Risk assessment tools for the prevention of pressure ulcers (Review)

Moore ZEH, Cowman S

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in The Cochrane Library 2010, Issue 12

http://www.thecochranelibrary.com

Copyright © 2010 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEADER</td>
<td>1</td>
</tr>
<tr>
<td>ABSTRACT</td>
<td>1</td>
</tr>
<tr>
<td>PLAIN LANGUAGE SUMMARY</td>
<td>2</td>
</tr>
<tr>
<td>BACKGROUND</td>
<td>2</td>
</tr>
<tr>
<td>OBJECTIVES</td>
<td>3</td>
</tr>
<tr>
<td>METHODS</td>
<td>4</td>
</tr>
<tr>
<td>Figure 1.</td>
<td>6</td>
</tr>
<tr>
<td>RESULTS</td>
<td>6</td>
</tr>
<tr>
<td>DISCUSSION</td>
<td>8</td>
</tr>
<tr>
<td>AUTHORS’ CONCLUSIONS</td>
<td>9</td>
</tr>
<tr>
<td>ACKNOWLEDGEMENTS</td>
<td>10</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>10</td>
</tr>
<tr>
<td>CHARACTERISTICS OF STUDIES</td>
<td>13</td>
</tr>
<tr>
<td>DATA AND ANALYSES</td>
<td>17</td>
</tr>
<tr>
<td>Analysis 1.1. Comparison 1 Comparison between Braden pressure ulcer risk assessment and training vs. unstructured pressure ulcer risk assessment following training alone, Outcome 1 Pressure ulcer incidence - Braden risk assessment and training vs. unstructured risk assessment following training alone.</td>
<td>17</td>
</tr>
<tr>
<td>Analysis 2.1. Comparison 2 Comparison between Braden pressure ulcer risk assessment and training vs. unstructured pressure ulcer risk assessment alone, Outcome 1 Pressure ulcer incidence - Braden risk assessment and training vs. unstructured risk assessment alone.</td>
<td>18</td>
</tr>
<tr>
<td>APPENDICES</td>
<td>18</td>
</tr>
<tr>
<td>WHAT’S NEW</td>
<td>24</td>
</tr>
<tr>
<td>HISTORY</td>
<td>24</td>
</tr>
<tr>
<td>CONTRIBUTIONS OF AUTHORS</td>
<td>25</td>
</tr>
<tr>
<td>DECLARATIONS OF INTEREST</td>
<td>25</td>
</tr>
<tr>
<td>SOURCES OF SUPPORT</td>
<td>25</td>
</tr>
<tr>
<td>INDEX TERMS</td>
<td>25</td>
</tr>
</tbody>
</table>
Risk assessment tools for the prevention of pressure ulcers

Zena EH Moore1, Seamus Cowman1

1Faculty of Nursing and Midwifery, Royal College of Surgeons in Ireland, Dublin, Ireland

Contact address: Zena EH Moore, Faculty of Nursing and Midwifery, Royal College of Surgeons in Ireland, 123 St Stephens Green, Dublin, Ireland. zmoore@rcsi.ie.

Editorial group: Cochrane Wounds Group.

Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 12, 2010.

Review content assessed as up-to-date: 7 November 2010.


ABSTRACT

Background
Pressure ulcer risk assessment is a component of the assessment process used to identify individuals at risk of developing a pressure ulcer. 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 clarify the role of 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
For this first update, we searched the 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) and Ovid EMBASE (2007 to 2010 Week 37) and EBSCO CINAHL (2007 to 17 September 2010).

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
For the original review, no studies were identified that met the inclusion criteria. For this first update, we identified and included one small, cluster randomised study. The study included 256 people randomised by ward into three groups in which 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. There was no statistically significant difference between the groups in terms of pressure ulcer incidence however the study was underpowered to detect a clinically important difference in pressure ulcer incidence.
Authors’ conclusions

One small RCT was identified which evaluated the effect of risk assessment on patient outcomes; there was no statistically significant difference in pressure ulcer incidence between patients who were assessed using structured risk assessment compared with those receiving unstructured risk assessment. Methodological limitations of this study prevent firm conclusions regarding whether the use of structured, systematic pressure ulcer risk assessment tools, in any healthcare setting, reduces the incidence of pressure ulcers. The effect of structured risk assessment tools on pressure ulcer incidence needs to be evaluated.

