Five-Layered Soft Silicone Foam Dressing to Prevent Pressure Ulcers in the Intensive Care Unit

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Background In critically ill patients, prevention of pressure ulcers is a challenge because of the high risk for multiple comorbid conditions, immobility, hemodynamic instability, and increased use of medical devices.
Objectives To compare the difference in incidence rates of hospital-acquired pressure ulcers (HAPUs) in critically ill patients between those treated with usual preventive care and a 5-layered soft silicone foam dressing versus a control group receiving usual care. Secondary goals were to examine risk factors for HAPUs in critically ill patients and to explicate cost savings related to prevention of pressure ulcers.
Methods A prospective, randomized controlled trial in the intensive care units at a 569-bed, level II trauma hospital. All 366 participants received standard pressure ulcer prevention; 184 were randomized to have a 5-layered soft silicone foam dressing applied to the sacrum (intervention group) and 182 to receive usual care (control group).
Results The incidence rate of HAPUs was significantly less in patients treated with the foam dressing than in the control group (0.7% vs 5.9%, $P=.01$). Time to injury survival analysis (Cox proportional hazard models) revealed the intervention group had 88% reduced risk of HAPU development (hazard ratio, 0.12 [95% CI, 0.02-0.98], $P=.048$).
Conclusion Use of a soft silicone foam dressing combined with preventive care yielded a statistically and clinically significant benefit in reducing the incidence rate and severity of HAPUs in intensive care patients. This novel, cost-effective method can reduce HAPU incidence in critically ill patients. (*American Journal of Critical Care.* 2016;25:e108-e119)

CE 1.0 Hour

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doi: http://dx.doi.org/10.4037/ajcc2016XXX

The National Pressure Ulcer Advisory Panel (NPUAP) defines a pressure ulcer as a localized injury to the skin and/or underlying tissue, usually over a bony prominence, resulting from sustained pressure (including pressure associated with shear).[1] Because of the loss of revenue associated with hospital-acquired pressure ulcers (HAPUs) and the required public reporting of them, the development of HAPUs is a great concern in today's health care environment. In critically ill patients, the prevention of pressure ulcers is complex because the severity of illness is high and preventive measures may be contraindicated or limited.[2,3]

NPUAP reported on trends in HAPU development from 2000 to 2010, and the incidence of HAPUs in intensive care units (ICUs) remains high, from 5.2% to 41%.[2] The numbers can vary widely, depending on the number of patients being examined, the type of ICU, risk assessment, and overall research methods.[3-10] For example, in a cohort study,[6] surgical ICUs had a higher incidence of HAPUs than coronary care units did. A small unit of 10 patients might appear to have a high HAPU rate when compared with a larger unit.[7,9,10] Reporting incidence by using a 1000-patient-day metric is a preferred method, but few data have been reported using that metric.[1,2] Bry et al[5] reported a mean facility-acquired pressure ulcer rate of 5.0 per 1000 patient days in the ICU compared with 1.1 per 1000 patient days in the general acute care units in the same US hospital. Because HAPUs are a nursing quality indicator, a high incidence of HAPUs in an organization may imply poor quality care.

Additionally, empirical evidence suggests that numerous risk factors can be predictive of pressure ulcers.[10-13] Some physiological (intrinsic) and nonphysiological (extrinsic) risk factors that may place adults at risk for pressure ulcer development are advanced age; comorbid conditions including diabetes mellitus, peripheral vascular disease, cerebral vascular accident, sepsis, cardiovascular disease, and hypotension; severity of illness (as indicated by Acute Physiology and Chronic Health Evaluation [APACHE] IV score)[14]; and iatrogenic factors such as the use of vasopressors.[11,12,15] A hypothesis exists that these physiological risk factors place the patients at risk because of impairment of the microcirculation system.[16] Microcirculation is controlled in part by central sympathetic vasoconstrictor impulses from the brain and secretions from localized endothelial cells. Because neural and endothelial control of blood flow is impaired during an illness state, the patient may be more susceptible to ischemic organ damage (eg, pressure ulcers).[15-17] Additional risk factors that have been correlated with pressure ulcer development are smoking history, dry skin, low body mass index, impaired mobility, altered mental status (ie, confusion), urinary and fecal incontinence, and malnutrition.[15,17,18]

Although research has indicated that many of these factors are significantly related to the development of HAPUs in ICU patients, the findings were not consistent in all of the studies in which these relationships were tested.[19,20] This inconsistency may in part be associated with the lack of valid risk assessment tools[21,22] specifically for critically ill patients, noted most recently by Richardson and Barrow.[23] In fact, their recent literature review on risk stratification and assessment tools has led to the development of a critical care pressure ulcer assessment tool (CALCULATE),[23,24] which consists of 8 key risk factors (too unstable to turn, impaired circulation, dialysis, mechanical ventilation, immobility, long surgery/cardiac arrest, low protein, fecal incontinence). CALCULATE gained face validity by consensus agreement of experts in the field.[23,24] However, further investigation is warranted to refine these risk factors to explain and validate a major part of the variance in pressure ulcer development and to further validate the CALCULATE tool.

