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Validation for the Children Health Promotion Scale: Development and Psychometric Testing

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Abstract

Background: Several investigators have developed health promoting lifestyle instruments for adult population. However, few instruments in Taiwan have focused on health-promoting lifestyle measurements from the perspective of children.

Methods: The Children Health Promotion scale (CHP) was developed to focus on health promotion among children. The content validity was supported on the observations of a 6-member panel of experts. Here, based on the responses of 681 Taiwanese children, we examined the construct validity and reliability of the CHP as well as its psychometric properties through factor analysis and reliability measures.

Results: The results of Kaiser-Meyer-Olkin (KMO) and Bartlett's sphericity tests indicated that our sample fulfilled the factor analysis criteria. Moreover, the factor analysis yielded a 6-factor instrument, explaining 52.5% of variance in all 32 items; the 6 factors were myopia prevention, stress management, health maintenance behaviors, nutritional behaviors, physical activities, and basic health-promoting behaviors. The Cronbach's alpha reliability coefficient for the total scale was 0.92 and alpha coefficients for the subscales ranged from 0.71 to 0.85.

Conclusion: The results of this study indicate that the CHP has satisfactory construct validity and reliability for Taiwanese children. School health providers can therefore use the CHP for children's health promotion efforts.

Keywords: health promotion; healthy lifestyle; instrument development; children

1. Introduction

Since the 1960s, health promotion research has increased substantially and has been extended to include individual, family, and community health promotion (Walker, Sechrist, & Pender, 1987). During the 1980s and early 1990s, research on health promotion increased, and the models of health enhancement were thus proposed (Pender & Barkaskas, 1992; Walker et al., 1987). This shift toward health promotion was illustrated by Pender and Barkaskas (1992), who described health-promoting behavior as an actualizing tendency "directed toward sustaining or increasing well-being, personal fulfillment, and self-actualization." This perspective has recently been expanded to include contextual or socioecological influences on health promotion.

Research has shown that practicing health promotion behaviors decreases the incidence of disease (Byers, Wick, & Beard, 2011; Gerçek & Şen, 2015), and lowers the mortality rate (Silva, 2014). Since 2013, distinguished global health leaders, health ministers, officials, and experts have been gathering in Taiwan to discuss and share insights on crucial worldwide health issues, such as communicable diseases, obesity, ageing, and health inequality (Health Promotion Administration, 2016; 2014a). Although research has long been focused on activities directed toward healthy lifestyle promotion, the special requirements of children's nursing care remain largely underreported. Many Taiwanese children follow unhealthy lifestyle practices, including high-fat diet, high-sugar diet, lack of exercise, physical inactivity (frequent use of televisions, computers, and mobile phones), and chronic exposure to environmental risk factors for vision and dental problems (Health Promotion Administration, 2014a; Lin, Chang, Luh, Hurng, & Yen, 2014; Liou, Yang, Wang, & Huang, 2015; Tsai et al., 2015). Reformation of the current status

is urgently required.

Recent evidence demonstrated that physical activity decreases from the age of school entry (Cheval, Courvoisier, & Chanal, 2016). Low physical activity is rapidly becoming the social norm in most countries and thus is becoming a critical risk factor for the obesity epidemic. In Taiwan in 2014, the prevalence of overweight and obese children was 34.0% and 25.0% for boys and girls respectively (Hsieh, Chen, Huang, Chen, Li, & Chang, 2014). Obesity also reduces physical activity, thus creating a vicious cycle of increasing body fat levels and declining physical activity. Unhealthy diet and lack of exercise are the main causes of obesity, which in turn is a major risk factor for chronic diseases and causes of several childhood morbidities (World Health Organization, 2016). Children should be encouraged to increase physical activities (Ryan, 2015) and consume various healthy foods by repeatedly and positively exposing them to new foods, by showing them that caregivers and family members enjoy healthy foods, and by limiting their exposure to unhealthy foods (to prevent developing preferences for extremely sweet foods and drinks) (De Lepeleere, De Smet, Verloigne, Cardon, & De Bourdeaudhuij, 2013; Nybery, Norman, Sundblom, Zeebari, & Schäfer Elinder, 2016). This will help to facilitate the development of healthy lifestyle habits in from an early age and improve learning ability, mental health, and well-being.

The prevalence of myopia had increased significantly globally. Scholars predict by 2050 there will be 4758 million people with myopia and high myopia (Holden et al., 2016). The incidence of myopia in elementary schoolchildren with aged 10-11 years is 55.53% in Taiwan (Chang, Wu, Niu, Chen, & Liao, 2016). The younger that children suffer from myopia, the faster their eyes deteriorate (Cruickshank, Logan, & Parulekar, 2015; Ohno-Matsui, Lai, Lai, & Cheung, 2016). Poor vision among schoolchildren has been a persistent main health issue considered by Taiwan's education and health authorities. Since 2010, Taiwan's implementation of its empirical vision care strategy during outdoor school activities has facilitated vision improvement among elementary schoolchildren (Wu, Tsai, Wu, Yang, & Kuo, 2013). Dental caries is one of the oral diseases in Taiwanese children. The prevalence of dental caries among 5-6-year-olds (79.32%) in Taiwan (Health Promotion Administration, 2014b) is significantly higher than the global goals for oral health among 5-6-year-olds children ($\leq 50\%$) (World Health Organization, 2000). To ensure oral hygiene and cleanliness, children should learn the correct methods of brushing teeth; in addition, they should rinse their mouths after meals and brush their teeth in the morning and at night. These activities should be supervised by healthcare providers to provide comprehensive preventive oral health care (Simmer-beck et al., 2011). Parent, family, and social support is associated with health promotion behaviors of schoolchildren (Forthofer, Dowda, McIver, Pate, & Barr-Anderson, 2016; Donnelly & Springer, 2015). Most children have very few opportunities to communicate with supportive adults, their ability to survive the turbulent phases of growing up and ways for protecting their health remain underdeveloped. However, these unhealthy lifestyle risk factors of schoolchildren have not been prioritized in health services of Taiwan.

In the past, public health institutions worldwide have increasingly emphasized the importance of healthy lifestyles. Nurses, particularly school nurses and community-health nurses in primary health care settings, can easily promote healthful habits by assessing the lifestyle patterns of children, intervening to facilitate positive behaviors, and intervening to discourage negative behaviors. Several investigators have developed health promoting lifestyle instruments for adult population (Chen, Chaou, Shiou, Wang, & Liao, 1996; Walker et al., 1987). However, few instruments in Taiwan have focused on health-promoting lifestyle measurements from the perspective of children, and school nurses in Taiwan lack suitable measurements for assessing the comprehensive health of children. Such instruments could aid in evaluating the success of nursing programs in promoting healthy lifestyle development. This study assessed the psychometric properties of a newly devised Children's Health Promotion scale (CHP) in Taiwanese children.

2. Methods

This study was approved by the Institutional Review Board of Chang Gung Hospital in Taiwan (approval number: 101-0617A3). Both the selected children and their parents were oriented on the objectives and procedures of this study, following which they provided written informed consent for participation.

Participants in this study included a representative sample of public and private elementary school students. We employed stratified random sampling according to school districts and different classes for random selection of representative samples. Urban and rural students, ranging from grades 4 to 6, were recruited from north, central, and south Taiwan.

The CHP was formulated on the basis of the Adolescent Health Promotion scale (AHP) conducted by Chen, Wang, Yang, & Liou (2003) and a review of literature. With consent from the author, a portion of the items were extracted for use in this study. The CHP was constructed in a 5-point response format to obtain data regarding the frequency of reported behaviors (never, rarely, sometimes, usually, always), with scores ranging from 1 to 5. The validity of

the content was assessed by 6 child counseling experts, employed at elementary schools, junior colleges, and universities; these experts included psychologists, health educators, and physicians at school health centers and nursing faculties. All experts were asked to rank the items' priorities, to delete or add information, and to provide an agreement score for each item. All experts rated more than 85% of the 35 items as "appropriate." On the basis of feedback from the content experts, we made editorial changes to the AHP, deleted some items, and added other items, produce a CHP instrument.

Next, this CHP instrument was tested among 12 children (elementary school students). Chinese Zhuyin phonetic symbols were used in this scale so that schoolchildren could read and understand the questions easily. As our CHP scale was adapted for children 9-12 years of age, hence five non-applicable questions were deleted from the original scale. 'Observe my body at least monthly', 'search for health information', 'search for health information', 'use adequate responses to unreasonable issue', and 'make an effort to choose foods without additives' were removed from the questionnaire. The questionnaire was 35 questions.

3. Results

There were 681 participants aged 9–12 years (mean, 11.2 years; median, 11 years). 326 (47.9%) were female and 355 (52.1%) male. The educational level of 335 (49.2%) of the participants' fathers was grade 12 (high school or vocational level) and that of 86.7% of the participants' mothers was grade 7–12. Most participants lived with both their parents (81.4%), whereas the other participants had single parents.

3.1 Content Validity

To understand the health promotion activities for schoolchildren's health, this scale adopted a structured survey, with a design based on literature reviews, focus group interviews, suggestions of health promotion experts and researchers with school health promotion experience. This research team selected survey items conforming to the aim of this study. The initial questionnaire contained 35 questions, with 5 points for "always: approximately 90% of the time, I have done it (81–100%)," 4 for "frequently: approximately 70% of the time, I have done it (51–81%)," 3 for "approximately half: approximately 50% of the time, I have done it (31–50%)," 2 for "occasionally: occasionally participate in this behavior, approximately 30% of the time, I have done it (11–30%)," and 1 for "never: never participated in this behavior, or less than approximately 10% of the time, I have done it (0–10%)." Relatively high scores on the scale represented relatively high levels of success in healthy lifestyle promotion. After the survey had been constructed and piloted, it was administered to 681 third to sixth grade schoolchildren. The Cronbach's alpha of the final scale was 0.92.

3.2 Factor Analysis

Before exploratory analysis, Kaiser-Meyer-Olkin (KMO) and Bartlett's sphericity tests were used to measure the sampling adequacy. The results showed that the KMO measure was 0.92 and the significance of Bartlett's sphericity was 0.000 ($\chi^2 = 8065.88$, $df = 681$, $p = 0.000$), indicating that the samples met the criteria for factor analysis (Hair, Anderson, Tatham, & Black, 1998). Principal component factor solution explained a variance of 52.5% and had eigenvalues of >1.00 . According to the scree plot (Figure 1), the slope of the curve became emergent at the sixth point, and factors 7-9 only contributed 5% of the accumulated variance. We eliminated 3 items because they did not load strongly on a single factor; thus, we decided on using a 6-factor instrument. The remaining 32 items were entered into the factor analysis. All items loaded on the expected factors, and the variance was 0.45 for most items, except for two items with variance <0.4 (Table 1). The factor analysis of the resulting 32-item instrument yielded a 6-factor solution with an explained variance of 52.49% (Table 2).

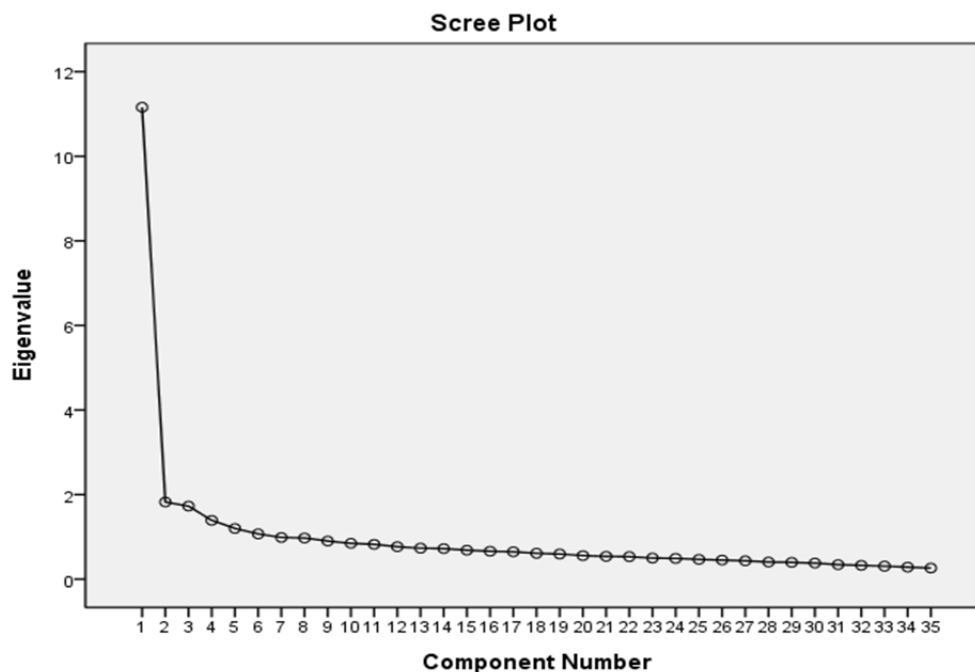


Figure 1 The scree plot

Table 1. Factor loadings and factor structure of the Children Health Promotion scale (N=681)

	1	2	3	4	5	6
28. When watching television, I take a 10-min break for every 30 min of television.	0.89					
29. When using computers and cellphones, I take a 10-min break for every 30 min of use.	0.78					
27. When reading or writing diligently, I take a break for 10 min every 30 min.	0.75					
32. During the day, I don't strain my eyes by looking at a computer, television, or cellphone screen for longer than 1 h.	0.73					
30. I quietly sit down and rest my eyes, away from any harmful light or glowing screens for some time.	0.64					
26. When writing, I maintain a distance of approximately 35 cm between my eyes and the book.	0.63					
31. I watch television or use computers in well-lit rooms.	0.43					
34. I wear a hat when I perform outdoor activities.	0.40					
8. I talk about my concerns with others.		0.88				
10. I talk about my troubles with others.		0.87				
23. Every time I am depressed, I try to find the reason for that feeling.		0.56				
9. I laugh or smile every day.		0.53				
7. When I have concerns, I contact healthy persons on my own initiative.		0.51				
15. I appreciate myself.		0.50				
12. After a meal, I brush and floss my teeth.			0.76			
17. It is somewhat depressing to me to recognize that my life will end.			0.67			
13. I wash my hands before each meal.			0.65			

11.	I obey laws when I buy consumable items.	0.60
16.	I detect and correct all my mistakes.	0.47
18.	When I am faced with a tough situation, I come up with new ways to handle it.	0.44
14.	I read the newspaper for news concerning health.	0.41
25.	I adjust my daily timetable to avoid haste.	0.40
20.	At least 3 times every week, I exercise enough to break a sweat for at least 20–30 minutes.	0.86
21.	In addition to physical education classes, I perform other physical activities (such as walking, swimming, and playing ball) weekly.	0.82
33.	When I go to school, I participate in outdoor activities during breaks.	0.65
19.	I commit myself to maintain daily habits of exercise.	0.60
3.	I consume high-fiber foods (such as whole grains, fruits, and vegetables).	0.60
2.	I try to eat no greasy and nonoil food every day.	0.58
5.	I include five food groups in each meal.	0.53
6.	I eat breakfast daily.	0.69
24.	I sleep for 6–8 h each night.	0.61
1.	I eat 3 meals per day at fixed times.	0.47

Table 2. Eigenvalues, cumulative percentage of variance explained by six factors on the Children Health Promotion scale (N=681)

Factor	Factor label	Eigenvalue	Variance Explained	Cumulative percentage %
1	Myopia prevention	11.16	31.88	31.88
2	Stress management	1.82	5.21	37.09
3	Health maintenance behavior	1.73	4.93	42.02
4	Physical activity	1.39	3.97	46.00
5	Nutritional behaviors	1.23	3.42	49.43
6	Basic health promoting behaviors	1.19	3.05	52.49

Factor 1, myopia prevention, was the strongest factor-explaining the greatest percentage of variance of the CHP. This factor was loaded with 8 items: when watching television, I take a 10-min break for every 30 min of television; when using computer and cellphones, I take a 10-min break for every 30 min of use; when reading or writing diligently, I take a break for 10 min every 30 min; During the day, I don't strain my eyes by looking at a computer, television, or cellphone screen for longer than 1 h; I quietly sit down and rest my eyes, away from any harmful light or glowing screens for some time; When writing, I maintain a distance of approximately 35 cm between my eyes and the book; I watch television or use computers in well-lit rooms; I wear a hat when I perform outdoor activities.

Factor 2 was stress management and included the following 6 items: When I have concerns, I contact healthy persons on my own initiative; I talk about my concerns with others; I laugh or smile every day; I talk about my troubles with others; I appreciate myself; Every time I am depressed, I try to find the reason for that feeling.

Factor 3 was health maintenance behaviors and included the following 8 items: I obey laws when I buy consumable items; After a meal, I brush and floss my teeth; I wash my hands before each meal; I detect and correct all my mistakes; When I am faced with a tough situation, I come up with new ways to handle it; I read the newspaper for news concerning health; I adjust my daily timetable to avoid haste; It is somewhat depressing to me to recognize that my life will end.

Factor 4 is physical activities and included the following 4 items: I commit myself to maintain daily habits of exercise; At least 3 times every week, I exercise enough to break a sweat for at least 20–30 minutes; when I go to school, I participate in outdoor activities during breaks; In addition to physical education classes, I perform other

physical activities (such as walking, swimming, and playing ball) weekly.

Factor 5 was nutritional behaviors and included the following 3 items: I consume high-fiber foods (such as whole grains, fruits, and vegetables); I try to eat non-greasy and non-oily food every day; I include five food groups in each meal.

Factor 6 contained basic health-promoting behaviors and included the following 3 items: I eat breakfast daily; I sleep for 6–8 h each night; I eat 3 meals per day at fixed times.

3.3 Reliability

Cronbach alpha was calculated as the measure of internal consistency for the final 32-item instrument; the total instrument demonstrated high internal consistency, with an alpha coefficient of 0.92 (Table 3). Alpha coefficients for the 6 subscales were in the range 0.71–0.85.

Table 3. Internal consistency of the Children Health Promotion scale and its subscale (N=681)

Subscale	Items	Item-subscale r	Alpha
1. Myopia prevention	8	0.43-0.88	0.85
2. Stress management	6	0.49-0.88	0.79
3. Health maintenance behavior	8	0.38-0.76	0.81
4. Physical activity	4	0.60-0.86	0.76
5. Nutritional behaviors	3	0.53-0.60	0.72
6. Basic health promoting behaviors	3	0.47-0.69	0.71
Total scale	32		0.92

3.4 Scoring

When the instrument was used as a whole, the possible range of scores was 32-160. The total mean score of the 681 respondents on the CHP was 102 (range, 41-143). Histograms of the distributions of the scores on the total instrument and the 6 subscales were fairly symmetrical within the range of scores used (skewness = -0.381, kurtosis = -0.099).

4. Discussion

The original CHP scale contained 35 questions. Three components were extracted through factor analysis. Because their coefficients were less than the absolute value of 0.32, question numbers 4 (drink at least 1500 mL of water daily), 22 (perform warm-up exercises before engaging in strenuous exercises), and 35 (make an effort to deal with unreasonable orders) were omitted; finally, only 32 questions were included. In Taiwan, the current health promotion scales analyze elderly, adult, and adolescent populations; however, no health promotion scales suitable for children has been reported thus far. A salient feature of this scale is the addition of Chinese Zhuyin phonetic symbols so that 9-12-year-old children can read and understand the questions.

Because children represent the future, ensuring their healthy growth and development must be a prime concern of all societies. Myopia is the primary threat to children's vision (Holden et al., 2016). Features of this scale were eye health care strategies included 8 protective behaviors (I quietly sit down and rest my eyes, away from any harmful light or glowing screens for some time; when writing, I maintain a distance of approximately 35 cm between my eyes and the book; etc) to avoid environmental risk factors for myopia during early life (Lyu, Zhang, Gong, Wang, Chen, & Guo, 2015; Ramamurthy, Yu Lin Chua, Lin Chua, & Saw, 2015). Health maintenance behaviors should be established in early and middle childhood. Specially, the protective behaviors of dental health in Taiwanese schoolchildren need to be assessed and oral hygiene activities should be educated from school-based child oral hygiene programs and supervised by adults to provide comprehensive preventive oral health care (Lai, Fann, Yen, Chen, Lai, & Chiu, 2016). The item 'I obey laws when I buy consumable items'. Unfortunately, most markets are overrun with adulterated food items. From an early age, schoolchildren should be encouraged to develop the habit of checking the ingredients and expiry dates of food items before purchasing them. The item 'When I am faced with a tough situation, I come up with new ways to handle it', can encourage schoolchildren to develop a positive outlook starting from an early age.

The results of this study not only make the government and schools more aware of the health protective factors that

are beneficial for schoolchildren, but they also propose an effective program to rectify the health promotion factors, resulting in an improvement on the healthy lifestyles of schoolchildren in Taiwan. In this study, the CHP measured the concept of health promotion and the health protection behaviors. This result is different from a study by Chen et al. (2003) who developed Adolescence Health Promotion (AHP) for Taiwanese adolescents defined health lifestyles only included the concept of health promoting. The research design and sample in this study had some limitations. Nevertheless, this CHP still focuses only on health promotion and therefore is unsuitable for detecting or identifying risk behaviors in Taiwanese children. This CHP scale focused on assessing physical health promotion. It may be appropriate that the number of mental health promotion questions can be increased in this instrument. Moreover, because the survey was conducted in the form of self-assessment questionnaires, inaccuracies in the results may be present because of young-age-related limitations in the participants (e.g., cognition and seriousness of questionnaire completion). Future researchers may elect to train pilot instructors to offer explanations while the children are completing the questionnaire to increase the accuracy of the survey.

This study supported the content validity of the CHP on the basis of reported studies and judgments of content experts. The instrument appeared to have sufficient validity and reliability for assessing health promotion behaviors of children populations. This CHP is designed to assess culture-specific health promotion of children in Taiwan aged 9–12 years and can be used as a practical guide for schoolchildren health assessment and identification of healthy behaviors for school health providers. Moreover, this instrument is an easy, practical and comprehensive screening tool for school nurses to assess health-promoting lifestyle behaviors of Taiwanese schoolchildren and can be used as an evaluation tool in school health centers for daily health counseling. The strength of this study is its focus on protection behaviors for health promotion. Specific interventions can be developed to promote healthy behaviors to children and to improve their well-being.

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Competing Interests Statement

The authors declare that there is no competing or potential conflict of interest regarding the publication of this paper.

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The Influence of Three Variables on the Performance of Personnel in the Private Hospital in Indonesia

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Abstract

Background: This study aims to look at the effect and its magnitude (value) of the variables: family health history, lifestyle behavior, and work environment on the performance of hospital personnel at the private hospital in Indonesia.

Methods: Cross sectional methods were used in this study and data were analyzed with the approach to SEM using Smart PLS Software. In this study, all services at the hospital were chosen as the unit of analysis with 87 hospital personnel being selected as the sample. Multistage random sampling was used. The research was conducted from January to February 2016.

Results: The results of the analysis showed the performance of hospital personnel in the private hospital was influenced by all the variables which meant that the theoretical model proposed in this study could be implemented. However, none of the variables in the research model showed critical influence, only 8.12 per cent, when compared to variables outside the model which was 91.88 per cent.

Conclusion: This study concluded that the three variables studied were not large enough as variables that could be used for interventions in improving the performance of hospital personnel. Therefore, the hospital management needed to look for other variables as effort to improve the performance of hospital personnel.

Keywords: family health history, work environment, lifestyle behavior, performance of hospital personnel, private hospital

1. Introduction

In developing countries, one of the main problems in the employment sector is the high rate of personnel turnover (Bonenberg, Aikins, Akweongo, & Wyss, 2014). It happens regularly with companies, and it is true for personnel in hospitals. This situation can disrupt organizational performance (Dawson, 2014).

Organizational performance can be impaired due to the turnover of employees because replacement of personnel does not mean the same level or better performance to the previous employee who has left the workplace (Dawson, 2014). Many reasons exist, but in general the reasons for leaving can be caused by external and internal factors (Lambrou, 2010). Namely factors related to: work environment, health, and other factors which are the main factors in the hospital (Lambrou, 2010).

Indonesia adopted a law for hospital in 2009 in article 1. Paragraph 1 states that the hospital is a health care institution which organizes personal health services with complete or perfect standard that provide services to inpatients, outpatients, and emergency care (Indonesia, 2009). The statement articulates that Indonesia should have high organizational performance (Guntur, Haerani, & Hasan, 2012). Provision of high performance at the hospitals can be achieved by the high performance of personnel at the hospitals (Dieleman & Harnmeijer, 2006). Hence, personnel turnover should be prevented, so that the existence and performance of personnel can always be consistent and further increase over time, through efforts that would improve the individual's performance (Bonenberg, Aikins, Akweongo, & Wyss, 2014).

Furthermore, different types of personnel involvement, such as working together would produce high hospital performance. Personnel are mainly composed of doctors, nurses, midwives, pharmacists, community health personnel, medical assistants, assistant pharmacists, public health workforce, as well as supporting health

personnel administration staff, ICT staffs, and maintenance personnel (Fulton et al., 2011).

To an organization, a collaborative work force within the personnel who have been together and along with the availability of the senior personnel will naturally produce optimal organizational performance (Dubois & Singh, 2009). Therefore, in order to produce optimal hospital services (Kieft, de Brouwer, Francke, & Delnoij, 2014) for patients, the hospital organization needs to maintain strong cooperation between the senior personnel and other hospital personnel.

Thus, to generate optimal service to patients, the hospital needs to have personnel that have competence, productive and responsive services in order to achieve patient satisfaction (Dieleman & Harnmeijer, 2006) which will help the hospital management to retain personnel and subsequently increase the number of patient visits.

This means that the recruitment process for the health personnel is very important as it relates to performance. The hospital needs to recruit qualified candidates that are able to perform well in their hospital duties. The performance of health personnel also relates to competence training, job security guarantees, and the perception of health personnel to provide service-based patients' safety (Aiyadh et al., 2014). Indicators related to the performance of hospital personnel are: the ability to set goals, follow work procedures, to have initiatives, ability to work together, to possess individual skills, and to possess professional licence.

In addition, other factors that are associated with hospital personnel performance are: leadership, peers, conditions, recognition and factors of reward system (Choudhary & Puranik, 2014). Work conditions related to performance, is organizational support such as safety procedures, and other supporting regulations (Kaynak, Toklu, Elci, & Toklu, 2016). The hospital work environment can influence the lifestyle behavior of hospital personnel; this in turn will also affect their performance. Lifestyle behavior can be measured and used as indicators which include: sports activities, eating habits, social activities and maintaining personal hygiene. Hospital work environment indicators also show that it can influence the results of optimal performance which include work rules, work's space, room temperature, noise and lighting.

The ability of a person to produce optimal performance cannot be separated from their health condition and their family's health history which can be learned from the history of physical and psychological status of their parents, their childhood psychological status, lifestyle of their childhood and personal growth and development of their personality. Key *et al.* provides evidence that if the above health conditions found in the health of the personnel, the performance ability of the personnel will decrease (Key et al., 2004). More over, self-rated health and psychosocial conditions from the work environment, and lifestyle factors influence performance of hospital nurses at work (Vilija Malinauskiene, Palmira Leisyte, 2011).

The aim of this study is to analyze the influence of variables on the history of the personnel's health, hospital work environment, and lifestyle behavior on the performance of hospital personnel at the private hospital in Indonesia.

2. Methods

This study used a cross-sectional design. The retrieval of data was held in January to February 2016 in the private hospital. The population was all hospital personnel in the private hospital. The inclusion criteria were hospital employees who had worked a minimum of 6 months, while the exclusion criteria were employees who were on leave or refused to participate in the study.

Sample selection was done by multistage random sampling and obtaining a sample of 87 from 243 personnel at the hospital. Instruments used were in the form of a list of questions (questionnaire), which measured all four variables which were: hospital personnel performance, hospital work environment, lifestyle behavior of hospital personnel and family's health history. The hospital personnel performance variables were measured by three raters (assessors) consisting of a direct supervisor, a team leader, and their colleagues in the hospital. A rater can only assessed a maximum of 5 personnel.

Thus, there were some (personnel) assessed by 2-4 colleagues without assessment by a supervisor or team leader. Three other variables were measured through hospital personnel's subjective perception.

Questionnaire used a scoring system based on the measurement scale of semantic differential with a 1-5 rating scale ratings. A value of 1 was the lowest and 5 was the highest value of a judgment or perception in a question. The number of questions in each variable varied from 6-12 questions.

The Endogen Variable (Dependent) used in the study was hospital personnel performance. Whereas exogenous variables (independent) were: lifestyle behavior of hospital personnel, the hospital work environment and the family's health history of health personnel. The research variables were latent variables. Therefore, to describe a latent variable some indicators were used as an observed variable.

The four variables had 3-6 indicator variables with a series of the questions. Variables of hospital personnel performance consists of indicators: the ability to set goals, to follow work procedures, to have initiative, to do basic tasks, to be able to work together, to use appropriate working standards. The indicator of the variables of the lifestyle behavior of hospital personnel consists of: sport activities, eating habits, social activities, and maintaining personal hygiene. The hospital work environment variable consists of: indicators like the work rules, the space of work, room temperature, noise and lighting levels. The family's health history variable consists of indicators: the history of physical and psychological status of their parents, their psychological status in their childhood, lifestyle of their childhood and growth and development of their personality.

The validity of the questions tested was done to all the questions about the variables and the reliability of the instruments held in conjunction with the collection of the field data. The validity of the questions on each variable whose value was <0.423 was not included in the further calculation process. The study also calculated the value of reliability of the instruments.

Variations of all the answer of the questions on the instruments were tested according to the characteristics of the respondent. This was to determine whether the variations of respondents' answers occurred as a result of the variations on its characteristics of those respondents. Tests were carried out using chi square test with SPSS program. If the value of the chi square test had a value of $p > 0.05$ then the questions or statements on such instruments were not influenced by the variations in the characteristics of the respondents.

Data with the concept of Structural Equation Modeling (SEM) were analyzed using software Smart-PLS that produced a measurement model (outer model) complete with a value of Confirmatory Factor Analysis (CFA) and Goodness of Fit (GOF). CFA value was measured by looking at the result of Smart-PLS on the value of lambda (loading factor). Lambda value had to be greater than 0.5 in the loading test, that is to say indicators were a reflection of its variables (Ghozali, 2008). When the lambda value had less than 0.5, then it had to be retested after the indicators modified on these variables.

Outer loading test (value loading factor) were furnished with ratings on discriminant analysis validity that of assessing indicators reflective of the variable by looking at the value of the cross-loading between the indicator value in the variable and the value of the indicator variable simply reads the value of the Average Variance Extractor (AVE) (Garson, 2016).

The AVE value had to have a value of 0.5 or greater (Ghozali, 2008). Furthermore, if the value of all measurement models were fit, then do an assessment to measure the magnitude of the reliability of each lambda to see the value of composite reliability. Value must be equal to or greater than 0.7. If the value is less than 0.7 indicators recommended not incorporating them into the model, especially for exploratory models (Chin, Lo, & Ramayah, 2013). Composite reliability needed to be reinforced with a Cronbach alpha value of each variable to determine the reflective indicator strength level to its variable. Strong relationship must have a value greater than 0.6 (Chin et al., 2013). All of these calculations can be seen in the results of Partial Least Square (PLS).

Structural model's values are the values of the relationships among the variables which were constructed by the model and already had an enough value of goodness of fit. These values can be seen in the calculation of BT or bootstrapping to see the value of the original sample, that is the path value and the value of T statistics that were significance. The path was significant when the value of T is greater than 1.44, namely with an error rate of 15 per cent (Ghozali, 2008).

The next step was to build equations to the model and calculate the value of Q Square or the goodness of fit of the model, which was assessing the magnitude of the variation of research data on to the phenomenon that was studied by calculating R square in each of the variables (Sujit & Rajesh, 2016).

3. Results

The instrument of this study had a reliability of 0.953 (0.952-0.954). The characteristics of all the endogenous variables (independent or dependent) and exogenous (independent) studied had normal distribution of data and were homogeneous. The spread of the characteristics of the respondents is presented in Table 1.

Table 1. Demographic characteristics of respondents

Variable	n	percent
<i>Gender</i>		
Male	10	11.5
Female	77	88.5
<i>Educational level</i>		
Diploma III	58	66.7
Bachelor	29	33.3
<i>Marital Status</i>		
Married	57	65.5
Unmarried	28	32.1
Widows and divorce	2	2.4

Source: An-Nisa Hospital, 2016.

Furthermore, testing the distribution characteristics of the respondents with the answers given by the respondents were used bivariate test, with χ^2 test (Chi Square test). The result obtained showed no variations for the answer of respondents' due to variations in their characteristics, because all test results χ^2 (chi square test) on each variable has a value of $p > 0.05$ (0.090-0.416). The test results for outer models of at each variable with its indicator, produces CFA with alpha values of 0.56-0.93 and the value of T is 2.6-15.6. GOF measurement model shows the results as shown in Table 2.

Table 2. GOF value of outer model

Variabel	AVE	Composite Reliability	Cronbachs Alpha	R Square
Performance of Hospital Personnel	0.825	0.966	0.964	0.062
Work Environment	0.524	0.844	0.789	0.122
Lifestyle Behavior	0.630	0.870	0.808	0.179
Family Health History	0.703	0.904	0.858	0

Note. Variable Error of Performance $1-R^2$ which is $1-0.062=0.938$.

Table 2 shows the value of GOF of outer model with a $\lambda > 0.5$ for all indicators in each variable (0.56-0.93) with significant value of T (greater than 1.44 or equal to 85 percent level of significance). The validity and reliability was also high (greater than required), then the reading process could be continued for GOF of the inner model (Figure 1).

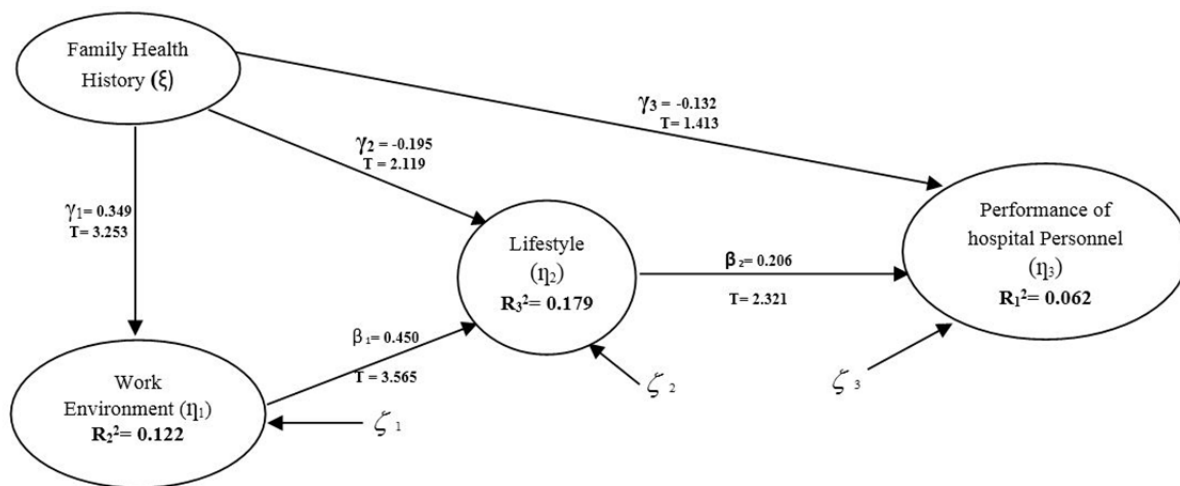


Figure 1. *Structural Model* - with path/ rho and T value

Source: Data analyzed with PLS and Bootstrapping T with *Software Smart PLS* version 3

Figure 1 the final inner model is a model that has been modified from the initial inner model by the researcher. Modifications needed to be done by eliminating the direct relationship between the work environment and the performance of the hospital personnel. The initial inner model which was proposed had a direct relationship between the 2 above variables. The effect caused the magnitude of the value of the relationship for each variable in the model to have a low T value, or in other words the calculation in the final inner model (figure 1) gave the value of T as greater than is presented in Table 3.

Table 3. Direct value of path/ rho to performance of hospital personnel variables with t value and status of significance on relationships among variables in *the Structural Model*

Relation Between Variable	Original Sample (Rho)	T Value	H ₀	Level Significant
Lifestyle -> performance	0.206	2.321	Fail to reject	Significant
environment -> Lifestyle	0.450	3.565	Fail to reject	Significant
health_hist-> Lifestyle	-0.195	2.119	Fail to reject	Significant
health_hist -> environment	0.349	3.253	Fail to reject	Significant
health_hist-> performance	-0.132	1.413	Fail to reject	Significant

Furthermore, figure 1 also shows that all the relationships among the variables in the model have a significant relationship to the value of $T > 1.44$ which meant an increase or decrease in the predictor variables on the dependent variable for 1 point. It will increase or decrease the value of rho with the level of accuracy of a minimum 85 percent. Comparison reverse occurs only between the variables of family health history with the performance of hospital personnel, because of its negative rho value.

Moreover, the calculation of the percentage of influence among variables against performances is described in Table 4.

Table 4. The value of the percentage effect of various variables directly and indirectly to the hospital personnels performance variable on theoretical model

	LV Correlation	Direct path	Indirect path	Total	Direct percent	Indirect percent	Total percent
Health_hist	-0.140	-0.132	-0.0003	-0.1323	-13.2	-0.03	-13.23
Environment	0.0264	N/A	0.00747	0.00747	N/A	0.75	0.75
Lifestyle	0.211	0.206	N/A	0.206	20.6	N/A	20.6
Health_hist_via	Environ_t_via	Lifestyle	0.0000	0.0000	N/A	0	
Total				0.08117	7.4	0.72	8.12

The influence of other variables outside the model that can affect performance variable has a percentage value is 100 – 8.12 per cent or **91.88**.

Table 4 shows that the predictive variables (work environment, family health history and lifestyle behavior) gave an effect of 8.12 per cent to the variable performance of hospital personnel. The strength of exogenous and or endogenous variables that were of an independent nature contributed in building an endogenous variable that was of a dependent nature on this theoretical model by looking at the value of R square on the endogenous variables (Table 2).

The magnitude of the variable error from the variable hospital personnel performances (1-R₁²) was (1-0.062). It meant that 93.8 percent of hospital personnel performances were affected by other factors than family health history, work environment and life style behavior. The mathematical model equations can be made as follows:

$$\eta_3 = \eta_2 \beta_2 + \xi_1 \gamma_3 + \zeta_3$$

Or

$$\eta_3 = 0.206 \beta_2 - 0.132 \xi_1 + 0.938$$

Hospital Personnels Performance= 0.206 LifeStyle Behavior - 0.132 Family Health History + 0.938

The above mathematical equation model describes the predictive variables which are: the work environment variable, family health history and lifestyle behavior which directly the influence on the hospital personnel performance variable. The value is 6.2 percent. 93.8 per cent is influenced by variables outside the model, including indirect predictor variables on the performance of the magnitude of 2.08 per cent (difference of 8.12 - 6.20 per cent).

In addition, calculating the value Q-square of used to assess the amount of diversity or variation of research data toward the phenomenon being studied, or can be read as the value of the strength for the confirmation model at the structural models which were delivered or could also be read as the value of predicted relevance at the structural model that was studied as presented in the following:

Q-square Value (Q Square predictive relevance value):

$$Q^2 = 1 - (1-R_1^2) (1-R_2^2)(1-R_3^2)$$

$$Q^2 = 1 - \{(1-0.122) *(1-0.1179)*(1-0.062)\} = 0.323854 \text{ or } 32.4 \text{ per cent}$$

Error Model of Q² = 100per cent - 32.4per cent = 67.6 per cent

The equation shows a model of the results of the analysis which can explain 32.4% on the diversity of data and the capability of studying the data phenomenon used in the study. Then 67.6% described other components that do not exist in this model. Moreover, the value of Q can be interpreted as the magnitude of the stability value of the structure of the model for predicting the same structure of the model at other hospitals in which the value was 32.4%.

4. Discussion

In general, this study proves that the theoretical model (original concept) which was modified by the researcher, statistically works in this population. Discussions focused on the obtained results, namely the interpretation of statistics that appeared which could give a meaning toward decision making by the management of private hospitals. It could be used as well, as study material at other private hospital in Indonesia, using the variables

studied.

Which could give meaning in the hospital, the biggest influence on the performance of health personnel is when all variables were given intervention. Lifestyle behavior variables had the largest direct effect among the three variables studied. Despite having the greatest impact in the study, lifestyle behavior variables did not provide sizeable results to impact the performance of health personnel. Variable life style in this study, measured by exercise habits, consumption habit patterns on eating and drinking, social activities, as well as individual and environmental hygiene. The results that had a significant effect on the model did not provide enough value to improve the performance of health personnel compared to the influence of the other variables outside the model, even if in the model all these variables were combined. Results of research conducted by Phiri (2014) states that health personnel who perform a less exercise, are obese in their lifestyle can lead to lower performance (Phiri, Draper, Lambert, & Kolbe-alexander, 2014). Furthermore, the improvement of a healthy lifestyle behavior of the personnel can be built through awareness of healthy behavior of the personnel by management supported through facility, physical activity by regular exercises (Koolhaas, Brouwer, Groothoff, & Klink, 2010). Meanwhile, another study also stated that without a healthy lifestyle behavior as indicated by the study, does not have a higher amount effect in percentage on the performance (Rabacow et al., 2014).

The work environment variables in this study were measured by indicators such as the work rules, the space of work, room temperature, noise and lighting levels. The results were influenced indirectly through the path of lifestyle variables on the performance of hospital personnel with the results which were not large enough to support the efforts to improve the performance of hospital personnel in the hospital and so that it can be said that the work environment needed not to be of major concern by hospital management to produce performance. These results were consistent with the research of Kaynak (2016) which stated that the safety procedures, organizational support, and other supporting regulations had an effect on the individual performance (Kaynak et al., 2016). Meanwhile, other studies said that variables of work environment were important to contribute toward the rising of performance such as the study that was done by Chandra and Priyono (Chandra & Priyono, 2015).

The variable of family health history was the basis for maintaining a better work environment in the generating of performance (Ulrich et al., 2009). Statistically, direct influence of family health history was inversely related to lifestyle and performance by a significant amount. This implies that family history of hospital personnel in the past was not good. It has given good results for the work environment, lifestyle and performance. The consequences of these findings, the researchers found that although the hospital personnel did not have good family health history, it could still yield positive linier results, particularly on the effects of the three variables in the research model such as work environment, lifestyle and performance.

Furthermore, this study showed us that the three variables which were proposed in the model could be supported by other variables outside the model. The results of other studies mention the individual performance was influenced by many factors which were crucial as performance indicators based on the targets' set, following the procedure, the initiative in work, doing basic tasks, the ability to cooperate, and carry out appropriate working standards (Al-Makhaita, Sabra, & Hafez, 2014; Nelson et al., 2014; Platis, Reklitis, & Zimeras, 2015).

The result showed improvement whereby ability and skills were necessary to increase the performance of the personnel. Some studies do not include the family history of health personnel as a variable that could influence the performance of the hospital personnel. Besides, to produce high performance level of the personnel needed to be taken into consideration in the recruitment process (Eqab Aiyadh, 2014). Family health history is a variable to be taken into consideration by hospital management during the recruitment process to get new positive personnel.

5. Conclusion

Finally, this study confirms that all three measured variables such as family health history, lifestyle, and the work environment did not have a large effect on the performance of hospital health personnel. This suggests that the performance of hospital health personnel was not always affected by variables in the model, but influence greater by the outside research model. The limitation of this study was the amount of sampling that was conducted only at one hospital. However the results could still be applied or generalized to other private hospitals with the same characteristics or class in a matter of hospital accreditations.

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Competing Interests Statement

The author declares that there is no competing or potential conflict of interest.

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Assessment of Quality of Life in Adults Living at Charity Homes in Saudi Arabia

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Abstract

There is a rising interest in the Quality of Life (QoL) research in the Arabian countries. The study aimed to analyze the association between the health satisfaction, environment, age, and the physical functions to determine the quality of life among adults living in charity homes in Jeddah, Saudi Arabia. The participants recruited for the study were adults, living in charity homes in Jeddah to analyze the results through a quantitative research design. The sample size included in the study was 136, which included the participants from different charity homes in Jeddah. SF-36 was appropriately used to examine the health status of the participants. WHOQOL-BRIEF questionnaire was used for the collection of primary data at the time of interviews. The statistically significant results have been evaluated through the independent t-test between the groups, based on the characteristics of the participants for average SF-36 domain scores. However, ANOVA test evaluated insignificant results on the basis of educational level as the p-value obtained is greater than the level of significance ($0.850 > 0.05$). Positive responses for all four domains of SF-36 instrument have been obtained, which recommended that further improvements in the charity homes is required to provide the awareness regarding the security and medication facilities.

Keywords: quality of life, homeless, charity homes, influencing factors, health care settings

1. Introduction

The important goal for nursing services and health professions in general in healthcare sector is to assist people in improving their quality of life (QoL). Therefore, it is important to determine the factors that influence QoL in the community. WHOQOL (World Health Organization Quality of Life Assessment Group) has defined QoL as individuals' perception of their position in life, regarding culture and value systems (WHOQOL, 1995). There is a considerable increase in the number of adult and elderly people across the world. The increase has been recorded at almost 300% in the older population of developed countries as well as developing countries (Aydin et al., 2015). It has brought the attention of healthcare professionals and policy makers towards long-term healthcare services and other associated issues. Elderly people are limited in their capability to live independently. They often face frailty issues, limited mobility, problems related to mental health, and physical health problems. There is a lack of literature on the information related to the prevalence of homeless population. The phenomenon of homelessness is associated with different risk behaviors. These aspects may include substance abuse, crime, exploitation, and even death. Ha et al. (2015) asserted that people get engaged in these behaviors because they are forced to do so for their survival (Ha et al., 2015).

In Saudi Arabia, Ministry of Social Affairs is in the process of reviewing the way shelter/charity homes are administered. The ministry also aims to shift their locations in South Jeddah (Saudi Gazette, 2015). It has always been a debatable issue in the local context. The studies must emphasize on several considerations that include improvement of work environment, privacy standards, and provision of services (Veenema et al., 2015). There is a need to demonstrate the issues related to security and safety measures in the charity homes.

The main purpose of this study was to investigate the relationship between physical function, health satisfaction, age, and environment that may determine the QoL of adult in charity home of Jeddah. The study analyzed quality of life among homeless adult people in the charity home in Jeddah. The outcome variable included four domains of the SF-36 instrument. WHOQOL-BRIEF questionnaire was used for the collection of primary data from the

patients at the charity home in Jeddah. The study found positive responses for all four domains of SF-36 instrument. The findings revealed the importance of health education programs by focusing on approaches related to family bonding. It would result in positive outcomes for vulnerable population.

2. Methods

2.1 Study Design

The study has adopted quantitative cross-sectional study design to assess the quality of life in adults living at charity homes in Saudi Arabia. The design was selected, based on a structured QoL questionnaire in a representative sample from the charity home. The study has been conducted, recruiting the residents of charity home in Jeddah, Saudi Arabia. The study has recruited adults, living in different charity homes in Jeddah to assess their quality of life. The mean score of QoL was estimated at 5% of type I error and a standard deviation of 8 QoL scores of the studied population. Using a precision of one QoL score of either side, the study has selected 136 participants for retrieving outcomes generously.

2.2 Data Collection Tools

The WHOQOL was used in this study, which evaluated the quality of life and described the development of WHOQOL-BREF, which is an abbreviated version of the WHOQOL-100. This instrument has many uses, including use in medical practice, research, audit, and in policy making. The researcher adopted the Arabic version to suit the culture and religion of the population under the study. Data was analyzed using SPSS (Statistical Package for the Social Sciences). The participants were interviewed on the basis of WHOQOL questionnaire and SF-36, which assisted to evaluate the health status and quality of life among every individual. The targeted population was the adults, living in charity homes in Jeddah, Saudi Arabia. All 136 adults were interviewed to have information collected effectively for further analysis. SF-36 or WHOQOL questionnaire was used as data collection instrument for proper reliability and validity of the data obtained.

2.3 Ethical Consideration

An approval from the charity home administration office was obtained. A verbal consent was taken from participants before interviewing. The collected data was treated confidentially.

2.4 Statistical Analysis

This study was conducted using the SF-36 QoL tool that provided the health status of adults living in charity homes. There are different reasons, why WHO developed a quality of life assessment. It helps to measure health status and also beyond health indicators, which included mortality and morbidity (World Health Organization., 2014). The validity and reliability of WHOQOL-BRIEF in Arabic version of QoL has also been evaluated to provide the validity of the instrument used for assessment of QoL among the patients at charity homes. Cronbach's alpha was used to estimate the reliability of the SF-36. The collected data was then analyzed through SPSS (Statistical Package of Social Sciences). Descriptive table has been generated, which represented mean and standard deviation of the responses. Independent samples test and ANOVA test have been applied to make comparison between the mean and analysis of variance along with its significance respectively. Independent t-test and ANOVA tests were used to examine the association between participants' characteristics and average SF-36 domain scores. Pearson's correlation coefficient was used to examine the correlation between the domains of SF-36.

3. Results

3.1 Strength of Association

Pearson's correlation coefficient value was greater than 0.40 that highlighted the level of agreement between domains of SF-36. Correlations >0.4 were considered acceptable. The responses of the questions were transformed into domain scores, and the correlation was determined between the domain scores of participants. A positive correlation was found between the domain scores of the participants. It implies that the participants that responded in the positive direction for physical domain also responded positively for psychological, social, and environmental domain.

3.2 Comparing the Means

In the study, descriptive analysis was performed, which has evaluated the percentages, frequencies, ranges, means, and standard deviations (SD). The results of independent t-test and ANOVA tests showed statistically significant differences between groups based on participants' characteristics for average SF-36 domain scores. For the independent t-test, participants were divided into two independent groups of male and female. The findings

showed significant variations in the mean total scores of males and females. The standard level of significance considered for the study is $\alpha=0.05$. The p-values less than 0.05 shows significant association between the targeted variables.

The independent sample t-test in Table 1 has shown significant mean differences (p-value=0.001). ANOVA test in Table 1 showed that the association between the variables is insignificant as the p-value is greater than the level of significance. ($0.850 > 0.05$). The level of significance was not below .05. Hence, statistically significant differences were not found in the mean total scores of participants based on education level. It ensures that domain variables are correlated with each other, and hypothesis is accepted.

Table 1. Independent samples test and ANOVA test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
								Lower		Upper
Total Score	Equal variances assumed	7.033	.009	3.536	121	.001	8.00081	2.26260	3.52140	12.48023
	Equal variances not assumed			8.597	47.104	.000	8.00081	.93062	6.12876	9.87286
ANOVA										
		Sum of Squares			Df	Mean Square	F	Sig.		
Between Groups		78.702			19	19.675	.340	.850		
Within Groups		6761.823			117	57.793				
Total		6840.525			136					

Along with statistical assurance, it is further plausible in general, since various studies and healthcare organizations positively claimed that physical activities and desirable environmental conditions, designed according to age, will result in highly satisfied health conditions. Further making significance level of ANOVA certain, Center for Disease Control and Prevention (CDC) suggested that various physical activities and healthy environment are necessary for people to improve their quality of life (CDC, 2015).

Significance level (0.850) in ANOVA table indicated that four determined domains of this study are strictly correlated. Each of them has their contribution in quality of life, specifically in charitable homes, where people are mostly unknown to each other. Together, these domains would have a positive synergy impact on quality of living, which is essential for each group.

This research study has utilized four different variables for conducting the research study. Four of the variables are seemed to be closely associated with the factor of quality of life. It has been evaluated from the findings that demographics of the participants played a major role in influencing quality of life during personal and professional life. The statistical approach has indicated that 136 participants participated in this study; out of which, 82 individuals were illiterate. From the statistical perspective, it has been evaluated that most of the illiterate individuals had poor extent of quality of life comparatively to the other classes. Individuals, having secondary or intermediate educational level, were also coping with the state of deprived quality of life. Therefore, the statistical interference has presented its outcomes that higher education or educational level has a direct impact on quality of life (Table 2).

Table 2. Descriptive statistics

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
Intermediate	29	94.11	8.334	1.634	90.74	97.48	78.0	105.0
Secondary	8	96.25	3.105	1.097	93.65	98.84	94.0	100.0
Bachelor	10	95.50	2.415	.763	93.77	97.22	92.0	97.0
Masters	5	94.50	103.0	103.0
PhD	1	101.00	101.0	101.0
Illiterate	82	95.46	8.033	.915	93.64	97.29	80.0	114.0
Missing	2	--	--	--	--	--	--	--
Total	136	95.27	7.518	.680	93.93	96.62	78.0	114.0

The second major factor, which has been identified in this study, was related to physical function. It has been evaluated by the statistical analysis that majority of the physically active individuals had appropriate level of quality of life. It has been further observed that physically fit individuals were able to perform their daily personal and professional tasks in an appropriate manner. Such participants had normal regulation of the body process, which in turn resulted in better performance. Therefore, it can be said that physical fitness is closely connected with better quality of life as reflected in Table 3.

The third major variable of the study is health satisfaction. It is a fact that the satisfaction level of the patients in regards of their health is directly associated with better recovery and quality of life. From the outcomes represented in Table 3, it has been observed that the individuals, having higher health satisfactory level, had enhanced level of quality of life. Comparatively, the participants, who were dissatisfied with their health, had deprived level of QOL. Therefore, it has been evaluated that health satisfaction had also similar impact on the quality of life.

Environmental domain is a vast area, which is necessary to be understood in regards of quality of life among general population. Three environmental factors have been identified by this research study as presented in Table 3, which mainly included pollution, crowd, and traffic. Three of these factors have been observed from the perspective of quality of life. It has been evaluated that environmental domain is closely connected while maintaining quality of life among general population. Table 3 has represented the environmental domain and quality of life among the adults living in charity homes. It can be observed that majority of the participants were satisfied with the quality of life provided in the charity homes of Jeddah, as only 80 participants showed their satisfaction concerning the environment and health. Whereas, 55 participants were discontented with the health and environmental status of the charity homes. Lower pollution, no crowd in daily routine, less traffic concerns could be the ways of improving quality of life among adults living in charity homes in Jeddah, Saudi Arabia.

Table 3. Health satisfaction and Quality of Life; physical fitness and Quality of Life; environmental domain and Quality of Life

	N	Max Score	Min Score
Satisfied	80	101.00	101.00
Dissatisfied	55	74.25	75.45
Total	136	87.625	176.45
Std. Deviation	Std. Error	Max	Min
7.33464	1.65456	95.00	105.00
2.10530	1.11789	68.00	70.00
6.51886	.68073	81.50	87.50
	Pollution	Crowd	Traffic
Better QOL	Lower pollution	No crowd in daily routine	Less traffic concerns
Poor QOL	Higher pollution	Heavy crowd	Excessive traffic concerns

4. Discussion

The results have demonstrated that there is a need of certain awareness programs to promote better quality of life among the adults in charity homes in Saudi Arabia. The results have identified the gaps concerning the management of the charity homes. According to CDC (2015), physical activities; such as regular exercise, are effective in enhancing bodily and mental conditions, particularly in aged people. It would prevent various cardiac conditions that are common to occur in people, aged 50 years or above. Moreover, it will assist them in keeping diabetic conditions in control. As it is generally accepted that diabetes is found among elderly people, charitable homes in Kingdom of Saudi Arabia (KSA) must institute various exercises, depending on age that will not improve their physical health, but keep them engaged in mental activity as well.

A study by Nante, et al. (2016) has conducted a study based on quality of life, which has shown that the educational qualification, length of stay, and gender were not associated with poorer health associated quality of life among refugees in Italy. Elderly refugees were observed with low scores in various dimensions of the SF-36. African refugees reported a significant HRQoL than others, which might be because of different health perspectives.

