TITLE: Efficacy of a heel offloading boot in reducing heel pressure injuries in patients in Australian intensive care units: a single-blinded randomised controlled trial.

ABSTRACT

Objectives: To compare time to incidence, extent of incidence and severity of heel pressure injuries (PIs) offloaded with the Prevalon^{TM} boot (intervention) or pillows (control).

Research methodology/design: Multi-centre, single-blinded randomised controlled trial of 394 critically ill patients. Patients were randomised to the intervention or control for heel offloading.

Setting: Three hospital intensive care units (ICU); two in greater Sydney, Australia, and one in regional New South Wales, Australia.

Main outcome measures: Primary outcome: time to hospital-acquired pressure injury (HAPI) heel development in patients within 28 days from admission and heel pressure injury stage. Secondary outcomes: incidence of heel pressure injury (PI) within 28 days of ICU admission; severity of heel PI; occurrence of plantar contractures (changed ankle dorsiflexion ≥5°) within 28 days of admission.

Results: Within 28 days of ICU admission, one PI was recorded in the intervention group and 11 in controls. Hazard of PI incidence within 28 days of ICU admission was significantly lower (p=0.0239) in heels assigned to the intervention (hazard ratio 0.0896 [95% CI 0.0110, 0.727]). Odds of PI incidence within 28 days of ICU admission were significantly lower (p=0.0261) in the intervention group (odds ratio 0.0883 [95% CI 0.0104, 0.749]). The PI recorded in the intervention was superficial (stage 1) whereas the PIs recorded in controls were more severe (stage 2 to 4).

Conclusion: The Prevalon™ boot significantly reduced heel PI occurence compared with heel offloading using pillows.

KEY WORDS

Critical care, heel offloading, heel protector, pressure injury, intensive care, prevention

IMPLICATIONS FOR CLINICAL PRACTICE

- In the context of immobile, critically unwell intensive care patients, the heel is often subject to prolonged pressure. This, coupled with minimal protective subcutaneous tissue means the heel is predisposed to tissue breakdown.
- The Prevalon™ boot, a heel suspension boot designed to relieve pressure on the heel, is easy to apply and remove, is made of soft material for improved ventilation and comfort and holds the foot and lower leg in position to avoid ankle plantar flexion and hip external rotation to prevent foot contractures.
- The Prevalon™ boot is an effective pressure relieving device and should be used instead of pillows to prevent the development of heel pressure injuries. It not only lowers the hazard and odds of developing heel pressure injuries, but also reduces pressure injury severity, should these occur.

INTRODUCTION

Patients in the intensive care unit (ICU) are almost four times more likely to develop a pressure injury (PI) of any kind than non-ICU patients due to their critical illness and inability to convey sensations of increased pressure and discomfort (Coyer et al., 2017). One of the most common locations on the body where PIs develop is the heel (Chaboyer et al., 2018; Delmore et al., 2015; Muntlin Athlin et al., 2016; Worsley et al., 2016). This is because there is little protective subcutaneous tissue and no muscle or fascia within the heel, making it vulnerable to pressure, friction, and shear forces (Gefen, 2017; Wong & Stotts, 2003). A systematic review of 22 studies identified the heel to be the second most common body location for PI development in adult ICU patients with an incidence of 38.9% (Chaboyer et al., 2018). However, the most effective heel pressure relief method is yet to be identified (Junkin & Gray, 2009; Wong & Stotts, 2003).

Numerous interventions have been investigated to prevent heel PIs (McGinnis & Stubbs, 2014). Offloading is one pressure-relieving technique which can be used to protect the heel from developing PIs (European Pressure Ulcer Advisory Panel et al., 2019). Offloading prevents the heel from direct contact with a surface, such as a mattress, by using an aid; for example, heel suspension boot, a pillow, or foam wedge applied under the foot and lower leg (Davies, 2018). Clegg and Palfreyman (2014) found that heel-suspension boots, compared with wedges and pillows, were more beneficial at preventing heel PIs. Randomised controlled trials (RCTs) have examined the efficacy of such boots, indicating significantly fewer patients developed heel PIs when using the boot compared with controls (Bååth et al., 2016; Donnelly et al., 2011; Meyers, 2017), however, these have been limited due to being single site studies, small sample sizes, or not within an ICU setting. Thus, there is still limited strong evidence supporting the prevention or reduction of heel PIs with heel suspension boots (European Pressure Ulcer Advisory Panel et al., 2019).

