Use of safety scalpels and other safety practices to reduce sharps injury in the operating room: What is the evidence?

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Accepted for publication Aug. 15, 2012

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DOI: 10.1503/cjs.003812

Background: The occupational hazard associated with percutaneous injury in the operating room (OR) has encouraged harm reduction through behaviour change and the use of safety-engineered surgical sharps. Some Canadian regulatory agencies have mandated the use of "safety scalpels." Our primary objective was to determine whether safety scalpels reduce the risk of percutaneous injury in the OR, while a secondary objective was to evaluate risk reduction associated with other safety practices.

Methods: We used evidence review methods described by the International Liaison Committee on Resuscitation and conducted a systematic, English-language search of Ovid, MEDLINE and EMBASE using the following search terms: "safety-engineered scalpel," "mistake proofing device," "retractable/removable blade/scalpel," "pass tray," "hands free passing," "neutral zone," "sharpless surgery," "double/cutproof gloving" and "blunt suture needles." Included articles were scored according to level of evidence; quality; and whether they were supportive, opposed or neutral to the study question(s).

Results: Of 72 included citations, none was supportive of the use of safety scalpels. There was high-level/quality evidence (Cochrane reviews) in support of risk reduction through double-gloving and use of blunt suture needles, with additional evidence supporting a pass tray/neutral zone for sharps handling (4 of 5 articles supportive) and use of suturing adjuncts (1 article supportive).

Conclusion: There is insufficient evidence to support regulated use of safety scalpels. Injury-reduction strategies should emphasize proven methods, including double-gloving, blunt suture needles and use of hands-free sharps transfer.

Contexte : Les risques professionnels associés aux lésions percutanées subies à la salle d'opération ont favorisé la réduction des préjudices grâce à des changements de comportement et à l'utilisation d'aiguilles et de lames chirurgicales conçues en fonction de la sécurité. Certaines agences de réglementation du Canada ont imposé l'utilisation de « scalpels de sécurité ». Nous voulions déterminer principalement si les scalpels de sécurité réduisent le risque de lésions percutanées à la salle d'opération et, dans un deuxième temps, évaluer la réduction du risque associée à d'autres mesures de sécurité.

Méthodes : Nous avons utilisé des méthodes d'examen des données probantes décrites par le Comité international de liaison sur la réanimation et procédé à une recherche systématique en anglais dans les bases de données Ovid, MEDLINE et EMBASE en utilisant les termes de recherche suivants : « safety-engineered scalpel », « mistake proofing device », « retractable/removable blade/scalpel », « pass tray », « hands free passing », « neutral zone », « sharpless surgery », « double/cutproof gloving » et « blunt suture needles ». Nous avons évalué les articles inclus en fonction du niveau de preuve, de la qualité et de la prise de position en faveur des questions à l'étude, contre celles ci ou neutre.

Résultats : Sur 72 citations incluses, aucune n'appuyait l'utilisation des scalpels de sécurité. Des éléments probants de haut niveau ou de grande qualité (examens Cochrane) appuyaient la réduction des risques par le port de doubles gants et l'utilisation d'aiguilles émoussées, et d'autres éléments de preuve appuyaient l'utilisation d'un plateau de transition ou d'une zone neutre pour la manipulation des aiguilles ou des lames (4 articles sur 5 en faveur) et l'utilisation de moyens auxiliaires de suture (1 article en faveur).

Conclusion : Il n'y a pas suffisamment de preuves pour appuyer l'utilisation réglementée de scalpels de sécurité. Les stratégies de réduction des traumatismes devraient mettre l'accent sur les méthodes éprouvées, y compris le port de doubles gants, l'usage d'aiguilles émoussées et l'utilisation de moyens mains libres de transfert des aiguilles et des lames.

