

Appendix 3 Critical appraisal checklists

Systematic Review Data Extraction /Validity Checklist Form

Type of review *unsystematic **ungraded systematic systematic

Objective _____

Question clearly formulated: yes no don't know/not stated

*Method

Explicit inclusion/exclusion criteria yes no don't know/not stated

Specify: Types of participants _____
 Types of interventions _____
 Types of outcome measures _____
 Eligible study design _____

Search strategy explicit? yes no not stated

Databases searched described yes no

Explicit assessment of study validity yes *no not stated

Number of reviewers used stated yes no

Reviewers blinded yes no not stated

Measure of reviewer agreement yes no not stated

Standardised method of data extraction yes no not stated

**Reject if methods section not clear*

Data synthesis

Qualitative overview yes no

Analytic Cohort/ One Sample Longitudinal Data Extraction/ Validity Checklist Form

* = fatal flaw/reject

**=less serious flaw requiring consideration in summing up study

Objective

Aim _____

Hypothesis clearly defined? yes no

Design appropriate to objective? yes *no

If 'no' explain why and reject _____

Sample

Diagnostic criteria stated clearly? yes *no *not stated

Diagnostic criteria adequate? yes **no

if 'no', why _____

Exposed group

Inclusion criteria (please state) _____

Exclusion criteria (please state) _____

How were exposed recruited? _____

Indicate if controls used **historical concurrent none (one-sample study)

Non-exposed

Inclusion criteria (please state) _____

Exclusion criteria (please state) _____

Non-exposed cohort selected from same population as exposed? yes *no **not stated

How were unexposed recruited? _____

If study of prognosis:

Exposed identified at an early and uniform point in the course of their disease/ exposure?
 yes *no not stated not relevant

Power calculations included? yes no not stated

Numbers required _____

Actual numbers recruited _____

Exposure

What was measured?

1. _____
2. _____
3. _____
4. _____

Who carried out measurements?

1. _____
2. _____
3. _____
4. _____

What was measurement tool(s)?

1. _____
2. _____
3. _____
4. _____

Was tool(s) validated?

- | | | | |
|----|------------------------------|-----------------------------|-------------------------------------|
| 1. | yes <input type="checkbox"/> | no <input type="checkbox"/> | not stated <input type="checkbox"/> |
| 2. | yes <input type="checkbox"/> | no <input type="checkbox"/> | not stated <input type="checkbox"/> |
| 3. | yes <input type="checkbox"/> | no <input type="checkbox"/> | not stated <input type="checkbox"/> |
| 4. | yes <input type="checkbox"/> | no <input type="checkbox"/> | not stated <input type="checkbox"/> |

Outcome

What and how often was measured?

1. _____
2. _____
3. _____
4. _____

Who carried out measurements?

1. _____
2. _____
3. _____
4. _____

What was measurement tool(s)?

1. _____
2. _____
3. _____
4. _____

Was tool(s) validated?

- | | | | |
|----|------------------------------|-----------------------------|-------------------------------------|
| 1. | yes <input type="checkbox"/> | no <input type="checkbox"/> | not stated <input type="checkbox"/> |
| 2. | yes <input type="checkbox"/> | no <input type="checkbox"/> | not stated <input type="checkbox"/> |
| 3. | yes <input type="checkbox"/> | no <input type="checkbox"/> | not stated <input type="checkbox"/> |
| 4. | yes <input type="checkbox"/> | no <input type="checkbox"/> | not stated <input type="checkbox"/> |

Data collectors blinded to exposure status of subjects?

- | | | | |
|----|------------------------------|-----------------------------|-------------------------------------|
| 1. | yes <input type="checkbox"/> | no <input type="checkbox"/> | not stated <input type="checkbox"/> |
| 2. | yes <input type="checkbox"/> | no <input type="checkbox"/> | not stated <input type="checkbox"/> |
| 3. | yes <input type="checkbox"/> | no <input type="checkbox"/> | not stated <input type="checkbox"/> |
| 4. | yes <input type="checkbox"/> | no <input type="checkbox"/> | not stated <input type="checkbox"/> |

Length of follow-up _____

Time frame for ascertainment of outcome appropriate? yes no not stated

Analysis

Table of demographic and clinical baseline characteristics of participants (please state key socio-demographic and prognostic variables, including proportions, mean, standard deviation, range as relevant)

80% of those followed-up included in analysis yes *no **not stated
 (if alternative sources of data used to complete dataset these should be specified) _____

Losses to follow-up differ from those contacted? **yes no **not stated

Attrition rate (by comparison group if appropriate)
 Specify numerator/denominator _____

Statistical analysis adequate and appropriate? yes **no

Unit of analysis _____

Method of analysis _____

Results (for each main endpoint record p-value; effect size; confidence interval)

Negative study without a power calculation? **yes no

Confounding satisfactorily dealt with? yes **no

Comments _____

Reviewer's judgement

Findings generalisable to guideline population? yes no

Clinically important differences in outcome? yes no

Outcomes true or substitute? true substitute

Exposure

What was measured?

- 1. _____
- 2. _____
- 3. _____
- 4. _____

Who carried out the measurement(s)

- 1. _____
- 2. _____
- 3. _____
- 4. _____

What was the measurement tool(s)

- 1. _____
- 2. _____
- 3. _____
- 4. _____

Was it validated?

- 1. _____
- 2. _____
- 3. _____
- 4. _____

Outcome(s) of interest (if relevant)

What was measured?

- 1. _____
- 2. _____
- 3. _____
- 4. _____

Who carried out the measurement(s)?

- 1. _____
- 2. _____
- 3. _____
- 4. _____

What was the measurement tool(s)?

1. _____
2. _____
3. _____
4. _____

Was it validated?

1. _____
2. _____
3. _____
4. _____

Outcome assessment blind?

yes

**no

Analysis

Characteristics of participants (state key socio-demographic and prognostic variables, with relevant statistics)

If face to face interview/procedure > 80% approached participated? yes **no not stated

If telephone interview > 60% approached participated? yes **no not stated

If postal survey > 50% approached participated? yes **no not stated

Response rate including numerator and demoninator _____

Statistical analysis appropriate and adequate? yes **no not stated

Statistical techniques used _____

Unit of analysis _____

Results (specify p-values; effect size and confidence intervals for each outcome)

Confounding dealt with? yes **no

Comments _____

Reviewer's judgement

Findings generalisable to guideline population? yes no

Clinically important differences in outcome? yes no

Benefits outweigh harms risk? yes no

Results biologically plausible? yes no

Subjective rating of risk of bias in study low moderate high

Author's conclusions _____

Variable	Baseline measurements

Do you agree with the author's conclusions? yes no

List specific reservations _____

Is the paper to be included? yes no

Variable	Result (p-value; effect size; confidence interval)

Describe _____

Are methods of data collection adequately described? *How were data elicited/type and range of questions*

Describe _____

Indicate

- Unstructured interviews
- Semi-structured interviews
- Focus groups
- Participant observation
- Non-participant observation (video/audio recordings)
- Existing documents
- Free written text or drawings

Data collected systematically? *Evidence of consistent use of interview guide/study protocol*

yes *no

Data analysis

Describe how data analysed (how were concepts, themes or categories developed and interpreted? _____

Indicate if:

- Conceptualized in terms of themes or typologies
- *Presented as a loose collection of descriptive material, with little analysis
- Responses to individual questions categorised and the range of categories reported
- Coded using coding categories developed post hoc and reported numerically

**Response rate _____

Describe results _____

- *Analysis and interpretation procedures discussed? yes no
- Evidence that supporting material is representative? *Sources should be given* yes *no
- Evidence of efforts to establish validity? *Evidence that accounts of the phenomenon reflect it accurately* yes no
- Evidence of efforts to establish reliability? *Evidence that accounts of the phenomenon are consistent over time or between researchers* yes *no
- *Respondent validation by feeding back data/researcher's interpretation? yes *no
- *Interpretations and theorisation's grounded/supported by data? *Excerpts from original data, summaries of examples or numerical data presented as evidence for interpretation made. Use of extracts of data alone to support theory avoided.* yes *no

Evaluation

- Findings transferable to guideline population? yes no
- Evidence support researcher's claims? yes **no
- Results of clinical importance? yes no
- Emergent relationships plausible? yes **no
- Limitations of methodology and biases discussed yes **no
- Risk of bias low moderate *high

Author's conclusions _____

- Do you agree with the author's conclusions? yes no

List specific reservations _____

- Is the paper to be included? yes no

Appendix 4

Studies included in update of AHCPR literature base

Study	Design including sampling strategy	Results	Comments	Conclusions
<p>Finucane (1995)</p> <p>To review data about the relationship between pressure sores and 1) nutritional status 2) nutrient intake and 3) tube feeding.</p>	Literature review.	<p><i>Findings in relation to pressure ulcer development.</i></p> <p>Low serum albumin associated with the development or presence of sores in seven studies, in five others it was not.</p> <p>Most measures of nutritional status were not associated with pressure sore outcomes.</p> <p>Poor nutritional intake associated with poor pressure sore outcome in four out of seven studies.</p>	Not all available data captured.	<p>Data on relationship between malnutrition and pressure ulcers is incomplete and contradictory.</p> <p>There is no real evidence that there is any association between malnutrition and development of pressure ulcers.</p> <p>No evidence to suggest that correcting malnutrition reduces the likelihood of developing pressure ulcers.</p>
<p>Garber et al (1996)</p> <p>Identify factors that result in severe pressure ulcers in persons with spinal cord injury.</p>	<p>Survey via interviews assessing demographic, SCI and ulcer characteristics, detection method, immediacy and appropriateness of action, time from detection to clinic visits, number of prior ulcers and knowledge and practice of ulcer prevention techniques.</p> <p>Sampling: convenience</p> <p>Setting: patients presenting at a community based outpatient plastic surgery clinic.</p> <p>N= 23 (20 men, 3 women), with ulcers that were of 12 weeks' duration or less.</p>	Individuals who waited longer to go to the clinic presented with more severe ulcers.	Small sample size.	<p>Education programmes should emphasise immediate visits to the physician on detection of an ulcer.</p> <p>Individuals with SCI should be encouraged to have another person inspect their skin regularly – even if they are capable of doing it themselves.</p>

<p>Brandeis et al (1994)</p> <p>To determine risk factors associated with the formation of stage II-IV pressure ulcers in nursing homes</p>	<p>Longitudinal cohort study</p> <p>4,232 nursing home residents in 78 homes, over 60 years of age, 73% women, admitted without pressure ulcers.</p> <p>Homes divided up based on incident rates of pressure ulcer formation – high and low incidence homes.</p> <p>Assessed at 3, 6 and 21 months for presence of pressure ulcers.</p> <p>Data collected on variables such as age, gender, antipsychotic medications, BMI, cognitive status, incontinence, mobility, and an ADL score.</p> <p>Pooled logistic regression.</p>	<p>In high incidence homes – faecal incontinence, difficulty with mobility, diabetes and difficulty feeding oneself were significant independent factors.</p> <p>In low incidence homes – difficulty with mobility, difficulty feeding oneself and male sex were significant independent factors.</p>	<p>The nursing homes themselves may play a greater role in pressure ulcer development than the characteristics of the residents because practice was not controlled for.</p> <p>Not all potential risk factors were investigated.</p> <p>Nursing home staff carried out measures with only intermittent checks on reliability.</p>	<p>By identifying and controlling for specific risk factors within certain populations pressure, ulcer incidence may be reduced.</p>
<p>Papantonio et al (1994)</p> <p>To examine the incidence and risk factors related to the development of sacral pressure ulcers following elective surgery</p>	<p>Cohort study</p> <p>Convenience sample of 136 adult patients (66% male) undergoing elective surgery.</p> <p>Measurement of pre-, intra-, and post- operative variables, such as demographics, BMI, pre-existing medical conditions, position on table, use of thermal under blankets, and skin condition.</p> <p>6 day follow up period.</p>	<p>Variables such as diabetes, increasing age, transfer from another hospital, respiratory disease and haematocrit levels were found to be associated with pressure ulcer development.</p>	<p>Assessments carried out by a number of different assessors.</p> <p>No strict inclusion criteria of patients.</p> <p>Size of ulcer not recorded and collapsed stage I and II damage may have overestimated damage.</p> <p>Limited to cardiac surgery.</p>	<p>People judged prior to surgery as being 'healthy' are at risk of developing pressure ulcers during cardiac surgery.</p>

