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Risk assessment tools for the prevention of pressure ulcers

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Abstract

English

Background

Use of pressure ulcer risk assessment tools or scales is a component of the assessment process used to identify individuals at risk of developing a pressure ulcer. Indeed, use of a risk assessment tool is recommended by many international pressure ulcer prevention guidelines, however it is not known whether using a risk assessment tool makes a difference to patient outcomes. We conducted a review to provide a summary of the evidence pertaining to pressure ulcer risk assessment in clinical practice.

Objectives

To determine whether using structured, systematic pressure ulcer risk assessment tools, in any health care setting, reduces the incidence of pressure ulcers.

Search methods

In December 2013, for this second update, we searched the Cochrane Wounds Group Specialised Register; The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*); Ovid MEDLINE; Ovid EMBASE; and EBSCO CINAHL.

Selection criteria

Randomised controlled trials (RCTs) comparing the use of structured, systematic, pressure ulcer risk assessment tools with no structured pressure ulcer risk assessment, or with unaided clinical judgement, or RCTs comparing the use of different structured pressure ulcer risk assessment tools.

Data collection and analysis

Two review authors independently assessed titles and abstracts of the studies identified by the search strategy for eligibility, obtained full versions of potentially relevant studies and screened these against the inclusion criteria.

Main results

We included two studies in this review. One small, cluster randomised study found no statistical difference in pressure ulcer incidence in patients who were assessed by nurses using the Braden risk assessment tool (n=74) compared with patients assessed by nurses who had receiving training and then used unstructured risk assessment (n=76) (RR 0.97, 95% CI 0.53 to 1.77) and those patients assessed by nurses using unstructured risk assessment alone (n=106) (RR 1.43, 95% CI 0.77 to 2.68). The second study was a large single blind randomised controlled study which compared the effect of risk assessment on pressure ulcer incidence using the Waterlow risk assessment tool (n=411), the Ramstadius risk screening tool (n=420) and no formal risk assessment (n=420). There was no statistical difference in pressure ulcer incidence between the three groups (Waterlow 7.5% (n=31); Ramstadius 5.4% (n=22); clinical judgement 6.8% (n=28) (RR 1.10, 95% CI 0.68 to 1.81; Waterlow vs no formal risk assessment), (RR 0.79, 95% CI 0.46 to 1.35; Ramstadius vs no formal risk assessment), (RR 1.44, 95% CI 0.85 to 2.44; Waterlow vs Ramstadius).

Authors' conclusions

Two studies were identified which evaluated the effect of risk assessment on patient outcomes; In one study, there was no statistically significant difference in pressure ulcer incidence between people who were assessed using the Braden risk assessment tool compared with those receiving unstructured risk assessment. Methodological limitations of this study prevent firm conclusions being drawn. However, a further high quality RCT identified no statistical differences in pressure ulcer incidence when people were assessed using either the Waterlow risk assessment tool, the Ramstadius risk assessment tool, or using clinical judgement alone. There is no reliable evidence to suggest that the use of structured, systematic pressure ulcer risk assessment tools reduces the incidence of pressure ulcers.

Plain language summary

English

Risk assessment tools used for preventing pressure ulcers

Pressure ulcers (also known as bed sores, pressure sores and decubitus ulcers) are areas of localised injury to the skin, underlying tissue or both, usually over a bony prominence, as a result of pressure, or pressure in combination with shear (tissue distortion resulting from squeezing and stretching soft tissues between bony structures and the skin). Pressure ulcers mainly occur in people who have limited mobility, nerve damage or both. Pressure ulcer risk assessment is part of the process used to identify individuals at risk of developing a pressure ulcer. Risk assessments generally use checklists and their use is recommended by pressure ulcer prevention guidelines. This review found two studies that were eligible for inclusion. The first study found no difference in the number of new pressure ulcers that developed in individuals assessed using the Braden risk assessment compared with an unstructured risk assessment. However, there were methodological limitations with this study. The second study also found no differences in the number of new pressure ulcers that developed in individuals assessed using the Waterlow risk assessment tool, the Ramstadius risk assessment tool, or using clinical judgement alone. This study did not have methodological limitations. Therefore, to date, there are no studies to suggest that the use of risk assessment tools, reduces the number of new pressure ulcers that develop.

Background

Description of the condition

Pressure ulcers (also known as pressure injuries, bed sores, pressure sores and decubitus ulcers) are localised injury to the skin, underlying tissue or both, usually over a bony prominence, as a result of pressure or pressure in combination with shear (EPUAP 2009). They occur in people who do not have the ability to reposition themselves in order to relieve pressure on bony prominences (Moore 2011). This ability is often diminished in the very old, the malnourished and those with an acute illness (Moore 2012). Prevalence rates in long-term care settings fluctuate from 8.8% to 53.2% and incidence rates vary from 7% to 71.6% (Moore 2011; Scott 2006). The most common anatomical sites for pressure ulcers to occur are the sacrum and the heels, and the majority are grade 1 or grade 2 in severity (Gallagher 2008; Moore 2011; Moore 2012). Furthermore, as age increases, so too does pressure ulcer prevalence and incidence (EPUAP 2009). Changing population demographics and the predicted rise in the number of older persons in the future (U.S. Census Bureau 2004) suggest that there will be a corresponding increase in the number of people with pressure ulcers unless effective preventative measures are put in place .

Pressure ulcers impact negatively on quality of life as it is known that individuals with pressure ulcers frequently experience pain, combined with fear, isolation and anxiety regarding wound healing (Fox 2002; Hopkins 2006; Spilsbury 2007). Importantly, it has also been shown that pressure ulcers are associated with an increased risk of death (Allman 1997). One study identified that the risk of dying for elderly patients with a pressure ulcer was three times greater than for those without a pressure ulcer (Berlowitz 1990) although it

is probable that pressure ulcers are usually a consequence of poor health rather than a cause of death. Further prospective cohort studies examined the factors predictive of mortality in older individuals admitted to hospital. Both studies (Bo 2003; Alarcon 1999) conducted a detailed geriatric assessment of 659 and 352 patients on admission, and followed these patients for 10 months. Using regression analysis, the authors identified an odds ratio of 3.64 ($P < 0.001$) (Bo 2003) and 4.19 ($P < 0.001$) (Alarcon 1999), respectively, of death in acutely ill elderly people with pressure ulcers, indicating that in these individuals having a pressure ulcer increases the risk of dying.

Pressure ulcers are a significant financial burden to health care systems. Bennett and colleagues (Bennett 2004) estimated that the total annual cost for pressure ulcer management in the UK is £1.4 to £2.1 billion, which is equivalent to 4% of the total UK healthcare expenditure. Similar findings have been noted in the Netherlands, where pressure ulcers have been found to be the third most expensive health problem (Haalboom 2000). It has been suggested that the length of hospital stay is two to three times greater for those with a pressure ulcer, than for similar cases without (30.4 days compared to 12.8 days) (Allman 1997).

Globally, the economic impact of pressure ulcers has yet to be established. However, it is known that pressure ulcers are common (EPUAP 2002) and affect patients in both community (Margolis 2002) and hospital settings (Gallagher 2008). Therefore, it is reasonable to suggest that pressure ulcer prevention strategies that can reduce prevalence and incidence rates will have a positive impact on patients and the health service as a whole (Moore 2011).

