Effect of three wound dressings on infection, healing comfort, and cost in patients with sternotomy wounds: a randomized trial

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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
Three types of dressing applied in the operating theatre on skin closure were evaluated in patients with sternotomy wounds. The three types of dressings were a dry absorbent dressing (DAD, Primapore; Smith & Nephew), a hydrocolloid dressing (HCD, Duoderm Thin ConvaTec; Mulgrave) and a hydroactive dressing (HAD, Opsite; Smith & Nephew).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised consecutive patients requiring a median sternotomy incision for cardiac surgery. Patients who were immunosuppressed were excluded.

Setting
The setting was a major metropolitan academically affiliated, tertiary referral centre in Melbourne, Australia. The study was conducted in Australia.

Dates to which data relate
Patients from whom the effectiveness and resource use data were collected were recruited from September 1999 to November 2001. The price year was not stated.

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

Link between effectiveness and cost data
The costing was undertaken prospectively on the same study sample as that used in the effectiveness analysis.

Study sample
Power calculations were reported. To detect a 15% difference in healing rate on a significance criterion of 0.05 confidence and with a power of 90%, 174 patients were required for each treatment group. From 1,197 patients undergoing cardiac surgery, 737 (61.6%) were recruited. Exclusions were due to patient refusal (3.9%), inability to understand the implications (4.6%), inability or insufficient time to obtain consent before the operation (65.6%), and
the patient's surgeon not participating (25.9%). Non-participating patients were younger, more likely to smoke and had poorer pre-existing renal function, which suggested a higher preoperative acuity and tendency to bypass trial recruitment. Of the 737 recruited patients, 243 (33%) were randomised to DAD, 227 (30.8%) to HAD, and 267 (36.2%) to HCD. Of these, 86% (n=632) were available for follow-up interview after discharge. The reasons why some patients were unavailable were adequately described. Consecutive patients meeting the inclusion criteria were randomised to the three groups with stratification across two operating theatres.

**Study design**
This was a randomised controlled study that was carried out in a single centre. Randomisation was carried out using sealed opaque envelopes, the unit of randomisation being the patient. Follow-up was 4 weeks after discharge. The authors stated that it was not feasible to blind the data collectors for the outcome assessment. However, inter-rater reliability was assessed until there was 100% agreement between all data collectors. No loss to follow-up was reported.

**Analysis of effectiveness**
The basis of the analysis was intention to treat. The primary outcomes evaluated were the incidence of wound healing, the incidence of sternal wound infection (SWI), the length of stay (LOS) and patient comfort. SWI was classified according to guidelines of the Centers for Disease Control and Prevention. Wound healing was evaluated by trained nurses, who had a high agreement in classifying them. Wound healing was measured by assessing both wound approximation and skin integrity. Patient comfort was assessed using four 10-cm visual analogue scales for dressing awareness, movement limitation, comfort with dressing changes, and overall satisfaction. The pre-randomisation and operative characteristics of the three groups were broadly similar.

**Effectiveness results**
The overall incidence of SWI was 2.9% (n=21). There was no difference among treatment groups (2.5% Primapore, 2.2% Duoderm, 4.0% Opsite; p=0.473).

Patients in the Primapore group were least likely to have an exuding wound (6.9% Primapore, 21.3% Duoderm, 13.8% Opsite; p=0.0001). The presence of exudates during day 1 to day 5 was associated with poorly sealed dressings (7.2% versus 45.1% and 17.4%; p=0.001).

One patient in each dressing group did not have total wound approximation at day 5.

The integrity of the surrounding skin was normal in more than 90% of patients from all groups. There were no statistically significant differences.

The majority of patients in all groups were unaware of their dressing.

Since the DAD group had their dressings removed on the second postoperative day, specific comparisons of patients comfort were focused on data from day 1 and day 2. On postoperative day 2, patients found that Opsite limited their ability to move more than other dressings (26.4% versus 22.8% for Duoderm versus 12.3% for Primapore; p=0.002). Duoderm Thin was less uncomfortable if a change was needed on day 1. (p=0.038). However, the overall satisfaction was higher in the Primapore group than in the other groups. Dissatisfaction was 18.9% with Primapore versus 28.1% with Duoderm and 35.2% with Opsite.

The median preoperative LOS was 1 day (range: 0 - 2) for patients without an SWI versus 1 day (range: 0 - 6) for those with an SWI, (p=0.013).

