

Randomised, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (pressure relieving support surfaces) trial

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

Abstract

Objective To compare whether differences exist between alternating pressure overlays and alternating pressure mattresses in the development of new pressure ulcers, healing of existing pressure ulcers, and patient acceptability.

Design Pragmatic, open, multicentre, randomised controlled trial.

Setting 11 hospitals in six NHS trusts.

Participants 1972 people admitted to hospital as acute or elective patients.

Interventions Participants were randomised to an alternating pressure mattress (n = 982) or an alternating pressure overlay (n = 990).

Main outcome measures The proportion of participants developing a new pressure ulcer of grade 2 or worse; time to development of new pressure ulcers; proportions of participants developing a new ulcer within 30 days; healing of existing pressure ulcers; and patient acceptability.

Results Intention to treat analysis found no difference in the proportions of participants developing a new pressure ulcer of grade 2 or worse (10.7% overlay patients, 10.3% mattress patients; difference 0.4%, 95% confidence interval -2.3% to 3.1%, P = 0.75).

More overlay patients requested change owing to dissatisfaction (23.3%) than mattress patients (18.9%, P = 0.02).

Conclusion No difference was found between alternating pressure mattresses and alternating pressure overlays in the proportion of people who develop a pressure ulcer.

Trial registration ISRCTN78646179

Introduction

Alternating pressure mattresses and alternating pressure overlays are commonly used for people at moderate to high risk of pressure ulceration. Alternating pressure surfaces consist of air filled sacs which sequentially inflate and deflate to relieve pressure for

short periods. They are provided as either a full size replacement mattress or a shallower overlay that is placed on top of a mattress. We compared whether differences exist between alternating pressure overlays and alternating pressure mattresses in the development of new pressure ulcers, healing of existing pressure ulcers, and patient acceptability.

Methods

The pressure relieving support surfaces (PRESSURE) trial is a randomised controlled trial in 11 hospitals in six NHS trusts. The target population was participants aged at least 55 years who had been admitted to vascular, orthopaedic, medical, or care of the elderly wards, either as acute or elective admissions, in the previous 24 hours. Other eligibility criteria were expected length of stay of at least seven days and either limitation of activity and mobility (see bmj.com¹) or an existing pressure ulcer of grade 2 (see bmj.com). Elective surgical patients without limitation of activity and mobility or an existing pressure ulcer were eligible if the average length of hospital stay for their surgical procedure was at least seven days and they were expected to have limitations of activity and mobility¹ for at least three days postoperatively. See bmj.com for exclusion criteria.

Procedures

Participants were randomly allocated to an alternating pressure overlay or an alternating pressure mattress (see bmj.com) within 24 hours of hospital admission. Elective surgical patients received their device on the day before surgery or after surgery at the point of transfer to bed.

The primary end point was the development of a new pressure ulcer of grade 2 or worse (see bmj.com) on any skin site after baseline skin assessment and before trial completion. Clinical research nurses assessed skin status. Patient acceptability was assessed indirectly from the number of people requesting a

Editorial by Vale and Noble and p 1416

Clinical Trials Research Unit, University of Leeds
Jane Nixon
deputy director
Kim Hawkins
assistant director (statistics)
Angela Phillips
senior trial coordinator
Su Mason
principal research fellow

Centre for Reviews and Dissemination, University of York
Gillian Cranny
research fellow

Department of Health Sciences, University of York, York YO10 5DD
Cynthia Iglesias
research fellow
David Torgerson
professor
Nicky Cullum
professor

School of Healthcare Studies, University of Leeds
E Andrea Nelson
reader

Correspondence to: N Cullum
nac2@york.ac.uk

BMJ 2006;332:1413-5



This is the abridged version of an article that was posted on bmj.com on 1 June 2006: <http://bmj.com/cgi/doi/10.1136/bmj.38849.478299.7C>

