4	-16.1 to 11.2
		3	Colorectal	14.9	-17.4 to 59.9
		4	Stomach	14.6	-4.8 to 38.0
		5	Esophagus	0.4	-15.4 to 19.1
	Total Five Cancer			8.7	-2.0 to 20.6
Male			All Site	2.3	-8.2 to 13.9
	Five Common Cancer	1	Skin	-5.4	-13.3 to 3.2
		2	Stomach	3.0	-6.1 to 12.9
		3	Colorectal	10.6	-1.0 to 23.5
		4	Bladder	1.3	-18.7 to 26.3
		5	Prostate	11.6	-9.3 to 37.4
	Total Five Cancer			2.4	-5.2 to 10.7

^.APC and AAPC is significantly different from zero at alpha = 0.05.

Cancers in men

There was an increasing and significant trend, according to the annual percentage change (APC) equal to 2.3% (CI: -8.2-13.9). The trend of five common cancers was 2.4% in women, which was not significant. Of five common cancers in women, stomach, colorectal, bladder, and prostate increased, with APC of 3.8%, 10.6%, and 14.6%, respectively. Skin cancer (APC equal to -5.4%) had decreasing trend. In above cancers, none of the trends in women showed significant changes. ($p > 0.05$) (Table 2).
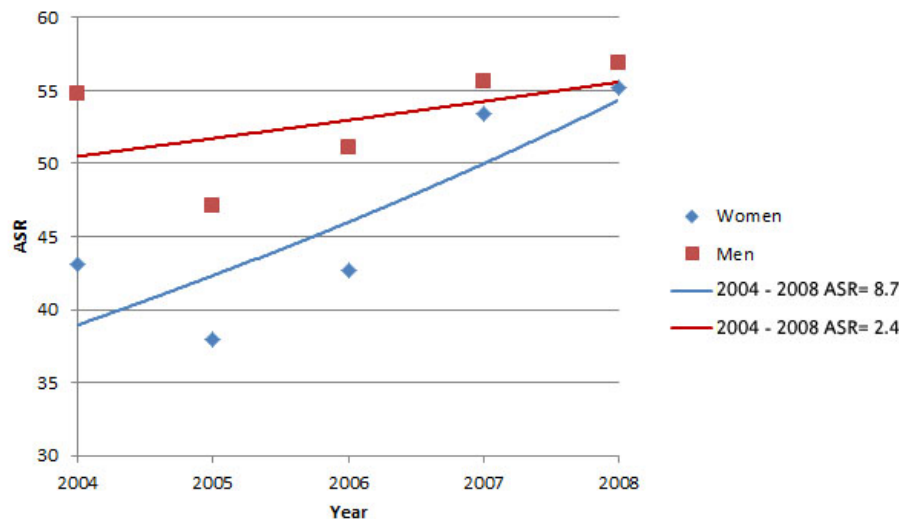
Figure 1. Overall trend of the five common cancers in men and women during 2004 to 2008 in Qom

4. Discussion

In this study, most patients were males (56.9%) and sex ratio was 1.32 (male to female). The prevalence of most of common cancers was high in men than women. Considering the mean standardized incidence, the most common cancer in women were breast, skin, colorectal, stomach and esophagus while in men the most common cancers included skin, stomach, colorectal, bladder and prostate, respectively. There was an increasing and significant trend, according to the annual percentage change (APC) equal to 8.08% (CI: 5.1-11.1) for all site cancer in women.

Based on the national report of cancer registry in 2009, most of patients were men (55.58%). The sex ratio of cancer incidence in the country was 125 (MoHotIRo, Summer 2011) and similar to other studies (JM, 1991; S. M. Jalali & S. A. K. I. Jalali, 2005; Samareh Pahlavan, 2006), male patients were high. Maisinneuve and Lowenfels reported that the prevalence of cancer was twice in men than women (Lowenfels, 2006). Studies performed in Belgium in 2003 (Buntinx, 2003), Canada and the United States (Asulin, 2004), and Western Europe (Black et al., 1997) indicted consistent findings, but the opposite occurred in Eastern Europe, except French (Black et al., 1997).

In our study, ASR was 89.87 per 100,000 in men and 76.09 per 100,000 in women. Based on the national report of cancer registry in 2009, ASR was 132.19 in men and 123.55 in women (MoHotIRo, Summer 2011). Cancer incidence in Europe was 446 in men and 284 in women, but the incidence was 303 in men and 204 in women per 100,000 people in the world (Buntinx et al., 2003), while the incidence was lower in Mediterranean countries (Trichopoulou et al., 2000). In Ardebil (the region in North West of Iran), cancer incidence was 132 per 100,000 in men and 96 per 100,000 in women (Sajadi & Derakhshan, 2003). In Polynesia, located in French, the incidence was 186 and 209 in men and women, respectively. The incidence was 132.6 and 133 in Pakistan in men and women, respectively (Gleize, 2000; Bhurgri & Hassan, 2002). ASR was 153 and 156 per 100,000 people in Khuzestan (the province in Western South of Iran) in men and women, respectively (Neda Amoori & Maria, 2014). ASR for all cancers was 164.3 and 130.9 in Western Azerbaijan, located in North West of Iran, in men and women, respectively(Mohammad, 2008). Therefore, the incidence of cancer in Iran, was lower than some areas in the word. It seems that the cancer incidence estimated in Iran wasn't real, and in dead we under estimate the incidence and mortality of cancer in Iran, due to problems such as The Low Quality of cancer registry System in Iran and this fact that in many cases we don't biopsy and therefore undiagnosed of disease

in this case. However, national data in Iran, show an increasing trend in incidence and mortality of cancer (Mohagheghi et al., 2009). In contrast to the situation, in certain developed countries in last decade the incidence and mortality of cancers were decreasing trend (Mousavi et al., 2007; Jemal et al., 2010; Bray et al., 2012). This difference might be due to fast changes in lifestyle, exposure to risk factors, aggregation of carcinogens, and air and environment pollution in Iran that led to increasing trend in cancer incidence.

The incidence of cancer is different in various regions. Five common cancers in men in the world are: lung, prostate, colorectal, stomach, and liver and in women, including breast, colorectal, lung, cervical, and stomach (Organization, 2012). In the country (Iran), five common cancers in men are skin, stomach, prostate, bladder, and colorectal cancer, while in women, breast, skin, colorectal, stomach, and esophagus (MoHotIRo., Summer 2011). Based on the national report of cancer registry in 2009, five common cancers in men were skin, stomach, colorectal, bladder, and lung, while in women, breast, colorectal, skin, stomach, and esophagus in Qom (MoHotIRo., Summer 2011). A study, conducted in East Azerbaijan, showed that five common cancer in men included stomach, skin, bladder, esophagus, and colorectal and in women breast, skin, esophagus, stomach, and colorectal (Mohammad et al., 2008). A study in Khuzestan indicated that the most common cancers in men comprised skin, stomach, lung, blood, prostate, and bladder and in women, breast, skin, colorectal, lung, and bladder (Neda Amoori & Maria, 2014).

In our study, five common cancers in men were skin, stomach, colorectal, bladder, and prostate and in women, breast, skin, colorectal, stomach and esophagus. There was a small difference between our results and national reports, but a considerable difference between them and world reports. The differences in the incidence of cancer should be investigated to perform identifying related risk factors. Other studies also expressed high incidence of stomach cancer in men and breast cancer in women. However, the differences in incidence of lung and colorectal cancers between our findings, and national and world statistics can relate to lifestyles and features of the area. Therefore, it is necessary to identification risk factors associated with these cancers and developing screening program. According to the high prevalence of stomach cancer in the country and Qom, it is required to endoscopy and detailed examination for individuals at risk. In recent decades, breast cancer is the first common cancer in women in the country and world, and is increasing. Other studies emphasized an increasing trend of the cancer (Afsoon Taghavi et al., 2012; Aboulfazl Afsharfard et al., 2013; Mitra Rahimzadeh, Mahmood, & Mohamad, 2014; Neda Amoori & Maria, 2014).

Our findings, similar to other studies (Krittika Suwanrungruang et al., 2006; Seyed et al., 2010; Edris Abdifard et al., 2013; Nikbakht Roya, 2013), showed that colorectal cancer is enhancing in both sexes and the trend is high in men than women. This may be due to dietary habits and changes in life style. Several studies indicated that high-fat diet, obesity, tobacco use, and lack of physical activity are risk factors for this cancer. Since colorectal cancer is the preventable disease, it is necessary to more investigate about risk factors affecting the cancer in Qom.

In our study, the incidence of bladder cancer was increasing in men so that the cancer was one of the common cancers in males in this region. Some studies also showed that the incidence of cancer is higher in men than women (Alireza Salehi et al., 2011; Mohammad Ahmadi et al., 2012). This may be due to high consumption of tobacco and Opium, and exposure to occupational carcinogens in men than women.

Our results revealed that the incidence of stomach cancer is increasing in both sex ,so in 2004-2008 was the second cancer in men and Third in women. Another study stated that the incidence of the stomach cancer have Increasing trend (Krittika Suwanrungruang et al., 2006). In the study, carried out in Khuzestan (one province of Iran), higher incidence of the cancer was seen in women than men (Neda Amoori & Maria, 2014). Risk factors attributed to the cancer are Helicobacter pylori, genetics, diet, and environmental factors. Hence, endoscopy and accurate examinations are essential for detection individuals at the risk factors.

5. Limitations

There were some limitations in our study. Data in our registry were limited to pathology, residency, sex, and age while other related variables like feeding pattern, job, and other lifestyle and socioeconomic factors have an important role in susceptibility to cancer. Additionally registration in that period of time was limited to the pathology system so a large number of cancers were missed. it should be stated that the cancer registry system in Iran is still not fully and equally in all area and sometimes the differences in the quality and coverage of data is observed.

6. Conclusion

It can conclude that the incidence of all cancer is increasing in this area. Therefore, the plan for the control and

prevention of this disease must be a high priority for health policy makers. Our findings was obtained from the descriptive study on the incidence trend of the disease in recent years and it is recommended that analytical studies should be conducted to obtain a causal relationship and solve problems related to the disease.

Conflict of Interests

Authors have no conflict of interests.

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Self Management Behaviors in Rheumatoid Arthritis Patients and Associated Factors in Tehran 2013

Mosharafeh Chaleshgar Kordasiabi[1], Maassoumeh Akhlaghi[2], Mohammad Hossein Baghianimoghadam[1], Mohammad Ali Morowatisharifabad[1], Mohsen Askarishahi[1], Behnaz Enjezab[3] & Zeinab Pajouhi[2]

[1] School of Public Health, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

[2] Rheumatology Research Center, Tehran University of Medical Science, Tehran, Iran

[3] Research Center for Nursing and Midwifery Care, Nursingand Midwifery School, Department of Midwifery, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Correspondence: Mohammad Hossein Baghianimoghadam, School of Public Health, Shahid Sadoughi University of Medical Sciences-Yazd, Iran. Tel: 98-913-152-0732. E-mail: baghianimoghadam@yahoo.com

Abstract

Introduction: Rheumatoid Arthritis (RA) is a systemic, autoimmune and inflammatory disease with an unknown etiology that is associated with progressive joint degeneration, limitation of physical activity and disability. The aim of the study was to evaluate self-management behaviors and their associated factors in RA patients.

Material and Method: This cross-sectional study was performed in 2013 on 185 patients in Iran. Data were selected through convenient sampling. The collected data included demographic variables, disease related variables, Arthritis Impact Measurement Scale 2 (AIMS-2SF), and Self-Management Behaviors (SMB). Data were analyzed by SPSS17 using Spearman correlation and logistic regression test.

Result: In this study drug management, regular follow-up, and food supplement were used as the most frequently applied SMB and aquatic exercise, diet, massage therapy, and relaxation were the least common SMBs. Age, education, health status, occupation, marital status, sex, DAS28 (Disease Activity Score 28 joints), and PGA (Physician Global Assessment) were significantly related with SMB.

Conclusion: The result of the study highlight the influence of demographic variables, health status, and disease related data on SMB. Thus, more studies are required to find factors influencing SMB in order to improve SMB.

Keywords: self management, Rheumatoid Arthritis, health status, Tehran

1. Introduction

Rheumatoid arthritis is an autoimmune, inflammatory, and systemic disorder with an unknown cause. Different stages of this disease include progressive joint destruction, causing limitations in the physical activity, disability, and early mortality as well as decreasing the quality of life in patients, i.e. social function, mental health, etc. Furthermore such issues impose both direct and indirect costs including hospital costs, treatment costs, absence from work, etc. Prevalence of RA varies in different populations from 0.018% to 10.7% world wide (Alamanos, Voulgari, & Drosos, 2006). It is more prevalent in adults aged 40-60 and affects women more than men with a ratio of 2:1 (Kvien, Uhlig, Odegard, & Heiberg, 2006). In 2008, the point prevalence of RA in Iran was estimated 0.33% (Davatchi et al., 2008). The point prevalence was estimated 0.98% in Zahedan during 2008-2009 and 0.51% in Sanandaj in 2012(Moghimi et al., 2013; Sandoughi et al., 2013). Patients affected by rheumatoid arthritis are at greater risk of depression and lower overall health, require more help to perform ADLs (activities of daily living), and have higher referral rates to physicians (Mendelson, McCullough, & Chan, 2011).

In order to reduce the burden of RA patients and empower them, it is required to educate patients on arthritis care and consequences they might face. Typically patients who are actively involved in treatment tend to cooperate more effectively with healthcare providers and eventually experience a better health status (Hibbard, Greenlick, Jimison, Capizzi, & Kunkel, 2001)

Chronic disease requires a person to adhere a self management behaviors in order to maintain optimal health and avoid life threatening complication. Thus patient with multimorbidity have to follow several complex self management behaviors prescribed by health care provider (Bratzke et al., 2015). According to the results of a study conducted by Clark et al. (1991) self-management is part of activities of daily living that individual must undertake in order to control or reduce symptoms of disease (Clark, Becker, Janz, & Lorig, 1991). According to Barlow et al. (2002) self-management is the individuals' ability to control the disease and lifestyle modification in accordance with the chronic condition. The principals of self care and self-management include health literacy, drug management, symptom control, psychological management, lifestyle, social support, and communication (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002). Self-management in RA patients includes drug management as prescribed by physician, complementary therapies (e.g. heat treatment, exercises, massage, etc.), hydrotherapy, resting, and spending time with family and friends to receive support or advice (Al-Qubaeissy, Fatoye, Goodwin, & Yohannes, 2013; Chang et al., 2009; Dagfinrud & Christie, 2007; Eversden, Maggs, & Nightingale, 2007; Field, Diego, Delgado, Garcia, & Funk, 2013; Katz, 2005; Nadrian, Morowatisharifabad, & Bahmanpour, 2011; Niedermann et al., 2011; Rezaei, Neshat Doost, Molavi, Abedi, & Karimifar, 2014; Sharma, 2014; Zwikker et al., 2014). Non-medical behavior increase positive effects of medical treatment.

In the past two decades. Ottawa Panel published evidence-based clinical practice guidelines (CPG) for education in the management of rheumatoid arthritis and osteoarthritis (OA) (Brosseau et al., 2004). Educating patients and utilizing CPG potentially decrease healthcare costs and contribute to the self-management of the patients. Also, it indirectly motivates health professionals to become more aware of it, which makes it one of the most effective strategies in dealing with the disease. However, apart from all the mentioned advantages, patients frequently encounter numerous problems in practicing the guideline on a daily activity due to lack of CPG knowledge, lack of time, and insufficient knowledge and training in implementing the recommendations correctly (Brosseau et al., 2004). Multiple studies have indicated the need for gaining more knowledge about the disease, medical care, and medical therapy in the treatment of RA (Bykerk & Keystone, 2005; Meesters, de Boer, van den Berg, Fiocco, & Vliet Vlieland, 2011). A number of studies have found some predictors of knowledge in RA patients such as age, duration, disease severity and willingness to self-educate about the disease (Neville et al., 1999; Niedermann et al., 2011).

This disease has an impact on the behaviour and mental health of adult RA patients. Although 12-17% of the population suffer from depression, this number is 17-27% among RA patients who suffer from major depression (Rhee et al., 2000). Depression has adverse effects on the patients overall health and functions (Morris, Yelin, Panopalis, Julian, & Katz, 2011). In a study conducted on RA patients, a correlation was found between disease activity and depression (Mostafa & Radwan, 2013). A review on a sample group of RA patients had arthrithis problem showed different results after the patients were engaged in complementary treatments such as Yoga, general health improvements were clearly observed both on physical and mental levels in RA patients (Sharma, 2014).

In guidelines on the management of RA patients published by the British Society for Rheumatology (BSR), American College of Rheumatology (ACR), and Ottawa Panel, the use of the physical exercise in RA patients is highly recommended to increase the rate of motion, muscle strength, improvements in physical activity and quality of life, without causing any damage to joints and tiredness (Luqmani et al., 2006). Some studies have reported the positive effects of an exercise program and aerobics on both physical and mental health conditions (Chang et al., 2009; Karatepe, Günaydin, & Kaya, 2011). Hydrotherapy is a one of the rehabilitative treatments used for RA patients that positive relationship between hydrotherapy and pain-relief (Al-Qubaeissy et al., 2013; Eversden et al., 2007; Hall, Swinkels, Briddon, & McCabe, 2008).

Multiple studies have been conducted on self management which have focused on evaluating and comparing educational interventions and assessing their effects on the knowledge, attitude, self-efficacy, health status, and quality of life in RA patients (Borman et al., 2007; Conn et al., 2013; Kanecki, Tyszko, Wislowska, & Lyczkowska-Piotrowska, 2013; Mendelson et al., 2011; Nadrian et al., 2011; Niedermann et al., 2011). Some of these studies have mainly focused on self-management behaviors based on behavioral and coping strategies in RA patients (Katz, 2005; McDonald-Miszczak & Wister, 2005) while some others have focused on estimating the impact of specific factors on health condition of RA patients such as physical activity, stress, yoga and hydrotherapy (Chang et al., 2009; Dagfinrud & Christie, 2007; Field et al., 2013; Karatepe et al., 2011; Law et al., 2010; Robinson et al., 2002; Sharma, 2014). Considering the fact that each of the mentioned SMB has a significant impact on improving the health status of RA patients and little research has been done in this area, the aim of this study was to explore into self-management behaviors and their associated factors in RA patients.

2. Material and Method

2.1 Participant and Procedure

This cross-sectional study was conducted on 185 patients who were visited in the Rheumatology Clinic of Shari'ati Hospital, Tehran, Iran in 2013. Inclusion criteria were age over 16, diagnosed of RA by a rheumatologist based on the criteria of the American College of Rheumatology (ACR), disease duration at least one year, no history other chronic diseases including cardiovascular diseases, asthma, cancer, psychological disorders (depression), no consumption of mood stabilizers and ability to speak Persian. A total of 500 patients were reviewed, 185 patients inter the study and 300 patients were excluded due to exclude criteria or unwilling to participate. Patients willingly participated in the research. Patients were selected through convenient sampling method between March 2013 to October 2013. Sample size estimated was performed based on d=0.5, α=0.01 and mean and standard deviation of SMB in a previous study by Nadrian et al (32.33±8.6) (Nadrian et al., 2011). Shariati hospital was general and referral govermental hospital.

2.2 Measures

2.2.1 Demographic Data

Background data gathered included age, marital status (single, married, divorce or widow), education (illitrate, primary, diploma, and university degree), occupation (house wife, staff, retired, other(farmer, unemployed, student, worker...)

2.2.2 Disease Related Data

Disease related data include the duration of the disease, levels of CPR and ESR, number of inflamed joints, Visual Analogue Scale (VAS), Physician Global Assessment (PGA), Disease Activity Score 28 joints (DAS28), Arthritis Impact Measurement Scale2- short form (AIMS2-SF), and self-management behaviors (SMB).

-VAS: is often used in clinical research to measure pain across a continuum of 0-100 (no pain to extreme pain) (Gould, 2001).

-DAS28: is an efficient tool to detect disease activity in RA patients that consists of 4 parts; 1) the number of joints affected with joint tenderness, 2) the number of swollen joints, 3) erythrocyte sedimentation rate (ESR), and 4) VAS (0-100), The overall scale is then determined by a standard formula (DAS-Score.nl).

-PGA: is the physician's assessment of RA patient based on clinical information (mechanical joint problem (i.e. deformity), objective evidence of disease activity (synovitis), the presence of extra articular disease, radiographic image of hand, etc.) that is rated on a scale of 1 to 4 indicating remission, mild, moderate and severe, respectively ("American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines (2002) Guidelines for the management of

rheumatoid arthritis.," 2002).

-Health status: is assessed by AIMS-2SF(Arthritis Impact Measurement Scales-short form) which consists of 26 questions on a Likert scale from 1 to 5 (1 for never and 5 for always). The instrument has 5 domains: physical status, emotional status, symptoms, social interactions, and role functionality. The score ranges from 0-10 with 10 indicating an optimal health status, and 0 the lowest health status (Taal, Rasker, & Riemsma, 2003). The range of scores on this scale was between 5-50. it's validity and reliability in Iran was confirmed in study by nadrian(α=0.93)(Nadrian et al., 2011).

2.3 Self-Management Behavior (SMB)

This questionnair derived from a study performed by Nadrian et al. (Nadrian et al., 2011), consists of 17 self-management activities in RA patients. The activities include hydrotherapic activities; use of hot water, pool, bags, and shower; use of stretch bandages, wrist bands and casts; regular drug management; exercise; etc. The responses are scaled from 1 to 5 on a Likert scale (1 for never and 5 for always). The total score between 17-85. It's validity and reliability in Iran was confirmed in study by Nadrian et al (α=0.68)(Nadrian et al., 2011). The overall score results are between 17 and 85 and the questionnaire takes 20 minutes to complete.

2.4 Statistical Analysis

Data was analyzed using SPSS 17 software. Spearman correlation coefficient test was used for examining the association between SMB and variables. Logistic regression analysis was used for determining which predictor variable are significant with SMB.

3. Results

This study was carried out on 185 RA patients (149 females and 36 males) with a mean age of 46.97±11.47 years. Most of the participants were female 80.5% (149), married 80.5% (149) and 67.6% (125) were houswives. The majority of patients 49.7% (92) had primary school educated and 10.5% (20) had a university degree.

The median duration of RA was 9 years with a range of 1 to 48 years and the mean score of DAS was 3.30±1.36. According to the physician's assessment, 44.3% of the patients were in remission and disease activity was mild in 18.9%, moderate in 27% and severe in 10.8% of the patients. Table 1 shows the demographic and clinical characteristic of RA patients.

Table1. Demographic and clinical characteristic of RA patients (N=185)

Variable	
Age*	46.97±11.47
Sex	
Female	149(80.5)
Male	36(19.5)
Marital status	
Single	21(11.4)
Married	149(80.5)
Divorced, Widow	15(8.1)
Occupation	
Houswife	125(67.6)
Staff	33(17.8)
Retired	14(7.6)
Others	13(7)
Education	
Illiterate	23(12.4)
Primary/guidance	92(49.7)
Diploma	50(27)
University degree	20(10.8)
PGA	
Controlled	82(44.3)
Mild	35(18.9)
Moderate	57(27)
Severe	20(10.8)
DAS28	3.30±1.36
Medaian disease duration	9
Health status**	6.98±9.21

*mean±SD;

**score range 0-10.

The frequency of the use of SMB is shown in Table 2. According to the results, relaxation (7%), aquatic exercises like swimming (20.6%), diet (27.1%), massage therapy (38.9%), using stress control (35.2%) and using hot water pools and hot water bags (36.2%) were the least frequent SMB reported by the patients in order of frequency while regular drug management (99.5%), regular follow-up (97.3%) and using food supplements

(93%) were the most frequently applied SMB.

The results of univariate logistic regression between some of the SMB and each behavior under investigation are demonstrated in Table 3. In order to perform regression analysis, SMB 5 scale, scored 1-5 were divided into binary scale of (0, 1) in which 0 represented never and seldom, and 1 represented occasional, sometimes and always.

Table 2. Frequency distribution of SMB in RA patients(n=185)

	Never N(%)	Seldom N(%)	Occasional N(%)	Sometimes N(%)	Always N(%)
Aquatic exercise(swimming)	127(68.6)	20(10.8)	15(8.1)	14(7.6)	9(4.9)
Usage of hot water pools, bags ,shower	98(53)	20(10.8)	29(15.7)	16(8.6)	22(11.9)
Joint warming	62(33.5)	10(5.4)	43(23.2)	20(10.8)	50(27)
Using stretch bandage, wrist bands, casts.	100(54.1)	6(3.2)	46(24.9)	14(7.6)	19(10.3)
Adequate rest	7(3.8)	9(4.9)	68(36.8)	35(18.9)	66(35.7)
Adaption between work or daily schedule and disease	41(22.2)	19(10.3)	50(27)	37(20)	38(20.5)
Food supplement or special food	12(6.5)	1(0.5)	3(1.6)	9(4.9)	160(86.5)
Diet	124(67)	11(5.9)	26(14.1)	12(6.5)	12(6.5)
Massage	102(55.1)	11(5.9)	40(21.6)	10(5.4)	22(11.9)
WatchingTV, studying	3(1.6)	9(4.9)	37(20)	28(15.1)	108(58.4)
Speak or consult to other	8(4.3)	33(17.8)	66(35.7)	22(11.9)	56(30.3)
Stress management	78(42.2)	42(22.7)	41(22.2)	15(8.1)	9(4.9)
Relaxation	167(90.3)	5(2.7)	3(1.6)	4(2.2)	6(3.2)
Drug management	0	1(0.5)	2(1.1)	9(4.9)	173(93.5)
Regular follow up to physician	2(1.1)	3(1.6)	1(0.5)	2(1.1)	177(95.7)
Changing the dose or intervals between drug management	3(1.6)	13(7)	15(8.1)	28(15.1)	126(68.1)
Exercise	0 min	10min	20min	30min	>30min
	102(55.1)	24(13)	13(7)	17(9.2)	29(15.7)

The result of univariate regression showed that age, education, health status, occupation, marital status, sex, DAS28, VAS and PGA were significantly related with SMB. Health status was associated with the use of aquatic exercises (P=0.013) and decrease use of cast and wrist (P=0.004). Swimming in Patients with high school education (P=0.09) and university education (P=0.007) more than 8,10.5 times than illiterate patients. Use of hot water pools, bags or showers was 2.35% times more in men than in women (P=0.023) and 5 times more in high school graduates than among illiterate patients (P=0.008).

One unit increase in DA28 increased the use of joint heating by 33% (P=0.017). One unit increase in VAS increased the use of casts and wrist bands by 1.5% (P=0.006)**.** Rest increased by 3.2% per each unit increase in the VAS unit (P=0.003).

Patients who were in the group of other occupations (students, unemployed, and farmer) sought sympathy for their problems 82% less than housewives (P=0.005). With worsening of the PGA, the use of relaxation was almost 3 times more than patients who were in remission phase (P=0.04) and Married patients used relaxation 74% less than single patients (P=0.013), moreover One unit increase in the patient's age decreased the use of relaxation by 8% (P<0.001), finally, with each one unit increase in the DAS28 score, patients were less likely to change the dose or duration of their medication without the instruction of their physician by 35% (P=0.019).

Table 3. Logestic regression analysis between SMB and characteristic

Self Management Behavior Yes=1 No=0	Effective Variable	Confidence interval 95 % for odds ratio			P-Value
		Upper bound	OR	Lower bound	
Aquatic Exercise(swimming)	Education				
	Illiterate*				
	Primary/guidance	16.99	3.706	0.808	0.09
	Diploma	3.90	8.25	1.74	0.008
	University degree	57.17	10.5	1.92	0.007
	Health status	1.01	1.048	1.088	0.013
Usage of hot water pools, Bags ,Shower	Education				
	Illiterate*				
	Primary/guidance	7.354	2.298	0.178	0.161
	Diploma	17.30	5.146	1.531	0.008
	University degree	10.54	2.558	0.62	0.194
	Sex				
	Female*				
	Male	4.924	2.352	1.123	0.023
Joint Warming	DAS28	1.684	1.332	1.053	0.017
Adequate Rest	VAS	1.054	1.032	1.01	0.003
Relaxation	PGA				
	Controlled*				
	mild	6.40	1.44	0.326	0.629
	Moderate	10.17	3.27	1.05	0.04
	Severe	-	-	-	-
	Marriage				
	Single*				
	married	o.754	0.263	0.092	0.013
	Age	0.965	0.923	0.883	<0.001
Changing the dose or intervals between drug management	DAS28	0.935	0.658	0.646	0.019

In order to evaluate the correlation between SMB, and disease related factors, spearman correlation coefficient test was used which revealed positive correlation between joint warming, exercise and use of cast with DAS28. Patient with high DAS are more heating, exercise and using cast and wrist bands than lower DAS. Relaxation had negative correlation with age. Younger patients report more relaxation than other. (Table 4)

Table 4. Matrix of corrlation coefficient of SMB and other factors in RA patients. (n=185)

SMB	mean±SD	DAS28	Duration of disease	PGA	Age
Aquatic exercise(swimming)	1.69±1.9	-0.089	-0.003	-0.073	-0.009
Usage of hot water pools, bags ,shower	2.16±1.44	0.045	0.016	0.129	0.073
Joint warming	2.92±1.61	0.182*	0.093	0.124	-0/092
Using stretch bandage, wrist bands, casts.	2.17±1.41	0.154*	0.142	0.056	0.102
Adequate rest	3.78±1.10	0.068	0.083	0.053	-0.028
Adaption between work or daily schedule and disease	3.06±1.42	0.109	-0.051	0.026	-0.023
Food supplement or special food	4.64±1.03	0.096	-0.038	0.005	-0.018
Diet	1.79±1.27	0.016	0.039	0.019	0.037
Massage	2.13±1.43	0.040	-0.039	0.086	-0.117
WatchingTV, studying	4.24±1.03	0.054	0.071	-0.036	-0.006
Speak or consult to other	3.46±1.21	0.025	-0.124	-0.090	-0.184
Stress management	2.11±1.18	-0.120	0.008	-0.031	-0.009
Relaxation	1.25±0.863	0.052	-0.095	0.107	-0.219**
Regular follow up to physician	4.91±0.336	0.035	-0.131	-0.002	-0.141
Changing the dose between drug management	4.89±0.583	-0.017	-0.030	0.043	-0.063
Exercise	4.41±1. 104	-0.205**	-0.099	-0.162*	0.005

**Significant at 0.01 level;

*Significant at 0.05 level.

4. Discussion

The purpose of this study was to assess various factors associated with SMB in RA patients. In this study, participants used a minimum of 3-4 SMB to control the disease and different behaviors were applied. About 97.3% of the patients were reported to have regular referrals to their physicians, 99.5% had regular drug management, 93% had supplement consumption, and 91.3% changed the pattern of medication. All of the patients were chosen from the Rheumatology Clinic, so patients were closely observed by a rheumatologist through regular physical exams. Moreover, these behaviors had a positive impact on physical health and disease control, So patients performed these behaviors regularly with more trust in their physician. Our findings confirmed the results of a study by Katz et al in which 86.5% of the patients used medications regularly to alleviate the pain (Katz, 2005). Moreover, 91% of the patients used adequate resting to maintain their quality of life whereas only 70% of the patients used this behavior in the study by Katz (Katz, 2005). The results of the current study indicated that resting had a positive correlation with the DAS28, severity and duration of the disease. This finding is similar to the results of a study by Kett (Kett, Flint, Openshaw, Raza, & Kumar, 2010).

RA patients to decrease stress, anxiety and depression, talked to close friends and relatives. McBain et al reported that social support had a significant relationship with the prevention of depression in RA patients (McBain, Shiley, & Newman, 2013). In a study conducted by Katz et al 54% of the patients used this behaviors to relieve pain (Katz, 2005). In our study, other occupations (students, unemployed, and workers) used this behavior less than housewives, which could be explained by the fact that the members of this group especially students spend most of their time studying and left with little time to talk to their relatives and friends.

