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**Foam dressings for treating pressure injuries in patients of any age in any care setting:
An abridged Cochrane Systematic Review**

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Abstract:

Background: Pressure injuries are localised areas of injury to the skin and/or underlying tissues.
Objectives: To assess foam dressings compared to other dressings in healing pressure injuries.
Design: Systematic review and meta-analysis
Data sources: The review team searched: the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials; Ovid MEDLINE; Ovid Embase; EBSCO CINAHL Plus and the NHS Economic Evaluation Database. Authors also searched clinical trials registries and scanned reference lists for reviews, meta-analyses and health technology reports. No restrictions were applied to language, publication date or study setting.
Study eligibility

criteria: Published or unpublished randomised controlled trials and cluster- randomised controlled trials that examined the clinical or cost effectiveness of foam dressings for healing pressure injuries. Participants: Patients of any age with a pressure injury of Stage II or above in any care setting. Interventions: Use of any foam wound dressing for treating Stage II pressure injuries or above. Study appraisal and synthesis methods: Full-text were assessed for eligibility using a priori criteria by two authors. Risk of bias was assessed using the Grading of Recommendations, Assessment, Development and Evaluation criteria, and Consolidated Health Economic Evaluation Reporting Standards. Risk ratio and mean difference with 95% confidence intervals were used to measure the effect. The review team used Review Manager 5 to enter narrative and qualitative data of included studies. Results: Authors found nine studies published between 1994 and 2016 involving 483 participants with pressure injuries at Stage II or above. Included studies compared foam dressings with other types of dressings. However, it was unclear if the foam dressing affected healing (RR 1.00, 95% CI 0.78 to 1.28), time to complete healing (MD 5.67 days 95% CI -4.03 to 15.37), adverse events (RR 0.33, 95% CI 0.01 to 7.65), or reduction in pressure injury size (MD 0.30 cm² per day, 95% CI - 0.15 to 0.75), as the certainty of the evidence was very low. Limitations: Using the Grading of Recommendations, Assessment, Development and Evaluation criteria, the certainty and completeness of evidence was low to very low, making it difficult to draw comparisons between foam and other dressings. Conclusions and implications: It is uncertain whether foam dressings are more clinically effective, more acceptable to users, or more cost effective compared to alternative dressings in treating pressure injuries.

Keywords:

Cost-effectiveness, foam dressings, meta-analysis, pressure injury, pressure ulcer, randomised controlled trial, systematic review

Introduction

Background

Pressure injuries also known as pressure ulcers, are a localised injury to the skin, underlying tissue, or both. Pressure injuries usually occur over a bony prominence, such as the sacrum (base of the spine), heel, elbow, hip - including the ischium, shoulder, spinous processes on vertebrae, ankle, toe, head or face (Lahmann, Halfens, & Dassen, 2006; Shanin, Dassen, & Halfens, 2008; Vanderwee, Clark, Dealey, Gunningberg, & Defloor, 2007). Pressure injuries result from unrelieved pressure, or pressure in combination with opposing forces - where body weight is pushing in one direction, and another part of the body, usually skin, in the opposite direction - or as a result of medical devices (National Pressure Ulcer Advisory

Panel, European Pressure Ulcer Advisory Panel and, & Pan Pacific Pressure Injury Alliance, 2016). Irreversible tissue damage may occur in vulnerable people after as little as 30 minutes of uninterrupted pressure (Kirman & Geibel, 2016).

Pressure injuries are an internationally recognised patient safety problem, estimated to affect 2.5 million people annually (House, Giles, & Whitcomb, 2011). The prevalence of pressure injuries depends on patient factors and treatment settings (Vanderwee et al., 2007; VanGilder, Amlung, Harrison, & Meyer, 2009). A multisite study undertaken in European acute care settings found a prevalence of 10.5% to 18.1% with individual countries reporting prevalence rates between 8.3% and 23% (Vanderwee et al., 2007). A survey in the United States (US) estimated pressure injury prevalence of up to 13% in acute care settings and 29% to 32% in longer term acute care settings (VanGilder et al., 2009). Notably, this survey excluded Stage I pressure injuries from prevalence calculations due to the substantial inaccuracies in their assessment (VanGilder et al., 2009). In Australia, pressure injury point prevalence studies conducted in Victoria across 136 metropolitan and rural health service sites between 2003 and 2006 showed a decrease in the prevalence of people with pressure injuries (stages I to IV) from 26.5% to 17.6%. However, the proportion of people with pressure injuries acquired in hospital remained unchanged (67.6% in 2003 versus 67.7% in 2006 (Quality Safety Branch., 2017).

Internationally, there has been substantial investment over recent decades in monitoring, preventing and treating pressure injury to reduce their incidence and associated costs. Consequently, there is increasing evidence of the economic burden of pressure injuries. Graves & Zheng (2014) estimated the direct health cost of pressure injuries in hospital and residential care settings in Australia for 2010-11 to be USD 1.65 billion (~Euro 1.42billion; USD1 ~ Euro0.86 ~ AUD1.34 ~ GBP0.75 at June 2018). Nguyen, Chaboyer, and Whitty (2015) estimated an annual treatment cost of AUD 983 million representing 1.9% of all public hospital expenditure, and an additional opportunity cost of AUD 819 million associated with 524,661 bed days lost, giving an overall cost of pressure injuries of AUD 1.8 billion (~USD 1.3 billion, Euro 1.2 billion) per annum. Dealey and colleagues (2012) estimated the approximate total cost of pressure injuries in the United Kingdom (UK) in 2011 as GBP 3.36 billion (~USD \$4.5 billion, Euro 3.8 billion) with an expected average cost of healing a Stage III or IV pressure injury of between GBP 9000 and GBP 14,000. In the USA,

total costs for pressure injury treatment were estimated at USD 9.1 to USD 11.6 billion (~ Euro 7.8 to 9.8 billion) in 2014 (U. S. Agency for Healthcare Research Quality, 2016).

