Comparative Effectiveness Review
Number 87

Effective Health Care Program

Pressure Ulcer Risk Assessment and Prevention: Comparative Effectiveness

Executive Summary

Background

Pressure ulcers are defined by the National Pressure Ulcer Advisory Panel (NPUAP) as "localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction."[1] Pressure ulcers are a common condition, affecting an estimated 3 million adults in the United States.[2] In 2006, pressure ulcers were reported in more than 500,000 hospital stays.[3] Estimates of pressure ulcer prevalence range from 0.4 to 38 percent in acute care hospitals, 2 to 24 percent in long-term nursing facilities, and 0 to 17 percent in home care settings.[4-6] The prevalence of facility-acquired pressure ulcers was 6 percent in 2008 and 5 percent in 2009.[6]

A number of risk factors are associated with increased risk of pressure ulcer development, including older age, black race, lower body weight,[7,8] physical or cognitive impairment, poor nutritional status, incontinence, and specific medical comorbidities that affect circulation such as diabetes or peripheral vascular disease. Pressure ulcers are often associated with pain and can contribute to decreased function or lead to complications such as infection.[2] In some cases, pressure ulcers may be difficult to successfully treat despite surgical and other invasive treatments. In the inpatient setting, pressure ulcers are associated with increased length of hospitalization and delayed return to function.[3] In addition,

Effective Health Care Program

The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

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the presence of pressure ulcers is associated with poorer general prognosis and may contribute to mortality risk.[3] Between 1990 and 2001, pressure ulcers were reported as a cause of death in nearly 115,000 people and listed as the underlying cause in more than 21,000.[9] Estimates of the costs of treatment for pressure ulcers vary, but range between $37,800 and $70,000 per case.[2,10]

A number of instruments have been developed to assess for risk of pressure ulcers. The three most widely used instruments are the Braden scale (6 items; total scores range from 6 to 23); the Norton scale (5 items; total scores range from 5 to 20); and the Waterlow scale (11 items; total scores range from 1 to 64).[2,11-13] All three scales include items related to activity, mobility, nutritional status, incontinence, and cognition, although they are weighted differently across studies.[12]

Recommended prevention strategies for pressure ulcers generally involve use of risk-assessment tools to identify people at higher risk for developing ulcers in conjunction with interventions for preventing ulcers.[14-16] A variety of diverse interventions are available for the prevention of pressure ulcers. Categories of preventive interventions include support surfaces (including mattresses, integrated bed systems, overlays, and cushions), repositioning, skin care (including lotions, dressings, and management of incontinence), and nutritional support.[15,16] Each of these broad categories encompasses a variety of interventions.

The purpose of this report is to review the comparative clinical utility and diagnostic accuracy of risk-assessment instruments for evaluating risk of pressure ulcers and to evaluate the benefits and harms of preventive interventions for pressure ulcers in different settings and patient populations.

Objectives

This Comparative Effectiveness Review (CER) topic was nominated by the American College of Physicians, which intends to develop a guideline on prevention and management of pressure ulcers (i.e., prevention of ulcers in people without ulcers at baseline). This report focuses on the comparative effectiveness of various pressure ulcer risk-assessment and prevention approaches; the treatment of pressure ulcers is addressed in a separate review.[17]

The following Key Questions are the focus of this report:

Key Question 1. For adults in various settings,[a] is the use of any risk-assessment tool[b] effective in reducing the incidence or severity of pressure ulcers compared with other risk-assessment tools, clinical judgment alone, and/or usual care?

Key Question 1a. Do the effectiveness and comparative effectiveness of risk-assessment tools differ according to setting?

Key Question 1b. Do the effectiveness and comparative effectiveness of risk-assessment tools differ according to patient characteristics[c] and other known risk factors for pressure ulcers, such as nutritional status or incontinence?

Key Question 2. How do various risk-assessment tools compare with one another in their ability to predict the incidence of pressure ulcers?

Key Question 2a. Does the predictive validity of various risk-assessment tools differ according to setting?

Key Question 2b. Does the predictive validity of various risk-assessment tools differ according to patient characteristics?

Key Question 3. In patients at increased risk of developing pressure ulcers, what are the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers?

Key Question 3a. Do the effectiveness and comparative effectiveness of preventive interventions differ according to risk level as determined by different risk-assessment methods and/or by particular risk factors?

Key Question 3b. Do the effectiveness and comparative effectiveness of preventive interventions differ according to setting?

Key Question 3c. Do the effectiveness and comparative effectiveness of preventive interventions differ according to patient characteristics?

Key Question 4. What are the harms of interventions for the prevention of pressure ulcers?

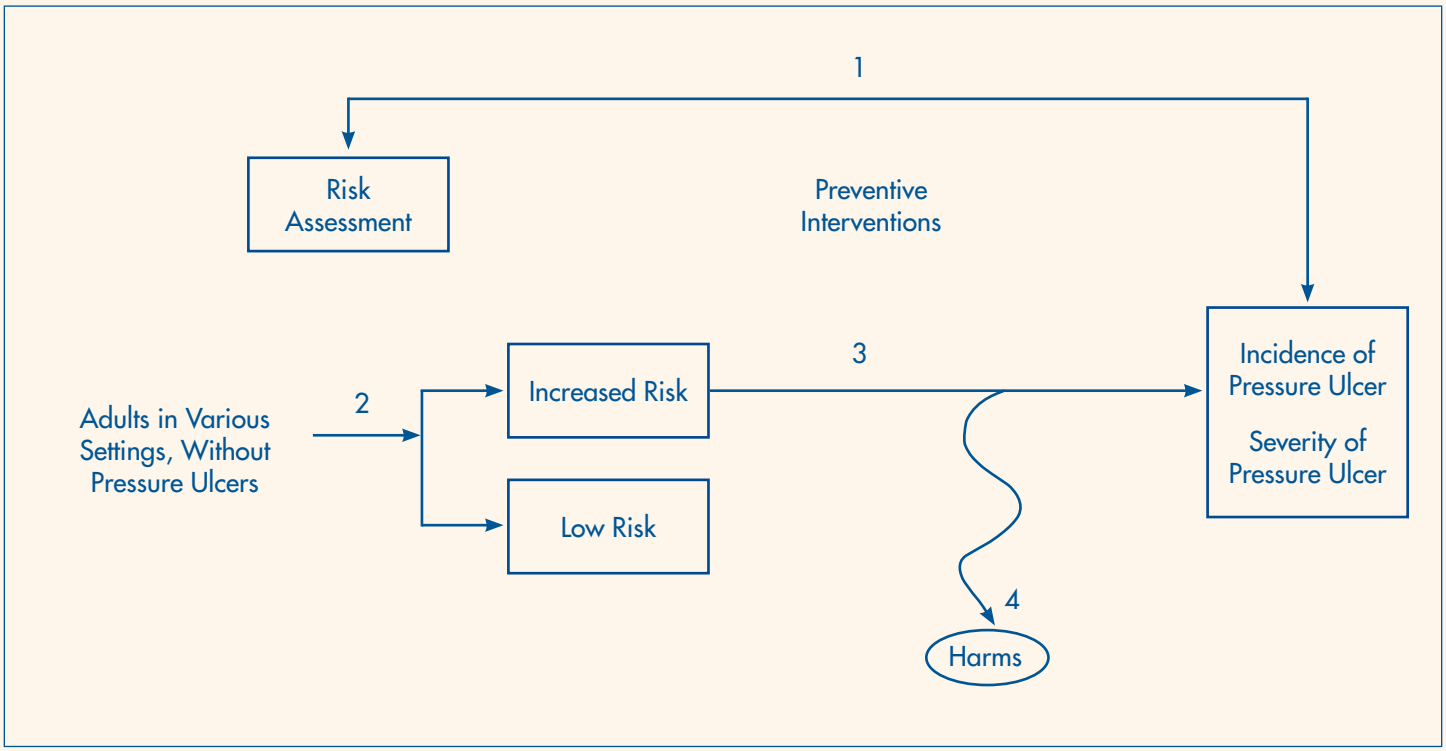
Key Question 4a. Do the harms of preventive interventions differ according to the type of intervention?

