Early intensive care unit mobility therapy in the treatment of acute respiratory failure*

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Objective: **Immobilization and subsequent weakness are consequences of critical illness. Despite the theoretical advantages of physical therapy to address this problem, it has not been shown that physical therapy initiated in the intensive care unit offers benefit.**

Design and Setting: **Prospective cohort study in a university medical intensive care unit that assessed whether a mobility protocol increased the proportion of intensive care unit patients receiving physical therapy vs. usual care.**

Patients: **Medical intensive care unit patients with acute respiratory failure requiring mechanical ventilation on admission: Protocol, n = 165; Usual Care, n = 165.**

Interventions: **An intensive care unit Mobility Team (critical care nurse, nursing assistant, physical therapist) initiated the protocol within 48 hrs of mechanical ventilation.**

Measurements and Main Results: **The primary outcome was the proportion of patients receiving physical therapy in patients surviving to hospital discharge. Baseline characteristics were similar between groups. Outcome data are reflective of survivors. More Protocol patients received at least one physical therapy session than did Usual Care (80% vs. 47%, $p \leq .001$). Protocol patients were out of bed earlier (5 vs. 11 days, $p \leq .001$), had therapy initiated more frequently in the intensive care unit (91% vs. 13%, $p \leq .001$), and had similar low complication rates compared with Usual Care. For Protocol patients, intensive care unit length of stay was 5.5 vs. 6.9 days for Usual Care ($p = .025$); hospital length of stay for Protocol patients was 11.2 vs. 14.5 days for Usual Care ($p = .006$) (intensive care unit/hospital length of stay adjusted for body mass index, Acute Physiology and Chronic Health Evaluation II, vasopressor). There were no untoward events during an intensive care unit Mobility session and no cost difference (survivors + nonsurvivors) between the two arms, including Mobility Team costs.**

Conclusions: **A Mobility Team using a mobility protocol initiated earlier physical therapy that was feasible, safe, did not increase costs, and was associated with decreased intensive care unit and hospital length of stay in survivors who received physical therapy during intensive care unit treatment compared with patients who received usual care. (Crit Care Med 2008; 36:2238–2243)**

KEY WORDS: respiratory failure; mechanical ventilation; mobility; intensive care units; physical therapy; passive range of motion

Immobility, deconditioning, and weakness are common problems in mechanically ventilated patients with acute respiratory failure, and may contribute to prolonged hospitalization (1, 2). Although physical therapy has a theoretical appeal and may address this problem, it has not been determined whether physical therapy has increased benefit when initiated early during intensive care unit (ICU) treatment. There may be perceived barriers to the consistent delivery of passive range of motion (PROM) and physical therapy in many ICUs, namely concern over apparatus dislodgment, integration of mobility with sedation needs, costs of physical therapists in ICUs and time restraints of both nurses and physical therapists (3). Although exercise has been shown to improve functional outcome in emphysema and heart failure in the outpatient setting, few data exist regarding whether early mobility of the medical ICU patient will improve outcomes (4, 5).

Physical therapy practice in the ICU setting varies greatly from one setting to another (6). One reason for the observed variability in the delivery of physical therapy to ICU patients may be the lack of a uniform protocolized approach for ICU delivery of physical therapy. Such protocols exists for other ICU interventions: weaning from mechanical ventilation, liberation from sedation, and early goal directed therapies for severe sepsis (7–9). To our knowledge there are no previous studies that assess efficacy, cost, or hospital or long-term benefits of early ICU Mobility therapy in medical ICU patients. As part of a quality improvement project we developed a standard physical therapy protocol for use in medical ICU patients. In our ICUs physical therapy is part of usual care; however, delivery and administration of physical therapy is often infrequent and occurs irregularly. The mobility protocol was designed to provide a mechanism (i.e., the protocol and Mobility Team) for standard and frequent (once every day) administration of physical

*See also p. 2444.

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therapy to acute respiratory failure patients.

The purpose of this study was to assess the frequency of physical therapy, site of initiation of physical therapy, and patient outcomes comparing respiratory failure patients who received usual care compared with patients who received physical therapy from a Mobility Team using the mobility protocol.