<p>Bergstrom and Braden (1992)</p> <p>To determine if dietary intake, nutritional status, and other physical markers are risk factors for the development of pressure ulcers in the elderly.</p>	<p>Cohort study</p> <p>200 newly admitted patients, 70% female, over 65 years of age, to a 250 bedded nursing home.</p> <p>Skin assessment, Braden Scale score, blood pressure, temperature, anthropometric measurements and dietary intake were studied weekly. Serum zinc, albumin, iron, copper and vitamin C were studied weekly for 4 weeks and biweekly for 8 weeks.</p> <p>Main outcome measure – the presence or absence of pressure ulcers.</p>	<p>Stage I pressure ulcers developed in 35% and stage II or worse in 38.5% of residents.</p> <p>Age, blood pressure, temperature, dietary protein, iron and Braden score emerged as significant predictors of pressure ulcer development in logistic regression analysis.</p>	<p>Background of patients unclear in relation to UK populations.</p> <p>Selection bias present.</p> <p>Results should be interpreted in the light of the pressure ulcer prevention practices of the nursing home in which the study took place.</p>	<p>These are factors that practitioners need to be aware that may increase a person's risk of developing pressure ulcers.</p> <p>A formal, structured risk assessment should be undertaken on people admitted to nursing homes.</p>
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Appendix 5

Studies excluded for AHCPR update

Authors	Reference	Reason for exclusion
van Marum R.J., Meijer J.H., Bertelsmann F.W., Ribbe M.W.	Arch Phys Med Rehabil (1997) 78 1003 – 1005	Not relevant in the context of the guideline. Key question for the guideline: are diabetic patients and/or those with cardiac autonomic neuropathy more prone to pressure ulcers? This paper does not provide the answer to the question.
Steinmetz J.A. and Langemo D.K.	Advances in Wound Care (1996) 9(3) 28 – 32	Not relevant in context of the guideline. Does demonstrate greater interface pressures on the back of head during anaesthesia – does not answer the question of whether pressure ulcers occur in these patients and what is an effective preventive strategy.
Bergstrom N., Braden B., Kemp M. et al	Journal of the American Geriatrics Society (1996) 44 (1) 22 – 30	Relevance to UK limited. One third of subjects drawn from Veteran's Administration Medical Centres (no direct counterparts in the UK). White race offered as predictive marker of the allocation of pressure ulcer preventative care, a finding not seen in UK/European studies – unhelpful to infer ethnicity determines care provision, and, main conclusion that risk assessment should form the basis of allocation of preventive care long been recognised in the UK.
Olson B., Langemo D., Burd C. et al	Journal of the Wound, Ostomy and Continence Nurses Society (1996) 23(1) 15 – 22	Lack of control of variables, methods unclear and conclusion reached without consideration of alternative explanations.
Baharestani M.M.	Advances in Wound Care (1994) 7(3) 40 – 52	Limited transferability. Very specific US sample. Finance raised as one of the main themes – different funding of health care between US and UK. Worth replicating in the UK.
Lewicki L.J., Mion L., Splane K.G. et al	AORN J (1997) 65(5) 933 – 941	Exposure to surgery not uniform. Timing of previous procedures and effect on pressure ulcer incidence unreported. Preoperative stay in hospital unreported. Pre- and post-operative pressure relief not reported.
Pang S.M-c, Wong T.K-s	Nursing Research (1998) 47(3) 147 – 153	Data unreported for total population. Sampling strategy not clear. Only a 76% follow-up. Skin status ambiguous among subjects that were withdrawn.

Appendix 6

Beds, mattresses and cushions for preventing and treating pressure sores

Cullum N., Deeks J., Sheldon T.A., Song F., Fletcher A.W

In: *The Cochrane Library*, Issue 1, 2000. Oxford: Update Software.

A substantive amendment to this systematic review was last made on 20 August 1999. Cochrane reviews are regularly checked and updated if necessary.

Objectives: To assess the effectiveness of pressure relieving beds, mattresses and cushions (support surfaces) in the prevention and treatment of pressure sores.

Search strategy: Searches of 19 databases, hand searching of journals, conference proceedings, and bibliographies.

Selection criteria: Randomised controlled trials evaluating support surfaces for the prevention or treatment of pressure sores. There was no restriction on articles based on language or publication status.

Data collection and analysis: Data extraction and assessment of study quality was undertaken by two reviewers independently. Trials with similar patients, comparisons, and outcomes were pooled. Where pooling was inappropriate, trials are discussed in a narrative review.

Main results:

Prevention: 29 RCTs of support surfaces for pressure sore prevention were identified. Some high specification foam mattresses were more effective than 'standard' hospital foam mattresses in moderate-high risk patients. Pressure relieving mattresses in the operating theatre reduced the incidence of pressure sores post-operatively. The relative merits of alternating and constant low pressure, and of the different alternating pressure devices are unclear. Seat cushions and simple, constant low-pressure devices have not been adequately evaluated. Limited evidence suggests that low air loss beds reduce the incidence of pressure sores in intensive care.

Treatment: 6 RCTs of support surfaces for pressure sore treatment were identified. There is good evidence that air-fluidised and low air loss beds improve healing rates. Seat cushions have not been adequately evaluated.

2 RCTs evaluated surfaces for both prevention and treatment in the same trial.

Reviewers' conclusions:

Prevention: There is good evidence of the effectiveness of high specification foam over standard hospital foam, and pressure relief in the operating theatre.

Treatment: There is good evidence of the effectiveness

of air-fluidised and low air loss devices as treatments. Overall, however, it is impossible to determine the most effective surface for either prevention or treatment.

Background

Pressure sores (also known as pressure ulcers, decubitus ulcers and bed sores) are areas of localised damage to the skin and underlying tissue, believed to be caused by pressure, shear or friction (Allman, 1997). They usually occur over bony prominences such as the base of the spine, hips and heels. Pressure sores occur in both hospital and community settings, most often in the elderly and immobile (for example orthopaedic patients), those with severe acute illness (for example patients in intensive care units) and in people with neurological deficits (for example patients with spinal cord injuries).

The development of pressure sores is quite common. For example, new pressure sores occurred in 4% - 10% of patients admitted to a UK district general hospital, depending on the case-mix (Clark and Watts). They represent a major burden of sickness and reduced quality of life for patients and their carers, and are costly to the NHS. The cost of preventing and treating pressure sores in a 600-bedded large general hospital has been roughly estimated at between £600,000 and £3 million per year (Clark and Watts).

A pressure sore can be defined as "a new or established area of skin and/or tissue discolouration or damage which persists after the removal of pressure and which is likely to be due to the effects of pressure on the tissues" (Dept of Health, 1993). Health care professionals attempt to reduce the incidence of severe pressure sores by the identification of people at high risk and the use of prevention strategies, such as pressure relieving equipment. It is essential that initiatives are based on the best available evidence of clinical and cost-effectiveness and we have undertaken a systematic review of the evidence for the effectiveness of pressure relieving support surfaces such as beds, mattresses, cushions, and repositioning interventions.

Identifying people at risk

Interventions to prevent pressure sores can be very expensive and it is important to ensure that resources are targeted towards patients who are at high risk of developing sores. Several scales have been developed to

identify those patients at high risk of developing a pressure sore. Most scales have been developed in an ad hoc fashion and it is unclear which is the most accurate. There is little evidence that using a pressure sore risk scale is better than clinical judgement or that it improves outcomes (Cullum et al, 1995). The predictive validity of pressure sore risk calculators was summarised in a previous systematic review and little research has been published since its completion (Cullum et al, 1995).

Interventions to relieve pressure

The aim of pressure sore prevention strategies is to reduce the magnitude and/or duration of pressure (including shear and friction) between a patient and their support surface (the “interface pressure”). This may be achieved by regular manual repositioning (for example “two hourly turning”), or by using pressure relieving support surfaces such as cushions, mattress overlays, replacement mattresses or whole bed replacements. The cost of these interventions varies widely; from over £30,000 for some bed replacements to less than £100 for some foam overlays. Information on the relative cost-effectiveness of this equipment is clearly needed to aid rational use.

Pressure relieving cushions, beds and mattresses either mould around the shape of the patient to distribute the patient's weight over a larger area (constant low pressure devices), or mechanically vary the pressure beneath the patient, so reducing the duration of the applied pressure (alternating pressure devices) (Bliss and Thomas, 1993). Constant low pressure devices (either overlays, mattresses or replacement beds) can be grouped according to their construction (foam, foam and air, foam and gel, profiled foam, hammocks, air suspension, water suspension and air-particulate suspension/air-fluidised). These devices fit or mould around the body so that the pressure is dispersed over a large area. Alternating pressure devices generate alternating high and low interface pressures between body and support, usually by alternate inflation and deflation of air-filled cells. Such devices are available as cushions, mattress overlays, and single- or multi-layer mattress replacements.

Turning beds, such as turning frames, net beds, and turning/tilting beds move those patients, either manually or automatically, who are unable to turn themselves. Pressure sore prevention is often not the reason for using turning and tilting beds; they may be used in intensive and critical care units for other reasons, for example to promote chest drainage.

Pressure sore treatment strategies usually comprise a combination of pressure relief (as above) and wound

care. Wound management strategies such as wound dressings, debridement techniques, physical therapies, antibiotics and antiseptics will be the focus of other systematic reviews undertaken by the Cochrane Wounds Group.

Objectives

The objective was to undertake a systematic review of reliable evaluations of pressure relieving beds, mattresses and cushions in pressure sore prevention and treatment.

Specific questions to be answered were:

- (a) do pressure relieving beds, mattresses and cushions reduce the incidence of new pressure sores compared to standard support surfaces?
- (b) do pressure relieving beds, mattresses and cushions increase the healing rate of existing pressure sores compared to standard support surfaces?
- (c) which types of pressure relieving surface are most effective in different patient groups and settings?

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) comparing beds, mattresses and cushions which measured the incidence of new pressure sores (in prevention studies) or pressure sore healing (in treatment studies) as objective measures of outcome.

There was no restriction on the basis of the language in which the study reports were written.

Types of participants

Prevention Studies: Patients receiving health care who were deemed to be at risk of pressure sore development, in any setting.

Treatment Studies: Patients with existing pressure sores, in any setting.

Types of intervention

Studies which evaluated the following interventions for pressure sore prevention or treatment were included:

1. Standard foam mattresses
2. Specialised foam mattresses/overlays (for example convoluted foam, cubed foam)
3. Gel-filled mattresses/overlays
4. Fibre-filled mattresses/overlays
5. Water-filled mattresses/overlays
6. Alternating pressure mattresses/overlays

7. Air fluidised beds
8. Low air loss beds
9. Sheepskins
10. Turning beds/frames
11. Bead beds
12. Wheelchair cushions
13. Operating table overlays

Types of outcome measures

Prevention Studies

1. Incidence of new pressure sores.
2. Grades of new pressure sores. A range of pressure sore grading systems is used in pressure sore trials. An example of a commonly used grading systems is presented below:

Grade 1: Persistent discolouration of the skin including non-blanchable erythema; blue/purple/black discolouration

Grade 2: Partial thickness skin loss involving epidermis and dermis

Grade 3: Full thickness skin loss involving damage or necrosis of subcutaneous tissues but not through the underlying fascia and not extending to the underlying bone, tendon or joint capsule

Grade 4: Full thickness skin loss with extensive destruction and tissue necrosis extending to the underlying bone, tendon or joint capsule.

