Protocol-Driven Ventilator Management in a Trauma Intensive Care Unit Population

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Hypothesis: The use of weaning and sedation protocols affects the intensive care unit (ICU) course of a trauma population.

Design: Nonrandomized before-after trial.

Setting: A level I trauma center.

Patients: Three hundred twenty-eight consecutive trauma patients receiving mechanical ventilation treated in the ICU between October 1, 1997, and November 1, 1999.

Intervention: Sedation and weaning protocols were used to treat patients receiving mechanical ventilation during the second year of this study.

Main Outcome Measures: Self-extubation rates, ventilator days, number of ICU days, and charges.

Results: There were 168 patients in the preprotocol group (year 1: October 1, 1997, to October 31, 1998) and 160 patients in the postprotocol group (year 2: November 1, 1998, to November 30, 1999). The groups were similar in age ($P = .68$), Injury Severity Score ($P = .06$), and Glasgow Coma Scale score ($P = .29$). There were no differences in self-extubation rates ($P = .57$), ventilator days ($P = .83$), ventilator charges ($P = .83$), number of ICU days ($P = .67$), or ICU charges ($P = .67$) between the 2 groups. No statistical difference was identified in any of these categories when long-term ventilator patients (defined as ventilator length of stay ≥3 SDs above the mean) were excluded.

Conclusions: Use of weaning and sedation protocols did not affect the measured outcomes in this study. These findings may reflect difficulties inherent in the protocols or with their utilization. Further subgroup analysis focusing on ventilator-associated pneumonias and mortality may demonstrate benefits not identified herein.

Arch Surg. 2002;137:1223-1227
A retrospective review was performed of 328 consecutive ventilated patients admitted to a level I trauma center between October 1, 1997, and November 1, 1999. Patients treated before protocol implementation (year 1: October 1, 1997, to October 31, 1998) were compared with those treated after implementation (year 2: November 1, 1998, to November 30, 1999). The 2 groups were compared regarding age, Injury Severity Score (ISS), and Glasgow Coma Scale score. Self-extubation rates were evaluated using nursing quality assurance documentation. Ventilator days and charges and ICU days and charges were also studied. Ventilator days were chosen as opposed to ventilator-free days because the previous number is objective and independent of the patient’s total number of ICU days. Many patients remain in the ICU awaiting transfer out of ICU, and this may bias the data. Cost data were extrapolated from cost-rates ratios available in the hospital system.

The findings were analyzed to ensure demographic similarity between the groups. The data were then evaluated to find differences in outcomes between the groups. Subgroup analysis was performed in which patients with ventilator lengths of stay greater than or equal to 3 SDs above the mean ventilator length of stay were excluded. These patients were defined as long-term ventilator patients for the purpose of this study and were removed in an attempt to differentiate them from the more short-term ventilator patients.

Compliance with the sedation protocol was determined by the charge nurse, and compliance with the weaning protocol was determined by the respiratory therapist overseeing the unit. These 2 people remained the same for the duration of the study. Compliance with the sedation protocol was determined based on the completeness of documentation and the appropriate correlation between the patient’s level of sedation and medication selection. The respiratory therapist followed the ventilator forms that were maintained on all patients in the ICU, ensured the accuracy of these forms, and supervised the remaining therapists to facilitate patients undergoing trials at the appropriate time and for the appropriate duration. The compliance for both protocols was then calculated as a percentage per month.

**SEDATION PROTOCOL**

This protocol was implemented on all mechanically ventilated patients managed in the Burn Trauma Unit. The medication dosage was titrated to a 7-point agitation scale, with +3 representing severe agitation and −3 representing deep sedation (Table 1). The nursing staff documented the sedation level every 4 hours and adjusted the medications appropriately to maintain a sedation level between 0 and −1. Documentation increased to every 2 hours if significant changes in medications or dosages were required.

Five medications were available for use with the protocol. Morphine sulfate (Wyeth Ayerst, Philadelphia, Pa) was the primary analgesic because of its efficacy and low cost. Lorazepam (Ativan; Wyeth Ayerst) was the most commonly used sedative. Other options included fentanyl citrate (Elkins-Sinn, Cherry Hill, NJ), midazolam hydrochloride (Versed; Roche, Nutley, NJ), and propofol (Diprivan; Astra Zeneca, Wilmington, Del). The latter 3 drugs were used when the patient was expected to be extubated quickly, so a shorter-acting medication was preferred, or when the former drugs were not effective. Drug selection was also modified by patient allergies. Standard dosages were used and titrated to the desired sedation level (Table 2). Daily sedation holidays were not performed.

