Preventing Pressure Ulcers: A Systematic Review

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Preventing Pressure Ulcers: A Systematic Review

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Context Pressure ulcers are common in a variety of patient settings and are associated with adverse health outcomes and high treatment costs.

Objective To systematically review the evidence examining interventions to prevent pressure ulcers.

Data Sources and Study Selection MEDLINE, EMBASE, and CINAHL (from inception through June 2006) and Cochrane databases (through issue 1, 2006) were searched to identify relevant randomized controlled trials (RCTs). UMI Proquest Digital Dissertations, ISI Web of Science, and Cambridge Scientific Abstracts were also searched. All searches used the terms *pressure ulcer*, *pressure sore*, *decubitus*, *bedsore*, *prevention*, *prophylactic*, *reduction*, *randomized*, and *clinical trials*. Bibliographies of identified articles were further reviewed.

Data Synthesis Fifty-nine RCTs were selected. Interventions assessed in these studies were grouped into 3 categories, ie, those addressing impairments in mobility, nutrition, or skin health. Methodological quality for the RCTs was variable and generally suboptimal. Effective strategies that addressed impaired mobility included the use of support surfaces, mattress overlays on operating tables, and specialized foam and specialized sheepskin overlays. While repositioning is a mainstay in most pressure ulcer prevention protocols, there is insufficient evidence to recommend specific turning regimens for patients with impaired mobility. In patients with nutritional impairments, dietary supplements may be beneficial. The incremental benefit of specific topical agents over simple moisturizers for patients with impaired skin health is unclear.

Conclusions Given current evidence, using support surfaces, repositioning the patient, optimizing nutritional status, and moisturizing sacral skin are appropriate strategies to prevent pressure ulcers. Although a number of RCTs have evaluated preventive strategies for pressure ulcers, many of them had important methodological limitations. There is a need for well-designed RCTs that follow standard criteria for reporting nonpharmacological interventions and that provide data on cost-effectiveness for these interventions.

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PRESSURE ULCERS REPRESENT A common but potentially preventable condition seen most often in high-risk populations such as elderly persons and those with physical impairments.[1] The epidemiology of pressure ulcers varies considerably by clinical setting, with incidence rates ranging from 0.4% to 38% in acute care, 2.2% to 23.9% in long-term care (LTC), 0% to 17% in home care.[2] In US acute care facilities alone, an estimated 2.5 million pressure ulcers are treated each year.[3] The development of pressure ulcers can interfere with functional recovery, may be complicated by pain and infection, and can contribute to excesses in hospital length of stay.[4] The presence of pressure ulcers is a marker of poor overall prognosis and may contribute to premature mortality in some patients.[5,6]

In addition to these adverse health outcomes, the financial impact of treating pressure ulcers is substantial. A Dutch study found that costs associated with care of pressure ulcers were the third highest after those for cancer and cardiovascular diseases.[7] The price of managing a single full-thickness pressure ulcer is as much as $70 000, and US expenditures for treating pressure ulcers have been estimated at $11 billion per year.[8,9] The development of pressure ulcers may also have important legal consequences: failure to prevent pressure ulcers in LTC settings has resulted in increasing litigation, with settlements favoring LTC residents in up to 87% of cases.[10] These consequences highlight the value of preventing pressure ulcers.

Pressure ulcers can be prevented in many cases, and a targeted preventive approach may be less costly than one focused on treatment of established ulcers.[2,11] A variety of preventive approaches have been proposed, and we undertook a systematic review to evaluate the evidence supporting these interventions.

See also Patient Page.

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METHODS

Sample Selection

We searched MEDLINE, EMBASE, and CINAHL from inception through June 2006, and the Cochrane Database

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through issue 1, 2006, to identify relevant randomized controlled trials (RCTs). We also searched UMI Proquest Digital Dissertations, ISI Web of Science, and Cambridge Scientific Abstracts. We used the following search terms: *pressure ulcer*, *pressure sore*, *decubitus*, *bedsore*, *prevention*, *prophylactic*, *reduction*, *randomized*, and *clinical trials*. One author (M.R.) further reviewed the bibliographies of identified articles. Criteria for selection of studies included RCTs that reported objective, clinically relevant outcome measures (such as incidence of pressure ulcers). There were no restrictions on language, publication date, or setting.

Classification

We grouped RCTs into 3 categories based on whether the intervention being evaluated addressed impairments in mobility, nutrition, or skin health. These impairments have been identified in previous research as important risk factors for development of pressure ulcers.[12]

We also classified studies by setting (acute care, LTC, rehabilitation facility), since the prevalence of pressure ulcers varies considerably between settings.[5,13-15]

Quality Assessment

Assessing the effectiveness of nonpharmacological treatments, such as those used to prevent pressure ulcers, creates unique methodological challenges. For example, it may be impossible to blind participants and clinicians to the intervention. To address these challenges, Boutron et al[16] recently developed a checklist to evaluate a report of a nonpharmacological trial (CLEAR NPT). We determined the methodological quality of the RCTs included in this systematic review using 6 elements from the CLEAR NPT: (1) adequate allocation sequence generation (ie, use of an appropriate method to generate the sequence of randomization); (2) concealed treatment allocation; (3) adequate participant blinding (where participant blinding was possible); (4) adequate outcome assessor blinding; (5) consistent follow-up schedule; and (6) intent-to-treat analysis. (Further details are provided at http://www.bichat.inserm.fr/equipes/Emi0357/docs/usersguidelines.pdf). Allocation concealment and double-blinding are strongly related to treatment effects.[17-19] More intensive follow-up in one arm of a trial (eg, more frequent turning) could contribute to reductions in the development of pressure ulcers, even if this was not part of the intervention being evaluated. Therefore, we examined trials to ensure that similar follow-up schedules were present in each group, unless a trial specifically set out to determine the frequency with which an intervention was applied.

