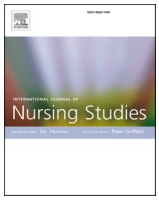
International Journal of Nursing Studies 173 (2026) 105258

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/locate/ns



EffEctiveness of Prophylactic fOam dressings in the prevention of saCral pressure injuries in at-risk hospitalised patients (EEPOC): A randomised control trial

Rachel M. Walker [a,b,c,*], Wendy Chaboyer [c], Lukman Thalib [d,g], Sharon Latimer [c,e], Haitham Tuffaha [f], Marie Cooke [c], Brigid M. Gillespie [c,e]

[a] College of Health Care Sciences, Nursing and Midwifery, James Cook University, Townsville, Queensland, Australia
[b] Townsville Institute of Health Research & Innovation, Townsville University Hospital, Townsville, Queensland, Australia
[c] NHMRC Centre of Research Excellence in Wiser Wound Care, School of Nursing and Midwifery, Griffith University, Southport, Queensland, Australia
[d] Department of Biomedical Engineering, Yildiz Technical University, Istanbul, Türkiye
[e] Nursing and Midwifery Education and Research Unit, Gold Coast University Hospital, Gold Coast Hospital and Health Service, Southport, Queensland, Australia
[f] Centre for the Business and Economics of Health, University of Queensland, Brisbane, Queensland, Australia
[g] School of Nursing and Midwifery, Edith Cowan University, Perth, Western Australia, Australia

ARTICLE INFO

Keywords:
Acute care
Adults
Adverse events
Nursing
Pressure injury/pressure ulcer
Prophylactic dressings
Randomised controlled trial

ABSTRACT

Background: Hospital-acquired pressure injuries are a serious patient safety issue with the sacrum the most common location. Silicone foam border dressings are increasingly used in hospitalised patients, yet their clinical and cost-effectiveness in preventing pressure injuries is unclear in some patient cohorts.
Objective: To determine the clinical and cost-effectiveness of a silicone foam border dressing in preventing sacral hospital acquired pressure injuries in at-risk medical-surgical patients.
Methods: A prospective, multi-site, parallel group, pragmatic, superiority randomised controlled trial was conducted in Southeast Queensland, Australia. Medical-surgical adult patients (≥18 years) at-risk of pressure injury were recruited and randomly allocated to either an intervention (sacral dressing plus routine care) or control (routine care only) group. The Primary outcome was development of a new sacral pressure injury. Daily, blinded, and independent outcome assessments were conducted off-site for up to 14 days using edited photographs of deidentified participants' sacra. Intention-To-Treat analyses were performed using both best-case and worse-case scenarios. Additional complete case analyses were conducted as part of sensitivity analyses. Secondary outcomes comprised time to onset of hospital-acquired sacral pressure injury, severity, incidence rates per 1000 trial days (days patients were in the trial), incidence rates per 1000 hospital days (days patients were in hospital), and cost-effectiveness that compared the difference in pressure injury incidence between groups.
Results: Of the 1121 eligible patients approached, 958 agreed to participate. There were no significant differences in baseline characteristics between intervention and control groups. Cumulative incidence of sacral pressure injury was 1.67 % (8/478) and 1.25 % (6/480) in the intervention and control groups respectively ($p = 0.592$). There was an increased risk of pressure injury for those in the intervention group (Relative Risk: 1.34 (95 % CI 0.47–3.83)), but the effect was not statistically significant and confidence intervals wide. Distribution of secondary outcomes was also similar in both the intervention and control groups. The intervention was more costly than the control showing an incremental cost of $99.90 (95 % CI $74.10–$125.60) associated with using the dressings.
Conclusions: The study did not provide evidence that silicone foam border dressings reduced the incidence of sacral hospital acquired pressure injuries in adult medical-surgical patients at risk of pressure injuries. Additionally, the silicone foam dressings incurred higher incremental costs than routine care.
Trial registration number: ACTRESN12619000763145, Registered 22/05/2019, first recruitment 10/07/2020.

* Corresponding author at: College of Healthcare Sciences, Building 25, Room 222, James Cook University, Bebegu Yumba Campus, Townsville, Queensland, 4811, Australia.
E-mail address: rachel.walker@jcu.edu.au (R.M. Walker).

https://doi.org/10.1016/j.ijnurstu.2025.105258
Received 2 February 2025; Received in revised form 9 October 2025; Accepted 19 October 2025
Available online 24 October 2025

What is already known

- Prophylactic dressings are increasingly used for pressure injury prevention.
- A recent systematic review concluded evidence supporting the use of prophylactic dressings in clinical trials was of low certainty.

What this paper adds

- Use of sacral prophylactic dressings did not decrease the incidence of pressure injuries in adult medical-surgical patients.
- Sacral silicone foam dressings were more costly than routine care.
- More trials are needed to identify patients who might benefit from this intervention.

1. Introduction

Hospitalised patients are at risk of developing pressure injuries, with rapid onset of injury to skin and/or tissue over bony prominences (European Pressure Ulcer Advisory Panel et al., 2019). These hospital-acquired complications are a persistent and serious threat to patient safety resulting in pain, infection and death (European Pressure Ulcer Advisory Panel et al., 2019). A meta-analysis of 15 studies, comprising almost 2 million patients identified hospital-acquired pressure injury prevalence in adults was 8.4 %, with the sacrum the most frequent anatomical site (Li et al., 2020). Hospital-acquired pressure injuries also pose a significant economic burden on healthcare systems, services, and communities. In Australian public hospitals, the total cost of pressure injuries was $9.11 billion per annum, with an associated treatment cost of $3.59 billion (Nghiem et al., 2022). In the United States, the estimated cost of hospital-acquired pressure injuries was $US26.8 billion (Padula and Delarmente, 2019), while a systematic review based on European and North American studies reported the treatment costs of pressure injury varied from €338.86 million to €2.59 billion (Demarré et al., 2015).

The use of prophylactic sacral dressings is recommended as a pressure injury prevention strategy (European Pressure Ulcer Advisory Panel et al., 2019). In many clinical settings, prophylactic sacral dressings form part of routine pressure injury prevention, yet their clinical effectiveness in some patient populations and contexts is uncertain (Padula et al., 2019; Santamaria et al., 2015; European Pressure Ulcer Advisory Panel et al., 2019). A meta-analysis of four superiority trials conducted in intensive care unit (ICU) patients, demonstrated these dressings were effective in preventing sacral pressure injuries (Relative Risk 0.22; 95 % CI 0.11–0.43; $p < 0.001$) (Lovegrove et al., 2022). However, authors of two high-quality trials of prophylactic silicone foam dressings in a range of acute care patient populations, acknowledged further rigorous testing in clinical practice was needed (Beeckman et al., 2021; Hahnel et al., 2020). More recently, authors of a Cochrane Review update (Patton et al., 2024), meta-analysed six trials ($n = 1247$) comparing silicone dressings with no dressing. They found silicone dressings may reduce pressure injury incidence at any stage (Relative Risk = 0.25, 95 % CI 0.16–0.41). However, the certainty of evidence was low due to heterogeneity across studies, particularly in terms of patient populations.

Research on the cost-effectiveness of prophylactic dressings is sparse. Authors of two trials involving intensive care patients, reported prophylactic silicone foam dressings led to cost savings (El Genedy et al., 2020; Santamaria et al., 2015b). They based this calculation on a rudimentary cost–benefit analysis that estimated labour costs by multiplying the average hourly wage of nurses by the frequency of dressing application. In the first trial, the cost of treating pressure injuries was calculated by multiplying incidence (for each stage) with patients' average hospital length of stay (Santamaria et al., 2015b). The second trial calculated an incremental cost-effectiveness ratio based on the average duration of patient admission, expressed as cost per pressure injury avoided (El Genedy et al., 2020). However, both studies relied on secondary data sources, which likely limited the accuracy and comprehensiveness of the data collected. More recently, authors of a large multi-centre trial of 1633 hospitalised patients, undertook cost-effectiveness analysis of a sacral silicone foam dressing, compared to routine pressure injury prevention measures (Neyt et al., 2024). Based on previous cost analyses (Demarré et al., 2015), and a bottom-up approach, the dressings were found to be cost neutral in a mixed patient cohort (critical, acute and aged care) (Neyt et al., 2024). Yet, there remains uncertainty about the treatment effects of sacral silicone foam dressings (Marshall et al., 2019), particularly in medical-surgical patient cohorts.

