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Effectiveness of prophylactic sacral protective dressings to prevent pressure injury: A systematic review and meta-analysis ☆

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ABSTRACT

Background: Pressure injury can cause significant patient physical pain, impact quality of life for individuals and their families, and increase hospital length of stay and healthcare costs. Within the hospital setting, it is considered to be largely preventable and regarded as an adverse event. In this context, prophylactic use of a protective sacral dressing to prevent pressure injury has been investigated by various researchers.
Objectives: Analyse the effectiveness of prophylactic sacral protective dressings to prevent pressure injury.
Design: Systematic review and meta-analysis of randomised controlled trials.
Data sources: Electronic database searches were undertaken in 2018 and 2019. Initial searches identified 557 articles. Following duplicate removal and screening, 49 full text articles were reviewed. Most were excluded, leaving six studies that met the criteria for full review.
Review methods: Two authors assessed study bias and extracted data, with a third reviewer as arbitrator. A random effects meta-analysis was conducted using sample sizes based on intention-to-treat analysis. Sub-group meta-analyses were conducted of three studies in the intensive care setting and four studies that used the same dressing.
Results: Overall, the six randomised controlled trials were judged to be of moderate quality. Due to visibility of the intervention, blinding was rare. Five studies were described as intention-to-treat; however two of these presented per-protocol analyses. All studies compared the intervention plus standard care to standard care. Five studies demonstrated statistically significant reduced pressure injury incidence in the intervention group. All studies were included in the meta-analysis (total $n = 1872$) and demonstrated homogeneity ($I^2 = 10\%$). Meta-analysis revealed an overall effect in favour of the intervention [risk ratio (RR) = 0.30, 95% CI 0.17–0.51] with a 95% prediction interval of 0.11–0.80. Sub-group analyses of intensive care studies and those using the same dressing demonstrated positive effects (RR = 0.17, 95% CI 0.06–0.49, $I^2 = 0\%$, and RR = 0.32, 95% CI 0.13–0.764, $I^2 = 31\%$; respectively).
Conclusions: The meta-analysis provides moderate evidence of the effectiveness of a prophylactic sacral dressing to prevent pressure injury, with an overall relative risk indicating that the intervention decreases pressure injury risk by 70%. Sub-group analysis of intensive care studies demonstrated a large relative risk reduction of 83% suggesting the dressing may be more effective in this high-risk group. The lower relative risk reduction of 68% found in four studies using the same dressing, in which there was moderate heterogeneity, indicates that further research is needed to clarify dressing choice.
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What is already known about the topic?

- Hospitalised patients are at risk of developing pressure injury, especially older patients and those with limited mobility.
- Despite significant improvements in pressure injury prevention, sacral pressure injury continues to occur in a significant proportion of hospitalised patients.

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What this paper adds

- The meta-analysis provides moderate evidence to indicate that prophylactic use of a protective sacral dressing may reduce the incidence of pressure injury by around two thirds, which is clinically significant.
- A preventative sacral dressing is more effective for intensive care patients.
- Further research is recommended to clarify which sacral dressing is most effective, and with larger sample sizes.

1. Introduction

Hospital-acquired pressure injury (PI) is considered an adverse event, requiring systematic preventive care (Australian Commission on Safety and Quality in Health Care, 2018). Also known as pressure sore or pressure ulcer, deep PI will cause pain and may impact quality of life (Jackson et al., 2017), resulting in increased hospital length of stay, and associated healthcare costs (Lim and Ang, 2017; Nguyen et al., 2015). Furthermore, PI is associated with increased within-hospital mortality (Padula and Pronovost, 2018), and even within 30 days following discharge (Lyder et al., 2012). Consequently, skin integrity maintenance is considered to be a benchmark of the quality of care provided (Sullivan and Woo, 2018), with its prevention guided by international prevention and treatment guidelines [National Pressure Ulcer Advisory Panel (NPUAP); European Pressure Ulcer Advisory Panel (EPUAP) and Pan-Pacific Pressure Injury Alliance (PPIA), 2014]. Despite the implication of the term 'pressure' injury, friction and shear forces are also involved in causing skin damage (NPUAP et al., 2014). Thus, preventative strategies should aim to reduce pressure, shear and friction forces, and should include the use of specialised support surfaces, repositioning and mobilisation strategies, avoidance of friction when repositioning, and management of nutrition and skin hydration (NPUAP et al., 2014).

2. Background

A relatively recent PI preventative intervention is the prophylactic use of a protective dressing, particularly on the sacrum and heels, which may consist of various layers of foam materials. Such dressings provide a flexible, smoothing and cushioning layer (Gefen et al., 2018) between the patient and the support surface in order to mitigate PI-causative forces (Padula, 2017). Currently, however, there are no national or international standards by which to evaluate such dressings (Gefen et al., 2018), and the effectiveness of protective sacral dressings is unclear. As well, there is some controversy concerning the extrapolation of evidence from studies of one dressing type to another (Gefen et al., 2018). Nonetheless, in the clinical setting, these dressings are commonly used prophylactically for patients at high or very high risk of PI, particularly critically ill patients (Santamaria and Santamaria, 2014), and are recommended for patient transport situations as a tangible reminder to healthcare professionals about PI prevention (Padula and Pronovost, 2018).

Several systematic reviews have investigated the effectiveness of prophylactically applied protective dressings. A 2013 Cochrane review of prophylactic application of soft silicone foam dressings noted reduced PI incidence across several studies, with evidence deemed inconclusive due to the low quality of the included studies (Moore and Webster, 2013). In an update to this review, the evidence was rated as very low certainty, and downgraded for very serious risk of bias and serious or very serious imprecision (Moore and Webster, 2018). Another systematic review (Clark et al., 2014) found no firm clinical evidence for any one type of protective dressing over another. These previous reviews have included studies with various experimental designs and studies that investigated dressings applied to any site. However, there is now a growing body of randomised controlled trials (RCT), so it is timely to conduct a superior systematic review, with a focus on the sacrum as the most common site for PI (Richard-Denis et al., 2017).

3. Objectives

The aim of this systematic review and meta-analysis was to investigate the strength of research evidence for the prophylactic use of sacral protective dressings to prevent PI, including RCT designs only.

4. Methods and analysis

4.1. Design

This systematic review and meta-analysis was conducted based on Cochrane guidelines (Higgins and Green, 2011). The protocol for this review was registered with PROSPERO International (ref: CRD42018091246; Fulbrook et al., 2018).

4.2. Eligibility criteria

This review sought to identify studies within the published peer-reviewed literature that focused on prevention of PI using protective sacral dressings, published in English between 2008 and 2019. Studies eligible for review included RCT only. Pilot and feasibility studies were excluded. The PICOS criteria were:

Population**:** Community- or hospital-based adult patients.

Intervention**:** Interventions reporting use of sacral dressings to prevent PI development.

Comparator**:** Comparisons between intervention (sacral protective dressing) and control group (no sacral protective dressing) or standard care or comparison group (alternative sacral dressing).

Outcomes: Incidence of sacral PI (no specific time limit).

Study design: Randomised controlled trials.

Limits: Peer-reviewed journals; publication range between 2008 and February 2019 written in English language.

