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Original Article

Pressure-reducing foam mattress prevents pressure ulcers in patients on mechanical ventilation

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Purpose: Hospital-acquired pressure injuries are a serious problem among critical care patients. To compare pressure-reducing foam mattresses with standard hospital foam mattresses in the prevention of pressure injury in patients under mechanical ventilation in a respiratory care center.

Method: This was a quasi-experimental study in the respiratory care center of a university hospital in Taiwan from January 2017 to June 2018. Sixty bedridden patients under mechanical ventilation at risk of developing pressure injury were according to a 1:1 ratio to pressure-reducing foam mattress or standard hospital foam mattress groups under the same context of standard care for 21 days. Primary endpoints were the mean total Braden scale score and the incidence of a new pressure injury of at least Category or Stage II during the study period.

Results: Primary endpoints were not significant different between the two groups at baseline and at the end of the study. However, the pressure-reducing foam mattress group had statistically significant higher comfort scores ($p < 0.001$) and sleep quality scores ($p < 0.001$) than did the standard hospital foam mattress group.

Conclusions: Mechanically ventilated patients on standard hospital foam mattresses had a tendency to develop more pressure injury. 2-hour turning schedule may have compensated for the absence of the pressure-reducing foam mattress for the patients under mechanical ventilation. Pressure-reducing foam mattresses improved the scores of comfort and sleep quality.

Keywords: pressure-reducing foam mattresses, mechanical ventilation, pressure injury

1. Introduction

Hospital-acquired pressure injuries (PIs) are a serious issue in the management and treatment of critical care patients[1]. PIs sustained in the intensive care unit delay recovery and increase the risks of infection and sepsis, morbidity, mortality, length of stay, and healthcare costs[2]. It has been shown that patients with PI have a higher incidence of complications, such as pneumonia and acute renal failure, and greater need for vasoactive drugs[2,3,4]. PIs are defined as localized damage to the skin and underlying soft tissue, usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or open ulcer

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and may be painful[5]. PIs can be prevented via various measures[6], such as repositioning of the patient and provision of appropriate support surfaces (i.e., beds and mattresses)[7,8,9].

A standard hospital foam mattress (SHFM) (non-high specification reactive foam mattress) typically constructed with cold foam can support 10%–20% of the body weight[10]. However, a pressure-reducing foam mattress (PRFM) (high specification reactive foam mattress) can reduce pressure in 10 different positions by nearly 20%–30% in comparison to SHFM[11]. Many studies have addressed the effects of PRFM on PI prevention in patients not on mechanical ventilation (MV)[12-16]. According to published guidelines regarding the prevention of PIs, a conflict exists in terms of body position between the prevention of ventilator-associated pneumonia and the prevention of PIs[5,9]. However, no studies have been conducted on the efficacies of PRFM and SHFM in the prevention of PIs in patients on MV.

2. Materials and Methods

2.1. Study design

A quasi-experimental design was used for this study, which was conducted in the respiratory care center (RCC) of a university hospital in Taiwan from January 2017 to June 2018. This study was approved by the Institutional Review Board of the university hospital (approval number CS17045). Written informed consent was obtained from all participating patients or their family members.

G*Power 3.1.5 was used to estimate the sample size based on the following criteria: effect size of Cohen's d=0.8, α error=0.05, and a power of 0.85 on two-tailed independent t-test, with an allocation ratio of 1 for two groups. Thirty eligible patients were estimated for each group[17] By setting a drop-out rate of 10%, we estimated the adaptive sample size as 60/0.90 = 66. However, five patients were transferred to general ward, one patient was transferred to another hospital due to critical condition, and two patients died. Finally, 52 patients completed this study. Patients who underwent breathing exercise training were registered at the beginning of the MV procedure. Eligible patients were assigned to one of two groups, namely PRFM and SHFM, at a 1:1 ratio.

2.2. Study subjects

Adult bedridden patients on MV who were unable to reposition themselves were recruited for this study. Inclusion criteria included no PIs on baseline visit and expected stay of more than 21 days in the RCC. Enrolled patients were conscious, clear, and able to accurately answer questionnaires. Moreover, they had no medical conditions for which repositioning or semi-Fowler's or high Fowler's position was contraindicated. Patients on MV for more than 24 hours before the start of this study or who declined to participate were excluded. Other exclusion criteria were receiving of hemodialysis and palliative care, pediatric patient, condition for which semi-Fowler's or high Fowler's position was contraindicated (e.g., suspected or confirmed spinal cord injury, pelvic fracture, or prone position), and having undergone intubation in a pre-hospital setting.

