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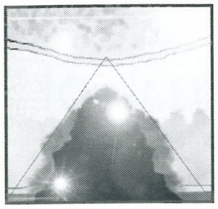

Continuous Bedside Pressure Mapping and Rates of Hospital-Associated Pressure Ulcers in a Medical Intensive Care Unit

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Background Critically ill patients are vulnerable to the development of hospital-associated pressure ulcers (HAPUs). Positioning of patients is an essential component of pressure ulcer prevention because it off-loads areas of high pressure. However, the effectiveness of such positioning is debatable. A continuous bedside pressure mapping (CBPM) device can provide real-time feedback of optimal body position though a pressure-sensing mat that displays pressure images at a patient's bedside, allowing off-loading of high-pressure areas and possibly preventing HAPU formation.

Methods A prospective controlled study was designed to determine if CBPM would reduce the number of HAPUs in patients treated in our medical intensive care unit. In 2 months, 422 patients were enrolled and assigned to beds equipped with or without a CBPM device. Patients' skin was assessed daily and weekly to determine the presence and progress of HAPUs. All patients were turned every 2 hours. CBPM patients were repositioned to off-load high-pressure points during turning, according to a graphic display. The number of newly formed HAPUs was the primary outcome measured. A χ^2 test was then used to compare the occurrence of HAPUs between groups.

Results HAPUs developed in 2 of 213 patients in the CBPM group (0.9%; both stage II) compared with 10 of 209 in the control group (4.8%; all stage II; $P = .02$).

Conclusion Significantly fewer HAPUs occurred in the CBPM group than the control group, indicating the effectiveness of real-time visual feedback in repositioning of patients to prevent the formation of new HAPUs. (*American Journal of Critical Care.* 2014;23:127-133)

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Pressure ulcer formation continues to be problematic in acute care settings, especially intensive care units (ICUs), despite comprehensive training, education, and newer prevention and treatment techniques. A review[1] of the ICU literature from 2000 to 2005 showed a pressure ulcer prevalence of 4% to 49% and an incidence of 3.8% to 12.4%. In the International Pressure Ulcer Prevalence Survey in 2009, facility-acquired pressure ulcer prevalence rates were highest in the medical ICU (MICU) at 12.1%.[2]

International guidelines for the prevention of pressure ulcers focus on evidence-based recommendations for risk assessment, skin assessment, nutrition, support surfaces, and repositioning.[3,4] Repositioning the patient to off-load areas of high pressure is an essential component of pressure ulcer prevention. However, it is not clear which repositioning protocols are most effective for preventing pressure ulcers. In a systematic review, researchers found insufficient evidence to recommend any specific turning regimens for patients with impaired mobility.[5] Sprigle and Sonenblum[6] emphasized that support surfaces can help to manage the magnitude of pressure, and frequency of turning and shifting of weight can help to manage the duration of pressure as a part of prevention efforts. Constant low-pressure surfaces such as foams, air, water, and elastomeric mattresses outperform conventional hospital mattresses in preventing ulcer formation.[7] But even though turning every 2 hours is the most common consensus-based repositioning recommendation, it is still more dogma than an evidence-based recommendation.[5,8] The discrepancy in outcomes may be due to clinicians' inability to assess the off-loading of high-pressure areas and thus failure to confirm successful and effective turning strategies.

Facility-acquired pressure ulcer prevalence rates are highest in the medical intensive care unit.

About the Authors
Robert Behrendt is a clinical quality facilitator in the Office of Clinical Quality and Safety, Henry Ford Health System, Detroit, Michigan. **Amir M. Ghaznavi** is a plastic surgery fellow and **Aamir Siddiqui** is a professor of surgery in the Division of Plastic and Reconstructive Surgery, Henry Ford Hospital, Detroit, Michigan. **Meredith Mahan** is a biostatistician in the Department of Public Health Sciences, Henry Ford Health System. **Susan Craft** is a staff nurse unit director in the medical intensive care unit at Henry Ford Hospital.