RESULTS

The search strategy identified 763 citations, from which 59 relevant RCTs were selected. A QUOROM (Quality of Reporting of Meta-analyses) flow diagram (FIGURE) shows an overview of the study selection process. The 59 selected studies enrolled a total of 13 845 patients: 9397 (67.9%) in acute care, 2367 (17.1%) in LTC, 333 (2.4%) in rehabilitation, and 1748 (12.6%) in mixed settings. Sample size was unclear for 1 trial.[20]

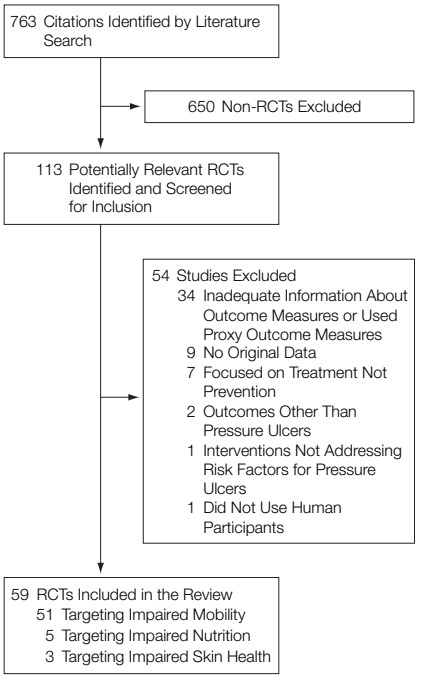
Interventions Targeting Impaired Mobility

Fifty-one RCTs evaluated interventions for impaired mobility and included 11 551 patients: 7984 (69.1%) in acute care, 1866 (16.2%) in LTC, 333 (2.9%) in rehabilitation, and 1368 (11.8%) in mixed settings (TABLE 1, TABLE 2, TABLE 3, and TABLE 4). The length of follow-up ranged from 1 to 224 days; in 5 trials the length of follow-up was unclear.

Support Surfaces. Specialized support surfaces (such as mattresses, beds, and cushions) reduce or relieve the pressure that the patient's body weight exerts on skin and subcutaneous tissues as it presses against the surface of a bed or chair. If a patient's mobility is compromised and this interface pressure is not relieved, the pressure can lead to impaired circulation and ulcer formation. Forty-eight of the 59 RCTs in our sample examined the role of support surfaces in preventing pressure ulcers (Tables 1-3).[20-67]

Pressure-reducing surfaces may be either static support surfaces (such as mattresses or mattress overlays that are applied to the top of a mattress and filled with air, water, gel, foam, or a combination of these) or dynamic support surfaces (which mechanically vary the pressure beneath the patient and thereby reduce the duration of the applied pressure). Dynamic support surfaces include alternating-pressure mattresses, low-air-loss beds, and air-fluidized mattresses. Alternating-pressure mattresses produce alternating high and low pressures between the patient and mattress, thus diminishing the period of high pressure. Low-air-loss mattresses consist of air sacs through which warmed air passes. Air-fluidized mattresses contain silicone-coated beads that liquefy when air

Figure. Flow Diagram of Included and Excluded Studies



RCT indicates randomized controlled trial.

Table 1. Randomized Controlled Trials Addressing Approaches to Impaired Mobility Using Static or Standard Support Surfaces (Participant Blinding Difficult or Not Possible) for Reduction of Pressure Ulcer Incidence*