Due to the continued reported high incidence of heel PIs in ICU patients, the purpose of this study was to compare the effect of the Prevalon™ heel boot to standard care (pillows) in preventing heel PIs (PI development rate, incidence, and PI severity) and plantar flexion contractures in patients in ICU. The Prevalon™ boot was chosen as it has shown in previous studies to be comfortable, easy to apply with less room for error, and its soft feel when compared to other heel devices (Rajpaul & Acton, 2016; Walsh & Plonczynski, 2007).

METHODS

Design and Setting

This study was a multi-centre, single blinded RCT, conducted in three hospital ICUs in greater Sydney (n = 2) and a regional area (n = 1) of New South Wales, Australia, from August 2019 to March 2021, notwithstanding a 6-month cessation period (April-September 2020) when sites were unable to recruit due to the COVID-19 pandemic. The study sites had a total of 96 ICU beds: 52, 36 and 14 beds in each respective institution. The largest ICU is located in a metropolitan, quaternary facility in Sydney, Australia, specialising in liver transplantation, trauma, neurovascular and cardiac surgery, and complex management of patients requiring advanced therapies such as extracorporeal membrane oxygenation (ECMO). This ICU is the largest adult critical care service in Australia admitting approximately 3,500 to 4,000 patients per year. The second largest ICU (36 beds) is located in a tertiary trauma hospital with adult, mixed medical, surgical, neurovascular, and cardiac surgery patients, and catering for 2,800-3,000 patient admissions per year. The smallest ICU (14 beds) is located in a regional general facility and has an average of 1,000 patient admissions per year.

The trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) http://www.ANZCTR.org.au/ACTRN12619000238178p.aspx. The study followed the

Consolidated Standards for Reporting of Trials (CONSORT) protocol (Schulz et al., 2010) (Figure 2).

Ethical Approval

This study was approved by the hospital research ethics committee ([redacted]). Approval was obtained with an 'opt-out' patient consent process in accordance with the Australian National Statement on Ethical Conduct in Human Research (The National Health and Medical Research Council et al., 2007), as the intervention was non-invasive, was part of preventative PI care, and subsequently minimised harm and offered benefits that justified any risk of harm. Hence consent was not required to be sought from patients. An 'opt-out' consent was offered to patients. At the first available opportunity the next of kin and the patient, when they were deemed competent, were given an 'opt-out' brochure regarding the trial and the process to withdraw from the trial if they wish. If they wished to withdraw, heel PI prevention usual management was continued and the patient's data was not used, unless consent to do so was obtained.

Participants

The study population was patients in the adult ICUs at high risk of developing a PI defined by PI risk assessment scales (Waterlow score $\geq$ 15 or Braden scale $\leq$ 12). Patients were excluded if they had a community or hospital-acquired PI (HAPI) on one or both heels diagnosed within 24 hours of admission to the ICU; previously enrolled in the present study; transferred from another ICU; imminent and inevitable death within 24 hours; physically unable to wear a boot, for example, an external fixation device *in situ*; or admitted to ICU more than 24 hours prior to screening.

Sample size

The sample size was estimated using results by Lyman (2009), who found two instances of heel HAPIs with the use of the Prevalon™ boot in 550 patients and 39 instances of heel HAPIs in 550 patients without the boot. At standard levels of significance (p=0.05), 338 heels in the control group and 338 heels in the treatment group (i.e. in total 676 experimental 'heels' or 338 patients assuming both heels are treated) were required to reject the null hypothesis that incidence rates for intervention patients are equal at 90% power, using the uncorrected chi-squared test. This corresponded to 169 controls and 169 patients in the intervention group (338 in total). Hence, we aimed to recruit a minimum of 338 patients.

Data Collection

Intervention

The intervention was the Prevalon™ boot (Figure 1), a device supporting the foot and ankle and elevating the heel to provide complete offloading at the heel to reduce risk of heel PIs. The boot also holds the foot in position to avoid foot and leg rotation to reduce flexion contracture risk and peroneal nerve damage.