MATERIALS AND METHODS

Study Population. Patients were identified prospectively and enrolled in the study within 48 hrs of intubation and 72 hrs of admission to the Medical Intensive Care Unit (MICU). Study inclusion criteria were age ≥18 yrs and mechanically ventilated via an endotracheal tube. Exclusion criteria were inability to walk without assistance before acute ICU illness (use of a cane or walkers were not exclusions), cognitive impairment before acute ICU illness (nonverbal), preadmission immunocompromised status (prednisone >20 mg/d for 2 wks), neuromuscular disease that could impair weaning (myasthenia gravis, amyotrophic lateral sclerosis, Guillian-Barre), acute stroke, body mass index (BMI) >45, hip fracture, unstable cervical spine or pathologic fracture, mechanical ventilation >48 hrs before transfer from an outside facility, current hospitalization or transferring hospital stay >72 hrs, cardiopulmonary resuscitation at admission, do not resuscitate at admission, hospitalization within 30 days before admission, cancer therapy within last 6 months, readmission to ICU within current hospitalization. The reason represented in the listing of immunocompromised as an exclusion was because of the potential difficulty in assessing muscle strength in patients on long-term corticosteroids.

It was determined *a priori* that only patients who survived to a hospital discharge would be included in the outcome analyses based on results of prestudy data that found few patients who died in the ICU achieved sufficient wakefulness to be considered for physical therapy before their death. Thus, outcome data were compared for patients in the Usual Care group with patients in the Protocol group who survived to hospital discharge. A sample size of 135 survivors per group provided 80% power to detect a difference in the percent of patients receiving physical therapy of at least 20% between groups, using a two sided test and a 5% significance level.

Protocol Development. As part of a quality improvement initiative to improve patient outcome, a mobility protocol was designed to initiate and deliver daily mobility therapy to MICU patients. The protocol was developed with involvement of nursing, physical therapy, and intensivists. All care delivered under this protocol was already governed by the hospital's Nursing and Physical Therapy Departments' policies and procedures, i.e., no new experimental movement procedures were introduced. This study had Wake Forest University Health Sciences Institutional Review Board approval and informed consent was waived.

Participants were assigned to receive the mobility protocol by unit using a block allocation design. The MICU physician service admitted patients to seven separate ICU units based on bed availability. The Mobility Team rotated among the ICUs (set order) until 50 patients per arm had been enrolled in a block, (but completed treatment on enrolled patients) and then the Mobility Team rotated to the next block of patients. Units were assigned to the intervention and control groups in each block to maintain the balance of enrollment over time. A total of three blocks were used over the course of the study, with each unit assigned to both intervention and control groups at different points in time. Patients in the other ICUs, without the Mobility Team, were also enrolled in the study but received usual physical therapy care (e.g., Usual Care group). Thus, eligible patients were designated to either the Protocol or Usual Care group, based on whether or not they were in one of the ICUs where the Mobility Team was assigned. Protocol patients received mobility therapy until transferred to a regular hospital bed. All patients were managed using protocols for sepsis resuscitation, intravenous insulin for glycemic control, sedation with daily interruption, and liberation from mechanical ventilation (7–10). The Mobility Team's representation was that across the seven ICUs to which a medicine service patient could be admitted, there was a 1:1 coverage of Mobility Team coverage of "Protocol" beds to "Usual Care" beds.

All patients were MICU service patients; there were no surgical or trauma admissions to the project. The MICU service is not geographically limited to just one unit in our hospital but has patients every day in each of the seven units. Patients are assigned beds on a first come, first serve basis. The ICU beds stay 95+% occupied. Each of the seven units accepted medical and surgical patients. Each of the ICUs had 11 beds except one unit that had nine beds. The medical patients were managed with the same general care protocols and physician staff (MICU attendings, fellows and house staff) no matter which of the seven ICUs they were assigned. All of the ICUs had a 1:2 nurse-to-patient ratio, and one respiratory therapist per unit, 24 hrs per day. Nursing staff, protocols, and respiratory therapists were similar across the study time. Also, the same set of medical service physicians would care for all of the patients on the medical service, concurrently, whether they were on the protocol arm or usual care arm, no matter to which unit the patient was admitted.

Demographic information, mortality, baseline assessments, on-project management information, physical therapy administration, and hospital outcomes were collected. Baseline assessments included medical history, diagnosis, BMI, and Acute Physiology and Chronic Health Evaluation (APACHE II) score (11). Data were also collected for arterial catheters, central vascular access devices, insulin, steroids, and neuromuscular blocking agents. The rates of ventilator-associated pneumonia, reintubation, pulmonary embolism, and deep vein thrombosis were recorded. Ventilator-associated pneumonia was determined by Infection Control nursing staff using Centers for Disease Control guidelines (12). Project outcome data included the number of ventilator days, days until first episode out of bed, ICU and hospital length of stay (LOS). A ventilator day was defined as any portion of a calendar day in which the patient required a ventilator. The first day out of bed was defined as when a patient's foot first touched the floor.

