A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation

[Feature Article]

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Abstract

Objective: To compare a practice of protocol-directed weaning from mechanical ventilation implemented by nurses and respiratory therapists with traditional physician-directed weaning.

Design: Randomized, controlled trial.

Setting: Medical and surgical intensive care units in two university-affiliated teaching hospitals.

Patients: Patients requiring mechanical ventilation (n = 357).

Interventions: Patients were randomly assigned to receive either protocol-directed (n = 179) or physician-directed (n = 178) weaning from mechanical ventilation.

Measurements and Main Results: The primary outcome measure was the duration of mechanical ventilation from tracheal intubation until discontinuation of mechanical ventilation. Other outcome measures included need for reintubation, length of hospital stay, hospital mortality rate, and hospital costs. The median duration of mechanical ventilation was 35 hrs for the protocol-directed group (first quartile 15 hrs; third quartile 114 hrs) compared with 44 hrs for the physician-directed group (first quartile 21 hrs; third quartile 209 hrs). Kaplan-Meier analysis demonstrated that patients randomized to protocol-directed weaning had significantly shorter durations of mechanical ventilation compared with patients randomized to physician-directed weaning (chi squared = 3.62, p = .057, log-rank test; chi squared = 5.12, p = .024, Wilcoxon test). Cox proportional-hazards regression analysis, adjusting for other covariates, showed that the rate of successful weaning was significantly greater for patients receiving protocol-directed

weaning compared with patients receiving physician-directed weaning (risk ratio 1.31; 95% confidence interval 1.15 to 1.50; p = .039). The hospital mortality rates for the two treatment groups were similar (protocol-directed 22.3% vs. physician-directed 23.6%; p = .779). Hospital cost savings for patients in the protocol-directed group were $42,960 compared with hospital costs for patients in the physician-directed group.

Conclusion: Protocol-guided weaning of mechanical ventilation, as performed by nurses and respiratory therapists, is safe and led to extubation more rapidly than physician-directed weaning. (Crit Care Med 1997; 25:567-574)

Key Words: mechanical ventilation; weaning; critical care; intensive care unit; outcomes; protocol-directed therapy; respiratory therapy; nursing

Mechanical ventilation is one of the most common forms of medical therapy administered within intensive care units (ICUs) [1]. "Weaning" patients from mechanical ventilation has been referred to as part of the "bread-and-butter" of respiratory care practices provided by physicians, respiratory therapists, and nurses working in ICUs, postanesthesia recovery units, intermediate care units, and other specialized hospital settings [2]. The American College of Chest Physicians Consensus Conference on Mechanical Ventilation [1] recently defined weaning as the gradual reduction of ventilatory support and its replacement with spontaneous ventilation. Despite consensus on what weaning is, continued controversy exists on how it should best be performed [3,4]. To date, randomized, controlled trials have focused on identifying the best technique for weaning patients from mechanical ventilation [5,6].

Our purpose was to conduct an outcomes study to assess the efficacy and efficiency of using protocols to wean patients from mechanical ventilation compared with a traditional practice of physician-directed weaning. We hypothesized that nurses and respiratory therapists could safely and effectively wean most patients from mechanical ventilation using protocol guidelines. Potential advantages of such an approach include reducing the duration of both mechanical ventilation and the weaning process. In addition, this approach would free physicians for other duties that cannot be delegated to nonphysicians (e.g., weaning the long-term ventilator-dependent patient) and would focus the role of bedside health-care providers in the ICU setting.

MATERIALS AND METHODS

Study Location and Patients.

The study was conducted at two university-affiliated teaching hospitals: Barnes Hospital (900 beds) and Jewish Hospital (450 beds). During a 4-month period (July 1995 to October 1995), all patients receiving mechanical ventilation in the medical and surgical ICUs of these two hospitals were eligible for this investigation. Each participating ICU had its own dedicated critical care nursing staff. This staff consisted of registered nurses who were under the supervision of a head nurse and a clinical nurse specialist. The usual staffing ratio of nurses to patients was 1:2, although this ratio varied depending on the patient's severity of illness. Barnes and Jewish Hospitals share the same respiratory therapy department. Each ICU had assigned rotating housestaff physicians who provided medical care to patients under attending physician

supervision. Three of the four ICUs (ICUs 1, 2, and 3) were directed by dedicated critical care physicians and had critical care fellows overseeing the housestaff physicians. The forth ICU was directed by a part-time critical care physician without critical care fellows.

