Randomized clinical study of hydrofiber dressing with silver or silver sulfadiazine in the management of partial-thickness burns

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 study compared the use of AQUACEL Ag dressing with silver sulfadiazine as dressings in the management of partial-thickness burns.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged at least 2 months old with burn injuries, who had been injured within the last 36 hours and who had superficial, mid-dermal or mixed partial-thickness burns that covered 5 to 40% of total body surface area. The exclusion criteria included electrical, chemical or frostbite burns, areas of deep-partial or full-thickness burns, fractures and/or brain injury, and inhalation injury. Further exclusion criteria were use of antibiotics and treatment with an active agent.

Setting
The setting was outpatient, tertiary care at specialist burn centres. The study was conducted in eight centres across the USA.

Dates to which data relate
The effectiveness and resource data were collected from January 2003 to September 2004. The price year was 2004.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample that provided the effectiveness data.

Study sample
Patients were randomly allocated to receive AQUACEL Ag dressing or silver sulfadiazine. The randomisation was stratified into four groups, according to the extent of the burn and age. Sixteen patients were needed in each group (64 patients in total, 32 in each arm) to provide an 80% power to detect a significant difference in cost-effectiveness. A sample size of 82 patients was selected to obtain a minimum of 64 patients. Eighty-four patients were recruited, 42 to each group. Only 40 patients were included in the silver sulfadiazine group as 2 did not receive the treatment.

Study design
The study was a multi-centred, randomised controlled trial that was carried out in eight centres. Randomisation was stratified according to burn size (5 to 20% or >20 to 40%) and age (0 to 3 years old or 4 years and older). Treatment was not blinded. The patients were followed weekly and cost-effectiveness was assessed at 21 days (3 weeks). There was no loss to follow-up.

**Analysis of effectiveness**

The primary measure of effectiveness was the rate of full re-epithelialisation (healing) within 21 days. This is a binary measure: burns were either 100% re-epithelialised (including small residual scabs/blisters and open areas less than 1 cm within an otherwise fully healed area), or less than 100% of the burn was re-epithelialised. An investigator assessed re-epithelialisation. Other outcomes included pain and anxiety during dressing changes, scarring and adverse events. The analysis was conducted on an intention to treat basis. The authors described this population as patients who completed at least one post-baseline visit.

**Effectiveness results**

At 21 days, 74% of patients treated with AQUACEL Ag were fully re-epithelialised, compared with 60% of patients treated with silver sulfadiazine. The difference was not significant, (p=0.222).

The median time to full re-epithelialisation was similar across the two treatments, 16 days for AQUACEL Ag compared with 17 days for silver sulfadiazine, (p=0.517).

AQUACEL Ag was associated with significantly less pain and anxiety during dressing changes for those aged 4 years or older. There were no significant differences in adverse events. Scarring was slightly better with AQUACEL Ag.

**Clinical conclusions**

The primary outcome was better in the AQUACEL Ag dressing group than in the silver sulfadiazine group, although the difference was not statistically significant. For the other outcomes, AQUACEL Ag was at least as good, if not better, than silver sulfadiazine.

**Measure of benefits used in the economic analysis**

The measure of benefit used was the rate of re-epithelialisation.

**Direct costs**

The study reported the direct cost to the hospital. This included the cost of the dressing (primary and secondary dressings), dressing changes (nurse and physician time), ancillary supplies and pain medication. Resource use was determined using a micro costing methodology, and valued using standard national sources of price and cost. Individual costs were summed to give a total cost per patient for each treatment regimen. The costs were not discounted as the time horizon was too short. The price year was 2004.

**Statistical analysis of costs**

Mean resource use and cost for specific categories of the cost estimation (dressing changes, dressing costs, total costs) were compared using an analysis of variance model, controlling for treatment group and strata. Significant differences were presented using p-values.

**Indirect Costs**

The productivity costs were not considered.

**Currency**
Sensitivity analysis
A univariate sensitivity analysis was undertaken, whereby the authors included the cost of treating complications in the cost analysis. A sub-group analysis of paediatric patients (up to 16 years old) was also undertaken.

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

Cost results
The average cost per patient receiving AQUACEL Ag dressing was $1,040, compared with $1,180 per patient treated with silver sulfadiazine. The cost-saving was $140.

The analysis of the components of cost found that, while the cost of primary dressings was significantly greater for the AQUACEL Ag dressing than for silver sulfadiazine ($684 versus $398, p=0.007), the cost of secondary dressings was significantly less, fewer dressing changes were needed, and the cost of pain medications was lower.

Synthesis of costs and benefits
The authors found that AQUACEL Ag dominated silver sulfadiazine (it was less costly and more effective at achieving full re-epithelialisation).

The inclusion of the cost of complications did not significantly affect the cost-effectiveness results. AQUACEL Ag was still dominant in the sub-group analysis of paediatric patients.

Authors' conclusions
A protocol of care with AQUACEL Ag was cost-effective relative to treatment with silver sulfadiazine in patients with partial-thickness burns.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. It was the 'gold' standard for topical treatment of partial-thickness and mid-dermal burns. You should decide if this represents a widely used technology in your own setting.

Validity of estimate of measure of effectiveness
The study was based on a randomised controlled trial. Power calculations were performed to ensure an adequate sample size. The study sample was representative of the study population and baseline characteristics were comparable between treatment groups. The method of randomisation, length of study and loss to follow-up were all reported, which suggests that the internal validity of the study is likely to be good. Blinding of the patients and clinicians to the treatment allocation was not possible but blinding of the researcher who collected the outcome information, and especially the investigator who assessed the rate of re-epithelialisation, should have been possible. This would have helped minimise potential biases in the data. The data analysis controlled for randomisation strata, which will also have helped minimise the effect of confounding factors.

Validity of estimate of measure of benefit
The rate of full re-epithelialisation was used as the summary benefit measure. It was obtained directly from the effectiveness analysis. Healed burns represent an important outcome measure but do not fully capture all the health benefits of the intervention. This may limit comparisons with other health interventions.
Validity of estimate of costs
The perspective of the analysis was not explicitly stated, but it appears to have been that of the health service or hospital. Given this perspective, it appears that all the relevant categories of cost have been included in the analysis. Resource use was valued using standard national sources of price and costs. The cost data were well reported and there was some analysis of the different cost components.

Other issues
The authors did not compare their findings with those from other studies, thus it was not possible to determine how far their results agreed with the rest of the literature. While this was a multi-centred study, the authors failed to acknowledge any possible variation in the data across centres. The authors do not appear to have presented their results selectively. They acknowledged that there were limitations to their analysis, including the fact that only direct medical costs were considered.

Implications of the study
Although the authors did not suggest any areas for future work, these may include undertaking a trial to assess the wider health benefits of AQUACEL Ag, and considering a societal perspective.

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