Plain Language Summary

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 (EPUAP 2009). They occur in people who do not have the ability to reposition themselves in order to relieve pressure on bony prominences. This ability is often diminished in the very old, the malnourished and those with an acute illness (Robertson 1990). Indeed, it is suggested that approximately 18% of hospitalised patients have a pressure ulcer (EPUAP 2002) and, although some of these pressure ulcers may be present on admission, most pressure ulcers occur during a hospital stay for the management of acute illness (Bridel 1996).

Pressure ulcer incidence rates range between 2.2% and 66% in the UK, and 0% and 65.6% in the USA and Canada (Kaltenthaler 2001). These figures are influenced by the location and condition of the patient group (hospital versus community setting, general hospital patients versus those with fractured neck of femur) with the highest incidence noted among elderly orthopaedic patients (Bridel 1996; Hanson 1993; Richardson 1981; Versluyksen 1986). Interestingly, a review of data from a six-year national incidence study in the USA found that the incidence in 1999 was 8% and in 2004 was 7%, demonstrating little change in overall figures (Whittington 2004).

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.

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
Pressure ulcer risk assessment 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.

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 2003). To date, there is little empirical evidence available concerning the reliability and validity of existing tools (Anthony 2008; Cullum 1995; Defloor 2004; Defloor 2005; McGough 1999; Pancorbo-Hidalgo 2006; Schoonhoven 2002a). 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 health 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.

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**

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 - 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 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*)

*Risk assessment tools for the prevention of pressure ulcers (Review)*

Copyright © 2010 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
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 2009). 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 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.

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 study using the Cochrane Collaboration tool for assessing risk of bias (Higgins 2009). 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) which presents the judgements in a cross-tabulation. This display of internal validity indicates the weight the reader may give to the results of each 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. Where heterogeneity was absent or low ($I^2 = 0\%$ to 25%) we planned to use a fixed-effect model; if there was evidence of heterogeneity ($I^2$ more than 25%), we planned to use a random-effects model. As only one study was eligible for inclusion in this review this was not applicable.

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

See: Characteristics of included studies; Characteristics of excluded 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.

Included studies

One RCT published in 2009 met the inclusion criteria (Saleh 2009). This cluster randomised study was conducted in nine wards.
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. The authors do not state if those who collected the data and assessed the study outcomes, were blinded to treatment allocation.

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

Risk of bias in included studies
Saleh 2009 stated that patients were randomly allocated to the risk assessment groups but did not report the method of randomisation. Furthermore, the allocation method used to assign groups is not reported. The authors did not mention blinding in the study report, nor did they report if an intention-to-treat (ITT) analysis was undertaken. 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. Based on this assessment this study would be judged to be overall at high risk of bias (Figure 1).

Effects of interventions
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 $\leq$ 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.

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. As, by definition, the risk of an event occurring in the control group is 1, then the RR reduction associated with using an experimental treatment is 1-RR. The RR indicates the relative benefit of a therapy but not the actual benefit, i.e. it does not take into account the number of people who would have developed a pressure ulcer anyway without the intervention.

Comparison 01: Comparison between Braden pressure ulcer risk assessment and training compared with unstructured pressure ulcer risk assessment following training alone
Following delivery of the training to the staff, Saleh 2009 enrolled 150 patients with a Braden score of $\leq$ 18, from six wards. Seventy-four patients were in the Braden scale group, and 76 patients were in the training group. 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 a further 106 patients from three wards with a Braden score of ≤ 18. These 106 patients were managed using unaided clinical judgement. The incidence of pressure ulcers in this clinical judgement group was compared with the 74 patients who were in the Braden scale group. 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).

