A Randomized Trial of Low-Air-Loss Beds for Treatment of Pressure Ulcers

Bruce A. Ferrell, MD; Dan Osterweil, MD; Peter Christenson, PhD

Objective.—To assess the effectiveness of low-air-loss beds for the treatment of pressure ulcers in nursing homes.

Design.—Prospective, randomized, clinical trial.

Setting.—Three teaching nursing homes in Los Angeles, Calif.

Subjects.—Eighty-four nursing home residents with trunk or trochanter pressure ulcers (Shea stage ≥2).

Interventions.—Subjects were randomly assigned to use either a low-air-loss bed (n=43) or a 10-cm corrugated foam mattress (n=41) throughout the healing of their ulcers.

Outcome Measures.—Ulcers were assessed twice weekly using surface area and two observational scales (median follow-up, 37.5 days; range, 4 to 571 days).

Results.—Groups were similar with respect to demographics, medical variables, wound care, and early dropouts. Results indicate more than a threefold improvement in median rate of healing for low-air-loss beds compared with foam mattresses (9.0 vs 2.5 mm^2/d; $P=.0002$). This finding was true for deep as well as superficial ulcers (deep ulcers, 9.9 vs 0.7 mm^2/d; $P=.02$; superficial ulcers, 9.0 vs 3.2 mm^2/d; $P=.004$). Cox regression models revealed that the bed, ulcer depth, and fecal continence had independent effects on healing. After controlling for fecal continence, the deep and superficial subgroups using low-air-loss beds remained 2.5 times more likely to heal in a given length of time compared with those using foam mattresses (combined cure probability ratio, 2.66; 95% confidence interval, 1.34 to 5.17; $P<.004$).

Conclusion.—Low-air-loss beds provide substantial improvement compared with foam mattresses despite other factors in pressure ulcer healing.

(*JAMA*. 1993;269:494-497)

PRESSURE ulcers are a common problem among nursing home residents, and often result in substantial morbidity and health service expenditure.[1-4] These lesions profoundly reduce quality of life for patients and are often associated with serious infections, pain, and death.[5] The prevalence of pressure ulcers in nursing homes has been estimated to range from 2% to 25%, and the 1-year incidence has been reported to be 13%.[3] The costs of prevention and treatment of these lesions has been estimated to be as high as $4000 to $40 000 per ulcer.[5,6] Even though third-party reimbursement for pressure ulcer therapy is available to some facilities, the costs of treatment remain highly prohibitive for most nursing homes.[1,3]

A number of investigators have described the treatment of pressure ulcers in nursing homes where resources are scant and healing is often protracted.[3,7,8] Here, pressure ulcers occur in the most frail patients with multiple coexisting problems including malnutrition, incontinence, vascular disease, and dementia.[3,4,9] It is in this setting that new technology may provide substantial improvements in pressure ulcer care. The Agency for Health Care Policy and Research has organized an expert panel to address these issues and to develop clinical guidelines.[10]

An important issue for the treatment of pressure ulcers is the relief of pressure. A variety of mattresses have been used for this purpose, including various foam pads, air mattresses, and water beds. Acceptance has grown for the use of pressure-reducing devices such as air-fluidized beds and low-air-loss beds. These high-tech beds have been shown to dramatically reduce skin-surface pressure to levels that are less than capillary-filling pressures, even under bony prominences.[11] The average cost for providing a low-air-loss bed is approximately $65 per day, doubling the cost of nursing home care for these patients in our facilities (total Medicaid [MediCal] reimbursement in our facilities is only $67 per day). Clinical trials of these devices have been infrequent.[2,8,12-14] To our knowledge, only one prospective randomized clinical trial reported effectiveness data in the English literature using air-fluidized therapy for pressure ulcers in a hospital setting with a relatively short treatment period (median, 13 days).[15] Therefore, we conducted a prospective, randomized trial in nursing homes to assess the effectiveness of low-air-loss bed therapy for pressure ulcer healing in this setting.

METHODS

Design

The study was a randomized controlled clinical trial designed to compare the rate of healing of pressure ulcers resulting from the use of a low-air-loss bed compared with the use of a conventional foam mattress.