Corresponding author: Aamir Siddiqui, MD, Division of Plastic and Reconstructive Surgery, K-16, Henry Ford Hospital, 2799 West Grand Blvd., Detroit, MI 48202 (e-mail: asiddiq1@hfhs.org).

New interface pressure mapping technology has been used to assist prevention strategies in ICU patients by identifying the magnitude of body pressure points[6,9,10] and to help improve body positioning. With this technology, clinicians are given real-time feedback on repositioning strategies to off-load the at-risk body surface areas on a pressure point after turning. In our own pilot study, continuous bedside pressure mapping (CBPM) was used in our MICU, in which 307 patients were placed on beds with CBPM and compared with 320 patients in a historical cohort group who had been placed on the same beds without the CBPM system 1 year earlier. During the 2-month study period, a pressure ulcer developed in 1 patient (0.3%) in the CBPM cohort compared with 16 patients (5%) in the historical cohort ($P = .001$). Further, in a survey of the MICU care providers, 90% of respondents reported that the CBPM contributed to improved pressure detection and relief, 88% indicated that the CBPM assisted them with repositioning protocols, and 84% reported that the pressure map facilitated more efficient and effective repositioning of patients.[11]

Thus, we designed a comparative study to determine the utility of the CBPM system in repositioning patients to prevent hospital-associated pressure ulcer (HAPU) formation. We hypothesized that use of the CBPM system with real-time graphic display of pressure points would improve effectiveness of patients' repositioning by off-loading pressure areas and thus lead to a reduction in the number of HAPUs occurring in MICU patients.

Methods

Study Design

This prospective controlled study was conducted during a 2-month period (August and September 2011) for all admissions to the MICU at Henry Ford Hospital in Detroit, Michigan, a tertiary-care hospital. Patients were admitted to the 68-bed MICU on the basis of bed availability. Patients were therefore arbitrarily assigned to a bed with the CBPM system (MAP System, Wellsense USA, Inc) or to the control group of beds without the CBPM system. The data from our pilot study revealed that the intervention group had a 0.3% rate of pressure ulcers in the 2 months and the control group had a 5% rate of pressure ulcers in the 2 months. A sample size of at least 172 patients in each group would be needed to perform a 2-group continuity-corrected χ^2 test with a 2-sided α of 0.05 to achieve 80% power to detect a magnitude of difference (an odds ratio of 2.9). Use of the CBPM system would improve our staff's ability to reposition patients to off-load existing pressure points during turning, leading to a reduction in the number of newly formed HAPUs. The primary outcome measure for the study was number of non-device-related HAPUs per group.

This study was approved by our health system's institutional review board and listed on clinicaltrials .gov (NCT01439581).

Preintervention Protocols

In our 68-bed MICU, patients are assigned to beds on the basis of next-bed availability regardless of each patient's characteristics. Our admission criteria are based on the guidelines provided by the Society for Critical Care Medicine.[12] Our scope of practice includes common diagnoses of MICU patients, including respiratory failure (our most common reason for admission), pulmonary hypertension, cardiopulmonary arrest and resuscitation, multisystem organ failure, various shock states, gastrointestinal hemorrhage, endocrine disorders (eg, diabetic ketoacidosis), sepsis, and other life-threatening conditions. The services of the MICU include rendering continuous, intensive medical and nursing care to critically ill adult medical patients. Important aspects of nursing care include medical and hemodynamic monitoring, medical assessment, complex disease management, education of patients, management of the discharge process, and support of patients and their families through the continuum of care. Major therapeutic techniques used include hemodynamic monitoring, continuous and intermittent renal replacement therapy, vasoactive drug infusions, and ventilator support. In our MICU, a pressure ulcer prevention bundle as outlined by the International Pressure Ulcer Prevention guidelines[3,4] is used; use of the bundle standardizes our care for pressure ulcer prevention and treatment. In this study, all MICU patients received the same standard of care for prevention, identification, and treatment of pressure ulcers.