Studies which reported the incidence of sores of Grade 2 or greater were regarded as more likely to be reliable as Grade 1 sores are notoriously difficult to identify.

Treatment Studies

3. Healing rates of existing sores. There is no consensus as to the most valid and reliable means of measuring healing rates of pressure sores. Trials were included if they measured healing by some objective method such as time to complete healing, or rate of change in the area/volume of the sore.

All Studies

4. Costs of the devices
5. Patient comfort
6. Durability of the devices
7. Reliability of the devices
8. Acceptability of the devices

Trials which only measured surrogate outcome

measures such as interface pressure were excluded on the basis that interface pressure measurements have not been demonstrated to reliably predict the clinical performance of support surfaces.

Search strategy for identification of studies

See: Collaborative Review Group search strategy

References to trials were sought from the Cochrane Wounds Group Specialist Trials Register, which is compiled through regular searching of the major health care databases including MEDLINE, Cinahl and EMBASE, hand searching of wound care journals and relevant conference proceedings. The following terms were used to search the Trials Register:

- bed*
- mattress*
- pressure-relief*
- cushion*
- overlay*

The searching strategies of the group are described in detail in the Scope of the Cochrane Wounds Group. Citations within obtained trials and reviews were scrutinised to identify additional studies. Details of unpublished studies were requested from equipment manufacturers.

Methods of the review

References identified from searches were reviewed by two reviewers who jointly made a decision to include or exclude a study against the eligibility criteria. References were entered into a bibliographic software package (ProCite). Details of eligible studies were extracted by the primary reviewer (NC) and summarised using a data extraction sheet. Data extraction was checked by a second reviewer.

The following data were extracted for each study:

- patient inclusion/exclusion criteria
- care setting
- key baseline variables by group, for example age, sex, baseline risk, baseline area of existing sores
- description of the interventions and numbers of patients randomised to each intervention
- description of any co-interventions/standard care
- follow up period
- outcomes (incidence and severity of new pressure sores; healing rates etc)
- acceptability and reliability of equipment if reported.

If data were missing from reports, then attempts were made to contact the authors to complete the information necessary for the critical appraisal. If studies were published more than once, the most detailed report was used as the basis of the data extraction.

The methodological quality of each trial was assessed by two researchers independently. The following quality criteria were used:

- description of inclusion and exclusion criteria used to derive the sample from the target population
- evidence of an a priori sample size calculation
- evidence of allocation concealment at randomisation
- description of baseline comparability of treatment groups
- evidence of blinded outcome assessment
- incident sores described by severity grading as well as frequency (Grade 1 sores are not breaks in the skin and are subject to more inter-rater variation)
- clear description of main interventions
- adequate description of associated care
- withdrawals reported by treatment group with reasons.

For each trial, relative risk with 95% confidence intervals was calculated for all important, dichotomous outcomes, for example number of patients developing new pressure sores. Relative risk is presented in preference to odds ratios as odds ratios give an inflated impression of the size of effect where event rates are high, as in the case of these trials (Deeks, 1998). Continuous outcome variables such as change in wound volume were summarised using weighted mean difference. Where outcomes for continuous variables were presented as medians without confidence intervals, standard deviations or some other measure of the precision of the result, the median was entered into the analysis table and the data were not used in data synthesis.

All calculations were made using Revman 3.1.1 software.

Where two or more studies have undertaken similar comparisons using similar outcome measures, they were tested for heterogeneity using Chi-square. Where clinical, methodological and statistical heterogeneity was not apparent, similar studies were pooled using a fixed effects model. Where clinical and methodological heterogeneity was absent, but there was statistical heterogeneity, a random effects model was applied. Where pooling was not possible or appropriate, trials are discussed in a narrative review.

Description of studies

Thirty seven eligible randomised controlled trials were identified. Twenty nine trials involved patients without pre-existing pressure sores (intact skin) and assessed the effectiveness of pressure relieving interventions for the prevention of pressure sores. Six trials involved patients with pressure sores, to assess the treatment efficacy of pressure relieving supports (Allman, 1987; Caley, 1994; Clark and Watts; Devine, 1995; Ferrell, 1993; Strauss, 1991) and two trials evaluated surface effects

for both prevention and treatment in the same trial (Ewing, 1964; Lazzara and Buschmann, 1991).

Study Settings

Three studies evaluated different operating table surfaces (Aronovitch, 1998; Nixon, 1998; Micropulse, 1998); seven evaluated different surfaces in intensive care units (Gebhardt, 1994; Gentilello, 1988; Inman, 1993; Laurent, 1997; Sideranko, 1992; Summer, 1989; Takala, 1996); six studies confined their evaluation to orthopaedic patients (Cooper, 1998; Exton-Smith, 1982; Goldstone, 1982; Hofman, 1994; Santy, 1994; Stapleton, 1986). The remaining studies looked at a variety of patients, for example those in nursing homes, care of the elderly, medical or surgical wards.

Only three trials evaluated cushions, one evaluated the use of sheepskins, and two looked at turning beds/kinetic therapy. The remaining studies evaluated different mattresses, mattress overlays and beds.

Methodological quality

The methodological quality of the trials was generally poor. Details of the quality of each individual study is included in the study table. True randomisation with allocation concealment was evident in only 8/36 (22%) of the RCTs. The eight trials with adequate allocation concealment were: Allman, 1987; Cooper, 1998; Devine, 1995; Economides, 1995; Ferrell, 1993; Gray and Campbell, 1994; Nixon, 1998; Clark and Watts. Of the remaining 28 trials, the method of randomisation was unclear in 18 cases and allocation concealment was inadequate in 10 trials, usually where allocation was by alternation.

Blinded outcome assessment is rarely used in wound care studies and this was certainly the case in these evaluations of pressure relieving surfaces. It can be difficult or impossible to disguise the surface that a patient is on for assessment of outcome, and patients are often too ill to be removed from their bed for assessment of their pressure areas. Nevertheless, some studies minimise bias in outcome assessment by having a second assessor and presenting inter-rater reliability data, or by presenting photographic evidence of pressure area status which can then be assessed by an assessor blinded to treatment. Of the 36 RCTs in this review, we could be confident that blinded outcome assessment had been used in only eight trials (Allman, 1987; Aronovitch, 1998; Conine, 1990; Conine, 1994; Kemp, 1993; Lim, 1988; Nixon, 1998; Strauss, 1991).

In studies of pressure sore prevention and treatment, it is extremely important for trialists to report on the baseline comparability of the treatment groups for important variables such as baseline risk. Risk of pressure sore development is usually reported as one of

various risk scores such as Norton, Waterlow, Gosnell or Braden. Some of the studies reviewed here did not present such baseline data.

Even more importantly in pressure sore treatment trials, it is essential to ensure baseline comparability for initial area of sores. A change in wound area is often expressed as the percentage change which, unlike the absolute change in area, takes into account the initial size of the wound. For two wounds healing at the same linear rate (as measured by diameter reduction) percentage area calculations will show a larger change for a small wound than a big wound. The converse is true when the absolute change in area is measured, since for any unit reduction in wound radius, a bigger area reduction will occur for a large wound. This has important consequences for the validity of trial results where there is poor comparability in initial wound size at baseline between the treatment groups.

In large trials, randomised allocation should ensure that the mean wound size and variance in each group is similar. In a small trial random allocation is unlikely to result in an even distribution of wound sizes. In a trial where there is poor comparability between groups for wound size at baseline, and the outcome is based on the change in area, the result can only be considered valid if it is obtained either: against the anticipated direction of the bias for wound size; or where percentage area change and absolute area change are in the same direction. If baseline data are not given, then it is not possible to determine the direction of bias and the validity of the result cannot be determined.

There were eight trials of beds, mattresses and cushions for treating pressure sores in this review and of these five – Allman, 1987; Clark and Watts; Devine, 1995; Ferrell, 1993; and Lazzara and Buschmann, 1991 – presented data for baseline ulcer area. Reports of treatment trials by Caley (1994) and Strauss (1991) did not present baseline ulcer areas whilst the trial by Ewing (1964) focused on the effect of sheepskin on resolving red skin and therefore the area of the damaged skin is less important.

The other major deficiency in most of these trials was the sample size used. Only 10 trials described an a priori sample size calculation. Twenty seven of the 36 trials involved a total of 100 patients or fewer. The largest trials identified were Andersen 1982 (482 patients in a 3-arm trial); Gebhardt 1994 (230 patients); Santy 1994 (505 patients in a 5-arm trial); Nixon 1998 (446 patients in a 2-arm trial).

Quality was not used to weight the studies in the analysis using any statistical technique, however methodological quality was drawn upon in the narrative interpretation of the results. Methodological flaws are discussed for each study in the Characteristics of Included Studies Table.

Results

The review is divided into two main sections: prevention and treatment.

How the results are presented and what the terms mean

Results of dichotomous variables are presented as relative risk (RR) with 95% confidence intervals (CI). Relative risk has been used rather than odds ratios as event rates are high in these trials and odds ratios would give an inflated impression of the magnitude of effect (Deeks, 1998). Relative risk is the pressure sore incidence rate in the experimental group divided by the incidence rate in the control group and indicates the likelihood of pressure sore development on an experimental bed compared with a comparison bed. As by definition, the risk of a sore developing in the control group is 1, then the relative risk reduction associated with using the experimental bed is $1 - RR$. The relative risk indicates the relative benefit of a therapy but not the actual benefit – that is it does not take into account the number of people who would have developed a sore anyway. The absolute risk reduction (ARR) can be calculated by subtracting the incidence rate in the experimental group from the incidence rate in the control group. The ARR tells us how much the reduction is due to the bed itself, and its inverse is the number needed to treat, or NNT. Thus an incidence rate of 30% on a control mattress reduced to 15% with an experimental mattress translates into an ARR of $30 - 15 = 15\%$ or 0.15, and an NNT of 7, in other words seven patients would need to receive the experimental mattress to prevent the development of one additional pressure sore.

Secondary outcomes such as comfort, durability, reliability and acceptability were not well reported and valid and reliable measures for these concepts are under-developed. Where data were presented, they appear in the Table of Included Studies. However they are not incorporated in the analysis.

Beds, mattresses and cushions: effectiveness in pressure sore prevention

Trials of the Standard Hospital Mattress

This section considers comparisons of standard foam hospital mattresses with other low-technology (low-tech), constant low pressure supports (CLP). We regarded the following as low-tech CLP: sheepskin, static air-filled supports; water-filled supports; contoured or textured foam supports; gel-filled supports; bead-filled supports; Silicore-filled supports. It should be emphasised however that there is no international definition of what constitutes a standard foam hospital

mattress and indeed this changes over time within countries and even individual hospitals. Where a description of the standard was provided, it is included in the Characteristics of Included Studies Table.

Seven RCTs comparing 'standard' mattresses/surfaces with 'low-tech' supports for the prevention of pressure sores were identified (Andersen, 1982; Ewing, 1964; Goldstone, 1982; Gray and Campbell, 1994; Hofman, 1994; Santy, 1994; Collier, 1996). When compared with standard hospital mattresses, the incidence and severity of pressure sores in 'high risk' patients was reduced when patients were placed on either the Comfortex DeCube mattress (RR 0.34, CI 0.14-0.85) (Hofman, 1994); the Beaufort bead bed (RR 0.32, CI 0.14-0.76) (Goldstone, 1982); the Softform mattress (RR 0.2, CI 0.09-0.45) (Gray and Campbell, 1994) or the water-filled mattress (RR 0.35, CI 0.15-0.79) (Andersen, 1982).