DISCUSSION

One eligible study (Saleh 2009) was included in this review, despite our having made every attempt to identify all relevant studies, including contacting experts in this field and searching conference proceedings to identify studies as yet unpublished. It is theoretically possible, though unlikely, that we did not manage to locate some potentially eligible studies. Saleh 2009 demonstrated 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.

Some methodological issues require consideration and limit the conclusions that can be drawn from this review. 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 2005). 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 design effect is the ratio between the number of subjects needed using cluster-randomisation and the number of subjects needed using simple random sampling (Kerry 1998). If there is a large intra-cluster correlation, there will be a corresponding large design effect, meaning that more subjects are required to achieve the same power as when the study uses simple randomisation (Kerry 1998). This study 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). Without an understanding of the intra-cluster correlation, the study risks losing power (Vierron 2009).

Concealment of group allocation was inadequately described in the study. Allocation concealment is a randomisation method that prevents the researcher influencing which group, experimental or control, a participant is allocated to (Higgins 2009), therein ensuring that the participant is assigned to a specific study group by chance (Higgins 2009). 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.

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 2009). Human behaviour is influenced by prior knowledge thus, without blinding, there is a risk that the size of the effect may be overestimated, resulting in a bias in favour of the treatment (Day 2000). 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.

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 does not report use of ITT. Pressure ulcer incidence is reported for all patients in the post-training groups, however a number of patients were excluded from commencing the study and the reason is unclear; i.e. whether it was that they did not meet inclusion criteria. Saleh 2009 does not report whether or not there were any withdrawals from the study, nor if an ITT analysis was appropriate or undertaken.

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). The authors of the one included trial (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.

Pressure ulcer risk assessment 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 2002; 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 (Callum 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. They further contend that clinical judgement is not as accurate as structured risk assessment, however how this is determined is not clear. 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.

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 argues 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.

One 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. If pressure ulcer risk assessment 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. There is a need for a large cluster-randomised study, correctly powered, with treatment groups comparable at baseline, allocation to groups concealed, blinded outcome assessment and intention-to-treat analysis, to confirm the role of risk assessment in the prevention of pressure ulcers.

**AUTHORS’ CONCLUSIONS**

**Implications for practice**

There is no high quality RCT evidence that identifies whether 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 high quality RCT evidence available to identify whether applying a policy of conducting risk assessment makes any difference to pressure ulcer incidence. Therefore, the effect of risk assessment on pressure ulcer incidence has yet to be established.

REFERENCES

References to studies included in this review

Saleh 2009 \textit{\{published data only\}}


References to studies excluded from this review

Anthony 1998 \textit{\{published data only\}}


Bale 1995 \textit{\{published data only\}}


Bergstrom 1998 \textit{\{published data only\}}


Chan 1997 \textit{\{published data only\}}


Defloor 2005 \textit{\{published data only\}}


Gunningberg 1999 \textit{\{published data only\}}


Gunningberg 2001 \textit{\{published data only\}}


Hodge 1990 \textit{\{published data only\}}


Lyne 1999 \textit{\{published data only\}}


Salvadena 1992 \textit{\{published data only\}}


Additional references

AHCPR 1992


Alarcon 1999


Allman 1997


Anthony 2008


Bennett 2004


Berlowitz 1990


AC KNOWLEDGEMENTS

The authors would like to acknowledge the contribution of the peer referees; Susanne Hempel, Jane Nixon, Janet Yarrow and the Wounds Group Editors; Nicky Cullum, Mieke Flour, Liz McNes and Gill Worthy. In addition the contribution of the Cochrane Copy Editor Elizabeth Royle, the Managing Editor Sally Bell-Syer and the Trials Search Co-ordinator Ruth Foxlee.
Bo 2003

