Pressure ulcer prevention: a randomized controlled trial of 2 risk-directed strategies for patient surface assignment

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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
Two programmes of patient surface assignment for the prevention of pressure ulcers (PUs) in the intensive care unit (ICU) were compared. One of the programmes emphasised the use of purchased products (experimental group), while the other relied on both purchased and rented surfaces (control group).

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of patients at risk for the development of PUs. The patients were included if they were aged at least 17 years, had an admission Acute Physiology and Chronic Health Evaluation (APACHE) II score of at least 15, and were expected to stay in the ICU for at least 3 days. The patients were excluded if they were admitted with an existing PU, were moribund and not expected to survive, were admitted for compassionate care, or were to be imminently transferred from the ICU.

Setting
The study was set in secondary care, i.e. a 30-bed multidisciplinary ICU. The economic study was carried out at the Richard Ivey Critical Care Trauma Centre, in London, Ontario, Canada.

Dates to which data relate
The effectiveness and resource use data were collected from April 1996 to March 1997. 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 effectiveness and cost data were collected prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
The study sample consisted of 144 consecutive, eligible patients at risk for the development of PUs. There were 107
patients with a mean age of 64.6 (+/- 15.2) years in the experimental group. Of these, 58.3% were men. There were 37 patients with a mean age of 65.9 (+/- 15.3) years in the control group. Of these, 60.5% were men. Originally, there were 149 eligible patients, but 5 (2 in the control group and 3 in the experimental group) did not receive their assigned intervention. Of these 5 patients, 2 were not assessed within 24 hours, one died prior to surface assignment, and 2 eligible admissions were missed.

The authors stated that the sample size was determined for a single-sided test that would compare the incidence of PU development between the two study groups. In the planning stage of the study, the hypothesis was that the two groups would be deemed equivalent if the difference in incidence was within 7%. Significance was set at an alpha-value of 0.05, and power at 0.90. Under these assumptions, 35 patients were required in the control group and 105 in the experimental group.

**Study design**
The study was a single-centre RCT (the Richard Ivey Critical Care Trauma Centre). The patients were allocated using a 3:1 ratio (experimental to control) computer-generated randomisation method with permuted blocks of 4, 8 and 12 prepared by the study co-ordinator and provided to the charge nurses in the form of a master list. The study was conducted in an unblinded manner. Four patients (one in the control group and 3 in the experimental group) withdrew (reasons not given) before the end of the trial. Thus, the final sample comprised 104 patient in the experimental group and 36 in the control group. The patients were followed until death or discharge from the ICU.

**Analysis of effectiveness**
The analysis appears to have been conducted on an intention to treat basis. The primary health outcome used in the study was the incidence of PUs. The two groups were shown to be comparable at analysis in terms of their age, gender, height, weight, body surface area, APACHE II score, ICU length of stay, and mortality.

**Effectiveness results**
No significant differences were detected between the groups with respect to the development, site or severity of PUs.

The incidence of PUs was 24.2% (26 out of 107) in the experimental group, and 29.7% (11 out of 37) in the control group.

The most common site for PUs was the coccyx or sacral area (24 to 32% of the observed PUs).

The predictors of PU development were the ICU length of stay and the Skin Ulcer Risk Evaluation score.

**Clinical conclusions**
No significant differences were detected between the groups in terms of the development, site or severity of PUs.

**Modelling**
A decision tree model was used. This was drawn up using both resource consumption and outcome data derived from the randomised controlled trial (RCT). Given the equivalence in PU incidence between the two groups, the model was constructed in order to determine the less costly of the two programmes.

**Measure of benefits used in the economic analysis**
No statistically significant difference was found in the primary health outcome used in the effectiveness analysis. A cost-minimisation analysis was therefore carried out.