Key Question 4b. Do the harms of preventive interventions differ according to setting?

Key Question 4c. Do the harms of preventive interventions differ according to patient characteristics?

[a]Including acute care hospital, long-term care facility, rehabilitation facility, operating room, home care, and wheelchair users in the community.
[b]The Braden scale, the Norton scale, the Waterlow scale, or others.
[c]Such as age, race or skin tone, physical impairment, body weight, or specific medical comorbidities (e.g., diabetes and peripheral vascular disease).

Figure A. Analytic framework: pressure ulcer risk assessment and prevention



Note: The numbers in the analytic framework correspond to the numbers of the Key Questions.

Analytic Framework

The analytic framework (Figure A) used to guide this report shows the target populations, preventive interventions, and health outcomes we examined.

Methods

Input From Stakeholders

The Key Questions for this CER were developed with input from Key Informants, representing clinicians, wound care researchers, and patient advocates, who helped refine Key Questions, identify important methodological and clinical issues, and define parameters for the review of evidence. The revised Key Questions were then posted to the Agency for Healthcare Research and Quality (AHRQ) public Web site for a 4-week public comment period. AHRQ and the Evidence-based Practice Center agreed on the final Key Questions after reviewing the public comments and receiving additional input from a Technical Expert Panel (TEP) convened for this report. The TEP consisted of people with expertise in pressure ulcer treatment and research from disciplines including geriatrics, primary care, hospital medicine, and nursing.

We then drafted a protocol for the CER, which was reviewed by the TEP. The final protocol developed prior to initiation of the review is available at http://effectivehealthcare.ahrq.gov/ehc/products/309/926/Pressure-Ulcer-Prevention_Protocol_20120110.pdf.

Search Strategy and Study Selection

A research librarian conducted searches on MEDLINE® (Ovid®) from 1946 to July 2012, CINAHL (EBSCOhost®) from 1988 through July 2012, and the Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews using Evidence-Based Medicine Reviews (Ovid®) through July 2012. The search strategies were peer reviewed by another information specialist and revised prior to finalization. We also hand-searched the reference lists of relevant studies. In addition, scientific information packets (SIPs) were requested from identified drug and device manufacturers of pressure ulcer treatments, who had the opportunity to submit data using the portal for submitting SIPs on the Effective Health Care Program Web site. Searches were updated prior to finalization of the report to identify any relevant new publications.

We developed criteria for inclusion and exclusion of studies based on the Key Questions and the populations, interventions, comparators, outcomes, timing, and setting (PICOTS) approach, as well as study designs. Papers were selected for review if they were about prevention of pressure ulcers, were relevant to a Key Question, and met the predefined inclusion criteria. We restricted inclusion to English-language articles. Studies of nonhuman subjects and studies with no original data were excluded. Abstracts and full-text articles were dual-reviewed for inclusion. Full-text articles were obtained for all studies that either investigator identified as potentially meeting inclusion criteria. Two investigators independently reviewed all full-text articles for final inclusion or exclusion. Discrepancies were resolved through discussion and consensus, with a third investigator making the final decision if necessary.

For studies of preventive interventions, studies that included patients with pressure ulcers at baseline were included if fewer than 20 percent had stage 2 ulcers and the study reported incident (new) ulcers. For studies of risk-prediction instruments, we excluded studies that enrolled >10 percent of patients with ulcers at baseline, since the presence of ulcers is in itself a marker of high risk. We evaluated patient subgroups defined by age, race, physical impairment, body weight, or specific medical comorbidities (e.g., urinary incontinence, diabetes, and peripheral vascular disease). We did not exclude studies based on setting.

For Key Question 1, we included studies that compared effects of using a risk-assessment instrument—such as the Braden, Norton, or Waterlow scales—with clinical judgment or another risk-assessment instrument. For Key Question 2, we included studies that reported the diagnostic accuracy of validated risk-assessment instruments for predicting incident pressure ulcers. For Key Questions 3 and 4, we included studies that compared interventions to prevent pressure ulcers with usual care or no treatment, or that compared one preventive intervention with another.

For Key Questions 1 and 4, we included controlled clinical trials and cohort studies. For Key Question 3, we included controlled clinical trials. For Key Question 2, we included prospective studies that reported diagnostic accuracy of risk-prediction instruments. We excluded systematic reviews, although we reviewed their reference lists for additional citations.

Data Extraction and Quality Assessment

We extracted the following information from included trials into evidence tables: study design, setting, inclusion and exclusion criteria, population characteristics (including sex, age, race, ethnicity, prevalent ulcers, and risk for ulcers), sample size, duration of followup, attrition, intervention characteristics, method for assessing ulcers, and results. Data extraction for each study was performed by two investigators: the first investigator extracted the data, and the second investigator independently reviewed the extracted data for accuracy and completeness.

For studies of diagnostic accuracy, we attempted to create two-by-two tables from information provided (usually sample size, prevalence, sensitivity, and specificity) and compared calculated measures of diagnostic accuracy based on the two-by-two tables with reported results. We noted discrepancies between calculated and reported results when present. When reported, we also extracted relative measures of risk (relative risk [RR], odds ratio, and hazards ratio) and the area under the receiver operating characteristic (AUROC) curve.

