ORIGINAL RESEARCH

JAN

Comparison of alternating pressure mattresses and overlays for prevention of pressure ulcers in ventilated intensive care patients: a quasi-experimental study

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Accepted for publication 1 December 2012

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MANZANO F., PÉREZ A.-M., COLMENERO M., AGUILAR M.-M., SÁNCHEZ-CANTALEJO E., RECHE A.-M., TALAVERA J., LÓPEZ F., BARCO S. F.-D. & FERNÁNDEZ-MONDEJAR E. (2013) Comparison of alternating pressure mattresses and overlays for prevention of pressure ulcers in ventilated intensive care patients: a quasi-experimental study. *Journal of Advanced Nursing* 69(9), 2099– 2106. doi: 10.1111/jan.12077

Abstract

Aim. To compare the effectiveness of alternating pressure air mattresses vs. overlays to prevent pressure ulcers in mechanically ventilated patients in intensive care units.

Background. Pressure ulcers prevention is an important issue in the nursing of critically ill patients. It is not clear whether alternating pressure air mattresses are more effective than overlays to prevent pressure ulcers.

Design. Prospective quasi-experimental study.

Methods. A prospective quasi-experimental study was conducted among patients in the medical-surgery intensive care unit of a university hospital on mechanical ventilation \geq 24 hours during two time periods (2001 and 2006). Overlays were used in 2001 and mattresses in 2006. Primary outcome was the incidence of pressure ulcers grade \geq II (according to the European Pressure Ulcer Advisory Panel) during intensive care unit stay.

Results. The study included 221 patients (116 in 2001 and 105 in 2006). Baseline characteristics were similar between groups except for a higher Acute Physiology and Chronic Health Evaluation III score, total and first-day respiratory Sequential Organ Failure Assessment Score on day 1 in overlay group. There was significantly lower incidence density in the mattress vs. overlay group (12.41 cases/1000 days vs. 18.67 cases/1000 days of stay). The multivariate analyses showed the use of the mattress to be a protective factor against pressure ulcer onset.

Conclusion. This quasi-experiment study that alternative pressure air mattresses were more effective than alternating pressure air overlays in preventing pressure ulcers in mechanically ventilated critical care patients.

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Introduction

Despite major technical advances in the prevention of pressure ulcers and development of pressure-relieving devices, Pressure ulcers remain a frequent complication in hospitalized patients (Schoonhoven et al. 2007), especially in those in intensive care units (ICUs) (Keller et al. 2002, de Laat & Schoonhoven 2006, Yepes et al. 2009). Pressure ulcers increase the morbidity of patients and impair their quality of life, adding to hospital treatment costs (Graves et al. 2005, Hopkins et al. 2006). In fact, they are considered as clinical indicators of the quality of health care (Pancorbo-Hidalgo et al. 2006, Olshansky 2008, Manzano & Rubio 2009). Critically ill patients, especially those requiring mechanical ventilation (MV), are susceptible to pressure ulcers due to their immobility and frequent exposure to pressure ulcer risk factors, such as age and cardiopulmonary disorder (Nijs et al.2009, Manzano et al. 2010).

Background

Preventive measures to avoid pressure ulcers include the use of pressure-relieving support surfaces (Reddy *et al.* 2006). Support surfaces have been substantially improved by technical advances over the past three decades, notably the development of dynamic devices such as alternating pressure air surfaces. These comprise air-filled cells that inflate and deflate sequentially to reduce pressure for short time periods and are available as full-size replacement mattresses or thinner overlays for placement on mattresses. These options may differ in contact interface pressure and consequently in their effects on blood perfusion and the appearance of pressure ulcers. Few studies have compared these

Keywords: beds, clinical trials, intensive care unit, mechanical ventilation, nursing, pressure ulcers, prevention

> two types of alternating pressure air surface, limiting the possibility of making a decision based on adequate evidence. It has been established that alternating pressure air systems are more effective than standard hospital foam mattresses to reduce the incidence of pressure ulcers (Andersen et al. 1983, Sanada et al. 2003), and there may also be advantages in using one or other type of alternating pressure air system, e.g. mattress or overlay (Vanderwee et al. 2008). A Cochrane review and various clinical trials found no differences in the effectiveness of the different types of alternating pressure air surface to prevent pressure ulcers (Exton-Smith et al. 1982, Hampton 1997, Taylor 1999, Theaker et al. 2005, Nixon et al. 2006, McInnes et al. 2008). However, the methods used in some of these trials have been questioned (McInnes et al. 2008), and most were conducted in care centres for the older people or in non-critical hospitalized patients. To date, no research has been published on this issue in ICU patients on MV, a population at high risk of pressure ulcers. In 2005, our medical -surgical ICU replaced alternating pressure air small-cell overlays with alternating pressure air mattresses, and a quasi-experimental study was designed to compare the effectiveness of these support surfaces to prevent pressure ulcers in ICU patients on MV.