Table 1 Development of new pressure ulcers by minimisation factors

Factor	No (%) in overlay group (n=989)	No (%) in mattress group (n=982)	Total (n=1971)
Type of admission:			
Acute	88/488 (18.0)	84/483 (17.4)	172/971 (17.7)
Elective	18/501 (3.6)	17/499 (3.4)	35/1000 (3.5)
Type of specialty:			
Vascular	3/36 (8.3)	6/38 (15.8)	9/74 (12.2)
Orthopaedic	75/785 (9.6)	66/779 (8.5)	141/1564 (9.0)
Elderly or medical	28/168 (16.7)	29/165 (17.6)	57/333 (17.1)
Existing grade 2 pressure ulcer:			
Yes	10/59 (16.9)	10/54 (18.5)	20/113 (17.7)
No	96/930 (10.3)	91/928 (9.8)	187/1858 (10.1)

change of surface. Healing end points included time to healing and grade of ulcer at trial completion. Trial completion was defined as participants fulfilling one of the following criteria: improved mobility and activity (see bmj.com¹), a pressure ulcer of at least grade 2 that had resolved for three consecutive days as well as improved mobility and activity, transfer to a non-participating ward or consultant, discharge from hospital, 60 days from randomisation, or death.

Statistical analysis

See bmj.com for sample size calculation. The analysis was by intention to treat.

The primary end point was compared between groups using a χ^2 test. We also carried out logistic regression analysis to adjust for minimisation factors and prespecified baseline covariates of skin trauma on any site, wound on any site, non-blanching erythema (grade 1b) on any site, patient's age, Braden nutrition score, haemoglobin level, Braden activity score, and diabetes. We used a log rank test to compare the time to development of a new pressure ulcer and a χ^2 test to compare the proportions of participants who developed a new pressure ulcer within 30 days of randomisation. As the data on area of new ulceration per

patient were skewed we compared the maximum total area between the groups using a Mann-Whitney U test. We used a χ^2 test to compare the proportions of participants between groups requesting a change owing to dissatisfaction with the trial surface. A log rank test was used to compare time to complete healing of existing ulcers between groups. We used a Cochran Armitage test for trend to compare the maximum grade of existing ulcers at trial completion between groups, on a per patient basis.

Results

Of 6155 people assessed for eligibility, 1972 were randomised (see bmj.com). One patient was excluded, providing an intention to treat population of 1971 people. The two groups were well balanced for baseline characteristics (see bmj.com).

Overall, 207 (10.5%) people developed a total of 305 new pressure ulcers, most of which were grade 2 (97.4%). Eight people developed grade 3 ulcers: three in the overlay group and five in the mattress group. More of the acute patients developed a new pressure ulcer than the elective patients; medical or elderly patients were more likely to develop a new pressure ulcer than vascular or orthopaedic patients, and more people with an existing grade 2 ulcer than without at randomisation developed a new ulcer (table 1).

One hundred and six (10.7%) people in the overlay group and 101 (10.3%) people in the mattress group developed one or more new grade 2 pressure ulcers: difference 0.4% (95% confidence interval -2.3% to 3.1%). In the adjusted analysis the odds ratio for developing a new pressure ulcer using the overlay compared with the mattress was 0.94 (95% confidence interval 0.68 to 1.29; table 2).

Factors that had a significant effect on the proportion of people developing a new pressure ulcer were admission for an acute condition, the presence of a wound, skin trauma or non-blanching erythema on any site at baseline, age, haemoglobin level, and diabetes (table 2).

No statistically significant differences between the groups were found for development of a pressure ulcer within 30 days (10.0% overlay *v* 9.3% mattress, $P = 0.58$, χ^2 test) or median time to development of a new pressure ulcer for the mattress group (56 days 95% confidence interval 48 days, upper limit not estimable); the median for the overlay group had not been reached ($P = 0.76$, log rank test). The groups had similar total areas for ulcers, with most new ulcers being small (median area 1.1 cm², range 0.1-68.1 cm²). No evidence was found of a difference in median ulcer area between the groups (1.2 cm² overlay *v* 1.1 cm² mattress, $P = 0.98$, Mann-Whitney U test).

Patient acceptability

In total 416 people requested one or more changes of device: 230 (23.3%) in the overlay group and 186 (18.9%) in the mattress group. Significantly more people allocated overlays requested a change (difference 4.4%, 95% confidence interval 0.7% to 7.9%; $P = 0.02$, χ^2 test).