Source	Patients Enrolled (Completed), No.	Length of Follow-up, d	Setting (Patient Population)	Intervention	CLEAR NPT Criterion†					Incidence Reduced?
					1	2	4	5	6	
				Static vs Standard						
Feuchtinger et al,[21] 2006	175 (175)	5	Acute care (OR)	Thermoactive specialized foam overlay on standard OR table vs standard OR table	No	No	Yes‡	Yes	Yes	No
Jolley et al,[22] 2004	593 (441)	8	Acute care	Specialized sheepskin overlay, with heel/elbow protectors, on standard hospital mattress vs standard hospital mattress	Yes	Yes	No	Yes	No	Yes
Russell et al,[23] 2003	1168 (1052)	17	Acute care and rehabilitation (elderly)	Specialized foam mattress vs standard hospital mattress	Yes	Yes	No	Yes	Yes	No
Geyer et al,[24] 2001	32 (25)	52	LTC	Specialized foam cushion vs standard cushion	Yes	Yes	Yes	Yes	Yes	No
Gunningberg et al,[25] 2000	119 (101)	0-14	Acute care (elderly orthopedic)	Specialized foam mattress vs standard hospital mattress	No	No	Yes	No	No	No
McGowan et al,[26] 2000	297 (279)	Unclear	Rehabilitation (elderly orthopedic)	Specialized sheepskin overlay, with heel/elbow protectors, on standard hospital mattress vs standard hospital mattress	No	No	No	Unclear	No	Yes
Schultz et al,[27] 1999	413 (171)	6	Acute care (OR)	Specialized foam OR mattress overlay and heel/elbow protectors vs standard OR mattress	No	No	No	No	No	No
Nixon et al,[28] 1998	446 (416)	8	Acute care (OR)	Specialized foam overlay on standard OR table vs standard OR table	Yes	Yes	Yes§	Yes	Yes	Yes
Tymec et al,[29] 1997	52 (36)	0-14	Acute care	Heel elevation device vs hospital pillow	Yes	No	No	Yes	No	No
Collier,[30] 1996	90 (81)	Unclear	Acute care (general medical)	Seven specialized foam mattresses vs standard hospital foam mattress	No	No	No	Unclear	No	No
Takala et al,[31] 1996	40 (24)	14	Acute care (ICU)	Air-filled pressure-reducing mattress vs standard hospital mattress	Yes	No	No	Yes	Yes	Yes
Gray and Smith,[32] 2000	170 (unclear)	10	Acute care (OR and medical oncology)	Specialized foam mattress vs standard hospital foam mattress	No	Yes	No	No	No	Yes
Hofman et al,[33] 1994	46 (36)	14	Acute care (elderly orthopedic)	Specialized foam mattress vs standard hospital mattress	No	No	No	Yes	No	Yes
Santy et al,[34] 1994	505 (354)	14	Acute care (orthopedic)	Four types of specialized foam mattresses vs standard hospital foam mattress	Yes	No	No	Yes	No	Yes
Goldstone et al,[35] 1982	Unclear (75)	Unclear	Acute care (elderly orthopedic; OR)	Mattress, cushion, and heel protector containing polystyrene beads on stretchers, OR table, and on wards vs standard hospital stretcher, OR table, and bed	Yes	No	No	Yes	No	Yes
Ewing et al,[36] 1964	36 (unclear)	180	Rehabilitation (elderly)	Sheepskin overlay on standard hospital mattress vs standard hospital mattress	No	No	No	No	No	No§
				Static vs Static						
Gray and Campbell,[37] 1994	100 (95)	10	Acute care	Two specialized foam mattresses	No	No	No	Yes	Yes	No
Cooper et al,[38] 1998	100 (84)	7	Acute care (elderly orthopedic)	Two dry-flotation pressure-reducing surfaces	No	Yes	No	Yes	No	No§
Vyhlidal et al,[39] 1997	40 (40)	21	Acute care	Specialized foam mattress and heel protector vs specialized foam overlay	Yes	No	No	Yes	No	Yes
Conine et al,[40] 1994	163 (141)	90	LTC	Specialized foam and gel cushion vs specialized foam cushion	No	No	Yes	Yes	No	Yes
Conine et al,[41] 1993	288 (248)	90	LTC	Two specialized foam cushions	No	No	Yes	Yes	No	No
Kemp et al,[42] 1993	84 (unclear)	30	Acute care and LTC (elderly)	Solid foam overlay vs convoluted foam overlay	Yes	No	No	Yes	No	Yes
Lazzara and Buschmann,[43] 1991	74 (57)	180	LTC	Air-filled mattress overlay vs gel mattress	Yes	No	No	No	No	No
Lim et al,[44] 1988	62 (52)	150	LTC	Two specialized foam cushions	No	No	Yes	Yes	No	No
Stapleton,[45] 1986	100 (100)	Unclear	Acute care (elderly female orthopedic)	Air-filled overlay vs specialized foam overlay vs siliconized hollow-fiber overlay	No	No	No	Unclear	No	No

Abbreviations: CLEAR NPT, checklist to evaluate a report of a nonpharmacological trial; ICU, intensive care unit; LTC, long-term care; OR, operating room.
*Standard support surfaces were standard hospital mattresses or tables/cushions; static surfaces were those not requiring electricity (eg, air, foam, gel, or water–filled overlays or mattresses).
†1, Adequate description of generation of allocation sequences; 2, Treatment allocation concealed and described; 4, Adequate blinding of outcome assessors; 5, Follow-up schedule identical in each group; and 6, Intent-to-treat analysis. Also see "Methods."
‡Intraoperative study, so participants also blinded.
§Statistical significance not reported.

Table 2. Randomized Controlled Trials Addressing Approaches to Impaired Mobility Using Dynamic Support Surfaces (Participant Blinding Difficult or Not Possible) for Reduction of Pressure Ulcer Incidence*