The study

Aims

To determine whether the use of alternating pressure air overlays instead of alternating pressure air mattresses reduce the onset of pressure ulcers in patients on mechanical ventilation in a medical–surgical intensive care unit.

Design

In a prospective quasi-experimental study, the development of pressure ulcers was recorded during two 5-month periods: January–March and June–July, 2001, when alternating pressure air overlays were used as support surfaces for ICU patients (Overlay Group); and February–June 2006, when alternating pressure air mattresses were used (Mattress Group).

The study was carried out in the 26-bed adult medical surgical ICU of the Virgen de las Nieves University Hospital in Granada (Spain). The hospital is a tertiary referral facility for speciality services, including heart surgery and liver transplantation. There is a ratio of one registered nurse for every two patients on MV.

Participants

All patients aged >18 years on invasive or non-invasive MV for \geq 24 hours during their ICU stay were considered eligible for the study. Exclusion criteria were the presence of pressure ulcers before starting MV and body weight >140 kg.

Intervention

The alternating pressure air overlays used during the first time period (LTM 661-EXCEL 1000/2000 Moretti, Arezzo, Italy) have a maximum cell height of 6.5 cm and cell cycle time of 6 minutes. They were used in combination with a standardized protocol for turning the patients every 4 hours according to the following repositioning schedule: semi-Fowler 30°, right-side lateral position 30°, semi-Fowler 30°, and left-side lateral position 30° (Defloor 2000). Adherence to the schedule was not monitored. The alternating pressure air mattresses used during the second time period (Total Duo2[®], Hill-Rom Corporate, Bastesville, IN, USA) offer either alternating low-pressure mode or continuous lowpressure mode, with a maximum cell height of 13.5 cm. The alternating low-pressure system was used in this study, applying the same turning and repositioning protocol as with the alternating pressure air overlays.

Data collection

Participants were included in the study within 24–48 hours of initiation of MV. Patients were followed up throughout their ICU stay.

The main outcome variable was the first episode of a pressure ulcer (\geq grade II) on any part of the body. Pressure ulcers caused by medical devices were not considered

as pressure ulcers. Pressure ulcers were classified into four grades according to the European Pressure Ulcer Advisory Panel (EPUAP; Beeckman *et al.* 2007).

In both groups, data were gathered on age, gender, body weight, presence of diabetes mellitus, hospital stay (days) before ICU admission, scale of Norton (Norton1996), Acute siology and Chronic Health Evaluation (APACHE) III score (Knaus *et al.* 1991), individual and total sequential organ failure assessment (SOFA) scores (Vincent *et al.* 1996), type of admission (medical or surgical), reason for MV (Table 1), and acute respiratory distress syndrome (Bernard *et al.* 1994). Data were gathered at ICU discharge on ICU mortality, total time on MV, and length of ICU stay. Post-ICU length of hospital stay and hospital mortality were also recorded.

Validity and reliability

Before the study, thirty nurses were selected as researchers and underwent a training programme on the definition and severity assessment of pressure ulcers and on the aims and methodology of the study. Patients were assessed once every 24 hours for pressure ulcer development. If the nurse in charge of the patient suspected the presence of a pressure ulcer, a nurse-researcher was informed, and the patient was then studied independently by three nurse-researchers to confirm the presence of a pressure ulcer and evaluate its severity.

Agreement regarding pressure ulcers (grade \geq II) among the nurse-researchers in both periods was measured with Light's kappa (κ -statistic). A value of 1 indicates perfect agreement, whereas a value of 0 indicates that agreement is no better than chance. The 95% confidence interval (CI) for each measurement was calculated with a bootstrap technique. The interrater reliability for the classification of pressure ulcers in the first period was $\kappa = 0.85$ (95% CI: 0.77–0.92) and in the second period was $\kappa = 0.87$ (95% CI: 0.79–0.91).

Ethical considerations

The study was approved by the ethics committee of the Virgen de las Nieves University Hospital, which waived the need for written consent. The data collected and generated were included in two databases as a data decoupling procedure to adhere to data protection legislation and to maintain individual privacy.