> Numerous risk factors can be predictive of pressure ulcers.

The cost of pressure ulcers is high, from $9.1 to $11.6 billion per year in the United States.[25] An actuarial analysis of claims data indicated that pressure ulcers had the largest annual cost: 394 699 cases cost $3.858 million to treat.[26] The Agency for Healthcare

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Research and Quality[20] reported in 2014 that hospitalizations of patients with pressure ulcers are longer, with a mean length of stay (LOS) from 13 to 14 days compared with 5 days for patients without pressure ulcers. Hospitalizations of patients with pressure ulcers are also more expensive, with the cost of care per individual patient ranging from $20 900 to $151 700 per pressure ulcer compared with a mean cost per hospitalization of $10 000 for patients without pressure ulcers.[20,25,26] Moreover, mortality rates in hospitalized patients with pressure ulcers reached from 4.2% to 11% compared with rates of only 2.6% among patients without pressure ulcers.[3,4,25,27-29] Further, more than 17 000 lawsuits related to pressure ulcers are filed annually.[26] Pressure ulcers are the second most common claim, after wrongful death; more claims are filed about pressure ulcers than about falls or emotional distress.[25]

Multilayered foam dressings are increasingly being used to reduce the incidence of pressure ulcers.

Risk for pressure ulcers in critically ill patients is generally assessed by using the Braden Scale.[30] The correlation between a low score on the Braden Scale (high risk) and HAPU development among critically ill patients is well established.[7-9,14-16,20-30] These patients are often exposed to pressure from being immobile and unconscious, thus unable to change positions independently.[4-9,31-34] Shear forces are present on the sacrum from head-of-bed elevation with mechanical ventilation.[15,27-29,35] Preventive care is frequently organized into a comprehensive plan, including the "SKIN" (surfaces, keep the patients turning, incontinence management, nutrition) bundle.[34] These bundles reduce pressure ulcer rates but have not eliminated HAPUs.[31-34,36]

Despite advances in support surfaces and the use of formalized prevention programs that are based on clinical practice guidelines,[37] the incidence of HAPUs among critically ill patients remains a worldwide problem that contributes significantly to increasing health care costs and patients' suffering, morbidity, and mortality.[6,12,15-18]

The use of sacral foam dressings to augment standard procedures for preventing pressure ulcers in ICUs has been reported but not rigorously tested in the United States.[38] The earliest work on the use of a dressing to mitigate external shear on the skin was reported in a porcine model in 2005.[39] Because of the uniqueness of using a wound dressing for prevention, the performance of several types of foam dressings in a laboratory setting was reported by Call and colleagues.[40,41] Testing included pressure and shear redistribution, friction control, and microclimate management. The forces of pressure, shear, and friction were transmitted from the support surface into some of the dressings, whereas others led to underhydration of the skin, increasing the risk for skin tears.[40,41] Thus, before deploying any dressings to help prevent pressure ulcers, testing is essential to determine if the dressing could reduce the deleterious effects of moisture, pressure, and shear on the body.[41-43]

Brindle and colleagues[44-46] reported on a quality improvement project that used a 5-layer soft silicone foam dressing in which a reduction in sacral pressure ulcer formation in patients in a surgical ICU was noted. Several other nonrandomized trials using concurrent controls or historical controls also showed reductions in the occurrence of sacral pressure ulcers in critically ill patients.[47-51] Santamaria et al[52] conducted a randomized clinical trial (RCT) in Melbourne, Australia, in which 440 patients admitted to the emergency department with planned placement in the ICU were randomly selected to have 5-layer soft silicone-bordered foam dressings used on the sacrum and heels. Both groups received standard pressure ulcer preventive care, which included the use of a low-airloss bed, regular repositioning, and skin care.[52] Skin was examined daily beneath the dressing, which was changed every 3 days, unless soiled earlier. The assessment for pressure ulcer formation ended with discharge from the ICU.[52] The incidence of pressure ulcers in the control group was 13.1% compared with 3.1% in the dressing group. This difference was statistically significant ($P = .001$), with an absolute risk reduction of 10%.[52]

Research Aim

The primary aim of this prospective, nonblinded RCT was to determine the difference in the incidence rate of sacral HAPU formation between 2 groups of critically ill patients. Both groups received usual care (SKIN bundle)[34]; additionally, the treatment group had a 5-layered soft silicone foam dressing applied to the sacrum (Mepilex Border Sacrum, Mölnlycke Health Care AB) within 24 hours of admission to the ICU. A secondary aim was to examine risk factors for HAPU development in critically ill patients, and a third aim was to explicate cost savings related to prevention of pressure ulcers.

Methods

The study was approved by the institutional review board of the hospital system and carried out within the ethical standards set forth in the Helsinki Declaration of 1975. The study was granted an exemption from the need to obtain consent from

participants because of the critical illness of the participants under the provisions of Code of Federal Regulations (45 CFR §46) and the research policies of the institutional review board and the health system. A letter from the principal investigator was provided to the patients' next-of-kin/and or significant others, informing them that their relative or significant others had been enrolled in the study. The letter provided a lay person's description of the aims of the research and gave them the option of withdrawing their relative or significant other from the study.

