"Constant force technology" versus low-air-loss therapy in the treatment of pressure 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
The PressureGuard CFT (Constant Force Technology) mattress by Span-America Medical Systems Inc., subsequently referred to as the "study mattress", and a low-air-loss (LAL) mattress were compared.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study examined patients with stage III or IV pressure ulcers on the trunk or pelvis. The patients had to be bed ridden.

Setting
The setting was secondary care. The economic study was carried out in two sites, San Diego (CA) and Fresno (CA), USA.

Dates to which data relate
The dates to which the effectiveness and resources use related were not stated. The price year was also not reported

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

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

Study sample
No power calculations were reported and no specific sample size was planned. However, the authors pointed out that the sample size was so small that it prohibited a statistical analysis of the results.

If a patient had more than one pressure ulcer, only the deeper one was followed in the study. A total of 20 patients were included in the study, 10 in each of the two groups. The mean age of the patients was 72.8 years (range: 36 - 100) in the study mattress group and 70.5 years (range: 48 - 90) in the LAL mattress group. Eighty per cent of the patients in the study group were nutritionally deficient versus 88% in the LAL group. Forty per cent of the patients in the study group were ventilator dependent, compared with 63% in the LAL group.
**Study design**
The study was a randomised controlled trial (RCT) that was carried out in two centres, the Vencor Hospital (San Diego) and the Horizon Health and Sub-Acute Centre (Fresno). The patients were randomised into the study in an alternating pattern, the first patient to the LAL group, the second to the study group, and so on. Group allocation was not concealed from the study physicians. The duration of follow-up was 8 weeks. However, the study exit criteria also included death, discharge from inpatient status or flap surgery. Data for patients not completing the full 8 weeks were calculated using the number of weeks they participated. Two of the LAL patients were switched from the LAL mattress to the study mattress during their treatment upon the request of the physician. The authors did not consider the outcomes of these two patients in their results.

**Analysis of effectiveness**
The analysis of the clinical study was conducted on the basis of treatment completers only. The primary heal outcomes used were meeting the goals of wound treatment, as determined by the team, and the rate of wound healing over time (maximum 8 weeks). The goals of wound treatment included progressive closure, preparation for flap surgery and maintenance of condition. Each wound was rated "achieved", "not achieved" or "exceeded". The rate of wound healing was expressed as a percentage of the original wound size. The authors reported measurements at 3 weeks and at exit from the study, to determine whether wound healing either slowed or accelerated.

According to the authors, the groups were evenly matched in terms of their average age and the percentage of patients who were nutritionally deficient. However, the LAL group was reported to have a higher proportion of ventilator-dependent patients than the study group. The authors stated that the groups were comparable at baseline over several characteristics.

**Effectiveness results**
All 10 patients on the study group achieved or exceeded their goals during the study period, compared with 5 of the 8 patients in the LAL group.

At the end of the study period, the average volume closed was nearly equal between the groups, 25.8 cm³ for the study group versus 22.2 cm³ for the LAL group. However, the average rate of closure per week was higher for the study group (3.5) than the LAL group (2.8), as was the average percentage closed (60% versus 39.6%).

**Clinical conclusions**
The authors concluded that improved patient outcomes, such as improved healing rates, were achieved when using the study mattress in comparison with the LAL mattress.

**Measure of benefits used in the economic analysis**
No summary benefit measure was used in the economic analysis. In effect, a cost-consequences approach was used.

**Direct costs**
The only costs included in the analysis were the rental costs of the LAL mattress and the purchase price of the study mattress. These costs were taken from the perspective of the hospital. The cost of the study mattress reflected the manufacturer's suggested retail price. The source of the weekly rental cost of an LAL mattress was not stated. Discounting was unnecessary, as the costs were incurred during 8 weeks, and was not undertaken. The price year was not reported.

**Statistical analysis of costs**
No statistical analysis was performed.
Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed to deal with uncertainty.

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

Cost results
The total rental cost of the LAL mattress was $1,960 per patient over the 8 weeks. The purchase price of the study mattress was $1,080.

Synthesis of costs and benefits
Not relevant as a cost-consequences analysis was carried out.

Authors' conclusions
The results showed that patient outcomes were improved when using an alternative pressure-reducing device, compared with the low-air-loss (LAL) mattress, without incurring costly rental or purchasing bills. In addition, further savings could be realised because the study mattress would be available for future use.

CRD COMMENTARY - Selection of comparators
No explicit justification was given for the comparator used, but it would appear to represent current practice in the authors' settings. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis used a RCT, which was appropriate for the study question. However, the method of randomisation was poor since the patients were alternately placed in the different groups and the allocation was not concealed from the physicians. Consequently, two patients were misallocated to the study mattress group. The study sample was so small it is hard to say whether it was representative of the study population. It also prevented any statistical analysis being conducted. The patient groups were shown to be comparable at analysis, with the exception that the LAL group had more ventilator-dependent patients. However, the analysis of effectiveness was not handled in a credible way, even though an RCT was used. For example, the outcomes were analysed for treatment completers only and allocation to the study groups was not random but alternate, meaning that researchers had the possibility of allocating patients where they wanted. Also, the outcome of meeting the goals of wound treatment was very subjective as it depended on the evaluation and opinion of the physicians and medical staff.

Validity of estimate of measure of benefit
No summary benefit measure was used. The analysis was, in effect, based on a cost-consequences approach.

Validity of estimate of costs
Not all of the categories of cost relevant to the perspective adopted were included in the analysis. The analysis only
included the 8-week rental costs of the LAL mattress and the purchase cost of the study mattress. Although the majority of the costs were omitted, these were unlikely to have affected the authors' conclusions, as all other costs (e.g. personnel, drugs) would have been similar for the two groups. The prices for the study mattress were derived from the manufacturer's recommended retail price, whilst those for the rental of a LAL mattress were not stated. No sensitivity analysis of the prices was conducted. The price year was not reported.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not addressed. The authors reported the small sample size of the study as a limitation, because it did not allow a statistical analysis of the results. Thus, there is the possibility that the effectiveness conclusions were due to chance rather than the effect of the study mattress. Another limitation was the use of two different LAL mattresses at the two sites, but it was stressed that both had very similar features. Given the limitations of the study, it is not possible to state categorically that the authors did not present their results selectively. It should also be remembered that one of the co-authors of this study is also the Clinical Support Manager for Span-America Medical Systems, the manufacturer of the study mattress, thus there was a clear conflict of interest.

Implications of the study
The authors stated that, in view of the potential cost-savings of the study mattress over the LAL mattress, additional studies involving a larger sample size should be undertaken.

Source of funding
None stated.

Bibliographic details

PubMedID
11889743

Other publications of related interest

Maklebust J. An update on horizontal patient support surfaces. Ostomy/Wound Management 1999;45(1 Suppl):70S-77S.


Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Aged; Aged, 80 and over; Air; Beds /economics /standards; Clinical Nursing Research; Cost Control; Cost-Benefit Analysis; Humans; Middle Aged; Pilot Projects; Pressure Ulcer /classification /economics /etiology /therapy; Prospective Studies; Severity of Illness Index; Skin Care /instrumentation /methods /nursing; Treatment Outcome; Wound Healing

AccessionNumber