Gargiulo et al. (2012) suggested that individuals with low education were observed to have adverse health issues. Similarly Pahwa et al. (2012) demonstrated that depressive symptoms are more common among the migrant women and individuals, having low educational background in Canada. Mental stress was seemed to be less common among the migrant women. Furthermore, a Swedish study represented that Iranian women had a decreased strength with a shorter time of residence (Koochek et al., 2007).

Lukas et al. (2013) investigated the approaches of pain management in the residents of nursing homes. It has been concluded that treatment approaches for the residents are suboptimal and required substantial improvement. Zaidi et al. (2012) investigated QoL in HIV-positive patients. The population of the study consisted of patients in Malaysian shelter homes, 27 research participants responded to the WHO questionnaire. The questionnaire was related to the QoL of HIV-infected people (WHOQOL-HIV BREF). Six analyzed domains included physical activity, psychological status, independence level, social relationships, environmental issues, and cultural beliefs (personal, religious, and spiritual). The participants responded positively for all six domains. The participants showed facilitated and improved living standard among the charity homes residents. Lynn et al. (2014) argued that there is insufficient information available related to self-harm in family shelters. The study also analyzed the prevalence of suicidal ideation and the effect of different risk factors.

Stated by Rubio-Tapia, et al. (2013); the celiac disease (CD) is frequently targeting adults causing diarrhea and related metabolism disturbance (Rubio-Tapia et al., 2013). It is caused mainly due to unhealthy food consumption that contains gluten. The consequent effect of CD leads to osteoporosis, miscarriage or infertility, and Type 1 diabetes and cancer at extreme.

The study recommended further improvements in charity homes related to awareness, safety, security, and medication facilities. It would result in positive health outcomes for the vulnerable population residing in these

charity homes. In order to attain desirable results for better quality of life in charitable homes, adults should be provided with healthy diet, workout sessions, teamwork, interacting activities, etc. It will boost inner energy and manage stress levels. Moreover, it is important to provide them an interactive environment that would improve their self-esteem and self-image. These attributes are extremely vital for such adults, so they can remain functional and ambitious in life. Similarly, the present study also suggested that management of charitable homes in KSA should arrange workshops and seminars that would teach adults to deal with constantly building stress, depression, and anger. It is essential to develop some self-management skills in these people, so they prosper in their future. Moreover, enhancement of self-management skills is also important to improve environmental factors of charitable homes. An interactive surrounding with fellows in charity home will give them an opportunity to share their intrinsic and extrinsic issues and desires, providing them mental and social peace.

Management of such homes must arrange proper employment opportunities through which they can further enhance their quality of life. The management can arrange various employment seminars, training and grooming sessions based on education levels of people. Quality of living will improve as independency, and self-confidence would develop in these adults. Besides, adults in charitable homes can help in improving national standards of living by reducing dependency ratio through this channel.

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Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Older Thai Peoples' Perceptions and Experiences of Major Depression

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Abstract

Background: Depressive disorders are common mental health problems and may be disabling among the general older population. Although older people have significant symptoms of depression, the symptoms are likely to be underreported. The condition often co-exist along with somatic ill and has often been unrecognized. *The aim* of the study was to explore and understand the perceptions and experiences of older Thai people diagnosed with major depressive disorder.

Methods: A qualitative inductive research design was used and latent content analysis was utilized. The data were collected through face-to-face, in-depth interviews. Fourteen older people diagnosed with major depressive disorder were selected for participant using purposive sampling.

Findings: Older Thai peoples' perceptions and experiences of depression were abstracted into two themes. First theme was *leading a life in detachment*, which included three subthemes: living with meaninglessness, holding distress with one's self, and feeling judged by surrounded people. The second theme was *inconvenience of approaching mental health treatment*, which included two subthemes: sensing an unapproachable health care service, and lacking knowledge about clinical depression.

Conclusion: Older Thai peoples' perceptions and experiences of major depression were affected with high level suspected existential loneliness that might even be worse in a collect oriented society as in the Thai context. Further, it seem hard to approach the mental health care. The central reason for this is interpreted as lack of mental health literacy, and in this case, specifically, knowledge on depression. Future studies should focus on relatives' experiences of living with an older family member that suffered from major depression, and on the state of mental health literacy in the rural Thai population.

Keywords: major depression, qualitative latent content analysis, rural, Thai

1. Introduction

Depression is the most common mental health problem worldwide (Barcelos-Ferreira, Izbicki, Steffens, & Bottino, 2010; Byers, Yaffe, Covinsky, Friedman, & Bruce, 2010; Fiest, Currie, Williams, & Wang, 2010; Monteso et al., 2012; Tiwari, Pandey, & Singh, 2012; Verhaak, Dekker, de Waal, van Marwijk, & Comijs, 2014), and is one of the leading causes of disabilities (Lopez, Mathers, Ezzati, Jamison, & Murray, 2006; Ferrari et al., 2013). It should be kept in mind that depression is the most important predictor of suicide ideation and suicide attempt (Indu et al., 2017). Globally an estimate of 350 million people experience depression, although many do not acknowledge that they are ill and do not seek treatment (World Health Organization, 2012). In Thailand, the prevalence of depression among a population aged over 45 years was 29.2% (Wangtongkum, Sucharitakul, Wongjareon, & Maneechompoo, 2008), but for the segment above 60 years of age it was only 12.78% (Thongtang et al., 2002). In general, females have higher rates of depression than males, especially older people with disabilities (Pagan-Rodriguez & Perez, 2012). Compared to older people without depression, older people with the diagnosis showed both central and peripheral signs of inflammation, and enhanced level of a specific translocator protein, which is associated with cardiovascular diseases (Su et al., 2016). Moreover, these patients showed significant gray matter reduction in the whole brain, which is associated with disruption of the neural network that regulates mood and behavior (Stratmann et al., 2014). This might be one reason why people with depression often display a complexity of health issues. Not seldom, this patient group demonstrates several somatic symptoms, which include gastrointestinal, skeletal muscle, and cardiovascular complaints, in contrast to describing non-physical criteria for depression

(Arroll et al., 2009; Hegeman, Kok, van der Mast, & Giltay, 2012). Older people with depression is often underdiagnosed, undertreated, or mistreated because depression may co-exists as a comorbidity in combination with somatic illness, and further, the older patients may believe that a depression is a part of normal life (Maiera, 2010; Gellis, 2010). However depression is not part of normal aging, in contrary older people as a population group displays the lowest prevalence (Smyer & Qualls, 1999). Besides, health care providers less often recognize that older patients suffer from depression (Piek et al., 2012). Old age depression may occur after stressful life events such as death of a beloved person, loneliness, serious health problems, and the lack of economic resources (Maiera, 2010; Monteso et al., 2012; Baiyewu, Yusuf, & Ogundele, 2015). An Asian comparative study identified stressful life event for a Thai population prior to the onset of depression, and found that any stressful life events, financial crisis, and serious illness were the three main events (Park et al., 2015). A systematic review revealed that older people with depression lowered the health related quality of life (Renaud & Bedard, 2013). The possibility of recurrence could occur even after more than a decade (Crona & Bradvik, 2012). At five years of follow-up, a study reported that the recurrence rate was 31.5% (Bukh, Andersen, & Kessing, 2016).

The majority of literature investigating depression in older people appears to be conducted quantitatively. Another field of the research have focused on the perspective of the patients with depression. For instance, a literature synthesis of older persons' narratives showed that, when suffering from depression they engaged three central strategies to survive; the need for courage, strength and self-reliance; the meaning of responsibility; and wearing a mask of normalcy to hide shame (Holm & Severinsson, 2014). While, the perspective from patients' family showed that to them the relative's major depression was trying and that it brought them into severe stressful life situations (Ahlstrom, Skarsater, & Danielson, 2009).

Due to the complexity of older peoples' health status with co-morbidities, the depression symptomatology it has often been undetected (Licht-Strunk, Beekman, Haan, & Marwijk, 2009). Besides, there may be some misunderstanding that depression is a part of normal aging process (Smyer & Qualls, 1999). Further, healthcare providers do not pay attention and are not sufficiently aware as they also display the position that depression is a part of the normal aging process (Bryant, 2010). It that respect, the healthcare providers lack knowledge and competence. Moreover, there is a need to more deeply comprehend how these older people understand and recognize depressive symptoms in their daily lives. The literature search identified no study on older people with depression and their experiences of living with the condition in a Thai rural context. To fill this gap in knowledge, the current study aimed to explore and understand the experiences and perceptions of older Thai people suffering from a diagnosed major depression.

2. Method

2.1 Design

This study had a *qualitative research design* and used an inductive approach inspired by Graneheim and Lundman (2004) and Patton (2015) and their interpretation of latent content analysis. The qualitative work is based on the ontological assumption that peoples' conceptualization is multiple and that subjective reality exists. This study focused on individuals' interpretation of a variation of experiences, aiming to gain better understanding of the experiences of older Thai people whom displayed depression.

2.2 Setting

The study took place in rural areas of Kanchanaburi, the western province in Thailand. Its territory covered an area of approximately 19,473 square kilometers. The province contained 13 districts, and had a population of approximately 885,000 people, the older people accounted to 12.86% (Bureau of registration of administration, 2016). Most of the inhabitants are employed in agriculture. Generally older people in the rural area of Thailand are considered poor. Each province had a provincial hospital and one hospital for every district and one health center for every sub-district (Tambon in Thai). Fifteen hospitals were located in Kanchanaburi. The setting was the primary care of public health in Thailand.

2.3 Participant and Sample Recruitment

The participants were recruited and selected using purposive sampling. The psychiatric nurses were asked to mediate the contact with patients who fulfilled the inclusion criteria that were 60 years of age and over, diagnosed with major depressive disorder according to the criteria of the Diagnostic and Statistical Manual of Mental Disorders (DSM V; F. 32) (American Psychiatric Association, 2013), being treated by antidepressant, and being able to speak and understand Thai and agree to take part in this study. Then the first author contacted the patients and gave verbal information about the details of the study, and that the interviews would be treated confidentially and for research purpose only. Afterward, the participants gave their informed consent. Twenty-two older Thai

people whom displayed depression were invited for participation but due to time limitation, a total of fourteen patients agreed to participate. All were women, age between 60 to 79 years (median 67 years), and half of them lost husband and currently living with their children.

2.4 Ethical Consideration

The study was conducted after approval from the Research Ethics Committee at Makaruk hospital (MKH, 118-2015). Participants were informed that their participation was voluntary and that they could withdraw at any point during the interview without any consequence on the healthcare provision. All data was handled according to the principle of confidentiality. If the interview awake any inconveniency, a pre-arrangement was made that the participants would be referred to the general practitioner. This was never needed as the interviewees expressed their gratitude to being listened and taken interest in.

2.5 Data Collection

The data was collected through face-to-face, individual in-depth interviews (Polit & beck, 2016). The first author contacted each participant to make an appointment that was convenient for the participant and asked for permission to use digital recording during the interview. Ten interviews were conducted in private room at the outpatient clinic and four interviews at the patients’ homes. First, the first author asked general questions and then used open-ended questions to encourage the participant to openly tell their stories. The interview questions were concentrated in the following domain; please tell me about your experience of depression? To probe further, the participants were asked these questions; could you please describe your experiences in more detail? Could you please give me some examples? The digital recorded interviews were transcribed into word document files. Each interview session took approximately 40-90 (median 55) minutes from June to November 2016. In all approximately 150 pages was generated.

2.6 Data Analysis

To analyze the data, qualitative latent content analysis described by Graneheim and Lundman (2004) and Patton (2015) was used. The first step, the text was read several times to achieve an overall understanding and marking each sentence revealed the experience of depression. The second step, then, the text that could be the words, phrases, sentences, and paragraphs was divided into meaning units that relate to the study aim. In the third step, the meaning units were condensed while still keeping the original essence of the text, which were then labeled with codes according to their content. The fourth step, the various codes with the similar content were then group together and identified into subthemes related to the objectives of the study. Finally, the subthemes were abstracted, sorted and formulated into themes. An example of the process of the analysis that is the way in which the themes were developed from meaning units, condensed meaning unit, coding, and subthemes are shown in Table 1. Please see below.

Tables 1. Example of analysis process

Meaning Units	Condensed meaning unit	Coding	Sub themes	Themes
I am always thinking that I don’t want to live. I then get a rope to hang my neck and think that no matter what other says, I will not live anymore. The idea just comes automatically.	She is always automatically thinking that she does not want to live. Then, she gets the rope to hang her neck.	Planning to die	Living with meaninglessness	Leading a life in detachment
The doctor appointed me every 2 month. It was not so often but I sometimes, couldn’t come as appointed because of inconvenience in travelling. I have to walk to hospital, which take a long time. I have to leave home very early otherwise it will too hot to walk in the sunlight and I would faint.	The doctor appointed the patient every second months, but the patient was not able to meet the doctor because of inconvenience in travelling.	Lacking access to health care services	Sensing an unapproachable health care services	Inconvenience of approaching mental health treatment.

2.7 Trustworthiness

To achieve credibility, the interviews were addressed by the heterogeneous participants. The participants were

recruited with various stage of their depression such as current episode, recover, and long term illness. The Thai version Patient Health Questionnaire (PHQ-9) was used to assess based on DSM-V criteria for major depressive episode. The authors attempted to increase the richness of data by starting from having a good relationship with the interviewees. They also allocated sufficient time for investigation and following step-by-step of data analysis process. The authors read and discussed the meaning units, including condensed meaning units, coding, subthemes, and themes and critical analysis during the whole process. Two participants were asked to review the findings (subtheme) and agree with the result that linked to their experiences (member checking). The research team had completely agreed with the findings after discussion.

3. Findings

Older Thai peoples' perceptions and experiences of depression were based on current situation as well as the context of their lives where are rural area in Thailand. In this study, the finding are abstracted their experiences into two themes: ***Leading a life in detachment and inconvenience of approaching mental health treatment***. These themes are discussed in more detail in the following sections. Please see table 2 below.

Table 2. Overview of themes and subthemes

Themes	Subthemes
Leading a life in detachment	Living with meaninglessness
	Holding distress with one's self
	Feeling judged by surrounded people
Inconvenience of approaching mental health treatment	Sensing an unapproachable health care service
	Lacking knowledge about clinical depression

3.1 *Leading a Life in Detachment*

This theme was based on the abstraction of the content in the following three subthemes: *living with meaninglessness, holding distress with one's self, and feeling judged by surrounded people*.

3.1.1 Living with Meaninglessness

The participants expressed that suffering from depression meant that they were living with meaninglessness. The meaninglessness became a central part of their lives. Several participants experienced that they lacked energy and were automatically thinking that they did not want to live. Please see table 1 above.

Another aspect of the experience of living with meaninglessness was a very inactively mode of living as the participants just wanted to lie down or quietly sit on the bed almost the whole day. Further, and there were no energy to paid attention to things that they needed to do such as cooking and washing. One participant said:

"I am doing activities with an absent-mind. It started with insomnia for a half month ago and afterwards, I became unhealthy skinny. I didn't want to meet people and didn't want to eat or do anything. When cooking, I did it with carelessness and didn't concern for its taste". (Participant 10)

Some participants displayed a meaningless life as they felt drawn to the past and always thought of the death of their spouse and love ones. They seldom looked at the future as stated by one participant.

"I always thought that before we lived together: me, my husband and our child. One day my husband and my child are died, how can I live? I thought and sometimes spoke out that I want my dead husband and child come back, please let me see the both of you. When time passed for a long while, I could stop thinking but for a few days later these thoughts was coming back. This cycle happened for several years". (Participant 11)

3.1.2 Holding Distress with One's Self

The signs and symptoms of depression occurred over time, but the participants did not understand that they were related to depression. There were times, where they did not want to talk to anyone, and where they kept the mental health concerns to themselves. Sometimes they wanted to talk to their children, but they did not want to disturb. They still held a burden of guilt and shame over not being an appropriate parent. This is an example of one informant statement.

"I was offended and felt uncomfortable or worried by my daughter's words. She said that she did not want a mother. This sentence kept repeating itself in my head. I did not know how to forget it and did not know how to talk about

it. It was not good to speak out. I did not know whom I could talk to. I then had to keep it to myself. I did not dare telling anyone". (Participant 9)

Frequently, the participants could not express their stress. The participants depended on financial resources and residence from their children. Further, they were worried that they should become a burden to their children, and how they should managed to live their lives being dependent.

"If I said something bad about the family, I would be in trouble if the children had heard it. I am alive because they provide me with a home and food. If they stopped giving it to me, I would starve to death. Sometimes, I told them I want to visit my cousins, but my children would suspect that I would bring unhappiness to the family by talking out side the closest family". (Participant 3)

Some participants described holding distress with one's self generating a feeling of loneliness. They found no joy to be with their relatives, although they were usually invited to jointly going to the temple. They withdrew from everyone and situation that they were in the past. One participant described this experience as followed:

"I was talking less because I was sick with a disease unlike anyone else. I did not want to talk at all and answer any invitation. I stayed only at home not going anywhere, which was different from the past, where I went to making merit on every Buddhist Holy Day". (Participant 13)

3.1.3 Feeling Judged by Surrounded People

Most of participants expressed that suffering from depression meant that they were feeling judged by surrounded people. Apparently, they withdrew from others and kept their distress to themselves. They have had trouble living with their neighbors. The participants expressed that they could not understand what was happening to them, and therefore they were unable to explain it to the neighbors. Frequently, the participants were judged that they were crazy by their neighbors. As stated by one participant:

"I just felt depressed without a reason that I barely couldn't hold on. When I talked to a neighbor who turned on radio, I switched off his radio asking him to shut it down because I felt uncomfortable to listen. I got home or when motorcycles rode pass my house, I used to quarrel with them or people surrounded my path. Other people said that I have gone crazy, and I thought that I brought the stigma to my family". (Participant 7)

Another aspect of the experience of living with feeling judged by surrounded people was participants always were seen that they faked their illness; because they looked like the appearance of normal people.

"For four or five years ago, if I was at home and there are children loudly playing around my house, I will come out and chase them away. Normally, I am kind but when I have symptoms, I will be frustrated, have a headache and can't sleep in the night without taking sleeping pills. People who usually see my symptoms said that I pretend to be sick. They asked why good-looking person like me have to pretend to be mentally ill. I became more stressful and tortured but I didn't know how to do". (Participant 14)

3.2 *Inconvenience of Approaching Mental Health Treatment*

This theme was based on the abstraction of the content in the following two subthemes: Sensing an unapproachable health care services, and Lacking knowledge about clinical depression.

3.2.1 Sensing an Unapproachable Health Care Service

Most of participants revealed that they sensed the health care services were hardly accessed or difficult to approach. Although each rural area had a hospital to provide treatment, the participants expressed that they could not go to the hospital because they lived alone and that travelling was difficult. Moreover, they were in a vulnerable position and relied on their children to pick them up to wherever. This is exemplified by the following:

"After I take all medicine as prescribed, I was better and could sleep but I don't go to take more medicine because I couldn't go by myself. I have to go with my child who said going to hospital was bothering him because it took him so much time and he couldn't take a day off so often". (Participant 6)

Some of participants were also described they tried to go to the health care services by themselves but it is so difficult to travel.

3.2.2 Lacking Knowledge about Clinical Depression

The majority of participants were unaware that they were experiencing depressive symptoms due to lack of knowledge about signs of clinical depression. Participants sensed something unusual such as being fed up with talking to others and felt depressed a long period. They asked themselves "what has happened to me?" and thought that it would come and go by itself. This is exemplified by the following citation.

“I saw my friends died one by one. It made me feel depressed, disheartened and thought-overwhelmed. After that I couldn’t sleep and couldn’t eat. I became skinny. I don’t want anything. I felt like this for about a year or two years but I didn’t come to see doctor because I thought that it would come and go by itself. However, it did not disappear, moreover, it got worse. I was skinnier and with a pale face. When I followed up my blood pressure at hypertension clinic, the doctor checked, asked some questions and said that I also had a depression”. (Participant 1)

Most of the participants used the law of karma, which according to belief in reincarnation basically meant that any bad deeds in the present life will be punished in the future life, to interpret their illness as the result of an accumulation of merit and demerit. Older people in Thailand are very subservient, which means that they often accept whatever is given to them without complaining. If they are poor or ill in this life, it is because of a consequence of a bad deed in a previous life. This led to that the participants did not visit mental health care providers, but they usually prayed for better health instead. As reported by one participant:

“I was so stressed and disappoint in my life. I’ve worked but never earn enough money for a living. My husband didn’t help in anything. He was alcoholic. My hope to depend on my son became hopeless; because he was also drug addicted and usually had quarrels with me without a reason. I were aggrieved and thought that I must have done many bad things in past life so I have to repay for them now”. (Participant 4)

When asked how the participants understood that they suffered from depression, all of them described that they knew it from the nurses’ screening that was conducted when they went to the hospital for other illness such as hypertension, diabetes mellitus. One participant stated:

“At first, I didn’t know what make me sick. I just too tired to work and one day I just fainted. When I went to the hospital, I know that I have diabetes. Later, when I came as appointed, the nurse asked me if I was stressed or worried. And she also asked me many more questions, which I rarely remembered but finally, found out that I also had depression”. (Participant 2)

4. Discussion

The purpose of this study was to describe older Thai people perceptions and experiences of living with major depression. The findings showed that they were: leading a life in detachment, and that they sensed inconvenience of approaching mental health treatment, where the patients were struggling in several aspects. This study found that the depression seemed to interfere negatively in different aspects in the older patients’ lives. It affected their views on themselves, their views on family, neighbors, community, and their views on health care. The findings are not unique for the Thai people at the individual patient level. However, the most persistent notion is that older Thai people with depression seemed existentially alone. The traditional Buddha world view may any even worsen the individual suffering as it states that today’s suffering many originate from former life mistakes and as such it should be tolerated and learned from (Nilmanat & Street, 2014). Many Thai individuals understand illness according to Buddhist construction of Karma and reincarnation, where the person that behaved morally bad in a previous life, by karmic healing activities may end the suffering, and ensure a better life next time, and therefore, there is no need to medically treat the illness in present life. The Thai culture is generally a collective oriented one and combined with the Buddhism, the existential loneliness might be even deeper due to that. The findings showed that older Thai people’ experienced the depression as *living with meaninglessness* and this seemed to be central part of their lives. They identified themselves as having been in a state of hopelessness, lacking motivation to live and planning to die. One participant captured the essence of the older people’s experience of depression in her statement, “I am always thinking that I don’t want to live. I then get a rope to hang my neck and think that no matter what other say, I will not live anymore. The idea just comes automatically”. This is in line with another study that showed that the patients suffering from depression had previously attempted suicide in 21.3% of the cases, and that the current depression episode was the largest predictor of past suicide attempt (Indu et al., 2017). Moreover, a ten years follow-up study found that depression was associated with an increased risk of 77% for all-causes mortality (van Dijk et al., 2016). This point to the fact that there is a need for a general increase in the population’s mental health literacy. When the people have mental health literacy, they can recognize, manage, and prevent themselves from mental disorder (Jorm, 2012).

Older people in this study expressed that they *holding distress with one’s self* as seem they were loneliness. Older people reported that they were not able to initiate and maintain relations with relatives and friends. Their suffering from depression were kept secret, as the older people wanted to hide this shameful and guilt from others. Older people may fear the consequences of disclosing the experience to health care providers, family, and friends. It might inhibit the older people from seeking treatments. This is in line with previous studies that reported that patients with depression did not seek treatment because they lacked knowledge (Epstein et al., 2010), and because

they hide due to a feeling of shame (Holm & Severinsson, 2014). This study has shown that the older people *feeling judged by surrounded people*. Older people spoke about that they were crazy and pretended to be ill, and they believed that they did not belong to the same community as their neighbors. Moreover, they believed that the neighbors thought badly about them. This could sign of that they felt stigmatized. This is in line with another study, which showed that self-stigma was positively correlated with depression (Oakley, Kanter, Taylor, Duguid, 2011). Stigma has been identified as a main factor associated with the lack of health care utilization in the treatment of depression and the stigma of mental illness may impair achievement of personal aspirations (Corrigan & Wassel, 2008). If older people choose not to seek treatment, they will be having serious health and psychosocial burdens of untreated depression. Our study also found that *sensing an unapproachable health care service* when older people suffered from depression. They expressed that they lacked access to health care services, and efficacy of treatment due to living in dependency on their children. Some older people revealed that they lived alone, and therefore it was difficult to travel because of lack of public transportation in rural area. They occasionally went to a hospital with neighbors when they had worse diseases. In the same way, another study found that women in rural area were less likely to seek treatment of depression (Cadigan & Skinner, 2015). Though, in our study the reason were of a more practical character. It is supported by a qualitative synthesis study that found that various help seeking behavior was likely due to a range of factors, and divided into four concepts; depression and help-seeking as a threat to individual's Identity, role of social networks in help-seeking, coping strategies as a main factor for treatment delay, and barriers to depression help-seeking (Doblyte & Jimenez-Mejias, 2017).

More important, the results of this study demonstrated that older people diagnosed with depression were *lacking knowledge about clinical depression*. Older people thought that symptoms were an inevitable part of old age and a result of karma affecting the present state, so even when they were depressed, disheartened, and overwhelmed for a year or two but they did not want to seek the health care services. Besides, they thought that it would come and go by itself, which is in consistency with previous studies (Maiera, 2010; Gellis, 2010). The results of knowledge about clinical depression are in accordance with the previous studies that found more than half of Korean American older adults had a serious lack of knowledge about various aspects of depression (Jang, Gum & Chiriboga, 2011), for instance, older people were not aware of sign and symptoms of depression. Then the older people suffered from severe depression and to the extent that they planned to die as the result showed. This result also showed that the depression was detected by tracking chronic illness. They were less likely to seek treatment for depression itself until the nurses checked and identified their depression. This can be an immediately concern for the healthcare provider for providing needed knowledge of depression.

5. Limitations of Study

There were 14 older Thai people, living in rural area, obtained purposively for this research. The findings were not referred to all older people especially in other culture. Moreover, the participants did not include any older person who lived in public nursing home. Variation would have been larger if both sexes had been involved in the study. However, with reference to our clinical as psychiatric nurses, we do not believe that the findings would have been different, and subsequently only having female informants is not seen as a limitation.

6. Clinical Implication

These findings points at lacking knowledge in some rural Thai older people that suffered from major depression, and there is no reason to assume that the general population differs in that respect. Therefore, the mental healthcare authorities should provide strategies for individual mental health care literacy. Mental healthcare providers play an important role in providing the knowledge of what are mental disorder, and how to seek mental healthcare.

7. Conclusion

This study provides new information on older Thai peoples' perceptions and experiences of major depression. These were affected with high level suspected existential loneliness that might even be worse in a collect oriented society as in the Thai context. Further, it seem hard to approach the mental health care. The central reason for this is interpreted as lack of mental health literacy, and in this case knowledge on depression. Future studies should focus on relatives' experiences of living with an older family member that suffered from major depression, and on the state of mental health literacy in the rural Thai population.

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Authors' Contribution

D. K. performed the collection of data, analysis and drafted the manuscript. L. K. contributed to the conception, design and analysis of this study. Further, L. K. and S. C. critically reviewed the manuscript and supervised the whole study process. All authors read and approved the final manuscript.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Analysis of SGOT, SGPT, and IgM anti PGL-1 in Multibacillary Leprosy Patient after Multi Drug Therapy

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Abstract

Introduction: Leprosy is a fairly dreaded disease, but it is curable. However, liver failure is one of the side effect of the treatment that challenging to manage.

Objectives: Assessing the effects of Multi Drug Therapy (MDT) on the liver function (SGOT, SGPT) and Mycobacterium Leprae Particle Agglutination (MLPA) test (IgM anti PGL-1) before and after treatment in patients with multibacillary (MB) leprosy.

Method: Twenty-eight patients who met the inclusion criteria were enrolled in this study which categorized as new MB leprosy patients in Dr. Wahidin Sudirohusodo Hospital, Makassar, Indonesia. In order to test the liver function, blood serum was taken to measure the SGOT and SGPT level with Boehringer Mannheim automatic analysis, while MLPA test measurement was performed with qualitative method. Blood serum was collected three times with the following period; before the treatment, 3 months, and 6 months after treatment. The data was analyzed using Friedman and Wilcoxon Signed Rank test with significant level $p < 0.001$.

Result: There were significant increases in SGOT and SGPT levels ($p < 0.001$) before and after MDT treatment between 3 to 6 months. Meanwhile, for IgM anti PGL-1, it was not significant ($p > 0.01$) before treatment and after 3 months treatment, but significant different ($p < 0.001$) on 6 months treatment.

Conclusion: MDT treatment on MB leprosy patient increase the SGOT and SGPT level but decrease the IgM anti PGL-1 after the 6 months of treatment.

Keywords: IgM anti PGL-1, multibacillary leprosy, Multi Drug Therapy, SGOT, SGPT

1. Introduction

Leprosy is a chronic granulomatous disease, which mainly affecting the skin, peripheral nerves and mucosa of the upper respiratory tract. Leprosy is caused by *Mycobacterium leprae* (*M. leprae*), an obligate intracellular bacterium. Manifestations of clinical symptoms have a broad spectrum, which classified as Tuberculoid (TT), Borderline Tuberculoid (BT), Borderline Borderline (BB), Borderline Lepromatous (BL) and Lepromatous Leprosy (LL). (Gaschignard et al., 2016).

Clinical manifestations of leprosy very various and among other diseases, it was known as the great imitators therefore it could imitate clinical symptoms of many diseases. These manifestations of leprosy depends on individual immunity response to *M. leprae* and it has a lot of similarity between patient with leprosy and connective tissue diseases both clinically and serologically (Hsieh & Wu, 2014).

Main purpose in leprosy eradication is to cut the chain of infection in order to decrease it's incidence, by treating and curing patients and also prevent the risk of disability (Ribeiro et al., 2015). Thus, in order to achieve these objectives, the principal strategy is still based on the early detection and treatment. Since introduced by WHO in 1982, multidrug therapy (MDT) has become a treatment strategy that has provided a highly effective cure for leprosy (WHO Expert Committee on Leprosy, 2012).

Among of side effect MDT drugs regiment is hepatotoxic and the simple examination to assess it is by measuring liver function through SGOT and SGPT tests (Amacher et al., 2013; Robles-Díaz et al., 2014). Progress in the field of immunology is very helpful in making the diagnosis and treatment including the use of serological tests for

leprosy (Setia et al., 2011). One of the serological test to assess IgM anti PGL-1 is Mycobacterium Leprae Particle Agglutination (MLPA). It is not only a simple and economical technique for early diagnosis and evaluation of leprosy treatment but also has high specificity and sensitivity (Eichelmann et al., 2013; Widodo, 2015).

The objective of this study is to analyze the liver function (SGOT, SGPT) and MLPA test (IgM anti PGL-1) in patient with MB leprosy before, 3 months, and 6 months after treatment with MDT-WHO regimen.

2. Material and Methods

This was a cohort study of 28 subjects, they are new patients with MB leprosy who visited Dr. Wahidin Sudirohusodo Hospital in Makassar, Indonesia. The subjects consist of 19 men (mean age 27.9 years) and 9 women (mean age 25.8 years). Venous blood (5cc) was collected after the patient signed the informed consent. To assess the liver function, the blood was centrifuged to obtain serum than SGOT and SGPT measurement was performed. The examination was conducted by automated Boehringer Mannheim analyser. While to assess MLPA test (IgM anti PGL-1) we assessed qualitatively using blood serum. This study was approved by the ethical committee of Faculty of Medicine, Hasanuddin University.

Statistical analysis was performed using SPSS 20.0.1 package for Windows (SPSS Inc., Chicago, IL, USA). The Friedman and Wilcoxon Signed Rank tests were used to analyze the significant difference of SGOT, SGPT and MLPA test (IgM anti PGL-1) before, 3 months, and 6 months after treatment. A value of $p < 0.001$ was considered statistically significant.

3. Results

Based on WHO classification, 28 patients were enrolled in this study can categorized as multibacillary leprosy: 4 BB-type patients (14.29 %), 17 BL-type patients (60.71 %) and 7 LL-type patients (25.00 %).

The result of this study showed that both SGOT and SGPT were increased after MDT treatment. Friedman test result was supported this finding by significant difference of SGOT and SGPT ($p < 0.001$) before and after treatment (Table 1 and Figure 1). Further statistical analysis using Wilcoxon Signed Rank test showed significant difference ($p < 0.001$) between before and 3, 6 months after treatment, but not for between 3 and 6 month ($p > 0.001$).

Table 1. Mean value of SGOT and SGPT from MB type leprosy patients before, after 3 months and 6 months of treatment and the result of Friedman test.

Time	SGOT (u/l)		Friedman test	SGPT (u/l)		Friedman test
	Mean	S D		Mean	S D	
Before	17.61	4.72		15.75	8.28	
3 month	24.50	5.32	$p < 0.001$	19.93	6.91	$p < 0.001$
6 month	26.07	6.63		22.04	7.68	

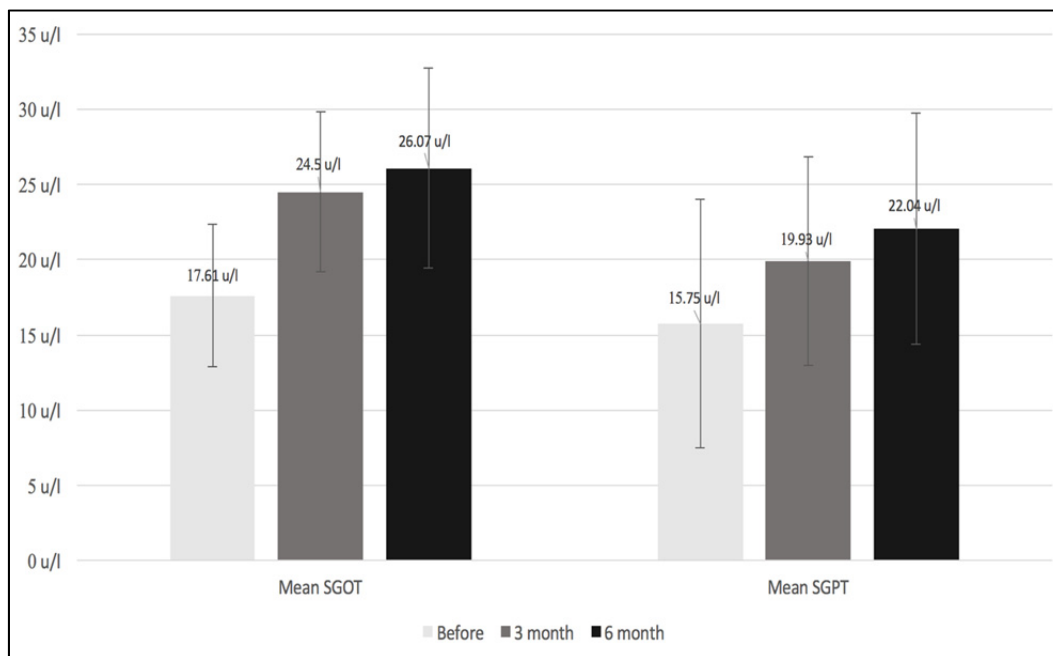


Figure 1. Mean and SD value of SGOT and SGPT from MB type leprosy patients before, 3 months and 6 months after treatment

The results of the MLPA test (IgM anti PGL-1) can be seen in Table 2 and Figure 2. Based on Friedman Test there is a significant difference during treatment ($p < 0.001$). Furthermore, statistical analysis using Wilcoxon Signed Rank test showed no significant differences ($p > 0.001$) before and 3 months after treatment. In contrast, after 6 months of treatment there was a significant difference ($p < 0.001$) compared before treatment.

Table 2. Mean value of IgM anti PGL-1 from MB type leprosy patients before, after 3 months and 6 months of treatment and the result of Friedman test

IgM anti PGL-1	Mean	S D	Friedman Test
Before	187.43	84.76	p < 0.001
3 month	197.71	82.65	
6 month	72.00	44.09	

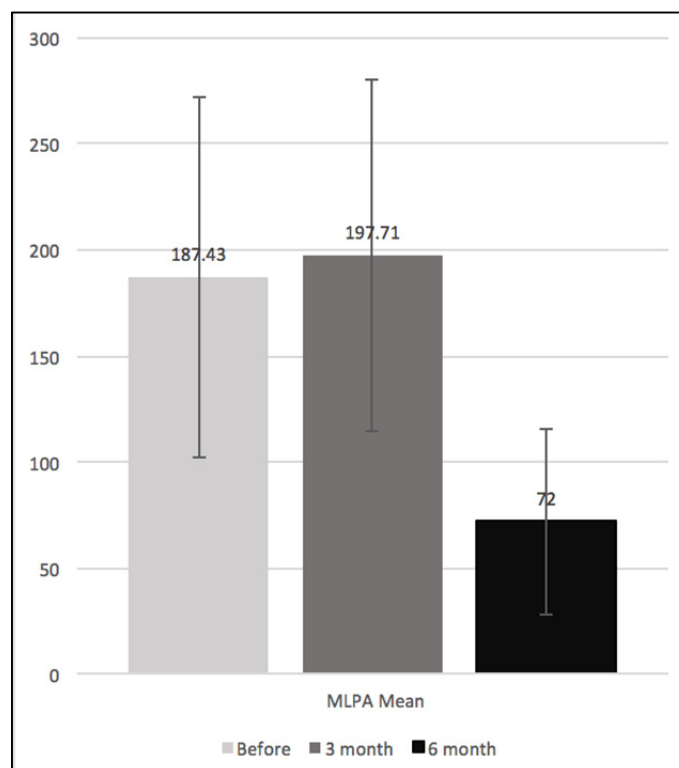


Figure 2. Mean and SD value of IgM anti PGL-1 from MB type leprosy patients before, 3 months and 6 months after treatment

4. Discussion

Twenty-eight leprosy patients who met the criteria of multibacillary leprosy patients (BB, BL and LL type) based on WHO classification participated in this study (WHO Expert Committee on Leprosy, 2012). All patients have not receiving any treatment before study.

Drug Induced Liver Injury (DILI) is one of the serious complications of drug therapy (Amacher et al., 2013; Borlak et al., 2014) that finally cause Acute Liver Failure (ALF) and liver transplantation (Corsini et al., 2012). The World Health Organization (WHO) (2012) recommends multibacillary type leprosy treatment using MDT that is a combination of dapsone, rifampicin, and clofazimine for 12 months to complete the treatment. Study by Deps et al. (2007) reported that 20–23.5% of patients who received MDT showed hepatic abnormalities.

Among three drugs (dapsone, rifampicin, clofazimine), rifampicin is the most important anti-leprosy and it is included in drug regimens for both paucibacillary (PB) and multibacillary (MB) types. It is also associated with the occurrence of DILI. (Borlak et al., 2014; Corsini et al., 2012). Schultz et al. (2014) found that using 600 mg or more of rifampicin given daily was a risk factor for hepatotoxicity. Clofazimine is very effective and safe when given daily in normal doses. The use of dapsone in appropriate doses rarely gives side effects. Although there are many side effects that may result such as skin allergic reactions, hemolytic anemia, methemoglobinemia, jaundice, agranulocytosis, psychotic reactions and 'dapsone syndrome' (Deps et al., 2007).

In this present study, we found that there was a significant increases in SGOT and SGPT level after treatment compared to before treatment. According to Kamble et al. (2017), values with an upper limit of 35 u/l for both SGOT and SGPT level are considered normal. So, the increasing of SGOT and SGPT (3 and 6 months) after treatment were still within normal limits (Table 1). We can conclude that the administration of MDT drugs up to 6 months is safe for liver function. This also corresponds to a study where the effect of rifampicin on liver toxicity is negligible because of low SGOT and SGPT levels (Parikh et al., 2014). However, in addition to our research data, there is a significant increase in SGOT and SGPT levels after MDT therapy, thus monitoring of liver function is important to be performed regularly especially in longer term MDT therapy.

Table 2 shows the IgM anti PGL-1 levels before treatment and almost no difference 3 months after treatment and subsequently decreased significantly 6 months after treatment. In this study, we used MLPA test to detect IgM anti-PGL-1 because MLPA is a simple and economical technique for early diagnosis and evaluation of

multibacillary leprosy treatment, and has a good specificity and sensitivity (Eichelmann et al., 2013; Geluk, 2013). The MLPA test specificity was 91% in MB leprosy patients and 21% in patients PB. The MLPA (IgM anti PGL-1) test can also be used for early detection of leprosy in order to reduce the risk of nerve damage (Geluk, 2013).

There was positive correlation between the level of IgM anti PGL-1 and the number of *M. leprae* in patient who appeared clinically with a large number of active lesions. Individuals with positive anti-PGL-1 IgM had a 7.2-fold higher risk of leprosy than individuals with negative anti-PGL-1 IgM. (Karim et al., 2015). The MLPA test can be used not only in diagnosing MB type leprosy cases but also for treatment evaluation (Datta et al., 2014). Our study showed that IgM anti PGL-1 was decreased 6 months after treatment, it means that the MDT regimen administered for 6 months may provide improvement in leprosy patients.

5. Conclusion

The administration of MDT drugs for 6 months in MB type leprosy patients increase SGOT and SGPT level although within normal limits, and also decreases the IgM anti PGL-1. Based on the results of this study we suggest that IgM anti PGL-1 can be used as markers in diagnosing and evaluating in cases of MB type leprosy patients.

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Competing Interests Statement

The authors declare that there are no conflicts of interest.

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Risk Factors Associated with Diabetes Mellitus in Local Population of Lahore, Pakistan

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Abstract

Background: Diabetes is the leading cause of morbidity and mortality amongst the people of Pakistan. In 2015, 7 million people had diabetes and the number is still on raise. Family history of diabetes, high body mass index, and other sociodemographic factors are the risk factors of diabetes. Persistent exposure to excessive glucose may be a reason behind diabetic complications like nephropathy, neuropathy, retinopathy, cardiomyopathy and gestational diabetes mellitus.

Methods: For the evaluation of laboratory parameters, 600 blood samples were collected at Akhuwat Diabetic Centre and from Jinnah Hospital, Lahore. Demographic data of the participants was collected by filling a questionnaire. Lipid profile, liver enzymes, and renal function tests were performed and statistical analysis was done.

Results: Type 2 diabetes mellitus among other types is the most prevalent form of diabetes in our population. Family history of diabetes ($p=0.002$), Body Mass Index (>25) $p<0.001$, high cholesterol ($p=0.04$), high triglyceride $p<0.001$, high LDL $p<0.001$ and low HDL $p<0.001$ are significantly associated with the incidence of diabetes. Hypertension among the other comorbidities is more common in diabetic patients.

Conclusion: Type 2 Diabetes Mellitus is highly prevalent in the local population. Improved lifestyle and proper medical monitoring can help to manage diabetes in our population.

Keywords: T2DM, BMI, lipid profile, liver enzymes, renal profile

1. Introduction

Diabetes Mellitus a metabolic disorder arises if body is incapable to synthesize sufficient insulin for metabolism, it could be due to improper insulin secretion, improper insulin action, or both. Persistent exposure to excessive glucose could be a dominant reason for cardiomyopathies nephropathies, retinopathies, neuropathies and a variety of different sorts of tissue injury. Diabetes mellitus additionally leads to vascular disease, hypertension, dyslipidemia, and obesity (Leech et al., 2011; Malandrino, Wu, Taveira, Whitlatch, & Smith, 2012; Zimmet, Magliano, Herman, & Shaw, 2014) (Figure 1).

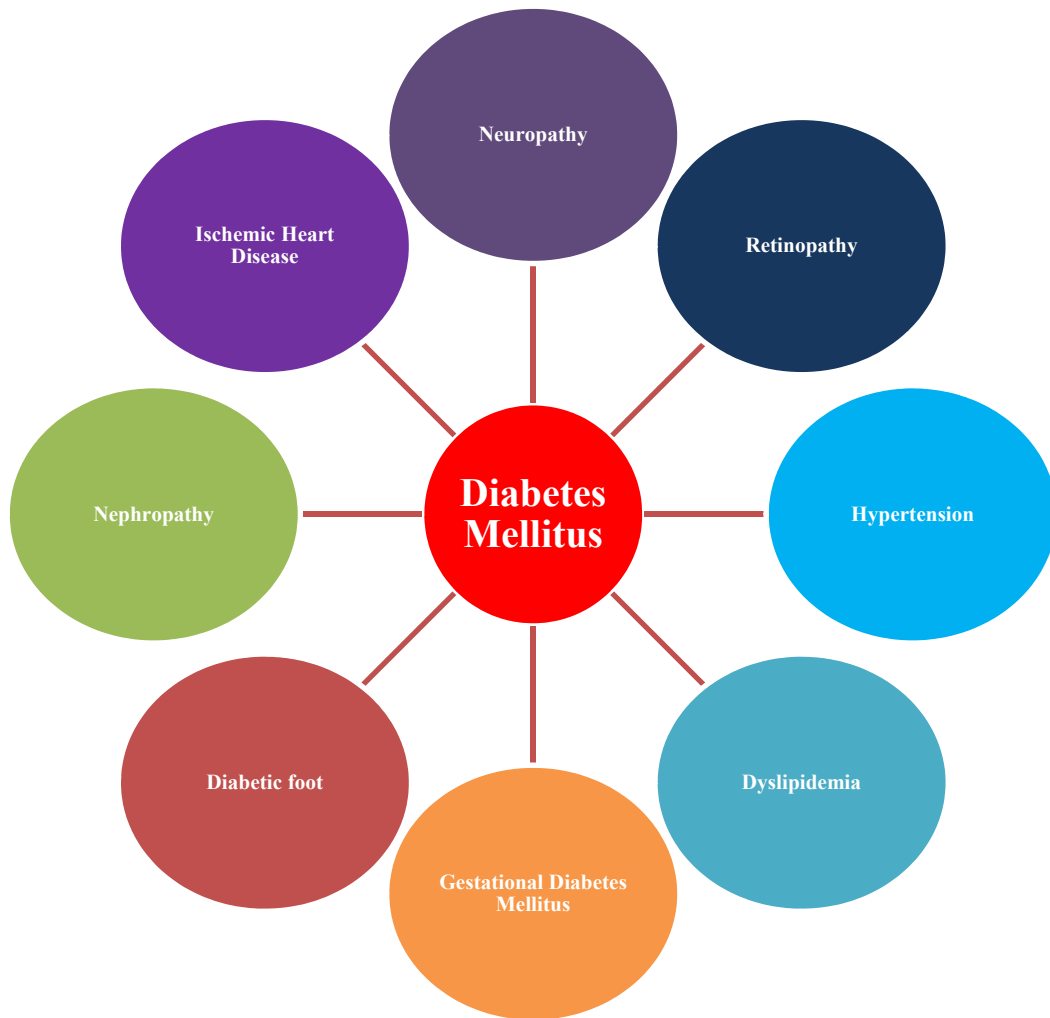


Figure 1. Diabetes-related complications

The most common type of diabetes is Type 2 (95%), while Type 1 only contributes 4-5% (Model, 2015; World Health, 2016). According to WHO in 2014, 422 million adults have diabetes worldwide (World Health, 2016). International Federation of Diabetes (IDF) reported that approximately 415 million people had diabetes in 2015 (*IDF Diabetes Atlas*, 2017) and almost 1.5 million deaths are directly attributed to diabetes each year (World Health, 2016). In Pakistan diabetes is one of the most prevalent metabolic disorder. In 2015, National Diabetes Action Plan of Pakistan reported over 7 million people suffering from diabetes (Sherin, 2015). According to International Diabetes Federation (IDF) report, the prevalence of diabetes in Pakistan in 2014 was approximately 7% (“International Diabetes Federation”, 2015). A diagnostic criterion for the diagnosis of diabetes mellitus defined by World Health Organization (WHO) and International Diabetes Federation (IDF) is presented in Figure 2 (*IDF Diabetes Atlas*, 2017).

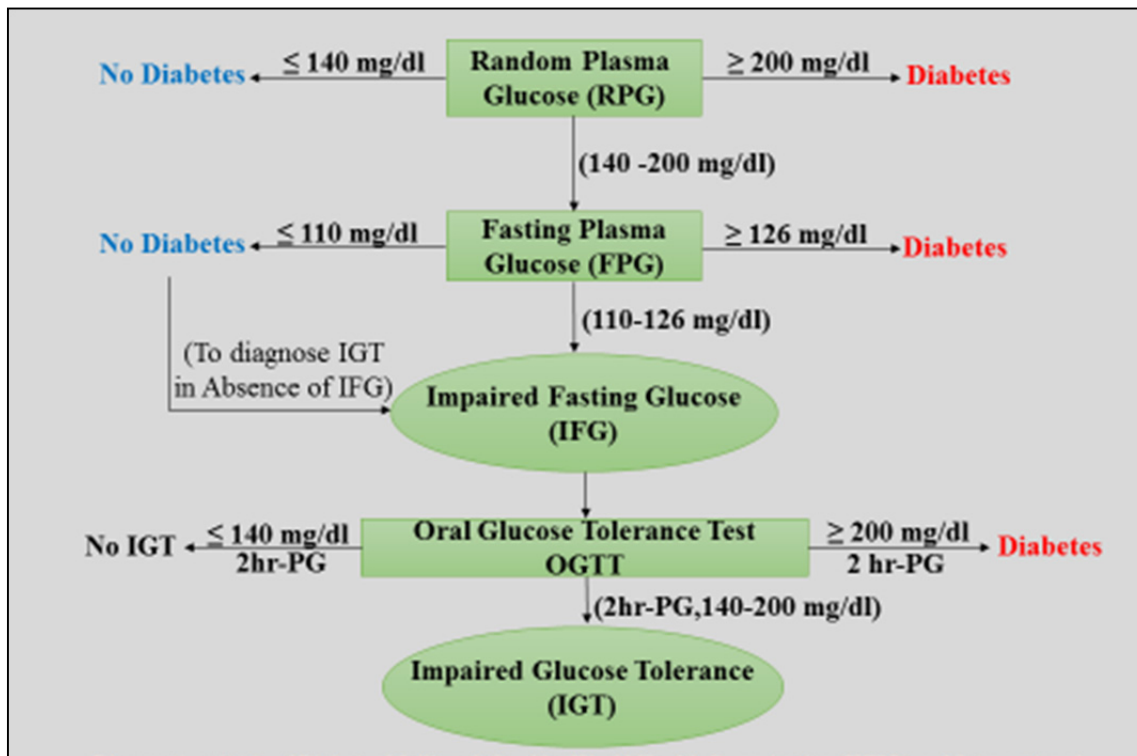


Figure 2. Diagnostic criteria of Diabetes Mellitus defined by World Health Organization (WHO) and International Federation of Diabetes (IFD)

Numerous studies on the prevalence and risk factors related to T2DM are dispersed in the Asian nation within the past, however, most of them are restricted to South Indian populations (Sethi, Kumar, Gupta, & Bhanwer, 2011). So this study was conducted to compare social and demographic features among diabetic and non-diabetic individuals in our local population. Another important aim of this study was to compare lipid profile, renal function tests and liver function tests in diabetic and non-diabetic individuals.

2. Materials and Methods

2.1 Study Design

A cross-sectional study was designed, in which 600 blood samples were collected from the participants visited Akhuwat Diabetic Centre, Township Lahore, and Jinnah Hospital Lahore from December 2016 to April 2017.

2.2 Sample Size

According to International Diabetes Federation (IDF) report, the prevalence of diabetes in Pakistan in 2014 was approximately 7% so using open epi software a minimum sample size for this study was 101 with 95% confidence interval ("International Diabetes Federation", 2015; Sherin, 2015).

2.3 Sample Collection, Transportation, and Storage

From all the subjects including in the study, 5ml blood was drawn from the median cubital vein of the arm with the help of sterilized 5cc syringe and collected in EDTA-containing tube, serum separating tube and sodium fluoride containing tube. Samples were carefully transported to Laboratory and stored at 2–8 °C for further processes.

2.4 Demographic Data

Demographic data of the participants was collected by filling a questionnaire, including the following particulars: age, gender, smoking, alcohol consumption, family history of diabetes, family history of hypertension, surgical history of the participants and any other comorbidity. Body mass index (BMI) of the participants was calculated by the following formulae:

$$\text{BMI} = \frac{\text{Weight of the person in Kgs}}{\text{Height of the person in m}^2}$$

2.5 Laboratory Analysis

Blood Sugar Random (BSR)

Blood Glucose of all participants was estimated by using kits of Cobas ® c311 by Roche Diagnostics, USA.

HbA1c

For all those participants who had elevated levels of Blood Glucose, estimation of blood glycated hemoglobin (HbA1c) was done (Cobas ® c311, Roche Diagnostics USA).

Lipid Profile

Serum Cholesterol, Triglyceride, High Density Lipoprotein (HDL) and Low Density Lipoprotein (LDL) were measured in all blood samples (Cobas ® c311 by Roche Diagnostics USA).

Renal Function Tests (RFTs)

For renal function test Serum Urea, Serum Creatinine and Serum Uric Acid were measured and kits of Cobas ® c311 by Roche Diagnostics USA were used.

Liver Function Test (LFTs)

Serum Total Bilirubin, Serum Alanine Aminotransferase (ALT), Serum Aspartate Aminotransferase (AST) and Serum Alkaline Phosphatase (ALP) were estimated by using kits of Cobas ® c311 by Roche Diagnostics USA.

2.6 Statistical Analysis

Data was stored in Microsoft EXCEL and analyzed using the Statistical Package for Social Sciences (SPSS 21.0. version). Descriptive analysis was done for the calculation of frequencies of different variables. Chi-square test was done to evaluate any significant association among qualitative variables and Independent T-test was done to compare mean difference between diabetic and non-diabetic group. Regression analysis was done to find out Odd Ratio (OR) and 95% Confidence Interval (CI) for different variables. P value less than 0.05 was considered as significant in this study.

3. Results

In this cross sectional study, blood samples from 600 participants were collected, of which 83% were diabetic and only 17 % were non diabetic. Table 1 presents the comparison of diabetic patients vs. non-diabetic group; of 500 diabetic patients 221 (44%) were male and 279 (56%) were females while 45% were non-diabetic males and 55% were non-diabetic females. Results of chi-square analysis indicate diabetes is gender independent. Diabetes was more prevalent in married people as 99% of the diabetic patients were married (p value <0.001). Two-hundred and eighty-two (56%) of diabetic patients with >10,000 PKR income were moderate while rest (44%) were with the poor socioeconomic background (≤10,000 PKR monthly income). Socio-economic status showed a borderline significant relation with the high prevalence of diabetes (p value = 0.05).

Smoking and Alcohol consumption did not show any statistical significance with diabetes. Results of this study indicate body mass index (BMI) was significantly associated with diabetes. Among 600 participants 362 were obese and 96% of these obese participants had diabetes (p value <0.001).

Table 1. Comparison of Diabetic and Non-Diabetic Group

Characteristics		Diabetic Group n= 500	Non-Diabetic Group n=100	p value
Gender	Male	221 (44%)	45 (45%)	0.88
	Female	279 (56%)	55 (55%)	
Marital Status	Married	497 (99%)	82 (82%)	<0.001
	Unmarried	3 (1%)	18 (18%)	
Socio-economic Status	Poor	218 (44%)	33 (33%)	0.05
	Moderate	282 (56%)	67 (67%)	
Smoking	Non-smoker	457 (91%)	88 (88%)	0.28
	Smokers	43 (9%)	12 (12%)	
Alcohol Consumption	Non-alcohol Consumer	498 (99.6%)	99 (99%)	0.43
	Alcohol Consumer	2 (0.4%)	1 (1%)	
BMI	Normal (≤ 25)	149 (30%)	89 (89%)	<0.001
	Obese (>25)	351 (70%)	11 (11%)	

Out of 500 diabetic patients 96.8% had Type-2 Diabetes Mellitus and others had Type-1 Diabetes Mellitus. Glycated hemoglobin (HbA1c) was raised ($>6.0\%$) in 464 (93%) of the diabetic patients and only 36 (7%) of the diabetic patients had their normal HbA1c (4.0-6.0%).

