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Pressure relieving support surfaces (PRESSURE) trial: cost effectiveness analysis

Cynthia Iglesias, Jane Nixon, Gillian Cranny, E Andrea Nelson, Kim Hawkins, Angela Phillips, David Torgerson, Su Mason, Nicky Cullum and PRESSURE Trial Group

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Pressure relieving support surfaces (PRESSURE) trial: cost effectiveness analysis

Cynthia Iglesias, Jane Nixon, Gillian Cranny, E Andrea Nelson, Kim Hawkins, Angela Phillips, David Torgerson, Su Mason, Nicky Cullum, on behalf of the PRESSURE Trial Group

Abstract

Objective To assess the cost effectiveness of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers in patients admitted to hospital.

Design Cost effectiveness analysis carried out alongside the pressure relieving support surfaces (PRESSURE) trial; a multicentre UK based pragmatic randomised controlled trial. **Setting** 11 hospitals in six UK NHS trusts.

Participants Intention to treat population comprising 1971 participants.

Main outcome measures Kaplan Meier estimates of restricted mean time to development of pressure ulcers and total costs for treatment in hospital.

Results Alternating pressure mattresses were associated with lower overall costs (£283.6 per patient on average, 95% confidence interval –£377.59 to £976.79) mainly due to reduced length of stay in hospital, and greater benefits (a delay in time to ulceration of 10.64 days on average, –24.40 to 3.09). The differences in health benefits and total costs for hospital stay between alternating pressure mattresses and alternating pressure overlays were not statistically significant; however, a cost effectiveness acceptability curve indicated that on average alternating pressure mattresses compared with alternating pressure overlays were associated with an 80% probability of being cost saving.

Conclusion Alternating pressure mattresses for the prevention of pressure ulcers are more likely to be cost effective and are more acceptable to patients than alternating pressure overlays.

Introduction

Older age, reduced mobility, impaired nutrition, vascular disease, faecal incontinence, and skin damage consistently emerge as risk factors for pressure ulcers.^{1 2} The annual cost to the UK NHS of implementing the current guidelines for the treatment of pressure ulcers was estimated in the region of £1.4b to £2.1b at 2000 prices.³ Experts differ in their views as to the extent to which pressure ulceration is preventable⁴; however most would agree that pressure ulcers are often the consequence of poor preventive strategies. Between April 2002 and April 2004, the NHS Litigation Authority (www.nhs.uk/home.htm) received 56 claims for pressure damage (NHS Litigation Authority, personal communication, 2005), these included four instances where the patient died. The average cost of a claim was reported as £37 295 (\$70 453; €54 713) but ranged up to £375 000. Inadequate nursing care, lack of assistance and care, and failure or

delay in diagnosis were often cited as causal. Early identification of vulnerable people and timely provision of a cost effective programme for the prevention of pressure ulceration in hospitals could prevent this cost to the NHS and the adverse health consequences of those affected.

Current National Institute for Health and Clinical Excellence guidelines on the prevention of pressure ulcers recommend the use of high specification foam mattress as the standard in vulnerable patients and surfaces such as alternating pressure mattresses for high risk people.⁵ This latter recommendation was based on expert opinion in the absence of research. Alternating pressure surfaces are available as whole mattress replacement systems (typically costing about £4000) and as overlays (typically £1000), which are placed on top of a standard hospital mattress. The relative costs and effects of these different systems are uncertain. We carried out an economic evaluation alongside a large multicentre pragmatic randomised controlled trial of alternating pressure mattresses and alternating pressure overlays. The clinical results of the trial are published in the accompanying paper.⁶

Methods

Full details of the trial's methods are available elsewhere.⁷ Briefly, eligible people were aged at least 55 years who were admitted to vascular, orthopaedic, medical, or care of the elderly wards, either as acute or elective admissions, in the previous 24 hours. Inclusion criteria were an expected length of stay of at least seven days, and an expected (if elective) or actual limitation of activities and mobility or an existing pressure ulcer of grade 2, or both. Trial completion was defined as improved mobility and activity, resolution of pressure ulcers for three consecutive days, transfer to non-participating wards or consultants, discharge from hospital, 60 days from randomisation, or death.

Interventions

Participants were randomised to receive an alternating pressure mattress or an alternating pressure overlay within 24 hours of hospital admission, using a remote telephone randomisation service providing concealed allocation. Rather than restrict the evaluation to prespecified products, we developed specifications for eligible surfaces to permit the hospitals to use mattresses and overlays from their existing stock or within their current rental contract (see Nixon et al⁶).