Incorrect posture at work time (home or office) may lead to joint destruction. Coordination and adaptation of daily tasks is an accommodation strategy to decrease the problems in RA patients. In this study, over half of the patients used this strategy in their daily activities. In the study by Katz, 50% of patients used to alleviate pain, 82% used to prevent of joint deformity (Katz, 2005). The low rate of this strategy in our study can be related to the lack of knowledge on facilities and available resources. Moreover this study showed that housewives used this strategy less than other groups although the frequency of this behavior was not significant. These issues should be considered in self-management programs to resolve their problems in patients.

In this study, it was found that over half of the patients used joint heating for alleviating pain, which was slightly

higher than the results of the study by Katz (2005). The current study revealed that patients with greater disease activity reported more joint heating than patients with less disease activity, which could be related to disease severity. Robinson and Valdes showed that heating reduced pain in OA and RA patients (Robinson et al., 2002; Valdes & Marik, 2010).

In the present study, half of the patients used wrist bands, casts, and bandage for pain relief, reducing joint deformity and movement limitation. In addition, their use lead to improvement in health status and not using this behavior increased disease activity although the increase was not significant, which could be due to the lack of knowledge and facilities. In the study by Katz (33%) was less than in the current study (Katz, 2005). Based on our results, SMB were more commonly used in severe disease activity and was less used when the patients were in remission. Our result are similar to those of Kett et al who showed that the use of self management strategies increased during the flare of RA (Kett et al., 2010). Continuous using of SMB should receive attention in all programs**.**

In our study some of the patients used massage therapy to reduce RA problems. Several studies have shown the impact of massage therapy on decreasing pain, depression, anxiety, muscle strength, and rate of motion in the shoulder, wrist, and hand (Bell, 2008; Donoyama & Shibasaki, 2010; Field et al., 2013; Field, Diego, Hernandez-Reif, & Shea, 2007). In this study few patients used hot water pools, hot water bags, or hot showers. These behaviors are used as therapeutic methods to improve RA problems such as pain and fatigue. In the current study, men used these behaviors two times more than women and educated patients used these behaviors more than illiterate patients. High educated patients tended to have more information on RA; hence, the effect of education may be through knowledge. A study by Dagfinrud showed that patients who used hot water pools felt much better after treatment compared to those who used similar exercises on land (Dagfinrud & Christie, 2007).

Studies have shown that depression and anxiety have adverse effects on pain, DAS28, quality of life, and functionality in the future (Abu Al-Fadl, Ismail, Thabit, & El-Serogy, 2014; Curtis, Groarke, Coughlan, & Gsel, 2005; Mann, 2010; morris et al., 2011; Rezaei et al., 2014; Treharne et al., 2007). Nevertheless, only third patients used various methods of stress management and meditation or relaxation (the least frequent SMB in our patients) which could be due to their lack of knowledge and skill. Therefore, it is recommended that patients, their families, and health professionals become more familiar with stress management and apply this techniques in daily living.

In our study, meditation was performed by patients with moderate disease activity approximately 3 times more than the patients in remission. Moreover married patients used this behavior 74% less than single patients. With an increase in age, the use of this SMB decreased. This finding is in line with the results of a study conducted by Mostafa was noted a significant relationship between depression, age and disease related factors (Mostafa & Radwan, 2013). The relationship between aging and depression seems to be driven by the socio demographic feature and health status of older patients such as marital status, level of limitation in daily activities, educational level, and cognitive impairment.

Diet is an important behavior for losing weight in order to prevent joint destruction. In the present study, some of the participants used this behavior in their daily living which could be due to family meal plans that is rich in carbohydrates and fat.

In our study, some patients used aquatic exercises such as swimming. Interestingly, patients with higher levels of education and health status using these behaviors more than illiterate patient. With higher levels of education, patients obtained more knowledge about the benefits of SMB such as aquatic exercises like swimming for improving health status. However, the role of health status in this behavior was not considerable, and this behavior could be influenced by other factors such as knowledge, cost, access to facilities, etc. According to the literature review, aquatic exercises have a greater positive psychological effect versus land exercises (Iversen, Chhabriya, & Shadick, 2011). The combination of aquatic exercises and SMB is beneficial to the physical health (Karatepe et al., 2011). Half of the participants in the present study spent more than 10 minutes per day exercising; nonetheless, with the increase in disease activity and pain, physical activity decreased. In addition, exercise increased with improvement in health status that could be related to the functional status. Various studies have shown that exercise has a positive impact on improving the function and quality of life of the RA patients (Chang et al., 2009; Karatepe et al., 2011). Contrary to our study, Iversen et al reported that patients with moderate to severe disease activity and more disability spent more time on physical activity and exercise (Iversen et al., 2011).

5. Conclusion

In the present study, patient used various types of SMB. Some behaviors such as drug management, frequent

referral to the physician, changing the dose or intervals between drug management, adequate rest and sympathy were seen in more than 90% while other behaviors like exercise, swimming, massage, heating, stress management, meditation, hot water pool and bag, and protecting the joints were performed less than the ideal. The education level, gender, occupation, age, health and marital status, DAS28, VAS, and PGA were recognized as factors influencing on SMB in RA patients. According to the literature, continuous use of self-management behaviors plays an important role in controlling RA patients; therefore, should be considered in designing, planning, implementing programs.

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Effect of Nurse-Led Telephone Follow ups (Tele-Nursing) on Depression, Anxiety and Stress in Hemodialysis Patients

Marzieh Kargar Jahromi[1], Shohreh Javadpour[2], Leila Taheri[3] & Farzad Poorgholami[4]

[1] Community Health Nursing, Faculty of Nursing & Para-Medicine, Jahrom University of Medical Sciences, Jahrom, Iran

[2] Critical Care Nursing, Faculty of Nursing & Para-Medicine, Jahrom University of Medical Sciences, Jahrom, Iran

[3] Pediatric Nursing, Faculty of Nursing & Para-Medicine, Jahrom University of Medical Sciences, Jahrom, Iran

[4] Medical Surgical Nursing, Faculty of Nursing & Para-Medicine, Jahrom University of Medical Sciences, Jahrom, Iran

Correspondence: Farzad Poorgholami, MSc in Medical Surgical Nursing, Jahrom University of Medical Science, Motahari St., Nursing & Para-Medical School, Jahrom, Iran. Tel: 98-71-5434-1501. E-mail: FarzadPoorgholami1393@gmail.com

Abstract

Introduction: Depressive and anxious patients on hemodialysis have a higher risk of death and hospitalizations. The aim of this study was to evaluate the effect of nurse-led telephone follow ups (tele-nursing) on depression, anxiety and stress in hemodialysis patients.

Method & Material: The subjects of the study who were selected based on double blind randomized clinical trial consisted of 60 patients with advanced chronic renal disease treated with hemodialysis. The patients were placed in two groups of 30 individuals. Before the intervention, a questionnaire was completed by patients. There was no telephone follow up in the control group and the patients received only routine care in the hospital. The participants allocated to the intervention group received telephone follow-up 30 days after dialysis shift, in addition to conventional treatment. Every session lasted 30 minutes, as possible. Then the DASS scale was filled out by the patients after completion of study by two groups.

Result: Significant differences were observed between the two groups in the posttest regarding the dimensions scores of DASS scale.

Conclusion: The result of this trial is expected to provide new knowledge to support the effective follow-up for hemodialysis patient in order to improve their emotional and health status.

Keywords: Tele-Nursing, depression, anxiety, stress, Hemodialysis patients

1. Introduction

Chronic Kidney Disease (CKD) is a silent disease that is frequently diagnosed in the advanced stages, when dialysis and renal transplantation are the only choices. A dialysis patient suffers from large burden of multiple somatic symptoms (Sajjadi, Kushyar, Vaghei, & Ismeili, 2008).

Cognitive disorders and Depression are prevalent in patients with chronic kidney disease. Elderly patients undergoing hemodialysis had higher levels of anxiety than the healthy elderly (Moser, Dracup, & Evangelista, 2010). Also anxiety decreases the quality of life of these patient and increases the length of hospital stay (Chen, Liu, Yeh, Chiang, Fu, & Hsieh, 2013).

The mean prevalence of clinical depression among hemodialysis patients approximately range from 20 to 30% with as many as in 42% of hemodialysis patients exhibiting some type of depressive affect (Hedayati, Grambow, Szczech, Stechuchak, Allen, & Bosworth, 2005; Watnick, Wang, Demadura, & Ganzini, 2005). These rates are substantially higher than the general population, where rates of depression are between 3% and 6%, and in older adults, where rates are between 6% and 10% (Rosengren, Hawken, & Ounpuu, 2004). Recent estimates project that, by 2050, rates of depression will increase by 35% in adults and more than double in older adults

(Wassertheil-Smoller, Shumaker, & Ockene, 2004).

Despite the high prevalence (up to 60%) and destructive consequences, depression is still a misdiagnosed disorder; It may be due to the superposed symptoms related to uremia (anorexia, fatigue, sleep disorders) and the absence of a systematic psychiatric evaluation (Bruce & Leaf, 2012).

The importance of the management of depression has been recently the center of focus in the nephrology literature. Screening of the patients for depression and providing proper care, has been recommended by several authors (Hedayati, Yalamanchili, & Finkelstein, 2012). However, the large number of undiagnosed and untreated depression in dialysis patients indicate the existence of barriers to optimal mental health care in these patients (Finkelstein, Wuerth, & Finkelstein, 2010).

Various methods have been used to reduce anxiety and its consequences (Harris & Richards, 2010). Telephone follow-up is considered a low cost and easily organized intervention, and a good way to manage symptoms and early recognition of complication, reassurance and quality aftercare; and also to exchange information and provide health education (McCorkle, Siefert, Dowd, Rohinson, & Pickett, 2007).

For this reasons, this study was conducted to evaluate the effect of nurse-led telephone follow ups (tele-nursing) on depression, anxiety and stress in hemodialysis patients in Iran.

2. Method & Material

2.1 Study Design and Sample

The subjects of the study who were selected based on double blind randomized clinical trial consisted of 60 patients with advanced chronic renal disease treated with hemodialysis. The study population was patients referring to dialysis ward at Motahhari hospital of Jahrom, Iran, from September to March 2014. Patients were recruited through convenience sampling method. Inclusion criteria included age between 18 to 65 years, not having cognitive and psychological disorders, understanding Persian language with at least primary education, reaching final stage of renal disease and being constantly under treatment, undergoing at least 6 months of treatment with hemodialysis, being under treatment of three times a week for three to four hours, no renal transplantation and immigration during intervention, and no formal training in relation to dialysis. Exclusion criteria included having a history of serious or adverse experiences in the last six months, being treated with antidepressant medications, hospitalization due to acute disease, and unwillingness to continue to participate in the study.

2.2 Instrument

A two-part questionnaire was used for data collection. The first part included seven questions on patients' demographic characteristics including age, sex, marital status, employment, education level, income level, and hemodialysis frequency in a week. The second part was the Depression Anxiety and Stress Scales (DASS) that is a widely used screening tool to assess symptoms of depression, anxiety, and stress in community settings. This instrument comprises three sub-scales: (1) the Depression sub-scale which measures hopelessness, low self-esteem, and low positive affect; (2) the Anxiety scale which assesses autonomic arousal, muscle-skeletal symptoms, situational anxiety and subjective experience of anxious arousal; and (3) the Stress scale which assesses tension, agitation, and negative affect. There are two forms of the DASS, the full 42-item and the short 21-item versions. Both assess the same domains. There is evidence of the validity of the DASS for the use in both clinical and community settings.

The DASS-21 consists of 21 items, with 7 items in each scale measuring the respective current symptoms of depression, anxiety, and stress. The DASS-21 uses a four-point scale to rate the severity, which ranges from 0 ("not apply to me at all") to 3 ("applied to me very much, or most of the time"). To obtain the total score and the scores for depression, anxiety, and stress, the individual score from the respective items were added up and multiplied by 2, as recommended by Lovibond and Lovibond (1995) who developed the tool. The range of the score of each area is from zero to 21, (Lovibond & Lovibond, 1995).Validity and reliability of this questionnaire was confirmed by Sahebi et al. (Sahebi, Asghari, & Salari, 2005).

2.3 Intervention

This study was approved by the Research Council and the Research Ethics committee of Jahrom University of Medical Sciences. Data collection was performed after explaining the research objectives, and obtaining written informed consent from the participants. All patients were assured of obscurity and confidentiality of their personal information, and the right to refuse participation or withdraw from the study at any time. Also the necessary permissions were sought from the hospital authorities and the hemodialysis unit. Sixty patients were

finally recruited in the trial, 30 in each group, by considering a possible attrition.

The questionnaires were completed by patients before the intervention. There was no telephone follow up in the control group and the patients received only routine care in the hospital.

The participants allocated to the intervention group receive telephone follow-up 30 days after dialysis shift in addition to conventional treatment. The content of the call followed a script to ensure consistency. The telephone follow-up consultations are structured and contain the following key subjects: communication, cognition/development, breathing/circulation, nutrition, elimination, sleep, pain/perception, skin/tissue, sexuality/reproduction, activity and psychosocial/spirituality/culture. All interventions are conducted by the researcher responsible for this trial. Every session lasted 30 minute as possible. Finally the DASS scale was filled out by the patients after completion of study by two groups.

2.4 Data Analysis

The data was analyzed by SPSS software version 15 and also descriptive and analytic statistics including Independent-Samples T test, Chi square, Paired t-Test and analysis of variance.

3. Result

In total, 54 patients completed the study. Despite the attempt of researchers to prevent attritions of samples through attending in the field and telephone follow up, but some of the patients did not complete the study. During the research, three patients in the control group and three patients in the intervention group (one patient because of death, two due to major complications, one patient due to inaccessibility by the researcher, and two patients because of declining to do hemodialysis) were excluded from the study.

Table 1 demonstrated socio-demographic characteristics of the patients. The mean age of participants was 69.13 (SD=11.82); Chi-square test showed that both groups were similar in terms of socio demographic characteristics.

The mean of depression, anxiety and stress scores in hemodialysis patients before intervention in each of the two groups are shown in Table 2. Using independent sample t-test, no significant difference was observed between the two groups in three dimensions of DASS scale before intervention. Significant differences were observed between the two groups in the posttest regarding the dimensions scores of DASS scale. The mean scores of the intervention group were higher than those of the controls (Table 3).

Table 1. Frequency distribution of the study units based on demographic variables in two groups

Group		Intervention	Control	P- value
		Relative frequency	Relative frequency	
Sex	Female	56	40%	0.42
	Male	44%	60%	
Marital status	Single	28%	16%	0.27
	Married	72%	84%	
Employment	Yes	40%	56%	0.42
	No	60%	44%	
Education level	Primary	4%	4%	0.63
	Junior high school	36%	36%	
	High school	56%	48%	
	Academic	4%	12%	
Hemodialysis frequency in a week	Twice	44%	28%	0.17
	Three times	56%	72%	
Income level	Poor (< 250$)	36%	20%	0.32
	Average (250-500$)	44%	72%	
	Good (>500$)	20%	8%	

Note. significance level of Chi-square test considered by P<05.

Table 2. Mean of depression, anxiety and stress scores before the intervention in the two groups

Group	Intervention		Control		P-value
Variable	M	SD	M	SD	
Depression Score	16.60	1.50	16.72	1.83	P=0.4
Anxiety Score	16.48	1.85	16.78	1.87	P=0.5
Stress Score	16.92	0.90	15.92	1.44	P=0.4

Note. significance level considered by P<05.

Table 3. Mean of depression, anxiety and stress scores after the intervention in the two groups

Group	Intervention		Control		P-value
Variable	M	SD	M	SD	
Depression Score	8.96	1.17	16.20	1.60	P=0.05
Anxiety Score	8.68	0.90	16.72	1.98	P=0.01
Stress Score	8.36	1.03	13.76	1.44	P=0.001

Note. significance level considered by P<05.

4. Discussion

This research was conducted to evaluate the effect of nurse-led telephone follow ups (tele-nursing) on depression, anxiety and stress in hemodialysis patients. Since the prevalence of chronic kidney disease is high in developing countries like Iran, we assess this population. Based on our findings, significant difference between the two groups regarding the dimensions scores of DASS scale after intervention. We found that tele-nursing program was associated with lower depression, anxiety and stress in intervention versus control group.

In a recent analysis, it was demonstrated that hemodialysis patients on dialysis had a higher risk of depression and anxiety. In other word anxiety and depression are the common non-psychotic mental disorders experienced by hemodialysis patients (Duarte, Miyazaki, Blay, & Sesso, 2009).

The effectiveness of non-pharmacologic interventions in reducing anxiety and depression has been proven in a few other reports as well. In one recent randomized controlled trial, cognitive behavioral therapy for 3 months improved depressive symptom scores significantly (Magela Salomé, de Almeida, & Silveira, 2014). A randomized controlled trial on exercise training reported promising results (Ouzouni, Kouidi, Sioulis, Grekas, & Deligiannis, 2009). Hosseini and colleagues (2009) concluded that psychological training is an appropriate alternative for physician when exposing depressed patients with kidney failure (Hosseini, Espahbodi, Mirzadeh Goudarzi, 2012).

Sundsli et al. (2014) in an article titled "self-care telephone talks as a health-promotion intervention in urban home-living persons 75+ years of age", concluded self-care telephone talks significantly improved mental health (Sundsli, Soderhamn, Espnes, & Soderhamn, 2014).

Rollman and colleagues (2009) found that telephone follow-up is associated with clinically significant improvements in health-related quality of life (Rollman, 2009).

Kirsten et al. (2014) in their study titled "telephone follow-up by nurse following total knee arthroplasty" have shown care related to information and contact with health professionals by telephone follow-up positively improved patient satisfaction (Kirsten, Konradsen, Solgaard, & Ostergaard, 2014).

Consistent with previous findings, in our study the telephone follow-up consultations containing the following key subjects: communication, cognition/development, breathing/circulation, nutrition, elimination, sleep, pain/perception, skin/tissue, sexuality/reproduction, activity and psychosocial/spirituality/culture improved the depressive symptom in intervention group.

Based on these findings, it was considered pertinent to assess the best scientific evidence regarding to the

telephone follow-up and to obtain information about working with mobile and the clinical and psychological effects for the individuals who received these interventions (Flanagan, 2009).

Tele nursing as a field, it is part of the telephone follow-up method; which mainly act as a form of monitoring for high-risk patients expose to invasive procedures, allowing them to lead a life as normal as possible. This care strategy is considered better for the service, by reducing the workload in the conventional outpatient monitoring system, allowing the professionals to focus on care for the patients who actually need hospital care (Mistiaen & Poot, 2006), which also reduces the patient's risk of readmissions and Basically, enhance their psychological symptom (Thompson-Coon et al., 2013; Naffe, 2013).

5. Conclusion

The result of this trial is expected to provide new knowledge to support the effective follow-up for hemodialysis patient in order to improve their emotional and health status. We expect this trial to confirm the importance of support by a clinical specialist nurse in improving mental health of hemodialysis patients especially for those in remote regions.

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Quality Management Systems Implementation Compared With Organizational Maturity in Hospital

Tayebeh Moradi[1], Mehdi Jafari[1,2], Mohammad Reza Maleki[2], Seyran Naghdi[3] & Hesam Ghiyasvand[4]

[1] Research Center for Health Services Management, Institute for Futures Studies in Health, Kerman University of Medical Sciences, Kerman, IR Iran

[2] School of Health Management and Information Sciences, Iran University of Medical Sciences, Tehran, IR Iran

[3] Research Center for Social Determinants of Health, Institute for Futures Studies in Health, Kerman University of Medical Sciences, Kerman, Iran

[4] Research Center for Modeling in Health, Institute for Futures Studies in Health, Kerman University of Medical Sciences, Kerman, Iran

Correspondence: Mehdi Jafari, School of Health Management and Information Sciences, Iran University of Medical Sciences, Tehran, IR Iran & Research Center for Medical Informatics, Institute for Futures Studies in Health, Kerman University of Medical Sciences, Kerman, IR Iran. Tel: 98-912-321-0131. E-mail: mjafari@iums.ac.ir

Abstract

Background: A quality management system can provide a framework for continuous improvement in order to increase the probability of customers and other stakeholders' satisfaction. The test maturity model helps organizations to assess the degree of maturity in implementing effective and sustained quality management systems; plan based on the current realities of the organization and prioritize their improvement programs.

Objectives: We aim to investigate and compare the level of organizational maturity in hospitals with the status of quality management systems implementation.

Materials and Methods: This analytical cross sectional study was conducted among hospital administrators and quality experts working in hospitals with over 200 beds located in Tehran. In the first step, 32 hospitals were selected and then 96 employees working in the selected hospitals were studied. The data were gathered using the implementation checklist of quality management systems and the organization maturity questionnaire derived from ISO 10014. The content validity was calculated using Lawshe method and the reliability was estimated using test - retest method and calculation of Cronbach's alpha coefficient. The descriptive and inferential statistics were used to analyze the data using SPSS 18 software.

Results: According to the table, the mean score of organizational maturity among hospitals in the first stage of quality management systems implementation was equal to those in the third stage and hypothesis was rejected (p-value = 0.093). In general, there is no significant difference in the organizational maturity between the first and third level hospitals (in terms of implementation of quality management systems).

Conclusions: Overall, the findings of the study show that there is no significant difference in the organizational maturity between the hospitals in different levels of the quality management systems implementation and in fact, the maturity of the organizations cannot be attributed to the implementation of such systems. As a result, hospitals should make changes in the quantity and quality of quality management systems in an effort to increase organizational maturity, whereby they improve the hospital efficiency and productivity.

Keywords: organizational maturity, Quality Management System, ISO 10014, hospital

1. Background

Nowadays, the quality and its promotion in hospitals is one of the important issues in health system management; so that the quality assurance of health services is considered as a part of governments' mission, one of the important tasks of health managers in countries as well as one of the main priorities in health sector reforms (Øvretveit, 2001; Marshall et al., 2006). In addition, the quality of services in hospitals as the most important

element of the health system has a special status (McKee & Healy, 2000). Quality management system is a management system to direct and control an organization with regard to quality issue (Jing, 2010). There are many definitions for such a system; a quality management system in itself is not able to make the organization more profitable, efficient and customer-oriented, but rather enables the organization to perform better than before (Aggelogiannopoulos, Drosinos, & Athanasopoulos, 2007). In other words, the quality management system can be viewed as a complex system of all parts and components of an organization that focuses on quality processes and activities (Lombarts, Rupp, Vallejo, Klazinga, & Suñol, 2009).

Currently, organizations need to have a new management tools and approaches in order to reconcile traditional evaluation methods with new and more prospective management methods. Although hospitals are one of the most complex industries, for now are managed using traditional methods (Van den Heuvel, Koning, Bogers, Berg, & van Dijen, 2005). The quality management systems approach encourages organizations to consider customer requirements, determine processes affecting the fulfillment of product or service accepted by customers and controls these processes (Lee, To, & Yu. 2009).

In recent years, many efforts have been made to improve the quality of health services in the country. Previous experiences suggest that although these programs have had undeniable positive effects, they have typically been involved in fragmentation and discontinuity in quality improvement processes due to lack of systematic and holistic approach. ISO standardization methods, implementation of total quality management programs, establishment of complaints-handling offices, client reference programs, excellence models such as EFQM and recently, clinical governance system are among plans with different approaches which have been announced and implemented with the aim of improving healthcare organizations and their services levels (Kaplan et al., 2010).

An appropriate quality management system is a structural framework which every organization should establish it prior to delivery products or provide services to their customers or consumers (Linderman, Schroeder, Zaheer, Liedtke, & Choo, 2004). Although common methods and concepts of quality management and excellence, such as ISO, 5S, EFQM and so on are useful, their ability to have a profoundly impact on the health sector should be questioned (Kaplan et al., 2010; Buciuniene, Malciankina, Lydeka, & Kazlauskaite, 2006).

S et al. in 2007, in a study titled "how Hospitals Choose a Quality Management System: Relevant Criteria in Large Spanish Hospitals" examined the implementation of three quality management system models including ISO 9001, Joint Commission (JC), EFQM, or a combination of them and selection criteria affecting Spanish hospitals of size > 400 beds when choosing a quality management system. According to the study, the term implementation of quality management systems refers to running the ISO 9001 model, hospital accreditation system and European model for Organizational Excellence (EFQM) or a combination of them. To gather the required data, the researchers sent a questionnaire to 101 hospitals. The results of the study showed that in the studied hospitals, 71.4% has used ISO 9001 quality management system; 11.9% JC, and 69% EFQM (Sangüesa, Mateo, & Ilzarbe, 2007).

Furthermore, organizations use models of organizational maturity to know whether they will continue their route towards maturity. Maturity models provide reference points for the organization to evaluate itself (or for external evaluation) based on best practices according to one or more specific guidelines (Nazar & Abbasi, 2009; Smith, 2010). The test maturity model helps organizations to assess the degree of maturity in implementing effective and sustained quality management systems; plan based on the current realities of the organization and prioritize their improvement programs (Eileen et al., 2005). Also, this model will help organizations to identify prerequisites for implementing the quality management system according to the maturity of the organization (Cooke-Davies & Arzymanow, 2003). Some of the maturity models provide limited guidance on how to achieve more maturity and most of them are in such a way that the users themselves must find the path to higher levels of maturity. Some of these models include capability Maturity Model Integration, organizational project management maturity model, ISO 9004.

One of them is self-assessment can provide a general overview of the organization performance and the degree of maturity of its management system. The self-assessment also can help organizations to identify areas needing improvement or innovation and prioritize next initiatives (ISO 10014, 2006; Wolniak, 2013; Boys, Karapetrovic, & Wilcock, 2004). The results of the assessment can be used as input to management investigations (ISO 9004, 2009). In this model, derived from the standard 10014, an organization is evaluated in eight dimensions to assess its maturity and readiness to accept the effective and efficient organization's quality management system. The dimensions are as followed: customer focus, leadership, employee involvement, process approach, system approach to management, continuous improvement, realistic approach to decision-making and communication with suppliers based on mutual interests.

There is a combination of 8 principles of the quality management, the plan–do–check–act cycle (PDCA) and process approach in this standard. Self assessment according to ISO 10014 considers five levels of maturity (level 1 represents the lowest level of maturity while level 5 is the highest). In this model, the maturity of an organization's quality management is reflected based on the presence or absence of balanced or unbalanced development of the abovementioned dimensions (ISO 10014, 2006).
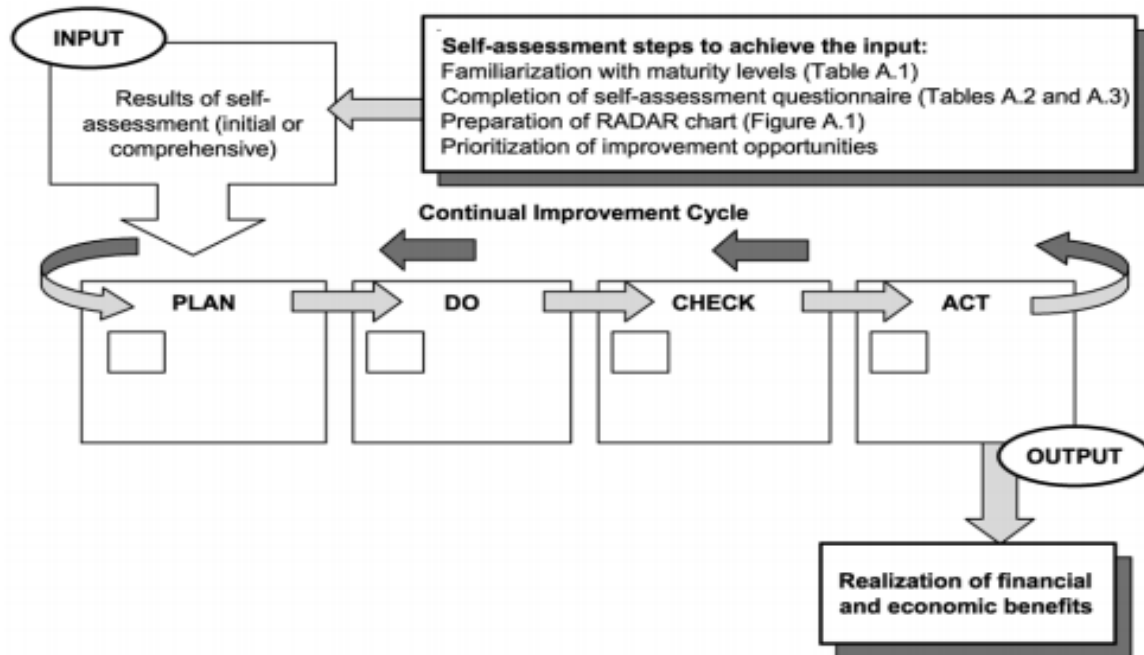

Diagram 1. Generic representation of the overall process in ISO 10014

In fact, this study may be a response to a question about why some efforts made in the field of implementing quality management systems in some organizations have not expectedly succeeded and the quality management systems in these organizations are survived just symbolically and apparently with the efforts and support by only a few individuals while in some organizations, the opposite happens.

According to the studies on this area of research, there has been no study on the relationship between the two variables, organizational maturity and implementation of quality management systems, in hospitals, both inside and outside the country yet. Most studies have examined only one of these two variables. While studies in this area have been conducted mainly in non-medical service organizations especially in the IT field, this study has examined the importance of organizational maturity dimensions and quality management systems in the hospital as the main healthcare services provider in addition to provide new insight into them.

2. Objectives

This study has investigated and compared the status of quality management systems implementation with the level of organizational maturity in selected hospitals in Tehran using the eight quality management principles.

3. Materials and Methods

This descriptive-analytical cross-sectional study considered from applied perspective has employed qualitative methods and been conducted in hospitals with over 200 beds located in Tehran. This study was carried out in two methodologically independent steps; accordingly, all elements of the study have been described separately for each step.

3.1 Step One: Determining the Status of the Quality Management Systems Implementation

The first setting of the study has been all hospitals in Tehran. Given that in practice, small hospitals do not follow such quality management system (Sangüesa, Mateo, & Ilzarbe, 2007) and there are a large number of hospitals in Tehran, the inclusion criteria for entering hospitals into study were determined as below:

1. Being located in Tehran

2. Having 200 beds and above.

There have been a total of 39 hospitals but seven hospitals of them were not willing to participate in the study. In terms of ownership, there were 21 public, 4 private, 4 Social Security Organization hospitals as well as 4 hospitals owned by other organizations.

At this step, in order to collect data about the implementation of quality management systems in studied hospitals, a checklist to investigate the current status of hospital has been used; This checklist included questions about the hospitals' characteristics and implementation steps of different quality management models in the studied hospitals such as: series of ISO standards (9001, 14001, and 18001), FOCUS-PDCA, EFQM and so on. The main objective of this step of the study is to classify hospitals based on quality management systems. Based on implementation steps of each of quality management models, we get the mark of each of models, from 2 to 6 that it depends on them. Then according to total score, we divide them into three groups. Therefore, hospitals with the points less than 11.7 were classified into level one, between 11.7 to 17.3, level tow and higher than 17.3, level three. Accordingly, in terms of the implementation of the quality management systems, 18 hospitals classified into the first and third levels were entered the second step of the study i.e. the completion of organizational maturity questionnaire.

3.2 Step Two: Measuring Organizational Maturity

At this step, all administrators and quality experts working in the first and third levels hospitals located in Tehran have been considered. Due to the limited number of them, only one inclusion criterion was used which was selecting those with one or more years job experience in the hospital since they should be relatively familiar with the hospital and its environment. Accordingly, a total of 96 hospital administrators and quality experts (including experts working in offices of the quality improvement, clinical governance, R&D, hospital experts) were selected in this step. Totally, average of 5 persons per hospital was questioned. The exclusion criterion of the study subjects was non-completion of the questionnaire after three times follow-up during 15 days and the return rate for the questionnaires in this study was 86.46 percent. In order to assess the level of organizational maturity, the standard 10014 designed questionnaire including the eight quality management principles (customer focus, leadership, employee involvement, process approach, system approach to management, continuous improvement, realistic approach to decision-making and communication with suppliers based on mutual interests) was used and the organizational maturity from the hospital administrators and quality experts' viewpoints on a five-level Likert scale (very high = 5, and very low = 1) was assessed.

