

Clinical Utility and Cost-effectiveness of an Air Suspension Bed in the Prevention of Pressure Ulcers

Kenn J. Inman, MSc; William J. Sibbald, MD, FRCPC, FCCP;
Frank S. Rutledge, MD, FRCPC; Barbara J. Clark, RN, BScN

Objective.—To determine, in critically ill patients at risk, both the clinical utility and cost-effectiveness of using an air suspension bed in the prevention of pressure ulcers.

Design.—Randomized, parallel group, controlled clinical trial with accompanying cost-effectiveness analysis.

Setting.—30-bed multidisciplinary intensive care unit.

Patients.—100 consecutive patients at risk for the development of pressure ulcers randomly assigned to receive treatment on either an air suspension bed or a standard intensive care unit bed. Patients considered at risk were those at least 17 years of age with an Acute Physiology and Chronic Health Evaluation II (APACHE II) score greater than 15 who had an expected intensive care unit stay of at least 3 days.

Main Outcome Measures.—The development of pressure ulcers by site and severity and the costs associated with each of the two programs.

Results.—The air suspension bed was associated with fewer patients developing single, multiple, or severe pressure ulcers. In patients at risk, the use of an air suspension bed in the prevention of pressure ulcers was a cost-effective therapy.

Conclusions.—Despite intense nursing care, pressure ulcers are more prevalent in the critically ill patient population than in the general hospital population. Air suspension therapy provides a clinically effective means of preventing pressure ulcers in these patients. In patients at risk, air suspension therapy was a cost-effective means of managing pressure ulcers compared with the standard hospital bed.

(JAMA 1993;269:1139-1142)

PRESSURE ulcers are an important and potentially costly complication of a critical illness, their occurrence due to factors both intrinsic and extrinsic to the patient.^{1,2} Extrinsic factors that ex-

ert a mechanical force on soft tissue include pressure, shear, moisture, and friction, while intrinsic factors include protein malnutrition, anemia, sensory loss, impaired mobility, advanced age, decreased mental status, incontinence, and infection. While various studies have reported the prevalence of pressure ulcers in the range of 3% to 4.5% for all hospitalized patients,^{3,4} pressure ulcers are more prevalent in the critical care setting due in part to the unique characteristics of this patient population. Depend-

ing on severity, the estimated costs to heal pressure ulcers range from \$5000 to \$40 000.⁵ Thus, in terms of both patient suffering and health care expenditures, pressure ulcers are an important problem in the intensive care unit (ICU).

In attempts to prevent the occurrence of pressure ulcers, various devices and therapies have been used, including air suspension beds. While these beds have been shown effective in the healing of pressure ulcers,⁶ early designs were plagued by problems of awkward nursing care and transfer of the patient. To overcome some of the difficulties in previous designs, an air suspension bed has been developed (KinAir, Kinetic Concepts Inc, San Antonio, Tex) utilizing improved materials and engineering. This bed provides a smooth, low-friction, low-shear surface with a high moisture vapor transmission rate, decreasing physical stresses on the skin.^{7,8} Each section of the bed has separate air-controlled settings to redistribute body weight away from bony prominences, resulting in interface pressures of less than 30 mm Hg.⁹

While the safety and efficacy of the air suspension bed have been documented in various case studies, no rigorous evaluation of its ability to prevent the development of pressure ulcers has been conducted. In addition, the current financial climate in both the US and Canadian health care sectors has resulted in a growing awareness of the need to assess the economic impact of new medical technologies. We therefore conducted a randomized controlled trial to test

From the Richard Ivey Critical Care Trauma Centre and the Management and Evaluative Research Group, Victoria Hospital Corp, and the Program in Critical Care Medicine, Faculty of Medicine, University of Western Ontario, London.