We assessed the quality of each study based on predefined criteria. The criteria used to assess quality are consistent with the approach recommended by AHRQ in the Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[18]

We rated the quality of each randomized trial based on the methods used for randomization, allocation concealment, and blinding; the similarity of compared groups at baseline; maintenance of comparable groups; adequate reporting of dropouts, attrition, crossover, adherence, and contamination; loss to followup; the use of intent-to-treat analysis; and ascertainment of outcomes.[19] For cluster randomized trials, we also evaluated whether the study evaluated cluster effects.[20]

We rated the quality of each cohort study based on whether it used nonbiased selection methods to create an inception cohort; whether it evaluated comparable groups; whether rates of loss to followup were reported and acceptable; whether it used accurate methods for ascertaining exposures, potential confounders, and outcomes; and whether it performed appropriate statistical analyses of potential confounders.[19] We rated the quality of each diagnostic-accuracy study based on whether it evaluated a representative spectrum of patients, whether it enrolled a random or consecutive sample of patients meeting predefined criteria, whether it used a credible reference standard, whether the same reference standard was applied to all patients, whether the reference standard

was interpreted independently from the test under evaluation, and whether thresholds were predefined.[19,21] In addition, unblinded use of a risk-prediction instrument (as was typical in the studies) could result in differential use of preventive interventions based on assessed risk, and thereby alter the likelihood of the predicted outcome and compromise measures of diagnostic accuracy (e.g., if more intense and effective interventions are used in higher risk patients). Therefore, we also assessed whether studies on diagnostic accuracy reported use of subsequent interventions and whether risk estimates (when reported) were adjusted for potential confounders.

Following assessment of individual quality criteria, individual studies were rated as "good," "fair," or "poor" quality.[22]

Data Synthesis and Rating the Strength of the Body of Evidence

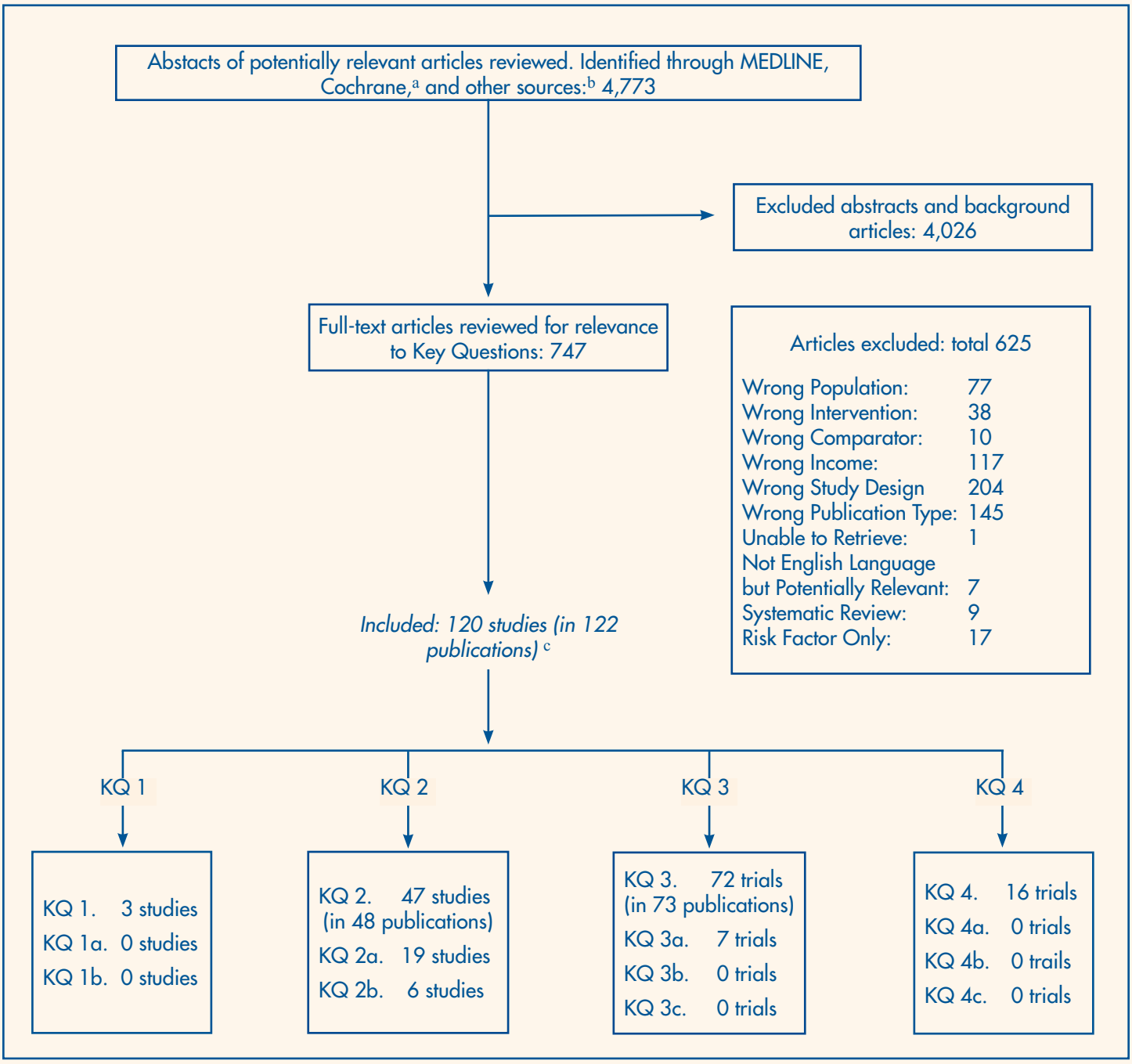
We did not attempt to pool studies on preventive interventions due to methodological limitations in the studies and substantial clinical diversity with respect to the populations, settings, comparisons, and outcomes evaluated (i.e., how pressure ulcers were assessed and graded). We also did not quantitatively pool results on diagnostic accuracy (such as creating summary receiver operating characteristic curves) due to differences across those studies in populations evaluated, differences in how pressure ulcers were assessed and graded, and methodological limitations in the studies. Instead, we created descriptive statistics with the median sensitivity and specificity at specific cutoffs and reported AUROCs, along with associated ranges. Although studies varied in what cutoffs were evaluated, and some evaluated a range of cutoffs without a prespecified threshold, we focused on cutoffs for the most common risk instruments (Braden, Norton, and Waterlow) based on recommended thresholds, which may vary depending on the setting and timing of assessments.The total range across studies for the various measures of diagnostic accuracy, rather than the interquartile range, was reported because the summary range highlighted the greater variability and uncertainty in the estimates.

We assessed the overall strength of evidence for each Key Question in accordance with the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[23] We synthesized the quality of the studies, the consistency of results within and between study designs, the directness of the evidence linking the intervention and health outcomes, and the precision of the estimate of effect (based on the number and size of studies and confidence intervals for the estimates). We were not able to formally assess for publication bias in studies of interventions due to small number of studies, methodological shortcomings, or differences across studies in designs, measured outcomes, and other factors. We rated the strength of evidence for each Key Question using the four categories recommended in the AHRQ Methods Guide.[23] A "high" grade indicates high confidence that the evidence reflects the true effect and that further research is very unlikely to change our confidence in the estimate of effect. A "moderate" grade indicates moderate confidence that the evidence reflects the true effect, and further research may change our confidence in the estimate of effect and may change the estimate. A "low" grade indicates low confidence that the evidence reflects the true effect, and further research is likely to change the confidence in the estimate of effect and is likely to change the estimate. An "insufficient" grade indicates that evidence either is unavailable or does not permit a conclusion.