Awareness of the transmissibility of blood-borne infectious agents, including HIV and hepatitis B has led to the identification of percutaneous sharps injury resulting in exposure to blood-borne pathogens as an important occupational health hazard for people employed in the health care industry. After inpatient wards, the second most common site of sharps injuries is the operating room (OR). About 40% of patients undergoing surgery have a potentially transmissible, blood-borne illness, which puts a substantial proportion of OR staff (nurses, surgeons, surgical assistants) who experience a sharps injury during surgery at risk of serious illness.[1]

The Occupational Safety and Health Administration (OSHA) from the U.S. Department of Labor signed The Needlestick Safety and Prevention Act into law in 2000.[2] The act effectively mandated employers to "identify, evaluate, and implement" safer medical devices, including devices used in the care of patients during surgery. Despite the legislation, the use of scalpels that have been specifically designed to reduce the risks of staff injury (hereafter referred to as "safety scalpels") in ORs in the United States has been estimated to be less than 10%.[1]

In Canada, jurisdictional responsibility for employee safety rests with individual provinces. Although many of the provinces have introduced occupational health regulations that require use of safety-engineered devices, most regulations target the use of hollow bore needles.[3] However, the province of British Columbia's employee safety regulatory agency, WorkSafeBC, has introduced a regulation mandating the use of safety scalpels in all ORs in the province.[4] Although exemptions from the regulation are permitted on the basis of "not clinically appropriate to patient care," a written justification is required, without which hospitals are judged to be noncompliant and subject to financial penalty.

Given the controversy surrounding this provincial regulation and a concern that it has been implemented without clear evidence of the effectiveness of safety scalpels in mitigating percutaneous sharps injury, the primary objective of the present study was to evaluate the evidence supporting the use of safety scalpels in reducing percutaneous injury in the OR. With an awareness of the potential benefits of other injury-mitigating practices or devices (e.g., double-gloving, blunt suture needles), the scope of our evaluation was broadened to include other devices or practices that might be associated with risk reduction of percutaneous injury.

Methods

We used evidence review methods described by the International Liaison Committee on Resuscitation (ILCOR).[5] Unlike Cochrane reviews, ILCOR evidence reviews permit consideration of literature other than randomized controlled trials (RCTs) or meta-analyses of RCTs in determining literature consensus. We selected search terms for this study based on a review of select articles on the topic and on expert surgical and nursing opinion. We performed a systematic, English-language search of Ovid, MEDLINE and EMBASE using the terms "safety-engineered scalpel," "mistake proofing device," "retractable/removable blade/scalpel," "pass tray," "hands free passing," "neutral zone," "double gloving," "cut-proof gloves," "glove liners" and "sharpless surgery."

Articles were included if they were RCTs or meta-analyses of RCTs (level 1), case series using concurrent (nonrandomized) controls (level 2), case series using retrospective controls (level 3) and case series without a control group (level 4). Exclusion criteria were nonhuman participants, non–English language, abstract only, review articles and articles without a study group intervention and/or a sharps injury outcome.

Two of us (K.D. and E.S.) evaluated all articles and classified them by evidence level and by the observed effect of the intervention on outcome (observed or reported percutaneous sharps injury or proxy, such as surgical glove perforation). The effect of the intervention was categorized as supportive (reduces sharps injury or proxy), neutral (no effect) or contradictory (increases sharps injury or proxy). Finally, each article was given a methodological quality score (i.e., good, fair, poor) based on criteria specific to each level of evidence, as described in the ILCOR evidence review guidelines.[6]

Results

The literature search yielded 362 citations. After excluding articles according to our criteria, 72 were eligible for inclusion, 62 of which dealt with either double-gloving or the use of blunt suture needles. Both subject article sets included recent Cochrane reviews that clearly confirmed the benefit of both practices in reducing percutaneous injury, surgical glove perforations (a proxy for percutaneous injury) or both.[7,8] Since our review would not add to pre-existing, strongly supportive evidence in favour of either practice, we excluded articles pertaining to double-gloving and the use of blunt suture needles. This left 10 articles for analysis; they are summarized in Table 1 and discussed in detail in the following sections (in addition to the Cochrane review summaries on the effects of double-gloving and sharp versus blunt suture needles on sharps injuries).