4.3. Search strategy

The following sources were electronically searched: CINAHL; MEDLINE; Scopus; and Web of Science. A search strategy using all identified keywords (MESH terms and text words) with filters was applied for each specific database (see Table 1) and conducted in

Table 1
Search strategy (MEDLINE).

1	*Pressure Ulcer/(9093)
2	(pressure ulcer* or pressure injur* or bed sore* or bedsore* or decubitus ulcer* or decubitus injur*).ti,kw,kf. (5784)
3	1 or 2 (9974)
4	exp Bandages/(22641)
5	(bandage* or dressing*).ti,ab,kw,kf. (24510)
6	4 or 5 (37312)
7	Sacrum/ (8110)
8	lumbosacral region/or sacrococcygeal region/ (14729)
9	(sacrum or sacral or lumbosacral or sacrococcygeal).ti,ab,kw,kf. (29489)
10	or/7–9 (41108)
11	3 and 6 and 10 (97)
12	*Pressure Ulcer/pc [Prevention & Control] (3004)
13	4 and 12 (127)
14	limit 13 to systematic reviews (15)
15	2 and 5 (359)
16	(systematic review or metaanal* or meta-anal*).ti,ab,kw,kf. (190303)
17	15 and 16 (20)
18	11 or 14 or 17 (127)
19	limit 18 to yr="2008 -Current" (86)

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March 2018 and updated in February 2019. A hand search of the reference lists of the selected articles was also conducted.

4.4. Data extraction

Two reviewers screened and agreed on the included studies and assessed study bias, with a third reviewer as arbitrator. Quantitative data were extracted from the included studies by one reviewer then cross-checked by two reviewers for completeness and accuracy.

4.5. Risk of bias

Risk of bias assessment was undertaken using the Revised Cochrane risk-of-bias tool for randomised trials (Higgins et al., 2019). For the purpose of meta-analysis, excluded participants in two studies (Santamaria et al., 2013, 2018) were re-included, therefore risk of bias assessment was based on principles of ITT i.e. participants were analysed in the intervention groups to which they were assigned, regardless of the intervention they actually received or whether the interventions were implemented as intended, and regardless of participant adherence (Higgins et al., 2019, p. 23). Two reviewers assessed bias independently. Disagreements were resolved through discussion, with a third reviewer as arbitrator.

4.6. Meta-analysis

For the purpose of this meta-analysis the primary outcome measure was sacral PI incidence, expressed as a dichotomous variable. The end-point represented the number of participants that developed a PI. Analysis was undertaken using *Review Manager* software (RevMan Version 5.3; The Cochrane Collaboration, 2014), using a random effects model (Mantel–Haenzel) with effect described using risk ratio (RR) with 95% confidence intervals (CI). With the exception of the study by Lee et al. (2019), all authors in the studies included in this systematic review identified their RCT design as intention-to-treat (ITT). However, two studies presented per-protocol analyses (Santamaria et al., 2013, 2018). In one study (Aloweni et al., 2017), two interventions were compared to the control group. For this meta-analysis, only data from the sacral dressing (intervention) group ($n = 129$) and the control group ($n = 202$) were used. In another study (Santamaria et al., 2018), two independent interventions (prophylactic sacral and heel dressings) were implemented simultaneously. Only the sacral dressing and associated outcomes were considered for the purpose of this meta-analysis.

For the purpose of the main meta-analysis, ITT data were used i.e. statistical analysis was undertaken according to the group to which participants were randomised originally, regardless of treatment (if any) received (McCoy, 2017). The ITT approach is considered to be the de facto standard for analysis of clinical trials (Ranganathan et al., 2016). In the study by Lee et al. (2019) five participants were excluded post-randomisation, however it was unclear in the publication to which groups they were randomised initially. Following personal communication with the authors (Lee, 2019) it was clarified that 36 participants were randomised initially to the intervention group, with one lost to follow up, and 35 participants to the control group with four lost to follow up. These data were used to calculate ITT incidence for this study and for meta-analysis.

When an intervention is designed to reduce an outcome, such as PI incidence, ITT analysis provides a larger sample size, which affects the incidence proportion by reducing it, thus the estimate of treatment effect is generally conservative (Gupta, 2011) but it provides a better representation of reality. On the other hand, per-protocol analysis provides an estimate of the true efficacy of those that completed the treatment as planned (Ranganathan et al., 2016). Therefore, for comparison, a secondary meta-analysis of all studies was conducted using per-protocol samples.

Initially, ITT data were analysed as a whole. Sensitivity analyses were conducted to adjust for the possibility of a cluster effect in the study by Santamaria et al. (2018) and the high level of bias assessed in the study by Lee et al. (2019). Sub-group analyses were conducted of three studies in the intensive care setting (Kalowes et al., 2016; Lee et al., 2019; Santamaria et al., 2013) and four studies that implemented the same dressing (Aloweni et al., 2017; Kalowes et al., 2016; Santamaria et al., 2013, 2018).

To identify bias from differences between studies, the forest plot was visually inspected to observe the confidence interval (CI) overlap (Ried, 2006). Heterogeneity is reported using Chi square and the I^2 statistic (Higgins and Thompson, 2002). Pooled data were considered homogenous when $I^2 < 30\%$ (Higgins and Green, 2011). As a measure of effect, risk ratios (RR) were calculated for individual studies, as well as overall. The overall RR was used to calculate the relative risk reduction (RRR) of the intervention. Finally, the main meta-analysis was rerun using the *metan* command with the *rfdist* option (Stata software, version 15) to obtain 95% prediction intervals for the overall effect. These were calculated to consider the potential effect of the intervention when applied to a future trial in an individual setting (IntHout et al., 2016; Riley et al., 2011), based on the extent of heterogeneity. A funnel plot was also generated to investigate potential reporting bias of the studies (Sterne et al., 2011). Further tests for symmetry were not undertaken due to the small number of studies.

5. Results

5.1. Study selection

The Preferred Reporting Items for Systematic Review (PRISMA) selection process is presented in Fig. 1. A total of 557 studies was retrieved and 321 duplicates were excluded. Abstract screening excluded studies that were non-specific to sacral dressing intervention, non-randomised studies, pilot/feasibility studies, those addressing healing and treatment of already developed PI, protocols, reviews, and descriptive studies. Further exclusion involved articles that did not involve or implement any intervention. Six studies met the criteria for inclusion in the final review (see Table 2).

5.2. Study characteristics

Five studies included in this review were conducted in acute settings in various countries, including intensive care units in Australia (Santamaria et al., 2013), Korea (Lee et al., 2019), and the United States (Kalowes et al., 2016); general medical-surgical wards in Singapore (Aloweni et al., 2017); and Italian orthopaedic wards (Forni et al., 2018). One Australian study was conducted in a residential aged care (nursing home) setting (Santamaria et al., 2018). A total of 1872 participants were involved in all studies, with initially randomised sample sizes ranging from 71 to 440 (see Table 2). For the purpose of this review, the sample in the fatty acids oil intervention arm of the study by Aloweni et al. (2017) and data relating to the heel dressing in the study by Santamaria et al. (2018) were excluded from analyses.