Description of the intervention

Use of pressure ulcer risk assessment tools or scales is a component of the assessment process used to identify individuals at risk of developing a pressure ulcer (EPUAP 2009). Risk assessments generally use checklists that alert practitioners to the most common risk factors that predispose individuals to pressure ulcer development. These checklists are often developed into risk assessment tools, for example the Norton Scale (Norton 1975), the Waterlow risk assessment scale (Waterlow 1985) and the Braden scale (Braden 1987). It is argued that there is a lack of consensus regarding which variables are the most important indicators of risk (Gould 2002). Therefore, it is not surprising that there are currently almost 40 risk assessment scales in use, most of which are based on the seminal work of Norton 1975, or have been designed in response to a review of the literature (Defloor 2004). It is clear, however, that the risk factors that predispose an individual to developing a pressure ulcer will vary among patients in different clinical settings (Henoch 2003) and it may not be possible to design one risk assessment tool that will meet the needs of all patients in all clinical settings.

How the intervention might work

Use of a risk assessment tool is recommended by many international pressure ulcer prevention guidelines (EPUAP 2009; NICE 2001; Rycroft-Malone 2000). The ideal risk assessment tool should be both reliable and valid, and sensitive and specific (NPUAP 1998). The tool must accurately identify those individuals who are at risk, as well as those not at risk

- and do this consistently (Defloor 2005). To date, there is little empirical evidence available concerning the reliability and validity of existing tools (Anthony 2008; Cullum 1995; Defloor 2004; Defloor 2005; Haalboom 1999; McGough 1999; Pancorbo-Hidalgo 2006; Schoonhoven 2002). Assessing reliability and validity is a real challenge in clinical practice because risk assessment scales are used to identify those who would develop a pressure ulcer should no interventions be put in place. It is common to use different pressure ulcer prevention strategies once risk has been identified, which will therefore appear to alter the predictive ability of the scale (Defloor 2004; Halfens 2000). Different studies using the same risk assessment tools, but in diverse heath care settings with diverse patient populations and prevention strategies in use, report varying levels of sensitivity and specificity (Gould 2002). It is of relevance to note that the prevention strategies which were in use in these studies are often not stated (Halfens 2000). Lack of clear knowledge of the sensitivity and specificity of risk assessment tools has far-reaching implications for practice, because clinical decisions - such as the use, or not, of pressure ulcer preventative strategies - are often made on the basis of the results of risk assessment, although it has been argued also that nurses often use their clinical judgement alone in deciding which preventative measures to use (Anthony 2008). Therefore, it is likely that some patients are receiving interventions that they do not require, and conversely others are not receiving interventions that they would benefit from (Defloor 2005). This inappropriate allocation of resources compounds the increasing burden of pressure ulcers, and adds to spiraling healthcare costs. It is important to note that the primary focus of interest for this systematic review is whether or not using a risk assessment tool makes any difference to pressure ulcer incidence, as such the review is not looking at the predictive validity of pressure ulcer risk tools.

Why it is important to do this review

Three systematic reviews that explored the effectiveness of pressure ulcer risk assessment tools in the prevention of pressure ulcers have been published previously. The Royal College of Nursing (UK) pressure ulcer prevention guidelines (NICE 2001) were based largely on the results of the review by McGough 1999. The first review searched from 1962 to 1995 (Cullum 1995), the second review from 1962 to 1999 (McGough 1999) and the third review from 1966 to 2003 (Pancorbo-Hidalgo 2006). Two reviews (Cullum 1995; McGough 1999) restricted their inclusion criteria to studies published only in the English language; the third review (Pancorbo-Hidalgo 2006) restricted the inclusion criteria to four languages: Spanish, English, French and Portuguese. The reviews concluded that they found no evidence that pressure ulcer risk assessment scales reduce the incidence of pressure ulcers. However, given the time since these reviews were written, and the language restrictions that were imposed, it is possible that other relevant literature was originally overlooked, or has been published in the meantime. Therefore, as the searches for these reviews are out of date, and the authors imposed language restrictions, it is timely to conduct a review with no language restrictions and recent searches in order to clarify the role of pressure ulcer risk assessment tools in clinical practice.

Objectives

The objective of this review was to answer the following question: does the use of structured, systematic pressure ulcer risk assessment tools, in any healthcare setting, reduce the incidence of pressure ulcers compared with no structured risk assessment or unaided clinical judgement?

Methods

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) comparing the use of structured, systematic, pressure ulcer risk assessment tools with no structured pressure ulcer risk assessment, or with unaided clinical judgement, or RCTs comparing the use of different structured pressure ulcer risk assessment tools were considered for this review. Studies that randomise individuals (RCTs) or cluster-randomised trials (cluster-RCTs) that randomise by groups, were eligible for inclusion.

Types of participants

Studies involving people without pressure ulcers, of any age, in any healthcare setting (primary, secondary and extended care) were eligible for inclusion.

Types of interventions

RCTs making the following comparisons were eligible for inclusion in this review.

- Pressure ulcer risk assessment using a specific structured, systematic pressure ulcer risk assessment tool compared with no structured pressure ulcer risk assessment tool or unaided clinical judgement.
- Comparisons between two different pressure ulcer risk assessment tools.

Types of outcome measures

Primary outcomes

The proportion of participants developing new pressure ulcers of any grade (for the purpose of this review a pressure ulcer was defined as a localised injury to the skin, underlying tissue or both, usually over a bony prominence, as a result of pressure, or pressure in combination with shear) (EPUAP 2009).

Secondary outcomes

- The severity of new pressure ulcers.
- Time to ulcer development.

- Pressure ulcer prevalence.

Search methods for identification of studies

The search methods for the original version of this review can be found in Appendix 1

Electronic searches

In December 2013, for this second update, the following electronic databases were searched for reports of relevant studies:

- The Cochrane Wounds Group Specialised Register (searched 19 December 2013);
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2013, Issue 11);
- Ovid MEDLINE (1948 to November Week 3 2013);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations, December 10 , 2013);
- Ovid EMBASE (1980 to 2013 Week 50);
- EBSCO CINAHL (1982 to 19 December 2013).

The following search strategy was used in The Cochrane Central Register of Controlled Trials (CENTRAL):

#1 MeSH descriptor: [Pressure Ulcer] this term only 524
#2 MeSH descriptor: [Skin Ulcer] this term only131
#3 decubitus or decubital 429
#4 skin near/3 breakdown* 82
#5 bedsore* or (bed next/1 sore*) 69
#6 decubitus next (ulcer* or sore*) 111
#7 pressure* next (wound* or sore* or ulcer* or injur* or damag*) 1237
#8 (#1 or #2 or #3 or #4 or #5 or #6 or #7) 1733
#9 MeSH descriptor: [Risk Assessment] this term only6724
#10 (anderson or braden or norton or knoll or waterlow or medley or maelor or arnold or gosnell) near (score* or scale* or tool* or assess*) 199
#11 risk near/2 assess* 14655
#12 (assess* or predict*) next (tool* or score* or scale*) 4087
#13 MeSH descriptor: [Nursing Assessment] explode all trees 497
#14 (knoll or norton or waterlow) next (modif*) 0
#15 birty* next para 1
#16 cubbin near jackson 2
#17 braden next dupa 1
#18 douglas next ward 1
#19 (wound* next assess*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*) 12
#20 (bed next sore*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*) 3

#21 decubit* near (tool* or score* or scale* or scoring or instrument* or equipment* or device*) 7
#22 (pressure next ulcer*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*) 117
#23 (pressure next sore*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*) 30
#24 bedsore* near (tool* or score* or scale* or scoring or instrument* or equipment* or device*) 1
#25 (pressure next injur*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*) 2
#26 (pressure next damag*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*) 1
#27 (pressure next wound*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*) 20
#28 #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 18066
#29 #8 and #28 424

The search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in Appendix 2, Appendix 3 and Appendix 4 respectively. The MEDLINE search was combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision); Ovid format (**Lefebvre 2011**). The EMBASE and CINAHL searches were combined with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN) (**SIGN 2010**). No date or language restrictions were applied.

