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Clinical effectiveness of a silicone foam dressing for the prevention of heel pressure ulcers in critically ill patients: Border II Trial

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• **Objective:** Critically ill patients are at high risk of developing pressure ulcers (PU), with the sacrum and heels being highly susceptible to pressure injuries. The objective of our study was to evaluate the clinical effectiveness of a new multi-layer, self-adhesive soft silicone foam heel dressing to prevent PU development in trauma and critically ill patients in the intensive care unit (ICU).

• **Method:** A cohort of critically ill patients were enrolled at the Royal Melbourne Hospital. Each patient had the multi-layer soft silicone foam dressing applied to each heel on admission to the emergency department. The dressings were retained with a tubular bandage for the duration of the patients' stay in the ICU. The skin under the dressings was examined daily and the dressings were replaced every three days. The comparator for our cohort study was the control group from the recently completed Border Trial.

• **Results:** Of the 191 patients in the initial cohort, excluding deaths, loss to follow-up and transfers to another ward, 150 patients were included in the final analysis. There was no difference in key demographic or physiological variables between the cohorts, apart from a longer ICU length of stay for our current cohort. No PUs developed in any of our intervention cohort patients compared with 14 patients in the control cohort (n=152; p<0.001) who developed a total of 19 heel PUs.

• **Conclusion:** We conclude, based on our results, that the multi-layer soft silicone foam dressing under investigation was clinically effective in reducing ICU-acquired heel PUs. The findings also support previous research on the clinical effectiveness of multi-layer soft silicone foam dressings for PU prevention in the ICU.

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pressure ulcer; Mepilex Border heel dressing; wound dressings; critical illness; intensive care unit

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Although standard strategies such as risk assessment, regular repositioning and the use of specialised support surfaces have been widely implemented in hospitals, pressure ulcer (PU) prevention remains a challenge, particularly among critically ill patients in the intensive care unit (ICU). Factors include the severity of the patients' illness, immobility and heavy reliance on medical devices.[1–3] The development of hospital-acquired PUs is also closely related to emergency admission for acute illnesses and prolonged stay in the emergency department (ED).[4] For trauma patients, long surgical procedures in the operating room (OR) also substantially increase the risk of PUs in ICU.[5] PUs can occur after as little as two hours of unrelieved pressure.[6] The literature highlights the importance of early identification of patients at risk for PU development and subsequent implementation of interventions to reduce hospital-acquired PU occurrence in the ICU. The strong correlation between low Braden Scale score (high risk) and PU development among critically ill trauma patients has been well established.[3]

Given the challenges in PU prevention, there is a growing interest in the use of dressings as an additional prevention strategy.[1] A recent systematic review combining high-quality randomised controlled trials (RCTs), cohort studies and case series shows clear evidence of the effectiveness of multi-layer soft silicone foam dressings in the prevention of PU development, particularly among immobile ICU patients.[7] The use of wound dressings is also reported to enhance the prevention of medical device-related PUs, which are often resistant to standard strategies.[2] At the Royal Melbourne Hospital (RMH), the large Border I RCT of ICU patients conducted by our group identified a 13.1% hospital-acquired PU incidence rate among critically ill and trauma ICU patients who were transferred from the ED. The trial intervention involved applying prophylactic multi-layer soft silicone foam dressings to the patients' sacral regions and heels at the time of their admission to the ED, which led to a reduction in the incidence rate of PUs in the ICU to 3% (p=0.001).[8]

The heels are highly susceptible to PU development in high-risk patients. Sustained pressure

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perpendicular to the skin over the calcaneus (at an intensity sufficient to cause capillary occlusion and tissue necrosis) is believed to be the major mechanism in ulcer formation.[9] Additionally, shear forces tangential to the heel have also been implicated in PU formation where it is believed that these forces are magnified in the presence of moisture (microclimate) at the skin/surface interface. Despite different dressings such as polyurethane foam,[10] multi-layer soft silicone foam[8] and hydrocellular[11] dressings having been used to protect the heel skin from ulcer development, these dressings are not specifically designed for PU prevention.

The significant financial burden of PUs on the health-care system has been widely recognised,[12,13] but there is limited evidence of cost savings using prophylactic dressings for PU prevention to date, apart from two reports that have demonstrated a reduction in incidence rates and subsequent cost reduction.[11,14] The aim of this prospective cohort study (the Border II study) was to evaluate the clinical effectiveness of the Mepilex Border Heel (Mölnlycke Health care AB, Göteborg Sweden) dressing in preventing hospital-acquired heel PUs in trauma and critically ill patients.

