

Feature Article

Prevention of Pressure Ulcers in the Intensive Care Unit

A Randomized Trial of 2 Viscoelastic Foam Support Surfaces

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Aims and objectives:

The aim of this study is to compare whether differences exist between 2 viscoelastic foam support surfaces in the development of new pressure ulcers.

Background:

There is evidence to support the use of viscoelastic foam over standard hospital foam to reduce pressure. A comparative effectiveness study was done to compare 2 viscoelastic foam support surfaces.

Design:

A randomized controlled trial was carried out.

Method:

The study was performed in 2 intensive care units between October 1, 2008, and January 4, 2010. Patients ($n = 105$) admitted to intensive care unit were randomly assigned to viscoelastic foam 1 ($n = 53$) or viscoelastic foam 2 support surface ($n = 52$).

Results:

In total, 42.8% of all patients developed a new pressure ulcer of stage 1 or worse. By stages, pressure ulcer incidence was 28.6%, 13.3%, and 1.0% for stages 1, 2, and 3, respectively. There was

no significant difference in pressure ulcer incidence between the viscoelastic foam 1 and 2 groups ($\chi^2 = 0.07$, $df = 1$, $P > .05$).

Conclusions:

No difference was found between 2 different viscoelastic foam surfaces in the prevention of pressure ulcers in patients treated in intensive care.

Relevance to Clinical Practice:

Pressure ulcer incidence in critically ill patients remains high. Nurses must compare current products for effectiveness and develop innovative systems, processes, or devices to deliver best practices.

KEY WORDS:

Braden Risk Assessment Scale, intensive care unit, pressure ulcer, randomization, risk factors, viscoelastic foam support surface

Pressure ulcers (PUs) are 1 of the most underrated medical problems in critically ill patients. Despite advances in medical technology and the use of formalized prevention programs based on clinical practice guidelines, the prevalence of PU during hospitalization continues to increase dramatically.^{1,2} Pressure ulcers are the third most expensive disorder to treat after cancer and cardiovascular disease.³

Critically ill patients are at a higher risk for PU than are patients in general care areas.⁴⁻⁶ Patients in many intensive care units (ICU) are often sedated and ventilated, which interferes with their mobility and ability to care for themselves. Movement is a natural response to pressure and is often lost during periods of critical illness. Critically ill patients may be further impacted by poor tissue perfusion associated with hemodynamic instability, skin maceration due to moisture, poor nutritional status,⁴ and conditions such as anemia, renal impairment, shock, or vascular failure.³

Observed prevalence rates of PUs were between 5% and 30% in hospitals⁷⁻¹¹ and between 1% and 56% in

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ICUs.¹²⁻¹⁵ In Turkey, research regarding the prevalence of PU in hospitals was limited.¹⁶ Huq et al found a prevalence rate of 7.2% in a university hospital setting (n = 922) in Turkey. In a university hospital, the incidence of PUs was 25% in general ICU, 22.1% in surgical ICU, and 18.3% in neurology ICU.^{17,18}

Prevention and treatment of PUs depend on multidisciplinary teamwork, but the roles of nurses are also very important.^{5,19,20} Nurses can alter tissue perfusion and pressure issues through turning and positioning, massage, use of support surfaces, proper skin care, and other nursing measures.^{21,22} Thus, hospital-acquired PU development is a nursing quality indicator that is assessed and monitored to reflect quality care.⁶ Although turning, positioning, and increasing passive activity seems like a common-sense PU prevention approach, no published data support the view that these activities can actually prevent PUs. Moreover, because nursing interventions and turning procedures have not been completely effective in preventing PU, foam-based support surfaces have been developed. Support surfaces decrease tissue interface pressure compared with a standard hospital mattress²³ and relieve stress on the skin.²⁴ Pressure redistributing support surfaces aim to reduce the magnitude and/or duration of pressure between an individual and the support surface used (interface pressure) to prevent or treat the PU.^{25,26}