At our institution, all patients who are admitted undergo a standard protocol for risk assessment, prevention measures, and treatment of pressure ulcers. Pressure ulcer risk is scored by using the standard Braden scale and the included 6 criteria of sensory perception, moisture, activity, mobility, nutrition, and friction and shear forces.[13] A Braden score is assigned on hospital admission, on transfer to another unit, and on a daily basis. For interrater reliability, a comprehensive skin assessment with Braden score is completed by 2 licensed personnel upon admission and unit transfer. All patients' skin is assessed at least every 8 hours for areas of erythema over bony prominences. All Braden scores were documented in the electronic medical record system on admission and on a daily basis along with which direction the patient is turned every 2 hours and extensive other information about the wound. In addition, a member of the hospital's Skin Integrity Committee performs weekly skin rounds to ensure that all HAPUs are assessed and treated appropriately.

> Patients were arbitrarily assigned to beds either with or without the mapping system.

Prevention measures to relieve and reduce pressure over bony prominences are initiated; these include use of pillows and/or wedges for support and bridging, as well as encouraging patients to shift position every 15 minutes if possible or turning patients every 2 hours. Any patient assigned a Braden score of 18 or less on admission triggers our hospital's nurse-driven pressure ulcer prevention protocol (NDPUPP) based on international guidelines.[14] The NDPUPP included measurement of levels of prealbumin and C-reactive protein, evaluation of need for specialty bed/mattress/overlay product, 2-hour turning schedule, use of pillows and/or wedges for support and bridging, suspension of heels off of bed surfaces, limit to 1 hour in a chair if patients cannot reposition themselves, and use of a static air seat cushion.

> All patients received the same care for pressure ulcer prevention, identification, and treatment.

Study Criteria

For the CBPM and control groups, skin was assessed according to the protocols previously mentioned. Upon a patient's MICU admission, any existing pressure ulcers were documented according to protocol. For the purposes of this study, inclusion criteria included all new HAPUs that were identified during MICU admission in an area of skin that had no other pressure ulcers. Ulcers were categorized according to the international guidelines[4]: stage I, nonblanchable erythema; stage II, partial thickness; stage III, full thickness skin loss;

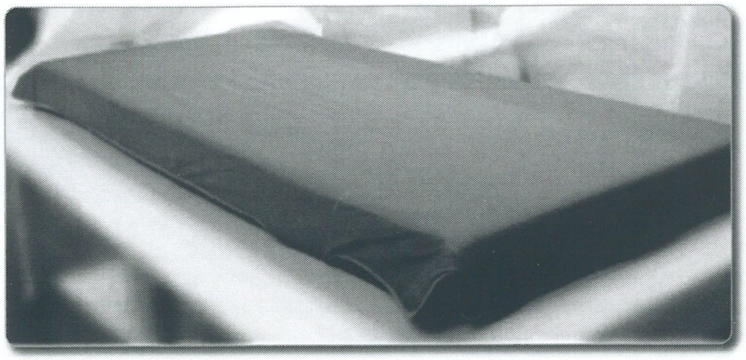

Figure 1 Continuous bedside pressure mapping coverlet secured over the mattress. The inside of the pressure-sensing mat contains an "intelligent textile" that generates a small electrical signal proportional to the pressure. The patient is completely insulated, and the electrical signal in the pressure-sensing mat is very small. The system has successfully passed all of the electrical safety tests required by US and international medical device standards.

Figure 2 Pressure map from a continuous bedside pressure monitor control unit, which automatically analyzes data and displays a real-time color graphic image of pressure points for the patient's body position. The color gradient from blue to red represents increasing pressure.

stage IV, full thickness tissue loss; or unstageable. The highest stage of any HAPU that developed was used for data analysis. HAPUs categorized as stages II through IV or unstageable that developed after MICU admission were included in the study data. All stage I HAPUs were excluded because these are not currently part of the Centers for Medicare and Medicaid Services' public reporting initiative guidelines.[15] Device-related HAPUs were also excluded because these were considered unrelated to the turning of the patient.

