Challenging the pressure sore paradigm

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This study determines the effectiveness of a new low-unit-cost system in patients at very high risk of developing pressure sores. In a prospective randomised controlled trial, a low-pressure inflatable mattress and cushion system (Repose) was compared to a dynamic support mattress (Nimbus II) used in conjunction with an alternating-pressure cushion (Alpha TranCell) in 80 patients with fractured neck of femur and high scores on a pressure sore risk assessment scale. All patients received best standard care, including turning at regular intervals. Skin condition was assessed in 17 locations on admission, preoperatively, and seven and 14 days postoperatively. No difference was found between the groups in skin condition or the occurrence and severity of pressure sores at any time point.

Clinical trial; Pressure ulcers; RCT; Support systems

In 1995, following a substantial review of the literature, the *Effective Health Care Bulletin*[1], concluded that a variety of foam-based mattresses, overlays and 'high-tech' systems were better than the standard NHS mattress in the prevention and treatment of pressure sores, but that more research was needed to assess their efficacy, particularly in patients at high risk of developing pressure damage.

Estimating the costs involved in the prevention and treatment of pressure damage is a complex task, involving many variables[2], as well as changes in clinical practice that have yet to be incorporated into cost studies[3]. The use of 'high-tech', high-unit-cost systems that require maintenance is bound to impact on the growing burden of pressure sore management to the NHS.

There is no doubt that advances in technology have helped significantly in developing our understanding of this condition, but 'high-tech' equipment must be used sensibly as part of an overall strategy, as it 'will not independently answer all patient needs'[4]. Elderly patients with fractured neck of femur are particularly at risk of developing pressure damage[5], with an incidence of 50% in those over the age of 70 years[6]; 70% of those who develop pressure sores do so in their first two weeks in hospital[7] and occupy 20% of orthopaedic beds[8]. The total monetary cost of managing these patients has been estimated as £288 million (1991-92)[9].

We conducted a prospective randomised trial to compare the effects on pressure damage prevalence by using two different support systems in patients with fractured neck of femur who were at high risk. As a secondary outcome, patient comfort was also evaluated through a rating system.

Method

This was a prospective, single-centre, randomised controlled trial involving 80 patients with fractured neck of femur (confirmed by x-ray), who were over 60 years old and identified as being 'at very high risk' of developing tissue damage (Medley score > 25)[10]. The Medley scale was chosen as it was specifically designed for use with orthopaedic patients. The sample size calculation[11] assumed $\alpha = 0.05$ and a power of 0.80 to detect a 30% difference in the development of pressure sores. Following ethical approval and confirmation of diagnosis, a concealed computer generated list was used to randomise eligible consecutive patients to one of the support systems. After baseline assessment in the A&E department, the ward research nurse prepared the appropriate mattress for each patient's arrival in the ward. All patients were treated with standard best practice as appropriate to their condition, including regular repositioning. The only difference between the groups was the support system used. Assessments were completed on four occasions: on