Reprint requests to the Management and Evaluative Research Group, Victoria Hospital Corp, Room 4B2, 3411 St. Joseph St, London, Ontario, Canada N6A 4C6 (M. Inman).

the following two hypotheses: first, that the use of air suspension therapy would be a clinically effective means of preventing pressure ulcers in critically ill patients at risk and, second, given its clinical utility, that implementing air suspension therapy would prove to be a cost-effective strategy for the prevention of pressure ulcers in both the Canadian and US health care settings.

MATERIALS AND METHODS

This study was reviewed and approved by the Review Board for Health Sciences Research Involving Human Subjects at the University of Western Ontario, London.

Study Population

Patients were evaluated for entry into the study on admission to the Critical Care Trauma Centre of Victoria Hospital, London, Ontario, from March 1989 through November 1990. Eligible patients were over 17 years of age, had an admission Acute Physiology and Chronic Health Evaluation II (APACHE II)¹¹ score greater than 16, and had an expected stay in the ICU of at least 3 days. Sample size was determined for a two-tailed test that would compare the incidence of pressure ulcer development in the two study groups. A priori, it was hypothesized that the incidence of pressure ulcer development would be 30% and 8% in the standard bed and air suspension bed groups, respectively. Significance was set at $\alpha=0.05$, with power set at $1-\beta=0.80$. Subject to the availability of the air suspension bed, 100 consecutive patients were randomly assigned to receive treatment with either the air suspension bed or a standard ICU bed. Patients randomized to the standard bed were rotated every 2 hours unless contraindicated.

Clinical Measurements

For each eligible patient, the following demographic information was collected: birth date, sex, body surface area (BSA), primary ICU admission diagnosis, ICU and hospital discharge dates, and ICU outcome (ie, survival or death). Illness severity was approximated by calculating the APACHE II score during the first 24 hours and at 72 hours after ICU admission. As an approximation of nursing care intensity, the Therapeutic Intervention Scoring System (TISS) score¹² was calculated daily. Physiologic variables that were collected on a daily basis included hemoglobin, total serum protein, and serum albumin. On entry and daily thereafter, a visual skin inspection of 13 bony prominences was performed by a trained critical care research nurse, and the presence or ab-

sence of pressure ulcers was recorded. If present, pressure ulcers were scored as described by Shea,¹ with the score corroborated by a member of the Victoria Hospital skin care team. Data were collected until (1) the patient was well enough to walk for more than 6 hours per day, (2) use of the air suspension bed was stopped at the request of the patient or physician, or (3) the patient died.

Statistical Analysis

All statistical analyses were conducted using the statistical package SPSS/PC + v3.1. Data analysis began with ensuring that the two study groups were similar with regard to potentially confounding variables. Unpaired *t* test and the Mann-Whitney *U* statistic were used to compare continuous variables, while categorical variables were compared using χ^2 analysis or Fisher's Exact Test where appropriate.

To assess potential differences in pressure ulcer development between the two study groups, stepwise logistic regression analyses were used. Specifically, four models were constructed using as dependent variables the development of (1) single pressure ulcers, (2) multiple pressure ulcers, (3) severe pressure ulcers (severity score > 1), and (4) resolution of the pressure ulcer. For each of the four models constructed, the independent variables entered included study group, admission and 72-hour APACHE II and TISS scores, primary ICU admission diagnosis, age, BSA, and 72-hour values for serum albumin, total serum protein, and hemoglobin. Seventy-two-hour values were used because it was thought that they were a more stable reflection of the patient's underlying physiologic state than were values obtained in the first 24 hours following admission to the ICU.