Results

The search and selection of articles are summarized in the study flow diagram (Figure B).

Figure B. Literature flow diagram



[a]Cochrane databases include the Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews.

[b]Other sources include reference lists, peer reviewer suggestions, etc.

[c]Some articles are included for more than one Key Question

Note: KQ = Key Question

Database searches resulted in 4,773 potentially relevant articles. After dual review of abstracts and titles, 747 articles were selected for full-text review, and 120 studies (in 122 publications) were determined by dual review at the full-text level to meet inclusion criteria and were included in this review.

One good- and two poor-quality studies evaluated effects of using a risk-assessment instrument on clinical outcomes. The good-quality trial found no difference between use of the Waterlow scale, the Ramstadius tool, or clinical judgment and subsequent pressure ulcer development. One poor-quality nonrandomized study found that use of the modified Norton scale (in conjunction with a standardized intervention protocol based on assessed risk) was associated with lower risk of pressure ulcers compared with clinical judgment, and one poor-quality trial found no difference between use of the Braden scale and clinical judgment. There was no evidence on the effectiveness of risk-assessment tools on clinical outcomes according to setting or patient characteristics.

Studies of diagnostic accuracy found that commonly used risk-assessment instruments (such as the Braden, Norton, and Waterlow scales) can identify patients at increased risk for ulcers, with no clear difference among instruments in diagnostic accuracy. Few studies evaluated the same risk-assessment instrument and stratified results according to setting or patient characteristics.

In higher-risk populations, good- and fair-quality randomized trials consistently found that more advanced static mattresses and overlays were associated with lower risk of pressure ulcers compared with standard mattresses (RR, 0.20 to 0.60), with no clear differences between different advanced static support surfaces. Evidence on the effectiveness and comparative effectiveness of other specific support surfaces, including alternating air mattresses and low-air-loss mattresses, was limited, with most trials showing no clear differences between these types of mattresses and various static mattresses and overlays. One fair-quality trial found that stepped care with alternating air mattresses was associated with substantially decreased risk of ulcers compared with stepped care primarily with static support surfaces. In lower risk populations of patients undergoing surgery, two trials found that use of a foam overlay was associated with an increased risk or trend toward increased risk of pressure ulcers compared with use of a standard operating room mattress. Evidence on effectiveness of other preventive interventions (nutritional supplementation; pads and dressings; lotions, creams, and cleansers; and intraoperative warming therapy for patients undergoing surgery) compared with standard care was sparse and insufficient to reach reliable conclusions. An exception was repositioning, for which there were three good- or fair-quality trials, although these reported somewhat inconsistent results. One trial found that a repositioning intervention was more effective than usual care in preventing pressure ulcers, although other trials of repositioning did not clearly find decreased risk of pressure ulcers compared with usual care.

Too few studies evaluated harms of preventive interventions to draw conclusions about their safety.

Table A summarizes the findings of this review.

Table A. Summary of evidence

Key Question and Subcategories	Strength of Evidence	Conclusion
Key Question 1. For adults in various settings, is the use of any risk-assessment tool effective in reducing the incidence or severity of pressure ulcers compared with other risk-assessment tools, clinical judgment alone, and/or usual care?		
Pressure ulcer incidence or severity: Waterlow scale vs. clinical judgment	Low	One good-quality randomized trial (n = 1,231) found no difference in pressure ulcer incidence between patients assessed with either the Waterlow scale or Ramstadius tool compared with clinical judgment alone (RR, 1.4; 95% CI, 0.82 to 2.4; and RR, 0.77; 95% CI, 0.44 to 1.4, respectively).
Pressure ulcer incidence or severity: Norton scale vs. clinical judgment	Insufficient	One poor-quality nonrandomized study (n = 240) found that use of a modified version of the Norton scale to guide use of preventive interventions was associated with lower risk of pressure ulcers compared with nurses' clinical judgment alone (RR, 0.11; 95% CI, 0.03 to 0.46).
Pressure ulcer incidence or severity: Braden scale vs. clinical judgment	Insufficient	One poor-quality cluster randomized trial (n = 521) found no difference between training in and use of the Braden score vs. nurses' clinical judgment in risk of incident pressure ulcers but included patients with prevalent ulcers.
Key Question 1a. Do the effectiveness and comparative effectiveness of risk-assessment tools differ according to setting?	Insufficient	No study evaluated how effectiveness of risk-assessment tools varies according to care setting.
Key Question 1b. Do the effectiveness and comparative effectiveness of risk-assessment tools differ according to patient characteristics and other known risk factors for pressure ulcers, such as nutritional status or incontinence?	Insufficient	No study evaluated how effectiveness of risk-assessment tools varies in subgroups defined by patient characteristics.
Key Question 2. How do various risk-assessment tools compare with one another in their ability to predict the incidence of pressure ulcers?		
Diagnostic accuracy: Braden scale	Moderate	In 2 good- and 5 fair-quality studies, the median AUROC for the Braden scale was 0.77 (range, 0.55 to 0.88). In 16 studies, based on a cutoff of ≤18, the median sensitivity was 0.74 (range, 0.33 to 1.0) and median specificity 0.68 (range, 0.34 to 0.86), for a positive likelihood ratio of 2.31 and negative likelihood ratio of 0.38.
Diagnostic accuracy: Norton scale	Moderate	In 3 studies (1 good and 2 fair quality), the median AUROC for the Norton scale was 0.74 (range, 0.56 to 0.75). In 5 studies, using a cutoff of ≤14, median sensitivity was 0.75 (range, 0.0 to 0.89) and median specificity 0.68 (range, 0.59 to 0.95), for a positive likelihood ratio of 1.83 and negative likelihood ratio of 0.42.