Figure 1: Prevalon™ heel boot

Control (Standard practice)

Standard hospital pillows were used in two out of three ICUs. These are foam covered in plastic with a cotton pillowcase. They are positioned under the full length of patients' calves to achieve

full offloading of the heels. One ICU used a Posey® Heel Protector boot comprising of a polyester filling covered in soft cotton and a hole for heel relief. Where the boot was unavailable, standard hospital pillows were used in this ICU.

Outcome measures

The primary outcome was time to HAPI development in heels of patients without pre-existing heel PIs within 28 days from ICU admission. Secondary outcomes included: incidence of heel PI within 28 days of ICU admission; severity of heel HAPIs staged according to the international staging system (European Pressure Ulcer Advisory Panel et al., 2019); occurrence of plantar contractures (patients with a change in ankle dorsiflexion of 5° or greater) within 28 days of admission.

Other variables

Demographic and clinical data collected on all patients included: age on admission, sex, type of admission (emergency or planned), severity of disease on admission to the ICU as measured by the Acute Physiology and Chronic Health Evaluation (APACHE) III classification system (operative or non-operative) where scores range from 0 to 71; higher scores imply greater risk of death of extended stay in ICU (Knaus et al., 1991), co-morbidities, patient outcome (died, discharged to home, transferred to another ward or transferred to another hospital), pre-existing heel PIs, heel HAPIs, length of hospital stay (days), and plantar foot measurements on enrolment and discharge.

Daily data collected included a visual skin inspection of the patient's heels, risk of developing a pressure injury, including degree of risk, was measured using the Braden Scale (Bergstrom et al., 1987), a scale made up of six subscales (sensory perception, moisture, activity, mobility, friction, and shear) and the Waterlow Assessment Tool (Waterlow, 1985), a seven-item tool that assesses build/weight, height, visual assessment of the skin, sex/age, continence, mobility,

and appetite, and special risk factors, divided into tissue malnutrition, neurological deficit, major surgery/trauma, and medication. Available range of motion (angle degree of flexion) at a joint was measured using a goniometer. Organ dysfunction was measured by the Sequential Organ Failure Assessment (SOFA) score (Vincent et al., 1998). The score measures six body systems and ranges form 0-24; higher scores imply greater risk of death of extended stay in ICU. Processes of care for PI prevention were recorded.

Procedure

All bedside nurses were trained in the application of the Prevalon^{TM} boot and data collection procedures. Training was provided face-to-face at the bedside by the investigators who are all recognised clinical experts. Training comprised a 30-minute education session on theory, demonstration, procedures, and benefits of the boot and a 2-minute video on its application. An information brochure and application guide for nursing staff or family members was left in a designated study folder with study procedures at the patient's bedside.

Patients who met the inclusion criteria were randomly allocated to either the control group (standard care with pillows) or the intervention group (the Prevalon^{TM} boot) using computerised block cluster randomisation, with randomised block sizes of 2, 4, 6 and 8, and clustering at the patient level, such that both heels of each patient received the same treatment. Neither clinical staff administering the intervention, nor patients were blinded to group allocation. The statistician conducting the data analysis was blinded to group allocation. Patients were given a unique study number, kept on a separate master log, to link to their medical record.

Daily data collected on all participants included 8-hourly heel skin inspection; shift-by-shift assessment of the boot or pillow position; shift-by-shift documentation of all skin assessment and PI prevention strategies; measurement of plantar flexion contractures by a trained nurse or physiotherapist using a goniometer at days 1 and 28 (or earlier if the patient in the intervention

no longer required the boot, was being transferred, or discharged). All protocol violations were recorded.

Data Analysis

Statistical methods

The sample was summarised descriptively by group and as a complete cohort. Data were analysed using the intention-to-treat principle. Group balance in key predictors was assessed. Uncontrolled exploratory testing was conducted, including a *Z*-test for binomial proportions to compare proportions of patient heels in which a heel HAPI was recorded within 28 days of ICU admission; and calculation of risk and odds ratio for HAPIs in the treatment groups (with associated 95% confidence intervals [CI]), absolute risk reduction (ARR) and number needed to treat (NNT).

For the primary outcome, a multilevel interval-censored parametric survival analysis (using the best fitting modelling distribution chosen from several candidate distributions) was conducted to assess time to HAPI incidence across treatment groups. Survival trajectories in both groups were plotted. Robust standard errors were used in the assessment of group significance for clustered data (heels clustered within patients).