Patients were entered into the trial if they were >18 yrs of age and required mechanical ventilation. Patients were excluded from the trial for the following reasons: a) head or facial burns or trauma; b) transfer from other hospitals with prior mechanical ventilation; or c) a requirement for mechanical ventilation due to brain death in order to allow organ retrieval. The study was approved by the Washington University School of Medicine Human Studies Committee and the Institutional Review Board of Jewish Hospital. Both waived the requirement for informed consent because this study was a quality assessment of two low-risk practices already in clinical use.

Study Design.

Patients were randomly assigned, at the time of ICU admission, to receive protocol-directed weaning implemented by nurses and respiratory therapists or physician-directed weaning from mechanical ventilation. Stratification according to ICU site was done to ensure the same distribution of patients from the four participating ICUs in the two study groups. This stratification was accomplished with separate, blocked, randomization schedules for each ICU, using opaque, sealed envelopes, which were opened at the time each patient was enrolled in the study. A stratified, randomization strategy was employed to reduce variation in the outcome measure due to differences in patient characteristics and medical practices among the four ICUs.

Before beginning this investigation, the medical directors from each ICU developed protocols to guide the assessment of weaning readiness and the weaning process for patients in their respective units. This work was done in advance to facilitate acceptance of the weaning protocols within the individual ICUs participating in this outcomes investigation. The main outcome measure examined was the duration of mechanical ventilation. This outcome was measured as the exact time from tracheal intubation and initiation of mechanical ventilation until the discontinuation of mechanical ventilation. Secondary outcome measures included the need for reintubation, the hospital length of stay, hospital mortality rate, and hospital costs. Additionally, the length of mechanical ventilation from the exact time of tracheal intubation until the start of the weaning process was recorded.

The nursing staffs and respiratory therapists from each ICU were thoroughly trained on the weaning protocols before their implementation. A 1-month training period was used, before beginning the investigation, to allow time for nurses and respiratory therapists to become familiar with the weaning protocols. Patients randomized to the protocol-directed group were assessed for weaning readiness and were weaned from mechanical ventilation according to the guidelines of the ICU protocols. Before the start of protocol-directed weaning, each patient's attending physician, or their designee, was notified. Any interjections by physicians in the protocol-directed weaning process were prospectively recorded. These interjections included physician orders that resulted in either a hastening or delaying of the weaning process, compared with the timetable for weaning outlined by the ICU's weaning protocol.

For patients randomized to the physician-directed group, the onset of weaning from mechanical ventilation and the progression of the weaning process were primarily determined by the housestaff physicians who oversaw the medical care of these patients. The housestaff physicians typically made daily rounds with each patient's attending physician and/or the critical care attending physician. Physicians weaned patients according to their personal preferences and biases. Nurses and respiratory therapists could not assess for weaning readiness, initiate weaning, or advance the weaning process among patients randomized to the physician-directed group without a physician's order. Weaning in both the protocol-directed and physician-directed groups could be performed at night. However, in the physician-directed group, this option required a physician's order.

Weaning Protocols.

Patients who received protocol-directed weaning entered a weaning protocol when their underlying indication for mechanical ventilation had resolved or significantly improved, according to predetermined protocol entry criteria. Patients had to meet all of these predetermined criteria, which included: a) PaO_2/FIO_2 ratio of >200; b) positive end-expiratory pressure of <or=to5 cm H_2O; c) heart rate of <140 beats/min; d) respiratory rate of <or=to35 breaths/min; e) awake and oriented mental status; and f) not requiring vasoactive or inotropic agents.

Patients progressed through the weaning protocols to extubation, unless they met any of the predetermined weaning failure criteria, in which case, the weaning protocol was interrupted. These criteria included the following: a) a respiratory rate of >35 breaths/min; b) oxygen saturation of arterial blood of <90%; c) heart rate of >or=to140 beats/min; d) systolic blood pressure of >180 or <90 mm Hg; e) the presence of somnolence, agitation, diaphoresis, or anxiety; f) requirement for vasopressors or inotropic agents; and g) chest pain or other limiting pain precluding further weaning attempts. Reinitiation of weaning usually occurred after a period of 6 to 12 hrs, according to the weaning protocol employed. Housestaff physicians in the individual ICUs were instructed by one of the investigators regarding the purpose and methods of this weaning study.

Intensive Care Units 1 and 4.

Patients randomized to protocol-directed weaning received daily trials of spontaneous breathing through the ventilator circuit. During the spontaneous breathing trials, a continuous positive airway pressure of <or=to5 cm H_2O and pressure support of <or=to6 cm H_2O were administered. Subsequent trials were increased in duration for <or=to2 hrs, and no more than two trials per day were permitted. Between the trials, patients were placed back on the mode and settings of mechanical ventilation that were present before beginning the spontaneous breathing trial. Patients able to breathe for between 1 and 2 hrs without meeting the weaning failure criteria were extubated.