Sample Size

A power analysis indicated that to detect a decrease in the incidence of pressure ulcers of 5% (from 6.9% to 2%) in the intervention group with power of 80% and an alpha of .05, a total of 370 patients (185 patients per group) would be required.[53]

Setting and Sample

This prospective open-label RCT used a convenience sample of all critically ill patients admitted to the cardiac, medical, surgical, and trauma ICUs in a 569-bed, level II trauma, Magnet hospital. Eligible patients (≥ 18 years old, Braden score[30] of ≤ 13 and intact sacral skin), were randomized at index admission (1:1 ratio) to either the control group (n = 182) receiving usual preventive care or the intervention group (n = 184) receiving usual care plus application of the Mepilex Border Sacrum foam dressing. Patients were excluded if they had a Braden score of 14 or higher, had existing sacral pressure ulcers, had moisture-related skin damage on admission, and/or they were receiving end-of-life care or undergoing withdrawal of life-sustaining treatments.

The sacral dressing was applied within 24 hours of admission to the ICU and remained in place throughout the course of each patient's ICU stay. All patients were examined daily by a member of the study team while in the ICU, to identify the development of any HAPUs on their sacrum or other areas on the body. The intervention dressing was changed every 3 days or more often if it became soiled or dislodged. The data collection period was November 2011 to December 2012. Patients remained in the study while in the ICU, and when they transferred out of the unit, no further skin assessments were completed by the study team, but rather the development of HAPUs was monitored via the electronic medical record.

Randomization

Randomly permuted block design was used with 1:1 randomization of patients within randomly selected blocks of 2, 4, or 6 patients. The ordering of patients within each block was also randomly assigned by using a computerized research randomizer.[54] The randomization of participants was undertaken by the principal investigator or study nurse, when patients were admitted to the ICU, and following eligibility screening. Enrollment and randomization procedures were carried out by the study nurse: (1) study team rounds daily, screens for new patients admitted to the ICU who meet inclusion criteria; (2) determine group allocation by accessing the randomization program; (3) if patient is randomized to the treatment group, apply the Mepilex Border Sacrum foam dressing to the patient's sacrum following the protocol, recording the time and date on the dressing.

Study Procedures

All study patients received standard evidence-based care for preventing pressure ulcers in critical care patients following the SKIN bundle,[34] which included the following: pressure ulcer risk scoring by using the Braden Scale[30] at admission and every shift, full skin assessment on every shift, and use of the TotalCare SpO2RT 2 Therapy Bed (Hill-Rom, Inc), routine positioning, heel off-loading, and incontinence skin care. Intervention patients had a single Mepilex Border Sacrum foam dressing applied to the sacrum, where it was maintained throughout the duration of the patient's ICU stay. The dressing was pulled back daily for routine skin assessment and was changed every 3 days or when it became soiled or dislodged. To avoid potential bias related to these procedures, an ICU expert clinical nurse specialist independently verified outcome assessments.

Estimated treatment costs were also tracked to evaluate the cost-effectiveness of the intervention.

During the course of the study, estimated treatment costs (material and labor costs) were also tracked to evaluate the cost-effectiveness of the intervention and correlate to a potential for reducing nursing time from labor-intensive treatments.

Data Collection

Baseline data for all patients were collected at index admission to the critical care units. A data collection form was designed to record nursing compliance related to the SKIN bundle[34] used for prevention. Data also were collected on potential risk factors for development of pressure ulcers, including age, sex, level of consciousness, days of mechanical ventilation, sedation, medications, daily Braden score,[30] therapeutic