Study design

We carried out an economic evaluation analysis in the intention to treat population of the pressure relieving support surfaces

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Table 1 Description of unit costs associated with using alternating pressure mattresses or alternating pressure overlays for patients admitted to hospital

Item	Unit cost (£)	Source
Hospital costs by specialty:		
Care of elderly people	165.00	Health service database 2003, Chartered Institute of Public Finance and Accountancy
Orthopaedic	385.00	Health service database 2003, Chartered Institute of Public Finance and Accountancy
Vascular	374.00	Health service database 2003, Chartered Institute of Public Finance and Accountancy
Surface costs:		
Overlay	1 010.50	Huntleigh and Hill-Rom retail price list
Mattress	4173.60	Huntleigh and Hill-Rom retail price list
Daily cost of overlay:		
2 year life span	1.38	Based on estimates of average unit cost provided by manufacturers
5 year life span	0.55	Based on estimates of average unit cost provided by manufacturers
7 year life span	0.40	Based on estimates of average unit cost provided by manufacturers
Daily cost of mattress:		
2 year life span	5.71	Based on estimates of average unit cost provided by manufacturers
5 year life span	2.25	Based on estimates of average unit cost provided by manufacturers
7 year life span	1.63	Based on estimates of average unit cost provided by manufacturers
Daily rental of mattress:		
Overlay	8.23	Huntleigh and Hill-Rom retail price list
Replacement	16.30	Huntleigh and Hill-Rom retail price list

(PRESSURE) trial.⁶ We estimated the mean health benefits and mean total costs associated with both surfaces.⁸⁻⁹

Data collection

To estimate the number of pressure ulcer free days, we recorded the time taken for the development of a new grade 2 pressure ulcer for each patient. To estimate average length of stay in hospital, we routinely recorded the dates of entry and discharge from hospital for each patient. We did not record use of wound dressings as the clinical research nurses routinely observed patients with pressure ulcers up to grade 2 were not receiving wound dressings.

Unit costs

Table 1 provides a description of the unit costs. We calculated hospital treatment costs per day on the basis of estimates from the Chartered Institute of Public Finance and Accountancy of the cost per patient day in a care of elderly people, orthopaedic, or general surgery ward.¹⁰ The unit purchasing and rental costs of each surface were estimated on the basis of UK retail prices provided by the manufacturers (Huntleigh Healthcare and Hill-Rom). Patients were assumed to have remained on the allocated surface during their entire hospital stay. No robust evidence of the expected life span of the alternating pressure devices was available; however, clinical experts suggested that adequately used and maintained surfaces could last from two to seven years, provided they were not in constant use. For the base case analysis we assumed a two year life span. The pricing year was 2002-3.

Health outcomes

We defined health benefit as the difference in the mean time to develop a pressure ulcer between the groups—that is, pressure ulcer free days. Survival analysis was used to calculate the restricted Kaplan Meier estimates of mean time to pressure ulcer development in each trial arm.

Table 2 Means (standard deviations) of cost estimates (£) of using alternating pressure overlays or alternating pressure mattresses for the prevention of pressure ulcers in patients admitted to hospital

Item	Overlay	Mattress
Resource use:		
Length of stay	20.36 (25.72)	19.14 (21.54)
Hospital costs:		
Base case	6793.33 (8196.52)	6509.73 (7347.56)
Rental	6967.81 (8357.40)	6747.48 (7558.25)
Five year life span of device	6776.43 (8177.07)	6443.49 (7278.95)
Seven year life span of device	6773.38 (8173.56)	6431.62 (7266.67)

Cost effectiveness analysis

We carried out a cost effectiveness analysis, from the perspective of the UK NHS and Personal Social Service, on the intention to treat population for the period of hospital stay.¹¹ The time horizon was shorter than one year—that is, the actual duration of hospital stay, consequently neither costs nor benefits were discounted.

To account for the skewed nature of data for costs and length of stay, we used generalised linear models to estimate the mean difference in overall hospital costs between the mattress and overlay groups. We used the Akaike Information criterion and the normal plot of deviance residuals to compare models assuming different distributions functions (Gaussian, gamma, inverse Gaussian) and link functions (identity, log).¹² The final model assumed a gamma distribution for the data with an identity link function.¹³ The coefficient estimates of a generalised linear model with an identity link function represent the difference between groups using arithmetic means. To preserve the correlation between health benefits and overall hospital cost, we used non-parametric bootstrapping techniques to estimate the bias corrected 95% confidence intervals of the mean differences in time to development of pressure ulcers and costs between the overlay and mattress groups.¹⁴ We used Stata version 8 for all statistical analyses.

Sensitivity analysis

The robustness of the results was explored in three different scenarios: both devices assumed to be rented rather than purchased, a five year life span for both devices, and a seven year life span for both devices.