A recent systematic review of 41 randomized controlled trials on pressure-relieving surfaces for prevention of PUs concluded that the relative effectiveness of alternating pressure surfaces was unknown.²⁷ In some randomized controlled trials, use of pressure-reducing surface led to lower incidence and severity of PUs than with a standard hospital foam.^{23,28-30} Cullum et al³¹ concluded that high-specification foam had increased effectiveness over standard hospital foam. A viscoelastic polyurethane foam mattress reduced pressure by 20% to 30% compared with the interface pressure measured on a standard hospital mattress.³² In their guidelines for prevention of PUs, experts from the National Institute for Health and Clinical Excellence recommended high specification foam mattresses as the standard for vulnerable patients and surfaces such as alternating pressure mattresses for high risk.³³

A basic strategy for reducing pressure near a bony prominence is to allow the prominence to submerge into the support surface. For elastic and viscoelastic support surfaces, the potential for submersion depends on their stiffness and thickness.^{20,34,35} Viscoelastic foams have unique properties in density, tensile strength, fatigue, and fracture toughness and are available as thermoactive and thermoinactive foams. Compared with other foams, viscoelastic foam properties result in better body adaptation, a larger contact surface, and more effective pressure reduction.³⁶

Use of specialized mattresses and beds to prevent PUs in the ICU is common, although indications are largely empirical.

In some studies, mattresses were beneficial, but only in populations outside the ICU environment.^{24,37} Then, research findings were extrapolated to the critically ill.³⁷ No randomized controlled trials of the effects of support surfaces as PU prevention have been conducted in Turkey. Therefore, the purpose of this study is to determine whether differences existed between the effects of 2 types of viscoelastic foam support surfaces on the development of new PUs, their stages, and locations in an ICU environment.

METHODS

Setting and Sample

This was a parallel group, randomized comparative study conducted in medical and surgical ICUs at Kocatepe University Hospital in Afyonkarahisar, Turkey, between October 1, 2008, and January 4, 2010. Of the 414 people assessed for study eligibility, 105 met criteria. The study sample composed 105 eligible patients, of which 43 (41%) were admitted to medical ICU and 62 (59%) to the surgical ICU. The medical and surgical ICUs are each 5-bed units in which 6 nurses work, 2 nurses per shift.

Eligibility criteria included patients older than 18 years whose expected length of stay was at least 7 days. Patients were not eligible if they had a PU of stage 1 or worse on admission or weighed more than 140 kg or less than 45 kg (as per mattress recommendations). Patients whose Braden score was higher than 18 were considered "no risk" and were not included in the study; 309 patients did not meet study criteria for multiple reasons and were excluded (Figure). After the first evaluation, patients who met the criteria were included in the study. Risk for PU was evaluated by the Braden Risk Assessment Scale.²⁶ Risk factors identified in the Braden Scale were used as part of usual care in both groups to develop an individualized plan of care.

This study was approved by the institutional review board of Afyon Kocatepe University. Written approvals to perform the study were received from the ethics board of the Ege University School of Nursing and the university Hospital Medical and nursing directors of Kocatepe University Hospital. Written consent of unconscious patients were obtained from their relatives.

Procedures

Randomization was performed through an independent, secure, 24-hour randomization automated telephone system, ensuring allocation concealment. We used minimization so that groups were parallel. Participants were assigned to a viscoelastic foam 1 or viscoelastic foam 2 mattress (see Table 1) within 24 hours of ICU admission. Elective surgical patients received their device on the day before surgery or after surgery at the point of transfer to bed.

The data collection form was designed to determine risk factors for the development of PUs and to document sociodemographic characteristics and medical conditions that