2.3. Interventions

PRFM (IMAGER-37, SEDA, Taiwan), also called high specification reactive foam mattress, consisted of a 7-cm-thick layer of viscoelastic and temperature-sensitive foam with a density of 93 ± 5kg/m^3, which was the most important feature for reducing risk of PI. A 5-cm-thick high-resilience foam underlayer of density 55 ± 5kg/m^3 was the most important feature for ensuring the stability of the viscoelastic layer and temperature-sensitive foam and supporting the weight of the user's body. These features provided for deep immersion and high level of envelopment and enabled the mattress to conform to the shape of the user's body. The hardness of the exclusive temperature-sensing viscoelastic and open-cell materials varied according to temperature. PRFM increased the surface area of the body in contact with the support surface and further reduced the magnitude of the interface pressure, thus decreasing the risk of PI development[5,8,9].

The control group used SHFM (NP 100 Surface, Hill-Rom, USA), constructed with a multi-zoned, high-density foam, and also referred to as non-high specification reactive foam mattress. It can only support 10%–20% of the user's body weight[10].

SHFM was similar in appearance to PRFM and the same type of bed cover was used in both groups.

There was no reason to suspect any harmful effects of PRFM or SHFM on patients.

2.4. Outcome measurements

The primary endpoints were new PI of at least Category or Stage II during the study period and low mean total score on Braden Scale for Predicting Pressure Sore Risk [18].

Six categories/stages of PI were defined based on the international NPIAP-EPIAP-PPPIA classification system [5,8], which takes into consideration the degree of injury to the skin and underlying tissue over a bony prominence, as follows: Category/Stage I: Nonblanchable Erythema; Category/Stage II: Partial Thickness Skin Loss; Category/Stage III: Full Thickness Skin Loss (without exposure of the bone, tendon, or muscle); Category/Stage IV: Full Thickness Skin Loss (exposure of the bone, tendon, or muscle); Unstageable: Depth Unknown; Suspected Deep Tissue Injury.

The Braden Scale consists of six subscales, namely sensory perception, moisture, activity, mobility, nutrition, and friction/shear force. Subscale scores are added to obtain a total score ranging from 6 to 23. A lower total Braden scale score represents a higher risk of PI. The recommended cutoff score for predicting the risk of PI development is 18 [19,20]. The Braden scale is the most widely tested currently available tool for predicting the risk of PIs in adult patients in clinical practice [21,22].

The secondary endpoints were comfort and sleep quality as assessed on questionnaire with a 5-point scale as follows: strongly disagree, disagree, neutral, agree, and strongly agree.

2.5. Study procedures

To ensure the reliability of data collection, all research nurses attended a training course on the specific definition of PI and the Braden Scale. The research nurses (endpoint assessors) assessed and recorded the condition of the skin of every patient over every bony prominence, based on the PI classification system, once a day. They also evaluated all patients using the Braden Scale once a week over a period of 21 days. All Braden scores and PI categories or stages were verified by the head nurse.

A 2-hour turning schedule was implemented by the staff nurses according to published guidelines [9] for all study participants. Under the principle of causing no harm to patients, the turning procedure was performed slowly to ensure that hemodynamic and oxygenation statuses remained stable. All patients on MV were supine and in semi-Fowler's or high Fowler's position with the head of the bed elevated at an angle of 30° to 70°. The staff nurses repositioned patients every two hours in the following sequence: left side with 30° tilt, supine, and right side with 30° tilt. These procedures were supervised and verified by the head nurse.

2.6. Statistical methods

Data analyses were performed using SAS (Version 9.4, SAS Institute Inc, Cary, NC, USA). A p value of <0.05 was considered statistically significant. Variables are presented as frequency (proportion) and interquartile ranges, as appropriate. The baseline characteristics were compared between groups using Fisher's exact test and Wilcoxon two-sample t-test. The primary endpoints (mean total Braden scale score and incidence of a new PI of at least Category or Stage II) were compared between groups using the Wilcoxon two-sample t-test and Fisher's exact test. The secondary endpoints (satisfactory comfort and good sleep quality scores) were compared using the Cochran–Armitage trend test.