In an unpublished British study of older people with hip fractures admitted to orthopaedic trauma wards, patients allocated to receive a NHS standard foam mattress (manufactured by Relyon) experienced over three times the rate of pressure sores as those using one of a number of foam alternatives (Clinifloat, Therarest, Transfoam and Vaperm) (Santy, 1994).

The four trials comparing foam alternatives with the standard hospital foam mattress (Gray and Campbell, 1994; Hofman, 1994; Santy, 1994; Collier, 1996) were pooled in the absence of significant heterogeneity (Chi-square 1.64, df=2). To avoid double counting the control patients in the trials with more than two comparison groups (Santy, 1994 and Collier, 1996), and in the absence of major differences between the effects of the different foams, the foam alternatives were pooled for the Santy (1994) and Collier (1998) trials. This approach maintains the randomisation but results in unequal comparison groups. This analysis yielded a pooled relative risk of 0.29, CI 0.19-0.43, ie. a relative reduction in pressure sore incidence of 0.71 or 71% (57%-81%). Therefore, various foam alternatives to the standard hospital mattress can reduce the incidence of pressure sores in patients at risk (Hofman, 1994; Santy, 1994 and Gray and Campbell, 1994) including elderly patients with fractured neck of femur.

One small trial of the standard hospital mattress with and without sheepskin overlays was inconclusive and of poor quality (Ewing, 1964).

Comparisons Between Foam Supports

This section covers results of studies which performed head-to-head comparisons of high-specification foam products (contoured foam, supports comprising foam of different densities).

Four RCTs (Collier, 1996; Santy, 1994; Kemp, 1993; Vyhldal, 1997) compared different foam alternatives. No patient developed a pressure sore in the Collier trial. Santy and colleagues compared five alternative foam mattresses (Clinifloat, Vaperm, Therarest, Transfoam, NHS standard foam) and found significant reductions in pressure sore incidence associated with Clinifloat, Therarest, Vaperm and Transfoam compared with standard; and Vaperm compared with Clinifloat.

Vyhldal (1997) and colleagues compared a 4 inch thick foam overlay (IRIS 3000) with a foam and fibre mattress replacement (MAXIFLOAT) and reported a significant reduction in pressure sore incidence (RR 0.42, CI 0.18-0.96) with the mattress replacement. This translates to a relative reduction in the incidence of pressure sores of 58% associated with use of the 5-section foam and fibre mattress replacement (an ARR of 0.35, or 35% and an NNT of 3, or one additional pressure sore prevented for every three patients receiving a Maxifloat mattress replacement).

Kemp (1993) compared a convoluted foam overlay with a solid foam overlay in only 84 patients and found no significant difference in pressure sore incidence rates. However this may be a Type 2 error, in other words the small sample size may have precluded detection of a significant difference.

Comparisons between 'low-tech' CLP supports

This section covers head-to-head comparisons of the following types of support: foams; static air-filled supports (including dry flotation); water-filled supports; gel-filled supports; Silicore-filled supports.

Six RCTs have compared different low-tech CLP devices for prevention (Andersen, 1982; Cooper, 1998; Lazzara and Buschmann; Sideranko, 1992; Stapleton, 1986; Takala, 1996). Most of these trials are seriously underpowered and/or have other methodological flaws.

A trial from Finland (Takala, 1996) comparing the Optima (Carital) constant low pressure mattress – which comprises 21 double air bags on a base – with the standard hospital mattress found that 36.8% of patients on the standard mattress developed sores compared with none on the Optima (RR 0.06; CI 0-0.99).

The remaining trials were all unique comparisons with low power and none found statistically significant differences between the surfaces tested.

Alternating Pressure Supports

A variety of alternating pressure (AP) supports are used in hospital and in the community. The depth of the air-cells and the mechanical robustness vary between devices and these factors may be important in

determining effectiveness. It is worth emphasising that most of the RCTs of AP supports did not adequately describe the equipment being evaluated, including the size of the air cells.

Ten RCTs of alternating pressure supports for pressure sore prevention were identified: between AP and standard hospital mattresses in one study (Andersen, 1982); between AP and various constant low pressure devices such as water in eight studies (Andersen, 1982; Sideranko, 1992), static air (Sideranko, 1992), Silicore (Conine, 1990; Daechsel, 1985; Stapleton, 1986), foam (Stapleton, 1986; Whitney, 1984), various (Gebhardt, 1994); and with other alternating pressure supports in two studies (Exton-Smith, 1982; Hampton, 1997).

Alternating Pressure Compared With Standard Foam Mattress

One RCT reported that the use of an alternating pressure surface reduces the incidence of pressure sores as compared with the standard foam mattress (RR 0.32, CI 0.14-0.74) (Andersen, 1982).

Alternating Pressure Compared With Constant Low Pressure

Seven trials have compared alternating pressure devices with various constant low pressure devices, however there is conflicting evidence as to their relative effectiveness. One study compared a range of AP supports with a range of CLP supports in a range of specialties in acute care settings (Gebhardt, 1994) and reported significantly more pressure sores in patients in the CLP group (34% compared with 13% in the AP group) (RR 0.38, CI 0.22-0.66).

In contrast, six small RCTs comparing different types of alternating pressure supports and a variety of constant low pressure devices such as the Silicore overlay (Conine, 1990; Daechsel, 1985; Stapleton, 1986), a water mattress (Andersen, 1982; Sideranko, 1992), a foam pad (Stapleton, 1986; Whitney, 1984) and a static air mattress (Sideranko, 1992) reported no difference in effectiveness. The studies which compared AP with Silicore or foam overlays were pooled (Conine, 1990; Daechsel, 1985; Stapleton, 1986; Whitney, 1984). To avoid double counting of the patients in the AP arm of the Stapleton 3-arm trial, and in the absence of obvious heterogeneity in the outcomes for Silicore and foam, the Silicore and foam arms were pooled against the AP arm (maintaining the randomisation, avoiding double counting, but resulting in unequal comparison groups). Overall the pooled RR for AP v Silicore or foam overlays (using a fixed effects model; Chi-square 0.03, df=3) was 0.91 (CI 0.71-1.17) indicating no significant difference between Silicore or foam overlays and AP.

The studies which compared AP with static water or static air mattresses were similarly considered together (Andersen, 1982; Sideranko, 1992). The Sideranko trial also had three comparison groups and for the purposes of the meta-analysis, the water and static air arms of this study were considered sufficiently similar to pool together against AP to avoid double counting of the AP patients. Pooling these two trials (Andersen, 1982 and Sideranko, 1992) to answer the question of whether AP is more effective than air or water filled mattresses using a random effects model (Chi-square 2.26, df=1) yielded a pooled RR of 1.57 (0.49-5.03) indicating no significant difference.

It is worth emphasising however that all these studies were small, and even when pooled underpowered to detect clinically important differences in effectiveness as statistically significant.

All seven RCTs comparing the various CLP devices and AP devices were pooled to try to answer the question of whether AP is more effective than CLP in pressure sore prevention. Double counting was avoided for the Sideranko (1992) and Stapleton (1986) trials as before. In view of the different devices evaluated in the studies, and the Chi-square of 12.62 (df=6), a random effects model was applied. This yielded an overall relative risk of 0.84 (0.57-1.23) suggesting no significant difference between the rates of pressure sore incidence on AP versus CLP.

Finally one trial used a complex factorial design to compare various combinations of standard, constant low pressure and alternating support in surgical intensive care patients intra- and post-ICU. This trial (which involved only 75 - 80 patients in each group) did not identify any significant effect of using alternating pressure in the ICU (Laurent, 1997).

Comparisons Between Different Alternating Pressure Devices

Alternating pressure devices differ somewhat in structure, including the size of the inflatable air cells. One early study of pressure sore prevention (Exton-Smith, 1982) compared two large-celled alternating pressure devices (Pegasus Airwave and the Large Cell Ripple - similar except the Airwave has two layers of cells). The authors reported that the Airwave System was significantly more effective than the Large Cell Ripple in preventing and reducing severity of pressure sores in a high risk group of elderly patients. However, the allocation was not truly random, and an intention-to-treat analysis would not have shown a statistically significant difference in the rate of pressure sores (16% vs 34%, $P > 0.05$).

More recently, Hampton (1997) compared the Pegasus

Airwave mattress with a new Cairwave Therapy system by the same manufacturer, in 75 patients. No patients developed a sore in either arm of this study.

Low Air-Loss Beds

One trial showed that low air-loss beds were more cost-effective at decreasing the incidence of pressure sores in critically ill patients than a standard (but poorly described) ICU bed (RR 0.24, CI 0.11-0.53) (Inman, 1993).

Air Fluidised Beds vs. Dry Flotation

One small trial in patients after plastic surgical repair of pressure sores showed no difference between an air-fluidised bed and the Roho dry flotation mattress in post-operative tissue breakdown rates (Economides, 1995).

Kinetic Turning Tables

Turning beds contain motors which constantly turn and tilt the patient, and are used in critical care settings primarily to prevent pneumonia and atelectasis. Four RCTs were identified in a meta-analysis of kinetic therapy (Choi, 1992) however only two of the trials could be obtained (Gentilello, 1988; Summer, 1989). Sample sizes in all the trials was small, and no beneficial effect of kinetic therapy on pressure sore incidence was detected.

Operating Table Overlays

Three RCTs have evaluated different methods of pressure relief on the operating table. The first compared a visco-elastic polymer pad with a standard table and found a relative reduction in the incidence of post-operative pressure sores of 47% associated with using the polymer pad for patients undergoing elective major general, gynaecological or vascular surgery (supine or lithotomy) (RR 0.53; CI 0.33-0.85) (Nixon, 1998).

Two further RCTs have compared the Micropulse alternating system (applied both during surgery and post-operatively) with a gel pad during surgery and standard mattress post-op and report a pooled relative risk of 0.21 (CI 0.06-0.7) in favour of the Micropulse system (Aronovitch, 1998; Micropulse, 1998).

Seat Cushions

There have been two RCTs comparing different types of seating cushion for preventing pressure sores; one study compared slab foam with bespoke contoured foam and found no difference (RR 1.06, CI 0.75-1.49) (Lim, 1988). The second study (Conine, 1994) compared the Jay gel and foam wheelchair cushion with a foam cushion in 141 patients and found fewer sores in the Jay cushion group, though this did not reach significance (RR 0.61, CI 0.37-1.00).

Beds, mattresses and cushions: effectiveness in pressure sore treatment

Air-Fluidised Therapy (AFT)

Three RCTs compared AFT with a range of conventional therapies for the treatment of pressure sores (Allman, 1987; Munro, 1989; Strauss, 1991). These studies measured outcomes in slightly different ways and none reported the variability around the mean healing rate data. Two studies showed enhanced healing associated with air-fluidised beds used in hospital (Allman, 1987; Munro, 1989]. A home-based study showed no significant difference (Strauss, 1991).

Low Air-Loss Therapy (LAL)

One trial was identified which compared LAL with a low-tech foam alternative and reported that the LAL bed was more effective in treating sores than a corrugated foam overlay (Ferrell, 1993). Only one trial has compared different types of low air-loss support surface (Caley, 1994) and showed no significant differences, but was too small and of questionable quality.

Alternating Pressure (AP)

One small RCT (41 patients) compared the effectiveness of the Nimbus I DFS (composed of rows of figure-of-8-shaped cells) and the Pegasus Airwave for the treatment of existing pressure sores but found no significant difference (Devine, 1995).

Seat Cushions

One treatment study involving only 25 patients found no significant difference between a dry flotation and an alternating pressure cushion in the number of sores completely healed (Clark and Watts).