**Direct costs**
The surface costs for those patients receiving a speciality surface were calculated as the sum of all median costs. In the experimental group, these costs included those for the static air overlay (Sof-Care overlay), alternating support mattress, and low-air-loss overlay (SPR Plus). In the control group, these costs included the mattress replacement-pressure reduction (Therarest) product, mattress replacement-pressure relief (First Step) product, mattress overlay (First Step Plus), and the low-air-loss bed (both KinAir III and Therapulse). The alternating support mattress is a mattress replacement. Thus, a daily discounted cost (discount rate, 5%) for its use was calculated using its purchase price and the assumption it would last for five years. In the control group, it was assumed that the less costly products would be purchased (Therarest and First Step), while the other products would be rented on a daily basis.

The total costs and the quantities were estimated from actual data and were also derived using modelling. A price year was not reported. The quantities of the resources were measured from April 1996 to March 1997.

Statistical analysis of costs
The costs were treated in a deterministic manner. Thus, no statistical analysis of the costs was carried out.

Indirect Costs
The indirect costs were not estimated and no rationale was provided for their exclusion. However, for the benefit of this study, the analysis was only carried out from the perspective of the senior hospital administration, rather than that of society.

Currency
Canadian dollars (Can$).

Sensitivity analysis
A sensitivity analysis was conducted in which all the experimental cost assumptions were varied from 50 to 200% of their baseline value. The control group costs were varied from 0 to 200% of their baseline values. It would appear that univariate analyses were performed.

Estimated benefits used in the economic analysis
No summary benefit measures were determined in the study. See the 'Effectiveness Results' section.

Cost results
The least costly strategy was observed in the experimental (purchase) group. Under the baseline assumptions, the surface costs per at-risk patient were Can$76 in the experimental group and Can$171 in the control group. The saving of Can$95 per at-risk patient translates into conservative annual savings of Can$47,500 at the authors' institution. The sensitivity analysis supported these findings. It also showed that the cost of Stage I ulcers in the control group had the greatest effect on the model. In other words, the control strategy becomes the less costly alternative only when its Stage I costs in those who are placed on a speciality surface are less than $91 (approximately 15% of the observed value of $645).

Synthesis of costs and benefits
The costs and the benefits were not combined because of the existence of clinical equivalence. Consequently, a cost-minimisation analysis was carried out.

Authors' conclusions
In terms of effectiveness, there were no significant differences between the two prevention strategies. However, the strategy that emphasised purchased rather than rented products was proven to be the more economical.
CRD COMMENTARY - Selection of comparators
The choice of the comparator was implicitly justified on the grounds of findings from the authors’ prior RCT, and the desire to improve the generalisability of their findings. The comparators seem to represent current practice in the authors' setting. You should assess whether they represent widely used interventions in your own setting.

Validity of estimate of measure of effectiveness
The validity of the measure of effectiveness will have been enhanced by the use of randomisation (although blinding was not used). Also, by the analysis being conducted on an intention to treat basis. The two groups were shown to be comparable at baseline. In addition, power calculations were undertaken prior to the study to ensure that the sample size was sufficient to detect any clinically significant differences.

Validity of estimate of measure of benefit
No summary measure of benefit was reported due to the cost-minimisation approach adopted. An assessment of the patients’ preferences in terms of quality issues would have been useful.

Validity of estimate of costs
A sensitivity analysis was used to test the robustness of the economic findings. Power calculations were performed to detect economically significant differences, but it was not stated whether these power calculations were conducted similarly to detect economically significant differences. Since patient and indirect costs are likely to have been significant in this study, perhaps a wider perspective should ideally have been considered. No price year was reported. Statistical analyses of the quantities were not carried out.

Other issues
The authors have considered some of the limitations of the trial, i.e. the nonblinded nature of the randomisation process, in the discussion section of the paper. They argued that the methods they have used should not introduce any significant bias. Apart from reference to the authors’ prior RCT, no comparisons were made with other studies that have been carried out in this field. Generalisability to other settings was not explicitly addressed in the discussion section, even though it was recognised as a weakness in the authors' previous study. However, their choice of a modelling technique is likely to have been made in order to improve generalisability. A specific study population consisting of patients at risk for the development of PUs was enrolled and this was reflected in the authors’ conclusions.

Implications of the study
In terms of further research, the authors themselves are carrying out a similar multi-site RCT in 11 high-risk units, in order to determine the extent to which these findings can be applied outside the ICU.

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