Table A. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Diagnostic accuracy: Waterlow scale	Moderate	In 4 studies (1 good and 3 fair quality), the median AUROC for the Waterlow scale was 0.61 (range, 0.54 to 0.66). In 2 studies, based on a cutoff of ≥10, sensitivities were 0.88 and 1.0, and specificities 0.13 and 0.29, for positive likelihood ratios of 1.15 and 1.24 and negative likelihood ratios of 0.0 and 0.41.
Diagnostic accuracy: Cubbin and Jackson scale	Moderate	In 3 studies (1 good and 2 fair quality), the median AUROC for the Cubbin and Jackson scale was 0.83 (range, 0.72 to 0.90). In 3 studies, based on a cutoff of ≤24 to 29, median sensitivity was 0.89 (range, 0.83 to 0.95) and median specificity was 0.61 (0.42 to 0.82), for positive likelihood ratios that ranged from 1.43 to 5.28 and negative likelihood ratios that ranged from 0.06 to 0.40.
Diagnostic accuracy: direct comparisons between risk-assessment scales	Moderate	In 2 good- and 4 fair-quality studies that directly compared risk-assessment tools, there were no clear differences between scales based on the AUROC.
Key Question 2a. Does the predictive validity of various risk-assessment tools differ according to setting?		
Diagnostic accuracy: Braden scale, across settings	Low	One fair-quality study found that a Braden scale score of ≤18 was associated with similar sensitivities and specificities in acute care and skilled nursing settings. Twenty-eight studies (10 good, 16 fair, and 2 poor quality) that evaluated the Braden scale in different settings found no clear differences in the AUROC or in sensitivities and specificities at standard (≤15 to 18) cutoffs.
Diagnostic accuracy: Cubbin and Jackson scale, ICU setting	Low	Two studies (1 good and 1 fair quality) found that the Cubbin and Jackson scale was associated with similar diagnostic accuracy compared with the Braden or Waterlow scales in intensive care patients.
Diagnostic accuracy: Braden scale, optimal cutoff in different settings	Low	One good-quality study reported a lower optimal cutoff on the Braden scale in an acute care setting (sensitivity 0.55 and specificity 0.94 at a cutoff of ≤15) than a long-term care setting (sensitivity 0.57 and specificity 0.61 at a cutoff of ≤18), but the statistical significance of differences in diagnostic accuracy was not reported. Two studies of surgical patients (1 good and 1 fair quality) found lower optimal cutoff scores than observed in studies of patients in other settings.
Key Question 2b. Does the predictive validity of various risk-assessment tools differ according to patient characteristics?		
Diagnostic accuracy: Braden scale, differences according to race	Low	One fair-quality study reported similar AUROCs for the Braden scale in black and white patients in acute care and skilled nursing settings.
Diagnostic accuracy: Braden scale, differences according to baseline pressure ulcer risk	Moderate	Three studies (1 good and 2 fair quality) found no clear difference in AUROC estimates based on the presence of higher or lower mean baseline pressure ulcer risk scores.

Table A. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Key Question 3. In patients at increased risk of developing pressure ulcers, what are the effectiveness and comparative effectiveness of preventive interventions in reducing the incidence or severity of pressure ulcers?		
Pressure ulcer incidence or severity: advanced static mattresses or overlays vs. standard hospital mattress	Moderate	One good-quality trial (n = 1,166) and 4 fair-quality trials (n = 83 to 543) found that a more advanced static mattress or overlay was associated with lower risk of incident pressure ulcers than a standard mattress (RR range, 0.16 to 0.82), although the difference was not statistically significant in 2 trials. Six poor-quality trials reported results that were generally consistent with these findings. Three trials found no difference in length of stay. The static support surfaces evaluated in the trials varied, although a subgroup of 3 trials each found that an Australian medical sheepskin overlay was associated with lower risk of ulcers than a standard mattress (RR, 0.30, 0.58, and 0.58).
Pressure ulcer incidence or severity: advanced static mattress or overlay vs. advanced static mattress or overlay	Moderate	Three fair-quality trials (n = 52 to 100) found no differences between different advanced static support mattresses or overlays in risk of pressure ulcers. One fair-quality trial (n = 40) of nursing home patients found that a foam replaceable-parts mattress was associated with lower risk of ulcers compared with a 4-inch thick, dimpled foam overlay (25% vs. 60%; RR, 0.42; 95% CI, 0.18 to 0.96). Six poor-quality trials (n = 37 to 407) also found no differences between different advanced static mattresses or overlays.
Pressure ulcer incidence or severity: low-air-loss bed vs. standard hospital mattress	Low	One fair-quality trial (n = 98) found that a low-air-loss bed was associated with lower likelihood of 1 or more pressure ulcers in ICU patients (12% vs. 51%; RR, 0.23; 95% CI, 0.10 to 0.51), but a small (n = 36) poor-quality trial found no difference between a low-air-loss mattress compared with a standard hospital bed following cardiovascular surgery.
Pressure ulcer incidence or severity: low-air-loss mattress compared with dual option (constant low pressure/alternating air) mattress	Low	One fair-quality trial (n = 62) found no clear difference between a low-air-loss mattress compared with the Hill-Rom Duo® mattress (options for constant low pressure or alternating air) in risk of ulcers.
Pressure ulcer incidence or severity: alternating air pressure overlay or mattress vs. standard hospital mattress	Low	Three poor-quality trials (n = 108 to 487) found lower incidence of pressure ulcers with use of an alternating air pressure mattress or overlay compared with a standard hospital mattress.
Pressure ulcer incidence or severity: alternating air pressure overlay or mattress vs. advanced static overlay or mattress	Moderate	Six trials (n = 32 to 487; 1 good quality, 1 fair quality, and 4 poor quality) found no difference between an alternating air pressure overlay or mattress compared with various advanced static mattresses or overlays in pressure ulcer incidence or severity.
Pressure ulcer incidence or severity: alternating air pressure overlay or mattress vs. alternating air pressure overlay or mattress	Moderate	Four trials (n = 44 to 1,972; 1 good quality, 2 fair quality, and 1 poor quality) found no clear differences between different alternating air mattresses or overlays. The good-quality (n = 1,972) trial found no difference in risk of stage 2 ulcers between an alternating air pressure overlay and an alternating air pressure mattress (RR, 1.0, 95% CI, 0.81 to 1.3; adjusted OR, 0.94, 95% CI, 0.68 to 1.3).

Table A. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: heel supports or boots vs. usual care	Low	One fair-quality trial (n = 239) of fracture patients found that the Heelift® Suspension Boot was associated with decreased risk of heel, foot, or ankle ulcers compared with usual care without leg elevation (7% vs. 26% for any ulcer, RR, 0.26, 95% CI, 0.12 to 0.53; 3.3% vs. 13.4% for stage 2 ulcers, RR, 0.25, 95% CI, 0.09 to 0.72). One poor-quality trial (n = 52) of hospitalized patients found no difference in risk of ulcers between a boot (Foot Waffle®) and usual care (hospital pillow to prop up legs).
Pressure ulcer incidence or severity: heel ulcer preventive intervention vs. heel ulcer preventive intervention	Insufficient	One poor-quality trial (n = 240) of hospitalized patients found no differences between three different types of boots (bunny boot, egg-crate heel lift positioner, and Foot Waffle®) in risk of ulcers, although the overall incidence of ulcers was low (5% over 3 years) and results could have been confounded by differential use of cointerventions.
Pressure ulcer incidence or severity: more sophisticated wheelchair cushions vs. standard wheelchair cushions	Low	Four fair-quality trials (n = 32 to 248) of older nursing home patients found inconsistent evidence on effects of more sophisticated wheelchair cushions compared with standard wheelchair cushions on risk of pressure ulcers, with the largest trial finding no difference between a contoured, individually customized foam cushion compared with a slab cushion. Results are difficult to interpret because the trials evaluated different cushions.
Pressure ulcer incidence or severity: nutritional supplementation vs. standard hospital diet	Low	Five of 6 trials (1 fair quality and 5 poor quality; n = 59 to 672) found no difference between nutritional supplementation compared with standard hospital diet in risk of pressure ulcers. Four trials evaluated supplementation by mouth and 2 evaluated enteral supplementation.
Pressure ulcer incidence or severity: repositioning intervention vs. usual care	Low	One fair-quality cluster trial (n = 213) found that repositioning at a 30-degree tilt every 3 hours was associated with lower risk of pressure ulcers compared with usual care (90-degree lateral repositioning every 6 hours during the night) after 28 days (3.0% vs. 11%; RR, 0.27; 95% CI, 0.08 to 0.93), and 1 fair-quality trial (n = 235) found no difference in risk of pressure ulcers between different repositioning intervals. Two other trials (n = 46 and 838) evaluated repositioning interventions but followed patients for only 1 night or were susceptible to confounding due to differential use of support surfaces.
Pressure ulcer incidence or severity: small unscheduled shifts in body position vs. usual care	Low	Two small (n = 15 and 19) poor-quality trials found that the addition of small unscheduled shifts in body position (using a small rolled towel to designated areas during nurse-patient interactions) to standard repositioning every 2 hours had no effect on risk on pressure ulcers, but the studies reported only 1 or 2 ulcers in each trial.

