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The Effect of a Silicone Border Foam Dressing for Prevention of Pressure Ulcers and Incontinence-Associated Dermatitis in Intensive Care Unit Patients

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ABSTRACT

PURPOSE: We measured the effect of a silicone border foam dressing on the development of pressure ulcers (PUs) and incontinence-associated dermatitis in intensive care unit (ICU) patients.

DESIGN: Nonrandomized comparison cohort (quasi-experimental) study.

SUBJECTS AND SETTINGS: One hundred and two patients (>40 years of age) with a Braden Scale score of 16 or less who were admitted to 2 ICUs at the Samsung Medical Center in Seoul, South Korea, participated in the study.

INSTRUMENTS: Pressure ulcer development was determined based on 2009 Guidelines from the National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel. Incontinence-associated dermatitis was measured using the Incontinence Associated Dermatitis and its Severity (IADS) instrument.

METHODS: Fifty-two subjects were assigned to the experimental group (standard PU preventive care routine plus application of the silicone border foam dressing), and 50 subjects were assigned to the control group (standard PU preventive care alone). The number of patients who developed PU in the experimental group was compared with that from the control group using the chi-square test (χ^2). The IADS score of the experimental group was measured and compared with those of the control group, using an independent *t* test. Logistic regression was carried out to analyze the relationship between the IADS score and PU development.

RESULTS: Both the incidence of PU development and IADS scores were significantly lower ($\chi^2 = 21.722$, $P < .001$, and $t = 2.166$, $P < .033$, respectively) in patients assigned to the experimental group as compared to those in the control group. The incidence of PU development significantly increased as the IADS score increased (odds ratio = 1.900, 95% CI = 1.237-2.917). A logistic regression analysis revealed that PU development was related to IADS score ($P = .003$) and that the risk of developing a pressure increased 1.9-fold for every 1-point increase in IADS score.

CONCLUSION: The application of a silicone border foam dressing decreased PU development and reduced the IADS score. Pressure ulcer development was found to be related to IADS score; the incidence of PU development significantly increased as IADS score increased.

KEY WORDS: dermatitis, fecal incontinence, incontinence-associated dermatitis, pressure ulcer, skin, skin care

Introduction

Maintaining immobile patients in a supine position in order to decrease shear forces and friction caused by sliding down in the bed may reduce the risk for pressure ulcer (PU) development, but most critically ill patients at risk of developing a PU cannot remain in a supine position due to respiratory or enteral feeding problems. As a result, many are positioned with the head of bed (HOB) elevated

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to a 30º angle. Critically ill patents are also at risk for pressure ulcer owing to immobility, impaired sensations, insensible fluid loss, urinary or fecal incontinence, and perspiration from skin folds.[1] Clinical practice guidelines from the National Pressure Ulcer Advisory Panel and the European Pressure Ulcer Advisory Panel summarize current evidence that strongly suggests an increased risk of sacral PU formation when the HOB is elevated.[2,3] Unfortunately, conflicting patient needs in critically ill ventilated patients exist; an HOB elevation of 40º protocol is often recommended to prevent pneumonia but an HOB elevation of no more than 30º is recommended for sacral PU prevention.[3]

While the etiology of incontinence-associated dermatitis (IAD) differs from PU, the 2 often coexist.[4,5] Maklebust and Magnan[6] reported that patients with fecal incontinence have a 22-fold increased risk for PU when compared to patients without fecal incontinence. Studies in critically ill patients suggest that PU occurrence is 4 times more likely than that in patients without moisture issues.[7] The nature of the relationship between IAD and PU is not entirely understood, but existing studies suggest that the skin affected by incontinence is less tolerant to pressure and shear.[8,9]

The purpose of this study was to evaluate whether application of a silicone border foam dressing to the sacral and coccygeal areas would decrease PU occurrence and IAD score among patients at risk in the intensive care unit (ICU), as compared to standard PU preventative care.