For the secondary outcome of proportion of heel HAPIs by 28 days, a multilevel logistic analysis was conducted to compare group incidence of heel HAPI, assuming the same 2-level structure. The effect of data clustering was assessed by comparing findings from exploratory *Z*-testing and the multilevel model. For the secondary outcome of plantar contracture, feet of patients for whom plantar contracture measurements were recorded at both admission and discharge; with positive and negative values compared separately using independent samples t-tests. The secondary outcome of HAPI severity was assessed descriptively.

RESULTS

Patient enrolment, group allocation, follow-up and analysis flow through the trial are presented in the flow diagram illustrated in Figure 2 according to the CONSORT protocol (Schulz et al., 2010).

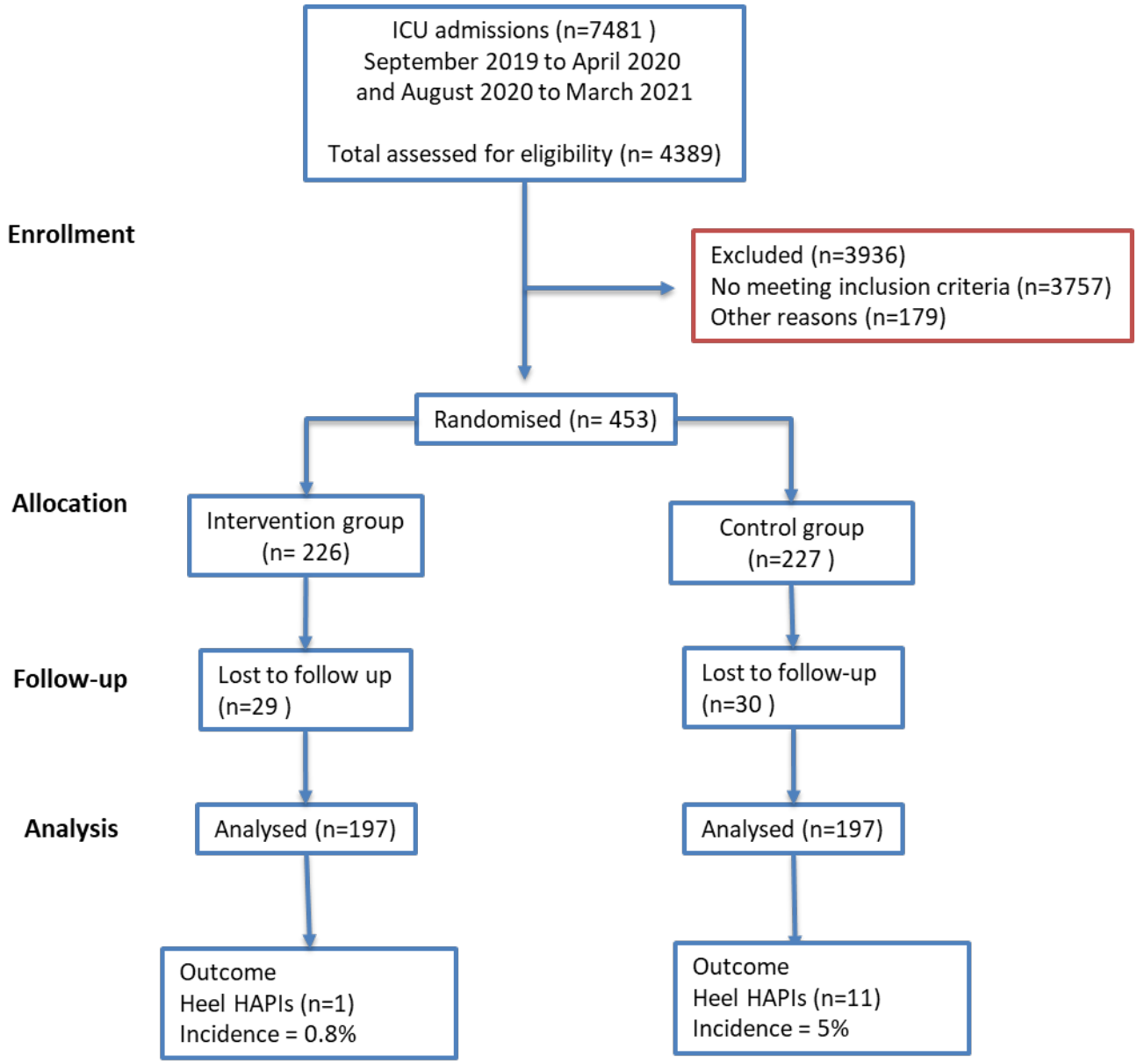


Figure 2. CONSORT flow diagram of the progress through the phases of this trial

No patients 'opted out' of the study. Usable data was collected on 394 ICU patients with 197 patients were randomly allocated to each group. Protocol deviations were recorded on seven patients. Three patients in the control group received the intervention. One control patient was admitted to ICU six days prior to enrolment in the study (outside the site exclusion timeframes). In the intervention group, one patient was not enrolled until 15 days after admission; the Prevalon^{TM} boot of another patient had to be removed 10 days after enrolment due to a fracture; and one patient was not in the Prevalon^{TM} boot for six days within the analysis period. All protocol deviations were disregarded under the intention-to-treat principle with analysis conducted according to treatment allocation in all cases. One pre-existing heel PI was recorded on a patient in the control group. The number of patient heels in the risk set (without pre-existing PIs) were hence 394 in the intervention group and 393 in the control group. Sample characteristics are summarised descriptively in Table 1.

