Prevention of wound contamination using DuraPrep solution plus Ioban 2 drapes


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
3M DuraPrep Surgical Solution (St. Paul, MN) in combination with 3M Ioban 2 Antimicrobial Incise Drapes (St. Paul, MN) was compared with povidone iodine scrub and paint in conjunction with 3M Ioban 2 Antimicrobial Incise Drapes.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing total joint replacement, either total hip arthroplasty (THA) or total knee arthroplasty (TKA), who were aged 18 years or older. Extensive exclusion criteria were imposed. These included known allergies or hypersensitivity to iodine, acrylate adhesives or adhesive tape. Patients were also excluded if they had surgery at a time when the study coordinator was not available, or when the laboratory would not be able to process the study samples.

Setting
The setting was secondary care. The study was conducted in Minnesota, USA.

Dates to which data relate
The dates during which the effectiveness and resource use evidence were collated were not reported. The unit cost data were measured for 2001 and 2002 and adjusted to 2002 prices.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
The study sample included all first-case and second-case patients of the day having primary or revision THA or TKA in the authors' setting and who met the eligibility criteria. Of the 179 patients enrolled, 179 patients met the study criteria. Eight-seven (44.8% female) were in the DuraPrep (DP) group and 92 (47% female) were in the povidone iodine (PVPI) group. The mean age was 67.5 years in the DP group and 67 years in the PVPI group. Power calculations were carried out. These suggested that the ideal number of patients was 100 in each of the study groups to provide 80%
power to detect a 20% difference in contamination risk. All patients gave written informed consent.

Study design
The authors designed a stratified randomised trial that was based at a single centre. Stratifying was based on two factors, joint and surgeon. The staff involved in the study were not blinded because of the skin preparations required. However, the microbiology laboratory staff were blinded to the treatment. The first patient treated by each surgeon was considered a "training patient", to allow "hands-on training of study procedures to ensure protocol compliance and consistency". Effectively, the authors accounted for some learning effects in their design. The authors described extensive methods taken by the surgeons to reduce the likelihood of infection. The patients were followed for up to 30 days after surgery.

Analysis of effectiveness
The patients were analysed on an intention to treat basis. There were no reports that any patients were treated by anything other than their randomised protocol. The primary health outcomes were wound contamination, and predictors of wound contamination (analysed by logistic regression), drape edge lift, and location of drape edge lift. The authors compared the groups in terms of the demographics, baseline characteristics and operative characteristics. They found no differences between the study groups.

Effectiveness results
Wound contamination was 28.0% in the DP group and 36.4% in the PVPI group (not statistically different).

There was no difference in risk of contamination between hip and knee procedures, or between men and women.

Possible predictors of wound contamination were the preparation used, randomised strata, age, gender, operation time, previous surgery, anaesthesiologists' assessment of condition, nurse interpretation of sedation score, transfusion required, area of drape lift, and log of preoperative skin microbial counts. However, none were found to be predictors.

Drape edge lift and total area of drape life were less in the DP group when adjusted and unadjusted for incision length, (p<0.0001).

Patients with contaminated wounds had larger areas of drape lift, (p<0.02). The length of drape lift along the wound was larger in patients with contaminated wounds, (p<0.03).

Clinical conclusions
The authors concluded "the antiseptic skin regimen of DuraPrep solution plus Ioban 2 incise drapes was not different from the PVPI skin preparation plus Ioban 2 incise drapes for the prevention of wound contamination".

Measure of benefits used in the economic analysis
The authors did not estimate a summary measure of health benefits. In effect, a cost-consequences analysis was conducted.

Direct costs
The costing was based on a sub-set of patients for whom data were available. The perspective for the cost analysis was not reported, but it appears to have been that of the health care provider. The costs were estimated for the immediate preparation for surgery and for the actual surgery for those patients in the clinical study. Operating cost data were obtained from the Mayo Clinic cost data warehouse, and a cost per minute was multiplied by the actual time taken for surgery. All operating room supplies costing less than $25 were included; anaesthesia and surgeon costs were excluded. The cost of the skin preparation and time to prepare the skin was noted specifically and nurse time was accounted for. The unit costs related to 2001 and 2002 and were reflated to 2002 prices. Discounting was not required because of the
short time horizon. A distinction was made between fixed and variable costs.