The strategic intervention focus was on prevention or limitation of PI incidence through prophylactic use of sacral protective dressings. Three different dressings were studied. Four studies trialled the *Mepilex® Border Sacrum* five-layer foam dressing (Mölnlycke Health Care AB) (Aloweni et al., 2017; Kalowes et al., 2016; Santamaria et al., 2013, 2018); one study trialled the *ALLEVYN Life® Sacrum* multi-layered hydrocellular foam dressing (Smith

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Table 2
Characteristics of included studies.

Authors, year, country	Design, randomisation	Aim	Setting and sample	Intervention(s)	Comparator(s)	Follow-up period	Primary outcome measure and main results	Comments
Aloweni et al., 2017, Singapore	RCT ITT analysis. Computer generated table. Ratio 1:1:2.	To evaluate the incremental effectiveness of silicone foam dressing and fatty acids oil spray, in addition to standard care, to prevent sacral PI in high-risk patients.	Medical-surgical wards ($n=8$). Patients aged $\geq$ 21 years, Braden score $\leq$ 14. ITT $n=461$; PP $n=397$.	Group 1: Five-layer foam dressing (*Mepilex® Border Sacrum*) plus standard care (ITT $n=129$). Group 2: Fatty acids oil plus standard care (ITT $n=130$). Dressing changed every 7 days or when soiled.	Control group: standard care (ITT $n=202$). Standard care described fully.	Until discharge or for a maximum of 2 weeks.	Sacral PI incidence (stage 1) within 2 weeks of hospitalisation. No statistically significant differences in PI incidence between all 3 groups. Statistically significant reduced PI incidence in Braden score $\leq$ 12 sub-group compared to control sub-group (0% vs 4.8%, $p=.04$).	A smaller sample was recruited than indicated by *a priori* power analysis. Unclear if only stage 1 PI were included in results.
Forni et al., 2018, Italy	RCT (open-label) ITT analysis. Internet-based randomisation (blocks of 10). Ratio 1:1.	To test whether applying a multi-layer polyurethane foam dressing prevents the onset of sacral PI in elderly patients.	Orthopaedic wards ($n=5$), postoperative ICU ($n=1$). Patients with hip fracture, aged $\geq$ 65 years. ITT $n=359$.	Multi-layered hydrocellular foam dressing (*ALLEVYN Life® Sacrum*) plus standard care (ITT $n=177$). Dressing replaced when detached, wet or dirty (protocol)	Control group: standard care (ITT $n=182$). Standard care described fully.	Until hospital discharge or a maximum of 8 days (reported in protocol).	Sacral PI incidence (any stage) within 8 days of hospitalisation. Significantly fewer participants in the intervention group developed PI (4.5% vs 15.4%, $p=.001$).	Sample size adjusted after first 100 enrolments.
Kalowes et al., 2016, USA	RCT (open-label) ITT analysis. Computerised block randomisation (2, 4 or 6 patients). Ratio 1:1.	To determine the incidence of sacral PI in critically ill patients using a preventative 5-layered soft silicone foam dressing.	Intensive care units ($n=4$). Patients $\geq$ 18 years, Braden score $\leq$ 13. ITT $n=366$.	Five-layer foam dressing (*Mepilex® Border Sacrum*) plus standard care ITT $n=184$); control group. Dressing changed every 3 days or when soiled.	Control group: standard care (ITT $n=182$). Standard care described fully.	Until ICU discharge.	Sacral PI incidence (any stage). PI incidence was less in the intervention group than in the control group (0.6%, $n=1/184$ vs 3.8%, $n=7/182$). Incidence per 1000 patient days was significantly different (intervention group 0.7% vs control group 5.9%, $p=.01$).	The end-point for reporting PI incidence is unclear. Sacrum and coccyx sites not distinguished. 2 PI on the buttocks were included in the results.
Lee et al., 2019, Korea	RCT Randomisation ratio approximately 1:1	To determine whether the application of silicone adhesive dressings with standard preventative care would reduce the impairment of skin integrity.	Intensive care unit ($n=2$). Patients $\geq$ years, Braden score $<$ 18. Total $n=71$ ($n=5$ excluded; 1 from intervention group, 4 from control group).	Silicone adhesive dressing (*ALLEVYN Gentle Border®)* plus standard care ($n=35$). Dressing changed every 3 days.	Control group: standard care ($n=31$). Standard care not described.	Until ICU discharge.	Incidence of coccyx, sacrum or buttock PI. Significantly fewer PIs in the intervention group compared to the control group (2.9% vs 29.0%, respectively; $p=.006$).	Randomisation process unclear. Unclear in publication how many dressings were applied per subject; clarified via personal communication – one dressing per participant. Coccyx, sacrum and buttock sites included in results; specific PI sites not reported.

(*Continued on next page*)

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Table 2 (*Continued*).

Authors, year, country	Design, randomisation	Aim	Setting and sample	Intervention(s)	Comparator(s)	Follow-up period	Primary outcome measure and main results	Comments
Santamaria et al., 2013, Australia	RCT (open-label) ITT analysis. Computer-generated random numbers. Ratio 1:1.	To investigate the effectiveness of a multi-layered soft silicone foam dressing applied in the emergency department to prevent [sacral] PI in ICU patients.	Emergency department/ICU ($n=1$). Emergency patients admitted to ICU, aged $\geq$ 18 years. ITT $n=440$; PP $n=313$).	Five-layer foam dressing (*Mepilex® Border Sacrum*) [and *Mepilex® Heel*] dressing plus standard care (PP $n=161$). Dressing changed every 3 days or sooner if dislodged or soiled.	Control group: standard care (PP $n=152$). Standard care not described.	Duration of ICU stay.	Within-ICU sacral PI incidence. Fewer sacral PIs in the intervention group compared to the control group (1.2% vs 5.3%, respectively; $p=.05$).	ITT analysis stated but PP analysis reported.
Santamaria et al., 2018, Australia	RCT ITT analysis. Cluster randomisation by facility. Computer generated random numbers. Ratio 1:1.	To examine the clinical effectiveness of a multi-layered soft silicone foam dressing used in addition to usual care to prevent the development of [sacral] PI among aged care residents compared with usual care only.	Australian residential aged care facilities ($n=40$). Bed-bound, Braden score $\leq$ 12. ITT $n=305$; PP $n=188$. Intervention control group ($n=17$ excluded from analysis).	Five-layer foam dressing (*Mepilex® Border Sacrum*) [and *Mepilex® Heel*] dressing plus standard care (PP $n=138$). Dressing changed every 3 days or sooner if dislodged or soiled.	Control group: standard care (PP $n=150$). Standard care described partially.	4 weeks or until discharge/death.	Sacral PI within 4 weeks. Significantly fewer sacral PIs in the intervention group compared to the control group (1.5% vs 8.7.0%, respectively; $p=.007$).	ITT analysis stated but PP analysis reported.

ICU = intensive care unit, ITT = intention-to-treat, ns = not significant, PI = pressure injury, PP = per-protocol, RCT = randomised controlled trial.