**PREPROTOCOL SEDATION MANAGEMENT**

Before use of the sedation protocol, the only sedation goals were to make the patient comfortable and compliant. No scale was used to determine adequacy of sedation, so no standard sedation/agitation level was documented. The appropriateness of sedation was left up to the nurse and physician caring for the patient. Medications similar to those used in the protocol were used. More interactions between the nursing staff and the physicians were required because standard titrations of medications were not as commonplace.

**WEANING PROTOCOL**

There were 2 phases to the pressure support weaning protocol. The rapid wean phase lasted approximately 20 minutes and was used on patients expected to extubate within 6 hours. This phase allowed the respiratory therapist to rapidly decrease the ventilator rate to zero and to set a pressure support designated as minimal, which was usually 5 to 8 cm H2O. Minimal pres-
sure support was chosen based on endotracheal or tracheostomy tube size and was defined as the pressure support necessary to overcome the resistance contributed by the tube. Once this part of the protocol was reached, weaning criteria were assessed and arterial blood gas values were obtained. Optimal extubation criteria included arterial oxygen saturation of 92% or greater, arterial carbon dioxide tension of 50 mm Hg or less, respiratory rate less than 30/min, systolic blood pressure maintained within 10 mm Hg of the baseline value, negative inspiratory force of 25 cm H2O or greater, and tidal volume greater than 400 mL for an average-sized adult. Failure to maintain these values resulted in termination of the wean. If the patient met these criteria, extubation ensued. The physician was notified before extubation only if he or she requested to be notified or if the values were marginal.

The extended weaning protocol allowed for twice-a-day work trials in which the pressure support was weaned by 2 cm H2O pressure to a maximum of 5 cm H2O per trial. The patient was worked for 2 hours on lower settings and then reset to the previous higher pressure support level to rest until the next trial. If the patient developed a respiratory rate greater than 30/min for longer than 5 minutes or a drop in arterial saturations or tidal volume such that adequate values as previously described were not maintained, the work trial was stopped. The ventilator was returned to the previous settings, and the patient rested until the next scheduled work trial in 12 hours. Once the ventilator settings had been minimized and maintained for 2 work trials of 2 hours each, the trial was extended to 4 hours. If the patient remained at a sedation level of zero, the criteria were assessed and arterial blood gas values were obtained. If the patient was not extubated, longer work trials occurred at lengths of 6 and 8 hours until the patient was strong enough to be extubated based on repeated measurements. Extubation could occur any time during the 24 hours once the patient met the criteria.

PREPROTOCOL WEANING MANAGEMENT

Before the weaning protocol, most patients were treated with a volume-driven ventilation mode. Patients with noncompliant lungs were occasionally treated with pressure control ventilation. Work trials were instituted after patients were weaned down on the rate with no change in pressure and with continued volume-driven cycles. The patient’s wean was affected by any of 7 full-time faculty members, 8 chief residents, and approximately 100 residents who rotated through the unit during the preprotocol study. The physicians had a more active role in determining the timing of extubation. The same extubation criteria as described in the previous subsection were used, but the measurements were usually obtained in the morning so that extubation could occur during morning rounds.

STATISTICAL ANALYSIS

Statistical analysis was performed using $\chi^2$ and paired t tests. Self-extubation data were evaluated using the Fisher exact test. Data are given as mean ± SD.

RESULTS

Three hundred twenty-eight patients (78 women and 250 men) were included in the study: 168 in the preprotocol group and 160 in the postprotocol group. Forty-one women and 127 men were treated before institution of the protocols and 37 women and 123 men were treated after institution of the protocols. There was no difference in the sex distribution between the 2 groups ($P = .93$).

Both groups experienced similar causes for their injuries. The most common mechanisms of injury were motor vehicle crashes (44%) and gunshot wounds (20%), followed by burns (9%), automobile/pedestrian accidents (8%), falls (7%), stabs (7%), assaults (4%), crush injuries (1%), and jet-ski accidents (<1%).

Patient demographic comparisons demonstrated no statistically significant difference in age in the preprotocol group vs the postprotocol group (39.6 ± 19.7 vs 38.7 ± 18.0 years; $P = .86$). The Glasgow Coma Scale score was 11.8 ± 8.8 for the preprotocol group and 11.2 ± 4.5 for the postprotocol group ($P = .29$). The 2 groups were also similar in ISS (preprotocol group: 18.1 ± 9.6; postprotocol group: 20.4 ± 11.4; $P = .06$).