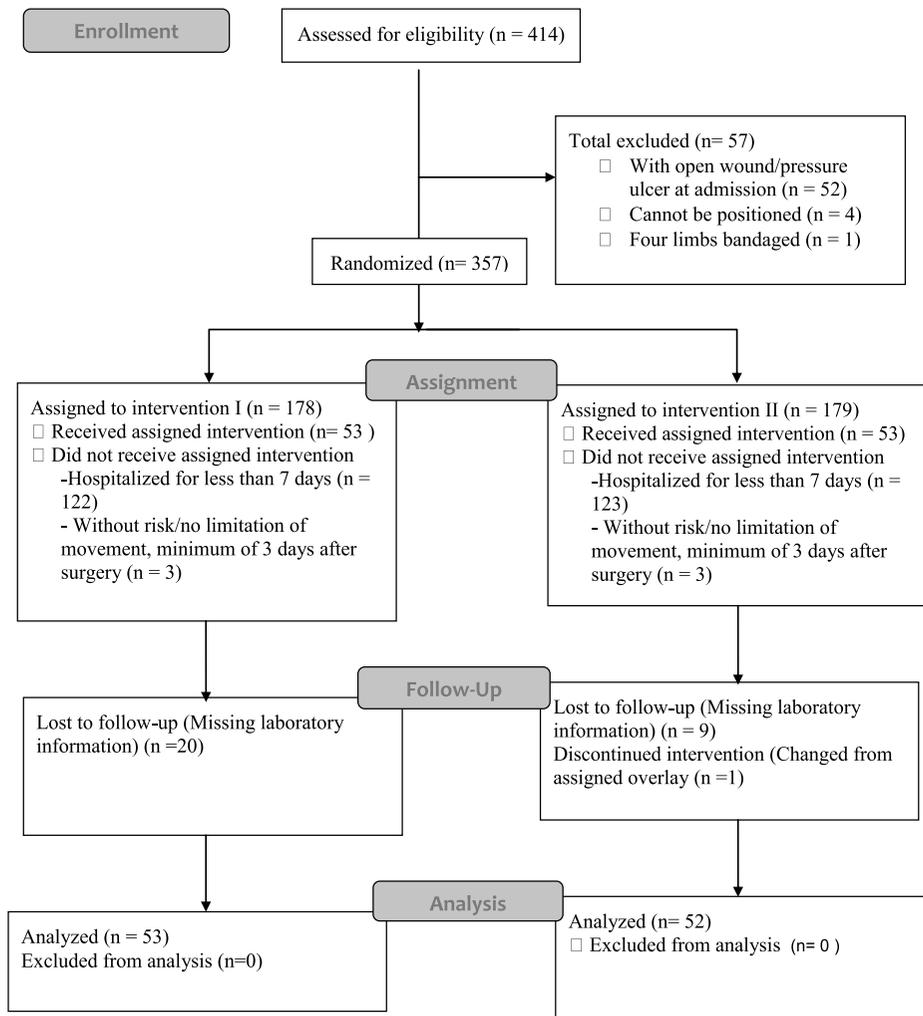


FIGURE. Flow of patients through the trial.

could be PU risk factors, including age, sex, mechanical ventilation, sedation, chronic disease, and surgical procedure (Table 2). The patient's level of consciousness, activity status (independent, partially dependent, dependent and sedated), body mass index, and changes in general condition were also recorded.

Nursing interventions to prevent the development of PU were recorded daily. These interventions were turning, repositioning, the cushions, the 30° tilt, nutritional support, skin care, diagnosis of skin problems (such as edema, dryness, thinning, adhesive tape allergy, circulatory disorder, dirt, itching), and incision wound dressing. Skin follow-up evaluations were completed daily.

The skin assessment instrument included a list of the most common sites for PUs: back of the head, scapula, trochanter, sacrum, ischium, malleolus, and heel. The instrument also included a staging system that classified PUs according to standards developed by the European Pressure Ulcer Advisory Panel.^{26,38} The severity of PUs was graded in 4 stages

based on European Pressure Ulcer Advisory Panel standards. Stage 1 reflected nonblanchable erythematous, with an intact skin surface. Stage 2 reflected epithelial damage, abrasion, or blister. Stage 3 reflected damage to the full thickness of the skin without a deep cavity, and stage 4 reflected damage to the full thickness of the skin with a deep cavity.³⁹

The Braden Risk Assessment Scale, used to identify patients at risk for PUs, consists of 6 subscales of mobility, activity, sensory perception, skin moisture, nutritional status, and friction/shear.²⁴ In acute care hospitals, a Braden score of 16 or lower is most commonly used to establish PU risk, particularly for ICU patients.³⁹ However, a score of 18 may be used for patients with extended stay, patients in elder care centers and long-term centers, or for patients receiving home care services.³⁹ To predict PU risk and plan care in ICU patients, Braden scale criteria were assessed upon admission, again in 48 hours, and then every day, based on recommendations from the literature.²⁴ Data were collected by ICU research nurses. Informational meetings