Protocol Implementation. The Mobility protocol was administered to the Protocol group 7 days per week exclusively by the Mobility Team (critical care nurse, nursing assistant, and physical therapist). The Mobility Team nurse had no direct bedside nursing care responsibilities. The registered nurse's role was to assess patients on admission to determine entry criteria, to evaluate patients for readiness to interact with the Mobility Team and to facilitate safety. In the Protocol group, physical therapy was initiated by the protocol's automatic physician's order; whereas, in the Usual Care group, physical therapy was initiated based on a physician's patient-specific order.

The protocol contained four levels of activity therapy (Fig. 1). When patients were unconscious, only PROM therapy was administered three times a day to all upper and lower extremity joints by the Mobility Team nursing assistant (level I of the protocol) (Fig. 1). At a minimum, five repetitions of PROM were provided for each joint. For the upper extremities PROM included finger flexion and extension; wrist flexion, extension, and ulnar and radial deviation; elbow flexion, extension, supination, and pronation; shoulder flexion, abduction, and internal and external rotation. Shoulder extension was deferred due to positioning in bed. Lower extremity PROM included toe flexion and extension; ankle dorsiflexion, plantarflexion, inversion, and eversion; knee flexion and extension; and hip flexion, abduction, adduction, internal and external rotation. Hip extension was generally deferred due to positioning in bed.

At level II of the protocol, physical therapy was initiated. The patient's ability to interact with the physical therapist was determined by the responses to the following commands: "Open (close) your eyes," "Look at me," "Open your mouth and put out your tongue," "Nod your head," and "Raise your eyebrows when I have counted up to 5" (2). The patient had to respond correctly to three of the five commands to be considered sufficiently alert to participate in physical therapy. Patients were progressed to active-assistive and active range

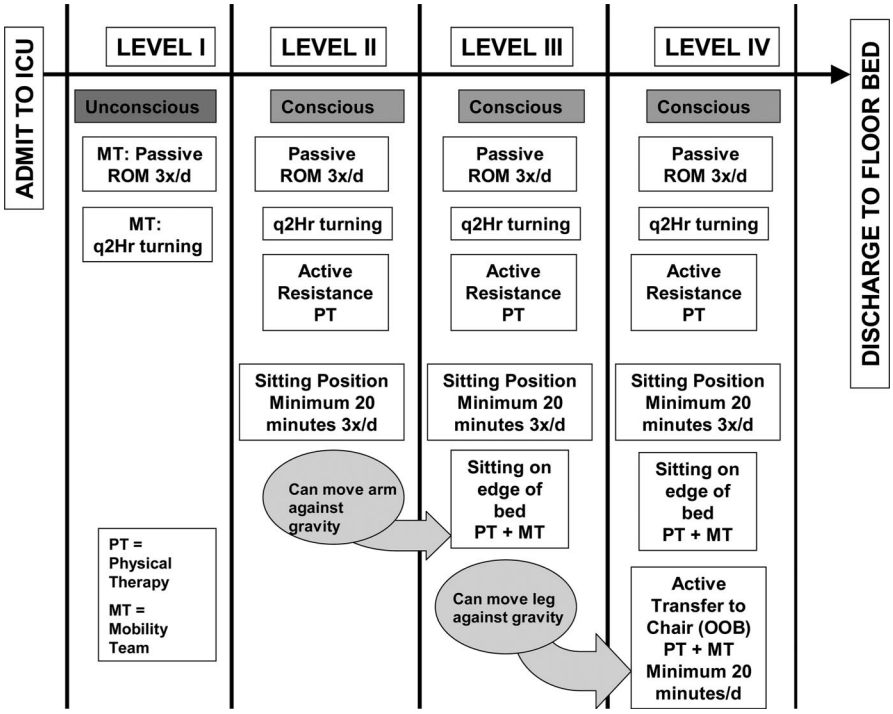

Figure 1. Passive range of motion therapy (*PROM*) started on day 1 of Protocol (level I). As patients demonstrated consciousness and increased strength (see circles with arrows above), they were moved to the next higher level. Physical therapy (*PT*) would be first attempted at level II. The Protocol's intervention ceased as a patient was transferred to a floor bed and then the patient within both "Protocol" and "Usual Care" groups would receive usual care mobility therapy (*MT*) as dictated by the floor physician teams. *ICU*, intensive care unit; *OOB*, out of bed.