The aim of the EEPOC trial was to assess the clinical effectiveness of a prophylactic silicone foam dressing to prevent sacral pressure injuries in acute medical-surgical adult patients. Our primary hypothesis was that the use of these dressings (the intervention) would reduce the cumulative incidence of sacral hospital-acquired pressure injuries within 14 days of study recruitment, compared to those assigned to routine care alone (the control). We also hypothesised that patients randomised to the intervention group would have better outcomes relative to 1) time to sacral hospital-acquired pressure injury development, 2) sacral hospital-acquired pressure injury incidence rates per 1000 trial days and per 1000 hospital days, 3) severity of sacral pressure injury and, 4) cost-effectiveness of the dressing.

2. Method

2.1. Trial design

The EEPOC trial was a prospective, multi-site, parallel group, pragmatic, superiority randomised controlled trial (RCT). The trial protocol was registered a priori and is reported elsewhere (Walker et al., 2023). The trial was undertaken in participating medical and surgical units at three metropolitan acute-care public hospitals in Southeast Queensland Australia, with a combined medical-surgical capacity of 1079 beds. Recruitment began on 10 July 2020, during the first year of the COVID-19 pandemic and ended on 30 June 2023. Due to extenuating circumstances resulting from COVID-19, the 2021 *Guidelines for Reporting Trial Protocols and Completed Trials Modified Due to the COVID-19 Pandemic and Other Extenuating Circumstances* statement was used as an extension to the CONSORT (Consolidated Standards of Reporting Trials) guidelines to report trial modifications while maintaining transparency, quality, and completeness (Orkin et al., 2021). A chronology of COVID-19 impacts on the trial is provided in Appendix 1.

2.2. Participants

2.2.1. Eligibility criteria

A consecutive sample of all eligible at-risk of pressure injury adult patients were recruited from medical-surgical wards at each study site. They were invited to participate in the trial by one of the 17 trained registered research nurses rostered to undertake trial activities at their respective sites. 'At-risk' patients were defined as those who had a completed pressure injury risk assessment score (Waterlow, 1985), or exhibited limited mobility, requiring human or resource assistance to move - as outlined in Table 1.

If eligible patients agreed to participate following screening, the designated research nurse at each site conducted a voluntary informed consent recruitment process. Recruited participants were randomised to either an intervention or control group. Regardless of group allocation, all participants received routine pressure injury care informed by national standards and international practice guidelines (Australian Commission on Safety and Quality in Health Care, 2021; European Pressure Ulcer Advisory Panel et al., 2019).

Routine care included regular skin inspection and assessment, use of a non-powered standard foam mattress or powered air mattress (as determined by the bedside clinician), possible multidisciplinary review,

Table 1
Inclusion and exclusion criteria.

Inclusion	Exclusion
1. ≥18 years of age	1. Unable to be turned (e.g., due to unstable spinal injury)
2. Assessed as being at-risk of hospital-acquired pressure injuries, screened by study staff within 36 h of hospital admission	2. Existing sacral pressure injury, other injury, allergy, or lesion in the sacral area at the time of recruitment
3. 'At-risk' of pressure injury was defined using the Waterlow (1985) Score, OR patients with limited mobility (where human or resource assistance was needed to move)	3. Urinary and/or faecal incontinence at the time of recruitment
4. Expected hospital length of stay ≥24 h following recruitment[a]	4. Unable to speak or understand English where no interpreter was present at the time of recruitment
5. Able to provide written informed consent in-person or proxy	

[a] Eligibility criteria were modified due to the COVID-19 pandemic to adapt to shorter patient hospital length-of-stay (≥24 h) following recruitment, to enable at least one outcome assessment.

and second hourly repositioning in accordance with hospital procedures, which were provided if a patient's condition warranted them.

2.3. Interventions

2.3.1. Intervention: prophylactic sacral dressing plus routine care

Intervention group participants, who were unable to be blinded to the intervention, received routine pressure injury care and had a prophylactic silicone foam sacral dressing applied by a research nurse, as per manufacturer instructions. The Mepilex® Border Sacrum dressing was selected due to its prolific use in clinical trials and other settings (Beeckman et al., 2021; Hahnel et al., 2020; Santamaria et al., 2015), and reported clinical effectiveness (Lovegrove et al., 2022). It was available in two sizes (large and small) to accommodate physical differences. Daily inspection of the dressing involved removing the topical device, assessing the skin then reapplying the device, as recommended by the manufacturer (Mölnlycke Health Care, 2019a, 2019b). This procedure was also used in other trials involving the same dressing (Santamaria et al., 2015; Beeckman et al., 2021).

Prior to and during data collection, Mölnlycke representatives provided team training on dressing application including regular skin inspection under the dressing. Everyday a research nurse at each site removed the Mepilex® Border Sacrum dressing completely to undertake thorough sacral skin inspection for erythema (yes/no) and blanching (capillary refill). A de-identified photograph of the participant's sacrum was taken and edited before the dressing was reapplied or replaced with a new dressing in accordance with the manufacturer's instructions. This process was repeated every day for up to 14 days. Deidentified photographs of participants' sacra were sent to an off-site, blinded, and independent outcome assessor to evaluate the primary outcome: sacral hospital-acquired pressure injuries (yes/no). The frequency of all dressing replacements, and the reason for dressing changes, were documented, as were dressing-related adverse skin reactions including blistering, rash, itchiness, discomfort and/or other signs and symptoms.

2.3.2. Control: routine care

Control group participants received routine pressure injury prevention care but did not have a prophylactic sacral dressing applied. However, like the intervention group, control patients also had their sacrum inspected and photographed by a research nurse every day following recruitment. Photographs were edited in the same way as the intervention group before being sent to an outcome assessor for evaluation.

2.4. Outcomes

2.4.1. Primary outcome

The primary outcome was the cumulative incidence of sacral hospital-acquired pressure injuries over 14 days (that is, the number of patients with a sacral pressure injury divided by the number of patients in the group).

2.4.2. Secondary outcomes

1. Time to onset of sacral hospital-acquired sacral pressure injuries in days up to 14 days.
2. Sacral hospital-acquired pressure injury incidence rates per 1000 trial days considered the number of new hospital-acquired pressure injuries per 1000 days patients were in the trial, while incidence rates per 1000 hospital days considered the number of new hospital-acquired pressure injuries per 1000 days patients were in hospital.
3. Severity of sacral hospital-acquired pressure injuries up to 14 days, was assessed using an internationally and nationally recognised classification system (European Pressure Ulcer Advisory Panel et al., 2019), based on the depth of skin and tissue damage. Classifications ranged from non-blanchable erythema (Stage I) to full thickness tissue loss (Stage IV) as well as unstageable damage, and suspected deep tissue injury.
4. Cost effectiveness of the dressing from the health system perspective.

Baseline data from health records were collected everyday by a research nurse at each site. Two of the sites had integrated electronic health records, while the third used paper records. Data included patient characteristics such as age, sex, and body mass index; comorbidities including diabetes, obesity, and malnutrition; smoking status; medications; mobilisation; days in trial; and length of hospital stay. Pressure injury prevention strategies were also recorded, including type of support surface, nutrition assessment, and repositioning frequency. Visual skin assessments were conducted daily to monitor pressure injury outcomes.