Table 1: Characteristics of the sample

Variable (frequency (valid %)	**Intervention (*n*=197)**	**Control (*n*=197)**	**All (*n*=394)**
Mean age (SD; range)	61.1 (15.5; 16.7 – 94.9)	59.2 (17.7; 17.0 – 94.0)	60.1 (16.7; 16.7 – 94.8)
Sex			
Male	128 (66.0%)	132 (67.7%)	260 (66.8%)
Female	66 (34.0%)	63 (32.3%)	129 (33.2%)
Type of admission			
Emergency	138 (70.0%)	135 (68.5%)	273 (69.5%)
Planned	60 (30.0%)	62 (31.5%)	120 (30.5%)
APACHE III diagnosis			
Operative	72 (36.5%)	62 (31.5%)	134 (34.0%)
Non-operative	125 (63.5%)	135 (68.5%)	260 (66.0%)

Co-morbidities[1]			
Circulatory system	91 (45.8%)	83 (42.6%)	174 (44.2%)
Endocrine, nutritional & metabolic	52 (26.1%)	41 (21.0%)	93 (23.6%)
Respiratory system	45 (22.6%)	40 (20.5%)	85 (21.6%)
Musculoskeletal system & connective tissue	35 (17.6%)	29 (14.9%)	64 (16.3%)
Digestive system	34 (17.1%)	29 (14.9%)	63 (16.0%)
Infectious & parasitic diseases (systemic or unspecified sites)	3 (1.51%)	3 (1.54%)	6 (1.52%)
General issues unrelated to principal diagnosis	3 (1.51%)	1 (0.51%)	4 (1.02%)
Hepatobiliary system & pancreas			
Kidney & urinary tract	24 (12.1%)	20 (10.3%)	44 (11.2%)
Mental diseases or disorders	23 (11.6%)	13 (6.67%)	36 (9.14%)
Nervous System	23 (11.6%)	12 (6.15%)	35 (8.88%)
Alcohol/drug use & alcohol/drug induced organic mental disorders	22 (11.1%)	24 (12.3%)	46 (11.7%)
Neoplastic disorders (haematological and solid neoplasms)	21 (10.6%)	13 (6.67%)	34 (8.63%)
Blood, blood-forming organs & immunological disorders	17 (8.54%)	24 (12.3%)	41 (10.4%)
Factors influencing health status & other contact with health services	14 (7.04%)	11 (5.64%)	25 (6.35%)
Female reproductive system	11 (5.53%)	10 (5.13%)	21 (5.33%)
Skin, subcutaneous system and breast	10 (5.03%)	7 (3.59%)	17 (4.31%)
Injuries, poisonings & toxic effects of drugs	1 (0.50%)	4 (2.05%)	5 (1.27%)
Eye	0 (0.00%)	2 (1.03%)	2 (0.51%)
Male reproductive system	6 (3.02%)	2 (1.03%)	8 (2.03%)
Ear, nose, mouth and throat	6 (3.02%)	7 (3.59%)	13 (3.30%)
Pregnancy, childbirth & puerperium	3 (1.51%)	7 (3.59%)	10 (2.54%)
	0 (0.00%)	1 (0.51%)	1 (0.25%)