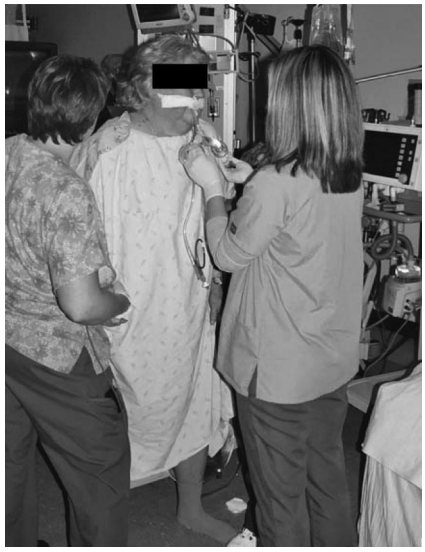

Figure 2. An orally intubated level intravenous patient, exercising while standing.

of motion exercise as they were alert and able to advance their participation, and were advanced through levels II through IV of the protocol. Advancement to the next level was based on limb strength during one effort (3/5 Medical Research Council strength in biceps for II–III advance, and 3/5 in quadriceps for III–IV advance). Five repetitions per exercise were typical goals. Weights were not used as part of the protocol. As patients progressed, the activity increasingly focused on functional activities such as transfer to edge of bed; safe transfers to and from bed, chair, or commode; seated balance activities; pregait standing activities (forward and lateral weight shifting, marching in place); and ambulation (Fig. 2).

The protocol's intervention ended when a patient was transferred to a regular bed. Patients in both arms would then receive "usual care." Patient transfer from the MICU to either the Intermediate Care Unit or floor nursing units was determined by the MICU physician team. At the time of assignment to a floor bed, MICU patients were transferred to a separate physician service that worked primarily with floor patients (the General Medicine Physician service, Family Practice or Neurology).

The following criteria were used to limit or withhold mobility interventions including a decline in hemodynamic or ventilatory status, definitions of hemodynamic or ventilatory decline were hypoxia with frequent desaturations below 88%, hypotension (mean arterial pressure <65 mm Hg), administration of a new pressor agent, new documented myocardial infarction by electrocardiogram and enzyme changes, dysrhythmia requiring the addition of a new antiarrhythmic agent, an increase in the positive end-expiratory pressure on the ventilator or a change to assist control mode once in a weaning mode. If mobility was withheld the patients were reevaluated the next day. If stable, the mobility protocol was reinitiated. There was no absolute limit in regard to F_{IO_2} and positive end-expiratory pressure to withhold Mobility.

Mobility was not initiated if the patient were deemed to be experiencing frequent desaturations.

Usual Care. Nursing practice for the Usual Care group included administration of PROM as delivered daily by the bedside nurse; unconscious patients were repositioned every 2 hrs. The administration of both PROM and Physical Therapy to ventilated, ICU patients is permitted and governed by Nursing and Physical Therapy department policies.

Outcomes. The primary outcome was the proportion of patients surviving to hospital discharge who received ICU physical therapy. Secondary outcomes included days until first out of bed, ventilator days, ICU LOS, and hospital LOS among survivors.

Statistical Analyses. All statistical analyses were performed with SAS version 9. Descriptive statistics included means and standard deviations for continuous measures and counts and percentages for categorical measures. All statistical tests were two-sided and significance was determined at the .05 probability level. Days to first out of bed, ventilator days, and ICU and hospital LOS data were log transformed for statistical analysis. Baseline data were analyzed reflective of all patients enrolled in the project (Usual Care group, n = 165 vs. Protocol group, n = 165). Basic comparisons between groups were done with a Student's *t*-test for continuous variables or chi-square for categorical variables. Project outcomes on the outcome population, participants who survived to hospital discharge, are reported as means (95% confidence intervals). Tests of univariate association with the project outcomes were done by using simple linear regression. Univariate predictor variables with $p < .1$ were included in the multiple linear regression analysis as possible confounders. A stepwise selection procedure was used to identify significant variables ($p < .05$) associated with the project outcomes.

Baseline BMI, APACHE II, and vasopressor usage (yes/no) were included in the multiple linear regression as confounders. The difference between the Usual Care and Protocol groups in project outcomes was adjusted for these confounders. The "adjusted means" are the least square means from the linear regression models. Both unadjusted and adjusted means (95% confidence intervals) are reported for study outcomes.

The effect of ICU unit was assessed by adding ICU unit to the multivariable models as a fixed effect and an interaction term for ICU and group (protocol/control). Both the ICU unit term and the interaction term were nonsignificant. The effect of the protocol on LOS outcomes was not different between the ICU units.

RESULTS

Patients were enrolled in the study for 24 consecutive months within 2004 to 2006. There were a total of 3032 patients admitted to the MICU service, of which 1605 were not intubated. Of the 1427 intubated admissions, 330 met study criteria and were assigned either to the Usual Care (n = 165) or the Protocol group (n = 165) based on block ICU allocation. Of the 1097 excluded, the exclusions were (some patients had more than one exclusion) hospital stay >72 hrs before intubation, 543; nonambulatory, 168; cancer therapy, 153; stroke, 120; immunocompromised, 59; cardiopulmonary resuscitation at admission, 51; cognitive impairment, 46; BMI >45, 42; cervical spine or hip fracture, 20; DNR at admission, 2.