2.5. Sample size

The target sample size was guided by Li et al. (2020) who reported a pooled cumulative incidence of hospital-acquired pressure injuries globally to be 8.4 % (95 % CI 7.6–9.3 %), which was consistent with meta-analysed Australian data (Rodgers et al., 2021). Prior to this, an Australian trial in emergency and intensive care settings reported the cumulative incidence of hospital-acquired pressure injuries in the range of 4 % to 13 % (Santamaria et al., 2015). Given these variations, we based our power calculation on a cumulative incidence of 10 %. The expected effect of the intervention on the primary outcome was assumed to be a 50 % reduction in cumulative incidence based on the incidence ratio obtained in our pilot trial (Walker et al., 2017). Thus, our sample size determination assumed a cumulative incidence of 5 % in the intervention group compared to 10 % in the control group. To obtain 90 % power with a two-sided α level of 0.05, a total 578 patients per group were required. To allow for attrition, a further 10 % would be recruited for a total sample of 1320.

2.6. Randomisation

Following eligibility assessment and consent, recruited participants were randomised to either the intervention group (dressing plus routine care) or control group (routine care only) using a 1:1 ratio, with permuted block sizes of four, six and eight, stratified by hospital and division (medical or surgical). Computer generated randomisation was determined by a central service via a secure university website, accessible to research nurses via a password protected study-specific electronic device.

2.7. Implementation

A standardised operating procedure manual was developed to ensure protocol and dressing application consistency. A research nurse entered data collected, including sacral photographs, directly into the secure electronic case record form (Harris et al., 2019, 2009), hosted at Griffith University. Daily pressure injury prevention data were collected from participants in both groups for up to 14 days or until study endpoints including new sacral hospital-acquired pressure injuries, transfer to ICU, medical-surgical unit discharge, withdrawal from the trial, or death, whichever occurred first. However, for intervention participants, additional endpoints included development of a skin reaction and persistent urinary and/or faecal incontinence. In these cases, the dressing was removed, and the participant exited from the study. These endpoints were reported using standard hospital incident reporting protocols, including human ethics reporting processes and serious adverse events.

2.8. Blinding

Given the visible nature of the intervention, patients, healthcare professionals, research nurses, trial coordinator and chief investigator (RMW) were not blinded to group allocation. However, research team members, including the independent outcome assessors, trial statistician and health economist, remained blinded to group allocation. On the day of recruitment, a research nurse at each site took high-resolution, de-identified digital photographs of participants' sacra that included study number, date, and time. Before forwarding images to an outcome assessor, photographs were edited using software to ensure atraumatic skin markings from the dressing were not visible and the edges of photos looked similar, thus reducing the risk of detection bias.

Unknown to each other, trained outcome assessors with expertise in wounds and pressure injury assessment evaluated photographs according to the established international classification system (European Pressure Ulcer Advisory Panel et al., 2019). One of four outcome assessors allocated on the day, received the photographs for evaluation from all sites via authenticated secure email and assessed the edited images for (erythema yes/no), blanching test (yes/no) and pressure injury assessment ('No hospital-acquired sacral pressure injury', 'Stage I', 'Stage II', 'Stage III', 'Stage IV', 'Unstageable', 'Suspected Deep Tissue Injury').

2.9. Statistical methods

Data were entered directly into the electronic case report form, and exported into RStudio version 2023.09.1 (R Core Team, 2023), and IBM SPSS Statistics (Version 30.0) (IBM Corp, 2020) for data analyses. All analyses were conducted using patients as the unit of measurement. Prior to analysis, a rigorous data cleaning process was undertaken to identify and verify outlying figures, addressing missing data and implausible entries by cross-checking against source records. We summarised baseline characteristics of binary and categorical data using counts and proportions, and continuous data as means and standard deviations, or medians and interquartile ranges, depending on the distribution. Inter-rater reliability between outcome assessors was evaluated using Cohen's κ statistic.

The primary outcome was development of new sacral hospital-acquired pressure injuries, with the main analysis focused on comparing cumulative incidence between the two groups. The Relative Risk of sacral hospital-acquired pressure injuries in the intervention group was compared to the control group with results reported along with 95 % CI and p values. The Number Needed to Treat was calculated to estimate the potential impact of pressure injury prevention in the intervention. As outlined in the study protocol, the main analysis adhered to the Intention-To-Treat principle. For a true Intention-To-Treat analysis, the primary outcome should be recorded for all randomised participants. However, in our trial, some participants had no data available for the primary outcome due to loss to follow up or withdrawal after randomisation, which hindered Intention-To-Treat analysis. To address this, we conservatively assumed that these participants did not develop a sacral hospital-acquired pressure injury (worst-case analyses) and repeated the analysis. To further evaluate the robustness of this assumption around missing primary outcome data, we conducted an Intention-To-Treat analysis assuming all participants' missing primary outcome data had a sacral hospital-acquired pressure injury (best-case analysis). While the development of sacral hospital-acquired pressure injuries in all missing patients was highly unlikely, the analysis provided an additional measure of robustness for our main findings. Finally, a complete case analysis was performed, excluding patients with missing primary outcome data.

Secondary outcomes were carried out using complete case analyses. Time to sacral hospital-acquired pressure injury onset was summarised as medians and interquartile ranges (IQR) and compared between intervention and control groups using the Mann–Whitney U test, given the non-normal distribution of the data. Incidence rates of sacral hospital-acquired pressure injuries were analysed using both time-at-risk and patient-based perspectives. These complementary measures provided a more comprehensive understanding of pressure injury risk. Severity of sacral hospital-acquired pressure injuries were reported descriptively due to the small number of cases and limited variability. The number of dressings used per patient and adverse events related to dressings ($n = 8$) were summarised using means (standard deviations, SD) and frequencies (percentages), respectively.

An economic evaluation from the health system perspective was conducted using patient-level trial data by an expert health economist. A cost-effectiveness analysis compared the costs and effects of prophylactic silicone foam sacral dressings (intervention) versus routine care (control) using the primary outcome (cumulative incidence) as the measure of effect. However, given the limited availability of data, this analysis was crude. The incremental cost per sacral hospital-acquired pressure injury avoided was calculated, as the difference in mean costs divided by the difference in incidence between the intervention and the control groups.

3. Data safety

A Data Safety Monitoring Board comprising a multidisciplinary group with experience in hospital-acquired pressure injuries, biostatistics and randomised trials was established by trial investigators to ensure the safety of participants, and to advise on the validity and credibility of the trial (National Health and Medical Research Council, 2016, 2018). An interim analysis was undertaken by the Board midway through the trial. Unblinded to group allocation, members of the Board were provided with deidentified data on recruitment, safety data for evidence of harm, and additional data analysis.

4. Ethics statement

The trial received ethics approval from the Gold Coast Hospital and Health Service Human Research Ethics Committee (HREC/2019/QGC/51088) and the Griffith University Human Research Ethics Committee (GU Ref No: 2019/685). The trial was registered with the Australian and New Zealand Clinical Trial Registry on 22 May 2019 (ACTRESN12619000763145). It had Queensland Civil and Administrative Tribunal approval for the recruitment of participants who may have impaired decision-making (e.g., cognitively impaired), with consent obtained from their legal guardian/person responsible (i.e., proxy). Informed consent was obtained from all patient participants or their proxies in the clinical trial. The first participant was recruited 10 July 2020.

5. Results

5.1. Recruitment

Between 10 July 2020 to 30 June 2023, 13,545 participants in medical-surgical units were screened. Of these, 1121 met the study criteria and were invited to participate although, 14.5 % (n = 163) were excluded for various reasons (Fig. 1). The COVID-19 pandemic significantly impacted our study. Recruitment was repeatedly disrupted resulting in a significant shortfall in participant numbers. Additionally, pandemic-related reductions in hospital length of stay affected our primary outcome, as pressure injury was measured up to 14 days in hospital. Thus, our baseline assumptions for incidence were higher than what were observed, and the estimated effect size exceeded the actual effect. To address shorter length of stay and ensure at least one outcome assessment, eligibility criteria were modified from ≥36 h to ≥24 h. Intention-to-Treat analysis included all 958 participants (85.5 %) who consented and were randomised to either the intervention group (n = 478, 49.9 %), or the control group (n = 480, 50.1 %).