Hypertension is highly prevalent in diabetic patients (45%) among all other comorbidities (Table 2).

Table 2. Prevalence of Comorbidities in Diabetic Patients

Comorbidities	Frequency (Percentage)
Hypertension (HTN)	226 (45%)
Surgical History	180 (36%)
Dyslipidemia	39 (8%)
Ischemic Heart Disease (IHD)	32 (6%)
Nephropathy	26 (5%)
Neuropathy	22 (4%)
Liver Disease	17 (3%)
Diabetic Foot	5 (1%)
Infectious Diseases	3 (0.6%)
Retinopathy	2 (0.4%)

Results indicate Lipid Profile (Serum Cholesterol, Triglyceride, HDL and LDL) was statistically associated with the incidence of diabetes mellitus. Serum Cholesterol (p value: 0.04; OR: 1.56; 95% CI: 1.00-2.45), Serum Triglyceride (p value: <0.001 ; OR: 3.86; 95% CI: 2.23-6.70), Serum HDL (p value: <0.001 OR: 3.24; 95% CI: 1.68-6.24) and Serum LDL (p value: <0.001 ; OR: 2.63; 95% CI: 1.43-3.89). Statistically Liver Function Tests (Serum Total Bilirubin, ALT, AST and ALP) and Renal Function Tests (Serum Urea, Creatinine and Uric Acid) did not show any association with diabetes mellitus (Table 3).

Table 3. Comparison of Lab Parameters among Diabetic and Non-Diabetic Group

Lab Parameter		Diabetic Group	Non-Diabetic Group	OR (95% CI)	p value
		n= 500	n= 100		
Cholesterol	≤200 mg/dL	229 (87%)	35 (13%)	1.56 (1.00-2.45)	0.04
	>200 mg/dL	271 (81%)	65 (19%)		
Triglycerides	30-200 mg/dL	279 (77%)	83 (23%)	3.86 (2.23-6.70)	<0.001
	>200 mg/dL	221 (93%)	17 (7%)		
HDL	35-65 mg/dL	357 (80%)	89 (20%)	3.24 (1.68-6.24)	<0.001
	<35 mg/dL	143 (93%)	11 (7%)		
LDL	60-130 mg/dL	293 (80%)	77 (20%)	2.63 (1.43-3.89)	<0.001
	>130 mg/dL	207 (90%)	23 (10%)		
Total	≤1.1 mg/dL	415 (84%)	81 (16%)	0.87 (0.50-1.51)	0.63
Bilirubin	>1.1 mg/dL	85 (82%)	19 (8%)		
ALT	≤42 IU/L	389 (84%)	76 (16%)	1.10 (0.60-1.83)	0.69
	>42 IU/L	111 (82%)	24 (18%)		
AST	≤41 IU/L	392 (84%)	75 (16%)	1.21 (0.73-1.99)	0.45
	>41 IU/L	108 (81%)	25 (19%)		
ALP	35-130 IU/L	367 (85%)	64 (15%)	1.55 (0.98-2.44)	0.058
	>130 IU/L	133 (79%)	36 (21%)		
Serum Urea	10-50 mg/dL	469 (83%)	93 (17%)	1.13 (0.48-2.66)	0.76
	>50 mg/dL	31 (82%)	7 (18%)		
Serum Creatinine	0.7-1.2 mg/dL	452 (83%)	93 (17%)	0.41 (0.61-3.21)	0.41
	>1.2 mg/dL	48 (87%)	7 (13%)		
Serum Uric Acid	3.4-7.0 mg/dL	445 (84%)	84 (16%)	1.54 (0.84-2.81)	0.16
	>7.0 mg/dL	55 (77%)	16 (23%)		

In this study family history of hypertension did not show any significant relation with the commencement of diabetes mellitus (p value: 0.11; OR: 1.44 and 95% CI: 0.91-2.26). However, family history of diabetes mellitus is significantly associated with the incidence of diabetes mellitus (p= 0.002, OR: 1.97 95% CI: 1.27-3.04). Results presented in Table 4.

Table 4. Comparison of Family History of Diabetes and Hypertension among Diabetic and Non-Diabetic Group

Characteristics		Diabetic Group	Non-Diabetic Group	OR (95% CI)	p value
		n= 500	n= 100		
Family history of HTN	Yes	287 (81%)	66 (19%)	1.44 (0.91-2.26)	0.11
	No	213 (86%)	34 (14%)		
Family history of Diabetes	Yes	343 (87%)	52 (13%)	1.97 (1.27-3.04)	0.002
	No	157 (77%)	48 (23%)		

4. Discussion

This study was designed to investigate the association of sociodemographic factors with the incidence of diabetes mellitus and to throw light on the relationship of diabetes mellitus with the lipid profile, liver function tests, and renal function tests.

Results of this study suggest a high prevalence of diabetes in a local population of Lahore, Pakistan. It has been showed in the National diabetic survey conducted by Diabetes Association of Pakistan (DAP) and World Health Organization (WHO) that the prevalence of diabetes was 11% in Pakistan in 1990s (“Milestones of the Diabetic Association of Pakistan,”; Sherin, 2015; World Health, 2016). According to International Diabetes Federation (IDF) report, the prevalence of diabetes in Pakistan in 2014 was approximately 7% (“International Diabetes Federation “, 2015; Sherin, 2015). According to WHO and IDF reports 422 million adults have diabetes in 2014 and 415 million people had diabetes in 2015 respectively (*IDF Diabetes Atlas*, 2017; World Health, 2016). In this study, although the percentage of diabetes is much higher than previously reported. This study has strength that it reflects the association of not only social demographic characteristics but also laboratory parameters with family history of diabetes. However, there is some limitation as samples were collected from the specialized therapeutic clinic, which may a reason behind the high frequency of diabetes in our participants. The data of this was not randomly collected from population which is a limitation of this current study.

Findings of this study suggest that diabetes is more prevalent in adult age (mean age 49.05 years). Study of Dai et al. in 2012 supported this fact that aging is an important risk factor for diabetes. Mitochondrial dysfunction starts with the aging, which disturbs the cellular physiology and helps in the development of pathological conditions like insulin resistance (D. F. Dai, 2012). The results of this study suggests that diabetes is prevalent in married people as compared to unmarried individuals, these results are in accordance with the earlier (Azimi-Nezhad et al., 2008; Corsi & Subramanian, 2012)

Current findings suggest that smoking and alcohol are not significant for the onset of diabetes in accordance with the previous reports (Carter et al., 2015; Holmes et al., 2014; Mokdad et al., 2003).

Body mass index (BMI) is significantly associated with the commencement of diabetes mellitus. Multi-various studies showed the positive connection of high BMI with the diabetes mellitus. Overweight/obesity contribute to fatty liver or insulin resistance and also disturbs body metabolism thus helps in the progression of diabetes (Sung, Jeong, Wild, & Byrne, 2012). Modern lifestyle, physical inactivity or psychological stress are the causes of abnormal BMI which leads to diabetes mellitus. Studies showed that there are 42% more risk for diabetes if BMI of a person is above 30.

It was also observed that Type 2 diabetes mellitus is the most prevalent type of diabetes among others. Dey *et al* in 2011 reported that 5-10% cases are suffering from Type 1 diabetes while 90–95% cases are of Type 2 diabetes mellitus (Dey & Attele, 2011). This high prevalence of Type 2 diabetes may be due to psychological behavior, hypertension, stress, obesity, moderate lifestyle with less physical activities and improper glycemic control. All these factors considered as risk factors for the diabetes mellitus (Sethi et al., 2011).

We reported a significant association of Lipid profile (Cholesterol, triglyceride, HDL and LDL) with diabetes. Results indicate Cholesterol, Triglyceride, and LDL were elevated whereas HDL which is considered as a good cholesterol was less in diabetic patients. Our results are consistent with previous reports (Khan, Sobki, & Khan, 2007; Meikle et al., 2013) those suggested hypercholesterolemia, hypertriglyceridemia, high LDL and low HDL levels are the significant risk factors for the cardiovascular disorders in diabetic patients (VinodMahato et al., 2011) and 8% of diabetic patients of this study have diabetic lipidus. In the study of Pandya *et al*, 82% of diabetic patients showed dyslipidemia (Pandya, Lakhani, Dadhania, & Trivedi, 2012). Major etiology behind diabetic lipidus is insulin resistance due to the interaction of insulin with apolipoproteins and adipocytes in obesity (Meikle, Wong, Barlow, & Kingwell, 2014). Dyslipidemia together with diabetes mellitus is the leading cause of Ischemic heart disease (IHD) as indicated by the prevalence of IDH in diabetic patients of the current study is 6%.

In contrast to previous studies our results did not suggest any association of Liver enzymes (ALT, AST, and ALP) with diabetes (Harris, 2005; Nannipieri et al., 2005; Vozarova et al., 2002). Liver enzymes are not directly linked with diabetes however abnormal liver enzymes may be due to obesity or any other complication that arise after diabetes. Similarly in our samples renal function test also did not show any statistical significant association with diabetes.

Bamanikar et al. concluded that serum urea and serum creatinine are the predictors of the nephropathy in diabetic patients (Bamanikar, Bamanikar, & Arora, 2016). Though mostly studies reported that renal function tests are associated with diabetes, the reason behind the results of this current study may be a short duration of diabetes onset, as nephropathy occurs after the prognosis of diabetes.

Uric acid is the metabolic end product of purines their levels raised in nephropathies. The current finding is supported by the results of Bandaru and Taniguchi they found a negative association between serum uric acid and diabetes while contradicted by others (Bandaru & Shankar, 2011; Kodama et al., 2009; Kramer, Von Mühlen,

Jassal, & Barrett-Connor, 2009; Taniguchi et al., 2001). Results of this study also showed that prevalence of nephropathy in diabetic patients is 5%.

Though studies have reported that there is a significant relationship between prognosis of diabetes and nephropathy. Studies have also revealed that presence of HTN in diabetic patients also trigger this relationship. Results of our study did not show any significance association between diabetes and nephropathy. So we further examined the relationship between hypertension and RFTs.

A high prevalence of hypertension in diabetic patients in contrast to other complications was also observed in this study. Increased body mass index is the main reason behind high prevalence of hypertension, as this study has indicated a high prevalence of increased BMI in diabetic patients. Colosia et al., in 2013 reported hypertension with or without obesity is very much prevalent in diabetic patients (Colosia, Palencia, & Khan, 2013). Other studies showed same results in Romania and Japan (Dorobantu, Darabont, Badila, & Ghiorghe, 2010; Nakano et al., 2004). Blood glucose damages the arteries and makes them hard (atherosclerosis), result in the high blood pressure and cardiovascular disorders.

The family history of diabetes was observed as a significant factor in the onset of diabetes. A person has 1.97% more chances if first degree relatives have a positive history of diabetes as showed in this study. The family history of diabetes and hypertension is important in the individuals with metabolic syndrome for the commencement of Type 2 diabetes mellitus (Das, Pal, & Ghosh, 2012; Ranasinghe, Cooray, Jayawardena, & Katulanda, 2015). Family history of diabetes is an independent risk factor for diabetes in the Local Population of Lahore, as reported in the study of Zafar et al., in 2013 (Zafar, Qureshi, & Sandhu).

Diabetic individuals are at high risk for developing complications like cardiovascular disease, nephropathy, neuropathy, retinopathy, dyslipidemia, diabetic foot, infectious diseases, and pregnancy complications (*IDF Diabetes Atlas*, 2017). Deshpande et al. in 2008 also reported high prevalence of complications in diabetic patients (Deshpande, Harris-Hayes, & Schootman, 2008). There is no exact estimation of complication in diabetic patients, but many studies showed the prevalence of individual complication of diabetes.

5. Conclusion

Type 2 Diabetes Mellitus is highly prevalent in the local population of Lahore, Pakistan. Family history along with other risk factors like high Cholesterol, Triglyceride, Body Mass Index (BMI >25) and low High-Density lipoproteins (HDL) contributes to the development of diabetes. An improved lifestyle and medical monitoring can manage to control diabetes in the local population. Further studies with a large cohort and to evaluate genetic risk factors are required in this population.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

Author's Contribution

SA perform lab work and draft this manuscript, ST, BT design this study and did sampling, NT, TR, SM and AM recruitment of patients and lab work, KJ design this study, statistical analysis and final revision of the manuscript.

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Evaluation of the Effect of Platelet Mediators to Increase the Skin's Collagen; A Randomized Clinical Trial

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Abstract

Objective: The aim of this paper is to evaluate the effect of platelet-rich plasma mediators on the reconstruction of facial skin collagen by a platelet cream. Additionally, the cream was composited with plasma and some herbal compounds, which carried those factors through the skin. This method as a non-invasive skin will help the skin rejuvenation.

Materials and Methods: This study is a randomized clinical trial; patients referred to the clinic with positive cases from skin wrinkles along with 20 MHz frequency ultrasound images of their skin faces. All individual enrolled in the study were randomly divided into two groups.

Group A 70cc cream including 60cc basic cream (emulsion of Lecithin and Eucerin) in addition of 5cc platelet-rich plasma and 5cc herbal extracted (Herdahelix, Musk and Genestein) to take a month received. Consequently, instructions for use of this cream is that 2.3g of the cream every night to be affected.

Group B (controls) received 70cc of the cream involving 6cc basic cream (emulsion of Lecithin and Eucerin) along with 10cc placebo (glycerin) that every night 2.3g of the cream to be applied on the face.

After a month increased the amount of facial skin collagen in each group was calculated and compared by ultrasound 20 MHz. In this project compare numerically and in terms of the amount of reflected energy (RE) was performed. In addition, the idea of using plant extracts and platelet mediators to penetrate into the skin was derived from Iranian traditional medicine.

Findings: Statistical analysis of the data collection was done by SPSS 18 software. Further, demographic characteristics including age, sex, occupation, socioeconomic status and education level had no effect on the response to treatment (P=0.221), but demographic indicator of age on response to treatment was effective (P=0.021).

Respond to the treatment (increase the amount of collagen in the skin) in group A and group B equal to 72.91% and 12.5% respectively. In group A with group B were significant differences in response to treatment, P = 0.000. The only side effect occurred in group A was mild irritation including redness and mild itching, which happened in 2 patients.

Conclusion: Employee non-invasive method of platelet cream rebuilds collagen in the skin effectively.

Keywords: Skin collagen reconstruction, platelet cream, Iranian traditional medicine, platelet rich plasma, numerical evaluation, skin collagen

1. Introduction

One of the most important materials used in cosmetics and people who suffer from infections or treatment actions due to drug deliveries and destruction their skin collagen tissue is the reconstruction skin cream or skin remodeling methods.

Help skin regeneration and rejuvenation of the skin by increasing the production of collagen, one of the most important issues in medicine today is cosmetic and medical skin. Especially the skin of patients has been suffered as a result of infection, blood disorder, or treatment of tissue damage, also for those interested in the use of tonic cosmetics for skin rejuvenation. The main indicator of reconstruction and skin rejuvenation is increases the amount of collagen in the dermis layer (Moody, McCarthy, & Hruza, 2003). There are two general methods for increasing the amount of collagen in the skin: invasive and non-invasive methods. Currently, platelet-rich plasma (PRP) injection method into the skin is one of effective invasive methods (Wroblewski, Mejia, & Wright, 2010). As in this method patients have faced to symptoms such as swelling, allergic reaction, infection, cellulites or other minor surgical complications. Therefore, a large number of patients are skeptical during referred to the skin clinic for usage this method.

Recently, non-invasive laser is one of new methods that increase skin collagen, which is named as "non-invasive laser procedure" (Trelles, Allones, Levy, Calderhead, & Moreno - Arias, 2004). But what is important in the assessment and calculation method of improving skin tone or collagen.

Until the last few years, the observer skin was based by taking image with medical report in diagnosis as well as treatment procedures. This method is qualitative and it will not be valid (Kono et al., 2007). Quantitative assessment increase collagen by measuring the energy reflected from the skin has solved this problem, which will be discussed in the materials and methods section.

The other thing, we will face in this study, the challenge of drug penetration to the skin. The project aimed to choice an uncomplicated method for making collagen.

In recent years, modern medicine through the skin for therapeutic purposes has been proposed. In 2008 and 2016 articles in this regard were published in Europe, two points in this article will draw attention. First is remove the keratin layer of the skin, another is the employed of nano-ingredients in those researches (Roberts, Pellett, & Elizabeth Cross, 2002).

Dermal absorption mechanism will take three important steps, local attract the same spot of skin, regional integration that occurs in the tissue adjacent, and finally systemic absorption, which aims to deliver drugs to the bloodstream via the skin (Moghimi, Williams, & Barry, 1998). An interesting point is that in ancient medicine enter the drug into the body through the skin is great interest. In traditional medicine in the field of pharmacy, one part is allocated to ointments that the skin drugs and has systemic absorption. About a thousand years ago Ibn Sina one of the Iranian scientists in field of traditional medicine said "drugs have two part as soft and thick segment, the soft may penetrate into the skin" (Abu-Asab, Amri, & Micozzi, 2013).

Particularly, in ancient medicine the musk has been proposed as an agent to increase the absorption of drugs, musk fragrance substance that is extracted from male deer navel and the best of its kind in China is being produced (Pooya, 2016). In modern medicine, the use of Genistein (SMH, 2008) and the roots of seaweed (*Fucus vesiculosus*) has been raised recently (Fujimura et al., 2001).

In traditional pharmacology some drugs well-known as laze, this kind of drugs are capable to penetrate into the skin for other drugs without harm tor skin tissue, function as well as its structure (Altmeyer & El-Gammal, 1992).

This study, we have used the combination of modern medicine and ideas of the ancient Iranian medicine simultaneously. Mediator or intermediates for the production of platelets include a variety of compounds like diverse granules, calcium ions, histamine, serotonin, dopamine, cytokines and fibroblastic growing factor (FGF). All mentioned compounds was blended with a triplet herbal extracted involving herdahelix, musk and

genistein. In particular, those materials make increasing amount of drug accumulation into the skin, and also genistein mimic the function of mRNA and stimulating fibroblasts as well. How to evaluate a little research comes in detail within the part of materials and methods.

2. Materials and Methods

This research was a randomized clinical trial conducted under the supervision and cooperation of the professors of Iran University of Medical Sciences and Tarbiat Modares University in Iran between May 15 and September 30, in 2016. Patients were referred to clinic of the Ibn Sina dermatology in Tehran, Iran. Inclusion criteria include parameters such as wrinkles, dermal regeneration, and *tonicity* of the skin that patients referred to the treatment center to address. Ultrasound image of the facial skin was taken from all individuals and it's as was used the basis for study and for comparison purposes. 146 patients were referred to the clinic during the course of the study; the inclusion criteria included the symptoms of rinkle and ultrasound image of face skin.

Exclusion criteria were included skin allergy, corticosteroids, chronic skin diseases, and pregnancy, cancer, skin

and anticoagulation drugs, and also, those who used tonic cosmetic creams during the past month. Therefore, from total individuals that participated in this study 40 people were excluded on the basis of exclusion criteria, and 106 people remained. The population of this study were based beyond 95% confidence ($\alpha = 0.05$) and then randomly divided into two groups.

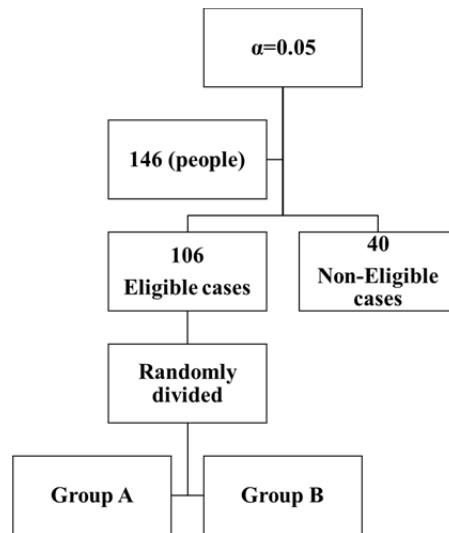


Figure 1. Demographic flowchart of clinical trial platelet cream along with inclusion and exclusion criteria

2.1 Platelet Cream Preparation Method

For group A the platelet cream was prepared including emulsion of Lecithin and Eucerin as basic cream (this cream purchased from Farabi Pharmaceutical Company of Iran). 10 cc of blood was taken from each patient, then placed in a centrifuge machine at a speed of 1200 rpm for 15 minutes (the centrifuge tube contains an anticoagulant). Finally, after completion of the plasma centrifuge, plasma plate was added to the cream base. At first, the amount of plasma solution is 5 cc. Then 5 cc of herbal extracts from herdahelix, musk and genistein were added. Finally, the total creams of group A were 70 cc.

For group B 60cc of basic cream group A along with 10cc glycerin was added as placebo. Consequently, 70 cc cream including placebo submitted to group B people. The cream was delivered to everyone in the two groups for one month's use. All people were advised to wash their face 2 hours before bed, rub it with a relatively rough texture, then dry the face. Then rub 2.3 g of the cream into the face skin slowly, also for each person, certain dishes with a capacity of 2.3 g of cream were prepared. In this study, the numerical comparison of the difference in skin tissue collagenization in two groups was very important. For the measurement of collagen before and after using the cream, ultrasound images of 20 MHz frequency were used. Therefore, the B-mode scanner and the DUB-USB-Luneburg Germany devices were used in current project. Sonographic images of both groups were obtained before and after the use of platelet and placebo creams. The reflection of the frequency transmitted to the skin tissue appears as an increase in the amount of brightness in the skin (Fleming, 2000). Whatever collagen content per unit volume, collagen fibers are seen in bright or gray stripes. But the basis for comparing the tissue repair of the skin should be expressed in numerical units. In this image, the reflection energy of ultrasound radiation was evaluated based on the base ROI, to transform into a meaningful and numerical physical quantity; the radius energy square was expressed as the numerical quantity as shown in equation. Finally, a comparison was made by converting the numerical values of these values.

$$[RE= (RIO)^2] \tag{Eq.1}$$

2.2 Statistical Analysis

The statistical analysis was used by SPSS18 software (SPSS Inc, Chicago, IL, USA) on numerical data concerning the software interpretation of reflected ultrasound waves.

3. Results

The results in the various aspects include; there is no significant correlation between demographic conditions of the participants and the amount of collagen in the skin through numerical evaluation of RE ($P = 0.267$). Since the demographic conditions in this research include age, sex, occupation, economic status and literacy level, hence the

age demographic index had a significant effect on response to treatment with $P = 0.021$. Moreover, the effective factor in responding to treatment is the amount of skin collagen compression; the better collagen production is in the skin with a higher collagen density. Based on the calculations performed in this study, the minimum and maximum of the RE value or the reflectance energy square was 10 and 25 respectively. [RE = 10-25]. But the amount of change in either the production or increase of collagen in the worst and best case was obtained 1 and 7 respectively. Noticeably, only one person in group A had the highest increase in collagen content. In group A, 2 patients left the study due to an allergic reaction, and 3 individuals did not continue the study. As in group B, 5 patients did not go on the study, so just 48 patients have remained in each group for completing the research.

In group A (intervention group), 13 patients did not respond to the use of cream. In other words, we had 27.03 percent negative or no response, while 35 patients responded to the intervention, with a positive therapeutic response of 72.91%.

In group B (placebo group) no significant change was observed, where in 48 people, only 6 individuals responded, which was also very minor [RE = 1-3]. The success rate of placebo was only 12.5%, with a little collagenization, but compared with group A with $P = 0.000$ was significantly lower.

The overall chart of the changes and the calculation of P_{value} and its comparison in the group are discussed in more detail below.

Table 1. Shows the RE and p -value changes for groups A and B during the 30-days study.

Group	Success %	RE Pre(mean)	RE Post(mean)	P_{value}
A	72.91	18.65±3.31	20.71±3.66	0.00
B	12.5	18.98±3.35	19.17±3.41	1.00

The following chart indicates the success rate of increase in collagen in column before and after using the cream.

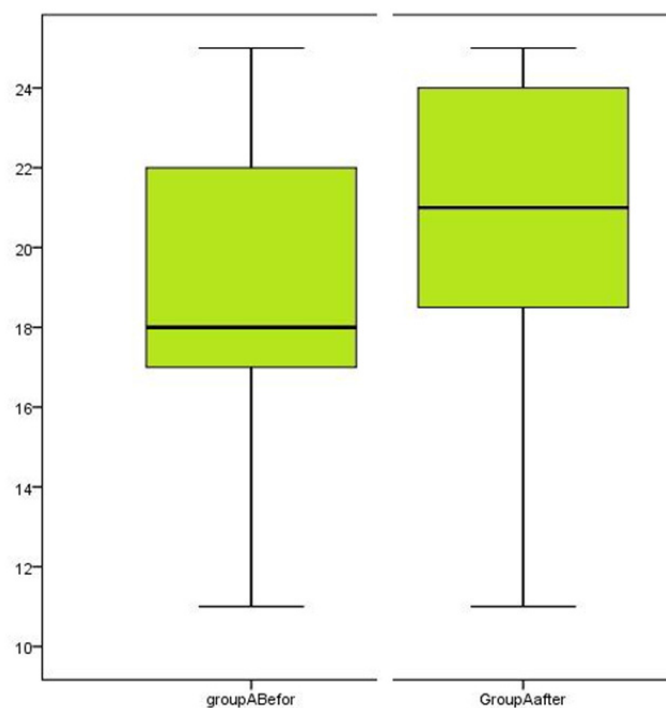


Figure 2. Changes of collagen in the skin before and after treatment based on the amount of reflected energy (RE)

3.1 Side Effects

As mentioned in the text above, in group A, only 2 patients showed allergic reactions in the form of redness and

mild itching, which were excluded and therapeutic measures were taken, yet in group B there was no specific symptom. Also no systemic complications were observed for any of the two groups.

4. Discussion

In this study 106 patients as the population of study were participated to reconstruction of skin collagen and increasing of skin tissue *toniste*.

Based on ultrasound technology, images of 20 MHz frequency were obtained from all individuals before the start of the study, and were reported numerically based on the reflectance energy square (RE^2). The participants randomly divided into two groups as the intervention group (A) and the control or placebo group (B). At the end of this study and after statistical analysis, the response rate was 72.91% in group A.

The motivation for choosing this study was to regeneration the skin with the employed of dermal penetration systems using complementary medicine. This is a new step in assessing the effect of skin medications on improving the tone of the skin of the human body.

There are two creative tips in this study, the first is the problem of non-invasive skin penetration, if successful, and a way to treat systemic skin problems is opened up to us. Thus, this success is due to traditional and complementary medicine, but it must be laboratory-tested, controlled and accurate.

In this study, we tried to discover a new way by examining the effect of treatment of skin problems through reflection energy and proving it numerically.

The second point is the beginning of a pathway to assess the claims of complementary and traditional medicine. One of the most important current medical science questions, and in particular the topics of the World Health Organization (WHO), is access to precise methods for evaluating and investigating allegations of traditional and complementary medicine. A detailed and standard statistical analysis is very promising in this regard. The role of placebo or induction in this study is interesting, but as it is seen, the results obtained in the control group occur partially. Traditional and alternative medicine seems to be a great source of experiences that will provide the basis for future research ideas in field of modern medical science.

In conclusion, we can say that the production of a tonic and organic cream is very important from the economic point of view in the cosmetics industry, and it will be economically and socially positive.

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Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Prevalence and Associated Factors of Regular Nonsteroidal Anti-Inflammatory Drugs Used in a Rural Community, Thailand

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Abstract

Background: In Thailand, 67.2% of the population widely uses analgesics including nonsteroidal anti-inflammatory drugs (NSAIDs), which may lead to serious side effects. However, the information of regular NSAIDs used in Thailand is still limited.

Methods: A mixed method cross-sectional study was conducted. Quantitative data were collected using questionnaires to determine the prevalence and factors associated with regular NSAID use. The qualitative study was conducted using group and in-depth interviews to determine the knowledge, attitudes and practices of NSAID users.

Results: Of 771 participants, the prevalence of NSAID use was 31.1 and regular NSAID use was 7.4. Age, pain at the hips or thighs and pain score were independent factors associated with regular NSAID use. The qualitative study indicated that the use of NSAIDs was influenced by drug effectiveness, sources of NSAIDs and consideration of benefits and risks of the drugs.

Conclusion: This was the first report on the prevalence and associated factors of regular NSAID use in Thailand. In this community, nonprescribed NSAIDs might cause some serious side effects and undesirable drug interaction. Information on side effects of pain medications should be disseminated to the public including guidelines on how to use pain medications.

Keywords: Nonsteroidal anti-inflammatory drugs (NSAIDs), Prevalence, Associated risks, Rural community, Thailand, Primary data

1. Introduction

Nonsteroidal anti-inflammatory drugs (NSAIDs) are widely used in medical therapeutics (Somia & Maria, 2014). Thus, they are prescribed to many patients, especially regarding musculoskeletal diseases. Data from the US found that people taking aspirin or NSAIDs regularly (taking aspirin or NSAIDs at least three times weekly more than three months in one year) comprised more than 43 million (19.0%) and 29 million people (12.1%), respectively and equal to prescribing NSAIDs more than 100 million times annually at a cost of more than 4.8 billion USD (Zhou et al., 2013). Regular NSAID use may cause some serious side effects especially gastrointestinal, cardiovascular and renal systems (Lertsrisatit & Jantawiyanchit, 2014; Polónia, 1997; Page & Henry, 2000; Sorensen et al., 2000; Laine, 2004; Wolfe, Lichtenstein, & Singh, 1999; Pope, Anderson, & Felson, 1993; Winkelmayr, Waikar, Mogun, & Solomon, 2008; Radford et al., 1996; Abraham & Keane, 1984).

Data from the 4th Thai National Health Survey Report by physical examination four times a year from 2008 to 2009 found that the population of Thailand is taking numerous painkillers (Akepalakorn, 2009). Considering the frequency of use found that people who took two to three days a week totaled 20.9% and those who used nearly every day and every day comprised 4.6 and 2.3%, respectively. By age group, prevalence of pain medications increased with age and the highest among those aged 70 to 79 years. Populations living outside municipalities

regularly consumed painkillers more than those living in municipalities. Populations in the northeast had the highest percentage (2.8%), followed by the central region. Sources of analgesics constituted health centers or hospitals (60.0%) and others from a pharmacy or retail store (Akepalakorn, 2009).

However, high prevalence of painkiller use was indicated, but the data of NSAID use in Thailand is limited. Thus, we have been interested in determining the prevalence and factors associated with regular NSAID use in a rural community. Thus, the cross-sectional study was conducted in a rural community, Chachoengsao Province, central Thailand. Both qualitative and quantitative methods were performed.

We gratefully acknowledge support, including funds and operation, from the Department of Military and Community Medicine, Department of Pharmacology, Phramongkutklo College of Medicine. We have no Conflict of interest to declare.

The researchers had interested in the prevalence of NSAIDs used in Baan Na Yao, Sanam Chai Khet District, Chachoengsao Province, and finding associated risk factors in the population to remind the situation and size of problems. The primary data will be made awareness of NSAIDs used in rural areas, clearly understanding characteristics of users, and enlightening associated factors using of the drugs. The data from this study can be reproduced and policies may be planned to reduce the using of NSAIDs and leading to reducing side effects that may occur from taking the drugs.

2. Method

A mixed method study was conducted in 2015 comprising a quantitative approach to determine prevalence and associated factors of NSAIDs using standardized questionnaire and a qualitative approach using group and in-depth interviews to describe the situations and problems of NSAIDs in the community. The study protocol was reviewed and approved by the Ethics Committee of the Royal Thai Army Medical Department. Informed consent was obtained from enrolled participants who completed a questionnaire and the providers of NSAIDs following standard protocols.

2.1 Study Population

The study was conducted in a rural community, Baan Na Yao Village, Sanamchaiket District, Chachengsao Province, central region of Thailand. Meanwhile in the central region, the people had immigrated from the northeastern and remained their traditional culture and lifestyle.

2.2 Participant Characteristics

Inclusion criteria

- People who had 18 years and older and lived in this area in November 2015
- People who had signed in the consent form

Exclusion criteria

- People who unable to communicate e.g. deafness, blindness or mute

Measures and Covariates

Primary Outcomes

1. Prevalence of regular NSAIDs used
2. Associated factors of regular NSAIDs used

Secondary Outcomes

1. Prevalence of NSAIDs Used
2. Types of NSAIDs
3. Sources of NSAIDs

2.3 Quantitative Study

2.3.1 Sample Size Calculation

Due to the previous study in Trends in the use of aspirin and nonsteroidal anti-inflammatory drugs in the general U.S. population (Zhou, 2013), the prevalence of regular NSAIDs used were 12%. The sample size calculating with infinite population were

$$n = \frac{Z^2(P)(1 - P)}{d^2}$$

n = Sample Size

Z = Z-value = 1.96

P = Percentage of population picking a choice = 0.12

d = Confidence interval = 20% of P = 0.024

$\alpha = 0.05$

Therefore, the sample size (n) was 705 participants

2.3.2 Sampling Procedures

Considering the high number of sample size, the total survey was done in the area.

After the participants agreed to sign a consent form to participate this study, a face-to-face interview using electronic questionnaire was performed. The questionnaire was checked for accuracy (IOC) by three pharmacologists to increase survey reliability. The questionnaire included three parts, i.e., 1) demographic and medical conditions including sex, age, educational level, occupation, income, medical payment, alcohol and smoking status, underlying diseases, pain symptoms and treatments, 2) NSAID use related behavior use including type of NSAIDs, dose, frequency, time and purpose and 3) NSAID sources. To identify the NSAIDs used, we showed an example of NSAIDs which found in this area and supplied by health centers, grocery stores, and pharmacies to the participants to identify whether they took these drugs before including ibuprofen, diclofenac, aspirin, mefenamic acid, piroxicam and specific COX-2 inhibitors.

Data were analyzed using statistical analysis software packages for computer (SPSS for Windows, version 23). Descriptive statistics included frequency, percentage, average, standard deviation and mode to analyze general data. Chi-square test was used to analyze the differences in the regular use of NSAID group by demographics, i.e., sex, age, education level, occupation and income. Risk factors related to the regular use of NSAIDs were determined by univariate and multivariate analysis.

2.4 Qualitative Study

The qualitative study was performed by group interviews to assess 1) knowledge and understanding of NSAID use, 2) knowledge and understanding of the factors associated with NSAID use, 3) reasons for choosing not to act or behavior conducted at risk of NSAID use and 4) problems of NSAID use from the quantitative study. Participants were purposively selected and categorized according to their living community. Each group comprised both regular and nonregular NSAID users. In-depth interviews were performed among the providers of NSAIDs in the community including medical personnel and shop owners who distributed NSAIDs. The participants' profiles were created based on information from questionnaires. The conversations during the interviews were recorded using a voice recorder. The data was collected continuously until no new information was added, i.e., data saturation was reached.

The recorded conversations were completely transcribed to text. Text-based data were manually sorted and coded. Data were revised, organized and summarized for analysis. The methods used included content analysis, direct quotations and selected words to give consideration to actual local words used by the participants.

2.5 Ethical Considerations

The study protocol, questionnaires and consent form were reviewed and approved by the Ethics Committee of the Royal Thai Army Medical Department. Written informed consent was obtained from all enrolled participants.

2.6 Operational Definitions and Abbreviations

Regular used = taking aspirin or NSAIDs at least three times weekly more than three months in one year

NSAIDs = nonsteroidal anti-inflammatory drugs

THB = Thai bath, which equal to approximately 0.03 USD

3. Results

3.1 Quantitative Study

Characteristics of the population in the study of 771 participants are listed in Table 1. Approximately 60% of the participants were female and more than 80% were aged above 40. Most participants had education level at primary and lower. Approximately 40% were agriculturalists. One half of them had income less than 5,000 THB monthly.

Table 1. Characteristics of the participants and prevalence of regular NSAID use

Characteristics	Total (%)	No. of regular NSAIDs use (%)	<i>p</i> -value
Sex			
Male	282 (36.6)	15 (5.3)	0.095
Female	489 (63.4)	42 (8.6)	
Age	52.3±14.2	54.5±14.8	0.267
Education level			
No education	56 (7.3)	7 (12.5)	0.314
Primary school	581 (75.3)	41 (7.1)	
Above primary school	134 (17.4)	9 (6.7)	
Occupation			
Non-occupation	285 (37.0)	21 (7.4)	0.997
Agricultural	294 (38.1)	22 (7.5)	
Others	192 (24.9)	14 (7.3)	
Average income (THB/month)			
< 5,000	394 (51.1)	36 (9.1)	0.058
≥ 5,000	377 (48.9)	21 (5.6)	
Smoking Status			
Nonsmoking	555 (72.0)	43 (7.7)	0.732
Former Smoker	93 (12.1)	7 (7.5)	
Current Smoker	123 (15.9)	7 (5.7)	
Drinking Status			
Nondrinking	449 (58.2)	37 (8.2)	0.549
Former drinker	106 (13.8)	6 (5.7)	
Current drinker	216 (28.0)	14 (6.5)	
Diabetes mellitus			
No	647 (84.4)	50 (7.7)	0.467
Yes	120 (15.6)	7 (5.8)	
Hypertension			
No	574 (74.8)	39 (6.8)	0.246
Yes	193 (25.2)	18 (9.3)	
Dyslipidemia			
No	634 (82.7)	44 (6.9)	0.257
Yes	133 (17.3)	13 (9.8)	
Chronic kidney diseases			
No	748 (97.5)	53 (7.1)	0.046
Yes	19 (2.5)	4 (21.1)	
Gout			
No	743 (96.9)	53 (7.1)	0.095
Yes	24 (3.1)	4 (16.7)	
Osteoarthritis			
No	687 (89.6)	47 (6.8)	0.068
Yes	80 (10.4)	10 (12.5)	

Table 1 shows that 63.4 percent were female, mostly population were aged above 40, had educated in primary and lower 82.7 percent. 38.5 percent were agriculturalists. 51.1 percent had income less than 5,000 THB per month, and shows the relationship of one variable. Chronic kidney disease was associated with the regular used of NSAIDs with statistical significance. Other diseases were not associated with the use of NSAIDs in regular use, significant statistically.

Fifty-seven participants (7.4%) took NSAIDs at least three times weekly for more than three months, indicating the prevalence of regularly used NSAIDs. In addition, 183 (23.7%) had been using NSAIDs in the last three months but did not meet the criteria for regular use. Both groups obtained NSAIDs from general/health promoting hospitals (62.3%), pharmacies (39.7%) and grocery stores (20.9%), and they may be received form multiple sources. Ibuprofen (58.3%), diclofenac (14.7%), mefenamic acid (12.7%), aspirin (10.0%), piroxicam (3%), specific COX-2 inhibitors (1%) and naproxen (0.3%) were identified as the NSAIDs used in this community. In addition, 2.6% of participants used their relatives' NSAIDs.

Univariate analysis for the factors associated with the regular use of NSAIDs is shown in Table 3. Those who had chronic kidney disease were significantly associated with regular NSAID use. Table 2 demonstrates that pain at the right elbow and right wrist and hips or thighs was significantly associated with regular NSAID use. The participants were asked to rate the intensity of pain that required NSAIDs using pain scores. Regular users scored their pain at 7.1 ± 2.1 , significantly higher than nonregular users (5.8 ± 2.3) (Independent t test, $p < 0.001$).

Univariate and multivariate analysis showed that for those aged ≥ 60 , hip or thigh pain and pain scores were independently associated with regular NSAID use (Table 3).

Table 2. Prevalence of regular NSAID use among the participants with different symptoms and locations of pain

Characteristics	No. (%)	No. of regular NSAIDs use (%)	<i>p</i> -value
Symptoms (N = 634)			
Headache	205 (32.3)	19 (9.3)	0.640
Toothache	75 (11.8)	8 (10.7)	0.478
Dysmenorrhoea	30 (4.7)	4 (13.3)	0.312
Myalgia	576 (90.9)	48 (8.3)	0.620
Locations of pain (N = 577)			
Left shoulder	23 (4.0)	4 (17.4)	0.122
Left elbow	37 (6.4)	4 (10.8)	0.543
Left wrist	42 (7.3)	5 (11.9)	0.388
Left knee	254 (44.0)	22 (8.7)	0.897
Left ankle	50 (8.7)	6 (12.0)	0.421
Right shoulder	23 (4.0)	4 (17.4)	0.122
Right elbow	30 (5.2)	6 (20.0)	0.034
Right wrist	38 (6.6)	7 (18.4)	0.033
Right knee	245 (42.5)	25 (10.2)	0.205
Right ankle	42 (7.3)	4 (9.5)	0.773
Neck	69 (12.0)	10 (14.5)	0.057
Upper/middle back	144 (25.0)	16 (11.1)	0.193
Lower back	133 (23.1)	14 (10.5)	0.337
Hip/thigh	149 (25.8)	20 (13.4)	0.016

Table 2 shows the relationship of variables demonstrated that pain right elbow and right wrist, and hips/thighs were associated in regular use of NSAIDs, significant statistically.

Table 3. Univariate and multivariate analysis for the factors associated with regular NSAID use

	NSAIDs use		Crude OR (95%CI)	p-value	Adjusted OR (95%CI)	p-value
	non-regular (%)	regular (%)				
Pain score						
			1.28 (1.1-1.5)	<0.001	1.2 (1.0-1.5)	0.045
Age (years)						
< 60	486 (93.3)	35 (6.7)	1		1	
≥ 60	227 (91.9)	20 (8.1)	1.2 (0.7-2.2)	0.489	2.5 (1.1-5.7)	0.033
Pain at hip/thigh						
No	399 (93.2)	29 (6.8)	1		1	
Yes	129 (86.6)	20 (13.4)	2.1 (1.2-3.9)	0.012	3.0 (1.3-6.9)	0.008
Pain at back						
No	400 (92.4)	33 (7.6)	1		1	
Yes	128 (88.9)	16 (11.1)	1.5 (0.8-2.8)	0.196	2.1 (0.9-5.0)	0.093
Source of drugs						
Others	74 (82.2)	16 (17.8)	1		1	
Hospital	108 (72.5)	41 (27.5)	1.8 (0.9-3.4)	0.089	1.7 (0.7-4.2)	0.235
Chronic kidney diseases						
No	695 (92.9)	53 (7.1)	1		1	
Yes	15 (78.9)	4 (21.1)	3.5 (1.1-10.9)	0.031	2.1 (0.3-14.4)	0.451
Osteoarthritis						
No	640 (93.2)	47 (6.8)	1		1	
Yes	70 (87.5)	10 (12.5)	1.9 (0.9-4.0)	0.072	1.1 (0.4-3.3)	0.836

Table 3 shows the relationship of multivariate analysis using multiple logistic regression analysis. Pain score, age, hip/thigh and the pain were associated with the use of NSAIDs in regular use, significant statistically. Adjusted for sex, income, hypertension, pain at left shoulder, right shoulder, right elbow, right wrist, neck, and upper/middle back

3.2 Qualitative Study

The results of qualitative research based on interviews with specific groups (group interview) and individual

in-depth interviews (in-depth interview). Group interviews included both regular used NSAIDs and the drugs user but non-regular used in the community. 5 cases for in-depth interview also included drugs supplier, hospital staffs, pharmacist, and a grocery-store owner. The detailed results of the research are as follows.

3.2.1 Characteristics of the Population

Two group interviews comprised those who attend the entire group of 10 participants, there were seven women, average age of participants was 45 years old most of the participants is agriculture. The educational level of the participants was primary school. The average income of the participants was less than 5000 THB.

Group interview	Group 1	Group 2
Participants	4	6
Sex	4 females	3 males, 3 females
Average age	39.75 years old	48.60 years old
Occupation	agriculture	agriculture, trader
Education	primary school	primary school
Average income (THB)	less than 5,000	less than 5,000

In-depth interviews consisted of five men, one woman, average age of the participants were 40.6 years old. The average income of the participants were 10,000–15,000 THB.

In-depth interview	Non-regular user	Hospital staff	Pharmacists	Shop owners
number	1 person	1 person	1 person	2 persons
sex	female	female	male	all 2 female
Average age (year)	51	28	50	33.5
Occupation	daily contractor	nursing assistant	pharmacist	personal business
Education	primary school	bachelor	bachelor	primary school
Average revenue (THB)	Less than 5,000	10,000–15,000	more than 20,000	15,000–20,000

3.3 The Villagers Used NSAIDs because of Their Effectiveness

Participants, who used NSAIDs, thought it could effectively and immediately reduce pain. The efficacy of NSAIDs was higher than common painkillers such as paracetamol. They considered that NSAIDs were medications for severe pain as mentioned by a 43-year-old male farmer: “The pink tablet (ibuprofen) can dramatically improve my pain symptom. I was energized suddenly, without pain anymore” and a 28-year-old female registered nurse also reported: “When the doctor once prescribed this medication and it works, they’ll remember the pill and request the same one.”

Pain was usually related to their work, mostly agriculture. The common reason for using NSAIDs was that they could work without pain troubles after taking these pills. A 32-year-old female entrepreneur said: “I may work too much, but when I took it, I could continue my work”.

3.4 Sources of NSAIDs in the Community

Most participants thought accessing health services in their community was not too difficult. However, they were not satisfied and these health services did not meet their needs. This might be due to long waiting time, failure to treat pain symptoms and that the most prescribed analgesic drug was paracetamol. When they wanted stronger painkillers (referring to NSAIDs), they had to go to the hospital many times because they received small quantities. Thus, they will go to a grocery store to buy NSAIDs illegally. An 80-year-old male freelancer commented: “It’s easier to buy the pills ourselves because it takes too long to see a doctor and sometimes we got only paracetamol”. This information was validated by a 28-year-old female registered nurse who confirmed: “We mainly prescribe paracetamol as the first line drug for pain. After that, we will consider giving NSAIDs when they still have the pain because NSAIDs have many side effects and are more dangerous”.

Alternatively, the villagers could buy NSAIDs with no prescription from a pharmacy or grocery store in the community. NSAIDs were requested according to the patients' need, not the indications. A 50-year-old male pharmacist affirmed: "I won't sell those (NSAIDs) to everyone because of side effects, but consumers remember that they must have been told that when they had severe pain then they would get it." A 32-year-old female merchant stated: "Most (consumers) wouldn't tell their symptoms, they just asked for the drug they wanted. If I had, I sold."

3.5 Benefits of NSAIDs and Knowledge about Side Effects

Most participants were aware of the side effects of NSAIDs including the main side effects on the gastrointestinal tract such as irritating stomach, stomachache and GI hemorrhage. A 55-years-old female daily contractor revealed: "My mother took this drug too much, and she got gastric bleeding then she died. The healthcare worker told that it affects our stomach, liver and kidney."

However, they still used them because pain-relieving effects made them better able to work. When they still presented pain symptoms without medication they could not work effectively, especially during the harvest season when they needed to harvest crops over a long time. Although the side effects of NSAIDs were explained, the villagers considered working was more important. A 48-year-old man farmer declared: "I'm scare about side effects, but I have to take it in order to continue my work". The administration and side effects of NSAIDs were better explained by health care professionals such as pharmacist. A 50-year-old man pharmacist revealed: "I always tell them they shouldn't take it before meals and don't take too much because it can cause abdominal pain". However, the advisory was not provided to every consumer. A 32-year-old female merchant expressed: "I wouldn't advise them because I don't know about side effects, I told them to ask at the clinic"

4. Discussion

The present study determined the situation of NSAID use in a rural community of central Thailand. This community mainly comprised farmers and villagers aged more than 50 years, which is relatively similar to most rural communities in Thailand. Higher risk of musculoskeletal injuries and chronic pain may occur due to their physical activities and age-related conditions. Thus, NSAIDs are sometimes required for their conditions. In the present study, a total of 31.1% of the participants had been using NSAIDs in the last three months. Our survey revealed that the regular NSAID users in this community totaled 7.4% which was relatively similar to results from a large-scale survey in the US (Zhou et al., 2013). The 2005 and 2010 National Health Interview Survey (NHIS) showed the prevalence of regular use of aspirin and NSAIDs among U.S. adults aged 18 years and older was 19.0% and 12.1%, respectively (Zhou et al., 2013). However, source of NSAIDs in this Thai rural community varied; not all participants got the drugs through the hospital prescription (Jarernsiripornkul, Phueanpinit, Pongwecharak, & Krska, 2016). As described in a study by Sri-Ngernyuan (1996-1997), drugs including NSAIDs were available at various sources in rural communities including grocery stores indicating the failure of the drug regulation system. In addition, our qualitative information indicated that other factors such as unsatisfactory treatment results by health promoting hospitals and inconvenience of going to the hospital led villagers to obtain NSAIDs from other sources such as pharmacies and grocery stores. A recent study in Thailand indicated that the adverse effects of NSAIDs were less disseminated compared with drug administration and indication in the university hospital setting (Jarernsiripornkul et al., 2016). Approximately 20% of the participants bought NSAIDs from grocery stores in the areas. These people may not have received proper information of NSAIDs including drug administration, indication and adverse effects. From the qualitative study, participants knew that NSAIDs could cause gastrointestinal adverse effects. However, the commonly used NSAIDs in this community including ibuprofen, diclofenac, mefenamic acid and aspirin also caused other adverse effects, some of which might be less common but severe including renal failure. NSAIDs affect renal functions including water and sodium retention, decreased renal blood flow, electrolyte imbalances and acute and chronic renal failure (Winkelmayer, Waikar, Mogun, & Solomon, 2008; Radford et al., 1996; Abraham & Keane, 1984). NSAIDs should be avoided (except aspirin) for patients with chronic kidney disease (CKD) because NSAIDs have been associated with disease progression among individuals with CKD (Winkelmayer, 2008; Radford et al., 1996; Abraham & Keane, 1984). In the present study, approximately 20% of (4 of 19) patients with CKD regularly used NSAIDs. Some participants especially the elderly in the community were likely to have multiple comorbid conditions such as hypertension and diabetes mellitus. Regular use of NSAIDs may interact with commonly prescribed medications possibly altering drug effectiveness or increased risk of adverse effects. For example, NSAIDs can induce increased blood pressure and may potentially reduce the efficacy of commonly used antihypertensive agents including diuretics, beta-blockers and ACE inhibitors (Polonia, 1997).

Univariate and multivariate analysis showed that participants aged more than 60 years were significantly

associated with regular NSAID use in this population. Risk of gastrointestinal, cardiovascular and renal adverse effects increased among elderly NSAIDs users. Thus, NSAIDs should be rarely prescribed and used with extreme caution among the elderly. In addition to the renal adverse effects mentioned above, the risk of gastrointestinal bleeding with NSAIDs increases with age. NSAID cardiovascular effects including fluid retention, hypertension, congestive heart failure, myocardial infarction and cerebrovascular accidents increase significant risk to the older age group as well. From the qualitative study, the adverse effects of NSAIDs mentioned by the participants were mainly gastrointestinal including stomachache and bleeding. Mortality caused by NSAID use in this community was mentioned by one of the participants.

Although NSAID adverse effects were emphasized by health care workers and pharmacists in this population, the villagers considered that these drugs could make them continue working. Common clinical problems in which NSAID use may be needed include acute or chronic pain from musculoskeletal injuries or degenerative conditions such as osteoarthritis which interrupted their working activities. We asked the participants to rate the highest pain scores to trigger their NSAID use. Our result showed that regular NSAID users had significantly higher pain score compared with the nonregular users. Thus, the patients with higher pain level needed more NSAIDs to relieve their pain regularly. Multivariate analysis also identified the pain score as an independent factor associated with regular NSAID use. Univariate analysis showed that pain at the right wrist, right elbow and hips or thighs were associated with regular NSAID use; however, multivariate analysis identified only pain at the hips or thighs was an associated independent factor. Joint and muscle pain was related to their occupation; most were farmers. Because they were concerned about not being able to work during farming season, they had to maintain their working ability using potent drugs like NSAIDs. Our qualitative data showed that most participants knew of the side effects of NSAIDs. However, they still used them for financial reasons. Safe pain management must be considered in the rural community to avoid the negative impact of regular NSAID use which may include a proper drug administration such as low dose/short term use in the high risk group. In addition, nonpharmacologic approaches, such as physiotherapy, exercise and local therapies, may be useful.

This information could be used to plan public health policy specific to legitimate pharmaceutical distribution. The Thai Food and Drug Administration should monitor the distribution of illegal drugs and campaign to execute selling and purchasing of correct doses. Side effects of pain medications should be well disseminated to the public including how to use pain medications as required. Most people know about the side effects, so not only could behavior modification be implemented, educating the public regarding proper alternative treatments may reduce the rate of drug use. However, this study was conducted in a limited population. Further studies should be conducted in all different regions of Thailand to determine the situation of regular NSAID use at the national level.

In conclusion, the prevalence of regular NSAID use in this rural community was 7.1%. Univariate and multivariate analysis showed that higher pain scores, age of more than 60 years and pain at the hips or thighs were associated with regular NSAID use. Most people with joint and muscle pain from heavy use were related to their occupation. They took NSAIDs to reduce the pain to be able to continue working. Another result was despite the public health system that aims to serve Thais properly; many patients had unsatisfactory treatment results, so some villagers chose to buy the drugs themselves from pharmacies or grocery stores. Most participants had understanding side effects of NSAIDs. However, they still used them because the pain-relieving effects could allow them to work in the following days to meet their economic needs at low financial status.

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Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Physician Shortage in Canada: A Review of Contributing Factors

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Abstract

The physician shortage in Canada is multifactorial. It is important to identify potential factors and policies contributing to the problem. An extensive literature review to retrieve primary source articles was performed using the PubMed database. Other sources of information included reports identified using the websites of organizations, associations, government bodies and Google scholar, as well as additional primary source articles identified using reference lists of retrieved articles and reports. Healthcare policy changes in the 1990's limited the growth of physician supply through the reduction of medical school enrolment, restrictions on recruitment of international medical graduates into the workforce, redistribution of family physician and specialist mix and loss of physicians to the US. Inadequate supply of primary care physicians is reflected in the low interest among medical students in a family medicine career and the shortage of physicians in rural areas. Reduction of physician productivity is characterized by an aging physician population, greater proportion of women in the workforce and the reduction of direct patient care hours among the new generation of physicians. The problem is further exacerbated by inefficiencies in healthcare expenditures, judging from high healthcare spending and low physician-to-population ratio. An understanding of factors contributing to the physician shortage is essential in order to develop successful strategies to alleviate inadequate physician supply.

Keywords: family physician, healthcare, international medical graduate, medical education, physician shortage, physician-to-population ratio, residency, rural physician

1. Introduction

In the 1970's Canada enjoyed one of the highest physician-to-population ratios among developed countries and the number of physicians per population was growing steadily until 1993, reaching 1.91 physicians/1000 (Canadian Medical Association [CMA], 2015). At that time the national consensus was that Canada had a surplus of physicians. This viewpoint was reflected in the 1992 Barer-Stoddart report on physician human resources (Barer & Stoddart, 1992), which argued that there was an oversupply of physicians in Canada. The Canadian government followed up on this by implementing various policies to control the growth of the physician supply.

As a result of these policies, the net inflow of physicians into the physician practice pool dropped from 1040 physicians per year in the period of 1990-1993 to 313 physicians in the period of 1994-2000 (Chan, 2002). The absolute physician-to-population ratio (physicians/1000) decreased from 1.91 in 1993 to 1.84 in 1997 before starting to gradually increase again, such that by 2006/2007 it was at the same level as in 1993 (CMA, 2015). Moreover, the aging general population (which utilizes more healthcare services) and aging physician population (which has a lower work intensity), suggests that the "real" physician-to-population ratio in 2006/2007 was still below its level in 1993. Recognizing the problem Canadian government made a significant effort to boost the number of physicians, including the 48% increase in medical school enrolment between 2003 (7808) and 2013 (11 565) (AFMC, 2014) and incorporation of more international medical graduates (IMG) into the workforce, among other things. Despite these efforts, in 2014 physician-to-population ratio was still at 2.24/1000, which ranked Canada 28th among 34 OECD countries with an average of 3.2/1000 (Canadian Collaborative Centre for Physician Resources [C3PR], 2013).