Discussion

The confidence with which we can draw firm conclusions from the studies detailed in this review is greatly tempered by (a) the poor quality of many of the trials and (b) the lack of replication of most comparisons. The clearest conclusion one can draw is that standard hospital mattresses have been consistently outperformed by a range of foam-based, low pressure mattresses and overlays, and also by 'higher-tech' pressure relieving beds and mattresses, both in the prevention and treatment of pressure sores. The application of this conclusion to current clinical practice is however hampered by the fact that the "standard" was poorly described in many of these studies, and what is standard varies by hospital, country and over time. Nevertheless, the effects of using alternative foam mattresses are noteworthy in their consistency. The results of three trials evaluating the use

of pressure relieving overlays on the operating table suggest that these are beneficial in reducing subsequent pressure sore incidence in high risk surgical patients. These three trials were of reasonable quality; the Nixon trial particularly was adequately powered with allocation concealment and blinded outcome assessment, lending further weight to the result. At present the most effective means of pressure relief on the operating table is unclear; Nixon and colleagues found a gel-filled overlay to be significantly better than a standard operating table, whilst a gel-filled overlay on the operating table was less effective than an alternating pressure overlay intra- and post-operatively (the Micropulse system) in the other two trials. It appears that low air-loss beds are effective in preventing and treating pressure sores compared with foam mattresses, but there are no studies comparing low air-loss therapy with alternating pressure surfaces and other 'high tech' low pressure supports. Most of the trials undertaken are under-powered and therefore run a great risk of failing to detect clinically significant differences as statistically significant. Other common methodological flaws such as open randomisation, lack of baseline comparability and lack of blind outcome assessment further reduce the confidence with which we can regard many of the individual study findings. Future trials should address these deficiencies and collect data on aspects of equipment performance such as reliability.

Reviewers' conclusions

Implications for practice

Patients at high risk of pressure sore development should not be placed on ordinary foam mattresses, however a number of higher specification foam mattresses have been shown to reduce pressure sore incidence in fairly high risk patients, including elderly people with fractured necks of femur.

The relative merits of higher-tech constant low pressure and alternating pressure are unclear. Whichever surfaces are used for high risk patients, the condition of the skin in pressure areas should be checked regularly for signs of impending tissue damage – persistent redness which does not blanch under pressure; discoloured skin such as bruising; damage to the epithelium, for example grazing. This recommendation does not come from directly from the review, but is consistent with good clinical practice.

Organisations should consider the use of pressure relief for high risk patients in the operating theatre, as this is associated with a reduction in post-operative incidence of pressure sores.

Good evidence from RCTs suggests that air-fluidised supports and low air-loss beds may improve pressure sore healing rates.

Seat cushions have not been adequately evaluated.

Implications for research

Independent, well-designed, multicentre RCTs are needed to compare the clinical and cost-effectiveness of different types of pressure relieving devices for patients at different levels of risk in a variety of settings. In particular, this research should aim to compare:

1. alternating pressure devices with other high-tech equipment (such as low air-loss and air-fluidised beds)
2. alternating pressure mattresses with less costly alternating pressure overlays and
3. alternating pressure devices with lower tech alternatives (such as different types of foam mattresses).

Future research must address the methodological deficiencies associated with much of the research described in this review. Patients should be truly randomised (with concealed allocation), trials should be of sufficient size to detect clinically important differences, and have clear criteria for measuring outcomes which ideally should be assessed without knowledge of the intervention received (blinded). Researchers should be encouraged to develop measures to assess patient experiences of pressure relieving equipment, for example comfort. The studies should also have adequate follow up and appropriate statistical analysis.

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Potential conflict of interest

None.

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Devine B.	Alternating pressure air mattresses in the management of established pressure sores.	Journal of Tissue Viability 1995 5: 94 – 98
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Appendix 7

Summary McGough Review

A systematic review of the effectiveness of risk assessment scales used in the prevention and management of pressure sores.

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Primary research question

Is there any evidence to demonstrate that the use of a pressure ulcer risk assessment scale reduces the incidence of pressure ulcers? The primary purpose of using such a scale is systematically to identify patients at risk of developing pressure damage and to target interventions to prevent this occurrence. It is not known whether the use of risk assessment scales is more sensitive and specific in detecting risk than experienced nurses' judgements.

In particular, the following questions were raised:

- I How specific and sensitive are the various pressure ulcer risk assessment scales?
- II Are certain scales more appropriate to specific clinical areas or specialties?
- III Have scales been tested for their practical use in the clinical environment?

Criteria for considering studies for this review

To ascertain the effectiveness of a risk assessment scale, the search was limited to randomised controlled trials evaluating the use of a risk assessment scale (RAS). The trials would compare the use of a scale to standard practice (nurses' judgement) or compare two or more scales. The main outcome measure was the incidence of pressure ulcers.

To examine the reliability and validity of the various scales, prospective inception cohort studies were sought.

Inclusion criteria

Studies were eligible for inclusion in the review if they met the following criteria:

1. Randomised controlled trials or prospective cohort studies reporting an evaluation of one or more RAS in the prevention of pressure ulcers

The inclusion criterion was limited to prospective studies due to the unreliability and susceptibility to bias of retrospective studies (Hennekens and Buring, 1987). Such biases may include patient selection (particularly if the inclusion criteria are less rigid), the unreliability of outcome assessment (especially when evaluating the incidence and severity of pressure ulcer development), unreported loss to follow-up and inaccuracy of data recording (missing or incomplete data) (Altman, 1996).

2. All patients included in study were free from pressure ulcers on entering the study

To ascertain the predictive validity of a scale, patients were initially free from the illness or condition under study. This is known as an inception cohort design and is regarded as the most powerful way of establishing the prognostic value of a scale (in this case, the incidence of pressure ulcers in the study population) (Sackett et al, 1991 p 177).

3. Follow-up data were included on at least 75% of patients

Studies that followed up fewer than 75% of patients would be excluded as this could potentially distort the results in a positive (or negative) way. The cut-off point of 75% was chosen to allow inclusion of studies, which followed up the majority of patients (Sackett et al, 1997).

4. Patients were assessed systematically for the development of pressure ulcers

Studies were considered eligible for inclusion if the researchers had reported that they had conducted a systematic series of assessments of the patients' skin. If not, the researchers would not be able to identify the original date of skin breakdown and link this to the level of risk.

5. They were written in the English language

Studies written in language other than English could not be included due to the lack of resources for translation.

6. Involved humans not animal studies

Exclusion criteria

1. Data were used to generate the scale and also for the calculation of sensitivity and specificity

It is self evident that the data used to generate a risk assessment scale will give high sensitivity and specificity.

Search Strategy

The search was conducted for reports published between 1966 (for Index Medicus On-line (MEDLINE)) until September 1997. The decisions about the inclusion of studies and the sources searched were taken by a sole reviewer and were limited due to lack of resources (for example, the cost of translation). Hand-searching of wound care journals, contact of active wound care researchers and performing citation searches to identify any studies missed by the main search were also conducted.

Electronic and on-line databases

One on-line database and several electronic databases were searched (Table 1). A full copy of the master search strategy used to search the main databases can be found in Annex B.

Electronic database searched	Search dates
MEDLINE	1966 – Sep. 1997
CINAHL	1982 – Sep. 1997
The Cochrane Library of Databases; incorporating the Database of Systematic Reviews, the Database of Abstracts of Reviews of Effectiveness, Controlled Clinical Trials Register and the Cochrane Review Methodology Database	1996 – Sep. 1997
EMBASE	1974 – Sep. 1997
System for Information and Grey Literature in Europe (SIGLE)	1981 – Sep. 1997
Psychological Abstracts (PsychLit)	1974 – Sep. 1997
Agency for Health Care Policy and Research	– Sep. 1997
English National Board Nursing database	1996 – Sep. 1997

Table 1. Electronic databases searched

Printed indexes

Two printed indexes were searched for potentially eligible papers (Table 2).

Printed index searched	Search dates
Applied Social Science Index and Abstracts (ASSIA) (1986 –)	1987 – Jan 1997
UK Health Service abstracts (1974 –)	May 1994 – Apr. 1996; June 1996 – Jan. 1997

Table 2. Printed indexes searched

Hand-search of main specialist journals

Journals were selected by running a specific search on the wound care journals indexed in MEDLINE and a table of contents constructed for each year searched. A hand-search was performed on these wound care journals (Table 3).

Journal hand-searched	Search dates
Advances in Wound Care (formerly Decubitus) (1988 –)	Jan. 1988 – Dec. 1996
Journal of Tissue Viability (formerly CARE - Science and Practice) (1981 –)	Jan. – Dec. 1996
Journal of Wound Care (1992 –)	Sep. 1992 – Dec. 1996
Journal of Wound Ostomy and Continence Nursing (formerly Journal of Enterostomal Therapy) (1974 –)	Nov. 1981 - Apr. 1991; Jan. 1994 - Nov. 1996

Table 3. Hand-search of specialist journals

'Grey' literature

The European Wound Management Association's (EWMA) conference proceedings were selected for searching due to their coverage of European studies, and their availability and accessibility. The EWMA conference proceedings were searched from 1991 to 1997 and the Proceedings of the first European Pressure Ulcer Advisory Panel Consensus Meeting in 1997.

Reference lists

A citation search was also performed of all relevant studies and literature reviews to locate any studies not identified through previous searching.

Active researchers in the field

To ascertain current or planned research activity in this field, a list was prepared of all researchers known to be either involved in the development or testing of scales or known to be involved in wound care research. Missing information would be obtained by contacting the authors.

Data extraction

Due to time and resource constraints the review was undertaken by a single reviewer (Amanda McGough). The reviewer re-checked the data extraction process three months later to minimise the potential of 'reviewer bias'. A summary sheet was developed to extract and record information and data from the studies. Where one study had been reported in duplicate papers, it was only included once in the review. All results concerning predictive validity were checked by re-calculating sensitivity, specificity, and positive and negative predictive values from the data reported in the paper. Where the values were missing, they were calculated if the raw data was reported in the paper.

Results

Effectiveness and predictive validity of pressure ulcer risk assessment scales. Sixty-six studies were identified through the search strategy and assessed as potentially eligible for inclusion in the review (Table IV).

Contacting active researchers in the field

In total, twenty-four out of thirty one researchers contacted replied; a response rate of 77%. No new studies were forthcoming however. Further information regarding study design and additional data were obtained for the Dutch testing of the Braden scale (Halfens, 1997).

