Supplementary Material*


Supplement. Pressure Ulcer Risk Assessment and Prevention: Update to a Comparative Effectiveness Review

* This supplementary material was provided by the authors to give readers further details on their article. The material was reviewed but not copyedited.
Pressure ulcer risk assessment and prevention: update to a comparative effectiveness review

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A systematic review on the comparative effectiveness of pressure ulcer risk assessment instruments and preventive interventions was published in July 2013, based on searches conducted through November 2012 (1, 2). It found evidence that more advanced static support surfaces are more effective than standard mattresses for preventing ulcers in higher-risk populations, but that the effectiveness of formal risk assessment instruments and associated intervention protocols and the effectiveness of other preventive interventions has not been clearly established. This update was performed to identify new studies published since the original review and to determine their impact on strength of assessment assessments and findings.

Methods

This update follows the protocol used for the original review, including the key questions and analytic framework, used for the original review. Details regarding the methods, including search strategies, and detailed inclusion criteria, are available in the original full report, available on the Agency for Healthcare Research and Quality website (2). The key questions addressed for this update were:

- Is the use of risk assessment tools effective in reducing the incidence or severity of pressure ulcers, and how does effectiveness vary according to setting and patient characteristics?
- In patients at increased risk of developing pressure ulcers, what is the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers, and how does effectiveness vary according to assessed risk level, setting, or patient characteristics?
- What are the harms of interventions for preventing pressure ulcers?

Data sources and searches

The original review performed searches through November 2012. For this update, we updated searches on Ovid MEDLINE, the Cochrane Library, and CINAHL (EBSCOhost) from through February 2014.

Study selection

English language articles that were relevant to a key question and met the inclusion criteria as defined in the original report were selected. Included studies were controlled clinical trials and cohort studies that compared pressure ulcer incidence or severity following use of a risk assessment instrument versus clinical judgment or another risk assessment instrument, and randomized trials of preventive interventions that reported pressure ulcer incidence or severity, resource utilization (such as duration of hospital stay), or harms in persons at higher risk of pressure ulcers. Trials in which >20% of subjects had stage 2 or higher ulcers at baseline were excluded.

Data extraction

Details about the study design, population, setting, interventions, analysis, follow-up and results were abstracted. Study quality was assessed using previously predefined criteria.
Data synthesis and analysis

We did not conduct meta-analysis due to methodological limitations in the studies and clinical heterogeneity. Based on new evidence identified for this update as well as the evidence previously reviewed for the original review, we assessed the overall strength of evidence of each body of evidence as “high,” “moderate,” “low,” or “insufficient” in accordance with the Agency for Healthcare Research and Quality Methods Guide for Comparative Effectiveness Reviews (3), based on the quality of studies, consistency between studies, precision of estimates, and directness of evidence.

Role of the funding source

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Results

Searches yielded 431 unique citations. Nine potentially relevant studies were identified in the abstract review stage. After review of the full-text articles, four studies were determined to meet inclusion criteria. Reasons for exclusion at the full-text stage were: non-randomized trial of a preventive intervention (4), protocol for a randomized intervention trial with no results (5), randomized trial published as abstract only (6), enrolled patients with ulcers at baseline (7), and results reported from two previously included trials (8). In addition, in the latter study, results were pooled across the two trials even though they evaluated different interventions (multi-stage alternating pressure air mattress in one trial and one-stage ALPAM in the other). Four randomized trial on the effectiveness of preventive interventions for reducing risk of pressure ulcers met inclusion criteria (Table 1): one trial each of repositioning (9), advanced static support surfaces (10), a clinical decision support system (11), and use of musical cues to prompt repositioning or movement (12). No new trial reported harms associated with preventive interventions, and as in the original report, no trial evaluated effects of risk assessment tools in reducing incidence or severity of pressure ulcers.

Support surfaces

Evidence from original report
The original report found more advanced static mattresses or overlays associated with lower risk of pressure ulcers than standard hospital mattresses, based on 12 trials (RRs 0.16 to 0.82 in one good-quality and four fair-quality trials) (1). Evidence was limited on the effects of low-air-loss beds (2 trials) or alternative air pressure overlays or mattresses (3 trials) versus standard hospital mattresses, but also indicated beneficial effects in preventing new pressure ulcers. Trials that compared difference advanced static mattresses or overlays or compared an alternative air pressure overlay or mattress versus an advanced static overlay or mattress found no clear difference in risk of pressure ulcers.