Intensive Care Unit 2.

Patients randomized to protocol-directed weaning received pressure support ventilation

titrated to achieve a ventilatory rate of <1.2 times their baseline rate during mechanical ventilation. Pressure-support ventilation was reduced in 2-cm H sub 2 O decrements until reaching 6 cm H_2 O, after which patients were extubated. During weaning, patients achieving a respiratory rate of >or=to1.2 times their baseline rate, or meeting any of the weaning failure criteria, had the pressure support increased by 2-cm H_2 O increments until these parameters were no longer met. The pace of weaning was determined by the patients' tolerance of reductions in pressure-support ventilation.

Intensive Care Unit 3.

Patients randomized to protocol-directed weaning received intermittent mandatory ventilation, with a ventilatory rate set at half or less than half the respiratory rate present during baseline ventilation. Positive end-expiratory pressure of <or=to5 cm H_2 O and pressure support of <or=to6 cm H_2 O were administered during weaning with intermittent mandatory ventilation. The ventilatory rate was subsequently decreased by 2 breaths/min at least once daily. More frequent decreases in the ventilatory rate were carried out in the patients who did not meet any weaning failure criteria. Patients who met weaning failure criteria had their ventilatory rate increased by 2-breaths/min increments until these parameters resolved. Patients tolerating a respiratory rate of <or=to4 breaths/min were placed on a ventilatory rate of zero for 30 mins to 1 hr before extubation.

Data Collection.

For all study patients, the following characteristics were prospectively recorded by one of the investigators: a) age, gender, ethnicity; b) indication for mechanical ventilation; c) PaO_2/FIO_2 ratio; d) severity of illness based on Acute Physiology and Chronic Health Evaluation (APACHE) II scores [7]; e) the Organ System Failure Index [8]; f) the presence of chronic obstructive pulmonary disease requiring medical treatment; g) the development of the acute respiratory distress syndrome (ARDS); h) the mode of mechanical ventilation (e.g., intermittent mandatory ventilation, pressure-support ventilation, and assist-control ventilation) used during acute patient management before beginning the weaning process; and i) the applied weaning strategy (e.g., intermittent mandatory ventilation, pressure-support ventilation, and intermittent trials of spontaneous breathing). Respiratory function was measured by respiratory therapists, before beginning the weaning process, according to either physician orders or the guidelines of the weaning protocols. Tidal volume and respiratory frequency were measured with a hand-held spirometer. Maximum inspiratory pressure was measured three times in succession with an aneroid manometer, and the most negative number was selected.

One of the investigators made daily rounds in the participating ICUs of each hospital. Patients entered into the study were prospectively followed until they were successfully weaned from mechanical ventilation, died, or were transferred to a long-term care facility with mechanical ventilation. Patients could not be entered into the study more than once. All study variables were prospectively recorded in data collection books maintained at each of the participating hospitals. The individuals performing the data collection and recording patient outcomes were not involved in the medical care of the study patients.

Definitions.

All definitions were selected prospectively as part of the original study design. APACHE II scores were calculated in a standard manner, using clinical data available from the first 24 hrs of intensive care [7]. The Organ System Failure Index has been previously described [8]. ARDS was defined on the basis of the following criteria: a) chest radiograph showing bilateral pulmonary infiltrates; b) PaO_2/FIO_2 ratio of <or=to200, regardless of the level of positive end-expiratory pressure; and c) a pulmonary artery occlusion pressure of <or=to18 mm Hg or no clinical evidence of increased left atrial pressure on the basis of the chest radiograph and other clinical data [9]. Medical therapy for chronic obstructive pulmonary disease included the use of corticosteroids, inhaled beta-adrenergic receptor agonists or anticholinergic agents, and theophylline. All financial data were derived from the finance offices of the study hospitals. Professional fees for the services of physicians were not included in these calculations.

Statistical Analysis.

We estimated sample size to provide 80% power to detect a difference in the weaning time between the two study groups of 1 day. We used an alpha-error of 0.05 (two-tailed) and a standard deviation of 3 days for mechanical ventilation, based on our previous investigations [8,10]. On the basis of these assumptions, 145 patients were needed in each of the two study groups. All comparisons were unpaired and all tests of significance were two-tailed. Continuous variables were compared using Student's t-test for normally distributed variables and the Wilcoxon's rank sum test for nonnormally distributed variables. The chi-square or Fisher's exact test was used to compare categorical variables.

