

Evaluating the effectiveness of silicone multilayer foam dressing in preventing heel pressure injury among critically ill patients in Singapore.

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ABSTRACT

Background: The heel has become the second most common site for the development of pressure ulcers in recent years. Hospitals worldwide have been implementing preventive measures to tackle pressure ulcers in patients, such as the use of offloading devices and dressing.

Aim: To evaluate the effectiveness of a soft silicone multilayer heel dressing (Mepilex® Heel) in reducing the incidence of heel pressure injuries (HPI) among critical ill patients in the intensive care unit (ICU).

Method: This was a quasi-experimental, pre-, and post-intervention study design conducted in three adult ICUs in an academic teaching hospital. A convenience sampling was used to recruit 326 patients (195 patients in pre-intervention, 131 patients in intervention group).

Result: Statistical analysis was made using Fisher exact test to compare between the two groups. The results showed a reduction of 86% in the incidence of HPI between the two groups (pre-intervention: 10.8% versus post-intervention: 1.5%). Patients in the intervention group were less likely to develop HPIs ($p < 0.007$).

Conclusion: A prophylactic multilayer foam heel dressing has shown to be effective at reducing the incidence of HPIs among critically ill patients in ICU, even with the tropical climate in Singapore.

Keywords: Prophylactic dressing, heel, pressure injury prevention, quasi-experimental.

INTRODUCTION

Preventing hospital-acquired pressure injuries (PIs) remains a top priority of hospitals worldwide¹. The incidence of PI is a quality-of-care indicator and a nursing-sensitive outcome². Patients who develop PIs experience added morbidity, pain, infection, loss of function, extended hospitalisation stay, and increased health care expenditure cost³. The cost of treating PIs varies, ranging from US\$20,000 to US\$70,000 per wound⁴⁻⁶. Specifically, heel pressure injury (HPI) is a physically

debilitating and painful condition that can lead to serious complications such as infection, cellulitis, osteomyelitis, septicaemia, limb amputation, and even death⁷.

Many factors contribute to the development of PIs, but the most common pathway is tissue ischaemia⁸. Studies have shown that tissues are only capable of sustaining pressure of around 30–32 mmHg for only a short duration of time, but when there is direct, sustained or moderate, repetitive pressure and shearing forces, it will lead to occlusion of the capillary vasculature and eventual tissue ischaemia^{9,10}.

The heel is one of the common areas for PIs due to factors such as its calcaneus pointed shape and the bony prominence with limited fats¹¹. Also, the muscle tissues entailing the heel are poorly equipped to absorb the compressive forces of pressure or shearing that are generated during limb movement or transfers¹¹. Additionally, the skin around the heel is often dry due to the lack of sebaceous glands^{12,13}.

A 10-year retrospective review (1990–2000) of PIs and a more recently published data on PIs have reported that HPI has risen from the sixth to the second most common site of PI^{14,15}. The reported incidence of HPI is estimated to be as high as 60% in the acute care setting¹³. Specifically, critically ill patients, elderly persons and surgical patients are at greater risk of developing PIs due to the severity of their illness, the use of sedation, prolonged period of immobility, and over-reliance on medical devices¹⁶. Reported incidence of PIs among critically ill patients ranged from 3.3% to 34.4%^{17–24}.

Prevention of HPI involves pressure relief and prevention of shearing or friction by using offloading devices⁸. The use of a multi-layer dressing in the prevention of PI is gaining popularity, especially after its efficacy was proven in the *in-vitro* computer modelling studies done by Levy and Gefen^{15,25}. Their studies found that anisotropic (directionally dependent stiffness properties) dressing facilitated more soft tissue protection compared to isotropic (same stiffness in every direction) dressing and multilayer dressing seemed to be beneficial over single-layer dressing as it is able to dissipate tissue strains by promoting internal shear within the dressing, thus diverting the loads from the tissues and has a protective effect^{15,25}.

A previous systematic review²⁶ on the use of prophylactic dressing in the prevention of PI suggested that soft foam silicone dressings may help reduce PI incidence associated with medical devices, especially among immobile patients in intensive care units (ICUs). However, all of the 10 studies included in the analysis were from different care settings, and only three reported on heel injuries, while the rest of the studies reported on sacrum, trochanter and nose. Furthermore, all of the studies were conducted in a different climate compared to Asia and there was no specific recommendations on the type of dressing materials²⁶.