Cost-effectiveness Analysis

The methods for the analysis of cost-effectiveness are similar to those used in other Canadian studies.¹³⁻¹⁵ The perspective taken for this analysis was that of a third-party payer. While this viewpoint is more limited in scope than that of society, capturing costs outside the hospital in the Canadian health care system is prohibitively difficult, precluding a more expanded viewpoint. In addition, since we were only interested in a comparison of these two alternatives (standard vs air suspension beds), costs common to both programs that did not vary with the presence or absence of a pressure ulcer (eg, inotropic support) were ignored.¹⁶

Effectiveness of the two alternatives was measured in terms of the number of ICU patients at risk in whom pressure

Table 1.—Estimated Costs per Patient Associated With the Prevention of Pressure Ulcers in Critically Ill Patients

Item	Costs, in 1988 \$	
	United States	Canada
Prophylactic*	405.00	483.00
Diagnostic		77
Stage 1	24.12	24.12
Stage 2	262.06	128.16
Stage 3 and 4	714.24	285.28
Treatment		
Stage 1	138.56	138.84
Stage 2	1696.27	871.16
Stage 3 and 4	12 124.59	5694.79

*The cost of leasing the air suspension bed is the only prophylactic cost included for the two interventions of interest. It is calculated as the product of the lease rate (\$454 in the United States and \$594 in Canada) and the median length of stay, 9 days.

ulcers developed, and effectiveness was expressed per 100 patients at risk. Costs associated with each program were divided into prophylactic, diagnostic, and treatment costs (Table 1), and estimates were reported in both US and Canadian 1988 dollars. Since both diagnostic and treatment costs vary with the severity of the pressure ulcer, these two categories were further broken down by pressure ulcer severity. An incremental comparison of the effect of introducing the air suspension bed was then conducted by calculating the cost-effectiveness ratio, the cost per pressure ulcer prevented. Finally, multiple sensitivity analyses were performed by varying estimates of both US and Canadian costs. Specifically, the subtotals from each of the prophylactic, diagnostic, and treatment categories were varied by 25% increments from 75% to 200% of the original estimates.

RESULTS

Characteristics of the Study Population

Of the 100 patients randomized, 98 successfully completed the study protocol. One patient from each study group was excluded from the analyses, as they did not have an ICU stay of at least 3 days. Neither of these patients developed a pressure ulcer during their hospitalization, and both patients survived to hospital discharge. No significant differences were found with respect to the potentially confounding variables outlined in Table 2. However, there was a trend for patients randomized to the standard ICU bed to have lower admission APACHE II scores and BSAs as well as higher TISS scores. In addition, patients randomized to the standard ICU bed had somewhat shorter lengths of stay than those randomized to the air suspension bed. The fact that these trends were present reinforced the need to include potential confounders in the stepwise logistic regression analyses.

Table 2.—Summary of the Study Population

Variable*	Bed Type		P
	Air Suspension (n=48)	Standard (n=49)	
Male, No. (%)	29 (59)	22 (45)	.84
Age, yr	63.4±14.4	65.4±13.9	.48
APACHE II score†			
Admission	26.1±5.5	24.0±5.3	.19
72 h	20.1±7.3	22.1±8.2	.19
TISS score†			
Admission	33.8±10.3	37.4±9.1	.06
72 h	34.3±8.2	37.2±8.9	.07
Height, m†	1.69±0.09	1.67±0.08	.29
Weight, kg†	61.1±20.6	75.3±23.1	.29
Body surface area, m ² †	1.80±0.21	1.84±0.26	.24
Length of stay, d†			
ICU	16.6±18.1	15.4±13.8	.16
Hospital	31.3±25.0	30.9±28.7	.84
Diagnoses, No. (%)	25 (51)	27 (55)	.84
Admission diagnosis, No. (%)			
Neurological	7 (14)	6 (12)	.64
Cardiovascular	13 (27)	10 (20)	
Sepsis/organ failure	23 (47)	25 (51)	
Respiratory failure	6 (12)	8 (16)	

*APACHE II indicates Acute Physiology and Chronic Health Evaluation II; TISS, Therapeutic Intervention Scoring System; and ICU, intensive care unit. †Values are mean±SE.