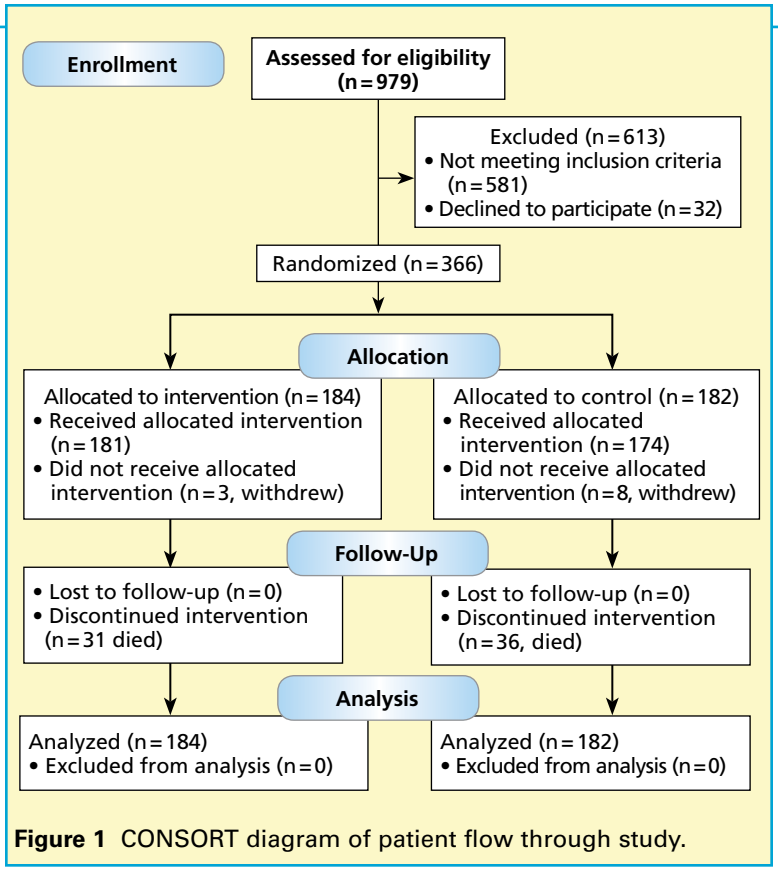

Figure 1 CONSORT diagram of patient flow through study.

procedures (eg, dialysis), mortality risk (APACHE IV score),[14] and APACHE III score, sociodemographic characteristics, physiological variables, medical conditions, and death. The hospital's electronic billing/receiving management system was used to retrieve data on ICU and hospital LOS, expressed in days. All patients were seen each day of their ICU stay by a member of the research team who checked to see if a HAPU had developed. When patients were transferred to medical/surgical units, the experimental dressing was removed. Pressure ulcer outcome data (incidence of pressure ulcers, ICU unit, location/stage of pressure ulcers, number of pressure ulcers per patient, LOS, mortality) were tracked throughout the hospital stay via the electronic medical record. Patients were followed up for 6 months after discharge; any readmissions with pressure ulcers or deaths were noted. Mortality data were gathered from the electronic medical record, Social Security records, and national obituary data bases.

Outcome Measures

The primary outcome measured in this clinical trial was the development of a pressure ulcer. Any pressure ulcer occurring during the period of the RCT was staged according to the NPUAP staging system.[1] To ensure data accuracy and consistency in pressure ulcer identification, staging, and documentation, all study nurses were trained for study procedures and underwent interrater reliability testing before data collection. The incidence rate of ICU HAPUs among the study cohort is reported. Incidence rate is calculated per 1000 patient days at risk and is reported per 1000 patient days.[1,2]

Analysis

The analysis was based on intention to treat, where all patients randomized to the treatment group were analyzed, regardless of protocol violations, whether they died, or were withdrawn from the study (CONSORT guidelines).[55] Data were entered into SPSS software (version 22, SPSS Inc) for analysis. Descriptive statistics were used to analyze patients' characteristics and all physiological and demographic variables. Pressure ulcer cumulative incidence was compared between the 2 groups and by anatomical site per patient through the calculation of inferential statistics and use of the Fisher exact test. Poisson regression analysis was used to analyze the significance of incidence rate ratio, comparing specific factor level (variables) against a reference category to identify final high-risk variables.

A survival analysis was used to determine the difference in pressure ulcer incidence rates per group and time to provide a hazard ratio between the groups. Hazard ratios were estimated by using Cox proportional hazard models.

Results

An overview of patients' flow through the RCT from study enrollment, to allocation, to follow-up, and analysis is outlined in Figure 1, according to the CONSORT statement.[55] No violations of the study protocol occurred in the intervention group. Intention-to-treat analysis was used, and all patients in the intervention group were included in the final analysis.

The sample population for this study was drawn from 2 units with a similar case mix index: a coronary care ICU with a variable population of cardiac, acutely ill medical and surgical patients, in addition to cardiovascular surgical patients, and a medical/surgical trauma unit, with fairly routine overflow of cardiac patients, given the hospital's admitting priorities of critically ill patients and the fluctuating census in both units. An estimated 50% of the sample was drawn equally from each study unit, with equivalence of patients enrolled in the control and intervention groups, depending on randomization. Table 1 provides an overview of patient/clinical characteristics of the sample and other study variables, comparing the control group with the intervention group.