Source	Patients Enrolled (Completed), No.	Length of Follow-up, d	Setting (Patient Population)	Intervention	CLEAR NPT Criterion†					Incidence Reduced?
					1	2	4	5	6	
Dynamic I vs Static										
Vanderwee et al,[46] 2005	447 (447)	40	Acute care	Alternating-pressure overlay on standard hospital mattress vs specialized foam overlay on standard hospital mattress and turning q4h	Yes	Yes	No	Yes	No	No
Russell and Lichtenstein,[47] 2000	198 (198)	7	Acute care (OR)	Alternating-pressure mattress vs standard OR table with gel pad	Yes	Yes	No	Yes	Yes	No
Aronovitch et al,[48] 1999	217 (170)	7	Acute care (OR)	Alternating-pressure OR mattress vs standard OR table with gel pad	No	No	No	Yes	Yes	Yes
Price et al,[49] 1999	80 (50)	14	Acute care (orthopedic)	Alternating-pressure mattress & cushion vs static air mattress & cushion	Yes	No	No	Yes	Yes	No
Dunlop,[50] 1998	175 (175)	7	Acute care (OR)	Alternating-pressure mattress vs standard OR mattress with gel pad	No	No	No	Yes	No	Yes‡
Bennett et al,[51] 1998	116 (98)	1	Acute care and LTC	Low-air-loss hydrotherapy mattress vs standard hospital mattress	Yes	No	No	Yes	No	No
Laurent,[52] 1997	312 (312)	Unclear	Acute care (ICU)	Alternating-pressure mattress (ICU) and specialized foam mattress (on ward) vs standard ICU mattress and standard hospital bed	Yes	No	No	Yes	No	No
Gebhardt,[53] 1994	230 (230)	0-16	Acute care	Alternating-pressure mattress vs various static (foam, air, water, gel) mattresses	No	No	No	Yes	Yes	Yes
Sideranko et al,[54] 1992	57 (57)	20 (Mean)	Acute care (ICU)	Alternating-pressure overlay vs static air overlay vs water mattress overlay	No	No	No	Yes	No	No
Conine et al,[55] 1990	187 (148)	90	LTC	Alternating-pressure overlay vs siliconized hollow-fiber overlay	Yes	No	Yes	Yes	No	No
Daechsel and Conine,[56] 1985	32 (32)	90	LTC	Alternating-pressure overlay vs siliconized hollow-fiber overlay	No	No	No	Yes	Yes	No
Whitney et al,[57] 1984	51 (51)	8.3 (Mean)	Acute care	Alternating-pressure mattress vs convoluted foam mattress	No	No	No	Unclear	Yes	No‡
Dynamic I vs Static vs Standard										
Andersen et al,[58] 1983	600 (482)	10	Acute care	Alternating-pressure air mattress vs water mattress vs standard hospital mattress	No	No	No	Yes	No	No difference between dynamic and static, but both better than standard
Dynamic II vs Static										
Economides et al,[59] 1995	12 (11)	14	Acute care (postoperative)	Air-fluidized bed vs dry flotation mattress	Yes	Yes	No	Yes	No	No‡
Dynamic I vs Dynamic I										
Nixon et al,[60] 2006	1972 (1971)	60	Acute care	Alternating-pressure mattress overlays vs alternating-pressure mattresses	Yes	Yes	No	Yes	Yes	No
Theaker et al,[61] 2005	62 (62)	14 d after discharge from ICU	Acute care (ICU)	Low-air-loss mattress vs alternating-pressure mattress	Yes	Yes	No	Yes	No	Yes
Taylor,[62] 1999	44 (44)	11 (Mean to discharge or death)	Acute care	Two types of alternating-pressure mattresses and cushions	Yes	Yes	No	Yes	No	Yes‡
Hampton,[20] 1997	Unclear (unclear)	20	Acute care	Two types of alternating-pressure mattresses	No	No	No	No	No	No‡
Inman et al,[63] 1993	100 (98)	17	Acute care (ICU)	Low-air-loss mattress vs standard ICU bed (alternating-pressure) and patients turned q2h	No	No	No	Yes	No	Yes
Exton-Smith et al,[64] 1982	66 (66)	14	Acute care (elderly)	Two types of alternating-pressure mattresses	No	No	No	No	No	Yes

Abbreviations: CLEAR NPT, checklist to evaluate a report of a nonpharmacological trial; ICU, intensive care unit; LTC, long-term care; OR, operating room.
*Dynamic support surfaces were those powered by electricity or pump (dynamic I: eg, alternating and low-air-loss mattresses; dynamic II: eg, air-fluidized beds [ie, electric beds containing silicone-coated beads] only); standard surfaces were standard hospital mattresses or tables/cushions; static surfaces were those not requiring electricity (eg, air, foam, gel, or water–filled overlays or mattresses).
†See Table 1 footnote for definitions of CLEAR NPT criteria. Also see "Methods."
‡Statistical significance not reported.

is pumped through them. Dynamic support surfaces are generally more expensive than static surfaces, with air-fluidized mattresses being the most expensive type of dynamic support surface.

In a well-designed study of 446 patients undergoing elective major surgery, Nixon et al[28] demonstrated that specialized foam mattress overlays on operating tables decreased the incidence of postoperative pressure ulcers. In other settings, specialized foam (eg, convoluted foam, cubed foam) and specialized sheepskin (denser and thicker than regular sheepskin) overlays were the only surfaces that were consistently superior to standard hospital mattresses in reducing incidence of pressure ulcers.[22,23,32-34,36,40]

Four RCTs examined various types of seat cushions for the prevention of pressure ulcers.[24,40,41,44] Three studies examined specialized foam cushions, with 1 study using a standard cushion for comparison and the other 2 studies using another type of specialized foam for comparison. The incidence of pressure ulcers was no different in the intervention groups. One study compared a specialized foam cushion with a combination specialized foam and gel cushion and found the latter to be significantly more effective.[40]