Baseline Characteristics. Demographic characteristics, diagnosis information, and baseline characteristics are reported in Table 1 for all patients enrolled in the project. There were no differences in baseline characteristics for the Usual Care and Protocol groups.

There were no differences in the proportions of patients in both groups receiving intravenous insulin and intravenous neuromuscular blocking agents for 1 or more days during their ICU stay. There was no statistical difference between the Usual Care and Protocol groups for the proportion of patients who received intravenous or oral corticosteroids on day 1 of their ICU stay (22.4% of patients vs. 21.8% of patients, respectively, $p = .8955$). A simple linear regression was done to assess the relationship between corticosteroid administration and study outcomes. No significant relationships were found ($p > .05$). The proportion of patients diagnosed with ventilator-associated pneumonia, pulmonary emboli, or deep vein thromboses was not statistically different for the Usual Care groups compared with Protocol group.

Process Measures, On-Project Management, and Safety Characteristics. No deaths, near-deaths or cardiopulmonary resuscitation occurred during physical therapy in either group. There were no adverse events such as accidental removal of a device during physical therapy and no differences in the numbers of arterial catheters, venous devices or reintubations between the two groups (Table 2). Of all combined passive and active sessions, only 1.4% were not initiated because of either a high or low blood pressure and 0.9% of sessions were not initiated because of either too high or too low a heart rate. The most frequent reason for ending a mobility session was patient fatigue occurring without a significant change in the patient's vital signs.

Mortality. In-hospital mortality occurred in 30 of 165 Usual Care patients (18.2%) and 20 of 165 (12.1%) of Protocol patients ($p = 0.125$). Of those patients with an in-hospital death, only five had received a physical therapy session (Usual Care, n = 2; Protocol, n = 3).

Table 1. Enrollment population baseline parameters

Parameter	Usual Care (n = 165)	Protocol (n = 165)	*p*
Diagnoses (no. and %)			.915
Acute lung injury: out-patient pneumonia	33 (20.1%)	32 (19.8%)	
Acute lung injury: severe sepsis (nonpneumonia)	23 (14.0%)	26 (16.0%)	
Acute lung injury: aspiration pneumonia	32 (19.5%)	27 (16.7%)	
Acute lung injury: pancreatitis	2 (1.2%)	4 (2.5%)	
Acute lung injury: other	10 (6.1%)	6 (3.7%)	
Coma	20 (12.2%)	25 (15.4%)	
Post-op	4 (2.4%)	7 (4.3%)	
Congestive heart failure	10 (6.1%)	12 (7.4%)	
Cardiac arrest[a]	6 (3.7%)	3 (1.9%)	
Acute on chronic lung dz: asthma	4 (2.4%)	4 (2.5%)	
Acute on chronic lung dz: chronic obstructive pulmonary disease	18 (11.0%)	14 (8.6%)	
Acute on chronic lung dz: nonasthma/non-chronic obstructive pulmonary disease	2 (1.2%)	2 (1.2%)	
Age in yrs (mean ± SD)	55.4 ± 16.8	54.0 ± 16.8	.782
Gender-male (no. and %)	88 (53.3%)	93 (56.4%)	.581
Body mass index (mean ± SD)	27.7 ± 7.1	29.0 ± 6.8	.376
Acute Physiology and Chronic Health Evaluation II	21.6 ± 8.0	23.5 ± 8.8	.092
Activity of daily living	96.5 ± 9.8	95.3 ± 12.6	.243
Charlson index	3.16 ± 2.23	2.87 ± 2.31	.249
Patients on vasopressors (no. and %)	60 (36.4%)	53 (32.1%)	.815
Patients with previous home O_2 (no. and %)	9 (5.5%)	13 (7.9%)	.378
Patients with previous chronic renal failure (no. and %)	9 (5.5%)	9 (5.5%)	1.00

dz, disease.

[a]Patients with cardiac arrest were patients transferred from an outside hospital and entered before subsequent records from the transferring hospital were obtained. These patients were entered without knowledge of their exclusion.