Identified by	Author
Author contact	Bodnar B and Myron P (1992) Salzberg CA, Byrne DW, Cayten CG, van Niewerburgh P, Murphy JG and Viehbeck M (1996) Watkinson C (1997)
CINAHL	Arikian VL, Kingery C, Beall K and Abbott R (1990) Bale S, Finlay I and Harding KG (1995) Bergstrom N, Braden BJ, Laguzza A and Holman V (1987) Birtwistle J (1994) Boettger JE (1997) Salvadalena G, Snyder ML and Brogdon KE (1992) Stotts NA (1988) Williams C (1991) Xakellis GC, Frantz RA, Arteaga M, Nguyen M and Lewis A (1992)
Citation search	Abruzzese RS (1985) Ameis A, Chiarcossi A and Jimenez J (1980) Andersen KE, Jensen O, Kvorning SA and Bach E (1982) Bergstrom N, Demuth PJ and Braden BJ (1987) Clark M and Farrar S (1991) Clarke M and Kadhom HM (1988) Ek A-C (1987) Ek A-C, Unosson M and Bjurulf P (1989) Goldstone LA and Goldstone J (1980) Goldstone LA and Roberts BV (1982) Gosnell DJ (1973) Lowthian P (1989) McNaughton V and Brazil K (1995) Moody BL, Fanale JE, Thompson M, Vaillancourt D, Symonds G and Bonasoro C (1988) Norton D, McLaren R, Extton-Smith AN (1962) Oot-Giromini BA (1993) Pritchard V (1986) Regan MB, Byers PH and Mayrovitz HN (1995) Smith I (1989)

ENB databases	Danchaivijitr S, Suthisanon L, Jitreecheue L and Tantiwatanapaibool Y (1995)
Cochrane Library of Databases	Williams AE and Davies C (1991)
Handsearch	Bale S, Purcell P, Finlay I and Harding KG (1995) Barnes J, Unsworth J and Fielden S (1995) Capobianco ML and McDonald DD (1996) Clark M, Cooper P, Wigglesworth C, Bridel J, Gray D and Deeks J (1995) Ek A-C (1994) Halfens RJ (1997)
MEDLINE	Bergstrom N and Braden B (1992) Braden BJ and Bergstrom N (1994) Dealey C (1989) Lincoln R, Roberts R, Maddox A, Levine S and Patterson C (1986) Pieper B, Sugrue M, Weiland M, Sprague K, Heimann C (1997) Wai-Han C, Kit-Wai C, French P, Yim-Sheung L and Lai-Kwan T (1997)
MEDLINE & CINAHL	Arnold M (1994) Aronovitch S, Millenbach Kelman GB and Wing P (1992) Barnes D and Payton RG (1993) Berglund B and Nordstrom G (1995) Bergstrom N, Braden B, Boynton P and Bruch S (1995) Bergstrom N, Braden B, Kemp M, Champagne M and Ruby E (1996) Cubbin B and Jackson C (1991) Edwards M (1995) Harrison M, Wells G, Fisher A and Prince M (1996) Healey F (1996) Hergenroeder P, Mosher C and Sevo D (1992) Hodge J, Mounter J, Gardner G and Rowley G (1990) Jiricka MK, Ryan P, Carvalho MA and Bukvich J (1995) Langemo DK, Olson B, Hunter S, Hanson D, Burd, C and Cathcart-Silberberg T (1991) Lewicki LJ, Mion L, Splane KG, Samstag D and Secic M (1997) Ramundo JM (1995) Towey AP and Erland SM (1988) VandenBosch T, Montoye C, Satwicz M, Durkee-Leonard K and Boylan-Lewis B (1996) Wardman C (1991)
National Research Register	Fonseca J (1996)

Table 4. Sources of eligible studies

Eighteen out of sixty six studies were included in the systematic review (Table 5).

Authors	Title	Reference
Andersen scale		
Andersen KE, Jensen O, Kvorning SA and Bach E	Prevention of pressure sores by identifying patients at risk	British Medical Journal 1982 284 1370-1

Braden scale		
Barnes D and Payton RG	Clinical application of the Braden scale in the acute care setting	Dermatology Nursing 1993 5 (5) 386-88
Bergstrom N and Braden B	Prospective study of pressure sore risk among institutionalised elderly	Journal of American Geriatric Society 1992 40 (8) 747-58
Bergstrom N, Braden BJ, Laguzza A and Holman V	The Braden scale for predicting pressure sore risk	Nursing Research July/August 1987 36 (4) 205-10
Bergstrom N, Demuth PJ and Braden BJ	A clinical trial of the Braden scale for predicting pressure sore risk	Nursing Clinics of North America June 1987 22 (2) 417-28
Braden BJ and Bergstrom N	Predictive validity of the Braden scale for pressure sore risk in a nursing home population	Research in Nursing and Health 1994 17 459-70
Capobianco ML and McDonald DD	Factors affecting the predictive validity of the Braden Scale	Advances in Wound Care 1996 9 (6) 32-6
Halfens RJ	The reliability and validity of the Braden scale	Proceedings of the 1st European Pressure Ulcer Advisory Panel 1997
Langemo DK, Olson B, Hunter S, Hanson D, Burd, C and Cathcart-Silberberg T	Incidence and prediction of pressure ulcers in five patient care settings	Decubitus 1991 4 (3) 25-36
Ramundo JM	Reliability and validity of the Braden scale in the home care setting	Journal of Wound Ostomy and Continence Nursing 1995 22 (3) 128-34
Salvadalena G, Snyder ML and Brogdon KE	Clinical trial of the Braden scale on an acute care medical unit	Journal of Enterostomal Therapy 1992 19 160-65
VandenBosch T, Montoye C, Satwicz M, Durkee-Leonard K and Boylan-Lewis B	Predictive validity of the Braden scale and nurse perception in identifying pressure ulcer risk	Applied Nursing Research 1996 May 9 (2) 80-86
Knoll scale		
Towey AP and Erland SM	Validity and reliability of an assessment tool for pressure ulcer risk	Decubitus 1988 1 (2) 40-48
Norton scale		
Norton D, McLaren R, Exton-Smith AN	An investigation of geriatric nursing problems in hospital	The National Corporation for the Care of Old People London. 1962
Stotts NA	Predicting pressure ulcer development in surgical patients	Heart and Lung 1988 17 (6) 1 641-47
Pressure Sore Prediction Score		
Lowthian P	Identifying and protecting patients who may get pressure sores	Nursing Standard 1989 4 (4) 26-29

Waterlow scale		
Edwards M	The levels of reliability and validity of the Waterlow Pressure Sore Risk Calculator	Journal of Wound Care 1995 4 (8) 373-378
Waterlow and Norton scales		
Wai-Han C, Kit-Wai C, French P, Yim-Sheung L and Lai-Kwan T	Which pressure sore risk calculator? A study of the effectiveness of the Norton scale in Hong Kong	International Journal of Nursing Studies 1997 34 (2) 165-9

Table V Studies included in the review**Studies excluded from the review**

Forty-eight studies were excluded from the systematic review as they failed to meet the inclusion criteria. Full details of all the studies excluded with the reasons for exclusion are listed in Table VI.

Authors	Reference	Reason for exclusion
Risk assessment scale not mentioned or incorporated into an educational programme		
Ameis A, Chiarcossi A and Jimenez J	Postgraduate Medicine 1980 67 (2) 177-184	Before and after study of effectiveness of educational programme in reducing incidence of pressure sores
Arikian VL, Kingery C, Beall K and Abbott R	Journal of Nursing Quality 1990 5 (1) 1-7	Interrupted time series design study of effectiveness of educational programme in reducing incidence of pressure sores
Bodnar B and Myron P	Decubitus 1992 5 (2) 49-52	Effectiveness of introduction of new prevention and treatment protocols evaluated through a prevalence study
Boettger JE	Journal of Wound Ostomy and Continence Nursing 1997 24 (1) 19-25	Retrospective before and after study to evaluate the effectiveness of a mattress replacement programme and implementation of AHCPR guidelines
Danchaivijitr S, Suthisanon L, Jitreecheue L and Tantiwatanapaibool Y	Journal of Medical Association of Thailand 1995 78 (1) S1-SS6	Before and after study of effectiveness of education on the incidence of pressure sores
McNaughton V and Brazil K	Journal of Gerontological Nursing 1995 21 (2) 45-9	Before and after prevalence study evaluating the effectiveness of a skin care team and educational programme
Moody BL, Fanale JE, Thompson M, Vaillancourt D, Symonds G and Bonasoro C	Archives of Internal Medicine 1988 148 2241-2243	Before and after study evaluating the effectiveness of an educational programme on the incidence of pressure sores
Regan MB, Byers PH and Mayrovitz HN	Advances in Wound Care 1995 8 (3) 49-55	Interrupted time series design to evaluate the effectiveness of an educational programme in reducing the incidence of pressure sores.
Arnold (modified Gosnell)		
Arnold M	Ostomy and Wound Management 1994 40 (3) 36-52	Scale adapted for self completion

Aronovitch et al (modified Knoll)		
Aronovitch S, Millenbach Kelman GB and Wing P	Decubitus 1992 5 (3) 70-6	Not inception cohort study of incidence of pressure sores
Bale et al (modified Norton)		
Bale S, Finlay I and Harding KG	Journal of Wound Care Nov 1995 4 (10) 465-68	Uncontrolled trial of effectiveness of risk assessment scale and allocated equipment in reducing incidence of pressure sores
Birty's PARA		
Birtwistle J	Care of the Critically Ill 1994 10 (4) 154-59	Clinical audit design used to evaluate the validity of the scale
Braden		
Bergstrom N, Braden B, Boynton P and Bruch S	Nursing Clinics of North America Sept 1995 30 (3) 539-51	Interrupted time series design studies (a&b) evaluating the effectiveness of a multidisciplinary skin care team and implementation of Braden scale on incidence of pressure sores.
Bergstrom N, Braden B, Kemp M, Champagne M and Ruby E	Journal of the American Geriatric Society 1996 44 22-30	No data forthcoming to calculate sensitivity and specificity despite contacting Bergstrom
Harrison M, Wells G, Fisher A and Prince M	Applied Nursing Research 1996, 9 (1) 9-17	Only 54% of patients followed up
Hergenroeder P, Mosher C and Sevo D	Decubitus 1992 5 (7) 47-52	No follow-up of patients to judge whether nurses' judgement was more accurate in predicting risk than Braden scale
Lewicki LJ, Mion L, Splane KG, Samstag D and Secic M	American Operating Room Nurses Journal 1997 65 (5) 933-42	No data available to calculate sensitivity and specificity
Oot-Giromini BA	Decubitus 1993 6 (5) 24-32	Not inception cohort study
Pieper B, Sugrue M, Weiland M, Sprague K, Heimann C	Journal of Wound Ostomy and Continence Nursing 1997 24 191-9	Not inception cohort study
Braden, DUPA		
Jiricka MK, Ryan P, Carvalho MA and Bukvich J	American Journal of Critical Care 1995 4 (5) 361-7	Not inception cohort
Braden, Norton		
Xakellis GC, Frantz RA, Arteaga M, Nguyen M and Lewis A	Journal of American Geriatric Society 1992 40 1250-54	Uncontrolled trial evaluating Norton and Braden scales. Outcome measured was nursing use of preventive interventions not incidence of pressure sores
Cubbin & Jackson (modified Norton)		
Cubbin B and Jackson C	Intensive Care Nursing 1991 7 40-44	New scale tested for responsiveness to change on five patients. No information given on research design and no data available for predictive validity

Douglas Ward Risk Calculator, Norton		
Pritchard V	Nursing Times 1986 59-60	Small uncontrolled trial comparing the predictive validity of the Douglas score versus Norton. No patients were followed up and no data given to calculate sensitivity and specificity
Ek (modified Norton)		
Berglund B and Nordstrom G	Scandinavian Journal of Caring Sciences 1995 9 (3) 165-9	Not inception cohort study of incidence
Ek A-C	Proceedings of the 4th European Wound Management conference 1994, 102-103	Not an inception cohort study of the incidence of pressure sores
Ek A-C	Scandinavian Journal of Caring Sciences 1987 1 7-13	Not inception cohort study and no data available to calculate the sensitivity and specificity of the modified Norton scale
Ek A-C	Scandinavian Journal of Caring Sciences 1987 1, 77-84	Prevalence study used to evaluate predictive validity of a modified Norton scale
Ek A-C, Unosson M and Bjurulf P	Scandinavian Journal of Caring Sciences 1989 3 (4) 183-87	Not inception cohort study and no data available to calculate the sensitivity and specificity of the modified Norton scale
Gosnell		
Gosnell DJ	Nursing Research 1973 22 (1) 55-59	More than 25% of patients were lost to follow-up
Knoll		
Abruzzese RS	In Lee BY (Ed) Chronic ulcers of the skin. New York. McGraw Hill. 1985 p1-19	No information regarding research design. No data given to calculate sensitivity and specificity
Medley		
Fonseca J	Printout from the National Research Register, UK June 1996 (unpublished abstract)	No information on research design and no data available to calculate sensitivity and specificity despite contacting authors
Norton		
Clarke M and Kadhom HM	Journal of Advanced Nursing 1988 13 365-373	No data available to calculate sensitivity and specificity
Goldstone LA and Goldstone J	Journal of Advanced Nursing 1982 7 419-26	Only 66% of patients followed up
Goldstone LA and Roberts BV	International Journal of Nursing Studies 1980 17 17-23	No information given on research design. Data not available to calculate sensitivity and specificity of scale
Hodge J, Mounter J, Gardner G and Rowley G	Australian Journal of Advanced Nursing November 1990 8 (1) 39-46	Uncontrolled trial of the effectiveness of the Norton scale