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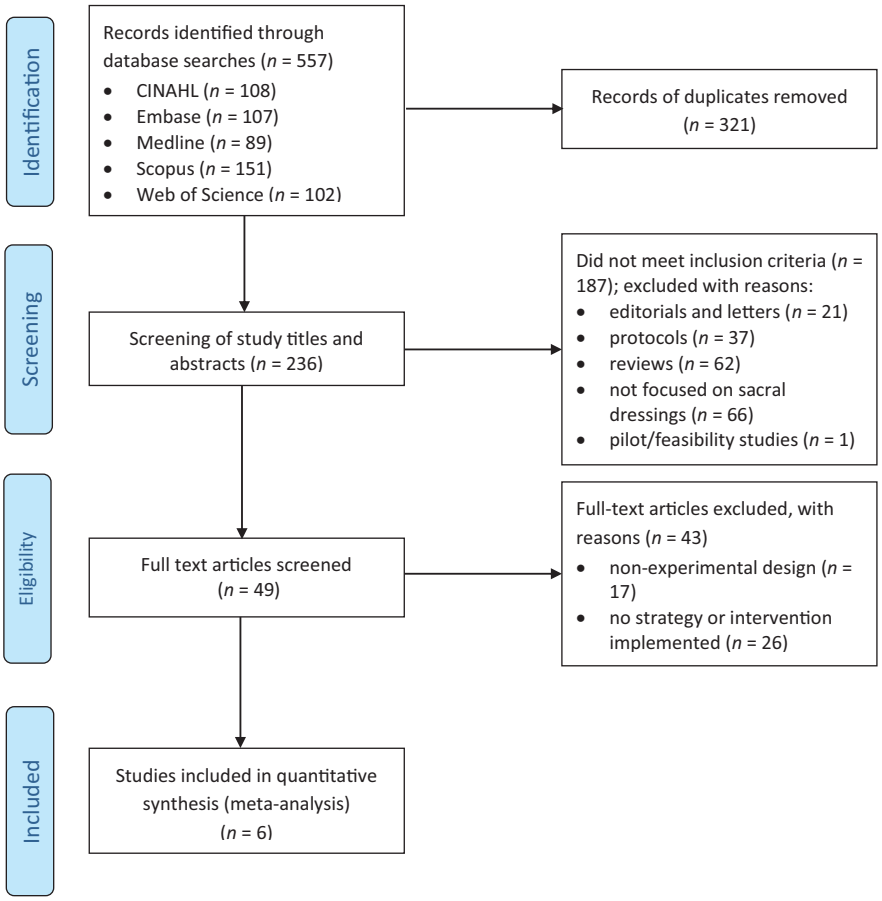


Fig. 1. PRISMA flow diagram: search and study selection.

Table 3
Risk of bias assessment.

Cochrane risk-of-bias domain		Aloweni et al. (2017)	Forni et al. (2018)	Kalowes et al. (2016)	Lee et al. (2019)	Santamaria et al. (2013)	Santamaria et al. (2018)
1	Randomisation process	+	+	+	−	+	+
2	Deviations from intended interventions	+	+	+	+	+	+
3	Missing outcome data	+	+	+	+	+	+
4	Measurement of the outcome	±	±	±	±	±	±
5	Selection of the reported result	±	+	±	±	+	±
Overall bias		±	±	±	−	±	±

+ = low risk, ± = some concerns, − = high risk.

and Nephew) (Forni et al., 2018), and another trialled *the AL-LEVYN Gentle Border®* multi-layered hydrocellular foam dressing coated with a silicone gel adhesive (Smith and Nephew) (Lee et al., 2019). In the study by Lee et al. (2019) the publication is unclear how many dressings were applied to each participant in the intervention group. This was clarified as one-per-patient via correspondence with the authors (Lee, 2019). All studies reported positive outcomes associated with the intervention.

5.3. Risk of bias within studies

Two studies referenced *a priori* protocols, which were accessed and reviewed as part of the bias assessment (Forni et al., 2018; Santamaria et al., 2013). A third study (Santamaria et al., 2018) reported protocol registration but it was unable to be sourced. All studies were assessed against ITT risk-of-bias criteria (Higgins et al., 2019).

The assessed bias of individual studies is shown in Table 3. All studies addressed the risk of bias through randomisation to ensure that treatment groups were similar at baseline (selection bias) with most specifying the randomisation procedures used. In the study by Lee et al. (2019), neither the method of randomisation nor allocation concealment was reported. Furthermore, a significantly larger proportion of participants in the intervention group were assessed to be at high risk of PI compared to the control group (69% vs 29%, respectively; $p = .002$), suggesting possible issues with the randomisation process. The study by Santamaria et al. (2018) was cluster-randomised (by facility) so concealment was not possible; however, randomisation was managed by a research team member blinded to the facilities, and facility managers were informed of their allocation after randomisation. In this case, lack of concealment was not considered to be an issue (Higgins and Green, 2011, ch. 16.3.2).

Several studies were described as 'open label' in either the publication or the protocol (Forni et al., 2018; Kalowes et al., 2016;

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Santamaria et al., 2013). None of the other studies addressed strategies to blind participants, those providing treatment, or assessors.

All studies addressed performance bias by using appropriate statistical analyses for their studies, although two studies that reported using an ITT design presented per-protocol analyses (Santamaria et al., 2013, 2018). In the study by Santamaria et al. (2013) a relatively large proportion of the initially randomised sample was lost to follow-up for various reasons, and did not have an outcome measure recorded, leading to a high risk of bias in the results. However, as suggested by Higgins et al. (2019), for the purpose of the meta-analysis the excluded participants in two studies (Santamaria et al., 2013, 2018) were "re-included" and risk of bias was assessed accordingly (see Table 3).

5.4. Risk of bias across studies

Overall, risk of bias across all studies demonstrated "some concerns" (see Table 3). However, one study was considered to have a high risk of bias in one domain (Lee et al., 2019). Due to the visibility of the dressings, blinding of participants and those implementing the dressing was not possible. Blinding of assessors was not attempted. The possibility that all assessors may have been influenced in their judgements by knowledge of the interventions means that there were some concerns about risk of bias in outcome measurement across all studies. Only two studies reported some form of *a priori* statistical analysis plan (Forni et al., 2018; Santamaria et al., 2013).

5.5. Study outcomes

Study outcomes are described using the values reported by the study authors. Where per-protocol analyses were reported, incidence was re-calculated using ITT samples (see Table 4). In three of the four studies that trialled the same dressing (*Mepilex® Border Sacrum*), the intervention group had improved outcomes which were statistically significant, including a reduction in PI incidence (Kalowes et al., 2016; Santamaria et al., 2013, 2018). However, in the other study (Aloweni et al., 2017), the reduction in PI incidence was statistically significant in a higher risk sub-group only (Braden score $\leq$ 12 only, $p = .04$). In the two studies that trialled the ALLEVYN Life® Sacrum dressing (Forni et al., 2018) and *ALLEVYN Gentle Border®* dressing (Lee et al., 2019), there were statistically significantly fewer sacral PI in the intervention groups ($p = .001$ and 0.006, respectively).

Three studies were conducted in intensive care settings (Kalowes et al., 2016; Lee et al., 2019; Santamaria et al., 2018). Initially randomised sample sizes ranged from 71 to 440. Both Kalowes et al. (2016) and Santamaria et al. (2013) described their studies as having an ITT design, but in only the former study was ITT analysis reported. There were some omissions regarding sample size reporting in the study by Lee et al. (2019) but these were clarified via personal communication with the authors.