The primary data analysis was an intention-to-treat analysis, comparing the duration of mechanical ventilation between patients randomized to receive protocol-directed weaning and physician-directed weaning. The probability of successful weaning over time for each treatment group was calculated according to the Kaplan-Meier method and compared by the log-rank and Wilcoxon tests [11] using the Lifetest procedure in the SAS statistical package [12]. We confirmed the results of these tests, while controlling for specific baseline covariates, by examining the relative probability of successful weaning over time using a Cox proportional-hazards model [13]. Baseline covariates (Table 1) were included in the model, along with the treatment group assignment, the mode of mechanical ventilation during acute patient management, and the specific weaning technique employed. Backward elimination was used to reduce the model to the subgroup of factors that independently contributed to the variation in the duration of mechanical ventilation. Eighty-two patients who died during the study period were classified as censored cases since these patients did not undergo weaning from mechanical ventilation. These eighty-two patients were included in all univariate analyses but were censored from the Kaplan-Meier analysis.

Characteristic	Protocol-Directed Weaning (n = 179)	Physician-Directed Weaning (n = 178)	*p* Value
Age (yr)	62.3 ± 17.3[a]	62.3 ± 16.8	.989
Gender (male/female)	86/93	82/96	.708
Race, n (%)			
White	67 (37.4)	65 (36.5)	.597
Black	111 (62.0)	110 (61.8)	
Other	1 (0.6)	3 (1.7)	
COPD, n (%)	50 (27.9)	33 (18.5)	.036
ARDS, n (%)	10 (5.6)	14 (7.9)	.390
APACHE II score	16.4 ± 5.9	17.7 ± 5.5	.026
Organ System Failure Index	1.2 ± 1.1	1.3 ± 1.3	.611
Hospital, n (%)			
Barnes	127 (70.9)	123 (69.1)	.703
Jewish	52 (29.1)	55 (30.9)	
ICU, n (%)			
Medical	83 (46.4)	94 (52.8)	.224
Surgical	96 (53.6)	84 (47.2)	
Indication for MV, n (%)			
Postoperative	86 (48.1)	76 (42.7)	.665
Trauma	7 (3.9)	7 (3.9)	
Pneumonia	4 (2.2)	10 (5.6)	
COPD/asthma	7 (3.9)	5 (2.8)	
Pulmonary edema	10 (5.6)	12 (6.7)	
Respiratory failure[b]	57 (31.8)	56 (31.5)	
Drug overdose	1 (0.6)	3 (1.7)	
Cardiac arrest/cardiogenic shock	7 (3.9)	9 (5.1)	

COPD, chronic obstructive pulmonary disease; ARDS, acute respiratory distress syndrome; APACHE, Acute Physiology and Chronic Health Evaluation; ICU, intensive care unit; MV, mechanical ventilation.

[a]Mean ± SD; [b]multifactorial, neurologic, upper airway protection, post endoscopic procedure, or unclear etiology for respiratory failure requiring mechanical ventilation.

Table 1. Patient characteristics at the time of randomization

RESULTS

Patients.

A total of 377 patients were enrolled in the study. Twelve patients were not randomized due to trauma or burns to the head and face. Eight other eligible patients were not randomized due to either oversight or mortality early after ICU admission. Thus, 357 patients were randomized and analyzed, of whom 179 (50.1%) received protocol-directed weaning and 178 (49.9%) received physician-directed weaning. There were 168 men and 189 women, with a median age of 66 yrs. At the time of randomization, no statistically significant differences were found between the two treatment groups for age, gender, ethnicity, presence of ARDS, the number of acquired organ system derangements as measured by the Organ System Failure Index, hospital location or type of ICU (i.e., medical vs. surgical), and indication for mechanical ventilation (Table 1). Patients receiving protocol-directed weaning did have a significantly greater rate of chronic obstructive pulmonary disease requiring medical treatment and significantly lower average APACHE II scores

Patients receiving protocol-directed weaning were more likely to have their respiratory function measured before beginning the weaning process compared with patients receiving physician-directed weaning (59.2% compared with 37.6%; p < .001). The two treatment groups were similar with respect to measures of respiratory function, the modes of mechanical ventilation employed for acute patient management before beginning the weaning process, and the strategies used for weaning patients from mechanical ventilation (p >or=to .174) (Table 2).