Table A. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: silicone border foam sacral dressing vs. no silicone border foam dressing	Low	One fair-quality (n = 85) trial of patients undergoing cardiac surgery found that a silicone border foam sacral dressing applied at ICU admission (the Mepilex® Border sacrum) was associated with lower likelihood of pressure ulcers compared with standard care (including preoperative placement of a silicone border foam dressing for surgery and use of a low-air-loss bed), but the difference was not statistically significant (2.0% vs. 12%; RR, 0.18; 95% CI, 0.02 to 1.5).
Pressure ulcer incidence or severity: REMOIS pad vs. no pad	Insufficient	One poor-quality randomized trial (n = 37) found that use of the REMOIS pad (consisting of a hydrocolloid skin adhesive layer, a support layer of urethane film, and an outer layer of multifilament nylon) on the greater trochanter was associated with decreased risk of stage 1 ulcers compared with no pad on the contralateral trochanter after 4 weeks (5.4% vs. 30%; RR, 0.18; 95% CI, 0.05 to 0.73).
Pressure ulcer incidence or severity: changing incontinence pad 3 vs. 2 times per day	Low	One fair-quality crossover trial (n = 81) found no statistically significant difference in risk of pressure ulcers between changing incontinence pads 3 times vs. twice after 4 weeks.
Pressure ulcer incidence or severity: intraoperative warming vs. usual care	Low	One fair-quality randomized trial (n = 324) of patients undergoing major surgery found no statistically significant difference in risk of pressure ulcers between patients who received an intraoperative warming intervention (forced-air warming and warming of all intravenous fluids) compared with usual care.
Pressure ulcer incidence or severity: corticotropin vs. sham	Insufficient	One poor-quality randomized trial (n = 85) of patients undergoing femur or hip surgery found no difference in risk of pressure ulcers between those who received 80 IU of corticotropin intramuscularly compared with a sham injection.
Pressure ulcer incidence or severity: polarized light	Insufficient	One small poor-quality randomized trial (n = 23) found no statistically significant difference between polarized light compared with standard care in risk of pressure ulcers.
Pressure ulcer incidence or severity: fatty acid cream vs. placebo	Low	One fair-quality trial (n = 331) and 1 poor-quality trial (n = 86) found that creams with fatty acids were associated with decreased risk of new pressure ulcers compared with placebo (RR, 0.42, 95% CI, 0.22 to 0.80; RR, 0.17, 95% CI, 0.04 to 0.70).
Pressure ulcer incidence or severity: other cream or lotion vs. placebo	Insufficient	Evidence from 3 poor-quality trials (n = 79 to 258) was insufficient to determine effectiveness of other creams or lotions for preventing pressure ulcers.
Pressure ulcer incidence or severity: skin cleanser vs. standard soap and water	Low	One fair-quality randomized trial (n = 93) found that the Clinisan™ cleanser was associated with lower risk of ulcer compared with standard soap and water in patients with incontinence at baseline (18% vs. 42%; RR, 0.43; 95% CI, 0.19 to 0.98).
Key Question 3a. Do the effectiveness and comparative effectiveness of preventive interventions differ according to risk level as determined by different risk-assessment methods and/or by particular risk factors?		

Table A. Summary of evidence (continued)

Key Question and Subcategories	Strength of Evidence	Conclusion
Pressure ulcer incidence or severity: static foam overlay vs. standard care, lower risk surgical population	Moderate	Two trials (1 good and 1 fair quality; n = 175 and 413) found that use of a static foam overlay was associated with increased risk of pressure ulcers compared with standard care in lower risk surgical patients, although the difference was not statistically significant in 1 trial (OR, 1.9, 95% CI, 1.0 to 3.7; RR, 1.6, 95% CI, 0.76 to 3.3).
Pressure ulcer incidence or severity: static dry polymer overlay vs. standard care, lower risk surgical population	Low	Two trials (1 good and 1 poor quality) found that a dry polymer overlay was associated with decreased risk of pressure ulcers compared with standard care in lower risk surgical patients.
Pressure ulcer incidence or severity: static foam block mattress vs. standard care, lower risk surgical population	Insufficient	One poor-quality trial found no significant difference between a static foam block mattress and a standard hospital mattress in pressure ulcer incidence.
Pressure ulcer incidence or severity: alternating air vs. static mattress or overlay, lower risk surgical population	Low	Two trials (1 good and 1 poor quality; n = 198 and 217) found no differences between alternating compared with static support surfaces in risk of pressure ulcer incidence or severity.
Key Question 3b. Do the effectiveness and comparative effectiveness of preventive interventions differ according to setting?	Insufficient	No study evaluated how effectiveness of preventive interventions varies according to care setting.
Key Question 3c. Do the effectiveness and comparative effectiveness of preventive interventions differ according to patient characteristics?	Insufficient	No study evaluated how effectiveness of preventive interventions varies in subgroups defined by patient characteristics.
Key Question 4. What are the harms of interventions for the prevention of pressure ulcers?		
Harms: support surfaces	Low	Nine of 48 trials of support surfaces reported harms. • Three trials (n = 297 to 588) reported cases of heat-related discomfort with sheepskin overlays, with 1 trial reporting increased risk of withdrawal due to heat discomfort compared with a standard mattress (5% vs. 0%; RR, 0.95; 95% CI, 0.93 to 0.98). • One trial (n = 39) that compared different dynamic mattresses reported some differences in pain and sleep disturbance, and 2 trials (n = 610 and 1,972) found no differences in risk of withdrawal due to discomfort. • One trial (n =198) reported no differences in risk of adverse events between a multicell pulsating dynamic mattress compared with a static gel pad overlay. • One trial (n = 239) of heel ulcer preventive interventions reported no difference in risk of adverse events between the Heelift® Suspension Boot and standard care in hip fracture patients. • One trial (n = 141) reported that a urethane and gel wheelchair pad (Jay® cushion) was associated with increased risk of withdrawal due to discomfort compared with a standard foam wheelchair pad (8% vs. 1%; RR, 6.2; 95% CI, 0.77 to 51).