Each question in the questionnaire (including 76 questions) was questioned with three options "relevant and important", "can be used but is not necessary" and "irrelevant"**.** After receiving the forms, the content validity ratio (CVR) and its index for the questionnaire were calculated using Lawshe method (Lawshe, 1975; Wynd, Schmidt, & Schaefer, 2003). Lawshe model is a way of achieving content validity and has been used in different fields such as health care. It involves a panel of subject matter experts considering the importance of individual items within an

instrument (Ayre & Scally, 2014). After calculating the CVR, 12 questions with CVR less than 0.8 were removed. Then, the questionnaire was distributed among experts again and according to the experts' opinion, 10 questions were merged and 13 questions with the CVR less than 0.8 were removed. Finally, the questionnaire was finalized with 41 questions.

To assess the reliability using the test- retest method, the questionnaire was distributed among 10 hospital administrators and quality improvement experts working in the selected hospitals and the questionnaire, once again, was distributed among the same individuals after two weeks; the Cronbach's alpha coefficient was equal to 0.843. Given that the closer Cronbach's alpha coefficient is to 1.0 the greater the internal consistency of the items in the scale; this value indicates the strong reliability due to high internal consistency of the questions in the questionnaire. To complete the organizational maturity questionnaire, the researcher visited to all studied hospitals in the first step of the study in person and after providing the introduction letter, distributed the questionnaire among the selected hospital administrators and experts in quality and clinical governance while describing the nature of the project and ensuring the confidentiality of their responses to get consent to participate. To facilitate responding, the research information form was also attached to the questionnaire in order to have access to the researcher and get answers to questions in the case of any question about the study and the questions. In this study, the implementation of quality management systems and the organizational maturity have been considered as the dependent variable and the independent variable, respectively. To analyze the collected data, in the first step, the output data about the implementation of quality management systems was obtained in three features. In the second step, the data about the organizational maturity level based on eight

quality management principles were gathered on a five-point Likert scale. In the third step, the relationship between the organizational maturity and the implementation of quality management systems in studied hospitals was examined.

The descriptive statistics (frequency ratio - the percentage, mean, variance and standard deviation) in the form of statistical tables, graphs and numerical indicators were used in order to analyze the data using the statistical software SPSS-18 and Excel. In order to assess the organizational maturity level and implementation of quality systems, first, the normality distribution of the response variables was examined using the Kolmogorov-Smirnov test. Then, the T-test and Mann-Whitney U test were used for the inferential analysis of the relationship between various dimensions of the organizational maturity and the first and third level hospitals in the implementation of quality management systems. Using the mean value can neutralize the effect of unequal sample size. If the p-value is less than 0.05, there is a significant difference between the eight dimensions of the organizational maturity in the first-level and third-level hospitals in implementing the quality management systems.

4. Results

In this study, all the systems implementing successfully, involving the establishment, having certification or documentation indicating successful implementation of the quality management models have been considered as the variable for the implementation of quality management systems. As shown in Table 1, the accreditation model with a maximum value of 78.13% (n = 25) and ISO 14001 with a minimum value of 3.13% (n = 1), respectively, have been the highest and the lowest quality management systems used in the studied hospitals.

Aside from the accreditation, the two models of ISO 9001 with value of 53.13% (n= 17) and the European model for Organizational Excellence (EFQM) with value of 41.63% (n=13) have been identified as the most frequently used models in the hospitals. The remaining models have been implemented or are being implemented in less than 20 percent of the hospitals.

Table 1. The distribution implementation of the quality management systems in studied hospitals

Quality Management Systems(QMSs)	Frequency	Percentage
Accreditation	25	78.13
ISO 9001	17	53.13
EFQM	13	40.63
BSC	6	18.75
5S	5	15.63
FOCUS-PDCA	5	15.63
ISO 18001	2	6.25
ISO 14001	1	3.13

The status of studied hospitals in terms of the implementation of the quality management system has been illustrated in Table 2.

Table 2. The levels of implementation of the quality management system in studied hospitals

Level of Hospital	Range of Score	Frequency	Percentage
First Level	11/7<	14	43.75
Second Level	11/7-17/3	14	43.75
Third Level	17/3>	4	12.50
Total	-	32	100.00

In the second step of this study, 83 subjects participated. According to the figure illustrating the scores of the organizational maturity in the hospitals and their level of the quality management systems implementation, the dimensions of the customer focus and the leadership (3.54) have had the highest average while the dimension of

the system approach to management has had the lowest average (3.18). The findings of the study showed that the mean score of the eight dimensions of the organizational maturity among hospitals in the third level hospitals has been higher than that in the first level hospitals. Table 3 shows the information about the frequency and the percentage frequency of the three different levels of the organizational maturity (low, medium and high) in the hospitals at the first and third level of implementing the quality management systems as well as all hospitals. Given that the scores of the organizational maturity in hospital have been between1.10 to 4.51, the scores less than 2.5, 2.5-3.5 and more than 3.5 were considered as the low, medium and high organizational maturity, respectively. According to the table, while the third-level hospitals has not had low organizational maturity and almost 55 percent of high organizational maturity has been attributed to them, the first-level hospitals have had 36.5% of the high organizational maturity.

Table 3. The three levels of the organizational maturity in the first and third - level hospitals at implementing the QMSs

Organizational Maturity	The first-level hospitals		The third-level hospitals		Total of Hospitals	
	n	%	n	%	n	%
Low	3	5.8	0	0	3	3.6
Medium	30	57.7	14	45.2	44	53
High	19	36.5	17	54.8	36	43.4
Total	52	100	31	100	83	100

The dimensions of the organizational maturity in the first- and third-level hospitals have been displayed in the following RADAR chart. According to the chart, the mean score for the eight dimensions of organizational maturity in third-level hospitals has been higher than that in the first level hospitals. The advantage of the RADAR chart compared to other charts is that the comparison of various positions of the chart at one level is possible.

The mean and standard deviation of the variable of the organizational maturity in terms of the levels of the quality management system implementation and the p-value of the test have been shown in Table 4.
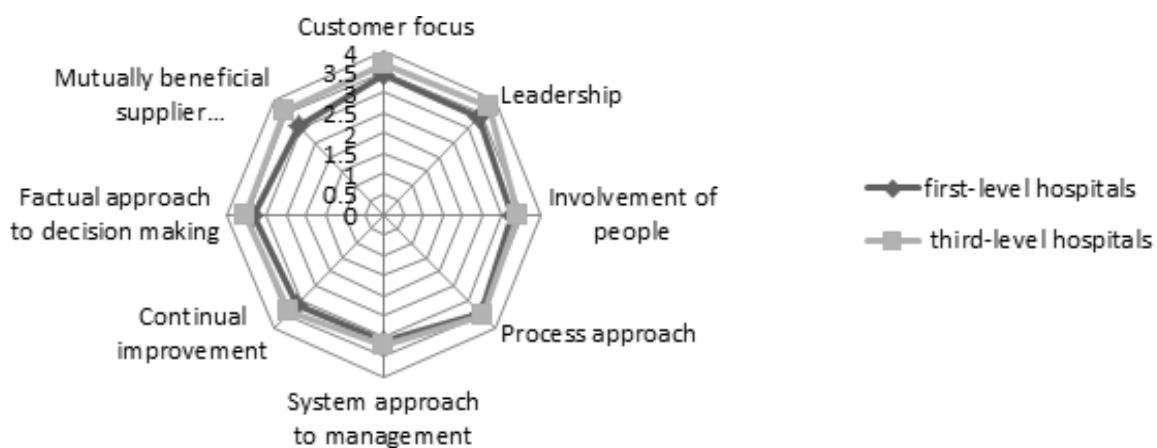

Diagram 2. The dimensions of organization in first-level hospitals and in third-level hospitals

Table 4. Compare quantity of the organizational maturity in terms of the levels of the quality management system implementation in studied hospitals

Organizational Maturity	Mean	SD
First-level hospitals	3.29	0.08
Third- level hospitals	3.53	0.10
P-value(Confidence Interval)	0.093(-0.515-0.040)	

As it has been illustrated in Table 4, the mean (SD) of the organizational maturity in the first-level hospitals and the third- level hospitals have been equal to 3.29 (0.08) and 3.53 (0.10), respectively.

5. Discussions

The findings of the study suggest that the most commonly used models among the studied system included accreditation model (has been announced by the Ministry of Health and Medical Education), ISO 9001, European model for Organizational Excellence and Balanced Scorecard, respectively. Meanwhile, the two models of ISO 14001 and OHSAS have been rarely used. The findings of this study are in consistence with those of Hashemzehy's study on the use of systems or approaches to evaluate the performance (i.e. quality management systems) in 2010. The results of that study showed that among the studied systems, two models of the organizational excellence and the Clinical Governance (43.8%) have been the most widely used systems and the implementation of the ISO approaches and the Balance Scorecard method (25% and 18.8%, respectively) has also been used considerably. The use of the Balanced Scorecard method by as much as 18.8% in Tehran hospitals seems to be quite interesting and beyond the expected (Hashemzehi, Iran nezhadparizi, & Tabibi ,2010); this value is close to the finding of the current study (18.75%). The results of a study titled "how Hospitals Choose a Quality Management System" by Sangüesa et al. in 2007, have been also similar to the results of the current study; so that the ISO (71.4%) has been identified as the most commonly used model and aside from ISO, the EFQM (69%) has been considered as the second widely used quality management system in Spain. Currently, the efficiency of the models of the quality management system has been completely approved; since the implementation of these models in many organizations have led to surprising results and has become a competitive advantage. But still the lack of effectiveness of the implementation of the mentioned models is questioned (Cooke-Davies & Arzymanow. 2003).

The results of this study also indicate that the scores on all dimensions of the organizational maturity are in the range between 3 and 4. In other words, the organizational maturity level in the studied hospitals can be regarded as average to good. However, at the first look, it seems that there should be a significant difference between the organizational maturity in different levels of implementing the quality management systems, according to the equality between the average organizational maturity between the first-level hospitals and the third-level ones in implementing the quality management systems (despite the mentioned default hypothesis) the hypothesis is rejected (p-value = 0.09). According to the findings of a study by Sower et al. in 2007, there is a significant relationship between the quality system maturity and the cost of quality usage by organizations. This study also suggested that the total cost of quality (COQ) declines as an organization's quality system matures. Thus the assessment of the organizational maturity in hospitals and health centers can be considered important and necessary (Sower, Quarles, & Broussard, 2007).

Observations and studies comparing hospital industry with other service industries have shown that health care providers will take a longer journey on the path towards quality improvement in order to achieve positive financial performance. Studies show that most of the major hospital systems which are not well financed are now in the phase of the intermediate stages of the quality evolution (maturity). Small hospitals (with simple facilities) are usually not well financed and are generally in the early stages. On the other hand, a substantial percentage of innovative healthcare systems (creative) are in the middle of the third phase of the quality maturity. Not surprisingly, a very few hospitals are near the final stages (Performance Strategy Change Improvement [PSCI], 2010).

Among the eight dimensions of organizational maturity, only the three ones including "customer focus", "leadership" and "communication with suppliers based on mutual interests" were significantly different between the first-level and third-level hospitals of implement quality management systems; but the value is also not so high. In other words, implementation of the studied quality management systems has impact on only three dimensions out of the eight organizational maturity dimensions and has affected these three dimensions more

than others.

Establishment of quality management models in hospitals is essential for their excellence; but the philosophy and purpose of its establishment in the organization should always be considered. On the other hand, in the case of lack of support from top management for implementation of quality approaches in organizations, not only the customer satisfaction does not improve but also costs and a waste of time is imposed on organizations. Maturity models can help managers design an appropriate quality management system in order to achieve successes in the current situation and also help hospital officials to prioritize corrective actions and develop improvement strategies. As a result, hospitals should make changes in the quantity and quality of quality management systems in an effort to increase organizational maturity, whereby they improve the hospital efficiency and productivity. In fact, the organization maturity can be considered as the same as the organization effectiveness in the establishment and implementation of quality management systems in the organization.

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The Determination of Predictive Construct of Physical Behavior Change on Osteoporosis Prevention Women Aged 30-50: A Trans-theoretical Method Study

Farideh Malekshahi[1], Alireza Hidarnia[1], Shamseddin Niknami[1] & Frakhondeh Aminshokravi[1]

[1] Department of Health Education, Faculty of Medical Sciences, Tarbiat Modares University, Tehran, Iran

Correspondence: Alireza Hidarnia, Department of Health Education, Faculty of Medical Sciences, Tarbiat Modares University, Tehran, Iran. Tel/Fax: 98-21-2384-2565. E-mail: Hidarnia@modares.ac.ir

Abstract

Osteoporosis is a major public health priority in Iran and throughout the world. The prevention of osteoporosis has recently become the ultimate goal of many health professionals. Behavior change is one of the most powerful strategies to prevent osteoporosis. This study aimed to determine the predictive construct of physical preventive behavior of osteoporosis in women aged 30-50 in Khorramabad, west of Iran. This study included 269 women selected from all the health centers of Khorramabad city according to the inclusion criteria of the study and through random cluster and systematic sampling. The data gathering tools were valid and reliable questionnaires of demographic information, stages of change, decisional balance, self-efficacy, and physical activity. Data were analyzed using descriptive and inferential statistics. The mean of the subjects' age was 38.72±7.003, and the mean of light weekly physical activity was 38.83±56.400. The results showed that the construct of self-efficacy had the highest predictive power of the preventive behavior. The results also showed that self-efficacy among the constructs of the Trans-theoretical Model was the only predictive construct for osteoporosis prevention behavior. Therefore, the findings of this study can serve as a base for educational interventions in behavioral changes to prevent of osteoporosis by health authorities.

Keywords: osteoporosis, trans-theoretical model, self-efficacy, prevention, physical activity, women

1. Introduction

Osteoporosis is the most common type of metabolic bone disease in which bone mass reduces with age. This disease has been known as an important health priority in community public health, particularly in women (Hazavehei et al., 2007; Tussing & Chapman-Novakofski, 2005). The disease remains asymptomatic until bone fracture, and therefore it is also referred to as "silent thief" (Chan et al., 2007). The prevalence of osteoporosis varies among countries and even within countries (Hazavehei et al., 2007). Previous studies have shown that the prevalence of osteoporosis in Iran is mostly at the age of 50 or over, 22.2% in females, and 11% in males (Adib & Nauroy, 2011; Salehi et al., 2009). A fracture due to osteoporosis happens every 3 seconds, and a fracture in the spine occurs every 22 seconds worldwide (PDO, 2006). So that one out of two women over the age of 50 experiences vertebral fractures, and one out of three men over 50 experiences hip fractures in their lifetime, and both of these conditions lead to significant morbidity and mortality (PDO, 2006; Schwellnus et al., 2011). According to global statistics, Iran, like other countries, will have a considerable population of the elderly the next 50 years, so that 14% of the population (11 million people) are 50 or over and 3.6% (2.6 million people) 70 or over, and around 34% of the population (42 million people) will be 50 and over by 2050 (Adib & Nauroy, 2011). The costs of the disease will be enormous (Khorsandi et al., 2011; Moayyeri et al., 2006) so that the medical cost of osteoporosis-related fractures has been more than 22 billion dollars in the USA (Blume & Curtis, 2011). If effective preventive measures are not taken and consistently promoted, it is predicted that the cost of osteoporosis will rise to 200 billion dollars in the world before the year 2040 (Blume & Curtis, 2011). Osteoporosis prevention and its subsequent fractures is the objective of many healthcare professionals (Tussing & Chapman-Novakofski, 2005). According to researches, obtaining a high bone density and maintaining it during lifetime play a major role in preventing osteoporosis in old age (Heaney & Weaver, 2003). Studies have shown that physical activity plays an important role in the prevention of osteoporosis (Lowe et al., 2011; Sharma et al., 2010; Khawaji et al, 2010; Khorsandi et al., 2011). Regular physical activity can have a positive effect on

bone mass during lifetime (Alev & Yurtkuran, 2003). Physical activity has obtained a special place in the context of medical science as a therapeutic method (DWS, 2005). Therefore, physical activity, particularly if it is accompanied by weight bearing, results in maintaining and even increasing bone mass through exerting mechanical pressure on bones (Maimoun et al., 2005; Habibzadeh et al., 2009; Ebrahim et al., 2010). Moreover, since behavior change is the basis and foundation of preventing many health-associated risks (Rollnick et al**.**, 2007), so it has been recommended as an effective way to prevent osteoporosis (Karimzadeh Shirazi et al., 2007; Glanz et al., 2008). Experts believe that the efficacy of health education and behavior change programs depends largely on the use of models and theories of health education (Butler, 2001; Araban et al., 2013). The first step of each health education is to choose suitable model for health education (Glans et al., 2008). On the other hand, since the prevention of behavioral factors influencing osteoporosis requires individuals' behavioral change (Glanz et al., 2008; Araban et al., 2013), the models and theories of health education and health promotion can be effective in designing interventions in this field at different levels (level 1, level 2 or even level 3) of prevention (Parker et al., 2004; Araban et al., 2013). A health education model which can be used to change behavior at individual level is the Prochaska Trans-theoretical model (Prochaska et al., 1992; Prochaska & Marcuse, 1994). The model has been used for a vast range of health behaviors since its introduction (Araban et al., 2013; Salehi et al., 2010; De Vet et al., 2007; Schüz et al., 2009; De Vet et al., 2008; Marcus et al, 1994; Prochaska & DiClement, 1983; Lawrence et al, 2005), this method can predict the way and time of behavioral change (Sharma & Romans, 2008).

The model has four constructs including "stages of change", "process of change", "self-efficacy", and "decisional balance" (Velicer et al., 2001) The construct of "stages of change" has been recognized as a comprehensive model of behavior change. This model focuses on an individual's preparation or effort to change and progress towards healthy behaviors. The importance of the model is for the reason that it shows the occurrence of change in the five stages (Parker et al., 2004) and suggests that people need different interventions at any stage (Figure 1). The first stage is "pre-contemplation" in which the individual does not speculate about behavior change within 6 months. Two groups of people fall into this stage: first, people who are unaware or have little information, these people are not aware of the consequences of behavior; second, those who have experienced change but have failed in the past, these people are resistant to change. The second stage is "contemplation" in which the individual thinks about behavior change in the future (within 6 months). People in this stage will weigh the benefits (pros) and the costs (cons) of behavior change and hence stay longer in this stage. The third stage is "preparation" in which the individual thinks about plans for behavior change in the near future and usually the next month. People in this stage have some plans for change and have taken actions. The next stage is "action" in which the individual has changed behavior during the last 6 months, and new behaviors can clearly be observed in this stage. The last stage is "maintenance" in which the individual has taken actions to maintain behavior change for a long time (6 months or more) (Glans et al., 2008). People in each stage require different interventions, and this categorization will enable us to intervene with regard to the stage which shows how a behavior changes in each of the stages. The processes of change include activities and strategies that will help the individual to progress in the change stages, and include two main types of cognitive processes (related to the individual's thoughts and feelings about unhealthy behavior) and behavioral processes (causing changes in unhealthy behavior). The application of these processes results in strengthening the individual in adopting new behavior and maintaining the behavior (Lee, 2004).

The third construct of the model is "decisional balance", which is defined as the benefits (pros) and costs (cons) of behavior change from the individual's view (Prochaska & Velicer, 1997; Yalcinkaya-Alkar & Karanci, 2007). According to this model, change occurs when the benefits are greater than the costs. This model is particularly important in the pre-contemplation and contemplation stages (Yasin et al., 2011; Prochaska et al., 2008), and the benefits and costs are similar to those in the health belief model (Prochaska & Velicer, 1997).

The fourth construct of the model is "self-efficacy", which refers to the individual's perceived confidence in the ability to perform a certain behavior successfully. The construct has been adopted from Bandura's social learning theory and Shiffman's model of consistency and relapse (Bandura, 1982, 1997, 2006). This construct is unique to the relevant behavior and has a pivotal role in changing behavior and moving toward higher stages of change. It also has a direct linear correlation with the stages of change. In this regard, some strategies have been recommended to enhance self-efficacy such as breaking the behavior into small, simple, and practical stages, taking advantage of persuasion, reducing stress, and using believable role patterns (Sharma & Romans, 2008).
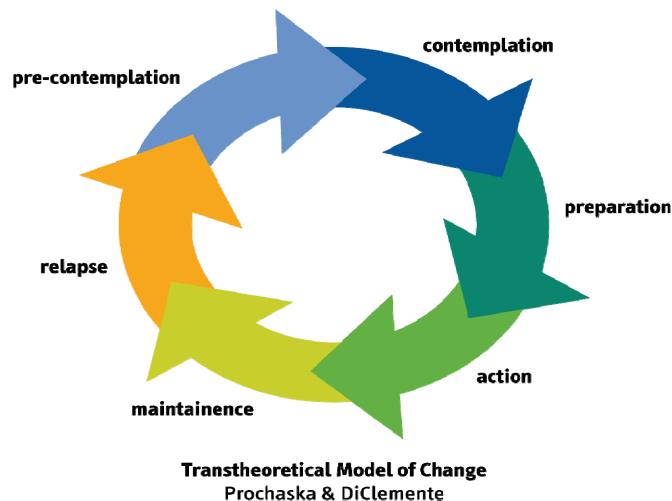
Figure 1. Stages of change in the TTM

This construct has a central role in changing behavior and entering the higher stages of behavioral change (Prochaska et al., 2008). Finally, the model usually interprets behavior change as an event, and evaluates overt behaviors in the end points.

In order to modify osteoporosis prevention behaviors such as regular physical activity that requires behavioral continuity unlike simpler and one-step behaviors, it is logical to apply those models which are sensitive to different stages and small steps of change (Araban et al., 2013). Therefore, the present study aimed to determine the predictors of behavior change in osteoporosis prevention in women aged 30-50 years in the city of Khorramabad (west of Iran). It is hoped that theory-based interventions are designed through identifying the factors influencing the behavior in order to take an important step in improving women's health.

2. Materials and Methods

This descriptive-inferential cross-sectional study included 269 women aged 30-50 years old referred to the health care centers of Khorramabad, west of Iran in 2013. The sample size was determined based on the number of the constructs of the Trans-theoretical Model. Therefore, 50 samples selected for each construct, and 7% was added (Hajizadeh & Asghari, 2011). Sampling was performed through the multi-stage cluster sampling. The city was divided into four areas of north, south, east, and west. Then, one health care center was chosen randomly from each area, and the samples were selected randomly from the individuals admitted to the health care centers considering the inclusion criteria of the study. The inclusion criteria of the study were as follows: females aged 30-50 years old with educational level at least grade five of primary school, lack of rheumatoid disease and mental disorder, lack of fractures, pregnancy, menopause and breast-feeding, and consent to participate in the study. Before entering the study, the participants were provided with the necessary information about the study, and those who showed their willingness to participate through verbal informed consent were included in the study. The study was approved by the ethics boards of Tarbiat Modares University and Lorestan University of Medical Sciences. To collect the demographic information, a questionnaire of demographic information was applied, which included age, educational level, marital status, number of children, housework, menstrual age and abnormality, income, height and weight, and tea as well as supplements consumption.

The stage of change in physical activity was measured using the Stages of Exercise Change Questionnaire (SECQ) a 5-item questionnaire, prepared by Marcus et al (Marcus BH et al., 1992). The questionnaire was applied after its content validity index (> 0.7), content validity ratio (0.59), and face validity (IF=5) were approved. The questionnaire put individuals in the stages of pre-contemplation (not thinking about behavioral change in osteoporosis prevention in the next 6 months), contemplation (thinking about behavioral change in osteoporosis prevention in the next 6 months), preparation (thinking about behavioral change in osteoporosis prevention in the next month), action (taking action to change in osteoporosis prevention in the previous day to 6 months), and maintenance (sustaining action in osteoporosis prevention for more than 6 months) (Sharma & Romans, 2008). Since the questionnaire was dynamic in nature, it had one question at five levels. Therefore, the common methods for determining reliability were not appropriate for the questionnaire (Araban et al., 2013).

However, since the process of validity confirmation was performed carefully, we can say that the questionnaire had the necessary reliability and validity. The questionnaire placed the individuals in one of the five stages. Therefore, a score of 1 to 5 was assigned to each stage. The preventive behavior in this study was defined as physical activity at least 5 days per week and for 30 minutes each time.

The questionnaire by Nigg et al. (1998) was applied to determine decisional balance (pros and cons), and Schowarzer and Renner's 5-point Health–specific Self-efficacy Scale to measure individuals' confidence in overcoming the current cons in performing regular physical activity. It should be noted that in this study one question was added by the researchers to the self-efficacy scale, and the decisional balance (pros and cons) scale included 11 questions for each variable equally (Karimzadeh Shirazi et al., 2007). Each question was scored based on a 5-point Likert scale ranging from 1 (*extremely important*) to 5 (*completely unimportant*). The total scores of the questionnaire for the constructs of pros and cons in decisional balance did not range from 11 to 55. The content validity for the pros (CVI=0.99, CVR=0.8), the content validity for the cons (CVI=0.88, CVR=0.70), and the face validity (IF=1.5) were approved. The reliability of these two questionnaires was approved with a Cronbach's alpha of 0.88. The self-efficacy questionnaire included six questions and was prepared based on the theory of Bandura's self-efficacy. The content validity (CVI=0.94, CVR=0.71), the face validity (IF=1.5), and the reliability of the questionnaire (Cronbach's alpha=0.82) were approved. The answers of this tool were on a Likert scale (*"I'm completely sure"* to *"I'm not sure"*) with a range of 6 to 24 scores.

The tool for assessing physical activity was the International Physical Activity Questionnaire (IPAQ). This tool records information on the amount of time spent by a person to walk (as exercise) and to do moderate or high physical activity in the past seven days. The tool was prepared by a group of international experts in 1998 in Geneva, and has already been so far applied in numerous studies, and its reliability and validity have been reported (Craig et al., 2003). The data were collected from the samples in one step and were analyzed with SPSS 16 using descriptive and inferential statistics (Chi-square test, Spearman and Mann-Whitney correlation coefficients). Logistic regression was performed to evaluate the predictive power of the model constructs in adopting the behaviors of osteoporosis prevention, so that the individuals in the stages of "pre-contemplation", "contemplation" and "preparation" were put into the "non-action" group (those without healthy behaviors), and those in the "action" and "maintenance" stages were included in the "action" group (those with healthy behaviors). The data were analyzed considering the significance level of 0.05.

3. Results

The results showed the highest frequency (41%) for the age group of 30-35, the lowest (17.8%) for the age group of 45-50, and the mean age of 38.72±7.003. Moreover, 36.8% had high school diplomas, and 26% had academic degrees. With respect to marital status, 75.1% of the subjects were married. Regarding occupation, 75.1% were housewives, the rest were employed, and 73.1% of the subjects were working in state organizations. Concerning income, low income (less than 500,000 Tomans monthly = 170 USD) with 46.5% and good income (more than 900,000 Tomans monthly = 300 USD) with 20.4% had the highest and lowest frequencies respectively. The mean age of menarche was 13.84±1.9, with the lowest menarche age of 9 (0.4%) and the highest of 21. In addition, the highest frequencies were found for the age of 14 (33.1%) and 13 (21.2%). Also, 11% of the subjects had experienced 1-5 miscarriages. Concerning number of children, 29.4% had two children. In terms of physical activity and housework, 7.8% of the subjects did not do housework, 33.8% did housework for 3 other individuals, and 22.7% for 4 other people. The results also showed that 76.6% of the women had no menstrual abnormalities, and only 23.4% had menstrual abnormalities out of whom 59 (21.9%) had the abnormality of irregularity. The mean and standard deviation of weekly light physical activity was 38.83±56.400 minutes, and the mean and standard deviation of moderate weekly physical activity was 4.77±29.119 minutes (Table 1).

Table 1. Demographic Information of Women 30-50 age

	Variables	*Percentage*
Age group	30-35	41
Marital status	married	75.1
Occupation	housewives	75.1
Income status	170USD	46.5
	300USD	20.4

Menarche age(y)	< 9	0.4
	13	21.2
	14	33.1
Number of children	2	29.4

The results of the construct of "stages of change" related to physical activity in the women showed that 43.5% of the women were in the pre-contemplation stage, and 9.4% in the maintenance stage in performing regular physical activity, as shown in Table 1. Also, in terms of the ranking of stages of change in physical activity, 82.9% were in the non-action phase and 17.1% in the action phase (Table 2). Table 3 shows the results of the constructs of stages of change related to physical activity in the women. Logistic regression was applied to determine the predictors of physical activity behavior (Table 4).

Results of the Mann-Whitney test showed a significant relationship between the constructs of stages of change and income ($p < 0.006$). Also, the findings of Pearson test showed a statistically significant relationship between the constructs of stages of change with educational level ($p < 0.043$), and occupation ($p < 0.014$).

Table 2. Frequency distribution of the stages of change related to the variable of physical activity in the studied women based on action and non-action

Ranking of the stages of change	Physical Activity	
	Frequency	Percentage
Non-action	223	82.9
Action	46	17.1

Table 3. Frequency distribution of the stages of change related to the variable of physical activity in the studied women

Stages of change	Physical Activity	
	Frequency	Percentage
Pre-contemplation	117	43.5
Contemplation	50	18.6
Preparation	56	20.8
Action	20	7.4
Maintenance	26	9.4

Table 4. Predictive variables of stages of change related to physical activity behavior based on the Trans-theoretical model constructs

Variable	Confidence interval		Odds ratio	P-value
	Upper	Lower		
Income	1.000	1.000	1	0.347
Educational level	2.046	0.971	1.409	0.071
Self-efficacy of physical activity	1.264	1.083	1.170	0.000
Pros of physical activity	1.025	0.933	1.046	0.123
Cons of physical Coactivity	1.109	0.988	0.978	0.358
Occupation	3.482	0.55	1.384	0.490

4. Discussion

The findings showed that only the construct of "self-efficacy" among the applied constructs of the Trans-theoretical Model had the predictive power for the behavior. The results of a comprehensive study by Schwarzer et al. indicated that self-efficacy could have a higher predictive power in health behaviors than the other constructs (Schwarzer & Fuchs, 1996). The results of Berry et al. and Kim's studies on exercise behavior, Swaim's study on the relationship between physical activity self-efficacy and physical activity behavior, and Dishman's et al study reported self-efficacy as the most important predictor of the behavior (Kim, 2004; Berry et al., 2005; Swaim et al., 2008; Gammage et al., 2009; Dishman et al, 2010; Khave et al, 2014). It seems that adopting preventive behaviors for osteoporosis is also more dependent on self-efficacy. Bandura, as the developer of the theory of self-efficacy, believes that self-efficacy is specific to a specific behavior. An individual may have high self-efficacy in one behavior and low self-efficacy in another one (Sharma & Romans, 2008; Bandura, 1977; Kim, 2004; Berry et al., 2005; Swaim et al., 2008; Gammage et al., 2009). Bandura a mentions four factors of success in performance, succession experiences, verbal encouragement, and physiological and emotional arousal as the sources of self-efficacy (Bandura, 2006). Therefore, self-efficacy is an important component of success, which falls in the field of positive psychology (Snyder & Lopez, 2002). The construct of self-efficacy, or belief in "*I can*", refers to a person's ability to perform tasks in certain circumstances. Additionally, another type of self-efficacy refers to the person's overall belief about his or her own abilities and capabilities (Mazloumi Mahmoud Abad et al., 2010).