Fourteen RCTs directly compared dynamic and static support surfaces.[46-59] The best-designed trial of these was conducted by Vanderwee et al,[46] who studied 447 patients and found no difference in pressure ulcer incidence between dynamic and static support surfaces. Only 3 trials found that dynamic support surfaces were better than static support surfaces,[48,50,53] and 1 of these trials did not report statistical significance.[50] One trial directly compared dynamic, static, and standard support surfaces and found no difference between the dynamic and static support surfaces but found that both were better than standard surfaces.[58] In a well-designed RCT of 1972 acute care patients, Nixon et al[60] found no difference in the incidence of pressure ulcers when dynamic support surface mattress overlays were used instead of dynamic support surface mattresses. The mattresses cost more than the overlays, but an economic evaluation conducted alongside the trial suggested that the mattresses may be more cost-effective and are more acceptable to patients than the overlays.[71]

Three RCTs compared beds that turn and rotate the patient with standard hospital beds or standard intensive care unit (ICU) beds.[65-67] Standard ICU beds were not clearly defined in these studies, but ICU beds are usually dynamic support surfaces. Rotating beds offered no advantage in reducing pressure ulcer incidence as compared with

Table 3. Randomized Controlled Trials Addressing Approaches to Impaired Mobility Using Rotating Support Surfaces (Participant Blinding Difficult or Not Possible) for Reduction of Pressure Ulcer Incidence*

Source	Patients Enrolled (Completed), No.	Length of Follow-up, d	Setting	Intervention	CLEAR NPT Criterion†					Incidence Reduced?
					1	2	4	5	6	
Keogh and Dealey,[65] 2001	100 (70)	10	Acute care	Rotating bed vs standard hospital bed	Yes	Yes	No	Yes	No	No
Summer et al,[66] 1989	86 (83)	9 (Mean to discharge from ICU)	Acute care (ICU)	Rotating bed vs standard ICU bed (alternating-pressure) and turning q2h	Yes	No	No	Yes	No	No
Gentilello et al,[67] 1988	65 (64)	4 d after patient allowed out of bed	Acute care (ICU)	Rotating bed vs standard ICU bed (alternating-pressure) and turning q2h	No	No	No	Yes	No	No

Abbreviations: CLEAR NPT, checklist to evaluate a report of a nonpharmacological trial; ICU, intensive care unit.
*Rotating surfaces were those in which an electric motor moves and/or rotates the bed and bedframe.
†See Table 1 footnote for definitions of CLEAR NPT criteria. Also see "Methods."

Table 4. Randomized Controlled Trials Addressing Approaches to Impaired Mobility Using Repositioning, Exercise, and Treatment of Incontinence (Participant Blinding Difficult or Not Possible) for Reduction of Pressure Ulcer Incidence

Source	Patients Enrolled (Completed), No.	Length of Follow-up, d	Setting	Intervention	CLEAR NPT Criterion*					Incidence Reduced?
					1	2	4	5	6	
				Repositioning						
Defloor et al,[68] 2005	838 (761)	28	LTC	1. Turning q2h on standard hospital mattress 2. Turning q3h on standard hospital mattress 3. Turning q4h on specialized foam mattress 4. Turning q6h on specialized foam mattress 5. Standard care (based on clinical judgment)	Yes	No	No	Yes	No	Yes: turning q4h on specialized foam mattress
Young,[69] 2004	46 (43)	1	Acute care	30° tilt vs 90° side-lying	Yes	Yes	Yes	Yes	Yes	No
				Exercise and Incontinence Care						
Bates-Jensen et al,[70] 2003	190 (144)	224	LTC	Exercise and incontinence care q2h vs standard care	No	No	Yes	Yes	No	No

Abbreviations: CLEAR NPT, checklist to evaluate a report of a nonpharmacological trial; LTC, long-term care.
*See Table 1 footnote for definitions of CLEAR NPT criteria. Also see "Methods."

either standard hospital beds or ICU beds.[65-67]

Repositioning. Patient repositioning is a mainstay in most pressure ulcer prevention protocols, which often recommend turning every 2 hours. The aim of repositioning, like that of specialized support surfaces, is to reduce or eliminate interface pressure and thereby maintain microcirculation to regions of the body at risk for pressure ulcers. We were able to identify only 2 trials that specifically evaluated repositioning strategies.[68,69] These trials included 884 participants (46 in acute care and 838 in LTC) (Table 4).

Defloor et al[68] investigated the effect of different turning regimens in a 4-week RCT involving 11 LTC facilities. They found that turning patients every 4 hours combined with the use of specialized foam mattresses significantly reduced the incidence of pressure ulcers compared with turning every 2 hours on standard hospital mattresses. However, the methodology of this study was limited: there was no information to indicate that patients were randomly allocated with concealed allocation, there was inadequate blinding of participants and outcome assessors, and no intent-to-treat analysis was performed. Furthermore, this study did not simply compare different repositioning schedules but rather combined different repositioning schedules with different support surfaces in the 2 comparison groups. Therefore, it is difficult to advocate turning patients every 4 hours rather than the standard of every 2 hours based on this study alone.

One RCT investigated the efficacy of different patient positions.[69] This small study of 46 elderly inpatients examined the difference between the 30° tilt position (the placement of pillows under one buttock and under each leg, so that the sacrum and heels are not in contact with the support surface) vs standard patient positioning (90° sidelying). No significant difference in outcomes was found between the 2 groups.