Table A. Summary of evidence (continued)		
Key Question and Subcategories	**Strength of Evidence**	**Conclusion**
Harms: nutritional supplementation	Low	One trial of nutritional supplementation found that tube feeds were tolerated poorly, with 54% having the tube removed within 1 week and 67% prior to completing the planned 2-week intervention. Four trials of nutritional supplementation by mouth did not report harms.
Harms: repositioning	Low	Two (n = 46 and 838) of 6 trials of repositioning interventions reported harms. Both trials reported more nonadherence due to intolerability of a 30-degree tilt position compared with standard positioning.
Harms: lotions and creams	Low	Three (n = 93 to 203) of 6 trials of lotions or creams reported harms. One trial found no differences in rash between different creams, and 2 trials each reported 1 case of a wet sore or rash.
Harms: dressings	Low	One (n = 37) of 3 trials of dressings reported harms. It reported that application of the REMOIS pad resulted in pruritus in 1 patient.
Key Question 4a. Do the harms of preventive interventions differ according to the type of intervention?	Insufficient	No study evaluated how harms of preventive interventions vary according to the type of intervention.
Key Question 4b. Do the harms of preventive interventions differ according to setting?	Insufficient	No study evaluated how harms of preventive interventions vary according to care setting.
Key Question 4c. Do the harms of preventive interventions differ according to patient characteristics?	Insufficient	No study evaluated how harms of preventive interventions vary in subgroups defined by patient characteristics.

Note: AUROC = area under the receiver operating characteristic; CI = confidence interval; ICU = intensive care unit; OR = odds ratio; RR = risk ratio.

Discussion

Key Findings and Strength of Evidence

Evidence on optimal methods to prevent pressure ulcers was extremely limited in a number of areas, including the effects of use of risk-assessment instruments on the subsequent incidence of pressure ulcers and benefits of preventive interventions other than support surfaces. Evidence on harms of preventive interventions was extremely sparse, with most trials not reporting harms at all and poor reporting of harms in those that did. Nonetheless, serious harms seem rare, consistent with what might be expected given the generally noninvasive nature of most of the preventive interventions evaluated (skin care, oral nutritional support, repositioning, and support surfaces). In addition, limited evidence was available to evaluate how the diagnostic accuracy of risk-assessment instruments or benefits and harms of preventive interventions might vary depending on differences in setting, patient characteristics, or other factors.

Only one good-quality study and two poor-quality studies attempted to evaluate the effects of standardized use of a risk-assessment instrument on the incidence of pressure ulcers. The good-quality trial found no difference in incidence of pressure ulcer development in patients assessed with the Waterlow scale, the Ramstadius tool, or clinical judgment alone. The two poor-quality studies evaluated the modified Norton scale and the Braden scale, with only a nonrandomized study of the Norton scale finding reduced risk of pressure ulcer compared with clinical judgment.

Studies of diagnostic accuracy found that commonly used risk-assessment instruments can identify patients at increased risk for pressure ulcers who might benefit from more intense or targeted interventions. No study that reported risk estimates attempted to control for the potential confounding effects of differential use of interventions. There was no clear difference among commonly used risk-assessment instruments in diagnostic accuracy, although direct comparisons were limited.

About three-quarters of the trials of preventive interventions focused on evaluations of support surfaces. In higher risk populations, good- and fair-quality randomized trials consistently found that more advanced static mattresses and overlays were associated with lower risk of pressure ulcers compared with standard mattresses (RR range, 0.20 to 0.60), with no clear differences between different advanced static support surfaces. Although the mattresses and overlays evaluated in the trials varied, three trials consistently found that an Australian medical sheepskin overlay was associated with lower risk of ulcers than a standard hospital mattress, although the sheepskin was also associated with heat-related discomfort, in some cases resulting in withdrawal. Evidence on the effectiveness and comparative effectiveness of other specific support surfaces, including alternating air mattresses and low-air-loss mattresses, was limited, with most trials showing no clear differences between these types of mattresses and various static mattresses and overlays. One fair-quality trial found that stepped care starting with alternating air mattresses was associated with substantially decreased risk of ulcers compared with stepped care primarily with static mattresses, suggesting that this might be both an effective and efficient approach, since care was initiated with the least expensive alternatives and advanced to more expensive alternatives based on a preset algorithm. In lower risk populations of patients undergoing surgery, two trials found that use of a foam overlay was associated with an increased risk of pressure ulcers compared with a standard operating room mattress. The few trials that evaluated length of stay found no differences among various support surfaces.

Evidence on other preventive interventions (nutritional supplementation; repositioning; pads and dressings; lotions, creams, and cleansers; and intraoperative warming therapy for patients undergoing surgery) was sparse and insufficient to reach reliable conclusions, in part because most trials had important methodological shortcomings. An exception was repositioning, for which there were three good- or fair-quality trials, although these reported somewhat inconsistent results. One trial found that a repositioning intervention was more effective than usual care in preventing pressure ulcers. Although other trials of repositioning did not clearly find decreased risk of pressure ulcers compared with usual care, the usual-care control group incorporated standard repositioning practices (i.e., the trials compared more intense repositioning vs. usual repositioning, not vs. no repositioning). A recently completed trial of repositioning, consisting of high-risk and moderate-risk arms that were randomized to repositioning at 2-, 3-, or 4-hour intervals, should provide more rigorous evidence on the effectiveness of repositioning.

Findings in Relationship to What Is Already Known

Our findings of limited evidence on effects of risk-assessment instruments in reducing the incidence or severity of pressure ulcers are consistent with those of other recent systematic reviews.[24,25] One of these reviews also evaluated the diagnostic accuracy of risk-assessment

instruments.[25] It reported higher sensitivity and lower specificity for the Waterlow (0.82 and 0.27) compared with the Norton (0.47 and 0.62) and Braden (0.57 and 0.68) scales, but that review pooled data without regard for differences in cutoff scores and across study settings, and it also included four studies that we excluded due to: retrospective study design,[26] inadequate reporting to determine eligibility for inclusion,[27] availability only in Spanish language,[28] or inability to obtain.[29]

Our findings on effectiveness of preventive interventions are generally consistent with those of other systematic reviews that found some evidence that more advanced static support surfaces are associated with decreased risk of pressure ulcers compared with standard hospital mattresses,[10,30] limited evidence on the effectiveness and comparative effectiveness of dynamic support surfaces,[10,30] and limited evidence on other preventive interventions.[10,31] All reviews noted methodological shortcomings in the trials and variability in interventions and comparisons across studies. These reviews differed from ours by including trials that enrolled patients with higher stage preexisting ulcers and including trials published only as abstracts.