Table 2. Postenrollment variables

	Usual Care (n = 165)	Protocol (n = 165)	*p*
Patients with arterial catheters (no. and %)	78 (47.3%)	69 (41.8%)	.320
Number of arterial catheters per patient (mean ± SD)	1.3 ± 0.6	1.4 ± 0.7	.557
Patients with central VAD (no. and %)	100 (60.6%)	91 (55.2%)	.316
Number of VADs per patient (mean ± SD)	2.1 ± 1.6	2.1 ± 1.4	.919
Patients reintubated (no. and %)	28 (17.0%)	28 (17.0%)	1.00
Patients receiving intravenous insulin in ICU (no. and %)	83 (50.3%)	82 (49.7%)	.912
Patients receiving neuromuscular blocking agent ≥1 d (no and %)	23 (13.9%)	31 (18.8%)	.234
Patients receiving steroids in first 24 hrs (no. and %)	37 (22.4%)	36 (21.8%)	.895
Patients with VAP (no. and %)	13 (7.9%)	5 (3.0%)	.087
Patients with pulmonary embolism by computed tomography angiogram (no. and %)	3 (1.8%)	4 (2.4%)	.702
Patients with deep vein thrombosis by lower extremity Doppler (no. and %)	3 (1.8%)	9 (5.4%)	.078
Intravenous sedation days per patient (mean ± SD)	5.15 ± 6.23	5.54 ± 9.10	.945
Discharge location	n = 135	n = 145	
Long term acute care (no. and %)	10 (7.4%)	10 (6.9%)	.868
Skilled nursing facility (no. and %)	15 (11.1%)	12 (8.3%)	.422
Rehabilitation hospital (no. and %)	12 (8.9%)	16 (11.0%)	.550
Home (no. and %)	98 (72.6%)	107 (73.8%)	.821

VAD, vascular access device; VAP, ventilator-associated pneumonia; ICU, intensive care unit.

Table 3. Outcomes (survivors)

	Usual Care (n = 135)	Protocol (n = 145)	p
Days to first out of bed	13.7 (11.7–15.7)	8.5 (6.6–10.5)	<.001
Days to first out of bed (adjusted[a])	11.3 (9.6–13.4)	5.0 (4.3–5.9)	<.001
Ventilator days	9.0 (7.5–10.4)	7.9 (6.4–9.3)	.298
Ventilator days (adjusted[a])	10.2 (8.7–11.7)	8.8 (7.4–10.3)	.163
ICU LOS days	8.1 (7.0–9.3)	7.6 (6.3–8.8)	.084
ICU LOS days (adjusted[a])	6.9 (5.9–8.0)	5.5 (4.7–6.3)	.025
Hospital LOS days	17.2 (14.2–20.2)	14.9 (12.6–17.1)	.048
Hospital LOS days (adjusted[a])	14.5 (12.7–16.7)	11.2 (9.7–12.8)	.006

Data are presented as means (confidence intervals).

Adjusted[a], adjusted for body mass index, Acute Physiology and Chronic Health Evaluation II, and vasopressors.

ICU, intensive care unit; LOS, length of stay.

Outcomes. In the Usual Care group, 64 of 135 (47.4%) underwent at least one physical therapy session at any time during their hospital stay compared with 116 of 145 patients (80.0%) of the Protocol group ($p \leq .001$). Of the 64 Usual Care patients who received physical therapy, eight (12.5%) patients had physical therapy initiated during ICU treatment compared with 106 of 116 Protocol patients (91.4%) ($p \leq .001$). Within the subset of patients who received at least one physical therapy session during their hospital stay, Usual Care patients had fewer sessions compared with Protocol patients, 4.1 sessions per patient vs. 5.5 sessions per patient, ($p = .037$). Within the analysis population, study outcomes are reported as unadjusted and adjusted means (95% confidence interval). After adjusting for BMI, APACHE II, and vasopressor usage, Usual Care patients were first out of bed in 11.3 days whereas Protocol patients were first out of bed in 5.0 days ($p < .001$) (Table 3). The proportion of Protocol patients who were able to advance to specific levels of the protocol is as follows: level I = 44 (26.7%), level II = 12 (7.3%), level III = 18 (10.9%), level IV = 91 (55.1%). The average number of days at each level is as follows: level I: mean (SD) = 7.1 (10.5); level II: mean (SD) = 2.3 (2.0); level III: mean (SD) = 2.2 (1.3); level IV: mean (SD) = 3.9 (3.5).

There was no significant difference in mean number of ventilator days between the two groups. Ventilator days (adjusted) comparing the Usual Care (n = 135) and Protocol (n = 145) groups were 10.2 vs. 8.8 days, respectively, $p = 0.163$. In the Usual Care group, 16 of 165 (9.7%) patients were readmitted to the ICU whereas 14 of 165 (8.5%) in the Protocol group were readmitted ($p = 0.702$) within the same hospital stay.

There was a significant difference between the Usual Care and Protocol groups in both ICU and hospital LOS measures. The adjusted ICU LOS for the Usual Care group was 6.9 days vs. the Protocol group 5.5 days, $p = .027$. The hospital LOS (adjusted) was 14.5 days for the Usual Care group (n = 135) and 11.2 days for the Protocol group (n = 145) ($p = .006$) (see Table 3 for unadjusted values of ICU and hospital LOS).