3. Results

Sixty-six patients on MV were assessed for eligibility, yielding a final study sample of 60 patients (Figure 1), who were assigned to the intervention (PRFM) group or the control (SHFM) group. Each group was comprised of 30 patients. After a follow-up period of 21 days, 23 patients in the intervention group completed the study. Seven patients were excluded, five were transferred to the general ward, one was transferred to another hospital due to critical condition, and one died. In the control group, 29 patients completed the study with one excluded due to death. The baseline characteristics of patients in both groups are summarized in Table 1. The patients in both groups had comparable characteristics at

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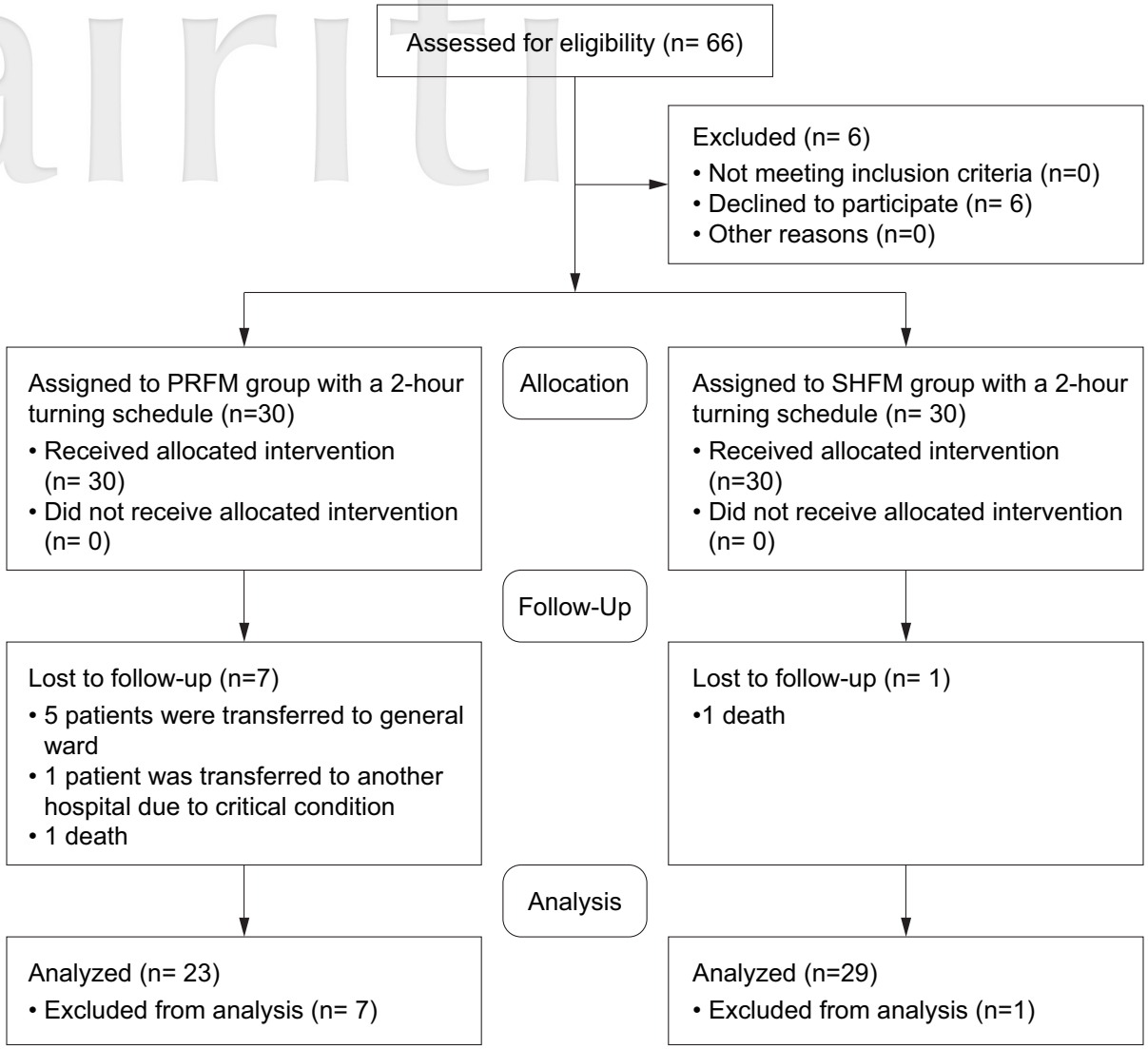

Figure 1. Study profile and flowchart of participants
PRFM, Pressure-reducing foam mattress
SHFM, Standard hospital foam mattress