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Fig 1. Trial profile

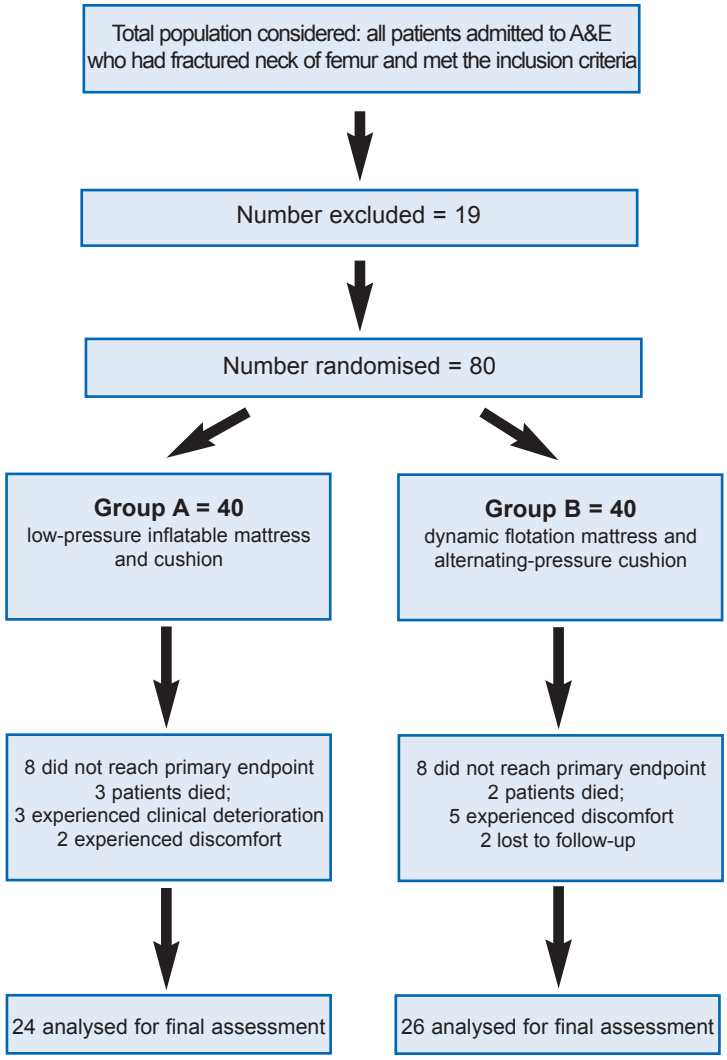

Table 1. Sample characteristics for both groups on entry to the study

	Group A	Group B
Males/females	11/29	5/35
Age (years): Mean (range)	83.5 (67.3-96.2)	80.9 (64.4-98.4)
Weight (Kg): Mean (s.d.)	60.9 (7.9) [6*]	56.0 (8.8) [10*]
Cigarette smoking	7 (29) [4*]	4 (36)
Medley score: Mean (s.d.)	27.6 (2.4)	28.3 (2.8)

*Denotes missing data

Table 2.
Biochemical markers and functional status at entry to the study

	Group A Mean (s.d)	Group B Mean (s.d)
Haemoglobin	12.3 (1.5)	12.4 (1.4)
White blood cells	9.4 (3.1)	9.8 (3.1)
Albumin	35.1 (4.8)	38.2 (4.1)
Urea	7.6 (3.2)	8.4 (4.3)
Barthel index	5.6 (1.9)(median = 6)	5.2 (2.3)(median = 6)
Abbreviated mental test	7.4 (3.2)(median = 8.5)	6.7 (3.6)(median = 8)

admission, preoperatively, seven days postoperatively, and a follow-up at 14 days postoperatively when possible.

Support surfaces

A low-unit-cost system (Repose) was allocated to Group A. This comprising a low-pressure inflatable mattress and cushion that are readily portable and require little maintenance. This system was developed and patented by the occupational therapy department of the University Hospital of Wales Healthcare NHS Trust in Cardiff. The system is manufactured using a special polyurethane material that has a multi-directional stretch, is vapour-permeable, waterproof and x-ray translucent.

The system allocated to Group B comprised a dynamic flotation mattress (Nimbus II) together with an alternating-presssure cushion for a chair (Alpha TranCell). The mattress can be adjusted according to the patient's weight, size and position and was chosen as the comparator mattress because it was the best care option available in the trust for the prevention and treatment of pressure damage in patients at very high risk. The alternating pressure cushion is designed for use on a chair or wheelchair. Cushions were also included as it was deemed important that pressure relief was provided from the time of entry into the study throughout the patient's hospital stay.

Assessment details

All patients were assessed using the following scale[11] to describe the condition of their skin: 0 = normal skin; 1 = persistent erythema of the skin; 2 = blister formation; 3 = superficial sub/cutaneous necrosis; 4 = deep subcutaneous necrosis.
Seventeen sites were assessed: the sacrum, left and right scapula, elbow, buttock, trochanter, calf, heel, and medial and lateral malleoli. Patients were not assessed blindly as it was considered that displacement for examination would cause excessive discomfort. A team of trained researchers completed all assessments.