New evidence
One new, fair-quality trial (n=41) compared a visco-elastic foam mattress plus static air overlay versus a visco-elastic foam mattresses alone in nursing home patients (55-67% had a Braden score at baseline between 6 and 12) (Table 1) (10). No trial in the original report compared the effectiveness of two support surfaces used in combination versus a single support surface. Although designed as a crossover trial, the new trial did not report analyses based on paired data. Other methodological shortcomings were unclear description of randomization and allocation concealment methods and failure to mask outcome assessors (Table 2). The trial found the combination intervention associated with decreased risk of incident stage 2 or higher ulcers after 6 months, but the difference was not statistically significant (5.1% vs. 20%, RR 0.26,
95% CI, 0.06 to 1.1). The static air overlay plus foam mattress intervention was also associated with lower likelihood for initiation of repositioning at night due to stage 1 ulcers. No stage 4 ulcers occurred with either intervention.

Repositioning

Evidence from original report
The original report found inconsistent evidence regarding effects of more intensive repositioning on risk of new pressure ulcers. More intense repositioning was associated with lower risk of incident ulcers in one fair-quality trial (n=213) that compared repositioning at a 30-degree tilt every 3 hours versus usual care (90-degree lateral repositioning every 6 hours during the night) (13), but with no difference in another fair-quality trial (n=235) that compared different repositioning intervals (alternating between the semi-Fowler 30-degree and lateral positions) (14). Challenges in interpreting these findings include differences between trials in the intervals and positions evaluated.

New evidence
One new, good-quality trial (n=942) evaluated effects of different repositioning intervals in nursing home patients (mean age 85 years, mean Braden score 13) (Tables 1 and 2) (9). Patients were stratified into moderate (Braden 13-14) or high risk (Braden 10-12) categories and randomized to repositioning every 2, 3, or 4 hours. All patients were cared for on an advanced static support surface (high-density foam mattress) and received additional preventive interventions (e.g., chair cushions, heel protector boots, heel elevation, barrier creams, and incontinence briefs). The trial found no difference between repositioning every 2, 3, or 4 hours in risk of any incident pressure ulcer in the entire sample (2.5% vs. 0.6% vs. 3.0%, p=0.68) or when patients were stratified as moderate- (2.9% vs. 0.0% vs. 3.5%, p=0.68) or high-risk (1.8% vs. 1.7% vs. 2.1%).

Other interventions

New evidence
Two new trials assessed interventions to facilitate the implementation of pressure ulcer prevention protocols or guidelines (Table 1) (11, 12). No studies of such interventions were included in the original report. Both trials were cluster randomized trials, one rated fair-quality (11) and the other poor-quality (12) (Table 2). Methodological shortcomings included inadequate description of randomization and allocation concealment methods, failure to blind outcome assessors, failure to report pressure ulcer status at baseline, and failure to account for clustering effects in the analyses; the poor-quality trial also reported baseline differences in intervention groups.

The fair-quality trial (11 sites, n=464) found no difference between a multi-component electronic clinical decision support system (including interactive education, reminders, monitoring, feedback, and leadership) for implementation of pressure ulcer prevention versus standard care (provision of a hard copy of standard guidelines) in a nursing home setting (mean age 84-85 years, baseline ulcer risk not reported) in risk of incident stage 2-4 ulcers (1.8% vs. 2.1%, RR 0.85, 95% CI, 0.23 to 3.1) (11). The poor-quality trial found immediate implementation of musical cues for movement or repositioning every 2 hours for 12 months in nursing home residents (8 facilities, n=1670) versus delayed implementation for 6 months in risk of incident pressure ulcers (6.0% vs. 9.4%, RR 0.64, 95% CI, 0.45 to 0.90) (12).

Discussion
The evidence identified for this update is summarized in Table 3, with updated strength of evidence ratings. We identified four new randomized trials of preventive interventions (9-12). The highest-quality of these found that more frequent repositioning was not more effective than a 4 hour interval in preventing
new ulcers (9). Although the overall evidence on repositioning remains difficult to interpret due to variability in the repositioning intervals and positions evaluated, the new trial is the largest study to date and was rated good-quality. Its findings are most applicable to settings in which patients are already receiving standard preventive interventions, including advanced static support surfaces.

The only new trial on support surfaces compared the combination of two static support surfaces versus a single static support surface (10). No study in the original report evaluated the utility of two support surfaces in combination. Given the small sample size (n=41), methodological shortcomings, and the failure of results to reach statistical significance, it was not possible to reach strong conclusions regarding the utility of combined advanced static support surfaces versus a single advanced static support surface.

Limited evidence is now available from two new trials on the effectiveness of interventions to facilitate implementation of pressure ulcer prevention protocols or guidelines (11, 12). In one trial, a multi-component electronic clinical decision support system was no more effective than provision of clinical practice guidelines in preventing ulcers (11). In the other, use of musical cues was associated with reduced risk of new pressure ulcers (12). Both trials had important methodological shortcomings, and it is not possible at this time to reliably determine optimal methods for promoting effective pressure ulcer preventive care.