Safety scalpels

We did not find any articles that specifically evaluated harm-reduction associated with the use of safety scalpels. One study from the Exposure Prevention Information Network (EPINet), a sharps injury registry in the United States that collects and reports injury data from the 66 hospitals that belong to the network, compared injuries

in surgical settings occurring before (1993–2000) and after (2001–2006) implementation of national needle stick legislation.[1] Although injuries in nonsurgical settings decreased, injuries in surgical settings increased by 6.5% (95% confidence interval [CI] 1.3%–12%) after the legislation was introduced. Scalpels accounted for 17% of all surgical setting injuries and were second in frequency to suture needles, which accounted for 43% of injuries. The proportion of injuries attributable to safety-engineered devices was less than 1% for both study periods (suggesting very low adoption rates of these devices), and no data on the injury rates of safety scalpels versus traditional

Table 1. Studies included in the review of practices to reduce sharps injury in the operating room

Study	Year	Study population	Methods	Reported outcome	Comment	Level of evidence
Jagger et al.[1]	2010	87 hospitals in the United States: 31 324 sharps injuries, 7186 to surgical personnel.	Compared injury rates in surgical and nonsurgical settings before and after passage of law mandating use of safety-engineered needles and other sharps.	Injuries increased in the surgical setting and decreased in the nonsurgical setting; 75% of injuries occur while passing or using devices.	Does not specifically address the issue. Low uptake of safety scalpels in the surgical community. Unsure of role of safety scalpels.	3 Fair (N)
Watt et al.[9]	2009	Systematic review of MEDLINE, EMBASE, CINAHL, Current Contents, PubMed, Cochrane Library and Australasian Medical Index.	19 articles were chosen based on an independent assessment by 2 reviewers.	Gloves plus liners decreased glove perforations in comparison with double latex gloves but lessen dexterity and sensation; HFT benefit was equivocal.	Quoted 1 study that modelled safety efficacy scenarios by comparing a scalpel blade remover used in conjunction with a pass tray versus a safety scalpel (with a variable rate of correct activation). Estimated that a pass tray was more likely to prevent injury than a safety scalpel.*	1 Good (S)
Stringer et al.[10]	2009	3 control hospitals and 3 intervention hospitals.	Observational study looking at HFT before and after an educational video. Observers noted percentage of hands-free passes and subsequent PIs, glove tears or mucocutaneous contamination.	HFT and the use of an HFT video were effective in reducing sharps injuries.	Data relied on circulating nurses to collect information. PI, glove tears, mucocutaneous contamination incidents were thought to be under-reported.	2 Good (S)
Stringer et al.[11]	2002	1 large urban hospital.	Observational study where the proportion of HFT and the incidence of PI, contaminations and glove tears were observed.	HFT was most effective in reducing PI when surgical blood loss was > 100 mL.	HFT was considered to be used when at least 75% of passes were hands-free. Glove type was not controlled. Incidents were self-reported.	2 Good (S)
Folin et al.[12]	2000	1 hospital in Sweden: 357 procedures in period 1 and 383 procedures in period 2.	For period 1, surgeon used traditional passing; in period 2, they used the HFT.	HFT decreased injuries.	Used voluntary reporting of injury by staff.	3 Fair (S)
Eggleston et al.[13]	1997	1 hospital: 156 cesarean deliveries studied.	Randomized prospective trial of HFT in cesarean deliveries.	No benefit from using HFT but also no adverse impact.	Types of gloves were not controlled.	1 Good (N)
Bebbington and Treissman[14]	1996	1 hospital.	Prospective randomized trial of obstetrical repairs after vaginal delivery comparing use of sharps holder (SutureMate) to usual technique; gloves were then analyzed for tears.	476 glove sets were evaluated, and SutureMate reduced the perforation rate. Family physicians were also included in the study and benefited the most from the device.	Choice of instruments, sutures, assistance, repair technique and positioning of the patient were at the discretion of the physician. No information on use of double-gloving.	1 Fair (S)
Tokars et al.[15]	1992	1 hospital.	Observational case series that correlated the degree of HFT during surgery with sharps injuries.	Use of HFT decreased sharps injuries.	HFT was classified as > two-thirds of sharps transferred being hands-free.	4 Fair (N)
Bell and McNicholl[16]	2009	1 UK hospital emergency department and department of plastic surgery.	Clinical study with no control group: 20 randomly selected patients had incisional wounds sutured with a "needle catcher" device.	Use of the needle catcher produced no needle stick injuries during the study.	No control group. Operators were allowed to practice with the device before use. An observer recorded data.	4 Poor (S)
Corlett et al.[17]	1993	100 laparotomy procedures at 1 hospital.	Randomized prospective study of abdominal closure techniques: hand used to support abdominal wall versus use of instruments.	Fewer glove perforations in the instrument group.	Surgeons self-reported glove perforations and also handed in gloves for testing for perforations.	1 Fair (S)