Healing of existing pressure ulcers

Overall, 113 people had pressure ulcers at randomisation and, of these, 39 (35%) healed: 34% in the overlay

Table 2 Adjusted analysis of proportion of patients developing a new pressure ulcer of grade 2 or worse

Variable	Odds ratio (95% CI)	P value
Support surface (overlay: mattress)	0.94 (0.68 to 1.29)	0.70
Hospital*		0.02
Admission* (acute: elective)	3.65 (2.27 to 5.85)	<0.0001
Specialty*:		
Vascular <i>v</i> care of elderly people	1.31 (0.51 to 3.33)	0.54
Orthopaedic <i>v</i> care of elderly people	1.28 (0.82 to 2.01)	
Existing pressure ulcer* (yes <i>v</i> no)	0.97 (0.52 to 1.79)	0.92
Baseline wound (yes <i>v</i> no)	2.96 (1.73 to 5.08)	<0.0001
Baseline skin trauma (yes <i>v</i> no)	1.67 (0.999 to 2.80)	0.05
Baseline ulcer grade 1b (yes <i>v</i> no)	1.95 (1.31 to 2.91)	0.001
Age (years)	1.02 (1.002 to 1.04)	0.03
Diabetes (yes <i>v</i> no)	1.61 (1.007 to 2.56)	0.047
Braden activity:		
Bedfast <i>v</i> walks frequently	0.70 (0.19 to 2.59)	0.22
Chairfast <i>v</i> walks frequently	0.36 (0.09 to 1.52)	
Walks occasionally <i>v</i> walks frequently	0.91 (0.16 to 5.08)	
Braden nutrition (very poor or inadequate <i>v</i> adequate or excellent)	1.31 (0.81 to 2.13)	0.28
Haemoglobin level on admission or preoperatively (g/l)	8.9 (8.2 to 9.7)	0.1

Small hospitals (<50 inpatient beds) were combined for analysis purposes to prevent problems from model convergence.

*Minimisation factors.

group and 35% in the mattress group. No statistically significant differences were found between the groups for median time to healing (20 days in both groups, $P=0.86$, log rank test) or the maximum final ulcer grade per patient ($P=0.96$, Cochran-Armitage test for trend).

In total, 349 (17.7%) participants were not placed on the assigned surface at baseline: of these a device was unavailable for 43% ($n=151$) and an alternative surface was allocated for 19% ($n=66$). More participants ($n=10$) randomised to an overlay than to a mattress ($n=2$) were not placed on the assigned surface because of a clinical decision. In addition, ward staff initiated the change in surface for 149 (15.1%) people in the overlay group and 142 (14.5%) people in the mattress group. The results of the cost effectiveness analysis are reported separately.²

Discussion

The proportion of patients allocated to an alternating pressure overlay or alternating pressure mattress who developed a new pressure ulcer of grade 2 or worse at any anatomical site did not differ. These conclusions were confirmed by logistic regression to adjust for pre-specified covariates and minimisation factors.

Most people develop pressure ulcers early in their hospital stay, but we found no statistically significant difference in the median time to new ulceration or in the proportion of people developing a new ulcer within 30 days. A cost effectiveness analysis undertaken alongside this trial,² however, concluded that an alternating pressure mattress was cost effective as it was associated with a delay in ulceration (measured by Kaplan Meier estimates) and reduced costs from a shorter hospital stay.

The patient acceptability results indicate greater dissatisfaction with the overlay. Significantly more people using overlays (23.3% *v* 18.9%) requested a change.

