Total contact casting for diabetic neuropathic ulcers

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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
Total contact casting for superficial plantar ulcers (Wagner grades I and II).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with diabetes mellitus, superficial plantar ulcers and having chronic sensory neuropathies.

Setting
Hospital inpatient and outpatient centres. It was not made clear whether all studies were conducted in the USA, although most evidently were.

Dates to which data relate
The effectiveness data were based on studies published between 1983 and 1995. Some estimates of resource use were based on a study published in 1987. No dates are given for unit costs (prices) - they are said to be "current". The study was published in 1996.

Source of effectiveness data
Estimates of final outcomes were based on a review of previously published studies.

Outcomes assessed in the review
The outcomes assessed were the healing time in days, the percentage of ulcers healed, the complication rate as a percentage, and the recurrence rate as a percentage.

Study designs and other criteria for inclusion in the review
No particular criteria were listed by the author, two of the studies were case descriptions of 1 patient. At least one was a randomised controlled trial.

Sources searched to identify primary studies
Not stated.
Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
None were described except for the data extraction, which was carried out by summary statistics.

Number of primary studies included
Results of 13 studies of TCC treatment were tabulated: 11 studies described more than 1 patient. Five studies using other methods of treatment were quoted in the text but were not included in the table of results. Outcomes for controls were provided by 5 studies, 1 of which also provided TCC data. A total of 22 studies was used in the review.

Methods of combining primary studies
Primary studies were not combined in a systematic way. The average of percentage recurrence rates was worked out as a simple arithmetic mean of the 5 studies to give recurrence rates, without reference to original data and without allowing for ranges or different numbers in studies. The method of combining studies to produce mean healing times and percentages healed was not explained. Complication rates were not combined.

Investigation of differences between primary studies
Differences between primary studies were not investigated. The author comments that studies used different definitions of a healed ulcer which makes comparisons difficult. He did not say how, or if, he had made allowance for this.

Results of the review
The mean healing times are approximate since only a bar chart was given. Using TCC, healing time was 45 days: using dressing changes and moulded insoles it was 88 days; using local ostectomy and wound debridement it was 130 days; and using CT-102 it was 140 days (median for this last case). The percentage of ulcers healed was also presented as a chart. Using TCC 90% were healed, using dressing changes and moulded insoles 67% were healed, using local ostectomy and wound debridement 57% were healed, and using CT-102 60% were healed. Complication rates were not combined and were only given for TCC. They varied from 6 to 43%. The only recurrence rate given was for TCC and was stated as 32%.

Measure of benefits used in the economic analysis
Mean healing time in days, percentage of ulcers healed, recurrence rate.

Direct costs
Costs were not discounted despite the fact that the period covered in the analysis was 2 years. The mean length of hospital stay was reported along with the number of cast changes. Average hospital stays for diabetes patients were based on a previous study. Hospital room costs were derived from the institution's data. This was a deliberately conservative estimate as costs of medications, diagnostic procedures and physicians services were not included. Costs were estimated for an 8 week outpatient duration of casting including 6 to 8 casts. It is not clear what cost boundary was represented, apart from that of the hospital. Costs were said to be current and the study was published in 1996. For the comparators, the only relevant information given was mean healing time in days which was based on reports from previously published studies.

Indirect Costs
It was stated that, as TCC allows patients to remain ambulatory, no loss of wages need occur. Apart from this, indirect costs were not considered.
Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
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Cost results
It was estimated that a low risk diabetes patient would average 5.3 days in hospital over a 2 year period. The average hospital room cost for a 5.3 day stay was estimated as $2,252. The outpatient costs to cover an 8 week duration of casting were estimated at $810 to $1,050.

Synthesis of costs and benefits
A synthesis was not undertaken since the intervention was reported as the dominant strategy.

Authors’ conclusions
An increasing use of TCC by physicians should result in a lower incidence of infection, hospitalisation, and lower extremity amputation and should reduce the costs associated with hospitalisation and lost income inpatients with chronic sensory neuropathies.

CRD COMMENTARY - Selection of comparators
(a) Daily dressing changes and moulded insoles and custom made shoes; (b) local ostectomy and wound debridement; and (c) CT-102. The comparators were taken from the studies reviewed and only one of these studies used any comparator within the study. However, the author provided no further justification for these strategies as meaningful comparators.

Validity of estimate of measure of benefit
The author stated that different studies use non comparable definitions of a healed ulcer. This renders the measure of benefit invalid. Other measures of benefit are taken from few studies and were combined in a superficial manner. In particular, primary study results were given equal weight despite differences in quality between them. The studies chosen were not shown to be drawn from a comprehensive survey. It is not possible to say that the results are unbiased.

Validity of estimate of costs
No adequate details of the methods of cost estimation were given. The costs of comparator treatments were not given. The dates of the prices used in the costing were not given.

Other issues
The author did justify his conclusions, given the uncertainties in the data. In particular, the dominance of the intervention over the comparators was not clear. It is not possible to generalise the cost results to other countries. It is not possible to say whether or not the results were presented selectively.
Implications of the study
No clear implications of this study can be derived, except for the necessity to carry out better designed studies directly comparing the intervention with relevant alternatives, as the author noted.

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None stated

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