5.2. Participant characteristics

Baseline demographic and clinical characteristics were similar between intervention and control groups indicating good prognostic

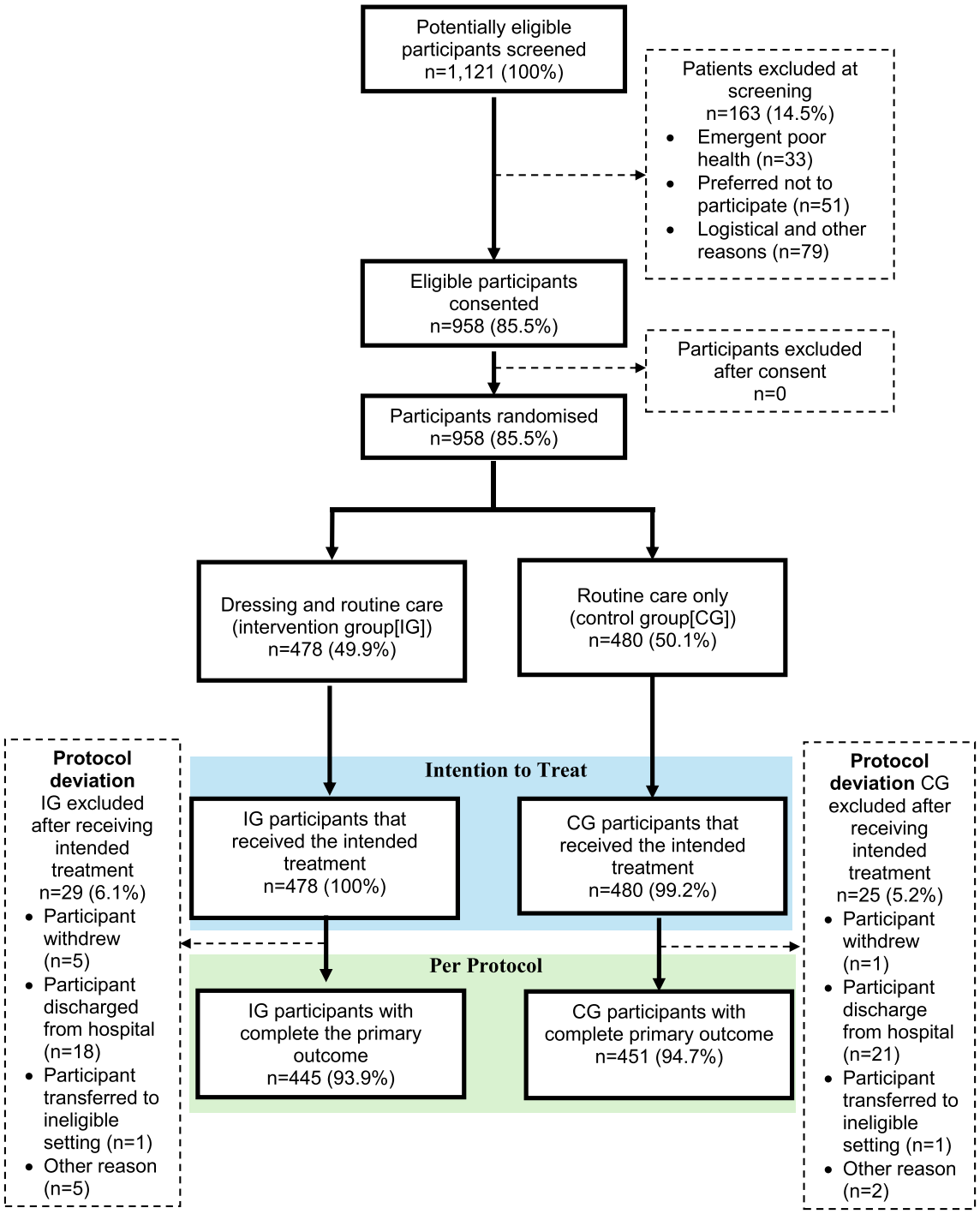


Fig. 1. EEPOC trial participant flow diagram.

balance (Table 2). The average age of participants was 65.8 years (SD 11.4; range 31.68 to 99.92). Most were males (n = 604, 63.0 %; intervention n = 296, 61.9 %; control n = 308, 64.2 %), independently mobile (n = 762; 79.5 %; intervention n = 384, 80.3 %; control n = 378, 78.8 %) and, recruited from surgical units (n = 610; 63.74 %; intervention 305, n = 64.8 %; control n = 305, 63.5 %).

5.3. Primary outcome

Eight participants in the intervention group (1.7 %), and six in the control group (1.3 %) developed sacral hospital-acquired pressure injuries, all classified as Stage I (refer to Table 3). The Relative Risk of pressure injury in the intervention group compared to the control group was 1.34 (95 % CI 0.47–3.83), though this difference was not statistically significant (p = 0.586). The Number Needed to Treat was −239 (95 % CI -51 -90), suggesting potential harm associated with the intervention; however, the wide CI indicated substantial uncertainty. Sensitivity analyses supported the robustness of these findings. In the best-case scenario, assuming all participants with missing primary outcome data did not develop pressure injuries, the Relative Risk for sacral hospital-acquired pressure injuries decreased slightly in both groups to 1.17 (95 % CI 0.76–1.81). A complete case analysis, including only participants with available primary outcome data reported a Relative Risk of 1.35 (95 % CI: 0.47–3.86), which was remarkably similar to our primary Intention-To-Treat analyses. Inter-rater reliability for the primary outcome assessment was high, with 98 % agreement and a Cohen's kappa of 0.978 (95 % CI: 0.96–0.99) indicating a high level of consistency between outcome assessors.

5.4. Secondary outcomes

There were non-significant differences in secondary outcomes between groups (refer to Table 4). Time to onset of sacral hospital-acquired pressure injury was slightly longer in the intervention group (median = 3.9, IQR = 1.9, 13.9), compared to the control group (median = 2.9, IQR = 1.1, 7.0), although this difference was not statistically significant (p = 0.383). Incidence of sacral hospital-acquired pressure injuries was 4.8/1000 trial days in the intervention group, versus 3.3/1000 trial days in the control group (Difference = 0.0015; 95 % CI 0.00683–0.00983, p value of the difference = 0.724). Similarly, incidence of sacral hospital-acquired pressure injury incidence per 1000 hospital stay days was slightly higher, but not statistically significant in the intervention group, 2.8 versus 1.9 in the control group (Difference = 0.001; 95 % CI 0.00543–0.00723, p value of the difference = 0.780).

Participants in the intervention group used a mean of 6.8 dressings (SD = 5.5). Skin reactions related to the dressing were reported in 46 participants (9.4 %), with discomfort (n = 29; 6.1 %), and itchiness (n = 14, 2.9 %) being the most frequently reported symptoms by patients. No deaths occurred during the study period. Fig. 2 illustrates time to sacral hospital-acquired pressure injuries. Among those who developed a pressure injury, the average time to onset in both groups was 13 days. The hazard ratio was 1.099 (95 % CI 0.385–3.137), indicating high uncertainty due to the low number of sacral hospital-acquired pressure injuries events.

5.5. Costs

Given there was no statistically significant difference in the cumulative incidence of sacral hospital-acquired pressure injury between the intervention and control groups, only the incremental cost (that is, the difference in the mean costs) was calculated. The incremental cost of the intervention compared with the control group was $99.90 (95 % CI $74.10–$125.60), indicating that the use of silicone foam dressings was associated with an additional cost of $99.90 per patient.

Table 2
Participant demographic and clinical characteristics (n = 958).