Variable	Protocol-Directed Weaning (n = 179)	Physician-Directed Weaning (n = 178)	*p* Value
Pao_2/Fio_2 ratio	273 ± 131[a]	272 ± 124	.854
Maximum inspiratory pressure ($cm H_2O$)	43.6 ± 15.4 [106][b]	40.9 ± 12.9 [67]	.452
Tidal volume (mL)	422 ± 207 [103]	442 ± 165 [65]	.174
Respiratory frequency (breaths/min)	22.0 ± 8.5 [104]	21.0 ± 4.8 [67]	.986
Mode of Mechanical Ventilation[c], n (%)			
Intermittent mandatory	45 (25.1)	48 (27.0)	.208
Pressure-support	56 (31.3)	41 (23.0)	
Assist-control	78 (43.6)	89 (50.0)	
Weaning Strategy[d], n (%)			
Intermittent mandatory ventilation	48 (30.6)	55 (35.7)	.389
Pressure-support ventilation	70 (44.6)	57 (37.0)	
Spontaneous breathing trials	39 (24.8) [157]	42 (27.3) [154]	

[a]Mean ± SD; [b]numbers in brackets represent number of patients for which data were available; [c]mode of mechanical ventilation used during acute patient management before beginning the weaning process; [d]represents patients who underwent active attempts at weaning from mechanical ventilation using the described weaning strategy.

Table 2. Respiratory function and ventilator strategies

Twenty-two (12.3%) patients in the protocol-directed weaning group and 24 (13.5%) patients in the physician-directed weaning group did not undergo any active weaning attempts due to their medical condition (p = .737). These patients all died while receiving mechanical ventilation. Thirteen (7.3%) patients randomized to the protocol-directed group had attending physician interference with their weaning process. In six of these patients, attending physician orders delayed weaning and extubation; in the remaining seven patients, attending physician orders resulted in earlier weaning and extubation times than was expected under the weaning protocols.

Duration of Mechanical Ventilation.

The average duration of mechanical ventilation for the entire study population was 85.6 +/-

148.8 hrs. The duration of mechanical ventilation before the start of weaning was significantly ($p = .016$) less among patients receiving protocol-directed weaning compared with physician-directed weaning (Table 3). In the group assigned to receive protocol-directed weaning, the mean duration of mechanical ventilation was significantly ($p = .029$) shorter compared with patients assigned to receive physician-directed weaning (Table 3). This difference in the duration of mechanical ventilation between the two treatment groups was primarily accounted for by two of the four participating ICUs (Table 4). Severity of illness, as assessed by APACHE II scores, was significantly lower in the protocol-directed weaning group of ICU 2 compared with the physician-directed weaning group (observed difference in APACHE II scores between the treatment groups in ICU 2 was -1.8 [95% confidence interval, -3.4 to -0.2]). No significant differences were found for APACHE II scores between the treatment groups in the other three ICUs ($p > .10$) (Table 4).

Outcome	Protocol-Directed Weaning (n = 179)	Physician-Directed Weaning (n = 178)	Observed Difference Between Groups (95% CI)[a]	p Value
Duration of MV before start of weaning (hr)	39.6 ± 81.7[b] [17][c]	58.3 ± 101.1 [22]	−18.7 (−40.2 to 2.8)	.016
Duration of MV (hr)	69.4 ± 123.7 [28]	102.0 ± 169.1 [35]	−32.6 (−63.4 to −1.8)	.029
Requiring MV for >7 days, n (%)	21 (11.7)	31 (17.4)	−5.7 (−13.0 to 1.6)	.128
Required reintubation, n (%)	23 (12.8)	18 (10.1)	2.7 (−4.0 to 9.4)	.417
Hospital mortality, n (%)	40 (22.3)	42 (23.6)	−1.3 (−10.1 to 7.5)	.779
Hospital length of stay (days)	12.7 ± 9.4 [11]	14.2 ± 11.7 [11]	−1.5 (−3.7 to 0.7)	.517

CI, confidence interval; MV, mechanical ventilation.
[a]Values are given as observed differences in population means or observed differences in percentages; [b]mean ± SD; [c]numbers in brackets represent median values.