Table 1. Distribution of Pairing Criteria Among the Groups

	Viscoelastic Foam 1 Group (n = 53)	Viscoelastic Foam 2 Group (n = 52)	Total (N = 105)	t Test, P
Age	64.77 ± 15.09	65.21 ± 15.26	64.99 ± 15.1	.88
Female weight, kg	71.18 ± 16.93	73.14 ± 21.07	72.16 ± 19	.84
Male weight, kg	73.22 ± 11.48	72.88 ± 13.26	73 ± 1.37	.84
Length of stay	17.13 ± 17.37	17.60 ± 18.77	17.36 ± 17.9	.89
Braden risk score	14.11 ± 3.349	13.06 ± 2.789	13.5 ± 3.11	.08
Glasgow Coma Scale score	11.30 ± 4.55	9.11 ± 4.89	10.22 ± 4.83	.02
Body mass index, kg/m ²	26.23 ± 5.53	26.78 ± 6.38	26.46 ± 5.87	.69
Hemoglobin level, g/dL	12.26 ± 2.49	11.53 ± 2.75	11.89 ± 2.64	.16
Hematocrit level, g/dL	37.06 ± 6.57	35.34 ± 8.48	36.19 ± 7.61	.25
Albumin level, g/dL	3.24 ± 1.12	2.74 ± 0.76	2.98 ± 0.98	.01
Total protein	6.10 ± 2.12	5.40 ± 3.53	5.97 ± 2.22	.70

Data are presented as mean ± SD.

were held on each unit related to the study procedure, stage system used for PUs, and completing the Braden Scale and skin assessment instruments.

Viscoelastic foam 1 was composed of 2 layers, a 7-cm support surface with 8 cm of high-flexibility foam. Viscoelastic foam 2, a breathable, open-cell type of viscoelastic foam, was composed of 3 layers, the top active viscoelastic layer, lower support layer, and side safety barrier.

Statistical Analyses

Data obtained from study participants were analyzed using Statistical Package for the Social Sciences for Windows, version 15.0. Patient characteristics were summarized as number and percentage or as mean and standard deviation. To compare patient characteristics by viscoelastic foam 1 and viscoelastic foam 2 groups, *t* tests were used. χ^2 tests were performed to assess differences between groups on categorical characteristics.

RESULTS

Of 105 patients enrolled in the study, 53 were assigned to the viscoelastic foam 1 group and 52 were assigned to the viscoelastic foam 2 group (Figure). The mean age of the patients in the study was 64.99 ± 15.10 years. The distributions of patient characteristics in both groups are shown in Table 1. Fewer patients were enrolled from the medical versus the surgical ICUs, 41% and 59%, respectively. Patients had multiple diagnoses: abdominal surgery, n = 41 (39%); respiratory disease such as pneumonia and chronic obstructive pulmonary diseases, n = 22 (21%); miscellaneous problems such as diabetic coma or chronic renal failure, n = 15 (14.4%); stroke, n = 13 (12.4%); and orthopedic trauma, n = 9 (8.6%). Mean Braden scores are provided

in Table 1. At baseline, Braden scores reflected moderate risk (score between 13 and 14) of PU development for both groups. Glasgow Coma Scale scores reflected moderate (score between 9 and 12) brain injury in both groups; however, viscoelastic foam 2 group patients had significantly lower scores. By the end of the ICU stay, 55 (52.4%) patients were transferred to clinical care units, 10 (9.5%) were transferred to different ICUs, 3 (2.9%) returned home, and 37 (35.2%) died.