Based on the results of our study, 79.9% of the women were in the no-action stage (pre-contemplation, contemplation, and preparation), and 20.1% were in the action stage (action and maintenance) through adopting regular physical activity. Also, most of the women (41.3%) were in the pre-contemplation stage and the lowest number (6.7%) in the action stage, while in Nigg et al.'s study most of the subjects (49.3%) were in the maintenance, the lowest number (2.1%) in the pre-contemplation stage, and 3.8% in the action stage (Nigg & Courneya, 1993). In Mazloumi et al.'s study (2010), 20% of the subjects were in the pre-contemplation stage, 40% in the contemplation stage, 13.6% in the preparation stage, 7.3% in the action stage, and 19% in the maintenance stage (Mazloumi Mahmoud Abad et al., 2010). Therefore, regular physical activity according to regular and specific patterns should be part of an overall strategy to prevent osteoporosis in women, so that an individual can change behavior intentionally (DiClemente, 2005). The results of our study did not show significant differences in the scores of the constructs in terms of marital status. However, Tol et al.'s study indicated that self-efficacy was associated with marital status (Tol et al., 2012). This contrast might be justified according to cultural and social contexts of the studies. Married people spend most of their time on daily life activities, and therefore spend less time on regular physical activity because of the higher responsibilities they have in compares with the other members of their families. However, this interpretation is not always correct. Investigating the relationship between the constructs of the Trans-theoretical Model and regular physical activity revealed that the studied women used more cognitive and behavioral processes in order to adopt physical activity behavior and possessed higher self-efficacy in physical activity when they were in higher stages of change. Based on the Trans-theoretical Model, individuals can go through the stages of change by gaining experience and skills. Returning to the previous stages may even happen, which is justifiable considering the circular nature of the model. The results of our study on decisional balance showed that the central components of pros and cons in this construct are crucial in making decisions on physical activity. The results showed that the individuals in the pre-contemplation stage had negative comments on physical activity such as being time-consuming and tedious (cons), while the women in the maintenance stage had positive comments on physical activity (pros) (Omar-Fauzee et al., 2009; Moeini et al., 2011).

The results showed no significant relationship between the construct of decisional balance and physical activity. This result is consistent with the results of Moeini et al. and Araban et al.'s studies, but inconsistent with the studies conducted by Kidd et al. and Omar-Fauzee et al (Omar-Fauzee et al., 2009; Kidd & Peters, 2010; Moeini et al., 2011; Araban et al., 2013). Therefore, these results suggest that the construct did not have the power to predict the behavior of physical activity. This predictive inability of the pros and cons constructs can be attributed to the high points of these two constructs in the studied population in our study. Therefore, as it is emphasized by Pawlak et al. (Pawlak & Colby, 2009), high scores of pros and low scores of cons cannot predict health behaviors. It is also possible that adopting preventive behaviors (physical activity) for osteoporosis is more dependent on self-efficacy.

The results of the present study showed that, among the constructs the Trans-theoretical Model, self-efficacy is the only construct that can predict the adoption of osteoporosis prevention behavior. Therefore, it is recommended to conduct more extensive studies to confirm our finding. The study did not use the construct of

processes of change due to the probable numerous items in the questionnaire in two behaviors of physical activity and calcium intake, and answering the questions took a long time, and these were the limitations of the study. This study is among the first studies carried out on behavior change to prevent osteoporosis in women aged 30-50 in Khorramabad based on the patterns of health education and enhancement.

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Knowledge, Attitude and Practice of Nurses about Standard Precautions for Hospital-Acquired Infection in Teaching Hospitals Affiliated to Zabol University of Medical Sciences (2014)

Hamed Sarani[1], Abbas Balouchi[2], Nosratollah Masinaeinezhad[3] & Ebrahim Ebrahimitabs[1]

[1] Pregnancy Health Research Center, Zahedan University of Medical Sciences, Zahedan, IR Iran

[2] Research Committee Center, School of Nursing and Midwifery, Zabol University of Medical Sciences, Zabol, IR Iran

[3] School of Nursing and Midwifery, Zabol University of Medical Sciences, Zabol, IR Iran

Correspondence: Abbas Balouchi, Research Committee Center, School of Nursing and Midwifery, Zabol University of Medical Sciences, Zabol, IR Iran. E-mail: abbasbalouche1990@gmail.com

Abstract

Background and Objectives: Hospital-acquired infection (HAI) is one of the common problems and difficulties faced by hospitals in all countries around the world. Since nurses are part of the healthcare team that plays a unique role in the control of hospital infection, this study is conducted to analyze the knowledge and practice of healthcare personnel about standard precautions for hospital infection.

Materials and Methods: This descriptive study was conducted on 170 nurses worked in medical surgical wards, pediatric wards, dialysis units of two teaching hospitals in Zabol city, Iran, in 2014. The sample population was selected through simple random sampling. The data collection instrument is composed of a researcher-made questionnaire titled "Hospital-acquired infection Control" based on precautions posited by the World Health Organization (WHO) and the United States Centers for Disease Control and Prevention (CDC). Data were fed into the SPSS software v.20 and were analyzed using descriptive and inferential statistics.

Results: The results show that 43% of the participants in this study had poor knowledge, 42% had average practice, and 37% had a moderate attitude about hospital infection. There was a significant relationship between knowledge and gender ($r = 00.8$ $p = 0.02$). However, the variables of age, marital status, employment, work experience, education, and place of work did not establish a significant relationship with the independent variables ($p>0.05$).

Conclusion: As the results indicate a low level of awareness among the personnel about hospital infection, it is suggested to provide training sessions on the prevention and control of HAI to increase the awareness of personnel and hold practical courses for practicing these principles.

Keywords: knowledge, attitude, practice, standard precautions, infection control

1. Introduction:

HAI is a major health problem in all societies. According to the WHO, 7.1 million cases of HAI occur every year. One out of every 20 people suffers from hospital infection. This leads to 99,000 cases of death every year and imposes an estimated cost of $ 32 million to society (Cardo et al., 2010). On arrival at the hospital, patients do not have HAI but they may develop it during the 72 hours or more after hospitalization (Horan et al., 1992). The WHO has provided a general definition of HAI and has renamed it as healthcare-associated infection. WHO launched its activities in 2005 under the slogan, "clean care is safer care". HAI is an infection that develops in a limited or vast scope because of pathogenic reactions associated with the infectious agent or its toxins in the hospital (but only if the infection is caused at least during the 48 to 72 hours after admission to the hospital or during a specified period of 3 to 10 days after dismissal. So the patient must not show symptoms of infection at the time of admission and the infection must not be in the incubation period (Boyce & Pittet, 2002; Safari & Shojaei, 2002). A study conducted by the WHO on 55 hospitals in 14 countries showed that 8.7% of the patients hospitalized in these hospitals became infected with healthcare-associated infection. Studies conducted in Iran on

the incidence of HAI and the subsequent increased length of stay and costs show that HAI is the most important socioeconomic medical problem in the country. Simutaneousley, through hospital treatment for acute diseses, people with long-term diseases will cure too and hospital treatment will become more sophisticated and therefore hospital stay will be longer which this leads in to HAI (Arbabisarjou, 2012). The incidence HAI in Iran has been reported to vary on a range from 1.9% to more than 25% (Angelillo et al., 1999).

Numerous factors are associated with high risk of HAI. The factors that can minimize the risk of HAI include the systematic treatment of patients, avoiding prolonged hospitalization, the use of antibiotics, the use of suction catheters, hand washing by health care personnel, and the use of sterilization techniques in therapeutic procedures (Ayliffe et al., 2000). The high costs of treating large numbers of patients and increasing occurrences of infection have posed a threat to standard precautions because these standards constitute the basic principles of HAI control. HAI control means the reduction of infection risk by patients, hospital personnel, and patient care attendants and the prevention of infection transmission by hospital personnel and patients' families (Amerioun et al., 2009). As members of the health care team, nurses play a very important role in HAI control (Saffari et al. 2008). Nurses must have sufficient information and necessary skills in this field (Saleh Moghadam, 2005). The results of a study conducted by Darawad et al. on nursing students in Yemen showed that most nursing students have low levels of knowledge, a positive attitude, and a moderate practice about infection control (Darawad & Al-Hussami, 2013). A study by Hinkin et al. showed that most students have acceptable levels of knowledge about infections, hand hygiene, the use of gloves and taking appropriate action after being injured by a sharp object but had low levels of knowledge about the use of gel and other disinfecting procedures. The results also showed that their level of knowledge depended on working pressure, time and access to facilities (Hinkin & Cutter, 2014). Ghanbari et al. conducted a study on 130 nurses. The results showed that most nurses do not have sufficient knowledge and practice about the prevention of hospital infection (Ghanbari et al., 2013).The observation of health procedures is therefore the most fundamental health principle and the most basic health behavior (Mac, 2002). The prevention of HAI requires attention to three concepts: knowledge, attitude, and practice (Saffari & Shojaei, 2002). For the occurrence of a behavior, the presence of such factors as motivation and emotion is necessary. This study was conducted to evaluate knowledge, attitude and practice of nurses against HAI.

2. Materials and Methods

The present study was conducted using a descriptive cross-sectional on 170 nurses working at teaching hospitals of Zabol, Iran, under the supervision of Zabol University of Medical Sciences in 2014. The sample population was selected through simple random sampling. Inclusion criteria were having at least a bachelor's degree and a work experience of at least three months. The only exclusion criterion was reluctance to participate in the study. The location of study covered internal medicine wards, Pediatrics wards, dialysis units, and surgical units of Amir al-Momenin hospital and Imam Khmoeini hospital in Zabol city, Iran. For data collection, it used a researcher-made questionnaire with confirmed validity and reliability by several preceding studies. The questionnaire consists of two main parts: the first part collects demographic information including gender, age, work experience, ward of activity, and a history of infection control training; the second part consists of three subsections: the first subsection, Knowledge, including 5 items about the nature of infection, mode of transmission, prevention of infection and the role of the nurse; the second subsection, practice, including 21 items measuring individual practice in relation to the adoption of preventive behaviors, hand washing, injection and dressing skills, and the observation of precautions; the third subsection, attitude, including 10 items measuring perceived threat by nurses about HAI of nurses and patients and perceived benefits by patients about the observation of standard precautions. In the Knowledge subsection, each correct answer to the items was scored 1 and each wrong answer was scored zero. In the end, the scores were calculated in percent - the number of correct answers multiplied by 100 divided by the total number of items. The practice subsection was comprised of 10 items rated on a 5-point Likert scale from 1 to 5 (Strongly Disagree=1, Disagree=2, Neutral=3, Agree=4, Strongly Agree= 5). The total scores ranged between 1 and 20 and the individual scores for each section were calculated in percent. Items in the practice checklist were rated on the Likert scale. Individual practice scores were calculated based on the frequency of adopting preventive behaviors against HAI (according to standard precautions) divided by the total number of listed behaviors multiplied by 100. Items in the attitude subsection were similarly rated on a five-point Likert scale. In analyzing the data in both sections of knowledge and practice of nurses in the context of standard precautions, the scores of nurses were categorized as low, medium, and good. Scores below 50 were labeled as poor, scores between 50 and 75 were labeled as average, and scores above 75 were considered as good. The study was conducted after obtaining informed consent from nurses. Data were collected via questionnaires and were analyzed with the SPSS software product v.20 using

descriptive statistics and correlation coefficient Pearson correlation test. Level of significance P value is ≤0.05 regarded as statistically significant.

3. Results

Of the 170 questionnaires distributed, 145 completed questionnaires were selected for analysis. The mean age of participants was equal to 41±1.13, and the mean duration of employment was 8± 2.1 years. The mean score of the participants on the knowledge of infection was poor (42.5±8). The highest levels of knowledge were related to hand hygiene with a mean of 74.5±24 and precautions to avoid needle stick injuries with a mean of 70±3. In addition, the lowest level of knowledge was related to precautions such as wearing the gown, gloves, mask and glasses during clinical procedures with a mean of 64±2.8. Of the 145 nurse participants in this study, 43% (n=63) had poor knowledge, 35% (n=51) had average knowledge, and 22% (n=31) of the nurses had good knowledge about the prevention of HAIs. Based on the Pearson correlation coefficient, there is no statistically significant relationship between knowledge and practice (r=00.8 p=0.3). However, there is a significant relationship between knowledge and gender (p = 0.02). Besides, the variables of age, marital status, employment, work experience, education, and place of work did not establish a significant relationship with the independent variables (p>0.05). Out of 145 participants in this study, 24% (n=34) of the nurses had poor practice, 42% (n=61) had average practice, and 34% (n=50) had good practice in the prevention of HAIs (Table 1). No statistically significant association was observed between knowledge and practice (p<0.05).

Table 1. Knowledge, attitude and practice of nurses about infection control standards

Variable	Level	Frequency (no.)	Percent (%)	Mean ± SD
Knowledge	Poor	63	43	
	Average	51	35	42±8.9
	Good	31	22	
Practice	Poor	34	24	
	Average	61	42	48±7.5
	Good	50	34	
Attitude	Poor	43	30	
	Average	54	37	40±6.2
	Good	48	33	

In relation to the attitude of nurses, the results showed that 30% (n=43) of nurses had a poor attitude, 37% (n=54) had an average attitude, and 33% (n=33) had a good attitude about infection control. A statistically significant relationship was found between the mean scores of nurses who had been trained and those who had not passed training courses (p<0.01). The results also showed that those who had more knowledge about infection control had a better practice. The results of the Pearson correlation coefficient test for the assessment of the relationship between the knowledge, attitude and practice of nurses showed that the attitude of nurses was significantly correlated with their practice (p<0.01 and r=46). The results also indicated that nurses who were less experienced had average levels of knowledge.

4. Discussion

The findings of this study showed that most nurses had a poor knowledge (43%), an average practice (42%), and a moderate attitude (37%) about HAI control. The results of this study are not consistent with the results of a study conducted by Yang Luo et al. in China on 1,444 nurses, in which they assessed the knowledge of nurses about standard precautions as average (Luo et al., 2010). In their study on the knowledge, attitude and practice of nurses in the context of HAI control, Ghadamgahi et al. concluded that most nurses do not have a good knowledge of HAI (Ghadmgahi et al., 2011). The results of this study are not consistent with the finding of the study by Gould et al. on 173 nurses working in three wards (ICU, Medical-surgical wards), in which they assessed the knowledge of nurses about standard precautions as low (Gould & Chamberlain, 1994). The results of a study by D'Alessandro et al. showed that 90.8% of students had a poor knowledge about infection control (D'Alessandro et al., 2014). The results of another study by Sodhi et al. showed that more than 90% of ICU nurses had a very good knowledge of infection control (Sodhi et al., 2013). Chan's study also showed that 56%

of nurses had a good knowledge about infection control and 79% of them had a good practice in relation to standard precautions for infection control (Chan et al., 2002). Allah-Bakhshian et al. assessed the knowledge, attitude and practice of ICU nurses working at training centers in Tabriz, Iran, about hospital infection control and concluded that the majority of nurses in this study had an average knowledge about HAI control (Allah-Bakhshian et al., 2010). It is important to note that the knowledge of nurses about HAI depends on many factors, including individual and educational characteristics, training courses, and managerial and motivational factors. In their study on the knowledge, attitude and practice of different groups of healthcare personnel about infection control, Suchitra et al. concluded that training has a positive impact on the improvement of knowledge, attitude and practice in healthcare personnel. They also suggested that the development of a continuous training program for all healthcare workers is necessary (Suchitra, 2007). Training courses have been shown to be effective in promoting the knowledge and practice of health care personnel in the UK (Elliott et al., 2005). Training and knowledge improvement are the most effective ways to fight HAI. Obviously, continuous training and knowledge improvement besides the use of appropriate and effective methods of disinfection and sterilization will reduce the frequency of developing HAI (Askarian et al., 2004). The results of a study by Nasirudeen et al. on the knowledge and practice of students in Singapore showed that 66.3% of them had a have good practice and 48.9% of them had a good knowledge about hand hygiene (Nasirudeen et al., 2012). It seems that since infection control topics are not included in academic nursing courses and since they are not dealt with in the work environment either, nurses have a poor knowledge in this area. Therefore, considering the guidelines on the treatment of hospital infection - that nurses should be trained and retrained at least twice a year (Bischoff et al., 2000)- differences in the results can be interpreted. There was a significant relationship between knowledge and gender which is consistent with the results of the study (Ghadmgahi et al., 2011). The results of the present study showed that nurses have a poor practice in the prevention of HAIs (Akyol, 2007). Bischoff et al. claimed that under normal conditions, the frequency of hand washing by doctors and nurses was at an unacceptably low level. A study in India reported less than desirable levels of practice among healthcare personnel (Bischoff et al., 2000). Akyol (2007) noted that hand hygiene compliance by healthcare workers was at a poor level. This is not consistent with the results of the study by Allah-Bakhshian in which almost all participants (99.1%) had an average practice in relation to infection control (Allah-Bakhshian et al., 2010). A study in Jamaica showed that 85% of nurses, despite having the knowledge, did not observe all safety precautions when performing nursing procedures (Figueroa et al., 1997). Mahmoudi and Hassani (2000) stated that the mere having of knowledge does not lead to good practice so attitudes should also change and belief structures should be reworked in a rigorous and scientific manner to achieve proper practice. There was a significant relationship between knowledge and practice in the present study. The study by Lou also reported a significant relationship between knowledge and practice(Luo et al., 2010). One of the limitations of this study is that the sample population does not represent all nurses in Iran.

5. Conclusion

According to the results, most nurses do not have a good knowledge and practice about infection control despite having an average efficacy. Therefore, it is necessary that Iran's Ministry of Health and Medical Education and the subsidiary universities do their best to inform the nurses and all the medical personnel about the prevention of HAIs according to world standards and tailored to each region's ecology by way of academic courses, posters, and conferences. It is also necessary to improve the knowledge of standard precautions, develop programs for HAI control, and hold training courses based on successful educational models.

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An Exploration of the Role of Hospital Committees to Enhance Productivity

Hassan Amirabadi zadeh[1], Mohammad Reza Maleki[1], Masoud Salehi[2] & Soudabeh Watankhah[3]

[1] School of Management and Medical Information Sciences, International Campus (IUMS-IC), Iran University of Medical Sciences, Tehran, Iran

[2] Department of Biostatistics, Faculty of Public Health, Iran University of Medical Sciences, Tehran, Iran

[3] Health Care Management Department, Faculty of Management and Medical Information Sciences, Iran University of Medical Sciences, Tehran, Iran

Correspondence: Mohammad Reza Maleki, School of Management and Medical Information Sciences, International Campus (IUMS-IC), Iran University of Medical Sciences, Tehran, Iran. E-mail: maleki.mr@iums.ac.ir

Abstract

Productivity is the main concern of hospitals as organizations providing health services. As the role of hospital committees is increasing and their productivity and performance improvement is very important, the present study was performed to identify weaknesses and strengths of committee sessions. This analytical-descriptive study was conducted cross- sectional from January to April in 2012. Summary of 405 committee session's agendas related to 11 kinds of committees in 8 hospitals (out of 23 hospitals) of capital cities in 3 provinces of Sistan and Balouchestan, South Khorasan and Khorasan Razavi in Iran were extracted. Data was collected through a form and was analyzed by SPSS16 software using descriptive statistics and variance analysis and content analysis technique. This study showed that the number of hospital committee's sessions holding in 2012 was more than 2011.The differences between public and private hospitals in terms of the following subjects were significant (P-Value < 0.001). In terms of the number of selected policies, participants of the committees, and the duration of the sessions the public hospitals had better conditions. And regarding documentation process, feedback of decisions to personnel and the implementation of the formulated policies in the committees, private hospitals performed better. According to the results of this study, to improve the productivity of hospital committees, it is suggested to motivate senior, tactical and operational managers to appropriately participate in the committees and necessary planning for the committees in advance is mandatory.

Keywords: hospital committee, management, productivity, team efficiency, team effectiveness

1. Introduction

More than two decades, organizations want to decrease grow of health care costs and also health organizations want to decrease health per capita and because in some cases, this resulted in quality being sacrificed for cost, a lot of patients could not take reception and they were deprived of service accessibility right and selection right. So, we suggest that by created productivity increase we can decrease costs and prevent quality fall (Goldberg & Kosinski, 2011). One way for productivity increase in recent years for improvement of health system in the world is paying attention to new structure and widespread organizational changes (Axler & Bogart, 1997). Also in Iran, for increasing productivity in hospitals, structure reform has been done to a large number including hospital committees (changing Committees number from 14 to 11 in 2011).

For productivity improvement, presence of vital information is necessary. At present, hospitals bear high stress for productivity improvement by internal performance without sacrificing quality of care. One of the main reasons for stress increase is ignorance of current information about hospitals which is very useful source for processes and productivity reform (Payne & Williams, 1991). And now in hospitals, documenting the activities such as setting the agenda related to hospital committee sessions and sending a copy to higher levels for planning is much emphasized.

Also, according to limited sources and control of health care costs, nowadays all beneficiaries search different

strategies for productivity of work force one of which is innovations designed to increase work force at hospitals (Hams, 1991). It is obvious for all personnel that one of hospital problems are related to budget deficit and managers should dominate on this problem by policies and programs of hospital committees. So, at hospitals we should use suitable strategies about cost control such as model of cost determination based on activities. In this model, resource costs are considered exactly according to implemented activities by list of sub activities of an activity and cost rate of every activity (Livens, Faun, & Kesteloot, 2003) and also with better information presentation, we can use hospital strategic programming from management system model of cost according to activity (ABM). By hospital services improvement and by help of health care presentation and by quality and productivity improvement we can lead to better management and control of current sources of hospital (Arid, 1996). Also, hospital committees should be more active in planning such as participating in setting strategic and operational programs in hospitals.

At implemented study in Faghihi hospital in which cost model was used, it was shown that recognized costs price by this model is remarkably different from current price tariffs at hospital and abundant amount of non-direct costs of current sources are not used suitably at hospitals (Rajabi & Dabiri, 2012). Another item related to current sources of hospital is human resource about which, budget common commission of health care organizations has recommended that medical members and personnel present effective solutions and mechanisms for screening and evaluation of related quality of services to patients and organizational performance improvement. Many health and therapy institutes meet their needs by creating organized committees (Tackett & Kent, 1994). For better use of human resources, managers search many solutions. For example, nurse managers and hospital managers for productivity and empowering of nurses want to create nurse council in which using a new approach for a successful strategy is proposal of rearranged engineering of functional council of nurse organization so as to increase values of organization and create excitement at personnel by productivity promotion (Gokenbach, 2007).

As we know, committees are tools for mixing distributed knowledge and abilities of various parts of organization at format of one active and integrated unit. Committees fortify another kind of power separation for people who are responsible for their jobs but cannot work solely as organizational units and because organizational responsibilities are beyond abilities of persons merely, using committees can be used as suitable method and prevent person dictatorship approach (Harder's, Trumann, & Setoff, 1998). Committees are managers assistant arms and a place for cooperative management that use experts, help solve current problems and assist in policy.

In Iran before autumn of 2011, there were 14 committees at hospitals which had 5 percent scores of hospital evaluation that led to hospital grade level and from December of 2011, this committees at hospital budget designation (replacing hospital evaluation case) changed to 11 committees that three of them were new, 2 committees were mixed and 7 committees from the 14 previous committees were unchanged. These 11 committees were sent to universities by ministry in the book of "hospital budget designation standards in Iran" and this instructions is the base of hospital committees performance. These eleven committees include:1- quality improvement committee 2- drug and therapy committee 3- medical ethics committee 4- medical documents and information technology committee 5- technical protection and job health committee 6- committee of mother and baby safety, promotion of natural born and feeding with mother milk 7- environmental health committee 8- committee of hospital infection control 9- death and side effects of pathology and tissues committee 10- committee of crisis and disasters 11- blood transfer medical committee (Jafari et al., 2010). Duty of each of these 11 official hospital committees has been announced in regulation sent by ministry and they have different duties but hospital managers can set duties similar to these duties for each committee. Kinds of committees, committees responsibilities and the minimum period of holding committees are determined by the ministry. Monitoring Committees in the context of accreditation and routine visits are planned by health deputy experts and accreditation team but adding new committees, the number and kind of committee members, setting internal regulations of committees and choosing kinds of decisions is determined by hospital.

The boss of committee can reduce sessions intervals and invite anyone necessary to the committees. Each committee has fixed members who have notification of the chief of the hospital for a certain period (usually for one year) and if the members aren't efficient, other members are appointed by the chief of the hospital.

In hospital committees, the issues and problems and future programs are transmitted to higher levels or committee secretary from hospital sections and units, are prioritizing by the secretary and proposed in the sessions according to their importance.

Committees don't usually have an income for their members and yet make each kind of decisions for hospitals and sometimes members aren't paid at all for their membership.

According to Gantt chart written for hospitals which announces the time of sessions which is usually for a six-month period, and this schedule is given to the members 2-3 days before holding   sessions, issues to be proposed in sessions, time and place of sessions is announced to the members.

One of indicators for evaluating hospital performance is activity of committees because a part of evaluation scores and accreditation in hospitals is hospital committees. (5% of evaluation scores for identifying hospital level.) and one of the most important and measurable indicators is the number of held hospital sessions and according to regulation sent by ministry the interval of sessions is specified.

Indicators specified in Table 1 show the performance position of committees and show committees favorability. Importance of committees and team working is very significant especially about purchase committee that committees not only evaluate primary materials before purchase but also review current materials at hospital that leads to favorite quality, quantity, productivity cost at purchase amount and present materials at hospital (Boergadine, 1997). A study was done by Sajadi et al. in 2007 about the influence of productivity committees the results of which showed that in general the maximum influence of productivity committees related to the improvement of presented services at centers and at second level, committees establishment had influence on increase of income and satisfaction of customers and also influence on centers cost decrease was at third place (Sajjadi & Toghiani, 2011). Up to now, we have not observed comprehensive study about the position of holding hospital committees sessions in Iran; So, as a part of doctorate thesis in health services management, this study was done for recognizing the performance of hospital committee's sessions.

The aim of this article is to identify the structure and performance position of the 11 hospital committees in presence number of committee boss, sessions participants number, kinds of bills, rate of attained bill goals , reasons for lack of bill implementation and … . We hope that identifying strengths and weaknesses and presenting them to managers will cause committees performance improvement and as a result, hospital productivity improvement.

2. Methods

The present study is analytical-descriptive and it was conducted cross-sectional from January to April of 2012 for identifying the performance position of   committees sessions in 8 hospitals among 23 existing private and governmental hospitals in the smallest and biggest hospitals (based on bed number) of centers of Sistan and Blouchestan, South Khorasan and Khorasan Razavi provinces in Iran. We chose these provinces because they were a sample of three financial statuses (good, intermediate and weak) in Iran.

Data is related to 2011 and 2012 agenda which was collected through the designed form after official correspondence and going to hospitals in 2012.

According to the conducted studies (Jackson & Olive, 2009; Kalaki, 2000; Rafiei, 1997) and existing regulations, there is a difference between the performance position of the biggest and the smallest governmental and private hospitals. So, we chose the smallest and biggest hospitals in order to better identify the kinds and causes of differences. On the other hand, because there wasn't any private hospital in South Khorasan and Sistan and Balouchestan provinces, the private hospitals we studied belonged only to Khorasan Razavi province.

Because of time and cost limitations, two hospitals were selected from every province (governmental and private). Four hundred and five numbers of held hospital committee session agendas at 2011 and 2012 (according to Table 1) were entered to related form. Our inclusion and exclusion criteria for the study was in a way that all the agendas (typed and hand written) were accepted but verbal comments mentioned by committee chairperson was not accepted.

Measuring tool for evaluating performance was a self-made form for recording the performance position of hospital committees that following 17 variables were measurable and by comparing these variables in different hospitals, committee performance position was measurable.

For validity, some experts commented on the form and because all the information was registered, there was no need for verifying reliability.

For completing this form, at first with the presence of hospital committee secretary, we listed date of all held committee sessions and we recorded for every session, number of participants, name of session secretary, the number of bills of the session, type of bills (future plans or according to the existing problems including: problems of human resource , problems of financial resource , processes and methods), percent of implemented bills and the reasons for not implementing bills(because of the lack of necessary attention, lack of human resource , lack of expert analysis , lack of experts cooperation , lack of financial resources , other reasons) . For sampling bills of every session for 2011 for every held committee session, we recorded 2 agendas one of them

from first half of the year (spring season) and the other from second half of the year (winter season) and for 2012 for every committee 3 agenda related to first, second and third seasons were selected. Data related to every session bill including: bill name, implemented actions, percent of attained goals, reason of lack of bill implementation and bill kind (bill related to present problems or future programs) was recorded from archive of committees agenda into provided form.

Data was extracted from all existing agendas in hospitals -typed or handwritten-and only agendas related to these 11 committees were considered and other agendas related to committees out of list of these 11 committees were not included in the study.

The entered data was controlled by two persons and the differences were corrected. We spent about 3 hours for taking note of every agenda .Then, we entered data to SPSS 16 software and extracted following data. We studied way of data distribution and also at the rest using variance analysis tests, and Post Hoc tests, Multivariate tests, Mauchly,s tests of Sphericity, Tests of within-subject Effects, Tests of Between-Subject Effects and…., we compared average of various variables among relevant groups.

3. Results

Descriptive findings of present study were collected from 405 agenda from 8 hospitals out of 23 existing private and governmental hospitals in 3 provinces.

Data collected in this study and its results are presented in Table 1 based on the studied items.

Table 1. Descriptive parameters of hospital committees sessions positions in 2011 and 2012

Row	Title	Year2011						Year2012					
		Number	Minimum	maximum	Total	Mean	Standard of deviation	number	Minimum	Maximum	Total	Mean	Standard of deviation
1	Held numbers	85	1	17	527	6.20	3.37	79	1	18	507	6.42	**2.93**
2	Sessions participators number	85	5	18	875	10.29	2.46	79	5	21	834	10.56	**2.65**
3	Presence number of committee chairman	85	0	11	304	3.58	2.64	79	0	12	328	4.15	**3.05**
4	Bill numbers of every session	85	1	18	437	5.14	3.50	79	1	13	393	4.97	**2.74**
5	Bills related to future programs of human resource	85	**0**	8	91	1.07	1.44	79	**0**	19	120	1.52	**2.61**
6	Bills related to future programs of financial resource	85	**0**	3	5	0.06	0.36	79	**0**	3	17	0.22	**0.59**
7	Bills related to future programs, process and methods	85	**0**	6	78	0.92	1.36	79	**0**	11	156	1.97	**2.43**
8	Bills related to current problems of human resource	85	**0**	8	113	1.33	1.64	79	**0**	6	110	1.39	**1.67**
9	Bills related to current problems of financial resource	85	**0**	13	206	2.42	3.30	79	**0**	27	332	4.20	**5.50**

10	Bills related to current problems, process and methods	85	**0**	24	343	4.04	4.77	79	**0**	24	427	5.41	**5.14**
11	Percent of attained bill goals	85	36	100	7229	85.05	15.20	79	30	100	6509	82.39	**14.68**
12	Lack of bill implementation because of lack of necessary attention	85	**0**	8	95	1.12	1.76	79	**0**	10	131	1.66	**2.12**
13	Lack of bill implementation because of lack of human resource shortage	85	**0**	4	34	0.40	0.79	79	**0**	3	28	0.35	**0.68**
14	Lack of bill implementation because of lack of expert analysis	85	**0**	5	37	0.44	0.79	79	**0**	9	67	0.85	**1.71**
15	Lack of bill implementation because of lack of experts cooperation	85	**0**	5	32	0.38	0.90	79	**0**	3	23	0.29	**0.72**
16	Lack of bill implementation because of lack of financial problems	84	**0**	4	31	0.37	0.88	79	**0**	5	65	0.82	**1.27**
17	Lack of bill implementation because of lack of other reasons	85	**0**	4	12	0.14	0.60	79	**0**	1	7	0.09	**0.29**

Above table shows that:

-Average of held hospital committee sessions in 2011 and 2012 year was 6.20±3.37 and 6.42±2.93 that the maximum number of held sessions in 2012 was 18.

