The Cost of Home Air-Fluidized Therapy for Pressure Sores

A Randomized Controlled Trial

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Background. Recurrent pressures sores are a serious problem that often cause chronically ill patients to be hospitalized. We hypothesized that home air-fluidized bed therapy may be a safe and effective way to treat these patients, thus avoiding the costs of hospitalization.

Methods. One hundred twelve patients with 3rd or 4th stage pressure sores were randomly assigned to 36 weeks of either (1) home air-fluidized bed therapy that included the services of a visiting nurse specialist as long as the patient had 3rd or 4th stage sores, or (2) conventional therapy.

Results. Compared with patients in the control group, patients receiving air-fluidized bed therapy spent fewer days in the hospital (11.4 days vs 25.5 days, $P < .01$) and used fewer total inpatient resources, as reflected both in charges ($13,263 vs $25,736, $P < .05$) and in Medicare DRG and physician payments ($6,646 vs $12,131, $P < .05$). Total resources used (inpatient and outpatient) were lower for patients treated with air-fluidized bed therapy, but the difference was not statistically significant. Clinical outcomes were similar.

Conclusions. Home air-fluidized bed therapy is safe, reduces hospitalizations, is no more costly than alternative therapy, and allows the patients to receive their needed care in a more desirable, nonhospital setting.

Key words. Decubitus ulcer; home care services; cost-benefit analysis; hospitalization. *J Fam Pract 1991; 33:52-59.*

Pressure sores are a recurrent problem for some patients with chronic, debilitating disorders, and often lead to serious morbidity and sometimes death.[1–6] The patients' medical conditions generally demand substantial health care resources and require both inpatient and outpatient care.[7–15] Partially by design and partially by default, much of this burden is borne by the Medicare and Medicaid programs.

Air-fluidized beds are an important and proven therapy for pressure sores.[16–20] Patients rest on a bed of beadlike ceramic spherules through which filtered air is circulated, thereby simulating the mechanics of "fluid" movement. The principal rationale for employing the therapy is to reduce capillary filling pressures in damaged tissues so as to permit healing. In addition, air-fluidized bed therapy is believed to eliminate shear and friction, reduce bacterial growth and pain, and increase comfort.

Air-fluidized beds have been used for institutionalized patients for two decades. One randomized controlled study has proven them to be more effective in treating pressure sores than conventional therapy (alternating air mattress covered by a foam pad).[16] In the current economic environment, however, where an emphasis has been placed on moving patients from the high-cost hospital setting to less expensive settings, many clinicians and patients have sought to use air-fluidized bed therapy in the home. In addition to providing patient comfort, the bed offers the potential of reducing costly hospitalizations among the debilitated patient population. While in the past many third-party payers refused to pay for home air-fluidized bed therapy, the Medicare program, in an important policy change, recently decided to cover the therapy "if such use is rea-

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sonable and necessary for the individual patient.[21] To evaluate the appropriateness of these third-party payer decisions, we performed a randomized, controlled study comparing air-fluidized bed therapy with conventional home therapy and examined: (1) costs of comparative therapies as borne by the patient, a private insurer, or the Medicare program; and (2) potential cost savings that would result from more extensive payer coverage and use of home air-fluidized bed therapy.

Methods

The study compared two treatment modalities in patients with 3rd or 4th stage pressure sores. One modality provided patients with air-fluidized bed therapy whenever they had 3rd or 4th stage sores, removing the therapy when the sores healed to 2nd stage or better; the other provided patients with conventional therapy as prescribed by their attending physicians. Conventional therapies, chosen by the attending physician on a patient-specific basis, included alternating pressure pads, air-support mattresses, water mattresses, and high-density foam pads. The air-fluidized bed chosen for the study was the CLINITRON Therapy Unit (Support Systems International, Charleston, SC). The air-fluidized bed therapy program provided by this manufacturer included furnishing the bed along with the consultative and technical services of a visiting nurse specialist.