Literature review

A search was conducted using the databases of PubMed and CINAHL from 2007 to 2017, with the following subject keywords: “pressure ulcer” OR “pressure injury” AND heels AND “prophylactic dressings” only found three relevant articles. The studies were varied in design, setting, and sample, as summarised in Table 1. In Santamaria’s paper, they only observed for any development of PI while their patients were in the emergency department, operating room and ICU but stop monitoring these patients once they were transferred to the general ward, hence it is possible that some of these patients may develop PI subsequently in the general ward. The findings from Sola *et al.*²⁷ found that the group on hydrocellular heel pad had less incidence of HPI than the polyurethane heel dressing group (2.49% versus 3.37%). However, in their study, both heel pad and dressing were applied only at night; therefore, it is possible that patients may still be exposed to shear and friction during the day.

Although there seems to be some evidence on the effectiveness of prophylactic dressing in prevention of HPI, it is challenging to generalise the findings given the differences in skin structure between Caucasians and Asians, and differences in temperature and humidity between temperate and tropical countries. Studies have reported that Asian skin has the weakest barrier function upon mechanical challenge compared to Caucasian skin, although both types of skin possesses a similar basal transepidermal water loss (TEWL) and ceramide levels^{28,29}. Hence, it is of interest to evaluate the effectiveness of prophylactic heel dressings among patients of Asian origin. Singapore is a tropical country with an average daily average daily temperature of 31° Celsius and mean humidity of 84%³⁰, hence it is also of interest to evaluate if the dressings stayed on and served as an effective protective layer.

Therefore this study aimed to evaluate the effectiveness of a soft silicone multilayer heel dressing (Mepilex® Heel) in reducing the incidence of HPI among critical ill patients requiring ICU care in Singapore. To the best of the authors’ knowledge, this is the first study done in an Asian context that examines the effectiveness of a silicone multilayer heel dressing among critically ill patients.

ETHICAL CONSIDERATIONS

This study was approved by the SingHealth Centralised Ethic Review Committee (ref no: 2016/2013) and has conformed to the ethical guidelines of the 1975 Declaration of Helsinki. A waiver of informed consent was granted by the review committee.

METHODOLOGY

Setting

This study was conducted in an academic 1751-bed, tertiary care institute in Singapore. The facility has three adult ICUs (surgical, medical, and neuroscience) with a total capacity of

Table 1: Summary of literature 2007–2017 on the effectiveness of prophylactic dressing in preventing heel pressure injury

	Authors, year	Study design	Setting, population and sample size	Interventions	Comparator	Results
1	Santamaria <i>et al.</i> , 2013	RCT	ED and ICU trauma and critically ill patients, n=440	Multi-layer soft silicone foam Sacrum dressings to sacrum and to both heels and retained with an elastic tubular bandage.	None	Incidence of HPI: there was 10% difference in incidence between the groups (3.1% intervention group versus 13.1% in control group).
2	Sola <i>et al.</i> , 2013	RCT	Medium-long stay hospital, high-risk patients, n=940	Hydrocellular heel pad (Allevyn Heel)	Classic padding consisting of synthetic padded bandage fastened with gauze bandage	Incidence of HPI: 2.49% in the classic padded bandage and 3.37% in the Hydrocellular heel pad group (p=0.82)
3	Santamaria <i>et al.</i> , 2015	Cohort	ED and ICU trauma and critically ill patients, n=412	Multi-layer soft silicone foam heel dressing on each heel, retained with a tubular bandage.	Received standard prevention care only with no heel dressing.	No HPIs developed in the intervention cohort patients versus 14 patients in the control cohort (n=152; p<0.001) who developed a total of 19 HPIs.

N: number of subjects; RCT: Randomised controlled trial; HPI: heel pressure injury; ED: emergency department; ICU: intensive care unit.

26 beds. The nurse-to-patient ratio is 1:1 for all ICUs as per staffing practice internationally³¹.

Study design

A quasi-experimental, pre-, and post-intervention study design was adopted instead of a randomised controlled trial (RCT) because it was not possible to randomise patients or the ICU because of the high potential risk of contamination of the intervention in the busy critical care area and also the ethical concerns of only providing prophylactic care to some critically ill patients and not others.

Sample size calculation

To detect a decrease in incidence rate of HPI from 10% to 2%, a total of 108 patients per group was needed in order to achieve a power of 80% and alpha of 0.05.

Sampling method and study population

A convenience sampling approach was adopted; patients were eligible to participate in this study if they were over 21 years old and admitted to any of the ICUs during the study period.

Exclusion criteria:

- Patients with pre-existing HPI or trauma to the heels;

- Patients with suspected or actual spinal injury that prevent them from being turned;
- Patients who needed lower limb cast;
- Patients with a pre-existing skin condition over the heels that interfere with the application of the heel dressing; and
- Patients with moulted heel or ischaemic heels due to receiving high dose of inotropes.