Population and Setting

The study population included residents of three teaching nursing homes affiliated with the UCLA School of Medicine, Los Angeles, Calif. These facilities included the Jewish Home for the Aging of Greater Los Angeles and the extended-care units of Sepulveda (Calif) and West Los Angeles Veterans Affairs Medical Centers. Residents of these facilities are typically old (aged >75 years), are of lower socioeconomic and educational backgrounds, are taking multiple medications, and have multiple medical problems. The study protocol was approved by the UCLA Health Sci-

From the Department of Medicine, UCLA School of Medicine, Los Angeles, Calif (Drs Ferrell and Osterweil); the Geriatric Research Education and Clinical Center, Sepulveda (Calif) Veterans Affairs Medical Center (Dr Ferrell), the Jewish Home for the Aging of Greater Los Angeles, Reseda, Calif (Dr Osterweil), and the UCLA Department of Biomathematics, Los Angeles, Calif (Dr Christenson).

Reprint requests to Sepulveda Veterans Affairs Medical Center (11E), 16111 Plummer St, Sepulveda, CA 91343 (Dr Ferrell).

ences Center Committee for the Protection of Human Subjects, as well as each facility's formal human-studies committee.

Sample and Selection

An estimated sample size of 60 subjects in each group was calculated based on pilot data assuming an α of .05 and a power of .80 to detect a 20% difference between two groups with respect to rate of decrease in surface area (square millimeters per day) of pressure ulcers. Interim analysis was conducted to test the validity of these assumptions. The study was terminated early, finding a much larger difference between the two groups than was originally anticipated.

The sample of residents with pressure ulcers was recruited between November 1987 and March 1991. Inclusion criteria included the following: (1) presence of a pressure ulcer on the trunk, buttocks, or trochanters; (2) informed consent from the patient or patient's proxy for health care decisions; and (3) approval of the primary care physician. Ulcers were defined by the presence of abrasion, bulla, skin necrosis, or ulcer formation as a result of pressure over a bony prominence (stage 2 or greater by the Shea scale[16]). Among potential subjects with more than one ulcer, the largest ulcer was chosen as the index ulcer. Exclusionary criteria included the following: (1) expected survival less than 1 month; (2) previous participation in the study; or (3) previous or planned surgical excision of the pressure ulcer.

Assignment

At each facility, groups of 10 subjects were separately randomized, five to each treatment. Assignments were sealed in individual envelopes and opened sequentially on establishment of subject criteria.

Treatments

One experimental subjects were assigned to a low-air-loss bed (Kinair bed, Kinetic Concepts International, San Antonio, Tex). Available clinically for more than 10 years, this bed consists of multiple inflatable fabric pillows attached to a modified hospital bed frame. An electrical blower (fan) maintains comfortable buoyancy of the pillows as the heated air escapes from the fabric air sacks. The design has the advantage of allowing subjects to assume a variety of elevated foot, knee, and head positions that are similar to a regular hospital bed. Pressure-reducing characteristics of this bed have been shown to reduce skin-surface pressures to near or below capillary-filling pressure, even under bony prominences.[11] Previous studies have demonstrated that the device is relatively light, portable, and easy to maintain, while safe and reliable for the treatment of patients with a variety of medical problems.[11,17] The control subjects were assigned to conventional pressure reduction, which in our facilities consists of a 10-cm convoluted foam mattress overlying a regular hospital mattress.

The remainder of the treatment protocol was similar between groups and consistent with each facility's routine policy and procedure for pressure ulcer management. This included mobilization as much as possible and turning patients every 2 hours while they were awake. Each facility's policy directed nurses to avoid head-of-bed elevations and to use turning sheets to avoid dragging patients on their beds. Attention was also directed toward appropriate nutritional support, infection control, and treatment of underlying and intercurrent illness. Subjects were followed up until the index ulcer was completely epithelialized (healed), the subject required transfer to another facility (usually for acute illness), or the subject died. If wounds became worse or showed no healing over 2 weeks, the primary physicians were notified and encouraged to use their best judgment to improve the treatment of problem ulcers. When the assignment of the bed was judged by the study team and the primary care physician to be contributing to decline or lack of healing, subjects were switched to an alternate type of bed. These subjects became protocol deviators, whose outcomes were censored at the time of assigned-treatment termination.