HFT = hands-free technique; N = neutral; PI = percutaneous injury; S = supportive.
*Fuentes H, Collier J, Sinnott M, et al. "Scalpel safety": modeling the effectiveness of different safety devices' ability to reduce scalpel blade injuries. *Int J Risk Safety Med* 2008;20:83-9.

scalpels were provided. A systematic review conducted on behalf of the Australian Government's Department of Health for the Royal Australasian College of Surgeons did not identify any RCTs that addressed the effect of safety scalpels on percutaneous injury in the OR.[9]

Use of a "hands-free" technique during surgery

Five studies examined the effects of a hands-free technique (HFT), which is defined as the prevention of simultaneous handling of the same surgical sharp by 2 members of the surgical team. One RCT evaluated glove perforations during 156 cesarean sections.[13] Surgical teams were randomly assigned to use either a surgical pass tray or to use traditional sharp instrument transfer techniques (control group). The glove perforation rate in the pass tray group was 19% versus 16.1% in the control group ($p = 0.50$). This study was adequately powered to detect a 15% difference in rates of glove perforation between groups.

A study by Folin and colleagues[12] was supportive of the use of HFT to reduce blood exposures during orthopedic surgery. In this study, blood exposures were recorded before and after the OR implementation of a hands-free/no touch technique. The total number of exposures after implementation was significantly reduced (compared with preimplementation controls) for scrub nurses, and there was a trend toward reduction for first assistants, but the number of exposures was not reduced for surgeons. Two studies by Stringer and colleagues[10,11] evaluated the effect of HFT (defined as having been implemented when at least 75% of all transfers were hands-free) on percutaneous injury rates among OR staff. Their first study, a case–control study of more than 10 000 surgeries in which HFT was used 75% or more of the time, reported that the incident (i.e., percutaneous injury, glove tear, contaminations) rates, which were adjusted for emergency status, time of day or nurses' perceptions of OR noise, were 35% lower (odds ratio 0.65, 95% CI 0.43–0.97) when the HFT was used.[10] In a second observational study of 3700 operations over a 6-month period at a large, urban hospital, use of the HFT reduced percutaneous injury rates by 59% (95% CI 23%–72%) after adjusting for type and duration of surgery, emergency status, noisiness, time of day and number of staff present in the OR.[11] Tokars and colleagues[15] prospectively observed nearly 1400 surgeries and evaluated the percutaneous injury risk associated with 10different practices, including the HFT. In this study, HFT use was categorized as less than one-third, one- to two-thirds and more than two-thirds. Compared with using HFT less than two-thirds of the time, using HFT more than two-thirds of the time was not associated with protection against percutaneous injury for either surgeons (odds ratio 1.0, 95% CI 0.6–1.5) or nurses (odds ratio 0.5, 95% CI 0.2–1.4).

Suturing adjuncts to reduce percutaneous injuries

This safety theme category included 2 suture assist devices and 1 suturing technique. Bebbington and Treissman[14] described the use of SutureMate in an RCT studying glove perforations during postdelivery vaginal repair. They observed a significant reduction of glove perforations in the SutureMate arm versus the control arm. A second study (case series reported in a letter to the editor) described a novel "needle catcher" device that was attached to the top of a tissue forcep and permitted suturing with "reduced needle exposure."[16] An RCT compared the incidence of glove perforation during laparotomy closure using either a "hand in" (i.e., hand supporting the abdominal wall during suture placement) technique versus a "no touch" (wound edges handled by forceps only) technique and demonstrated a significant reduction in the rate of glove perforation with the no touch technique.[17]

Use of blunt suture needles

There is abundant high-quality evidence that the use of blunt suture needles significantly reduces the risk of percutaneous injury among surgical staff across a spectrum of operations. A recently published Cochrane review evaluated 10 RCTs involving nearly 3000 surgeries, including abdominal closure, cesarean sections, vaginal repair or hip replacements, reported outcomes of either glove perforations or self-reported needle stick injuries.[8] The use of blunt needles compared with traditional suture needles reduced the risk of glove perforation, with a relative risk (RR) of 0.46 (95% CI 0.38– 0.54), and reduced the risk of self-reported injury, with an RR of 0.31 (95% CI 0.14– 0.68).