Pre-intervention

The pre-intervention group's study period ran from April 2016 to September 2016. All patients who met the inclusion criteria received the standard PI preventive measures such as daily PI risk assessment, regular repositioning, pressure-redistributing overlay or alternating air mattress and skin care such as barrier or emollient cream.

Intervention

The intervention group's study period started from November 2016 to September 2017, which includes recruitment, data collection and training of nurses in all three ICUs on the application of the prophylactic heel dressings. All eligible patients received the standard PI preventive measures in

Table 2: Pressure injury classification according to European Pressure Ulcer Advisory Panel (EPUAP)

Category	Description
Category/Stage I: Non-blanchable erythema	Intact skin with non-blanchable redness of a localised area usually over a bony prominence
Category/Stage II: Partial thickness	Partial-thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. Intact or open/ruptured serum filled blister
Category/Stage III: Full-thickness skin loss	Full-thickness tissue loss. Subcutaneous fat may be visible but bone, tendon, or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss
Category/Stage IV: Full-thickness tissue loss	Full-thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed
Unstageable: Depth unknown	Full-thickness tissue loss in which the base of the pressure ulcer is covered by slough (yellow, tan, gray, green, or brown) and/or eschar (tan, brown, or black) in the pressure ulcer bed
Suspected deep tissue injury: depth unknown	Purple or maroon localised area or discoloured, intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear

addition to prophylactic foam heel dressings that were applied to both heels within four hours upon admission to the ICU. The heel dressing was changed every three days or whenever soiled.

The prophylactic heel dressing used in this study was Mepilex® Heel which is a soft, self-adherent foam dressing that has been theorised to substantially reduce the mechanical loading in the soft tissue and prevent shearing through its multilayer structure^{15,32}. It also provides a protective barrier and cushioning between the surface of the patient's skin and the bedding surface, thus reducing the impact of the pressure, friction and shear forces. Additionally, the dressing conforms to the body, manages excess moisture, and can easily be placed and removed to allow for visual inspection of the heels.

Measurements and outcome assessments

The patients' heels were assessed daily for development of PI to their heels and the conditions were documented by the registered nurses who cared for the patient as per standard hospital practice. Data were censored when patients were able to sit out of bed or discharged. The staging of PI was according to the National Pressure Ulcer Advisory Panel (NPUAP) and European Pressure Ulcer Advisory Panel (EPUAP)³³ (Table 2).

Patients were also monitored if any sensitivity reactions developed such as redness or itchiness while on the heel dressing. If any sensitivity reactions occurred, the heel dressing will be removed immediately and patients will be taken out of the study.

To control for potential confounders, other data such as patients' demographic, medical and surgical information, severity of illness according to Acute Physiology and Chronic Health Evaluation II (APACHE) score, and total length of observation expressed in days were collected. All data were gathered via the hospital electronic patient management system.

APACHE II provides a general measure of severity of disease. An increasing score (range 0 to 71) is closely correlated with the subsequent risk of mortality³⁴.

The primary endpoint was incidence rate of hospital-acquired HPI in both groups expressed as the number of patients with newly acquired HPI in each group and divide by the number of patients examined for HPI in each group during the study period (pre-intervention: 5 months; intervention: 10 months).

STATISTICAL METHOD

Data analysis was performed using the Statistical Package for Social Sciences, version 23.0, computer software (IBM, Armonk, New York). The continuous data are expressed as the mean and SD. Descriptive statistics were used to examine the distributions of the demographic, clinical, and hospitalisation data. Between group differences in demographics and APACHE II score, were evaluated using chi-square tests or student t-tests. HPI incidence was compared between the two groups using the Fisher exact test. Odds regression was used to control for differences in demographic or clinical factors among the two groups. The level of statistical significance was set at $P < 0.05$.

Table 3: Demographic, clinical, and hospitalisation data between 2 groups

Demographics		Pre n (%)	Post n (%)	Chi-square	p-value
Gender	Male	113 (57.9%)	90 (68.7%)	3.897	0.048
	Female	82 (42.1%)	41 (31.3%)		
Race	Chinese	133 (68.2%)	94 (71.8%)	2.293	0.514
	Malay	35 (17.9%)	18 (13.7%)		
	Indian	14 (7.2%)	13 (9.9%)		
	Others	13 (6.7%)	6 (4.6%)		
		Pre Mean (SD)	Post Mean (SD)	T-test	P-value
Age		61.0 (15.60)	60.7 (15.67)	0.193	0.847
Clinical factors					
Length of observation		6.4 (9.63)	4.4 (4.73)	2.584	0.01
APACHE II		21.7 (7.70)	22.6 (7.10)	-1.065	0.288