Measurements

Healing was assessed twice weekly by one of two research nurses. Wound surface area was measured by tracing the epithelial border of the ulcer on plastic film (similar to plastic food wrap). The area from these tracings was measured with a polar planimeter (model L20M, Los Angeles Scientific Instrument Company, Calif). The precision of this instrument is within 1 mm^2. The reliability of our methods was evaluated prior to the study by comparing our two nurses' assessments of 10 ulcers of various size and severity. Surface-area measurements indicated a test-retest reliability Pearson's r of .991. Interrater reliability indicated a Pearson's r of .995. Wounds were also assessed using the four-point Shea scale[16] (test-retest weighted κ=0.929; interrater weighted κ=0.830) and the Sessing scale (copyright by Daphne Sessing, RN, Los Angeles, Calif). The Sessing scale is a descriptive scale similar to the Shea scale,[16] which is undergoing development for the assessment of ulcer healing. This observational scale categorizes ulcers by seven verbal descriptions of ulcers in various stages of healing. Unlike the Shea scale, descriptions include color, presence of granulation tissue, evidence of infection, drainage, odor, and eschar (content validity index, 100%; test-retest weighted κ=0.901; interrater weighted κ=0.800).

Data Analysis

Demographic, health characteristics, and treatment variables were compared using Student's t tests for normally distributed continuous data, and χ^2 or Wilcoxon rank-sum tests were used to compare categorical variables or variables with nonnormal distributions, respectively. Healing rates were adjusted for follow-up using Kaplan-Meier life-table methods, with further covariate adjustment by Cox regression models.[18] Significant differences were accepted at the $P<.05$ level.

RESULTS

As shown in Table 1, randomization resulted in two subject groups with no significant differences with respect to demographic characteristics. There were also no differences between the two groups in the initial size or severity of their pressure ulcers. Although on average, the low-air-loss bed group had a lower serum albumin level ($P<.03$), there were no differences between the two groups with respect to the other medical characteristics.

A variety of additional wound treatments were ordered by attending physicians during the study period (median, 4.0 treatments). There were no significant differences between the two groups with respect to physician ordering of local-wound–care strategies or systemic antibiotics (usually for reasons other than pressure ulcer treatment). For example, subjects using the low-air-loss bed were treated with saline-soaked gauze dressings during 56% of the follow-up days, compared with 51% for the foam-mattress group. Likewise there were no differences in exposures to individual or multiple treatment strategies including topical enzymic agents, bedside surgical débridement, semipermeable dressings, or irrigation with dilute antiseptics (ie, povidone-iodine solution, Dakin's solution, or hydrogen peroxide). Overall, any potential bias of our results based on a specific type or number of local treatments appeared to be "washed out" by the overall number of subjects and heterogeneity of physicians' orders for local wound-care strategies.

Table 1.—Demographic and Medical Characteristics

Characteristic	Low-Air-Loss Bed (n=43)	Foam Mattress (n=41)	P
Age, y (25th, 75th percentiles)	85 (71, 92)	84 (68, 91)	.88
Women, No. (%)	21 (49)	21 (51)	.99
Superficial ulcers, No. (%)*	25 (58)	27 (66)	.47
Deep ulcers, No. (%)†	18 (42)	14 (34)	.47
Initial surface area, cm^2, median (25th, 75th percentiles)	4.3 (2.6, 14.0)	4.1 (0.97, 8.95)	.31
Body mass index, kg/m^2, median (25th, 75th percentiles)	19.4 (17.4, 23.9)	20.7 (18.0, 24.4)	.32
Albumin, g/L, median (25th, 75th percentiles)	30.0 (25.0, 34.0)	33.0 (28.0, 35.0)	.03
Total protein, g/L, median (25th, 75th percentiles)	62.0 (55.0, 68.0)	64.0 (56.0, 68.0)	.72
Total lymphocyte count, $\times 10^9$/L, median (25th, 75th percentiles)	1.84 (1.27, 2.23)	1.83 (1.12, 2.30)	.56
Hematocrit, median (25th, 75th percentiles)	0.35 (0.30, 0.38)	0.35 (0.32, 0.39)	.31
Catheter use, No. (%)	25 (58)	27 (66)	.47
Fecal incontinence, No. (%)	36 (84)	29 (71)	.25
Dementia, No. (%)	18 (42)	16 (40)	.96
Contractures, No. (%)	18 (42)	17 (43)	.87
Diabetes, No. (%)	11 (26)	8 (20)	.83
No. of medical problems, median (25th, 75th percentiles)	5 (4, 7)	5 (4, 6)	.84