Double-gloving

A Cochrane review to assess the effects of double-gloving on innermost glove perforations unequivocally supports double-gloving as a safety strategy.[7] Fourteen RCTs comparing double-gloving versus 1 set of surgical latex gloves demonstrated significantly more perforations of single gloves (odds ratio 4.10, 95% CI 3.30–5.09). Variants of double-gloving (i.e., triple-gloving, knitted-gloving, wearing cloth liners between latex gloves) were also shown to protect against innermost glove perforations.

Discussion

Data from the National Institute for Occupational Health and Safety suggest that every year 600 000–800 000 American health care workers experience percutaneous sharps injuries.[18,19] Although most injuries occur in non-OR settings, about 25% occur among OR personnel.[1] Operating room nurses or technicians are twice as likely as surgeons or surgical residents to be injured. The phenomenon of

injury under-reporting is well documented, with estimates ranging from 10% to 30% of all sustained injuries.[20,21] In addition to the risk of infectious transmission from patient to OR staff associated with blood or bodily fluid exposure, OR staff glove perforations occurring during surgery may also increase the risk of surgical site infection.[22]

These data clearly reflect a need to increase OR safety through the adoption of practices and/or technology that reduce the risk of sharps injury. However, before adopting OR practice changes or safety-engineered devices intended to increase workplace safety, it is essential that careful consideration be given to the evidence in support of such changes. What may appear intuitively to be a safe practice or device may prove to be no safer or even less safe after adoption. Such an unexpected outcome likely reflects a combination of factors, including a failure on the part of OR staff to correctly follow safety protocols, a flawed design or inadequate testing of a device before its release and a general resistance to the adoption of new practices or devices over those that are traditional and familiar.

We undertook this study to determine what evidence exists to support the use of safety scalpels. In anticipation of scant data specific to safety scalpels, we expanded our search to include other safety-engineered devices or practices that might reduce the risks of percutaneous sharps injury during surgery. Rather than conduct a Cochrane-type systematic review, we used an alternative method of evidence review adapted from the ILCOR, which permits inclusion of evidence other than RCTs or meta-analyses of RCTs. Our review confirms the protective benefit of double-gloving and the use of blunt suture needles. In addition, our review suggests there is likely to be a safety benefit associated with modified techniques of OR sharps handling; an HFT of sharps passing between members of the OR staff and the avoidance of the "hand in" method of abdominal wall retraction during suture closure both appear to reduce the risks of percutaneous injury.

Our review also confirmed the lack of evidence to support the routine use of safety scalpels. Not only are there no reported outcome studies related to safety scalpel use, sharps injury surveillance data as collected by EPINet does not clearly distinguish the use of safety scalpels from disposable (but not safety-engineered) scalpels.[23,24] Another limitation of EPINet surveillance data is that it is provided voluntarily by a very small subset of health care centres (66) in the United States; therefore, the data may not accurately reflect true injury rates attributable to scalpels. Canadian sharps injury surveillance occurs through the 12–volunteer hospital Canadian Needle Stick Surveillance Network (CNSSN), which monitors health care workers exposed to blood and bodily fluids and their seroconversion as a result of exposure. No injury data specific to the use of scalpels is collected or reported in Canada.

Safety scalpels are disposable scalpels with a safety mechanism that typically involves a retractable plastic guard that, when actively deployed, sheaths the scalpel blade. At least 24 such devices have been developed by surgical instrument companies and approved for use in the United States.[25] An essential step in the development of novel therapeutics and medical devices is the process of "failure mode and effects analysis."[26] With this methodology, a step-by-step process for identifying all possible device failures with a prediction of the consequences of failures and prioritization by impact severity (for staff and patients), frequency of occurrence and ease of detection of device failure is conducted. It is not clear how many (if any) of the safety scalpels currently approved for use have been subject to this rigorous evaluative process, which is particularly concerning when one considers that both patients and staff may be adversely affected if the device is not used or does not perform in the intended manner.