-Average number of participants in hospital committees sessions at 2011 and 2012 was 10.29±2.46 and 10.56±2.65 that in some sessions, number of participants was 21.

-Average of bill number in 2011 was 5.14±3.50 and in 2012 it was 4.97±2.74 that in some held committees of 2011, the number of bills reached up to 18.

-Most bills at hospital committees in 2011 and 2012 were related to current problems related to processes and methods, financial sources and human resource in order.

Rate of chairman presence in committees was about 57. %.

The most reasons for not implementing bills were lack of follow-up and lack of expert analysis.

The most bills were related to solving current problems of existing methods and processes which requires restructuring and integration processing.

The lowest reason for not implementing bills has been financial problems although we had thought that financial problems are the main cause of not implementing bills.

It seems that in private hospitals because of the nature of hospital, the most emphasis has been on efficiency and in governmental hospitals the most emphasis has been on effectiveness.

In the studied hospitals in 2012, only 75% of committees were held according to the predicting program. This percent has been 57% in 2011and perhaps one of the reasons for decreasing the number of hospital committees

by the ministry has been the high number of committees one of its results being not holding committee sessions according to the ministry regulation.

-Among the studied reasons for not implementing hospital committees bills , (not follow-up required, lack of human resources, not expert analysis of bills ,lack of expert cooperation, financial   problems) the most reasons was not expert analysis of bills one of its causes being a high number of bills in each session.(5 numbers).In this regard, forming sub-committees is offered.

This study showed that the average number of every session bills was 2 cases in private hospitals in 2011 and 6 cases in 2012.

As it is shown in Diagram 1, the comparison of committees performance in the studied hospitals for the variable "the number of held sessions" was done between 2011 and 2012.

The results of Duncan test in terms of hospitals performance position in committee sessions held in 2011 and unilateral variance analysis showed that held sessions of committees at 2011 had meaningful difference among hospitals statistically (p <0.001) but the differences between committees in each hospital was not meaningful. This observed meaningful difference is emanated from current difference in held committee sessions of hospitals 6, 2, 7, 8 and 4 as the least average number of held sessions and in hospitals 3 as the most average number with other hospitals (Diagram 1).
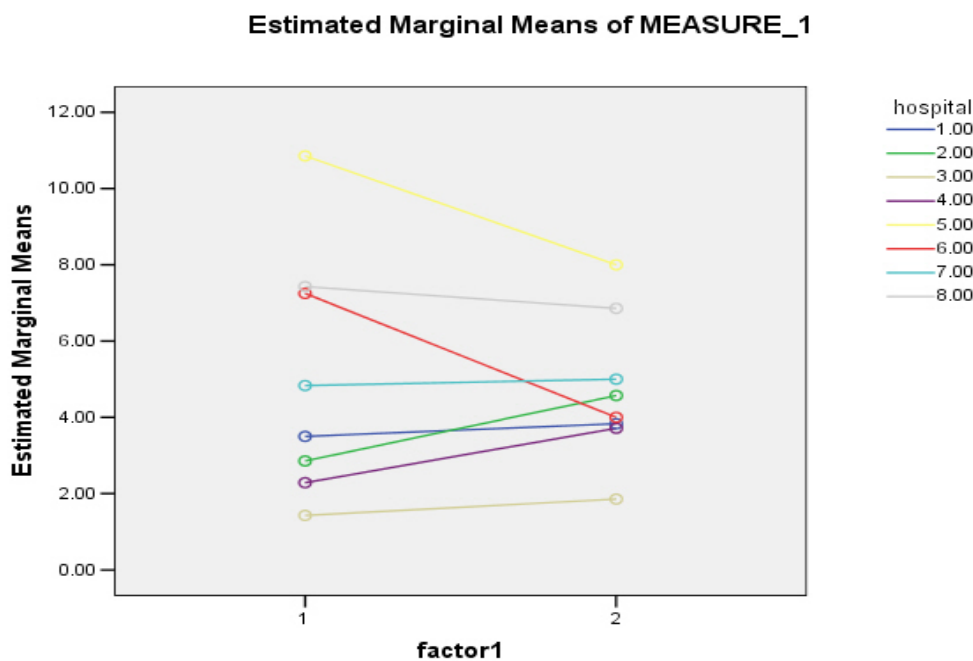

Diagram 1. Average of bills in 2011 and 2012

Also, repeated measurement analysis of the effect of time variable in 2011 year (first factor) and 2012 year (second factor) and hospital influence in variables of "average of participant members at committees", "average of bills at committees", "average of implemented bills" showed that average of this variables in different years among different hospitals has not meaningful difference from statistical aspect (P=0.208, P= 0.070) and (P=0.275, P=0.001) and P=0.497, P= 0.153). Eye-catching point related to meaningful bilateral influence of time and hospital from statistical view about variable of average of participating   members in committees and average of bills in committees (p= 0.001 and p= 0.035). According to Table 1, we can observe that this bilateral influence of different hospitals behavior is the variable of bills in different years as we see that the average position of hospital numbers 5 and 6 in 2011 and 2012 show falling steep vector, the average position of hospital numbers 4 and 2 in 2011 and 2012 show rising steep vector and average position of hospital numbers 1 and 7in 2011 and 2012 show fixed steep vector. These changes are meaningful from statistical aspect.

About the size of committees, depending on the kind of committee, there are 5-21 members that in big hospitals

the number of members is high (with the average of 14), but in small hospitals it is less (with the average of 9) and in private hospitals the number of members is much less than governmental hospitals (ratio of 7 to 12). The most number of members relates to "quality improvement committee" and "drug and therapy committee" and the lowest number relates to "medical ethics committee" and "medical documents and information technology committee".

Time of sessions differs from 25 minutes to 90 minutes which is much less in private hospitals than governmental ones.

4. Discussion

Today committees are a manifestation of employee participation in decision-making and team working decreases errors and increases bills acceptability and their implementation.

About nature of committees, we can say that organizational structures and groups and teams performance are different from each other in entity and kind of decision-making. For example, interaction kind between team members, decision-making methods leading to final decision, interactions between management domain and personnel, personnel costs and present priorities at hospitals are done by committees. All of these items are proposed and verified at committees before implementation in hospital that it shows role of collective decision-making (Goodman, 1995). Also, the results of our study showed that the committee performance during the studied years, within hospitals and among different hospitals is different. A study showed that there were no significant statistical relationship between BOR and type of hospitals as educational or non-educational and also the location 9.of these hospitals in poor or rich areas. But BOR and hospital size measured by their number of active beds, had a positive significant relationship statistically. So, we can say that the kind and number of committees can be similar in educational or non-educational hospitals whether they are located in poor or rich areas but the number and kind of committees can be different based on hospital size (Bastani, Vatankhah, & Salehi, 2013). Also, in our study it was found that committees performance in rich and poor areas and in educational and non-educational hospitals don't have meaningful difference with each other.

It seems at past decades, bases of health care have been weakened and some of analysts believe that the most important point is that an efficient and simple structure at team working prevents acute condition (Shinkman, 2000). Efficient and effective presence of committee members in sessions can increase performance of hospital committees. Regarding the importance of committees in planning and decision-making for current problems as well as preventing future problems, powerful and active committee members can improve committee efficiency (Rate of implemented bills improves). A study of Meraji et al. in Mashhad showed that position of number of held sessions, rate of participants in sessions and distance among sessions were at medium but results in kind of bills and promotion of ethical values were at good level and also in the study of Meraji, presence of representative of university president in ethics committee was 28% that it shows importance of holding hospital committees sessions from view of related managers (Meraji et al., 2014). Our study also shows that besides decreasing the number of hospital committees from 14 committees to 11 committees, the rate of hospital chief attendance in committees sessions in 2012 has been more than 2011 (Table 1).

Our study also showed 58% presences of hospital chief at sessions which indicate the weak presence of higher level managers in committees and this can show managers lack of time and the delegation of managing committees to other people. In this regard, merging committees is offered.

Kind, number and necessity of committees in various countries are different for example in Brazil, presence of hospital infection committee for monitoring hospital infections is necessary but presence of drug and therapy committee is not obligatory and it existed at limited range in hospitals. Data of 2003 show that in 250 governmental and private hospitals in Brazil, only there were 29 drug and therapy committees (Marques & Zucchi, 2006). In Iran, there are 11official committees in hospitals and we observe their number is functionally more than that and sometimes it reaches to 30 committees. Hospital committees are held for hospital goals materialization, help planning, organizing and harmonizing hospital activities and creating active participation ground for all personnel (Standard, 1997). In our study it was shown that about the number of held committees sessions during 2011 and 2012, the most number was related to committee of hospital infection control (113 times), death and side effects of pathology and tissues committee (102 times), drug and therapy committee (89 times) and the least number was related to medical ethics committee (71 times), committee of mother and baby safety and promotion of natural born and feeding with mother milk (79 times) and quality improvement committee (79 times). It seems that the same structure and regulation for all hospitals (governmental, private, specialized, public, small, big, …) as it is now, can't bring hospital committees efficiency. Instead, flexibility in hospital committees   kind, number, session intervals and plans will be more effective.

Decision-making about rate of medical interferences happens at high probability in all health care systems all over the world. Up to now, a little attention has been paid to this question that what role ethical committees can or should play at hospital level? Quantitative and qualitative findings show that remarkable request for ethical consultation was directly expressed by physicians (Stretch, Hurst, & Danis, 2010), but our study shows that among 11 held committees in 2011 and 2012, the least holding was related to ethical committee. Study done by Gaudine et al., as "evolution of medical ethical committees in Canada (2008)" showed that rate of hospitals ethical committee has increased from 58% in1984 to 85% in 2008 (Gaudine et al., 2010).

Another study by Csikai at Pennsylvania as "position of hospitals ethical committees at Pennsylvania (2008)" showed similar results. From 208 studied hospitals, 183 hospitals (88%) had ethical committee (Csikai, 1998). Also in the study of Meraji et al. in Mashhad city, 73% of research population hospitals had ethical committee (Meraji et al., 2014). Also ,our study showed that in 2011 only 75% of research population hospitals had ethical committee and in 2012, at 100% research population hospitals this committee sessions was held which shows ascending growth of ethical committee. Study of Ralph in New Zealand as "ethical committee at Oakland hospitals" showed that from 23 studied hospitals, 3 hospitals had ethical committees, 2 hospitals wanted to create these committees and other hospitals expressed problems of their ethical committees at other committees (Pinnock & Crosthwaite, 2004). Also, our study showed that the lowest number of committees held, the lowest bills and the lowest implementation of bills among the 11 committees, was related to ethical committee in 2011 but this three factors improved in 2012.

Rate of bill implementation will promote hospital performance and will bring more job motivation for committee members. It is hoped that all committee bills are implemented but as Table 1 shows, rate of bill implementation is 85% and it has been implemented more in private than governmental hospitals but rate of bills in governmental hospitals in 2011 was three times more than private hospitals which can show higher identification of problems and longer time spent in every session for governmental hospitals. Also, it seems that the high number of bills in each session has caused decreasing the rate of implementing bills. Our offering is that more than 3 bills in each session leads to decreasing implementing bills.

In this research, we have studied the causes of the lack of bill implementation and have found the factors mentioned in table 1. So, by paying attention to these factors, managers should plan for reducing or removing these factors and hold training courses for members and practitioners.

One of important cases in hospital committees is the kind of bills made in committees whether it is related to current problems or predicting future problems (prevention before cure) and the other point is that the subjects relate to which of current hospital resources. In this regard, in a study that was done in Tehran TaminEjtemaei hospitals it was found that prediction of training periods for hospital personnel has a high importance. This study showed that mangers and experts of health care in an environment with high load of job need to have management skills and effective leadership and one of these skills is management of time. It has relationship with promotion of performance quality and it can decrease or delete much amount of managers' job stress. Also they have expressed that prevention of time waste can lead to improvement of managers' ability, human resource maintenance, stress decrease and as a result, job satisfaction and mental healthiness increases among managers (Ebrahimi, 2006). Our study showed that around 25% of bills related to future hospital program and especially holding training courses and 75% related to current problems and specially the subjects related to current processes and methods (Table 1). It seems that Current problems being high, prevents planning for future which is itself the cause of not prioritizing plans.

In summary, we can say that the kind of proposed bills in sessions is related to the priority, importance and scope of the bill. This study showed that the most bills are related to current problems which shows existing immediate problems and fewer bills are based on futures and foresight. The most current problems are related to current processes and methods in hospitals . These processes and methods require promotion and these issues are proposed in committees to be analyzed by experts and to be solved.

A study which has been done at medical colleges and general hospital of health ministry in Thailand showed that average of participants number at hospital committees were 14 persons (Panichkul et al., 2011). Also in our study, average of participants number in hospital committees was 85% of total members of each committee. Because of the rate of 84% for the implementation of the bills, it is better that instead of making more bills, more expert time is spent on every bill so that the rate of bill implementation increases.

In a study done by Meraji et.al in hospitals of Mashhad universities, average of hospital committee bills was 4 -5 that is similar to our study (Meraji et al., 2014). Our study shows that average of participants number in hospital committees in 2011 and 2012 is10 to 11 persons which coordinates the offered number of committee members in

the most resources.

As we all know, the importance of team working, personnel active participation and presence of hospital chief can promote productivity of hospital committees and a lot of studies have been done at this ground such as Torani et al. (2008) in their study with the title of "effective factors on comprehensive quality implementation" in which they gained these results that rate of personnel participation and rate of paying attention to team working were not at acceptable range and needed boost and continuous improvement (Tourani, Tabibi, & Shahbazi, 2008). Our study also showed that average of committee members participation in sessions was 84% and average presence of hospital chief at committees was 58%. In Meraji et al. study in Mashhad, 72% of sessions were held with all members (6 persons). We can say that attending the boss of committee in the session is one of the effective factors on the way of session holding and making bills because it had been seen that in the time of boss presence, the number of bills and the rate of members cooperation has increased.

According to the role of hospital chief on the improvement of hospital committees performance, our study shows that only in %58 of sessions, hospital chief has attended (in some committees, hospital chief has endowed committee responsibility to one of his deputies) .So, for improving the performance of committees, chief presence has an important role and done studies prove the matter that the efficacy of committees in decision-making increases when the chief attends in the session (The number of the bills have been high). For example, Toufighi (2001) in his study gained the result that one of the most important obstacles of widespread quality management is manager's weak support and necessary obligations in processes implementation (Toufighi, 1999).

Rostami in 2002 in his study with title of "crisis factors of widespread quality management" concluded that rate of irregular participation of leaders at strategic committees show their low obligation to this factor (Rostami, 2003) and our study also showed bills usually are not sent to higher levels of hospitals unless for specific items and on the other side, from higher levels of hospitals, feedback from committees performance at province level are not sent to sub hospitals.

As it is shown in Axler study, governmental and private hospitals take into account the processes of re-engineering for the improvement of efficiency and effectiveness, and it was also found in our study that one of the existing problems is related to processes and methods and by designing re-engineering in the structure of hospital committees, we will observe the improvement of hospital committees.

In Hames study, the importance of management committees in innovation is emphasized about which our study also shows that one of the most reasons for lack of bill implementation is lack of exact expert analysis which in turn can be the cause of lack of access to necessary information and knowledge.

Now, from the lowest level in hospital to the university level, obtained information isn't used enough for the improvement of committees performance and it is used partially.

In Gokenbach study, it is said that committees play an important role in the improvement of productivity that for this purpose, one of the proposed committees by health ministry is quality improvement committee in order for the hospital productivity to be increased.

The weakness of our study was that some of the agenda were handwritten and reading was very difficult. Some of the registered subjects in the agenda were not clear and had ambiguity. On the other hand, because of season random sampling, sometimes the number of sessions was not identical. The other point is that because of the lack of studies related to our subject in recent years, we had to use some studies from several years before.

The strength of our study is the exact studying of the performance of hospital committee sessions during 2 years. The other strength of our study is that we have studied the kind of bills whether it is related to current problems or predicting future problems.

These findings provide some empirical evidence confirming the relationship between committees performance position with hospital productivity. The more the boss presence in committee sessions and the more the track of bills, the better the performance of committee and the more satisfaction of employees. These study findings confirm a number of the findings that have been identified by studies undertaken in some other countries before.

5. Conclusion

At general conclusion, we can say that because performance position of each hospital committee and quality of committee sessions can lead to more committee productivity and also committees are tools for distributed knowledge and abilities mixing of persons and various parts of hospital in a form of active and integrated units and they can have effective role in decision-making, managers should recognize sessions results and provide

ground for committees improvement. Some suggestions of our study are:

-paying enough attention to regular holding of hospital committees according to previous prediction of Gaunt table, - selection of competent members for every committee,- programming for their active participation;

- holding training courses for members justification about committees duties and instructions, -increasing the implementation of bills and other recognized factors in this study.

Authors Contribution

All authors contributed to this manuscript. Dr. Maleki & Dr. Vatankhah conceived and designed the study; Amirabadizadeh executed the study; Dr. Salehi contributed analysis tools; Dr. Salehi and Dr. Maleki analyzed the data; Amirabadi Zadeh wrote the paper. All authors read and approved the final manuscript.

Acknowledgements

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Functional Status Assessment of COPD Based on Ability to Perform Daily Living Activities: A Systematic Review of Paper and Pencil Instruments

Fateme Monjazebi[1], Asghar Dalvandi[1], Abbas Ebadi[2], Hamid Reza Khankeh[3], Mahdi Rahgozar[4] & Jörg Richter[5]

[1] Department of Nursing, University of Welfare and Rehabilitation Sciences, Tehran, Iran

[2] Behavioral Sciences Research Center and Nursing Faculty, Baqiyatallah University of Medical Sciences, Tehran, Iran

[3] Department of Health in Emergency and Disaster, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran

[4] Department of Statistics, University of Welfare and Rehabilitation Sciences, Tehran, Iran

[5] Department of Psychology, University of Hull, Hull, United Kingdom

Correspondence: Asghar Dalvandi, Department of Nursing, University of Welfare and Rehabilitation Sciences, Tehran, Iran. Tel: 98-021-2218-0036. E-mail: asghar.dalvandi@gmail.com

Abstract

Context: Activity of daily living (ADL) is an important predictor of mortality in patients with chronic obstructive pulmonary disease (COPD). Increasing ADL is important in patients with COPD and assessment of ADL is one of the best ways to evaluate the status of COPD patients.

Objectives: The objective of this systematic review was to provide an overview of the psychometric properties of paper and pencil instruments measuring ADL in patients with COPD.

Data Sources: English papers published from 1980 to 2014 regarding ADL in patients with COPD were searched in Web of Science, MEDLINE, Google Scholar, Cochrane, PubMed, ProQuest, and CINAHL databases using the following keywords: "COPD", "ADL", "activities of daily living", "daily activities", "instrument", "questionnaire", "paper-and-pencil instruments", and "measure". Following the Internet search, manual search was also done to find article references.

Study Selection: A total of 186 articles were found. Of those, 31 met the inclusion criteria. Full texts of articles meeting the inclusion criteria were studied. Consensus-based standards for the selection of health measurement instruments"(COSMIN) were used to assess the quality of the studies.

Data Extraction: Data extraction form based on research aims developed by researchers and psychometric experts, with 17 questions was used.

Results: In these articles, 14 pen and paper instruments were identified for examining ADL in patients with COPD; of which, 4 dealt directly with ADL while 9 assessed other criteria i.e. dyspnea as ADL indicator. The majority of instruments only dealt with two main dimensions of ADL: Basic Activities of Daily Living (BADL) and Instrumental Activities of Daily Living (IADL), and did not consider Advanced Activities of Daily Living (AADL), which is influenced by cultural and motivational factors.

Conclusion: Despite several ADL instruments identified, complete psychometric processes have only been done in a few of them. Selection of the appropriate instrument should focus on the aim of the study and the target construct.

Keywords: activity of daily living, instrument, paper and pencil instruments, chronic obstructive pulmonary disease, systematic review

1. Introduction

Chronic obstructive pulmonary disease is a major chronic health problem throughout the world (Vestbo, Hurd, &

Rodriguez-Roisin, 2012). Functional status impairment is a common finding in COPD patients (R. Garrod, Marshall, Barley, Fredericks, & Hagan, 2007). Functional status is defined as one's ability to perform normal ADLs, to meet basic needs, play usual roles and maintain and improve health (Leidy, 1994). Functional status is a multidimensional concept, which focuses on the capacity to perform ADLs (Skumlien, Hagelund, Bjortuft, & Ryg, 2006).

Chronic obstructive pulmonary disease is typically accompanied by dyspnea (Gullick & Stainton, 2008) and dyspnea is usually associated with decreased functional status and physical ADLs (Peruzza et al., 2003). Decrease in functional status will ultimately lead to sedentary life and compromised health (Kapella, Larson, Covey, & Alex, 2011).

Studies indicate that 78% of patients with COPD have dyspnea even when walking at home, and are faced with difficulties in ADLs (Álvarez-Gutiérrez et al., 2007). Insufficient physical activity is the main cause of disability, severe loss of pulmonary function, early death (Troosters et al., 2010), anxiety and depression in the elderly with COPD (Stuart, Rogers, Balanos, & Wood, 2011). Various studies have demonstrated associations of more physical activity with reduced mortality rate and fewer hospitalizations in patients with COPD (Haggerty, Stockdale-Woolley, & ZuWallack, 1999). The World Health Organization's Global Initiative for COPD (GOLD) report states that increasing physical activities in everyday life is among the important goals of treatment in patients with COPD (Pitta, Troosters, Spruit, Decramer, & Gosselink, 2005).

Most people with COPD experience a decline in functional status, but little is known about the magnitude of decline or factors that contribute to it (Kapella et al., 2011).

One way to assess the functional status is to ask patients via an ADL questionnaire (Skumlien et al., 2006). Measuring ADL is one of the best ways to evaluate the level of health (Resnick, 2000), assess the progress of the disease, and assess the efficacy of rehabilitation or other treatments in patients with COPD (Janaudis-Ferreira, Beauchamp, Robles, Goldstein, & Brooks, 2014) to provide the healthcare system and the medical staff with information for appropriate intervention consistent with the patients' needs (Rabe et al., 2007).

ADLs include activities and tasks that people routinely perform in their daily life inside/outside their homes (Barlow, 2012). Vriendt et al. divided ADL into 3 domains namely basic activities of daily living (BADLs) including self-care behaviors, such as dressing and bathing, instrumental activities of daily living (IADLs), such as cooking, house chores, and shopping and AADLs, including voluntary behaviors influenced by cultural and motivational factors, which indicate satisfying activities beyond personal independence. The combination of all three domains of ADL includes all the activities that a person performs in daily life (De Vriendt et al., 2012).

In the past decades, physical activity assessment instruments were traditionally and predominantly used in epidemiological research to measure activity as treatment outcome and an indicator of health (Lagerros & Lagiou, 2007); but new research showed that instruments made for measuring ADL can be used for evaluation of treatment outcomes and planning rehabilitation and care interventions (Palange et al., 2007). Several studies showed that measuring activity by paper-and pencil instruments could evaluate and detect small differences in levels of physical activity created as a result of treatment or a specific intervention. Use of this instrument has become commonplace in research and in clinical practice (Frei et al., 2011). Paper-and-pencil instruments are questionnaires routinely used in clinical practice and in clinical research. These instruments extract self-reported data from patients directly. They are affordable and convenient, do not require special equipment or training, and can easily be performed at any time or place. These instruments and tests can be performed in research and in daily clinical work (Stull, Kline Leidy, Jones, & Ståhl, 2007). There are theoretical arguments regarding the need for an instrument to demonstrate good reliability, validity, and responsiveness (Mokkink et al., 2010a).

A review of studies showed that experts and researchers have used several instruments for measuring ADL in patients with COPD. Despite the importance of ADL measurement, and international guidelines on COPD and its treatment, none suggested a method, an instrument, checklist or a questionnaire to evaluate ADL. Thus, the goal of this study was to review the existing instruments for evaluation of ADL in patients with COPD, and assess psychometrics of instruments according to the COSMIN taxonomy (consensus based standards for the selection of health measurement instrument).

2. Materials and Methods

This systematic review was carried out according to the "University of York's Center for Reviews and Dissemination Guidance" (*Systematic Reviews. CRD guidance for undertaking reviews in health care*, January 2009). According to this guideline, the first step is the development of a protocol, which consists of the main goal and a set of predetermined stages and methods to perform a systematic review (Liberati et al., 2009). In this

study, the protocol consisted of designing the question for systematic review, inclusion criteria, search strategy, selection and extraction of data, evaluation of quality of studies, data synthesis, and publication of findings determined by the researcher.

As GOLD report states that increasing physical activities is an important goal of treatment in patients with COPD (Pitta et al., 2005), the question addressed in this systematic review was "what are the existing instruments for evaluation of ADL in patients with COPD to assess the efficacy of an intervention for physical activity enhancement".

2.1 Study Selection

Published articles over the past three decades (from 1980 to 2013) in English on ADL in patients with COPD were searched in Web of Science, MEDLINE, Google Scholar, Cochrane, PubMed, ProQuest, and CINAHL data bases using the following keywords: "Chronic obstructive pulmonary disease", "COPD", "activity of daily living", "ADL", "activities of daily living", "day to day activities", "daily life activities", "daily activities", "instrument", "questionnaire", "test", "assessment", "paper-and-pencil instruments", and "measure". Following the Internet search, manual search was carried out to find article references relevant to our study. Titles of relevant references were searched and full texts of articles meeting the inclusion criteria were studied.

2.2 The Inclusion Criteria for Articles Were

1. Articles written in English.
2. Original articles describing a paper-and-pencil instrument development and validation or psychometric process to evaluate BADL, IADL, and AADL in patients with COPD.

2.3 The Exclusion Criteria for Articles Were

3. Any article that included instruments that examined ADL in only one limb.
4. Any article that included instruments that measured ADL in other pulmonary diseases.
5. Any article that included laboratory, semi-laboratory, or field instruments.
6. Any article that used generic instruments to measure ADL in patients with COPD.
7. Articles that used paper-and-pencil instruments to evaluate BADL, IADL, and AADL in patients with COPD.

2.4 Quality Appraisal and Data Extraction

The quality of articles that met the inclusion criteria was assessed. The COSMIN checklist for assessing the methodological quality of studies on measurement was used (Mokkink et al., 2010a). The psychometric qualities of each study were independently assessed by two researchers. Disagreements between the researchers were resolved by discussion or by a third researcher. To extract main data from studies, an initial data extraction form was prepared (Table 1). The form was developed by researchers based on the COSMIN taxonomy (consensus based standards for the selection of health measurement instrument) (Mokkink et al., 2010b). This form consisted of questions about specific psychometric criteria. After entering data from four studies, the form was revised, and data from studies were entered in the final form. The most important psychometrics properties according to the COSMIN taxonomy included content validity, construct validity, criterion validity, stability, internal consistency, responsiveness, and interpretability.

Table 1. Data extraction form

	Data extraction form
1	Is the tool based on a theoretical framework or a qualitative study?
2	Have patients' experiences been used in construction of items?
3	Is the tool one dimensional or multidimensional?
4	Have content, construct, and criterion validities been provided?
5	Has reliability of the tool been determined?
6	Has sensitivity of the tool been determined?
7	Has the tool designer identified intended population?
8	Has the tool been designed for a particular group of patients with COPD?

9	Can the tool be used for all patients with COPD (illiterate, low literate, disabled)?
10	Is it easy and simple to use the tool?
11	Is the tool time consuming?
12	Can the tool be used in daily clinical work with the least facilities and equipment?
13	Has the tool been translated into other languages? if not, can it be easily translated?
14	Are there any evidence and documents that the tool has been used in clinic?
15	Are there any guidelines that recommend use of the tool in clinic?
16	Is scoring method simple in this tool?
17	Has the tool designer determined a cut-off point?

Table 2. Tools that measure activity of daily living in COPD patients

Test	Assessed construct	Scaling	Domains	Number of items	Validity			Reliability		Interpretability	Responsiveness
					V1	V2	V3	R1	R2		
Capacity of daily living during the morning (CDLM) (Partridge, et al., 2010)	BADL	Scoring according to 3- or 4-point Likert scale, depending on type of question (for instance: Yes, I can do this on my own- Yes, but I need help with that- No I cannot do that- for other reasons I cannot do that.	All basic activities that a person performs in the morning, including taking a shower, toweling the body, dressing, preparing breakfast, taking a walk around the house, etc.	6 items	–	–	✓	✓	✓	✓	–
Manchester respiratory ADL questionnaire (MRADL) (Yohannes, Roomi, Winn, & Connolly, 2000)	BADL IADL Leisure activity	4-point Likert scale (not at all, with help, alone but with difficulty, alone with ease)	Basic daily activities that a person performs, and leisure time activities	21 items	✓	–	✓	✓	✓	–	✓
Functional performance inventory (FPI) (Knebel, 2010; Larson, Kapella, Wirtz, Covey, & Berry, 1998; Leidy, 1999; Ozkan,	BADL IADL Leisure activity	4-point Likert scale (from I do this alone, to I cannot do this anymore)	Basic and instrumental daily activities a person performs, and also religious and social activities	65 items	✓	–	✓	✓	✓	–	–

Test	Construct	Scaling	Domains	Item number	V1	V2	V3	R1	R2	Interpretability	Responsiveness
Gemicioglu, Durna, & Demir, 2009)											
Functional performance inventory-short form (FPI-SF) (Ai-Min Guo, et al., 2011; Leidy, Hamilton, & Becker, 2012)	BADL IADL Leisure activity	4-point Likert scale (from I do this alone, to I cannot do this anymore)	Basic and instrumental daily activities a person performs, and also religious and social activities	32 items	✓	✓	✓	✓	✓	–	–

V1 - Content Validity; V2 - Criterion Validity; V3 - Construct Validity; R1 – Stability; R2 - Internal Consistency.

Table 3. Instruments were designed to measure dyspnea as an indicator of ADL

Test	Construct	Scaling	Domains	Item number	Validity			Reliability		Interpretability	Responsiveness
					V1	V2	V3	R1	R2		
The London chest ADL scale (LCADL)(Bisca, Proenca, Salomao, Hernandes, & Pitta, 2014; Carpes, Mayer, Simon, Jardim, & Garrod, 2008; Garrido, et al., 2006; R Garrod, Bestall, Paul, Wedzicha, & Jones, 2000; Kovelis, et al., 2011)	Dyspnea	5-point Likert scale (from performing tasks without dyspnea to inability to perform tasks due to dyspnea)	Basic daily life activities and leisure time	15 items	–	✓	✓	✓	✓	–	✓
COPD activity rating scale (CARS)(Morimoto, Takai, Nakajima, & Kagawa, 2003)	Dyspnea and the amount of help the individual needs to perform his daily activities.	3- point Likert scale (dependent, somewhat dependent, and independent)	Basic daily life activities and social activities	12 items	–	–	✓	✓	✓	–	✓
The Nagasaki University respiratory ADL questionnaire (ADL-D)(Yoza, Ariyoshi, Honda, Taniguchi, & Senjyu, 2009)	Dyspnea	5- point Likert scale (from performing tasks without dyspnea to inability to perform tasks	Basic activities	15 items	–	✓	✓	–	✓	–	–

		due to dyspnea)									
Pulmonary functional status scale (PFSS)(Weaver, Narsavage, & Guilfoyle, 1998)	Dyspnea BADL IADL	4- point Likert scale (from performing tasks with huge difficulty to performing tasks without difficulty, and 5- point Likert scale (from not doing the task to doing the task 3 times or more per week)	Basic daily life activities and spiritual, psychological and sexual activities	56 items	✓	✓	✓	✓	✓	–	–
The pulmonary functional status and dyspnea questionnaire (PFSDQ)(Lareau, 1994; Lareau, Carrieri-Kohlman, Janson-Bjerklie, & Roos, 1994)	Dyspnea BADL IADL	Likert scales: 0-7 for activities, 0-10 for dyspnea	Basic daily life activities and social activities and leisure time	164 items	✓	–	✓	✓	✓	–	–
The modified version of the pulmonary functional status and dyspnea questionnaire (PFSDQ-M) (A. M. Guo, Han, Wang, Lin, & Wu, 2010; Kovelis, et al., 2008; Kovelis, et al., 2011; Lareau, Meek, & Roos, 1998; Wingårdh, Engström, & Claesson, 2007)	BADL	Tool has two parts. First it measures patient's dyspnea, and then, daily activities. Scoring is based on 11-point Likert scale (from fully active to fully inactive)	Basic activities that a person performs daily, including: taking a shower, dressing, preparing food, walking	40 items	–	–	✓	✓	✓	–	✓
Short-form pulmonary functional status scale (PFSS-11)(Chen, Narsavage, Culp, & Weaver, 2010; Narsavage, Chen, Culp, & Weaver, 2009)	Dyspnea BADL IADL	4- point Likert scale (from performing tasks with huge difficulty to performing tasks without difficulty, and	Basic daily life activities and emotional activities	11 items	–	–	✓	✓	✓	–	✓

		5- point Likert scale (from not doing the task to doing the task 3 times or more per week)									
Disability related to COPD tool (DIRECT)(Aguilaniu, et al., 2011)	The amount of inability in performing BADL IADL AADL	Different Likert scales scoring for each question (3, 4, or 5 points)	Basic and advanced daily activities	10 items	✓	✓	✓	✓	✓	–	–
Shortness of breath with daily activities (SOBDA)(W. Chen, et al., 2010; Howard, et al., 2012; Watkins, et al., 2013; T. Wilcox, et al., 2010; T. K. Wilcox, et al., 2013)	Dyspnea in performing BADL IADL	Not explained	Basic and instrumental activities	37 items	✓	✓	✓	✓	✓	–	✓

V1 - Content Validity; V2 - Criterion Validity; V3 - Construct Validity; R1 – Stability; R2 - Internal Consistency.