Results

A total of 1972 participants were randomised from 10 of the 11 hospitals participating in the randomised controlled trial comparing alternating pressure mattresses with alternating pressure overlays for the prevention of pressure ulcers. One patient who had been inadvertently randomised twice was excluded, leaving an intention to treat population of 1971 participants.

Cost and health benefits

In the base case analysis the generalised linear model which best described overall hospital costs indicated that on average the mattress group resulted in a mean reduction in total hospital cost of £283.60 (95% confidence interval –£377.59 to £976.79, $P = 0.418$; table 2). This difference was not statistically significant.

The difference in Kaplan Meier restricted estimates of the mean time to development of pressure ulcers indicated that participants in the mattress group took 10.64 days longer to develop a pressure ulcer than participants in the overlay group (table 3).

Table 3 Economic evaluation of alternating pressure overlays compared with alternating pressure mattresses for the prevention of pressure ulcers in patients admitted to hospital

Overlay-mattress	Mean (95% bias corrected confidence interval)
Base case analysis:	
Differential health benefit (days)	-10.64 (-24.40 to 3.09)
Differential cost (£)	283.60 (-377.59 to 976.79)
Sensitivity analyses:	
Differential rental cost (£)	220.33 (-459.85 to 927.00)
Differential cost for five year life span (£)	332.95 (-325.27 to 1020.77)
Differential cost for seven year life span (£)	341.76 (-315.92 to 1028.63)

This difference was not, however, statistically significant (95% bias corrected confidence interval -24.40 to 3.09 days).

Cost effectiveness analysis

The base case economic analysis indicated that the mattresses are a dominant strategy when compared with the overlays; they are associated with a delay in the development of pressure ulcers and lower hospital costs. The sampling uncertainty associated with this result was investigated in an incremental cost effectiveness plane. Figure 1 shows the results of 1000 replicates of a non-parametric bootstrap of the estimated mean difference in cost and benefits. The majority of point estimates fall in the north west and south west quadrants of the cost effectiveness plane, suggesting that the overlays are associated with a more rapid development of pressure ulcers than are the mattresses.

Figure 2 is a cost effectiveness acceptability curve that represents the uncertainty associated with the decision to consider the mattresses a dominant alternative when compared with the overlays. The mattresses are associated with an 80% probability of being cost saving (the probability associated with a willingness to pay of zero) compared with the overlay. Similarly, a probability of about 15% was associated with overlays being cost effective for a range of willingness to pay values from £25 to £30 000 for an extra pressure ulcer free day.

Sensitivity analyses

The results from the base case analysis were fairly robust to considering feasible variations in the life span of the pressure relieving surfaces or in changing provision between rental and purchase. The three sensitivity analyses in table 3 suggest that alternating pressure overlays are more costly and associated with a more rapid development of new grade 2 pressure ulcers than are alternating pressure mattresses.

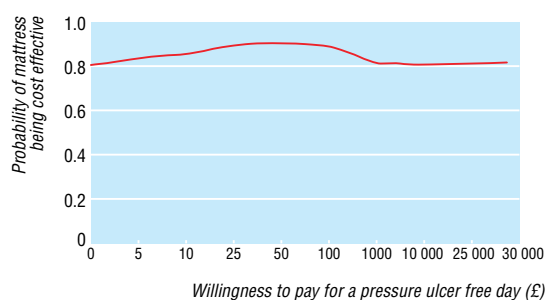


Fig 2 Cost effectiveness acceptability curve for alternating pressure mattresses

Discussion

Alternating pressure mattresses to prevent pressure ulceration in patients admitted to hospital are associated with lower costs and greater benefits and are more likely to be cost saving than alternating pressure overlays.

In this study we defined costs as mattress costs and hospital costs. During the trial we observed that grade 2 pressure ulcers did not usually receive dressings and other nursing care therefore we did not estimate for further treatment costs.⁷ The health benefits associated with the interventions were captured as pressure ulcer free days. We chose this approach rather than the more usual method of trying to capture a patient's utility through changes in quality of life because concurrent illness would dominate any quality of life measurement. Furthermore, the emphasis of our study was on prevention and participants who developed new ulcers were not followed-up until the ulcer healed. Although we did follow the healing of ulcers present at baseline, we did not have quality of life data that related to the time of ulceration (before admission) and therefore could not examine how quality of life changes with the status of pressure ulcers. The effect of pressure ulcer healing on people's health related quality of life may be the subject of future studies.