Rationale

Pressure injuries are an internationally recognised patient safety problem and serve as a clinical indicator for the standard of care provided. As a result, there has been significant investment in strategies aimed at pressure injury prevention. However, pressure injuries remain prevalent in many care settings. Dressings are widely used to treat pressure injury and understanding the existing evidence base and questions around clinical and cost-effectiveness of different dressing types is important for effective decision making.

Objectives

The clinical question assessed by the review team focussed on: patients of any age and in any care setting; with a Stage II (or above) pressure injury; treated with any type of foam dressing to heal or reduce their injury in any time period. Hence the objectives of this review were to assess the clinical and cost effectiveness of foam wound dressings for healing pressure injuries in people with existing pressure injuries in any care setting.

Methods

Protocol and registration

The Cochrane Review on which this abridged version is based was published in 2017 (Walker, Gillespie, Thalib, Higgins, & Whitty, 2017)

Types of studies

The review team included all randomised controlled trials (RCTs) and cluster-RCTs irrespective of publication status or language. Review authors excluded non-randomised, clinical controlled trials and cross-over trials. The critical review of health economic evidence included, where possible, comparative full and partial economic evaluations conducted within the framework of eligible studies (that is., cost-effectiveness analyses, cost-utility analyses, cost-benefit analyses and cost analyses that included a dressing intervention and a relevant comparator), as well as eligible studies reporting more limited information, such as estimates of resource use or costs associated with dressings and a comparator.

Review authors only considered health economics studies conducted alongside clinical effectiveness studies that were included in this review.

Types of participants

The review authors included studies that recruited people of any age with a diagnosis of pressure injury of Stage II or above in any care setting using the National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, and Pan Pacific Pressure Injury Alliance International Pressure Ulcer Classification System Criteria (2016). The team also used alternative pressure injury classification systems, such as the Stirling (Reid & Morison, 1994), and Torrance classification systems (Harker, 2000), as well as earlier versions published by the National Pressure Ulcer Advisory Panel (1989), based on close alignment to contemporary National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, & Pan Pacific Pressure Injury Alliance criteria (2016). Review authors excluded studies involving participants with Stage I pressure injury because although 'at-risk' signs and symptoms of potential pressure injury such as non-blanchable redness, pain, hardness or softness, heat or coolness are present, the skin remains intact and therefore is unlikely to require a dressing (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, & Pan Pacific Pressure Injury Alliance, 2016).

Types of interventions

The primary intervention under investigation was the use of any foam wound dressing for treating Stage II pressure injuries or above. The review team included any trial in which the presence or absence of a foam dressing was the only systematic difference between treatment groups, and anticipated that comparisons would include:

- different types of foam dressings compared with each other;
- foam dressings compared with other dressings or active treatments, or both, and;
- foam dressings compared with no dressing treatment.

Review authors presented data for short-term (8 weeks or less) and medium follow-up (up to 24 weeks).

Primary outcomes for the review were:

- Incidence of healed pressure injuries (proportion of participants in whom a pressure injury healed);
- Time to complete healing;

- Adverse events (such as wound and/or systematic infection).

Secondary outcomes included reduction in pressure injury size, quality of life, patient satisfaction/acceptability, pressure injury recurrence (Stage II or above), or pain associated with a pressure injury and/or dressing removal. The review team considered pressure injury associated cost, utility scores representing health-related quality of life, incremental cost per event, or net health or monetary benefit, as economic outcomes.

Information sources and search strategy

The search strategy was guided by the Cochrane Wounds Review Group and used electronic databases and specialised registers to identify reports of relevant clinical trials and economic studies up to February 2017 including: the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 1) in the Cochrane Library; Ovid MEDLINE including In-Process & Other Non-Indexed Citations Ovid Embase; EBSCO CINAHL Plus, and; the NHS Economic Evaluation Database (NHS EED) in the Cochrane Library.

Review authors also searched the following clinical trials registries up to March 2017: ClinicalTrials.gov; World Health Organization (WHO) International and Clinical Trials Registry Platform and scanned reference lists of relevant included studies as well as reviews, meta-analyses and health technology reports to identify additional studies. There were no restrictions with respect to language, date of publication or study setting. The complete search strategy is detailed in Supplementary file 1.

Study selection

Two review authors independently assessed titles and abstracts of all citations retrieved by the search for relevance against the inclusion criteria. The review team retrieved full-text versions of potentially eligible studies and independently assessed the full papers for eligibility, with disagreements resolved through input by a third author (Higgins & Deeks, 2011). When the eligibility of a study was unclear, review authors attempted to contact study authors.

Data collection process and extraction

Two authors independently extracted and summarised data from eligible studies and cross-checked for accuracy and agreement. Data extraction included a comprehensive range of

variables that included study design integrity as well as economic estimates and specific items of interest. In cases where data were not clear or reported, review authors assumed that missing data were due to loss of follow-up (missing at random) and analysed the available information.

Risk of bias in individual studies

The review team linked Cochrane risk of bias ratings to the Grading of Recommendations, Assessment, Development and Evaluation assessment using an adaptation by Guyatt and colleagues (2011), to define the four risk of bias ratings from very high risk of bias to low risk of bias with an unclear option due to insufficient information (Westby, Dumville, Soares, Stubbs, & Norman, 2017).