Table 1
Characteristics of patients in the study

Characteristic[a]	Overall (N = 366)	Intervention group (n = 184)	Control group (n = 182)	*P*[b]
Age, mean (SD), y	65.9 (17.0)	64.6 (17.7)	67.3 (16.2)	.14
Sex				.84
Male	203 (55.5)	103 (56.0)	100 (54.9)	
Female	163 (44.5)	81 (44.0)	82 (45.1)	
Race				.12
White	152 (44.3)	78 (45.1)	74 (43.5)	
African American	73 (21.3)	35 (20.2)	38 (22.4)	
Hispanic	61 (17.8)	27 (15.6)	34 (20.0)	
Asian/Pacific Islander	47 (13.7)	24 (13.9)	23 (13.5)	
Other/not specified	10 (2.9)	9 (5.2)	1 (0.6)	
Braden score (baseline), mean (SD)	11.9 (1.4)	11.8 (1.3)	11.9 (1.4)	.32
≥4 Comorbid conditions	133 (36.3)	66 (35.9)	67 (36.8)	.85
APACHE III score, mean (SD)	52.5 (26.2)	58.6 (29.3)	49.5 (23.6)	
Length of stay, median (interquartile range), d				
Hospital	14.0 (8-25)	15.0 (8-26)	13.0 (8-24)	.67
Intensive care unit	7.0 (4-13)	8.0 (4-14)	7.0 (4-13)	.53
Risk factors				
Pulmonary edema	15 (4.1)	10 (5.4)	5 (2.8)	.20
Mechanical ventilation	226 (61.9)	105 (57.1)	121 (66.9)	.05
Sedation	120 (32.9)	59 (32.1)	61 (33.7)	.74
Vasopressor	266 (72.9)	135 (73.4)	131 (72.4)	.83
Past pressure ulcer	3 (0.8)	2 (1.1)	1 (0.6)	.51[c]
Traction	1 (0.3)	1 (0.5)	0 (0.0)	.50[c]
Bed rest	352 (96.4)	177 (96.2)	175 (96.7)	.80
Dialysis	27 (7.4)	14 (7.6)	13 (7.2)	.88
Quadriplegia	3 (0.8)	2 (1.1)	1 (0.6)	.58
Restraint	154 (42.3)	81 (44.0)	73 (40.6)	.50
Supine position	49 (13.4)	28 (15.2)	21 (11.6)	.31
SKIN bundle compliance	366 (100)	184 (100)	182 (100)	—
Analysis of patients with pressure ulcers (characteristics)				
No. of patients who had pressure ulcers develop (incidence rate)	8 (2.2)	1 (0.5)	7 (3.8)	.01[c]
Pressure ulcer stage				
I	0 (0)	0 (0)	0 (0)	
II	4 (50)	0 (0)	4 (57)	
III	0 (0)	0 (0)	0 (0)	
IV	0 (0)	0 (0)	0 (0)	
Unstageable	2 (25)	0 (0)	2 (29)	
Deep tissue injury	2 (25)	1 (100)	1 (14)	
Pressure ulcer location				
Coccyx/sacrum	6 (75)	1 (100)	5 (71)	
Buttocks	2 (25)	0 (0)	2 (29)	
Occiput	0 (0)	0 (0)	0 (0)	
Hand	0 (0)	0 (0)	0 (0)	
Wrist	0 (0)	0 (0)	0 (0)	
Elbow	0 (0)	0 (0)	0 (0)	
Heel	0 (0)	0 (0)	0 (0)	
Ischium	0 (0)	0 (0)	0 (0)	

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; SKIN, surfaces, keep patients turning, incontinence management, nutrition.

[a] Values in columns 2 through 4 are number (valid percentage) of patients unless otherwise indicated in this column. Because of rounding, percentages may not total 100.

[b] Chi-square test for categorical factors, independent *t* test for normally distributed continuous variables, and Mann-Whitney U test for skewed continuous variables showed no significant between-group differences (expected because of the randomized controlled study design).

[c] Poisson regression.

Table 2
Pressure ulcer development by risk factors with adequate power to investigate

Risk factor	Patients (N = 366)	Pressure ulcer cases (N = 8)	Patient days at risk[a]	Incidence rate (95% CI)[b]	Incidence rate ratio (95% CI)	*P*[c] (LR)	*P*[d] (Wald)
Mechanical ventilation						.06[e]	—
No	140	0	503	0.0	Not applicable		
Yes	226	8	2032	3.9 (2.0-7.9)			
Sedation						.02[e]	.06
No	246	1	1336	0.7 (0.1-5.3)	0.13 (0.02-1.04)		
Yes	120	7	1199	5.8 (2.8-12.2)	Reference		
Vasopressor						.11[f]	.18
No	100	1	950	1.1 (0.1-7.5)	Reference		
Yes	266	7	1585	4.4 (2.1-9.3)			
Bed rest						.57	—
No	14	0	50	0.0	Not applicable		
Yes	352	8	2485	3.2 (1.6-6.4)			
Dialysis						.06	.04
No	339	5	2240	2.2 (0.9-5.4)	0.22 (0.05-0.92)		
Yes	27	3	295	10.2 (3.3-31.5)	Reference		
Restraint						.64	.64
No	211	4	1476	2.7 (1.0-7.2)	0.72 (0.18-2.86)		
Yes	154	4	1056	3.8 (1.4-10.1)	Reference		

[a] Patient days at risk for each patient, defined by time from study enrollment to appearance of pressure ulcer, discharge from intensive care unit, or day 28 in intensive care unit. Overall: 2559 person days.
[b] *P* value based on Poisson regression (LR statistic for type 3 analysis tested significance of relationship between factor and outcome). Overall incidence rate, mean (95% CI): 3.1 (1.6-6.3). Incidence rate is reported per 1000 patient days.
[c] Contrast estimate by using logistic regression (LR) to test significance of incidence rate ratio, comparing specific factor level against reference category showed significance.
[d] Contrast estimate by using Wald statistic to test significance of incidence rate ratio, comparing specific factor level against reference category showed significance. Dash indicates zero cell value.
[e] Significant at $P \leq .05$.
[f] Significant at $P \leq .01$.