Characteristic	Intervention (n = 478)	Control (n = 480)	p-Value[a]
Age in years (mean, SD)	65.3 ± 11.9	66.3 ± 10.8	0.148
Male gender (n, column %)	296 (61.9 %)	308 (64.2 %)	0.472
Body Mass Index (kg/m^2) at baseline (mean, SD)	29.2 ± 6.9	29.3 ± 6.0	0.720
Comorbidities at baseline (n. column %)			
Cardiovascular disease	238 (49.8 %)	252 (52.5 %)	0.402
Diabetes mellitus	125 (26.2 %)	118 (24.6 %)	0.577
Respiratory disease	90 (18.8 %)	96 (20.0 %)	0.647
Heart failure	22 (4.6 %)	21 (4.4 %)	0.865
Malignancy/metastatic carcinoma	107 (22.4 %)	122 (25.4 %)	0.271
Skin disease (e.g., dermatitis, eczema)	3 (0.6 %)	7 (1.5 %)	0.206
Renal disease	77 (16.1 %)	95 (19.8 %)	0.138
Cerebral Vascular Accident	15 (3.1 %)	12 (2.5 %)	0.551
Obesity	82 (17.2 %)	87 (18.1 %)	0.694
Malnutrition	17 (3.6 %)	13 (2.7 %)	0.451
Type of admission (n, column %)			0.932
Medical	173 (36.2 %)	175 (36.5 %)	
Surgical	305 (63.8 %)	305 (63.5 %)	
Trial site (n, column %)			0.999
Site A	176 (36.7 %)	177 (36.9 %)	
Site B	200 (41.8 %)	201 (41.9 %)	
Site C	102 (21.3 %)	102 (21.3 %)	
Waterlow Score < 36-h after admission (n, column %)			0.360
At-risk (10–14)	195 (41.8 %)	219 (46.1 %)	
High risk (15–19)	181 (40.7 %)	156 (34.6 %)	
Very high risk (>20)	80 (18.0 %)	88 (19.5 %)	
Smoking status at baseline (n, column %)			0.430
Never smoked	258 (54.0 %)	260 (54.2 %)	
Current smoker	84 (17.6 %)	71 (14.8 %)	
Ex-smoker	136 (28.5 %)	149 (31.0 %)	
Current medications at baseline (n, column %)			
Cytotoxics	47 (9.8 %)	45 (9.4 %)	0.810
Steroids	59 (12.3 %)	71 (14.8 %)	0.269
Anti-inflammatories	41 (8.6 %)	48 (10.0 %)	0.448
Anti-coagulants	355 (74.3 %)	346 (72.1 %)	0.445
None of the above	71 (14.9 %)	64 (13.3 %)	0.499
Usual place of residence (n, column %)			0.294
Independent living	458 (96.0 %)	454 (94.6 %)	
Aged care, Helpers etc.	19 (3.9 %)	26 (5.3 %)	
Assistance to mobilise at baseline (n, column %)			
Assistance to get out of bed[b]	60 (12.6 %)	75 (15.6 %)	0.172
Assistance to walk	94 (19.7 %)	102 (21.3 %)	0.543
Independently mobile	384 (80.3 %)	378 (78.8 %)	0.543
PIP strategies at baseline (n, column %)			
Mobilisation/repositioning plan in place	38 (7.9 %)	29 (6.0 %)	0.247
Wedges	4 (0.8 %)	3 (0.6 %)	0.725
Heel/elbow booties	6 (1.3 %)	3 (0.6 %)	0.341
Pillows for heel elevation	19 (4.0 %)	17 (3.5 %)	0.724

(continued on next page)

Table 2 (*continued*)

Characteristic	Intervention (n = 478)	Control (n = 480)	p-Value[a]
Air mattress[c]	29 (6.1 %)	29 (6.0 %)	0.987
Nutrition care plan	99 (20.7 %)	104 (21 %)	0.718
Reposition strategies	96 (20.1 %)	100 (20.8 %)	0.774
Other[d]	5 (1.0 %)	2 (0.4 %)	0.286
None	279 (58.4 %)	285 (59.4 %)	0.752
Hospital stay and time in trial			
Length of hospital stay, days (median, IQR, 25:75 %)	5 (3, 8)	5 (3, 8)	0.558
Time in trial, days (median, IQR, 25:75 %)	3.0 (1.9, 5.3)	3.2 (1.9, 6.3)	0.049

PIP = pressure injury prevention, SD = standard deviation, PIP = pressure injury prevention, IQR = interquartile range.

[a] Means were compared using independent t-test, medians were compared using Mann–Whitney U test and categorical variables were compared between groups using Z test for proportions or Chi-square tests.

[b] Percentages do not tally to 100 %, as some participants required assistance to get out of bed and assistance to walk.

[c] As an alternative to standard foam mattresses which were used at all sites.

[d] Includes other special support surfaces, chair cushions and barrier creams.

6. Discussion

The aim of this trial was to evaluate the clinical and cost-effectiveness of prophylactic dressings in preventing sacral hospital-acquired pressure injuries among hospitalised at-risk medical and surgical patients. Intention-To-Treat analysis of 958 participants showed a slight increase in sacral hospital-acquired pressure injury incidence in the intervention group, however differences were not statistically significant, demonstrating inconclusive results relative to dressing effectiveness.

Despite our follow-up period being similar to Beeckman's trial, that recruited patients from intensive care and non-intensive care settings (Beeckman et al., 2021), it was significantly shorter than Hahnel (Hahnel et al., 2020) and Santamaria's (Santamaria et al., 2015) trials, both of which focused on intensive care populations. Despite these differences, the absence of effectiveness does not necessarily mean the absence of effect (Alderson, 2004). That is, while our results were unable to demonstrate group differences in hospital-acquired pressure injuries, we cannot conclude the dressing was ineffective (Gewandter et al., 2017), given the low incidence of hospital-acquired pressure injuries in both groups. Rather, there are several plausible explanations for our results.

Firstly, the EEPOC trial was not adequately powered to identify differences between groups. When a trial is under-powered, it limits the ability to conclude if the treatment is effective, as more events, such as sacral hospital-acquired pressure injuries, would be needed to manifest the treatment effect, if any. Our power calculation was based on a significantly higher incidence of hospital-acquired pressure injuries than what was observed. Actual incidence of hospital-acquired pressure injury was lower-than-expected, that meant our sample size lacked statistical power to identify any differences had they existed. Our inclusion criteria 'at risk of hospital-acquired pressure injuries' was defined in three ways, including patients with limited mobility. However, these broad definitions led to the recruitment of many independently mobile patients, demonstrating how eligibility criteria can be a factor in 'failed trials' (Fogel, 2018). In addition, had we not used the Waterlow Score to determine 'at-risk,' and only included patients with limited mobility, we may have seen different results. This could also explain why our findings contrasted with other European trials that reported reductions in sacral hospital-acquired pressure injuries using silicone foam boarder dressings (Beeckman et al., 2021; Hahnel et al., 2020). Notably, Beeckman (Beeckman et al., 2021), reported a significant reduction in Stage II pressure injury in patients when combining Mepilex or Allevyn dressings in their analysis (Relative Risk = 0.59, 95 % CI 0.35–0.98, p = 0.04). Similarly, in Hahnel's ICU-RCT (Hahnel et al., 2020), cumulative sacral pressure incidence of Stage II and above was 2.8 % in the intervention, and 10.5 % in the control group (p = 0.001), whereas we had no Stage II pressure injuries. More recently, a Cochrane

Table 4
Comparison of secondary outcomes between the intervention and control group based on complete case analyses (n = 898).

	Intervention group (n = 445)	Control group (n = 451)	P-value[a]
Time to sacral HAPI onset in days (median, IQR)	2.9 (1.1, 7.0)	3.9 (1.9, 13.9)	0.383
Sacral HAPI severity (n, column %)			
Stage I (non-blanchable erythema)	8 (1.8 %)	6 (1.3 %)	
Stage II (partial thickness skin loss)	0	0	
Stage III (full thickness skin loss)	0	0	
Stage IV (full thickness tissue loss)	0	0	
Unstageable (depth unknown)	0	0	
Suspected deep tissue injury	0	0	
Sacral HAPI incidence per 1000 trial bed days	4.8	3.3	0.724
Sacral HAPI incidence per 1000 admitted bed days	2.8	1.9	0.780

HAPI = hospital-acquired pressure Injury; IQR = interquartile-range.

[a] Statistical significance set as alpha < 0.05.

Table 3
Analyses of primary outcome for ITT population with missing values assumed to be no sacral HAPI events versus all missing outcome means having a sacral HAPI along with complete case analyses.