Patient Selection

Based on a clinical evaluation by the visiting nurse specialist, patients' sores were categorized using Shea's stages as follows: a 1st stage sore is limited to the epidermis, with acute inflammatory response in all soft tissue; in a 2nd stage sore there is acute and chronic inflammation that involves the dermis; a 3rd stage sore is an inflammatory reaction with fibrosis extending into subcutaneous tissues: and a 4th stage sore extends beyond the deep fascia and involves muscle or bone.[22]

A patient was eligible for inclusion in the study if he or she met all of the following enrollment criteria: (1) had at least one 3rd stage or 4th stage pressure sore; (2) had an attending physician who believed that the patient would probably require future hospitalization for pressure-sore–related care; (3) had severely limited mobility; (4) had adequate social support to use home air-fluidized bed therapy (usually the assistance of a relative, friend, or paid caregiver); (5) was likely to comply with the home care regimen; (6) was likely to live at least 1 year; (7) was at least 16 years of age; (8) had been out of the hospital for at least 3 weeks; and (9) had a personal physician who was willing to closely manage care in the patient's home. Both the visiting nurse specialist and the attending physician had to attest that the patient met all criteria. Patients were excluded from the study if they were febrile or septic or otherwise required immediate hospitalization, since such patients would incur costs even before the air-fluidized bed therapy was provided. Patients were also excluded if they had pressure sores on radiated skin, as these sores are not generally treatable with air-fluidized bed therapy.

Patient Enrollment

In each of three major metropolitan areas, a nurse who was an expert at using air-fluidized bed therapy served as the study's home care coordinator (HCC). Each HCC actively sought patients by contacting local physicians, home health nurses, and hospital discharge planners. Candidates who were believed to meet study criteria were discussed with the project management team physician (M.J.S.) or nurse (J.G.) who was on call, who would then make the final decision about enrolling the patient. Using forms created by a computerized random-number–generating system, the study physician or nurse would assign the patient to either the air-fluidized bed therapy group or the control group.

Data Collection

For air-fluidized bed therapy patients, the HCCs conducted a home visit weekly for the first 4 weeks, and then biweekly for as long as the patient remained on the air-fluidized bed. During these visits the HCCs queried the patient about his or her use of health care resources (eg, hospital care, physician visits) since the previous visit. Once the patient's pressure sores healed to a 2nd stage or better, the air-fluidized bed was removed from the patient's home, and the HCC thereafter telephoned the patient biweekly to ask about the use of health care resources. If the condition of the patient's pressure sores regressed to a 3rd or 4th stage sore, the air-fluidized bed therapy was reintroduced. The HCC also measured and photographed (at standard distances with identical cameras and lenses) each patient's sores at predetermined times, including at the initial visit, at the end of each air-fluidized bed therapy episode (ie, when the patient was moved from the bed), after any hospital discharge, and at the end of the 36-week study period.

For the control group, the HCC visited each patient biweekly for the first 4 weeks and then telephoned biweekly to ask about the patient's use of health resources. The HCC also measured and photographed the patient's

pressure sores at the beginning of the study, after each hospital discharge, and during the final visit at the end of the 36-week study period.

Members of the project management team contacted patients regularly to verify the accuracy of claims, and visited each metropolitan area at least once to oversee data collection efforts.

Treatment Protocol

Care of the pressure sores was directed by the patient's attending physician. Virtually all patients in both the home air-fluidized bed therapy group and the control group had moist or wet-to-dry dressings. For air-fluidized bed therapy patients, the HCC provided technical and consultative services identical to those provided to patients not in the study. The HCC regularly checked that the bed was functioning appropriately and that the caregiver was properly using it. If a mechanical problem with the air-fluidized therapy bed occurred, the HCC would arrange for its correction. The HCC also followed the healing progress of the patient's pressure sores. If the sores were healing, no changes in care were made. If the sores were not healing, the HCC would contact the patient's physician or other providers so that they could try alternative therapies. For control patients, the HCC simply noted the condition of the sores, and contacted the attending physician or other providers only in emergency situations.