Searching other resources

We searched citations in all retrieved and relevant studies identified by these strategies for further studies. We contacted experts in the wound care field, namely council members of the European Pressure Ulcer Advisory Panel, the European Wound Management Association, The National Pressure Ulcer Advisory Panel and the World Union of Wound Healing Societies to identify any studies not located through the primary search.

Data collection and analysis

Selection of studies

Two review authors independently assessed titles and, where available, abstracts of the studies identified by the search strategy for their eligibility (as identified in the selection criteria) for inclusion in the review. Two review authors obtained full versions of potentially relevant studies and screened these against the inclusion criteria independently. Any differences in opinion were resolved by discussion and, where necessary, reference to the Wounds Group editorial base.

Data extraction and management

For this update, one review author extracted and summarised trial data. Data entry was checked by the second review author independently. We extracted and summarised details of the eligible study using a data extraction sheet. Specifically, we extracted the following information:

- author; title; source; date of study;
- country; care setting;
- inclusion and exclusion criteria;
- participant baseline characteristics by group;
- design details; study type; sample size;
- allocation;
- intervention details; concurrent interventions;
- is risk assessment part of a wider assessment programme/package;
- frequency of risk assessment; length of follow up;
- patient length of stay;
- which health professional administered the tool;
- outcome measures;
- verification of diagnosis;
- analysis;
- loss to follow up;
- results; and conclusions.

Assessment of risk of bias in included studies

Two review authors independently assessed the included studies using the Cochrane Collaboration tool for assessing risk of bias (**Higgins 2011**). This tool addresses six specific domains: namely, sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues (e.g. extreme baseline imbalance) (see Appendix 5 for details of criteria on which each judgement was based). We assessed blinding and completeness of outcome data for each outcome separately. We completed a 'Risk of bias' table for the eligible study. We have presented an assessment of risk of bias using a 'Risk of bias' summary figure (Figure 1). This display of internal validity indicates the weight the reader may give to the results of each study.

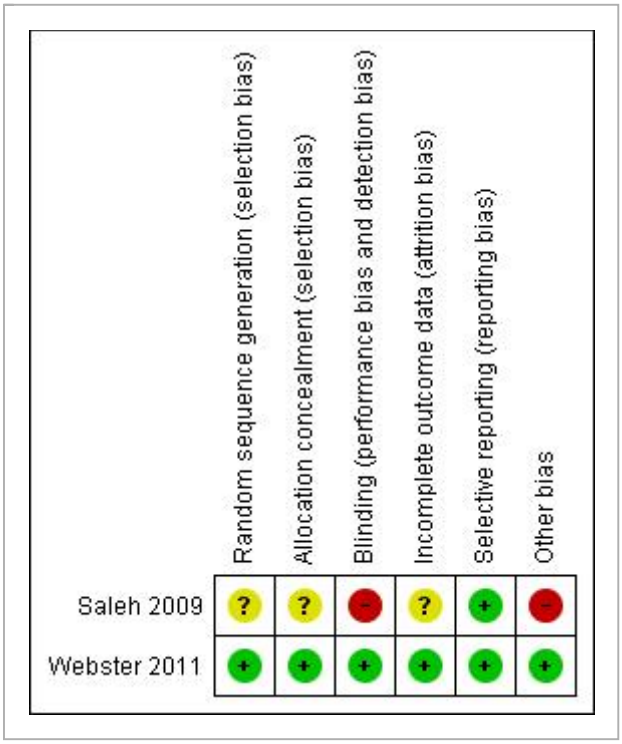

Figure 1.

Open in figure viewer

Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

Assessment of heterogeneity

We planned to explore clinical heterogeneity by examining potentially influential factors, e.g. care setting or patient characteristics. Statistical heterogeneity was to be assessed using the I^2 statistic (Higgins 2003). This examines the percentage of total variation across studies due to heterogeneity rather than to chance. Values of I^2 over 75% indicate a high level of heterogeneity. We intended to carry out statistical pooling on groups of studies which were considered to be sufficiently similar. However, owing to the lack of homogeneity of the studies included, in terms of the interventions evaluated, statistical pooling was not relevant.

Data synthesis

We entered quantitative data into RevMan 5 (RevMan 2008) and analysed using the RevMan Analysis software. For dichotomous outcomes, we calculated risk ratio (RR) plus 95% confidence intervals (CI).

Results

Description of studies

Results of the search

The initial search identified 105 titles. Following independent review of the abstracts by the two review authors, we retrieved 10 citations in full. Two review authors independently assessed the papers and applied the inclusion and exclusion criteria. No papers were identified that met the inclusion criteria. Fifty-two letters were written to wound care experts and 16 replies were received, yielding a response rate of 31%. We identified no further trials through this process. The search for the first update identified 98 citations. Following review of the abstracts, we retrieved one citation in full (Saleh 2009). For the second update 171 titles were identified. Following review of the abstracts 1 further study met the inclusion criteria (Webster 2011).

Included studies

Two studies met the inclusion criteria. The first study was published in 2009 (Saleh 2009). This cluster randomised study was conducted within a military hospital in Saudi Arabia and compared the effect of three different methods of pressure ulcer risk assessment on the incidence of pressure ulcers in hospitalised individuals with a Braden score of less than or equal to 18 (Braden 1987). The methods of risk assessment were: the Braden pressure ulcer risk assessment tool and training; unstructured risk assessment and training; and unstructured risk assessment alone (see Characteristics of included studies). The Braden pressure ulcer risk assessment scale comprises six sub-scales: sensory perception, moisture, activity, mobility, nutrition and friction/shear. Each sub-scale is ranked numerically from 1 to 4; a score of 4 indicates no problem with regard to the specific sub-scale, whereas a score of 1 indicates a significant problem. The friction and shear sub-scale is scored 1 to 3. The scores for each of the sub-scales are totaled to give a final score ranging from 6 to 23; as scores become lower, predicted risk becomes higher (Braden 1987). Data were collected by the lead researcher, who was the Tissue Viability Nurse Specialist at the study site, and two staff nurses trained in the data collection procedure.