Braden 1987

Bridel 1996

Clark 1991

Cullum 1995

Day 2000

Defloor 2004

Defloor 2005

Donner 2004

Elley 2004

EPUAP 2002

EPUAP 2009

Fox 2002

Friedman 1996

Gould 2002

Haalboom 1999

Haalboom 2000

Hahn 2005

Halfens 2000

Hanson 1993

Hencloch 2003

Higgins 2003

Higgins 2005

Higgins 2009
Risk assessment tools for the prevention of pressure ulcers (Review)


NICE 2001

Norton 1975

NPUAP 1998

Pancorbo-Hidalgo 2006

Puffer 2005

RevMan 2008

Richardson 1981

Robertson 1990

Rycroft-Malone 2000

Schoonhoven 2002

Schoonhoven 2002a
SIGN 2010

Spilsbury 2007

Thompson 1999

Versluysen 1986

Vierron 2009

Waterlow 1985

Whittington 2000

Whittington 2004

* Indicates the major publication for the study
## 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

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>No</td>
<td>The authors write: “for pragmatism, this study randomly allocated nine wards into three groups”</td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>The authors write: “for pragmatism, this study randomly allocated nine wards into three groups”</td>
</tr>
<tr>
<td>Blinding? All outcomes</td>
<td>No</td>
<td>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 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.</td>
</tr>
</tbody>
</table>
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.

The study protocol was not available but the important outcome measures stated in the methods section are reported in the results.

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.

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthony 1998</td>
<td>Did not look at the effect of risk assessment on pressure ulcer development, as some patients already had pressure ulcers</td>
</tr>
<tr>
<td>Bale 1995</td>
<td>Not a RCT</td>
</tr>
<tr>
<td>Bergstrom 1998</td>
<td>Not a RCT: random allocation to Braden, but no control group. The authors are focusing on sensitivity and specificity</td>
</tr>
<tr>
<td>Chan 1997</td>
<td>Not a RCT, descriptive statistics only</td>
</tr>
<tr>
<td>Defloor 2005</td>
<td>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</td>
</tr>
<tr>
<td>Reference</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>Gunningberg 1999</td>
<td>Clinical trial but no random allocation</td>
</tr>
<tr>
<td>Gunningberg 2001</td>
<td>This was an audit of nursing records and not a RCT</td>
</tr>
<tr>
<td>Hodge 1990</td>
<td>Quasi-experimental</td>
</tr>
<tr>
<td>Lyne 1999</td>
<td>This was a retrospective chart analysis and was not a RCT</td>
</tr>
<tr>
<td>Salvadena 1992</td>
<td>Only looked at sensitivity and specificity</td>
</tr>
</tbody>
</table>
## Data and Analyses

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

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

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

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

### Analysis 1.1. Comparison 1
Comparison between Braden pressure ulcer risk assessment and training vs. unstructured pressure ulcer risk assessment following training alone, Outcome 1 Pressure ulcer incidence - Braden risk assessment and training vs. unstructured risk assessment following training alone.

**Review:** Risk assessment tools for the prevention of pressure ulcers

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

**Outcome:** 1 Pressure ulcer incidence - Braden risk assessment and training vs. unstructured risk assessment following training alone

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Braden plus training</th>
<th>Training alone</th>
<th>Risk Ratio (M-H, Fixed, 95% CI)</th>
<th>Weight</th>
<th>Risk Ratio (M-H, Fixed, 95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saleh 2009</td>
<td>16/74</td>
<td>17/76</td>
<td></td>
<td>100.0 %</td>
<td>0.97 [0.53, 1.77]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>74</td>
<td>76</td>
<td>100.0 %</td>
<td></td>
<td>0.97 [0.53, 1.77]</td>
</tr>
</tbody>
</table>

Total events: 16 (Braden plus training), 17 (Training alone)

Heterogeneity: not applicable

Test for overall effect: Z = 0.11 (P = 0.91)

Test for subgroup differences: Not applicable
Analysis 2.1. Comparison 2 Comparison between Braden pressure ulcer risk assessment and training vs. unstructured pressure ulcer risk assessment alone, Outcome 1 Pressure ulcer incidence - Braden risk assessment and training vs. unstructured risk assessment alone.