Lincoln R, Roberts R, Maddox A, Levine S and Patterson C	Journal of Enterostomal Therapy 1986 13 (4) 132-8	Only 72% of patients followed-up
Norton, Waterlow		
Dealey C	Care Science and Practice 1989 7 (1) 5-7	Not inception cohort study
Smith I	Care Science and Practice 1989 7 (4) 93-95	Not inception cohort study
Wardman C	Nursing Times 27 March 1991 87 (13) 74-8	Not inception cohort study
Williams AE and Davies C	Journal of District Nursing 1991 March 4-6	Not inception cohort study
Norton, Waterlow, Lowthian, Braden, Knoll and NPRU		
Clark M and Farrar S	Proceedings of the 1st annual conference of the European Wound Management Association, 1991 pp158-62	More than 25% of sample lost to follow-up
Unnamed (Salzberg)		
Salzberg CA, Byrne DW, Cayten CG, van Niewerburgh P, Murphy JG and Viehbeck M	American Journal of Physical Medicine and Rehabilitation 1996 75 (2) 96-104	Data used to calculate sensitivity and specificity were derived from same cohort study
Unnamed (modified Norton)		
Bale S, Purcell P, Finlay I and Harding KG	Proceedings of the 2nd European Wound Management conference 1992, 127-129	Not inception cohort study of incidence
Waterlow, Braden		
Barnes J, Unsworth J and Fielden S	Proceedings of the 5th European Wound Management conference 1995, 41-43	Not inception cohort study of incidence to test predictive validity of scales
Waterlow, Norton, Braden, PSPS and Gosnell		
Clark M, Cooper P, Wigglesworth C, Bridel J, Gray D and Deeks J	Proceedings of the 5th European Wound Management conference 1995, 43	Study not completed within time frame of the review
Watkinson PSRAS, Braden		
Watkinson C	Professional Nurse February 1997 12 (5) 341-4	Not inception cohort study
Williams (modified Medley)		
Williams C	Nursing Times September 4 1991 87 (36) 66-8	Uncontrolled study evaluating the predictive validity of modified Medley and Norton scores but no patients followed up

York (modified Waterlow)		
Healey F	Nursing Times March 13 1996 92 (11) 80-4	Not inception cohort

Table VI – Studies excluded from the review

Appraisal criteria used in review of predictive validity

Six criteria were selected to appraise the quality of the design and the reporting of the studies included in the review.

Description of selecting the sample

The method of selecting the sample was deemed to be important as various methods could be employed for selection and particular methods will bias the results if the sample is unrepresentative of the patient population under study. For instance, when consecutive admissions constitute the sample and the case mix is subject to seasonal variation, an unrepresentative sample may be unintentionally selected. This is illustrated in the following example. An orthopaedic population studied during the winter months when the population is dominated by elderly people admitted with fractured neck of femur (a well known 'high risk' group) (Versluysen 1986), will give very different results in summer (when the patients might be younger, healthier individuals suffering sports injuries). A random sample would be the most valid way to ensure that the sample selected was representative of the population under study.

Estimation of the prevalence of pressure sores within the study population

Each study was assessed to ascertain whether the authors had reported their estimation of the prevalence of pressure sores within the patient population studied. This estimation is critical to the calculation of predictive validity; particularly positive predictive power and negative predictive power of a scale. A lack of reporting could indicate that the authors might have weakened the study by under or over estimating the prevalence (Altman, 1991).

Blinding of the outcome of the risk assessment to nurses undertaking the skin assessment

'Blinding' is an important concept in research design as it minimises the internal bias in assessing outcome (Pocock, 1983). This is an important consideration in studies of predictive validity as the outcome measure is a subjective evaluation of skin integrity. If the nurse undertaking the skin assessment knows that the patient is classified as 'at risk', he or she may be more likely to record redness of the skin as an early sign of pressure damage.

Establishing the inter-rater reliability of the risk assessments and skin assessments

Wound grading systems used to rate pressure damage are both categorical and subjective (Healey, 1996). It is important that a study calculates the strength of inter-rater reliability for both the risk and skin assessments made by nurses collecting the data to ensure that the assessments have high reliability. Altman (1991) suggests that there is no firm agreement regarding the threshold for the strength of agreement and suggests that the guidelines produced by Landis and Koch (1977) where a kappa score of 0.61 or above is rated as 'good' or 'very good' may be followed.

Blinding of the nurses delivering care to the patients to the skin assessments

A lack of blinding to the outcome of the formal skin assessment may prompt the nurses caring for the patient to implement additional preventative measures, altering the plan of care. Thus the patient who is known to have a grade 1 pressure sore may receive a pressure reducing mattress or be repositioned more frequently to relieve pressure.

Full account of the patients lost to follow-up

A study should be explicit in its reporting of patients entering the trial. Results would be viewed with suspicion if it is not made clear how many patients were lost to follow-up and the reasons for the loss made clear.

Testing of risk assessment scales

Effectiveness of risk assessment scales

No randomised controlled trials of the effectiveness of risk assessment scales in reducing the incidence of pressure sores were found in the search.

Nine studies were identified which evaluated the effectiveness of education (incorporating risk assessment scales) in reducing the incidence of pressure sores. All nine studies were observational in nature (Ameis et al., 1980; Arikian et al., 1990; Bergstrom et al., 1995; Bodnar and Myron P. 1992; Boettger, 1997; Danchaivijitr et al., 1995; McNaughton and Brazil, 1995; Moody et al., 1988 and Regan et al., 1995).

Although studies conducted by Bergstrom and colleagues (1995) and Moody and colleagues (1988)

demonstrate falls in incidence, it is difficult to disentangle the effects of introducing an educational programme (which may incorporate the use of a risk assessment scale) from other initiatives introduced at the same time. We cannot conclude that the staff educational programme alone has been instrumental in reducing the incidence of pressure sores. Other factors, such as the staff delivering care becoming familiar with prevention protocols, the influence of monitoring of incidence and the familiarity with pressure relieving equipment may all contribute to the fall in incidence. The staff will also be aware of the research study and they may not be blinded to the skin assessments.

The quality of the reporting of the studies was poor with many details missing regarding the research methodology employed, checking of inter-rater reliability, name of the grading system used and whether all grades of pressure sores were included.

Predictive validity of risk assessment scales compared to nursing judgement

Two clinical trials examined the predictive validity of a risk assessment scale compared to nursing judgement (Salvadaleña et al., 1992 and VandenBosch et al., 1996). Both studies took place in community hospitals in the USA and compared the predictive validity of the Braden scale to nursing judgement. Two separate teams of nurses undertook the risk assessment using the Braden scale and a skin assessment at 48 to 72 hour intervals and each team was blinded to the outcome of the assessment performed by the other team. Both studies utilised the same method for obtaining nurses' judgement: on entry to the study, the risk assessment team asked the nurses caring for the patient to clinically judge the patient's risk of developing a pressure sore during their hospital stay. However, nine graduate nurses were employed as data collectors in the Salvadaleña study whereas the VandenBosch study utilised sixteen nurses employed at the hospital. The length of follow-up was determined by the patient's length of stay on the unit in the Salvadaleña study.

The pressure sore grading system used to grade the sores in both studies was not named although both report that the system used was developed by Bergstrom and colleagues (VandenBosch et al., 1996). Both studies included grade 1 pressure sores but used different definitions in grading. Salvadaleña et al defined a grade 1 sore as "... an area of redness suspected to be a stage 1 ulcer" which remained red after the patient had been repositioned and a second observation performed after 10 minutes (p.162). VandenBosch and colleagues' definition was strikingly different; "non blanchable erythema of intact skin that

does not disappear for 24 hours after pressure is relieved" (p.82). This may help to explain the high proportion of grade 1 sores reported in the Salvadaleña study. The definition of a grade 1 pressure sore used in this study (unresolved redness after 10 minutes of pressure relief) is not consistent with other grading systems and has been criticised (Bergstrom, 1993).

The higher incidence of pressure sores in the VandenBosch trial may reflect the fact that the sample was drawn from tertiary care centre where the expected length of stay was greater (up to seven days) and included acute rehabilitation patients. The researchers acknowledge that there may have been doubts about the reliability of skin assessments due to the size of the data collection team. Inter-rater reliability of skin assessments was only checked once before the start of the study and no data are given for the percentage of grade one sores included in the calculation of incidence. In the Salvadaleña trial (1992), twenty patients developed pressure sores and 80% of sores were graded as stage 1. The authors noted that one third of the grade 1 pressure sores documented had resolved by the second skin assessment and a recalculation of the predictive power of the Braden scale was performed. Sensitivity increased from 40% to 57%, specificity increased from 70% to 74% and the positive and negative predictive values were 17% and 95% respectively. The corresponding figures for nursing judgement were not given and it is not possible to calculate them from the data. The exclusion of grade 1 sore considerable weakens the power of the study as the incidence rate falls to 5% (five patients).

Salvadaleña and colleagues found that length of stay, body weight (in pounds) and low diastolic blood pressure (in mm Hg) were significantly different between patients with and without pressure sores (including grade 1 sores). The Braden score was not found to be significantly different between these two groups of patients. However, VandenBosch and colleagues reported that the only significant difference between patients with and without pressure sores was the Braden score.

Salvadaleña and colleagues found that nursing judgement was more accurate (in having higher sensitivity and specificity values) than the Braden scale although the authors concluded that neither method was highly predictive. The Braden scale was demonstrated to have lower sensitivity and specificity than has been reported elsewhere (Effective Health Care Bulletin, 1995). The authors acknowledge that the heterogeneity of the patient group may have been a contributory factor. The lower predictive validity may also be explained by the lack of blinding of the Braden

score and the nurses' prediction. For those patients whom the nurses identified to be at risk, further preventive care may have been implemented. However, the authors noted that when a nurse judged that the patient was at risk of developing pressure sores during the hospital stay, preventive interventions were only implemented 27% of the time. VandenBosch and colleagues concluded that the Braden scale was more useful than nursing judgement alone and that the two should be used in conjunction. However, the predictive values of both nursing and Braden scale predictions are similar which casts doubt on the authors' claim that use of the Braden scale represents 'added value' to pressure sore prevention.

Sensitivity and specificity of risk assessment scales

Several inception cohort studies investigated the predictive validity of the scales. Out of 43 scales found, only the Andersen, Braden, Knoll, Norton and Waterlow scales have been tested for their predictive validity. The Braden scale (USA) and the Norton scale (UK) have been more frequently tested for their predictive validity (Table VII).

The predictive validity of risk assessment scales has been shown to be variable both in comparison of scales and in assessments of the same scale. The results cannot be pooled quantitatively due to the heterogeneity of the populations studied and the variation in outcome assessments. Thus it is not possible to make a valid comparison of one or more risk assessment scales.

Out of the six risk assessment scales tested for their predictive validity, the Braden scale has been subjected to the most testing across a greater variety of clinical settings, both in the hospital and in the community. Although Bergstrom and colleagues have demonstrated that the predictive validity estimates for the Braden scale have been high, other researchers have failed to replicate these findings (Salvadalena et al., 1992; Barnes and Payton, 1993; Capobianco and McDonald, 1996; Halfens, 1997; Langemo et al., 1991 and Ramundo, 1995). Obviously, the different patient populations studied may partially account for the variation, as the incidence of pressure sores within each setting will vary. However, this cannot explain the difference in predictive validity values obtained in the same care setting such as a medical-surgical acute care unit (Barnes and Payton, 1993; Bergstrom et al., 1987a&b; Capobianco and McDonald, 1996; Halfens, 1997 and Langemo et al., 1991).