Saleh 2009 included nine wards within a military hospital and randomly allocated these wards into three groups. Group A nurses (the Braden scale group) received a mandatory wound care management study day, pressure ulcer prevention training programme and specific training on the application of the Braden scale. These nurses were required to implement the Braden scale on their patients in the post-intervention stage. Group B nurses (the training group) were identical to group A but were not required to implement the Braden scale. Group C nurses (the clinical judgement group) received only a mandatory wound care management study day. Data were collected from all patients with Braden scores of ≤ 18 across the nine wards; follow up was for eight weeks. Patients were nursed on either standard foam mattresses, alternating pressure redistribution devices, gel overlay mattresses or air fluidised mattresses. Repositioning schedules were every two hours, three to four hours, or six hours. The procedure for allocation of mattresses and repositioning schedules are not reported by the study authors. Incidence was recorded as the

development of a pressure ulcer during the study period. Pressure ulcers were identified according to the National Pressure Ulcer Advisory Panel (USA) pressure ulcer classification system (**NPUAP 1998**). **Saleh 2009** did not identify the grade of pressure ulcer damage specifically for each participant but rather reported 'pressure ulcer present' - yes or no.

The second study was published in 2011 (**Webster 2011**). This single blind RCT was conducted among 1231 patients admitted to internal medicine or oncology wards within a tertiary referral teaching hospital in Australia. Participants were allocated to either a Waterlow (n=410) or Ramstadius (n=411) screening tool group or to a clinical judgement group (n=410) where no formal risk screening instrument was used. (see Characteristics of included studies). The Waterlow risk assessment tool comprises 7 sub-scales, Build/weight for height; skin type; nutrition; sex/age; continence; mobility; special risks. Each sub-scale is scored individually according to an allocated score to each component of the sub-scale, with the scores added to give an overall risk status. As scores become higher, the predicted risk become correspondingly higher (10+= low risk; 15+= high risk; 20+= very high risk) (**Waterlow 1985**). The main focus of the Ramstadius risk screening tool (**Ramstadius 2000**) is on mobility status, it is a non numerical tool and begins with the assessment of mobility as yes/no. If the patient can reposition themselves independently no further assessment is required and the patient is deemed not to be at risk. Conversely, if problems with mobility are identified, the patient is deemed to be at high risk and further assessment of risk factors, namely age, medication, skin integrity, temperature, decreased blood volume, dyspnoea and presence of an existing pressure ulcer is undertaken. No scores are given, rather an algorithm is provided to direct interventions which may be appropriate for the specific risk factor.

Following assignment to the screening method, a copy of the instrument was placed in the patient's medical record for use by the ward nurse in their admission assessment. Research assistants who were trained in pressure ulcer staging, and who were blinded to the screening method, visually inspected patients for evidence of pressure ulcer formation daily (except weekends). Follow up was for four days. Pressure ulcers were staged according to the NPUAP pressure ulcer staging system (**Black 2007**). The pressure ulcers that developed were either stage 1 or stage 2, data collection ceased once a pressure ulcer was identified.The authors report that there were no differences in measured processes of care, including use of special mattresses, documentation of an explicit pressure care plan, referral to the specialist skin integrity nurse or referral to a dietician between the three groups.

Excluded studies

The Characteristics of excluded studies table summarises the 10 studies that were excluded from the review.

Risk of bias in included studies

See Figure 1, for the summary of the risk of bias of the included studies.

Allocation (selection bias)

Methods used for generating the allocation sequence and for concealing the group allocation were unclear in the study of Saleh 2009. However, Webster 2011 reports that a computer-generated randomised list, with a phone randomisation method was used.

Blinding (performance and detection bias)

Saleh 2009 did not mention blinding in the study report, whereas Webster 2011 reports that the patient and the outcome assessor were blinded to group assignment.

Incomplete outcome data (attrition bias)

Saleh 2009 does not report if an intention-to-treat (ITT) analysis was undertaken. Webster 2011 reports that the number of participants allocated to each group were analysed for the primary outcome at the end of the study.

Selective reporting (reporting bias)

The two studies, Saleh 2009 and Webster 2011 report all outcomes mentioned in the methods of the papers, however we did not seek the trial protocols.

Other potential sources of bias

In the study of Saleh 2009 the groups were not comparable at baseline for medical diagnoses, pressure ulcer prevention practices, use of barrier creams and use of vitamin supplementary therapy. Furthermore, this was a cluster randomised study but the study authors did not report if they adjusted for the clustering in the sample size calculation and in the analysis. The study of Webster 2011 was not judged to be at risk from other potential sources of bias.

Based on this assessment the study of Saleh 2009 would be judged to be overall at high risk of bias, whereas the study of Webster 2011 would be judged to be overall at low risk of bias.

Effects of interventions

How the results are presented and what the terms mean

Results for dichotomous variables are presented as RR with 95% CI. Risk ratio is the rate of the event of interest (e.g. pressure ulcers developed) in the experimental group divided by the rate of this event in the control group and indicates the chances of pressure ulcer development for people in the experimental group compared with the control group. An RR of 1 means there is no difference in risk between the two study groups, an RR of < 1 means the event is less likely to occur in the experimental group than in the control group and an RR of > 1 means the event is more likely to occur in the experimental group than in the control group.

Comparison 01: Comparison between Braden pressure ulcer risk assessment and training compared with unstructured pressure ulcer risk assessment following the same training alone

This study randomly allocated nine wards into three groups; groups A, B and C. The randomisation resulted in unequal allocation across the groups and no explanation for this was given in the study report.

Following delivery of the training to the staff, Saleh 2009 enrolled 150 patients with a Braden score of ≤18, from six wards. Seventy-four patients were in the Braden scale group (Group A), and 76 patients were in the training group (Group B). The ward, not the patient, was the unit of randomisation and therefore this would be a cluster RCT study design, however, it is unclear from the trial report if the analysis of data accounted for the clustering. The authors did not describe the characteristics of the participants in terms of age, gender or underlying health status specifically for each group. The patients were followed up for a period of eight weeks. Sixteen pressure ulcers developed in the Braden scale group and 17 pressure ulcers developed in the training group. There was no statistically significant difference in pressure ulcer risk between the groups (RR 0.97, 95% CI 0.53 to 1.77) (Analysis 1.1).

Comparison 02: Comparison between Braden pressure ulcer risk assessment and training compared with unstructured pressure ulcer risk assessment alone

Following delivery of the training to the staff, Saleh 2009 enrolled 106 patients from three wards with a Braden score of ≤ 18. These 106 patients were managed using unaided clinical judgement (Group C). The incidence of pressure ulcers in this clinical judgement group was compared with the 74 patients who were in the Braden scale group (Group A). The ward, not the patient, was the unit of randomisation, however, it is unclear from the trial report if the analysis of data accounted for the clustering. The authors did not describe the characteristics of the participants, in terms of age, gender or underlying health status, specifically for each group. The patients were followed up for a period of eight weeks. Sixteen pressure ulcers developed in the Braden scale group and 16 pressure ulcers also developed in the clinical judgement group. There was no statistically significant difference between the groups in terms of pressure ulcer risk (RR 1.43, 95% CI 0.77 to 2.68) (Analysis 2.1).