Primary outcome	All (%)	Intervention n/N (%)	Control n/N (%)	Difference cumulative incidence per 1000 patients (95 % CI)	RR (95 % CI)	P-value	NNT (95 % CI)
ITT with missing data on primary outcome (n = 62) assumed to be no sacral HAPI							
HAPI	14/958 (1.46 %)	8/478 (1.67 %)	6/480 (1.25 %)	4.2 (0.5 to 15)	1.34 (0.47 to 3.83)	0.586	−239 (harm) (−51 to 90)
ITT with missing data on primary outcome (n = 62) assumed to have developed a sacral HAPI							
HAPI	76/958 (7.93 %)	41/478 (8.58 %)	35/480 (7.29 %)	12.5 (4.6 to 27)	1.17 (0.76 to 1.81)	0.462	−78 (harm) (−21 to 47)
Complete case analyses with only those who had primary outcome recorded (n = 896)							
HAPI	14/896 (1.56 %)	8/445 (1.80 %)	6/451 (1.33 %)	4.5 (0.5 to 16)	1.35 (0.47 to 3.86)	0.574	−213 (harm) (−47 to 86)

ITT = intention-to-treat, RR = relative risk, NNT = number needed to treat, HAPI = hospital acquired pressure injury.

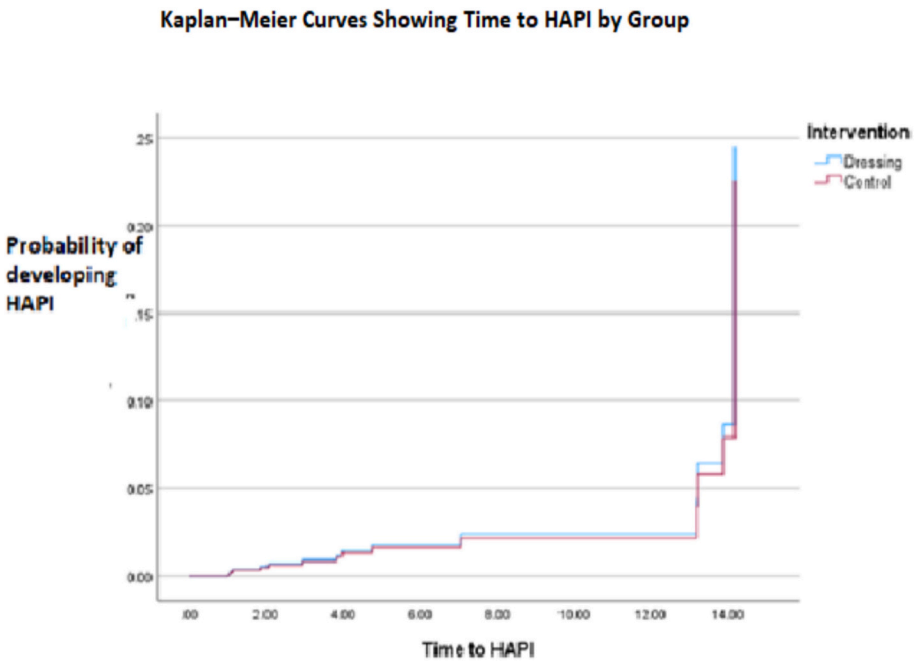


Fig. 2. Kaplan–Meier curves representing time to sacral hospital-acquired pressure injuries (event) for intervention and control group participants.

Review (Patton et al., 2024), highlighted the uncertainty of silicone foam dressings compared to no dressings for all stages of pressure injury. Yet, sub-analysis of four trials, reported silicone foam dressings may decrease sacral and heel pressure injury incidence with moderate certainty, downgraded twice for high risk or unclear risk of bias across multiple domains (Patton et al., 2024).

Secondly, our trial participants were generally younger and more mobile compared to patients in other dressing trials. Increasing age is a well-established risk factor for pressure injuries (Wang et al., 2024), and our acute medical-surgical cohort had a mean age of 66 years (intervention M 65.1. SD11.9; control M 66.3, SD10.8). This is comparable to the mean age of participants in Hahnel's (Hahnel et al., 2020) intensive care trial (M63.5 years,SD15.4), despite their cohort being at higher risk of pressure injury due to restricted mobility and higher levels of care. However Beeckman's RCT (Beeckman et al., 2021), included 1633 participants, with the majority (87.5 %) recruited in medical and surgical wards (61 %), with a mean age of 79.6 years (SD 12.2). In contrast, our study cohort was relatively mobile, with almost all participants able to reposition themselves independently in bed (intervention group n = 434, 98 %; control group n = 442, 98 %), and mobilise unaided (intervention group n = 316, 71 %; control group n = 316, 70 %). This likely contributed to the lower frequency of pressure injury prevention measures in our trial as shown in Table 2. For example, health record data identified the majority of participants used a standard foam mattress during their hospitalisation compared to participants who required an air mattress (intervention group n = 29, 6 %; control group n = 29, 6 %). Moreover, the high rate of elective surgeries at each site likely contributed to the higher proportion of mobile participants recruited for planned surgical admissions, which may explain why participants had no pressure injury prevention strategies in place (intervention group n = 279, 58 %; control group n-285, 59 %).

Thirdly, the amplified focus on patient safety during COVID-19 may have increased nurses' awareness of pressure injury risk assessment and prevention. For example, mandatory health service training in pressure injury prevention programs has been developed by the Australian Commission on Safety and Quality in Health Care (2021). These programs provide a range of evidence-based resources aimed at reducing high-priority hospital-acquired complications such as pressure injuries. Heightened surveillance may have therefore inadvertently contributed to the low incidence of pressure injuries in our trial, as nurses increased their pressure injury prevention practices.

Finally, contextual differences across countries and healthcare systems should be considered when comparing our results with other studies. While recent evidence from a Cochrane Review suggests silicone dressings may decrease sacral and heel pressure injury incidence, the overall certainty of evidence supporting dressings for pressure injury prevention remains low or very low; primarily due to high levels of bias in trial design, particularly sequence generation (Patton et al., 2024). Additionally, the use of prophylactic dressings appears to be more costly, given the incidence of pressure injuries did not differ significantly between groups. As outlined in the trial protocol (Walker et al., 2023), our process evaluation will enable us to better understand the health contexts in which the trial was implemented, and other related factors that may have influenced intervention outcomes.

6.1. *Strengths and limitations*

To date, the EEPOC trial is the largest multi-site superiority randomised trial in Australian medical-surgical cohorts within real-world pragmatic settings. The trial used robust implementation methods, including secure web-based randomisation that enabled treatment concealment and achieved good prognostic balance across a wide range of known potential confounders. Electronic case record forms replaced traditional paper-based data collection to allow simultaneous data entry and photograph editing with secure cloud-based storage. A key strength was the use of blinded outcome assessment, conducted by independent wound experts, that enabled accurate classification of sacral skin based on pressure injury stages. Research nurses received ongoing training on the protocol and standard operating procedures to reinforce consistency to ensure participants received identical verbal and written information about the trial. The definition of pressure injury was based on internationally recognised guidelines, developed collaboratively by advisory groups in Europe, the United States and the Pan Pacific region, that continue to provide the most recent evidence to inform best practice in pressure injury prevention (European Pressure Ulcer Advisory Panel et al., 2019). While our trial did not demonstrate statistically significant differences in sacral hospital-acquired pressure injury incidence between groups, its contribution in the field remains valuable. As such, our

findings will contribute to future meta-analyses and evidence syntheses, helping to refine clinical guidelines and inform targeted prevention strategies for at-risk patient populations.

However, several limitations should be acknowledged. Baseline data on pressure injury incidence prior to the intervention were not collected, which limited our ability to assess changes directly attributable to the dressing. Additionally, the generalisability of our findings may have been constrained by characteristics of the study population. Most participants in the trial were independently mobile and not critically ill, differing from intensive care populations where pressure injury risk is typically higher. As a result, the applicability of our findings to higher-risk groups remains uncertain.