Grading of Recommendations, Assessment, Development and Evaluation ratings started at 'high' as only RCTs and cluster-RCTs were included in this review. The review team downgraded studies according to five factors: 1) limitations in the design and implementation suggesting the high likelihood of bias; 2) indirectness of evidence (population, intervention, control, outcomes); 3) unexplained heterogeneity or inconsistency of results; 4) imprecision of results; 5) high probability of bias (Schünemann et al., 2011).

Summary measures

For measures of treatment effect, review authors calculated risk ratio (RR) with 95% confidence intervals (CI) for dichotomous outcomes and mean difference (MD) with 95% CIs for trials with continuous outcomes that used the same assessment scale. When trials used different assessment scales, review authors planned to use the standardised mean difference (SMD) with 95% CIs. Review authors planned to report time-to-event data (e.g. time-to-healing) as hazard ratio (HR) when possible (Deeks, Higgins, & Altman, 2011).

The review team presented a narrative description of the economic data.

Syntheses of results

The review authors analysed quantitative data using RevMan 5 (Nordic Cochrane Centre, 2014). For dichotomous outcomes, review authors calculated RR plus 95% CI and explored the robustness of meta-analyses using appropriate meta-analytical models based on the level of heterogeneity (Deeks et al., 2011).

Results of individual studies

The nine trials included 483 participants. The trials were small, and based on their reported data review authors calculated a median sample size of 29 and inter-quartile range (IQR) of 24. Although there was clinical and methodological heterogeneity, review authors undertook meta-analysis where there was similarity between dressings, follow-up periods and stages of pressure injury subgroups. Where there was no similarity, review authors summarised studies narratively.

Results

Study selection

The search generated 1,352 records. In total, the review team excluded 1,326 studies and assessed 26 as full text articles for eligibility. Refer to Figure 1 (Moher, 2009).

Figure 1 here

Study characteristics

Nine randomised controlled trials with a total of 483 participants met the inclusion criteria for this review but only eight were suitable for meta-analyses (Bale et al., 1997; Banks & Harding, 1994a; Meaume et al., 2003; Payne et al., 2009; Seeley, Jensen, & Hutcherson, 1999; Sopata, Lucak, & Ciupinska, 2002; Souliotis, Kalemikerakis, Saridi, Papageorgiou, & Kalokerinou, 2016; Thomas et al., 1997). The study by Bale and colleagues (1998), was not included in the meta-analyses as it used multiple subgroup analyses for which results may have been misleading. Supplementary file 2 outlines the methodology, participants and interventions of the included trials.

Health settings comprised community, aged and palliative-care facilities. Six included studies used an intention-to-treat approach (Polit & Gillespie, 2010), where there was limited or no participant loss following randomisation (Bale et al., 1998; Meaume et al., 2003; Payne et al., 2009; Seeley et al., 1999; Sopata et al., 2002; Thomas et al., 1997). The remaining studies (Banks & Harding, 1994a; Souliotis et al., 2016), used a per-protocol approach.

Participants were recruited from the UK (Bale et al., 1998; Banks & Harding, 1994a; Thomas et al., 1997), Greece (Souliotis et al., 2016), Belgium, France and Italy (Meaume et al., 2003); a Poland (Sopata et al., 2002), and the US (Payne et al., 2009; Seeley et al., 1999). Five centres referred to in Bale et al. (1997) were not specified although presumably they were in the UK.

Participants' mean age in eight trials was ≥ 73 years (Bale et al., 1998; Bale et al., 1997; Banks & Harding, 1994a; Meaume et al., 2003; Payne et al., 2009; Seeley et al., 1999; Souliotis et al., 2016; Thomas et al., 1997). The study by Sopata and colleagues (2002) was the exception with a mean aged of 59 years. The most predominant pressure injury site was the sacrum (Bale et al., 1997; Banks & Harding, 1994a; Meaume et al., 2003; Payne et al., 2009; Seeley et al., 1999; Souliotis et al., 2016; Thomas et al., 1997).

In the included studies, foam dressings consisted of hydrocellular foam (Bale et al., 1998; Seeley et al., 1999); hydropolymer foam (Meaume et al., 2003; Thomas et al., 1997); polyurethane foam (Bale et al., 1997; Banks & Harding, 1994a; Payne et al., 2009; Sopata et al., 2002); silicone foam (Meaume et al., 2003); as well as foam dressings with antimicrobial (silver and silver-sulfadiazine), and analgesic (ibuprofen) properties (Souliotis et al., 2016). Where possible, review authors considered foam dressings as a single group. Four studies compared a foam dressing with a hydrocolloid dressing (Bale et al., 1998; Bale et al., 1997; Seeley et al., 1999; Thomas et al., 1997), three compared foam dressing(s) with basic wound contact dressings (Banks & Harding, 1994a; Payne et al., 2009; Souliotis et al., 2016), one compared a foam dressing with a hydrogel dressing (Sopata et al., 2002) and one study compared two different types of foam dressing (Meaume et al., 2003). Table 1 summarises the outcomes reported in included trials.

Table 1 here

The primary outcome, incidence of healed pressure injuries was the most frequently reported followed by adverse events, and time to complete healing. For secondary outcomes, five trials reported reduction in pressure injury size, two reported patient satisfaction and pain. None of the included studies reported outcomes for quality of life or pressure injury recurrence.

Economic outcomes were reported in three trials.