In the United States, Kalowes et al. (2016) compared the difference in incidence rates of hospital-acquired PI in critically ill patients between those treated with standard care plus a sacral protective dressing (*Mepilex® Border Sacrum*) versus a standard care control group. There were significantly fewer PI within the intervention group compared to the control group ($n = 1/184$, 0.6% and $n = 7/182$, 3.8%; respectively). Incidence rates were not directly compared statistically, although incidence per 1000 patient days was reported and found to be significantly lower in the intervention group (0.7%) compared to the control group (5.9%, $p = .01$). Patients in the intervention group had an 88% reduced risk of hospital-acquired PI development [HR 0.12 (95% CI, 0.02–0.98), $p = .048$].

In a Korean study of intensive care patients (Lee et al., 2019), application of *ALLEVYN Gentle Border®* dressing was used for the intervention group, in addition to standard preventive care, while the control group received standard care only. In both groups, only Stage 1 PI were reported, with significantly fewer participants in the intervention group ($n = 1$, 2.9%) compared to the control group ($n = 9$, 29.0%) having a PI ($p = .006$). In this study, 71 participants were randomised initially, and five were lost to follow-up. Correspondence with the authors clarified that 36 participants were randomised initially to the intervention group and 35 to the control group. One participant in the intervention group and four from the control group were subsequently lost to follow up (Lee, 2019).

In an Australian study (Santamaria et al., 2013), a sacral protective dressing (*Mepilex® Border Sacrum*) was applied prophylactically in the intervention group. Both intervention and control groups received standard care. (In this study, a prophylactic heel dressing was also applied to the intervention group, but these results are not relevant to this review.) All participants were recruited initially in the emergency department (where the intervention was commenced) and subsequently transferred to intensive care. Although the authors described their study as having an ITT design, per-protocol results were reported. Pressure injuries specific to the sacral area were significantly fewer in the intervention group compared to the control group ($n = 2/161$, 1.2% vs $n = 8/152$, 5.3%, respectively; $p = .05$).

In another Australian study, Santamaria et al. (2018) conducted a cluster-randomised trial in which residential aged-care facilities were randomised 1:1 to intervention or control groups. Similarly to the study reported above (Santamaria et al., 2013), it was described as having an ITT design, but per-protocol results were reported. Of 150 participants randomised initially, 138 participants in the intervention group facilities received the sacral protective dressing (*Mepilex® Border Sacrum*) in addition to standard PI preventive care (according to international guidelines), whereas 150 participants ($n = 155$ randomised initially) in the control facilities received standard PI preventive care. Overall, the intervention group had significantly fewer sacral PI compared to the control group (2/138 vs 13/150; $p = .007$), representing a reported incidence of 1.5% and 8.7%, respectively. In both groups, half of the sacral PI were Stage 1 and half were Stage 2.

Aloweni et al. (2017) conducted an ITT study of Singaporean medical/surgical patients that had been admitted to hospital within the previous 48 hours and were at high risk of PI development (defined by a Braden score of $\leq$ 14). Participants were randomised to one of two intervention groups and one control group at a ratio of 1:1:2. Participants randomised to group 1 received a sacral protective dressing (*Mepilex® Border Sacrum*) and standard care ($n = 129$). Those in group 2 received fatty acids oil spray to the sacrum and standard care ($n = 130$), while group 3 received standard care only ($n = 202$). (Group 2 results were not considered relevant to this review and are not reported further.) Participants in the sacral dressing intervention group had a PI incidence of 3.9% ($n = 5$) compared to 5.0% ($n = 10$) in the control group; these two groups were not directly compared statistically. Of note, there was a 22% dropout rate (reasons not given) in the intervention group compared to 8% in the control group. Sub-group analysis of participants at greater risk of PI (defined as Braden score $\leq$ 12; $n = 143$) revealed a statistically significant lower incidence of PI in the intervention group (0/60, 0%) compared to the control group (4/83, 4.8%; $p = .04$).

An Italian ITT study by Forni et al. (2018) trialled the application of *ALLEVYN Life® Sacrum* in older patients (aged $\geq$ 65 years). The intervention group received a prophylactic sacral dressing in addition to standard PI preventative care, whereas the control group received standard care only. All participants were patients

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Table 4
Results of individual studies.

Author, year	Sample size	Model or test(s) used	Outcome: sacral PI incidence			Significance *p*	Effect size/risk
			Group		Incidence % (*n*)		
Aloweni et al., 2017	ITT $n=461$ (PP $n=397$).	• ITT analysis • Chi-square test • Fisher's exact test	ITT ($n=461$)	Intervention: silicone foam dressing ($n=129$)	3.9 (5)	.840	NA
				Control ($n=202$)	5.0 (10)		
				Intervention: fatty acids oil ($n=130$)	5.4 (7)		
			PP ($n=397$)	Intervention: silicone foam dressing ($n=100$)	5.0 (5)	.920	NA
				Control ($n=185$)	5.4 (10)		
				Intervention: fatty acids oil ($n=112$)	6.2 (7)		
			Braden score ≤ 12 (ITT $n=143$)	Intervention: silicone foam dressing (ITT $n=60$)	0 (0)	.040	NR
				Control (ITT $n=83$)	4.8 (4)		
			Braden score >12 (ITT $n=188$)	Intervention: silicone foam dressing (ITT $n=69$)	7.2 (5)	.054	NR
				Control (ITT $n=119$)	5.0 (6)		
Forni et al., 2018	ITT $n=359$	• ITT analysis • Fisher's exact test • ANOVA • Mann–Whitney *U* test • Pearson correlation • Logistic regression • Kaplan–Meier survival analysis • Log Rank test • Cox Regression analysis • Multivariate analysis	Intervention: multi-layer polyurethane foam dressing plus standard care (ITT $n=177$)		All sacral PI 4.5 (8)	.001	RR 0.29 (95% CI 0.14-0.61), Time-to-injury HR 4.4 (95% CI, 1.8-10.6; $p=.0018$)
			Control: standard care (ITT $n=182$)		All sacral PI 15.4 (28)		
			Intervention: multi-layer polyurethane foam dressing plus standard care (ITT $n=177$)		>stage 1 PI 3.4 (6)	.021	NR
			Control: standard care (ITT $n=182$)		>stage 1 PI 9.3 (17)		
Kalowes et al., 2016	ITT $n=366$	• ITT analysis • Chi-square test • Fisher exact test • *t* test • Mann–Whitney *U* test • Poisson regression • Time-to-injury survival analysis	Intervention: 5-layered soft silicone foam dressing plus standard care (ITT $n=184$)		[a].6 (1) (per 1000 patient days = 0.7)	NR (per 1000 patient days = 0.01)	RRR = 88%. Time-to-injury HR 0.12 (95% CI, 0.02-0.98; $p=.048$)
			Control: standard care (ITT $n=182$)		[a]3.8 (7) (per 1000 patient days = 5.9)		
Lee et al., 2019	ITT $n=71$ (PP $n=66$)	• Chi-square test • Fisher exact test • *t* test	Intervention: silicone adhesive dressing (ITT $n=36$; PP $n=35$)		[a]ITT: 2.8 (1) PP: 2.9 (1)	.006 (PP)	NR
			Control: standard care (ITT $n=35$; PP $n=31$)		[a]ITT: 25.7 (9) PP: 29.0 (9)		
Santamaria et al., 2013	ITT $n=440$ (PP $n=313$)	• ITT analysis stated but PP analysis applied • Fisher's exact test • Survival analysis • Cox regression analysis	Intervention: 5-layered soft silicone foam dressing plus standard care (ITT $n=219$; PP $n=161$)		[a]ITT: 0.9 (2) PP: 1.2 (2)	.05 (PP)	NR
			Control: standard care (ITT $n=221$; PP $n=152$)		[a]ITT: 3.6 (8) PP: 5.3 (8)		
Santamaria et al., 2018	ITT $n=305$ (PP $n=288$)	• ITT analysis stated but PP analysis applied • Poisson regression analysis • Kaplan–Meier survival analysis	Intervention: 5-layered soft silicone foam dressing plus standard care (ITT $n=150$; PP $n=138$)		[a]ITT: 1.3 (2) PP: 1.5 (2)	.007 (PP)	NR
			Control: standard care (ITT $n=155$; PP $n=150$)		[a]ITT: 8.4 (13) PP: 8.7 (13)		
			Control: standard care (ITT $n=41$; PP $n=33$)		[a]ITT: 2.4 (1) PP: 3.0 (1)		