Exercise and Treatment of Incontinence. Investigators in 1 trial[70] addressed the risk factors of immobility and incontinence (fecal and urinary) by examining skin health outcomes of a combined exercise and incontinence intervention (Table 4). Individuals with incontinence were recruited from 4 facilities. In the intervention group, research staff provided exercise and incontinence care for 2 hours per day for 32 weeks. The control group received usual care from LTC staff. This multifaceted intervention did not reduce pressure ulcer incidence relative to usual care.[70]

Quality of RCTs Targeting Impaired Mobility. The quality of the 51 RCTs that examined impaired mobility was generally suboptimal (Tables 1-4). Of the 51 studies, 25 (49.0%) adequately described the generation of random allocation sequences, and only 14 (27.4%) gave information that indicated patients were randomly allocated with concealed allocation. There was inadequate blinding of patients, but this may be difficult when studying interventions involving support surfaces, repositioning, or exercise and treatment of incontinence. We therefore did not include ratings for the CLEAR NPT criterion of adequate participant blinding in Tables 1 and 2. In some cases, however, it may be feasible to have a blinded observer perform outcome assessments, but this was described in only 10 (19.6%) of the 51 studies. The follow-up schedules in the study groups were consistent in 40 (78.4%) of the 51 studies. Intent-to-treat analyses were performed in 14 (27.4%) of the 51 studies. Only 3 (6.3%) of the 48 studies examining the role of support surfaces fulfilled all 5 of the applicable criteria we selected from the CLEAR NPT checklist.[24,28,69] Of these 3 studies, 2 were small: 1 had a sample size of 32 patients,[24] and another enrolled only 46 patients.[69] Small sample size was a potential limitation of many studies; the mean number of participants was 226 (range, 11-1972). Participants in RCTs represented heterogeneous populations (including patients from general medical and oncology wards, as well as a variety of subspecialty surgical services including orthopedics, vascular surgery, and cardiothoracic surgery wards).

Interventions Targeting Impaired Nutrition. Five RCTs targeted impaired nutrition and included a total of 1475 patients: 974 (66.0%) in acute care and 501 (34.0%) in LTC (**TABLE 5**).[72-76] The length of follow-up ranged from 14 to 182 days. The intervention for all 5 RCTs consisted of mixed nutritional supplements.

The relationship between nutritional intake and prevention of pressure ulcers is often assumed but is based on limited evidence. The only RCT to find that nutritional supplementation was beneficial was conducted by Bourdel-Marchasson et al.[73] This was also the largest and best designed of the intervention trials targeting impaired nutrition, suggesting that the smaller trials may have reported negative outcomes because they were underpowered. The trial by Bourdel-Marchasson et al studied 672 critically ill inpatients older than 65 years and compared standard diet alone to standard diet plus 2 oral nutritional supplements per day. Patients in the control group had a relative risk of pressure ulcer development of 1.57 (95% confidence interval, 1.30-2.38; $P = .04$), compared with those in the intervention group.[73]

Quality of RCTs Targeting Impaired Nutrition. Several important methodological limitations were identified for the 5 RCTs that examined the efficacy of nutritional supplementation. None of the 5 studies provided information to indicate that patients were randomly allocated with concealed allocation. Only 1 of the studies provided adequate blinding of participants and outcome assessors. Three of the studies demonstrated consistent follow-up between study groups. Only 1 of the studies performed intent-to-treat analysis. None fulfilled more than 3 of the 6 CLEAR NPT criteria (Table 5).

Interventions Targeting Impaired Skin Health. Three RCTs targeted impaired skin health and included a total of 819 patients: 439 (53.6%) in acute

care and 380 (46.4%) in mixed settings (TABLE 6).[77-79] The length of follow-up ranged from 21 to 30 days.

Dry sacral skin is a known risk factor for the development of pressure ulcers.[12] All 3 RCTs examined specific topical agents; none evaluated simply moisturizing skin as an intervention.

Torra i Bou et al[77] compared the effects of a hyperoxygenated fatty acid preparation with those of a placebo treatment. Fatty acids have been thought to protect against friction and pressure and also to reduce hyperproliferative skin growth. Pressure ulcer incidence during the study was 7.32% in the intervention group vs 17.37% in the placebo group ($P \leq .006$). van der Cammen et al[78] hypothesized that topical nicotinate could enhance subcutaneous vascular supply but did not find any benefits of topical nicotinate when compared with a lotion containing hexachlorophene, squalene, and allantoin. Green et al[79] proposed that hexachlorophene could act as a bactericidal agent and that allantoin might stimulate cell proliferation and tissue growth. They suggested that a lotion containing hexachlorophene, squalene, and allantoin was superior to a simple moisturizing lotion, but they did not provide any measure of statistical significance for this finding.

Quality of RCTs Targeting Impaired Skin Health. Methodology for the 3 RCTs that examined skin health was limited, though all were double-blinded. None of the 3 studies gave information to indicate that patients were randomly allocated with concealed allocation. One of the studies showed consistency of follow-up between study groups. None performed intent-to-treat analysis. None fulfilled more than 3 of the 6 CLEAR NPT criteria.