Methods

Design

The Border II study was designed as a prospective cohort study of trauma and critically ill patients who were admitted to the RMH ED and subsequently transferred to the ICU. Eligible patients had the foam heel dressing (Mepilex Border Heel dressing; Mölnlycke Health care AB, Göteborg Sweden) applied to both heels and retained with Tubifast tubular bandage (Mölnlycke Health care AB, Göteborg Sweden) in addition to standard PU prevention care (PU risk assessment, regular re-positioning, nutritional support, and incontinence management). The comparator for the trial cohort was a control group of patients from the Border I trial[8] previously conducted at RMH. The Border I control group patients received standard PU prevention care only. All patients (Border I and the current trial) were cared for on the Hill-Rom Versa-Care low air loss bed (Hill-Rom, Batesville, IN) for the duration of their care in the ICU.

Sample size

We estimated that based on a total sample size of 150 patients, we would have 80% power to detect a reduction in PU incidence of 10% (from 13% to 3%) with a 2-sided alpha of 0.05.

Setting

The study was undertaken at the RMH, Australia, which is a large university teaching hospital and part of a multi-healthcare facility group, Melbourne Health. The RMH is one of the two Melbourne trauma centres in the state of Victoria with more than 65,000 ED presentations and a 40% admission rate.

Ethical considerations

The study was approved by the Melbourne Human Research Ethics committee in 2013 and registered with the commonwealth government clinical trial notification scheme. The study was granted an exemption from the need to obtain consent from participants due to the critical illness of participants under the provisions of Victorian legislation and