APACHE II: Acute Physiology and Chronic Health Evaluation II; NS: not significant; ICU: intensive care unit. P value significant at < 0.05

Table 4: Details on heel pressure injuries

		Pre n (%)	Post n (%)	Fisher exact	p-value
Developed heel PI	No	174 (89.2%)	129 (98.5%)	9.947	<0.0001
	Yes	21 (10.8%)	2 (1.5%)		

Pre-intervention		
	Right heel	Left heel
Stage I	15	16
Stage II	1	0
Stage III	0	0
Stage IV	0	0
Unstaged	0	0
SDTI	1	1
Total		34

Intervention		
	Right Heel	Left Heel
Stage I	2	2
Total		4

*Pressure injury stage according to EPUAP

Table 5: Odds regression to control for differences between variables

		Odds ratio	95% CI	p-value
Gender	Male	Reference group	-	0.343
	Female	0.634	0.247–1.627	
Groups	No heel dressing	Reference group	-	0.007
	Heel dressing	0.131	0.030–0.573	
Length of observation	-	1.022	0.986–1.059	0.228

RESULTS

Data from 326 patients (195 patients in pre-intervention; 131 patients in intervention group) were analysed. Four patients dropped out in the intervention group; three were due to treatment-needs in ICU and one patient verbalised that the heel dressing was uncomfortable and requested to remove it.

The demographic, clinical and hospitalisation data revealed that both groups were comparable on major physiological and demographic characteristics on admission to the ICU except for gender and length of observation (Table 3). Patients in the pre-intervention group were observed for longer period than patients in the intervention group (6 versus 4 days; $p=0.01$).

There was an 86% reduction in the incidence rate of HPI between the two groups (pre-intervention: 10.8% versus 1.5%: post-intervention). Data on the incidence of HPI between the two groups and details of the HPIs are presented in Table 4.

After controlling for gender, length of observation and groups (pre-intervention and intervention), the results of the regression indicated that patients in the intervention group were less likely to develop HPIs (odds ratio [OR], 0.13; 95% CI, 0.03 to 0.57; $p < 0.007$) (Table 5).

DISCUSSION

This is the first study done in the tropics and solely on Asian patients on the use of soft silicone multilayer foam heel dressing in preventing HPI. Our findings were similar to Santamaria *et al.*'s²³ study, in which multilayer, soft silicone foam dressing was effective in reducing the incidence of HPI. Their study managed to achieve zero HPI in their intervention group, whereas we had two HPIs in our intervention group. The difference in findings may be due to factors such as the climate, skin type, ethnicity and differences in the starting point of the study. To illustrate, in Santamaria's²³ study, intervention started in the emergency department and continued to the operating room and the ICU, whereas we only began recruiting when the patients were admitted in ICU.

Our study's endpoint was when patients were able to sit out of bed as it was cumbersome to walk with the heel dressing. However, studies have shown that mobile patients may also

develop PI^{8,35}; hence it may also be necessary to protect the heels when patients are sleeping at night. For example, in Sola *et al.*²⁷, they found that a classic bandage heel pad was effective at preventing incidence of HPIs; therefore, future studies may consider using some form of heel protection at night for high-risk patients. Manufacturers may also consider designing a prophylactic heel dressing or pad that can be easily reapplied when patients are resting in bed.

LIMITATIONS AND IMPLICATIONS FOR FUTURE RESEARCH

This was a single-site study and we were unable to conduct an RCT as we anticipate a high potential risk of contamination between the intervention and control group due to the busy setting of the ICU. Nonetheless the baseline characteristics of patients in all three ICUs were homogenous; hence, the data were comparable between the two groups.

Another limitation factor was that we were unable to blind data outcome assessors due to the nature of the study; however, we had employed different team members to perform cross-checking of the data collected in order to ensure its data accuracy. Therefore, our results can only be viewed in the context of the critically ill patients in an acute care setting and cannot be generalised to chronic care area.

However, although all three ICUs shared the same standard PI prevention measures, all three ICUs had different types of foam mattress from various manufacturers; thus we were unable to determine whether the use of different support surfaces could have influenced the results. Future studies may consider measuring the incremental effectiveness of support surfaces when used in conjunction with prophylactic silicone foam dressing in the prevention of PIs among critically ill patients.

CONCLUSION

A prophylactic multilayer foam heel dressing is effective at reducing the incidence of PI among critically ill patients in ICU. It seems that the Asian skin type and a more humid climate did not interfere with the effectiveness of the silicone foam dressing in prevention of heel injuries. The patients were able to tolerate the silicone dressing well and the heel dressing was able to stay in place when patients were not ambulating.

DISCLOSURE OF INTEREST

The authors have no disclosure of interest to report.

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