Length of hospital stay (days)	13.6 (14.9; 1 – 94)	14.1 (15.0; 1 – 118)	13.8 (14.95; 1 – 118)
Patient outcome			
Transferred to a ward	127 (65.5%)	139 (70.6%)	266 (68.9%)
Died	52 (26.8%)	42 (21.3%)	94 (24.2%)
Transferred to another hospital	13 (6.70%)	9 (4.57%)	22 (5.67%)
Discharged home	2 (1.03%)	4 (2.03%)	6 (15.5%)
APACHE III score	69.8 (27.7; 9 – 136)	71.8 (29.1; 10 – 139)	70.8 (29.3; 9 – 139)
SOFA score	8.98 (3.80; 0 – 19)	10.0 (3.86; (1 – 20)	9.51 (3.87; 0 – 20)

[1]More than one option could be selected

Table 2 shows the heel HAPIs recorded per group. The HAPI recorded in the intervention group was initially observed four days after ICU admission. The HAPIs recorded in the control group were initially observed various days after admission: three days (four instances), four days (two instances), six days (two instances), eight days, nine days, and 21 days (one instance each).

Table 2. Patients experiencing ICU-acquired heel pressure injury

	Intervention (n=197)	Control (n=197)	Total patients (n=394)	Total heel PIs
Both Heels	0	3	3	6
Single Heel	1	5	6	6
Total	1	8	9	12

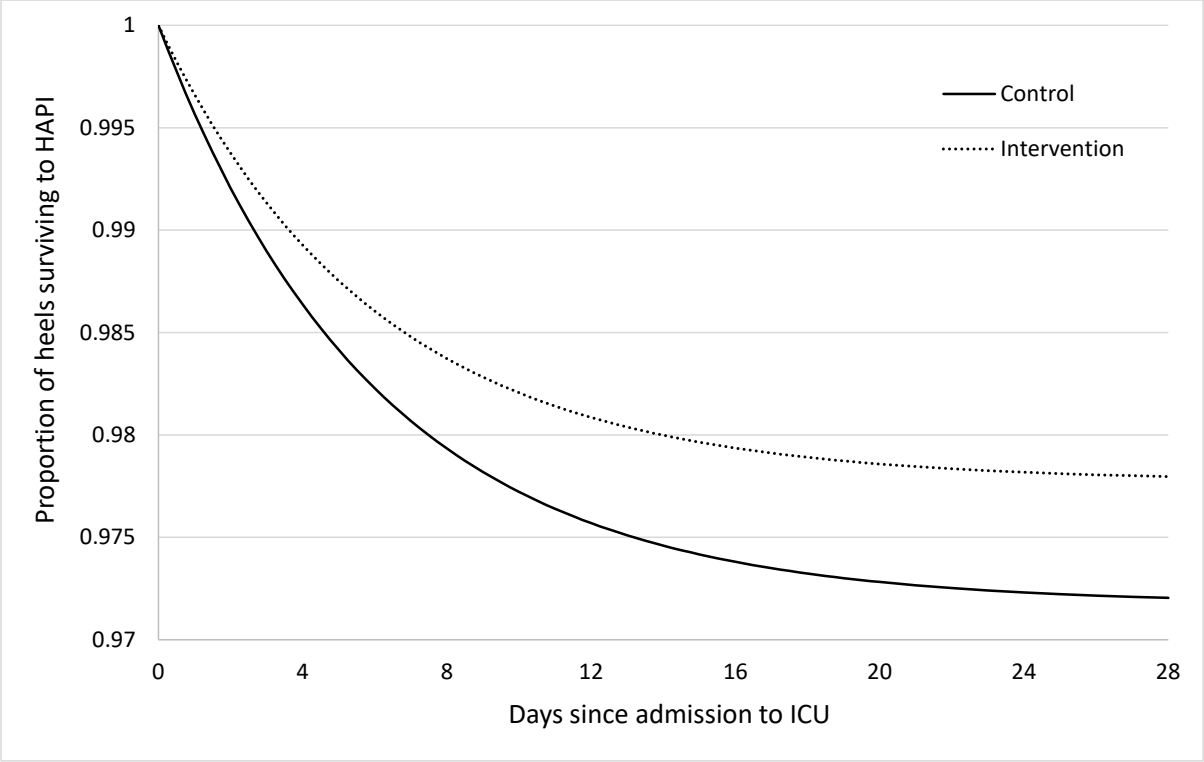
The proportion of HAPI heels 28 days after admission was 2.54×10^{-3} in the intervention group and 0.0280 in the control group (Z=2.91; p=0.0036). The relative risk of a heel HAPI in the intervention group compared to the control group was 0.0907 (95% CI 0.0121, 0.699). The odds ratio for heel HAPIs in the intervention group compared to the control group was 0.0884 (95% CI 0.0144, 0.688).