In all, 60 (57.2%) patients did not develop PUs, 31 (58.4%) patients in the viscoelastic foam 1 group and 29 (59.7%) in the viscoelastic foam 2 group. Of 45 (42.87%) patients who developed PUs, there were no differences in the incidence of PUs between the 2 groups. Stage of PU did not differ by group, nor did the frequency in which patients in each group developed a stage 1 or 3 PU. However, more patients in the viscoelastic foam 1 group had higher frequency of developing stage 2 PUs (see Table 3). For patients who developed PUs, the median time to development of the first PU was 4 days and ranged from 1 to 15 days. Numerically, patients in the viscoelastic foam 1 group developed stage 1 PU during the first week more often than did patients in the viscoelastic foam 2 group, but statistically, there were no differences between these groups. In both groups, PUs developed most often on the sacrum and shoulder bone and there were no differences in the site of PU development by viscoelastic foam group (see Table 3).

DISCUSSION

The proportion of patients allocated to viscoelastic foam 1 or viscoelastic foam 2 who developed a new PU of grade 1 or worse at any anatomical site did not differ. Our results support the findings of Nixon et al,²⁷ who studied a similar support surface.

Table 2. Baseline Characteristics of Patients in the Viscoelastic Foam Support Surface Groups

Demographic Characteristic	Viscoelastic Foam 1 Group (n = 53)	Viscoelastic Foam 2 Group (n = 52)	Total (N = 105)	P ^a
Age				
17–55 y	13 (24.5)	12 (23)	25 (23.8)	.18
≥56 y	40 (75.4)	40 (77)	80 (76.2)	
Sex				
Female	27 (50.9)	23 (44.2)	50 (47.6)	.49
Male	26 (49.1)	29 (55.8)	55 (52.3)	
Weight loss status				
Without weight loss	34 (64.2)	37 (71.2)	71 (67.6)	.26
With weight loss	9 (17.0)	5 (9.6)	14 (13.3)	
Unknown	10 (18.9)	10 (19.2)	20 (19.4)	
Ventilation status				
Ventilated	23 (43.4)	25 (48.1)	48 (45.7)	.48
Not ventilated	30 (56.6)	27 (51.9)	57 (54.3)	
Sedation status				
Sedated	16 (30.2)	18 (34.6)	34 (32.3)	.62
Not sedated	37 (69.8)	34 (65.4)	71 (67.7)	
Diabetes status				
Without diabetes	32 (60.4)	35 (67.3)	67 (63.8)	.61
With diabetes	17 (32.1)	15 (28.8)	32 (30.4)	
Unknown	4 (7.5)	2 (3.8)	6 (5.71)	
Smoking status				
Nonsmoker	40 (75.5)	36 (69.2)	76 (72.3)	.5
Smoker	8 (15.1)	5 (9.6)	3 (12.3)	
Unknown	5 (9.4)	11 (21.2)	16 (15.23)	
Braden risk score				
15–18	27 (50.9)	13 (25.0)	40 (38.1)	.02
13–14	8 (15.1)	18 (34.6)	26 (24.8)	
10–12	13 (24.5)	15 (28.8)	28 (26.7)	
≤9	5 (9.4)	6 (11.5)	11 (10.5)	
Glasgow coma score				
15–14 (light)	26 (49.1)	16 (30.8)	42 (40.0)	.02
13–9 (middle)	15 (28.3)	11 (21.2)	26 (24.8)	
8–3 (heavy)	12 (22.6)	25 (48.1)	37 (35.2)	

Data are presented as n (%).
^aχ² test.

Viscoelastic foam support surfaces are in common use in European countries such as the United Kingdom and are generally thought of as representing “state of the art” preventive measures in PU avoidance,³⁷ but they are rarely used in Turkey. At study initiation, the reported rate of PU

development among critically ill patients was as high as 42.8%.³⁷ A study in Turkey (2005) reported a PU incidence of 54.8% among postoperative surgical patients.¹⁶ No other studies were found to determine the PU incidence or prevalence in ICUs in Turkey.¹⁶ Compared with other reports,