Comparison 03: Comparison between Waterlow pressure ulcer risk assessment and no formal risk assessment

Webster 2011 enrolled 411 participants in the Waterlow group and 410 participants into the group receiving no formal risk assessment. Following eligibility assessment, a research nurse allocated patients to study group using a phone, computer generated randomisation, randomisation was blocked and stratified by type of patient (oncology and medical) and by presence or absence of pressure ulcers on admission and mobility status (no pressure ulcer, pressure ulcer and able to move independently, no pressure ulcer but unable to move independently, and pressure ulcer and unable to move independently). The patient and the outcome assessor were blinded to group assignment.The incidence of hospital-acquired pressure ulcers was similar between the groups (Waterlow 7.5% n=31; clinical judgement

6.8% (n=28). There was no statistically significant difference between the groups in terms of pressure ulcer risk (RR 1.10, 95% CI 0.68 to 1.81) (Analysis 3.1).

Comparison 04: Comparison between Ramstadius risk screening and no formal risk assessment

Webster 2011 enrolled 410 participants in the Ramstadius risk screening group and 410 participants into the no formal risk assessment group. Following eligibility assessment, a research nurse allocated patients to study group using a phone, computer generated randomisation, randomisation was blocked and stratified by type of patient (oncology and medical) and by presence or absence of pressure ulcers on admission and mobility status (no pressure ulcer, pressure ulcer and able to move independently, no pressure ulcer but unable to move independently, and pressure ulcer and unable to move independently). The patient and the outcome assessor were blinded to group assignment.The incidence of hospital-acquired pressure ulcers was similar between the groups (Ramstadius 5.4% n=22; clinical judgement 6.8% (n=28). There was no statistically significant difference between the groups in terms of pressure ulcer risk (RR 0.79, 95% CI 0.46 to 1.35) (Analysis 4.1).

Comparison 05: Comparison between Waterlow pressure ulcer risk assessment and Ramstadius risk screening

Webster 2011 enrolled 411 participants in the Waterlow group and 410 participants in the Ramstadius risk screening group. Following eligibility assessment, a research nurse allocated patients to study group using a phone, computer generated randomisation, randomisation was blocked and stratified by type of patient (oncology and medical) and by presence or absence of pressure ulcers on admission and mobility status (no pressure ulcer, pressure ulcer and able to move independently, no pressure ulcer but unable to move independently, and pressure ulcer and unable to move independently). The patient and the outcome assessor were blinded to group assignment.The incidence of hospital-acquired pressure ulcers was similar between the groups (Waterlow 7.5% n=31; Ramstadius 5.4% n=22). There was no statistically significant difference between the groups in terms of pressure ulcer risk (RR 1.44, 95% CI 0.85 to 2.44) (Analysis 5.1).

Discussion

Two eligible studies (Saleh 2009; Webster 2011) were included in this review. Saleh 2009 found no statistically significant differences in pressure ulcer incidence when patients were risk assessed using the Braden scale compared with a risk assessment following pressure ulcer prevention training, or when comparing risk assessment with using clinical judgement alone. Similiarly, Webster 2011 found no statistically significant differences in pressure ulcer incidence when patients were risk assessed using the Waterlow risk assessment tool, the Ramstadius risk screening tool, or using no formal risk assessment.

Some methodological issues require consideration and limit the conclusions that can be drawn from this review. In the study of Saleh 2009 randomisation was not at the individual level but rather at the unit level, where each ward served as the unit of randomisation and all patients within the ward were in the same group. This type of randomisation is called cluster-

randomisation (Medical Research Council 2002). Cluster-randomised trials increase efficiency and study protocol compliance whilst avoiding contamination (Donner 2004). Contamination is said to occur when an intervention is given to an individual but may affect others within the trial (Puffer 2005) or when the intervention is given by accident to the control group.

The disadvantages of cluster-randomisation is that all the individuals in the cluster cannot be assumed to be independent of one another and, furthermore, the analysis is not at the level of randomisation but is at the group level (Elley 2004). A way to overcome the disadvantages is to allow for the effects of clustering in the analysis of the data using, for example, regression models (Hahn 2005). Normally, with individual randomisation, one would expect there to be a variance in the responses within study groups. Clustering can exert an effect on this variance yielding a correlation of responses within the clusters. When cluster-randomisation is used, this needs to be considered during both the sample size calculation and the data analysis. The study by Saleh 2009 was small and the authors did not report that they accounted for the use of cluster-randomisation in either the sample size calculation, nor in the analysis (Saleh 2009). Conversely, the study of Webster 2011 randomised at the individual level, thereby enhancing the comparability between the study groups.

Concealment of group allocation was inadequately described in the study of Saleh 2009. Allocation concealment is a randomisation method that prevents the researcher influencing which group, experimental or control, a participant is allocated to (Higgins 2011), therein ensuring that the participant is assigned to a specific study group by chance (Higgins 2011). It has been suggested that lack of a clear description of allocation concealment leads to bias in assessing the outcome of studies (Moher 2001); the size of the effect could be overestimated and so give a false impression of the value of the intervention. The study of Webster 2011 used computer generated, phone randomisation, thereby minimising the risk of selection bias.

Blinding of the study is said to be complete if the investigators, the participants, the outcome assessor and the individual analysing the data have no idea which group the participant is allocated to (Higgins 2011). Saleh 2009 did not report blinding of the patient, the staff, the data collector or the data analyst. Whilst it would not have been feasible to blind care givers as they must know the allocation because they are conducting the risk assessment, it would have been possible to blind the outcome assessors and data analyst. Webster 2011 ensured that the patient and the outcome assessor were blinded to group assignment, thereby minimising the risk of performance bias and detection bias.

Intention-to-treat analysis (ITT) means that participants are analysed according to the group they were originally allocated to even if they did not adhere to the study protocol or complete the study. The rationale for using ITT analysis is two-fold; it maintains treatment groups that are similar (apart from random variation) and therefore validates the use of randomisation (Hollis 1999), and allows for handling of protocol deviations, further protecting the randomisation process (Hollis 1999). In essence, omitting those who do not complete the study from the final analysis may bias the outcomes of the study because those who do not complete may do so because of adverse effects of the intervention (Montori 2001). Saleh 2009 did not report use of ITT; pressure ulcer incidence is reported for all patients in the post-training groups but it is not clear whether any randomised patients withdrew. Conversely, Webster 2011 ensured that all the participants allocated to

each group were analysed for the primary outcome, thereby minimising the risk of attrition bias.

Baseline data refers to the data collected from each participant before beginning the trial (Friedman 1996). This includes demographic information, medical condition, prognostic factors and, where appropriate, socioeconomic information. This allows the researcher to determine if participants in both arms of the study are comparable at the outset of the study (Friedman 1996) and allows those evaluating the study to determine if the characteristics of those participating in the study are similar to those normally encountered in clinical practice (Friedman 1996). Webster 2011 provides details of the baseline characteristics of the participants and does not identify statistically significant differences at baseline between the study groups. Saleh 2009 report that, overall, the groups were not comparable at baseline for medical diagnoses, pressure ulcer prevention practices, use of barrier creams and use of vitamin supplementary therapy. This was not an issue in the study of Webster 2011.

Use of pressure ulcer risk assessment tools or scales is a component of the assessment process used to identify individuals at risk of developing a pressure ulcer and is recommended by many international guidelines (AHCPR 1992; EPUAP 2009; NICE 2001). This review identified no RCT evidence to suggest that conducting a structured risk assessment makes any difference to pressure ulcer incidence. This finding is in keeping with previous reviews (Cullum 1995; McGough 1999; Pancorbo-Hidalgo 2006) which also found a lack of published literature that reliably assesses whether the use of a risk assessment tool reduces the incidence of pressure ulcers.