Statistical analyses

For each time period, the incidence density of pressure ulcers (\geq grade II) in patients with MV \geq 24 hours was

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Table 1 Baseline and follow-up characteristics of patients allocated to Overlay Group or Mattress Group.

	Overlay Group	Mattress Group	
Characteristics	(n = 116)	(n = 105)	P value
Age, years			
Mean (SD)	63 (14)	64 (14)	0.41
Median (IQR)	69 (60–74)	67 (55–74)	0.53
Male, <i>n</i> (%)	74 (64)	66 (63)	0.88
Body weight, kg	75 (12)	76 (15)	0.76
Diabetes mellitus, n (%)	30 (26)	33 (31)	0.36
Pre-ICU LOS, median days (IQR)	3 (0–9)	3 (0–9)	0.97
Norton Scale, points	8.23 (1)	9 (6.4)	0.22
APACHE III score at admission	78 (23)	62 (29)	<0.001
Total SOFA on day 1, points	8.7 (3.6)	7.6 (3.6)	0.01
First-day respiratory SOFA	2.9 (0.8)	2.46 (0.8)	<0.001
Type of admission			
Medical	60 (48.7)	63 (52.3)	0.22
Surgical	56 (57.1)	42 (42.9)	
Reasons for MV onset, n (%)			
Neurological	5 (4.3)	8 (7.6)	0.24
Cardiologic	26 (22.4)	20 (19)	
Respiratory failure	22 (19)	23 (21.9)	
Heart surgery	42 (36.2)	26 (24.8)	
Trauma	1 (0.9)	5 (4.8)	
Gastrointestinal	14 (12.1)	14 (13.3)	
Septic Shock	6 (5.2)	9 (8.6)	
ARDS, <i>n</i> (%)	23 (51.1)	22 (48.9)	0.84
Fourth-day cardiovascular SOFA	1.49 (1.7)	1.9(1.9)	0.16
Days on MV			
Mean (SD)	11 (16)	11.5 (14)	0.78
Median (IQR)	6 (2–13)	6 (2–14)	0.66
ICU LOS, days			
Mean (SD)	15 (17)	16.7 (19)	0.49
Median (IQR)	10.5 (4-18)	9 (5–22)	0.63
Hospital LOS, days			
Mean (SD)	21.7 (22)	26 (26)	0.16
Median (IQR)	17 (9–29)	19 (8–35)	0.29
ICU mortality, n (%)	58 (50)	40 (38.1)	0.07
Hospital mortality, n (%)	64 (55-2)	51 (48.6)	0.37

SD, standard deviation; IQR, interquartile range; ICU, intensive care unit; LOS, length of stay; APACHE, Acute Physiology and Chronic Health Evaluation; SOFA, sequential organ failure assessment; MV, mechanical ventilation; ARDS, acute respiratory distress syndrome.

computed per 1000 patient-days of ICU stay and the cumulative incidence was calculated. Distributions of categorical variables were expressed as proportions and compared using the Fisher's exact or chi-squared tests, as appropriate. Continuous variables were expressed as means [standard deviation or medians with interquartile range (IQR)] and compared by means of the Student's *t*-test. Kaplan–Meier survival analysis and log-rank test were used to evaluate the effect of the different support surfaces on the incidence of pressure ulcers (\geq grade II). The hazard ratio of pressure ulcers (grade \geq II) over time was examined by a Coxproportional-hazard multivariate model. Variables with a

P value ≤ 0.10 in the univariate analysis were included in the model to determine the independent variables associated with the development of pressure ulcers. The proportional hazard assumption was tested for all variables included in the model by graphical methods. Risks are expressed as hazard ratio with 95% CI. A two-sided *P* < 0.05 was considered statistically significant. We conducted a subgroup analysis for the primary outcome according to the ICU stay of the ventilated patients (≤ 14 days vs. >14 days). Analyses were performed by intention to treat. R program, version 2.9.1 (GNU General Public License), was used for all statistical analyses.

Results

Of the 232 ventilated patients eligible for the study (122 patients in Overlay Group and 110 in Mattress Group), 15 were excluded (10 from Overlay Group; 5 from Mattress Group), as shown in the patient flow chart in Figure 1. Table 1 gives the baseline characteristics of the groups; the overlay group had a higher APACHE III score [78 (23) vs. 62 (29) points, respectively, P < 0.001], total SOFA score [8.7 (3.6) vs. 7.6 (3.6), P = 0.01], and respiratory SOFA score on day 1 [2.9 (0.8) vs. 2.46 (0.8), P < 0.001], but there were no differences in age, gender distribution, MV duration, or ICU length of stay. The hospital mortality was 55% in the Overlay Group and 48.6% in the Mattress Group (P = 0.37).