Cost Modeling

Patients were directed to keep copies of all bills and receipts for health care services they received and items they purchased during the study. In addition, at the regularly scheduled home visits and in the telephone calls, the HCCs asked specifically about hospitalizations, physician visits, nursing home admissions, home visits by a nurse or home health care aide, and other outpatient services. All inpatient costs were classified as either pressure-sore related or not pressure-sore related. The former was defined as any hospital admission specifically for treating a pressure sore or a complication, generally assigned to diagnosis-related groups (DRGs) 263, 264, 217, or 271.* DRG assignments were made by a registered record administrator using a commercial computerized version of the fourth revision of Medicare's GROUPER program.[23] All other admissions were considered not to be pressure-sore related, even if the patient also received therapy for a sore.

Patients were followed for a 36-week period and divided into the following groups: (1) patients who completed the 36-week home care regimen; (2) patients who died during the study; (3) "completely dropped" patients, ie, those who did not follow the prescribed home care and data reporting regimen or, in one case, died before the air-fluidized bed was installed; and (4) "partially dropped" patients, ie, patients who enrolled in the study and followed the study protocol for only part of the 36-week study period. For this latter group, cost data were collected up until the time at which they stopped following the protocol, and then the average daily costs were calculated. The 36-week cost was then estimated based on the average daily cost multiplied by 252, the number of days in 36 weeks.

Costs were evaluated from two perspectives: an individual or insurer who pays charges; and the Medicare program, which pays a combination of DRG payments, reasonable charges, and costs, depending on the site of service.

Private insurance cost model. The total charges that each patient incurred during the 36-week study period were estimated. Whenever possible, charges were taken directly from bills or receipts. Because of the importance of hospitalizations, a copy of every summary hospital bill (ie, the UB-82 form) was acquired, either from the patient or directly from the hospital. For other health care services or items, if charges were not available, the amount for each service was estimated based on local charges or a Medicare contractor's listing of average charges to Medicare patients by CPT-4 code. The model also assumed a charge of $70 for each day a patient was receiving air-fluidized bed therapy. This charge, identified by the manufacturer as its current price, covered the cost of the bed, the HCC's services, and any necessary equipment services.

Medicare cost model. The total amount that would be paid by the Medicare program over the 36-week period was estimated based on the assumption that all study patients were Medicare beneficiaries. Hospital DRG payments were calculated for the specific hospitals in which the patients were hospitalized, including adjustments for teaching status, area wage index, and care for a disproportionate share of poor patients. Data for calculating these payments were obtained from the hospital UB-82 form, hospital-specific databases purchased from the Medicare program, and published information.[24] In accordance with standard procedure, Medicare physician payments were estimated at 80% of the prevailing charge for the service as identified in a Medicare list. Nursing

**DRG 263 denotes skin graft and/or debridement for skin ulcer or cellulitis with complications or comorbidities; DRG 264 denotes skin graft and/or debridement for skin ulcer or cellulitis without complications or comorbidities; DRG 217 denotes wound debridement and skin graft, except hand, for musculoskeletal and connective tissue disease; and DRG 271 denotes skin ulcers.*

Table 1. Characteristics of 112 Patients* with Pressure Sores, Recruited and Randomized to Study or Control Group

Characteristics	Air-Fluidized Bed Therapy Patients (n = 58) No. (%)	Control Patients (n = 54) No. (%)
Mean age (y)	65	63
Sex		
Male	29 (50)	28 (52)
Female	29 (50)	26 (48)
Payer		
Medicare†	43 (74)	45 (83)
Medicaid	5 (9)	4 (7)
Other	10 (17)	5 (9)
Education		
Less than high school	22 (38)	19 (35)
High school graduate	19 (33)	16 (30)
At least some college	11 (19)	11 (20)
Home support from		
Family	48 (83)	48 (89)
Friends	13 (22)	13 (24)
Paid support	56 (97)	50 (93)
Self-care	6 (10)	7 (13)
Immobility from		
Paraplegia	10 (17)	14 (26)
Quadriplegia	10 (17)	5 (9)
Parkinson's disease	9 (16)	6 (11)
Multiple sclerosis	8 (14)	12 (22)
Alzheimer's disease	10 (17)	11 (20)
Stroke	11 (19)	12 (22)
Spinal cord trauma	9 (16)	11 (20)
Other	23 (40)	7 (13)
Incontinence		
Bladder	5 (9)	8 (15)
Bowel	39 (67)	40 (74)

**Includes data on all patients who enrolled in study including those who died during the study, those who participated for only part of the study; and those who did not follow the prescribed home care and data reporting regimen.*
†Includes all patients for whom Medicare is the primary payer.

home costs were based on actual charges submitted by the patient, less a coinsurance payment consistent with Medicare guidelines. It was assumed that Medicare would also pay for 80% of the $70-per-day charge for air-fluidized bed therapy.