That the mattress is likely to be economically dominant may initially seem counterintuitive. The mattress has a higher purchase cost and no statistically significant effect on the proportion of patients developing an ulcer, the time to ulceration, the severity of ulcers, or length of stay. However, the purchase cost of these pressure relieving surfaces is low when viewed over their life span, and the difference in costs between overlays and mattresses is small over this time period. For a two year life span, the average cost per day would be £1.38 for an

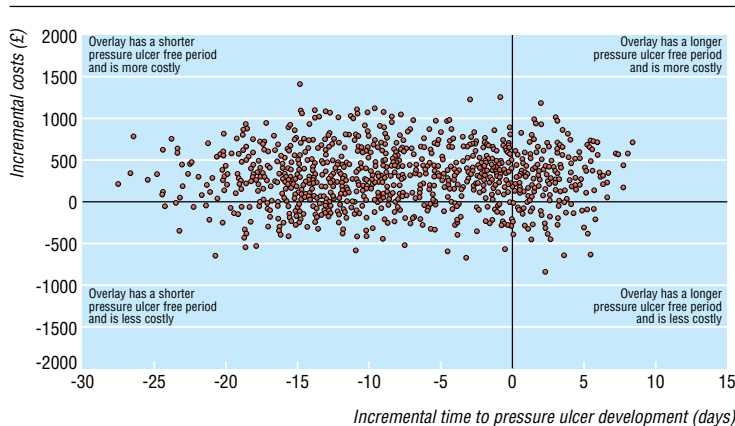


Fig 1 Incremental cost effectiveness plane of using alternating pressure overlays or alternating pressure mattresses for the prevention of pressure ulcers in patients admitted to hospital

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overlay and £5.71 for a mattress (table 1). This cost difference is small in the context of the daily inpatient treatment costs of £165-£385 (depending on specialty) and the reduced length of stay (on average, 1.22 of a day less) for mattress recipients in this trial and translates into an average reduction in costs of £283.6 per patient. The health benefit associated with the interventions was measured as the difference in mean time to develop a pressure ulcer, and also favoured the mattress (on average by 10.64 days). The accompanying clinical paper for this trial reports the median (rather than mean) time to ulceration, as is common practice owing to the skewed distribution of time to event data.⁶ By contrast, and as recommended for economic analyses, we use the mean time to pressure ulceration since the median would greatly underestimate the costs.^{8,9}

The delay in ulceration associated with alternating pressure mattresses is crucial because the longer a patient avoids ulceration the less likely they are to go on to develop a pressure ulcer; a delay in ulceration allows the patient time to recover sufficiently from their acute episode so that their risk of ulceration recedes. We argue that although time to ulceration was a secondary end point in this trial, it should be considered as a primary end point in future studies since it is more informative economically and clinically. Furthermore, many of the risk factors for pressure ulceration in the participants do not completely disappear on discharge from an acute hospital (for example, impaired mobility), and simple proportions of pressure ulcers developed ignore the censored nature of these data.

Total cost is a function of length of hospital stay which itself is mainly a function of overall health status. Patients who are more ill are both more at risk of pressure ulcers¹⁵ and likely to have longer lengths of stay. It is probable that good nursing care, such as the provision of a support surface, will completely prevent pressure ulcers in a proportion of patients and will merely delay the appearance of ulcers in others. If the appearance of an ulcer is a proxy for acuity, and more acutely ill patients consume more healthcare resources, then delays in pressure ulceration suggest a potentially lower consumption of healthcare resources. The longer length of stay in patients with pressure ulcers is probably a consequence of comorbidities rather than the pressure ulcer itself. We found no effect when we tested to see whether the surfaces had a differential effect on length of stay depending on the presence of a pressure ulcer; overall lengths of stay for patients who developed a pressure ulcer on either surface were similar.

Since there are no robust estimates of the cost of a pressure ulcer we were not able to estimate the savings from pressure ulcers prevented. Such a costing study would need to be large, with a considerable length of follow-up, carried out in several centres to ensure generalisability, and would require careful observation of clinical practice in nursing care. It was not possible to undertake such a costing study within this trial.

Our results oppose those from the model based cost effectiveness analysis by Fleurence because data in that trial were based on expert opinion whereas we collected data within the trial.¹⁶ Furthermore, the previous model disregarded the fact that pressure ulcers are rarely the main reason for people being admitted to hospital. Thus the marginal cost of treating a pressure ulcer in hospital may be small compared with the overall costs of hospital treatment. In this sense our analysis reflects actual practice. Our assumption that participants remained on the allocated pressure relieving surface over their entire hospital stay is a conservative one; in reality patients are moved on to standard mattresses or higher specification surfaces after major changes in their risk of pressure ulcers. Given participants in the

overlay group developed pressure ulcers earlier than those on the mattresses, this assumption will have over-estimated the cost of the mattresses, thus strengthening our conclusions.

