Research comparing three heel ulcer-prevention devices

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 assessed three devices used in the prevention of heel ulcers. The first device was the High-Cushion Kodel Heel Protector (bunny boot). This consisted of a 1-size, ventilated polyester fleece. The second device was the Egg Crate Heel Lift Positioner (egg crate). This consisted of a long polyurethane egg-crate strip with a window through which the heel can dangle. The third device was the Waffle Air Cushion (foot waffle). This consisted of an inflatable plastic pillow with ventilation holes and a window through which the heel can dangle. The foot waffle was available in small, medium and large sizes. All three devices were attached to patients using a Velcro strap.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised moderate- to high-risk patients admitted to hospital for at least 72 hours. Moderate- to high-risk status was defined as a Braden Score of less than or equal to 14. Patients with hip surgery were excluded, as were patients with a pre-existing pressure ulcer on the foot or a foot deformity.

Setting
The setting was tertiary care. The economic study was carried out in south Texas, USA.

Dates to which data relate
The effectiveness data and resource use data were collected from October 1997 to August 2001. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The resource use data were collected prospectively for the same patient sample as that used in the effectiveness study.

Study sample
A prospective power calculation with alpha set at 0.05, a desired power of 0.80 and an expected effect size of 0.10, indicated that a sample size of 550 was required. Consecutive patients admitted to the participating hospitals were assessed for study entry criteria, and then consent was sought for their participation in the study. The final study sample
consisted of 338 patients. Fifty-three patients were excluded from the study for wearing their assigned device for less than 48 hours. A further 45 patients were excluded from the analysis because they had incomplete data. Two hundred and forty patients were therefore included in the analysis. Of these, 77 were randomised to the bunny boot, 87 to the egg crate and 76 to the foot waffle. The mean age of the patients analysed was 63.9 years and 139 (57.9%) were male. There was evidence that the initial study sample was representative of the distribution of minorities in the military population.

Study design
This was a randomised trial that was conducted in two centres. The patients were randomised using sealed envelopes. The patients were followed until they were discharged from hospital, their Braden score rose above 14, or they developed a pressure ulcer. The mean follow-up time was 7.5 days. There was no blinding to treatment.

Analysis of effectiveness
The analysis of effectiveness was conducted on the basis of treatment completers with complete data. The analysis was based on the left leg only given the dependence on both legs. The primary health outcome was the proportion of patients developing a pressure ulcer, the definition of which was based on the National Pressure Ulcer Advisory Panel Quick Reference Guide Number 3. At analysis, there were significantly fewer men assigned to the bunny boot than the other two devices. There was no adjustment for confounding variables.

Effectiveness results
Three pressure ulcers (3.9%) developed in the bunny boot group, compared with 4 (4.6%) in the egg crate group and 5 (6.6%) in the waffle crate group. There were no significant differences between groups, (p=0.416).

The study results indicated that certain co-morbidities were associated with an increased risk of pressure ulcer. These included peripheral vascular disease, diabetes, hypertension and alcoholism.

The analysis did not account for the fact that the bunny boot was not used as intended and was, instead, supplemented with standard pillows.

Clinical conclusions
The authors concluded that there is no difference between the devices in terms of pressure ulcer prevention. A post hoc power analysis indicated that a sample size of 6,225 would be required to detect the postulated effect size of 0.01.

Measure of benefits used in the economic analysis
The authors demonstrated that the clinical effectiveness of the three devices was equal, thus they performed a cost-minimisation analysis. It is likely that the study was underpowered to detect a difference between devices, but a post-hoc analysis indicated that any potential effect size was very small.

Direct costs
The study included the direct hospital costs. These consisted of the price of each device and the cost of pillows used to supplement the bunny boot device. The authors did not provide the source of the price data. Discounting was not relevant given the short timeframe of the study. The study reported the cost per device.

Statistical analysis of costs
Owing to the minimal amount of cost data included in the analysis, no statistical analyses were performed.

Indirect Costs
The indirect costs were not included in the analysis.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analyses were conducted.

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

**Cost results**
The bunny boot cost $2.70 per pair, and was typically supplemented with 2 pillows worth $7 each, bringing the total cost of the device to $16.70.

The egg crate cost $29.67 per pair.

The foot waffle cost $26.62 per pair.

The bunny boot was significantly cheaper than the other two devices, (p=0.001).

The authors stated that patients randomised to receive the bunny boot often required more than one device, as they were easily lost. This increased resource use associated with the bunny boot was not accounted for in the cost-minimisation comparison.

**Synthesis of costs and benefits**
Not relevant.

**Authors' conclusions**
The bunny boot was the most cost-effective device for preventing foot ulcers.

**CRD COMMENTARY - Selection of comparators**
The authors did not provide an explicit justification for their selection of the comparators. The study did not include a no treatment arm against which to compare the devices. The authors acknowledged that other studies had indicated that simple standard pillows might be a relevant alternative. You must decide whether the three devices included in this study represent a useful comparison in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a randomised trial, which was appropriate for the study question. There was no indication that the patients at baseline were not representative of the study population. However, in the final analysis, the prevalence of pressure ulcers was much lower than that predicted in the literature for the study population. It is difficult to interpret this difference given that the study failed to include a no treatment arm as a control. The patient groups were shown to differ significantly in the proportion of males in each group. This potential confounder was not adjusted for in the analysis. However, given that the study was underpowered and there were very few events, it is unlikely that this omission will have affected the study results. Although a randomised trial was conducted, the outcomes were analysed for treatment completers with complete data only, which introduces the possibility of bias into the study results. The characteristics of patients with missing data were not described. Although there was no blinding to
treatment, the development of a pressure ulcer should be a relatively objective outcome measure.

**Validity of estimate of measure of benefit**
The effectiveness analysis was based on the therapeutic equivalence of alternative treatments. The economic analysis therefore included only costs.

**Validity of estimate of costs**
The study included only the price of the devices assessed and the cost of pillows used to supplement the bunny boot device. The study did not include the cost of the nurses' time when fitting the devices, the cost of replacing lost devices, the cost of training family members and nurses, or the cost of continually assessing patients. These omissions could well affect the authors' conclusions, particularly as the 'Discussion' indicated that the bunny boot required replacement more often than the other two devices. The authors did not report the source of the price data. This study is unlikely to provide useful evidence to support the cost to a hospital of using the devices examined.

**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 did not present their results selectively. The authors' conclusions that the bunny boot is the most cost-effective device were not justified given the minimal cost data included in the analysis, and the fact that the bunny boot was supplemented with a potentially effective alternative through the use of additional pillows. The authors acknowledged that the widespread use of supplementary pillows was a limitation of the analysis. They also acknowledged that process characteristics of the study, such as the daily assessments of patients, might also have influenced the study results.

**Implications of the study**
The authors recommended that future research assesses the use of pillows as a pressure-relief device for heels.

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**Bibliographic details**

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