Continuous Bedside Pressure Mapping

The CBPM system (MAP System) consists of a pressure-sensing mat and a control unit that provides digital imaging of pressures. The mat is a thin, enclosed sensing pad that can be placed over a mattress and under any standard bed sheet (see Figure 1). It is not disposable but rather is a reusable mat that can be strapped to the mattress. It can be cleaned with the same cleaning materials that hospitals use on their mattresses. If placed on top of a true low-air-loss surface, where the air is coming through the top layer of the mattress, it may impair that air flow. But bed linens, patients' bedclothes, or incontinence pads may still be used along with the sensor mat. However, if these are used in excess, they may interfere with the accuracy of the image displayed on the device screen.

The mat contains thousands of sensors designed to measure levels of pressure between 0 and 180 mm Hg. Each pressure-sensing cell is approximately 1 square inch (6.25 cm) and takes measurement samples twice per second to ensure the live image of the pressure map is updated with every movement in a real-time manner. The system continuously retrieves data from the sensors and transfers it to the system control unit (see Figure 2), which processes and graphically displays the pressure distribution data at different parts of the patient's body. Red signifies areas of high pressure, adjusted in this study to be greater than 75 mm Hg, and blue areas show low pressures of less than 10 mm Hg. The colors from green to orange signify increasing pressure between 10 and 75 mm Hg. Caregivers can then use the real-time image to identify areas of high interface pressure and more efficiently reduce pressure levels while conducting their standard routine turning protocols. MICU nurses were trained by MAP System personnel to ensure compliance with instructions for use and to minimize risk to study patients. During repositioning, if a high-pressure zone is not relieved in the case of an obese patient (>100 kg) or clinically unstable, then the caregivers were advised to minimize the high-pressure area, not eliminate it. For this study, each patient's CBPM system was programmed to alert staff to turn patients every 2 hours to match the 2-hour turning protocol for the control group.

Data Analysis

Data on patients' characteristics were collected by using the MICU's electronic medical record (Metavision, iMDsoft). Patients were asked about pressure ulcers present on admission, HAPUs, and Braden scale score, in addition to direct and indirect markers of acuity such as positive end-expiratory pressure, ventilator support, hemodynamic status, circulatory support, and serum biochemistry. The highest value during the patients' treatment course in the MICU was included in our study. The health system's corporate database (Bi/Web, Hummingbird Communications Ltd) was also queried to collect data on patients' demographics, comorbid conditions, and confounding factors between the 2 groups.

Categorical data were presented as counts and percentages, whereas continuous data were presented as mean, standard deviation, median, minimum, and maximum. Analyses were done at the admission level with no adjustment for repeated measures. The proportion of patients in each group with pressure ulcers was analyzed by using a χ^2 test. Patients with HAPU development were compared with patients without HAPUs by using Wilcoxon Mann-Whitney tests, χ^2 tests, and Fisher exact tests as appropriate. All data were analyzed by using SAS 9.2 software (SAS Institute Inc) and statistical significance was set at P less than .05.

Table
Characteristics of patients[a]

Variable	Continuous bedside pressure monitoring group (n = 213)	Control group (n = 209)
Age, mean (SD), years	58.7 (14.9)	57.2 (18.3)
Male sex, % of patients	49	53
Length of stay, mean (SD), days	5.3 (9.4)	5.4 (7.0)
Ventilator time, mean (SD), days	6.1 (7.0)	6.5 (7.2)
Positive end-expiratory pressure ≥ 8 cm H_2O, % of patients	10	11
Lactate ≥ 4 mg/dL, % of patients	14.6	13.9
Mean arterial pressure ≤55 mm Hg, % of patients	42.3	45.0
No. of admission diagnoses, mean (SD)	6.1 (2.9)	5.8 (3.1)
Braden score on admission, mean (SD)	16.7 (4.2)	15.7 (3.9)

[a]All χ^2 tests yielded P values > .05 for all variables.

Results

During the 2-month study period, 422 patients were enrolled (213 patients in the CBPM group and 209 patients in the control group). Patients' demographics and characteristics did not differ significantly by group (see Table). Patients ranged in age from 18 to 96 years, with 49% males in the CBPM group and 53% males in the control group. In the CBPM group, 2 of 213 patients (0.9%) had HAPUs develop; both were stage II pressure ulcers. In the control group, 10 of 209 patients (4.8%) had HAPUs develop, all of which were stage II pressure ulcers ($P = .02$). No other stage of HAPUs developed during the course of the study.