Assessing Clinical Outcomes

In addition to determining patient survival, the study assessed clinical outcome through reviews by two independent nurses who were experts in the care of pressure sores and who were blinded to treatment category. For each patient who completed the 36-week regimen and for whom there were interpretable photographs, a clinical description of the pressure sores and copies of all photographs throughout the study were assembled. Independently, the two nurses reviewed the materials and categorized each patient at the end of 36 weeks into one of the following categories: improved (sore that progressed to a lower stage or, if the stage was unchanged, clearly showed a smaller surface area, reduced inflammation, or less eschar); unchanged (no obvious changes); worse (sores that progressed to a higher stage or covered a greater surface area, or showed more inflammation, or more eschar); or not assessable.

Statistical Analyses

Data were analyzed using SAS software for the microcomputer. Tests of statistical significance were based on *t* tests (with two-sided alternatives) or chi-square analysis, as appropriate.

Results

A total of 112 patients were entered into the study. Individuals who were evaluated but not accepted into the study were those who failed to meet the study criteria, usually because the pressure sore was of insufficient severity or because the patient refused to undergo the randomization process. The air-fluidized bed therapy group (n = 58) and the control group (n = 54) were very similar with regard to age, sex, education, principal payer, type of home support, reasons for immobility, and continence (Table 1); no differences were statistically significant. As expected, most patients were covered under the Medicare program.

Excluding patients in the "completely dropped" category, there were 47 patients in the group that received air-fluidized bed therapy and 50 patients in the control group who were receiving conventional therapy (Table 2). The patients in both groups proved to be seriously ill: 24% of the air-fluidized bed therapy patients and 35% of

Table 2. Status Following 36-Week Study Period of Patients with Pressure Sores Who Received Either Home Air-Fluidized Bed Therapy or Routine Care

Patient Status	Air-Fluidized Bed Therapy Patients n = 58 No. (%)	Control Patients n = 54 No. (%)	Total N = 112 No. (%)
Completed study	29 (50)	30 (56)	59 (53)
Died during study	14 (24)	19 (35)	33 (29)
Partially dropped from study*	4 (7)	1 (2)	5 (4)
Completely dropped from study†	11 (19)	4 (7)	15 (19)

**Patients who enrolled in study and followed the protocol for only part of the 36-week study period.*
†Patients who did not follow the prescribed home care and data reporting regimen; one patient died before air-fluidized bed was installed.

Table 3. Hospitalization of Patients Treated with Home Air-Fluidized Bed Therapy and Patients in the Control Group During 36-Week Study Period*

	Air-Fluidized Bed Therapy Patients (n = 47) Mean (SD)	Control Patients (n = 50) Mean (SD)	*P* Value
Patient study days	206 (78)	199 (81)	NS
Home air-fluidized bed therapy days	116 (78)	N/A	N/A
Total study hospitalizations per patient			
Decubitus related	0.2 (0.5)	0.6 (0.9)	≤.05
Not decubitus related	0.8 (1.1)	0.6 (1.0)	NS
Total	1.0 (1.1)	1.2 (1.2)	NS
Mean length of stay for each hospitalization (days)	11.5 (8.8)	21.5 (23.8)	≤.05
Total study hospital days per patient			
Decubitus related	3.6 (8.7)	16.9 (30.6)	≤.01
Not decubitus related	7.8 (11.5)	8.6 (20.4)	NS
Total	11.4 (13.4)	25.5 (35.1)	≤.01

**Includes data on patients who completed the study as well as those who died during the study and those who participated in only part of the 36-week regimen.*
SD—standard deviation; NS—not significant; N/A—not applicable.

the control patients died during the study ($P = >.05$). Fifteen patients were categorized as "completely dropped" and 5 patients were categorized as "partially dropped." Compared with others, the "completely dropped" patients were slightly younger; more of them suffered from paraplegia or a spinal cord injury, and more of them relied on self-care, although these differences were not statistically significant.