[a] Incidence values calculated, ANOVA = analysis of variance, CI = confidence interval, HR = hazard ratio, ITT = intention-to-treat, NA = not applicable, NR = not reported, PP = per-protocol, RR = relative risk, RRR = relative risk reduction.

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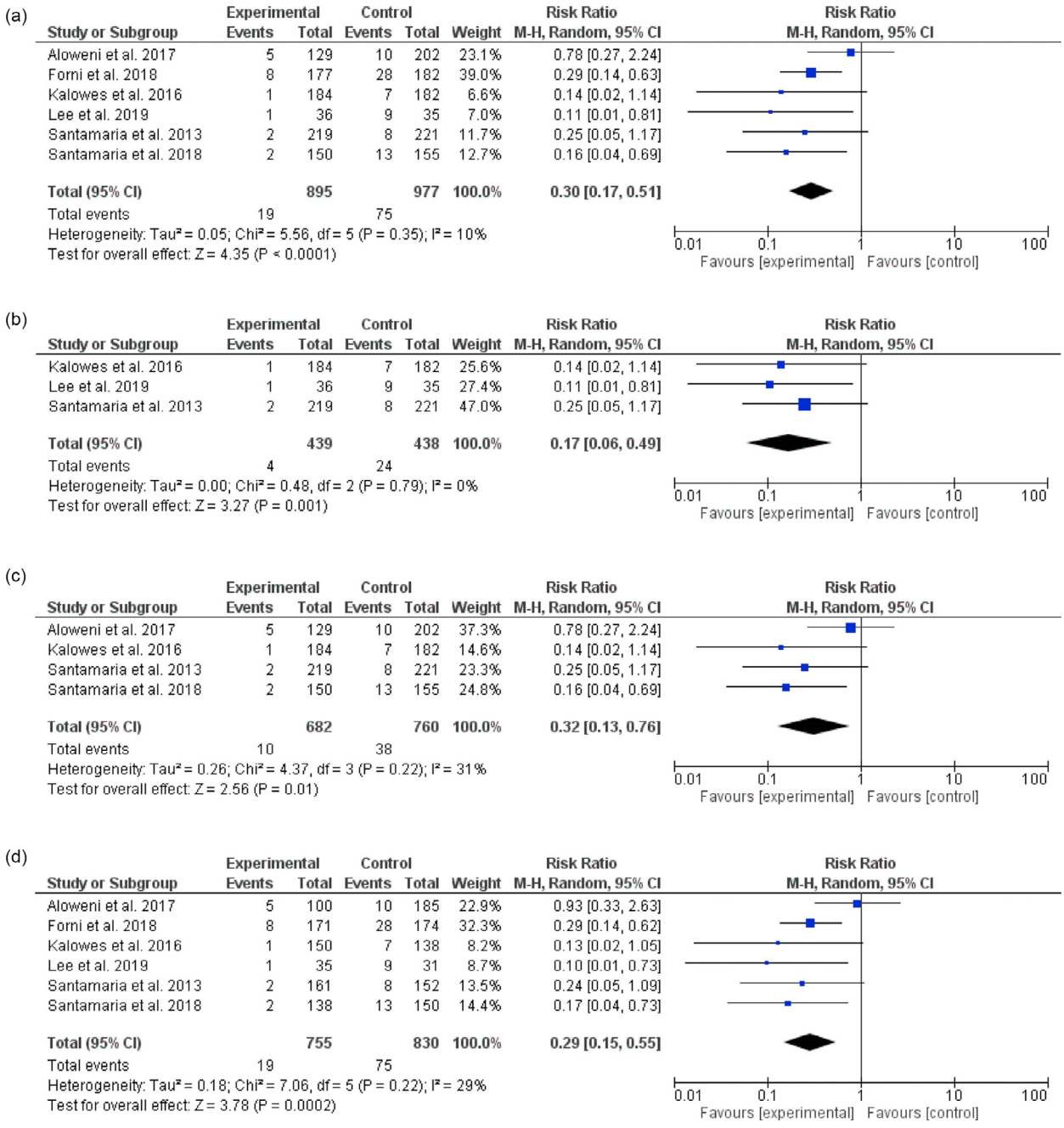


Fig. 2. (a) Forest plot: all studies ($n = 1872$). (b) Forest plot: intensive care studies ($n = 877$). (c) Forest plot: same dressing studies ($n = 1442$). (d) Forest plot: all studies per-protocol ($n = 1585$).

with a hip fracture. In both groups PI occurred, though there were significantly fewer in the intervention group ($n = 8$; 4.5%) compared to the control group ($n = 28$; 15.4%; $p = .001$). As well, the onset of PI in the intervention group (time to injury) occurred, on average, on the sixth day compared to the fourth day for the control group [hazard ratio (HR) 4.4; 95% CI, 1.8–10.6; $p = .001$].

