The cost and efficacy of two wound treatments

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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
The use of wet-to-dry normal saline gauze dressings and amorphous hydrogel dressings in wound care.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study sample comprised patients aged 25 years or older who required home nursing care for perioperative arterial surgical wound dehiscence and nonhealing arterial and diabetic ulcerations. The inclusion criteria specified that patients should have wounds below the inguinal ligament and that those wounds should be superficial, without undermined areas. Only those patients with seven sequential weeks of single wound treatment and without missing data were included.

Setting
The setting was secondary care. The economic study was carried out in the USA.

Dates to which data relate
The dates to which the data related were not stated. As the study was a retrospective case note review, one would have expected a timeframe for the dates from which the case note data were retrieved.

The charge data related to the first year of the study, although the actual year was not specified. A price year was not specified, which may limit the generalisability of the study. If all charge data related to the same year, then no inflationary adjustment will have been necessary.

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

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness analysis. The costs and effects were collected simultaneously.

Study sample
A sample size calculation was undertaken in the planning phase of the study. This found that 37 patients per treatment
group would be required to ensure a power of 0.81 to detect an effect size of 0.25. The investigators also assumed that 75% of the records would be excluded due to missing data. They therefore aimed to obtain 150 records per treatment group.

The planned study sample was appropriate for the research question, but as it consisted of predominately Caucasian patients (96%) the generalisability of the study to other ethnic groups may be questionable. The exclusion of records with missing data may also mean that the study sample was not representative of the wider patient population eligible for these treatments.

Of the 320 records initially retrieved for the study, 260 (81%) were rejected due to missing data. A preliminary analysis of the 60 remaining records showed a very small difference in effect size and so the data collection was halted. A further 10 (3%) with wet-to-dry normal saline dressings and wound sizes of less than 1 cm2 or greater than 20 cm2 were rejected as outliers, to ensure that all of the study variables better approximated a normal distribution. The final study sample consisted of 50 patients, 25 in each treatment group.

Study design
The study design was a retrospective cohort study. Patients who had been assigned to one of three home health agencies were included. The study period was 7 weeks and the study only included patients without missing data. The data were collected from home health records using an investigator-constructed data form with questions on demographic variables, co-morbidity, characteristics of the wound, and charge data.

Analysis of effectiveness
Records that did not fit the assumption of a normal distribution in wound surface area were excluded prior to the analysis. The primary health outcome was wound healing, which was defined as an improvement in wound size, predominant tissue type of the wound and the type of exudates, and which eventually led to wound closure.

At analysis, the groups were shown to be comparable in terms of age, gender, principal diagnosis, wound exudate, predominant tissue of the wound and a combined co-morbidity measure, the Charlson co-morbidity index (CCI). The groups were not comparable in terms of principal procedure, use of beta-blockers, history of chronic obstructive pulmonary disease, diabetes, location of the wound and use of secondary dressings. No adjustment for these confounders was made.

Effectiveness results
An analysis of covariance (ANCOVA) analysis showed that, after adjusting for the CCI score, there was no statistically significant relationship between treatment group and wound closure, (p=0.91), or rate of wound closure, (p=0.66). There was also no significant difference between the two treatment groups over time, (p=0.75).

Clinical conclusions
Wet-to-dry normal saline gauze dressings were as effective as amorphous hydrogel dressings in treating superficial arterial and diabetic wounds.

Measure of benefits used in the economic analysis
As the effectiveness was assumed to be equal between the treatment groups, a cost-minimisation analysis was, in effect, undertaken. However, although the clinical study failed to show a significant difference in effect, this was not evidence of equality of effect.

Direct costs
Some components of resource use and cost data were reported separately. The study included health service costs to the health care payer. These were the cost of home visits, primary and secondary dressings, and the treatment of wound
complications or co-morbid conditions that affected wound healing, in terms of visits to emergency departments, visits to physicians, readmissions to hospital and intravenous or oral antibiotic home therapy. The definitions of wound complications and conditions that affect wound healing were not provided.

Resource use was obtained from home health records and transformed into costs using charge data. Discounting and extrapolation were irrelevant, as the study period was limited to 7 weeks. The study reported the average costs for each treatment group. The date to which the data referred was not specified other than to say that the charge data related to the study year.