Table 3. Pressure Ulcers (PUs) by Foam Surface

Distribution of New PUs	Viscoelastic Foam 1 Group (n = 53)	Viscoelastic Foam 2 Group (n = 52)	Total (N = 105)	P ^a
Developed new PU stage/patient				.44
New stage 1	12 (22.6)	16 (30.7)	28 (26.6)	
New stage 2	9 (16.9)	7 (9.6)	14 (13.3)	
New stage 3	1 (1.9)	–	1 (1.0)	
Total	22 (42.8)	23 (40.3)	55 (42.8)	
Number who developed stage 2 new PU per patient				.62
1	23 (43.4)	19 (36.4)	42 (40.9)	
2	7 (9.4)	6 (7.6)	11 (10.4)	
3	3 (3.7)	1 (1.9)	3 (2.8)	
4	1 (1.8)	1 (1.9)	2 (1.8)	
Location of new PU/patient				
Sacrum	13 (26.4)	12 (23.1)	25 (49.5)	.81
Shoulder bones	10 (18.9)	9 (17.2)	19 (36.1)	.90
Elbow	5 (9.5)	1 (1.9)	6 (11.4)	.31
Malleoli	4 (7.5)	2 (3.9)	6 (11.4)	.41
Heel	3 (5.7)	3 (5.7)	6 (11.4)	.98
Trochanter	6 (8.4)	3 (5.7)	9 (14.1)	.56
Ischium	3 (5.7)	3 (5.7)	6 (11.4)	.85
Days to PU development				.11
1–7 d	13 (59.1)	6 (28.6)	19 (44.2)	
8–14 d	7 (31.8)	10 (47.6)	17 (9.5)	
≥15 d	2 (9.1)	5 (23.8)	7 (16.3)	

Data are presented as n (%).
^aχ² test.

incidence of PU in our ICU environment was high. Others reported PU rates between 3% and 33%.¹⁶ In 1 study, the primary randomized controlled end-point was the development of a new stage 2 PU or higher, representing a break in the skin.²⁷ Thus, it is difficult to compare results between studies. Stage 1 PU development is an important precursor of stage 2 PU development, increasing the odds approximately 6-fold.²⁷ In our study, incidence of PUs stage 2 or higher was 14.3% and was midrange compared with the ICU PU incidence rates of 3% to 33% that also involved stage 2 PUs or higher.¹⁶

Regardless of group assignment, 44% of the patients developed PUs in the first week after admission. Our results were similar with those of other studies.^{25,30,37} Of patients treated in ICUs for extended stays (maximum 120 days), only 14 patients had no PU development.³⁷

In this study, there was no statistical difference between the 2 groups in incidence of PUs. Our findings of no differ-

ences between groups in incidence of PUs were similar to those reported in 4 other viscoelastic foam bed studies.^{25,30,37} In a systematic review of randomized controlled trial, Cullum et al⁴² summarized that patients at high risk for PU should not receive regular foam mattresses; high-specification foam was preferred. In a newer systematic review, McInnes et al⁴² reported that there was insufficient evidence to guide the selection of the optimal alternative foam mattress. Furthermore, there was insufficient evidence based on randomized controlled trials to support the merits of higher-tech constant low-pressure and alternating-pressure mattresses.⁴²

The main limitation of this trial was the lack of blinded outcome assessments; it was difficult to mask viscoelastic foam support surfaces and it would be unethical to frequently move critically ill patients from bed to bed. We took steps to minimize the potential for bias by collecting independent skin assessments carried out by both staff nurses in the ICU and the research nurses. Although ICU

nurses were not blind to patient assignments, we have no evidence that lack of blinding influenced patient care delivery.²⁷ Another major limitation of this study was that it had a small sample size with a limited number of participants and very few PUs beyond stage 2. Research was conducted at a single center using 2 products with similar properties. A multi-center study might help expand our understanding of the efficacy of support surface in the prevention of large PUs.

CONCLUSION

There were no differences in the incidence of PUs between the 2 viscoelastic foam support surfaces used in the care of patients treated in the ICU. Because the support surfaces offered similar protection from PU development, clinical managers and clinical nurse specialists should choose the most economical option, unless other support surface features with evidence of efficacy differ between options. It is important to continue conducting comparative effectiveness research on products, devices, and services used in the treatment of critically ill patients so that patient quality and safety are enhanced and adverse events, such as PUs, are minimized.

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