Pressure ulcer risk assessment tools are widely used in clinical practice, although not necessarily in all healthcare settings (Anthony 2008; Defloor 2005) and as such it is impossible to unlearn what has been gained during the experience of using a risk assessment tool. This means that use of an individual's clinical judgement alone, without use of a risk assessment tool, will ultimately be influenced by prior knowledge of risk assessment tools. Thus, it is possible that within the clinical setting risk assessment follows a structured format similar to that of the current risk assessment tools even in the absence of a paper/electronic version of the tool (Anthony 2008). One therefore might not see a difference in pressure ulcer incidence because the tool does not add to the quality of the clinical judgement. Indeed, Defloor 2005 argues that if nurses act according to risk assessment scales, 80% of the patients would unnecessarily receive preventive measures. Furthermore, use of preventative measures impacts negatively on the predictive ability of the risk assessment tool. One may consider the presence of a pressure ulcer in an individual identified to be at risk to be a success of the risk assessment process; however, this actually indicates a failure of prevention methods (Defloor 2005). It would be interesting to determine what information is gathered using clinical judgement alone to assess whether this matches the data collected using structured risk assessment. If there were a relationship between the two methods of assessment then a reduction in pressure ulcer incidence, due to the introduction of structured risk assessment, would not be anticipated. Thus, in the studies of Webster 2011 and Saleh 2009, it is unclear what impact prior knowledge of pressure ulcer risk assessment had on the clinical judgement of the participants and as such this should be bone in mind in consideration of the generalisability of findings to other healthcare settings.

It has been argued that pressure ulcer risk assessment is in itself not an intervention but rather a precursor to the development of an appropriate plan of care to combat or reduce the impact of the risk factors identified (Lindgren 2002). Anthony 2008 suggests that if a risk assessment tool is working well, then a reduction in the incidence of pressure ulcers should follow. Presumably this means that the risk assessment is followed by appropriate risk intervention, and that these interventions are available and effective. It is evident from the literature, however, that this is not always the case (EPUAP 2002; Moore 2004). Indeed, EPUAP 2002 found that only 9.7% of patients in a pan-European prevalence study were receiving adequate preventative measures in terms of repositioning and provision of pressure redistributing devices. Furthermore, in a survey of registered nurses Moore 2004 found that pressure ulcer prevention was not always a high priority, with some nurses admitting to being less interested in pressure ulcer prevention than other aspects of nursing care. Fundamentally, risk assessment alone will make no difference unless it is followed up by an intervention to combat risk, and these interventions need to be available. Interestingly, the method of risk assessment employed in the Webster 2011 study did not influence the interventions offered to patients, indeed, there were no differences in measured processes of care, including use of special mattresses, documentation of an explicit pressure care plan, referral to the specialist skin integrity nurse or referral to a dietician between the three groups. Thus, although risk assessment is suggested to be a precursor to planning and implementing care, it appears that this may not always be the case.

One cluster RCT at high risk of bias has explored the impact of pressure ulcer risk assessment on patient outcomes (Saleh 2009). However, methodological issues with the study make it difficult to draw firm conclusions. However, a further large RCT (Webster 2011) at low risk of bias, identified no statistical differences in pressure ulcer incidence when patients were assessed using either the Waterlow risk assessment tool, the Ramstadius risk assessment tool, or using clinical judgement alone. However, as the studies included here were within two specific clinical settings (military hospital and internal medicine or oncology) there is limited generalisability to other high risk groups for example elderly residents of care homes. Therefore, as yet, there is no RCT evidence to suggest that conducting pressure ulcer risk assessment makes any difference to the number of pressure ulcers that develop. If the use of risk assessment tools/scales continues to be used in clinical practice, in the absence of empirical knowledge regarding its effect on clinical outcomes, issues will arise concerning resource utilisation and this in turn will add to increasing healthcare costs.

Authors' conclusions

Implications for practice

There is no RCT evidence to suggest that undertaking structured pressure ulcer risk assessment reduces the incidence of pressure ulcers.

Implications for research

Pressure ulcer risk assessment is an integral component of pressure ulcer prevention and is widely utilised in clinical practice. To date, there is no RCT evidence to suggest that undertaking structured pressure ulcer risk assessment makes any difference to pressure ulcer incidence. However, as there is limited generalisability of the findings from this review to other high risk groups there is a need to conduct further research aimed at establishing, among other high risk groups, whether the conduct of risk assessment makes any difference to pressure ulcer incidence. Future research should ensure that the following are incorporated:

1. True randomisation;
2. Adequate allocation concealment;
3. Blinded outcome assessment;
4. Intention to treat analysis;
5. Baseline comparability of groups;
6. Adequate sample size; and
7. Reporting of studies in accordance with the CONSORT guidelines (Moher 2001)

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Data and analyses

Download statistical data

Comparison 1. Comparison between Braden pressure ulcer risk assessment and training vs. unstructured pressure ulcer risk assessment following training alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence - Braden risk assessment and training vs. unstructured risk assessment following training alone	1	150	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.53, 1.77]

Comparison 2. Comparison between Braden pressure ulcer risk assessment and training vs. unstructured pressure ulcer risk assessment alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence - Braden risk assessment and training vs. unstructured risk assessment alone	1	180	Risk Ratio (M-H, Fixed, 95% CI)	1.43 [0.77, 2.68]

Comparison 3. Comparison between Waterlow and no formal risk assessment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure Ulcer incidence: Waterlow versus no formal risk assessment	1	821	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.68, 1.81]

Comparison 4. Comparison between Ramstadius and no formal risk assessment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure Ulcer incidence: Ramstadius versus no formal risk assessment	1	820	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.46, 1.35]

Comparison 5. Comparison between Waterlow and Ramstadius

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure Ulcer Incidence: Waterlow versus Ramstadius	1	831	Risk Ratio (M-H, Fixed, 95% CI)	1.44 [0.85, 2.44]

Appendices

Appendix 1. Search methods section - First Update 2010

Electronic searches

For this first update the following databases were searched:

- Cochrane Wounds Group Specialised Register (searched 21 September 2010)
- The Cochrane Central Register of Controlled Trials (CENTRAL) - *The Cochrane Library* 2010 Issue 3
- Ovid MEDLINE - 2007 to September Week 1 2010
- Ovid MEDLINE - In-Process & Other Non-Indexed Citations, September 20, 2010
- Ovid EMBASE - 2007 to 2010 Week 37
- EBSCO CINAHL - 2007 to 17 September 2010

The following search strategy was used in The Cochrane Central Register of Controlled Trials (CENTRAL):

#1 MeSH descriptor Pressure Ulcer, this term only
#2 MeSH descriptor Skin Ulcer, this term only
#3 decubitus or decubital
#4 skin near/3 breakdown*
#5 bedsore* or (bed next/1 sore*)
#6 decubitus next (ulcer* or sore*)
#7 pressure* next (wound* or sore* or ulcer* or injur* or damag*)
#8 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7)
#9 MeSH descriptor Risk Assessment, this term only
#10 (anderson or braden or norton or knoll or waterlow or medley or maelor or arnold or gosnell) near (score* or scale* or tool* or assess*)
#11 risk near/2 assess*
#12 (assess* or predict*) next (tool* or score* or scale*)
#13 MeSH descriptor Nursing Assessment explode all trees
#14 (knoll or norton or waterlow) next (modif*)
#15 birty* next para
#16 cubbin near jackson
#17 braden next dupa
#18 douglas next ward
#19 (wound* next assess*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
#20 (bed next sore*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
#21 decubit* near (tool* or score* or scale* or scoring or instrument* or equipment* or device*)

#22 (pressure next ulcer*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
#23 (pressure next sore*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
#24 bedsore* near (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
#25 (pressure next injur*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
#26 (pressure next damag*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
#27 (pressure next wound*) near (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
#28 ((#9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27)
#29 (#8 AND #28)

The search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in Appendix 2, Appendix 3 and Appendix 4 respectively. The MEDLINE search was combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision); Ovid format. The EMBASE and CINAHL searches were combined with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN). No date or language restrictions were applied.