Review: Risk assessment tools for the prevention of pressure ulcers

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

Outcome: 1 Pressure ulcer incidence - Braden risk assessment and training vs. unstructured risk assessment alone

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Braden plus training</th>
<th>Clinical judgement</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
<th>Weight 100.0 %</th>
<th>Risk Ratio M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saleh 2009</td>
<td>16/74</td>
<td>16/106</td>
<td>1.43 [ 0.77, 2.68 ]</td>
<td>100.0 %</td>
<td>1.43 [ 0.77, 2.68 ]</td>
</tr>
</tbody>
</table>

Total (95% CI) 74 106 1.43 [ 0.77, 2.68 ]

Total events: 16 (Braden plus training), 16 (Clinical judgement)

Heterogeneity: not applicable

Test for overall effect: Z = 1.12 (P = 0.26)

Test for subgroup differences: Not applicable

APPENDICES

Appendix 1. Search methods section - Original version 2008

Electronic searches

The following databases were searched:
MEDLINE (January 1966 to April Week 3, 2008)
EMBASE (1974 to Week 17, 2008)
CINAHL (1982 to April Week 4, 2008)
The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, issue 2, 2008)
The Cochrane Wounds Group Specialised Register (Searched 29/4/2008)

The following search strategy was used in CENTRAL to identify relevant studies and was adapted where necessary to allow for the variations in indexing between databases:

#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
Risk assessment tools for the prevention of pressure ulcers (Review)

The Ovid MEDLINE search was combined with the Cochrane highly sensitive search strategy for identifying reports of randomised controlled trials (Higgins 2006). The Ovid EMBASE and CINAHL searches were combined with the trial filters developed by the Scottish Intercollegiate Guidelines Network.

Citations in all retrieved and relevant publications identified by these strategies were searched for further studies. 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, were contacted 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$)).mp.
6 (decubitus adj (ulcer$ 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.
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$)).mp.
8 or/1-7
9 exp Risk Assessment/
10 ((anderson or braden or norton or knoll or waterlow or mcclor or arnold or gosnell) adj10 (score$ 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 birt* para or AB birt* 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 maclor or arnold or gosnell ) or AB ( anderson or braden or norton or knoll or waterlow or maclor 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?

Yes, 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.

No, 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 ‘Yes’ or ‘No’.

2. **Was the treatment allocation adequately concealed?**

**Yes, 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.

**No, 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 nonopaque 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 ‘Yes’ or ‘No’. 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?**

**Yes, 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.

**No, 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 ‘Yes’ or ‘No’.
- The study did not address this outcome.
4. Were incomplete outcome data adequately addressed?

**Yes, 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.

**No, 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 ‘Yes’ or ‘No’ (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?

**Yes, 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).

**No, 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 ‘Yes’ or ‘No’. It is likely that the majority of studies will fall into this category.

6. **Other sources of potential bias:**

**Yes, low risk of bias**

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

**No, 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
• stopped early due to some data-dependent process (including a formal-stopping rule); or
• had extreme baseline imbalance; 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**

Last assessed as up-to-date: 7 November 2010.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 November 2010</td>
<td>New search has been performed</td>
<td>New searches completed for the first update, one new study included in the</td>
</tr>
<tr>
<td></td>
<td></td>
<td>review and risk of bias assessment completed (Saleh 2009).</td>
</tr>
</tbody>
</table>
HISTORY


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 first update - Seamus Cowman.
Preparation of the first update - Zena Moore.

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources
• The Faculty Board, Faculty of Nursing & Midwifery, RCSI, Dublin 2, Ireland.
• Royal College of Surgeons in Ireland, Ireland.

External sources
• Health Research Board of Ireland, Ireland.

INDEX TERMS

Medical Subject Headings (MeSH)
Pressure Ulcer [*prevention & control]; Risk Assessment [methods]

MeSH check words
Humans