Fig 1. Flow of participants in the study cohorts

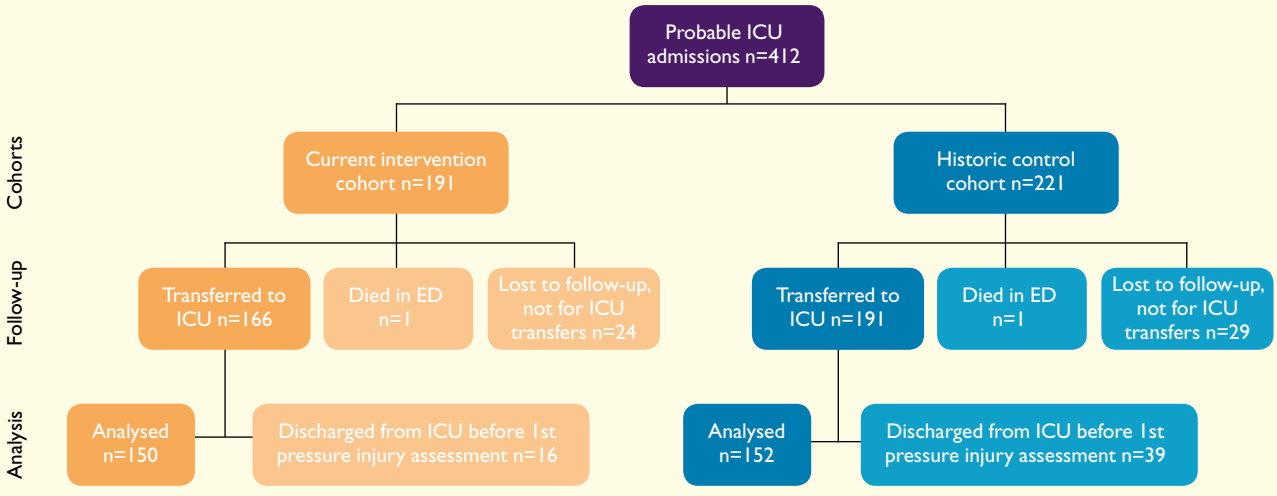

Table 1. Patient demographics

	Intervention cohort (n=191) mean (SD)	Control cohort (n=221) mean (SD)	p
Demographic characteristics			
Age years	55 (19.7)	56 (20.5)	0.98
Gender			
Male/female (missing cases)	123/67 (1)	132/82 (7)	0.82
Physiological characteristics			
Mean arterial pressure mmHg	91 (21.8)	93 (22.7)	0.58
Temperature °C	36 (1.8)	36.2 (1.6)	0.43
Heart rate	96 (25.9)	95 (26.6)	0.70
SpO_2 %	97	98	0.30
Braden score	11 (2.9)	12 (3.9)	0.88
Australasian Triage Scale	2 (0.7)	2 (0.8)	0.96
Acute Physiology and Chronic Health Evaluation II	18.9	19.5	0.73
Emergency department admission classification			
Critical illness	120	147	0.66
Major trauma	70	65	0.75
Length of stay (hours)			
Emergency department	7 (5)	6 (4)	0.36
Operating room	5 (4)	5 (4)	0.98
Intensive care unit	107 (123)	86 (101)	0.007
Mechanical ventilation			
Emergency department yes/no (missing cases)	122/65 (4)	140/67 (14)	0.32
Intensive care unit (missing cases)	127/41 (23)	153/39 (29)	0.29
Transfer to operating room from emergency department			
Cases	21	20	0.78

additionally as it was standard clinical practice in the ICU to use heel dressings to prevent PUs. However a letter was provided to next of kin informing them that their relative had been enrolled into the study, providing a non-technical description of the aims of the research and giving them the option of withdrawing their relative.

Inclusion and exclusion criteria

Potential study subjects included all major trauma and critically ill patients who were admitted to the ED and subsequently transferred to the ICU. Data collection commenced in late July 2013 and was completed in mid March 2014. Patients were excluded if they were under 18 years of age, had a pre-existing heel PU, had trauma to the heels or had spinal injuries which precluded repositioning.

Intervention

The foam heel dressing was applied to each heel on admission to the hospital in ED and changed every three days or when soiled or dislodged, for the duration of the ICU stay. The dressing was retained on each heel by a tubular bandage.

Data collection

Data included reasons for admission, physiological variables, comorbidities, Australasian Triage Scale (ATS) score[15] and ventilation status. The ED electronic patient information system (Ascribe-Symphony) and the ICU Australian & New Zealand Intensive Care Society (ANZICS) databases were used to retrieve data on patients' length of stay in the ED, OR and ICU expressed in hours and Acute Physiology and Chronic Health Evaluation II (APACHE II) score.[16]

In the ICU, all patients had a Braden PU risk assessment score[17] calculated and updated daily. Patients were reviewed to determine if a hospital-acquired PU had developed every 24 hours, for the duration of their ICU stay or until they were ambulant, by a member of the research team. The daily review involved partially peeling back the adhesive border of the dressings so that the heel skin could be visualised

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and assessed for pressure-related injuries, following which the dressing was reapplied. PUs were identified according to the definitions provided by the Australian Wound Management Association (AWMA): Clinical practice guidelines for the prediction, prevention and management of PUs.[18] Any PU that developed during the course of the study was categorised using the four-point category system and we included all categories from category I through to category IV. All members of the research team underwent inter-rater reliability testing before the study started.

Outcome measures

The primary outcome measured in the study was the incidence rate of hospital-acquired heel PUs in the ICU expressed as the total number of heel PUs developed in the study group.

Data analysis

Data analysis was based on intention to treat[19] where all patients included in the study were analysed regardless of death in the ED or transfer to another ward from the ED. Descriptive statistics were calculated for all physiological and demographic variables and differences in these were analysed with chi-squared where data was not normally distributed. PU incidence rates between the two cohorts were explored through the calculation of inferential statistics (inferences from our data to more general populations).

Results

We enrolled 191 eligible patients into the trial, of which one died in the ED before ICU admission, 24 were lost to follow-up or transferred to another ward, and 16 were discharged from the ICU before the first PU assessment, leaving 150 patients included in the final analysis (Fig 1). In the Border I control patient group (the comparator cohort for this study; n=221), one patient died in the ED before ICU admission, 29 were lost to follow-up or transferred to another ward, and 39 were discharged from the ICU before the first PU assessment by the research team, leaving 152 patients in the final analysis (Fig 1).

Table 2. Heel pressure ulcer incidence rates

	Control cohort (n=152)	Intervention cohort (n=150)	p
Pressure ulcers developed	14	0	<0.001
Incidence (%)	9.2	0	<0.001
Total numbers of pressure ulcers	19	0	<0.001
Category I	15	0	
Category II	2	0	
Category III	0	0	
Category IV	2	0	

Demographics

Table 1 reveals that patient demographics in the current intervention cohort were comparable with those in the Border I control cohort except for the patients' length of stay in the ICU. Patients in the current Border II trial had a longer average length of stay in the ICU when compared to that in the Border I control group (107 hours versus 86 hours; p=0.007).

Pressure ulcer incidence rates

No patients in the intervention group developed a heel PU during their ICU stay while the foam heel dressing was used. In the Border I control cohort, 14 patients developed a heel PU. The total number of heel PUs in the control cohort was 19 (Table 2).