The incidence density of pressure ulcers grade >II was 18.67 cases per 1000 days of ICU stay in the Overlay Group, and 12.41 cases per 1000 days in the Mattress Group (P = 0.003). Figure 2 depicts the inter-group comparison of pressure ulcer incidence using the Kaplan-Meier method (log-rank, test P = 0.003). A pressure ulcer grade \geq II was developed by 21.6% (25/116) of patients in the Overlay Group vs. 16.2% (17/105) patients in the Mattress Group (P = 0.31). The relative risk of a pressure ulcer in the Mattress Group was 0.75 (95% CI: 0.35-1.39) with respect to the Overlay Group. In the adjusted analyses, the hazard ratio for developing a pressure ulcer was 0.44 (95% CI: 0.21-0.92), indicating a significantly lower risk of a new pressure ulcer in the Mattress Group in comparison with the Overlay Group (P = 0.038, Table 2). Age was also an independent predictive factor for a pressure ulcer, with

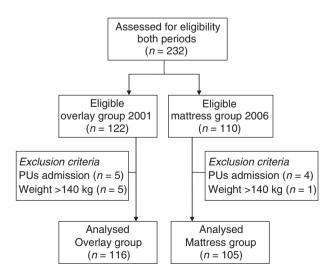


Figure 1 Study flow diagram. PUs, pressure ulcers.

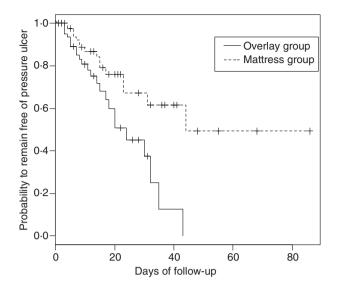


Figure 2 This panel shows Kaplan–Meier curves for the probability to remain free of pressure ulcers, which was less for the Mattress vs. the Overlay Group (log-rank test, P = 0.003).

an hazard ratio of 1.05 per year (95% CI: 1.02-1.09; Table 2).

Among patients with an ICU stay ≤ 14 days, no intergroup difference was found (P = 0.75) in pressure ulcer incidence (15.6% [15/96] of Overlay patients vs. 13.9% [10/72] of Mattress patients), with a relative risk of pressure ulcer in the Mattress vs. the Overlay Group of 0.42 (95% CI: 0.19–0.92). Among patients with an ICU stay >14 days, a significant intergroup difference (P = 0.03) was found [50% (10/20) of Overlay patients vs. 21.2% (7/31) of Mattress patients] (Figure 3), with a relative risk of a pressure ulcer in the Mattress vs. Overlay Group of 0.89 (95% CI: 0.42–1.83).

Discussion

The main study finding was that the use of an alternating pressure air mattress rather than alternating pressure air

Table 2 Independent variables associated in the Cox-proportional-hazard multivariate analysis with development of pressure ulcers (\geq grade II) in ventilated patients.

	HR (95% CI)	P value
Age	1.05 (1.02–1.09)	<0.0001
Mattress Group	0.44 (0.21-0.92)	0.029
APACHE III score	1.004 (0.99–1.02)	0.57
SOFA respiratory first day	0.95 (0.64–1.41)	0.80

HR, hazard ratio; APACHE, Acute Physiology and Chronic Health Evaluation; SOFA, sequential organ failure assessment.

What is already known about the topic

- Mechanically ventilated patients in intensive care units form a group with a high level of risk of pressure ulcer development.
- Continuous technical advances in support surfaces, a key aspect of pressure ulcer prevention, require evaluation in the clinical setting.

What this paper adds

- The finding that alternating pressure mattresses are more effective than alternating pressure air overlays to prevent pressure ulcers in mechanically ventilated patients.
- This seems to be more important for patients with longer duration of mechanical ventilation.

