The clinical and cost effectiveness of externally applied negative pressure wound therapy in the treatment of wounds in home healthcare Medicare patients

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 health intervention examined in the study was externally applied negative pressure wound therapy (NPWT), a treatment for chronic wounds. The treatment involved applying initially continuous topical negative pressure to an entire wound in order to remove excess fluid from the interstitial space of the wound, enhancing vascular perfusion through vessels compressed by the excess fluid pressure.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised Medicare-qualified patients suffering from chronic wounds, who failed previous interventions and completed NPWT at home.

Setting
The setting of the study was home care. The economic study was carried out in Texas, USA.

Dates to which data relate
Effectiveness evidence and quantities of resources used were gathered from December 1995 to October 1998 for the main intervention and in 1993 for the comparator. No price year was reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study for the health intervention examined in the study and from a published study for the comparator.

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
No power calculations were performed. The method of sample selection was not reported. Initially, 1,262 patients were selected, but a final sample of 1,032 patients (517 men, mean age: 65.9 years, range: 1 - 99 years) providing data of 1,170 wounds was included in the analysis. The patient records excluded were not complete and hardly legible. A sub sample of 847 patients providing data of 964 wounds was also considered, excluding wounds with no specified location.
or age. A further sub sample of patients (43 pressure ulcers stages III and IV located on the trochanter and trunk) was also analysed and then compared with patients in the comparison group. No baseline characteristics were reported.

**Study design**
This was a retrospective study based on a single cohort of patients. It was carried out at patients' houses in Texas. Patients were followed for 180 days. Assessment of the reliability and accuracy of the retrospective review of patients' charts was conducted through an audit and an overall accuracy rate of 95.12% was found.

**Analysis of effectiveness**
All patients included in the study group (and study subgroups) were accounted for in the effectiveness analysis. The primary health outcomes were reduction rate in wound area and volume after 30 days of treatment (healing rates).

**Effectiveness results**
After 30 days of treatment, area and volume reduction rates were 5.0 cm² (17.9% from starting area) and 27.0 cm³ (40.6% from starting volume) in the main study group (1,170 wounds) and 4.5 cm² (18.0% from starting area) and 25.4 cm³ (43.6% from starting volume) in the subgroup of 964 wounds, respectively. Finally, in the subgroup of 43 patients with an average initial surface area of 22.2 cm² and treated for 89 days, the average daily reduction rate was 0.230 cm².

**Clinical conclusions**
The NPWT intervention was effective in terms of healing rates in all patient groups considered in the study.

**Outcomes assessed in the review**
The outcome assessed from the literature was the average daily reduction rate obtained with saline-soaked gauze dressing applied to patients placed either on a LAL bed (43 subjects) or a foam mattress bed (41 subjects).

**Study designs and other criteria for inclusion in the review**
Not reported.

**Sources searched to identify primary studies**
Not stated.

**Criteria used to ensure the validity of primary studies**
Not reported.

**Methods used to judge relevance and validity, and for extracting data**
Not reported.

**Number of primary studies included**
Only one primary study was used as source of the effectiveness evidence for the comparator.

**Methods of combining primary studies**
Not relevant.
Investigation of differences between primary studies
Not relevant.

Results of the review
The average daily reduction rate with saline-soaked gauze dressing was 0.025 cm² in patients treated for 40 days with an initial surface area of 4.1 cm² and placed on a foam mattress bed and 0.090 cm² in patients treated for 33 days with an initial surface area of 4.3 cm² and placed on a LAL bed.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the effectiveness analysis; therefore a cost-consequences analysis was carried out.

Direct costs
Discounting was not relevant due to the short time horizon of the study. Unit costs and quantities of resources were reported only for nursing visits. The cost/resource boundary adopted was presumably that of the reimbursement agency. The cost items included in the analysis were materials and nursing visits. Estimated costs were derived from reimbursement rates, but the actual source was not reported. Resources used were collected from December 1995 to October 1998 for the main intervention and in 1993 for the comparator. The price year was not reported.

Statistical analysis of costs
Statistical analyses of costs were not conducted.

Indirect Costs
Indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were carried out.

Estimated benefits used in the economic analysis
See effectiveness results above.

Cost results
Estimated materials costs and nursing visit costs per day were $107.46 and $42.50 in the intervention group (subgroup of 43 patients utilising NPWT) and $10.00 and $85.00 in the comparator group (gauze and LAL bed). Total treatment costs were $14,546 in the intervention group and $23,465 in the control group.

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
The authors concluded that NPWT was a cost-effective intervention for several chronic wounds in comparison with an
approach based on saline and gauze, since NPWT improved healing times and reduced treatment costs.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was determined by the technology examined in the study found in the literature and comparable with the study population considered in the present study. You, as a user of this database, should assess whether it represents a widely used technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis of the effectiveness was based on a retrospective review of patients' charts and the basic data collection was not made for study research. To overcome this possible limitation, an audit was conducted to assess the accuracy of available data. Power calculations were not performed and the method of sample selection was not reported. In addition, data from the comparison group were not derived from the study sample, but from the most closely matched patient population observed in the literature. However, some differences in the two studies were reported, such as the setting of the study. Moreover, as the authors acknowledge, demographics and other baseline characteristics of patients in the study obtained from the literature were not reported.

Validity of estimate of measure of benefit
No benefit measure was used in the economic analysis. Although healing rates appear as the most natural outcomes of a treatment for pressure ulcers, it would have been interesting to have adopted a summary benefit measure reflecting patients' preferences for the interventions.

Validity of estimate of costs
The analysis of costs included only a few items, which were assessed presumably from the perspective of the reimbursement agency. Quantities of resources used and unit costs were reported only for one item (nursing visits). No price year was reported. Statistical analyses of costs were not carried out. Indirect costs were not included, but could have been relevant in terms of productivity losses not only for the patients, but also for caregivers.

Other issues
The authors did not compare their findings with those from other studies. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not conducted. The authors reported some limitations of their analysis, mainly related to the retrospective design and the use of only a single primary study as providing data for the comparator. Effectiveness results were reported fully, but the authors’ conclusions might be too strong, given the limitations mentioned.

Implications of the study
The authors made no further recommendations. It would seem reasonable to consider future research that uses a better design and that collects more data on possible confounding variables, as well as complete costing.

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