Table 3. Outcome measures

ICU No.	Patient Population	Protocol-Directed Weaning (n = 179) No. of Patients	APACHE II Score	Duration of MV	Physician-Directed Weaning (n = 178) No. of Patients	APACHE II Score	Duration of MV	p Value[a]
1	Medical	51	19.2 ± 6.0[b]	73.3 ± 83.0 [48][c]	55	18.6 ± 6.3	107.2 ± 180.9 [44]	.582
2	Surgical[d]	76	13.6 ± 5.3	68.9 ± 164.8 [17.5]	68	15.4 ± 4.5	105.2 ± 200.8 [22.5]	.019
3	Medical	32	19.3 ± 4.8	77.1 ± 89.5 [35]	39	20.9 ± 4.9	114.3 ± 113.8 [65]	.062
4	Surgical	20	15.0 ± 3.8	48.7 ± 66.3 [28]	16	16.9 ± 3.5	40.8 ± 45.6 [26]	.799

No., number; APACHE, Acute Physiology and Chronic Health Evaluation.
[a]Comparing durations of mechanical ventilation between treatment groups, using Wilcoxon's rank sum test; [b]mean ± SD; [c]numbers in brackets represent median values; [d]$p = .027$, comparing APACHE II scores between treatment groups in ICU 2 ($p > .10$ for comparison of APACHE II scores in all other ICUs).

Table 4. Duration of mechanical ventilation (MV) according to the participating intensive care units (ICUs)

Kaplan-Meier plots of the probability of successful weaning over time for each treatment group are shown in Figure 1. The median duration of mechanical ventilation was 35 hrs for patients receiving protocol-directed weaning (first quartile 15 hrs; third quartile 114 hrs; 22.3% censored) compared with 44 hrs for patients receiving physician-directed weaning (first quartile 21 hrs; third quartile 209 hrs; 23.6% censored). Statistical tests suggest that the survival functions are different between the two treatment groups, favoring a shorter duration of mechanical ventilation for the protocol-directed patients (chi squared = 3.62, p = .057, log-rank test; chi squared = 5.12, p = .024, Wilcoxon test).