More specifically, Table 1 illuminates demographics, potential risk factors for pressure ulcer development, and the pattern and analysis of patients who had pressure ulcers develop (eg, incidence, stage, location, number of pressure ulcers per patient, study group). The baseline characteristics of the 366 patients presented illustrate that the groups did not differ significantly in demographics, major physiological variables, including the APACHE III severity-of-illness score. Throughout the course of the study, we also tracked whether the ICU nurses were compliant with the use of the hospital's SKIN bundle, and we found a 100% compliance rate in both units.

For the overall group, the mean age was 65.9 years, the mean Braden score was 11.9, the mean ICU LOS was 7.0 days, and the mean hospital LOS was 14 days. The top 3 admitting diagnoses were sepsis or septic shock (22.5%), acute respiratory failure or distress (22%), and cardiovascular diseases (32%). Among these patients, the highest incidence of pressure ulcers was significantly correlated to patients with sepsis, followed by acute respiratory failure, pulmonary thromboembolism, and pneumonia ($P = .001$). The presence of sepsis was independently and strongly associated with pressure ulcer occurrence in this study. Among the 8 patients who had pressure ulcers develop, geographically 4 were located in the CCU and the remaining 4 were from the mixed ICU. Hence, we did not experience a higher incidence of pressure ulcers in the surgical ICU as previous researchers have reported.[8]

In this study (Table 2), the following variables were empirically found to be associated as risk factors for pressure ulcers: mechanical ventilation, sedation, vasopressors, and dialysis. Analysis indicated that incidence of HAPUs was higher among patients receiving sedation and vasopressor medications (norepinephrine). Researchers in previous studies[11,15-17,55-60] have reported sedation and vasopressor medications to be significant predictors of pressure ulcers in ICU patients.

During the course of the study, a high severity of illness (case mix index) was noted across the study sample, with a predicted (APACHE IV) mortality risk of 0.60% to 0.90%. The 30-day overall

mortality rate ratio was 0.87 (95% CI, 0.54-1.41), whereas 31 patients in the intervention group died (mortality rate, 17%; 95% CI, 12-24) and 36 patients in the control group died (mortality rate, 19.6%; 95% CI, 14-27; Table 3).

The cumulative incidence of HAPUs was significantly lower in the intervention group treated with the Mepilex Border Sacrum foam dressing (0.7% vs 5.9%, $P = .01$; Table 4). Among the 366 patients in the study, 8 had pressure ulcers develop, with 2559 patient days at risk, yielding a calculated incidence rate ratio of 3.1 (95% CI, 1.6-6.3).

Time-to-injury survival analysis (Cox proportional hazard models) revealed that the patients in the intervention group had a hazard ratio of 0.12 (95% CI, 0.02-0.98; $P = .048$) compared with patients in the control group (Figure 2). Therefore, patients treated with dressings had an 88% reduced risk of HAPUs developing. On the analysis of the patients who had HAPUs develop, all had pressure ulcers develop on the sacrum or buttocks, including 1 suspected deep tissue injury. The majority (n = 6, 75%) of the pressure ulcers developed in the first week of ICU admission.

No adverse events related to the experimental (Mepilex Border Sacrum) foam dressing were noted. In fact, the dressing remained in place, was atraumatic to skin, and impermeable to urine and feces. Moreover, no evidence of skin fungal infections or dermatitis was seen.

Discussion

In an environment of health care cost reduction and liability, it is imperative that the incidence of HAPUs be reduced. Numerous interventions have been examined and implemented, including the use of SKIN bundles,[3,4] yet there remains a steady incidence of pressure ulcers in ICU patients, resistant to complete eradication.

Exploratory analysis of study variables was performed, to determine potential predictors of pressure ulcers. Age was first examined; however, analysis revealed no significant association. Yet other studies demonstrate that advanced age is a triggering factor for these ulcers, with 50% to 70% of these injuries developing in patients more than 70 years old.[5-9,12,13,16-18] On the other hand, analysis did reveal 4 variables that were significantly related to pressure ulcers (mechanical ventilation, sedation, vasopressors, and dialysis), thus they were included in the final model. This finding is consistent with published reports, where the presence of respiratory failure, sepsis and shock in particular, has been significantly related to development of pressure ulcers in critically ill patients.[15-19,32,33,49-51,57,58]

Furthermore, in a recent study, Delmore and colleagues[61] attempted to develop a statistical model

Table 3
Mortality ratio across cohort

Variable	Intervention group (n = 184)	Control group (n = 182)
No. of patients who died	31	36
Mortality rate,[a] mean (95% CI)	17 (12-24)	20 (14-27)
Mortality rate ratio, mean (95% CI)	0.87 (0.54-1.41), $P = .57$	

[a] Mortality rate refers to number of patients per 100 patients treated.