Risk of bias within studies

Eight of the nine included studies were at high risk of bias for one or more domains (Figure 2). Overall, the quality of reporting was limited due to lack of clarity and detail. Five trials were assessed as having a high risk of bias for blinding of personnel, and seven trials as being high risk of bias for blinding of outcome assessment. Some studies had unclear or high risk of attrition bias due to their per-protocol approach, or reported incomplete outcome data with insufficient descriptions for follow-up and comparator data.

Figure 2 here

Synthesis of results

Included studies were synthesised according to outcome measures and assessed for risk of bias according to the dressings being compared.

Comparison 1: hydropolymer foam dressing compared with silicone foam dressing (short-term follow-up, 8 weeks or less)

This comparison included one trial with 38 participants (Meaume et al., 2003). It compared a foam dressing (hydropolymer foam) with another foam dressing (silicone foam). For primary outcome *incidence of healed pressure injuries*, it was unclear if alternative types of foam dressings affected the incidence of healed pressure injuries over a short-term follow-up period: RR 0.89 (95% CI 0.45 to 1.75). It was also unclear if the alternative foam dressings affected the risk of primary outcome *adverse events* in people with pressure injuries: RR 0.37 (95% CI 0.04 to 3.25). The certainty of evidence was very low due to high risk of bias (lack of blinding) and serious imprecision of results due to low number of events and wide confidence intervals. Meaume and colleagues (2003) did not report primary outcome: *time to complete healing*.

For secondary outcomes, *reduction in pressure injury size* was measured in cm² from tracings of each participant's wound at baseline and final assessment (Meaume et al., 2003). Wounds dressed with the silicone foam dressing had a mean reduction in wound area of 3.1 cm² compared with 3.3 cm² in the hydropolymer foam dressing. No standard deviation or standard error data were reported and so could not be analysed further. Evidence was limited due to lack of blinding, a small sample size and incomplete reporting. Meaume and colleagues (2003) did not report any other secondary outcomes, or any economic outcomes.

Comparison 2: foam (hydrocellular, hydropolymer and polyurethane dressings compared with hydrocolloid dressings (short-term follow-up, 8 weeks or less))

This comparison included four trials with 230 participants (Bale et al., 1998; Bale et al., 1997; Seeley et al., 1999; Thomas et al., 1997).

Only three trials reported *incidence of healed pressure injuries* (Bale et al., 1997; Seeley et al., 1999; Thomas et al., 1997). Follow-up times ranged from four weeks (Bale et al., 1997), six weeks (Thomas et al., 1997) and eight weeks (Seeley et al., 1999). It was unclear whether foam dressings affected the incidence of healed pressure injuries compared with hydrocolloid dressings over a short-term period: RR 0.85 (95% CI 0.54 to 1.34) (Refer Figure 3). None of the trials included in this comparison reported *time to complete healing* (Bale et al., 1997; Seeley et al., 1999; Thomas et al., 1997). Bale and colleagues (1998) did not report any primary outcomes.

Figure 3 here

Three studies reported dressing-related *adverse events* (Bale et al., 1997; Seeley et al., 1999; Thomas et al., 1997). Once again it was uncertain if foam dressings affected the risk of adverse events compared with hydrocolloid dressings RR 0.88 (95% CI 0.37 to 2.11) (Refer to Figure 4. The certainty of evidence was very low due to uncertain blinding and allocation concealment, small sample size, wide confidence intervals and incomplete reporting.

Figure 4 here

Bale et al., (1998) and Thomas et al., (1997) (n = 131) reported on secondary outcomes *reduction in pressure injury size*. However, data were not separated by wound type in both studies preventing further analysis. As such it was unclear if foam dressings led to reduction in pressure injury size compared to hydrocolloid dressings due to lack of blinding and allocation concealment, small sample size and incomplete reporting. Bale (1997) and Seeley (1999) did not report reduction in pressure injury size.

Seeley (1999) used a 4-point rating scale (0 = none, 1 = mild, 2 = moderate, 3 = severe) to assess secondary outcome pain. It was uncertain if the foam dressing affected wound pain (mean 0.15, SD 0.8, n = 20) compared with the hydrocolloid dressing (MD -0.32, 95% CI -

0.86 to 0.22). Thomas (1997) recorded pain and discomfort associated with the dressing (comfortable or otherwise and reported $p=0.023$) however did not report any further details.

Comparison 3: polyurethane foam dressing compared with hydrogel dressing (short-term follow-up, 8 weeks or less)

This trial included 34 participants and compared foam dressing with hydrogel dressing over a short-term follow-up (2002). It was uncertain whether treatment with a foam dressing affected the *incidence of healed pressure injuries* compared with a hydrogel dressing: RR 1.00 (95% CI 0.78 to 1.28). *Time to complete healing* was reported in days (mean \pm SD). Compared to the hydrogel dressings, foam dressings were associated with an increased number of treatment days MD 5.67 days, (95% CI -4.03 to 15.37), although this increase was not statistically significant. One *adverse event* was reported in the hydrogel dressing group (1/17) where the Stage II pressure injury increased in size. It was unclear if foam dressings affected the incidence of adverse events compared with hydrogel dressings: RR 0.33 (95% CI 0.01 to 7.65). The review team assessed the evidence as very low certainty due to lack of blinding, due small sample size and wide confidence intervals.

Sopata and colleagues (2002) reported only one secondary outcome - *reduction of pressure injury size* - for healed pressure injuries only ($n = 30$). The mean difference was 0.30 cm² per day (95% CI -0.15 to 0.75). It was unclear if foam or hydrogel dressings had any impact on the reduction of pressure injury size. While Sopata and colleagues (2002) compared wound-healing rates with Banks & Harding (1994a), no supporting data were presented. Evidence was downgraded due to lack of blinding, small sample size, wide confidence intervals and incomplete reporting.