The ARR for heel HAPIs in the intervention group compared to the control group was 2.54%, corresponding to 39.3 heels to be treated. Hence, 40 heels from 20 patients (assuming both heels of a patient were treated) would need to receive the intervention to prevent one incidence of heel HAPI.

Primary outcome

The Gompertz proportional hazards distribution was the best fitting model of time to HAPI incidence. This model revealed that group allocation was significantly associated with hazard of PI at the 5% significance level (p=0.0239). The hazard ratio for treatment was 0.0896 (95% CI 0.0110, 0.727), i.e. hazard of PI from admission to ICU was 11.2 times less in the intervention group than in controls.

Time to HAPI occurrence in heels of patients in the control and intervention groups is illustrated in Figure 3. After 28 days, expected heel skin integrity survival to HAPI is 97.2% in the control group and 97.8% in the intervention group. Negligible change in survival is predicted after about 16 days from admission; hence median survival was not calculated. No other covariates were included in the model due to well-balanced treatment groups (Table 1).



Secondary outcomes

The multilevel logistic model revealed group allocation to be significantly associated with the incidence of HAPI at the 5% significance level (p=0.0261). The odds ratio for HAPI in the intervention group compared to the control group was 0.0883 (95% CI 0.0104, 0.749). Hence, odds of a heel HAPI by 28 days in patients in the intervention group were 11.3 times less than the odds of a heel HAPI by 28 days in controls. As for the primary analysis, no other covariates were included in the model due to well-balanced treatment groups.

The discrepancy between the significance levels obtained from this analysis and the exploratory analysis can be accounted for by data clustering: 6 out of 12 HAPIs were observed in patients who developed a HAPI on both heels.

Table 3 presents heel HAPI severity. The single HAPI observed in the intervention group was a Stage 1 PI; the least severe stage. Six of the 11 HAPIs observed in controls were designated stages indicating more severe PI: including two Stage 2 PIs and four deep tissue injuries.

Table 3. Severity of ICU-acquired pressure injuries per heel, by group

	Intervention (n=1)	Control (n=11)	Total (n=12)
Stage 1	1	5	6
Stage 2	0	2	2
Stage 3	0	0	0
Stage 4	0	0	0
Suspected Deep Tissue	0	4	4

Dorsiflexion measurements were taken on both admission and discharge on either the left ankle, right ankle or both ankles on 185 patients (47.0%); including 91 patients in the intervention group (46.2%) and 94 controls (47.7%). Positive plantar flexion contractures were recorded in 112 feet from intervention group patients and 94 feet from control group patients. Mean plantar contracture measured in these feet was 9.04° (SD 8.06°) in the intervention group and 9.48° (SD 7.85°) in controls; a difference of 0.44°. Negative plantar contractures were recorded in 35 feet from intervention group patients and 51 feet from controls. Mean plantar contracture measured in these feet was 9.94° (SD 15.6°) in the intervention group and 6.35° (SD 4.51°) in controls; a difference of 3.59°.

Independent samples t-tests revealed no evidence at the 5% significance level for group differences in positive plantar contractures (p=0.695, 95% CI -1.76°, 2.64°) or negative plantar contractures (p=0.200, 95% CI -1.99°, 9.16°). Table 4 presents patient dorsiflexion changes.