Searching other resources

We searched citations in all retrieved and relevant publications identified by these strategies for further studies. We contacted experts in the wound care field, namely council members of the European Pressure Ulcer Advisory Panel, the European Wound Management Association, The National Pressure Ulcer Advisory Panel and the World Union of Wound Healing Societies to identify any studies not located through the primary search. There were no restrictions on articles on the basis of language or date of publication.

Appendix 2. Ovid MEDLINE search strategy

1 exp Pressure Ulcer/
2 exp Skin Ulcer/
3 (decubitus or decubital).mp.
4 (skin adj3 breakdown$).mp.
5 (bedsore$ or (bed adj1 sore$)).mp.
6 (decubitus adj (ulce$ or sore$)).mp.
7 (pressure$ adj (wound$ or sore$ or ulcer$ or injur$ or damag$)).mp.
8 or/1-7
9 exp Risk Assessment/
10 ((anderson or braden or norton or knoll or waterlow or medley or maelor or arnold or gosnell) adj10 (score$ or scale$ or tool$ or assess$)).mp.
11 (risk adj2 assess$).mp.
12 ((assess$ or predict$) adj10 (tool$ or score$ or scale$)).mp.

13 exp Nursing Assessment/
14 ((knoll or norton or waterlow) adj modif$).mp.
15 (birty$ adj para).mp.
16 (cubbin adj10 jackson).mp.
17 (braden adj dupa).mp.
18 (douglas adj ward).mp.
19 (wound$ adj assess$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
20 (bed sore$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
21 (decubit$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
22 (pressure ulcer$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
23 (pressure sore$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
24 (bedsore$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
25 (pressure injur$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
26 (pressure damag$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
27 (pressure wound$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
28 or/9-27
29 8 and 28

Appendix 3. Ovid EMBASE search strategy

1 exp Decubitus/
2 exp Skin Ulcer/
3 (decubitus or decubital).mp.
4 (skin adj3 breakdown$).mp.
5 (bedsore$ or (bed adj1 sore$)).mp.
6 (decubitus adj (ulce$ or sore$)).mp.
7 (pressure$ adj (wound$ or sore$ or ulcer$ or injur$ or damag$)).mp.
8 or/1-7
9 exp Risk Assessment/
10 ((anderson or braden or norton or knoll or waterlow or medley or maelor or arnold or gosnell) adj10 (score$ or scale$ or tool$ or assess$)).mp.
11 (risk adj2 assess$).mp.
12 ((assess$ or predict$) adj10 (tool$ or score$ or scale$)).mp.
13 exp Nursing Assessment/
14 ((knoll or norton or waterlow) adj modif$).mp.
15 (birty$ adj para).mp.
16 (cubbin adj10 jackson).mp.

17 (braden adj dupa).mp.
18 (douglas adj ward).mp.
19 (wound$ adj assess$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
20 (bed sore$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
21 (decubit$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
22 (pressure ulcer$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
23 (pressure sore$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
24 (bedsore$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
25 (pressure injur$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
26 (pressure damag$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
27 (pressure wound$ adj10 (tool$ or score$ or scale$ or scoring or instrument$ or equipment$ or device$)).mp.
28 or/9-27
29 8 and 28

Appendix 4. EBSCO CINAHL search strategy

S34 S5 and S33
S33 S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32
S32 AB pressure wound* and AB (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S31 TI pressure wound* and TI (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S30 AB pressure damag* and AB (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S29 TI pressure damag* and TI (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S28 AB pressure injur* and AB (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S27 TI pressure injur* and TI (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S26 AB bedsore* and AB (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S25 TI bedsore* and TI (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S24 AB pressure sore* and AB (tool* or score* or scale* or scoring or instrument* or equipment* or device*)

S23 TI pressure sore* and TI (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S22 AB pressure ulcer* and AB (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S21 TI pressure ulcer* and TI (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S20 AB decubit* and AB (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S19 TI decubit* and TI (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S18 AB bed sore* and AB (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S17 TI bed sore* and TI (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S16 AB wound* assess* and AB (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S15 TI wound* assess* and TI (tool* or score* or scale* or scoring or instrument* or equipment* or device*)
S14 TI douglas ward or AB douglas ward
S13 TI braden dupa or AB braden dupa
S12 TI cubbin N10 jackson or AB cubbin N10 jackson
S11 TI birty* para or AB birty* para
S10 (MH "Nursing Assessment")
S9 AB (assess* or predict*) and AB (tool* or score* or scale*)
S8 TI (assess* or predict*) and TI (tool* or score* or scale*)
S7 TI risk N2 assess* or AB risk N2 assess*
S6 TI (anderson or braden or norton or knoll or waterlow or medley or maelor or arnold or gosnell) or AB (anderson or braden or norton or knoll or waterlow or medley or maelor or arnold or gosnell)
S5 S1 or S2 or S3 or S4
S4 TI decubitus or AB decubitus
S3 TI (bed sore* or bedsore*) or AB (bed sore* or bedsore*)
S2 TI (pressure ulcer* or pressure sore*) or AB (pressure ulcer* or pressure sore*)
S1 (MH "Pressure Ulcer")

Appendix 5. Risk of bias criteria

1. Was the allocation sequence randomly generated?

Low risk of bias

The investigators describe a random component in the sequence generation process such as: referring to a random number table; using a computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots.

High risk of bias

The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number.

Unclear

Insufficient information about the sequence generation process to permit judgement of low or high risk of bias.

2. Was the treatment allocation adequately concealed?

Low risk of bias

Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomisation); sequentially-numbered drug containers of identical appearance; sequentially-numbered, opaque, sealed envelopes.

High risk of bias

Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

Unclear

Insufficient information to permit judgement of low or high risk of bias. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement, for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

3. Blinding - was knowledge of the allocated interventions adequately prevented during the study?

Low risk of bias

Any one of the following.

- No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.

- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

High risk of bias

Any one of the following.

- No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding.
- Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.

Unclear

Any one of the following.

- Insufficient information to permit judgement of low or high risk of bias.
- The study did not address this outcome.

4. Were incomplete outcome data adequately addressed?

Low risk of bias

Any one of the following.

- No missing outcome data.
- Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size.
- Missing data have been imputed using appropriate methods.