Comparison 4: foam (polyurethane, silver and ibuprofen-releasing) foam dressings* compared with basic wound contact dressings (gauze, saline-soaked gauze, low-adherence dressing secured by a vapour-permeable film) (short to medium-term follow-up, 4 to 24 weeks)

Three trials (Banks & Harding, 1994a; Payne et al., 2009; Souliotis et al., 2016) comprising 181 participants compared foam dressings with basic wound contact dressings. Follow-up times ranged from short-term - 4 weeks - for Payne et al., (2009), medium term - 12 weeks - for Banks & Harding (1994a) and just over 17 weeks for Souliotis et al., (2016).

For short-term follow-up of primary outcomes, it was uncertain if there is a difference in the *incidence of healed pressure injury* for Payne and colleagues (2009) (n = 36) RR 1.33 (95% CI 0.62 to 2.88). For medium-term follow-up of *incidence of healed pressure injury*, it was unclear if foam dressings impacted on the incidence of healed pressure injury compared with the control dressing which consisted of a layer of knitted viscous multifilament yarns in Banks & Harding (1994a) (n = 50) RR 1.17 (95% CI 0.79 to 1.72).

Based on 95 patients, Souliotis and colleagues (2016) compared a foam dressing to basic dressing on time to complete wound healing. Based on their data, review authors estimated the foam dressings were significantly associated with a decreased time to complete healing with an average median time of 35.8 days (95% CI 14.8 to 56.8). Souliotis et al., (2016) reported 12 *adverse events* related to wound infections in the foam dressings group (n = 48), compared with 21 in the basic wound contact dressing group: RR 0.58 (95% CI 0.33 to 1.05). The review team assessed this as very low certainty evidence with a high risk of bias due to lack of blinding, small sample size, wide confidence intervals and incomplete reporting. Banks & Harding (1994a) and Payne et al., (2009) did not report *time to complete healing* or *adverse events*.

For secondary outcome *reduction in pressure injury size*, Payne et al., (2009) (n = 36) documented the size of participants' pressure injuries, but did not report the final assessment of wound size to enable comparison. Banks & Harding (1994a) and Souliotis et al., (2016) did not report reduction in pressure injury size. Banks & Harding (1994a) reported mean scores, for secondary outcome patient satisfaction/acceptability but did not provide any other information, such as standard deviation or variance data, from which review authors could make a meaningful interpretation. Payne (2009), Souliotis (2016) and colleagues did not report patient satisfaction / acceptability.

Banks & Harding (1994a) also used a patient acceptability questionnaire to record pain on dressing removal using a scale from 0 = painful to 10 = painless, but did not provide any other information, which review authors could make a meaningful interpretation. Payne et al., (2009), Souliotis et al., (2016) and Thomas et al., (1997) did not report pain, and none of the studies included in this comparison reported quality of life.

Economic outcomes

For economic outcomes, Bale (1998) compared material costs (of dressings and saline) for the participant subgroups using foam and hydrocolloid dressings. Costs were reported as GBP using a 1994-cost year. The total cost of treatment was GBP 844 (mean GBP 50 per participant, $n = 17$) for using the foam dressing compared to GBP 1142 (mean GBP 76 per participant, $n = 15$) for the hydrocolloid dressing (statistical significance of the difference not reported). The study authors did not draw conclusions regarding the cost-effectiveness of foam dressings for the management of PI. The Consolidated Health Economic Evaluation Reporting Standards checklist assessment indicated methods were inconsistently described or absent, and reporting of results incomplete.

Both Payne (2009), Souliotis (2016) and colleagues' reported the economic outcomes *cost and incremental cost per event*. Payne et al., (2009) ($n = 36$) analysed treatment costs (dressings, other materials, and nurse time) until pressure injury healing or 28 days, whichever occurred first. They reported costs as USD using a cost year of 2006/7. The polyurethane foam dressing was less costly per participant (USD 315) than saline-soaked gauze (USD 781), representing a mean saving of USD 466 per participant in the foam group ($P = 0.055$). The study authors reported the foam dressing to be dominant; that is, less costly and more effective in terms of number of participants healed by 28 days and pressure injury-free days per participant. They concluded that the foam dressing was cost-effective compared to saline-soaked gauze for the treatment of Stage II pressure injury. However, the study was not powered to detect differences in time to healing which was not observed to differ between groups at the 5% level.

Souliotis and colleagues (2016) reported total and per-participant treatment costs (including dressings, labour and materials) in the home setting until healing (medium-term follow-up, 8 to 24 weeks). The cost year was not stated. Treatment costs over the study period (to pressure injury healing) indicated foam dressings were less costly overall (EUR 63,543 for 47 participants) and per participant (EUR 1351) than plain gauze overall (EUR 186,638 for 48 participants) or per participant (EUR 3888). However, they did not report the statistical significance of this difference. Therefore, although the study authors also reported a shorter average healing time for the foam dressing than the gauze dressing group, it is not possible to draw strong conclusions around cost effectiveness.

For both Payne (2009) and Souliotis (2016), a lack of data prevented further analysis and review authors are uncertain about the relative impact of foam dressings on economic outcomes compared with basic wound contact dressings.

Banks & Harding (1994a) did not report economic outcomes.

Discussion

Summary of evidence

This review of nine trials with 483 participants includes all the currently available RCT evidence evaluating foam dressings to treat pressure injuries (stage II or above). The review team also sought economic outcomes, such as cost, utility scores and incremental costs.