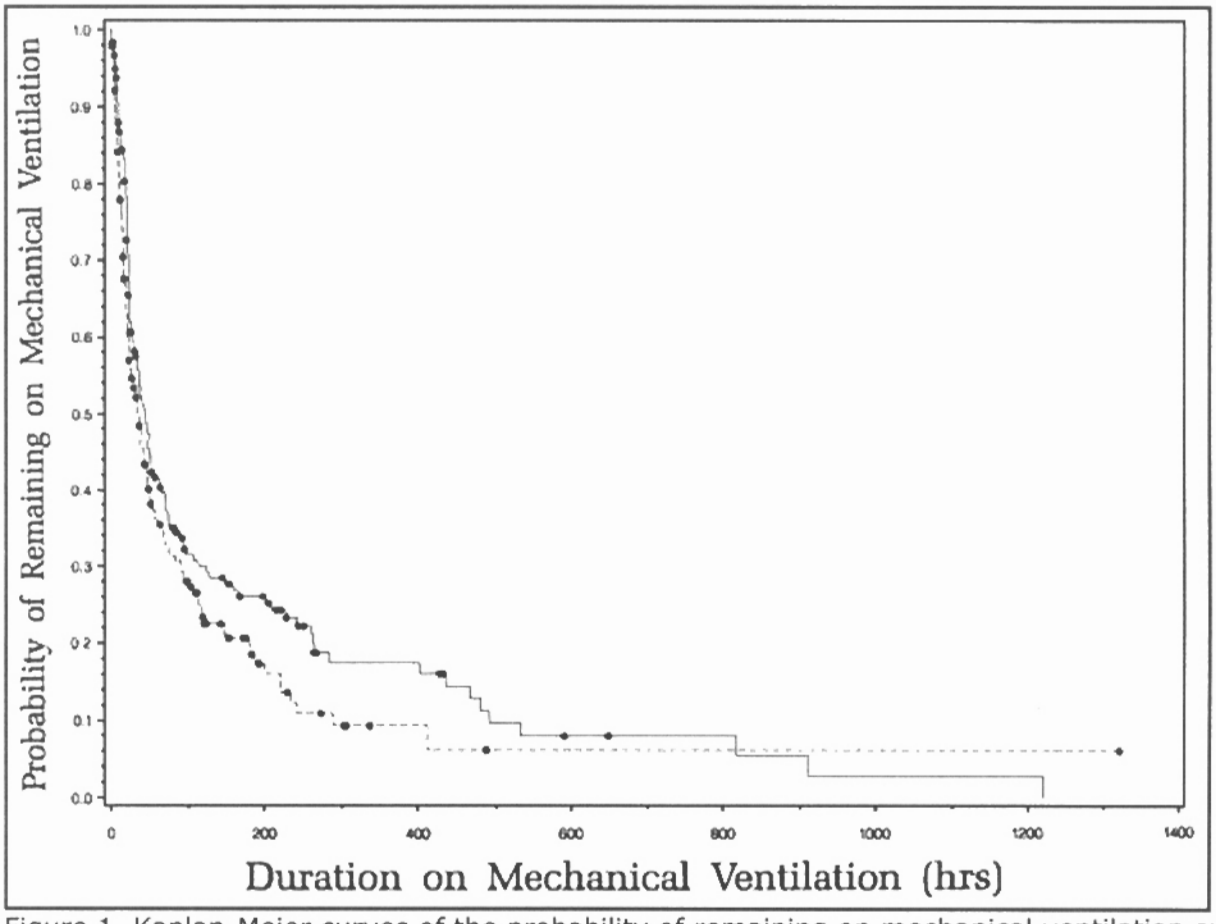

Figure 1. Kaplan-Meier curves of the probability of remaining on mechanical ventilation over time between patients receiving protocol-directed weaning (dashed line) and physician-directed weaning (solid line). Censored cases are shown by solid circles.

Cox proportional-hazards regression analysis identified five factors that independently predicted the duration of mechanical ventilation before successful weaning (Table 5). The adjusted rate of successful weaning was statistically higher with protocol-directed weaning than with physician-directed weaning (risk ratio 1.31; 95% confidence interval 1.15 to 1.50; p = .039). We tested the validity of the proportional-hazards assumption and found no evidence of an increasing or decreasing trend over time in the hazard ratio [12,13].

Variable	Risk Ratio of Successful Weaning	95% CI	p Value
Protocol-directed vs. physician-directed weaning	1.31	1.15 to 1.50	.039
Gender (male vs. female)	1.30	1.14 to 1.48	.043
APACHE II score (5-point increments)	0.71	0.66 to 0.77	<.001
Organ System Failure Index (one-organ increments)	0.60	0.55 to 0.65	<.001
Presence of ARDS	0.25	0.18 to 0.36	<.001

CI, confidence interval; APACHE, Acute Physiology and Chronic Health Evaluation; ARDS, acute respiratory distress syndrome.

Table 5. Independent predictors of duration of mechanical ventilation using Cox proportional-hazards regression analysis

Secondary Outcomes.

No statistically significant differences were found between the treatment groups for any of the secondary outcomes examined (Table 3). One patient randomized to each treatment group required nocturnal ventilation at the time of hospital discharge. The hospital costs for patients in the physician-directed group were not statistically different from the hospital costs for patients in the protocol-directed group ($27,680 +/- 26,823 vs. $27,439 +/- 25,873; p = .932). Hospital cost savings for patients in the protocol-directed group were $42,960 compared with hospital costs for patients in the physician-directed group.

DISCUSSION

This study is unique in employing a randomized, controlled study design to examine the effect of weaning protocols on the duration of mechanical ventilation. We found that nurses and respiratory therapists, using protocol guidance, weaned patients from mechanical ventilation safely and more quickly than the team following the traditional practice of physician-directed weaning. Our data suggest that the reduction in the duration of mechanical ventilation, for patients in the protocol-directed group, was due to both initiating the weaning process earlier and shortening its duration (Table 3). Although the hospital length of stay, total hospital costs, and hospital mortality rate were lower and the need for reintubation was higher in the group receiving protocol-directed weaning, none of these differences reached statistical significance (p >or=to .417). Finally, this study demonstrated a total savings of $42,960 in hospital costs for patients in the protocol-directed group compared with patients in the physician-directed group during the 4-month study period.

Shortening the duration of mechanical ventilation represents an important quality of life outcome due to patient discomfort associated with the administration of this form of treatment. Additionally, the associated reduction in hospital costs is an important issue for both patients and their medical care payers. Protocols for the administration of medical therapies are increasingly being used in the ICU setting. Our results support the conclusions of other investigators who have

suggested that nurses and respiratory therapists, using protocol guidelines, can safely and effectively participate in the weaning of mechanical ventilation [14-17]. Similarly, nursing-implemented protocols have been shown to be an effective method for weaning potentially toxic levels of oxygen from patients requiring mechanical ventilation [18]. Nonphysicians are increasingly being employed to administer and oversee medical therapies and procedures traditionally performed by physicians in critically ill patients [19-21].

The importance of nonphysician participation in the weaning process is emphasized by a study [22] describing the influence of protocol-guided nursing care on the outcomes of patients requiring mechanical ventilation. These authors [22] demonstrated that below a specific threshold, describing the available work force of nurses relative to the number of patients and severity of illness of patients, the duration of weaning and mechanical ventilation markedly increased, despite using a weaning protocol. Subsequently, increasing the number of nurses, to a predetermined level based on patient characteristics, significantly decreased the duration of mechanical ventilation [22]. Other investigators [23] have suggested that protocol-guided mechanical ventilation and weaning for patients with ARDS, carried out by physicians and nonphysicians, has improved patient survival compared with traditional physician-directed management. Therefore, the available data suggest that not only are nurses and respiratory therapists able to wean patients from mechanical ventilation using protocols, but their participation seems essential for this process to occur in a timely manner [14,18,22,23].