Methods

A quasi-experimental research design (comparison cohort study) was used for data collection. The study setting was the Samsung Medical Center in Seoul, South Korea. Data were collected between August and October 2011. Patients were admitted to 1 of 2 medical ICUs.

Participants or a proxy provided informed consent. Approval for the study was obtained from the institutional review board of the Samsung Medical Center. The experimental group and the control group consisted of patients aged 40 years or older who were admitted to different wards. Inclusion criteria were: (1) patients did not have IAD or PU before participation in the study and (2) a Braden Scale score of 16 or less. Persons with a contraindication to changing positions were excluded from study participation.

We determined sample size, using a 2-group comparison of proportions power calculation.[10] Significance levels and power analysis for required sample size were calculated via 2-tail tests. In the case of experimental group, active intervention group, PU occurrence rate (p_1) was projected to be 10% and the occurrence of the comparison group to be 35% (p_2). These expectations were based on prior facility rates and literature review. We determined that 51 patients were needed for each which met the criteria of our power analysis and allowed a 15% dropout rate in each group.

Study Procedures

On admission to the critical care unit, demographic information was recorded for each patient along with the main reason for ICU admission. Pressure ulcer risk was evaluated using the Braden Scale for Pressure Sore Risk. We also evaluated other potential risk factors for pressure ulcer including cardiac arrest, use of vasopressive medications for more than 48 hours, surgical procedure lasting more than 8 hours, systemic edema from fluid overloading or weeping edema, use of traction or external fixators, malnutrition (operationally defined as prealbumin <20 mg/dL or albumin <3.5 mg/dL, or fasting >3 days), liver failure, diabetes mellitus, sedation or use of paralytic agents, mechanical ventilation more than 48 hours, spinal cord injury, nitric oxide ventilation, past history of PU, and use of left or right ventricular assist devices.

Presence of urinary incontinence or fecal incontinence and the patient's body mass index were also recorded.[1] A body mass index 35 or greater was operationally defined as morbid obesity and considered a risk factor for PU development.

Prior to the start of the study, primary wound care nurses (PWNs) from both active intervention and control wards were shown the correct method for applying the silicone border foam dressing to the sacrum, ensuring that it covered the gluteal cleft and coccyx. In addition, all nurses who acted as data collectors were taught how to evaluate the skin status of the patient and stage PUs. Pressure ulcer development was based on clinical practice guidelines from the NPUAP; PUs were categorized as stage 1, 2, 3, 4, suspected deep tissue injury, or unstageable. Incontinence-associated dermatitis was assessed using the IAD and its Severity (IADS) instrument.[11]

Subjects in both study groups were cared for via the standard PU preventive care regimen and replacement on a same pressure redistribution mattress (Hill-Rom KCI San Antonio, TX) and turning and repositioning were provided to all patients regularly as a standard care routinely used by the hospital.

A silicone border foam dressing (Mepilex Border, Mölnlycke Health Care, Gothenburg, Sweden) was applied to subjects in the experimental group for 9 days, but not to those in the control group. Dressings were changed every 3 days or more often if found to be soiled or inadvertently detached. At each dressing change, the surrounding skin was cleaned and dried.

Skin assessments, including presence of PU and IAD, were evaluated by 2 PWNs who made patient rounds every 3 days during the 9 days the patient was in the study. The worst scores for the PU and IAD status during the data collection period were used, and the other data were collected using electronic medical recording.

TABLE 1.

Comparisons Between Active Intervention and Comparison (Control) Groups (N = 102)