There were no statistical differences in discharge locations between groups (specifically there was no higher percentage of Protocol patients who were transferred to Long Term Acute Care hospitals on mechanical ventilation vs. the Usual Care group) (Table 2). Time to hospital discharge in days for both groups is represented in Table 3.

Hospital Costs. The total direct inpatient costs for the Protocol group *inclusive* of the Mobility Team salaries were $6,805,082 and for the Usual Care group, $7,309,871. The average cost per patient was $44,302 for the Usual Care group and $41,142 for the Protocol group, $p = 0.262$. The cost of the Mobility Team salary and benefits for the study duration (24 months) was $251,258.

DISCUSSION

Although physical deconditioning of ICU patients, possibly most pronounced in acute respiratory distress syndrome (1, 13) has previously been described, there is a paucity of data describing outcomes of early mobility therapy. We found that implementation of an early mobility protocol by a Mobility Team resulted in more physical therapy sessions and importantly, was associated with shorter LOS for hospital survivors. This study shows that a mobility protocol, in the ICU setting, safely increased the proportion of acute respiratory failure patients who received physical therapy without adverse events. Our report is similar to previous studies that show ICU mobility is feasible and safe (14, 15) and extends these previous reports by documenting that early ICU mobility was associated with statistically significant shortened days in bed, and reduced ICU and hospital LOS for hospital survivors, without increasing cost. If this project is replicated, such data may be important in justifying budgetary support for early physical therapy in ICU patients.

Although cost was not statistically different between groups, the absolute difference in cost appears to be less for the Protocol group, including the cost of the Mobility Team, likely because of LOS-related cost reductions. Confirmation of these data could be useful to justify the initiation of such a program to hospital administrators. Although the relationship between costs and the Mobility intervention is an association and not causation, it may be that early mobility interventions are cost saving.

Although the mechanisms of our Protocol's reduced ICU and hospital LOS in survivors are unclear, several factors may have influenced the outcome. Protocolization of this care may have served as a significant factor. Previous ICU studies have shown that protocolized delivery of care by nursing and respiratory therapy staff increased the percentage of patients for whom care may be delivered, such as daily awakening and weaning (7, 8). Another factor may be that an *independent*, *multidisciplinary* team (nursing assistants, nurse and physical therapist) delivered the protocol compared with usual care which relied on a physical therapist working with the various bedside caregivers when available. Additionally, within Usual Care, initiation of physical therapy was dependent on receipt of the MICU team's order; whereas, Mobility commenced for the Protocol group when the patient first met criteria as assessed by the Mobility Team's nurse. The Mobility team may have reduced the frequency of missed opportunities for physical therapy sessions as they were freed from other patient care responsibilities. This effect may be due to more uniform skill level, the high priority the Mobility Team placed on physical therapy, or it may highlight pervasive time constraints for the routine bedside caregivers resulting in limited time to provide physical ther-

apy. That there is limited time a bedside practitioner might be able to spend on mobilization and still achieve other care goals may have been a factor. A recent nursing survey found that time for direct patient care declined 6% in a 3-yr period from 1999 to 2001 (16). Time required for charting and care documentation was given the most frequent reason for the decline in direct patient care.

Mobility therapy was available more frequently in the Protocol group than in the Usual Care group (7 days compared with 5 days a week) which may have contributed to a shorter hospital stay in these patients. Future targeted dose and duration studies of the exercise delivered by an ICU Mobility Team may clarify mechanisms, as major advances in the understanding of the physical therapy dose-response relationship in the ambulatory setting have been recently shown (17, 18). These types of investigations in the ICU may provide further benefit by defining the upper or lower limitations of benefit of early physical therapy. Finally, future ICU investigations may need to consider the timing of mobility therapy as an independent outcome variable when assessing survivors' ICU-free days or hospital-free days.

ICU nursing unit assignment rather than randomization was used to allocate patients to receive the mobility protocol. However, patients were enrolled within 48 hrs of intubation, there was no drop-out or crossover of patients between groups (i.e., every patient enrolled in the study is accounted for in the baseline parameters), and there were no differences in the patients' baseline characteristics of home oxygen dependence or chronic renal failure. Further, both groups received care directed by a single physician group, the MICU physicians and sedation, sepsis management, glucose control and ventilator weaning were all controlled by protocol.

A limitation is that the mobility protocol was limited in its delivery to within the ICU setting. It is to be determined if similar or more robust results may be achieved if the active intervention were carried out through the portion of the hospital stay when the patients were in the regular floor settings and if patients with more numerous comorbidities were examined. These results were associated with an ICU population specifically restricted by exclusion criteria to select a proportion of patients with a higher probability of overall survivorship than the general medical ICU population. Whether similar results could be reproduced in medical ICU populations with more severe diseases, or inclusion after 72 hrs, remains unknown. Furthermore, whether an early physical therapy program could be applied to surgical ICU patients (with postoperative pain and associated analgesic requirements) also remains unknown.