The Waterlow Score may have contributed to the misclassification of patients' pressure injury risk. Developed in the 1980s without robust statistical validation, it provides an overall pressure injury risk score. Despite concerns about its predictive validity (Pancorbo-Hidalgo et al., 2006; Webster et al., 2010), the Waterlow Score is still widely used in Australian clinical practice and was the preferred PI risk assessment tool in two of the three study sites. As a result, it was adopted to assess eligibility in our trial, which may have resulted in patients being categorised as high risk, when in fact, they were at lower risk for developing pressure injury.

The involvement of research nurses collecting photographic data, along with nurses and patients being aware of the study, may have influenced behaviour, as participants in the intervention group were not blinded. Nurses and participants may therefore have altered their activities, by repositioning more frequently, to reduce pressure on the sacrum, potentially affecting trial outcomes.

Recruitment ended before we reached our target sample size due to staffing constraints and waning support for the trial at the study sites due to COVID-19. Yet, a large number of patients were screened for eligibility and all suitable individuals were invited to participate during the data collection period.

Limitations in collected data meant the economic evaluation only captured dressing costs and the time to administer the dressing. It did not account for downstream costs for managing pressure injuries or the impact of sacral hospital-acquired pressure injuries on patient's quality of life (Neyt et al., 2024). To fully capture the impact of pressure injuries on other health resource utilisation (e.g., hospital stay), and health related quality of life, an economic evaluation using decision modelling and multiple sources of evidence (e.g., a meta-analysis of clinical trials), is therefore warranted (Tuffaha et al., 2016).

7. Conclusions

This trial evaluated the clinical and cost-effectiveness of prophylactic silicone foam dressings for preventing sacral hospital-acquired pressure injuries in at-risk medical and surgical patients. The incidence of hospital-acquired sacral pressure injuries in the intervention was not statistically different to the control group, limiting our ability to draw definitive conclusions about the dressing's effectiveness in the hospital settings studied. Cost-effectiveness analysis also indicated the dressings were more costly, without demonstrating a difference in pressure injury rates between the groups.

Several factors may explain these findings, with the primary issue being the low incidence of hospital-acquired pressure injuries in both groups, which reduced statistical power to detect significant group differences. Despite this, the trial's methodological strengths, including blinded outcome assessment and the use of electronic data capture, enhanced its rigour. Contextual influences such as heightened patient safety surveillance during the trial period may have also influenced the results. Given previous evidence supporting silicone foam dressings for pressure injury prevention, further research is warranted. Future trials could focus on high risk populations or care settings, such as intensive care units, where the intervention is more likely to demonstrate clinical and economic benefit. Finally, collecting baseline pressure injury incidence data before the intervention would help identify vulnerable patient populations and enable more accurate evaluation of effectiveness by comparing pre- and post intervention incidence rates.

CRediT authorship contribution statement

Rachel M. Walker: Writing – review & editing, Writing – original draft, Validation, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Wendy Chaboyer:** Writing – review & editing, Methodology, Investigation. **Lukman Thalib:** Writing – review & editing, Validation, Methodology, Formal analysis, Data curation. **Sharon Latimer:** Writing – review & editing, Validation, Methodology, Investigation. **Haitham Tuffaha:** Writing – review & editing, Validation, Methodology. **Marie Cooke:** Writing – review & editing, Validation, Methodology. **Brigid M. Gillespie:** Writing – review & editing, Writing – original draft, Validation, Resources, Project administration, Methodology, Investigation, Formal analysis, Conceptualization.

Funding

The EEPOC trial was funded by the Australian Federal Government's National Health and Medical Research Council (NHMRC) Project Grant APP1158379. The NHMRC played no part in study design, data collection, management, analysis, and interpretation of data, writing of the report, or the decision to submit the report for publication.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

The EEPOC trial would not have been successful without the determined efforts of clinical trial coordinators Dr Ishtar Lockwood and Hui Min (Isabel) Wang, Monday to Friday research nurses Jodie Deakin, Jiayi Liu and Kunjalben Patel, outcome assessors and weekend research nurses. We also acknowledge nurse leaders at each site, particularly Rosalind Probert and Dr Jill Campbell as well as associates Dr Claudia Bull, Dr Kim Edmonds and Dr Mohammadreza Amiri.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnurstu.2025.105258.

Data availability

The data underlying this article cannot be shared publicly due to Human Research Ethics Committee conditions.

References

Alderson, P., 2004. Absence of evidence is not evidence of absence. Br. Med. J. 328, 476–477. https://doi.org/10.1136/Bmj.328.7438.476.

Australian Commission on Safety and Quality in Health Care, 2021. National Safety And Quality Health Service Standards, p. 2. Available: Https://Www.Safetyandquality.Gov.Au/Sites/Default/Files/2021-05/National_Safety_And_Quality_Health_Service_Nsqhs_Standards_Second_Edition_-_Updated_May_2021.Pdf.

Beeckman, D., Fourie, A., Raepsaet, C., Van Damme, N., Manderlier, B., De Meyer, D., Beele, H., Smet, S., Demarré, L., Vossaert, R., 2021. Silicone adhesive multilayer foam dressings as adjuvant prophylactic therapy to prevent hospital-acquired pressure ulcers: a pragmatic noncommercial multicentre randomized open-label parallel-group medical device trial. British Journal Of Dermatology 185, 52–61. https://doi.org/10.1111/Bjd.19689.

Demarré, L., Van Lancker, A., Van Hecke, A., Verhaeghe, S., Grypdonck, M., Lemey, J., Annemans, L., Beeckman, D., 2015. The cost of prevention and treatment of pressure