Applicability

The studies included in this review generally enrolled patients at higher risk for pressure ulcers, although eligibility criteria varied among studies. The studies are most applicable to acute care and long-term care settings, with few studies evaluating patients in community or home settings, including specific populations such as wheelchair-bound people in the community. Some trials specifically evaluated lower risk patients undergoing surgery and were reviewed separately. (See Key Question 3a.) Although black and Hispanic patients represent the fastest growing populations of frail elderly in the United States, these populations were largely underrepresented in the studies.[32]

Another important issue in interpreting the applicability of this review is that patients in studies of diagnostic accuracy, as well as in studies of interventions, generally received standard-of-care treatments. For example, no study of diagnostic accuracy blinded caregivers to the results of risk-assessment scores; and this lack of blinding would be expected to lead to the use of more intensive preventive interventions and care in higher risk people. If such interventions are truly effective, they would be expected to result in underestimates of pressure ulcers. For trials of preventive interventions, usual care includes repositioning every 2 to 4 hours, skin care, standard nutrition, and standard support surfaces. Therefore, most trials of preventive interventions represent comparisons of more intensive interventions plus multicomponent standard care compared with standard care alone, rather than compared with no care. One factor that may affect applicability is that the more intensive preventive interventions evaluated in many of the studies included in this review may require additional training or resources.

Evidence to evaluate potential differences in comparative benefits or harms in patient subgroups based on baseline pressure ulcer risk, specific risk factors for ulcers, setting of care, and other factors was very limited, precluding any reliable conclusions.

Implications for Clinical and Policy Decisionmaking

Our review has potential implications for clinical and policy decisionmaking. Despite insufficient evidence to determine whether use of risk-assessment instruments reduces risk of incident pressure ulcers, studies suggest that: (a) commonly used instruments can predict which patients are more likely to develop an ulcer, and (b) there are no clear differences in diagnostic accuracy. Decisions about whether to use risk-assessment instruments and which risk-assessment instrument to use may depend on considerations such as a desire to standardize and monitor practices within a clinical setting, ease of use, and nursing or other caregiver preferences.

Evidence suggests that more advanced static support surfaces are more effective than standard mattresses for reducing risk of pressure ulcers, although more evidence is needed to understand the effectiveness and comparative effectiveness of dynamic and other support surfaces. Despite limited evidence showing that they are more effective at preventing pressure ulcers compared with static mattresses and overlays, alternating air and low-air-loss mattresses and overlays are used in hospitals in many areas of the United States. Such support surfaces can be quite costly, although one trial found that a stepped-care approach that utilized lower cost dynamic support surfaces before switching to higher cost interventions in patients with early ulcers could be effective as well as efficient; this finding warrants further study.[33] Although evidence is insufficient to guide recommendations on use of other preventive interventions, these findings are contingent on an understanding that usual-care practices were the comparator treatment in most studies. Therefore, it would be inappropriate to conclude that standard repositioning, skin care, nutrition, and other practices should be abandoned, as these were the basis of usual-care comparisons.

Although studies of preventive interventions primarily focused on effects on pressure ulcer incidence and severity, other factors such as effects on resource utilization (including length of hospitalization and costs) and patient preferences may affect clinical decisions. However, cost and patient preferences were outside the scope of this report, and data on resource utilization were limited to a few studies that found no effects of various support surfaces on length of stay.

Limitations of the Comparative Effectiveness Review Process

We excluded non-English-language articles, which could result in language bias, although a recent systematic review found little empirical evidence that exclusion of non-English-language articles leads to biased estimates for interventions not involving complementary or alternative medicine.[34] In addition, we did not exclude poor-quality studies a priori. Rather, we described the limitations of the studies, emphasized higher quality studies when synthesizing the evidence, and performed sensitivity analyses that excluded poor-quality studies.

We did not attempt to pool studies of diagnostic accuracy due to clinical heterogeneity across studies and methodological shortcomings. Rather, we synthesized results qualitatively and described the range of results in order to highlight the greater uncertainty in findings.

We did not formally assess for publication bias with funnel plots due to small numbers (<10) of studies for all comparisons and due to important clinical heterogeneity and methodological shortcomings in the available studies.

Limitations of the Evidence Base

We identified a number of limitations in the evidence base on preventive interventions. Most included studies had important methodological shortcomings, with 4 of 47 studies of diagnostic accuracy and 35 of 72 studies of preventive interventions rated poor quality, and only 12 studies of diagnostic accuracy and 6 studies of preventive interventions rated good quality. Few studies of diagnostic accuracy reported measures of discrimination, such as the AUROC; many studies failed to predefine cutoff thresholds; few studies reported differential use of interventions according to baseline risk score (which could affect estimates of diagnostic accuracy); and some studies evaluated modified or ad hoc versions of standard risk-assessment instruments. An important limitation of the evidence on preventive interventions is that few trials compared the same intervention, and methods for assessing and reporting ulcers varied. There was almost no evidence to determine how the diagnostic accuracy of risk-assessment instruments or the effectiveness and comparative effectiveness of preventive interventions vary according to care setting, patient characteristics, or other factors. Harms were reported in only 16 of 72 trials of preventive interventions and were poorly reported when any data were provided. Only about half of the studies reported funding source. Among those that did report funding source, most were sponsored by institutions or government organizations.

Future Research

Future research is needed on the effectiveness of the standardized use of risk-assessment instruments compared with clinical judgment or nonstandardized use in preventing pressure ulcers. Studies should evaluate validated risk-assessment instruments and employ a clearly described protocol for the use of preventive interventions based on the risk-assessment score. In addition to comparing the risk and severity of ulcers across groups, studies should also report effects on the use of preventive interventions as well as other important outcomes, such as length of hospital stay and measures of resource utilization.

Future research that simultaneously evaluates the diagnostic accuracy of different risk-assessment instruments is needed to provide more direct evidence on how their performance compares with one another. Studies should, at a minimum, report how use of preventive interventions differed across intervention groups, and should consider reporting adjusted risk estimates to account for such potential confounders. Studies of diagnostic accuracy should also use predefined standardized cutoffs and routinely report measures of discrimination, such as the AUROC.

More research is needed to understand the effectiveness of preventive interventions. It is critical that future studies of preventive interventions adhere to methodological standards, including appropriate use of blinding (such as blinding of outcome assessors even when blinding of patients and caregivers is not feasible), and clearly describe usual care and other comparison treatments. Studies should routinely report baseline pressure ulcer risk in enrolled patients and consider predefined subgroup analyses to help better understand how preventive interventions might be optimally targeted. More studies are needed to better understand the comparative effectiveness of dynamic and reactive support surfaces compared with static support surfaces, as well as strategies such as stepped-care approaches that might be more efficient than using costly interventions in all patients.

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Full Report

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