The median postoperative LOS was 7 days for patients without SWIs (range: 5 - 8) versus 11 days for those with SWIs (range: 7.75 - 19.5), (p=0.001).

There were no differences between the treatment groups in the frequency of unhealed wounds at follow-up. There were 14 unhealed wounds (30.4%) in the Primapore group, 16 (34.8%) in the Duoderm Thin group, and 16 (34.8%) in the Opsite group.
Clinical conclusions
The three dressing products evaluated were similar in terms of the prevention of wound infections and the rate of wound healing. The DAD was the most comfortable product for sternotomy wounds following cardiac surgery.

Measure of benefits used in the economic analysis
No summary measure of benefit was derived. The study was, in effect, a cost-consequences analysis.

Direct costs
Discounting was appropriately not carried out as the time horizon was less than two years. The quantities and the costs were not reported separately. The only item evaluated included the number of dressings required for each treatment group and its unit cost. All other cost categories were excluded. The quantities were estimated using actual data from the study patients. The dressing costs were calculated according to the number of dressings required per patient at day 5. Dressings were changed if poorly sealed before day 2 for patients treated with the Primapore dressing, or before day 5 for patients treated with either Duoderm Thin or Opsite dressings. The sources of the cost data were not reported. Resource use was measured from September 1999 to November 2001. The price year was not stated. The total costs and mean costs per patient (with interquartile ranges, IQR) were reported.

Statistical analysis of costs
The costs were treated stochastically. The authors used t-tests for continuous variables if normally distributed or adequately transformed, otherwise non-parametric tests such as the Mann-Whitney U-test or Kruskal Wallis were used.

Indirect Costs
This cost component was not considered.

Currency
Australian dollars (Aus$).

Sensitivity analysis
No sensitivity analysis was performed.

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

Cost results
The median total costs were Aus$138.84 for the Primapore group, Aus$1,705.62 for the Duoderm group, and Aus$472.23 for the Opsite group.

The median dressing cost per patient was Aus$0.52 (IQR: 0.52 - 0.52) for the Primapore group, Aus$3.93 (IQR: 3.93 - 7.86) for the Duoderm group, and Aus$1.59 (IQR: 1.59 - 3.18) for the Opsite group, (p=0.001).

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
In the context of no additional benefit for the prevention of wound infections, or in the rate of wound healing for any of the three dressing products examined, dry absorbent dressings (DADs) were the most comfortable and cost-effective products for sternotomy wounds following cardiac surgery.

CRD COMMENTARY - Selection of comparators
The authors explicitly justified their choice of the comparators. The comparators appear to represent current practice in the authors' setting. You should judge if the dressings selected reflect practice in your own setting.

Validity of estimate of measure of effectiveness
The type of study undertaken, a randomised controlled trial (RCT), was the best possible design to evaluate the study question. The sample was representative of the study population and the groups were comparable at baseline. The low incidence of SWIs detected probably limits the study's power to detect small differences, but seems to exclude clinically important differences. Although the authors stated that the outcome assessment was not blinded because of feasibility problems, this had the potential to introduce some unpredictable bias in the results.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The study was, in effect, a cost-consequences study.

Validity of estimate of costs
The main limitation of the study lay in the cost analysis. More specifically, only the costs of the dressings used and the number used in each group, derived from the RCT, were included. A relevant cost category excluded was the personnel time required to change and remove dressings, which would probably have increased the cost-advantages of the Primapore group. Other excluded categories (e.g. LOS and laboratory costs) would have had a low impact on differences among the groups. The perspective of the study was not reported, nor was the source of the prices. The authors reported only median costs, although mean values would probably have been more useful to decision-makers in other settings. The unit costs and the quantities were not reported separately, thus limiting the possible extrapolation to other settings.

Other issues
The authors made adequate comparisons of their clinical results with other studies, demonstrating similar effectiveness among dressing types. Generalisability to other settings was not explored. The authors reported some limitations to their study. First, the reliability of the visual analogue scales used to measure dressing comfort has not been tested, and in this setting they might not have been adequately sensitive to variations in comfort. Second, the data were only collected for the first 5 postoperative days, where the day of surgery was day 0. Finally, given the late presentation of wound infection, it might have been useful to have continued to collect data until and beyond patient discharge. The authors also acknowledged the short time horizon selected for data collection (5 days, while the median presentation time of wound infection was 38.5 days).

Implications of the study
The authors recommended that controlled studies, to evaluate the impact of dressing application techniques on wound healing and infection, should be carried out.

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