Table 3.—Multiple Logistic Regression Analysis of the Effect of the Air Suspension Bed and Other Predictors on the Presence of Single Pressure Ulcers

Variable*	β Coefficient±SE	Odds Ratio† (95% Confidence Interval)	P†
Air suspension bed	-1.73±0.43	0.18 (0.08-0.41)	.0001
ICU length of stay	0.07±0.02	1.07 (1.03-1.12)	.0003
APACHE II score on day 3	0.11±0.04	1.12 (1.03-1.21)	.000
Total serum albumin level on day 3	-0.16±0.07	0.85 (0.74-0.97)	.01
Admission TISS score	-0.08±0.03	0.92 (0.87-0.98)	.03

*ICU indicates intensive care unit; APACHE II, Acute Physiology and Chronic Health Evaluation II; and TISS, Therapeutic Intervention Scoring System. †Adjusted odds ratio from the final logistic regression equation. ‡From the final logistic regression equation.

Pressure Ulcer Development

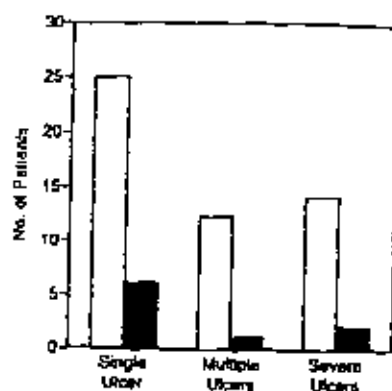
In total, 59 and eight pressure ulcers were detected in the standard and air suspension bed groups, respectively, with the sacrum/trochanter being the most common site (60%). The Figure summarizes the number of patients developing single, multiple, and severe pressure ulcers by study group. Results of the stepwise logistic regression analyses appear in Tables 3 through 5. Treatment using the air suspension bed was associated with significantly fewer patients developing single (Table 3), multiple (Table 4), or severe (Table 5) pressure ulcers. No significant differences were found with regard to the resolution of pressure ulcers.

Other significant predictors of pressure ulcer development included length of ICU stay, 72-hour APACHE II score, 72-hour total serum albumin level, and admission TISS score (Table 3). With the exception of the TISS and APACHE

II scores, similar results were found for the model predicting multiple pressure ulcer development (Table 4). Significant predictors of severe pressure ulcer development were ICU length of stay and admission TISS score (Table 5). Regarding the resolution of pressure ulcers, the number of resolved ulcers (15 of 47) in this analysis precluded finding anything but large differences between the two study groups. As such, the stepwise logistic regression yielded no significant predictors.

Cost-effectiveness

In both the United States and Canada, the air suspension bed proved to be a dominant medical technology, providing a more clinically effective treatment less expensively than the traditional approach of frequent patient rotation (Table 6). In the United States the air suspension bed remained dominant through all of the sce-



Occurrence of pressure ulcers in the study population. Open bars indicate patients treated on a standard bed; solid bars, patients treated on an air suspension bed.

narios in the sensitivity analyses. In Canada the situation was somewhat different. Specifically, if prophylactic costs were underestimated by at least 25%, the air suspension bed lost dominance over the standard bed. The resulting cost-effectiveness ratios (cost per pressure ulcer prevented) for 125%, 150%, 175%, and 200% increases in prophylactic costs were \$162.84, \$333.63, \$514.41, and \$690.19, respectively. Only in one other scenario did the air suspension bed lose dominance in the Canadian setting; when treatment costs were overestimated. If treatment costs were only 75% of that estimated, the resulting cost-effectiveness ratio was \$81.15 per pressure ulcer prevented.

COMMENT

Despite its increasing use in the ICU, there has been surprisingly little research reported on the prevention of pressure ulcers using air suspension therapy. Therefore, we conducted a randomized controlled trial to address both the clinical utility and cost-effectiveness of implementing this technology in our ICU. Our data support the following three conclusions: First, despite increased nursing attention and frequent patient rotation, pressure ulcers are more prevalent in the ICU than in the general hospital population. Second, the use of air suspension therapy is clinically effective, with significantly fewer patients developing single, multiple, or severe pressure ulcers. Finally, air suspension therapy is a cost-effective means of preventing pressure ulcers in the critically ill patient at risk when used in the manner outlined in this study.