Overall, the certainty of the evidence was poor. The review team judged Grading of Recommendations, Assessment, Development and Evaluation assessments as being of low to very low certainty for all included trials, due to serious risk of bias related to lack of blinding and allocation concealment, and imprecision due to small samples or lack of data, or both. Most evidence for all included trials was at high risk of bias due to limitations in design and implementation (related to lack of blinding or allocation concealment, or both) and serious imprecision of results (related to all or a combination of small sample size, wide confidence intervals and lack of reporting). Therefore, review authors are unable to draw reliable conclusions about clinical advantages, cost-effectiveness or patient satisfaction/acceptability between the different types of foam dressings or foam dressing compared with other dressings.

More specifically, review authors found uncertain evidence about whether foam dressings presented any substantial clinical advantages when compared with other dressings in terms of impact on incidence of pressure injury, increasing the time to healing of pressure injuries, preventing adverse events associated with pressure injuries, or reducing the size of pressure injury. There was also limited available evidence to base conclusions about the comparative impacts of foam dressings for pressure injuries on quality of life, pain, and satisfaction and acceptability for participants. Evidence that would have benefitted decision makers such as rigorous cost evaluations and longer-term cost-effectiveness evaluations and quality of life outcomes was incomplete or absent.

There was an overlap of investigators in the teams of four trials (Bale et al., 1998; Bale et al., 1997; Banks & Harding, 1994a; Thomas et al., 1997). These trials are dated by 20 or more years; hence, review authors were unable to contact the study authors with requests for additional information. Where review authors were able to contact study authors, they no longer had access to data or could not recall details of individual trials (Bale et al., 1998; Bale et al., 1997; Banks & Harding, 1994a; Sopata et al., 2002; Thomas et al., 1997). Apart from an included trial published in 2016, the date of publication for the remaining eight trials (1994 to 2009), may also explain the absence of a standardised approach - such as the Consolidated Standards of Reporting Trials statement (Schulz, Altman, Moher, & Consort Group, 2010) - to report methods and results. Consequently, there was a high degree of variability between studies in terms of dressings used, follow-up periods, interventions and outcomes.

There was methodological diversity due to: selection bias related to the generation of randomisation sequences (Bale et al., 1998; Payne et al., 2009; Sopata et al., 2002; Souliotis et al., 2016; Thomas et al., 1997); allocation concealment (Bale et al., 1998; Bale et al., 1997; Payne et al., 2009; Sopata et al., 2002; Souliotis et al., 2016); lack of blinding of participants and personnel (Meaume et al., 2003; Payne et al., 2009; Seeley et al., 1999; Sopata et al., 2002; Souliotis et al., 2016); outcome assessment (Bale et al., 1998; Meaume et al., 2003; Payne et al., 2009; Seeley et al., 1999; Souliotis et al., 2016; Thomas et al., 1997); and attrition bias (Bale et al., 1997). While the review team acknowledge that it is difficult to blind participants and personnel in studies where there is physical evidence of treatment allocation, none of the eight included studies demonstrated blind-to-intervention assessment. Other sources of bias included industry sponsorship, disclosed in three of the nine included trials (Bale et al., 1998; Bale et al., 1997; Payne et al., 2009).

Limitations

The review considered the evidence that it was possible to obtain and included studies that were not published in English-language journals. It is possible that there may be unpublished data that review authors have not been able to access, as well a potential for publication bias; however, this is very unlikely given the range of findings from this review. There were deviations from the protocol related to alternative pressure injury classification systems, namely the Stirling (Reid & Morison, 1994) and Torrance classification systems (Harker, 2000), and earlier versions published by the National Pressure Ulcer Advisory Panel

(NPUAP, 1989) that deviated from the contemporary International National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, & Pan Pacific Pressure Injury Alliance Pressure Ulcer Classification System Criteria (2016). The review team accepted these alternative classification systems on the condition that the definitions of stage/grade closely matched the contemporary International National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and, & Pan Pacific Pressure Injury Alliance Pressure Ulcer Classification System Criteria. Review authors also included studies that recruited participants with Stage II pressure injuries or above alongside patients with other types of chronic wounds, such as venous and arterial leg ulcers or diabetic foot ulcers, if the results for people with relevant pressure injuries were presented separately (or this data were available from study authors). Similarly, when a study included both Stage I and more advanced pressure injuries, review authors included it in the review only if data for Stage II and above were reported separately, or if the data were available on request from study authors. Review authors also included studies where pressure injuries from Stage II and above were reported collectively. It was not possible to evaluate the wider possibility of publication bias as there was variability of reporting between the included studies, and there were challenges in contacting or sourcing additional information from authors due to age of the studies. Because of this heterogeneity, review authors were only able to combine studies for comparison based on their shared outcomes.

Conclusions and implications for nursing

This comprehensive review of current evidence found no conclusive indication of differential effects of foam dressings compared with alternative wound treatments on the outcomes that matter for pressure injuries (including healing), or cost-effectiveness. The review team assessed all included trials (Bale et al., 1998; Bale et al., 1997; Banks & Harding, 1994a; Meaume et al., 2003; Payne et al., 2009; Seeley et al., 1999; Sopata et al., 2002; Souliotis et al., 2016; Thomas et al., 1997) as having low- to very low-quality evidence due to risk of bias stemming from unblinded outcome assessment, and occasional selective reporting; inconsistent reporting and; imprecision of results from small and underpowered trials, with relatively short follow-up times (mean 8 weeks).