An additional observation of this investigation was that variability existed among the participating ICUs in terms of the success of the weaning protocols. The use of a weaning protocol seemed to have the least effect in ICU 4, which lacked a full-time medical director and critical care fellows. This finding suggests that differences in the structure and process of medical care may have existed among these units, in addition to differences in the weaning protocols themselves, which could have accounted for this variability [24]. Potential differences among the study units, accounting for their variable responses to the use of weaning protocols, include the following factors: a) the training and experience of physicians and nonphysicians in weaning patients from mechanical ventilation; b) the supervision of the various staffs; and c) the flexibility with which adjustments in medical personnel could be made in response to changes in patient numbers and severity of illness. Historically, physicians in ICU 4 have delegated much of the weaning function to the nursing staff. This fact may have accounted for the lack of influence of a weaning protocol on the duration of mechanical ventilation between the study groups of that unit.

Much controversy exists concerning the best weaning strategy [3,4]. Although our study was not designed to address this issue, the variable weaning strategies we employed allowed interunit comparisons to be made among the ICUs. We observed no significant differences in the duration of mechanical ventilation between the protocol-directed patients in the two medical ICUs using either spontaneous breathing trials (ICU 1) or intermittent mandatory ventilation (ICU 3) as their primary strategy for weaning (73.3 +/- 83.0 vs. 77.1 +/- 89.5 hrs; p = .705). Similarly, there was no significant difference in the duration of mechanical ventilation between the protocol-directed patients in the two surgical ICUs employing either pressure support ventilation (ICU 2) or spontaneous breathing trials (ICU 4) (68.9 +/- 164.8 vs. 48.7 +/- 66.3 hrs; p = .708). These data, along with the discrepant results of recent randomized, controlled trials [5,6], suggest that

the method in which weaning strategies are implemented may be as important, if not more important, than the specific weaning approaches selected for clinical use.

Our study had several limitations. First, it was performed at two hospitals with medical and surgical housestaff training programs. This fact may explain the observed difference in the duration of mechanical ventilation before the start of weaning between the two treatment groups. Nonphysicians using protocol guidance were able to begin the weaning process faster than physicians (i.e., physicians-in-training may prolong the weaning process). Second, different weaning protocols were employed in each of the participating ICUs, making this factor an important potential determinant of weaning success [5,6]. However, we minimized the influence of this variability by stratifying our randomization within each ICU and controlling for both ICU location and the employed weaning strategies in our multivariate analysis (Table 5). Third, we could not absolutely restrict interference with the weaning protocols from the patients' physicians. This approach was necessary to ensure "buy-in" from the attending physicians for the performance of this investigation. Fourth, we did not obtain complete compliance with the weaning protocols. Thus, the observed rate of obtaining weaning parameters was only 60% in the protocol-directed group.

Another important limitation of this study is the possibility of bias on the part of the respiratory therapists and nurses administering patient care, who could not be blinded to the randomization process. It is possible that the respiratory therapists and the nursing staffs of the ICUs wanted to make the protocol-directed patients wean faster than the physician-directed patients. This bias could have influenced the actions of these individuals and may explain our study results. However, to minimize this source of bias, the investigators regularly counseled these patient care staffs in order to emphasize their adherence to the usual practices of care for patients in the physician-directed groups. Additionally, it is possible that the treating physicians were biased in wanting the physician-directed patients to wean faster than the protocol-directed patients. This competitive spirit, among the physicians overseeing the care of these patients, should have negated any bias among the respiratory therapists and nurses favoring the protocol-directed patients.

In summary, we have shown that protocol-directed weaning of mechanical ventilation, performed by nurses and respiratory therapists, is safe and resulted in a shorter duration of mechanical ventilation compared with a traditional practice of physician-directed weaning. The implementation of protocol-directed weaning resulted in the initiation of the weaning process earlier and a more rapid progression of weaning to the point of discontinuation of mechanical ventilation. Focusing the efforts of these healthcare workers enabled improvements in patient outcomes to occur without added costs [25,26]. With the current economic pressures to reduce medical care costs, hospitals can use methods similar to the methods outlined in this study to evaluate new strategies for providing intensive care. The adoption of these methods will help ensure that managed care-type efficiency protocols, which would result in either worse patient outcomes or greater costs, are not imposed as part of routine medical management [22].

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