Baseline blood test were performed to monitor haemoglobin (Hb), white blood cell count (WBC), urea and albumin levels. The Barthel Index[12] and the Abbreviated Mental Test[13] were also completed to assess comparability of groups.
Comfort was measured using a 100mm visual analogue scale.

Analysis of data

No patient was excluded from all the analyses. In many patients the data were incomplete, but they have been included in the analyses for those time points where data are present. This was a pragmatic trial following normal hospital practice as closely as possible. The main analysis for outcome variables involved ANCOVA, using the corresponding baseline value as covariate; 95% confidence intervals for adjusted difference were calculated. Confirmatory non-parametric tests comparing changes between the two groups were also performed. The statistical analyses were completed blind to the randomisation code.

Results

The overall trial profile is given in Fig 1, including reasons for patient withdrawal Data were not available for the 14 day follow up assessment for a further 12 patients who were transferred to wards or hospitals that were not involved in the study or were discharged home.

Demographics and baseline comparability

The sample characteristics and baseline clinical measures, which were not statistically significant between the groups, can be found in Tables 1 and 2. Patients in Group B were, on average, two years older and approximately 5 kg lighter in weight than those in Group A, while a few more patients in Group A were cigarette smokers. None of these differences is statistically significant and all are probably explained by the sex distribution of the groups, with more males in Group A.

More patients in Group B had surgery to insert a dynamic hip screw, but there were no discernible differences in the types of fracture (Table 3). Those in Group B experienced a longer interval from admission to operation, but this difference is not significant.

Development of pressure damage

Table 4 contains the maximum score at any site by assessment and treatment. The majority of patients in both groups had a maximum score of zero (normal skin) at all assessment points. On admission, 14 (35%) patients in group A and 13 (32%) in Group B had a score higher than zero, but this fell respectively to seven (19.4%) and eight (21.6%) preoperatively, six (18.7%) and five (16.1%) at seven days. At the final assessment point, 9/50 patients had a score higher than zero (five in Group A and four in Group B). There was no statistically significant difference between the groups at any time point or in terms of progression over assessment stages.

Table 5 presents the data only for those patients who completed the trial, giving details of their scores at admission and at 14 days post-surgery. Again, there is a reduction in the proportion presenting with a sore by the end of the trail, although there is no statistical difference between the groups.

In accordance with the principle of analysis by intention to treat, we developed alternative analyses for the primary outcome variables in which subjects withdrawing due to discomfort were allocated 'worst-case scenario' scores from the time of their withdrawal. The resulting comparisons favoured Group A but did not reach statistical significance.

Comfort ratings

Comfort scores improved over time for both groups, possibly reflecting improving health status. The differences between the groups are not statistically

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Table 3. Details of treatment

Patient details	Group A	Group B
Fracture type		
Subscapular	13	9
Transcervical	4	2
Intratrochanter	19	21
Subtrochanter	2	1
Missing data	2	7
Side: Left	20	21
Right	19	19
Missing data	1	0
Type of operation		
Dynamic hip screw	16	24
Hemiarthroplasty	11	9
Other	9	3
No operation	1	1
Missing data	3	3
Days from admission to operation		
Mean (s.d.)	1.9 (1.0)	2.7 (2.0)
Missing data	3	3

Table 4. Maximum pressure sore score by assessment time and treatment group

Assessment stage		Condition of Skin				Number of patients with a pressure ulcer
		Normal (0)	Persistent erythema (1)	Blister formation (2)	Superficial sub/ cutaneous necrosis (3)	
Admission:	Group A	26	12	1	1	14/40
	Group B	27	11	0	2	13/40
Pre-operative:	Group A	29	6	1	0	7/36
	Group B	29	4	1	3	8/37
7 days post surgery	Group A	26	3	2	1	6/32
	Group B	26	4	1	0	5/31
14 days post surgery:	Group A	19	2	0	3	5/24
	Group B	22	2	1	1	4/26