In this study, the incidence of pressure ulcer development on the standard bed was 51%. This may seem high, but it must

Table 4.—Multiple Logistic Regression Analysis of the Effect of the Air Suspension Bed and Other Predictors on the Presence of Multiple Pressure Ulcers

Variable*	β Coefficient:SE	Odds Ratio (95% Confidence Interval)	P†
Air suspension bed	-2.22±0.82	0.11 (0.02-0.54)	.007
ICU length of stay	0.07±0.02	1.07 (1.03-1.12)	.001
Total serum albumin level on day 3	-0.24±0.10	0.79 (0.65-0.96)	.02

*ICU indicates intensive care unit.
†Adjusted odds ratio from the final logistic regression equation.
‡From the final logistic regression equation.

Table 5.—Multiple Logistic Regression Analysis of the Effect of the Air Suspension Bed and Other Predictors on the Presence of Severe* Pressure Ulcers

Variable†	β Coefficient:SE	Odds Ratio† (95% Confidence Interval)	P‡
Air suspension bed	-1.85±0.53	0.16 (0.06-0.44)	.0005
ICU length of stay	0.06±0.02	1.06 (1.02-1.10)	.002
Admission TISS score	-0.09±0.03	0.91 (0.86-0.97)	.02

*Pressure ulcers with a severity score greater than 1.
†ICU indicates intensive care unit; TISS, Therapeutic Intervention Scoring System.
‡Adjusted odds ratio from the final logistic regression equation.
§From the final logistic regression equation.

Table 6.—Cost-effectiveness of the Air Suspension Bed Using US and Canadian Costs

Bed Type	Cost per 100 Patients at Risk, \$	Pressure Ulcers per 100 Patients at Risk	Cost Saved per 100 Patients at Risk	Pressure Ulcers Prevented per 100 Patients at Risk	Cost-effectiveness Ratio*
US Costs					
Standard ICU bed	125 177.12	83			
Air suspension bed	51 019.52	16	74 157.60	64	<0
Canadian Costs					
Standard ICU bed	56 347.40	80			
Air suspension bed	50 044.80	16	6302.60	64	<0

*Cost per pressure sore prevented.

be interpreted within the context of the study design. The eligibility criteria used for the study limited entry to those patients with substantial risk for pressure ulcer development. Among those excluded by these criteria were patients admitted following myocardial infarction, vascular and cardiac surgery, and drug overdoses. These patients account for approximately 50% of our current admissions and, hence, their inclusion would have substantially lowered the "global" ICU incidence of pressure ulcer development.

Independent of the air suspension bed, other significant predictors of pressure ulcer development included length of ICU stay, 72-hour APACHE II score, 72-hour serum albumin level, and admission TISS score. Total serum albumin level has previously been shown to be associated with the development of pressure ulcers,¹ and albumin depletion has been considered an intrinsic risk factor. (It may seem paradoxical that the risk of developing pressure ulcers increased with each APACHE II point and decreased with each increase in TISS points. APACHE II attempts to quantify a patient's illness severity through examination of both physiologic and

chronic health parameters. Patients with high scores are, in essence, at greater risk. Unlike the APACHE II score, the TISS score is derived from routine ICU interventions. Higher TISS scores indicate more patient interventions attended to by the nurse and thus an increased likelihood that patients will be moved in bed more frequently than patients with lower TISS scores. Interestingly, examination of the change in APACHE II scores revealed that patients treated on an air suspension bed had larger reductions than patients treated on a standard bed. However, to attribute this to the treatment group is beyond valid interpretation.