Currently, there is a well-recognized physician shortage in Canada. Statistics Canada reported that 15.3% of Canadians aged 12 and older lack a regular family physician (FP) (Statistics Canada, 2011). The situation in rural areas is particularly alarming. Data shows that less than 10% of the total physician workforce practices in rural areas and access to specialists is even worse with only 2% of specialists residing in rural areas, where 18% of the

Canadian population lives (C3PR, 2013). Physician shortage is further exacerbated by an aging physician pool (in 2013 41% of Canada's 74 526 physicians were aged 55 or older (C3PR, 2013)) and aging general population (Canadians aged 65 and older consume 45% of the total healthcare budget (Canadian Institute for Health Information [CIHI], 2014)).

The nature of physician shortage in Canada is multifactorial. It is important to identify past and present factors contributing to the shortage currently seen in the country. An extensive literature review was performed to determine which factors most significantly contribute to the problem. Understanding of these factors is essential in order to develop successful strategies to alleviate inadequate physician supply.

2. Methods

To ensure comprehensive analysis of the topic several search strategies were used to locate both peer-reviewed primary source articles and reports relevant to the topic.

An extensive literature review of the PubMed database was conducted using a combination of MeSH terms ("Canada", "physicians", "medically underserved area", "health manpower", "career choice", "health expenditures", "health care reform", "students, medical", "internship and residency", "choice behavior" and "health services needs and demand") and keywords ("healthcare", "healthcare policy", "physician shortage", "physician workforce", "primary care physicians", "family physicians", "rural physicians", "physician demographics", "recruitment", "retention", "international medical graduates" and "medical education"). The search was limited to articles published in English language and date exclusion was applied as follows: articles published in the last 10 years were used in searches related to physician shortage and physician workforce; articles published in the last 5 years were used in searches related to healthcare reform and health services needs. No date exclusion was used in searches related to healthcare policies, medically underserved areas, medical students and their career choices, health expenditures and residency training. Google Scholar was searched using the following combination of terms: "Canada", "physician shortage", "physician workforce", "physician facts", "medical education", "health spending" and "international medical graduates". Titles and abstracts returned from every search were screened for their relevance to the topic and after excluding review articles, news, editorials and commentaries, articles judged as eligible were retrieved and thoroughly reviewed. Articles were selected for the final analysis based on their relevance to various aspects of physician shortage in Canada, such as government policies that contributed to the problem, the supply of primary care and rural physicians, changing physician demographics and emigration of Canadian physicians.

Reports from organizations, associations and government bodies were identified using different sources. The search of websites of Canadian Institute of Health Information (CIHI), Canadian Medical Association (CMA), Canadian Resident Matching Service (CaRMS), Association of Faculties of Medicine of Canada (AFMC) and Canadian Post M.D. Education Registry (CAPER) was conducted. The reference lists of articles identified using PubMed were also screened for relevant reports.

Furthermore, reference lists of retrieved articles and reports were used to identify additional articles used in the final analysis.

3. Results

The physician shortage in Canada is multifactorial but four main factors were identified that most significantly contribute to the problem— government healthcare policies implemented in the 1990's, inadequate supply of primary care physicians (PCP), shortage of physicians in rural areas and reduction in physician productivity.

3.1 Policies Responsible for Limited Growth of Physician Supply

A number of policies implemented in the 1990's significantly contributed to the physician shortage observed in Canada. In his 2002 report to the Canadian Institute of Health Information, Chan (2002) identified policies that contributed to observed drop in physician supply. Policies that directly limited growth of physician supply included: 5% and 10% reduction in medical school enrolment in 1987 and 1993 respectively; restriction on IMGs entering Canadian workforce, which resulted in the drop of IMGs practicing in Canada from 28% in 1986 to 22% in 2004 (CIHI, 2007); and various retirement incentives. Indirect policies, the unintended consequences of which were a reduction in physician supply included: elimination of one-year rotating internship and making a two-year family medicine (FM) residency a minimum requirement for practice; increase in the ratio of specialist to FM residency positions, which not only increased total time spent in residency training but also decreased the number of physicians starting practice as FP from 80% in the early 1990's to 45% in 2000; and policies that resulted in exodus of physicians to the US. The latter included: physician remuneration and expenditure caps, limits on interprovincial physician migration, financial penalties for practicing in "over-serviced" areas and sharp decline in

opportunities for physicians to return to postgraduate training.

Ryten, Thurber and Buske (1998) showed that 1 out of 9 Canadian graduates from the “class of 1989” was practicing in the US in 1996 (193/1722). A cross-sectional analysis of the 2006 American Medical Association physician masterfile identified 8162 Canadian medical graduates who provided direct patient care in the US in 2006 (2491 PCPs and 5671 specialists) (Phillips, Petterson, Fryer, & Rosser, 2007). Considering the number of physicians in Canada in 2006 (CMA, 2006), Canadian-educated PCPs and specialists practicing in the US in 2006 represented a substantial proportion of the Canadian physician workforce— 7.7% (2491/32 241) and 18.5% (5671/30 656) for PCPs and specialists, respectively. In contrast, only 408 US medical school graduates practiced as fee-for-service physicians in Canada in 2004. Although net physician migration to the US has stopped in the last decade, the efforts to address this potential issue in the future would be beneficial. For example, a recent study performed by the Royal College of Physicians and Surgeons of Canada [RCFSC] reported a growing number of specialists and subspecialists in Canada experiencing employment issues (RCPSC, 2013). Around 20% of newly certified Canadian specialists, who have not been able to secure a position, cited that they would look for work outside Canada. Predicted shortage of more than 90 000 physicians in the US by 2020 (Association of American Medical Colleges [AAMC], 2010; Council on Graduate Medical Education [COGME], 2005) can offer attractive opportunities for unemployed Canadian specialists.

3.2 Inadequate Supply of Primary Care Physicians

The inadequate supply of PCPs in Canada is reflected in the low interest in primary care careers among current medical students. This is a concern because the preference of Canadian medical graduates has an important impact of the mix of practicing physicians in the country. Scott, Wright, Brenneis and Gowans (2009) conducted a study to assess how closely career preferences of students entering eight Canadian medical schools align with the current primary care and specialist mix in Canada. A survey of 3225 newly admitted medical students showed only 25.9% interest in FM. A 2011 study used the data from 2007 National Physician survey for medical students to show 30.2% and 31.4% interest in FM among preclinical and clinical students, respectively (Vanasse, Orzanco, Courteau, & Scott, 2011).

Even though preferences change over time there is a strong correlation between the initial preference and ultimate postgraduate training choice. For example, Scott, Gowans, Wright and Brenneis (2012) conducted a survey at eight Canadian medical schools to show that 46.4% of students had matched to their top career choice and 77.5% had matched to one of their top three choices indicated upon medical school entry. Another study compared the specialty choice of 519 alumni of the University of Washington School of Medicine with the their interest upon medical school entry (students were surveyed on their interests upon entry) and found that 70% of the graduates had a stable career choices (Carline & Greer, 1991). Zeldow, Preston and Daughtery (1992), who compared career interests of 121 students at one mid-western medical school in the US to actual National Residency Match Program (NRMP) outcomes, reported interesting results. At orientation, 45% of student had correctly identified their ultimate career choice and by the end of the second year this number had increased to 69%.

There are a number of studies that looked at personal student characteristics associated with the subsequent choice of residency in FM (Feldman et al., 2008; Gill, McLeod, Duerksen, & Szafran, 2012; Scott et al., 2011; Vanasse et al., 2011). Vanasse et al. (2011) analyzed the data available from the 2007 National Physician Survey for medical students to show that those who hoped to become FPs as opposed to specialists were more likely to be from rural regions and small towns. Interestingly, desire for research was negatively associated with an FM career preference compared to specialist career preference. Among the most important factors linked with an FM career were desires for public health activities and short residency to pay off debt. Other factors associated with an FM career included flexible work hours and continuing medical education.

Scott et al. (2011) reported similar results among Canadian medical students. Students who chose a career in FM were older on average, a smaller proportion of them had family members or friends practicing medicine, and a greater proportion came from rural areas and volunteered in a developing nation. Societal orientation, desire for a varied scope of practice and lower interest in research were among factors associated with an FM career choice. On the other hand, students who chose specialty careers were influenced by prestige, higher income, research and living in urban areas (Feldman et al., 2008, Gill et al., 2012; Vanasse et al., 2011). Lower remuneration compared to specialists was also shown to be an important factor in the lack of interest in FM (Morra, Regehr, & Ginsburg, 2009). The importance of payment as a factor in career decision-making increased with higher debt and advanced training. Besides this, there are currently few opportunities for practicing FPs to reenter postgraduate training. This may discourage students who feel that entering FM would eliminate options to retrain as a specialist later on.

A relative lack of PCPs is reflected in high numbers of medical specialists currently practicing in Canada. The

2013 RCPSC Employment study (RCPSC, 2013) reported a growing number of specialist and subspecialists in Canada who are unemployed or under-employed. For example, 16% of them could not find work and 31% had plans to further pursue training to become employable. Furthermore, the proportion of specialist reporting employment issues increased from 13% to 17% from 2011 to 2012 and that of subspecialist increased from 15% to 21% over the same period. More research is needed to understand whether high rate of specialists' unemployment is attributed to the saturation of the market or inadequacy of resources to hire specialists or both.

3.3 Rural Physician Shortage

The Canadian shortage of physicians is especially acute in rural areas (see section 1). Moreover, high physician turnover in rural Canada is a problem. For example, it was reported that in 2007 the average length of practice of physicians in rural areas was 9.5 years compared to 12.6 years in urban areas (CIHI, 2007). Not surprisingly, rural population had a higher overall mortality rate compared to their urban counterparts and performed worse on several health-related measures (CIHI, 2006).

Unpopularity of rural FM among medical students is reflected in their low interest in this specialty. Feldman et al. (2008) showed only an 11.1% interest in rural FM among first year students in Canadian Medical Schools. The interest ranged from 4.7% at the University of Toronto to 20.2% at McMaster University. Scott et al. (2009) obtained similar results. This is especially a concern since rural FPs provide most of care in rural areas.

Several factors contribute to the unpopularity of rural practice among physicians. The university of Western Ontario conducted a study to compare the scope of practice and the degree of personal and professional satisfaction of rural FMs to their urban counterparts (Incitti, Rourke, Rourke, & Kennard, 2003). Compared to their urban counterparts FPs were more involved in hospital work, including attending births, emergency services, performing anesthesia, assisting in operating rooms and performing minor surgical procedures in addition to their office practices. Rural physicians were less satisfied with various aspects of their practice, such as work hours, having a professional backup and accessibility of continuing medical education (CME). Rural physicians also seemed to be less content with different aspects of their personal lives, including spousal work opportunities, educational opportunities for children and cultural activities. A qualitative study in the single rural community in the province of Newfoundland and Labrador (Mayo & Mathews, 2006) showed that families who were integrated into the community and families with employed physicians' spouses were more content with rural areas. On the other hand, absence of family and friends and limited recreational opportunities negatively influenced contentment.

A 2005 CIHI study showed an inverse relationship between the size of the community and family physician's scope of practice (CIHI, 2005). For instance, whereas only 15% of FPs in metropolitan areas worked in emergency departments (ED), about 74% of FP in remote rural communities provided ED coverage. Another example is postpartum care, where less than 40% of FPs provided postpartum care in metropolitan areas, compared to 65% of FPs in remote rural communities. Greater proportion of rural FPs were found to be engaged in cancer care, cardiology, chronic disease management, geriatric medicine, home care, hospitalist care, prenatal care and surgical assisting, among other things. FPs in rural communities also performed a wider range of clinical procedures than their urban counterparts, such as joint aspirations, casting/splinting, endometrial aspirations, lumbar punctures and skin biopsies.

To summarize, rural physicians have a significantly wider scope of practice and need to maintain competence in different clinical areas despite having higher work loads, inaccessibility of CME, having no professional backup and limited specialist consultation (judging from low numbers of rural specialists, as reported in section 1).

3.4 Changing Physician Demographics and Work Preferences

The physician shortage can be attributed to both the inadequacy of the physician supply, as outlined above, and the relative reduction in the amount of direct patient care. Several factors specifically contribute to the reduction of direct patient care hours: the increase in the proportion of female physicians, reduction of direct patient care hours among the new generation of physicians and the aging physician workforce.

In 1986, 18% of all Canadian physicians were female (CIHI, 2007) and this number steadily increased to 39% in 2014 (CIHI, 2015). Every year since 2002 females constituted more than 55% of incoming students at Canadian medical schools (AFMC, 2014) and the number of female physicians increased by 23.7% between 2010 and 2014, while the number of male physicians increased by 9.5% in the same time period (CIHI, 2015). It is well documented that female physicians work fewer hours on average than male physicians (Chan, 2002; Crossley, Hurley, & Jeon, 2009; Hedden et al., 2014; Sarma, Thind, & Chu, 2011; Watson, Slade, Buske, & Tepper, 2006). Chan (2002) estimated that, overall, female physicians had a 21% lower practice activity than male physicians, based on their practice activity, as reported by the amount of fee-for-service billings in the National Physician

Database. Not surprisingly, this difference was highest during the childbearing ages of 35-44 (female to male ratio of 0.77) and lowest during the ages of 25-29 (female to male ratio of 0.92). The study by Incitti et al. (2003) (described in 3.3) reported, that 47% of urban female physicians in Ontario worked less than 40 hours per week, while 10% of urban male physicians did so. Interestingly, only 16% and 9% of rural female and male FPs, respectively, worked less than 40 hours per week. A 2005 CIHI study estimates showed that average full-time equivalent (FTE) was 0.69 and 0.89 for female and male physicians, respectively (CIHI, 2005). Hedden et al. (2014) performed a systematic review of articles on the subject published between 1991 and 2013. The authors confirmed that female PCPs report working fewer hours, have fewer patient encounters and deliver fewer services than male physicians, but mentioned that female physicians spend longer with each patient, deal with more separate problems in one visit and see higher proportion of female patients. Moreover, authors pointed out that once family factors had been accounted for, gender had no effect on hours spent working. CMA data also shows that female physicians spend more time on teaching activities and indirect patient care (CMA, 2014).

Physicians' total hours of work and hours spent on direct patient care have fallen in many developed countries over the last several decades. A CMA physician resource questionnaire mailed to 7922 physicians showed that in 2003, FPs under the age of 45 spent 21% less time providing direct patient care than FPs of the same age group in 1982, while FPs over the age of 55 spent more hours on patient care than their same-age peers two decades earlier (Buske, 2004). Watson et al. (2006) showed a similar trend for a period 1991-2001 measured in terms of office assessments. In 2001, FPs under the age of 35 provided 18% less, those aged 35-44 provided 23% less, and those aged 45-54 provided 12% less office assessments, while FPs aged 55-64 provided 11% more, and those aged 65 and older provided 45% more office assessments than their same-age peers ten years earlier. Crossley et al. (2009) argued that there is a decline in patient care hours in all age cohorts of physicians and not just younger physicians. Irrespective of details, data from the national physician surveys conducted by CMA (CMA, 2014) confirms that direct patient care hours decreased from 35.6 per week in 1997 to 31 hours per week in 2014. Importantly, the decline in direct patient care hours could not be attributed to reallocation of work from direct patient care to other activities (research, teaching, administration, etc.), but rather results from decline of total weekly hours of work (53.2 and 48.7 hours per week in 1997 and 2014, respectively).

The aging physician demographic is also shaping the supply of physicians' services. The proportion of physicians aged 65 and older had increased from 7% to 15% between 1981 and 2014 (Canadian Labour and Business Centre [CLBC], 2003; CIHI, 2015) and the average age of physicians in Canada increased from 46.4 to 50.1 years between 1996 in 2014 (CIHI, 2015). It is not surprising that older physicians work less (Chan, 2002; Crossley et al., 2009; Sarma et al., 2011). For example, Chan (2002), estimated that physicians over 65 have a workload of 0.66 that of national average.

There are rising concerns about the decline of physicians' productivity in Canada and there are no current efforts to control the work hours of physicians in practice. Although ways to address productivity of a physician human resource is beyond the scope of this article, it is worth mentioning the estimates provided by Crossley et al. (2009), who calculated that increasing hours of direct patient care by 5% among current practicing physicians will have a greater impact on effective physician supply than large increases in several Canadian medical school enrolments.

4. Discussion

Although it is important to understand various factors that contribute to the observed shortage of physicians in Canada, it is just as important to address strategies that can help alleviate shortages in various aspects of healthcare discussed above. This section will try to address main difficulties of solving the physician shortage in Canada and offer some tentative solutions.

4.1. Costs Involved in Training More Physicians

Both long- and short-term goals should be considered while trying to address Canada's need for more physicians. Training new physicians locally is the priority, but will take time and considerable investment. Experiences from significant expansion of medical educational programs at the Laurentian University and the University of British Columbia uncovered one-time costs of \$1 000 000 and \$1 500 000 per spot, respectively (Health Canada, 2009). Expansion at the University of Washington medical school showed similar numbers. Moreover, it was estimated that training a new physician costs around \$180 000–\$294 000 (Health Canada, 2009). In 2013, total health spending in Canada reached \$211 billion, which constituted 11.2% of the country's GDP (CIHI, 2013). This makes Canada one of the top spenders on health, as a percentage of its economy, among OECD countries. Substantial costs involved in training more physicians will put a significant strain on an already outstretched budget.

4.2. Targeting Interest in Primary Care Careers

Addressing disparity in the number of PCPs presents a challenge. Data from the 2015 CaRMS match (CaRMS, 2015) showed that only 38.5% of Canadian medical graduates indicated FM as their first choice. Judging from the low interest in medical students' primary care careers, and taking into consideration the relative stability of career choices (as described in section 3.2) and current 51/49 ratio between FPs and specialists (CIHI, 2015), suggests that many future FPs will choose FM not by choice but by limitation of specialist residency spots. This can result in many students finding themselves in careers that they don't enjoy and are not suited for, which in turn could impact physician performance and quality of health delivery.

One of the possible solutions is to consider student factors upon medical school admission that were shown to be positively associated with an FM career choice later on. This could serve, as an important strategy for admission committees to select an appropriate mix of students to meet the healthcare needs of the region. It was shown earlier (see section 3.2) that interest in research was inversely related to interest in FM and directly related to interest in specialist careers. This suggests that introducing optional research components into an FM postgraduate training curriculum could attract student who are interested in research but traditionally associate research with specialist careers.

Bethune et al. (2007) provided interesting findings that showed changes in medical students' interest in FM as they progressed through their training. Their survey of medical students conducted at the Memorial University of Newfoundland from 1999 to 2006 revealed that there was a dramatic loss of interest in FM as a career choice during the first two years of medical school. One of the most plausible explanations why this might be occurring is the "hidden curriculum". Frederic Hafferty first coined this term in 1998 (Hafferty, 1998) and described it as what students learn outside the formal learning environment and stressed the impact of interpersonal interactions and role models in the learning process. During their training students internalize standards, values and norms that characterize their desirable profession. To understand the influence of academic discourse on medical students' identification with FM, Rodriguez et al. (2015) conducted 18 focus groups with 132 medical students and 67 faculty members from UK, Canada, France and Spain. Authors reported that in UK FM was considered a prestigious specialty, students were broadly exposed to various aspects of FM and had positive role models throughout their training, faculty praised the knowledge and skills of FPs and students were more likely to pursue an FM career. In Canada, students reported FM as lacking prestige, faculty often encouraged the brightest students to pursue a specialty career and many students did not identify themselves with FM. Other studies confirm the view of low prestige associated with an FM career among medical students in Canada (Feldman et al., 2008, Gill et al., 2012). Students from the schools where "badmouthing" primary care was prevalent were less likely to choose primary care, while the reverse was true for students identifying positive experiences during their primary care clerkships (Erikson, Danish, Jones, Sandberg, & Carle, 2013). Increasing the prestige of FM among students is a difficult task given preconceived notions about the discipline that pervade the medical education system. On a positive note, it is possible to achieve this, as experience of the Memorial University of Newfoundland has shown. The low interest in FM among students prompted the school to introduce an FM course, where second year students work with FPs in a community for 2 weeks. Also, the arrival of new dean who was a rural FP most likely changed the atmosphere at the school. As a result, there was a dramatic increase in FM interest among graduates (Bethune et al., 2007; Eggertson, 2012).

4.3. Strategies to Increase Interest in Rural Medicine

There are numerous strategies to recruit and retain physicians in rural areas. Current incentive programs offered to physicians to attract them to rural areas put a substantial strain on municipal budgets and are probably ineffective in long-term physician retention (Chan et al., 2005). Rural communities often have to rely on an ad hoc patching of shortages by locum physicians and there is no guarantee of physician supply in any given rural area. Strong institutional commitment is essential for Canadian faculties of medicine to identify the challenges and develop successful strategies in order to provide a consistent output of physicians to rural communities. Numerous studies have shown that there are three factors most strongly associated with physicians choosing rural practice: students' rural background, positive rural clinical clerkship experience and targeted rural postgraduate training.

One of the best predictors of rural practice is enrolling medical students from rural areas (Dunbabin & Levitt, 2003; Dolea, Stormont, & Braichet, 2010, Feldman et al., 2008). Retention of rural physicians is also strongly correlated with students' rural origins (Rabinowitz, Diamond, Hojat, & Hazelwood, 1999; Brooks, Walsh, Mardon, Lewis, & Clawson, 2002). A 2002 study (Dhalla et al., 2002) found that most Canadian medical students were of urban origin and higher socioeconomic status than the national average and only 10.8% of students were from rural areas. Realizing the problem, in 2005 Canada opened its only new medical school in the last 50 years—Northern Ontario School of Medicine. Ninety one (91) percent of the students are from Northern Ontario and between 2009 and

2012 61% of graduates have chosen FM residencies (largest percentage of any medical school in Canada), 65% of graduates were still practicing in Northern Ontario (rural area) in 2013 and many of them indicated their intention to stay in the region (Strasser et al., 2013). The Memorial University of Newfoundland has also shown commitment to increase the number of students with rural background and made rural medicine a part of its curriculum. As a result, 30%-40% of incoming students are from rural areas and data shows a very high rural retention rate 10 years after graduation (Eggertson, 2012; Mathews, Edwards, & Rourke, 2008). Other schools should also aim to boost the number of students of rural origin. Interestingly, Australia experienced similar problems. To boost the percentage of medical students from rural areas Australian government started to offer financial incentives to rural students, medical schools developed schemes to target rural applicants and have substantially revised their curricula. From 1989 to 2000 the proportion of students from rural areas increased from 10% to 25% (Dunbabin & Levitt, 2003) and the rural retention rate is around 40% (Eley, Synnott, Baker, & Chater, 2012).

Studies show that rural exposure during medical education facilitates future rural practice (Chan et al., 2005; Hancock, Steinbach, Nesbitt, Adler, & Auerswald, 2009; Rourke, Incitti, Rourke, & Kennard, 2005). Although medical schools have been increasingly targeting students from rural areas, most of the physicians practicing in rural areas do not have a rural background. A Canadian survey of rural FPs found that two thirds of rural physicians grew up in urban areas (Chan et al., 2005). In this study, rural physicians with rural background cited growing up in rural community as the most influential factor in choosing rural practice, while for urban residents the exposure to rural medicine during medical school and residency was the most influential factor to choose rural practice. Rural training might offer not only the skills essential for rural practice but also an exposure to rural lifestyle and challenges of rural practice, which were also both cited as highly influential by rural physicians with urban background. These students would have difficulty appreciating rural practice without rural exposure during their medical education and/or postgraduate training.

Rural postgraduate educational experiences are also highly important for recruitment and retention of physicians in rural areas (Rourke et al., 2005). A University of Calgary study showed that an interest of specialty residents in rural practice increased from 45% to 76% following a rural rotation (Myhre & Hohman, 2012). Other studies have reported a strong positive relationship between a length of rural exposure during residency and subsequent rural practice (Hogenbirk, Mian, & Pong, 2011; Tate & Aoki, 2012).

There is a growing body of evidence showing that positive association between rural origins, rural exposure and eventual rural practice is at risk of being lost unless continuation of rural pathway is provided (Eley et al., 2012; Strasser, Hogenbirk, Lewenberg, Story, & Kevat, 2010). A Canadian study of 1269 University of Manitoba graduates between 1965 and 2000 reported that a continuum of rural educational exposure from high school through residency training was strongly associated with rural practice (Tate & Aoki, 2012). In addition, time spent in rural training and increasing distance from metropolitan area (Winnipeg) positively correlated with likelihood of practice in a rural region as well. That is, there needs to be a smooth transition between rural-oriented undergraduate training and rural residency to keep the rural intentions alive. Medical school's educational and training curriculum with a strong rural commitment plays an important role in changing rural practice perception among students so they can come to appreciate rural healthcare, rural lifestyle and people in the community.

4.4 The Role of International Medical Graduates in Addressing Physician Shortage

A recent study by Di Matteo (2014) estimated that contribution of increasing physician numbers to provincial health spending ranges from 3.2% to 13.3% of the health spending increase and thus represents a modest health care cost concern. Indeed, physicians' compensation makes up only 15% of Canadian healthcare budget (CIHI, 2014).

Increasing the physician workforce can be accomplished by either increasing medical school enrolment or by incorporating more doctors trained abroad into the workforce. It is much more expensive to increase medical school spots than to bring more graduates of international medical schools. Although there is recognition that Canada should not rely excessively on IMGs to meet its healthcare needs, IMGs and Canadians studying abroad (CSA) in particular offer an attractive short-term to mid-term solution to the current physician shortage. CaRMS estimates showed that in 2010 there were around 3,500 CSAs in foreign medical schools and over 90% of them were eager to return to Canada for postgraduate training (CaRMS, 2010). While Canadian Medical graduates' (CMG) residency match rate was 97.3% in 2011 (2507/2576) (CaRMS, 2011), the match rate of CSAs in 2011 was 38.5% (182/473) in Canada overall (this number had decreased to 31.5% in 2014 CaRMS match, owing mostly to the increase in the number of CSAs applying (287/911) (CaRMS, 2014)) and 23.9% (112/469) specifically in the province of Ontario (Thomson & Cohl, 2011). Where do the rest of them end up? Data shows that in 2011 Canada

issued 303 “Statement of need” letters to Canadian IMGs applying for J1 visa in the US, which had increased to 494 by 2012 (CAPER, 2014). Essentially, we currently observe a significant number of qualified and educated medical professionals who match successfully through NRMP in the US and will most likely stay to practice there instead of in their home country.

Attracting more Canadian IMGs/CSAs to Canada can offer a relief in shortage of PCPs. Mok et al. (2011) analyzed data from CAPER to compare CMGs and IMGs who completed residency training in Canada between 1989 and 2007. The proportion of CMG who trained in FM declined from 54% to 38%, while the proportion of IMGs who trained in FM increased from 19% to 37%. Moreover, attracting more IMGs/CSAs to Canada could help address a significant physician shortage in underserved areas, since most IMGs/CSAs entering postgraduate training in Canada sign a “return of service” commitment, obliging them to practice in an underserved community for a number of years after completion of residency depending on the province. In 2004, IMGs accounted for 26% of all physicians in rural Canada, compared with 22% in urban areas; IMGs also accounted for 27% of rural FPs compared with 23% of FPs in urban areas (CIHI, 2005). A cross-sectional study of FPs in southwestern Ontario found that IMGs, in comparison to CMGs, were more likely to practice in small towns and isolated communities and were more likely to accept new patients in their practices (Thind et al., 2007). Attracting more IMGs/CSAs offers an opportunity to specifically address inadequate numbers of PCPs in rural areas.

Although increasing opportunities for IMGs in Canada is suggested as a potential solution to help mitigate physician shortages, there are important considerations that should be taken into account. These include long-term retention rates of IMGs in rural areas and assessment of the equivalency of their medical training. CAPER (2014) data shows that the percentage of IMGs who were still active in jurisdiction they first registered in between 1998 and 2008 was 33.5% while that of CMGs was 66%, although it is unclear what percentage of that constituted specifically rural, underserved areas. Mathews et al. (2008) compared retention rates of FPs in Newfoundland and Labrador between 1997-2000 and 2004. Their data shows that retention among Memorial medical graduates was higher than retention of either IMGs or CMGs from another provinces. Interestingly, IMGs retention was no worse than the retention of CMGs from another provinces. A possible solution to retention rates would be to offer postgraduate training positions to CSAs with local background roots, as there is a strong correlation between rural origin and practice location. There are also legitimate questions about competence of IMGs. A 2005 study that analyzed mortality rates of 127 275 patients admitted to Ontario hospitals for acute myocardial infarction did not find significant differences between patients cared for by IMGs and CMGs (Ko, Austin, Chan, & Tu, 2005). Furthermore, patients in both groups had a similar likelihood of receiving secondary preventive medications at 90 days and cardiac invasive procedures at 1 year. A similar US study of 244 153 hospitalizations with acute myocardial infarction and congestive heart failure showed that IMGs were comparable to US medical graduates in terms of patient mortality (Norcini et al., 2010).

To summarize, IMGs and CSAs in particular have an important role to play in meeting Canada’s physician workforce needs. Specifically, they can provide a relief in physician shortages areas, fill specialties, which cannot attract Canadian graduates and work in underservices rural regions.

4.5 Study Limitations and Future Directions

This article cited a number of studies that relied on questionnaire-based surveys. All of them were limited by not including all medical students, residents or physicians in the country, depending on the study. The accuracy of these studies might be lower than in the case of an entire population and might not be applicable to the entire country. Respondents in the surveys were often forced to select a specific answer, which might have resulted in misclassification of variables in the studies. A number of studies did not follow their sample cohorts in time but rather provided a cross-sectional snapshot in time and, thus, were unable to capture variables that might have changed over time. Two specific studies conducted by Chan (2002) and CIHI (2005), which looked at physician FTE results, relied on the data from the National Physician Database, which contained primarily fee-for-service information and not alternative payment information. As such, this could have had a large impact on FTE results for physicians relying primarily on alternative payment methods.

This article did not provide an in depth analysis of healthcare costs. Although Canada spends more on healthcare as a percentage of its economy than most other OECD countries, its physician-to-population ratio is one of the lowest (CIHI, 2013), suggesting that there is a need for a thorough research and investigation of strategies to increase efficiency of healthcare expenditures. Furthermore, improvement of productivity of physician human resource was also beyond the scope of this article.

It is well accepted that physician shortage translates into inadequate healthcare of a population. Higher physician-to-population ratio, on the other hand, does not necessarily translate into better healthcare outcomes as

suggested by Watson and McGrail (2009), who used OECD data to assess the degree to which avoidable mortality is related to physician density. This implies that healthcare outcomes depend on other factors besides physician density, such as FP-to-specialist ratio, increased demands of an aging population, distribution of physicians throughout the country, wait times, healthcare accessibility, doctor-patient communication, intergenerational differences in physician workload and strength of primary healthcare infrastructure.

This study did not try to assess the balance between primary care providers and specialists. Current ratio of FPs to specialists in Canada is around 51/49 (CIHI, 2015). It is uncertain whether this ratio represents an optimal balance to meet the population healthcare needs. Multiple international and Canadian studies have shown that stronger primary care infrastructure improves population health outcomes (Starfield, Shi, Grover, & Macinko, 2005; Starfield, 2012). For example, an increase in the number of primary care providers is associated with reduction in total population mortality; decrease in hospitalizations, surgeries, emergency visits and readmissions; greater number of preventive care visits and earlier cancer diagnosis. Excessive specialist-to-population ratio, on the other hand, is associated with higher overall mortality and specifically mortality from heart disease and cancer; greater number of surgeries, procedures and readmissions; later cancer diagnosis and higher expenditures (Starfield et al., 2005; Starfield, 2012). Despite the proven benefits of primary care orientation, the primary care alone cannot provide adequate population healthcare needs, as ongoing care by PCPs must be complemented by specialists. Thus, further research is needed to understand what would be an ideal mix of physicians in Canada, based on population needs and availability of resources.

5. Conclusion

The nature of the physician shortage in Canada is multifactorial. Factors that most significantly contribute to the problem include past healthcare policies, changing physician and population demographics, medical student career preferences, uneven physician distribution and decline in physician productivity. It is important to acknowledge these factors and policies in order to address the issues at hand and develop successful strategies to alleviate inadequate physician supply. It is essential to understand that decisions that are made today will take at least a decade to reveal their full effect and will impact the healthcare delivery of subsequent generations of Canadians.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Work-Life Balance among Teaching Hospital Nurses in Malaysia

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Abstract

Extreme workload and poor working environment have a negative impact on the emotional and physical statuses among nurses. The study has contributed to evaluate work-life balance and its related factors among teaching hospital nurses. It was aimed to examine the work-life balance and its related factors among teaching hospital nurses. A cross-sectional study using a universal sampling technique was conducted. 1002 nurses were included from the Teaching hospital of Klang Valley, Malaysia. The instrument was adapted from NIOSH Generic Job Stress Questionnaire and QoL questionnaire from WHO, and it was used to measure the quality of work-life balance. Non-work activities, job requirement, supervisor support, job satisfaction, manageability, social and environmental variables have independently influenced work-life balance among nurses. Furthermore, quality of life variables has positively influenced the work-life balance ($P < 0.050$). Work life balance and organizational commitment can have a positive relationship. Whereas, Nurses working in fixed shifts were observed with greater work-life balance as compared to the nurses working in multiple shifts. A friendly environment in the professional sector plays a major role for developing motivation and enthusiasm among workers.

Keywords: environment, nurses, teaching, workload, work-life balance, Malaysia

1. Introduction

Work-life balance is an idea that includes the prioritizing between the lifestyle and work along with balancing career and lifestyle together, which often seems a difficult goal in an individual's life. Working environment offered by an employer has a significant influence on the emotional health of the workers. The engagement of employees to promote programs has the substantial impact on the performance of employees (Anitha, 2014; Engel et al., 2014). Numerous researches have indicated that the employees would have a higher level of participation and motivation towards job matters, when their employers offer a good working environment (Engel et al., 2014; Timilsina Bhandari et al., 2015; Hinami et al., 2012). The staff ultimately relies on the management and their practices for job satisfaction (Buerhaus et al., 2015). Nevertheless, excessive workload and poor working environment affects greatly on psychological aspects due to ever-growing trends of the healthcare industry nowadays (Engel et al., 2014).

Buerhaus et al. (2015) has identified that excessive working hours within clinical settings for nurses can cause severe depression and imbalance hormones. As a result, the nurses tend to consume more food, smoke frequently and drink alcoholic beverages to eradicate fatigue, stress and sleepiness from their life (Antunes et al., 2010; Spiegel et al., 2009). Different studies have shown that nurses tend to make more errors during work like needle stick injuries and medication errors, which may also cause patient dissatisfaction (Stimpfel et al., 2012; Kunaviktikul et al., 2015; Trinkoff et al., 2011).

A study conducted by Sakthivel & Jayakrishnan (Sakthivel & Jayakrishnan, 2012) has indicated that the work-life balance among nurses is an important phenomenon because of providing healthcare to the patients. Focusing on the work-life balance as the main variable, it has been evaluated from the recent research that job satisfaction and work-life balance in the nursing profession are important factors for the delivery of quality healthcare among

patients (Azeem & Altalhi, 2015; Azeem & Akhtar, 2014).

The study has the potential to contribute in the nursing practice along with evidence based practices by recognizing the crucial factors, leading to work-life imbalance, experienced by nurses in Malaysia. It has intended to identify the requirements to restructure the working conditions of the nurses, and to lessen schedule irregularity and work imbalance. These two aspects have been considered as the main factors that led to increase in stress and resulted in negative attitudes and poor psychological health.

1.1 Aim of Study

The general objective of the study is to examine work-life balance and its related factors among teaching hospital nurses. In addition, the specific objective is to identify factors of social demography, jobs nature, and quality of life towards work-life balance among nurses.

2. Study Background

The study has introduced a conceptual framework, which described the factors influencing the job satisfaction and work-life balance. A good place to work without stress, better satisfaction and motivation, reduced absenteeism, and lower turnover should be controlled by the hospital administration. The conceptual framework has proposed certain job related factors among nurses as shown in Figure 1.



Figure 1. Conceptual framework of factors influencing nurses' intention to stay

2.1 Social Factors

Shu-Yu et al. (2014) mentioned that there is no relationship between the marital status and work-life balance. Even though the married population dominated the study, it did not present the factor for influencing work-life balance. It is further evaluated that the irregular sleeping pattern of nurses might affect the personal role in the family; consequently, having inadequate time spending for their family (Spiegel et al., 2009; Stimpfel et al., 2012; Kunaviktikul et al., 2015). Moreover, long working hours have affected energy level after work, so nurses seemed to have difficulty in compensating time with their family (Almalki et al., 2012).

HA1: Quality of Life is significantly influenced from the physical, psychological, social and environmental factors among nurses.

2.2 Health Factors

An epidemiological study showed an association between long working hours and obesity. Nurses, who work

under pressure and long working hours, tend to compensate their stressful work-life, sleepiness, and fatigue by consuming more foods and alcoholic drink (Antunes et al., 2010). By the time, nurses who practically used to have such kind of lifestyles would be obese and have chronic diseases like diabetic mellitus and hypertension (Spiegel et al., 2009). A study by Stimpfel et al. (2012) has examined the information from different states of nurses, their patients, and hospitals. It has been reported that shifts greater than thirteen hours were interconnected to the dissatisfaction of patients. Particularly, patients observed that nurses were not interacting well and they were unable to provide help, whenever they needed. The results showed that nurses had greater risk of burnout, in case of working more than thirteen hours per day. Relatively, less sleep increases the chances for reduced job performance, obesity, and wide range of chronic diseases (Caruso, 2014). A review on shift works and obesity by Antunes et al. (2010) has concluded that there is a comparable epidemiological evidence for a relationship between obesity and shift work. Long working hours and obesity have been examined by few studies and concluded that there is a positive association between obesity and long working hours (Bannai & Tamakoshi, 2014; Solovieva et al., 2013; Luckhaupt et al., 2014).

HA2: There is a positive association between chronic and mental diseases and long working hours among nurses.

2.3 Role Factors

Nurses, who have currently become a major group in the health care system, are reflected as a severe group and observed suffering from the poor quality of work-life balance. The stakeholders of healthcare have suggested that nurses' practitioners could help to mitigate the adverse impact of primary healthcare (Buerhaus et al., 2015). As a result, Malaysian nurses tend to migrate developed countries, which offer greater working environment, better career pathway, and better lifestyles (Timilsina Bhandari et al., 2015; Hinami et al., 2012; Buerhaus et al., 2015; Barnett et al., 2010).

HA3: Imbalance between the personal and organizational commitments will lead to some negative consequences among nurses.

2.4 Management Factors

Makabe et al. (2015) mentioned that work shift pattern resulted in inadequate period for nurses in getting enough rest between the shift. As the transition period between shifts is fast, it might distort the brain activity from wakefulness to sleep (Smith et al., 1999). Wilkins (2007) stated that sleep deprivation turned nurses to have low concentration level and cannot communicate in good manners with clients. This aspect might be one of the important causes which burn out syndrome between patients and nurses (Engel et al., 2014).

HA4: Work shift flexibility assist nurses to work and communicate with patients in good manners

3. Methodology

3.1 Study Design and Participants

The study opted a cross-sectional research design and involved 1002 respondents from University Malaya Medical Centre (UMMC), Petaling Jaya, Selangor. The survey was conducted in one of the teaching hospitals in Klang Valley. The survey questionnaires were distributed among 1002 nurses working in the hospital. The quantitative research design was opted to analyze the data through SPSS (Statistical Package of Social Sciences). Nurses, working in the UMMC, were included in the study regardless of their caste, religion, language, and other socio-demographic background. Both married and unmarried nurses were included; however, nurses, who have left working at UMMC, were excluded. Nurses from different educational background were also included. The study was commenced only among female employees and included hospital nurses of all positions ranging from lower rank to the top rank, who were working currently in hospitals. The data was collected from the nurses, who were not on leave and performing their duties in the hospitals at the time of data collection. The respondents, who understand Malay and English language and provided the consent to participate in the study, were included. Moreover, the boxes were kept safely and were impossible for the completed questionnaires to be visible or collected by others. After a month, the boxes were collected from the nursing offices for the analysis. Meanwhile, the data of each respondent was kept private and confidential.

The age of respondents was ranged from 20 to 59 years with the mean age 28.84 (SD= 8.86). Regarding gender, majority of respondents were female (94.0%); while, men were only 6.0%. Respectively, the total number of 773 nurses (77.1%) was from a diploma educational background. While, another 167 nurses (16.7%) were from certificate level, and 62 nurses (6.2%) were from degree and master educational background. Meanwhile, the total number of nurses per shift in average were 6.67 (SD=3.10). Additionally, an average total number of healthcare assistants were 3.26 (SD=3.28). In the day shift, the average time of the official break in minutes was 33.23 (SD=

18.04) and for the unofficial break was 14.53 (SD= 10.58). In contrary, the average time of official breaks in night shift was 40.58 (SD= 17.63) and for the unofficial break was 32.39 (SD= 17.76). The percentage of annual leaves taken by the participants was 62.6%.

Table 1. Association between socio demographic characteristics and work life balance (N=1002)

Socio Demographic			r-value	p-value
Age			0.02	.470
Experiences (months)			0.02	.584
	Mean	SD	t-value	p-value
Gender			1.52	.130
Woman	14.15	2.96		
Man	13.55	2.95		
			F-stat (df)	p-value
Marital Status			0.43 (2)	.651
Married	14.06	2.98		
Single; Never Married	14.14	2.85		
Single; Divorced	14.55	4.08		
Religion			0.76 (2)	.516
Buddhism	14.52	2.05		
Others	13.48	3.50		
Muslim	14.13	2.97		
Hindu	13.66	2.98		
Educational Level			1.72 (2)	.180
Certificate	14.49	3.03		
Diploma	14.02	2.97		
Degree & Master	14.21	2.66		

3.2 Measurement

The questionnaire was adapted by NIOSH Generic Job Stress Questionnaire (Deguchi et al., 2016) and also composed with Sense of Coherence (SOC) questionnaires from the original author, Antonousky (Shu-Yu et al., 2014) and Quality of Life questionnaires from WHO (Smoth et al., 1999). 25 variables were established from the questionnaire and computed accordingly as in the previous version of study (Deguchi et al., 2016). The reliability test was examined in a pilot study involving 20 nurses, who did not participate in the main study. The Cronbach's Alpha was 0.97, which exceeded requirement value of 0.70 (Deguchi et al., 2016).

3.3 Procedure

Universal sampling approach has been applied in the study. Firstly, the objectives and potential benefits of the study have been focused through permission letter and the proposal was sent to the Director of Clinical Research Centre (CRC) of UMMC. Nurse Managers in each unit distributed the questionnaire to the nurses, according to the inclusion criteria. The respondents were allowed to complete the survey within a month. However, duration time for filling in the assessment was only 20-30 minutes.

3.4 Data Analysis

Raw data from the questionnaire was entered into the Statistical Package of Social Science (SPSS) version 20. The level of significance chosen for all analysis was $P < .05$. Multiple Linear Regression tests were applied to model the relationship between variables of interest. While, one way ANOVA test was applied to determine the association between job nature and work-life balance. Afterwards, Pearson Correlation test was used to determine a relationship between continuous data. Age, experiences, number of nurses and assistant nurses, break hour, overtime hours, annual leaves, control scale, non-work activities, job requirement, social support, mental demand, doctor-nurse relationship, job satisfaction were obtained. Balance of work and private life, sense of coherence and

quality of life towards work-life balance have also been assessed.

4. Results

The relationship between socio-demographic characteristics and work-life balance has been presented. However, none of the characteristics have shown significant value (p -value= .050) to relate with work-life balance. For instance, marital status did not show any significant value ($P < .050$). It was similar to educational level as the P -value was .180, which exceeded the maximum p -value as shown in table 1.

The fixed shift showed a significant association towards work-life balance (p -value= .038). Nurses, who were working in fixed shift, have greater work-life balance score (mean=14.33, SD= 2.69) as compared to nurses that are not working in fixed shift (mean= 13.94, SD=2.82). Moreover, there was a significant relationship between annual leaves and work-life balance (p -value=.018, r -value=0.08). All of the four sub-categories showed a significant relationship into work-life balance with task control (p -value<.001, r -value= -0.17), decision control (p -value<.001, r -value= -0.14), physical environment control (p -value<.001, r -value= -0.12), and resource control (p -value<.001, r -value= -0.13). Furthermore, non-work activities of nurses presented a significant relationship with work-life balance (p -value=.002, r -value= -0.10). Job requirement has also been observed with significant relationship regarding work-life balance (p -value<.001, r -value= -0.19) as shown in Table 2.

The Quality of life (QoL) has been assessed in four variables, including physical, psychological, social and environmental. All the four variables were significantly related to work-life balance where ($P < .050$). There is a significant linear relationship between non-work activities and WLB ($p < .001$). There is a significant linear relationship between job requirements and WLB ($p < .001$). Those with scores of 10 in WLB will have 1 less square in job requirements. There is a significant linear relationship between supervisor support and WLB ($p < .001$). There is a significant linear relationship between management and WLB ($p < .001$). Nurses who have the higher level of manageability of their work will have higher levels of WLB. There is a significant linear relationship between social life and WLB ($p < .001$). There is a significant linear relationship between environmental support and WLB ($p < .001$). Nurses who claimed to have good environmental support were observed with highest score of their WLB. With 7 significant variables, the model explained 25.0% of the variation of the WLB in the study sample. ($R^2 = 0.25$) as shown in Table 3.

Table 2. Association between Job Nature and Work-life Balance (N=1002)

			F-stat (df)	p-value
Nurse Manager	13.78	2.69		
Senior Staff Nurse	14.12	3.04		
Staff Nurse	14.13	2.97		
Work shift			.45 (2)	.637
Rotating Shift	14.13	2.98		
Permanent Shift	14.05	2.86		
Office Hour	13.65	2.71		
Unit Type			2.01 (2)	.134
OPD	14.27	3.06		
Ward	13.92	2.93		
ICU/OR/Cardiac	13.80	2.24		
			r-value	p-value
Number of Beds			-0.04	.176
Total Registered Nurses			-0.07	.034*
Total Assistant Nurse			-0.04	.160
Break during working hour				
Official Day Break			0.07	.030*
Official Night Break			0.02	.573
Unofficial Day Break			0.02	.573

* Other variables are mentioned in the detailed table

Table 3. Multivariable Analysis of Respondents (N=1002)

Quality Of Life	R-value	p-value			
Physical	0.15	<.001*			
Psychological	0.08	.013*			
Social	0.15	<.001*			
Environment	0.21	<.001*			
MLR (Multiple Linear Regression)					
Variables	Adj. B	95.0% CI		t-stat.	p-value
		Lower	Upper		
Fixed Shift	0.29	-0.04	0.63	1.74	.082
Total Registered Nurses	-0.001	-0.04	0.02	-0.48	.631
Official Day Break	0.001	-0.005	0.01	0.83	.404
Annual Leaves	0.001	-0.003	0.01	1.08	.281
Task Control	-0.241	-0.68	0.20	-1.07	.284
Decision Control	-0.23	-0.63	0.18	-1.10	.268
Physical Environment Control	-0.17	-0.51	0.18	-0.95	.343
Resource Control	-0.15	-0.51	0.21	-0.81	.416
Non-work Activities	-0.20	-0.30	-0.09	-3.52	<.001*
Job Requirement	-0.12	-0.18	-0.06	-3.86	<.001*

*Other variables have been discussed in the detailed tables

The analysis was based on multiple regressions, which has predicted the work-life-balance in the form of equation: Work-life balance = $13.78 - (0.20 \times \text{Non-work activities}) - (0.12 \times \text{Job requirements}) - (0.09 \times \text{Supervisor support}) + (1.78 \times \text{Job satisfaction}) + (0.14 \times \text{Manageability}) + (0.01 \times \text{Social variable in QoL}) + (0.02 \times \text{Environmental variable in QoL})$. It is understandable that any imbalance between the personal and organizational commitments along with inefficiency in managing the priorities of life would lead to some serious consequences in every variable. The outcomes would result in the form of reduced job satisfaction, poor productivity and performance, low level of commitment towards the organization, increase in absenteeism and an ultimate intention to leave the organization. Thus, the work-life balance and the perception of the employee well-being have been recognized as an essential element for the success and growth of both; the employee and the organization. Work shift flexibility assist nurses to work and communicate with patients in good manners, so hypothesis 4 has been accepted.

5. Discussion

The present study has focused on the work-life balance among teaching hospital nurses in Malaysia. The factors related to the work-life imbalance among nurses have been evaluated, which may assist the healthcare management to decrease the workload among the nurses. The above conducted tests for analysis have suggested that there is a need to carefully monitor the level of all factors regarding work place, demographic, motivation, stress and other benefits to enhance the quality of life among nurses. This practice is expected to provide satisfaction in the personal life of nurses.

Nurses, working in fixed shifts, were observed with greater work-life balance as compared to the nurses working in rotational shifts or multiple shifts. The results also supported the outcomes of past study, which observed that the fixed shift significantly affects work-life balance (Makabe et al., 2015). However, the results were not consistent, when defining the relationship between work shift patterns towards work-life balance. Meanwhile, there was a significant relationship between total registered nurse (RN), break during working hour, and overtime hours towards work-life balance. Such finding was similar to previous studies, where all of these three variables were interrelated and significantly affected work-life balance among nurses (Kunaviktikul et al., 2015; Almalki et al., 2012; Smith et al., 1999). Shortage of nurses was identified as the main problem. Due to the shortage of staff, nurses are also given non-nursing tasks (Almalki et al., 2012).

According to the present study, there is also a positive influence of annual leaves on work-life balance among nurses. Physical, psychological, social and environmental factors were observed to be significantly associated with the work-life balance. According to a study, a large number of nurses spent most of the time on work as compared to private life, so they have poor work life pattern (Makabe et al., 2015). Only 36.9% of nurses from the population study can balance their working time and private life. Whereas, almost 63.1% of the nurses have poor work-life balance; thus, it increased the rate of turnover, poor job satisfaction, and ultimately poor Quality of Life (QoL) (Hinami et al., 2012). The present study can be compared with the previous study conducted by Makabe (Makabe et al., 2015) in Japan, where the prevalence of improper proportion between work life and private life among nurses was very poor. The maintenance and development of data source regarding the nurse's workforce would expand the chances of policy researchers to understand the clinical practices (Almalki et al., 2012).

Regarding control scale that assessed autonomous power, the result could be comparable to the previous findings. For certain extent, it causes job dissatisfaction and frustration among nurses. Other studies in Thailand also presented nurses as an individual, who have been given power and opportunity to acquire good spirit, more enthusiasm, less stress and more commitment in the task (Antunes et al., 2010; Spiegel et al., 2009; Stimpfel et al., 2012; Kunaviktikul et al. 2015; Trinkoff et al., 2011; Shu-Yu et al., 2014; Makabe et al., 2015; Smith et al., 1999; Deguchi et al., 2016).

Experiences and educational level play significant roles in determining association with the work-life balance, where it can affect nurses physically, psychologically and socially. Experience and high education of nurses have shown high order thinking skills in managing conflicts as compared to non-experienced and low educational level of nurses (Almalki et al., 2012; Haus & Smolensky, 2006). Ministry of Health indicated that Malaysia would be in critical shortage of nurses in the year 2020, due to the massive loss of Malaysian nurses through migration to other countries (Barnett et al., 2010). Ironically, the nurses' ratio to population of Malaysia as required by the WHO, which is 1:200 (Chu & Moy, 2015).

WHO has indicated that South American countries have a ratio of 1.25 nurses for every 1000 population. Southeast Asian countries mostly indicated ratios of below than 3.30 nurses for every 1000 population except Singapore, which is a developed country with 9.60 nurses for 1000 population (Kimmman et al., 2012; Gaughan et al., 2013). Makabe et al. (2015) agreed that steps should be taken to solve problems of the workplace itself and create positive work-life balance to find solution for turnover among developing countries' nurses.

Social support was significant in determining association with the working environment. The study was related to previous studies, which showed a lack of supervisor guidance, poor peer support, and de-motivated family members were determinants in defining the level of job dissatisfaction (Buerhaus et al., 2015). Due to the challenging job of nurses, this group of people need accompany in dealing with the stress at work place and home. Nurses working in internal and external wards especially the married ones experiences greater stress (Chiang & Chang, 2012).

Serious attention has been given to the concept of work-life balance by different organizations, researchers, and HR practitioners. The main reason for this attraction could be due to the increasing demand of work along with increased family demands. This study has attempted to identify the work-life balance in the nursing sector and to investigate the issues that are faced with their possible outcomes. Additionally, the study has also endeavored to identify new score and possible scope for further research with a notion to achieve better modeling and to ensure higher work-life balance and delivery of performance. In conclusion, non-work activities, job requirement, SV support, job satisfaction, manageability, social and environmental variables are significantly associated with work-life balance. Therefore, necessary measures should be taken to eradicate the issues that have affected personal life satisfaction and their work periodically.

This kind of research could be initiated among both private and government hospitals of several different common departments including the OP, ICU, Medical and Surgery; therefore, the research would be helpful to obtain a wider picture regarding work life balance among female nurses in different departments of hospital.

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Ethical Consideration

The research got approval from the Kuliyyah of Nursing Research Committee, IIUM first, and then proceeded with International Islamic University Malaysia Research Committee (IREC). Moreover, the permission has also

been obtained by IRB committee to conduct the study. Thus, after gaining the approval from IREC and IRB, the research had been sent to the University Malaya Medical Centre (UMMC) and finally approached to each nursing department and units in the hospital.

Competing Interests Statement

The authors declare that they have no competing or potential conflicts of interest.

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Influence of the Subtle Energetic Changes on the Treatment Response in Patients with Insomnia

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Abstract

The article examines the questions of the treatment of insomnia in patients who do not have neurological, mental, and somatic disorders. A nonmedicamental method of sleep disturbance correction in persons with psychophysiological insomnia is considered. In particular, it is proposed to use AM-therapy as a method of insomnia treatment which implies that the patients sleep on the special activated mattresses. To assess the condition of patients before and after the treatment, clinical, psychophysiological and electroencephalographic (EEG) methods are used. The effectiveness of applying this type of insomnia therapy is provided by the improvement of the psychological indicators and EEG data.

Keywords: insomnia, therapy, subtle energy

1. Introduction

Insomnia is one of the prevalent diseases in the world – from 28 to 45% of the world population suffer the symptoms of insomnia. Women are prone to insomnia 1.3 times more often than men. People over 65 years meet difficulties with sleeping 1.5 times more often than younger ones. People older than 60 years complain about poor quality of sleep 3-4 times more often than those of the average age. Sleeping pills (hypnotics) of nonprescription group are widely used for the treatment of insomnia. But uncontrolled constant usage of such pills causes significant secondary changes in sleep patterns and adversely affects the quality characteristics of the waking period (Doghranji, 2006; Morphy, Dunn, Lewis, Boardman, & Croft, 2007; Meyer, 1998).

Quality of sleep is a component of quality of life. Often chronic sleep disorders lead to the use of nootropics, psychostimulants, antidepressants, antipsychotics, antihypertensives and antimalarial drugs, antibiotics, hormones, certain antiarrhythmic drugs and vitamins (vitamin C).

The history of pharmacotherapy of sleep disorders has had several stages. Before the beginning of the XX century bromine and opium were used in the treatment of insomnia. In 1903, barbiturates started to be applied. In the early 1950s neuroleptics (mainly phenothiazine derivatives), and antihistamines began to be used. All of these drugs can be attributed to the first generation of sleeping pills, which usage as a hypnotic is currently extremely limited. With its advent in 1960, diazepam and oxazepam open the era of the benzodiazepine hypnotics' second generation (Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008; Walsh et al., 2000; Roehrs, Papineau, Rosenthal, & Roth, 1999).