Implications for practice and/or policy

- Patients with persistent acute respiratory failure require a specific high-technology mattress, e.g. alternating pressure air mattress, as a support surface.
- We suggest not using small-cell alternating-pressure air overlays in this patient population.

overlay significantly reduced the incidence of pressure ulcers of grade II or above in ICU patients mechanically ventilated for ≥ 24 hours. It is not clear why the mattresses may per-

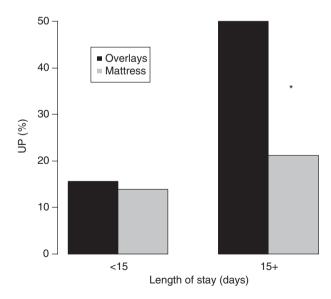


Figure 3 Distribution of cumulative incidence of pressure ulcers as a function of length of intensive care unit stay (in intervals) (*P = 0.03).

form better. It has been reported that the depth of air-cells, the cell cycle time, and the amount of pressure can affect cells during peak inflation and deflation phases, and that the effectiveness against pressure ulcers may be determined by the rate at which pressure is ramped up and down during inflation and deflation as well as by the mechanical robustness of devices (McLeod 1997, Thompson *et al.* 2008).

The most recent reviews on the effect of support surfaces on pressure ulcer onset found no clear evidence on the comparative effectiveness of different types of alternating pressure air support (McInnes et al. 2008). Of five clinical trials on the effect of different types of alternating pressure air support on pressure ulcer incidence, only one found one type of alternating pressure air support to be superior to another (Exton-Smith et al. 1982), and when the results of this study were analysed according to the intention to treat rather than the protocol, the statistical significance of the difference disappeared (McInnes et al. 2008). A large and robust trial in surgical patients found no difference in clinical effectiveness between alternating pressure air mattresses and overlays (RR: 1.04; 95% CI: 0.81 to 1.35), but reported that overlays were probably more cost effective (Nixon et al. 2006). One reason for the discrepancy with our findings may be the difference in study populations, given that non-critical hospitalized patients are at lower risk of developing a pressure ulcer. Furthermore, the cell height of the overlays used by Nixon's group was 12.5 cm vs. 6.5 cm in the present study. The other clinical trials on the effectiveness of different alternating pressure air supports had only small sample sizes and found no significant differences (Hampton 1997, Taylor 1999, Theaker et al. 2005). Thus, our quasi-experimental study is the first to report that the use as support surface of alternating pressure air mattresses in comparison with alternating pressure air overlays is a protective factor against pressure ulcer onset, with an adjusted risk of 0.44 (95% CI: 0.21-0.92) in critical care patients on MV. The strengths of our study include the patient population, known to be at very high risk of pressure ulcers, the daily follow-up of the patients throughout their ICU stay, with no loss of patients to the follow-up, and the analysis by intention to treat.

The greater protective effect of the mattresses was more important with longer ICU stay, reaching significance in patients with an ICU stay of more than 2 weeks (Figure 3), when patients are more likely to develop pressure ulcers and the comparative benefit would be more evident.

Our findings on these specific alternating pressure air support systems can be extrapolated to medical and surgical ICU patients on MV, but not to trauma or neurosurgical patients, who were not represented in our study. Furthermore, these results are not applicable to overlays with a cell height >6 cm.

Limitation

Weaknesses of this quasi-experimental, non-randomized study include the difference between the groups in baseline severity of illness, with the overlay group showing significantly higher APACHE III and first-day respiratory SOFA scores. Nonetheless, when these confounders were considered in the multivariate Cox regression analysis, the effect of alternating pressure air mattresses entered the model as an independent protective factor against pressure ulcer onset, whereas neither the APACHE III score nor the first-day respiratory SOFA score remained in the model. A further weakness was that correct implementation of the postural change schedule was not monitored in either period, and it is widely accepted that adherence to preventive measures can be highly inconsistent (Graham et al. 2006, Van den Heede et al. 2006). We are therefore unable to determine whether the schedule would have been more rigorously implemented in 2006 than in 2001, contributing to the better outcomes in the second period, or the reverse, further confirming the superiority of the alternating pressure air mattresses. Finally, it was not possible to perform this study in a blinded manner.

Conclusion

This quasi-experiment study that alternative pressure air mattresses were more effective than alternating pressure air overlays in preventing pressure ulcers in mechanically ventilated critical care patients, but a more robust design, such as a randomized controlled trial, should be carried out to further test this hypothesis.

Acknowledgements

This study would have not been possible without the collaboration of the nursing staff in ICU.

Funding

This research received no specific grant from any funding agency in the public, commercial or, not-for-profit sectors.

Conflict of interest

No conflict of interest has been declared by the authors.

Author contributions

All authors meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/ethical_1author. html)] and have agreed on the final version:

- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

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