**Statistical analysis of costs**
Differences in cost between the two groups were tested using the Wilcoxon rank-sum test.

**Indirect Costs**
Indirect costs, estimating the broader economic impacts, were not estimated.

**Currency**
US dollars ($).

**Sensitivity analysis**
There was no report that sensitivity analyses were carried out.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The time to prepare patients was 3.5 (+/- 0.91) minutes in the DP group and 9.7 (+/- 1.44) minutes in the PVPI group, (p<0.0001).

The cost of preparation was $4.77 (standard deviation, SD=1.0) in the DP group and $3.25 (SD=0.0) in the PVPI group, (p<0.0001).

The cost of time was $88.58 (SD=22.63) in the DP group and $245.66 (SD=34.99) in the PVPI group, (p<0.0001).

The total cost was $93.36 (SD=23.27) in the DP group and $248.91 (SD=34.99) in the PVPI group, (p<0.0001).

**Synthesis of costs and benefits**
Not relevant.

**Authors' conclusions**
There was no difference in clinical outcome. DuraPrep was associated with reduced drape lift, savings in time and a decreased cost in treating the patient.

**CRD COMMENTARY - Selection of comparators**
The authors compared DuraPrep Surgical Solution plus Ioban 2 Antimicrobial Incise Drapes with povidone iodine scrub and paint in conjunction with Ioban 2 Antimicrobial Incise Drapes. It was unclear if either of these was standard practice in the authors' setting, or whether there were alternative justifications for this choice of comparators. You should decide if this represents a valid comparison in your own setting.

**Validity of estimate of measure of effectiveness**
The authors designed a stratified randomised trial to assess the differences between the two treatments. The ability of this design to ensure comparability between the patient groups was demonstrated by the finding that there were no statistically significant differences between the groups at baseline. The study sample was representative of the study...
population as it included patients undergoing primary or revision hip or knee arthroplasty, and so were at risk of wound contamination. Statistical analyses were undertaken to explore differences in outcomes, and the stratified design also helped to reduce any bias due to the joint under operation or the surgeon operating. When comparing outcomes in the two groups the authors controlled for incision length, a potential confounding factor for contamination.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The reader is referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The cost analysis would have benefited from the authors explicitly stating the perspective from which the analysis was carried out. Given the costs estimated in the study, the perspective appears to have been that of the health care provider. Indirect costs, which would suggest a societal perspective, were not estimated. Statistical analyses were carried out and these enabled the authors to demonstrate a statistically significant difference in the cost of the treatments. More details of the analysis would have been useful to readers, for instance breaking down the results into constituent parts and providing a sensitivity analysis. These efforts might have enabled the reader to assess whether the outcomes are potentially applicable to other settings and populations. Further, a longer time horizon might be considered in future analyses, as this would enable an estimate of the longer term costs of treating infections.

Other issues
The authors were unable to draw comparisons of their work as they reported that the specific comparison of drape lift and wound contamination had not been studied before. However, some comparisons with clinical studies were possible and were discussed. The issue of generalisability to other settings was not addressed. In addition, generalisability is limited by the use of institution-specific cost data and the lack of sensitivity analyses. The results were presented clearly and the authors do not appear to have been selective in their reporting. The conclusions were an accurate reflection of the scope of the study and the results presented. The authors discussed the low power of the study to detect clinically significant differences as a potential limitation.

Implications of the study
The authors presented a balance between the cost and time savings and the lack of clinical difference between the technologies, and emphasised that these should be taken into consideration when making clinical decisions. They suggested that further work be undertaken to increase the power of the study and to explore the size of the drape lift area further.

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