The analysis of risk factors confirmed the association of non-blanching erythema^{3,4} and increasing age^{5,6} with pressure ulceration whereas diabetes had only previously been identified as a factor in elderly nursing home residents^{7,8} and anaemia in intensive care patients.⁹

Our trial has several strengths; it was adequately powered to detect a clinically important effect on pressure ulcer risk even at fairly low rates of ulcer incidence, it was pragmatic and the findings are highly likely to be representative of what would happen in usual clinical practice, and it had broad specifications for eligible mattresses and overlays that ensured the results are likely to be applicable to any surfaces that match these specifications. Finally, the rate of pressure ulceration (10%) was well within the range of risk reported in previous trials in similar populations incorporating an alternating pressure arm.¹⁰

The main limitation of our trial was the lack of blinded outcome assessment; this is probably impossible to achieve in such trials because it is difficult to disguise or mask the mattresses and it would be unethical to frequently move seriously ill, elderly people for skin assessment. We therefore collected independent skin assessments carried out by both the ward staff and the

What is already known on this topic

No trials have directly compared alternating pressure replacement mattresses with less costly overlays in the prevention of pressure ulcers

What this study adds

No difference was found between alternating pressure replacement mattresses and alternating pressure overlays in proportion of people who develop pressure ulcers

clinical research nurses.¹¹ Although ward nurses were not blind to allocation, we have no evidence that this influenced the care given. The frequent mattress changes were a strength of this trial as they represent the use of mattresses in real life and provide generalisable data.

We thank the following; the clinical research nurses: Helen Barrow, Caroline Cooper, Fiona Corcoran, Patricia Hutchinson, Yvonne Meades, Dawn Parkes, Fiona Smith, Ann Fotheringham, Sarah Gowland, Ann Warriner, Patricia Hutchinson, Caroline Smith, Richard Buckland, Monica Clark, Morag Doherty, Andrew Young, and Helen Marson; the participants and their relatives; ward nursing and medical staff of the six participating NHS trusts; and the independent trial steering committee for their guidance: Jenny Hewison (chair), David Machin, and Gerben ter Riet.

Contributors: See bmj.com.

Funding: UK Department of Health through its health technology assessment programme. The opinions and conclusions expressed here are those of the authors and do not necessarily reflect those of the UK NHS or the Department of Health.

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.

- Bergstrom N, Braden BJ, Laguzza A, Holman V. The Braden scale for predicting pressure sore risk. *Nurs Res* 1987;36:205-10.
- Iglesias C, Nixon J, Cranny G, Nelson EA, Hawkins K, Phillips A, et al. Pressure relieving support surfaces (PRESSURE) trial: cost effectiveness analysis. *BMJ* 2006;332:1416-8.
- Allman RM, Goode PS, Patrick MM, Burst N, Bartolucci AA. Pressure ulcer risk factors among hospitalized patients with activity limitation. *JAMA* 1995;273:865-70.
- Reed RL, Hepburn K, Adelson R, Center B, McKnight P. Low serum albumin levels, confusion, and fecal incontinence: are these risk factors for pressure ulcers in mobility-impaired hospitalized adults? *Gerontology* 2003;49:255-9.
- Baumgarten M, Margolis D, Berlin JA, Strom BL, Garino J, Kagan SH, et al. Risk factors for pressure ulcers among elderly hip fracture patients. *Wound Repair Regen* 2003;11:96-103.
- Papanikolaou P, Clark M, Lyne PA. Improving the accuracy of pressure ulcer risk calculators: some preliminary evidence. *Int J Nurs Stud* 2002;39:187-94.
- Brandeis GH, Ooi WL, Hossain M, Morris JN, Lipsitz LA. A longitudinal study of risk factors associated with the formation of pressure ulcers in nursing homes. *J Am Geriatr Soc* 1994;42:388-93.
- Berlowitz DR, Brandeis GH, Morris JN, Ash AS, Anderson JJ, Kader B, et al. Deriving a risk-adjustment model for pressure ulcer development using the minimum data set. *J Am Geriatr Soc* 2001;49:866-71.
- Theaker C, Mannan M, Ives N, Soni N. Risk factors for pressure sores in the critically ill. *Anaesthesia* 2000;55:221-4.
- Cullum N, McInnes E, Bell-Syer SE, Legood R. Support surfaces for pressure ulcer prevention. *Cochrane Database Syst Rev* 2004;CD001735.
- Nixon J, Thorpe H, Barrow H, Phillips A, Nelson EA, Mason S, et al. Reliability of pressure ulcer classification and diagnosis. *J Adv Nurs* 2005;50:613-23.

(Accepted 24 March 2006)

doi 10.1136/bmj.38849.478299.7C