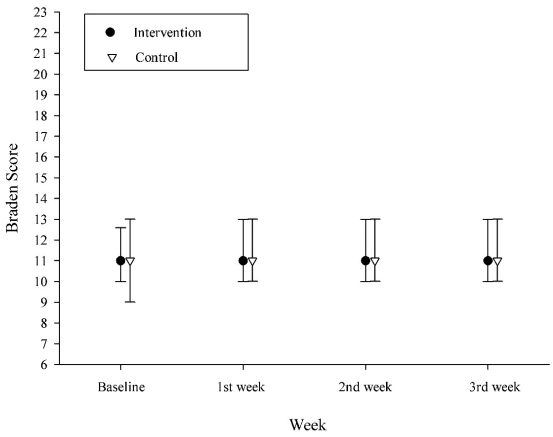

Figure 2. Mean total Braden scale scores of both groups (primary endpoint).
The error bars show the 90/10 percentiles.
There were no significant differences in Braden scores at baseline or during the 1st week, 2nd week, or 3rd week between the groups on Wilcoxon Two-Sample Test.

baseline, except for gender (Table 1). The mean total Braden Scale scores of both groups are presented in Figure 2. There were no significant differences with regard to the mean total Braden Scale scores on admission or during the 1st week, 2nd week, or 3rd

Table 1. Baseline demographics and clinical characteristics of study population

Characteristics	Intervention group (*n*=23)	Control group (*n*=29)	*P* value
Gender, *n* (%)			0.0491
Male	9(39.13)	20(68.97)	
Female	14(60.87)	9(31.03)	
Age, *n* (%)			0.5635
>= 65	16(69.57)	17(58.62)	
< 65	7(30.43)	12(41.38)	
Long-term bed-ridden, *n* (%)	4(17.39)	6(20.69)	1.0000
Comorbidities, *n* (%)			0.6538
Lung diseases	12(52.17)	14(48.28)	
Brain diseases	11(47.83)	12(41.38)	
Heart diseases	0(0.00)	2(6.90)	
Renal diseases	0(0.00)	1(3.45)	
Hemoglobin (g/dl), Median (Q1-Q3)	10.3 (9.0-12.0)	9.3 (8.4-11.4)	0.1929
Albumin (mg/dl), Median (Q1-Q3)	3.0 (2.8-3.3)	3.3 (2.7-3.6)	0.2814
Risk Factors, *n* (%)			
Edema	9(39.13)	8(27.59)	0.5525
Pain	0 (0.00)	0 (0.00)	1.0000
Malnutrition	10(43.48)	10(34.48)	0.5736
Diarrhea or incontinence	5(21.74)	3(10.34)	0.4411
Terminal cancer	0 (0.00)	0 (0.00)	1.0000
Long term steroid user	0 (0.00)	0 (0.00)	1.0000
Catheters	18(78.26)	20(68.97)	0.5388
External compression	0 (0.00)	0 (0.00)	1.0000
Poor circulation	1(4.35)	0(0.00)	0.4423
BIPAP user	0(0.00)	1(3.45)	1.0000
Lordosis	0 (0.00)	0 (0.00)	1.0000

Fisher's exact test was used for nominal variables.
Wilcoxon Two-Sample Test was used for hemoglobin and albumin values.

week between groups. Mean scores were less than 12, which indicated that all patients were at risk of PI [19,20]. The PI incidence rates did not significantly differ between the groups (3.4% for the control group versus 0% for the intervention group, $p = 1$) (Table 2).

The results of assessments of patient comfort and sleep quality for the two types of mattresses are presented in Table 3. All patients in the intervention group agreed that PRFM provided satisfactory comfort. Among them, 18 (78.26%) strongly agreed,

Table 2. Pressure ulcer incidence (primary endpoint)

	Intervention group (n=23)	Control group (n=29)	*p*-value
Pressure Ulcer Incidence Rate	0.00% (0/23)	3.45% (1/29)	1*

*Fisher's exact test

Table 3. Assessments of patient comfort and sleep quality for the two types of mattresses (secondary endpoints)