Table 5. Maximum pressure sore score for patients who completed the trial

Assessment stage		Condition of Skin				Number of patients with a pressure ulcer
		Normal (0)	Persistent erythema (1)	Blister formation (2)	Superficial sub/ cutaneous necrosis (3)	
Admission:	Group A	13	9	2	0	11/24
	Group B	18	8	0	0	8/26
14 days post surgery:	Group A	19	2	0	3	5/24
	Group B	22	2	1	1	4/26

Table 6. Comfort ratings across time points

	Admission		Pre-operative		Seven days		Fourteen days	
	Mean (sd)	Median (range)	Mean (sd)	Median (range)	Mean (sd)	Median (range)	Mean (sd)	Median (range)
Group A	38 (18)	35 (7-86) (N = 40)	47 (17)	45 (10-85) (N = 36)	54 (18)	51 (15-87) (N = 32)	67 (18)	72 (25-90) (N = 24)
Group B	31 (16)	30 (7-70) (N = 40)	42 (18)	40 (10-80) (N = 37)	54 (23)	55 (15-93) (N = 31)	60 (25)	60 (15-96) (N = 26)

KEY ISSUES FOR PRACTICE

- In this study there was no statistical difference between the 'low-tech' system and a dynamic floatation system.
- Clinicians needs to consider a wide range of options for patients in need of a pressure-relieving support system, as 'high-tech' solutions may not necessarily be needed in all cases.
- Even at high risk, patients may be cared for on an appropriate 'low-tech' support system.
- Further research is needed in this important area of care.

significant at any of the time points when initial scores are taken into account using either ANCOVA or confirmatory non-parametric analysis. It is interesting to note that the comfort scores from Group A were higher for three of the four assessment stages than for Group B (Table 6), possibly highlighting the difficulty some patients may have in tolerating alternating-pressure systems.

Discussion

The primary objective of the study was to compare the effects of using two different support systems on the skin condition of elderly patients 'at very high risk' who were admitted to hospital because of a fracture proximal to the neck of femur. No major difference between the groups was detected and the vast majority of patients did not develop visible skin damage. Patients received standardised nursing care at all times and this, in conjunction with the two systems used, may explain the difference in prevalence compared with the figures available in the literature[6,11]. There was also no statistically significant difference between the groups in patient comfort ratings.

This trial reflects many of the problems associated with conducting studies in chronic wound management, especially in an elderly frail population and particularly in terms of attrition rates[14]. Although care was regulated as closely as possible, a number of nurses were involved in the day-to-day management of the patients, which may have resulted in nursing bias. No threats to internal or external validity were identified. While routine practice in the trust includes providing various types of mattress for patients admitted with fractured neck of femur, the comparator was chosen as the best option available. The new mattress was compared with the 'best' available 'high-tech' mattress.

Although the total cost of providing pressure-relieving services was not fully documented, the unit costs of the mattresses involved is an important component in any total package of care. For this study, the cost of providing the support system used in Group A on a basis of single-patient use would be less than £5,000 (1998 prices), which is less that 50% of the cost quoted for providing the alternating-pressure system used in Group B. These figures suggest that further detailed studies to measure the relative costs of alternative systems are urgently required.

Given the high unit costs of many 'high-tech' approaches to the prevention of pressure damage, it is worth considering the use of alternatives with a lower unit cost. In this study no statistically significant difference was found at any time point between the low-pressure overlay system and the dynamic support system.

The low-pressure overlay appears to offer a similar level of benefit in preventing the development of pressure sores and merits further investigation due to the potential for major cost reduction.

This study was undertaken with financial support from Frontier Therapeutics and University Hospital of Wales.

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  Clinical trial; pressure ulcers; RCT; Repose v Nimbus™. [1]
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