Health Care Resource Use

Air-fluidized bed therapy patients used the bed for an average of 116 days, or for 56% of the average available time (Table 3). The data suggest that this therapy resulted in a markedly changed hospitalization profile. Although the overall 36-week hospitalization rates for the two groups were quite similar (60% for air-fluidized bed therapy patients, 64% for control patients), the mix and duration of admissions were different. Air-fluidized bed therapy patients had significantly fewer pressure-sore–related hospitalizations per patient (.23 vs .58, $P < .05$), but slightly more hospitalizations for other problems. Most important, however, and regardless of the reason for admission, the average length of stay per hospitalization was significantly lower in air-fluidized bed therapy patients (11.5 days vs 21.5 days, $P < .05$), resulting in 55% fewer days hospitalized over the 36-week study period ($P < .01$).

Table 4 is a summary of the costs of resource use in the air-fluidized bed therapy and control populations. The lower hospitalization rate and shorter length of stay for air-fluidized bed therapy patients translate into significantly lower inpatient charges compared with those generated by control patients ($13,263 vs $25,736, $P < .05$), with almost all of the savings due to fewer decubitus-related admissions. Outpatient charges were generally similar for the two groups, except for the charge for the air-fluidized bed therapy. The net result was that the total charges for control patients were 20% higher over the 36 weeks, although the difference was not statistically significant ($P = .34$). The average total charge per patient in the home air-fluidized bed therapy group was quite sensitive to the daily therapy charge. Over the 36-week study period, a 25% change in the daily rate would have led to a 13% change in total charges.

The Medicare payment portion of Table 4 provides 36-week Medicare costs under an alternative model in which each study patient is a Medicare beneficiary. The payments include any patient co-payment or deductible. Notably, the Medicare obligations are substantially less than what would be paid by charge-paying payers. Total Medicare costs over the 36-week study period are nearly identical for the air-fluidized bed therapy patients ($16,415) and control patients ($16,800).

Resource use clearly varied by patient status, although small numbers in some categories make conclusions difficult (Table 5). Patients who survived the entire 36-week study and were not dropped incurred the greatest average costs. Those who died during the study incurred the greatest costs while they were alive, but overall had the lowest costs of any group.

Safety and Efficacy

Patients and their families were overwhelmingly pleased with the air-fluidized bed therapy and had few problems with its use. One patient was unable to initiate therapy because the house structure could not support the weight of the bed. Six beds had minor bead leaks and seven overheated, but all of these problems were easily and quickly corrected (usually within 24 hours) by the manufacturer's service technician. Several patients noted dry skin, and one experienced mild dehydration, which was readily treated with oral hydration. There were no data to suggest that patient characteristics or type of pressure sore care (eg, moist or wet-to-dry dressings) affected safety or efficacy.

Home air-fluidized bed therapy was effective in healing most decubiti to 2nd stage or better. Of the 47 patients receiving air-fluidized bed therapy, 29 healed to a 2nd stage or better and were removed from the bed. On average, the length of therapy for these patients was 93

Table 4. Costs of Health Care Resources Used Per Patient During the 36-Week Study Period*

	Air-Fluidized Bed Therapy Patients Mean, $ (SD, $)	Control Patients Mean, $ (SD, $)	*P* Value
Medical charges per patient			
Inpatient			
Decubitus related	3,590 (9,143)	16,329 (29,207)	≤.01
Not decubitus related	9,673 (14,824)	9,407 (21,619)	NS
Total inpatient	13,263 (16,807)	25,736 (34,977)	≤.05
Outpatient			
Home health aide	4,217 (4,477)	4,244 (6,530)	NS
Visiting nurse	2,248 (2,856)	2,827 (3,486)	NS
Air-fluidized therapy	8,461 (5,601)	N/A (N/A)	N/A
Other	827 (2,206)	1,941 (6,473)	NS
Total outpatient	15,753 (8,747)	9,011 (9,737)	≤.01
Total	29,016 (19,484)	34,747 (37,499)	NS
Medicare payment costs per patient			
Inpatient			
Decubitus related	2,432 (5,610)	7,626 (12,555)	≤.01
Not decubitus related	4,214 (6,340)	4,505 (8,537)	NS
Total inpatient	6,646 (7,737)	12,131 (14,456)	≤.05
Outpatient			
Home health aide	0 (0)	0 (0)	N/A
Visiting nurse	2,248 (2,856)	2,827 (3,486)	NS
Air-fluidized therapy	6,769 (4,481)	N/A (N/A)	N/A
Other	753 (2,158)	1,842 (6,410)	NS
Total outpatient	9,769 (6,079)	4,669 (7,115)	≤.001
Total	16,415 (9,199)	16,800 (17,143)	NS