5.6. Meta-analysis

All six studies that met the criteria for systematic review were included in the main meta-analysis. Regardless of whether or not the study was identified by its authors as having an ITT design, or whether per-protocol results were reported, initially randomised sample sizes were used in the meta-analysis. Across all studies, a total of 1872 participants (895 intervention and 977 controls) were randomised. Initial visual inspection of the forest plot revealed overlapping confidence intervals across all studies suggesting homogeneity (see Fig. 2). This was confirmed by the Chi squared test ($t = 5.56$, $df = 5$, $p = .35$) and $I^2 = 10\%$. The overall RR was 0.30 (95% CI 0.17–0.51) with a significant effect size ($Z = 4.35$, $p < .0001$). Based on assignment to intervention, with an absolute risk reduction (ARR) of 5.6%, the number needed to treat (NNT) to prevent one PI was calculated at 18.0. Calculation of the relative risk reduction (RRR) revealed that the intervention decreased the risk of sacral PI by 70%. The 95% prediction interval was estimated at 0.11–0.80. As this interval does not contain values above 1,

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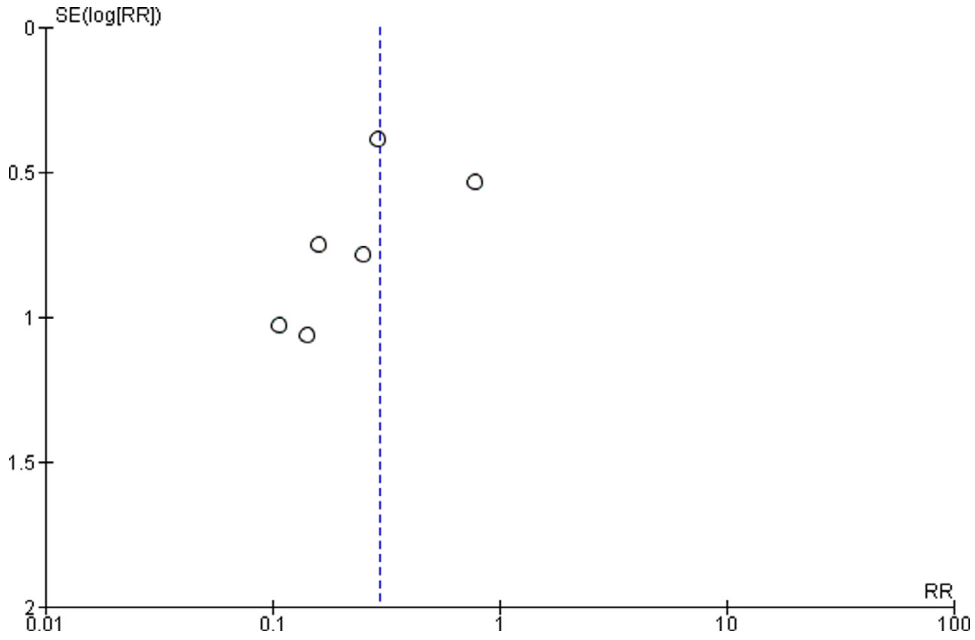


Fig. 3. Funnel plot: all studies.

the intervention should be beneficial in any setting. Inspection of the funnel plot revealed an inverted funnel-shaped symmetrical distribution, indicating that reporting bias is unlikely (see Fig. 3).

5.6.1. Sensitivity analyses

Sensitivity analyses were undertaken to determine the robustness of the outcomes reported above. In the first instance, a meta-analysis was performed of the five individually randomised studies only (Aloweni et al., 2017; Forni et al., 2018; Kalowes et al., 2016; Lee et al., 2019; Santamaria et al., 2013). All were also single-centre studies. Analysis revealed that heterogeneity (Chi squared test $t = 4.70$, $df = 4$, $p = .32$; $I^2 = 15\%$) and RR (0.32, 95% CI 0.18–0.59; effect size $Z = 3.63$, $p = .0003$) were similar to the values found for all studies. Secondly, a sensitivity analysis was undertaken to exclude the study by Lee et al. (2019), which was assessed to have a high level of bias. Again, similar values were found (Chi squared test $t = 4.440$, $df = 4$, $p = .35$; $I^2 = 10\%$ and RR = 0.32, 95% CI 0.18–0.56; effect size $Z = 3.97$, $p = .0001$). Finally, both Lee et al. (2019) and Santamaria et al. (2018) were excluded from the meta-analysis. Whist heterogeneity remained similar (Chi squared test $t = 43.38$, $df = 3$, $p = .34$; $I^2 = 11\%$), RR was slightly less favourable (RR = 0.36, 95% CI 0.20–0.66; effect size $Z = 3.30$, $p = .001$).

5.6.2. Sub-group meta-analyses

Intensive care studies. A sub-group meta-analysis was conducted of the three studies that recruited intensive care participants (Kalowes et al., 2016; Lee et al., 2019; Santamaria et al., 2013). A total of 877 participants (439 intervention and 438 controls) were randomised. Visual inspection of the forest plot revealed closely overlapping confidence intervals, indicating homogeneity (see Fig. 2(b)), which was confirmed by the Chi squared test ($t = 0.48$, $df = 2$, $p = .79$) and $I^2 = 0\%$. The calculated RR of 0.17 (95% CI 0.06–0.49) with a significant effect size ($Z = 3.27$, $p = .001$) revealed that the intervention decreased the risk of sacral PI development by 83% in this sub-group. Based on assignment to intervention, with an ARR of 4.6%, the NNT would be 21.9.

Same dressing studies. A sub-group meta-analysis was conducted of the four studies that implemented the *Mepilex® Border Sacrum* dressing (Aloweni et al., 2017; Kalowes et al., 2016; Santamaria et al., 2013, 2018). A total of 1442 participants (682 intervention and 760 controls) were randomised initially. Visual inspection of the forest plot revealed overlapping confidence intervals (see Fig. 2(c)). Although the Chi squared test was insignificant ($t = 4.37$, $df = 3$, $p = .22$) the I^2 index of 31% suggests moderate heterogeneity. The overall RR of 0.32 (95% CI 0.13–0.76) with a significant effect size ($Z = 2.56$, $p = .01$) revealed that the intervention decreased the risk of sacral PI development by 68% in this sub-group. Based on assignment to intervention, with an ARR of 3.5%, the NNT would be 28.3.

In contrast, in the two studies that used alternative dressings from the same manufacturer (Forni et al., 2018; Lee et al., 2019), based on assignment to intervention, with an ARR of 12.8%, the NNT would be 7.8. However, because the two dressings are not directly comparable, a sub-group meta-analysis was not conducted for these two studies.

5.6.3. Per-protocol meta-analysis

A secondary meta-analysis was undertaken using only data from participants that received the intervention or standard care and for whom an outcome was measured. A total of 1585 participants adhered to the interventions (755 intervention and 830 controls) and were included in the analysis. Visual inspection of the forest plot revealed overlapping confidence intervals (see Fig. 2(d)), however, although the Chi squared test was insignificant ($t = 7.06$, $df = 5$, $p = .22$), the I^2 index of 29% indicates some heterogeneity. The overall RR of 0.29 (95% CI 0.15–0.55) with a significant effect size ($Z = 3.78$, $p = .0002$) was similar to that found when all initially randomised (ITT) participants were included. Based on adherence to intervention, with an ARR of 6.5% the NNT would be 15.3.

6. Discussion

The aim of this review was to systematically examine published literature for evidence of the effectiveness of prophylactically applied sacral protective dressings to prevent PI development. Six RCTs were identified that met the inclusion criteria, with a total of 1872 participants across all studies; demonstrating a modest body of research in this area. Overall, the risk of bias across all studies was assessed as having some concerns. None of the studies were

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blinded. Whilst blinding of participants and those implementing the dressing would be very difficult, it may be possible to blind assessors. This was attempted in an Australian pilot study (Walker et al., 2017) using photographs. However, it was not well achieved because skin marks left by the sacral dressing enabled assessors to identify the intervention group of a significant proportion of participants.