The study was not blinded and therefore a potential bias is associated with the physicians, nurses, physical therapists, and respiratory therapists who cared for patients in both arms of the study. Despite these limitations, this project was associated with decreased ICU and hospital LOS in survivors. This is the first study to show that early physical therapy compared with a group receiving Usual Care (with relatively little ICU-based physical therapy) was associated with important outcomes in the ICU. Future studies with in-hospital functional measurements may provide clarification as to the effect of physical therapy on sedation assessments and more importantly on how early mobilization may have affected long-term functional outcomes. These results were obtained in the Protocol group that was compared with a Usual Care group which received relatively little ICU-based physical therapy. This Usual Care group may not be representative of the baseline level of physical therapy administered in other hospitals' ICUs.

CONCLUSIONS

We conclude that mobility therapy delivered early in the course of acute respiratory failure patients receiving mechanical ventilation is feasible, safe, did not increase cost, and was associated with decreased ICU and hospital LOS in survivors.

REFERENCES

1. Herridge MS, Cheung AM, Tansey CM, et al: One-year outcomes in survivors of the acute respiratory distress syndrome. *N Engl J Med* 2003; 348:683–693
2. DeJonghe B, Sharshar T, Lefaucheur JP, et al: Paresis acquired in the intensive care unit: A prospective multicenter study. *JAMA* 2002; 288:2859–2867
3. Morris PE. Moving our critically ill patients: Mobility barriers and benefits. *Crit Care Clin* 2007; 23:1–20
4. Ries AL, Make BJ, Lee SM, et al: The effects of pulmonary rehabilitation in the National Emphysema Treatment Trial. *Chest* 2005; 128:3799–3809
5. Belardinelli R, Georgiou D, Cianci G, et al: Randomized, controlled trial of long-term moderate exercise training in chronic heart failure: Effects on functional capacity, quality of life, and clinical outcome. *Circulation* 1999; 99:1173–1182
6. Norrenberg M, Vincent JL: A profile of European intensive care unit physiotherapists. European Society of Intensive Care Medicine. *Intensive Care Med* 2000; 26:988–994
7. Ely EW, Baker AM, Dunagan DP, et al: Effect on the duration of mechanical ventilation of identifying patients capable of breathing spontaneously. *N Engl J Med* 1996; 335: 1864–1869
8. Kress JP, Pohlman AS, O'Connor MF, et al: Daily interruption of sedative infusions in critically ill patients undergoing mechanical ventilation. *N Engl J Med* 2000; 342: 1471–1477
9. Rivers E, Nguyen B, Havstad S, et al: Early goal-directed therapy in the treatment of severe sepsis and septic shock. *N Engl J Med* 2001; 345:1368–1377
10. Van den Berghe G, Wouters P, Weekers F, et al: Intensive insulin therapy in critically ill patients. *N Engl J Med* 2001; 345:1359–1367
11. Knaus WA, Draper EA, Wagner DP, et al: APACHE II: A severity of disease classification system. *Crit Care Med* 1985; 13: 818–829
12. Horan TC, Gaynes RP: Surveillance of nosocomial infections. *In:* Hospital Epidemiology and Infection Control. Mayhall CG (Ed.). Philadelphia, Lippincott Williams & Wilkins, 2004, pp 1659–1702
13. Schweickert WD, Hall J: ICU-acquired weakness. *Chest* 2007; 131:1541–1549
14. Stiller K, Phillips AC, Lambert P: The safety of mobilisation and its effect on haemodynamic and respiratory status of intensive care patients. *Physiother Theory Practice* 2004; 20:175–185
15. Bailey PR, Thomsen GEM, Spuhler VJR, et al: Early activity is feasible and safe in respiratory failure patients. *Critical Care Med* 2007; 35:139–145
16. Lacey LM, Shaver K: Reductions in the amount of time spent in direct patient care by staff nurses in North Carolina. North Carolina Center for Nursing 2002; Available at: http://www.nursenc.org/research/chgs_time_alloctn. Accessed September 3, 2007
17. Church TS, Earnest CP, Skinner JS, et al: Effects of different doses of physical activity on cardiorespiratory fitness among sedentary, overweight or obese postmenopausal women with elevated blood pressure: A randomized controlled trial. *JAMA* 2007; 297: 2081–2091
18. Lee IM: Dose-response relation between physical activity and fitness: Even a little is good; more is better. *JAMA* 2007; 297: 2137–2139