ulcers: a systematic review. Int. J. Nurs. Stud. 52, 1754–1774. https://doi.org/10.1016/J.Ijnurstu.2015.06.006.
El Genedy, M., Hahnel, E., Tomova-Simitchieva, T., Padula, W.V., Hauß, A., Löber, N., Blume-Peytavi, U., Kottner, J., 2020. Cost-effectiveness of multi-layered silicone foam dressings for prevention of sacral and heel pressure ulcers in high-risk intensive care unit patients: an economic analysis of a randomised controlled trial. Int. Wound J. 17, 1291–1299. https://doi.org/10.1111/Iwj.13390.
European Pressure Ulcer Advisory Panel, National Pressure Ulcer Advisory Panel, Pan Pacific Pressure Injury Alliance, 2019. Prevention and treatment of pressure ulcers/injuries: clinical practice guidelines. Available:, The International Guideline. https://internationalguideline.com/2019 (Online).
Fogel, D.B., 2018. Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: a review. Contemporary Clinical Trials Communications 11, 156–164. https://doi.org/10.1016/J.Conctc.2018.08.001.
Gewandter, J.S., Mcdermott, M.P., Kitt, R.A., Chaudari, J., Koch, J.G., Evans, S.R., Gross, R.A., Markman, J.D., Turk, D.C., Dworkin, R.H., 2017. Interpretation of CIs in clinical trials with non-significant results: systematic review and recommendations. Br. Med. J. 7, E017288. https://doi.org/10.1136/Bmjopen-2017-017288.
Hahnel, E., El Genedy, M., Tomova-Simitchieva, T., Hauß, A., Stroux, A., Lechner, A., Richter, C., Akdeniz, M., Blume-Peytavi, U., Löber, N., 2020. The effectiveness of two silicone dressings for sacral and heel pressure ulcer prevention compared with no dressings in high-risk intensive care unit patients: a randomized controlled parallel-group trial. Br. J. Dermatol. 183, 256–264. https://doi.org/10.1111/Bjd.18621.
Harris, P.A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., Conde, J.G., 2009. Research Electronic Data Capture (Redcap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J. Biomed. Inform. 42, 377–381. https://doi.org/10.1016/J.Jbi.2008.08.010.
Harris, P.A., Taylor, R., Minor, B.L., Elliott, V., Fernandez, M., O'neal, L., Mcleod, L., Delacqua, G., Delacqua, F., Kirby, J., 2019. The Redcap Consortium: building an international community of software platform partners. J. Biomed. Inform. 95, 103208. https://doi.org/10.1016/J.Jbi.2019.103208.
IBM Corp, 2020. IBM SPSS Statistics for Windows (Version 30.0) (Computer Software, Armonk, New York).
Li, Z., Lin, F., Thalib, L., Chaboyer, W., 2020. Global prevalence and incidence of pressure injuries in hospitalised adult patients: a systematic review and meta-analysis. Int. J. Nurs. Stud. 105, 103546. https://doi.org/10.1016/J.Ijnurstu.2020.103546.
Lovegrove, J., Fulbrook, P., Miles, S., Steele, M., 2022. Effectiveness of interventions to prevent pressure injury in adults admitted to intensive care settings: a systematic review and meta-analysis of randomised controlled trials. Aust. Crit. Care 35, 186–203. https://doi.org/10.1016/J.Aucc.2021.04.007.
Marshall, C., Shore, J., Arber, M., Cikalo, M., Oladapo, T., Peel, A., Mccool, R., Jenks, M., 2019. Mepilex border sacrum and heel dressings for the prevention of pressure ulcers: a NICE medical technology guidance. Appl. Health Econ. Health Policy 17, 453–465. https://doi.org/10.1007/S40258-019-00465-8.
Mölnlycke Health Care, 2019a. Mepilex® border sacrum product application guide. In: Ephamplet. Mölnlycke, Göteborg, Sweden. Available: https://www.molnlycke.com.au/products-solutions/mepilex-border-sacrum/.
Mölnlycke Health Care, 2019b. Mepilex® border self adherent soft silicone multi-layer foam dressing. In: Ephamplet. Mölnlycke, Göteborg, Sweden. Available: https://www.molnlycke.com.au/products-solutions/mepilex-border-sacrum/.
National Health and Medical Research Council, 2016. Safety monitoring and reporting in clinical trials involving therapeutic goods. Available: Https://Www.Nhmrc.Gov.Au/About-Us/Publications/Safety-Monitoring-And-Reporting-Clinical-Trials-Involving-Therapeutic-Goods.
National Health and Medical Research Council, 2018. Data Safety Monitoring Boards. Available: https://www.australianclinicaltrials.gov.au/sites/default/files/content/for%20researchers/data%20safety%20monitoring%20boards_1.pdf (Online, Canberra, Australia, Accessed).
Neyt, M., De Meester, C., Devriese, S., Marynen, L., Beeckman, D., 2024. Silicone adhesive multilayer foam dressings to prevent hospital-acquired sacrum pressure ulcers: an economic evaluation based on a publicly funded pragmatic randomized controlled trial linked with real-world data. J. Tissue Viability. https://doi.org/10.1016/J.Jtv.2024.08.011.
Nghiem, S., Campbell, J., Walker, R.M., Byrnes, J.C.W., 2022. Pressure injuries in Australian public hospitals: a cost of illness study. Int. J. Nurs. Stud. 130, 104191. https://doi.org/10.1016/J.Ijnurstu.2022.104191.
Orkin, A.M., Gill, P.J., Ghersi, D., Campbell, L., Sugarman, J., Emsley, R., Steg, P.G., Weijer, C., Simes, J., Rombey, T., Williams, H.C., Wittes, J., Moher, D., Richards, D. P., Kasamon, Y., Getz, K., Hopewell, S., Dickersin, K., Wu, T., Ayala, A.P., Schulz, K. F., Calleja, S., Boutron, I., Ross, J.S., Golub, R.M., Khan, K.M., Mulrow, C., Siegfried, N., Heber, J., Lee, N., Kearney, P.R., Wanyenze, R.K., Hróbjartsson, A., Williams, R., Bhandari, N., Jüni, P., Chan, A.W., 2021. Guidelines for reporting trial protocols and completed trials modified due to the Covid-19 pandemic and other extenuating circumstances: the Conserve 2021 statement. JAMA 326, 257–265. https://doi.org/10.1001/Jama.2021.9941.
Padula, W.V., Delarmente, B.A., 2019. The national cost of hospital-acquired pressure injuries in the United States. Int. Wound J. 16, 634–640. https://doi.org/10.1111/Iwj.13071.
Padula, W.V., Pronovost, P.J., Makic, M.B., Wald, H.L., Moran, D., Mishra, M.K., Meltzer, D.O., 2019. Value of hospital resources for effective pressure injury prevention: a cost-effectiveness analysis. BMJ Qual. Saf. 28, 132–141. https://doi.org/10.1136/Bmjqs-2017-007505.
Pancorbo-Hidalgo, P.L., Garcia-Fernandez, F.P., Lopez-Medina, I.M., Alvarez-Nieto, C., 2006. Risk assessment scales for pressure ulcer prevention: a systematic review. J. Adv. Nurs. 54, 94–110. https://doi.org/10.1111/J.1365-2648.2006.03794.X.
Patton, D., Moore, Z., Walker, R., Chaboyer, W., Latimer, S., Boland, F., Avsar, P., 2024. Dressings and topical agents for preventing pressure ulcers. Cochrane Database Syst. Rev. https://doi.org/10.1002/14651858.Cd009362.Pub3.
R Core Team, 2023. R: a language and environment for statistical computing. Available:, R Foundation For Statistical Computing. https://www.r-project.org/.
Rodgers, K., Sim, J., Clifton, R., 2021. Systematic review of pressure injury prevalence in Australian and New Zealand hospitals. Collegian (Royal College Of Nursing, Australia) 28, 310–323. https://doi.org/10.1016/J.Colegn.2020.08.012.
Santamaria, N., Gerdtz, M., Sage, S., Mccann, J., Freeman, A., Vassiliou, T., De Vincentis, S., Ng, A.W., Manias, E., Liu, W., Knott, J., 2015. A randomised controlled trial of the effectiveness of soft silicone multi-layered foam dressings in the prevention of sacral and heel pressure ulcers in trauma and critically ill patients: the Border Trial. Int. Wound J. 12, 302–308. https://doi.org/10.1111/Iwj.12101.
Santamaria, N., Liu, W., Gerdtz, M., Sage, S., Mccann, J., Freeman, A., Vassiliou, T., Devincentis, S., Ng, A.W., Manias, E., Knott, J., Liew, D., 2015b. The cost-benefit of using soft silicone multilayered foam dressings to prevent sacral and heel pressure ulcers in trauma and critically ill patients: a within-trial analysis of the Border Trial. Int. Wound J. 12, 344–350. https://doi.org/10.1111/Iwj.12160.
Tuffaha, H.W., Roberts, S., Chaboyer, W., Gordon, L.G., Scuffham, P.A., 2016. Cost-effectiveness analysis of nutritional support for the prevention of pressure ulcers in high-risk hospitalized patients. Adv. Skin Wound Care 29, 261–267. https://doi.org/10.1097/01.Asw.0000482992.87682.4c.
Walker, R., Huxley, L., Juttner, M., Burmeister, E., Scott, J., Aitken, L.M., 2017. A pilot randomized controlled trial using prophylactic dressings to minimize sacral pressure injuries in high-risk hospitalized patients. Clin. Nurs. Res. 26, 484–503. https://doi.org/10.1177/1054773816629689.
Walker, R.M., Chaboyer, W., Cooke, M., Whitty, J.A., Thalib, L., Lockwood, I., Latimer, S., Campbell, J., Probert, R., Gillespie, B.M., 2023. Effectiveness of prophylactic foam dressings in the prevention of sacral pressure injuries in at-risk hospitalised patients: the EEPOC trial. Trials 24, 70. https://doi.org/10.1186/S13063-022-06999-Y.
Wang, I., Walker, R.M., Gillespie, B.M., Scott, I., Sugathapala, R., Chaboyer, W., 2024. Risk factors predicting hospital-acquired pressure injury in adult patients: an overview of reviews. Int. J. Nurs. Stud. 150, 104642. https://doi.org/10.1016/J.Ijnurstu.2023.104642.
Waterlow, J., 1985. Pressure sores: a risk assessment card. Nurs. Times 81, 49–55.
Webster, J., Gavin, N., Nicholas, C., Coleman, K., Gardner, G., 2010. Validity of the Waterlow scale and risk of pressure injury in acute care. Br. J. Nurs. 19, S14. S16, S18 Passim. 10.12968/Bjon.2010.19.Sup2.47246.