Only six patients treated on an air suspension bed developed pressure ulcers compared with 25 patients on a standard bed. From the final logistic regression equation, patients treated on an air suspension bed were about 18% (odds ratio, 0.18) as likely to develop a pressure ulcer as patients on a standard bed. Patients treated on an air suspension bed were also less likely (odds ratio, 0.11) to develop multiple pressure ulcers. Only one patient developed multiple pressure ulcers on an air suspension bed compared with 12 patients on

a standard bed. Since the goal of this therapy is to alleviate pressure from the affected area, the higher rate of multiple pressure ulcers in the standard bed group may have been due to the redistribution of pressure from one area to another. Finally, significantly fewer (odds ratio, 0.16) patients developed severe pressure ulcers on an air suspension bed than on a standard bed. These results may be directly related to the air suspension bed's ability to reduce the pressure exerted over bony prominences²⁰ and therefore to maintain an adequate blood supply to the affected areas.

Valid economic evaluations are predicated on sound information regarding clinical utility. Efficacy as a measure of clinical utility can be defined as the ability of a new technology to achieve its stated goals under strictly controlled conditions.¹⁷ Clinical effectiveness, in contrast, is defined as the new technology's ability to achieve the same benefits under less controlled conditions.²¹ It is now acknowledged that the randomized controlled trial provides the best source of evidence regarding clinical utility.²² Therefore, in examining the clinical effectiveness of the air suspension bed, we designed the trial as pragmatically as possible, with relatively few entrance criteria and liberal study end points. We believe that the resulting analysis of cost-effectiveness is more applicable than if the trial had been conducted under more controlled circumstances.

Cost-effectiveness analysis can be defined as the relationship between inputs and outputs, or the cost and consequences, of at least two health care alternatives.¹⁶ Recently, there has been an increased awareness of the need to assess the economic impact of introducing new medical technologies. Using cost-effectiveness analysis, it has been proposed that new technologies be introduced when one of three conditions are met¹³: First, the new technology is less costly and at least as effective as the current standard. Second, the new technology is more costly and more effective than the current standard, its added benefits being worth its added costs. Third, the new technology is less effective and less costly, the added benefit of the current standard not being worth its added cost. In Canada, tentative guidelines for the adoption and utilization of new medical technologies have been established in concord with these conditions.²³

Based on both the initial results and those of the sensitivity analyses, we contend that the air suspension bed fulfills the first condition when applied in a critically ill patient population at risk. The

air suspension bed was dominant, providing increased effectiveness in the form of fewer pressure ulcers, for less money than the current program of a standard ICU bed and frequent patient rotation. This finding was evident in both the U.S. and Canadian health care settings, albeit to different degrees.

Results of the sensitivity analyses indicated that, in the United States, the air suspension bed retained dominance over the standard bed, regardless of any changes made in the prophylactic, diagnostic, or treatment costs. In Canada, the air suspension bed was dominant in the original analysis but lost this advantage if the estimates of prophylactic costs were underestimated or if treatment costs were overestimated. It is unlikely that either of these two condi-

tions occurred. In the case of prophylactic costs, the lease rate is the single primary cost, as the lessor assumes responsibility for the delivery, maintenance, and removal of the bed. Furthermore, no prophylactic costs were attributed to the standard bed, although there is surely a cost for maintaining a skin care team in the hospital. Thus, it is unlikely that prophylactic costs were underestimated. It is also unlikely that treatment costs were overestimated, since there are set procedures for the diagnosis and treatment of pressure ulcers in our facility. In addition, total treatment costs were not captured. In this evaluation it was not possible to determine which patients who were discharged from the hospital with a pressure ulcer required home care. Thus, if

anything, costs for the treatment of pressure ulcers have been underestimated as a result of the viewpoint chosen for the analysis.

In summary, the air suspension bed proved to be a clinically effective means of preventing pressure ulcers in a population of critically ill adults at risk. Furthermore, it provided these benefits at a lower cost to third-party payers than the existing methods of frequent patient rotation for the prevention of pressure ulcers.

Financial support was provided by Kinetic Concepts Inc, San Antonio, Tex, maker of the KinAir air suspension bed.

The authors thank Jody Warren and the staff of Price Waterhouse Inc for their support during this study. In addition, the authors thank Lesley Rose for her patience and diligence in preparation of the manuscript.

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