COMMENT

We identified 59 RCTs evaluating interventions to prevent pressure ulcers. Our review suggests that the methodology for pressure ulcer prevention trials is suboptimal overall, although more recent studies have shown improvements in methodological quality.[24,28,60,71] In pressure ulcer prevention trials, it is sometimes not feasible to ensure that partici-

Table 5. Randomized Controlled Trials Addressing Approaches to Impaired Nutrition (Participant Blinding Possible) for Reduction of Pressure Ulcer Incidence

Source	Patients Enrolled (Completed), No.	Length of Follow-up, d	Setting	Intervention*	CLEAR NPT Criterion†						Incidence Reduced?
					1	2	3	4	5	6	
Houwing et al,[72] 2003	103 (103)	28	Acute care (orthopedic)	Nutritional supplement vs noncaloric placebo	No	No	Yes	Yes	Yes	No	No
Bourdel-Marchasson et al,[73] 2000	672 (351)	15	Acute care	Standard hospital diet with daily oral nutritional supplement vs standard hospital diet	No	No	No	No	Yes	Yes	Yes
Hartgrink et al,[74] 1998	140 (101)	14	Acute care (orthopedic with nasogastric tube feeding)	Standard hospital diet and overnight nasogastric feeding pump vs standard hospital diet	No	No	No	No	Yes	No	No
Ek et al,[75] 1991	501 (403)	182	LTC	Standard hospital diet with daily oral nutritional supplement vs standard hospital diet	No	No	No	No	Unclear	No	No
Delmi et al,[76] 1990	59 (52)	180	Acute care (elderly orthopedic)	Standard hospital diet with daily oral nutritional supplement vs standard hospital diet	No	No	No	No	Yes	No	No

Abbreviations: CLEAR NPT, checklist to evaluate a report of a nonpharmacological trial; LTC, long-term care.
*All interventions consisted of mixed nutritional supplements.
†1, Adequate description of generation of allocation sequences; 2, Treatment allocation concealed and described; 3, Adequate blinding of participants; 4, Adequate blinding of outcome assessors; 5, Follow-up schedule identical in each group; and 6, Intent-to-treat analysis. Also see "Methods."

Table 6. Randomized Controlled Trials Addressing Approaches to Impaired Skin Health (Participant Blinding Possible) for Reduction of Pressure Ulcer Incidence

Source	Patients Enrolled (Completed), No.	Length of Follow-up, d	Setting	Intervention vs Control	CLEAR NPT Criterion*						Incidence Reduced?
					1	2	3	4	5	6	
Torra i Bou et al,[77] 2005	380 (331)	30	Acute care and LTC	Hyperoxygenated fatty acid compound vs placebo compound (triisotearin)	No	No	Yes	Yes	No	No	Yes
van der Cammen et al,[78] 1987	120 (104)	21	Acute care	Topical nicotinate containing lotion vs hexachlorophene, squalene, and allantoin–containing lotion	No	No	Yes	Yes	No	No	No
Green et al,[79] 1974	319 (167)	21	Acute care	Hexachlorophene, squalene, and allantoin–containing lotion vs placebo lotion	No	No	Yes	Yes	Yes	No	Yes†

Abbreviations: CLEAR NPT, checklist to evaluate a report of a nonpharmacological trial; LTC, long-term care.
*See Table 4 footnote for definitions of CLEAR NPT criteria. Also see "Methods."
†Statistical significance not reported.

pants are blinded, and other aspects of these trials may be difficult to standardize. To address these issues, we used the CLEAR NPT quality-rating guidelines developed specifically for nonpharmacological interventions.[16] Only 3 of the 58 RCTs in this review fulfilled all of the criteria we selected from the CLEAR NPT checklist.[24,28,69]

Of the 59 trials, 43 (72.3%) took place in acute care settings. This seems appropriate, given that the majority of pressure ulcers (60%) develop during acute care hospitalizations.[9]

The trials reviewed were generally short, but follow-up ranged from 1 to 224 days. Although pressure ulcers can develop within 2 to 6 hours, the incidence of pressure ulcers has been found to rise with increasing duration of stay in LTC, and continues to rise for at least 2 years.[80] While days or weeks of follow-up may be adequate for patients with reversible risk factors (eg, relatively healthy patients in perioperative settings), patients with indefinite immobility (eg, paraplegia) may require longer follow-up.

How Do Clinicians Best Prevent Pressure Ulcers With the Available Evidence?

Mattress overlays on operating tables may decrease the incidence of postoperative pressure ulcers.[28] For hospital inpatients, however, the choice may be different; although dynamic support surface mattresses are initially more expensive than dynamic support surface mattress overlays, inpatients prefer the mattresses and they may be more cost-effective than overlays in the long run.[60,71] Specialized foam and specialized sheepskin overlays reduce pressure ulcer incidence compared with standard hospital mattresses.[22,23,32-34,36,40] The choice between dynamic support surfaces and static support surfaces such as specialized foam or sheepskin is not clear, as only a few of the RCTs that compared these interventions showed any difference in outcomes.[46-59] Costs may be an important factor to consider when choosing between these strategies.

On the basis of 1 RCT, it appears that use of nutritional supplements may be of benefit in the prevention of pressure ulcers, though which specific nutrients offer the best protection remains unclear.[73] It seems reasonable to recommend consultation with a dietician for patients at risk of developing pressure ulcers to ensure adequate general nutrition.