Variables	Total, *M* ± SD or N (%)	Control (n = 50), *M* ± SD or N (%)	Experimental (n = 52), *M* ± SD or N (%)	*P*
Gender				
Male	65 (64%)	28 (56%)	37 (71%)	.007
Female	37 (36%)	22 (44%)	15 (29%)	
Age, y	64 ± 11.9	66 ± 15.0	62 ± 8.3	.098
1st major problem for ICU admission				
Respiratory	58 (57%)	25 (50%)	33 (63%)	
Neurovascular	10 (14%)	7 (14%)	3 (6%)	
Cardiovascular	13 (9%)	7 (14%)	6 (12%)	
Digestive	21 (20%)	11 (22%)	10 (19%)	
Any one of ICU high risk criteria 1	57 (56%)	25 (50%)	32 (62%)	.241
Cardiac arrest	9	6	3	
Vasopressive med. for > 48 h	34	18	16	
Shock[a]	42	16	26	
Surgical procedure > 8 h	1	1	0	
Any 5 of ICU high risk criteria 2	43 (42%)	22 (44%)	21 (40%)	.712
General edema/weeping	40	13	27	
Traction/external fixators	0	0	0	
Morbid obesity	1	1	0	
Malnutrition[b]	87	41	46	
Liver failure	17	12	5	
Diabetes mellitus	22	12	10	
Sedation/paralytics > 48 h	30	12	18	
Mechanical ventilation > 48 h	54	19	35	
Spinal cord injury	20	19	1	
Bed rest	86	34	52	
Restraint	23	14	9	
Nitric oxide ventilation	0	0	0	
Past history of PUs	3	3	0	
Heart drive lines	3	2	1	
ICU high-risk criteria (1 or 2)	76 (75%)	35 (70%)	41 (79%)	.305
Urinary				
Continence	91 (89%)	44 (88%)	47 (90%)	.698
Incontinence	11 (11%)	6 (12%)	5 (10%)	
Stool form				
Normal	77 (76%)	37 (74%)	40 (77%)	.732
Loose	25 (25%)	13 (26%)	12 (23%)	
BMI	22 ± 3.8	22 ± 3.9	21 ± 3.6	.476
Braden Scale score	12.7 ± 2.0	13.1 ± 1.9	12.4 ± 2.0	.084

Abbreviations: BMI, body mass index; ICU, intensive care unit; PU, pressure ulcer.

[a]Septic, hypovolemic, cardiogenic shock.

[b]Prealbumin <2.0, albumin <2.5 or nothing by mouth greater than 3 days.

TABLE 2.

Effect of a Silicone Border Foam Dressing on PU Occurrence (N = 102)

Variables	Total N (%)	Control (n = 50), n (%)	Experimental (n = 52), n (%)	*P*
Developed pressure ulcers				
Yes	26 (26%)	23 (46%)	3 (6%)	< .001
Stage 1	18 (18%)	17 (34%)	1 (2%)	
Stage 2	7 (7%)	6 (12%)	1 (2%)	
Deep tissue injury	1 (1%)	0 (0%)	1 (2%)	
No	76 (74%)	27 (54%)	49 (94%)	
Intact	61 (61%)	27 (54%)	34 (65%)	
Blanching erythema	15 (15%)	0 (0%)	15 (29%)	

Instruments

The incidence of IAD was measured using the IADS instrument, developed by Borchert and colleagues[11] The IADS is designed to aid nurses to identify and quantitatively measure the presence and severity of IAD. The rater examines 13 anatomical areas, including perianal skin, buttocks, crease between buttocks, genitalia, lower abdomen, upper thigh, and crease between genitalia and thigh. The IADS evaluates IAD severity based on several characteristics; a higher score indicates greater severity.

Unlike previous instruments for evaluating IAD,[12-15] the IADS separates IAD attributes from risk factors and does not require staff to measure affected skin area in square centimeters. The IADS has undergone initial validation.[11] We obtained permission from Borchert's group to use the IADS instrument in this study. To further establish reliability of the IADS, 2 PWNs were presented with 5 computer-based case examinations of the IADS; the interrater reliability of IADS scores was 0.979. The Braden Scale for Pressure Sore Risk, which evaluates a patient's risk of developing PU, was also used. It assesses 6 parameters with total scores ranging from 6 to 23, lower scores indicate higher risk.[16]

Data Analysis

Group characteristics and main study outcomes (incidence and stage of PU occurrence and severity of IAD) were compared using χ^2 test or independent-groups *t* tests. The Spearman correlation analysis was used to identify associations between PU occurrence and IADS score. We used logistic regression to further characterize the relationship between IADS score and PU development. All analyses were performed using the SPSS statistical software (SPSS version 18.0; SPSS Inc, Chicago, Illinois).