Discussion

The significantly lower occurrence of HAPUs in our study's CBPM group versus the control group in the MICU suggests that real-time visual feedback from the CBPM system may be a way to improve the effectiveness of repositioning patients. Although our group and others have studied the feasibility of using pressure mapping systems for the prevention of pressure ulcers,[6,9-11] to our knowledge, this study is the first to examine the technology's use as an assistance tool for staff to assess effectiveness of repositioning patients. Anecdotal feedback from the nurses confirmed that the mapping function helped them feel more confident about the effectiveness of the off-loading endeavor. To some degree, perhaps it was also an equalizer for novice nurses with respect to more experienced nurses. Repositioning MICU patients with all the connections and monitors is not always straightforward. There are many challenges to repositioning an ICU patient; however, pressure mapping may provide a simple visual cue to indicate if even small changes in position are effective. The goal is to off-load the at-risk tissue in the least disruptive manner. The CBPM allowed them to accomplish this goal.

Validity studies have compared sensor systems with commonly used risk assessment tools for pressure ulcer development. Suriadi et al[10] compared use of the Braden score and a multipad pressure-sensor instrument (Cello, Cape Co Ltd) in predicting the development of pressure ulcers in the ICU. They suggested either the Braden score, or the multipad pressure evaluator could be used to predict risk. However, pressure ulcer risk using the multipad instrument was predicted on the basis of interface pressure measurements at the sacrum only. Zimlichman et al[16] evaluated a motion score derived from the EverOn system (Earlysense LTD), a piezoelectric sensor system placed under the mattress. They found its continuous-motion monitoring technology useful and results in alignment with the Norton pressure ulcer risk-assessment scale for predicting HAPUs in medical patients.

Sakai et al[9] studied the KINOTEX system (NITTA Corp), a thermoelastic polymer mattress with built-in sensors for recording of whole-body interface pressure, in a small group of postoperative patients in the ICU. They found that high pressure of more than 100 mm Hg lasting more than 8.1 hours resulted in pressure ulcers compared with blanchable redness and no redness at about 4.6 hours duration, suggesting that the system might lead to reduced frequency in turning of patients. Nanjo et al[17] suggested that frequent repositioning involving lateral tilt and head elevation might cause, instead of prevent, sacral skin "leaf-type" pressure ulcers in ICU patients. Sprigle and Sonenblum[6] suggested that published interface pressure mapping values may not be translatable to other patients elsewhere. We agree that interface pressure mapping technology is best considered as an adjunct to the patient care protocols used to prevent HAPU. We use the CBPM system to educate staff to validate effective patient repositioning as a part of the bundle of standard patient care protocols aimed at reducing the incidence of HAPUs in the MICU setting.

Our restricted definition of HAPU in this study may be seen as a limitation. Many published studies do include stage I ulcers. We did not include them because our institution at the time did not track them routinely. The clinical and financial impact of stage I ulcers is much less significant than stage II through IV. We do not believe that leaving them out affects our results. Although patients were not randomized, they were assigned arbitrarily to the next available bed. Comparison of the 2 cohort groups confirmed similarity in the patient profiles. To the best of our ability, we believe that the 2 populations were evenly matched. Lack of blinding of the outcome assessment, however, may have influenced the study results in unknown ways.

Conclusion

This study showed the CBPM technology using bedside visual feedback of a patient's pressure points in bed helped the MICU staff to improve the effectiveness of repositioning patients, based on the significant reduction in the formation of new and lower staged HAPUs in the CBPM group as compared with controls. However, this study cannot isolate a direct causality between the CBPM technology and the observed reduction in HAPU rates. Our data do suggest that the use of CBPM may be a useful technology to add to the current pressure ulcer prevention protocols. More empirical evidence is needed to further validate our findings. Future studies may include the measurement of specific pressure levels of patients using the CBPM device and if these measurements correlate with the reduction of new or current HAPUs.

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