A comparison of diabetic foot ulcer outcomes using negative pressure wound therapy versus historical standard of care

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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 study compared the use of negative pressure wound therapy (NPWT) as a treatment for diabetic foot ulcers with standard wet-to-moist wound therapy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis

Study population
The study population used for the NPWT group included patients for whom: the wound was categorised as a diabetic ulcer or neuropathic ulcer; wound treatment was carried out using NPWT; the wound was of a chronic nature; debridement of necrotic tissue was performed; comprehensive diabetes management was included with the case plan; a reduction in the pressure of the affected ulcer was carried out, as needed; and a description of the wound size and duration was available prior to NPWT.

The inclusion criteria for the control group (standard wound therapy) included: chronic wounds categorised as diabetic or neuropathic ulcers; appropriate offloading, as needed; the presence of adequate perfusion; infection control (if present); and debridement of necrotic tissue.

Setting
The study setting was the community and outpatient care. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness data were derived from datasets of patients treated for diabetic foot ulcers between 1996 and 2004 and from studies published between 1992 and 1998. The price year was not reported.

Study designs and other criteria for inclusion in the review
The effectiveness data used in the economic model were the attainment of successful treatment end points and expected discharge from wound care clinical services (i.e. they no longer required wound care services).

Sources searched to identify primary studies
The effectiveness data for the NPWT group were derived from a dataset of routinely collected data maintained by Kinetics Concepts Inc., which included patients who were treated for wound care with NPWT between 1996 and 2004.

The effectiveness data for the standard therapy group were derived from a meta-analysis (Margolis et al. 2000, see ‘Other Publications of Related Interest’ below for bibliographic details), which pooled data on 586 patients with neuropathic diabetic foot ulcers who had participated in five different trials.
Methods used to derive estimates of effectiveness
The authors reported that an extensive literature review was performed using the PubMed and Cochrane databases to identify effectiveness data for the standard therapy group. After prioritisation, the authors selected the Margolis et al. 2000 paper as the most appropriate study from which to derive effectiveness data.

Measure of benefits used in the economic analysis
The measure of benefits used was the successful attainment of the treatment end point, defined as no longer requiring wound care services.

Direct costs
The direct costs to the health care payer were included in the analysis. These comprised the costs of supplies, nursing visits and physician visits. The authors assumed either one or two home nursing visits per day, based on data reported in the literature. The costs of wet-to-moist supplies were based on three daily dressing changes. Supplies of NPWT were based on standard usage guidelines. The unit costs for supplies were derived from published studies, and the authors made assumptions about resources and unit costs of physician visits. Since the costs were incurred over a 20-week period, discounting was not relevant and was therefore not performed. The price year was not reported. The authors reported the average costs.

Statistical analysis of costs
The costs were reported as point estimates (i.e. the data were deterministic).

Indirect Costs
Productivity costs were not included.

Currency
US dollars ($).

Sensitivity analysis
The only uncertainty investigated by the authors was the daily number of visits undertaken by the nurse, which was varied between one and two.

Estimated benefits used in the economic analysis
After 20 weeks, 46.3% of wounds treated with NPWT and 32.8% of wounds treated with wet-to-moist therapy achieved a successful treatment end point, (p<0.001).

Cost results
The 20-week costs for the NPWT group were $16,733 per patient, compared with $15,228 and $28,691 respectively for standard wet-to-moist therapy, depending on whether the nurse visited once- or twice-daily.

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

Authors’ conclusions
The authors concluded that negative pressure wound therapy (NPWT) could improve the proportion of diabetic foot ulcers attaining a successful treatment end point and decrease resource utilisation compared with standard wet-to-moist therapy.

CRD COMMENTARY - Selection of comparators
A justification was given for using standard wet to moist therapy as the comparator. It represented current practice in the authors’ setting. You should decide if the comparator used represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data for the NPWT were derived from a retrospective dataset of 2,091 patients, whereas those for the control group were derived from 586 patients included in a meta-analysis. The authors appropriately reported the methods used in their literature review, including the sources used to identify potential studies and the reasons why the
meta-analysis was selected as the most appropriate study. In order to make the patient groups as comparable as possible, the authors matched patients by excluding those older than 70 years and those with wounds of less than 1 month's duration. However, even after matching, the NPWT group differed from the control group. To minimise bias, the authors also undertook logistic regression analyses to control for other variables.

**Validity of estimate of measure of benefit**
The proportion of patients attaining the primary end point (i.e. no longer requiring wound care services) was derived directly from the meta-analysis for the control group and from the analysis of the retrospective dataset. The measure of benefit used was narrow and did not fully capture the health benefits of the intervention. Furthermore, it will also hinder comparisons across other health care interventions.

**Validity of estimate of costs**
The analysis of the costs was performed from the perspective of the health care system paying for the treatment. Given that perspective, it appears that all the relevant categories of costs have been included in the analysis. However, important cost items were omitted from the analysis, such as hospitalisations and treatments for diabetic ulcer complications. As NPWT was found to be more effective than standard therapy, it is possible that these omissions might have biased the results against NPWT. The resource use quantities and unit costs were either derived from the authors’ assumptions or from the published literature. The authors provided no rationale for some of the assumptions they made. Discounting was not relevant, as the costs were incurred during a very short time, and was appropriately not performed. The only uncertainty investigated by the authors was the daily number of visits undertaken by the nurse. Given the imbalance in the patient groups in terms of wound characteristics and the assumptions made in the costing study, a more thorough sensitivity analysis was required. The price year was not reported, which will hinder any future inflation exercises.

**Other issues**
The authors reported that their findings were consistent with the results from smaller, prospective studies and a larger randomised controlled trial. When the authors assumed that the wet-to-moist therapy group required one nursing visit per day, NPWT was found to be more effective, but more costly than wet-to-moist therapy. Consequently, an incremental cost-effectiveness analysis should have been performed. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively. However, because of the limitations of the study, the authors’ conclusions should be treated with some caution. The authors reported a number of further limitations to their study. In particular, some variability existed in the end point definitions used in the study, and there were important between-group differences that could have influenced their findings.

**Implications of the study**
The authors reported that their study provides important data with which to facilitate the design and conduct of further large-scale trials intended to examine the utility of NPWT in the treatment of diabetic foot ulcers and its potential for preventing amputations.

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**Other publications of related interest**
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Subject indexing assigned by NLM

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