**Includes data on patients who completed the study as well as those who died during the study and those who participated in only part of the 36-week regimen. SD—standard deviation; NS—not significant; N/A—not applicable.*

days (standard deviation of 42 days). Five were returned to the air-fluidized bed after a recurrence of a 3rd or 4th stage pressure sore. Baseline characteristics of the five patients were not markedly different from those of patients who did not return for a second period of air-fluidized bed therapy, although the sample size was too small for definitive analyses.

Most patients who survived and completed the 36-week study demonstrated overall clinical improvement, regardless of treatment (Table 6). Two independent nurse reviewers, who were blinded to treatment category, used strict criteria to review records for each case. Patients with missing or uninterpretable pressure sore photographs or visiting nurse notes (7 air-fluidized bed therapy patients and 17 control patients) were removed from the review. Compared with control patients, a higher proportion of air-fluidized bed therapy patients was classified as improved, although the difference was not significant.

Table 5. Average Costs Per Patient of Health Resources Used, by Patient Status

	Average Total Medical Charges Per Patient		Average Total Medicare Costs Per Patient	
Patient Status	Air-Fluidized Bed Therapy Patients (n) Charge, $	Control Patients (n) Charge, $	Air-Fluidized Bed Therapy Patients (n) Charge, $	Control Patients (n) Charge, $
Completed study	(29) 32,903	(30) 40,094	(29) 17,436	(30) 18,874
Died during study	(14) 21,827	(19) 23,738	(14) 14,613	(19) 11,578
Partially dropped from study*	(4) 26,005	(1) 83,525	(4) 15,330	(1) 53,749
Total	(47) 29,016	(50) 34,747	(47) 16,415	(50) 16,800

**Patients who enrolled in study and followed the protocol for only part of the 36-week study period.*

Table 6. Independent Nurse Reviewers' Assessments of Patients' Pressure Sores

	Reviewer 1		Reviewer 2	
Assessment	Air-Fluidized Bed Therapy Patients (n = 22) No. (%)	Control Patients (n = 13) No. (%)	Air-Fluidized Bed Therapy Patients (n = 22) No. (%)	Control Patients (n = 13) No. (%)
Improved	20 (91)	8 (62)	18 (82)	10 (77)
No change	2 (9)	5 (38)	4 (18)	3 (23)

Discussion

Before our study, Allman et al[16] demonstrated that hospital-based air-fluidized bed therapy is safe and more effective than conventional therapy for pressure sores. Our study suggests that the therapy is also safe and highly effective in the home setting. Although some mechanical and other complications are associated with air-fluidized bed therapy,[25] the patients in the current study experienced few problems. Compared with the control group, the air-fluidized bed therapy patients had a lower death rate, although the difference was not statistically significant. Of surviving air-fluidized bed therapy patients, 29 successfully completed one course of therapy, at the end of which all 3rd and 4th stage pressure sores had healed to 2nd stage or better. These patients were assessed as having a high rate of overall clinical improvement.

