Executive Summary

Scalpel safety in the Operative Setting

(Adapted from the report of the Review Group by Amber Watt)

Objective

To identify and assess the efficacy and effectiveness of devices and procedures designed to lower the incidence of scalpel injuries in the operative setting, through a systematic review of the literature.

Methods

Search strategy – Studies were identified by searching MEDLINE, EMBASE, CINAHL, The Cochrane Library, Current Contents, PubMed and AMI from inception to December 2006. The Clinical Trials Database (US), NHS CRD Database (UK), The National Research Register (UK) and the Meta Register of Controlled Trials were also searched in January 2007.

Study selection – Included for review were randomised controlled trials (clinic and laboratory based), randomised comparative studies, non-randomised comparative studies, observational studies, surveys and modelled data. Outcomes examined included rates of glove perforation, injuries and user satisfaction.

Data collection and analysis – Data from the included studies was extracted by an ASERNIP-S researcher using standardised extraction tables developed *a priori* and checked by a second researcher. Studies that were sufficiently homogeneous were examined by meta-analysis. Heterogenous studies that did not meet the criteria for meta-analysis were reported qualitatively.

Results

A total of 19 studies were included in this review: 13 examining cut-resistant gloves and glove liners; three assessing the hands-free passing technique; one reporting on protective footwear; one investigating the feasibility of sharpless surgery and one evaluating a single-handed scalpel blade remover. Seven of these studies were randomised trials (NHMRC Level II), three were non-randomised comparative studies (Level III-2), two were comparative studies with historical controls (Level III-3), one was a Level IV study and seven were experimental studies to which the NHMRC Hierarchy of Evidence could not be applied.

In both clinical and experimental (laboratory) conditions, the use of a cut-resistant glove or glove liner reduced the number of inner latex glove perforations in comparison to double latex. While statistical pooling of the data pertaining to cloth gloves confirmed a significant protective effect resulting from the use of cloth gloves, there were not enough studies reporting outcomes on each
glove material to be able to determine which material was the most effective in lowering the rate of inner latex glove perforation overall. Furthermore, given the aggregate outcomes reported, it was not possible to determine precisely how many injuries were directly attributable to scalpels, and how many were as a result of other sharp instruments.

Cut-resistant gloves and glove liners were found to lessen the wearer’s dexterity and tactile sensation and result in minor impairment when tested against a number of comparators.

Based on the evidence reported in three studies, benefit derived from the use of hands-free passing technique appeared equivocal, but its implementation may provide greater potential benefits in operations involving more than 100ml of blood loss. While the procedure did not appear to impact adversely on injury rates, it must also be acknowledged that there will remain the need for occasional hand-to-hand passing between members of the operative team, particularly in complex or emergent situations.

One study indicated that sharpless surgery provided a feasible alternative to the use of traditional sharps in surgery.

Theoretical modelling data presented in one study indicated that the use of a passive single-handed scalpel blade remover in conjunction with a passing tray had the potential to prevent approximately as many injuries as an active safety scalpel with a 100% activation rate, and up to five times as many injuries as a safety scalpel with a lower activation rate.

Evidence from one study indicated that materials such as non-pliable leather, rubber with leather lining and new rubber provided superior foot protection from dropped scalpel blades under experimental conditions.

**Classifications and Recommendations**

On the basis of the evidence presented in this systematic review, the ASERNIP-S Review Group agreed on the following classifications and recommendations concerning scalpel safety in the operative setting:

**Classifications**

**Evidence rating**
The evidence base in this review is rated as poor, limited by the quantity and quality of the available evidence. Specific limitations of the evidence included the diversity of interventions and outcomes considered, the lack of a standard comparator and the differences in clinical settings and experimental environments in which the interventions were employed.

A dearth of data also prevented the examination of a number of interventions and outcomes, particularly those related to engineering controls. There were no studies identified that prospectively examined the use of safety/protective scalpels, disposable scalpels or scalpels with round-tipped blades.
Effectiveness
Effectiveness outcomes were considered for those interventions that were undertaken in clinical settings:

Cut-resistant gloves & glove liners
Based on the published literature, the effectiveness of cut-resistant gloves and glove liners in the clinical setting cannot be determined.

Hands-free passing technique
Based on the published literature, the effectiveness of the hands-free passing technique in the clinical setting cannot be determined.

Sharpless surgery
Based on the published literature, the effectiveness of sharpless surgery in the clinical setting cannot be determined.

Pass tray & single-handed scalpel blade remover
Based on the published literature, the effectiveness of a pass tray used in conjunction with a single-handed scalpel blade remover in the clinical setting cannot be determined.

Efficacy
Efficacy outcomes were considered for those interventions that were undertaken in laboratory experimental settings:

Cut-resistant gloves & glove liners
Based on the published literature, the efficacy of cut-resistant gloves and glove liners in experimental settings cannot be determined.

Protective footwear
Based on the published literature, the efficacy of protective footwear in experimental settings cannot be determined.

Clinical and research recommendations
There are few studies published that systematically assess the effectiveness of safety devices in reducing percutaneous injuries, despite the proliferation of such devices. As noted in this review, available reports show substantial variation in study methodology and measurement of outcomes. Standardisation of these features needs to be considered by trial designers in order to compile a clinically relevant and statistically valid body of evidence by which to assess new safety procedures and devices; however, the undertaking of randomised controlled trials (particularly of cut-resistant gloves and glove liners) is both feasible and desirable.
Additionally, the undertaking of a suitably detailed audit of scalpel injuries would assist in contextualising the incidence, prevalence and epidemiology of these injuries within the Australian healthcare setting, allowing targeted interventions to specific areas of the operative process where large numbers of injuries are occurring.

However, it should be emphasised that a large part of preventing sharps injuries involves creating a culture of safety within an institution and its operative personnel. The concept of ‘scalpel safety’ must be reinforced through practice and education in order to achieve lowered rates of scalpel injury in the operative setting in the long-term.

Review Group Membership

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Important note

The information contained in this report is a distillation of the best available evidence located at the time the searches were completed as stated in the protocol. Please consult with your medical practitioner if you have further questions relating to the information provided, as the clinical context may vary from patient to patient.

For further information about ASERNIP-S

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