Although neither the difference in mean overall hospital costs nor the difference in mean time to development of pressure ulcers between the two surfaces were statistically significant, decision makers need to make a decision. Failing to do so until statistically significant evidence becomes available would deny patients the possibility of experiencing the expected health benefits at an earlier stage and prevent the realisation of expected savings to the NHS.⁹ Although there was considerable uncertainty around the point estimates of mean health benefits and costs shown in table 3, this should not result in large decision uncertainty for decision makers since even for large willingness to pay values (fig 2) the probability of the overlays being cost effective is only between 10% and 20%.¹⁷

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Competing interests: JN has been reimbursed for attending conferences, has been paid speakers' fees, and received research funding from Huntleigh Healthcare.

Ethical approval: This study was approved by the North West multicentre research ethics committee and local ethics committees.

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What is already known on this topic

No previous trial based economic evaluation has compared alternating pressure mattresses with the less costly alternating pressure overlays

What this study adds

Alternating pressure mattresses were associated with lower costs and greater benefits and are more likely to be cost saving than alternating pressure overlays

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School of Healthcare Studies, University of Leeds
E Andrea Nelson *reader*
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Additional educational resources

Horstkotte D, Follath F, Gutschik E, Lengyel M, Oto A, Pavie A, et al. Guidelines on prevention, diagnosis and treatment of infective endocarditis: executive summary. *Eur Heart J* 2004;25:267-76 (www.escardio.org/knowledge/guidelines/)—A comprehensive document covering all aspects of the investigation and management of infective endocarditis

Baddour LM, Wilson WR, Bayer AS, Fowler VG Jr, Bolger AF, Levison ME, et al. Infective endocarditis: diagnosis, antimicrobial therapy, and management of complications. (circ.ahajournals.org/cgi/content/full/111/23/e394)—Up to date American Heart Association guidelines on the management of endocarditis

British National Formulary (www.bnf.org)—Detailed explanation of current prophylaxis recommendations
International Collaboration on Endocarditis (endocarditis.org/ice/index.html)

Information for patients

American Heart Association patient information sheet (www.americanheart.org/presenter.jhtml?identifier=4436)—A good basic guide written for non-medical personnel

American National Institute for Health information sheet (www.nlm.nih.gov/medlineplus/ency/article/000681.htm)—A brief description of infective endocarditis from a patient's perspective

Patient UK (www.patient.co.uk/showdoc/27000162/)—A simple description of infective endocarditis from a UK based site (partially funded by advertisements)

sites in 16 countries, the initial merger of existing databases has yielded a primary group of 2200 well characterised patients with definite infective endocarditis by the Duke criteria, allowing the assessment of regional differences in presentation and outcome. Indeed, analysis of the dataset has already enabled valuable insight into emerging epidemiological patterns of the disease and its clinical presentation.^{w18-w21} In future, this platform will provide the basis for sorely needed adequately sized randomised clinical trials in the management and treatment of infective endocarditis.^{w22 w23}

The future

Several exciting developments offer the prospect of improved prevention and treatment of infective endocarditis. Vaccines targeted at specific bacterial adhesins may inhibit valve colonisation, and newer antibacterial agents with novel effects may attenuate the invasive properties of virulent organisms such as *Staph aureus*.¹ Finally, modified biomaterials in development may reduce the risk of infective endocarditis in patients with artificial heart valves or other intracardiac prosthetic material. However, despite these advances, the diagnosis and management of infective endocarditis remain a considerable challenge across the range of medical disciplines.

Contributors: The *BMJ* approached BDP to write the review. RPB compiled the first draft, and BDP revised it. VKB read the paper to ensure accuracy from an Indian perspective.

Competing interests: None declared.

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Corrections and clarifications

Pressure relieving support surfaces (PRESSURE) trial: cost effectiveness analysis

This research article by Cynthia Iglesias and colleagues (*BMJ* 2006;332:1416-8, 17 Jun) should have included the trial registration identifier Current Controlled Trials ISRCTN78646179.

Correction for Nixon et al

In the correction (*BMJ* 2006;333:30, 1 Jul) to the article "Randomised, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (pressure relieving support surfaces) trial" (*BMJ* 2006;332 1413-5, 17 Jun), we incorrectly referred to haemoglobin levels rather than odds ratios. We should have said: "In table 4 of the full version on bmj.com (table 2 of the abridged version), the odds ratio for haemoglobin levels on admission or preoperatively should be 0.89 (0.82 to 0.97), and the corresponding P value should be 0.01."