However, a group of benzodiazepines has brought certain problems into a clinical practice of insomnia: benzodiazepines cause addiction and require an increase of the daily dose; moreover, benzodiazepines lead to the increased manifestations of sleep apnea as a result of muscle relaxant.

The third generation of hypnotics includes the relatively new drugs developed in 1980-1990 years: derivatives of tsiklopirrolana - zopiclone (imovan) and derivatives of imidazopyridine - zolpidem (ivadal) which almost meet the requirements for the ideal sleeping pills. A new direction in the treatment of insomnia is the use of synthetic analogues of the hormone melatonin. Third generation hypnotics (zopiclone, zolpidem and zaleplon) and

melatonin are rarely used as the expected clinical effect is not well known (Doghranji, 2006; Lie, Tu, Shen, & Wong, 2015).

When the hypnotics are prescribed, the half-life of drugs should be taken into account. Hypnotics with a short half-life are most often used for the therapy of presomnial disorders among working people engaged in potentially hazardous activities. Drugs with long half-life are used only for the normalization of sleep in case of violation of its duration. Among the third generations of sleeping pills, barbiturates are of the greatest danger considering the risk of the toxic effects.

Potentially possible severity of barbiturate intoxication depends on the drug dose. Mild poisoning occurs when amount of barbiturates 3-4 times exceeds the therapeutic (hypnotics) dose. Poisoning of moderate and severe degree takes place when barbiturate dose exceeds therapeutic one by 5-10 times.

The development of acute poisoning by hypnotic drugs depends on the dose of the drug and its mechanism of action, combination with other agents, reinforcing effects of sleeping pills, as well as the individual reaction (Ringdahl, Pereira, & Delzell, 2004; Kay-Stacey & Attarian, 2016).

With an overdose of hypnotic drugs the polysynaptic brain structure is oppressed and weakens impulses which activate the reticular formation on the cerebral cortex. In large doses, barbiturates depress the respiratory and vasomotor centers.

Therefore, it is relevant to study a non-drug treatment of insomnia.

Previous work (Krizhanovsky & Lim, 2014) shows the changes of healthy people state under the influence of specialized mattresses, with a basis of cotton eco-friendly materials of filler and cover exposed to activation (AM) in the area of natural energy fields.

This work is devoted to revealing the differences between the states of patients with psychophysiological insomnia using an ordinary mattress (OM) with a basis of cotton eco-friendly materials of filler and cover and using the similar mattresses but exposed to activation (AM, activated mattress) in the area of natural energy fields in Malaysia within 1 day, so called AM therapy (Figure 1). Activated mattress contains the optical memorable material received from a mix of the photoaddressed polymer and, at least, one additive. A certain ratio of the influences having various directions of polarization is written down in the optical memorable layer by means of the polarized light. Technical result is storage of favorable electromagnetic influence impact on a mattress and a resonance at useful frequencies for the person.



Figure 1. Activated mattress

2. Method

The study was conducted on the basis of Sports Medicine Clinics of The Russian State University of Physical Education, Sport, Youth and Tourism in Moscow. Evaluation of the subjective state of clinical parameters is performed in 18 patients with psychophysiological insomnia without comorbidities.

In order to obtain the most reliable data, the following patient selection parameters are applied. The age of patients

varies from 22 to 50 years with a mean age of 36 years. The criterion for exclusion from the study is the presence of arrhythmias, pacemakers, injuries and brain tumors, mental illness, thyrotoxicosis. Among the patients, women account for 61% (n = 11) and men - for 39% (n = 7).



Figure 2. The process of patient sleeping on AM

All patients are volunteers and they are matched to the same type of sleep disorders - psychophysiological insomnia. All patients have signed the informed consent to participation in the research.

We divide patients into two groups with nine people in each one, so that patients of group 1 are truly informed that they are to be affected by the AM during their sleep and the patients of group 2 are wrongly informed that they are to be influenced by AM during their sleep (in fact they used placebo cover). The mattress is placed under the patient (Figure 2).

The analysis of human state is carried out with the help of polysomnography, blood pressure assessment, heart rate and psychological testing. EEG study is conducted on "Neurosoft" electroencephalograph, made in Russia, Ivanovo. The standard scheme of bipolar leads with 21 channels is applied. And the bridge type of electrodes is used.

Efficiency of the therapy is estimated by the means of clinical and psychometric methods of a research in 2 weeks influence.

All personal cards of patients are processed by the means of the descriptive and comparative statistics. The descriptive statistics are executed for all analyzable indices depending on the variable type. The analysis of the quantitative variables defines their arithmetic average, the minimum and maximum values, a standard deviation, and the analysis of qualitative variables – their frequency and part (as a percentage) in the total number.

Statistical analysis is carried out according to the distribution of sample by using of T-test and Fischer parametric criteria or Wilcoxon and Kolmogorov-Smirnov nonparametric test with the help of Statistica 10.0 software.

3. Results

The vast majority (76.5%) of patients with insomnia associate it with the beginning of some traumatic situation (acute financial difficulties, problems at work or in the family and other circumstances).

Clinically registered sleep disorders are detected in all patients and, come to the fore in the clinical picture of a neurotic state.

The most frequent complaints are difficulties in falling asleep at night (72.4%), frequent (more than 3-4 times per night) nocturnal awakenings (62.3%), difficulties with morning awakening (41.6%), daytime sleepiness (39.6%), lack of a sense of rest after a night's sleep (35.1%), sudden nocturnal awakening with difficulties in falling asleep again (28.3%). Statistically significant differences between the groups as well as gender-based pre-treatment differences are not revealed. Analysis of the relations between subjective measures of sleep patterns shows that the difficult morning awakening is associated with the duration of sleep ($p < 0.05$) and with the lack of sense of relaxation after sleep ($p < 0.05$).

Surface sleep is significantly ($p < 0.05$) correlated with the lack of sense of relaxation after sleep. Whereas, no

statistically significant links are found between sleep duration and the feeling of cheerfulness in the morning. But there is a link between the lack of sleep and subjective sensations in the morning (lethargy, fatigue, irritability, headaches). The early final awakening is not accompanied by poor health state in the morning. Subjectively, patients in this group in most cases experience morning alertness and working capacity.

Based on the data, it can be stated that long-term falling asleep and difficulty in the morning awakening are associated with the feeling of lack of rest after sleep. On the contrary, the morning state of health is almost not connected with the middle insomnia.

After two weeks of therapy, we find a significant improvement in sleep quality according to the visual analog scale with the dynamics of the studied parameter in the Group 1 from 3.2 to 7.5 points, and in the Group 2 - from 3.1 to 3.6 points (Table. 1). Differences are not significant in the second group.

Table 1. Dynamics of the quality parameter of sleep on a visual analog scale of self-assessment.

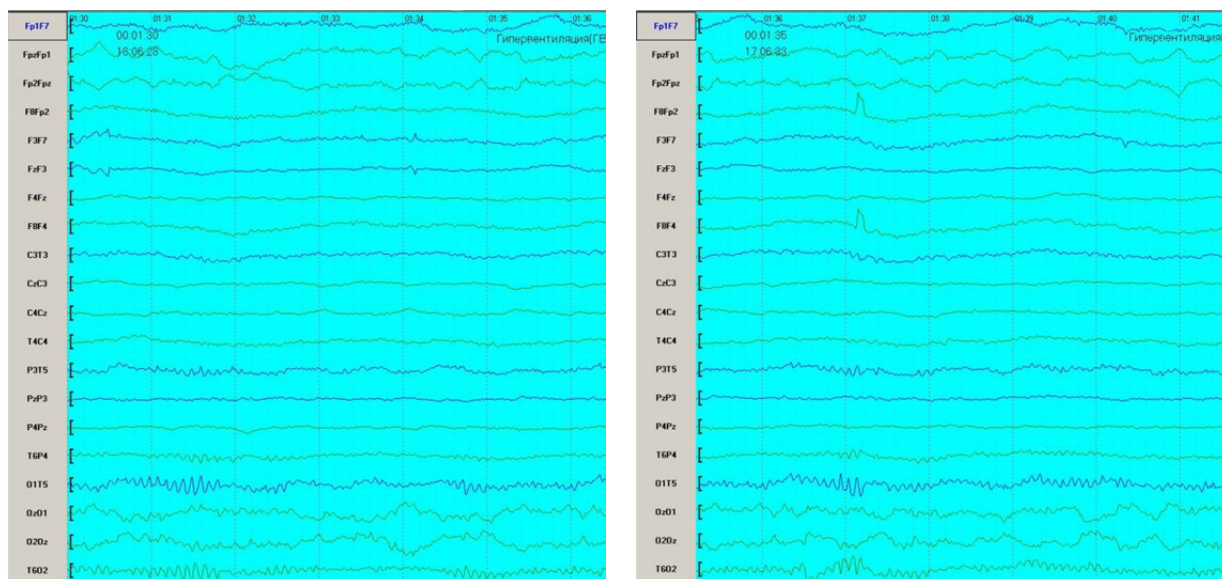
Group	Parameter, points	
	before treatment	after treatment
1-st	3.2 ± 0,23*	7.5 ± 0,38*
2-nd	3.3 ± 0,25	3.6 ± 0,22

* Significant differences between groups, P < 0.05.

We find that the use of AM significantly reduces the sensation of a lack of sleep when waking up and the presence of postsomnia disorders such as daytime sleepiness (Table 2, Figures 1 and 2).

Table 2. Dynamics of sleep quality parameters in the treatment process

	Value of parameters, %			
	Group 1		Group 2	
	before treatment	after treatment	before treatment	after treatment
The inability to sleep for more than 30 minutes	70	20	72	69
Falling asleep within 20-30 minutes after bedtime	3	22	3.8	4
Night waking up (3-4 per night)	65	12	62	58
Sense of lack of sleep after a night	45	10	46	42
Daytime sleepiness	18	4,2	19	15



* Significant differences between groups, P <0.05.

Figure 3. Patient P EEG data before and after two weeks of the study

A significant decrease is revealed in the level of reactive anxiety after AM-therapy in both groups. In the first group, after the treatment the average score on a Spielberger-Hanin scale of reactive anxiety is 36.2 ± 1.78 which is significantly lower than the respective value of 42.2 ± 1.21 before the treatment. And in the second group the values after and before the treatment are 39.8 ± 1.88 and 40.9 ± 1.38 accordingly. EEG changes in results are shown in the examples (Figures 3, 4).

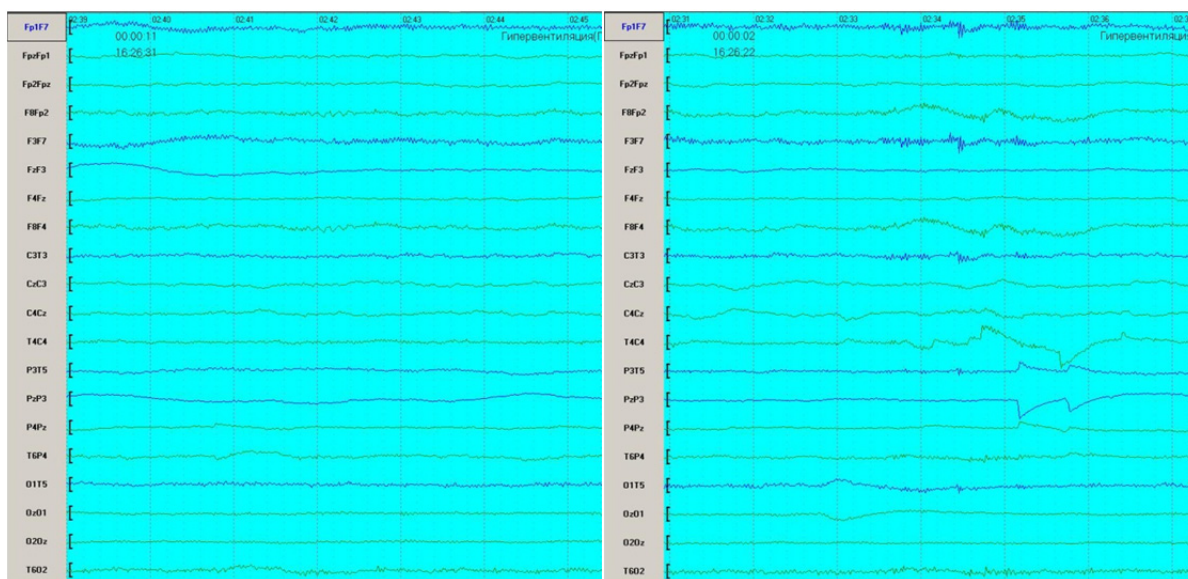


Figure 4. Patient O EEG data before and after two weeks of the study.

The process of the placement of sensors for measuring EEG is displayed in Figure 5.



Figure 5. The process of EEG study

Compared with the initial data, a more clear response to the process of opening-closing of the eyes is observed on the EEG pattern after AM-therapy. There is a greater representation of the beta rhythm in the anterior (front) leads. These changes indicate a full-fledged functioning of the cerebral cortex.

4. Discussion

The dynamics of the individual qualitative and quantitative characteristics of sleep disorders in AM therapy tend to be positive for the Group 1. Whereas positive changes in the Group 2 are explained by the proper sleep hygiene in the clinic, as well as the placebo effect. Moreover, the changes in the second group are not significant.

AM-therapy acts positively against insomnia, it helps to reduce anxiety and to improve the state of mood. It is important to note that AM-therapy helps patients to fall asleep within 20-30 minutes. This is manifested by the EEG pattern, which also shows a clear reaction to the eyes opening-closing process. These changes in the EEG show full-fledged functioning of the cerebral cortex. Furthermore, the study reveals that AM therapy leads to the improvement of sleep quality and to the reduction of the number of nighttime awakenings and daytime sleepiness. AM therapy approach as a way of insomnia relief, together with the sleep hygiene, helps to effectively monitor the status of sleeping avoiding drug therapy which causes muscle relaxant and has a synaptic influence on patients with the same as in a given research symptoms of insomnia.

Competing Interests Statement

The authors declare that they has no competing or potential conflicts of interest.

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What Geriatrics Know about Specific Medications

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Abstract

The study has aimed to investigate the Medication Knowledge (MK) in elders and identify factors that affect knowledge and the areas that are needed to be enhanced. Moreover, the perception of elders in regards to knowledge provided by healthcare professionals (HCPs) has also been studied. A cross-sectional survey has been performed, which is comprised of elders in ambulatory care settings. A questionnaire about Medication Knowledge Assessment (MKAQ) has been prepared for data collection. Illiteracy, polypharmacy, and multiple clinic follow-ups have been identified as significant factors contributing towards inadequate knowledge. The study revealed that significant number of elders are self-dependent in taking and managing their medicines despite of increased age and multiple medical problems. 73% of the elders were aware about the place to keep their medications and 82% knew about the next date of refill. However, male patients were found to be well-aware about direction of use ($P = 0.04$) and indications ($P = 0.03$). Evidence-based approaches individualized to the needs of elders, which are obligatory to be developed for advancing MK. The impact of these interventions should be studied in future on improving knowledge.

Keywords: geriatrics, healthcare professionals, knowledge, medication, polypharmacy

1. Introduction

The population of elders is getting increased at a constant rate across the globe. By 2050, the aging population is expected to increase by three folds in United States (Wiener & Tilly, 2002; Boffetta et al., 2014). A normal aging seems to be associated with hearing impairment and cognitive decline (Wayne & Johnsrude, 2015). In cognitive function, the elders are at an increased risk of the pathological cause of decline with increased risks of neuropsychiatric disorders, such as depression and cerebrovascular accidents (Swe et al., 2010). Elderly people are mostly observed to suffer from multiple medical conditions; therefore, polypharmacy is common in this age group (Maher et al., 2014). These factors were added to the burden of challenge, which enables elderly people to obtain and retain medication knowledge. Furthermore, the polypharmacy seems to be associated with decreased adherence. The patient related factors have been examined by World Health Organization (WHO) as one of the most fundamental aspects, which are associated with adherence besides socioeconomic factors, healthcare system, diseases, and therapy related factors (Wu et al., 2008).

1.1 Aim of the Study

There are very limited studies, which have highlighted the Medication Knowledge and its impact on elderly people. Hence, the enhancement of medication knowledge among elders is challenging and needs to be individualized. This study aimed to understand the knowledge of elders about their medication. Moreover, it examined the key areas of strengths and weaknesses in knowledge as well as to understand the way through which this knowledge can be utilized for a better medication management and improves the overall outcomes.

2. Method

A cross-sectional survey has been performed in an ambulatory care setting at a tertiary care center of King Fahd Medical City, Riyadh, Saudi Arabia from January to November 2014.

2.1 Participants

The participants were comprised of elders, who were attending the outpatient pharmacy for prescriptions dispensing during the study period. The age of patients was 65 years and above. The total sample size of the study included 448 patients, with or without their caregivers. From the selected sample, 18 patients were excluded, because they were diagnosed with dementia. Moreover, almost 10 patients were also excluded because they required help of their primary caregiver to fill the questionnaire. Thus, a total of 420 geriatrics patients (≥ 65 Years old) were included for analysis.

2.2 Data Collection

A questionnaire has been structured about the Medication Knowledge Assessment (MKAQ). The questionnaires were filled out by study participants and their caregivers. The major components of MKAQ included investigating the knowledge medication in certain areas, such as number of medications, names, indications, directions of use and common side effects of each medication. The knowledge and answers about side effects were classified as “correct”, “incorrect” or “I do not know”. Baseline characteristics were recorded including the number of clinics followed outside the tertiary care center and the use of pain medications outside the prescriptions medication list. Polypharmacy has been classified as receiving five or more medications; whereas, the illiteracy was defined as the inability to write or read. Furthermore, the perception of elders concerning the education and knowledge of medication provided by HCPs has also been evaluated. After the questionnaires have been filled out, participant’s satisfaction was obtained. No formal satisfaction survey was done; however, a simple question has been asked, whether they found this interview helpful or not regarding enhancing the understanding of their medications.

2.3 Ethical Consideration

The study has been approved by Institutional review Board at the center, and informed consent has also been obtained. The research has been carried out in compliance with the ethical rules for human experimentation, which are stated in the Declaration of Helsinki (Amdur & Biddle, 1997).

2.4 Data Analysis

SPSS software has been used to conduct statistical analysis to analyze the results of the study. The computation of baseline characteristic data regarding the patients, such as mean age, gender, the number of medications used by patients, the percentage of patients using herbal or Over the Counter medication (OTC) were analyzed. The patients’ knowledge of different aspects of the questionnaire was acquired through descriptive statistics. Moreover, the relationship between level of education and various aspects of knowledge have been evaluated through chi-square test. T-test has also been conducted for the measurement of the statistical relationship between a number of medications and various aspects of knowledge.

3. Results

Despite the increased age and multiple medical problems, a significant number of elders are still self-dependent in taking and managing their medications (47%). It has been identified through outcomes that approximately 50% of elders were illiterate. Moreover, the use of OTC drugs has been observed among 20% of elder patients. Approximately, 6% of the patients used pain killers besides the prescribed medications; however, the usage of herbal medication has also been found among 8% of the patients. Table 1 has pointed out the details regarding the baseline characteristics of study participants.

Table 1. Baseline Characteristics of Patients

		Number	Percentage
Gender	Male	235	56%
	Female	185	44%
Mean age		7+/_3	
Level of Education	Illiterate (Unable to read or write)	208	49.5 %
	Primary School	86	20.5%
	Intermediate	82	19.5 %
	Secondary	30	7,2 %
	University	14	3.3%
Nationality	Saudi	413	98%
	Non-Saudi	7	2%
Social Status	Married	258	61%
	Widowed	153	36.4%
	Unknown	9	2.1%
Follow in more than 1 Hospital		33	8%
Pain medications		29	7%
			Acetaminophen (23)
			NSAIDS (3)
			Unknown (3)
Mean Number of Medications		7+/_3	47.4%
Who Gives the Medications	Self	199	47.4%
	Family Member	162	38.6%
	Housemaid	59	14%
Herbs Use		36	8.6%
OTC use		83	20%

3.1 Knowledge of Elders about Medications

With respect to self-medications, it has been observed that elders were least aware regarding the names of their medications. A percentage of merely 3% to 18% of elderly patients have appropriate knowledge about the medications. Almost 17% of elderly patients have correctly identified the directions of using their medications; whereas, just less than 10% have awareness about side effects of their medications. The elders were most knowledgeable about where to keep their medications (73%), and about the next refill date (82%), which have been demonstrated in Table 2.

Table 2. Relations of studied Parameters with Level of Education and Polypharmacy

Studied Parameters	Percentage of Knowledge Results	Relationship with Level of Education (Chi-Square)	Relationship with Number of Medications (T-Test)
Names of Medication	3%	P = 0.001	P = 0.821 (NS)
Indications	18%	P = 0.005	P = 0.001
Directions of Use	17%	P = 0.001	P = 0.004
Side Effects	I don't know (65%)		
	Incorrect (26%)	P = 0.032	P = 0.55 (NS)
	Correct (9%)		
Next Refill	73%	P = 0.43 (NS)	P = 0.79 (NS)
Storage	82%	P = 0.75 (NS)	P = 0.13 (NS)

Note. NS = Non-Significant results. P-value less than 0.05 = Significant.

It is evaluated through outcomes, that age factor has no relationship with Medication Knowledge; however, male patients were found to have more knowledge about indications ($P = 0.03$) and direction of use ($P = 0.04$). The knowledge about the name of medication, its indications, directions of use, and side effects have been observed to be associated with the education level of elderly patients. On the other hand, a number of medications have a significant association with the directions of use and indications of medication. Concerning the next refill and storage of medications, it has been observed that elder patients scored best within these areas. Therefore, it can be said that this knowledge cannot be influenced by the level of education and number of medications.

3.2 Perceived Knowledge Provided by HCPs about Medications

It is noteworthy that majority of the elders (almost three quarters) expressed that the information provided by HCPs about their medications was inadequate. It has been assessed that majority of the elders found this interview useful for enhancing the knowledge regarding their medications (Table 3).

Table 3. Knowledge perceived by health care professionals

Degree of Clearance	Number/Percentage	Comments
Clear and Adequate	113.4 (27%)	Knowledge perceived by Healthcare professionals was clear.
To Certain Extent	205.8 (49%)	49% of the participants had perceived the knowledge to some extent
Not at All	100.8 (24%)	24% of the participants had not perceived knowledge at all.

4. Discussion

The provision of instructions as well as appropriate information encompassed the labeling of medications to assure an efficient and safe usage of medications among patients. In actual practice, the labeling of medication has usually been observed inconsistent and difficult for the patients to understand. Due to this unclear information, the chances of medication errors can be enhanced, which might result in loss of life as well (Alkhani et al., 2013). It is the primary responsibility of health regulations that the information contained in medication pamphlets including their names, should be written in the native language, besides the language of origin. The prescriptions dispensed by ambulatory care pharmacies should have instructions for use in the native language. Despite that, there seems to be a major gap in Medication Knowledge among the elders. Past studies have indicated that illiteracy is one of the major aspects. Therefore, Medication Knowledge is strongly related to adherence as well as optimal outcomes for geriatric population (Franks et al., 2005; Okuyan et al., 2013). From the outcomes, it has been examined that illiteracy was the strongest factor, which seems to be associated with all aspects of Medication Knowledge and may be the main explanation for this concern. The literacy rates were observed to vary among populations and illiteracy in general and limited health literacy was shown to be associated with increased mortality among elderly

patients (Sudore et al., 2006; Baker et al., 2007). Hence, it has evaluated the importance of literacy, which serves as a significant means to overcome certain communities for the improvement of medication knowledge in elderly populations.

Earlier conducted studies reflected some conflicting outcomes in contrast with the results of this study, regarding the assessment of knowledge. Some studies have shown good knowledge with regards to the name, indications, and directions of use (Barat et al., 2001; Chan et al., 2013). The poor knowledge regarding the side effects of medication has been observed to be consistent with studies conducted earlier (Barat et al., 2001; Modig et al., 2009). Furthermore, it has been evaluated that there is an inverse association between adherence and poor knowledge (Okuyan et al., 2013; Barat et al., 2001).

Generally, Polypharmacy refers to the group of medications, which are likely to be taken by an individual. Among the elderly patients, polypharmacy has been observed as a common issue, with increasing requirements of medications in accordance with the morbidities associated with age (Rambhade et al., 2012; Kim et al., 2014). Moreover, it has also been classified as an import factor that affected many aspects of medication knowledge. With respect to this study, polypharmacy has been considered as it is associated with the knowledge of names, indications, and directions of use. It has been evaluated by Pasina et al. (2014) that there is a poor association among adherence and polypharmacy. Further attempts should be made to optimize polypharmacy in elderly population, as supported by other studies (Eckardt et al., 2014; Loffler et al., 2014).

It has been evaluated that HCPs usually provide adequate information with respect to their medications. This is the reason due to which elderly patients have been observed to gain reasonable scores about the knowledge of next refills as well as the storage of their medications. The latter observation supported that knowledge can be improved as the elders grasped this aspect of knowledge more clearly. The outcomes of the study highlighted the need for research to enhance the ability of HCPs and to educate the elders regarding their medications. Studies have advocated that providing more time and availability to answer questions can improve knowledge in elders (Modig et al., 2012). With visual, auditory, and educational background limitations, the best modality of education needs to be individualized. As half of the elders depend on caregivers for their medications, the caregivers should also be targeted to further enhance the knowledge of medications. The same recommendation has been supported by the work of Mannucci et al. (2014). Prospective comparative studies are required for identification of the best education aids for elders, as well as for their caregivers to enhance knowledge. A proposed knowledge enhancement regarding the medication among the elders and their caregivers can be observed from Figure 1.

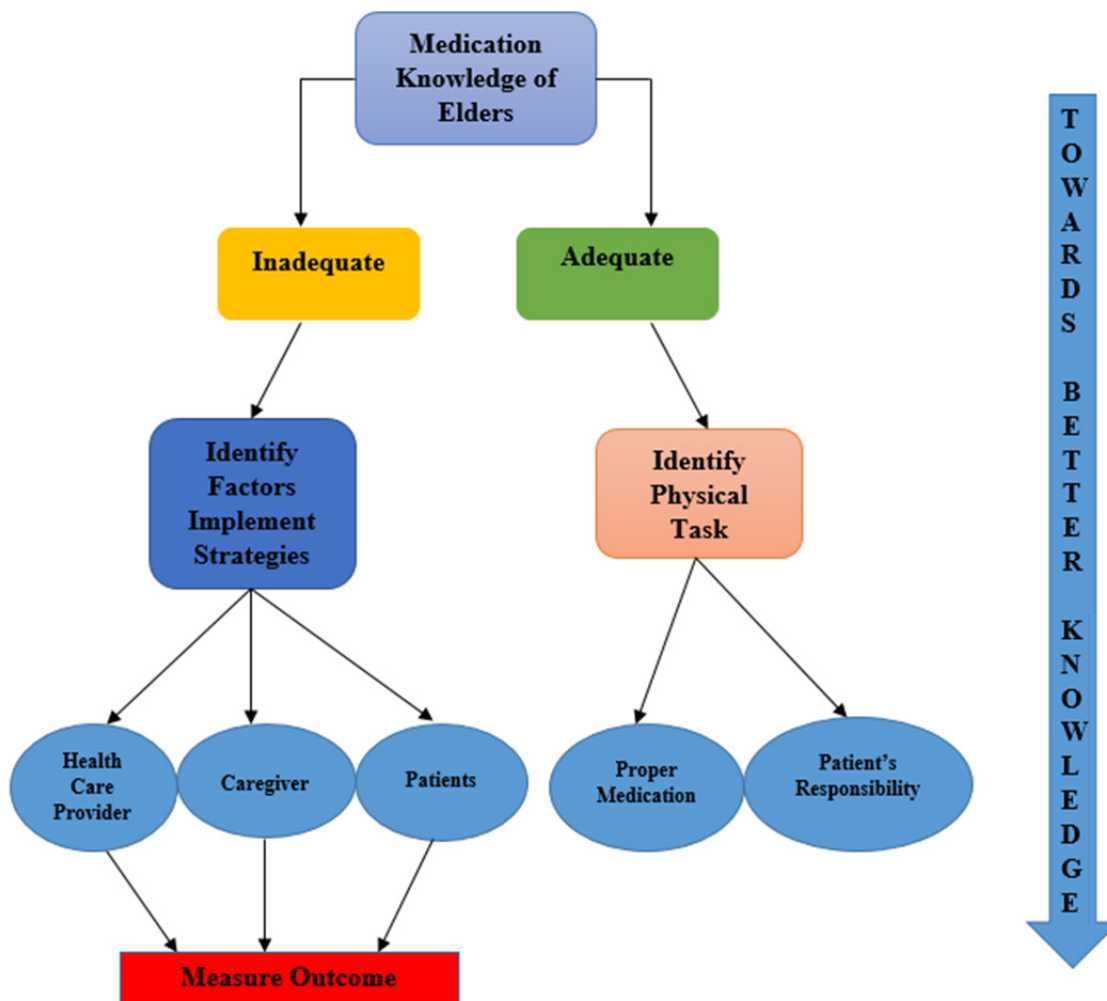


Figure 1. Proposed Schema for Elders about their Medication

In the population, the elders were willing to participate in clinical studies. Reviewing medication knowledge was welcomed and perceived as having a positive impact on medication knowledge. Regular medication reviews in elders exploring knowledge and understanding of their medications have also been encouraged.

The HCPs are needed to have awareness about medications among elder patients. The elder patients seemed to be least knowledgeable about the side effects. Factors contributing to poor knowledge, including illiteracy and polypharmacy, are observed to be prevalent aspects; however, not appropriate always. It has been considered by most of the elders that insufficient knowledge has been provided usually by healthcare professionals on the medications. Although, reaching knowledge perfection may not be a practical goal with multiple limitations; however, there is certainly an enormous opportunity for improvement. HCP needs to rethink and evaluate the currently implemented practices to provide an appropriate education to the elders about their medications. Limitations that affects on acquiring knowledge should be identified, and the interventions should be individualized and tailored. Many elders are more dependent on caregivers, and improving caregivers' knowledge will ultimately improve medication knowledge.

Prospective studies are needed to identify best tools, which would be suitable for the elders and their caregivers for knowledge enhancement. The impact of these interventions in improving knowledge, safety, adherence and overall outcomes are required to be measured. The elders showed willingness to participate in trials appropriately. Regular medication reviews among elders should be encouraged that will improve the overall safety of medications.

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Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Evaluation of Heart Rate in Daily Life Based on 10 Million Samples Database

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Abstract

This research uses a very-large amount of heart rate data (approximately 10 millions entries) collected on one million persons to investigate heart rate trends in daily life. Trends were examined regarding both human characteristics (gender, age, BMI), and environmental properties (hour of the day, day of the week, season). Concerning the relation between heart rate and gender, women's heart rate trend was significantly lower compared to men's. As for the relation between heart rate and age, on one hand, women's heart rate tends to become lower with aging. On the other hand, men's heart rate tends to keep increasing until the 50's. Also, men's heart rate is lower than women's in the 10's and 20's, the trend becomes opposite from the 30's. In the relation between heart rate and BMI (Body Mass Index), heart rate is significantly higher for users with higher BMI. Regarding diurnal fluctuation of heart rate, it has been confirmed to take its lowest between 3 A.M. and 6 A.M., then increasing regularly until the peak between noon and 3 P.M., after which it decreases during the evening through the night. As for in-week fluctuation, the trend of higher heart rate during the week and lower heart rate during week-ends and holidays has been confirmed. Specially, heart rate remarkably increases from Sunday to Monday. Finally, concerning seasonal fluctuation trend, heart rate is decreasing from summer to autumn, and is at his highest level in winter. The results of this research tend to correspond with previous studies that have been carried out on smaller samples and fewer subjects, demonstrating the credibility and validity of the data measured by our system. Moreover, on a public health point of view, we can say that it is important to take into account various human properties and spatio-temporal characteristics when having a comparative analysis of people's health distribution. We think the knowledge obtained in this research can be applied practically to the whole society as an indication for health care and various diseases prevention.

Keywords: smartphone, large amount of measurement data, heart rate, daily life

1. Introduction

1.1 Social and Technological Background

Japan is entering a super aging society, the elderly who need medical care and nursing care rapidly increases, and the burden of medical care and nursing care expenses is expected to increase more and more. In addition, with the advancement of informatization, various stressors are increased along with the rapid changing lifestyle, and consequently results in an increasing number of people claiming a deterioration of their quality of life (QOL) and a collapse of the mind and body from fatigue and stress. According to the epidemiological survey conducted in 1999 by the Ministry of Health, Labor and Welfare (MHLW) division for Fatigue Research, the percentage of people who are aware of fatigue represents about 60% (47.2 million) of the working population, half (29.6 million) being shown to suffer from chronic fatigue lasting more than six months (Kitani, 200). According to statistics of the Ministry of Health, Labor and Welfare, from a study carried out in 2010 about the percentage of worries and stress in daily life, 46.5% of people are living with some stress (MHLW, 2010).

In such social environment, in the future, it can be said that not only to treat at a medical institution after suffering from a disease but also to grasp scientifically and manage their own health status daily, is very important for prevention. Though human vital signs include body temperature, blood pressure, heart rate (pulse rate), etc., heart

rate is particularly an important indicator to grasp the state of the circulatory system, and it is said that symptoms of disease appear in heart rate (Yamashina, 2011). In addition, it is said that the average lifetime total heart rate of Japanese, whose average life expectancy exceeds 80 years, is about 3 billion times, and cardiovascular aging and blood vessel disorder progresses at each heartbeat. If so, it can be said that it is important to accumulate heartbeats or carefully consider the heart rate every day (Yamashina, 2011).

In previous studies, there are several examples analyzing the relationship between heart rate, aging, BMI, and diurnal variation (Mason, 2007, Nakayama, 1999, Saito, 1998, Vandewale, 2007). However, in these previous studies, many are analyzing based on the heart rate at rest measured at a facility such as a medical institution, and there are only few studies based on the heart rate during everyday life taking into account the influence of external factors such as mental stress due to work, physical activity, climate, etc. In addition, the target subjects number are small or medium, and there are no studies currently targeting large scale big data. Also, there are still few research examples that examined the trend of heart rate on long-term daily life such as weekly fluctuation of heart rate and seasonal fluctuation of heart rate.

1.2 Purpose of This Research

In a previous work, in order to collect a large amount of vital data, the authors have developed a system (COCOLOLO) that can analyze the heart rate variability from the color of the skin (change in brightness) by hitting the fingertips on the camera of a smartphone. Currently, this system is practically downloaded and used by about 1.3 million users (as of January 2017) practically as Apple Inc.'s iPhone application (WINFrontier, itunes) and Google Inc.'s Android application (WINFrontier, google play) (in Japanese). By using this system, it became possible to easily grasp heart rate variability and record data, anytime, anywhere, at any time in everyday life.

In this research, we analyze the trend of heart rate in daily life of people based on massive measurement data (about 10 million samples), collected using this smartphone application software. The following five items were analyzed and compared with the results measured by dedicated equipment in previous research, and the reliability and validity of the data measured in this system were investigated: heart rate and gender/age, heart rate and BMI, heart rate diurnal fluctuation, heart rate in-week fluctuation, heart rate seasonal fluctuation

2. System Outline and Measured Data

In this research, we used the above described heart rate variability analysis system that uses smartphones' camera (see Figure 1). This is a client/server system that consists of a smartphone, which is the client terminal, and a server that performs heart rate variability analysis processing. As humans heart beats, the amount of hemoglobin contained in the blood flow increases and decreases, so the apparent color of the skin at the fingertip changes slightly influenced by this phenomenon (Toritani, 2012). Therefore, by using a smartphone, a pulse wave waveform can be detected from the color (change in brightness) of the skin by applying a fingertip to the camera part, and the heart rate variation is analyzed from the fluctuations of the pulse wave.

The present system improves analysis accuracy by applying unique filtering method to remove noise, and as for the heart rate, compared with a system using a dedicated fingerpiece pulse wave sensor, it shows a correlation of 0.99 as shown in Figure 2, which can be assumed as almost the same accuracy 0.99 (Komazawa, 2016). By using this system, it became possible to measure heart rate variability easily, anytime, anywhere, at any occasion in daily life. In addition, by establishing the technology of collecting, storing, and processing health data, the user's vital data are transmitted to the server in real time, and it became possible to analyze and evaluate the heart rate at that time of daily life is measured based on large-scale measurement data.

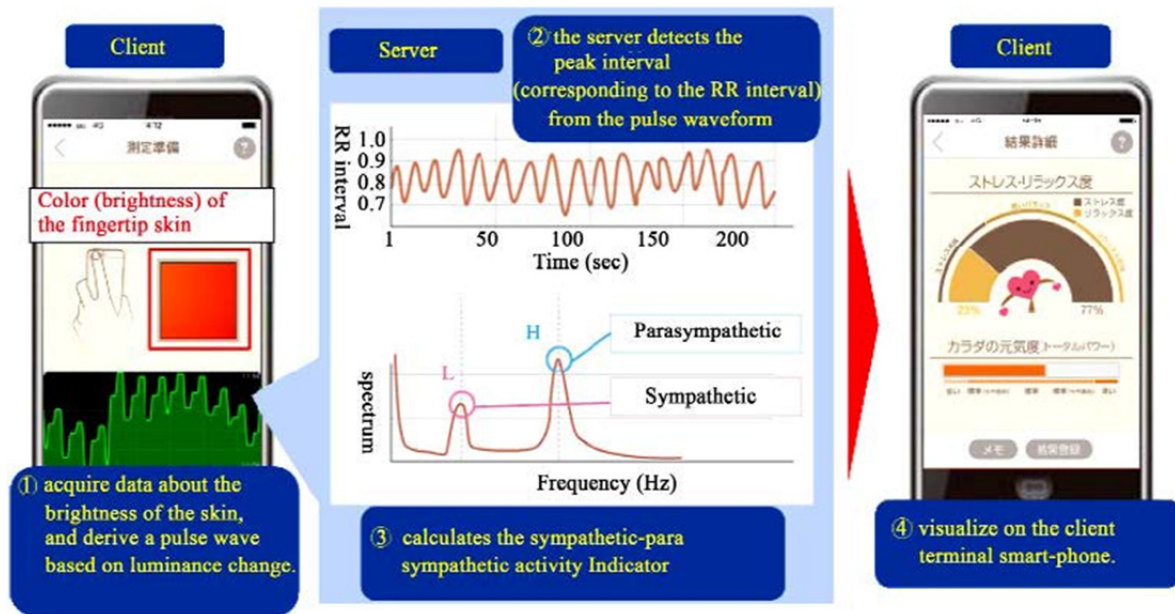


Figure 1. Smartphone application based measurement system outline

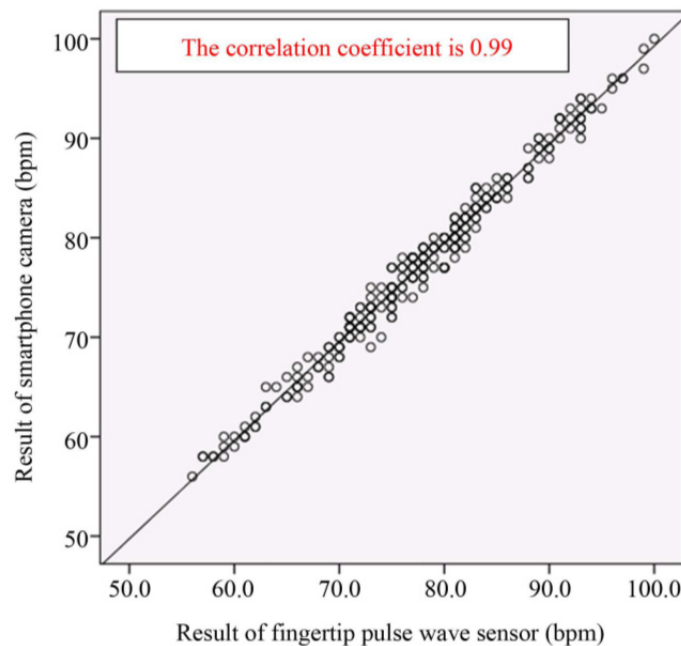


Figure 2. Correlation between heart rate measured by finger plethysmograph and heart rate estimated from smartphone camera (developed system)

In this study, 11443795 data (male: 3082010, female: 8361785) measured between February 2015 and February 2017 from 944775 persons (male: 260144, female: 684631) were analyzed based on big data of heart rate during daily life. Measurements with more than 20% of the pulse peak interval missing were excluded from the analysis targets. Regarding the use of measurement data, consent of the examiner is obtained based on the ethical regulations of WINFrontier Corporation. Table 1 shows the attributes of the users (left), and the attributes of measured data (right). We used IBM SPSS Statics Version 22 for statistical processing in this study. The significance level of the test was set at 5%.

Table 1. Characteristics of system's users (left) and measured data (right)

Age	Man	Female	Total	Age	Man	Female	Total
10's	34,439	98,208	132,647	10's	144,916	497,383	642,299
20's	68,097	220,821	288,918	20's	369,902	1,393,155	1,763,057
30's	47,365	123,664	171,029	30's	452,934	1,410,187	1,863,121
40's	53,497	136,054	189,551	40's	821,942	2,514,356	3,336,298
50's	41,271	88,911	130,182	50's	861,684	2,064,789	2,296,473
60's~	15,475	16,973	32,448	60's~	430,632	481,915	912,547
Total	260,144	684,631	944,775	Total	3,082,010	8,361,785	11,443,795

3. Analysis of Measured Data

3.1 Relation between Heart Rate and Gender

3.1.1 Gender Differences in Heart Rate at Rest

There is a gender difference in heart rate, and it has been reported that women's heart rate is generally higher than men's (Sagie, 1992, Singh, 1999). In a previous study, resting heart rate was analyzed from electrocardiogram of 46129 citizens who participated in a clinical trial of a new drug (Mason et al., 2007). The median of resting heart rate was 68 (bpm) for women and 66 (bpm) for men. In another study about heart rate and life expectancy, it has reported that a correlation exists between mammalian heart rate and lifespan (Levine, 1997). According to this study, animals with low heart rate such as elephants have a longer life expectancy, and small animals with higher heart rate such as rats report shorter life span. An epidemiological study that investigated the relationship between heart rate and mortality rate or the incidence of cardiovascular accidents, studied during an average 16.5 years 8800 men and women between 30 and 59 years old in 1980 (Okamura, 2002). This study showed the tendency that both number of death and cardiovascular mortality were higher with higher heart rate. Thus, as the heart rate is lower, the risk of death decreases and the lifespan becomes longer, which was also evident in previous studies. However, according to data released by the Ministry of Health, Labor and Welfare, the average life expectancy as of 2015 was 80.79 years for men and 87.05 years for women (MHLW, 2015), such in view of the heart rate at rest in previous studies, we cannot explain women longevity.

3.1.2 Gender Differences in Heart Rate in Daily Life

The heart rate at rest measured in previous studies is greatly influenced by physical internal factors, but it is hard to say if the influence of external factors such as physical activity, climate, mental stress due to work, and such is taken into consideration. Therefore, in this research, we analyzed gender difference in heart rate from 10 million cases of heart rate data measured in daily life by using formerly described smartphone system (COCOLOLO). Figure 3 shows the average value of the heart rate of men and women. The results of the student's t test are shown in Table 2. As a result, the average value of men was 72.53 (bpm), and the average value of women was 71.53 (bpm), women's heart rate tending to be significantly lower by about 1 beat per minute. This tendency is in conflict with the gender difference of the heart rate at rest reported by previous studies.

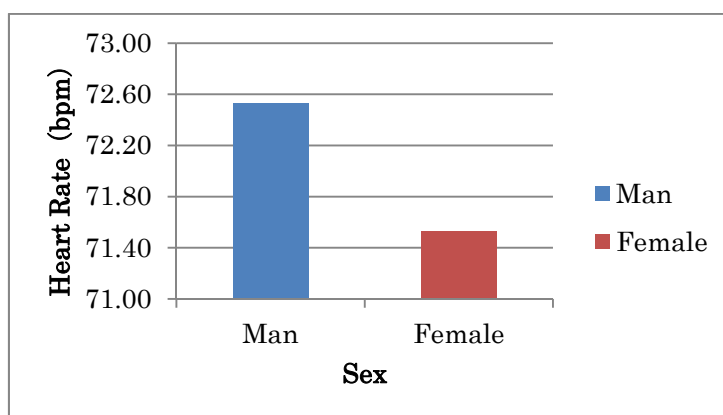


Figure 3. Relationship between heart rate and gender in daily life in this study

Table 2. Result of student's t test (comparison of men and women heart rate)

Gender	N	Mean	Std. Deviation	Std. Error Mean
Men	3082010	72.53	12.335	0.007
Women	8361785	71.53	10.858	0.004

3.2 Relation between Heart Rate and Age

Next, we examined the relationship between heart rate and age. The previous study by Nakayama (1999), the resting heart rate measured during general medical examination on 8623 men and 4919 women, showed that in all ages men have a lower resting heart rate than in women (Nakayama, 1999). In the later study by Mason (2007), the age trend of resting heart rate for 46129 citizens who participated in clinical trials of new drugs were also analysed. The results confirmed previous tendency that the resting heart rate of men in each age group tend to be lower by 2 to 4 beats per minute than the resting heart rate of women (Mason, 2007).

In this study, we analyzed relationship between heart rate and age from 10 million cases of heart rate data measured in daily life. We classified the data into six age groups from teenagers to 60s and over, and we conducted multiple comparisons by the method of Games-Howell in order to investigate the difference between the age groups. The results are shown in Figure 4. As a result, when looking at the tendency by age, the heart rate of the woman tended to decrease as the age increased with the peak at 72.43 (bpm) in the thirties. Meanwhile, men showed a tendency to increase in heart rate with a peak at 73.62 (bpm) in the forties. The tendency by this age agrees roughly with the trend excluding the teenagers in the study by Mason (2007). We can consider that this trend of heart rate by age is not only influenced by internal factors such as aging, but also external factors such as work and physical activity, in which men may be more involved than women.

Previous studies have shown that stress caused by work contributes to increase blood pressure, accelerates the development of cardiovascular organ disorders such as cardiac hypertrophy, and is also related to the risk of coronary arrhythmia (Schnall, 1990, Tennant, 2000). Men have a tendency of heart rate being shaky after their 60s, which correspond to the age many people are retiring from work. Being in a situation that the stress from work is reduced, and the relaxation of mind can be kept easier, which possibly contribute to heart rate decline. In the present study, the heart rate of women showed a tendency significantly lower than that of men, specially from the 30s, which correspond to the age when responsibilities at work became heavier. Thus, in terms of heart rate during daily life, this result may explain why women lived longer.

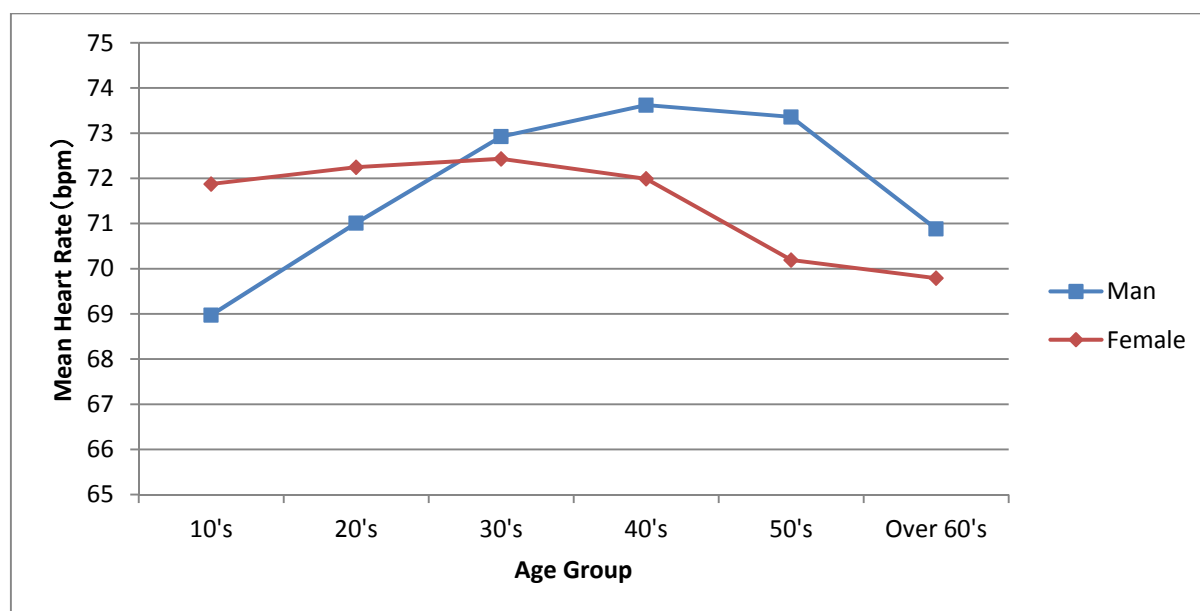


Figure 4. Relationship between heart rate and age in daily life in this study

3.3 Relationship between Heart Rate and BMI

In this section, we examined the relationship between heart rate and Body-Mass Index (BMI). BMI is the ratio of the weight (kg) to the square of the height (m), and represents the degree of obesity of a person. Moreover, the degree of obesity is calculated from BMI according to the criteria defined by the Japan Society for the Study of Obesity (Ogawa, 2015). In a previous study, Saito (1998) analyzed the relationship between resting heart rate and the degree of obesity for 4695 men and 1849 women aged from 18 to 22, who underwent routine physical examinations at college. The results confirmed that the obese persons tend to have a significantly higher heart rate compared with the non-obese persons (Saito, 1998).

In this study, we analyzed the relationship between heart rate and BMI, from 10 million cases of heart rate data measured in daily life. Here, we classified the degree of obesity from low body weight to obese into four groups, and we conducted multiple comparisons by the method of Games-Howell in order to investigate the difference between the groups. The results are shown in Figure 5. As the BMI increases, the heart rate tends to be significantly higher in both men and women. In addition, the heart rate tends to be the lowest in the case of the standard weight compared to the low body weight, and the heart rate of obese persons (2 degrees or more) is significantly higher by about 5 beats per minute than the heart rate of standard weight persons. Thus, the results of this study confirm the trend of previous studies.

In Framingham study, it is reported that the higher the heart rate, the higher the total death and the risk of death from cardiovascular events in high blood pressure patients (Gillman, 1993). In addition, lack of exercise increases the risk of various cardiovascular diseases, and it has been shown that there is a blood pressure lowering effect by moderate exercise habits (Rogers, 1996). Thus, it is reported that as obese people tend to have high blood pressure and high heart rate, the risk of various diseases increases, such a good balance of dietary habits and regular physical exercises habit help keeping a standard weight, which is very important for diseases prevention and healthcare.

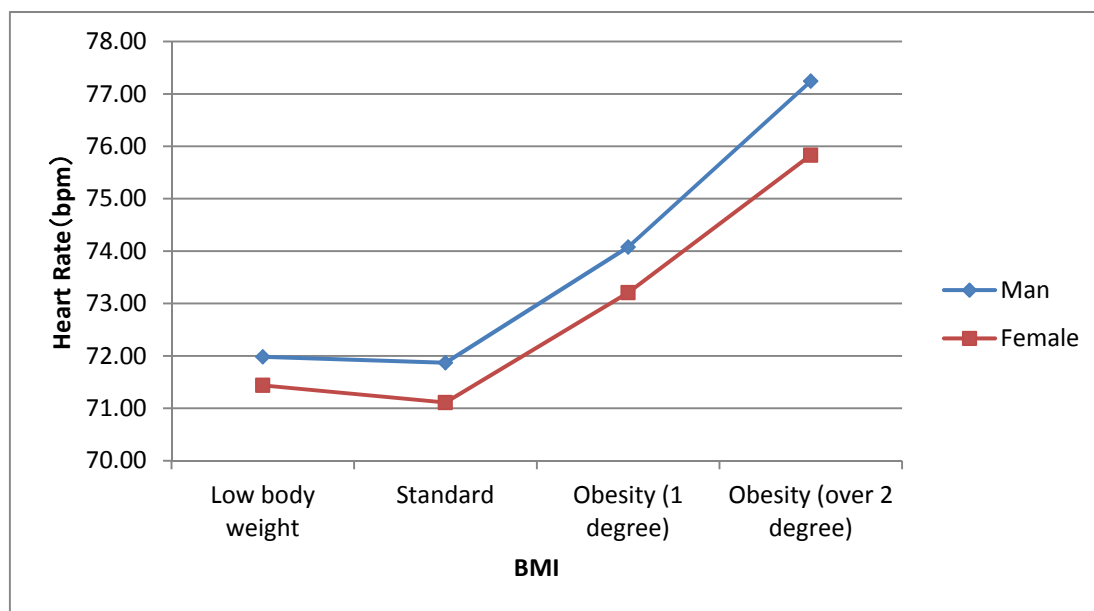


Figure 5. Relationship between resting heart rate and non obesity, obesity in this study

3.4 Daily Fluctuation of Heart Rate

The diurnal variation, also called circadian rhythm, is a mechanism that oscillates with a 24-hour cycle. It is known that the fundamental function of the body such as body temperature and hormone secretions also show a rhythm of about 24 hours. Circadian rhythm also discernable even in a condition where there is no change in light or temperature, so it is clear that the organism has a clock mechanism in the body, called the body clock. A previous study, which carried out a constant routine experiment on 8 healthy men kept in lying position and arousal for more than 24 hours, has shown that there is a circadian rhythm in resting heart rate under constant conditions (Vandewale, 2007). It confirmed a circadian rhythm with the lowest heart rate was early in the morning, then rising

from there, up to a peak appearing during the day, to finally decrease from the evening to the night.

In this study, we analyzed the daily fluctuation of heart rate from 10 million cases of heart rate data measured in daily life. In this case, we classified the measurement time into eight groups of 3 hours, and we conducted multiple comparisons by the method of Games-Howell in order to investigate the difference between the groups. The results are shown in Figure 6. Heart rate during everyday life was lowest between 3 and 6 a.m. as in previous study, rising from there to a maximum at 12 to 15 o'clock during the day, after which the heart rate drops as it goes from evening to night, confirming the presence of a circadian rhythm. The average maximum heart rate was higher by about 7 beats per minute in the daytime than at dawn.

It was reported in a previous study that the incidence of myocardial infarction from 6 a.m. to noon was 3 times more frequent than in the evening, corresponding to the time zone when the heart rate most increases according to our study (Muller, 1989). Thus, in helping being aware of his heart rate, we think our system may help in preventing such diseases.