No new trial reported harms associated with preventive intervention or measures of resource utilization, and no new trial evaluated the effectiveness of risk assessment methods in preventing ulcers. We also identified no new trials on other preventive interventions reviewed in the original report, such as nutritional supplementation, dressings, or lotions and cleansers.

In summary, new evidence on pressure ulcer prevention is most notable for a new trial that found that repositioning every four hours is as effective as more frequent repositioning in preventing ulcers in patients receiving standard preventive care(9). Evidence and conclusions regarding advanced static support surfaces is largely unchanged. There remains no evidence on the effectiveness of formal risk assessment instruments and associated intervention protocols, or on other preventive interventions, for which evidence remains very limited. More evidence is also needed to determine effective methods for implementing protocols and guidelines for preventing pressure ulcers.
References


3. Agency for Healthcare Research and Quality. Methods Guide for Effectiveness and Comparative Effectiveness Reviews [Internet]. Rockville, MD; 2008-.


## Table 1. New trials of interventions to prevent pressure ulcers

<table>
<thead>
<tr>
<th>Author, Year Quality Rating</th>
<th>Setting Country Followup</th>
<th>Intervention (N)</th>
<th>Baseline Demographics</th>
<th>Baseline Ulcer Risk Score, Pressure Ulcers at Baseline</th>
<th>Pressure Ulcer Incidence and Severity</th>
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<tbody>
<tr>
<td><strong>Supp ort surfaces</strong></td>
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<tr>
<td>van Leen, 2013(11)</td>
<td>Nursing home the Netherlands 6 months</td>
<td>A: Static air overlay mattress with visco-elastic foam mattress (n=20) B: Visco-elastic foam mattress (n=21) Crossover design</td>
<td>Mean age: 79 vs. 81 years Sex: 70% vs. 86% female Race: Not reported Braden score between 6 and 12: 55% vs. 67% Pressure ulcers at baseline: Excluded</td>
<td>Stage 2 or higher ulcer: 5.1% (2/39) vs. 20% (8/40), RR 0.26 (95% CI, 0.06 to 1.1) Stage 2 ulcer: 5.1% (2/39) vs. 15% (6/40), RR 0.34 (95% CI, 0.07 to 1.6) Stage 3 ulcer: 0% (0/39) vs. 7.5% (3/40), RR 0.15 (95% CI, 0.08 to 2.7) Stage 4 ulcer: 0% (0/39) vs. 0% (0/40) Initiation of repositioning at night due to stage 1 ulcer: 2.6% (1/39) vs. 20% (8/40), RR 0.13 (95% CI, 0.02 to 0.98)</td>
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<td><strong>Repositioning</strong></td>
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<tr>
<td>Bergstrom et al, 2013 (9)</td>
<td>Nursing home United States and Canada 3 weeks</td>
<td>A: Repositioning every 2 hours (n=321) B: Repositioning every 3 hours (n=326) C: Repositioning every 4 hours (n=295) All groups received care on high-density foam mattress and received other standard preventive interventions</td>
<td>n=942 Mean age: 85 vs. 84 vs. 86 years Sex: 77% vs. 77% vs. 78% female Race: 82% vs. 82% vs. 77% White Mean Braden score: 12.9 vs. 12.8 vs. 12.9 Pressure ulcers at baseline: Excluded</td>
<td>Any pressure ulcer, all participants: 2.5% (8/321) vs. 0.6% (2/326) vs. 3.0% (9/295), p=0.68 Any pressure ulcer, participants at moderate risk at baseline (Braden 13-14): 2.9% (6/210) vs. 0.0% (0/209) vs. 3.5% (7/198), p=0.68 Any pressure ulcer, participants at high risk at baseline (Braden 10-12): 1.8% (2/111) vs. 1.7% (2/117) vs. 2.1% (2/97), p=0.90</td>
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<tr>
<td><strong>Interventions for implementation of pressure ulcer prevention protocols or guidelines</strong></td>
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<tr>
<td>Beeckman, 2013(11)</td>
<td>Nursing home Belgium 16 weeks</td>
<td>A: Multi-component electronic clinical decision support system including interactive education, reminders, monitoring, feedback, and leadership for implementation of pressure ulcer prevention guidelines (6 wards, n=225) B: Provision of hard copy of standard pressure ulcer prevention guidelines (5 wards, n=239)</td>
<td>Cluster randomized trial, 11 wards randomized, n=464 Mean age: 84 vs. 85 years Sex: 76% vs. 83% female Race: Not reported Baseline ulcer risk: Not reported Pressure ulcer at baseline: Not reported</td>
<td>Stage 1-4 pressure ulcer: 7.1% (16/225) vs. 14.6% (35/239), RR 0.49 (95% CI, 0.28 to 0.85) Stage 2-4 pressure ulcer: 1.8% (4/225) vs. 2.1% (5/239), RR 0.85 (95% CI, 0.23 to 3.1)</td>
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<tr>
<td>Yap et al, 2013(12)</td>
<td>Long-term care facility United States 12 months</td>
<td>A: Musical cues for movement or repositioning every 2 hours from months 1-12 (4 facilities, n=948) B: Musical cues only in months 7-12 (4 facilities, n=722)</td>
<td>Cluster randomized trial, 8 facilities, n=1670 Mean age: 77 vs. 76 years Sex: 63% vs. 65% female Race: 89% vs. 87% non-Hispanic white Baseline ulcer risk: Not reported Pressure ulcer at admission: Not reported</td>
<td>Any new pressure ulcer: 6.0% (55/913) vs. (9.4%) 68/721, RR 0.64 (95% CI, 0.45 to 0.90); OR 0.52 (95% CI, 0.25 to 1.08 based on rate per number of Minimum Data Set 2.0 assessments) and OR 0.58 (95% CI, 0.34 to 1.00 based on rate per number of Minimum Data Set 3.0 assessments)</td>
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CI = confidence interval; OR = odds ratio; RR = relative risk.
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<tbody>
<tr>
<td>Beeckman, 2013 (11)</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Yes</td>
<td>Unclear (pressure ulcer status at baseline)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No analysis of clustering effects</td>
<td>Fair</td>
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<tr>
<td>Bergstrom, 2013 (9)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>None noted</td>
<td>Good</td>
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<td>van Leen, 2013 (10)</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Crossover design; analysis did not account for paired effects</td>
<td>Fair</td>
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<tr>
<td>Yap, 2013 (12)</td>
<td>Unclear</td>
<td>Unclear</td>
<td>No</td>
<td>Unclear (pressure ulcer status at baseline)</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No analysis of clustering effects</td>
<td>Poor</td>
</tr>
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</table>
### Table 3. Summary of Evidence