Despite a lack of evidence for their effectiveness, there have been recommendations and, in some instances, imposed regulations mandating the use of safety scalpels to reduce occupational injury risk in the OR. In British Columbia, WorkSafeBC has mandated the use of safety scalpels in all ORs in the province. Although surgeons can request operative case-specific exemption from the use of safety scalpels if they feel its use is "clinically inappropriate," — meaning that the use of the safety scalpel somehow compromises the surgeon's ability to perform the operation in a safe and familiar manner — WorkSafeBC has imposed a blanket implementation of a single vendor–contracted safety scalpel without having obtained surgeon feedback and without having attempted to monitor or report pre-versus postimplementation injury rates. The outcome of this implementation should serve as a warning for Canadian surgeons in other provinces who may face similar imposed regulations in the future. Surgeons in British Columbia have publicly expressed their dissatisfaction with, first, the cumbersome shape of the handle and difficulty of safety sheath deployment, especially when gloves are greasy, and second, the obscured view of the surgical field resulting from the profile of the safety shield.[27] Equally concerning has been the reporting of several injuries in B.C. hospitals that have been directly attributed to attempts to deploy the safety shield. These injuries have included a stab laceration to a nurse during surgery in a patient with hepatitis B and the inadvertent disengagement of a sheathed blade into a patient wound (Dr. N. van Laeken, Providence Health Care, Vancouver, BC: personal communication; 2012). In both cases, a causal analysis (conducted by the hospital's quality and safety committee) concluded that the injuries likely resulted from a lack of familiarity with the operation of the safety scalpel, a frequently overlooked risk associated with imposed technology changes in the OR.

Although regulatory agencies, such as WorkSafeBC, have advocated for widespread use of safety scalpels,

organizations that specifically advocate for surgeons and the quality of the care they provide have not. The American College of Surgeons (ACS) recommends the adoption of the practices of double-gloving, use of blunt suture needles and the adoption of a "neutral zone or hands-free technique" for surgical sharps passing. With regard to the use of safety-engineered scalpels, the ACS states:

> Engineering sharps injury prevention (ESIP) mechanical devices hold promise in providing varying degrees of mechanical protection from sharps injuries involving suture needles and scalpel blades. Manufacturers of ESIP devices approved by the U.S. Food and Drug Administration have been allowed to claim prevention of sharps injury as a feature of their use… There are no studies published to date that demonstrate the clinical effectiveness of ESIP devices. The ACS recommends the use of ESIP devices as an adjunctive safety measure to reduce sharps injuries during surgery except in situations where it may compromise the safe conduct of the operation or safety of the patient.[28]

Limitations

A limitation of this study is the fact that its results cannot be used to specifically inform practice changes targeting injury reduction in Canadian ORs. However, this is not so much a limitation of the study or its design, but rather of the limited reporting of non–needle stick sharps injuries in North America. A lack of data that specifically classify sharps injuries by sharps type (i.e., conventional v. safety-engineered) makes it impossible to prove or refute the hypothesis that safety scalpels will reduce occupational injury. Another limitation of the study is that it fails to address the issue of patient safety associated with the adoption of safety scalpels, which must be considered when one is proposing OR practice or equipment change. It seems unlikely that such specific risk–outcome data will ever be available, so as a result, changes in OR practice based on best available evidence and/or expert consensus will need to be evaluated in a prospective manner to be sure that employee and patient safety outcomes are consistent with expectations.

Conclusion

At this time, there is insufficient evidence to support regulated use of safety-engineered scalpels. Injury-reduction strategies should focus on the use of hands-free sharps transfer techniques and double-gloving of OR staff, as these practices are supported by evidence and should be relatively easy to implement in our ORs. Safety-engineered surgical equipment targeting sharps injury reduction should be subject to rigorous safety systems evaluation (failure mode and effects analysis) before coming to market. Finally, any new device or practice that is introduced into the OR to improve staff safety must be shown to be equally safe for the patients, whose treatment may be modified as a result.

Competing interests: None declared.

Contributors: K. DeGirolamo, D. Courtemanche, E. Skarsgard and A. Kennedy designed the study. K. DeGirolamo, D. Courtemanche and A. Kennedy acquired the data, which K. DeGirolamo, D. Courtemanche, W. Hill and E. Skarsgard analyzed. K. DeGirolamo, D. Courtemanche and E. Skarsgard wrote the article. All authors reviewed the article and approved its publication.

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