All studies were included in the meta-analysis, which demonstrated a statistically significant overall reduction in PI associated with sacral dressing use (RR 0.30, $p = .0001$). This suggests that prophylactic use of a sacral dressing could correspond to a reduction in PI incidence by approximately two thirds, which would be clinically significant. However, a factor that can exaggerate the effect of the intervention is the content of standard care, as well as adherence to it. In this review, standard care was described fully in three studies (Aloweni et al., 2017; Forni et al., 2018; Kalowes et al., 2016) and partially in one (Santamaria et al., 2018) but descriptions of standard care varied across studies, and adherence was monitored in none. It is also important to note that a prophylactically applied protective dressing is only one intervention that may reduce PI in the clinical context, and should be considered to be part of a bundle of PI preventative care that is prescribed and applied according to each patient's assessed PI risk level (Lovegrove et al., 2018).

Five studies demonstrated a statistically significant reduction in PI development associated with use of a preventative sacral dressing (Forni et al., 2018; Kalowes et al., 2016; Lee et al., 2019; Santamaria et al., 2013, 2018). However, in the study by Aloweni et al. (2017) in a medical/surgical ward setting a statistically significant reduction in PI was shown in a higher risk sub-group only. The positive effect associated with dressing use was demonstrated predominantly in samples that were at higher risk of PI, with four studies including risk assessment cut-off scores within their inclusion criteria (Aloweni et al., 2017; Kalowes et al., 2016; Lee et al., 2019; Santamaria et al., 2018). Of these, three studies used the Braden scale to determine risk level (Kalowes et al., 2016; Lee et al., 2019; Santamaria et al., 2018), but all used different cut-off values. Further research is needed to determine which at-risk groups would benefit most from prophylactic dressing use.

Three different sacral dressings were trialled (*Mepilex® Border Sacrum; ALLEVYN Life® Sacrum; ALLEVYN Gentle Border®*) with four studies using *Mepilex® Border Sacrum* (Aloweni et al., 2017; Kalowes et al., 2016; Santamaria et al., 2013, 2018). Sub-group meta-analysis of these trials also demonstrated a statistically significant overall effect (RR = 0.32, $p = .01$) but with moderate heterogeneity. Individually, three of these studies demonstrated statistically significant PI incidence reduction in the intervention group compared to the control group (Kalowes et al., 2016; Santamaria et al., 2013; 2018); however, only Kalowes et al. (2016) presented ITT analyses. In a fourth study, which presented ITT results (Aloweni et al., 2017), a statistically significant reduction was demonstrated in a higher risk sub-group only. In the trials that used *ALLEVYN Life® Sacrum* (Forni et al., 2018) and *ALLEVYN Gentle Border®* (Lee et al., 2019) dressings, statistically significant reductions in PI incidence in the intervention groups were also reported. However, the latter study reported per-protocol analyses. A further finding by Forni et al. (2018) was that the protective sacral dressing delayed development of PI, with PI onset observed on the fourth day of admission in the control group and on the sixth day in the intervention group.

Including the results of this meta-analysis, as yet, there is insufficient evidence available to indicate superiority of one dressing product over another and further research is needed. However, a recent Australian cluster-controlled trial in an intensive care setting (Stanskiewicz et al., 2019) found no difference in the incidence of sacral PI when two dressings (*Mepilex® Border Sacrum; ALLEVYN Gentle Border®)* were compared 3-monthly over a period of 18 months. Caution is needed before recommending clinical use of a particular dressing as there has been recent controversy regarding the extrapolation of evidence from one type of dressing to another (Gefen et al., 2018).

Several studies were conducted with intensive care patients as participants (Kalowes et al., 2016; Lee et al., 2019; Santamaria et al., 2013). Sub-group meta-analysis of these studies revealed a statistically significant overall effect (RR = 0.17, $p = .001$) in a homogenous sample ($I^2 = 0\%$) giving a relative risk reduction of 83% in PI incidence associated with use of a prophylactic sacral dressing; equating to a NNT of 22 patients to avoid one PI. Given that, worldwide, intensive care patients have a high incidence of PI (Chaboyer et al., 2018; Lahmann et al., 2012) that is higher than other hospitalised patients (Coyer et al., 2017), routine use of such dressings would likely have a significant clinical impact. As well, the cost associated with treating PI and, in some countries, institutionally-incurred financial penalties may well justify the cost of purchasing and implementing sacral dressings for all intensive care patients.

Although it was not included in the purpose of this review, cost-benefit is an important factor to consider when determining the clinical value of preventative sacral dressings. One of the studies included in this review (Santamaria et al., 2013) was used in a later cost-benefit analysis (Santamaria et al., 2015). This was a within-trial analysis and only marginal costs associated with the intervention were calculated. The average net cost of the intervention was found to be lower than that of PI treatment costs. In another Australian study, in a hospital setting (Santamaria and Santamaria, 2014), the cost effectiveness of introducing a prophylactic dressing was estimated, concluding that an annual saving of about 55% could be achieved in the prevention of PI.

7. Limitations

Of the six studies included in this review, five reported using an ITT analysis. However, only three studies followed this through when reporting their results (Aloweni et al., 2017; Forni et al., 2018; Kalowes et al., 2016). Using ITT analysis ensures unbiased conclusions are drawn (McCoy, 2017) whereas per-protocol analysis violates the principle of randomisation, may lead to differential exclusion of participants with severe disease in the control group, can lead to reduced study power, and may provide an exaggerated treatment effect (Ranganathan et al., 2016). For these reasons, in this review, risk of bias assessment and meta-analysis were based on ITT data. Overall, the included studies were judged to be of moderate to good quality but there were some concerns regarding potential risk of bias regarding outcome measurement. In the main, this was due largely to the open-label nature of the trials. Due to the obvious visibility of the sacral dressing it was very difficult for assessors to be blinded to the intervention, and the possibility that this influenced their assessments cannot be excluded. It is hard to see how assessors could be blinded effectively for this type of study, since using a sham dressing would probably be unethical due to the potential for it to cause harm.

In terms of application to practice, the pooled effects of the meta-analysis should be interpreted with a degree of caution due to the mild heterogeneity of the studies. The true differences in effects between studies may be due to unexplained factors. However, the prediction interval does not contain values above 1, suggesting that the sacral dressing should be effective in most settings.

8. Conclusions

This systematic review and meta-analysis provides moderate quality evidence that prophylactic application of sacral protective

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dressings reduces the risk of PI incidence. However, further research is needed to determine which groups have the potential to benefit most from the use of such dressings before they can be recommended for routine use in clinical practice. Further research is also required to help clarify which dressing type is most beneficial. The review has revealed some aspects of bias in several studies, and there is potential to use more rigorous designs in future studies. In particular, *a priori* publication of a protocol including a statistical analysis plan, with ITT analysis is recommended.

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Declaration of Competing Interest

None.

CRediT authorship contribution statement

Paul Fulbrook: Conceptualization, Data curation, Formal analysis, Writing - original draft, Validation, Writing - review & editing. **Vainess Mbuzi:** Conceptualization, Data curation, Formal analysis, Writing - original draft, Validation, Writing - review & editing. **Sandra Miles:** Conceptualization, Data curation, Formal analysis, Writing - original draft, Validation, Writing - review & editing.

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