Table 4
Pressure ulcer rate and incidence rate ratio

Variable	Intervention group (n = 184)	Control group (n = 182)
No. of patients who had a pressure ulcer develop	1	7
Patient days at risk	1374	1185
Incidence rate,[a] mean (95% CI)	0.7 (0.1-5.2)	5.9 (2.8-12.4)
Incidence rate ratio, mean (95% CI)	0.12 (0.02-1.00), $P = .01$	

[a] Incidence rate is reported per 1000 patient days.

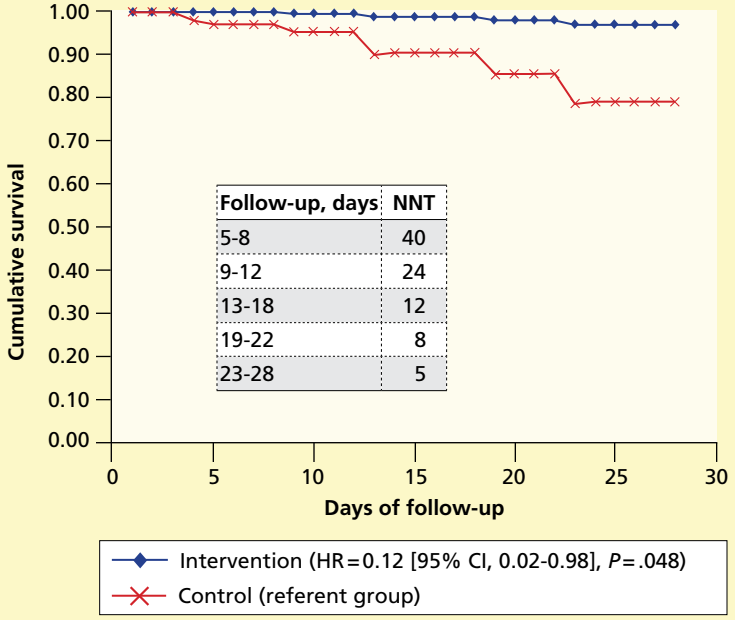

Figure 2 Hazard ratio estimated risk by using Cox proportional hazards regression.

Abbreviations: HR, hazard ratio; NNT, number needed to treat.

MEPILEX® BORDER DRESSING ALGORITHM

Mepilex® Dressing Aids in Prevention of Pressure Ulcers (PUs) by Protecting Skin from Moisture, Friction and Shear in Combination with Comprehensive PU SKIN Bundle

High Risk Inclusion Criteria, if Any Present Apply Mepilex® Border Silicone Dressing:	If Patient Meets 3 or More Criteria, Apply Mepilex® Border Silicone Dressing
❑ **All** ICU patients are 'high risk' for PUs, including medical device related (MDRPU). **Apply** Mepilex® Border Sacrum; and/or Mepilex Transfer®/Lite® to prevent MDRPU.	❑ BMI below 20 for age 65 or above
❑ Braden© scale ≤13	❑ Weeping edema or anasarca in upper or lower extremities
❑ Mechanical ventilation	❑ Age >65 years old
❑ Recent cardiac arrest (CA)	❑ Diabetes mellitus
❑ Hemodynamically unstable	❑ Renal or liver failure
❑ Vasopressor medications for 48 hours	❑ Under nutrition (recent unintended weight loss, decreased PO intake 1 week)
❑ Altered level of consciousness (LOC)	❑ Nothing by mouth (NPO) >3 days
❑ SHOCK (septic, hypovolemic, cardiogenic)	❑ Albumin ≤2.5 or prealbumin ≤18 g/dL
❑ Quadriplegic, paraplegic, or hemiplegic	❑ Prolonged bed rest 2-4 hours, AND patient unable to shift weight independently
❑ Traction (Skeletal)	❑ Hip surgery or lower extremity pinning
❑ On a Roto Prone or Roto Rest bed	❑ Restraints
❑ Anticipated operative, cath lab or interventional procedure lasting >4 hours	❑ Fecal/urinary incontinence
References: 23, 24, 27, 29, 30, 34, 45, 51	❑ Metastatic cancer

Figure 3 Algorithm for use of Mepilex dressings (Mölnlycke Health Care AB).

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); cath lab, catheterization laboratory; ICU, intensive care unit; PO, by mouth.

Courtesy Long Beach Memorial, Miller Children's and Women's Hospital, Long Beach, California.

to predict the development of acute skin failure, defined as "an event in which the skin and underlying tissue die due to hypoperfusion." The authors posit that pressure ulcers and skin failure are 2 distinct, yet related, clinical phenomena.[61] Findings of the Delmore study validate key risk factors—peripheral artery disease, mechanical ventilation, respiratory failure, liver failure, and severe sepsis/septic shock—to be significant independent predictors of acute skin failure, thus those factors were included as key variables for a predictor model.[61,62] These variables are well supported in the literature as risk factors for pressure ulcers; however, based on their results, the authors posit to recategorize these risks or clinical situations that would currently be classified as "unavoidable pressure ulcers" to now be referred to as acute skin failure, given the nature of the pathophysiological changes inherent in the development of pressure ulcers. Much more research is warranted to validate these findings further (predictor model acute skin failure) before discerning new definitions of nomenclature related to unavoidable pressure ulcers, skin failure, and pressure ulcers.