3. Results

PubMed database search using the above-mentioned keywords yielded 1,463 articles, and following search in other databases, 376 articles were found. After exclusion of repeated articles, titles and abstracts of 1,424 articles were reviewed. At this stage, 1,265 articles were excluded. Ultimately, 159 articles were included in the study for full text review. Then, relevant references, whose full texts had been studied, were manually searched in various databases. Twenty-seven articles were added to the study after manual assessment of references, and the full texts of 186 articles were reviewed. After this evaluation, 155 articles were excluded.

The most common reason for excluding these studies was that they were either laboratory, semi-laboratory, field tests or performance-based tests, compared two instruments, examined daily physical activity in only one limb, used generic instruments to measure ADL, investigated correlation of physical activity with other variables, investigated the effect of COPD on ADL, assessed physical activity in patients with COPD after lung transplant, or assessed instrument for diseases other than COPD.

The remaining 31 articles were evaluated for extraction of data and led to identification of 13 paper-and pencil instruments for investigating ADL in COPD patients.

Flowchart 1 shows article search and selection method in every stage. Of the 13 identified instruments, four instruments (CDLM, MRADL, FPI, FPI-SF) were developed to examine ADL in COPD patients (Table 2 shows instruments that measure ADL in COPD patients).

Nine instruments (LCADL, CARS, ADL-D, PFSS, PFSDQ, PFSDQ-M, PFSS-11, DIRECT, SOBDA) were designed to measure dyspnea as an indicator of ADL (Table 3 shows instruments designed to measure dyspnea as an ADL indicator). FPI and FPI-SF were based on a theoretical framework that accounts for important and effective factors in performing ADL in patients with COPD.

Two instruments (PFSDQ-M) and (CDLM) were designed to measure BADL, and ADL-D included only dyspnea. Most of them (n=8) combined BADL with IADL and leisure activity. The initial search of the literature

revealed that researchers have classified ADL in various forms. But the classification system suggested by Vriendt (De Vriendt et al., 2012) and colleagues has been used in the majority of studies. In fact the majority of instruments only dealt with the two main dimensions of ADLs (BADL and IADL), and did not consider its advanced dimension (AADL), which is influenced by cultural and motivational factors. Just one instrument (CARS) included questions regarding the amount of help an individual needed to perform daily activities. Two instruments namely DIRECT and PFSS addressed sexual activity, and one (FPI) assessed religious activity.

The results showed that construction of ADL measuring instruments varied between studies, but because some of the instruments did not include information about their psychometric properties we could not compare them. In some instruments, patient information had not been used when creating the items (for example "COPD Activity Rating Scale" or CARS). In fact, many instruments followed an unclear process in construction of items, even though using information from individuals for whom the instrument is constructed and should be completed is important. Tables 2 and 3 show the evidence for the psychometric properties of the ADL instruments developed for COPD patients. Validity and reliability were the most common psychometric properties evaluated. Information on content validity of seven instruments (MRADL, FPI-SF, FPI, DIRECT, SOBDA, PFSS and PFSDQ) was available. For these instruments, interviews, focus groups and review of the literature had been performed to provide content validity. Criterion validity was reported for five instruments (FPI-SF, LCADL, ADL-D, PFSS and DIRECT). Information on construct validity was given related to all instruments. All instruments had undergone an evaluation method (stability or internal consistency) for reliability. Information on interpretability was provided only for one instrument (CDLM). Although responsiveness represents an important dimension of psychometric instruments, it was reported for only six instruments (MRADL, LCADL, CARS, PFSDQ-M, PFSS-11 and SOBDA).

4. Discussion

In the past decades, physical activity assessment instruments were traditionally and predominantly used in epidemiological research to measure activity as the treatment outcome and an indicator of health (Lagerros & Lagiou, 2007). When the results of several studies showed that activity measuring paper-and pencil instruments can evaluate and detect small differences in level of physical activity created as a result of treatment or a specific intervention, use of this instrument became commonplace in research and in clinical practice (Frei et al., 2011). The increased number of published articles focusing on ADL in patients with COPD indicates that not only lung function, but also activity is impaired in COPD patients (Kocks, Asijee, Tsiligianni, Kerstjens, & van der Molen, 2011). The results showed that only 31 studies assessed psychometric properties of ADL instruments in patients with COPD, and our extensive search strategy led to the identification of 13 paper-and-pencil instruments.

Our study results showed that, although specific instruments exist for measuring ADL in patients with COPD, some experts still measure ADL in patients using generic scales, such as the Barthel index (Lee, Lee, & MacKenzie, 2006); even though inability to perform ADL in patients with COPD is different from other diseases and conditions. This difference originates from the fact that due to dyspnea COPD patients are sometimes unable to carry out the task, despite having the physical capacity to do it (Yohannes, Baldwin, & Connolly, 2002).

Despite the importance of ADL measurement in COPD patients, and large number of professional scientific and international guidelines on COPD and how to treat and care for it, none of these guidelines have suggested an appropriate instrument, or checklist for measuring ADL (Pauwels, Buist, Calverley, Jenkins, & Hurd, 2012). Janaudis believes that lack of attention to ADL measurement in COPD patients is due to the clinical staff's lack of time to test instruments, or use a method beyond assessment of lung function and oxygenation, which is frequently used today or lack of knowledge about the most appropriate ADL instrument or questionnaire for measuring ADL in this particular patient group (Janaudis-Ferreira et al., 2014).

Although the American Association of Psychology (APA) has clearly stated that "the construct that the instrument is to measure must be expressed in a theoretical framework" ("American Educational Research Association, American Psychological Association, National Council on Measurement in Education: Joint Committee on Standards for Educational Psychological Testing. Standards for educational and psychological testing, 1999), our study shows that none of the existing instruments is based on a proper theoretical framework that accounts for important and effective factors in performing ADL in patients with COPD. While, in patients with COPD, ADL depends on a number of variables like symptoms of the disease, fitness, level of independence and level of need for mobility aids or other people's help. The majority of instruments do not account for these. Not establishing these instruments on a proper theoretical framework is indicative of inadequate and incorrect perception of the concept of daily physical activity in patients with COPD. One of the problems in this regard is the inability to measure changes in physical activity resulting from treatment or rehabilitation and interventions

to improve physical activity in patients with COPD because the instrument cannot accurately measure the concept of daily physical activity.

Physical activity is a complex construct made up of many concepts. The construct of physical activity can include the ability to perform ADL and its associated symptoms, such as pain and dyspnea. As the present study shows, in most ADL measuring instruments, the construct measured is either BADL or IADL, while according to new definitions, ADL consists of three dimensions. Therefore, the majority of instruments do not measure the third dimension of ADL (AADL), which includes "voluntary behaviors affected by cultural and motivational factors, and indicate satisfactory activities beyond personal independence" (De Vriendt et al., 2012). When a study only aims to measure BADL or IADL, using an existing instrument would be suitable, but, if the researcher intends to measure all three dimensions of ADL, they will have serious difficulties in finding an appropriate measure. Considering that one of the aims of systematic review studies is to identify the need for further studies, there is a clear need for the development of an instrument that is derived from the concept of ADL in patients with COPD that evaluates all three dimensions of ADL.

Paper-and-pencil instruments should have strong psychometric features, especially in terms of content validity of their items. Content validity is indicative of how accurately the instrument can measure the construct for which it was designed. Paper-and-pencil instruments should also have high construct validity and reliability (Frei et al., 2011). Furthermore, since they should be able to identify small changes, they should have a high sensitivity to change (Revicki, Hays, Cella, & Sloan, 2008). However, the current study shows that the most important limitation for selection of instruments for measuring ADL in patients with COPD is the lack of information about psychometrics of the instrument. Psychometrics has either not been fully investigated with the instruments or has not been sufficiently reported. For instance, regarding interpretability and sensitivity of instruments, very few studies have mentioned these two dimensions of psychometrics. In most studies, attention had been paid to construct validity, and to a lesser extent to content validity. Only half of the studies used in the present investigation had gone through a thorough content validation process, and had used an empirical, qualitative approach, such as an interview, for constructing items. The lack of full psychometric information limits the evidence-based selection of a suitable instrument for researchers and clinicians.

Study results showed that only one of the ADL instruments was designed according to cultural and lifestyle dimensions and other instruments had not considered this issue; while, clearly, people's culture and lifestyle vary in different countries, and as a result their ADL will also be different. However, the AADL dimension is affected by culture and lifestyle more than the other two dimensions.

None of the instruments specified the group of patients the instrument was developed for. A strong point in paper-and-pencil instruments is that they can be used in both hospital and laboratory settings and in the patients' real life environment. Most paper-and-pencil instruments are designed in such a way that illiterate, low literate, disabled, and frail people cannot answer them. People with mobility or comprehension problems such as patients with reading and comprehension problems cannot answer these questions either. When these people are not accounted for in designing of instruments, a proportion of the population with COPD and their right for evaluation will be neglected (Jahagirdar, Kroll, Ritchie, & Wyke, 2013).

The ultimate aim of all studies conducted on clinical instruments or tests should be the assessment of ADL effects on management and treatment outcomes of patients (Craig et al., 2011). Systematic review of studies conducted for construction of clinical instruments or tests should draw researchers' attention toward weaknesses and strengths of studies in order to propose the need for better studies on intended instruments (Henry & Hayes, 2006). However, no systematic review can provide a definite estimate of accuracy and rigor of a test or an instrument; it can only reduce the gap between correct clinical decisions and evidence, and provide a basis for future studies (*Systematic Reviews. CRD guidance for undertaking reviews in health care*, January 2009).

In conclusion, the current study revealed that psychometric properties were not complete for any of the tools, which measure ADL in patients with COPD. We recommend that a proper conceptual framework first be designed for daily physical activity in patients with COPD, followed by a paper-and-pencil instrument for measuring daily physical activity in these patients. Despite several ADL instruments identified, complete psychometric process has been done in only a few. Selection of the appropriate instrument should focus on the aim of the study and the target construct. The strength of this study was in researchers' adherence to methodology of systematic reviews in studies that expressed how systematic reviews should be performed. Although researchers tried to adhere to the protocol in all stages of the study and gather all relevant articles in the first stage of the study, there is still a chance that a relevant tool may have been missed. Sometimes, there is a difference of opinion about the inclusion or exclusion of a tool, which takes a long time to agree upon. In such

cases, researchers tried to consider the most scientifically defensible criterion in changing the protocol, and to remain faithful to the protocol in all stages of the study.

The most important limitation of this systematic review was that many tools used different surrogate or substitute terms, such as the phrase "functional status", and argued that functional status indicated level of participation of the person in activity, and that it was synonymous to "activities of daily living" [108]. However, considering that such synonymous or substitute statements were not part of the study inclusion criteria, these tools were excluded. It is recommended that a study be conducted to analyze the concept of ADL in patients with COPD, to clarify if ADL construct is synonymous or a surrogate of statements or constructs.

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Authors' Contributions

Conceiving and designing the study: Fateme Monjazebi, Asghar Dalvandi, Abbas Ebadi. Acquisition of data: Fateme Monjazebi, Asghar Dalvandi. Analysis and interpretation of data: Fateme Monjazebi, Abbas Ebadi, Mahdi Rahgozar. Drafting of the manuscript, Fateme Monjazebi. Critical revision of the manuscript for important intellectual content: Hamid Reza Khanke and Jörg Richter. Study supervision: Asghar Dalvandi, Abbas Ebadi, Mahdi Rahgozar, Jörg Richter, Hamid Reza Khanke.

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Study of Relationship Between Depression and Quality of Life in Patients With Chronic Schizophrenia

Najmeh Abedi Shargh[1], Bahareh Rostami[1], Bahareh Kosari[2], Zakiye Toosi[3] & Ghazaleh Ashrafzadeh Majelan[4,5]

[1] Health Promotion Research Center, Zahedan University of Medical Sciences, Zahedan, Iran

[2] Department of Psychology, Neyshabur Branch, Islamic Azad University, Neyshabur, Iran

[3] Department of Clinical Psychology, Shahrood Branch, Islamic Azad University, Shahrood, Iran

[4] Zahedan University of Medical Sciences, Zahedan, Iran

[5] Department of Clinical Psychology, Zahedan Branch, Islamic Azad University, Zahedan, Iran

Correspondence: Najmeh Abedi Shargh, Health Promotion Research Center, Zahedan University of Medical Sciences, Daneshgah street, Zahedan 987-98138, Iran. Tel: 98-54-332-95745. E-mail: Najme.Abedi@gmail.com

Abstract

Depression is among the personality traits of schizophrenic patients, which results from psychotic features or is a consequence of a period of psychosis. Depression in schizophrenic patients is one of the important factors affecting their quality of life. The study population of this descriptive and analytic study consists of patients with chronic schizophrenia in Zahedan in 2014. The sample included 60 patients who simultaneously suffered from depression and were selected using random sampling (30 males and 30 females). The research instruments included the Schizophrenia Quality of Life Scale (SQLS) and the Beck Depression Inventory (the inventory was filled out by the tester). In order to form a statistics analysis, we used Pearson correlation and regression multivariate. Investigating the study hypotheses showed that there was a negative correlation between the high level of depression and low quality of life. the relationship between depression and the quality of life subscales showed that in women, the variable of symptoms and complications was a significant predictor; however, the other two variables (energy and motivation and psychosocial) were not significant predictors. In case of men, psychosocial variable was a significant predictor; however, the other two variables (energy and motivation and symptoms and complications) were not significant predictors. In general, depression on these patients makes discontent of life on them; therefore, elimination of their depression on their treatment is necessary.

Keywords: depression, Quality of life, chronic schizophrenia

1. Introduction

Depression in schizophrenic patients is one of the important factors affecting their quality of life (Dan et al., 2011). In general, depression in schizophrenic patients leads to dissatisfaction with the quality of life. Therefore, depression in such patients should be treated. Research shows that efforts to reduce the symptoms of depression in schizophrenia may improve the quality of life in such patients (Cotton et al., 2010; Bow-Thomas, 1999). In their study, Cotton et al., found that depression was the strongest predictor of quality of life. Symptoms of depression in schizophrenia are common and they can occur at any stage of this disorder. Moreover, drug therapy in schizophrenic patients must be accompanied by psychosocial interventions. Early diagnosis and timely interventions improve the quality of life and reduce the severity of the illness in such patients (Babinkostova et al., 2011). The close relationship between major depression and schizophrenia supports the hypothesis that these two disorders may be from the same pathology or be a result of it (Hafner, 2005; Muller et al., 2006). Symptoms of depression are among the major risk factors for suicide in such patients (Yan, 2012; Kao et al., 2011). According to Kao et al. (2011), schizophrenia is associated with high risk of suicide, depression, and psychopathic symptoms; and low quality of life–especially dissatisfaction with social relations–must be considered while assessing the suicide risk in such patients. Therefore, depression in such patients should be treated. Given the frequency of schizophrenic patients and the high cost of treating them at health and psychiatric centers, providing facilities for patients to recover and adapt themselves to their condition (disease acceptance and tolerance) and improving their quality of life is of great importance. In addition to severe disease symptoms,

schizophrenic patients, who are hospitalized and treated at psychiatric centers for many years, also suffer from the pain of being away from their families, acquaintances, and relatives. In fact, they will suffer from social isolation and feeling of frustration after a while and they will eventually become depressed and indifferent, which reduces their quality of life (Fadayi, 2004). Given the aforesaid factors, this study aims to investigate the relationship between depression and quality of life in patients with chronic schizophrenia.

2. Method

The study population of this descriptive and analytic study consists of patients with chronic schizophrenia in Zahedan in 2014. Based on the conducted studies (14), the sample included 60 patients who simultaneously suffered from depression and were selected using random sampling (30 males and 30 females). The inclusion criteria were as follows: being diagnosed with schizophrenia for at least a year, being ate the age 30-60, willingness for participation in the study, and being able to communicate with the researcher appropriately. The research instruments included the Schizophrenia Quality of Life Scale (SQLS) and the Beck Depression Inventory (the inventory was filled out by the tester). The SQLS consisted of 30 questions assessing the quality of life in schizophrenic patients in three areas, including psychosocial (15 questions), energy and motivation (7 questions), and symptoms and complications (8 questions). Answer choices included never (0 point), rarely (1 point), sometimes (2 points), often (3 points), and always (4 points). Therefore, those gaining more points possess a lower quality of life, and adversely, fewer points indicate a higher quality of life. Research has proven this questionnaire to be of high reliability and validity for assessment of the quality of life in schizophrenic patients. This questionnaire has been standardized for Iranian cultural context. Content validity check was conducted in order to validate the questionnaire (by asking 10 experts to provide their opinion), test-retest was used to assess its reliability, and its reliability (r=0.89) was confirmed (Fruzande, 1999).

The Beck Depression Inventory (BDI-II) consisted of 21 questions, which was designed to assess feedbacks and symptoms of depression in patients. This scale determines different degrees of depression from mild to severe. The scores of this inventory range from 0 to 63. Beck et al., (1996) obtained the 1-week test-retest reliability coefficient as 0.93. In Iran, studies conducted by Partovi (1976), Vahabzadeh (1974), and Chegini (2003) showed that the reliability of the Beck Depression Inventory was high, ranging from 0.70 to 0.90. The following scores can be applied to show the overall level of depression: 0-13 (no or minimal depression), 14-19 (mild depression), 20-28 (moderate depression), and 29-63 (severe depression) (Azkhosh, 2008).

3. Results

In this section, demographic characteristics are described using the frequency and percentage indices. The subjects' demographic characteristics are shown in table 1-4. The study group consisted of 30 women (50%) and 30 men (50%). In terms of age, the group consisted of seventeen 20-30 year-old individuals (28.3%), forty 40-50 year-old individuals (50%), and thirteen 50-60 year-old individuals (21.7%). In terms of marital status, 42 (70%) and 18 (30%) were single and married respectively. In terms of length of stay in the center, 1 (1.7%), 14 (23.3%), 24 (40%), 11 (18.3%), 8 (13.3%), and 2 (3.3%) stayed there for less than 2 years, 2-4 years, 4-6 years, 6-8 years, 8-10 years, and more than 10 years respectively. In terms of level of education, 14 (23.3%) were illiterate, 26 (43.3%) had primary education, 15 (25%) had secondary education, and 5 (8%) had a high school diploma or a higher degree.

Table 1. Sample characteristics: demographic variables

		Frequency	*Percent*
Sex	Female	30	50
	Male	30	50
Age	30-40	17	28/3
	40-50	30	50
	50-60	13	21/7
Married	Single	42	70
	Married	18	30
Inhabitancy on center	Under 2 years	1	1/7
	2-4 years	14	23/3

	4-6 years	24	40
	6-8 years	11	18/3
	8-10 years	8	13/3
	More than 10 years	2	3/3
	Illiterate	14	23/3
Education level	Primary	26	43/3
	Guidance	15	25
	Diploma and more	5	8

Pearson's correlation test was employed to determine the relationship between depression and quality of life in schizophrenic patients. In this study, $P<0.05$ was used as the significance level. There was a significant negative correlation between high level of depression and low quality of life (one-tailed test, P=0.01, n=60, r=-0.30). (Women: one-tailed test, P=0.043, n=30, r=-0.31; Men: one-tailed test, P=0.041, n=30, r=-0.32).

Table 2. The result of person correlation

Variable	number	sexuality	correlation	significant	
Depression & SQLS	30	female	-0.31	0.043	(1-tailed)
	30	male	-0.32	0.041	
	60	Female & male	-0.30	0.01	

Multivariate regression analysis was employed to determine the relationship between depression and the quality of life subscales. A significant model about women and men was obtained using the Enter method. (Women: P=0.043 & F3 26= 3.12 & Adjusted R2 value=0.18; Men: P=0.041 & F3 26= 3.18 & Adjusted R2 value=0.18). This model explains 18% of the variance. In case of women, the variable of symptoms and complications was a significant predictor; however, the other two variables (energy and motivation and psychosocial) were not significant predictors. In case of men, psychosocial variable was a significant predictor; however, the other two variables (energy and motivation and symptoms and complications) were not significant predictors.

Table 3. Coefficient among the level of SQLS & Depression

Variable		female		Male	
		correlation	significant	correlation	significant
Depression &	Motivation	-0.24	0.10	-0.36	0.02
	Symptom	-0.45	0.006	-0.12	0.26
	Psychosocial	-0.08	0.34	-0.39	0.01

Table 4. Predictors of SQLS — Regression Analysis by enter method

	Predictor	ß value	R^2 value	Adjusted R^2 value	F value	Significance	Confidence interval	
Female			0.51	0.180	3.12	0.043	0.756	2.44
	Motivation	0.25				0.22	-0.026	0.107
	Symptom	0.51				0.01	0/013	0.096
	Psychosocial	-0.28				0.21	-0.053	0/012

Male		0.52	0.184	3.18	0.041	-0.924	1.55
	Motivation	0.296			0.14	-0.017	0.12
	Symptom	-0.390			0.12	-0.075	0.01
	Psychosocial	.533			0.04	-0003	0.09

4. Discussion

Investigating the study hypotheses showed that there was a negative correlation between the high level of depression and low quality of life. According to Strauss et al. (2012), negative symptoms and depression are a predictive factor for well-being in schizophrenic patients. According to Naber et al. (2013), fewer symptoms of depression and higher quality of life in schizophrenic patients can predict early recovery in psychopathology, quality of life, and well-being. The studies conducted by Babinkostova et al. (2011), Kao et al. (2011), Renwick et al. (2012), and Conton et al. (2010), Priebe et al. (2011) also confirm this result. In a study titled "A comparative study on quality of life of patients of schizophrenia with and without depression", Dan et al., (2011) showed that the overall score of depression had no relationship with the quality of life in schizophrenic patients; however, symptoms of psychopathology had a strong negative correlation with the quality of life. Konarzewska et al. (2012) showed that symptoms of depression and alcohol dependence do not affect the MAST score of schizophrenic patients; however, dissatisfaction with the quality of life had a relationship with higher MAST scores only in schizophrenic alcohol-dependent women. These different results might be due to cultural differences, implementation method, difference in sample size and demographic characteristics, difference in the type of questionnaire, and place of implementation. According to Taghavi et al. (2008), the frequency of depression in schizophrenic patients under treatment was 39.9%, which was high in females, and single, divorced, unemployed, and illiterate individuals. Moreover, the level of depression in acute and complete remission phases was high and low respectively. In his study on Chinese schizophrenic patients, Yan (2012) found that quality of life had an impact on suicidal thoughts. Sense of coherence and acceptance of disease and depression in schizophrenic patients affect the quality of life in such patients (Badura-Brzoza, 2012). Concerning the second hypothesis, the results of multivariate regression analysis in determining the relationship between depression and the quality of life subscales showed that in women, the variable of symptoms and complications was a significant predictor; however, the other two variables (energy and motivation and psychosocial) were not significant predictors. Despite new antipsychotics, such patients still suffer from poor social functioning and a high level of physical discomfort, which reduces their quality of life (Hwang, 2009). Since women pay more attention to physical symptoms and their bodies than men, symptoms and complications are predictive factors for depression in women. In case of men, psychosocial variable was a significant predictor; however, the other two variables (energy and motivation and symptoms and complications) were not significant predictors. In his studies, Renwick (2012) showed that depression had reduced the quality of life in these patients in areas such as psychological well-being and social relations, which is consistent with the results of the studies by Cotton (2010). In our study population, the men and women had no significant difference in terms of demographic variables such as level of education, marital status, age, and length of stay. There was a difference only in ethnic factor, including native and non-native (P=0.004). In women, 53.3% were native and 46.7% were non-native. In men, 86.7% were native and 13.3% were non-native. This shows that the two groups are different in terms of ethnic factor, which can justify the difference between men and women in terms of predictor variables of depression. Moreover, in our study population, men and women had no difference in terms of depression (P=0.84, df=58, n=60, t=0.2); however, they were different in terms of quality of life (P=0.024, df=58, n=60, t=2.32) and women enjoyed a higher quality of life, which might be due to men's paying more attention to psychosocial factors. A study conducted by Khodadadi et al., (2010) on the quality of life in schizophrenic patients in terms of individual, social, and clinical characteristics showed that 40.4% of these samples were really dissatisfied with having negative psychological feelings. A study by Solanki et al. (2010) also shows that the lowest quality of life score in schizophrenic patients was observed in social communication dimension. According to the World Health Organization, quality of life means individuals' perception of their lives based on their culture, system of values, goals, expectations, standards, and concerns (Divanon et al., 2006). This perception might be different in men and women and cause difference in predictive factors for depression. In general, research has shown that symptoms of depression in schizophrenia can lead to dissatisfaction with the quality of life, impairment in psychological functioning, higher recurrence rate, longer hospitalization, lack of response to medical treatment, occupational impairment, less activity, cognitive impairment, poor social functioning, substance abuse, negative

attributional style, and suicide (Hausmann et al., 2002; Siris, 2000).

Conflict of Interest

The authors declare no conflict of interest in this study.

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The Effectiveness of Mindfulness-Based Cognitive Group Therapy on Marital Satisfaction and General Health in Woman With Infertility

Najmeh Abedi Shargh[1], Nour Mohammad Bakhshani[2], Mohammad Davoud Mohebbi[3], Khadije Mahmudian[1], Masood Ahovan[4], Mojgan Mokhtari[5] & Alireza Gangali[2]

[1] Health Promotion Research Center, Zahedan University of Medical Sciences, Zahedan, Iran

[2] Children and Adolescents Research Center, Zahedan University of Medical Sciences, Zahedan, Iran

[3] Department of Psychiatry, Zahedan University of Medical Sciences, Bahran Psychiatry Teaching Hospital, Zahedan, Iran

[4] Departmant of Counseling, Faculty of Psychology and Education, University of Allameh Tabatabai, Tehran, Iran

[5] Deptartment of Obstetrics and Gynecology, Faculty of Medicine, Zahedan University of Medical Sciences, Zahedan, Iran

Correspondence: Najmeh Abedi Shargh, Health Promotion Research Center, Zahedan University of Medical Sciences, Zahedan, Iran. E-mail: abedishargh@hotmail.com

Abstract

Infertility affects around 80 million people around the world and it has been estimated that psychological problems in infertile couples is within the range of 25-60%. The purpose of this study was to determine the effectiveness of Mindfulness-based cognitive group therapy on consciousness regarding marital satisfaction and general health in woman with infertility. Recent work is a clinical trial with a pre/posttest plan for control group. Covering 60 women who were selected by in access method and arranged randomly in interference (30) and control (30) groups. Before and after implementation of independent variable, all subjects were measured in both groups using Enrich questionnaire and marital satisfaction questionnaire. Results of covariance analysis of posttest, after controlling the scores of pretest illustrated the meaningful difference of marital satisfaction and mental health scores in interference and control groups after treatment and the fact that MBCT treatment in infertile women revealed that this method has an appropriate contribution to improvement of marital satisfaction and mental health. Necessary trainings for infertile people through consultation services can improve their mental health and marital satisfaction and significantly help reducing infertile couples' problems.

Keywords: mindfulness, infertility, marital satisfaction, general health

1. Introduction

De Brardis (2014) in his studies entitled "Psychopathology, emotional aspects and psychological counseling in infertility: A review" demonstrated that infertility affects around 80 million people around the world and it has been estimated that psychological problems in infertile couples is within the range of 25-60%. Depression and anxiety in infertile couples is considerably higher than fertile ones and the mental effect of this issue is higher in females compared to males. Psychological consultation can be a useful aid. A study performed by Tao (2012) revealed that male-based infertility has no negative contribution to marital factors. Moreover, infertile male participants expressed higher marital satisfaction from their wives, while females feel their marital relationship less stable and these factors include sexual satisfaction, age of couple, educational level and life quality. Results of various studies demonstrates that mental factors such as depression or anxiety can be a thread for outcome of treating infertility and By improving mental health, psychological treatments together with infertility treatment o effectiveness of infertility treatments, encourage the infertile person to follow up the treatment as well (Shahrestani et al., 2012). Treatment recognition is defined based on the consciousness of someone regarding treatment process whose emphasis is over actively attending emotions and instantaneous thoughts of the patient without judging or evaluating that thought or feeling. After attention accompanied with consciousness, patient enters a strengthening situation made by him/herself and this trend finally leads to matching and improvement of

thoughts and totally the quality of life (Younesi et al., 2008). In a study performed by Shahrestani et al. (2012) entitled effectiveness of group cognition therapy based on the consciousness in improvement of perceived stress dimensions and illogical cognitions in infertile women under IVF treatment, results demonstrated that cognition therapy based on consciousness is effective in improvement of illogical cognitions of parents and perceived stress of infertile women under IVF treatment. Results of Fili et al. (2012) corresponding to comparison of effectiveness of behavioral cognitions therapy and cognition therapy based on consciousness, revealed that by treatment methods can reduce rumination of infertile women. In a research performed by Galhardo et al. (2013), results demonstrated that women participating in Mindfulness plans based on plans until its end, showed a meaningful decrease in depression, exterior and interior shame, being trapped and failure. Furthermore, they had a considerable statistical improvement in concentration skills and self-efficiency in confronting infertility, in control group, there was no significant changes in psychological action except reduction of self-judgment. The purpose of this study was to the effectiveness of Mindfulness-based cognitive group therapy on Mindfulness regarding marital satisfaction and general health in woman with infertility.

2. Materials and Methods

Recent work is a clinical trial with a pre/posttest plan for control group. Studied community included all infertile women visiting female clinic of Ali Abitaleb hospital of Zahedan city in 2014 covering 60 women who were selected by in access method and arranged randomly in interference (30) and control (30) groups. Criteria for entering the study are as follows: recognition of infertility by obstetricians, minimum one year of recognition, being within the range of 20-45 years, minimum educational level of fifth grade of elementary school. Criteria for leaving the study were as follows: pregnancy before infertility recognition and psychological or drug treatments for mental or physical problem other than infertility. For interference group, the method of recognition therapy based on Mindfulness is applied according to the method described in reference book (Crane, 2009).

2.1 The Contents of an 8-Session MBCT Program According to Crane's Book

2.1.1 First Week: Automatic Pilot

Activities per session;

Mindful eating of a raisin;

Body scan meditation.