There is a compelling need to evaluate the clinical and cost-effectiveness of foam dressings to treat pressure injuries. Currently there is no evidence of a difference in healing between pressure injuries dressed with foam dressings and those treated with the other dressings that

have been evaluated. In terms of dressing choice, any investment in future research must maximise its value in terms of clinical and cost-effectiveness to decision makers. Given the large number of dressing options, the design of future trials should be driven by high priority questions from patients and other decision makers. It is also important for researchers to ensure that the outcomes that are collected in research studies are those that matter to patients, carers and health professionals and that the follow-up times for trials are long enough to capture these. Where trials are conducted, good practice guidelines must be followed for their design, implementation and reporting. Further reviews are being conducted to synthesise evidence regarding the effect of other dressings on the treatment of pressure injuries. It would be useful to conduct further evidence synthesis (overviews of reviews, network meta-analyses or both) to aid decision making about the choice of dressings for pressure injuries across all dressing options.

What is already known about the topic?

- Pressure injuries can occur in people of all ages in all health settings.
- Pressure injuries are often painful, complex and costly to treat for health providers.
- There is a plethora of dressings available on the market, although little evidence about their effectiveness in treating pressure injuries.

What this paper adds

- Findings show certainty of evidence from reviewed studies is low to very low, with high risk of bias due to lack of blinding, small sample sizes and incomplete reporting.
- There is no clear evidence that foam dressings are any better or worse than other dressings for treating pressure injuries.
- There is a compelling need for high-quality clinical trials to evaluate their clinical and cost effectiveness.

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Figure Captions

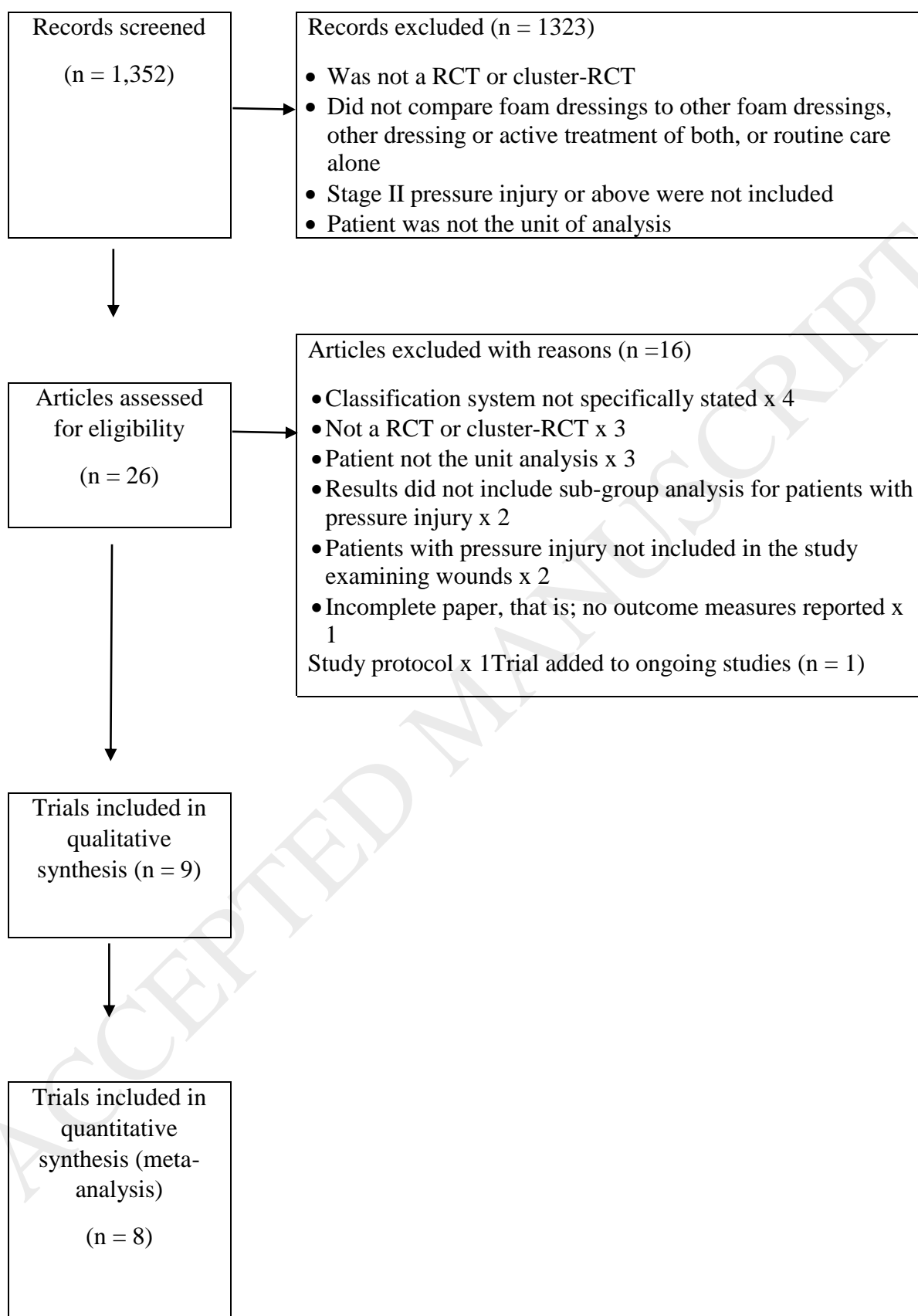


Figure 1: Study flow diagram

| | Random sequence generation (selection bias) | Allocation concealment (selection bias) | Blinding of participants and personnel (performance bias) | Blinding of outcome assessment (detection bias) | Incomplete outcome data (attrition bias) | Selective reporting (reporting bias) | Other bias |
|----------------|---|---|---|---|--|--------------------------------------|------------|
| Bale 1997 | ? | ? | ? | ? | - | + | + |
| Bale 1998 | ? | ? | ? | - | + | ? | - |
| Banks 1994a | + | + | ? | ? | ? | ? | - |
| Meaume 2003 | + | + | - | - | + | + | + |
| Payne 2009 | ? | - | - | - | + | ? | + |
| Seeley 1999 | + | + | - | - | + | + | ? |
| Sopata 2002 | ? | ? | ? | - | + | + | + |
| Souliotis 2016 | ? | + | - | - | ? | ? | + |
| Thomas 1997 | ? | - | - | - | + | ? | + |