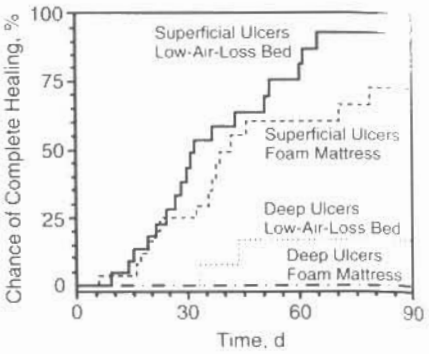
*Stage 2 ulcers.[16]
†Stages 3 and 4.[16]

Table 2.—Overall Results

	Low-Air-Loss Bed (n=43)	Foam Mattress (n=41)	P
Decrease in size of ulcers, mm^2/d, median (25th, 75th percentiles)	9.0 (4.0, 19.8)	2.5 (0.5, 6.5)	.0002
Superficial ulcers, mm^2/d, median (25th, 75th percentiles)*	9.0 (3.7, 13.1)	3.2 (0.3, 6.7)	.004
Deep ulcers, mm^2/d, median (25th, 75th percentiles)†	9.9 (4.4, 34.7)	0.7 (−2.5, 11.5)	.02
Follow-up days, median (25th, 75th, percentiles)	33 (15, 60)	40 (21.5, 90.5)	.56
Completely healed, No. (%)	26 (60)	19 (46)	.19
Died, No. (%)	11 (26)	7 (17)	.34
Transferred to another facility, No. (%)	4 (9)	4 (10)	.94
Discontinued at subject's request, No. (%)	2 (5)	2 (5)	.96
Protocol deviators, No. (%)	0	9 (22)	.001

*n=25
†n=18

Table 2 illustrates the outcomes of the study. Overall, ulcer surface area for the low-air-loss bed group decreased more than three times faster than did the ulcer surface area on subjects in the foam-mattress group (9.0 vs. 2.5 mm^2/d, respectively; P=.0002). Subgroups of deep and superficial ulcers also demonstrated a significant decrease in surface area for the low-air-loss bed group compared with the foam-mattress group (deep ulcers, 9.9 vs 0.7 mm^2/d; P=.02; superficial ulcers, 9.0 vs 3.2 mm^2/d; P=.004). Treatment termination because of subject request, death, or facility transfer occurred equally in the two groups (Table 2). Median follow-up time was similar between the two groups, although the low-air-loss bed group showed moderately, but not significantly, more complete healers (60% vs 46%; P=.19) (Table 2). Using life-table methods to account for early treatment termination also revealed no group differences. Nine subjects using the foam mattress were deviated from the protocol because their ulcers became substantially worse or failed to heal. Each of these nine subjects had undergone at least 30 days of treatment (median, 68 days). Five of these subjects were subsequently treated with low-air-loss beds, three received air mattresses, and one subject received air-fluidized therapy. Only three of these patients completely healed within 4 to 12 months (one using an air mattress, two using low-air-loss beds). Five patients died within 1 to 12 months without complete healing and one subject remained unchanged using an air mattress for more than 12 months following the study.



Life-table curve illustrating the observed chances of complete healing of pressure ulcers in a given number of days.

The Shea and Sessing scales also demonstrated significantly improved overall outcomes for the low-air-loss group. By the Shea scale, the low-air-loss group improved by a median change of 2.0 stages (25th and 75th percentiles, 0, 2, respectively) compared with 1.0 stage (25th and 75th percentiles, 0, 2, respectively) for the foam-mattress group (P<.05). By the Sessing scale, the low-air-loss group improved by a mean change of 3.0 stages (25th and 75th percentiles, 1, 3, respectively) compared with only 1.0 stage (25th and 75th percentiles, 0, 3, respectively) for the foam-mattress group (P<.01).

The Figure shows that more superficial ulcers than deep ulcers were healed in a given period.

To explore whether healing was influenced by other subject characteristics, we examined 26 demographic and medical variables as potential explanatory or confounding factors. Each individual factor was included with bed type in separate Cox regression models. Significant modifying factors were then examined pairwise with bed type in separate Cox regression models. Although several interrelated factors were associated with healing, independent explanatory variables included only bed type, depth of pressure ulcer, and fecal incontinence. After adjusting for fecal continence and depth of pressure ulcer, no other factors were found to significantly modify the effect of the bed.