Results

The average age of participants was 64 ± 11 years (mean ± SD); more than half were 65 years of age or older. The average Braden Scale score of the experimental group was 12.4 ± 2.0. The average Braden Scale score of the control group was 13.1 ± 1.9. Forty-one subjects (79%) in the experimental group, and 35 subjects (70%) in the control group, were found to be at risk of PU development. The homogeneity of the 2 groups was analyzed using a χ^2 test or independent groups *t* test to compare patient demographics, IAD risk factors, and risk factors for PU development described earlier. No significant differences were found between 2 groups (Table 1).

Intervention Effect

Subjects in the intervention group managed by a silicone border foam dressing showed a significantly lower occurrence of PU development when compared to patients in the control group (6% vs 46%, χ^2= 21.722, $P < .001$) (Table 2). Subjects in the intervention group also had significantly lower IADS score compared to those in the comparison group (0.54 ± 0.73 and 0.98 ± 1.25, $t = 2.166$, $P < .033$) (Table 3).

TABLE 3.

Incontinence-Associated Dermatitis and Its Severity Scores (N = 47)

Variables	Total, N (%)	Control (n = 25), *M* ± SD (n)	Experimental (n = 22), *M* ± SD (N)	*P*
IADS score		0.98 ± 1.25	0.54 ± 0.73	< .033

Abbreviation: IADS, incontinence-associated dermatitis and its severity.

TABLE 4.

Logistic Regression Analysis of Relationship Between IADS Score and PU Occurrence (N = 102)

	B	SE	*P*	OR	95% CI for OR
Constant	−1.643	0.321	< .001	0.193	
IADS score	0.642	0.219	.003	1.900	1.237–2.917

Abbreviations: CI, confidence interval; IADS, incontinence-associated dermatitis and its severity; PU, pressure ulcer; OR, odds ratio.

Analysis using a Spearman correlation revealed a statistically significant and direct proportional association between PU occurrence and IADS score (r = 0.264; P = .005). Subjects with higher IADS scores were more likely to develop a PU during their stay in the critical care unit.

Logistic regression analysis was completed in order to further characterize the relationship between IADS score and PU development. This analysis indicated that the likelihood of developing a PU increased by a ratio of 1.9 for every 1-point increase in IADS score (odds ratio = 1.9, 95% CI = 1.237-2.917) (Table 4).

Discussion

Study findings revealed that the use of a silicone border foam dressing lowered the occurrence of hospital-acquired PU development. This finding is consistent with a prior study which reported that the application of a silicone border foam dressing provided additional protection from PU development.[1]

The occurrence of stage 1 PU was significantly higher in the control group than in the experimental group. We hypothesize that this result suggests that use of a silicone border foam dressing may reduce PU risk by diminishing or delaying evolution of blanching erythema into a stage I PU characterized by nonblanching erythema. Additional research is needed to confirm or refute this hypothesis.

Analysis also revealed that lower IADS scores were significantly lower in the experimental group as compared to the comparison group. One study reported that a relationship between IADS was related to PU development[17] and similarly, the development of PU was higher in the patients with the higher score of IADS. We hypothesize that this difference is at least partly attributable to protection afforded by the dressing to the sacrum and the gluteal fold along the coccyx. Additional research is needed to confirm this hypothesis.

Results of our study revealed an association between PU occurrence and IADS score. Although the etiology of IAD clearly differs from that of pressure ulceration, the conditions often coexist.[4–6,8] Additional research is needed to further clarify the nature of this relationship.

Conclusions

Use of a silicone border foam dressing application was found to reduce the occurrence of PU and IADS scores in a group of critically ill patients. Further analysis revealed that the occurrence of PU was associated with IADS scores, indicating that patients with higher IADS scores increased the likelihood of PU development. Additional research is needed to further characterize the efficacy of this preventive dressing and the nature of the association between IAD and pressure ulceration.

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