Table 4. Dorsiflexion change

Plantar flexion contractures	Intervention (n=91)	Control (n=94)	Total (n=185)
Dorsiflexion change: 5° or more	66 (72.5%)	59 (62.8%)	125 (67.6%)
Dorsiflexion change: less than 5°	25 (27.5%)	35 (37.2%)	60 (32.4%)

DISCUSSION

Heels are one of the most common body locations highly susceptible to PI development (European Pressure Ulcer Advisory Panel et al., 2019; Rodgers et al., 2021). The heel is unique in structure that is richly vascularised and well adapted to the task of shock absorption (Cichowitz et al., 2009). However, in the context of the immobile, critically unwell ICU patient, the heel is often subject to prolonged pressure from resting on the mattress or being incorrectly supported with a pillow in direct contact; this, coupled with very minimal protective subcutaneous tissue, predisposes it to tissue breakdown (Delmore et al., 2015). Our study revealed that the hazard of developing a heel PI, and the odds of developing a heel PI within 28 days of admission, were both over 11 times lower in critically ill patients using the Prevalon^{TM} boot compared with standard care. However, the intention-to-treat principle will have resulted in conservatism in the results. Our study also revealed that 20 patients required the boot (both heels) to prevent the incidence of a single heel PI. This is consistent with previous studies examining the Prevalon^{TM} boot (Meyers, 2017; Meyers, 2010).

Our study demonstrated that heel PIs were more common and more severe in patients in the control group than in the intervention group. Over 50% of heel PIs observed in controls were more severe than Stage 2. Similar to our findings, Coyer et al. (2017) reported that the development of heel PIs leads to both skin damage and higher stages, with almost 50% being suspected deep tissue injury. One possible reason for this increase in severity is that the tissue of the posterior aspect of heels may be less tolerant to ischemia, since the tissue has high metabolic demand to provide oxygen and nutrients to the epidermis, which protects underlying tissue from external force (Arao et al., 2013). Deep tissue injuries may develop if the forces applied exceed the tolerable level, particularly if concentrated within a particular area (Arao et al., 2013). Further, extensive pressure damage in the heel can be concealed by intact skin (Cichowitz et al., 2009). Atypical foot anatomies characterized by a heavy-weight foot, sharp

posterior calcaneus and thin soft tissue padding are theoretically more prone to heel PIs (Gefen, 2010). Further, risk factors associated with PI formation in the heel during hospitalisation include diabetes mellitus, vascular disease and immobility all of which were common characteristics of our sample (Afzali Borojeny et al., 2020; Delmore et al., 2015).

We were unable to demonstrate any group difference in plantar flexion contractures between admission and discharge. Further, there was no evidence of a group effect on either positive or negative plantar flexion contractures. One previous study of the Prevalon^{TM} boot on 53 patients in an ICU led to a 50% reduction in the prevalence of abnormal heel position and that the boot prevented plantar flexion contractures compared with pillows (Meyers, 2010). Another RCT in three ICUs (neurotrauma, medical, and surgical) in one hospital involving 54 patients also found a significantly greater decrease in goniometric scores compared to the control group by day 3 and the last study day (Meyers, 2017).

Limitations and Strengths

A limitation of our study was that the patients, investigators (excluding the statistician) and data collectors were unavoidably not blinded to group assignment. This could possibly introduce risk of bias including differential treatment of groups or biased assessment of outcome (Day & Altman, 2000; Karanicolas et al., 2010). Further, there may a limitation in the inter-user reliability of goniometric measurements of plantar flexion contractures between trained nurses or physiotherapists.

Strengths of our study include: the multi-site settings thereby increasing the generalisability of findings; high levels of power (>90%); conservatism due to adoption of the intention-to-treat principle (protocol deviations may have contributed to apparently inflated estimates of HAPI hazard and incidence in the intervention group); effective randomisation leading to well-balanced groups; rigorous statistical analysis; and regular inspection of patients' heels in ICU,

ensuring that no HAPI was missed and time of occurrence of all HAPIs identified within 24 hours.

CONCLUSION

Overall, the Prevalon™ boot can be used by ICU patients in metropolitan and regional settings. Use of the Prevalon™ boot statistically significantly reduced PI development when compared with heel offloading using pillows. The findings support that the Prevalon™ boot may be used to prevent development of heel PIs in critically ill patients.

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