Table 3 presents the statistical comparisons of cure probability (hazard ratios) obtained from the Cox regression models, adjusted for fecal continence. For this study, the Cox hazard ratio is the cure probability ratio (the probability of cure under one condition divided by the probability of cure under the other condition, for subjects who have been under each condition for the same period). As is shown in Table 3, the cure

Table 3.—Comparison of Pressure Ulcer Cure Probability*

Subgroup	Cure Probability Ratio†	95% Confidence Interval	P
Low-Air-Loss Bed Compared With Foam Mattress			
Superficial ulcers	2.60	1.24-5.41	.01
Deep ulcers	2.97	0.61-14.5	.18
All ulcers	2.66	1.34-5.17	.004
Superficial Compared With Deep-Pressure Ulcers			
Low-air-loss bed	11.57	3.55-37.6	<.0001
Foam mattress	13.25	2.60-67.5	<.0001
Combined beds	12.05	4.16-34.9	<.0001

*All estimates from Cox regression models, adjusted for fecal continence.
†Probability of cure under one condition, divided by probability of cure under the other condition for subjects under [illegible] condition for the same period.

probability ratio indicates that for any given length of time, subjects in the low-air-loss bed group were about 2.5 times more likely to heal than were subjects in the foam-mattress group ($P<.004$). Likewise, for any given length of time, subjects with superficial ulcers were about 12 times more likely to heal than were subjects with deep ulcers regardless of the type of bed they used ($P<.0001$). We also analyzed probability ratios using alternate outcomes including 25%, 50%, and 75% of complete healing. Results of these analyses qualitatively supported the overall effectiveness of the bed. The insignificance ($P=.18$) for deep-ulcer subgroup comparison was most likely owing to fewer subjects with deep ulcers (n=32) and greater heterogeneity of those subjects.

The fact that nine subjects from the control group were prematurely removed from their assigned treatment because they failed to heal in a reasonable time could have systematically biased our results. We recalculated life-table healing rates by assuming first, that all pressure ulcers would have healed on the day after treatment ended, and second, that they would not have healed by the end of the study. Statistical significance of group differences in healing under each of these assumptions remained essentially unchanged.

COMMENT

The results of this prospective, randomized trial demonstrate the effectiveness of low-air-loss beds compared with foam mattresses for healing pressure ulcers in frail, elderly nursing home residents. Overall, use of the low-air-loss bed resulted in a threefold increase in speed of wound contraction compared with use of a foam mattress. These findings remain true across severity of pressure ulcers. Furthermore, the data suggest that when controlled for depth of ulcer and fecal incontinence, patients who use a low-air-loss bed are 2.5 times more likely to heal in a given length of time than are those who use a foam mattress.

Despite the the potential for confounding effects in wound healing, analysis of our data indicated that in addition to the type of bed, only two other factors (pressure ulcer depth and fecal continence) could have had an independent effect on overall healing. In controlling for fecal continence and ulcer depth, our findings remained consistent, indicating improved healing for subjects treated on a low-air-loss bed, regardless of the size or severity of the ulcer.

While other investigators have stressed the importance of tightly managing multiple factors that may influence healing, our study characterizes the effect of the bed under more "real-life" conditions. In the final analysis, treatments prescribed by physicians did not seem to bias our results. In fact, 53% of our control subjects were completely healed within 6 weeks compared with 42% reported by Berlowitz and Wilking.[9]

It seems reasonable, therefore, to consider using this technology for selected nursing home residents for whom goals of nursing home care include the cure of pressure ulcers. The value of rapidly restoring comfort, functional status, and quality of life following a pressure ulcer injury may be enormous for selected residents in this setting. Although we did not evaluate costs associated with pressure ulcer healing in this study, the ability to speed healing rates by twofold to threefold indicates the potential for substantial savings in this setting. Considering the strained monetary resources and conflicting priorities of consumers and society, these issues raise philosophical and ethical considerations, because low-air-loss bed technology may be economically rationed despite its compelling effectiveness as shown by our data.

This study was supported in part by the Jewish Home for the Aging of Greater Los Angeles (Calif); the Sepulveda (Calif) Veterans Affairs Geriatric Research Education and Clinical Center; the West Los Angeles (Calif) Veterans Affairs Geriatric Research Education and Clinical Center and a gift by Kinetic Concepts International, San Antonio, Tex.

We acknowledge the expert assistance of Marilyn Lerner, RN, and Susan Bench, BSN, for their major efforts in data collection and management, Charles Marshall, MD, for his administrative assistance, and Steve Castle, MD, for his experienced advice and review during the preparation of the manuscript.

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