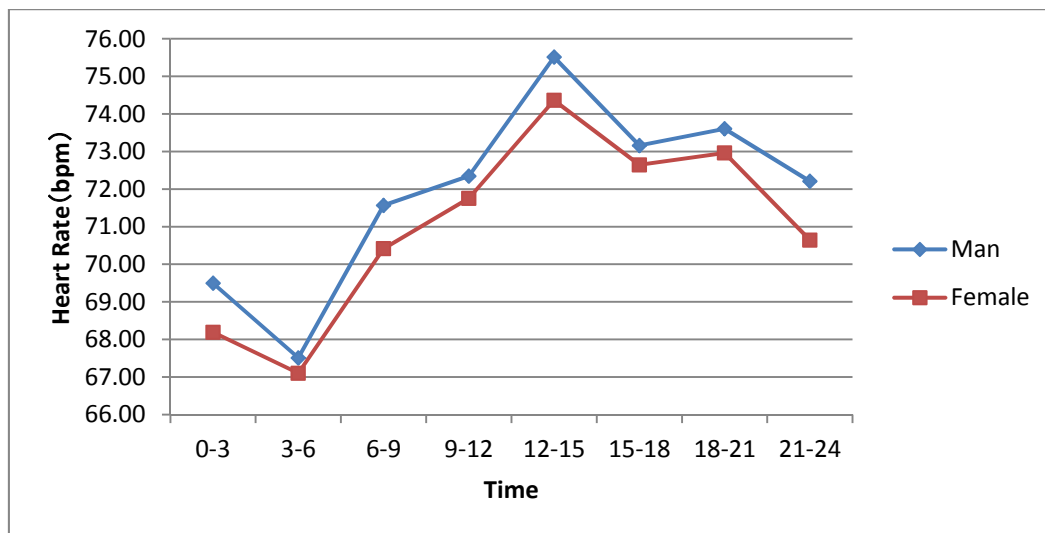


Figure 6. Daily fluctuation of resting heart rate in this study

3.5 Weekly Fluctuation of Heart Rate

In a previous study, a health check was conducted for the residents of certain towns and villages in Hokkaido to prevent the occurrence of cardiovascular disorders, and as one of the trials, 944 people aged 40 to 65 were targeted to analyze the trend of blood pressure between days of the week (Ohtsuka, 2011). This study revealed that the measured blood pressure value and daytime / nighttime blood pressure fluctuation differed depending on the day of the week. Blood pressure on Saturdays and Sundays showed a tendency to decrease significantly compared with blood pressure on weekdays. Specially, it had a tendency to rise rapidly on Monday after falling on weekends. These tendencies appeared more strongly by civil servants (employees), but also appeared significantly among farmers (self-employed persons).

In this study, we divided into seven groups for each day of the week, and we conducted multiple comparisons by the method of Games-Howell in order to investigate the difference between the groups. The results are shown in Figure 7. For both men and women, the heart rate tended to decrease on weekends and to rise on weekdays, which tendency generally agrees with the weekly fluctuation in blood pressure of previous study. In particular, the difference in heart rate between Sunday and Monday is remarkable, heart rate on Mondays being 1.5 bpm higher for men and 1 bpm higher for women than on Sundays. We can reasonably assume that work stress may have a large impact. Therefore, among weekdays it is possible that the burden on the mind and body may be bigger on Mondays.

Concerning the relationship between the incidence of various diseases and the days of the week, the research group of Professor K. Kurafuri, analyzed the incidence of stroke for 12529 patients over the age of 40. The fluctuation due to the day of the week clearly showed a tendency regardless of age and gender of high occurrence rate on Monday, while being the lowest on Sunday (Kurashiki, 2004). In addition, in a survey conducted by the Osaka

Acute Coronary Insufficiency Study (OACIS) group consisting of 25 centers, the examination of the number of occurrences by day of week for those who had an acute myocardial infarction during the four years from 1998 to 2001 revealed that myocardial infarction occurs more frequently on Monday (Kinjo, 2003).

We can consider that the rapid rise in heart rate from Sunday to Monday, as shown in the present study, may contribute to the weekly fluctuation of the incidence of such disease. Also, the difference in heart rate between Sunday and Monday for men tends to be larger than for women. According to the multiobjective cohort study by the National Cancer Center, the incidence and the mortality rate of myocardial infarction and stroke tend to be higher in men than in women, and there is a possibility that there is a cause-and-effect relationship with the gender difference of the day-of-week variation shown in this study (NCC, 2010). So, it is very important to understand the weekly fluctuation of vital signs to prevent various diseases by for example lowering the burden of work on Monday morning.

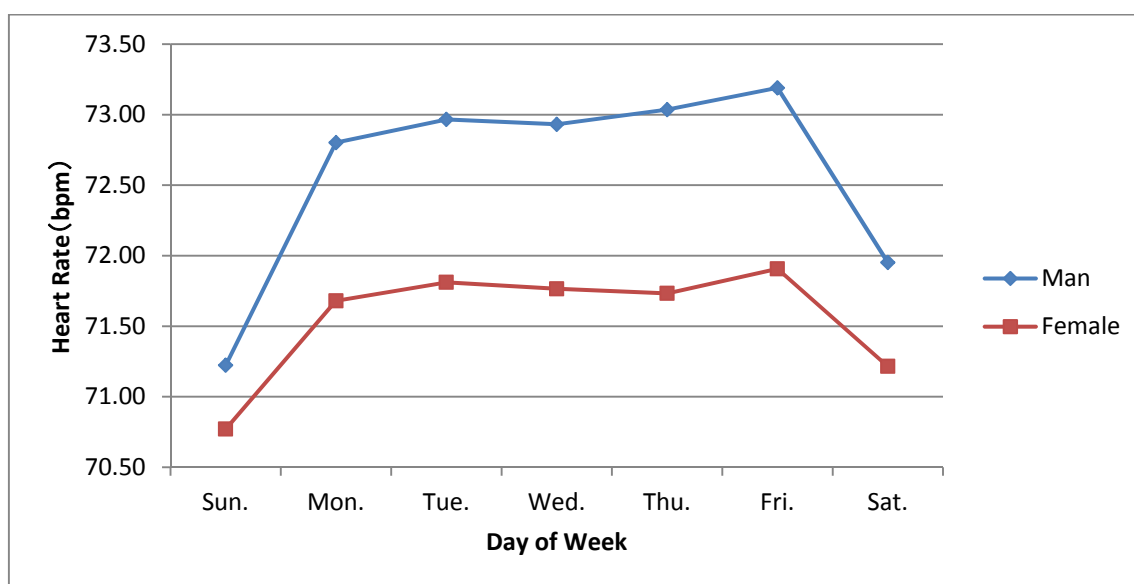


Figure 3. Weekly variation of heart rate during daily life in this study

3.6 Seasonal Fluctuation of Heart Rate

In this section, the seasonal variation of the heart rate was verified. Previous studies have investigated the relationship between blood pressure and seasonal fluctuation in the Sub-Arctic inhabitants. In that study, it is confirmed that blood pressure decreases in summer and increases in winter. It is thought to be a physiological phenomenon in which the blood pressure is elevated due to artery contraction when the temperature is low like in winter (Hopstock, 2013). Moreover, from the observation of blood pressure for every season in Japan, it is clear that blood pressure is generally low in summer and high in winter (Takahashi, 1955). In addition, according a study on hypertensive patients who measured blood pressure by home sphygmomanometer six times a day for five consecutive years while administering an antihypertensive treatment, the autumn showed the lowest trend and winter the highest (Maeda, 1993).

In this study, seasonal fluctuation of heart rate was analyzed from 10 million cases of heart rate data measured in daily life. We separated data for each month to create 12 groups, and conducted multiple comparisons by the method of Games-Howell in order to investigate the difference between the groups. The results are shown in Figure 8. The heart rate trend of both men and women showed a tendency to decline as summer approaches, until fall, to then increase in winter. We can assume that external factors such as climate comfort may be affecting the heart rate since it tends to be the lower in autumn than in summer. There is also a tendency common to men and women that the heart rate has a difference of about 1.5 bpm between its maximum and minimum through the year. The tendency showed by our results is generally consistent with the seasonal fluctuation in blood pressure reported in previous studies.

In an investigation conducted by nationwide hospitals of the Japan Organization of Occupational Health and Safety, on 46031 patients hospitalized for stroke, it has been verified that cases of cerebral haemorrhage and subarachnoid

hemorrhage, occur significantly more often in winter than in summer (Toyota, 2011). This seasonal difference may be related to the seasonal fluctuation of heart rate in daily life as shown in our study. So, understanding the seasonal variation of vital signs can be said to be very important in preventing various diseases.

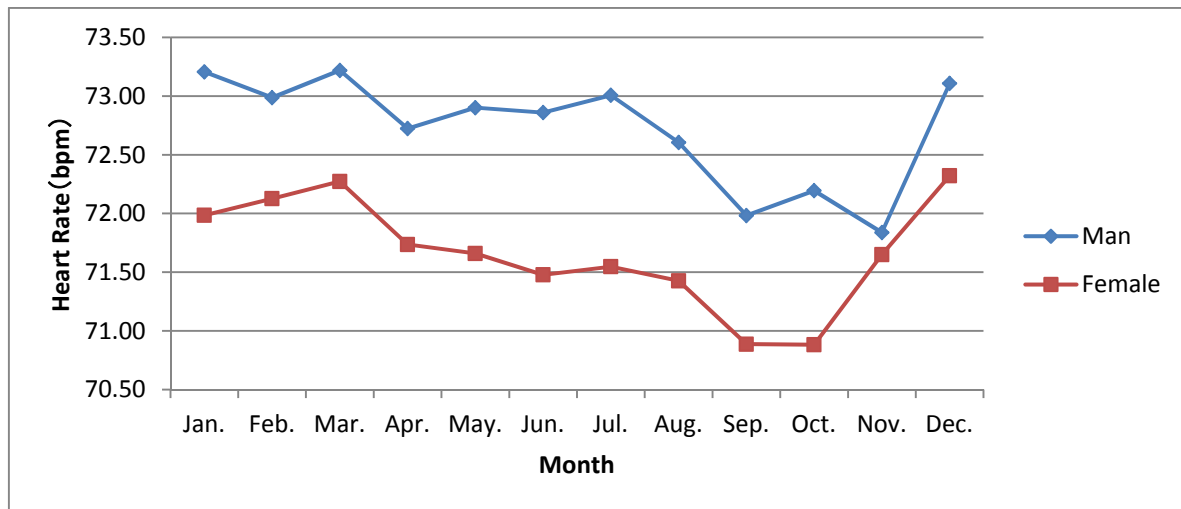


Figure 8. Seasonal variation of heart rate during daily life in this study

4. Conclusion

In this study, we attempted to analyze the trend of heart rate during people's daily life based on heart rate big data (10 million measures on nearly 1 million people). As a result, the following points were clarified.

- In the relationship between heart rate and gender, women tend to have a significantly lower heart rate than men. In the relationship between heart rate and age, heart rate is decreasing as age increases for women, while it tends to rise from 40 to 50 years old for men. Up to their 20s, men have lower heart rate than women, though from the 30s and later women then tend to have lower heart rate than men. These results may explain the reason why women live longer could be explained from the viewpoint of heart rate during daily life.
- In its relationship with BMI, heart rate tends to increase significantly as BMI increases, showing the importance of balanced diet, and regular physical activity.
- Concerning the relation between heart rate and age, our study revealed some differences with previous studies. While it has been reported that women tend to have higher average heart rate than men in all ages, our study showed a tendency that average heart rate of men was higher than women's after 30's. This result suggests that average heart rate in daily life may be an explanation of the reason why women tend to live longer than men.
- Regarding the daily fluctuation of the heart rate, the time interval between 3 - 6 a.m. shows the lowest heart rate, then rising to reach its maximum between 12 - 15 o'clock, to finally decrease as it goes from evening to night, confirming a circadian rhythm.
- As for the weekly fluctuation of the heart rate, it suddenly decreases on the weekend to be higher on weekdays. Especially the rise in heart rate from Sunday to Monday is remarkable.
- Regarding the seasonal fluctuation of the heart rate, it decreased from summer to autumn to take its maximum in winter.

The results of this research tend to be roughly in agreement with the results in previous research measured by dedicated equipment, in restricted conditions, and on a smaller or less sample number. It was possible to show the reliability and validity of the data measured in this system. From the viewpoint of public health, it can be said that it is important to compare and analyze people's health distribution according different attributes and spatiotemporal spaces. We believe that the findings obtained in this study can be used by the whole society as an indicator for health management and prevention of various diseases.

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Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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A Deep Look into Interactional Pathology among Couples with Morbidly Jealous Male Partners: A Phenomenological Study

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Abstract

The purpose of this phenomenological study was to gain a deeper understanding of interactional pathology among couples with the morbidly jealous male partners by examining the lived experiences of 5 female partners. The study attempted to answer the main research question which was, "How do women experience their communication with their morbidly jealous husbands?" along with some sub questions in different dimensions of marital life. The major data collection tool consisted of semi-structured interviews (Seidman, 2013). Forty to sixty-minute interviews were conducted with each participant. Data analysis included a three-phase process: description, reduction, and interpretation. The latter was completed using the qualitative content analysis by Colaizzi (Colaizzi, 1973). Four categories of lived experiences indicating interactional difficulty among the couples were obtained from the data analysis. These interactional damages were evident in the experiences of all the women interviewed and consisted of themes related to boundaries, control, intimacy and 'meta-damages'. The results of the study revealed that the damages begin with those related to boundaries, develop to control and intimacy rooted in meta-damages and finally terminate marital relationships.

Keywords: lived experiences, morbidly jealous husbands, interactional damages, partners, pathology

1. Introduction

The foundation of every family is communication between couples. Indeed, good communication is the foundation of a strong marriage. Many marriages could be saved if spouses improved the ways they communicate with each other. Many theories have attended to couple communication (e.g. Baxter, 1988; Blaisure & Allen, 1995; Bochner, 1985; Burr, 1973; Canary & Stafford, 1992). Couple communication may be impaired by different factors such as the role of gender, age of marriage, low education (Bumpass, Martin, and Sweet, 1991), distancing behavior (Roberts, 2000), and genetics (McGue & Lykken, 1992; Jocklin et al., 1996). Storaasli and Markman (1990) found that women considered money and issues with relatives as more intense problems in their relationships, while men reported children as a more intense problem. Amato and DeBoer (2011) believed marital dissolution is related to the level of conflict in the marriage and Stieglitz et al. (2012) attended to infidelity and jealousy in marital conflict. The present study is interested in the type of jealousy that can be described as morbid jealousy and the communication damages experienced by women who have a morbidly jealous partner.

In this context, morbid jealousy can be what leads to marital conflicts. Morbid jealousy refers to negative emotions and 'irrational' thoughts such as spouse infidelity. Together, they stimulate unacceptable behavior, in which the main problem is rumination of one partner on the faithfulness of the other based on unsubstantiated evidence (Cobb, 1979). Mullen (1990) introduced four features for morbid jealousy, i.e., an underlying mental disorder

appear before or with the jealousy; the underlying disorder coexist with the jealousy; the course of morbid jealousy closely relates to that of the underlying disorder; and the jealousy has no root in reality (Mullen, 1990). (It may be helpful to give examples of each-this is excellent examples!)

Vauhkonen (1968) believed that jealousy in normal people occurs in response to firm evidence, i.e., they are, though difficult, ready to change their beliefs and reactions when new information becomes available, and perceive a single rival. In contrast, for morbidly jealous individuals irrelevant occurrences would be conclusive evidence of infidelity by which refuse to change their beliefs even when they encounter conflicting information, and thus accuse the partner of infidelity.

Some researchers point out to delusions and obsessions among individuals with morbid jealousy (e.g. Enoch & Trethowan, 1979; Shepherd, 1961). Infidelity delusions can be seen in both delusional disorders and schizophrenia. In schizophrenia, these delusions are persecutory delusions in which, for example, the partner thinks her/his partner is being poisoned to reduce sexual potency, but in delusional disorders the delusions of infidelity are without any other pathological features (Kingham & Gordon, 2004). Stein et al. (1994) regarded obsessional jealousy as associated with shame and discomfort. Kingham and Gordon (2004) introduced delusions in morbid jealousy with some characteristics which exist in one's own thought, are ego-syntonic, regarded as true, but not resisted. Obsessions in morbid jealousy, on the other hand, are characterized by being in one's own thought, ego-dystonic, acknowledged to be senseless, and usually resisted

Marazziti et al (2003) introduced differential diagnosis criteria for obsessional jealousy of which the following are more severe: Time taken up by jealous concerns, difficulty in putting the concerns out of the mind, impairment of the relationship, limitation of the partner's freedom, and checking on the partner's behavior. Kingham and Gordon (2004) believed morbid jealousy may appear as an overvalued delusion, obsession or a combination of both. Therefore, it is a symptom rather than a diagnosis.

Many researchers have attended to emotion in marital communication. For example, Bloch, Hasse and Levenson (2014) showed downregulation of negative emotions during marital conflicts leads to marital satisfaction and more constructive communication. Sanford (2012) attends to emotional encoding and decoding between couples. "A clearly encoded emotion can be defined as one that is expressed with sufficient clarity so that it is recognized by outside observers. In contrast, emotion decoding via objective observation occurs when a person recognizes an emotion that was expressed overtly by his or her partner. This can be defined as perceiving the same emotion in a partner as that which is perceived by outside observers" (p. 1). Iveniuk et al. (2014) showed high neuroticism and low positivity of men are associated with more conflict among couples. Randall et al. (2013) showed the association between marital cooperation and emotional coordination. Malouff et al. (2014) showed a positive and significant association between emotion intelligence and romantic relationship satisfaction. He also found that a significant relationship between an individual's emotional intelligence and the partner's level of satisfaction with the relationship In Iran aslo some researchers have investigated the role of emotion in marital life. Rajabi, Mousavian Nejad and Taghi Pour (2014) found emotion was significantly and positively associated with marital satisfaction but significantly and negatively related to conflict. Gharehbaghy Aguilar-Vafaie (2010) examined the relationship between emotional security and role conflict. Pirsaghi et al. (2015) reported a significant association between emotional schema and marital conflict Although many studies have examined the role of emotion in marital life, there is no research on morbid jealousy in men and its effects on their communication with their spouses.

Taking into account the previous research in this area, therapeutic actions in family therapy need more knowledge about communication pathology women experience in living with husbands who suffer from morbid jealousy symptoms. Findings of the present study would help to fill the knowledge gap in the literature regarding morbid jealousy and compensate lack of research on exact communication pathology. Considering what was mentioned above, the present study aimed at answering the question: what are the interactive damages incurred among couples with a morbidly jealous husband?

2. Method

This study was a phenomenological qualitative study. Phenomenology is the study of experiences of phenomena and structure thereof, which analyses from individuals' point of view (Moustakas, 1994). Five female participants were recruited through the use of purposeful sampling methods. The present study attempted to establish a good correspondence between the research question and the sampling (Bryman, 2004). The inclusion criteria were formed based on currently married participants who have been married for at least one year or more to a morbidly jealous spouse. It needs to be mentioned that the individuals aged 24 to 35 were interviewed. The reason for age restriction was to form a more coherent group and, thus, make comparison between the subjects more relevant.

Table 1 shows the demographic characteristics. The participants were required to meet the following inclusion criteria: (a) the participant can understand the researchers' questions; (b) they have no acute and chronic physical illnesses or mental disorders; (c) they are willing to participate and able to provide information.

Table 1. Demographic characteristics of participants

Participant	Age	Marital status	NO. of Children	The length of marriage
1	33	Married	2 (one boy and one girl)	13 years
2	34	Married	2 (one boy and one girl)	18 years
3	26	Married	-	1 year
4	35	Married	3 (one boy and two girls)	19 years
5	24	Married	-	1 year

The transcripts and tape recordings were not labeled with participants' names to maintain confidentiality throughout all stages of the study. Ethical approval was obtained from the ethical committee of Isfahan University as well

Data collection was conducted using a semi-structured interview. The questions were mainly open ended questions with a small number of closed questions relating to information such as age, the length of the marriage and number of children and so on. The interviewer could ask additional exploring questions in response to what are viewed as significant replies only after sufficient rapport and empathy were developed between the researcher and the participant. Each participant was presented with a similar set of questions relating to their overall experiences of living with a morbidly jealous husband and the impact it had on their interaction and communication. An example of an open ended question included in the interview schedule is: "What are your main problems with your husband in your marital life?" The researchers attempted to use language that was comprehensible and relevant to each participant. Data collection continued until data saturation. All interviews were recorded and transcribed and each interview was assigned a code. Then, the researchers listened to the recordings and made notes. Key words, phrases, and statement were transcribed. The seven-step method of Colaizzi (1978) was used to analyze the data as follows:

- 1) The researchers read all participants' descriptions and tried to empathize with them.
- 2) To extract important themes, the researchers found the related words, phrases and sentences, and coded them afterwards.
- 3) All the extracted codes were given formulated meaning.
- 4) The formulated meanings were organized into clusters of themes. To make them reliable, the researchers checked the main descriptions.
- 5) Results were then integrated into an exhaustive description of the phenomenon under study.
- 6) The exhaustive description of the investigated phenomenon was formulated as an unequivocal statement of identification when possible.
- 7) Finally, to clarify the acquired ideas and make them reliable, the findings were referred back to the participants for the validity approval.

To evaluate the credibility of data analysis, the researchers had numerous negotiations until agreements were achieved on each aspect of the process. Then, an expert in phenomenological method reviewed the analysis of data and confirmed that appropriate procedure had been followed.

For the validity and reliability of data analysis and with reference to Golafshani (2003), the researchers had numerous negotiations until agreements were achieved on each aspect of the process. To provide details of the method and abundance of evidence and triangulation, the extracted themes were examined from a family therapist's perspective. Also an expert in the phenomenological method reviewed the analysis of data and confirmed that appropriate procedure had been followed. Logical connections between data and conclusions were obtained by the researchers as well.

3. Results

A total of 306 conceptual codes, 4 themes and 27 subthemes were extracted through the analysis of the interviews.

Table 2 shows the main themes and subthemes derived from experiences of the participants who lived with morbidly jealous husbands/ a morbidly jealous husband.

Table 2. The main themes and sub- themes along with one example for each sub-theme that is derived from the participants' experiences with a morbidly jealous husband

Number of Codes	Themes	Subthemes
65	Damages related to boundaries	Intense emotions at the beginning of the relationship Improper handling Restricting the means of communication Dependenc Expressing emotions without considering privacy Rigid boundaries Distrusting others Poor intergenerational boundaries
63	Damages related to intimacy	Inappropriate sexual intimacy Inappropriate affective intimacy Inappropriate intellectual intimacy Inappropriate practical intimacy Inappropriate physical intimacy Inappropriate intimacy with children
116	Damages related to control	Control through unreasonable demands) Control through acting out anger Control through creating confusion Control through intrusive curiosity Control through religion Control through growth restriction Control through contempt Control through sensitivity Control through revenge
48	Meta-damages	Cognitive meta-damages Practical meta-damages Emotional meta-damages Intergenerational meta-damages

The themes and subthemes are presented with clarifying samples as follows:

Theme 1: Damages related to boundaries (the concept of boundaries in the present study is defined as the determining rules to let information and people into and out of the family)

One of the main themes in the experiences of women living with morbidly jealous husbands was the damages related to boundaries with nine subthemes: Intense emotions at the beginning of the relationship, improper coping, restricting the means of communication (for example?), dependency ,expressing emotions without considering privacy, rigid boundaries, distrusting others, and poor intergenerational boundaries. Every subtheme is presented with one example as follows:

- Intense emotions at the beginning of the relationship (the subtheme was chosen because the reason to form that marital relation was intense emotions not contemplation).

"We actually loved each other at the beginning of our relationship."

- Improper handling (the subtheme was chosen because the communication of the woman or couple with other people was stressful)

"He doesn't like me to go to my friends' house or visit my family. He doesn't allow me to communicate with my friends and family"

- Restricting the means of communication (the subtheme was chosen because morbidly jealous men limit their wives' access to the means of communication).

"He objects to using the internet and mobile phones."

- Dependency (the subtheme was chosen because the man cannot decide without his family)

"He needs to consult his mother about everything. When I ask him why, he says, "it is none of your business."

- Expressing emotions without considering privacy (the subtheme was chosen because the man expresses his intense emotions at any time and place)

"In the presence of our children, he beats and insults me"

- Rigid boundaries (the subtheme was chosen because the man wasn't able to establish the minimum connection)

"He has no relationship with others; his boundaries are so rigid and inflexible that nobody can get close either physically or emotionally."

- Distrusting others (the subtheme was chosen because the man wasn't able to establish minimum trust)

"When I was alone at home I was not allowed to open the door to anyone, even her grandmother."

- Poor intergenerational boundaries (the subtheme was chosen because there are no appropriate boundaries between the extended family and nuclear family)
- " His mother is always meddling in our life."

Theme 2: Damages related to intimacy (intimacy in the present study was defined as the marital closeness between couples in different aspects of their marital life)

One of the main themes in the experience of women with morbidly jealous husbands was the damages related to intimacy with six subthemes: Inappropriate sexual intimacy, inappropriate affective intimacy, inappropriate intellectual intimacy, inappropriate practical intimacy, inappropriate physical intimacy, and inappropriate intimacy with children.

- Inappropriate sexual intimacy (the subtheme was chosen because the couple couldn't build a favorable sexual relationship for both sides)

"We have very little sex without any attention to my demands"

- Inappropriate affective intimacy (the subtheme was chosen because the couple couldn't build a favorable mutual affective relationship)

"Actually I don't know who should I talk to? He expects me to love him but he can't love me back."

- Inappropriate intellectual intimacy (the subtheme was chosen because the man couldn't make logical decision and sees his wife as second)

"He always was at his mother and sister's service but misery and discomfort were mine"

- Inappropriate practical intimacy (the subtheme was chosen because the couple weren't close enough in the management of life affairs)

"He doesn't help around the house; he has no incentive to help out."

- Inappropriate physical intimacy (the subtheme was chosen because the couple weren't able to have appropriate physical closeness)

"We prefer not to go out anywhere together because he gets on our nerves" (I am not certain if the example fits inappropriate physical intimacy)

Theme 3: Damages related to control (control in the present study is defined as the specific rules determining power division and manipulating tactics)

One of the main themes in the experience of women with morbidly jealous husbands was the damages related to

control with nine subthemes: Control through unreasonable demands, control through acting out anger, control through creating confusion, control through curiosity, control through religion, control through growth restriction, control through contempt, control through sensitivity, and control through revenge.

- Control through unreasonable demands and expectations (the subtheme was chosen because the man manipulated his wife by intense demands)

"While we were moving forward, his demands and exceptions came up; he told me i mustn't go to my brother's house and no man should see me."

- Control through acting out anger (the subtheme was chosen because the man manipulated his wife by anger and aggression)

"He has a broadsword; he threatens us with it."

- Control through creating confusion (the subtheme was chosen because the man manipulated his wife and gained power by his vague demands)

"what he demands is not clear."

- Control through intrusive curiosity (the subtheme was chosen because the man manipulated his wife and gained power by officiousness in all affairs even in those totally personal matters related to women).

"Where are you going? Why are you going? Who do you go alone? Why do you laugh? What did that man say? Why did you wear this dress? Why did you buy it? Who called? Who was in your mother's house when you went there? He is always asking and asking the same questions."

- Control through religion (the subtheme was chosen because the man manipulated his wife and gained power by religion)

"He tells me, according to Islam, women are not allowed to go out without their husband's permission."

- Control through growth restriction/ individuation/industry (the subtheme was chosen because the man manipulated his wife and gained power by blocking he woman's progress)

"He doesn't allow me to work; he likes me to depend on him."

- Control through contempt (the subtheme was chosen because the man manipulated his wife and gained power by putting the woman down)

"On holydays when he buys me something, he tells me off."

- Control through sensitivity (the subtheme was chosen because the man manipulated his wife and gained power by being emotionally alert and overreacting to some of the woman's activities)

"He just watches that no one is close to me and I don't go anywhere."

- Control through revenge (the subtheme was chosen because the man manipulated his wife and gained power by retaliation and revenge)

"My father was sick but he didn't let me go to my father's house. He said, "your father scorned me and I never forget it."

Theme 4: Meta-damages (meta-damages in the present study are defined as the damages that cover other damages)

One of the main themes in the experience of women with morbidly jealous husbands was meta-damages with four subthemes: Cognitive meta-damages, practical meta-damages, emotional meta-damages and intergenerational meta-damages. Every subtheme is presented along with one example as follows:

- Cognitive meta-damages (the subtheme was chosen because the man had the beliefs that damaged boundaries, intimacy, and control tactics)

"women should stay at home; no one should see you; man is the boss"

- Practical meta-damages (the subtheme was chosen because the man was showing behaviors that damaged boundaries, intimacy, and control tactics)

"He can't keep secrets; he says all our marital problems to his family and his family supports him and scorns me so much that their son can dominate me."

- Emotional meta-damages (the subtheme was chosen because the man had emotions that damaged boundaries, intimacy, and control tactics)

"He is implacable, cruel, and unjust."

- Intergenerational meta-damages (the subtheme was chosen because the man had problems in his family. For example, his parents had many conflicts)

"All his family members have problems, for example his father thinks his wife has relations with other men."

4. Discussion

As the researchers in the present study were interested in exploring interactional damages among couples with the morbidly jealous men, they interviewed five women living with morbid jealous husbands. They asked them to narrate their experiences of their communication with their husbands. Analysis and interpretation of their experiences revealed four types of interactional damages: Damages related to boundaries, damages related to intimacy, damages related to control, and meta-damages. Since, damages were more frequent in control dimension, the researchers concluded that the signs of morbid jealousy in men appear in boundaries theme. That is, at first the husbands have many problems in regulating their internal and external interactions and close relationships with their wife and other relatives, friends, and people. These men decrease the negative emotions of morbid jealousy by unorganized boundaries. The boundaries are rigid and extremely inflexible for their wives and extremely open and flexible for some others (e. g. he told all our life secrets to his mother). It is clear that the boundaries are extremely inflexible for their wives.

Inappropriate boundaries cause to use wrong tactics (such as wrong controlling behavior) to protect these boundaries. The goal of illogical boundaries is to limit and minimize women's communication to external world. They have to use illogical safety and security tactics that cause the control experiences of women to become bitter experiences. On the other hand, due to inappropriate boundaries, illogical security tactics not only motivate the men to show dangerous behavior to protect their families and waste their energy but also damage intimacy as the most important component of couples' relationship. As a result, the couples' relationship falls apart. Emotional distance can create more distance between couples and more pessimistic attitude for men towards their wives and activate more negative emotions such as morbid jealousy. More morbid jealousy can cause more restriction and constraint for the women, which makes their protection easier. Simultaneously, they use strict control tactics to protect boundaries. Diagram 1 shows the relationship between the variables that eventually leads to marriage failure.

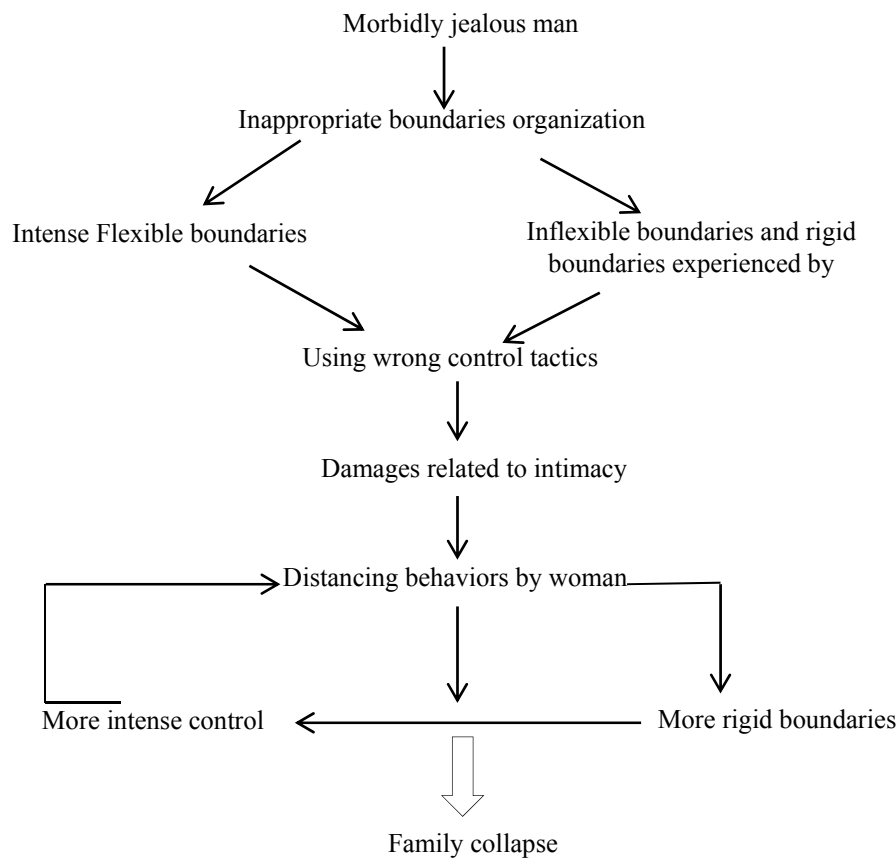


Figure 1. The process of pathology in families with morbidly jealous men

The findings of the study indicated there are other communication damages that can provide the stimulus to other damages. In fact, morbidly jealous men have false beliefs, emotions, and behaviors towards their wives that damage boundaries, control tactics, and intimacy. In total, the researchers found that the men use pessimistic attitude as a defiant mechanism to protect family boundaries and create control tactics. Pessimistic attitude is an obstacle to establish pillars of trust between these men and their wives that contributes to the destruction of a context to trigger mistrust towards their wives. Therefore, couples' life is a painful experience in its different dimensions.

Taking into account the findings, the first signs of morbid jealousy occur in boundaries development. With inappropriate boundaries development, the signs develop to control tactics simultaneously, and the emphatic and logical tactics change to punishment and reprimand. In these conditions, the communication style is dominant and recessive, intimacy is lost, and the relationships will be more of an obligation than passion. With regard to above-mentioned findings, the couple's life is, thus, doomed to failure.

Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Knowledge Translation Platform Increasing Use of Research Evidence in Physical Activity Policy Making - A Case Study in Finland

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Abstract

Background: Knowledge Translation Platform (KTP) in partnerships between policymakers, stakeholders, and researchers was established in order to enhance evidence-informed policymaking on physical activity. The article aims to give answers to specific questions, such as what were the main knowledge translation tools to improve access to research evidence in physical activity policy in Finland; which factors facilitated the improvements in use of research evidence, and what kind of procedures were implemented to improve the use of research evidence in policy making.

Methods: The study triangulated qualitative data from documents, reviews and observations of meetings between 2012 and 2013. Purposive sampling of meeting documents was used and data was analysed using a thematic content analysis of documents.

Results: KTP contributed to an increased awareness of the importance of the use of research evidence in physical activity policymaking, and strengthened relationships between policymakers, stakeholders and researchers. Support from policymakers and professionals as well as a window of opportunity facilitated KTP activities. Based on the KTP experience, institutionalization within the government could help to keep the use of research evidence high on the agenda.

Conclusions: The case study provided unique insights into what counts for developing use of research evidence in policymaking. The expectations of the public policy were to give a larger role to evidence-informed policymaking, but expectations conflicted between the interests of various stakeholders. The establishment of KTP was a promising development in supporting the use of research evidence in physical activity policymaking. Real-time lesson drawing from the experiences of KTP can support improvements in the functioning of KTP in the short term, while making the case for sustaining their work in the long term.

Keywords: knowledge translation, knowledge translation platform, physical activity, policymaking, research evidence

List of Abbreviations

KE knowledge exchange theory

KT knowledge translation

KTP knowledge translation platform

MEC Ministry of Education and Culture

1. Background

As defined by Lavis, Boyko, Oxman, Lewin, & Fretheim (2009) evidence-informed policy making refers to the use of the best available data and research evidence at the time of informing policymakers. The use or non-use of research evidence in policy making is an issue of growing interests and concern among both academic researchers and policymakers (Hunter, 2009; European Commission, 2010). Several reports and papers conclude with calls for a better translation of research into practice and policy (Giles-Corti, Sallis, Sugiyama, Frank, Lowe, & Owen, 2015; Haskell, Blair, & Hill, 2009; Ojajärvi, Pyykkönen, & Valtonen, 2013; Valtioneuvoston kanslia, 2011; Ilmakunnas,

Junka, & Uusitalo, 2008).

Knowledge Translation (KT) has appeared as one of the methods for closing the gap between knowledge and practice. Straus, Tetroe, & Graham (2009) defined KT as ‘a dynamic and iterative process that includes the synthesis, dissemination, exchange and ethically sound application of knowledge to improve health, provide more effective health services and products, and strengthen the health services’.

Lavis, Robertson, Woodside, McLeod, Abelson, & Knowledge Transfer Research Group (2003) proposed an integrated KT model for policy making. That means creation of a Knowledge Translation Platform (KTP) to build linkages and exchange efforts across health systems. KTP works to align the research efforts of researchers with the need of policymakers and influencing policy dialogue with research evidence.

Knowledge Exchange (KE) has been used for closing the gaps between knowledge to practice (Straus et al 2009). In addition, KE theory is a collaborative problem-solving process among public health practitioners, researchers, and decision-makers, which takes place through linkages and exchanges. It results in a mutual learning through the process of planning, producing, disseminating, and applying existing or new research to decision-making (Ontario Public Health Standards, 2008). KE is about getting the right information to the right people in the right format at the right time by KTP.

This study sought to gain a better understanding of knowledge translation processes, and aims to describe KT tools towards the promotion of evidence-informed policy making by taking physical activity as a case. It examines the process of increasing the use of research evidence on the physical activity promotion agenda in Finland through the lenses of KT and applying that theoretical model to the practical policy making process applied from the backward design of knowledge translation by El-Jardali & Fadlallah, 2015. The use of research evidence in public health and specifically in the promotion of physical activity is claimed to be weak (Pratt, Perez, Goenka, Brownson, Bauman, Sarmiento, & Hallal, 2015). However, the health benefits of physical activity are well-known (Lee, Shiroma, Lobelo, Puska, Blair, & Katzmarzyk, 2012; Proper, Singh, van Mechelen, & Chinapaw, 2011), but the challenges remain in the methods used to assemble research evidence and the political context in which that research evidence is deployed or not deployed in order to inform policy making and practice. The article aims to give answers to specific questions, such as what were the main KT tools established to improve access to research evidence in physical activity policy in the Ministry of Education and Culture; which context factors facilitated or hindered the improvements of access to research evidence for physical activity policy making, and what kind of processes with KT tools were implemented to improve the use of research evidence in policy making.

2. Methods

In this study, the working group at the Ministry of Education and Culture (MEC) functioned as a knowledge translation platform (KTP): an intermediary to build up capacity to increase the use of research evidence in policy making for physical activity. KTP was formed by MEC, and included the Secretary General of the National Sports Council, senior planning officer of MEC and a contracted expert from the Finnish Society for Sport Sciences, various representatives of institutes, and professionals to improve access to research evidence in policy making in the MEC.

The structured reflection of the work on KTP drew on multiple sources of qualitative data, namely: i) documents, reviews, reports, minutes and presentations from the meetings and conference of KTP; and ii) observation of the meetings and conference of KTP (Table 1). A purposive sampling strategy was used (Palinkas, Horwitz, Green, Wisdom, Duan, & Hoagwood, 2015). Data generated from the meetings was triangulated with the documents, reviews and observation of deliberations to confirm, challenge, and refine emerging themes. The reliability and validity of the data were enhanced through iterative data collection. The study was based on participant-observations by the author, and makes no attempt to present the views of other participants, but highlights that the research evidence in policy making have a meaning and is powerful when used as arguments and that the process is unavoidably social and political.

Table 1. Collected data, sources, and objectives

Methods (sample size)	Sources	Objectives
Observation of deliberations in meetings and conferences (8 meetings and one conference)	Observation of deliberations at the meetings and conference	Describe the climate, activities, and lessons learned, including facilitating factors and challenges in relation to use of research evidence
Analysis of documents and review (1 report, minutes and consultations)	Report of KTP 2013	Identify outcomes achieved, and lessons learned, including facilitating factors and challenges
Two research projects providing research results on the use of research evidence in policymaking	Project reports and articles	To identify the facilitators and barriers for the use of research evidence in physical activity policy making

Individuals and representatives of associations were purposefully invited into KTP based on their interest to increase the use of research evidence for policymaking.

The overall goal of KTP was to promote the generation and use of research evidence in physical activity policymaking as a mean to improve health e.g. increases physical activity in population. Fifteen members were invited to join KTP. They represented MEC (chair), the National Sports Council (secretary), two professors from the University of Jyväskylä, and one person from each of the following bodies: the Finnish Society of Sport Science, Ministry of Finance, Statistics Finland, Youth Research Society, Regional Authority, Association of Sport Clubs, UKK Institute, enterprise, and the National Institute for Health and Welfare. Six of the participants had researcher training at least at the doctoral level, and gender balance was applied in the working group.

The process of knowledge translation to increase the use of research evidence in physical activity policymaking in a Finnish context used a set of knowledge translation tools for policymaking. The tools were the following: 1) Priority setting for the use of research evidence in policymaking; 2) Development of a working group (e.g. KTP) on 'Improving accessibility for information, knowledge and research evidence for sport and physical activity policymaking'; 3) Research evidence in policymaking from two coinciding research projects; 4) Convening national policy dialogue and evaluation of policy dialogue, and 5) Report of the process of the knowledge translation platform and dissemination of the results to politicians and policymakers. (Figure 1).

KTP pursued the goal to increase use of research evidence by harnessing existing methods and approaches to improve both the quality of research evidence and its uptake in policy making. The backward design of knowledge translation was used as analytical frame for the analysis of tools and process (El-Jardali & Fadlallah, 2015). Documents and deliberations held in the meetings and conferences were sampled and prioritised by the author based on their relevance to the work undertaken by KTP. Findings from the observations and analysis of documents were summarized using thematic analysis approach and were then used as an input to review the use of research evidence in physical activity policy making.

3. Results

3.1 Priority Setting for Evidence-Informed Policy Making in Physical Activity

Interventions to increase use of research evidence in physical activity policy making require processes involving complex mix of factors, such as leadership, changing environments and organizational history and culture. In this kind of complex system of physical activity promotion, the type of evidence that can inform policy making is not reducible to experimental designs or clinical trials as implemented in clinical medicine. Nor can it be assumed that the results communicated by researchers would be accepted without questions as to why, how and in what ways the situation can be transformed.

MEC—is in charge of physical activity policy and has nominated various working groups to improve the use of research evidence in policy making (Opetusministeriö, 2006; Opetus- ja kulttuuriministeriö, 2013). The government of Finland attached priority to evidence-informed policy making (Valtioneuvoston kanslia, 2011). In addition, the Ministry of Finance (Prime Minister's Office, 2013) had established a multi-country research project, 'The government for the future', underlining horizontal policymaking, systematic use of research evidence in policymaking and promoting innovation and building learning capacity.

Therefore, MEC also inaugurated discussion and appointed a working group (e.g. KTP) to facilitate the use of research evidence in policymaking. MEC aimed to get the research community to respond to the needs of the administration to produce research evidence for policymaking on time. The urgent issues were the challenges of

decreasing physical activity in the population, increasing overweight and impoverished social determinants of health (Kestilä, Mäki-Opas, Kunst, Borodulin, Rahkonen, & Prättälä, 2014; Roskam, Kunst, VanOyen, Demarest, Klumbiene, Regidor et al., 2010). All these issues required research to generate new understanding of renewal of physical activity policy making and practice.

As a daily task, MEC prepared guidelines and measures to be carried out in the physical activity policy making, decisions and implementation. All these activities required a broad knowledge base and capability of cross-sector thinking and ways of working. The legislative and regulatory control of policies required the development of social justification and research evidence on physical activity. The research evidence needed for the policymaking consisted of basic indicators for physical activity clubs and organisations, development of physical activity in population groups, and anticipating knowledge and information needs for social changes. In addition, the state administration needed data for monitoring and evaluating the impact of policies to design new measures in various topics related to physical activity.

Despite the work done, access to research evidence and follow up information has not been satisfying for policy making in physical activity or for the evaluation of the impacts of decisions (Valtonen & Ojajärvi, 2013). The challenges between policy making and follow up information has remained around the following three issues: production of research evidence with better quality and impact on policy making; better organised, filed, processed and interpreted research evidence to improve use of research evidence; and the impact of research evidence to the actual physical activity policies (Valtonen & Ojajärvi, 2013).

The administration of MEC underlined that researchers should produce and disseminate research evidence in practical and accessible ways (Valtonen & Ojajärvi, 2013). But there was the collision of the two worlds: the academic peer reviewed publications versus research evidence produced for the use of policymakers with an impact. The third issue was how to get busy policymakers and academics to interact and understand each other so that both benefitted in terms of using research evidence in policymaking and researchers identifying new research topics and issues to be funded. Certainly research evidence in policymaking was, if not completely ignored, and then often used inconsistently, discontinuously and disproportionately (Valtonen & Ojajärvi, 2013).

3.2 Creation of the Knowledge Translation Platform

KTP aimed for better accessibility and physical activity information and increased use of research evidence in policymaking. KTP was chaired by the MEC and its Sports and Physical Activity Section during 2012–2013. The receptive climate for the use of research evidence in physical activity policymaking encouraged the participants to develop a priority for KTP in political, administrative and economical contexts. It was also noted that several processes for the increased use of research evidence were undergoing change including reforms of funding for research institutes and universities (Virtanen, Stenvall, & Rannisto, 2015).

The tasks of KTP established by MEC were exposed to discussion and changes. In KTP the tasks were subsequently defined as to map the present use of research evidence and the level and quality of research evidence used in policymaking. KTP defined the role of stakeholders in policymaking from the point of view of using research evidence. KTP made proposals and suggestions to improve interaction and actions necessary for the further use of research evidence in physical activity policymaking and to renew the current practices and roles of various stakeholders. Finally, KTP discussed the possibilities of improving access to research evidence through information and communication technology.

3.3 Collected Research Evidence on the Use of Research Evidence for Policymaking to Inform KTP

Two research projects were conducted in order to understand the use of research evidence in physical activity policymaking. One of the research projects was conducted by media researchers at the University of Helsinki and managed by the Society of Sport Science. The results indicated that the main problems were related to the separation of the institutes in the field of research and the lack of public debate and interaction between different institutes and actors (Valtonen & Ojajärvi, 2013). The fragmentation of production of research evidence, strong scientific and disciplinary differences and disputes and competition between organizations hindered cooperation and use of research evidence for physical activity policymaking. Therefore, the structures and consolidated networks of interaction on annual basis was recommended to share information, discuss issues and topics and increase interaction and communications to bring together policymakers, researchers, and other professionals in substance-specific items (Valtonen & Ojajärvi, 2013).

In addition, the study informed that there was a need for a clarification of the roles of producers of research evidence, translators and users of research evidence and structural connections between different stakeholders. However, in practice, the actors had several roles in relation to knowledge: every actor worked in at least two, if

not all three of the roles as producer, broker and beneficiary in promoting research evidence into policymaking (Valtonen & Ojajarvi, 2013).

The study conducted interviews in which many expressed their distrust in relation to media and its use of research evidence in public debates (Valtonen & Ojajarvi, 2013). The role of the media as simplifying and distributing the research evidence was not appreciated and understood for the benefit of researchers or research funding. Further on the interviewees considered that media and public discussion was held to be no more than a channel for citizens, not for the creation of public opinion or support for the use of research evidence for physical activity policy making. Among the interviewees there was a strong reluctance to discuss research evidence on physical activity in the media even if the media was considered to be a key producer and broker of research evidence for policymaking.

The second project and its findings supported KTP on the use of research evidence in physical activity policies from the international perspective (REsearch into POLicy to enhance Physical Activity REPOPA). The goal of the research was to explain the use of the research evidence and other evidence in policymaking of physical activity at various administrative levels in six European Union member states. Part of the study analysed policy actions in the field of five Finnish physical activity policies.

The results of REPOPA showed that policymaking at all levels of the Government arose from the variety of processes with a blend of different data, strategic documents and resources. In addition, the policymaking occurred in the streams and chains of decisions and public discussion in media influence on policies and policymaking. On the basis of access to research evidence, the interviewed policymakers underlined the access to research evidence as necessity for the sake of the credibility of the policy measures. However, the initiative for the policy measures was often the political will complemented by the evidence from the management and organization information, experience-based information, information from physical activity culture in general and the exploitation of existing good practice (Hämäläinen & Villa, 2014). REPOPA showed that research evidence was on the background of physical activity policies, but the systematic breakdown of the studies was not included due to the nature of the policymaking for the development of the current processes.

According to REPOPA study physical activity policies were usually prepared in the working groups including expertise input. The experiences of the experts involved filtered research evidence and interpreted research evidence during the process of policymaking, but it was impossible to trace to certain research results (Hämäläinen & Villa, 2014). On the basis of the results in REPOPA the policymaking used research evidence, empirical knowledge, media related information and political information. The research data used included reports, studies, statistics, and population based surveys. Experience-based evidence was collected from the policy networks, meetings and appointments, best practices, projects and learning from successes and failures in physical activity implementation. In particular, the policy measures were influenced by the internet and media-set trends as well as a variety of newsletters and publications, in particular at regional and local level policymaking. In general, the research evidence was used in the justification parts of policies (Hämäläinen & Villa, 2014).

3.4 Convening National Policy Dialogue

As the use of research evidence on physical activity and access to research evidence is more than to collect, store or disseminate research evidence for policymaking, the focus of KTP moved from the research–practice nexus into applied use of research evidence in policy making. Applied use of research evidence required enhanced cooperation, interaction and networking between researchers, practitioners and policymakers. As the studies showed, the physical activity sector missed the opportunities to discuss physical activity policies with researchers, practitioners and policymakers on issues such as how research evidence could improve the present situation, the future scenarios and foresights for physical activity in society, and what direction society in general should take.

Therefore KTP invited about 50 participants from different stakeholders groups and 26 representatives of various stakeholders participated into the open consultation on the use of research evidence in policymaking and how to enhance the processes to get research evidence into policymaking.

The use of research evidence in practice was collected from stakeholders by a semi-structured online survey. Responders represented municipalities, organisations and professionals. In addition, hearing of stakeholders was organised with discussion on the results of the online survey. The semi-structured online survey focused on the following issues:

- 1) Describing the level and quality of physical activity policymaking and use of research evidence (weaknesses and strengths);
- 2) Describing role in producing and disseminating research evidence for physical activity in policymaking;

- 3) Changing roles of stakeholders in order to increase access to research evidence in policymaking;
- 4) Strengthening proposals for the use of research evidence in producing disseminating and sharing and using research evidence (decision making, promotion of physical activity, etc.);
- 5) Increasing the most useful sources and systems for physical activity and use of research evidence in policymaking;
- 6) Evaluating the need for an IT system/portal to collect research evidence, evaluation and follow up information;
- 7) Describing other processes from other sectors to promote the access to research evidence.

All the answers were combined into one document. In the stakeholders meeting, responses to each question were presented by the invited discussant and discussed further with all other stakeholders.

Responses to the semi-structured online survey underlined the need to manage the use of research evidence and produce new knowledge, which is easily available, organized, combined and retrieved. In addition the responses emphasized that the experts need more ability to apply their knowledge in a variety of problem-solving situations in a new way and to operate in an open, networking based environment to acquire and use research evidence in policymaking. Further on professionals and experts need more training in the use of research evidence in policymaking and implementation.

The stakeholders also discussed on the data system and its architecture for the collection of research evidence in order to deal with the vast number of sources. According to the stakeholders the aims should be to improve the effectiveness of the strategic and social support for the research evidence in physical activity policymaking to achieve the objectives of physical activity policy.

The discussion with stakeholders brought up relatively strong scientific borders of disciplines and added to the dialogue a debate on the contribution of each discipline to research evidence in policymaking: from essential research evidence to securing the missing research evidence. The discussion realised, that there was lack of good practices in the use of research evidence in physical activity policymaking and, therefore, the policymaking process and use of research evidence in its various phases needed to be described in the Finnish context.

3.5 Report of KTP Process and Dissemination of the Results to Politicians and Policymakers

The mandate of KTP was to make a proposal on the development of the role of various actors and how to increase the use of research evidence. KTP indicated that the responsibility of specific roles in producing, interpreting and disseminating should be clarified. For the increased use of research evidence in physical activity policymaking, the division of work and the perception of the roles in the production and dissemination of research evidence for policymaking should be made clear. The resources and how to organize the production and dissemination should be agreed so as to avoid duplication of work. The coordination of the production of research evidence and intermediaries for the interpretation of research evidence needed to be strengthening. The roles of the researchers and use of research evidence in policymaking should be sufficiently known by all stakeholders.

The report of the KTP was delivered to MEC for further action. The KTP considered that research evidence in physical activity was dispersed, but the decision-making needed often punctual delivery at the right time. Academic research reporting practices did not support the use of active transmission of research evidence for decision making. Therefore there was a need for different actors to increase dialogue between the disciplines. KTP encouraged the use of research evidence in policymaking and in the preparation of a systematic decision-making at the various stages of the process. This required change of culture and needed measures from MEC to sharpen and control policy to make research communities produce research evidence for the purpose of policymaking. In addition the National Sports Council was asked to identify the various players in the physical activity policy and their key roles. Further on the researchers were asked to produce high-quality, reliable and relevant scientific research. The existing scientists and science communities should open databases to other researchers. Moreover increased communication, networking and exchange between research topics, researchers, practitioners, decision makers and the scientific communities were recommended. The renewed interaction in the preparatory phase of the planning and policy making should ensure the broad consensus on the use of research evidence.

4. Discussion

The application of KT tools to generate improved evidence-informed policymaking was an interesting experiment in the Finnish context. This process served as a demonstration of stakeholders participation and consultation in policymaking.

In this case study a window of opportunity emerged for the enhancement of use of research evidence in physical

activity policymaking. MEC took the opportunity and invited professionals and other stakeholders for KTP. By establishing priorities, KTP, a policy dialogue and research projects, MEC was able to inform policy makers. The dialogue brought together many representatives, which were dependent or affected by future decisions related to use of research evidence in physical activity policy making. In the policy dialogue diverse participants were able to share problems and its elements in the use of research evidence in physical activity policy making and discuss the challenges between different types of research evidence.

The results of this study support the observations on gaps by Hawkes et al. (2015) in understanding the mechanisms influencing the use of research evidence on policymaking processes and how policymakers can be encouraged to use research evidence. Hardly any resources were directed at capacity development to promote greater use of research evidence in policy makers in this study either.

The stakeholders had various roles in policymaking. That meant that the role of each participant varied from knowledge broker to researchers and others, such as facilitator, transferring knowledge for policymaking, transforming knowledge, knowledge manager (like librarian), linkage agent (like towards researchers), capacity builder (training and education institutes) or participant as representative of certain project, programme, or institute to defend a stand, proposal or similar. The role of participants in a knowledge platform can be constantly changing depending on topics, issues or concerns under discussions and decisions for a policy. Therefore the role of participant in KTP or consultation varied and provided multitude of possibilities for interpretations on each interventions.

Hallsworth (2011) mentioned that both political aims and desires contribute to policymaking and political climate. Political appetite for using research evidence might be the greatest driver for the capacity strengthening (Hallsworth, 2011). In this study the driving force to increase use of research evidence in policymaking in Finnish physical activity policy was both political desire and administrative needs.

The study also confirmed the conclusions of Hawkes et al. (2015) that policymaking processes should be strengthened through organizational capacity building and through data depositories, upgrading of institutional infrastructures and variety of multimedia/social media messages. To increase the capacity to have access to research evidence. In this study, increased interactions between policymakers and researchers were considered to be vital to increase the uptake of research evidence also.

Based on Clark & Weale (2012) the nonexistence of institutional norms and rules around the use of evidence, rise a concern that decisions on health policy are more subject to value-based decision making rather than evidence informed processes or even more provincial norms and interest of decision makers (Buse, Mays, & Walt, 2012). Therefore KTP provided the first ever experiment on developing dialogues and improved use of research evidence in physical activity policymaking.

According to Hawkes et al. (2015) the capacity for the access, analysis and interpretation of research evidence lay outside of policymakers and mostly within specialized agencies. Stakeholders have different roles in research evidence, such as identifying information and research evidence, redistribution of research knowledge and rescaling and transforming knowledge to policymakers or other people. In KTP stakeholders of various institutes performed activities in relation to the use of research evidence. Stakeholders articulated on research evidence, communicated research evidence, identified and mediated research evidence, educated and created concepts in common language rather than in research language. The important issue was how to translate the research evidence for policymakers and identify the interesting and appealing approaches to each of policymaker and make arguments at the right time and in the right place to the right policymakers. The gaps and links between research, policymaking and practice nexuses became important and crucial to enhance the use of research evidence in KTP and the overall process.