Dry sacral skin is known to be a risk factor for developing pressure ulcers. Moisturizing skin is inexpensive and unlikely to be of harm, so it would be a reasonable strategy to implement to prevent pressure ulcers. The incremental benefit and cost-effectiveness of specific topical agents over simple moisturizers is unclear.[77-79]

Future Research

There is a mismatch between the high prevalence and costs associated with pressure ulcers and the amount of good-quality research focused on their prevention. The majority of RCTs we reviewed focused on support surfaces, though these are often some of the most expensive interventions to implement. The cost of support surfaces varies considerably, from less than $100 for some types of foam to more than $30 000 for certain specialty beds.[81] Given the labor-intensive nature of nursing care and the costs associated with various products, considerable work still must be performed to adequately determine the overall cost-effectiveness of interventions to prevent pressure ulcers and the appropriate targeting of these interventions to match these high costs with those individuals most likely to derive benefit. Recent studies have started to formally examine cost-effectiveness in this area.[71,82]

Future studies should also attempt to define the interventions required to prevent pressure ulcers specifically among high-risk populations. Risk factors for development of pressure ulcers include being bed- or chair-bound, being unable to reposition without assistance, difficulty with ambulation, history of stroke, fecal incontinence (which is strongly correlated with immobility), low body weight, lymphopenia, difficulty with independent feeding, impaired nutritional intake, nonblanchable erythema of intact skin (ie, a stage 1 pressure ulcer), and dry sacral skin.[1,3,12,83-87] Advanced age has not been identified as an independent risk factor for pressure ulcers. The negative results of some studies may reflect the fact that interventions were not appropriately targeted. For example, nutritional supplements may be of limited benefit in people who are not malnourished. Strategies to reduce pressure ulcers should be directed toward high-risk patients, and focused interventions should be targeted to patients with deficiencies in the specific domain being investigated.

In addition to examining these focused interventions, future studies of pressure ulcer prevention may benefit from viewing pressure ulcers from a geriatric medicine perspective. Geriatric syndromes such as falls and urinary incontinence tend to develop when compensatory mechanisms are compromised by the accumulated effect of impairments in multiple domains.[88] In the case of pressure ulcers, coexistent impairments in mobility, nutritional status, and skin health often conspire together to produce ulcers. Thus, multifactorial interventions delivered by a multidisciplinary team may prove effective in preventing pressure ulcers, similar to interventions used to prevent other geriatric syndromes.[89]

Although it may not be possible for patients to be blinded to treatment when studying interventions involving support surfaces, repositioning, or exercise and treatment of incontinence, it is often feasible to have a blinded observer perform outcome assessments. This would be achievable particularly for studies taking place in the operating room (because the blinded observer could perform an assessment immediately after the patient has been transferred to another surface), for patients who are rela-

tively easy to transfer (so they can be moved to another surface during assessments), and for some mattress overlays and seat cushions. Blinding of observers is particularly difficult in studies of dynamic support surfaces (since they are electric and may move or make noise) or when patients are critically ill and cannot safely be moved to another surface for assessments.

Several guidelines on the prevention of pressure ulcers have been developed.[90-92] Unfortunately, many physicians and nurses report feeling that they lack education regarding pressure ulcer management, suggesting that guidelines are not reaching their intended audience.[93,94] More effective resources should be expended on knowledge translation of existing evidence. Guidelines alone may not work that well.[95,96] In addition, further well-designed RCTs that follow standard criteria for reporting nonpharmacological interventions (such as the CLEAR NPT checklist)[16] are needed. Head-to-head comparisons of the most promising interventions are also required to evaluate which ones are the most effective.

Limitations

One limitation of our review is that incomplete reporting in the RCTs might have influenced our assessment. However, available evidence suggests that what is reported about key features of a study generally reveal what is actually performed.[97,98]

We assessed study quality using selected features of a previously developed checklist.[16] We believe that the key components of this checklist were used. In addition, there are several ways to define study quality.[18,99] Recent research has concentrated on 2 main issues: which components of the quality assessment are predictive of valid results and what checklist best assesses quality. Despite the many quality scales and checklists that have been created, the optimal approach is still unclear.[99-101] To avoid arbitrary quality scoring, we simply recorded whether the various components of the checklist were reported in the RCTs that we reviewed.

CONCLUSIONS

The methodological quality of RCTs evaluating interventions to prevent pressure ulcers is suboptimal but provides some valuable information on which to base recommendations for effective approaches to prevent this common condition. Specifically, the most promising interventions are using appropriate support surfaces (mattress overlays on operating tables, specialized foam overlays, and specialized sheepskin overlays), optimizing nutritional status, and moisturizing sacral skin. Repositioning is a mainstay of ulcer prevention, but it is not known whether certain strategies have advantages over others.

Further well-designed RCTs that follow standard criteria for reporting nonpharmacological interventions are needed. In particular, given the heterogeneity of the study populations involved in the RCTs we reviewed, further study is needed to confirm the generalizability of these interventions' effectiveness to different patient populations and settings. The prospective collection of data on cost-effectiveness in such RCTs would provide valuable information.

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Study concept and design; drafting of the manuscript: Reddy, Rochon.
Acquisition of data; analysis and interpretation of data; statistical analysis: Reddy, Gill.
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Books say: she did this because. Life says: she did this. Books are where things are explained to you; life is where things aren't. . . . Books make sense of life. The only problem is that the lives they make sense of are other people's lives, never your own.
—Julian Barnes (1946-)