We found that the use of 5-layered soft silicone foam dressings further reduced HAPU formation when the dressings were applied within 24 hours of admission to the ICU. Santamaria et al[52] had similar results when placing the dressing on the sacrum/heels while the patient was in the emergency department. However, not all patients are admitted to the ICU through the emergency department, some are direct admissions and some transfer to the ICU from other hospital areas.[53] Participants in this RCT were at risk for acute skin failure; however, the use of the preventive dressing reduced pressure ulcers in that high-risk group of patients also.

As a result of our study findings, our 5-hospital system has now mandated the use of Mepilex Border Sacrum foam dressings for prevention for all patients who are at high risk for pressure ulceration in all care areas, including procedural and operating rooms. An evidence-based algorithm[23,27,29,34,52,57,61] was developed to guide clinicians practicing in ICUs and all medical/surgical areas on how to identify patients with high-risk conditions that would create the milieu for pressure ulcer development, warranting the application of the Mepilex dressings (Figure 3).

Cost savings for our health system have been significant. Although we did not conduct a comprehensive (bottoms-up) cost analysis, during the study, our system projected the cost of prevention related to estimated consumption of resources based on adherence to NPUAP prevention guidelines with financial investment.[1] This adherence presumably lowers the probability of pressure ulcer incidence. HAPUs tend to be very expensive because of the extended LOS (estimated 4-10 days), and complications due to age (ie, elderly patients) and comorbid conditions (eg, diabetes, obesity, unconsciousness).[62,63] Our health system's annual cost for the prophylactic dressings is $130 000. This amount does not include the savings in legal fees to defend against claims of HAPUs. However, according to a recent systematic review by Demarre and colleagues,[64] the cost of pressure ulcer prevention lowers the overall mean cost per patient by more than $1200 to $1500 per patient day. Organizational estimates demonstrate that a savings of more than $1 million has been amortized in the past 2 years, after dressing purchase. This estimate is most

likely conservative, given that the Society of Actuaries[26] estimates the cost of treating a pressure ulcer ranges from $2000 to $20 000 per ulcer, depending on severity. This cost savings estimate related to prevention is also consistent with other cost analysis studies of pressure ulcers.[63-66]

Our robust prevention program, now including the dressing, has yielded a substantial cost savings and has contributed to our sustained pressure ulcer incidence of *zero* to 0.2 (all stages of HAPUs) in the past 2 years since completion of this trial.

Limitations

This study is limited by the single-site versus multisite study design. These results can be viewed only in the context of critically ill patients in the ICU and cannot be generalized to other populations of patients. The risk for bias in reporting findings is appreciated; however, it was impossible to blind data collectors because of the nature of the treatment intervention. Future multisite studies are warranted to investigate the prophylactic use of Mepilex Border dressings on all bony prominences (as this study was limited to sacral pressure ulcers), among high-risk patients in the operating room, the emergency department, and all general care areas.

Conclusion

Our findings have demonstrated a statistically and clinically significant benefit for the application of the 5-layered Mepilex Border Sacrum foam dressing for the prevention of pressure ulcers when used in combination with thorough risk assessment and evidence-based pressure ulcer prevention via the SKIN bundle.[34] HAPU formation can be delayed or potentially eliminated in patients with life-threatening illness. Prevention should drive practice, thus efforts to prevent pressure ulcers in all patients should always begin on admission to the hospital.[18] Early identification of patients at risk can aid in the deployment of all evidence-based interventions to prevent the development of pressure ulcers throughout the hospital stay.

ACKNOWLEDGMENTS

The investigators thank the many dedicated ICU nurses who supported this study and the members of the research study team who were vigilant in the daily data collection in the ICU of the Long Beach Memorial, Miller Children's and Women's Hospital Long Beach. We are grateful to the ICU leadership team, Dr Maged Tanios, MD, MBA, medical director, and Alaine Schauer, RN, MBA, clinical operations director, for their support throughout the conduct of this randomized controlled trial.

FINANCIAL DISCLOSURES

None reported.

eLetters

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For more about preventing pressure ulcers, visit the *Critical Care Nurse* website, **www.ccnnonline.org**, and read the article by Cooper et al, "Against All Odds: Preventing Pressure Ulcers in High-Risk Cardiac Surgery Patients" (October 2015).

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1. Discuss the effects of prophylactically using a 5-layered soft silicone foam dressing to prevent pressure ulcers in the intensive care unit.
2. Identify key risk factors that place critically ill patients at increased risk for pressure ulcers.
3. Discuss how the use of soft silicone foam dressings combined with evidence-based strategies can potentially eliminate pressure ulcers, resulting in significant cost savings for health care systems.

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