Evaluating the role of alternative therapy in burn wound management: randomized trial comparing moist exposed burn ointment with conventional methods in the management of patients with second-degree burns

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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 a moist exposed burn ointment (MEBO), compared with conventional burn wound management (CBWM), for the treatment of partial-thickness burns.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised all patients with partial-thickness burns who were admitted to the Singapore National Burns Center between 1 April 1997 and 24 October 1998. The study population was aged between 6 and 80 years. Patients with chemical and electrical burns were excluded. Partial-thickness burns were defined as burns that affect the epidermis and the dermis to variable depths (Muir et al., see Other Publications of Related Interest). The health technology was targeted at patients with partial-thickness burns.

Setting
The setting was secondary care. The patients were treated in the Singapore National Burns Center at the Singapore General Hospital.

Dates to which data relate
The effectiveness data and cost data were collected between 1 April 1997 and 24 October 1998.

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

Link between effectiveness and cost data
It appears that the costing has been undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
The sample size was determined in the planning phase of the study to assure a given statistical power. The sample selection process considered all patients admitted with partial-thickness burns, which were not electrical or chemical
burns, who were aged between 6 and 80 years. No patients refused to participate in the study. However, one patient did withdraw consent for an unknown reason after randomisation. A total of 115 patients started the trial.

**Study design**
The study was a randomised controlled trial that was carried out at a single centre. The patients were randomised to treatment either by telephone to the National Medical Research Council Clinical Trials and Epidemiology Research Unit (Singapore), or by sealed envelopes (for patients requiring allocation outside of normal working hours). The length of follow-up was unclear. In the CBWM group (n=58), one patient with burns of 68% body surface area (BSA) (which violated the inclusion criteria) was wrongly assigned, one patient was repatriated to his county, and one withdrew consent. Thus, the CBWM group comprised 55 patients. All of the 57 patients in the MEBO group remained in the study.

**Analysis of effectiveness**
The primary health outcomes were time to 75% BSA healing and the methicillin-resistant Staphylococcus aureus (MRSA) infection rate.

**Effectiveness results**
Eighty-six per cent of patients had more than 20% BSA (range: 1.5 - 37.5) at admission. For the first 20 days after the burn had occurred, the CBWM group had a faster rate of healing than the MEBO group, but this was subsequently reversed.

The time to 75% of initial BSA healing could be assessed for 25 patients in the CBWM group and 36 patients in the MEBO group. The median time to 75% healing, as shown by the Kaplan-Meier curves, was 17 days in the MEBO group and 20 days in the CBWM group, (hazard ratio, HR=0.67, 95% confidence interval, CI: 0.41 - 1.11; p=0.11). A Cox regression model, in which there is an adjustment comparison for the initial burn BSA at randomisation, gave an HR of 0.61 (95% CI: 0.36 - 1.02; p=0.061).

In the 2 weeks after randomisation, there were 17 patients in the CBWM group with an MRSA infection and 16 in the MEBO group. At 14 days, the MRSA infection rate was 35.5% for the CBWM group and 37.4% for the MEBO group. The HR was unaffected by the MRSA infection rate, but an adjustment for initial burn BSA increased the HR to 1.61 (95% CI: 0.81 - 3.17; p=0.17), although it remained statistically non significant.

The request for paracetamol was similar in both groups. In the first week, 97% of patients in the CBWM group and 85% in the MEBO group requested analgesia. This pattern continued in week two.

**Clinical conclusions**
The use of MEBO results in a lower infection rate and a lower use of analgesia.

**Measure of benefits used in the economic analysis**
The summary measure of benefit used was pain measurement. A nurse assessed the patients for pain using a numerical scale from 1 to 10, where 0 represented no pain, 1 to 2 slight pain, 3 to 4 mild pain, 5 moderate pain, 6 to 9 moderately severe pain, and 10 severe pain. The assessment was carried out three times daily (on waking, straight after the first dressing, and 8 hours later) until the final dressing before discharge.