Findings from the study on knowledge platform work are congruent with those previously reported by policymakers, stakeholders, and researchers on evidence-informed policymaking (El-Jardali, Lavis, Ataya, Jamal, Ammar, & Raouf, 2012; Wallace, Byrne, & Clarke, 2012; LaRocca, Yost, Dobbins, Ciliska, & Butt, 2012; El-Jardali, Jamal, Ataya, Jaafar, Raouf, Matta, & et al. 2011; Wallace, Nwosu, & Clarke, 2012; Scott, Albrecht, O'Leary, Ball, Hartling, Hofmeyer, & et al. 2012; Barwick, Schachter, Bennett, McGowan, Ly, Wilson, & et al. 2012). Gaps in research production in relation to priorities of MEC, as well as a lack of skills among research users to acquire, assess, adapt, and use research evidence, were reported to hinder the use of research evidence in policymaking. Similar results have been reported by El-Jardali et al. (2011). There is little empirical evidence on effective KT approaches and how KT strategies can be tailored for different contexts and disciplines (Wallace, Nwosu, & Clarke, 2012; Scott et al., 2012; Barwick et al., 2012).

This study supports the positive views on deliberative dialogues, where very favourably and strong intentions to act are presented and learned in dialogues (Moat, Lavis, Clancy, El-Jardali, & Pantoja 2014). Furthermore, making changes to the existing institutional structures and incentives of researchers in terms of research funding and use of research in policymaking, have suggested as strategies to encourage policymakers to use of research evidence in policymaking initiatives. Researcher and policymakers has been described as living in different worlds and often researchers tend to think that merely publishing research results in the scientific community would be sufficient for the take up of the findings and recommendations in policies (Brownson, Royer, Ewing, & McBride, 2005). More and more funding agencies demand more effective ways of dissemination and application of research findings; researchers are partially responding to this shift, recognizing that the completing the research is not the end to the process but, rather the start of applying and implementation of research results (Smits & Denis, 2014). This was particularly mentioned in KTP and stakeholder dialogue in the Finnish context.

Better science communication is one of the keys to resolving this kind of dilemma. Better communications with the public and policymakers can help scientists send clearer messages in relation to the accomplishments, promises, and uncertainties of their work (Pratt et al. 2015; Malta & Barbosa da Silva, 2012). Better communication between researchers, policy makers and media was a key finding of KTP and dialogue with stakeholders. This addressed the scientists' role in enhancing and advising on physical activity services, facilities and opportunities. The result might bring productive dialogues about science and the political, social and moral implications.

Interactive processes are defined as knowledge translation in terms of exchanges, synthesis, dialogue and interaction between researchers and user of research findings (Canadian Institutes of Health Research, 2004). However, the challenges and problems in the societies are multiple and complex. This requires two-way communication and involvement from researchers with their users of research findings e.g. therefore, users should have an influence on research questions also. Therefore citizen participation in policymaking should be encouraged.

5. Conclusions

While the study is descriptive by nature, the case study revealed complexity in policymaking and in the construction of tools for increased use of research evidence in policymaking. The possibility of applying a more robust knowledge translation approach to tackle the physical activity and use of research evidence in policymaking could prove to be a valuable mean to bring research evidence into policymaking (Figure 1).

In Finland, a window of opportunity to enhance the use of research evidence in policymaking was identified due to the renewal of physical activity policy and reviewing law concerning physical activity. MEC and the Finnish Society of Sport Sciences provided the support and leadership for the attempt to increase the use of research evidence in policymaking.

The process and policy dialogue with stakeholders helped inform policymakers at the governmental level. The policy dialogue, which was informed by a pre-circulated questionnaire helped trigger and support multiple actions by policymakers directly related to the integration of research evidence of physical activity into policymaking, as well as actions aimed at strengthening other aspects of physical activity. Participants pointed out that the policy dialogue was an important opportunity for diverse groups of people to deliberate about the problems and its elements. Policy dialogue brought together participants, who could be involved in or affected by future decisions related to the use of research evidence in physical activity policy making (See Figure 1).

Framing of the problems of the use of research evidence in policymaking seemed to be critical. The key informants in KTP and policy dialogue helped in refining the problems. The policy dialogue also served to validate the research evidence synthesised in the policymaking process, whereby the policy to address the problems was mostly supported by the research evidence, but also by the results of policy dialogue. The choices made by the participants to pursue issues might not have been influenced only by the strength of the research evidence supporting it, but also by the feasibility of application in Finland. The policy dialogue was instrumental in contextualising the challenges of the use of research evidence in policymaking, especially from the production side of research evidence (See Figure 1). This further emphasised the importance of taking the local context into consideration when discussing use of research evidence and deciding on options to pursue. The studies have shown that the uptake of evidence by policymakers and its usefulness in supporting evidence-informed physical activity policies is influenced by contextual factors, such as institutions, interests and values in the local context (Moat, Lavis, & Abelson, 2013).

Related studies have shown that follow-up activities can help continue building the capacity of stakeholders to add the use of research evidence in policymaking. Such activities include dissemination of dialogue summaries,

providing customised debriefings, or offering providing newly published systematic reviews (Lavis et al. 2009; Boyko, Lavis, Abelson, Dobbins, & Carter, 2012). However there is not strong evidence that this would be happening in physical activity policy implementation in Finland.

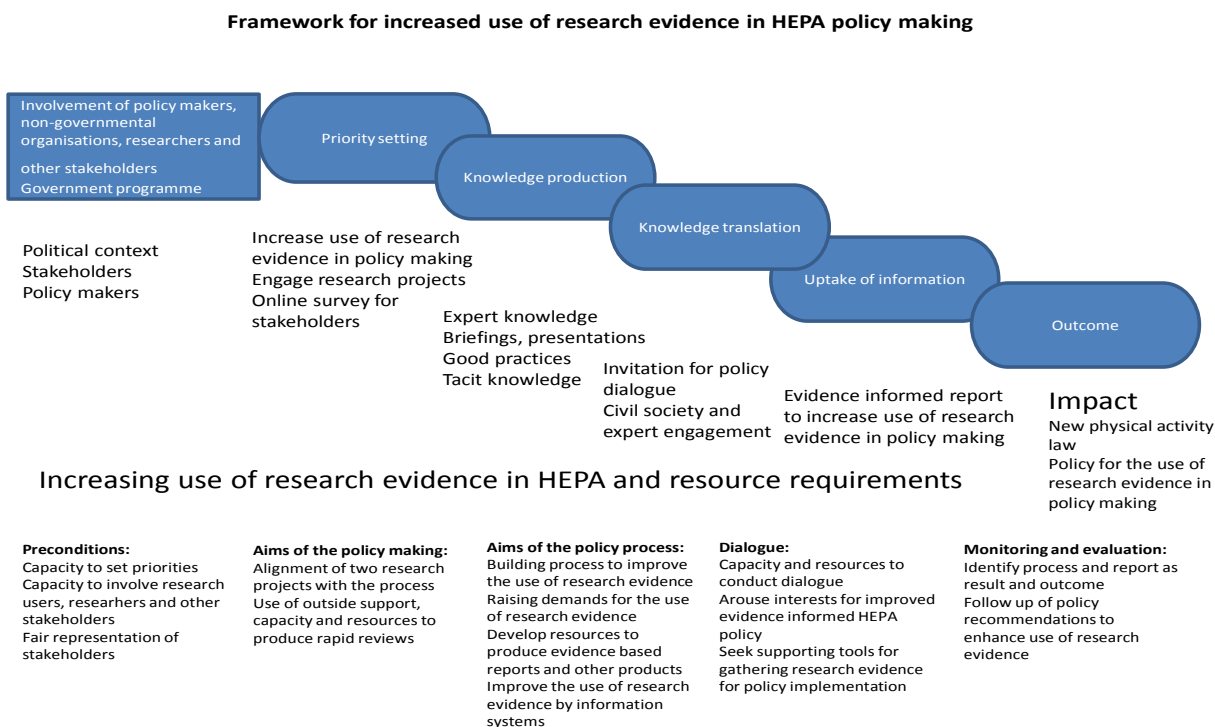


Figure 1. Framework for increased use of research evidence in HEPA policy making

Ethics

The national research groups collected ethical clearance documents from the ethical committees in various countries, also in Finland. A package was submitted to the European Commission (Funding Agency) before starting data gathering.

Authors’ Contributions

R-MH drafted and wrote the manuscript.

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Availability of Data and Materials

Minutes of the meetings are not available for public. Report of the working groups is mentioned in the list of references: Opetus- ja kulttuuriministeriö. 2013. Liikuntatiedon saavutettavuuden kehittäminen. Liikuntatiedon saavutettavuuden kehittämishanke –työryhmä.

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Competing Interests Statement

The author declares that she has no competing interests.

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A Longitudinal Analysis of the Mortality Spectrum of Children under 5 Years from 1990 to 2015 in Hubei Province of China

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Abstract

Objectives: This research analyzed trends of the mortality spectrum resulted from dynamics of the health care service for children under 5 years.

Methods: It was sampled 23 surveillance sites to establish a population-based surveillance network for children under 5 years by implementing a multistage randomized, stratified and cluster sampling since 1990 in Hubei province of China.

Results: Among children under 5 years, the mortality rates of pneumonia, birth asphyxia, preterm birth/low birth weight and accidental asphyxia declined from 12.9, 6.6, 4.3 and 3.5 in 1990 to 0.9, 0.7, 1.1 and 0.7 per 1,000 live births in 2015 respectively, and manifested a distinguished milestone at which pneumonia and birth asphyxia had been replaced by preterm birth/low birth weight after 2005 ($P < 0.05$). The death proportions of pneumonia and birth asphyxia decreased from 22.2% and 11.4% in 1990 to 10.3% and 7.7% in 2015, while the death proportions of preterm birth/low birth weight and accidental asphyxia increased from 7.4% and 6.0% in 1990 to 12.9% and 8.6% in 2015 accordingly. The proportions of clinical diagnosis, emergence treatment and death place at the county/district hospitals increased from 9.0%, 27.4% and 28.7% in 1990 to 75.5%, 67.7% and 60.4% in 2015, and had the significant differences between 1990 and 2015 in Hubei province ($P < 0.01$).

Conclusions: It was suggested that the trends of the mortality spectrum were mainly due to the improvement of the health care service for children under 5 years in Hubei province.

Keywords: mortality spectrum; mortality rates; health care service

1. Introduction

Since child health and wellbeing continued to be one of the internationally recognized health challenges, the government of China formulated the National Program of Action for Child Development in which under-5-mortality rate (U_5MR) decreased one-third from 1990 to 2000, one-fifth from 2000 to 2010 respectively. Furthermore, the United Nations proposed the Millennium Development Goal 4 (MDG4) in which U_5MR reduced two-thirds from 1990 to 2015 (Julie, Linda, Alan, & Christopher, 2010; Robert et al., 2010; You, Wardlaw, Salama, & Jones, 2010).

However, there have been rare longitudinal reports on the mortality spectrum of the primary death causes for children under 5 years during a 25-year period in many countries. The government of China established a nationwide surveillance network in 1990 to monitor the mortality rates of the primary death causes for children under 5 years (Wang et al., 2011). Therefore, it possessed the considerable application value, and provided the precious history data on child health and development in China.

This research was aimed to analyze the trends of the mortality spectrum of the major death causes, to provide the scientific basis for the government at all levels to develop the necessary policies of maternal and child health in Hubei province.

2. Methods

2.1 Surveillance Network

Hubei province is situated in the central region of China, and flowed through by the Yangtze River which is the third longest one around the world. In this research, it has been sampled 23 surveillance sites (1 metropolis, 4 middle cities and 18 counties) to establish a population-based surveillance network for children under 5 years by implementing a multistage randomized, stratified and cluster sampling since 1990. This network had a large surveillance population of 4 millions who was in accordance with the demographic and geographic features in Hubei province of China.

All live births are defined as fetuses born more than 28 gestational weeks or 1,000 gram birth weight with at least one of the following vital signs: heartbeat, breathing, pulsation of umbilical cord or contraction of voluntary muscle. All mortalities of children under 5 years are classified as children dying from live birth to their fifth birthday. In this research, all information about live births and child mortalities were from their mothers who have been permanent residents, or who have lived in the surveillance areas for more than one year. Meanwhile, all live births and child mortalities were identified by the trained and licensed professionals of Hubei Maternal and Child Health Hospital (HMCHH).

2.2 Death Classification

The mortality code for children under 5 years was classified into 34 categories of the major death causes in accordance with the International Classification of Diseases, tenth edition (ICD-10), for example pneumonia, birth asphyxia, preterm birth/low birth weight, accidental asphyxia and the other death causes.

2.3 Data Collection

Based on an organization with three vertical levels of the surveillance system, the surveillance data were collected and reported by the trained and licensed health providers from 1990 across Hubei province. For child deaths inside the hospitals, the related information was collected via medical chart review. For child deaths outside the hospitals, the related information was collected via household visit. All data were then finally reported to HMCHH as the final data review of the surveillance system in Hubei province.

2.4 Quality Control

Quality inspection was conducted once quarterly in all the towns/streets by a sampling ratio of 100%, twice annually in all the counties/districts by a sampling ratio of 25%, and once annually across Hubei province by a sampling ratio of 10% based on the population framework. The error rates of the death diagnosis and questionnaire items were less than 5% and 1%, and the missing rates of the mortality and live birth reports were no more than 15% and 10% respectively. This research was approved by the Ethics Committee of HMCHH. Written informed consents were obtained from all the parents or guardians of children under 5 years.

2.5 Statistical Analysis

The database was managed with Visual FoxPro (VFP 6.0), and the data were analyzed by Statistical Analysis System (SAS 8.1). Chi-square test was utilized to examine the differences in the mortality rates and health care service for children under 5 years between 1990 and 2015, and P value <0.05 was considered as the statistical significance.

3. Results

3.1 Mortality Spectrum of the Primary Death Causes

U_5MR gradually declined from 58.1 in 1990 to 8.7 per 1,000 live births in 2015, and showed the dramatic decrease over the past 25 years in Hubei province ($\chi^2=94.88$, $P<0.01$). As for Hubei province, U_5MR was at the average level from 1990 to 2015 in China.

Among children under 5 years, the mortality rates of pneumonia, birth asphyxia, preterm birth/low birth weight and accidental asphyxia decreased from 12.9, 6.6, 4.3 and 3.5 in 1990 to 0.9, 0.7, 1.1 and 0.7 per 1,000 live births in 2015 respectively. This research manifested a distinguished milestone at which the mortality rates of pneumonia and birth asphyxia had been replaced by that of preterm birth/low birth weight after 2005 in Hubei province ($P<0.05$) as shown in Figure 1.

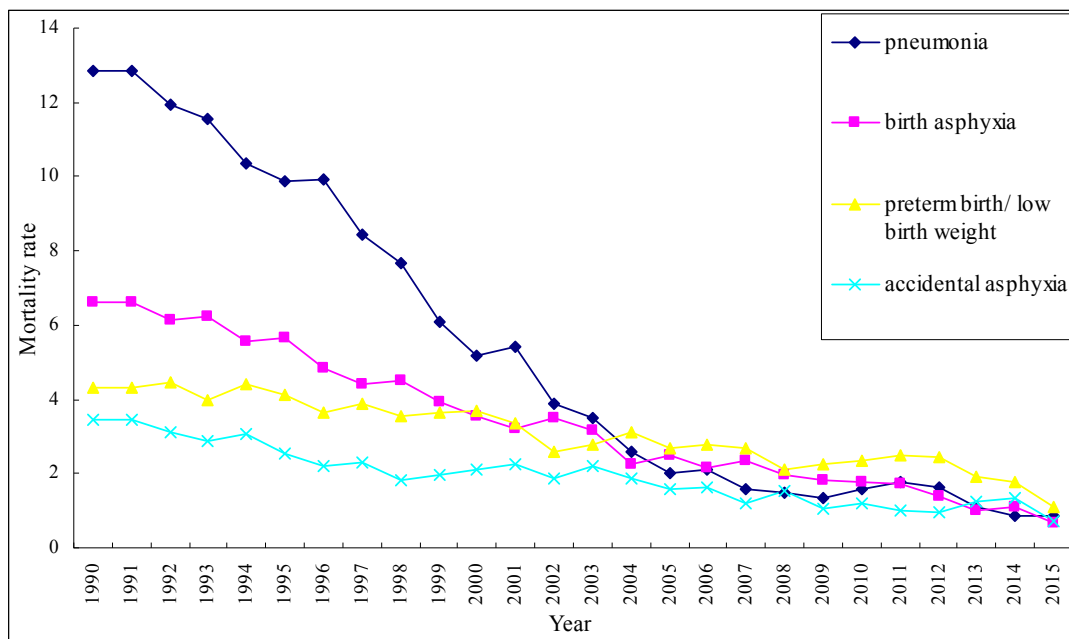


Figure 1. Mortality rates of the primary death causes for children under 5 years between 1990 and 2015 in Hubei province of China (per 1,000 live births)

Primary death causes: pneumonia ($\chi^2=142.91$, $P<0.01$), birth asphyxia ($\chi^2=35.68$, $P<0.01$), preterm birth/low birth weight ($\chi^2=5.82$, $P<0.05$) and accidental asphyxia ($\chi^2=6.37$, $P<0.05$). Chi-square test: significant differences between 1990 and 2015.

3.2 Death Proportions of the Primary Death Causes

The death proportions of the primary death causes for children under 5 years accounted for 47.0% in 1990 and 39.5% in 2015 respectively, and had a significant reduction from 1990 to 2015 in Hubei province.

Among children under 5 years, the death proportions of pneumonia and birth asphyxia decreased from 22.2% and 11.4% in 1990 to 10.3% and 7.7% in 2015, while the death proportions of preterm birth/low birth weight and accidental asphyxia increased from 7.4% and 6.0% in 1990 to 12.9% and 8.6% in 2015 accordingly. This research also displayed the dynamic trends in which the death proportions of pneumonia and birth asphyxia were gradually replaced by that of preterm birth/low birth weight from 1990 to 2015 as shown in Figure 2.

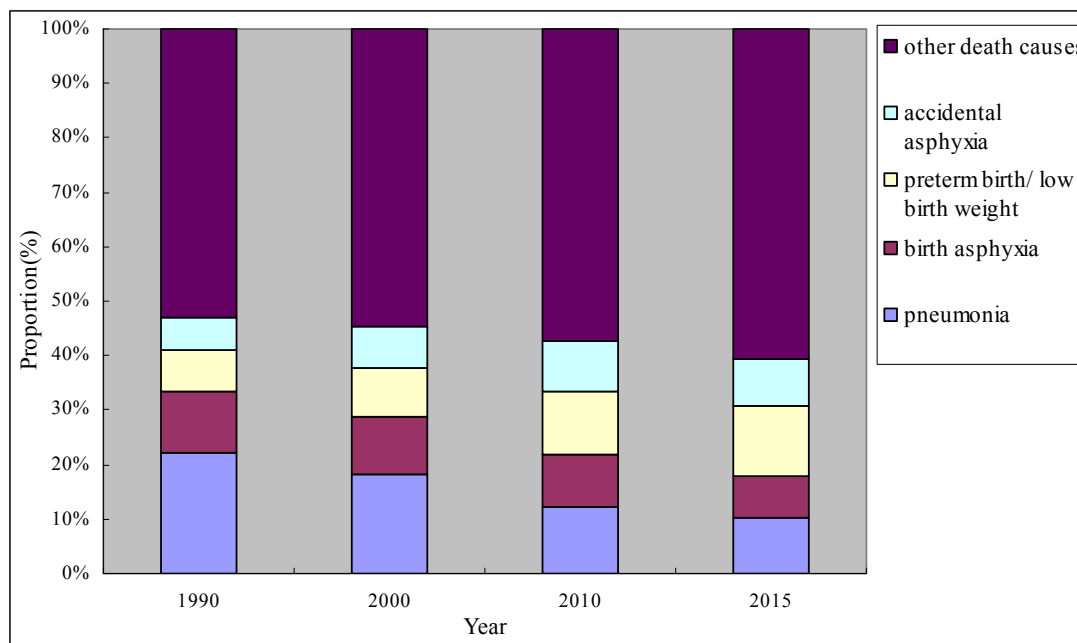


Figure 2. Proportions of the primary death causes for children under 5 years between 1990 and 2015 in Hubei Province of China (%)

Primary death causes: pneumonia, birth asphyxia, preterm birth/low birth weight and accidental asphyxia. The other death causes were excluded from the causes listed above.

3.3 Health Care Service

The proportions of clinical diagnosis, emergence treatment and death place at the county/district hospitals increased from 9.0%, 27.4% and 28.7% in 1990 to 75.5%, 67.7% and 60.4% in 2015 respectively, and there were the significant differences between 1990 and 2015 in Hubei province ($P < 0.01$) as shown in Table 1.

Table 1. Proportions of the health care service for children under 5 years between 1990 and 2015 in Hubei province of China

Health care service		Proportion (%)				χ^2^*	P
		1990	2000	2010	2015		
Clinical Diagnosis	In or above the county/district hospitals	9.0	30.3	61.3	75.5	50.18	<0.01
	At the town/street health centers	31.3	26.2	14.5	6.3		
	At the village health rooms	32.6	21.3	7.7	4.2		
	Without diagnosis	27.1	22.2	16.5	14.0		
Emergence treatment	Inpatient treatment	27.4	42.1	62.0	67.7	52.32	<0.01
	Outpatient treatment	35.2	26.2	14.9	12.0		
	Without treatment	37.4	31.7	23.1	20.3		
Death place	In or above the county/district hospitals	28.7	40.7	57.7	60.4	68.45	<0.01
	On the way to the hospitals	11.2	8.6	11.9	9.9		
	At home	60.1	50.7	30.4	29.7		

* Chi-square test: significant differences between 1990 and 2015.

4. Discussion

U₅MR is interpreted as a measure of socioeconomic, environmental and cultural factors in a country or region (Walter et al., 2011). During the last two decades, child health has been steadily improving, though it still sustained a vast disparity in many countries. It was reported that U₅MR in all the African countries was very high in the top ten countries, meanwhile those in all the European countries was very low in the last ten countries reported by several international organizations. This research manifested that U₅MR in Hubei province was lower than those in all the developing countries which have represented the substantial progress across all the countries (Kenneth, Danzhen, Mie, & Mikkel, 2012; Julie et al., 2010).

However, U₅MR has a close correlation with the internal structure of the death causes for children under 5 years. Bourgeois recognized that the death causes were classified as the endogenous causes (for example birth asphyxia, preterm birth/low birth weight) and the exogenous causes (for example pneumonia) in accordance with the preventable degree of the mortality spectrum in children under 5 years. The endogenous causes were caused by some congenital malformations, genetic diseases or childbirth-related problems, while the exogenous causes were caused by some infections, malnutrition or unintentional injuries (Tatjana et al., 2013; Li et al., 2012; Khaled, 2000). The preventable mortality might be considerably controlled by a series of intervention measures of the national policies and health strategies for children under 5 years in China. This research showed that the mortality spectrum of the primary death causes manifested a distinguished milestone at which the mortality rates of pneumonia and birth asphyxia had been replaced by that of preterm birth/low birth weight after 2005 in Hubei province. Consequently, it was suggested that preterm birth/low birth weight was becoming the chief death cause for children under 5 years after the other death causes could be effectively controlled in Hubei province.

As mentioned above, it's worth nothing that preterm birth/low birth weight was becoming the primary death cause for children under 5 years in Hubei province, which was probably related with the high-aged puerperal, assisted reproductive technique, short reproductive interval and inferior pregnant health for fertile women (Brian et al., 2013; Rajvir & Vrijesh, 2013; Betrán et al., 2007; Meredith, Laura, Joyce, Gary, & Maurizio, 2003). Meanwhile, pneumonia and birth asphyxia had been gradually replaced by preterm birth/low birth weight in Hubei province, which were correlated with the acute respiratory infection management (ARI), expanded immunization program, effective asphyxia resuscitation and vigorous antibiotic treatment (Maurice et al., 2010; Wang et al., 2005). Therefore, the Chinese Government has been closely cooperated with some international organizations in pursuing several projects of health and wellbeing for children under 5 years. From now on, it should be an emphasis on our future work to reduce the mortality rates of preterm birth/low birth weight in Hubei province.

Historical studies of various political systems have revealed that governments were the most successful in promoting child health in many countries (Tariku & Eshetu, 2013; Bamgboye, Cecilia, Adejuwonlo, & Duro, 2012). As for the trends of the mortality spectrum, it was mainly due to the improvement of the health care service for children under 5 years in China, such as clinical diagnosis, emergence treatment and death place at the county/district hospitals. This research has indicated that the health care service for children under 5 years was significantly improved between 1990 and 2015 in Hubei province. Therefore, stronger health systems would effectively contribute to the national health progress towards reaching the target of MDG4 (Anna et al., 2012; Chandrakant & Vinod, 2010).

5. Conclusions

The trends of the mortality spectrum were correlated with the improvement of the health care service for children under 5 years in Hubei province of China. In this research, pneumonia, birth asphyxia, preterm birth/low birth weight and accidental asphyxia were the major contributors to the mortality rates for children under 5 years over the past 25 years. There was a distinguished milestone of the mortality spectrum in which the major death causes have been transformed from pneumonia and birth asphyxia to preterm birth/low birth weight after 2005. Moreover, the proportions of clinical diagnosis, emergence treatment and death place at the county/district hospitals were significantly improved from 1990 to 2015. Nevertheless, rapid reduction of the mortality rates and adjusted structure of the primary death causes would remain a health priority for children under 5 years in Hubei province.

Contributors

Zhonggui Xiong designed the preliminary methods, and analyzed the surveillance data in this research. Yusong Xu and Xiangdong Li critiqued the preliminary methods and results of this updated analysis. Junxin Shi reviewed the final version of the manuscript. All the authors contributed to the subsequent versions of the

manuscript in this research.

Conflicts of Interest

We declared that we had no conflicts of interest in this research.

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The Role of Health Education Intervention towards Improving Knowledge, Attitude and Practice of Onchocerciasis in Enugu State, Southern Nigeria

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Abstract

Background: Onchocerciasis or river blindness constitutes a major burden to households especially in resource-poor settings, causing debilitation and reduction in household productivity. It is an endemic disease in Nigeria. The study aimed to determine the effect of health education on knowledge, attitudes and practices towards onchocerciasis.

Methods: This study was an intervention study carried out among 282 respondents. A multistage sampling technique was used to select the study sample.

Results: Both study and control groups had poor knowledge, 40.4% and 41.2% respectively pre-intervention. However, most of the respondents had good practices, but attitudes towards the disease is poor as most respondents do not see onchocerciasis as a serious problem. Knowledge of respondents improved significantly among the study group ($X^2=37.814$, $P=0.046$) compared to control group ($X^2=1.756$, $P=0.416$) post-intervention. Also, practices ($X^2=21.378$, $P=0.039$) towards onchocerciasis improved significantly, but changes in attitudes was not statistically significant post-intervention among study group ($X^2=35.908$, $P=0.278$).

Conclusions: From our study, health education was shown to improve knowledge and practices on onchocerciasis in the study group compared to control group. Health promotion interventions such as health education campaigns should be scaled-up in onchocerciasis-endemic communities.

Keywords: onchocerciasis, health education, knowledge, attitudes, Nigeria

List of Abbreviations

APOC: African Programme for Onchocerciasis Control

CDTI: Community Directed Treatment with Ivermectin

KAP: Knowledge, Attitudes, and Practices

LGA: Local Government Area

CDDs: Community Drug Distributors

FMOH: Federal Ministry of Health

PHWs: Public Health Workers

WHO: World Health Organization

1. Background

Onchocerciasis is a chronic parasitic disease caused by the filarial worm *Onchocerca volvulus*. The disease is transmitted from man to man through the bites of the blackfly *Simulium* spp of the family Simuliidae (Eezzuduemhoi & Wilson, 2013). The disease is endemic in 30 African countries, Yemen, and in small foci in Central America and South America (Opara, Usip, & Akpabio, 2018; World Health Organization, 1995; World Health Organization, 2013). Globally, at least 18 million individuals have onchocerciasis, and 99% reside in Africa. Also, WHO estimated that 750,000 people are blind or have reduced vision as a result of the disease. West Africa is among the most endemic areas in the world, and Nigeria has the largest number of persons with onchocerciasis, accounting for about a third of the global prevalence, and as one of the largest countries in West Africa she has been reported to have a high incidence of onchocerciasis infection with 7 million persons infected with the disease and 40 million at risk (Opara, Usip, & Akpabio, 2018). The fear of blindness resulted in depopulation of fertile river valleys, thus onchocerciasis is a major obstacle to socio-economic development in the Savannah regions of West Africa. The fertility of riverine lands and associated high blindness rate are opposing forces which respectively attract and repel human settlement along fast flowing rivers near vector breeding sites.

Although onchocerciasis has existed in Nigeria for centuries, it was not until 1908 that the first report was published (Buddent, 2013). Since then, various authors (World Health Organization, 2015; World Health Organization, 2012; Hoerauf, Buttner, Adjei et al., 2003) have contributed to the existing knowledge of its natural endemicity and the socio-economic importance of the disease. Consequently, many studies have been conducted to assess knowledge, attitude and practices towards onchocerciasis. In a research by Manafa and Isamah conducted in Oji River local government area of Enugu State, Nigeria, questionnaires, focused group discussions and key informant interviews were used to determine the socio-cultural factors affecting the transmission of onchocerciasis. The result showed low knowledge about the cause, prevention and complications of onchocerciasis among members of a community. Majority are aware of the disease which they recognized once their bodies starts itching or musculo skeletal pains develops, but only 64.4, 34.0, 1.4 and 3.6% respectively attributed chronic itching, nodules, had vision and leopard skin to blackfly bites (2013, Manafah & Isamah, 2002).

Knowledge, Attitudes and Practices (KAPs) was low in another recent study in four endemic communities in Ondo State Nigeria, where in-depth interviews were conducted on people's knowledge, attitudes, and practices regarding onchocerciasis. However, health education intervention showed a significant improvement in the knowledge attitudes, and practices (KAP) of the respondents. The knowledge of Onchocerciasis aetiology increased to 79.8%, 71.5%, 81.2% and 74% from 48.5%, 48.7%, 34% and 45.3% respectively post-intervention. The study demonstrated that a community-based health education can be effective in Onchocerciasis control (Manafa, Awolola, & Isamah, 2003).

According to World Health Organization (WHO), health education is defined as any combination of learning experience designed to help individuals and communities improve their health by increasing their knowledge or influencing their attitude (Nandha & Krishnamoorthy, 2011). Health education has been linked to improvement in knowledge, attitude and practices of various diseases, especially vector borne disease such as onchocerciasis (World Health Organization, 2013), and it has been recommended as a way of influencing people's knowledge about onchocerciasis (Ogbuokiri, 2013; Shu, Nwadike, Onwujekwe et al., 1999; Adeoye, Ashaye, & Onakpoya, 2010). Some studies conducted in Nigeria showed that higher proportion of people had improved knowledge about onchocerciasis post health education intervention (Shu, Okonkwo & Onyejekwe 2008, Manafa, Awolola, & Isamah 2003).

Knowledge, Attitudes and practices is crucial for the African Program for Onchocerciasis Control (APOC) to achieve the ultimate goal of reducing the public health and socio-economic problems associated with the disease within a period of 12-15 years using the strategy of yearly community directed treatment with ivermectin (CDTI). It is expected that health education should be designed in such a way as to improve the community awareness of the etiology, symptoms treatment, prevention and control of onchocerciasis and the need to comply with the treatment plan as a strategy for controlling the disease (Mbanefo, Eneanya, & Nwaorgu, 2010). This study was therefore conducted to determine the effectiveness of health education intervention on the knowledge, attitude and practice on onchocerciasis in this part of Nigeria.

2. Methods

2.1 Study Area

This study was carried out in Enugu state, Southern Nigeria. The state is made up of 17 LGAs, and has a population of 5,590,513 according 2006 population census. The State is predominantly agricultural with yam tubers, palm

produce and rice being their main produce (Nigeria Business Directory, 2013).

2.2 Study Population

The study population was randomly selected from adult males and females aged 15 years and above. Inclusion Criteria are those who were permanent residents (i.e., residents for at least a year) in each ward in the selected communities.

Visitors from outside the selected communities or staying temporarily and children who were less than 15 years were excluded.

2.3 Sampling Method

All the LGAs in Enugu State except Enugu North and Enugu South were reported to be onchocerciasis endemic (Shu, Okonkwo, & Onwujekwe, 2008). Two LGAs were randomly selected by balloting, then one community was randomly selected from each of the selected LGA. By use of balloting, one community was chosen for the intervention while the other community served as control. Cluster units such as town halls, schools, churches-were randomly selected.

2.4 Study Design

This was an intervention study carried out from April to June, 2013. It comprised of a study and a control group. The control group was similar to the study group in terms of endemicity of onchocerciasis, population density and socio-economic status. The community selected as the study group was in Enugu East LGA and the community which served as the control was in Nkanu West LGA. The study was carried out in 3 phases for the study group and 2 phases for the control group a distance of about 10km apart.

Phase 1: Two hundred and eighty two (282) respondents participated in the baseline survey.

Phase 2: Health education on onchocerciasis was carried out in the study area only; health education was done in 3 different clusters in the intervention community-the local government council hall, the community town hall and the premises of the community secondary school-in three sessions, each session lasting for 40 minutes, for 3 days.

Phase 3: It took place one month after the intervention in the study area. Same questionnaire as in the baseline survey was administered to the study and control groups.

2.5 Educational Content of Study Intervention

Content of the health education intervention included lessons on the causative agent, transmission, clinical manifestations, treatment and control of onchocerciasis. Lessons were delivered both in English and in Igbo (the local dialect). It involved the use of illustrated pictorial materials. Questions were entertained from the participants after each session.

2.6 Man Power Training and Supervision

Two field workers (one for each group) helped in administering the questionnaires. The field workers were trained, this is to enhance the validity of the study. The field workers were supervised by the researchers.

2.7 Data Analysis

Data were analyzed using Statistical package for social Sciences (SPSS) Inc., Chicago, II, USA and the level of significance was at 5% confidence.

2.8 Scoring of Knowledge, Attitude, and Practice

Ten (10) questions on knowledge of onchocerciasis were scored, each right answer was one point. The scores less than 40% (0 to 4 points) were poor knowledge; 41% to 60% (5 to 6 points) fair knowledge greater than 60% (greater than 6 points) good knowledge. The same was done for practice with five (5) key questions. Those who got 3 and above questions right had good practice, while 1 or 2 had poor practice. For attitude, there are three key questions (3) in which those who got all three questions right have good attitude, those who got 2 questions right had fair attitude and those who got only 1 question right had poor attitude.

2.9 Limitation of the Study

Mobilization of community members to participate in the health education intervention.

3. Results

Two hundred and eight two community members participated in the research, and the response rate was 100% in the pre-intervention and post intervention.

Table 1. Demographic characteristics of the participants

Demographic characteristics	Study group		Control group	
	N=141	%	N=141	%
Sex:				
Male	51	36.2	41	29.1
Female	90	63.8	100	70.9
Age Group (Years):				
15-24	88	62.4	78	55.3
25-34	15	10.6	31	22.0
35-44	18	12.8	11	7.8
45-54	13	9.2	15	10.6
55-64	0	0.0	5	3.6
>64	7	5.0	1	0.7
Educational status:				
No- formal	12	8.5	13	9.2
Primary	19	13.5	15	10.6
Secondary	94	66.7	74	52.5
Tertiary	16	11.3	39	27.7
Occupation:				
Unemployed	0	0.0	22	15.6
Student	80	56.7	67	47.5
Farming	27	19.1	11	7.8
Trading	5	3.6	10	7.1
Civil servants	28	19.9	29	20.6
Others	1	0.7	1	1.4
Marital status:				
Married	46	32.6	43	30.5
Single	89	63.1	93	66.0
Divorced/separated	0	0.0	2	1.4
Widowed	6	4.3	3	2.1
Tribe:				
Igbo	140	99.3	134	95.1
Yoruba	1	0.7	4	2.8
Others	0	0.0	3	2.1
Religion:				
Christianity	139	98.6	141	100.0
Islam	1	0.7	0	0.0
Others	1	0.7	0	0.0

Table 1 shows Two hundred and eight two (282) persons participated in the study of which 141 belonged to the study group and 141 to the control group. Majority are females in the study group 63.8% and control group 70.9%. The mean age is 28.0 ± 13.8 for the study group and 28.32 ± 11.8 for the control group.

Table 2. Knowledge of respondents on Onchocerciasis

Variables	Study group		Control group	
	N=141	%	N=141	%
What is Onchocerciasis:				
Disease	57	40.4	58	41.2
Type of blindness	41	29.1	56	39.7
River	37	26.3	20	14.2
Drug	1	0.7	2	1.4
Fly	1	0.7	1	0.7
Not known	4	2.8	4	2.8
Symptoms of onchocerciasis:				
Stooling and vomiting	47	33.3	37	26.2
Blindness	41	29.1	38	27.0
Nodules	23	16.3	20	14.2
Leopard skin	11	7.8	5	2.5
Rashes	13	9.2	19	13.5
Not known	6	4.3	22	15.6
Causes of onchocerciasis:				
Contaminated food/water	43	30.5	32	22.7
Bite of black fly	34	24.6	35	24.8
Mosquito bite	29	20.6	15	10.6
Contact with infected person	7	5.0	13	9.2
Witchcraft	19	13.5	25	17.7
Not known	9	6.4	21	15.0
Prevention of onchocerciasis:				
Drinking clean water	55	39.0	44	31.2
Protection from mosquitoes	30	21.3	10	7.1
Protection from black flies	27	19.1	46	32.6
Avoid contact with infected person	9	6.4	15	10.6
Not known	20	14.2	26	18.5
Choice of drugs:				
Ivermectin	78	55.3	71	50.3
Malaria tablets	27	19.1	10	7.1
Haematinics	16	11.4	18	12.8
Herbs and concoctions	9	6.4	15	10.6
Not known	11	7.8	27	19.2

Table 2 shows that 40.4% and 41.2% of respondents in study and control groups respectively knew that onchocerciasis is a disease. Among the study group, 36.2% of respondents believed that onchocerciasis is caused by drinking contaminated water, while it was 29.8% in control group. Study group (30.5%) believed that River Blindness is transmitted through contaminated food/water, while Control group (24.8%) knew that the disease is transmitted through the bite of the black fly. 13.5% and 17.7% of study group and control group respectively believed witchcraft is the cause of onchocerciasis.

Table 3. Heard of onchocerciasis and sources of information by the respondents

Variables	Study group		Control group	
	N = 141	%	N = 141	%
Heard of onchocerciasis before:				
Yes	71	50.4	90	64.0
No	70	49.6	51	36.0
Sources of information:				
Health worker	21	30.4	17	19.1
Radio/Television	13	18.4	29	31.9
Neighbor	2	2.8	4	4.3
School	13	18.4	19	21.3
Church	3	3.6	9	10.6
No idea	18	26.2	12	12.8

Table 3 shows that 50.4% and 64% of respondents among the study and control groups respectively had heard onchocerciasis. Health workers 30.4% were the major sources of information for study group, while it was radio/television 31.9% for the control group.

Table 4. Respondent's attitudes and practices towards onchocerciasis

Variables	Study group		Control group	
	N =141	%	N=141	%
Is it important to know more about onchocerciasis?				
Yes	102	72.3	137	97.2
No	23	16.3	4	2.8
Don't know	16	1.4	0	0.0
Are you satisfied with receiving drugs from CDDs?				
Yes	59	42.0	42	30.0
No	82	58.0	99	70.0
Do you think it is important to take drugs as at when given by CDDs?				
Yes	110	78.0	124	84.9
No	31	22.0	17	12.1
Have you participated in the CDTI program before?				
Yes	35	25.0	21	15.0
No	106	75.0	120	85.0
Do you take the drug Mectizan?				
Yes	61	43.3	43	30.5
No	80	56.7	98	69.5
Do black flies interfere with your occupation/				
Yes	48	34.0	31	22.0
No	26	18.5	59	41.8
Not known	67	47.5	51	36.2
Do you control the black flies?				
Yes	117	83.0	55	39.0
No	24	17.0	86	61.0
Have you missed any dosing round for ivermectin before				
Yes	65	46.1	42	29.8
No	76	53.9	99	70.2
Do you have challenges getting drugs from the CDDs?				
Yes	34	24.0	37	26.0
No	107	76.0	104	74.0

Table 4 shows that most respondents in the study group (78.0%) and control group (84.9%) think it is important to take the drugs as at when given by the CDDs. Majority of the respondents both in the study and control groups, 75% and 85% respectively have not participated in the CDTI Programme at one time or the other before. In addition, majority of the respondents in the study group (56.7%) and in the control group (69.5%) claimed that they do not take ivermectin.

Table 5. Effect of Health Education on knowledge, attitude and Practices towards onchocerciasis

Variables	Study Group				X ²	P-Value	Control Group				X ²	P-Value
	Pre-Intervention		Post-Intervention				Pre-Intervention		Post-Intervention			
	N	%	N	%			N	%	N	%		
What is Onchocerciasis:												
Disease	57	40.4	88	26.4			58	41.2	62	44.0		
Type of blindness	41	29.1	21	15.0			56	39.7	53	37.6		
River	37	26.3	14	10.0			20	14.2	21	14.9		
Drug	1	0.7	8	5.7			2	1.4	1	0.7		
Fly	1	0.7	9	6.4	27.879	0.038	1	0.7	3	2.1	5.153	0.094
Not known	4	2.8	1	0.7			4	2.8	1	0.7		
What causes onchocerciasis?												
Drinking contaminated water	43	30.5	13	9.2			32	22.7	35	24.8		
Bad blood from mosquitoes	34	24.6	35	24.8			35	24.8	20	14.2		
Filarial worm (Arikwa)	29	20.6	55	39.0	46.851	0.047	15	10.6	43	30.5	7.657	0.634
Strange body sensations	7	5.0	12	8.5			13	9.2	14	10.0		
Witchcraft	19	13.5	8	5.7			25	17.7	4	2.8		
Not known	9	6.4	17	12.0			21	15.0	25	17.7		
Transmission of onchocerciasis:												
Through contaminated food/water	34	24.0	85	60.3			35	24.8	49	34.8		
Through mosquito bite	29	20.6	22	15.6			15	10.6	13	9.2		
Contact with infected person	50	35.5	7	5.0	16.296	0.037	13	9.2	1	0.7	16.296	0.079
Can not be transmitted	19	13.5	12	8.5			25	17.7	22	15.6		
Not known	9	6.4	7	4.9			21	15.0	32	22.7		
Drug of choice for infected person:												
Ivermectin (Mectizan)	78	55.3	103	73.3			71	50.3	75	53.2		
Malaria tablets	27	19.1	10	7.1			10	7.1	5	3.5		
Haematinics	16	11.4	2	1.4	22.395	0.0246	18	12.8	18	12.8	8.554	0.086
Herbs and concoctions	9	6.4	10	7.1			15	10.6	15	10.6		
Not known	11	7.8	16	4.2			27	19.2	28	19.9		
Is it important to know more about onchocerciasis?												
Yes	102	72.3	119	84.4			137	97.2	113	80.2		
No	23	16.3	22	15.6	17.331	0.043	4	2.8	16	11.3	21.066	0.028
Don't know	16	11.4	0	0.0			0	0.0	12	8.5		

Table 5 shows there is a statistically significant difference between pre and post intervention among study group on the knowledge of what is onchocerciasis ($X^2=27.879$, $df=4$, $P=0.038$), the causative agent of onchocerciasis ($X^2=46.851$, $df=5$, $P=0.047$) and mode of transmission of onchocerciasis ($X^2=16.296$, $df=5$, $P=0.037$). In the control group, there is no statistically significant difference in their response on the knowledge of what is onchocerciasis ($X^2=5.153$, $df=4$, $P=0.094$), the causative agent of onchocerciasis ($X^2=7.657$, $df=5$, $P=0.634$) and mode of transmission ($X^2=16.296$, $df=5$, $P=0.079$).

Table 6. Knowledge, Attitude and Practices of Respondents Before and after Health Education

Variables	Study Group					Control Group						
	Pre-Intervention		Post-Intervention		X ²	P-Value	Pre-Intervention		Post-Intervention		X ²	P-Value
	N	%	N	%			N	%	N	%		
Knowledge of Respondents												
Poor	49	30.0	20	14.2	37.814	0.046	42	29.8	43	30.5	1.756	0.416
Fair	72	51.0	57	40.4			76	53.9	67	47.5		
Good	20	14.0	64	45.5			23	16.3	31	22.0		
Attitude of Respondents												
Poor	80	56.7	81	57.5	35.908	0.278	99	70.2	106	75.2	1.757	0.415
Fair	36	25.5	34	24.1			27	19.2	26	18.4		
Good	25	17.8	26	14.2			15	10.6	9	6.4		
Practice of Respondents												
Good	117	82.9	113	80.0	21.378	0.539	65	48.9	66	46.8	12.532	0.246
Poor	24	17.1	28	20.0			76	51.1	75	53.2		

Table 6 shows that there is a statistically significant difference in knowledge of respondents in the study group before and after intervention ($x^2=37.814$, $P=0.046$), while there is no statistically significant difference in the knowledge of Respondents in control group before and after intervention ($x^2= 1.756$, $p = 0.416$). On the attitude of respondents there is no statistically significant difference in the study group and control group before and after intervention ($x^2 = 35.908$, $P=0.278$) and ($x^2 = 1.757$, $P = 0.415$) respectively. There is also, no statistically significant difference in the practice of respondents in the study and control groups before and after intervention ($x^2=21.378$, $P= 0.539$) and ($x^2 = 12.532$, $P=0.246$) respectively.

Table 7. Effect of Educational status on the Knowledge, Attitude and Practices of Respondents in study and control groups before intervention

Variables	Knowledge													
	Study Group					X ²	P Value	Control Group					X ²	P value
	Poor	Fair	Good	N	%			Poor	Fair	Good	N	%		
Educational Status														
Non-formal	6	4	2	12	8.5	23.452	0.032	4	5	4	13	9.2	33.237	0.026
Primary	9	7	3	19	13.5			4	6	5	15	10.6		
Secondary	31	28	35	94	66.7			29	19	26	74	52.5		
Tertiary	1	1	4	6	11.3			39	27.7					
Attitude														
Non formal	7	4	1	12	8.5	15.259	0.018	3	5	5	13	9.2	21.872	0.037
Primary	12	4	3	19	13.5			4	4	7	15	10.6		
Secondary	27	37	30	94	66.7			28	16	30	74	52.5		
Tertiary	1	2	3	6	11.3			7	12	20	39	27.7		
Practice														
Non formal	5	3	4	12	8.5	3.176	0.038	7	3	3	13	9.2	8.793	0.042
Primary	9	4	6	19	13.5			6	7	2	15	10.6		
Secondary	22	30	4	94	66.7			24	18	3	74	52.5		
Tertiary	0	2	4	6	11.3			2	14	23	39	27.7		

Table 7 shows that the effect of educational status on knowledge ($\chi^2 = 23.452, P=0.032$), attitude ($\chi^2=15.259, P=0.018$) and practice ($\chi^2=3.176, P=0.038$) of Respondent is statistically significant in both the study and control groups.

Table 8. Effect of occupation on the Knowledge, Attitude and Practices of Respondents in study and control groups before intervention

Variables	Knowledge													
	Study Group		Poor	Fair	Good	X ²	P Value	Control Group		Poor	Fair	Good	X ²	P value
	N	%	N	N	N			N	%	N	N	N		
Occupation of Respondents														
Unemployed	0	0.0	0	0	0	32.648	0.001	22	15.6	7	8	7	46.852	0.002
Student	80	56.7	25	29	26			67	47.5	13	26	28		
Farming	27	19.1	13	7	7			11	7.8	8	1	2		
Trading	5	3.6	1	2	2			10	7.1	6	2	2		
Civil Servant	28	19.9	3	9	16			29	20.6	5	11	13		
Others	1	0.7	1	0	0			1	1.4	1	0	0		
Attitude														
Unemployed	0	0.0	0	0	0	16.883	0.077	22	15.6	9	9	4	23.892	0.065
Student	80	56.7	19	29	32			67	47.5	26	17	24		
Farming	27	19.1	10	11	6			11	7.8	6	3	2		
Trading	5	3.6	3	1	1			10	7.1	4	4	2		
Civil Servant	28	19.9	6	14	8			29	20.6	4	10	15		
Others	1	0.7	0	1	0			1	1.4	0	0	1		
Practice														
Unemployed	0	0.0	0	0	0	24.862	0.002	22	15.6	8	10	4	19.452	0.004
Student	80	56.7	37	29	14			67	47.5	19	28	20		
Farming	27	19.1	14	7	6			11	7.8	3	6	2		
Trading	5	3.6	2	2	1			10	7.1	3	4	3		
Civil Servant	28	19.9	3	20	5			29	20.6	10	7	12		
Others	1	0.7	1	0	0			1	1.4	0	1	0		

Table 8 shows that the effect of occupation on knowledge ($\chi^2 = 32.648, P = 0.001$) and practice ($\chi^2 = 24.862, P=0.002$) of Respondents is statistically significant in both the study and control groups. However, its effect on attitude is not statistically significant in both the study and control groups ($\chi^2=16.883, p=0.077$).

4. Discussion

Our study examined the effect of health education intervention towards improving the knowledge, attitudes and practice (KAP) on onchocerciasis among residents of Enugu State. Most respondents in the study and control groups pre-intervention knew that onchocerciasis is a disease and that blindness is one of the symptoms of the disease. This may probably be due to the endemicity of the disease in the study area. However, majority of the respondents in both the study and control groups, 51 (36.2%) and 42 (29.8%) respectively believed that onchocerciasis is caused by drinking of contaminated water. This study also revealed that a good number of the respondents do not know the mode of transmission of onchocerciasis. Only 34 (24.0%) in the study group and 35 (24.8%) in the control group that onchocerciasis can be transmitted through black flies. Majority of the respondents both in the study group 43 (30.5%) and in the control group 32 (22.7%) believed that the disease can be transmitted through contaminated food and water. Misconceptions about the mode of transmission of onchocerciasis by majority of the respondents in this study is consistent with the findings of a study conducted in

Quara District, North Western Ethiopia, in which majority of the participants held at least one misconception about the mode of transmission of disease (Weldegereal, Medhin, & Weldegabriel, 2014). Majority of the respondents 78 (55.3%) in the study group and 71 (50.3%) in the control group, however, knew that ivermectin (Mectizam) is the choice drug for treatment of onchocerciasis. This high percentage of knowledge of ivermectin as choice drug for treatment of onchocerciasis and the corresponding significant increase in the knowledge of ivermectin as choice drug for treatment of onchocerciasis after the health education intervention show that the CDDs and other public health workers (PHWs) concentrate more on the treatment aspect of their job which includes public health education on the aetiology and control of the disease. This is similar to the findings in a study by Brieger et al in which the post-intervention showed an increase in the number of villagers from 1.6% to 19.3% who could identify tablets as a form of treatment, and this also showed that PHWs concentrate on the treatment aspect of their job (Brieger, Ramakrishna, & Adeniyi, 2008).

In our study, majority of the respondents both in the study group 80(56.8%) and the control group 98(69.5%) do not take ivermectin. Among those that do not take ivermectin, 14(17.5%) in the study group and 20(20.4%) in the control group believed incompetence of the CDDs was the reason for not taking the drug. These findings may be attributed to poor health seeking behavior similar to the findings of a study by Adeoye et al which showed that respondents do not see onchocerciasis as a serious health problem (Manafa, Awolola, & Isamah, 2003). Those who claimed to control the vector in the study group and control groups was 117 (83.0%) and 79 (56%) respectively. Most respondents claimed that they protect themselves from the bites of black flies by putting on clothes that covers the arms and goes down to the ankles e.g, long sleeve shirts and trousers, wrappers etc.

The respondents in the study group showed a statistically significant difference in their response before and after the health education intervention concerning the knowledge on onchocerciasis. Our findings are similar to what was reported in a study among school children in Okpatu, Nigeria, where a statistically significant higher proportion of the children knew about causative agent, clinical manifestation, diagnosis, treatment, and prevention of onchocerciasis post intervention (Shu, Okonkwo, & Onwujekwe, 2008). Our study also revealed that only 26 (14.0%) and 23 (16.3%) of respondents in the study and control groups respectively have good knowledge, and only 25 (17.8%) and 15 (10.6%) have good attitude towards onchocerciasis both in the study group and in the control group. This is consistent with the findings of a study by Weldegebreel et al, where the values for good knowledge and attitude were below average (Brieger, Ramakrishna, & Adeniyi, 2008). Another study reported a significant increase in knowledge of respondents, when the results of the pre-intervention was compared to post intervention survey, which took place about one month after the health education intervention among the study group (Aireen, 2014). However, the findings of our study showed there was no significant increase in the attitude and practice of respondents before and after health education intervention. This is contrary to the result of the study conducted in Osse, Ondo State Nigeria, where a significant increase in the knowledge, attitude and practice of respondents was reported (Manafa, Awolola, & Isamah, 2003). However the difference could be attributed to difference in socio-cultural beliefs and health seeking behaviour of the respondents. The findings of this study showed that the effect of Educational status on knowledge, attitude and practice was statistically significant in the study and control groups. Also in this study, occupation was shown to have a statistically significant effect in knowledge and practice, but not on attitude.

5. Conclusion

Majority of the respondents in this study do not have good knowledge and attitude on onchocerciasis. However, most of the respondents have good practice on the disease which is mostly due to protection from the flies during occupational activities and the CDDs concentration on the treatment aspect of their job. From this study, health education was shown to significantly improve knowledge on onchocerciasis in the study group, which can subsequently influence their attitude and practice.

6. Recommendations

In view of the findings from this study, it is recommended that regular community-based health education become an important part of the onchocerciasis control programme.

Community Directed Distributors and other health workers in these communities should not only focus on the distribution aspect of the CDTI programme, but should equally focus on conducting health education, just before the drug distribution exercise, in order to sensitize and improve participation of community members.

Ethics Approval and Consent to Participate

Approval for the study was obtained from the ethical committee of the University of Nigeria Teaching Hospital, Enugu. Written consent was obtained from all respondents. The same type of health education given to the

intervention group was offered to the control group at the end of the study.

Consent to Publish

All authors consented to publish in the Global Journal of Health Science.

Availability of Data and Materials

Some materials such as administered questionnaires are still available, but the data stored in SPSS is not longer available. The research was conducted about two years ago

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Authors Contribution

Omotowo participated in study design, analysis, interpretation and revised the manuscript. Ezeoke participated in study design and revised the manuscript. Ajuba participated in data collection, analysis. Ogochukwu participated in study design, data collection and written the manuscript, while Meka participated in data collection and analysis. Eyisi participated in study design and data analysis. All authors read and approved the final manuscript.

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Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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Perception of the Saudi Community towards Human Papilloma Virus Vaccination in Jeddah, Saudi Arabia

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Abstract

To examine the awareness and perception of Saudi community towards Human Papillomavirus Vaccination. A cross-sectional study has examined the perception and awareness of Saudi individuals towards Human Papillomavirus HPV vaccination. A sample of 278 Saudi individuals were included. A close-ended survey questionnaire was employed to collect the data of Papillomavirus HPV vaccination. Around, 78.30% female and male participants were unaware of the availability of HPV vaccination against cervical cancer. 90.06% of females supported cervical cancer screening Pap smear by gynecologist after enduring vaccination. Only, 40.66% visited the gynecologist for screening. Results demonstrated 85.77% female agreed on receiving expensive vaccination. Conversely, 97.48% supported on HPV vaccination free of charge. A lack of knowledge about HPV, Pap smear, and cervical cancer. The data obtained can be used as a standard to devise effective awareness programs. Data was collected particularly from Saudi Arabia for evaluating Saudi community perception. Both males and females were observed to be interested in taking vaccination and prevention initiatives against the cervical cancer, whereas, there is a lack of awareness observed among the males and females included in the study.