The principal hypothesis to this study, that home air-fluidized bed therapy can reduce hospitalization days, was clearly proven. Patients who were provided with the therapy had 55% fewer hospital days than control patients. No other variables could explain the differences in length of hospitalization. This finding translated into significantly lower inpatient charges and Medicare hospital payments over the 36-week study period. Compared with control patients, the air-fluidized bed therapy patients incurred greater outpatient expenses as a result of daily charges for the bed therapy. The net result was, however, that air-fluidized bed therapy patients incurred somewhat lower total charges and had slightly more improved medical outcomes, although the differences were not statistically significant. Technical difficulties in obtaining photographs for all the patients, particularly the control patients, limited the outcome of the analysis. Nevertheless, the central finding of fewer hospitalizations and lower costs supported our principal hypothesis.

The Medicare data highlight the tremendous impact of the program's DRG-based payment system. For patients with pressure sores, payments for inpatient care of Medicare beneficiaries are less than 50% of incurred charges, while the hospitals' costs are generally about 60% to 70% of total charges.[26] Hospitals are therefore losing considerable sums caring for these seriously ill patients who often stay longer and incur greater costs than the average DRG case. Conversely, the Medicare program experiences a windfall with this type of resource-intensive case, since payments are geared toward the average case. Thus, even though Medicare is unlikely to save money by covering home air-fluidized bed therapy, the recent Medicare decision to cover air-fluidized bed therapy is justified and provides more appropriate payment for these patients and allows them to receive treatment in a more desirable setting.

Although pressure sores have long been recognized as a serious, recurrent, and expensive problem in patients with debilitating disorders, previous studies have focused on institutionalized patients.[1–15] Thus, the current study of home care provides important new information. Even though selection criteria demanded that patients be clinically stable, have adequate home support, and have attending physicians attest that they believed the patient would live at least 1 year, the 36-week death rate was 30%. We were unable to identify any other baseline characteristics that explained or correlated with death; thus, we concluded that chronic pressure sores in homebound patients are clearly a risk factor for mortality.

The generally positive findings of this study must, of course, be interpreted with an understanding of the nature and extent of home air-fluidized bed therapy and the specific patient population chosen for study. As defined in this study, air-fluidized bed therapy is more than simply a bed; it includes the consultative and technical services of a visiting nurse specialist. This nurse not only oversees the technical aspects of the therapy but also may suggest changes in pressure sore therapy, interacts with the attending physician, and provides social service support. Patients chosen as the control group for this study received the regular care prescribed by their attending physicians, which only rarely and sporadically included home nurse visits. An alternative control group could have been patients without home air-fluidized bed therapy who were seen regularly by visiting nurses. There are no known studies, however, that suggest that the services of the visiting nurse in the absence of air-fluidized bed therapy have had an effect on patient outcome. In one well-designed and well-executed study of patients with

chronic obstructive lung disease, home care increased costs significantly but had no impact on patient outcome.[27]

While we believe randomization was successful, one potential bias needs further discussion. Compared with patients in the control group, significantly more patients assigned to the air-fluidized bed therapy group were dropped. This reflects chiefly that in order to stay enrolled, the air-fluidized bed therapy patients had to use the bed appropriately and accept visits from and answer questions by the HCC. In contrast, control group patients answered most questions by telephone, and fewer were dropped from the study. Thus, if the costs of care for the "completely dropped" patients were found to be greater than the costs of care for the patients retained in the study, the total costs of the air-fluidized bed therapy group might be underestimated. Unfortunately, since we were unable to collect cost data from the "completely dropped" patients, we are unable to test for this potential bias. Although patients in this category had baseline characteristics that were similar to other patients, we cannot rule out the bias.

Another factor may have biased the study against air-fluidized bed therapy. The costs incurred by "partially dropped" patients were prorated to calculate what the costs would have been for the full 36-week period. Since all patients assigned to air-fluidized bed therapy began incurring costs for the bed immediately on entering the study, the substantial costs incurred during that period were included in the estimate of the 36-week costs. Had we been able to follow the "partially dropped" patients for 36-weeks, we probably would have found that most stopped using the bed during the study period, resulting in lower total costs than imputed.

In conclusion, the results of this study suggest that home air-fluidized bed therapy is a safe and effective treatment for pressure sores, significantly reduces the patient's need to be hospitalized, is no more costly than alternative treatments, and may save resources. Third-party payers should consider providing coverage for home air-fluidized bed therapy for properly selected patients in order to reduce hospital and other health care costs.

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