**Direct costs**
The direct costs included in the study were those related to the hospital, consumables and the time to dress wounds. No further details of the costs were provided. Discounting was not undertaken because the time horizon of the study was less than 2 years.
Statistical analysis of costs
The costs were calculated according to the time for healing. Kaplan-Meier curves were used to estimate the healing times and time to MRSA colonisation or infection. A Cox regression model was used to adjust for differences in patient characteristics and treatments for initial burn BSA.

Indirect Costs
No indirect costs were included in the study.

Currency
Singapore dollars (Sin$).

Sensitivity analysis
A sensitivity analysis was not carried out.

Estimated benefits used in the economic analysis
A total of 111 patients were considered in the pain analysis.

After 7 days, the pain scores were:
for the morning session, 3.3 in both the MEBO and CBWM groups;
for the afternoon session, 2.9 in the MEBO group and 3.4 in the CBWM group and
for the evening session, 2.7 in both groups.

After 14 days, the pain scores were:
for the morning session, 3.1 in the MEBO group and 2.5 in the CBWM group;
for the afternoon session, 3.4 in the MEBO group and 2.4 in the CBWM group; and
for the evening session, 2.9 in the MEBO group and 2.2 in the CBWM group.

Cost results
The mean difference in the cost of hospitalisation per patient was lower in the MEBO group by Sin$493. The mean cost was Sin$10,180 (range: 697 - 79,301) for the CBWM group and Sin$9,697 (range: 990 - 55,533) for the MEBO group.

The mean difference in the cost of consumables per patient was lower in the MEBO group by Sin$360. The mean cost was Sin$975 (range: 22 - 6,651) for the CBWM group and Sin$595 (range: 22 - 3,027) for the MEBO group.

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

Authors' conclusions
Moist exposed burn ointment (MEBO) is effective for the treatment of second-degree burns. It is especially useful for treating burns on the face, neck and hands. MEBO was less expensive than the alternative and provided greater pain relief in the first 5 days following injury.
CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. The comparator represented standard treatment. You should decide if this is a widely used health technology in your own setting. A ‘do nothing’ option was not included in the analysis.

Validity of estimate of measure of effectiveness
The basis of the analysis was a randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population. The patient groups were not comparable at analysis, although an appropriate statistical analysis was undertaken to account for potential biases and confounding factors.

Validity of estimate of measure of benefit
The estimation of benefit was obtained directly, using a numerical rating scale to assess the level of pain the patient was experiencing. It is difficult to compare the findings of this study with those from other studies, particularly those in different disease areas, because of this outcome measure. The quality-adjusted life-year (QALY) would have been a more appropriate summary measure of benefit for a study of this nature.

Validity of estimate of costs
The costs appear to have been estimated from the perspective of the health care provider. Although the authors reported that hospital and consumable costs and the time to dress wounds were estimated, no further details of the costs were provided. It was unclear whether, for each category of costs, all the relevant costs were included in the analysis. In addition, it was unclear whether such omissions were likely to have affected the authors’ conclusions. The results from the trial were extrapolated using Kaplan-Meier techniques. A statistical analysis of the prices was not performed.

Other issues
The authors did not make appropriate comparisons of their findings with those from other studies. They also did not address the issue of generalisability to other settings. The authors do not appear to have presented their results selectively. The study involved patients with partial-thickness burns and this was reflected in the conclusions.

Implications of the study
MEBO was as effective as conventional therapy, and will be particularly effective in the treatment of partial-thickness burns on the face, neck and hands.

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Bibliographic details

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Aged; Anti-Bacterial Agents /administration & dosage; Anti-Inflammatory Agents, Non-Steroidal /administration & dosage; Bandages /economics; Berberine; Burns /therapy /economics; China; Comparative Study; Complementary Therapies /economics; Drugs, Chinese Herbal; Health Care Costs; Hospitalization /economics; Humans; Middle Aged; Ointments /economics; Pain Measurement; Plant Extracts; Prospective Studies; Research Support, Non-U.S. Gov't; Sesame Oil; Sitosterols; Treatment Outcome; Wound Healing

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