Keywords: HPV Virus, HPV vaccination, cervical Cancer

1. Introduction

Saudi Arabian community lies among the semi-developed countries of the world. New medical inventions, medications, procedures, and vaccinations are generally adopted in the developed countries that deal with similar infections like Human Papilloma Virus (HPV) vaccination, first licensed in the year 2006 (WHO, 2009). World Health Organization advocated that vaccination of HPV needs to be introduced into “national immunization programs” where cervical cancer prevention is a priority for improving public health. The introduction is economically sustainable and programmatically feasible, and where the cost-effectiveness factors have been duly considered (WHO, 2015). Limited data is available from Middle Eastern region regarding the level of awareness and knowledge of Saudi community towards HPV vaccine and infection further leading to cervical cancer. Therefore, this study aimed to examine the knowledge of Saudi community about the existence of vaccination.

Cervical cancer is considered to be the second most widespread types of cancer among women across the world. About 500,000 cervical cancer cases are diagnosed annually with around 90% of the cases originated in developing nations (Hughes, 2009). Approximately, 89% of the cervical cancers cases in Saudi Arabia was concerned with HPV infection, and 78.7% (70/89) of HPV-positive tumors were infected with HPV-16/18 (Alsbeih et al., 2011). No published research has managed to assess awareness of this issue in the Saudi Arabian community. Exploring information on this issue may help decision makers and community health professionals to identify the needs towards combating this type of female cancer. Around 80% of the mortality cases have been identified in the developing countries and 87% in the developed regions due to cervical cancer (Abudukadeer et al., 2015; International Agency for Research on Cancer. 2012). Cervical cancer has been recognized as one of the common cancers among females with an estimation of 266,000 death cases and 528,000 new cases in 2012 worldwide (International Agency for Research on Cancer, 2012).

Saudi Arabia Ministry of Health (MOH) 2013 revealed that one of the main risk factor of cancer worldwide is infections caused from HPV virus, consequently initiating cervical cancer (Ministry of health portal kingdom of Saudi Arabia, 2013). Moreover, MOH 2014 stated that immunizations protect from virus causing cancer, such as (HPV), which may lead to cervical cancer (Ministry of health portal kingdom of Saudi Arabia, 2014). In 2011,

HPV prevalence was determined in women of Saudi Arabia. Approximately, 89% of cervical cancers were linked with the infections of HPV and 78.7% of the HPV-positive tumors were associated and infected with HPV-16/18 (Ministry of health portal kingdom of Saudi Arabia, 2013). In the year 2012, out of hundred cervical cancer patients, 82 cases demonstrated positive HPV sequences (Alsbeih et al., 2013). Conversely, about 43% of the specimens were infected with HPV. The most widespread genotypes included HPV 188.0%, HPV 16 (30%), followed by type HPV 45, taking place at 5.0% (Turki et al., 2013). In 2014, 92% of cervical tumors were infected with HPV, out of which 78% are HPV-16 and -18 genotypes. Hence, it can be concluded that in women of Saudi Arabia there is alarming increase in the prevalence of HPV (Alsbeih, 2014).

WHO found that “every year more than 270,000 women die from cervical cancer; and more than 85% of such deaths occur in low-and middle-income countries”. Around 45 countries had introduced HPV vaccination by the end of 2012; majority of these include developed countries (WHO, 2013). Six years after the introduction of HPV vaccine in the Danish vaccination program, decline in cervical lesions risk was observed at community level (Balduf-Felskov et al., 2014). Further decline was observed in the number of cervical cancer patients after five years of implementing HPV vaccine in the Australian vaccination program on April 2007 (Gertig et al., 2013). The reduction in the existence of cervical cancer was observed after four years of introduction of vaccine within the vaccination programs of United States and other countries (Hariri et al., 2013).

In Saudi Arabia, limited data is available on the prevalence of HPV infection. The HPV prevalence in numerous other Middle Eastern states was found to be same as the rest of the world (Hajjaj et al., 2006). The studies conducted in Saudi Arabia concluded that the occurrence of abnormalities related to epithelial cell in western region of a country was observed to be 2.2%, 1.5%, and 5.0% (Helmerhorst, 2006; WHO, 2007; Conry et al., 2009). Additionally, few sub-fertile females attending fertility consulting clinics relate to the occurrence of cervical cytology abnormality. Such data paucity relates back to the nonexistence of national screening program in Saudi Arabia for cervical cancer.

The objective of the study was:

- To identify the level of awareness of the Saudi community toward human papilloma virus (HPV) vaccination.
- To identify the level of awareness of cervical cancer screening in early stages to determine the existence of cancer and its treatment.
- To explore the attitude and perception of the Saudi community towards human papilloma virus (HPV) vaccination.

2. Method

A population based survey was conducted by employing a set of standardize data collection sheets demanding a band of questions based on Likert scale. A self-administered questionnaire was constructed and pre-tested to collect the data from male and female clients in the waiting area. All the participants were included, who were above 15 years of age and were recruited from the Saudi Airlines medical center in Jeddah, Saudi Arabia. The data collection procedure was done over the course of one month (September 2014) and filled by the participants. The target population was selected randomly covering different age groups and jobs. The participants were selected through random sampling approach and then cluster sampling was applied to create clusters of the participants involved in the study. This technique assisted to identify and include the participants in the study. The sample size taken for the study was 278 including both males and females. 163 female participants and 115 male participants were recruited for the data collection. The collected data was analyzed through SPSS or Statistical Package for the Social Science software version 22. The frequencies of participant’s responses concerning their awareness have been obtained through the analysis. A written and verbal approval was obtained from the participants and was approved by the faculty committee of research.

3. Results

Table 1 indicated the responses of male and female participants, who were well aware about the availability of HPV vaccination against cervical cancer. Around, 13 males (4.78%) and 46 female (16.91%) were fully aware of availability of HPV vaccination. The majority of the respondents i.e. 100 male 36.76% and 113 female 41.54% were not at all aware of such availability. Therefore, it can be determined that HPV awareness has been found generally low in Saudi community. Currently, increase in the knowledge and awareness of HPV is likely to be associated with the HPV vaccines availability.

Table 1. Participants' knowledge about the availability of HPV vaccination

Gender	Responses	
	Yes	No
Male	4.78%	36.76%
Female	16.91	41.54%

Table 2 indicated responses of unmarried female participants, who like to take HPV vaccination before getting married. The results indicated that 64 females (90.14%) desire to receive this vaccination before marriage, while 7 female (9.86%) restrain from getting vaccinated. Hence, majority of the females get the human papillomavirus (HPV) vaccine before getting married as they believe that it can aid to prevent the risk of cervical cancer. People are reluctant to get vaccinated before they are sexually active. While, other females are concerned about their safety as they consider these vaccines to be extremely effective and harmless.

Table 2. Responses of the participants

Responses of female participants who like to take HPV vaccination before getting married	
Yes	No
90.14%	9.86%
Married female participants who would have taken the HPV vaccination if they knew about it prior to their marriage	
Yes	No
93.41%	6.59%
Responses of married female participants who visited the gynaecologist to perform cervical cancer screening (Pap smear)	
Yes	No
40.66%	59.34%
Female participants support cervical cancer screening (Pap smear) for married women by gynecologist even after taking the vaccination	
Yes	No
90.06%	9.94%
Male participants who supported giving the vaccination to their daughters prior to the marriage	
Yes	No
94.69%	5.31%
Male participants who allow their wives to go to a gynaecologist for screening of cervical cancer (Pap smear)	
Yes	No
95.58%	4.42%

It has also been indicated that the responses of married female participants, who would have taken the HPV vaccination if they knew about it prior to their marriage. Majority of the female respondents 85 women (93.41%) provided positive responses sufficient for the intended analysis, while 6 women (6.59%) were reluctant to get vaccinated before marriage.

The efficacy of Papanicolaou (Pap) smear screening in diminishing the mortality of cervical cancer is almost collectively accepted. The responses of married female participants visiting a gynecologist for routine (Pap smear) screening have also been presented. Thirty women (40.66%) indicated that they visited the gynecologist to perform cervical cancer screening Pap smear, while 54 women (59.34%) had a very negative stance toward Pap smear screening (Table 2). 145 female respondents (90.06%) supported cervical cancer screening (Pap smear) of married women conducted by a gynecologist, even after taking the vaccination. On the other hand, 16 female participants (9.94%) had a negative perception about it. Whereas, 107 male participants (94.69%) supported the opinion that HPV vaccination should be given to their daughters before they get married. On the contrary, 6 male

participants (5.31%) did not support these views.

It has been demonstrated that 108 male participants (95.58%) permitted their wives to go to the gynecologist for the performance of cervical cancer screening (Pap smear). While, 4.42% male participant did not allow their wives to go to a gynecologist for screening of cervical cancer (Pap smear). This means that majority of the male participants supported their wives to undertake a Pap smear screening.

There is a critical need to ascertain that vaccines are available to the medically underserved population in the Saudi community. The findings have highlighted the awareness of male and female participants about the HPV vaccination availability at private hospitals or clinics. It costed one thousand Saudi riyals. Hence, majority of the respondents i.e. 96 male (35.04%) and 139 female (50.73%) were ready to pay for HPV vaccination. While, 16 male (5.84%) and 113 female (8.39%) considered it to be expensive.

Table 3. Male and Female responses, who supported HPV vaccination

Responses of male and female participants who supported taking the HPV vaccination only if it is available at private hospitals or clinics costing around 1000 SAR		
Gender	Responses	
	Yes	No
Male	35.04%	5.84%
Female	50.73%	8.39%

Male and female participants who support the addition of HPV vaccination free of charge to pre-marriage national examination program conducted by Saudi Arabia Ministry of healthcare		
Gender	Responses	
	Yes	No
Male	40.65%	0.72%
Female	56.83%	1.80%

It has been observed through the analysis that male and female participants, who support the introduction of HPV vaccination before marriage. It is a free of cost national examination program conducted by Saudi Arabia ministry of healthcare. Majority of the participants 113 males (40.65%) and 158 females 56.83% supported this program. While, 2 male (0.72%) and 5 female 1.80% refuted in particular.

4. Discussion

This study aimed to examine the level of awareness among Saudi community towards human papilloma virus (HPV) vaccination and cervical cancer screening. Around 6.51 million females aged 15 years and above are at risk of creating cervical tumor in Saudi Arabia, according to WHO. Whereas, it has also been reported that 55 females die from cervical tumor every year and 152 females are diagnosed with the cervical growth in Saudi Arabia (World Health Organization, 2014). Thorough investigation is being conducted to combat malignancy in acknowledgement of the worldwide pervasiveness to make this disease treatable.

Lack of clinical knowledge, primary and secondary prevention along with risk factors regarding cervical malignancies have been renowned in both developed and developing countries (Notara et al., 2012; Kamzol et al., 2013). The obligatory treatment in society is able to swift the recession and its poor observance, which may cause lack of knowledge about HPV indicators. Additionally, the HPV defamatory group mentalities could unfavorably affect the early treatment and its determination. The practices and knowledge of HPV might play a crucial role in permitting early adherence and findings to HPV control. Therefore, the study recruited a small sample of participants to gain knowledge about the perspectives of Saudi Arabian society related to the origin of woman cervical cancer caused by HPV. The results were concluded on the basis of previous studies. In addition, the study explored the availability of HPV vaccine, its price if not offered free of cost, and willingness of women to buy this vaccine. The diversity among the participants assisted to analyze their opinions and convert it into real data. Participants varied in gender and age. More females were recruited than male because females get more advantage from this vaccine. Thus, 58.6% of participants were females and 41.4% were males.

Saudi Arabian societies lack in the awareness about HPV vaccinations availability in the world. They totally

depend on the Saudi ministry of health announcements for administration of vaccinations. In general, high percentages from both male and female participants (78.30%) were not aware about the availability of HPV vaccination against cervical cancer. With regards to HPV vaccination, majority of the married female participants would have taken the vaccination if they knew prior to their marriage. Whereas, unmarried female participants desire to take vaccination before marriage. These results are supported by the findings of a study conducted by Johargy et al. (2016), which has observed that the adult females has lack of knowledge, prevention, vaccination and transmission about the HPV and infection. It has been recommended that written, visual and verbal communication through internet should be utilized efficiently and intensively for the HPV teaching and knowledge related with cervical cancer. A study conducted among the medical students in Al-Ahia, Saudi Arabia has established that health professionals are the reliable and best medium that may assist to raise the knowledge and awareness of the people about the alarming but preventable disease (Mulhim et al., 2014).

With regards to visiting the gynecologist, more than half of married female (59.34%) did not perform cervical cancer screening Pap smear. Additionally, 90.06% of the female participants supported the fact that cervical cancer screening (Pap smear) for married women should be conducted by the gynecologist even after taking the vaccination. About, 94.69% male participant supported the fact that vaccination should be administered to their daughters prior to their marriage; whereas, 95.58% allowed their wives to go to a gynecologist for undertaking cervical cancer screening (Pap smear).

The study demonstrated that 85.77% of both male and female agreed about female taking the vaccination at private hospitals at a cost of 1000 SR. 97.48% of both male and female participant supported the addition of HPV vaccination free of charge to pre-marriage national examination program prepared by Saudi Arabia Ministry of Health. Results of the present study are consistent with the data related to national trends demonstrating substantial augmentation in the awareness of HPV over prior decades (Gerend et al., 2008; Klug et al., 2008). When comparing the findings of the current study with past evidence, it is essential to consider the ways through which the HPV knowledge was examined. The present study measures the perceptions and knowledge of respondents through closed-ended yes/no items. Data from a recent research indicates that higher knowledge of HPV considerably utilize close ended queries than open ended. Hence, the present study improved and extended upon prior studies aimed to examine the knowledge of HPV (CDC, 2008).

Healthcare workers play a significant role as a health promoter and educator. Therefore, low compliance and unsatisfactory knowledge with screening suggestions may lead to negative influence on the public in undergoing a Pap smear. The significance of having diagnostic tests should be re-highlighted and the importance of this issue in trainings for female health care workers should also be promoted (Nilaweera et al., 2012). Strategies for vaccination concerning HPV purely depend on the target audience for vaccination. Various catch-up vaccinations are considered in few nations with financial means including Saudi Arabia. In terms of HPV vaccination program, available data from numerous developed nations indicate that school-based vaccination result in higher coverage of vaccines in comparison to provider-based vaccination (Brabin et al., 2008; LaMontagne et al., 2011). PATH or (Program for Appropriate Technology in Health) conducted demonstration projects in low income countries that also indicated that vaccination programs conducted at school attains high vaccine coverage (80–95%) (Luciani et al., 2009). However, it also reveals that such program tend to miss a large number of girls population, not attending school.

5. Conclusion

The results of the study have indicated that there is a lack of awareness about HPV vaccination against cervical cancer in Saudi Arabia. It has been observed that both males and females are interested to take prevention initiatives by taking vaccinations either at any cost or free of charge offered by the Health Ministry. However, some of the participants refused to pay for HPV vaccination because it was too expensive. Moreover, females were also unaware about the importance of cervical cancer screening (Pap smear) for early disease detection and treatment. Further initiative should be implemented that can translate findings into strategies and messages to promote the vaccination of HPV throughout Saudi community. It is therefore recommended:

- The HPV vaccination should be made available all over the Kingdom of Saudi Arabia
- Ministry of health should distribute HPV vaccination free of cost as a part of pre-marriage national examination program.
- Ministry of Health and private hospitals should put in efforts to raise awareness among Saudi population through medical camping about the virus and its vaccination.
- Married females should be encouraged to get screened for cervical cancer Pap smear by gynecologist.

- Effective educational programs should be conducted to raise knowledge and awareness about the HPV vaccination and boost public confidence regarding the safety of vaccine.
- Evidence based behavioral interventions are needed to be implemented.

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Competing Interests Statement

The authors declare that they has no competing or potential conflicts of interest.

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Finite Element Analysis of Screw-Tightening Torque Applied to Custom and Conventional Abutment

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Abstract

The aim of this study was to design an abutment with an esthetic emergence profile contour using CAD technology and compare the stress distribution within the structure between the custom abutment and conventional abutment according to the screw tightening torque using 3D finite element analysis (FEA). The maximum tensile principal stress was found in the endpoint of the screw head and the start point of the screw line with regard to the application of the tightening torque of the screw. A similar pattern was observed in all of the following screws: 10N-cm, 20N-cm, and 30N-cm. The tightening torque of the screw had a significant impact on the changes in the stress of the abutment and screw fixture. This study also found that the condition in which the screw load was applied showed a more realistic description of the behavior of a single fixed dental implant than the condition in which the screw load was not applied. This study examined the optimal tightening torque value of the screw for the denture used in this study at a location slightly higher than 20N-cm. The difference in the custom abutment and conventional abutment did not have a significant impact on the supporting bone with regard to the external load. In regard to the stress occurring in the screw, the custom abutment had a lower degree of stress than the conventional type. Therefore, a screw fracture would occur less frequently in a custom abutment than a conventional abutment.

Keywords: custom abutment, CAD/CAM System, Finite Elements Analysis

1. Introduction

As implant prostheses have become more generalized, there has been a significant increase in aesthetic interest. Accordingly, it is important to continuously solve the issues of producing functionally excellent and aesthetically successful implants. Because the small diameter and uniform round shape of the fixture are different from the form of the tooth root of natural teeth, it is difficult to produce a crown in the form of lost natural teeth, and there are issues regarding the design of the abutment structure that supports a restoration (Bichacho, 1998; Ting, Wenhe, Ning, & Chunbo, 2010). The conventional abutment used in the fixture restoration is standardized, and the ease of use and suitability is excellent. On the other hand, there is a limitation in applying conventional abutments to all clinical cases. In other words, the use of a conventional abutment is limited in oral conditions, such as inappropriate location and angle of the fixture and poor thickness of the gum around that (Rieder, 1996). To solve the problems of conventional abutments, with the rapid development of latest computer technology, custom abutment production systems using computer-aided design and computer-aided manufacturing (CAD/CAM) have been introduced to dental clinics (Luthardt, Sandkuhl, Herold, & Walter, 2001; McLaren & Terry, 2002). The abutment production of the CAD/CAM system for dental clinics does not require a casting process that causes casting failure or inappropriateness, which can occur in abutment production, compared to existing casting methods, in the production of the abutment in the casting method. In addition, with the decreasing working hours of the operator, it was reported that the suitability and mechanical properties of the abutment are also excellent (Grossmann, Pasciuta, & Finger, 2006). A custom abutment can give an angle suitable for the oral health status in software or represent an appropriate margin shape in the gingival form, so an ideal upper implant can be produced. In addition, because its production is customized for individuals, an additional emergence profile can be given. Furthermore, the production of aesthetic implants is easy and oral hygiene management is relatively simple, which is good for the health of the surrounding tissues (Heydecke, Sierraalta, & Razzoog, 2002). Because implant prosthesis restorations are generally assembled systems that consist of three elements including upper implant,

abutment and fixture, the mechanical properties of each part change according to the conditions of the connection. Therefore, the transfer of power for each part differs, and there are differences in the joints and the distribution of internal stress of each part. (Wang et al., 2009) A fixture and an abutment are connected through a screw, and the conditions of the connection by the tightening torque can be an important factor affecting implant restoration (Alkan, Sertgöz, & Ekici, 2004). Prosthetic treatment using implants shows an approximately 5-10% failure rate, and it was reported that most cases are accompanied by a screw loosening phenomenon (Jung RE, Pjetursson BE, Glauser, Zembic, Zwahlen, & Lang, 2008), (Jemt, Linden, & Lekholm, 1992). To prevent this phenomenon, it was reported that the stability could be improved by giving an appropriate full weight load when connecting a fixture to an abutment (Jorneus, Jemt, & Carlsson, 1994; Binon, Franz, Brunski, & Gulbransen, 1994; Norton, 1999). The screw tightening torque affects the transfer of power, i.e., stress distribution between a fixture and the cortical bone and between an upper implant and the fixture. If the screw tightening torque is appropriate and the connection between the fixture and abutment is stable, even under the action of masticatory pressure, it would be as solid as the structure of the integrated fixture, and no screw loosening would occur. Similarly, despite the importance of the screw tightening torque in the restoration of implant prostheses, there has been little systematic research on the screw tightening torque of a custom abutment. An effective design, which can disperse an occlusal load during mandible function exercise and the load on the cortical bone, is required (Geng, Tan, & Liu, 2001; Clelland, Ismail, Zachi, & Pipko, 1991; Rieger, Adams, & Kinzel, 1990). Therefore, this study would design an abutment with an aesthetic emergence profile using CAD technology and compare the bio-mechanical difference between the custom abutment and conventional abutment according to the screw tightening torque through 3D finite-element analysis.

2. Materials and Method

2.1 Custom Abutment Design

To design a custom abutment, the proper position of the implant was acquired. For an implant-level impression, the position of the encoded healing abutment was arranged (MyD, RaphaBio, Seoul, Korea). An intraoral scanner (Trios, 3Shape, Copenhagen, Denmark) was used to obtain the scan data of the encoded healing abutment-level. The scan data was entered into the corresponding CAD software (MyD) (Figure 1A). First, using the surface fitting tool, the digital model of the encoded healing abutment and the library data was aligned into the scan body (Figure 1B). The result of the aligned model was obtained (Figure 1C). To obtain a functionally and esthetically proper result, a virtual prosthesis was selected from the authors' library database of artificial teeth (Figure 1D). The virtual artificial teeth were then fixed with CAD software of modification, movement, and rotation (Figure 1E). In addition, the shapes of the custom abutment were designed using the ball control with the recorded step. The long axis of the virtual prosthesis was set as the reference direction. In accordance with the long axis, the convergence angle of the custom abutment was set to 3.75° , and the radius of curvature upon upper angle area was set to 0.7 mm (Figure 1F). The margin was designed as a 1 mm-wide rounded shoulder (Figure 1G). Red ball control was used to set the length and width of the anatomical emergence profile design (Figure 1H). To satisfy the individual esthetics and cleaning needs, the cervical margin was set to 0.8–1 mm under an individual gingival margin. Twelve small-sized yellow ball controls were used to adjust the length and the volume of the collars under the cervical margin. This collar design allows the maximum tissue volume and stability of the gingiva. The abutment was also designed according to the natural shape of the prepared teeth (Figure 1I).

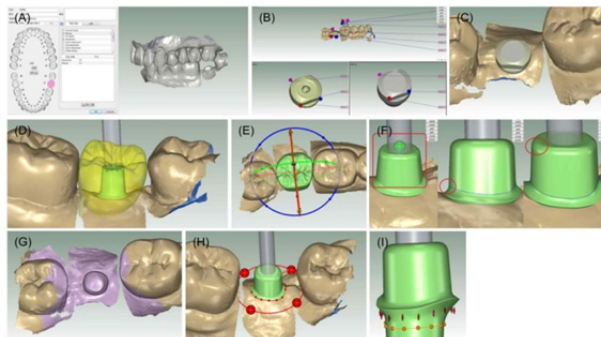


Figure 1. CAD for the custom abutment: (A) Entering the case information and scan data import; (B) Aligning the scanned body; (C) Overlapping of the scanned body; (D), (E) and (F) Setting the location and size of the abutment and the guide of path; (G), (F) Setting the location and the size of the abutment and the path guide; (G) Setting the design of the margin; (H) Setting the primary emergence profile; (I) Designing the abutment collar area

2.2 Finite-Element Model

For the path guide, (I) the abutment axial plane and angle site and (J) the margin and radius of abutment were set. For the cortical bone and cancellous bone of the human body, the entire structure part was assumed to be substances with isotropy, homogenization, and linear elasticity for finite-element analysis by anisotropy or numerical calculations. For modeling and finite-element stress analysis, the finite-element analysis general program, NX 10 (NX10.0.0.24, SIEMENS, Germany) Software was used. After the STL file of the custom abutment produced with the method described above was retrieved in the NX, a reverse design of the custom abutment was carried out using the method for producing the surface based on STL Geometry. Figure 2 shows 3-D images of the custom and conventional abutments. Only differing the shapes of the custom and conventional abutments, the fixture, screw, cortical bone, and cancellous bone were modeled in the same manner. The diameter of the screw was 1.8 mm, and the distance between the screw head and helix was 5.1 mm. In addition, the model employed in this study was a Dio implant system (4.5 mm diameter \times 11.5 mm; Dio, Busan, Korea), abutment screw (\varnothing 1.8 mm \times 8.5 mm; Dio), and custom abutment. The abutments, screws, and fixtures used in this study were used to examine the properties of the Ti-6Al-4V material actually produced. Table 1 lists the properties of the material used in this study (Akça & Iplikçioğlu, 2001). The Ti-6Al-4V alloy was reported to have an elastic coefficient of 117.0GPa and a Poisson's

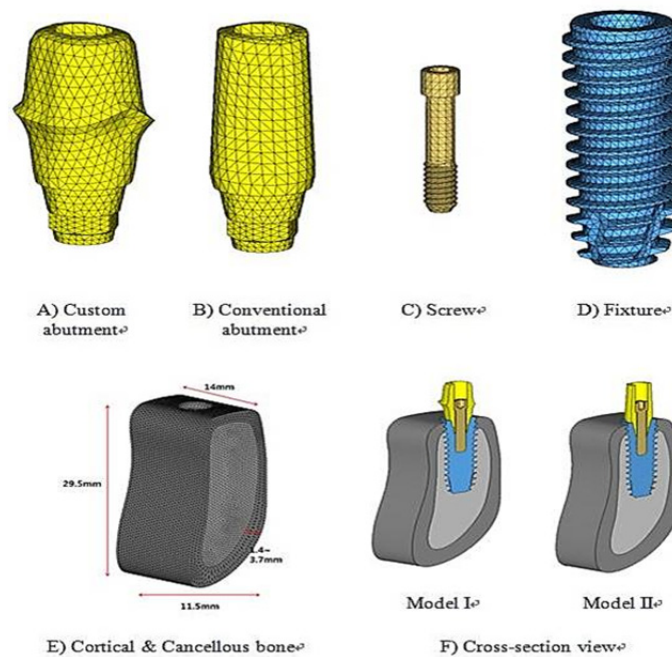


Figure 2. Three dimension analysis structure (Model 1): Custom Abutment, implant and screw in the bone

Ratio of 0.35; its yield strength is 880MPa for Grade 5 and its maximum tensile strength reaches 950 MPa. (Clelland, Ismail, Zachi, & Pipko, 1991), (Jemt, Laney, & Harris, 1991) The cortical bone was modeled in an image, in which the cortical bone with a thickness of 1.4-3.7 mm surrounded the outer angle of the cancellous bone. In contrast, the conventional abutment (4.5 mm diameter \times 11.5 mm; Dio, Busan, Korea) was designed by describing the image selling standard. The fixture was implemented with a diameter of 4mm and a length of 13 mm. Figure 2-f shows a section of the 3-D images of the custom and conventional models. The implant was positioned in the cortical and cancellous bone block. Such a configuration allowed a delicate simulation of all models in NX 10 (Siemens PLM Software, Germany). The three-dimensional CAD geometry models was imported into ABAQUS Workbench 6.12 to generate finite elements and perform the numerical simulation. All components were meshed with a 10-node tetrahedron element (mean size: 0.5 mm) using C3D10 type elements readily available in the ABAQUS element library (Table 1).

Table 1. Properties of the materials of the finite element model (Akça & Iplikçioğlu., 2001; Liu, Pearlman, Cooper, Hong, Wang, & Salatin, 2010)

Material	Elastic modulus (GPa)	Poisson ratio
Ti-6Al-4V (abutment, fixture, screw)	117.0	0.35
Supporting Bone	Cortical bone	13.7
	Cancellous bone	1.85

Table 2. Quantity of the elements of the finite element model

Material	Element	Shape	Mean Size
Abutment	Custom	4,732	Tetra 10 Node 0.5mm
	Conventional	3,329	
Screw	6,193		
Fixture	21,419		
Supporting Bone	Cortical bone	75,530	
	Cancellous bone	85,114	

2.3 Load and Bond Condition

A perfect bond was presumed because the fixture and cortical bone, and the fixture and screw are combined by the helix, and the fixture and abutment are also combined firmly by the screw tightening torque. On the other hand, a contact condition with a friction coefficient of 0.3 was used on the outside of the screw head and the inside of the abutment. Figure. 3-a shows this boundary condition. As in the Figure, both sides were bonded completely so that no movements to the X-, Y- and Z-axes could be made.

For the screw tightening torque, axial forces that come under 10N·cm, 20N·cm, and 30N·cm were calculated, and it was applied to the middle of the screw head and the helix, as shown in Figure. 3-b. For the screw axial force, the equation 1 (Brown, M, & B. Durbin, 2013) was used and the torque coefficient was assumed to be 0.2. Table 3 lists the calculated axial force.

$$T = KDF \quad (1)$$

where T = tightening torque (N·m), F = axial force (N), D = screw diameter (m), and K = torque coefficient.

A one point force of 175 N was applied 30° oblique to the long axis of the implant coming from the buccal direction. The equivalent stress on the abutment screw caused by the loading conditions were analyzed (Figure. 3-a). (Dong, Kebin, Jiang, Hua, Wenxiu, & Yuyu, 2015)

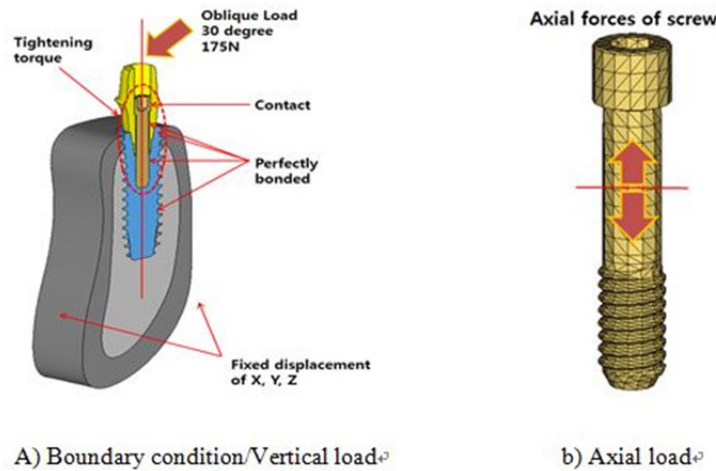


Figure 3. Quantity of the elements of the finite element model

Table 3. Axial force of the screw with regard to the tightening torque of the screw

Tightening torque	Diameter	Torque coefficient	Screw tension
10 N·cm	1.8mm	0.2	228 N
20 N·cm			556 N
30 N·cm			833 N

2.4 Fatigue Analysis

Goodman’s fatigue life theory (Budynas & Nisbett, 2008) was reported to be appropriate for a fatigue life evaluation by the static and dynamic loads. (Mahmut & Hasan, 2011)

$$\sigma_a = \frac{\Delta\sigma}{2} = \frac{\sigma_{max} - \sigma_{min}}{2} \tag{2}$$

$$\sigma_m = \frac{\sigma_{max} + \sigma_{min}}{2} \tag{3}$$

$$\frac{\sigma_a}{\sigma_e} + \frac{\sigma_m}{\sigma_u} = \frac{1}{n} \tag{4}$$

Goodman fatigue life theory using the mean stress σ_m and stress amplitude σ_a can be defined as follows: where σ_e is the fatigue limit; σ_u is the maximum tensile strength; and n is the fatigue safety coefficient. The Goodman safety coefficient was calculated, placing the fatigue limit of 510MPa in the above expression when the fatigue cycle of the Ti-6Al-4V material was 10^7 times, as listed in Table 6.

3. Results

3.1 Action of Screw Tightening Torque

By the action of the screw tightening torque, the tensile strength acts in the screw while compression strength acts in the abutment and fixture. Figure 4 shows the section of the custom prosthesis to which 20N·cm was applied, as well as the Max. and Min. Principal. The maximum tensile principal stress appeared in the bottom part of the screw head, and then in the part where the helix began. The maximum compressive stress occurred in the abutment connected to the screw head while in the fixture, it occurred in the part connected to the helix of the screw. In each load and bonding condition of this experiment, the action of the screw tightening torque showed a similar trend in the conventional abutment and custom abutment (Figures of 10N·cm and 30N·cm analysis are attached to the appendix).

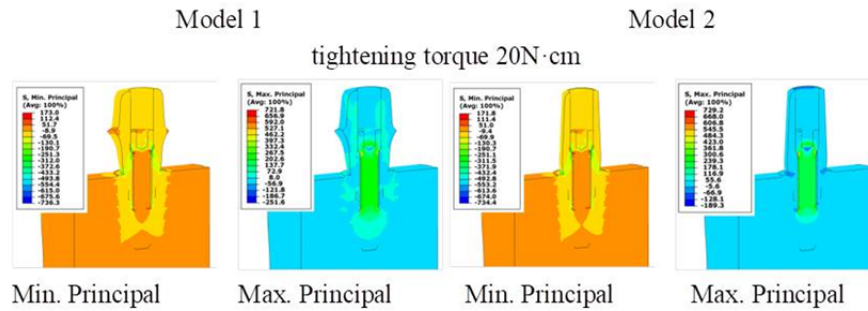


Figure 4. Results of the principal stress with regard to the tightening torque of 20N·cm screw in Models 1 and 2

3.2 Stress Behaviors of Custom/Conventional Abutment Prosthesis

Table 4 lists the stress when only the screw tightening torque was applied while no oblique loading was applied. Figure 5 shows the distribution of the custom and conventional stress when the screw tightening torque was 20N·cm. The highest stress occurred in the screw by the screw tightening torque, followed by the abutment and fixture. In addition, the maximum stress on the screw appeared at the bottom part of the screw head. The custom and conventional stress to the screw by the 10N·cm tightening torque were 287.2 MPa and 286.5 MPa, respectively, which are 33% of the yield strength of the material. The screw stress at 20N·cm was 573.9 MPa and 572.4 MPa, respectively, in the custom and conventional abutment, and 65% of the yield strength of the material which is at a slightly lower level than 75%. When a 30N·cm tightening torque was applied, the screw stress was 859.7 MPa and 857.6 MPa in the custom and conventional abutments, respectively, which is approximately 880MPa, the yield strength of Ti-6Al-4V. Figure 6 shows the distribution of the principal stress to the cortical bone when only a 20N·cm tightening torque was applied. For the cortical bone, the Max. and Min. Principal appeared in the opposite part, where the screw of the fixture came into contact with the cancellous bone. For the cancellous bone, Max. and Min. Principal appeared in a similar part in the helix, where it came into contact with the cortical bone. Table 4 shows that the difference in the shape of the custom and conventional abutments had little effect on the Max. and Min. Principal stress on the cortical bone. Table 5 lists the value of the stress of an analysis conducted, assuming the case in which there was no screw tightening torque and a case in which tightening torques of 10N·cm, 20N·cm, and 30N·cm were given and an oblique loading of 175N was applied together. An analysis without the screw tightening torque showed that the maximum stress occurred in the abutment, followed by the fixture and screw.

Table 4. Results of the stress distribution in Models 1 and 2 when applying only the tightening torque of the screw (unit: Mpa)

		10N·cm		20N·cm		30N·cm	
		Model I	Model II	Model I	Model II	Model I	Model II
Abutment (Von Mises Stress)		259.9	258.0	519.3	515.2	778.4	772.1
Screw (Von Mises Stress)		287.2	286.5	573.9	572.4	859.6	857.6
Fixture (Von Mises Stress)		204.3	204.3	408.6	408.5	612.0	612.0
Cortical bone	Max. Principal	1.5	1.5	3.0	3.0	4.5	4.5
	Min. Principal	-2.3	-2.4	-4.7	-4.8	-7.0	-7.1
Cancellous bone	Max. Principal	0.4	0.4	0.9	0.9	1.3	1.3
	Min. Principal	-0.7	-0.7	-1.4	-1.5	-2.1	-2.2

Model 1: custom-abutment implant system

Model 2: conventional-abutment implant system

Table 5. Results of the stress distribution in Models 1 and 2 with regard to the application of a tightening torque and oblique load of the screw (Unit: MPa)

		0		10N-cm		20N-cm		30N-cm	
		Model I	Model II	Model I	Model II	Model I	Model II	Model I	Model II
Abutment (Von Mises Stress)		274.6	265.1	347.0	334.9	536.9	568.6	822.7	823.7
Screw (Von Mises Stress)		49.2	54.9	309.9	317.6	593.5	601.4	879.7	887.2
Fixture (Von Mises Stress)		168.5	173.4	217.1	217.3	421.1	420.2	624.5	623.6
Cortical bone	Max.Principal	23.5	23.7	24.9	25.1	26.2	26.4	27.5	27.7
	Min.Principal	-35.2	-35.6	-36.6	-37	-37.9	-38.4	-39.1	4.9
Cancellous bone	Max.Principal	4.7	4.7	4.7	4.7	4.8	4.8	4.8	4.8
	Min.Principal	-2.2	-2.2	-2.7	-2.8	-3.3	-3.4	-3.9	-4.0

Model 1: custom-abutment implant system

Model 2: conventional-abutment implant system

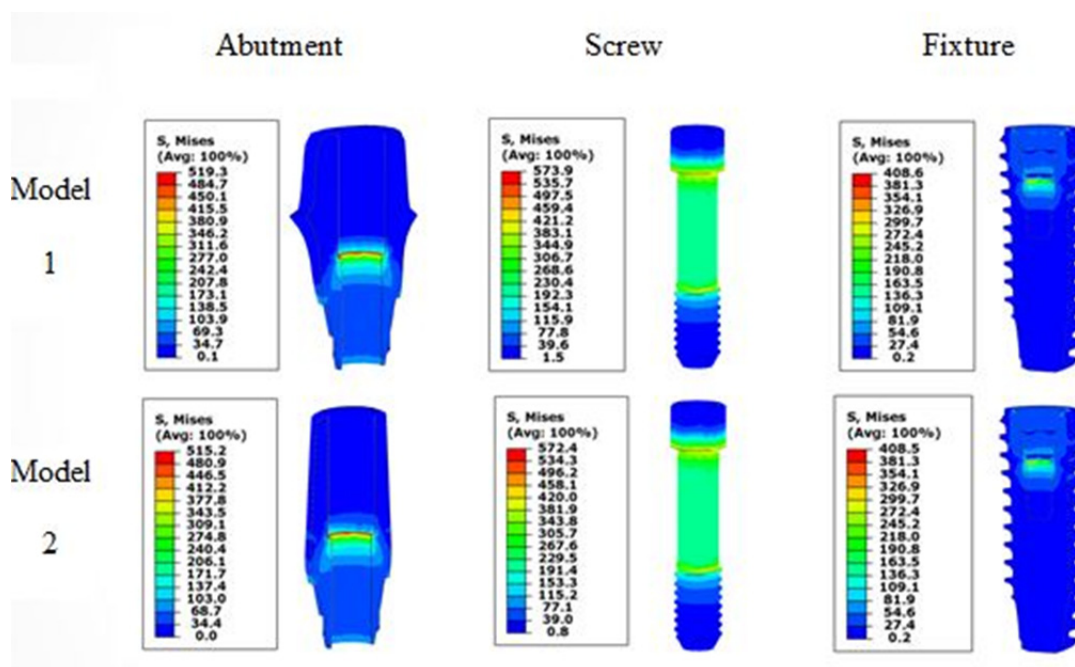


Figure 5. Von Mises stress distribution in Models 1 and 2 with the application of a tightening torque of 20N-cm screw

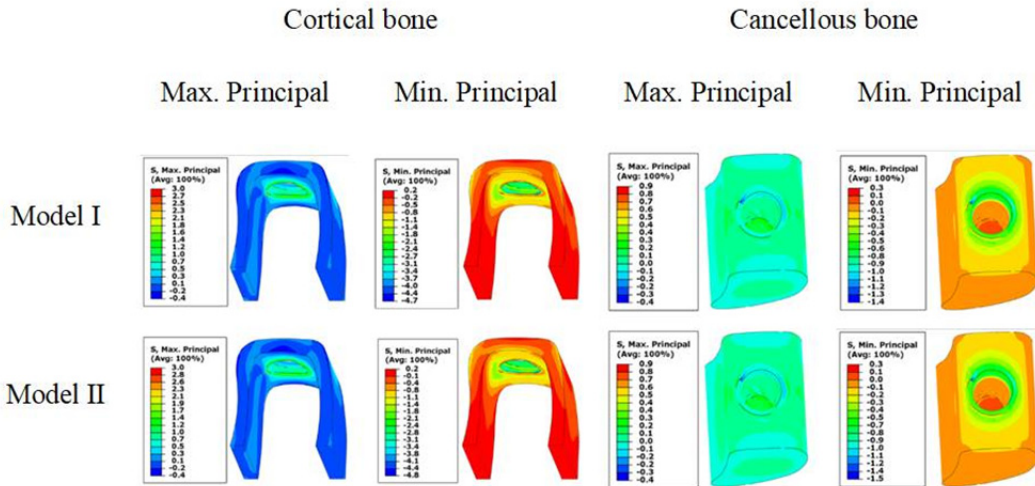


Figure 6. Principal stress distribution of the supporting bone in Models 1 and 2 with the application of tightening torque of a 20N·cm screw

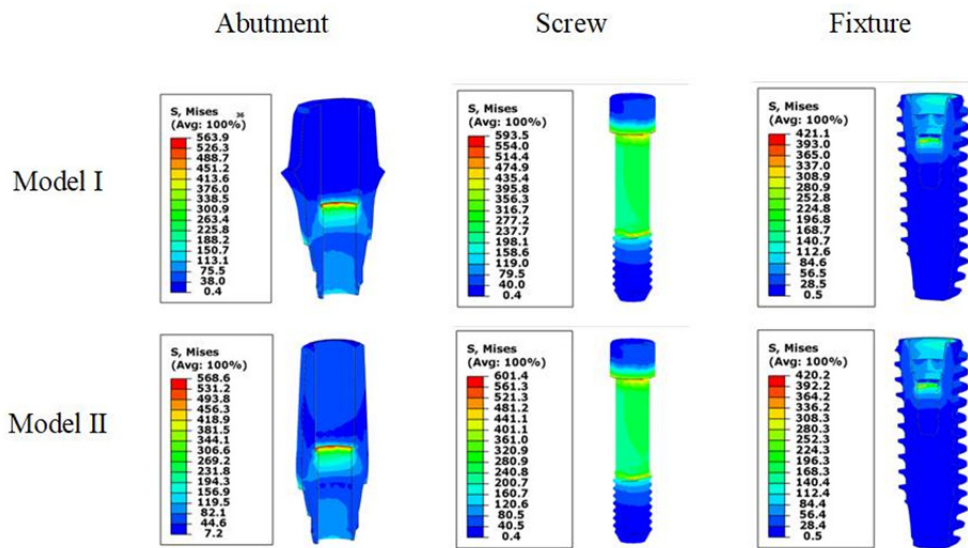


Figure 7. Von Mises stress distribution in Models 1 and 2 with the application of a tightening torque and oblique load of a 20N·cm screw

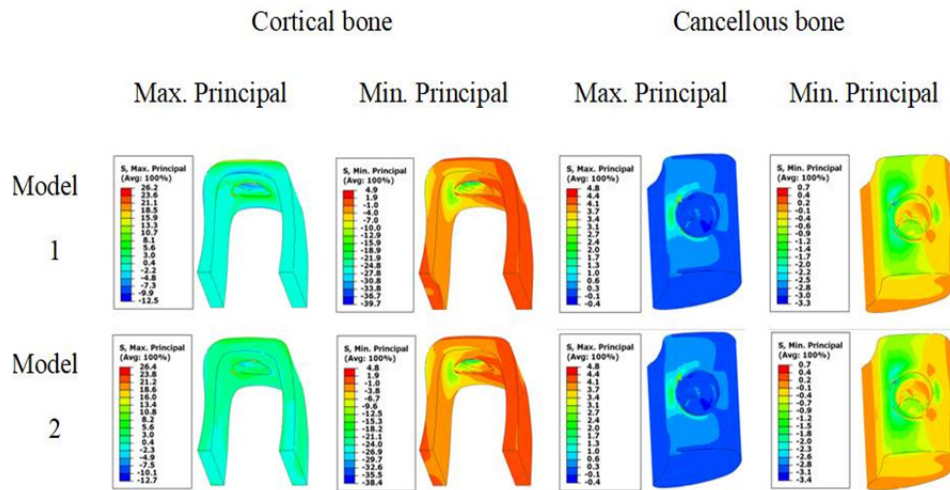


Figure 8. Principal stress distribution of the supporting bone in Models 1 and 2 with the application of a tightening torque and oblique load of a 20N·cm screw

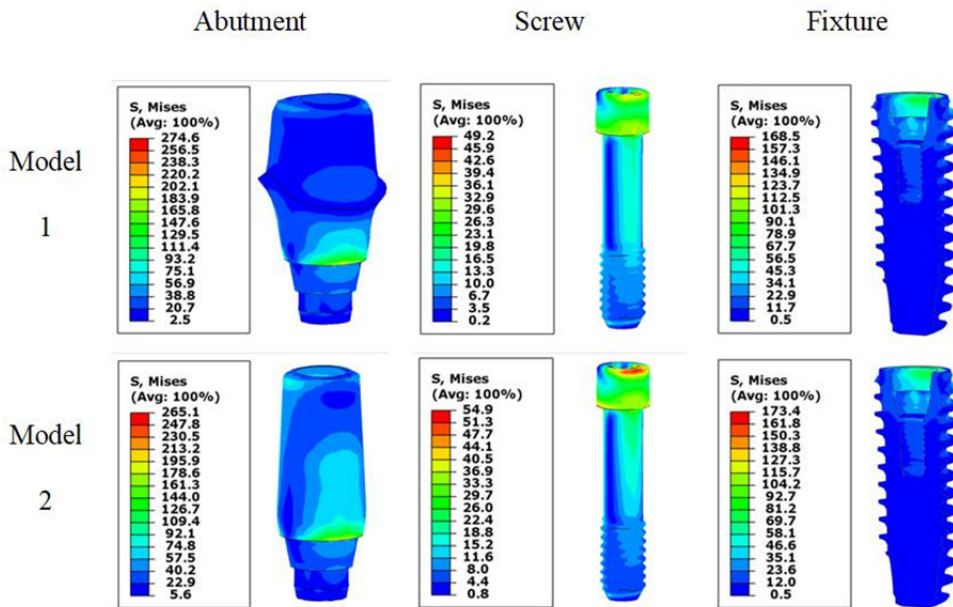


Figure 9. Von Mises stress distribution in Models 1 and 2 with the application of an oblique load when the tightening torque of screw is 0

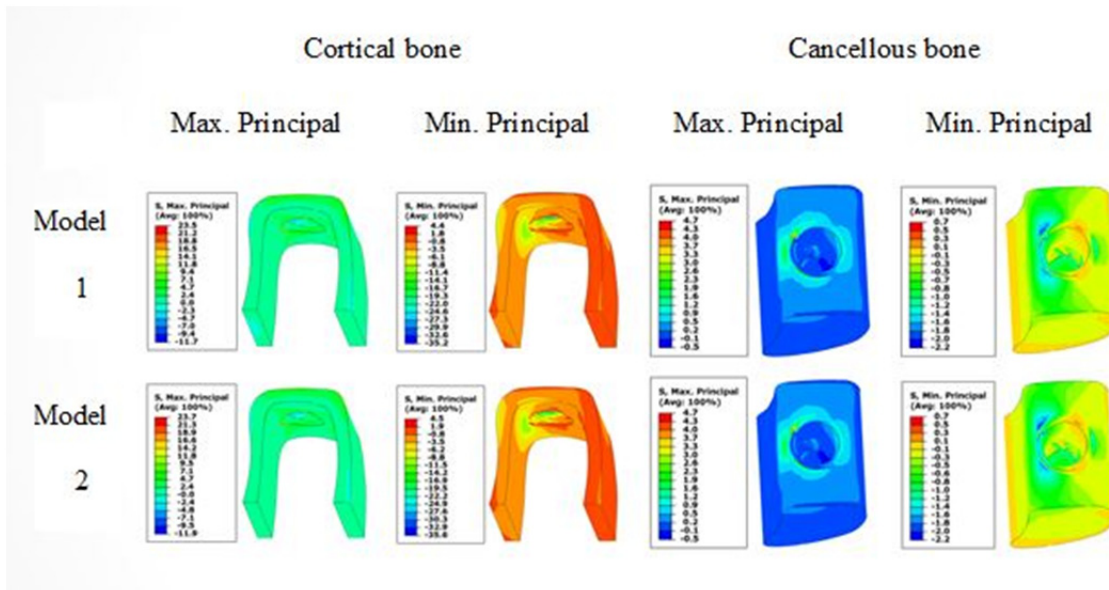


Figure 10. Principal stress distribution of the supporting bone in Models 1 and 2 with the application of an oblique load when the tightening torque of screw is 0

3.3 Fatigue Analysis

Based on table 6 for the under oblique load, the highest value of SF occurred at 10N cm. The second level of SF was at 20N cm, which were approximately at the same level. In addition, 30N cm had the third level of SF. The highest value of SF (3.0) was observed at 10N cm. A comparison of the SF of two type models showed a slight difference.

Table 6. Goodman safety factor value of the models in which the tightening torque and oblique load of screw are applied

Classification	10N-cm		20N-cm		30N-cm	
	Model I	Model II	Model I	Model II	Model I	Model II
Abutment	2.5	2.6	1.6	1.6	1.1	1.1
Screw	3.0	3.1	1.6	1.5	1.1	1.1
Fixture	4.4	4.4	2.2	2.2	1.5	1.5

4. Discussion

The aim of this study was to design an abutment with an aesthetic emergence profile using CAD technology and compare the bio-mechanical difference between the custom abutment and conventional abutment according to the condition of the screw tightening torque through a 3D finite-element analysis. In studies conducted previously to utilize the effect of the application of screw tightening torque, a method using the elongation displacement of the screw used by Sakaguchi and Borgersen et al. (Sakaguchi & Borgersen, 1995) and a method using the thermal contraction of the screw used by Alkan et al. (Alkan, Sertgoz, & Ekici, 2004) have been reported. Errors might appear in the research results in situations where abnormal physical conditions are given in the object of analysis, e.g., the screw in the method of screw thermal contraction, while it might be impossible to apply stress in both directions of the structure analyzed using the structure displacement method. Therefore, the tightening torque in this study was implemented so that only the torque would be applied by generating a tensile force as the screw is elongated by the turning force when the screw is connected in the fixture structure and the compressive stress that occurs in the screw head part contacting the inside of the fixture and in the contact interface between the female screw part and the male screw part. The problems raised as demerits of a screw maintenance fixture include that it requires more accurate suitability than a cement fixed type and that there is a reduction of the occlusal area because

of the hole for screw formed in the implant. The greatest clinical issues include loosening of the screw used to maintain and fix the implant and the problem caused by fractures from complex factors, such as the iterative masticatory load, incorrect fitting of the implant, application of a non-functional force, occlusal overload, abnormal occlusal relationship, fixture implant design or the defect of material. (Hebel & Gajjar, 1997; Singer & Serfaty, 1996; Chae, Jong, & June, 1997; Jorneus, Jent, & Carlsson, 1992; Kallus & Bessing, 1994; Haack et al., 1995; Burguete et al., 1994; Naert et al., 1992; Jemt et al., 1991; Rangert et al., 1995; Moon, 2002; Balshi, 1996; W. Becker & B. E. Becker, 1995). From the result of the action of the screw tightening torque (Figure 3-b), the compressive stress appeared in the abutment and fixture around the screw. Therefore, the axial force of the screw tightening torque was properly reflected in the analytical model. The key indicators, such as an abutment, fixture, and screw, were used to judge the fracture of a metal material with ductility to determine if the maximum torsional energy, Von Mises stress has reached the yield strength of the material. On the other hand, because a material with fragility like the cortical bone can judge the fracture through principal stress, this study showed the results of the analysis with the Von Mises stress for the abutment, fixture and screw and with the principal stress for the cortical bone. The maximum tensile stress and compression strength of the cortical bone were 100-130 MPa and 170-190 MPa, respectively, and that both the compressive stress and tensile stress of the cancellous bone should be below 5 MPa so that no fracture occurs. The results of Max. and Min. Principal stress on the cortical bone in Table 4 of this study show a stress below 5MPa, and that there is no large impact of the difference in the shape between the custom and conventional abutment on stress to the cortical bone. According to Paul Binon (Binon et al., 1994), many studies of the screw showed that the tightening torque applied to the screw to prevent loosening is appropriate when it is 75% of the torque that causes the material fracture. The screw is in charge of fixing an abutment to a fixture so that it does not move. On the other hand, screw loosening occurs if the tightening torque is weak, whereas if it is too high, the screw is broken and loses its function as an artificial tooth, and there is great difficulty in removing the helix of the broken screw. Therefore, proper management of the tightening torque is very important. According to the result of an analysis of the screw stress by a 10N·cm tightening torque, it was judged that screw loosening may occur if the masticatory load is conveyed repeatedly to the prosthesis. In contrast, in the 30N·cm one, the screw would be fractured if a strong external power is applied to the prosthesis from dozens to millions of times. In addition, in Table 5, as a result of the analysis, assuming a case in which no screw tightening torque was applied and a cases in which 10N·cm, 20N·cm, and 30N·cm full weight loads were applied with an oblique loading, when screw tightening torque was not applied, the maximum stress occurred in the abutment, followed by the fixture and screw. This tends to be different from the case, in which screw tightening torque was applied, and considering that the damage on implants occurs mostly in the screw in the clinic, it was judged that the cause for the occurrence in the clinic was not detected appropriately. In the results of the 20N·cm screw tightening torque and oblique loading in Table 5, the screw stress of Model 1 was 7.9 Mpa lower than that of Model 2 and the fixture was 0.9 MPa higher. The difference was within 1.5% of the total stress, but a custom abutment is better than a conventional one considering that a loss of function by prosthetic fracture occurs mostly in the screw. The difference between the custom and conventional abutments had little effect on the cortical bone. The Max. and Min. Principal stress on the cortical bone summarized in Table 5 is within the fracture criterion mentioned above, and there was almost no difference between the two models. In addition, fracture can occur in a metal material, even below the yield strength by the iterative load, which is called fatigue fracture. (Shackelford & James, 2005) This should be considered together because in a prosthesis, the screw tightening torque, static load and external force, dynamic load act simultaneously.

Table 6 lists the safety factor of custom implant system with three different tightening torques under the loading condition of oblique. The SF is often calculated based on the yield stress over the design stress. The minimum criterion value of the SF was assumed to be 1, which explains why the load generated in the structure reaches the failure limitation. All results of the safety coefficient exceeded the critical mass safety coefficient 1.0 that could endure a 175N oblique load 10 times. On the other hand, since the Goodman's safety coefficient of architectures or main machine parts is designed to be higher than 2.0-2.5, it was judged to be necessary to secure a safety coefficient at least about 1.5 for the prosthesis. Therefore, it is appropriate to determine the screw tightening torque around 20N·cm. The limitations of this study include the differences in the homogenization and isotropy of the cortical bone, which were set up as the initial hypotheses, and the actual occlusal force in the human body is a dynamic load, which is different from the static load in the duration and size of stress, so it is necessary to conduct studies of more precise material properties, model composition, and load application. In addition, because the parameter value of the custom abutment in a form limited to some patients was used, it is essential to conduct a study that can set up clinically allowable category guidelines in designing custom abutment in the future.

5. Conclusion

This study examined the stress behaviors of custom and conventional prostheses by an external load, and the following conclusion was obtained. *The screw tightening torque affected the changes in the stress* of the abutment, screw, and fixture. The status, in which the screw load was applied, described more realistic prosthesis fracture behavior than the one in which it was not. With the finite-element model used in this study, the appropriate screw tightening torque showed a stable stress dispersion when a 20N·cm screw tightening torque was applied more than when 10N·cm and 30N·cm ones were applied. The difference between the custom and conventional abutment has little effect on the cortical bone by the external load. Less screw fracture occurred in the custom abutment because the stress occurring in the screw showed a lower result in the custom abutment than in the conventional one.

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Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

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