The clinical efficacy and cost effectiveness of the vacuum-assisted closure technique in the management of acute and chronic wounds: a randomized controlled trial


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
Vacuum-assisted closure (VAC), also known as topical negative pressure, was evaluated for the treatment of acute and chronic wounds. It was compared with treatment using modern dressings. The technique entails an open cell foam dressing inserted into the wound and use of a vacuum pump to apply a continuous sub atmospheric pressure of 125 mmHg. Depending on the wound type and according to the hospital protocol, dressings used in the comparator group were hydrocolloid dressings, alginate, acetic acid or sodium hypochlorite. Dressings in both groups were changed three times a week.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis

Study population
The population comprised patients with any type of wound (acute or chronic) presenting to the study hospital. Exclusion criteria were the use of steroid drugs, residual malignant cells in the wound, radiotherapy, deep fistulas, sepsis, osteomyelitis, active bleedings, active psychiatric diagnosis and age younger than 18 years old.

Setting
The setting was inpatient care at the Rijnstate hospital, Arnhem, The Netherlands.

Dates to which data relate
Patients were recruited and clinical and cost data evaluated from March 2002 to May 2004. The price year was not reported.

Link between effectiveness and cost data
Clinical and resource use data were collected from the same sample of patients. The data appear to have been collected prospectively.

Study sample
Consecutive patients from all departments of the hospital who fulfilled the entry criteria were invited to participate. A sample size calculation was reported, using healing time as the outcome of interest. The authors stated that they did not know the exact number of patients who were excluded. Sixty-five patients were randomised, 32 to VAC and 33 to conventional treatment.

Study design
This was a single-centre, randomised controlled trial. Block randomisation for every 20 patients was performed using closed envelopes. Eighteen of the 65 patients were lost to follow-up, and the reasons were reported in detail. The length of follow-up was not explicitly stated. Intention-to-treat analysis was not reported, and the authors stated that patients lost to follow-up, death, early dismissal or lack of cooperation were censored. Baseline differences between the groups were adjusted using Cox regression.
Analysis of effectiveness
All patients were evaluated three times per week. A visual analogue scale for pain, use of antibiotics, granulation surface, materials used and nurse time were recorded. Photographs and bacterial swabs were taken once a week. Surfaces were evaluated using a standardised drape. The authors stated that clinical observations and measurements could not be blinded because of the marks on VAC-treated wounds. Time-to-event analysis techniques and Cox regression were used to evaluate the outcomes. Median healing times were compared using Mann-Whitney U-tests.

There were baseline differences between the groups. Specifically, the conventional arm had more vascular disease, more use of anticoagulants and more chronic wounds than the VAC group.

Eighteen patients were lost to follow-up. Thus, in the end, 26 were included for the VAC analysis and 21 for the comparator. The reasons for exclusion were described.

Effectiveness results
The VAC group had a median healing time 4 days shorter than the control group (16 versus 20 days), without reaching statistical significance, (p=0.32).

Subgroup analysis showed a trend for faster healing in diabetics or patients with vascular disease in the VAC group.

Clinical conclusions
VAC had wound closure times at least as fast as conventional treatment with modern wound dressings. The authors stated that those who benefit are mostly diabetic and cardiovascular patients.

Measure of benefits used in the economic analysis
There was no summary measure of benefit. In effect, a cost-consequences analysis was carried out.

Direct costs
The cost categories included in the analysis were those of the dressing materials and the nursing time involved. Although few details were provided, the costs appear to have been those of the hospital. Resource use was measured during the clinical trial. Nurse time was measured and reported. The unit costs and resource use were not reported separately. Discounting was not relevant given the short-term time horizon.

Statistical analysis of costs
The costs and time involvement were compared between the two groups using the Mann-Whitney U-test.

Indirect Costs
No productivity costs were reported.

Currency
Euros (EUR).

Sensitivity analysis
The groups were compared statistically (see 'Statistical Analysis Of Quantities/Costs' section). No specific sub-group comparison was reported in relation to the costs.

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

Cost results
The total costs per day were significantly higher in the VAC group than in the conventional group (EUR 24 versus EUR 14, p<0.0001). However, taking into account that VAC seemed to have a faster healing time, the total costs for the whole treatment were not significantly different (EUR 353 versus EUR 273, p=0.09).

The total labour time costs were significantly lower in the VAC group than in the conventional group (EUR 81 versus EUR 176, p=0.04), owing mainly to a difference of 6 minutes/day in labour time in favour of the VAC group.
The VAC group had a total of 3 hours less nurse time per whole treatment period.

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

**Authors' conclusions**
With similar total costs to modern wound dressings, vacuum-assisted closure (VAC) saves nurse time and is more comfortable for the patients.

**CRD COMMENTARY - Selection of comparators**
The comparator chosen (modern wound dressings in all types of wounds) was explicitly justified. It appears to have represented the current mix of dressings used in the authors’ setting. As the dressings mix or the wound types could differ from setting to setting, you should take this into account before extrapolating the study results.

**Validity of estimate of measure of effectiveness**
Though the study was a randomised controlled trial, there are some issues that could compromise its internal validity. In particular, the significant loss to follow-up (around 30%), the lack of any mention of an intention-to-treat analysis, and possibly the use of closed envelopes (which could diminish allocation concealment). Appropriate analysis was carried out to adjust for baseline differences. Sub-group analysis was reported but was selectively interpreted by the authors. Also, as the authors stated that they did not know the exact number of patients who met the inclusion criteria but were excluded, it is difficult to know whether the sample was representative of the study population. Power and sample size details were adequately reported.

**Validity of estimate of measure of benefit**
As there was no summary measure of benefit, the reader is referred to the comments in the 'Validity of Estimate of Measure of Effectiveness' field.

**Validity of estimate of costs**
The cost data were generally described only briefly. Though the perspective seems to have been that of a single institution, this was not clearly stated. The sources of the unit costs were not described, but appear to have been those of the hospital. If treatment received affects cost categories other than nurse time and dressing materials, the study would not detect those differences. The price year was not reported, which could limit the extrapolation of this exercise to other dates. Discounting was appropriately not taken into account, given the short time horizon of the study. The only quantity that was adequately reported was nurse time. The costs were compared using non-parametric tests in order to compare medians, while most decision-makers would be interested in comparing mean costs using parametric assumptions. The study seems to have been underpowered to detect total cost-differences, as the sample size calculation did not explicitly consider the detection of cost-differences.

**Other issues**
The authors made some broad comparisons of their study with others that had used VAC. The generalisability to other settings was not directly addressed. The authors appear to have presented some results selectively, especially the sub-group analysis. The authors did not report any other specific limitations.

**Implications of the study**
VAC and modern dressings appear to lack significant differences, although a possible difference was detected in a sub-group analysis in cardiovascular and diabetes patients. Nevertheless, other aspects of VAC, such as greater patient comfort and less use of nurse time, make this alternative an attractive wound treating option. As the authors stated, more research is needed with VAC in general, and specifically in the sub-group of cardiovascular or diabetic patients.

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