Discussion

Study population

We enrolled a total of 191 patients, aiming to achieve a similar number of patients in the final analysis (n=150) to the Border I control group (n=152). In the Border I control group, we enrolled 221 patients to achieve 152 valid cases for final analysis. The demographic profile of 191 patients in the Border II intervention cohort were largely similar to those of 221 patients in the Border I control cohort except for a significantly longer average length of stay in ICU. We believe that this finding was due to a small number of patients in the Border II study who had protracted length of stay in the ICU. However, the prolonged ICU length of stay in the Border II study would not favour our evaluation of the effectiveness of the heel dressing in PU prevention because the increased ICU length of stay could be expected to increase the risk of PU development.

Pressure ulcer incidence rates

No patient in the intervention cohort developed a hospital-acquired heel PU during their ICU stay. By contrast, the Border I control cohort who did not receive prophylactic heel dressings had a 9.2% hospital-acquired heel PU incidence rate in the ICU, significantly higher than our intervention cohort (p<0.001). Our findings are consistent with the international evidence[7,20,21] for the effectiveness of the use of the foam dressings. However, there are currently few studies that have investigated the use of these dressings in the prevention of heel PUs. We note that Forni et al.[10] reported significantly reduced heel PU incidence using prophylactic polyurethane dressings inside plaster casts to protect the heel (3.6% PU) compared with patients with casts and no dressings (42.9% PU), however the protective mechanisms of prophylactic polyurethane compared with multilayer silicone dressings may be different

given that our study did not include patients with lower limb plaster casts.

Usability of the dressing

The zero PU incidence rate in our intervention cohort suggests an enhanced pressure redistribution capacity and shear protection of the foam heel dressing. This finding is consistent with the results of research, based on finite element model variants of the heel, which show that foam heel dressings consistently and substantially reduce mechanical loading in the soft tissue and that their multi-layer structure promotes internal shear, which, in turn, diverts loads from the tissues.[22,23] However, our research team encountered some challenges that are commonly encountered when applying dressings to the heel region. The adhesive border tabs and margins rolled up very easily and became difficult to unravel after they were partially peeled back for skin inspection, which made dressing reapplication challenging in some cases particularly when wearing gloves. In addition, we found the foam heel dressing to be difficult to maintain in place when patients were restless or agitated. Also once the adhesive border of the dressing began to roll due to patient movement, the dressing soon became dislodged. As a consequence each new heel dressing was retained with tubular bandage to prevent it being dislodged.

Limitations

We used a prospective cohort design in the Border II study and compared this with our data from the Border I control patient cohort. There is a possibility that the patients in these two studies were distinct given that they were recruited over two different time periods. However, our patient demographics comparison showed very few differences except for the patients' ICU length of stay. Therefore, we believe that the baseline characteristics of the intervention and control cohorts in this report were comparable. The study results cannot be generalised due to the nature of a single-site study. An additional limitation was the possibility of a 'halo' effect in the PUs care received by patients who had the dressings in place. We do not believe that this was the case as standard clinical practice in our ICU for the preceding 12 months was the use of heel dressings for the prevention of PUs. Clinical staff were used to this protective intervention and the only difference was that we used the Mepilex Border Heel dressing rather than the standard dressing (Mepilex Heel dressing) in our study.

Conclusion

Our findings provide additional evidence to support the use of prophylactic multi-layer soft silicone foam dressings in the prevention of hospital-acquired PUs among critically ill patients. This prospective cohort study suggests that the application of border heel dressing is highly effective in preventing hospital-acquired heel PUs among trauma and critically ill patients when the intervention is commenced in the ED. Health care and hospital policy-makers should consider the adoption of prophylactic dressings for high-risk ED/ICU patients when developing new clinical guidelines for PU prevention. However, we emphasise the importance of high-quality bedside nursing care in PU prevention and stress that the use of these dressings in additional to contemporary PU prevention measures. We believe that early risk assessment and early, active intervention for high-risk patients with evidence-based strategies by bedside nurses is indispensible in PU prevention.

There is a need for large-scale comparative clinical studies to investigate the effectiveness of the new dressing product in PU prevention across different health-care settings and with different populations that are at high-risk of developing hospital-acquired PUs. Additionally there is a need for studies to investigate the effectiveness of different dressing construction and materials. It is not clear at this stage if there is an 'optimal' design for a prophylactic PU dressing. ■

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