2.1.2 Second Week: Removing Barriers

Treatment with body scan meditation, ten minutes of breathing with mindfulness and meditation.

2.1.3 Third Week: Mindfulness with Breathing (Body Movements Using This Technique)

Conscious movement;

"Stretching and breathing exercises", maintaining the expansion of thoughts and the mind through following meditative practices and concentrating on conscious breathing and body parts. This practice might start with a short-time mindful thought, such as "seeing" or "listening".

2.1.4 Fourth Week: Staying in the Present Moment

5 minutes of seeing/listening to mindful-based cognitive method (awareness of breathing, body parts, sounds, thoughts and informed choices);

3 minutes of breathing- presenting patterned practices to be applied when experiencing uneasy feelings;

Mindful walking.

2.1.5 Fifth Week: Acceptance and Allowance

Meditation meetings with awareness of breathing and body parts. Putting emphasis on how to react to whatever we think and feel, and whatever originates from physical feelings. Creating a difficult condition for practice and discovering the effects of practices on mind and body;

3 minutes of breathing.

2.1.6 Sixth Week: Thoughts are not Real

Meditation meetings- Awareness of breathing and body- presenting patient problems during the practice, and discovering the effects of the practice on body and mind;

3 minutes of breathing.

2.1.7 Seventh Week: How Can We Best Take Care of Ourselves

Meditation meetings- Awareness of breathing, body parts, sounds, thoughts and emotions;

3 minutes of breathing, presenting a problem during the practice and discovering its effect on body and mind.

2.1.8 Eighth Week: How to Use These Points in Future Decisions

Body scan meditation, end of treatment.

In this period, no psychological treatment was applied for control group. Before and after implementation of independent variable, all subjects were measured in both groups using Enrich questionnaire.

Marital satisfaction questionnaire (Olson et al., 1989) included 35 articles and 4 micro-scales of marital satisfaction, communications, conflict resolution and ideal deviation. In the study of Olson, Alpha coefficient of the questionnaire for micro-scales of marital satisfaction, communications, conflict resolution and ideal deviation is 0.74, 0.78, 0.61 and 0.80, respectively. The validity level of the tool through retest for micro-scales was 0.86, 0.81, 0.90 and 0.92, respectively.

General health questionnaire (GHQ-28): this questionnaire includes four micro-scales of body complaint, anxiety, depression and social malfunction. Yaghoubi (1995) reported the sensitivity of the test as much as 0.86 and its characteristic as 0.82. This work also reports the general validity of the tests as much as 0.88 and validity of micro-scales within the range of 0.50-0.81.9 (Oraki et al., 2012).

3. Results

In this section, demographic characteristics are described using the frequency and percentage indices. The subjects' demographic characteristics are shown in table 1.

As seen in Table 1, the age range of the samples was as follows: 15 (25%) were 20-28, 38 (63.33%) were 29-37, and 7 (11.66%) were 38-45. In terms of the duration of infertility, 12 (20%) have been infertile for 1-3 years, 42 (70%) for 4-7 years, and 6 (10%) for 8-10 years. The highest percentage of the duration of infertility was therefore 4-7 years. In terms of education level, more than half of the participants (53.33%) held a fifth grade elementary school degree.

Table 1. The frequency distribution of infertile women according to some demographic features

Variable	Range	Frequency	Percent
Age (year)	20-28	15	25
	29-37	38	63.33
	38-45	7	11.66
Duration of infertility(year)	1-3	12	20
	4-7	42	70
	8-10	6	10
Education level	Elementary	32	53.33
	Secondary	13	21.66
	Diploma	10	16.66
	Bachelor's degree	5	8.33

Table 2 shows the moderate averages; that is, the effect of random variable is eliminated statistically.

Average of interference group for the variable of marital satisfaction is as much as 1.154 while this is 1.07 for control group which shows the improvement of marital satisfaction of interference group after treatment. Average of moderated scores of mental health in control group and interference group was 55.09 and 45.306, respectively which demonstrates the improvement of average scores in interference group after treatment.

Table 2. Estimated Marginal Means group (Dependent Variable: posttest)

	group	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
Marital satisfaction	Interference	1.154E2[a]	2.762	109.833	120.898
	Control	1.070E2[a]	2.762	101.423	112.488
Mental health	Interference	55.094[b]	2.116	50.856	59.331
	Control	45.306[b]	2.116	41.069	49.544

a. Covariates appearing in the model are evaluated at the following values: Marital satisfaction = 97.6833.

b. Covariates appearing in the model are evaluated at the following values: Mental health = 41.6500.

Results of investigation of statistical presumptions revealed that both presumptions of equality of variances and normality are applicable ($p<0.05$). Results of covariance analysis of posttest, after controlling the scores of pretest illustrated the meaningful difference of marital satisfaction and mental health scores in interference and control groups after treatment and the fact that women have higher marital satisfaction and mental health after applying independent variable (Table 3).

Table 3. Summary of results from ANCOVA of variance related to score Mean of marital satisfaction and mental health   post   test

	source	Sum of Squares	df	Mean Square	F	Sig	Partial Eta Squared
Marital satisfaction	Pretest	5658.905	1	5658.905	22.885	.000	.286
	group	1060.956	1	1060.956	4.291	.043	.070
Mental health	Pretest	4731.948	1	4731.948	35.224	.000	.382
	group	1436.348	1	1436.348	10.692	.002	.158

4. Discussion and Conclusion

Results of MBCT treatment in infertile women revealed that this method has an appropriate contribution to improvement of marital satisfaction which was compatible with similar works. Stress of infertility is correlated to the reduction of marital satisfaction (Gana et al., 2014; Rockliff et al., 2014; Mosalanejad et al., 2014; Cserepes et al., 2013; Tao et al., 2012). Mindfulness is sometimes related to romantic relations (Barnes et al., 2007). Furthermore, infertility consultation improves sexual and marital satisfaction in infertile couples (Vizheh et al., 2013). There is a positive relationship between Mindfulness and marital satisfaction and Mindfulness skills may lead to marital satisfaction (OmidBeiki et al., 2014). Carson et al. (2004) showed that Mindfulness treatment improves marital satisfaction. It must be noted that this compatibility may be the result of MBCT treatment characteristics since with regard to MBCT, it is always implied that this strategy is appropriate for those who are depressed, anxious or are not martially satisfied. In study of the second hypothesis, research findings revealed that women treated by MBCT, have meaningfully different mental health from those who are not treated by this treatment method. This means that MCBT treatment is effective in improving mental health of infertile women of Zahedan. This results are in agreement with that of Galhardo et al. (2013), Shahrestani et al. (2012), and Fili et al. (2012). Infertility is one of the factors which lead to lower mental health (Hasanpour et al., 2014; Baghianimoghadam et al. 2013; Ahmadi Forooshany et al., 2012; Peterson et al., 2003). Sherratt et al., (2013) showed that MBCT treatment is effective in reducing infertility-related psychological problems and will result in higher wellbeing scores and psychological distress. Research shows that Mindfulness leads to improvement of mental health (Pots et al., 2014; Tran et al., 2014; Caldwell et al., 2014). In explaining the reason of the effectiveness of MCBT in improving psychological health of infertile women, it can be said that one of the factors resulting in reduction of mental health of infertile women, is daily life stresses and social pressures. Therefore, it seems that MBCT can help people recognize situations which lead to stress and sadness and apply MBCT strategies to confront them. Another explanation for the effectiveness of the aforesaid interference is mental support which leads to the change of vision of infertile women toward themselves. They no longer feel loneliness nor consider their problem as unique and get an environment in which they are able to address their feelings and problems.

Researches prove the mental inconveniences such as anxiety, depression and mental disturbances. Necessary trainings for infertile people through consultation services can improve their mental health and marital satisfaction and significantly help reducing infertile couples' problems. In fact, the MBCT exercises seem to be effective in the cognitive system and information processing as people become more aware of the present time through techniques such as paying attention to breathing and body and concentrating on here and now. A widespread application of this technique is therefore recommended, given that this type of education is effective and this technique is beneficial in the considered domains. Based on the findings of the present study and considering the effectiveness of MBCT training, a continuous MBCT usage can be suggested to improve the participants' life and reduce their problems.

Marital satisfaction is a variable influenced by the characteristics of both men and women. Due to men's lack of cooperation and sometimes not being accompanied by women, only the female sample was used. It is suggested that their husbands also be studied by coordinating the families better in future studies. Some other studies are also suggested to be performed on samples with different types of infertility dividing them according to their gender, and study the effect of demographic variables such as age, education, income, and job on infertility levels and types of problems caused by it.

Acknowledgements

Conflict of Interest

The authors declare no conflict of interest in this study.

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Comparison of the Effects of Maternal Supportive Care and Acupressure (at BL32 Acupoint) on Labor Length and Infant's Apgar Score

Marzieh Akbarzadeh[1], Zahra Masoudi[2], Najaf Zare[3] & Maryam Kasraeian[4]

[1] Maternal-Fetal Medicine Research Center, Department of Midwifery, School of Nursing and Midwifery, Shiraz University of Medical Sciences, Shiraz, Iran

[2] Traditional Medicine and History of Medicine Research Center, Department of Midwifery, School of Nursing and Midwifery, Shiraz University of Medical Sciences, Shiraz, Iran

[3] Department of Biostatistics , School of Medicine, Infertility Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

[4] Maternal-Fetal Medicine Research Center, Department of Obstetrics & Gynecology, Shiraz University of Medical Sciences, Shiraz, Iran

Correspondence: Marzieh Akbarzadeh, Maternal-Fetal Medicine Research Center, Department of Obstetrics & Gynecology, Shiraz University of Medical Sciences, P.O.Box: 71345-1359, Shiraz, Iran. Tel: 98-071-647-4254. E-mail: akbarzadm@sums.com

Abstract

Background and Objectives: Prolonged labor leads to increase of cesarean deliveries, reduction of fetal heart rate, and maternal as well as infantile complications. Therefore, many women tend to use pharmacological or non-pharmacological methods for reduction of labor length. The present study aimed to compare the effects of maternal supportive care and acupressure (at BL32 acupoint) on labor length and infant's Apgar score.

Methods: In this clinical trial, 150 women with low-risk pregnancy were randomly divided into supportive care, acupressure, and control groups each containing 50 subjects. The data were collected using a questionnaire including demographic and pregnancy characteristics. Then, the data were analyzed using Chi-square test and one-way ANOVA.

Results: The mean length of the first and second stages of labor was respectively 157.0 ± 29.5 and 58.9 ± 25.8 minutes in the supportive care group, 161.7 ± 37.3 and 56.1 ± 31.4 minutes in the acupressure group, ad 281.0 ± 79.8 and 128.4 ± 44.9 minutes in the control group. The difference between the length of labor stages was significant in the three study groups ($P<0.001$). Moreover, the frequency of Apgar score≥8 in the first and 5th minutes was higher in the supportive care and acupressure groups compared to the control group, and the difference was statistically significant ($P<0.001$).

Conclusion: Continuous support and acupressure could reduce the length of labor stages and increase the infants' Apgar scores. Therefore, these methods, as effective non-pharmacological strategies, can be introduced to the medical staff to improve the delivery outcomes.

Keywords: acupressure, Apgar score, Doula, labor

1. Introduction

Delivery pain is an acute pain which rapidly increases and is affected by physiological, psychological, social, cultural, and environmental factors (Leeman et al., 2003). Excessive pain intensifies mother's fear and anxiety during delivery and stimulates sympathetic nervous system. These, in turn, enhance secretion of catecholamines, such as epinephrine and norepinephrine, eventually leading to more pain, prolonged labor stages, and dissatisfaction with the delivery experience (Sercekus & Okumus, 2007). Prolonged labor results in anxiety, fear, and fatigue which play a major role in reduction of mother's self-confidence and self-esteem. Thus, the women experiencing prolonged labor tend to make use of analgesic methods. Prolonged labor also increases the probability of damage, prenatal mortality, utilization of oxytocin, and rate of cesarean and instrumental delivery

(Kaptchuk, 2002; May& Elton, 1998; Rabl, Ahner, Bitschnau, Zeisler, & Husslein, 2001). Furthermore, the relationship between chronic stress and delivery outcomes indicates the necessity of interventions for reducing this factor (Fink et al., 2011). Nowadays, various pharmacological and non-pharmacological methods are used for decreasing labor pain. Yet, since pharmacological methods might be accompanied by some complications for both mother and fetus, non-pharmacological ones are more welcomed. Up to now, a large number of non-pharmacological methods have been proposed for reduction of labor pain with acupressure and supportive care being two important ones (Kimber et al., 2008).

Acupressure is a comprehensive treatment method which dates back to 5000 years ago. In this method, similar to acupuncture, specific reflex points on the body are used for treatment. By pressing these points, muscle tension is removed and blood circulation and vital energy are improved (Yang, 2001). Some researchers believe that reduction of pain following stimulation of acupoints is due to the fact that it prevents transfer of pain stimulants and increases the blood endorphin levels (Chung, Hung, Kuo, & Huang, 2003). Park et al. (2003) stated that acupressure increased the intensity of uterine contractions (Park, Cho, Kwon, Ahn, Lim, & Chang, 2003). In the same line, Skilnand et al. (2002) showed that the first stage of labor was shorter among the participants who underwent acupressure (Skilnand, Fossen, & Heiberg, 2002). Overall, various acupoints are employed for induction and control of delivery and BL32 (Ciliao) is one of these points (Cook & Wilcox, 1997).

The other non-pharmacological method used in the current study was supportive care. This method involved continuous presence of doula and provision of psychological support (reassuring, encouraging, and guiding the mother), physical support (palpation, massage, coldness, hotness, hydrotherapy, position change, and movement), informing and guiding the mother, and facilitation of creation of relationship (helping the woman to express her needs) (Simkin & Bolding, 2004). According to most doulas, mothers cannot predict how labor affects them because they do not know about the delivery process and judge themselves negatively (Gilliland, 2011). On the other hand, self-confidence and the ability to adapt with labor are the predictors of labor pain experience. By supportive care, women can successfully cope with labor pain and stress and feel strong and mentally calm (Simkin & Bolding, 2004). In the study by Kennel et al. (1991), doula's continuous support reduced the labor length by 1-2 hours and increased the mother's capability to control laborthereby resulting in a positive delivery experience (Kennel, Klaus, McGrath, Robertson, & Hinkley, 1991).

Considering the effects of prolonged labor on the delivery outcomes, the present study aims to compare the effects of maternal supportive care and acupressure (at BL32 acupoint) on labor length and infant's Apgar score.

2. Methods

2.1 Study Design

This randomized clinical trial was conducted in the delivery ward of the selected educational center of Shiraz University of Medical Sciences (Shoushtari hospital in Iran) in 2012.

2.2 Setting and Sample

Considering d=5, α=0.05, 1-β=0.90, SD=7, and the following formula, a 126-subject sample size was determined for the study (42 in each group). However, due to the possibility of loss, the sample size was increased to 150 subjects (50 in each group):

$$n = \frac{2(Z_{1-\alpha/_2} + Z_{1-\beta})^2 SD^2}{d^2}$$

Then, the subjects were selected through simple random sampling and were divided into supportive care, acupressure, and control groups using stratified block randomization. In doing so, a number was randomly selected from the table of random numbers and the researcher moved toward the right or left column or row and wrote the 5 digit numbers down. Since the participants were divided into 3 groups in this study, 3-therapy method was used and classification was performed as follows: A: supportive care group, B: acupressure group, and C: control group. Accordingly, ABC: 1, ACB: 2, BAC: 3, BCA: 4, CAB: 5, and CBA: 6. It should be noted that numbers 0, 7, and 9 were ignored.

2.3 Ethical Considerations

Ethical Committee Approval Code in Medical Research,

Shiraz University of Medical Sciences in Iran is CT-P-4985.

2.4 Measurements

The inclusion criteria of the study were being primiparous or multiparous, being physically and mentally healthy,

having at least diploma, being 18-35 years old, singleton pregnancy, cephalic presentation, gestational age of 37-42 weeks, 4cm dilation, and having at least 2-3 uterine contractions in 10 minutes. After signing written informed consents, the selected women were divided into acupressure, supportive care, and control groups through permuted block randomization. The women with preeclampsia, induced labor, non-cephalic presentation, cephalopelvic disproportion, multiple birth, and those who smoked, suffered from underlying diseases, and were unwilling to take part in the study were excluded from the research.

2.5 Procedure

In the supportive care group, the researcher as the doula accompanied the mother since hospitalization up to delivery. Emotional supports during labor included palpation, kindly massaging the mother, and reassuring her. The doula also provided the mother with information about the origin of pain and process of delivery. Besides, physical support included helping the mother to change her position and move during labor.

In the acupressure group, in 3-4 and 7-8cm dilation, the participants were located in the appropriate position and BL32 acupoint was pressed. This acupoint is located in the second hole of sacral bone (16).The pressure was continuously and gently applied by both thumbs for 30 minutes (Figure 1). Before sampling, the researcher was trained regarding performance of acupressure by a physical medicine and rehabilitation specialist, so that equal pressure was applied in each performance. After the training, the pressure applied by the right and the left thumb was measured as 1405 and 1277 mmHg, respectively. The pressure was applied by the beginning and stopped at the end of the contractions. Since the interventions were not performed continuously and the researcher took a rest during the contractions, no problems were faced for application of pressure.
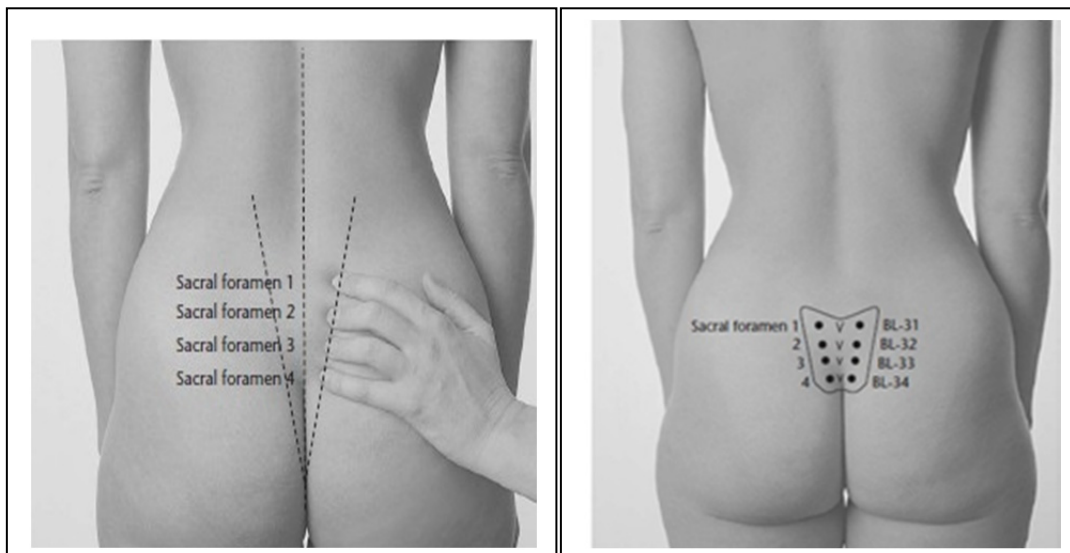

Figure 1. Location of the BL 32 point; Reference:

http://acupunctureschoolonline.com/bl-31%E2%80%93bl-34-eight-liao-baliao-acupuncture-points.html

The control group only received the hospital's routine care services.

After the interventions, the three study groups were compared regarding the length of the first and second stages of labor as well as the infants' Apgar scores.

2.6 Data Analysis

The data were analyzed using Chi-square test and one-way ANOVA. Post-hoc test was also used to identify the groups with significant differences.

3. Results

The results of Chi-square test showed no significant difference among the three groups regarding age distribution and the participants' mean age (P=0.496). Also, no significant difference was found among the three groups concerning the mothers' level of education (P=0.584) and occupation (P=0.781). Additionally, the participants' mean gestational age was 38.9 ± 1.1 weeks and the results of one-way ANOVA indicated no significant difference among the three groups regarding the mean gestational age (P=0.158).

According to the results of one-way ANOVA, the mean length of the first stage of labor was higher in the control group (281.0±79.8) compared to the supportive care (157.0±29.5) and acupressure groups (161.7±37.3). Thus, the control group's mean length of the first stage of labor was 124.0 minutes higher compared to the supportive care group and 119.3 minutes higher compared to the acupressure group, and the difference was statistically significant (P<0.001).

Also, the mean length of the second stage of labor in the control group was 69.5 minutes higher compared to the supportive care group and 72.3 minutes higher compared to the acupressure group, and the difference was statistically significant (P<0.001). According to the results of post-hoc and Least Significant Difference (LSD) tests in the first and second stages of labor, a significant difference was found between the supportive care and the control group as well as between the acupressure and the control group. Overall, the mean length of the first and second stages of labor was lower in the two intervention groups in comparison to the control group. The lowest mean lengths of the first and second stages of labor (157.0±29.5 and 58.9±25.8, respectively) were related to the supportive care group, while the highest mean lengths (281.0±79.8 and 128.4±44.9, respectively) were observed in the control group (Table 1).

The results of Chi-square test revealed a significant difference among the three groups regarding the first- and fifth-minute Apgar scores (P<0.001). As Table 2 depicts, the frequency of first-minute Apgar scores<8 in the control group was higher compared to the supportive care and acupressure groups by 46% and 34%, respectively. Also, the frequency of fifth-minute Apgar scores<8 in the control group was higher compared to the supportive care and acupressure groups by 20% and 18%, respectively. The frequency of first-minute Apgar scores≥8 was higher in the acupressure and supportive care groups (86% and 74%) compared to the control group (40%). The frequency of fifth-minute Apgar scores≥8 was also higher in the acupressure and supportive care groups in comparison to the control group (98%, 96%, and 78%, respectively) (Table 2).

Table 1. Comparison of the mean duration of the first and second stages of labor in the intervention and control groups

stage of labor	Group	stage of labor	Group (n=50)			P value
			Supportive care	Acupressure	Control	
First stage		Duration (min) M±SD	157.0±29.5	161.7±37.3	281.0±79.8	0.000
		Maximum	210	240	560	
		First stage Minimum	100	60	170	
	CT	Upper limit	165.3	172.3	304.2	
		Lower limit	148.6	151.0	258.8	
		Duration (min) M±SD	58.9±25.8	56.1±31.4	128.4±44.9	
Second stage		Maximum	130	180	200	0.000
		Minimum	20	15	50	
	CT	Upper limit	66.2	65.0	141.1	
		Lower limit	51.5	47.1	115.6	

Significance level: P<0.05. SD: standard deviation.

Table 2. Comparison of the first and fifth minute Apgar scores of the infants in the intervention and control groups

Stage of labor	Group	(n=50)			P value
		Supportive care	Acupressure	Control	
Apgar score after birth	<8	7(14)	13(26)	30(60)	0.000
First minute apgar score	≥8	43(86)	37(74)	20(40)	
Apgar score after birth	<8	1(2)	2(4)	11(22)	0.000
Five minute apgar score	≥8	49(98)	48(96)	39(78)	

Significance level: P<0.05. SD: standard deviation.

4. Discussion

The findings of the present study revealed a significant difference between the supportive care as well as the acupressure group and the control group regarding the mean length of the first and second stages of labor (P<0.001). In fact, the mean length of the first and second stages of labor in the control group was respectively 124 and 69.5 minutes higher compared to the supportive care group.

Providing the mother with psychological and emotional support is one of the dimensions of supporting the mother by the doula. In this respect, the findings of the current study were in line with those of the study by Kennel et al. (1991). In that study, women who had experienced delivery acted as doulas and the results indicated a 25% decrease in the labor length in the supported group compared to the control group. A large number of studies have also shown a reduction in the labor length in the supported women compared to those receiving hospital's routine care. This reduction was reported as 2.8 hours in the study by Zhang et al. (1996), 44 minutes in the study by Scott (Scott, Berkowitz, & Klaus, 1999), and 0.58 hours in the study by Hodnett (Hodnett, Gates, Hofmeyr, Sakala, & Weston, 2011). In the study conducted by Campell, the mean length of the first stage of labor was 10.4 ± 4.3 hours in the supported group and 11.7 ± 4.8 hours in the control group. In addition, the mean length of the second stage of labor was 58 ± 51 and 64 ± 57 minutes in the supported and the control group, respectively (Campell, Lake, & Falk, 2006). Similarly, Longer showed that the mean length of labor was 4.56 hours in the supported group and 5.58 hours in the control group (Langer, Campero, Garcia, & Reynoso, 1998). Also, Hofmeyr et al. (1991), Chalmers (1993), Klaus and Kennell (1997), and Pascali-Bonaro (Pascali-Bonaro & Kroeger, 2004) reported that the mean length of labor was lower in the supported group in comparison to the control group. The findings of all the aforementioned studies were in agreement with those of the present study. In all these studies, doulas accompanied the mothers since hospitalization up to the delivery and supported her psychologically. According to these researchers, supporting the mother during delivery can lead to considerable changes in the delivery process, including modification of uterine function, improvement of uterine contractions, creation of effective contractions, and reduction of labor length.

On the contrary to the results of the current study, Bruggemann showed that the mean length of the first stage of labor was 3.4 hours in the supported group and 3.8 hours in the control group (Bruggemann, Parpinelli, Osis, Cecatti, & Neto, 2007). Similarly, Bruggemann and McGrath (McGrath & Kennell, 2008) revealed no significant difference between the intervention (presence of doula) and the control group regarding the mean length of labor. The difference between the results of these studies and the present one might be due to the fact that they were conducted on the individuals from high social levels and the study participants could take their family members to the delivery room either with or without the doula. Therefore, both groups were highly supported and the effect of presence of doula could not be truly investigated.

Overall, presence of doula before the delivery, encouragement, consolation, and palpation of the women, and suggestion of positions which are effective in fetal descent, increase production of oxytocin, enhance women's threshold of pain, and modify delivery pain patterns, thereby decreasing the labor length (Taylor, Klein, Lewis, & Gruenewald, 2000).

According to the western medicine perspective, acupressure can create balance during delivery, reduce delivery pain, and improve the delivery process by increasing the uterine contractions (Beal, 1992). Acupressure is a simple, inexpensive non-pharmacological method for controlling delivery. In general, various acupoints are used for induction and control of delivery (Cook & Wilcox, 1997). In the present study, acupressure was performed at BL32 acupoint and the results revealed a 119.3 minute reduction in the first stage and a 72.3 minute reduction in the second stage compared to the control group, which was statistically significant (P<0.001). In comparison to the supportive care group, the mean length of the first and second stages of labor was higher in the acupressure group; however, the difference was not statistically significant (P>0.005).

Lee et al. compared labor length in acupressure and palpation groups (Lee, Chang, & Kang, 2004). In that study, the active phase of delivery was considered from 3cm dilation to complete dilation. The study results demonstrated that the length of the active phase of delivery was significantly lower in the experimental group compared to the control group, which is consistent with the findings of the current study.

Zeisler stated that acupuncture played a critical role in puberty, acceleration of opening of the cervix, and reduction of labor length. Therefore, due to the positive effects of this method on reduction of labor length, he introduced it as an effective method in controlling labor (Zeisler, Tempfer, Mayerhofer, Barrada, & Husslein, 1998). Reduction of labor length might have resulted from the reduction of pain and its resultant anxiety. In fact, acupressure might lead to release of endogenous opioids and decrease pain and anxiety.

Reduction of delivery pain in the acupressure group can be justified by gate control theory of pain and Melzack's

neuromatrix theory. Based on gate control theory of pain, acupressure activates thick nerve fibers and closes the pain gate and in this way, prevents pain transfer. According to this theory, stimulation of skin creates nervous impulses which are transferred to the spinal cord system. These impulses are either inhibited or increased in the spine. The impulses which are transferred by the thick fibers close the pain gate and, consequently, reduce pain. Moreover, stimulation of thick fibers impulses by pressure leads to more closure of the gate (Setax & Pomeranz, 2006).

According to Melzack's theory, pain matrix is composed of three main nervous components, namely sensory way which passes the thalamus and sensory cortex, emotional way which passes the limbic system, and body self-recognition way which includes parietal lobe of cortex. Thus, pain can be sensory, emotional, and cognitive (Chalmers & Wolman, 1993). Hence, in the present study, acupressure affected the sensory way, prevented message transfer to the brain, and reduced the perception of pain.

In contrast, Lawrence mentioned that acupuncture had no effects on reduction of labor length (Lawrence, Lewis, Hofmeyr, Dowswell, & Styles, 2009). The difference between that study and the present one might be due to different definitions of the first stage of labor. In the present study and other similar studies, the first stage of labor began from 3cm dilation to complete dilation. Lawrence, however, considered this stage from the time the number, length, and intensity of contractions were sufficient for opening of the cervix. It is noteworthy that in none of the above-mentioned studies, acupuncture or acupressure increased the first stage of labor. Moreover, not only these non-pharmacological methods did not reduce or inhibit the uterine contractions, but they also sedated the delivery pain and improved the delivery progress.

The findings of the current study showed that the length of the second stage of labor was shorter among the women who received acupressure at BL32 acupoint compared to the control group. In contrast, Lee et al. conducted a clinical trial and indicated no significant difference between the acupressure and the palpation group regarding the mean length of the second stage of labor; i.e., since the complete dilation up to delivery (30.3$\pm$22.6 minutes in the acupressure group and 44.8$\pm$40.0 minutes in the palpation group). They reported that acupressure was only effective in reduction of the first stage of labor (138.6$\pm$62.0 in the acupressure group and 191.2$\pm$83.7 in the control group).The difference between Lee's study and the present one might be due to the fact that Lee applied pressure during the contractions. Thus, length of pressure application was different relative to the length of contractions. In the present study, on the other hand, application of pressure was started at the beginning of contractions with similar lengths and intervals for all the participants.

The findings of the current study revealed a significant difference among the three groups regarding the first- and fifth-minute Apgar scores (P<0.001). The frequency of Apgar scores<8 in the first and fifth minutes was higher in the control group compared to the supportive care and acupressure groups. Additionally, the frequency of first- and fifth-minute Apgar scores$\geq$8 was higher in the supportive care and acupressure groups in comparison to the control group.

After 50 years, Apgar scoring system is still the best method for evaluation of newborn infants' prognosis (Casey, McIntire, & Leveno, 2001). Apgar score has been proved to be the best standard method for evaluation of infants' health immediately after birth (Jepson, Talashek, & Tichy, 1991). First-minute Apgar score indicated the newborn infants' need for resuscitation. Besides, fifth-minute Apgar score determines the probability of death or nervous complications more precisely (Roland, 1987). Apgar score, in fact, predicts infants' chance of survival (Casey et al., 2001). Cunningham et al. demonstrated that prolonged labor was accompanied by Apgar scores<7 due to long labor stages and disruption of delivery phases (Cunningham, Leveno, Bloom, Hauth, Rouse, & Spong, 2010). Furthermore, several researchers have shown that increase in the length of the second stage of labor endangered both maternal and fetal health (Saunders, Paterson, & Wadsworth, 1992) and increased the risk of complications as well as prenatal mortality (Piper, Bolling, & Newton, 1991).

In the study performed by Flan, the mean of first-minute Apgar scores was 8.8 (7-10) in the active group and 7.5 (1-10) in the resting group. Besides, the two groups' means of fifth-minute Apgar scores were 9.9 (9-10) and 9.4 (7-10), respectively (Flynn & Kelly, 1987). In the same line, Hemminki (Hemminki & Lenck, 1985), Andrews (Andrews & Chrzanowski, 1990), and Ben et al. (2010) revealed that mother's activity during delivery pain reduced the length of labor stages, improved maternal and fetal outcomes, improved infants' first- and fifth-minute Apgar scores, and reduced the rate of transfer to the neonatal ward. These results were all in agreement with those of the present study. However, Liu (1989) and Stewart (Stewart & Calder, 1984) reported that mother's activity had no effects on improvement of infants' Apgar scores. The difference between these two studies and the current one might result from the fact that they only investigated physically supporting the mother. In the present study, however, the doula provided the mother with physical support (suggestion of

appropriate positions and activities) as well as emotional and mental support which reduced mothers' anxiety, improved her self-confidence, and decreased labor disorders.