*+ = low risk of bias, - = high risk of bias, ? = unclear risk of bias

Figure 2: Risk of bias summary for included studies using GRADE*

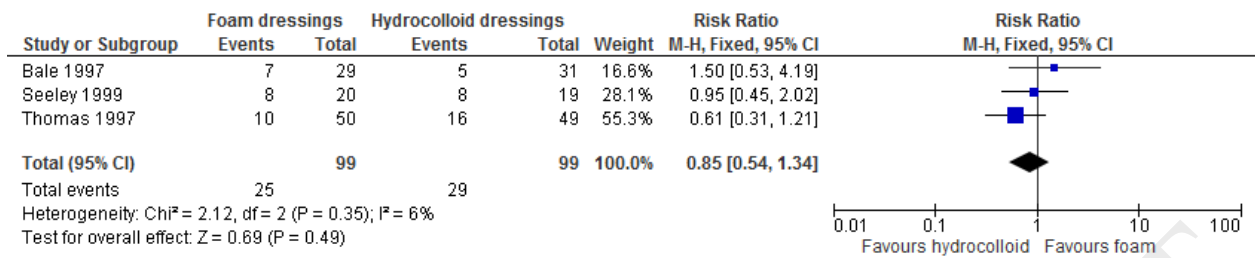


Figure 3: Incidence of healing, short-term follow-up

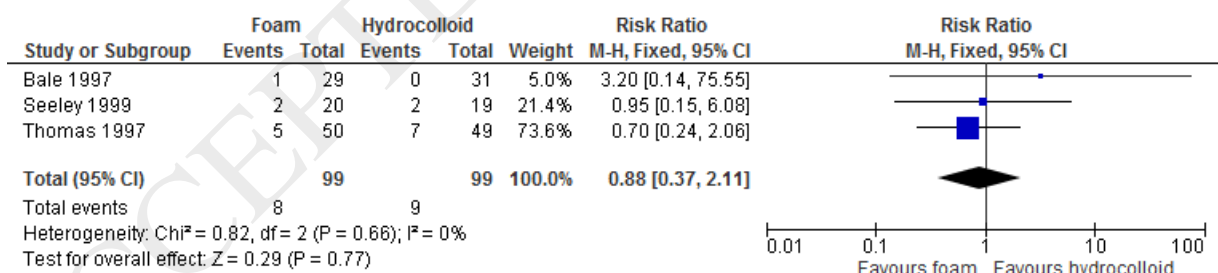


Figure 4: Adverse events, short-term follow-up

Table 1 : Summary of outcomes

| | <i>Number of participants included in quantitative analysis</i> | <i>Follow-up periods</i> | <i>Studies reporting quantitative outcomes</i> | <i>Studies reporting qualitative outcomes</i> |
|---------------------------------|---|---------------------------------|---|---|
| Primary outcome(s) | | | | |
| <i>Incidence of healed PI</i> | 170 | Short term (8 weeks or less) | Bale et al., 1997; Meaume et al., 2003; Payne et al., 2009; Seeley et al., 1999; Sopata et al., 2002*; Thomas et al., 1997 | |
| | 24 | Medium term (8 to 24 weeks) | Banks & Harding 1994a | |
| <i>Time to complete healing</i> | 17 | Short term | Sopata et al., 2002; | |
| | 48 | Medium term | Souliotis et al., 2016 | |
| <i>Adverse events</i> | 154 | Short term | Bale et al., 1997; Meaume et al., 2003; Seeley et al., 1999; Sopata et al., 2002; Thomas et al., 1997 | |
| | 48 | Medium term | Souliotis et al., 2016 | |
| Secondary outcomes | | | | |

| | | | | |
|--|--------------|-------------|--|---|
| <i>Reduction in ulcer size</i> | 15 | Short term | | Bale et al., 1988; Meaume et al., 2003; Payne et al., 2009; Sopata et al., 2002; Thomas et al., 1997 |
| <i>Quality of life (using any validated tool)</i> | Not reported | | | |
| <i>Patient satisfaction/acceptability (using any validated tool)</i> | | Short term | | Bale et al., 1998; |
| | | Medium term | | Banks & Harding 1994a |
| <i>PI recurrence (Stage II or above)</i> | Not reported | | | |
| <i>Pain associated with PI or dressing removal (using any validated tool)</i> | | Short term | | Seeley et al., 1999; Thomas et al., 1997 |
| | | Medium term | | Banks & Harding 1994a; |
| Economic outcomes | | | | |
| <i>PI associated costs, utility scores representing health-related quality of life, incremental cost per event</i> | | Short term | | Bale et al., 1998; Payne et al., 2009 |
| | | Medium term | | Souliotis et al., 2016 |

* In Sopata et al., (2002) one participant in the foam dressing group had two PI and one or more participants in the hydrogel dressing group had more than one wound. As we could not identify these patients in communication with the study author, we allocated one wound to each participant in the analysis.