<table>
<thead>
<tr>
<th>Strength of evidence of findings from original AHRQ report *</th>
<th>Number of studies identified (number of new trials) / Number of subjects (number in new trials)</th>
<th>Overall quality</th>
<th>Consistency (High, Moderate, Low)</th>
<th>Directness (Direct or Indirect)</th>
<th>Precision (High, Moderate, Low)</th>
<th>Overall strength of evidence rating, including new evidence</th>
<th>Summary of findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effectiveness of preventive interventions</strong></td>
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<tr>
<td>Advanced static mattress or overlay used in combination vs. advanced static mattress or overlay alone</td>
<td>1 randomized trial (1) N=41 (41)</td>
<td>Fair</td>
<td>Cannot determine (1 study)</td>
<td>Direct</td>
<td>Low</td>
<td>Insufficient</td>
<td>One trial found the combination of a static air overlay plus visco-elastic foam mattress associated with decreased risk of incident stage 2 or higher ulcers after 6 months versus a visco-elastic foam mattress alone, but the difference was not statistically significant (5.1% vs. 20%, RR 0.26, 95% CI, 0.06 to 1.1).</td>
</tr>
<tr>
<td>Repositioning interventions vs. usual care</td>
<td>5 randomized trials (1) N=2,274 (942)</td>
<td>Fair</td>
<td>Moderate</td>
<td>Direct</td>
<td>Moderate</td>
<td>Moderate</td>
<td>More intense repositioning intervention associated with lower risk of ulcers in one good- (n=213) and one fair-quality trial (n=235), but no difference in one fair-quality trial (n=235). In the good-quality trial, risk of stage 2-4 ulcers with repositioning every 2, 3, and 4 hours was 2.5% vs. 0.6% vs. 3.0%, respectively (p=0.68).</td>
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<tr>
<td>Multicomponent electronic clinical decision support system vs. provision of guideline</td>
<td>1 randomized trial (1) N=464 (464)</td>
<td>Fair</td>
<td>Cannot determine (1 study)</td>
<td>Direct</td>
<td>Low</td>
<td>Low</td>
<td>No difference between a multicomponent electronic clinical decision support system and provision of guidelines in incident stage 2-4 ulcers in one fair-quality trial (1.8% vs. 2.1%, RR 0.85, 95% CI, 0.23 to 3.1).</td>
</tr>
<tr>
<td>Immediate vs. delayed implementation of musical cues to facilitate repositioning and movement</td>
<td>1 randomized trial (1) N=1670</td>
<td>Poor</td>
<td>Cannot determine (1 study)</td>
<td>Direct</td>
<td>Moderate</td>
<td>Insufficient</td>
<td>Immediate implementation of musical cues associated with lower risk of incident ulcers in one poor-quality trial (6.0% vs. 9.4%, RR 0.64, 95% CI, 0.45 to 0.90).</td>
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</tbody>
</table>

*Strength of evidence as reported in references 1 and 2.