Author(s)	Setting	Scale tested	Cut-off	Sample size	Minimum grade included	Length of follow-up	Selection of sample	Apriori sample size?
Andersen et al 1982	Acute care	Andersen	≥2	3398	I	3 months	Consecutive admissions	No
Barnes & Payton 1993	Acute care (medical -surgical)	Braden	≥ 16	361	I	15 days or until death /discharge	Consecutive admissions	No
Bergstrom & Braden 1992	Nursing home & extended care	Braden	≥ 17	200	I	12 weeks or until discharge / death	Consecutive admissions	No
Bergstrom et al 1987 a & b	Acute care (medical – surgical)	Braden	Not set	99 & 100	I	Not specified	Consecutive admissions	No
Bergstrom et al 1987	Adult Intensive Care Unit	Braden	Not spec	60	I	2 weeks or until discharge	Consecutive admissions	No
Braden & Bergstrom 1994	Nursing home	Braden	≥ 18	102	I	4 weeks or until discharge	Random sample	No
Capobianco & McDonald 1996	Acute care (medical - surgical)	Braden	≥ 18	50	I	2 weeks or until discharge	Convenience sample	No
Halfens 1997	Acute care (medical, surgical, orthopaedic and neuro surgery)	Braden	≥ 20	320	I	Not specified	Consecutive admissions	No
Langemo et al 1991	Acute and skilled care (medical and surgical patients)	Braden	Not spec	190	I	2 – 4 weeks or until discharge	Consecutive admissions	No
Ramundo 1995	Home care setting	Braden	≥ 18	48	I	4 weeks or until discharge	Consecutive admissions	No
Towey & Erland 1988	Long term care	Knoll	> 12	60	I	4 weeks	?Consecutive admissions	No
Norton et al 1962	Elderly care unit	Norton	≥ 12	250	II	8 weeks or until discharge	?Consecutive admissions	Unclear
Stotts 1988	Tertiary care centre (cardio-vascular and neuro-surgery)	Mod. Norton	≥ 14	387	I	3 weeks	Consecutive admissions	Unclear
Lowthian 1989	Orthopaedic hospital	Pressure Sore Prediction Score	> 6	1244	I	3 weeks	Consecutive admissions	No
Edwards 1995	Community	Waterlow	NS	31	I	8 weeks or until discharge/ death or admission to hospital	Random sample	No
Wai-Han et al 1996	Elderly care unit	Norton & Waterlow	≥ 14 NS	185	I	4 weeks or until discharge/ death or transfer	Consecutive admissions	No

- A Blinding of nurses undertaking skin assessment to risk score
 B Nurses undertaking skin assessments were blinded to the risk assessment scores and nurses undertaking risk assessments were blinded to the outcome of skin assessments
 C Inter-rater reliability calculated by Pearson's Product Moment Correlation
 D Inter-rater reliability calculated by intraclass correlation
 E Inter-rater reliability calculated by percentage of agreement
 F Inter-rater reliability calculated by Cronbach's a

Table VII – Summary of predictive validity studies

Blinding of assessments	Inter-rater reliability	Blinding of RA score to caring nurses	Patients lost to follow-up accounted for	Incidence	Sensitivity	Specificity	Positive predictive value	Negative predictive value
No	No	No	Yes	1%	88%	87%	7%	100%
Unclear	0.87 ^C	Unclear	None lost to follow-up	6%	73%	91%	33%	91%
No	No	Unclear	None lost to follow-up	74%	97%	19%	77%	71%
No	No	No	None lost to follow-up	7% & 9%	100% & 100%	90% & 64%	70% & 25%	97% & 100%
Yes ^A	0.89 ^C	No	None lost to follow-up	40%	83%	64%	61%	85%
Yes ^B	0.95 ^D	Unclear	None lost to follow-up	28%	79%	74%	54%	90%
Yes ^A	No	Unclear	None lost to follow-up	28%	71%	83%	63%	88%
Yes ^A	0.85 ^F	Yes	None lost to follow-up	15%	74%	70%	30%	94%
Yes ^B	0.9 – 0.99 ^E	No	None lost to follow-up	AC 15% SC 28%	AC 64% SC 57%	AC 87% SC 61%	AC 47% SC 36%	AC 93% SC 79%
No	0.8 ^C	No	None lost to follow-up	17%	100%	34%	21%	100%
No	No	No	None lost to follow-up	47%	86%	56%	50%	82%
Unclear	Unclear	Unclear	None lost to follow-up	24%	63%	70%	39%	86%
No	100% ^E	Yes	None lost to follow-up	17%	16%	94%	38%	84%
No	No	No	None lost to follow-up	4%	89%	76%	14%	99%
No	93% ^E	No	Yes	6%	100%	10%	7%	100%
No	No	No	None lost to follow-up	4%	NS 75% WS 88%	NS 67% WS 28%	NS 9% WS 5%	NS 98% WS 98%

The methodology employed varies from study to study. Although all the studies are incidence studies of patients who are initially free from pressure sores on entry to the study, the operational details given show that each research study has small but important differences. The frequency of risk assessment varies across the studies from alternate days (Barnes and Payton, 1993) to weekly assessments (Bergstrom and Braden, 1992). Different data collectors were employed from nurses caring for the patients (Langemo et al., 1991) to teams of graduate nurses employed by the researchers (Braden and Bergstrom, 1994). It is unlikely that the research team employed in the Braden studies conducted by Bergstrom and colleagues is representative of the nurses using the Braden scale in routine practice.

Problems of bias

Selection of the sample

Most studies used either a convenience sample (patients already present in the care setting) or sampled patients admitted to the care setting during the study period (consecutive admissions). Only two studies (Bergstrom and Braden, 1994; Edwards, 1995) employed a random sample technique to obtain their cohort. The danger in choosing a method other than a random sample technique is that the patients will not be representative of the larger population from which they are drawn and any inferences drawn from the results will not be valid when generalised to the whole population.

Reliability of risk assessment

Eight studies reported reliability testing of the risk assessment scale used in the study. Neither the methodology nor the statistical analysis employed to generate and test the reliability data was consistent across the eight studies. Most studies tested the reliability of risk assessment once before the study commenced and many used either Pearson's Product Moment Correlation or percentage of agreement to test the data (Bergstrom et al., 1987; Ramundo, 1995; Barnes and Payton, 1993; Langemo et al., 1991; Stotts, 1988 and Edwards, 1995). Altman (1991) argued that the method comparison studies are subject to frequent errors and that percentage agreement method is unreliable as some agreement must occur by chance. The most appropriate test to use to measure reliability of measurement between raters is kappa where a maximum value of 1.0 indicates perfect agreement. None of the studies used this method of analysis when testing the reliability of the risk assessment scale.

The risk assessment scale should be tested before the start of the study and then at regular intervals during

the study to ensure reliability. If the risk assessments are unreliable, patients may not be consistently classified into the 'at risk' or 'not at risk' categories and the resulting sensitivity and specificity values obtained will be invalid.

Definition of a pressure sore, frequency and reliability of outcome assessment

Many of the studies failed to give an adequate description of the wound grading scale used in the skin assessment and the frequency of skin assessment varied across the different research designs. If the skin assessment was performed too infrequently, the researcher may have missed a grade 1 pressure sore that could have resolved by the next assessment and therefore would not be accounted for in the calculation of incidence. None of the studies report reliability testing of the skin assessment tool used in the study and this is judged to be a major flaw in the studies included in this review. The subjectivity of the earlier grades of pressure damage has been demonstrated earlier in this thesis and all of the studies (except Norton et al 1962) included a grade 1 pressure sore in their calculation of incidence. Indeed, as Salvadalena and colleagues noted (1992), the majority of the patients with pressure sores were classified as having a grade 1 pressure sore. If the skin assessments were unreliable, then the predictive validity values obtained would not be valid.

Blinding of nurses performing skin assessment to risk status

Five studies ensured that the nurses carrying out the skin assessments were unaware of the outcome of the risk assessments (Bergstrom et al 1987; Braden and Bergstrom 1994; Capobianco and McDonald 1996; Halfens 1997 and Langemo et al 1991). This is an important consideration in critical appraisal. If the nurse is aware of the patient's risk status, he or she may have graded tissue damage as a grade 1 pressure sore, especially if she or he actually undertook the risk assessment and scored the patient to be 'at risk'. Thus the possibility of bias introduced through knowing the outcome of the risk assessment cannot be ruled out in the remaining studies.

Blinding of nurses caring for patients to risk status

Halfens (1997) and Stotts (1988) reported that the nurses caring for the patients were unaware of the patients' risk status (as scored by the risk assessment scale). If the nurses caring for the patients were not blinded to the outcome of the risk assessment, they may have changed the plan of care accordingly, which could have accounted for the differences in the incidence of pressure ulcers. This would also contribute to the

differences in sensitivity and specificity as the nurse may have instigated new or additional preventive measures as a result of the assessments.

Testing of risk assessment scales for practicability

None of the scales had been tested for their practicability in the clinical settings.

Summary

There is no evidence that risk assessment scales are effective in reducing the incidence of pressure sores or that they improve preventative care. There is little evidence that risk assessment scales are better than clinical nursing judgement. Few scales out of those identified through the search have been tested for their predictive validity and the quality of many of these studies is poor. No scale appears to be more accurate in identifying those patients at most risk from developing pressure sores although the Braden scale has been more extensively tested than other scales. Further studies testing the Braden scale for predictive validity have never replicated the high sensitivity and specificity figures obtained by Braden, Bergstrom and colleagues.

Annex A

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Annex B

Searching electronic databases

The example below is the search conducted on MEDLINE on Ovid from 1966 until June 1997. The main subject heading followed is decubitus ulcer for MEDLINE and pressure ulcer for CINAHL. The searches were repeated for the years 1996 and 1997 to ensure that all potentially eligible papers were identified at the beginning and at the end of the review.

1	exp decubitus ulcer	3798
2	decubitus ulcer\$.tw.	830
3	pressure ulcer\$.tw.	
4	bed?sore\$.tw.	163
5	pressure ulcer\$.tw.	1145
6	pressure damage.tw.	35
7	*decubitus ulcer/pc	904
8	1 or 2 or 3 or 4 or 5 or 6 or 7	4248
9	exp Risk Factors/	102962
10	Risk Assessment/	2490
11	exp risk assessment/	2490
12	exp Severity of illness index/	10007
13	clinical assessment.ti,ab,sh.	4270
14	exp Risk management/	4482
15	risk assessment.tw.	3559
16	risk assessment scale\$.tw.	42
17	risk assessment score\$.tw.	9
18	risk assessment scale\$.tw.	15
19	risk factor\$.tw.	51667
20	risk calculator\$.tw.	10
21	risk score\$.tw.	452
22	risk predict\$.tw.	354
23	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	147438
24	8 and 23	443
25	exp Reproducibility of Results/	27235
26	exp Nursing assessment/	11271
27	exp Observer Variation/	4828
28	(reliability and validity).ti,ab,sh.	4435
29	(sensitivity and specificity).ti,ab,sh.	28818
30	exp evaluation studies/	259653
31	exp Nursing research/	10011
32	exp Research design/	95680
33	clinical research.ti,ab,sh.	5898
34	exp Nursing audit/	1142
35	exp Prospective studies/	84109
36	predictive validity.ti,ab,sh.	591
37	exp Psychometrics/	14621
38	exp Nursing evaluation research/	1574
39	25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38	450759
40	24 and 39	214

1 Evidence refers to research evidence, clinical expertise and patient preferences