	PRFM group (N=23)	SHFM group (N=29)	*p*- value
Mattress provided satisfactory comfort, *n (%)*			<0.001#
Strongly disagree	0(0)	0(0)	
Disagree	0(0)	0(0)	
Neutral	0(0)	4(13.79)	
Agree	5(21.74)	18(62.07)	
Strongly agree	18(78.26)	7(24.14)	
Mattress provided good sleep quality, *n (%)*			<0.001#
Strongly disagree	0(0)	0(0)	
Disagree	0(0)	0(0)	
Neutral	0(0)	11(37.93)	
Agree	6(26.09)	17(58.62)	
Strongly agree	17(73.91)	1(3.45)	

Comparisons were made using Cochran-Armitage trend test.
PRFM pressure-reducing foam mattress
SHFM standard hospital foam mattress

whereas in the control group only 7 (24.14%) strongly agreed that SHFM provided satisfactory comfort ($p < 0.001$). All patients in the intervention group agreed that PRFM provided good sleep quality. Among them, 17 (73.91%) strongly agreed, whereas in the control group only 1 (3.45%) strongly agreed that SHFM provided good sleep quality ($p < 0.001$).

4. Discussion

Although one patient in the control group developed PI, there were no significant differences in the incidence rate of PI between the two groups. However, more patients in the PRFM group strongly agreed that the mattress provided satisfactory comfort and good sleep quality.

Among patients on MV, activity and mobility limitations are the main risk factors for PI [5,9]. Repositioning schedules and appropriate support surfaces are two key PI prevention measures [7]. Previous studies have evaluated the diverse effects of PRFM and SHFM on PI prevention and reported that the use of PRFM results in a significant reduction in the incidence rate of PIs when compared with the use of SHFM [3,16]. However, patients in those studies were not on MV. Moreover, Gray and Campbell did not include a turning regime. In a study by Russell et al., not all patients were turned every 2 hours. The number of patients turned once every 2 hours was

low when compared with the numbers of patients turned infrequently or once every 4 hours in terms of the development of non-blanchable erythema or worse. In this study, the lack of a significant difference in incidence of PI between the groups may be attributed to the 2-hour turning schedule. Manual repositioning regimens are strongly recommended for the prevention of PIs [23]. They have the effect of redistributing the interface pressure between the bony prominences of the patient and the mattress surface, reducing the duration and magnitude of the pressure experienced by tissues, as well as tissue hypoxia and damage to the tissues [5,9,24].

For patients on MV, sustained semi-Fowler's (30° to 45° angle) or high Fowler's (60° to 90° angle) position optimizes breathing and prevents ventilator-associated pneumonia [9,25]. Maintaining these positions can induce pressure or shear on the sacrum, coccyx, and shoulder; reduce or occlude local blood supply; and cause PI development [9,26]. In our study, all patients were kept at an angle of 30° to 70°. One patient in the control group developed PI even on a 2-hour turning schedule. However, no patients in the intervention group developed PI, which indicated that PRFM reduces pressure even in sustained semi-Fowler's or high Fowler's position and resolves the conflict of body position in the prevention of ventilator-associated pneumonia versus the prevention of PI. A study by Defloor showed that PRFM reduces pressure in 30°, 60°, and 90° supine positions by nearly 20%–30% in comparison to SHFM [11]. The results of this study supported these findings. G*Power 3.1.5 analysis yielded an estimate of 30 patients per group. As the incidence of PI in the two groups was low, there were no significant differences. PRFM may have a significant effect on PI prevention in patients on MV who are bedridden for longer periods.

The patients in our study were not only on MV but also under potential risk of respiratory instability, combined with other severe comorbidities. Repositioning patients every 2 hours can cause cardiovascular instability [9]; disturb sleep quality; increase the discomfort of patients with wounds, stiff joints, bone pain, or contractures; and increase the workload of nurses [27]. Additionally, in the prevention of PI, turning of patients is not cost-effective. It is also time-consuming for nurses [28,29]. PRFM causes no harm to patients while turning of patients may not be feasible for critically ill individuals [9]. PRFM may be safer than turning of patients in the prevention of PIs among patients on MV. Our study revealed that no patients in the PRFM group developed PIs. However, patients in the SHFM group had a higher tendency to develop PI. Therefore, further studies on the prevention of PIs with PRFM and a less frequent turning schedule in patients on MV are warranted. If PIs can be prevented, with less frequent turning, in patients on MV, nurses can concentrate more of their time on other nursing interventions.

This study is based on a quasi-experimental design. There was a potential bias that might affect our results and limit our conclusions. Further randomized controlled trials are needed to explore the protection from PI that is provided by PRFM. The external validity was limited, as the material and function of SHFM differ by company.

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