High risk of bias

Any one of the following.

- Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size.
- 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

Unclear

Any one of the following.

- Insufficient reporting of attrition/exclusions to permit judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided).
- The study did not address this outcome.

5. Are reports of the study free of suggestion of selective outcome reporting?

Low risk of bias

Any of the following.

- The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
- The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon)

High risk of bias

Any one of the following.

- Not all of the study's pre-specified primary outcomes have been reported.
- One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified.

- One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect).
- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis.
- The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Unclear

Insufficient information to permit judgement of low or high risk of bias. It is likely that the majority of studies will fall into this category.

6. Other sources of potential bias

Low risk of bias

The study appears to be free of other sources of bias.

High risk of bias

There is at least one important risk of bias. For example, the study:

- had a potential source of bias related to the specific study design used; or
- has been claimed to have been fraudulent; or
- had some other problem.

Unclear

There may be a risk of bias, but there is either:

- insufficient information to assess whether an important risk of bias exists; or
- insufficient rationale or evidence that an identified problem will introduce bias.

What's new

Date	Event	Description
19 December 2013	New citation required and conclusions have changed	One new study at low risk of bias included in the review (Webster 2011). Conclusions updated.
19 December 2013	New search has been performed	New searches completed for the second update, one new study included.

History

Protocol first published: Issue 2, 2007
Review first published: Issue 3, 2008

Date	Event	Description
8 November 2010	New search has been performed	New searches completed for the first update, one new study included in the review and risk of bias assessment completed (Saleh 2009).

Contributions of authors

Protocol development - Zena Moore.
Commenting on draft of protocol - Seamus Cowman.
Review of articles and data extraction - Zena Moore and Seamus Cowman.
Preparation of review and responding to peer referee comments - Zena Moore.
Commenting on draft review and the updates - Seamus Cowman.
Preparation of the updated reviews - Zena Moore.

Contributions of editorial base:

Nicky Cullum: edited the review, advised on methodology, interpretation and review content. Approved the final review prior to submission.
Liz McInnes, Editor: approved the updated review prior to submission.
Sally Bell-Syer: coordinated the editorial process. Advised on methodology, interpretation and content. Edited the review and the update.
Ruth Foxlee: designed the search strategy, ran the searches and edited the search methods section.

Declarations of interest

The author, Zena Moore, is a member of the medical advisory board of Systagenix Wound Management. The author, Zena Moore, has received an honorarium for speaking at professional meetings for KCI, ConvaTec, Systagenix Wound Management, Fanin Health Care, Molnlycke Health Care and Smith & Nephew.
Seamus Cowman - none.

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- Royal College of Surgeons in Ireland, Ireland.

External sources

- Health Research Board of Ireland, Ireland.
- NIHR/Department of Health (England), (Cochrane Wounds Group), UK.

Characteristics of studies

Characteristics of included studies [ordered by study ID]

Saleh 2009

Methods	RCT, allocation by ward (cluster). No details provided regarding the randomisation process.	
Participants	Patients in a military hospital with a Braden score of less than or equal to 18. For the Braden group, 74 patients post-test. For the training group, 76 patients post-test. For the clinical judgement group, 106 patients post-test.	
Interventions	Group A: Braden risk assessment and training n = 74 Group B: training alone n = 76 Group C: clinical judgement alone n = 106	
Outcomes	Pressure ulcers developed Group A: Braden risk assessment and training n = 16 Group B: training alone n = 17 Group C: clinical judgement alone n = 16	
Notes	The groups were not comparable at baseline for medical diagnoses, pressure ulcer prevention practices, use of barrier creams and use of vitamin supplementary therapy. The type of mattress the patients lay on was not the same for all participants. The repositioning schedules for each participant was not the same	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "for pragmatism, this study randomly allocated nine wards into three groups"
Allocation concealment (selection bias)	Unclear risk	Quote: "for pragmatism, this study randomly allocated nine wards into three groups"
Blinding (performance bias and	High risk	The authors report that the data were collected by one of the authors, who was the Tissue Viability Nurse Specialist at the hospital, and 2 staff nurses. The two staff nurses were recruited

detection bias) All outcomes		to the wound care team and each had medical–surgical nursing experience of six to eight years. There is no mention of blinding of the patient, the staff, the data collector or the data analyst within the text.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Pressure ulcer incidence is reported for all patients in the post-test groups, however a number of patients were excluded and it is unclear if these patients were excluded before the start of the study, i.e. that they did not meet inclusion criteria. This is not specifically stated by the authors.
Selective reporting (reporting bias)	Low risk	The study protocol was not available but the important outcome measures stated in the methods section are reported in the results.
Other bias	High risk	Use of cluster-randomisation, i.e. wards were the unit of randomisation not patients. No allowance for this is made in the sample size calculation and the data analysis. The groups were not comparable at baseline for medical diagnoses, pressure ulcer prevention practices, use of barrier creams and use of vitamin supplementary therapy. The type of mattress used was not the same for all participants. The repositioning schedules for each participant was not the same.

Webster 2011

Methods	A single blind randomised controlled trial.
Participants	1231 patients admitted to internal medicine or oncology wards
Interventions	Participants allocated to either: A. Waterlow (n=410) B. Ramstadius (n=411) screening tool group C. Clinical judgement group (n=410) where no formal risk screening instrument was used.
Outcomes	Incidence of hospital acquired pressure ulcers. The incidence of hospital-acquired pressure ulcers was similar between the groups: A. Waterlow 31/411 (7.5%) B. Ramstadius 22/410 (5.4%), C. Clinical judgement 28/410 (6.8%) p=0.4
Notes	
Risk of bias	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A computer-generated randomised list was used"
Allocation concealment (selection bias)	Low risk	Quote: "A phone randomisation method was used"
Blinding (performance bias and detection bias) All outcomes	Low risk	Quote: "The patient and the outcome assessor were blinded to group assignment"
Incomplete outcome data (attrition bias) All outcomes	Low risk	The number of participants allocated to each group were analysed for the primary outcome
Selective reporting (reporting bias)	Low risk	The authors report all outcomes alluded to in the paper
Other bias	Low risk	The study was funded by research grants from the Queensland Nursing Council, the Royal Brisbane and Women's Hospital Private Practice Fund, the Royal Brisbane and Women's Hospital Research Foundation and a Queensland Health Nursing Research Grant.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Anthony 1998	Did not look at the effect of risk assessment on pressure ulcer development, as some patients already had pressure ulcers
Bale 1995	Not a RCT
Bergstrom 1998	Not a RCT: random allocation to Braden, but no control group. The authors are focusing on sensitivity and specificity.
Chan 1997	Not a RCT, descriptive statistics only
Defloor 2005	Clinical trial, random allocation to turning group, but not to risk assessment tool, patients assessed using Braden and Norton. Looked at the sensitivity and specificity of Braden and Norton among the 2 groups: turning and no turning.
Gunningberg 1999	Clinical trial but no random allocation

Study	Reason for exclusion
Gunningberg 2001	This was an audit of nursing records and not a RCT
Hodge 1990	Quasi-experimental
Lyne 1999	This was a retrospective chart analysis and was not a RCT
Salvadena 1992	Only looked at sensitivity and specificity

References

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