**Statistical analysis of costs**
The costs were analysed using ANCOVA, adjusting for CCI score. The use of ANCOVA was justified by performing tests for no interaction between the covariate and treatment group, (p=0.63), and the assumption of equality of error variance, (p=0.167). The study had not been powered with respect to detecting a difference in cost.

**Indirect Costs**
The indirect costs were not included in the analysis, which was consistent with the perspective of the study.

**Currency**
US dollars ($). The price data related to the study year.

**Sensitivity analysis**
No sensitivity analyses were conducted.

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

**Cost results**
The total cost of wound care was $2,634 with amorphous hydrogel dressings and $3,744 with wet-to-dry normal saline gauze dressings.

An ANCOVA, adjusted for CCI score, revealed there to be a statistically significant difference in the costs between the treatment groups (p=0.006).

Adverse treatment effects were probably implicitly included in this study, as they would likely result in higher utilisation of health care resources for wound care.

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

**Authors’ conclusions**
Amorphous hydrogel dressings are better value for home treatment of superficial arterial and diabetic ulcerations.

**CRD COMMENTARY - Selection of comparators**
The choice of wet-to-dry normal saline gauze dressings was justified by asserting that they are second only to dry gauze dressings as the most frequent topical wound treatment. Implicitly, wet-to-dry dressings are more suitable as a comparator than dry dressings, as dry dressings are unlikely to be a sensible alternative for wound care that requires a
moist environment. As such, wet-to-dry dressings represent current practice for the treatment of wounds that require a moist environment. You must decide whether this comparator represents current practice in your own setting.

**Validity of estimate of measure of effectiveness**

The analysis used a retrospective cohort design in which the patients were shown to differ in known covariates between the treatment groups, and in which they could have potentially differed in unobserved covariates. Thus, the results may have been affected by selection bias. Since the study sample was predominantly white and included only patients with complete data, it is unlikely to have been representative of a wider population. The patient groups were shown not to be comparable at analysis, but there was no attempt to adjust for the observed confounders. The failure to find a significant effect is not evidence of equivalence. The study fell short of the sample size required to detect a minimum effect size of 0.25 in the rate of wound closure.

**Validity of estimate of measure of benefit**

The study found no significant treatment effect on wound closure or rate of wound closure. Since this was taken to be evidence of equivalence, a cost-minimisation analysis was, in effect, performed.

**Validity of estimate of costs**

All the categories of costs relevant to the perspective adopted were included in the analysis, although the inclusion of only antibiotics among medication costs could potentially have been widened to include painkilling drugs. The omission of painkilling drugs is unlikely to have affected the authors’ conclusions, as the predominant component of the cost was charges for home visits (96% in the wet-to-dry dressing group and 93% in the amorphous hydrogel group). The average number of home visits was reported separately from the average cost.

Resource use was obtained from the home health records of patients in the study. The prices used were charges in the authors' setting, which was appropriate given the perspective of the analysis. No sensitivity analyses were conducted since the data were derived from a case-control study. The date to which the prices related was not reported. No extrapolation was performed and discounting was irrelevant given the duration of the study.

**Other issues**

The authors compared the results of their study with several other studies. For example, a study of the two wound dressings on pressure ulcers that also found no significant difference in wound healing, and a study comparing two different types of amorphous hydrogel dressings. The results were also compared with a cost-effectiveness study involving hypertonic hydrogel dressings, which found that treatment with hydrogel dressings was cheaper than treatment with wet-to-dry gauze dressings. The authors pointed out that, in each case, there were differences between their study and the comparator, and so they did not draw conclusions from the comparisons. The issue of generalisability to patients who do not require home nursing care, but have non-professional help with their wound dressings instead, was also discussed. Home nursing care significantly impacted on the costs, and the authors supposed that it might also significantly impact on the outcomes. The authors do not appear to have presented the results selectively and their conclusions reflected the scope of the analysis.

The authors reported that the study design was inferior to a prospective, randomised trial where data items may be measured with greater accuracy and the types of data recorded can be at the discretion of the trialist rather than on the basis of their availability in case notes. The authors acknowledged that some of the variables used in their analysis were not ideal, such as the CCI.

**Implications of the study**

The authors concluded that patients within Medicare's prospective payment system should be given amorphous hydrogel dressings rather than wet-to-dry normal saline gauze dressings, as they are cheaper and less resource-intensive. The authors recommended that the study be replicated as a prospective randomised, controlled trial.
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Other publications of related interest


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