5. Conclusion

The findings of the present study showed that supportive care and acupressure reduced the length of labor and increased the infants' Apgar scores compared to the control group. Therefore, these two non-pharmacological methods which are easy to perform and are not accompanied by any side effects can be employed during labor to achieve better delivery outcomes.

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Authors' Contributions

MA, ZM conceived of study which was designed.

The data was collected by ZM.

ZM, MA & NZ & MK analyses the data and helped to draft and revise the manuscript.

ZM & MA conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

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Competing Interests of Statement

The authors declare that they have no known competing interests.

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Prevalence and Reporting of Needle Stick Injuries: A Survey of Surgery Team Members in Kermanshah University of Medical Sciences in 2012

Alireza Khatony[1], Alireza Abdi[1], Faranak Jafari[1] & Kamran Vafaei[1]

[1] Nursing and Midwifery School, Kermanshah University of Medical Sciences, Kermanshah, Iran

Correspondence: Alireza Abdi, Nursing and Midwifery School, Kermanshah University of Medical Sciences, Kermanshah, Iran. Tel: 98-918-337-0389. E-mail: A_abdi61@yahoo.com

Abstract

Background: Surgeons are one of the groups, most highly exposed to the risk of needle stick injuries at work. The present study aims to determine the prevalence and reporting of needle stick injuries during the first 6 months of 2012, in faculty surgeons affiliated to the Kermanshah University of Medical Sciences.

Methods: In a cross-sectional descriptive-analytical survey, 29 surgeons were studied based on the census method. A reliable and valid questionnaire was used as a research instrument to collect the data. Data was analyzed using SPSS v.16 and based on descriptive and inferential statistics.

Results: Among 29 recruited surgeons, 5 (17.2%) had needle stick injuries during the 6 months, only one of whom had followed the established guidelines about reporting and following treatment. The most common instrument causing injury was the suture needle (60%). Significant differences were found in both groups of the injured and non-injured in term of gender (X^2=5.612, P=0.003), and number of patients (Z=2.40, P=0.016) and daily working hours (Z=2.85, P=0.04).

Conclusions: In relation to the relatively high prevalence of needle stick injuries among the surgeons and their lack of reporting, it is suggested that the Safety Guidelines in the operating room are carefully observed. Moreover, safer and lower risk surgical Instruments should be used.

Keywords: surgeon, injury, needle stick

1. Background

Needle stick injury is defined as a penetrating wound typically induced by a needle point or other sharp instrument or object which could be infected with another person's secretions (Galoughi, 2010). Approximately, 600, 000 to 800,000 cases of needle stick injuries happen in the USA annually (Rapparini, 2006). Findings of a study in China (2011) indicate that each health care personnel experience at least 4 times needle stick injuries during their employment period (Shi et al., 2011). Despite thorough precautions needle stick injuries cannot be avoided. These injuries can lead to transmission of blood-borne viral infections such as AIDS, hepatitis B (HBV) and hepatitis C (HCV) to health care employees, patients and their family members. As a result, 6-30% of HBV transmissions, 5-10% of HCV infections and 0.03% AIDS transmission are due to needle stick injuries (Askarian & Malekmakan, 2006; Thomas & Murray, 2009). Veeken et al. (1991) and Rapparini (2006) stated that needle stick injuries are the most common cause of AIDS infection in health care workers (Rapparini, 2006; Veeken et al., 1991).

The prevalence of needle stick injuries differs according to working conditions, specialization and work environment. Surgeons are more vulnerable to needle stick injuries due to continuous exposure to patients' secretions and blood (OÇÖConnor et al., 2011). Results of a study in Iran indicated that operating rooms where the staff have the highest exposure to sharp instruments such as needles, suture needles and surgical blades had the highest prevalence of needle stick injuries (Galougahi, 2010). In another study in England, 19% of all the needle stick injuries in a health center were related to the operating rooms(Thomas & Murray, 2009).

Despite the high prevalence of needle stick injuries, evidence indicates that surgeons do not report their injuries or take follow up remedial action due to lack of time, lack of belief in infection transmission through needle stick

injuries and deficiencies in infection control systems (Kelly, 2009).

Due to the importance of the issue and uncertainty of prevalence and reporting of needle stick injuries in surgeon specialists affiliated to Kermanshah University of Medical Sciences (KUMS), this study was conducted to explain the prevalence and reporting of needle stick injuries in surgeons of KUMS during the first six months of 2012.

2. Methods

This study is a cross-sectional descriptive-analytical survey conducted in 2012 in the educational hospitals of KUMS. The population includes all the faculty surgeons of KUMS (n=37), a list of whom was received from the university's Deputy Chancellor of Health. Twenty nine of them were studied based on census method and others did not participate in the study due to unwillingness or not being available. Inclusion criteria were attendance at work during the first six months of 2012 and willingness to complete the questionnaire.

The research instrument used to collect the data was a two-part questionnaire. The first part was related to personal and occupational information, including 7 questions about age, gender, specialization, work experience in the medical profession, work experience as a surgeon, the mean number of operations per day and daily working hours.

The second part of the questionnaire included 12 questions about needle stick injury experiences, the instruments causing the injuries, the type of surgery, surgery duration times, the probable cause of injury, actions taken, and the prevalence of vaccination against HBV. The questionnaire was taken from an England study on "the prevalence and reporting of needle stick injuries in surgeons" by Thomas et al. (Thomas & Murray, 2009). First, the questionnaire was translated into Persian and then into English. The two translations were scrutinized for discrepancies. Content validity was considered the indicator of questionnaire validity. Hence, the questionnaire was given to 12 faculties and modified based on their comments. For internal consistency, Cronbach alpha was calculated for the questionnaire as 0.78.

In order to collect the data, written permission was first obtained from the KUMS Vice Chancellor for Research and Technology for this project, then it was approved as no. 91049. A list of surgeons and their work place was received from the health deputy of KUMS. Next, the researcher collected data by visiting the operating rooms. The aim of the study was explained to the participants, their informed consent was obtained, and then they were asked to complete the questionnaire. All the participants were assured of the confidentiality and anonymity of their personal information, following which the completed questionnaires were gathered. The time required for completing the questionnaires was less than 10 minutes. The data was collected over a period of 3 months from September to November, 2012.

Data was entered into the 16th version of the Statistical Package for Social Sciences (SPSS v.16.0; SPSS Inc., Chicago, IL, USA) software and analyzed by descriptive (frequency percent, mean and standard deviation) and inferential statistics (chi-square and Mann–Whitney U test). The chi-square was used to determine the differences between two groups of the injured and non- injured in terms of gender and specialization variables. The Mann–Whitney U test was implemented to compare the participants' mean work experience, operation experience, number of operations performed and daily working hours in both groups. In order to determine the normality of quantitative variables (age, operation experience, daily working hours and number of operations per day) the Shapiroo-Wilk test was used, of which the P value was less than 0.05. The significance level for all tests was 0.05.

3. Results

3.1 Participant Characteristics

Of the 37 surgeon faculty members of KUMS, 6 persons (16.2%) were unwilling to participate in the study and 2 individuals (5.4%) were also not available due to absence. Therefore data was analyzed on 29 participants (78.4 %). Of the 29 participants, 26 (89.7%) were males and 3 (10.3%) females. The mean and standard deviation (SD) of age was 49.96 ± 7.45 yrs. Most of the participants specialized in general surgery (8 members, 27.6%), orthopedic (5, 17.2%), nephrology (5, 17.2%), and neurosurgery (4, 13.8%), respectively. Two specialists each (6.9%) in ophthalmology, cardiovascular surgery and ENT (ear, nose and throat), and one urologist, were the other research participants.

3.2 Comparing Injured and Non-Injured Groups

Over the past 6 months, 5 persons (17.2%) were injured, 3 of whom (60%) were female and 2 were male. The chi-square test showed a significant difference between the genders in both the injured and non-injured groups

(P = 0.003, X^2 = 12.56, df = 1). However, there was no significant difference between the two age groups. Of the total injury cases, 4 (80%) happened in the morning and the others (20%) occurred during the evening shift. The chi-square test found no significant difference between the two groups in terms of their work shifts.

About 82% of the sample (n=24) had been vaccinated against hepatitis B. The mean and SD of surgical work experience of the participants was 14±6.25 yrs. than it was 12.6±2.5 and 13.91±6.8 yrs. in the injured and non-injured groups respectively. There was no significant difference between the two groups in terms of surgical work experience. The mean and SD of daily work was 11.31±2.8 hours per day, this rate was higher in the injured group (11.95±2.6 vs. 8.2±0.83 hours). The Mann-Whitney U test showed that the two groups (the injured and non-injured) differed significantly in terms of daily work hours (P= 0.04, Z=2.85).

The mean and SD number of daily surgeries was 7.85±3.31 cases, which was higher in the injured group than the non-injured group (8.25±3.22 vs. 4.4±1.34). The two groups differed significantly according to the number of surgeries per day (P= 0.016; Z= 2.40). (Table 1)

Table 1. comparison of the demographic characteristics between injured and non-injured groups

groups variables		Injured (means± SD)	Non-injured (means± SD)	Total (means± SD)	Statistical values
Age (year)		45.80± 4.81	50.83± 7.68	49.96± 7.45	Z= 1.35 P= 0.174
working experience in medical profession (year)		16.60± 2.07	19.37± 6.51	18.89± 6.05	Z= 1.39 P=0.165
working experience as surgeon (year)		12.6 ± 2.5	13.91±6.8	14.0±6.25	Z= 0.694 P= 0.487
Operations numbers per day		8.25± 3.22	4.4±1.34	7.85 ± 3.31	Z= 2.40 *P= 0.016
daily working hours		11.95± 2.6	8.2 ±0.83	11.31 ± 2.8	Z=2.85 *P= 0.04
sex	male	2 (7.7%)	24 (92.3%)	26 (100%)	$x^2 = 12.56$ *P=0.003
	female	0.0%	3 (100%)	3 (100%)	
Injection HB Vaccine	yes	5 (20.8%)	19 (79.2 %)	24 (100%)	$x^2 = 2.09$ P=0.553
	no	0 (0.0%)	5 (100%)	5(100%)	

*significant.

3.3 Measures After Injury

The cause of 60% of the injuries was a suture needle, and the remaining 40%, 20% each were made by needles and scalpels. All of those who were injured (5 people) mentioned carelessness as the cause of injury. The most common measures taken after the injury by affected surgeons included changing their gloves (100%), pressure on the injured region (60%) and disinfecting with alcohol and Betadine (60%), respectively. Among those affected, only one participant was referred for blood tests in the laboratory (Figure 1).
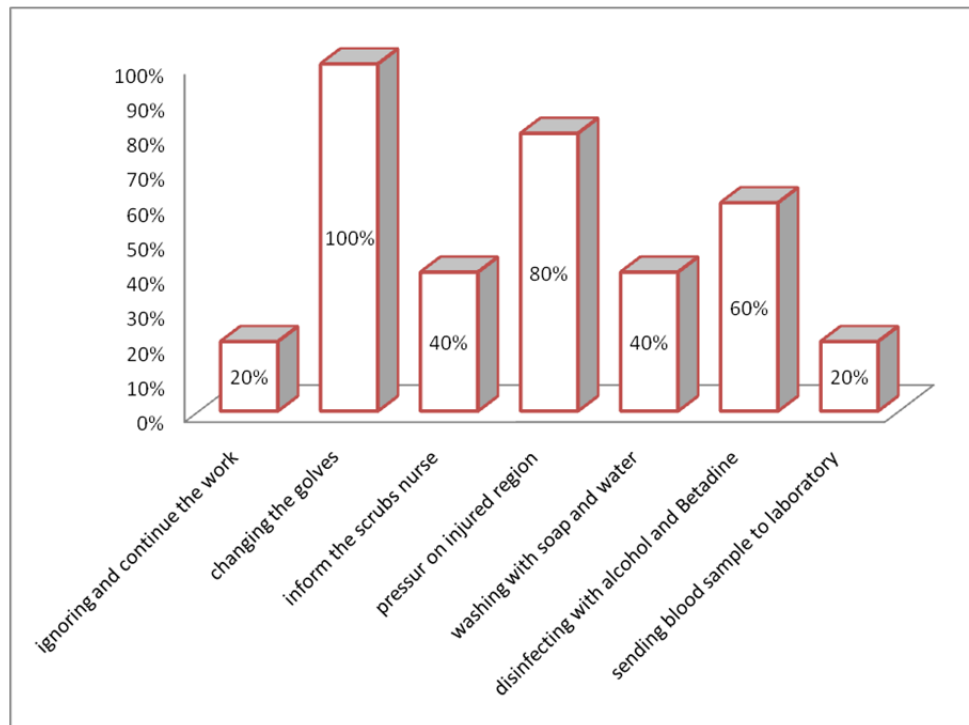
Figure 1. Frequency percentage of measures taken after needle stick injury of surgeons

4. Discussion

The purpose of this study was to evaluate the prevalence and reporting rate of needle stick injuries from sharp objects in surgeons. The results showed that the frequency of injuries was nearly high (17.2% over 6 month). In comparison, Thomas et al. (2009) reported the UK incidence of injury from sharp objects in surgeons as 44% over 6 months (Thomas & Murray, 2009). In another study conducted in China, at 93.09% during their working period, operating room staff and surgeons had the highest incidence of injury from sharp objects after the delivery ward staff, (Shi et al., 2011). In a German study compared with other medical hospital personnel, physicians had the highest rate of needle stick injury (Wicker et al., 2008). A study conducted in India, showed surgeon's assistants were more exposed to needle stick injuries than other health care workers (Rele, et al 2002). Similar studies in Pakistan and England demonstrated working in operating rooms is the main factor increasing prevalence of needle stick injuries (Afridi et al., 2013; Gaballah et al., 2012). Results of these studies are consistent with findings of our research on needle stick injuries. In this regard, the researchers believed that the relatively high prevalence of needle stick injuries in surgeons is due to exposure to instruments such as scalpels, suture needles and sharp forceps, as well as failure to follow the instructions and standards for correct use of the instruments, not wearing protective equipment and not disposing of sharp objects after use, all play an important role in increasing the risk of injury in surgeons.

The most common cause of injury in our study was using the suture needle during surgery. In this regard, the study of Eftaei et al. (2009) in Nigeria also indicated that more than 86% of the injuries in surgeons have occurred during suturing (Efetie & Salami, 2009). In the study of Shi et al., the most common cause of injury was also syringes and needles, and suture needles were the cause of 17% of reported injuries (Shi et al., 2011). Lack of attention to the application of such sharp instruments as suture needles, which surgeons mostly deal with, and also using non-standard instruments could increase the risk of needle stick injuries. Hoffman and colleagues suggested that the main cause of injury was the improper use of equipment and sharp objects (Hofmann et al., 2002). Gurgia and De Weerd, (2009) have noted the use of safety equipment and taking safety precautions during procedures as important factors in reducing the injuries caused by sharp objects.

In recent studies, it has been suggested that surgeons use new surgical techniques such as blunt suture needles and electrosurgical suspension apparatus to reduce the risk of needle stick injuries (Parantainen et al., 2011; Weber et al., 2000). Such measures as placing a tip along the needle forceps after using the suture needle, have been recommended to prevent accidental penetration of the skin (Gurgia & De Weerd, 2009). Providing standard

and low risk instruments, as well as holding regular training courses on new techniques for their safe and low-risk operation, can also reduce the prevalence of needle stick injuries in surgeons.

The results of this study showed that the reporting rate in surgeons was low and follow-up treatment and tests after they received a needle stick injury was rare. Most considered replacing the gloves and disinfecting the injury site sufficient. The results of the study by Thomas and colleagues showed that only 9% of surgeons who suffered from needle stick injuries reported their injuries and more than 70% of them only took initial actions (Thomas & Murray, 2009). In a similar study in Nigeria, 9.2% of surgeons observed the protocols, and the reporting and follow-up interventions after experiencing injuries with sharp objects (Efetie & Salami, 2009). The results of the present study are consistent with the findings of these studies. Previous research on other medical personnel has recorded higher levels of reporting of needle stick injuries. For instance in a study by Khader et al. 23% of dentists injured by needles and sharp objects reported the incident (Khader et al., 2009). In another study conducted on health care workers in an Indian hospital, 68% of injuries from sharp objects were reported and follow-up action was taken (Jayanth et al., 2009).

There are several reasons for non-reporting of needle stick injuries by surgeons. A UK study mentioned two causes, including low risk of contamination and time-consuming reporting processes (Wicker et al., 2008). Kennedy et al. also found surgeons' fail to follow up and report injuries. Issues such as time-consuming processes, low transmission probability from sharp object injuries, reluctance to interrupt surgery and follow instrument use instructions, and the low efficacy of treatment and prevention of post-injury were also recorded by Kennedy et al. (2009). In the present study, the low number of reported injuries, in addition to the aforementioned reasons, were due to surgeons' high workloads and difficulties following the post injury instruction processes.

In the current study, the rate of injury was significantly higher in females than males and the surgeons who performed more surgeries per day and worked more hours daily had higher injuries. In terms of experience, age and shift work, there was no significant difference between the injured and the non-injured groups. The research of Galogahi et al. in Tehran, showed that age, gender and work experience were not related to the frequency of injury from sharp objects incurred by medical staff (Galougahi, 2010). But Khader et al. stated that with the increasing the age of surgeons and the higher numbers of patients, the rate of injuries had increased significantly (Khader et al., 2009). In another study, the surgeons who had less experience were more susceptible to injury from sharp objects (Jayanth et al., 2009), and in a study by Kummar et al., the intensity of their daily work was mentioned as a predisposing factor to needle stick injury in medical staff (Kumar et al., 2011). This is in line with the current research findings. The excessive workloads and long working hours may lead to fatigue and poor concentration in surgeons, and thus increase the chance of injury from sharp objects.

5. Conclusions

The results indicate a relatively high prevalence of injuries from sharp objects and low levels of reporting and follow-up. Regular workshops on new techniques for safe operation are suggested to reduce the exposure of surgeons to injuries by sharp objects. Due to the small sample size of this study, it is difficult to determine the effect and relationship of gender, work experience, and the workload of surgeons on the frequency of needle stick injuries. Hence, more studies are necessary in this field. It is recommended that the factors associated with the follow-up and reporting of needle stick injuries in surgeons be assessed with a larger sample size.

Conflict of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Hydroxyurea: Clinical and Hematological Effects in Patients With Sickle Cell Anemia

Bijan Keikhaei[1], Homayon Yousefi[1] & Mohammad Bahadoram[2]

[1] Health Research Institute, Research Centre of Thalassemia and Hemoglobinopathies, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

[2] Medical Student Research Committee & Social Determinant of Health Research center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

Correspondence: Bijan Keikhaei, Thalassemia & Hemoglobinopathy Research Center, Ahvaz Jundishapur University of Medical Science, Ahvaz, Iran. Tel: 98-916-617-3271. E-mail: keikhaeib@yahoo.com

Abstract

Background and Aim: It is well known that hydroxyurea impacts on clinical and hematologic indices in sickle cell disease (SCD), we aimed to evaluate the effect of hydroxyurea on clinical and hematological improvement of sickle cell anemia.

Methods and Materials: In this cohort study 48 patients with sickle cell disease were enrolled and pain crisis, severity of pain, acute chest syndrome, the number of hospitalization, the rate of transfusion, spleen size, total Hb, HbF levels, MCV, MCH were compared before and after treatment with HU 10 mg/kg/day/for one year.

Results: In patients with Sickle cell disease Hu significantly decreased the rate of transfusion, hospitalization, spleen size and significantly increased Hb, RBC indices and HbF. Furthermore, we did not find any remarkable adverse effect related to HU during the one year follow up in patients.

Conclusion: We demonstrated that in the course of one year hydroxyurea 10 mg/kg/day can significantly increase HbF, total hemoglobin and RBC indices without any notable side effect in patients with SCD.

Keywords: hydroxyurea, sickle cell anemia, hematological improvement

1. Introduction

Sickle cell disease (SCD) is an autosomal recessive inherited hemoglobinopathy. This condition causes vaso occlusive phenomena and hemolysis due to the substitution of the amino acid valine for glutamic acid at the sixth position on the beta globin chain.As a resulta hemoglobin tetramer (alpha2/beta S2) known as Hemoglobin S (HbS) is produced that is low soluble and polymerized when it is deoxygenated (Inati et al., 2008). SCD occurs worldwide but it is more prevalent in Africans, and its mortality rate in children in developed world is about 0.5-1.0 per 100,000 due to infection, acute chest syndrome and stroke. Regular transfusion is meant to sustain hemoglobin rate above 10. Transfusion helps with ease of movement and slows progressive hyperplasia of bone marrow and hence reduces the risk of heart dialation and face and limb changes due to bone deformation (Bain, 2009; Pack-Mabien & Haynes, 2009; Booth et al., 2010; Keikhaei et al., 2013; Bavarsad Shahripour et al., 2014). The level of Fetal hemoglobin (HbF) in patients with Sickle-cell anemia is different. HbF restricted the intracellular polymerization of sickle hemoglobin, hence, it has a positive impact on SCD (Green and Barral 2011). Recently, it's been demonstrated that some chemical agents such as placental gonadotropin, progesterone, Azacitidine, Milrinone, erythropoietin, arginine butyrate, phenylbutyrate and hydroxyurea rise hemoglobin level with hydroxyurea being the least dangerous of them. Therefore, some drugs such as hydroxyurea (HU) and 5-azacytidinethat motivate HbF formation are practicing treatments for SCD so as to reduce the severity and frequency of SCD episodes (Green & Barral, 2014). Hydroxyurea has a decreasing effect on anemia and reduces the need for HbF due to frequent transfusions. Hydroxyurea is a urea analog which was first synthesized in 1869 by a German chemist. The chief action of hydroxyurea is inhibiting ribonuklexid d-phosphate ridaktaz (RDR) enzyme which partly provides cells with deoxyribonucleotide while copying DNA during cell division. Several studies indicated that 60% of patients with SCD, response to HU treatment, also these studies emphasized 44%

of patients experienced reduction of painful episodes; however the mentioned studies detected the occurrence of clinical response after long term treatment with HU (Wong et al., 2014). In addition, a number of studies indicated that hydroxyurea have other mechanisms such as leukocyte count decreasing, red blood cell volume alteration, phosphatidylserine exposure reduction and some other mechanisms that result in several clinical advantages in patients with SCD (Agrawal et al., 2014; Green & Barral, 2014; Wong et al., 2014). In this study we investigated the effect of hydroxyurea on clinical and hematological improvement of sickle cell anemia.We decided to address concerns about safety and effectiveness of HU in patients referred to Shafa hospital, Ahvaz, Iran.

2. Methods

In this cohort study, 48 children aged 6-18 years were recruited. All the children had sickle cell disease and were admitted to Shafa Hospital, Ahvaz, Iran, from 2013 to 2014. The criteria for enrollment were sickle cell disease and written consent for participating in the study. Patients were excluded if they had active liver disease, creatinine more than 1.5 mg/dl and treatment other than Hu. The study procedure was explained for all patients and their parents and written informed consent was taken. The study was signed by ethical committee of Ahvaz University of medical sciences and research center for thalassemia and hemoglobinopathy. Specific questionnaires were designed for all children and demographic data such as age and sex and duration of disease were recorded. Moreover clinical manifestations of patients such as pain crisis, severity of pain, chest pain syndrome, the number of hospitalization, number of visits by specialist because of pain and the rate of transfusion were registered. Furthermore, blood test such as CBC, and Hb electrophoresis, HbF measurement, liver and kidney function tests were performed for all patients before treatment and repeated periodically. Then hydroxyurea 10 mg/kg/day was administered for one year. Hydroxyurea dosage was determined according to pediatric section's assessment of endurance and weight of the patient. During this time the patients were referred monthly to Shafa Hospital to receive their medicine. They were watched closely by the pediatric section in case there was a need to repeat tests or take a particular measure. At the end of the study all tests were measured again and any possible adverse effects related to HU were evaluated and recorded. Toxicity for this drug was defined as follows: Neutrophils less than 2000 µl, Platelets less than 80000 µl, Hemoglobin less than 4.5 g/dL, Reticulocyte count less than 0.8%, In case of toxicity with any of the above criteria, the drug was discontinued and after normalization of complete blood cell count, it was continued as 10 mg for every kg of body weight.

Data were analyzed using SPSS version 21.Categorical data were presented as numbers (%), and continuous data as mean ± SD. We used the Chai_2 test to compare categorical variables. α< 0.05 was consider significant.

3. Results

In this study 48 patients with SCD were treated with HU and evaluated. These patients consisted of 24 males and 24 females. The minimum age was 6 and the maximum was 18. The initiating age for anemia symptoms for this group of patients was between 2 and 7 years old. The mean initiating age was 13.7 years. No patient had splenectomy. We showed that in patients with Sickle cell disease Hu significantly (P=0.001) decreased the rate of transfusion and 100% of patients became completely transfusion free.

Table 1. Clinical manifestations and hematologic indexes in patients with sickle cell disease

Variables		Sickle Cell Disease		P-value
		Pre Treatment	Post Treatment	
Transfusion	yes	32(66.7%)	0	0.001
	No	16(33.3%)	100	
Hospitalization	No	2(4.2%)	39(68.7)	0.03
	1	9(18.8%)	10(20.8%)	
	2	14(29.2%)	3(6.3%)	
	3	19(39.6%)	2(4.2%)	
	4	4(8.5%)	0	
	total	46(93%)	15(31.3%)	
Visit And	no	0	45(93.8%)	0.01

Hospitalization	1-2	13(27.1%)	1(2.1%)	
Because Of Pain	3-4	34(70.8%)	2(4.2%)	
	>4	1(2.1%)	0	
	total	48(100%)	3(6.3%)	
Crisis	1	9(18%)	17(79.2%)	0.002
	>1	39(81.3%)	31(20.8%)	
ACS	1	18%	79.2%	0.002
	>1	81.3%	20.8%	
Hb(G/L)	<6	4(9.1%)	0	0.002
	6-8	13(27.3%)	9(2.1%)	
	8-10	25(52.3%)	28(18.8%)	
	10-12	4(9.1%)	10(20.8%)	
	>12	1(2.3%)	1(58.3%)	
MCH(Fl)	<20	2(4.2%)	8(16.7%)	
	20-27	27(56.3%)	5(10.4%)	
	27-30	8(16.7%)	3(6.2%)	
	>30	11(22.9%)	32(66.7%)	
HbF	<5%	8(16.7%)	0	0.02
	5-10%	9(18.8%)	0	
	10-15%	5(10.4%)	5(10.4%)	
	15-20%	6(12.5%)	5(10.4%)	
	20-25%	6(12.5%)	14(29.9%)	
	>25%	14(29.9%)	24(50.4%)	
MCV	<80	28(58.3%)	27(56.3%)	0.2
	80-100	18(37.5%)	15(31.3%)	
	>100	2(4.2%)	6(12.5%)	

Moreover, HU treatment significantly decreased the rate of hospitalization from 93% to 31.5 %(P=0.03) and number of visits by specialist because of pain reduction from 100% to 6.3% after treatment (P=0.01). The number of pain crisis > 1 decreased from 81.3% to 20.8% (p=0.002).The number of ACS >1 decreased from 81.3% to 20.8 %(p=0.002). Additionally, HU therapy significantly reduced the serum level of MCH<30, Hb F < 20%, MCV<100fl, Hb<10 and significantly increased MCH>30, HbF > 20%, MCV>100fl, Hb>10. (table1). Regarding response to treatment, in the first 6 months, 60% of patients (24) yeilded more than two fold and in Hbf at end of treatment, this increase was observed in 70% of patients. We showed HU therapy to be well tolerated by our patients and remarkable adverse effects were not reported in patients after one year treatments with HU 10mg/kg/day. Evaluating satisfaction rate of this group of patients, it is revealed that the reason for satisfaction is primarily due to decrease or absence of transfusion and also reduction in bone pain during the course of treatment. Furthermore, reducing fatigue and lethargy was expressed as another reason for satisfaction from patients.

4. Discussion

Previous trial detected that Hydroxyurea is an antimetabolite inhibitor that increases the serum level of total Hb, Hb F, MCH and MCV. Furthermore, it increases transfusion intervals and significantly improves clinical abnormalities (Karimi et al., 2005; Segal et al., 2008). We recruited 48 children with SCD treated with hydroxyurea 10mg/kg/day for one year. We revealed HU significantly decrease the rate of transfusion, hospitalization and number of visits by specialist, moreover improve the level of Hb, MCH, Hb F and MCV. In agreement with our results, Hashemi et al. in a study indicated that Hydroxyurea treatment decreases the numbers of regular transfusion requirement (Hashemi et al., 2009). Moreover, another study in harmony with our

findings by Neves et al. showed HU treatment for the duration of one year significantly increases MCV in patients with sickle cell disease (Neves et al., 2012). As mentioned before the valuable effects of HU are fetal hemoglobin induction, decreased cell adhesive properties, inflammation and hypercoagulability (Karimi et al., 2005; Segal et al., 2008). Our results confirmed these findings and showed the level of Hb F improved in our patients after one year of treatment. Consistently, a study by Jeffrey indicated that induction of fetal hemoglobin is an essential mechanism for clinical advantages of hydroxyurea treatmen (Lebensburger et al., 2010). Additionally, another study by Cokicwas in tune with this finding and showed hydroxyurea treatment to increase the level of Hb F in patients with sickle cell disease (Cokic et al., 2003). Other studies also have exposed similar outcomes. A practice by Patel et al. in 2014 supported our results and revealed that treatment with HU at dose 10mg/kg/day significantly increases HbF, total hemoglobin, MCV, and MCH levels (Patel et al., 2014). Furthermore another experience in 2012 by Patel et al. revealed significant increase in serum level of Hb F, total hemoglobin (Hb), MCV and MCH after treatment with hydroxyurea(Patel et al., 2014).

In current trial, the number of pain crisis > 1 decreased from 81.3% to 64.6% after treatment. However the difference was not significant (P=0.08).In contrast Patel et al. in their survey described that HU significantly decreased the rate of pain crisis in patients with SCD (Patel et al., 2014).

The side effects of hydroxyurea are one of the most important concerns. Since some experiments reported several adverse events in patients treated with HU, for example,Ghasemi et al. (2014) indicated dermatologic (39.28%), neurologic (23.2%), gastrointestinal (17.5%) and hematologic (10.71%) events in patients with thalassemia and sickle cell disease.Nonetheless, they highlighted that side effects were transient and non-significant and HU was well tolerated by all patients (Ghasemi et al., 2014). Hence, in current practice we followed up patients both for advantages and possible side effects. All patients in this survey tolerated HU treatment well and did not show any significant adverse effects. Consistently, other studies supported these findings and exposed that HU is a safe agent without remarkable adverse events in children with SCD (Patel et al., 2012)., Also Zamani et al. found no malignancy in five years follow upand only detected one patient with transient thrombocytopenia.

While the carcinogenic effects of long-term HUtherapy is a thoughtful concern no malignancy were found in previous studies regarding HU treatment in patients with sickle cell disease and HU was confirmed to be a safe agent in studies with 5 to 10 yr follow-up (Zamani et al., 2009).

Several limitations are inherent to the present study such as small sample size and short duration of study that limit the ability to generalize the results of our survey.Moreover, this was not a comparative study so we could not compare the effect of HU with other treatment modalities.Further comparative studies are recommended with longer follow-up and larger scales to validate the findings reported here and to answer the question regarding whether HU is a true disease modifiers.

5. Conclusion

The results showed hydroxyurea 10 mg/kg/day for one year durationin patients with SCD significantly increased HbF, total hemoglobin, MCV, MCH, and without any remarkable adverse events.

Acknowledgements

Conflict of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

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