The number of ventilator days was 6.3 ± 10.1 in the preprotocol group and 6.1 ± 9.1 in the postprotocol group ($P = .83$). The number of ICU days was 9.0 ± 13.2 in the preprotocol and 9.6 ± 12.2 in the postprotocol group ($P = .67$) (Table 3). Self-extubation rates were also similar: 6 patients in the preprotocol group and 4 in the postprotocol group (Fisher exact test).

There did not seem to be any charge savings with institution of the protocols. The ventilator charge in the preprotocol group was $1523 ± 2421$ and in the postprotocol group was $1467 ± 2190$ ($P = .83$). The ICU charge was $156900 ± 230400$ in the preprotocol group and $167600 ± 212000$ in the postprotocol group ($P = .67$) (Table 3).

Long-term ventilator patients were defined as those whose ventilator length of stay was 3 SDs or greater above the mean of the study group. These patients were excluded from both years for the subgroup analysis. Based on these criteria, 12 patients were excluded, leaving 316 patients in the study population (162 in the preprotocol group and 154 in the postprotocol group). This analysis included 74 women (38 in the preprotocol group and 36 in the postprotocol group) and 242 men (124 in the preprotocol group and 118 in the postprotocol group). There was no statistical difference in sex distribution ($P = .86$).

Patient demographic comparisons revealed no differences in the subgroup populations. The age of the preprotocol group was 40.13 ± 18.9 years and of the postprotocol group was 39.14 ± 18.21 years ($P = .64$). The ISS for the preprotocol group was 17.93 ± 9.62 and for the postprotocol group was 20.04 ± 11.31 ($P = .09$). The Glasgow Coma Scale scores for the preprotocol and postprotocol groups were 11.78 ± 4.74 and 11.34 ± 4.43, respectively ($P = .41$).

Patient outcomes did not differ between the subgroups. The number of ventilator days in the preproto-

<table>
<thead>
<tr>
<th>Table 3. Patient Outcomes*</th>
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<tbody>
<tr>
<td>Outcome</td>
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<tr>
<td>Ventilator days, No.</td>
</tr>
<tr>
<td>Ventilator charge, $</td>
</tr>
<tr>
<td>ICU days, No.</td>
</tr>
<tr>
<td>ICU charge, $</td>
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</tbody>
</table>

*Data are given as mean ± SD. ICU indicates intensive care unit.
col and postprotocol groups was 4.93 ± 6.96 and 4.94 ± 6.35, respectively \( (P = .98) \). The ICU stay for the preprotocol and postprotocol groups was 7.74 ± 11.26 and 8.61 ± 10.04 days, respectively \( (P = .48) \) (Table 4).

Self-extubation rates decreased by half with institution of the protocols (6 patients in the preprotocol group and 3 in the postprotocol group) \( (P = .32 \) by Fisher exact test).

Charges were also similar between the subgroups. Ventilator charges were $1184.16 ± $1669.69 for the preprotocol group and $1187.76 ± $1524.30 for the postprotocol group \( (P = .98) \). The overall ICU charges were $13481.59 ± $19605.49 for the preprotocol group and $14995.81 ± $17471.57 for the postprotocol group \( (P = .48) \) (Table 4).

Compliance in the sedation protocol ranged from 82% to 100%, with 1 outlier at 75%, and in the weaning protocol from 85% to 100%, with 1 outlier at 50% (Table 5).

A power analysis was performed to exclude the possibility of a type II error given the fact that no differences were seen in ventilator dependence or ICU length of stay. Brochard et al\(^3\) demonstrated a decrease in the weaning period from 9.3 days for intermittent mandatory ventilation and T-piece trials (trials of unsupported spontaneous ventilation in which humidified gas was supplied via a T piece connected to the endotracheal tube) to 5.7 days for pressure support trials. This difference represented a statistically significant 39% decrease in the weaning period. Based on the findings of Brochard et al\(^3\), we used an effect size of 0.39 with a standard deviation of 0.05. The sample size of 328 patients provided a power of 0.97.\(^6\)

### Table 4. Patient Outcomes in Subgroup Analysis*

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Year 1 (Preprotocol)</th>
<th>Year 2 (Postprotocol)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilator days, No.</td>
<td>4.93 ± 6.96</td>
<td>4.94 ± 6.35</td>
<td>.98</td>
</tr>
<tr>
<td>Ventilator charge, $</td>
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<td>$1187.76 ± $1524.30</td>
<td>.98</td>
</tr>
<tr>
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<td></td>
</tr>
</tbody>
</table>

*Data are given as mean ± SD. ICU indicates intensive care unit.

### Table 5. Patient Compliance With the Protocols

<table>
<thead>
<tr>
<th>Month</th>
<th>Sedation Protocol</th>
<th>Weaning Protocol</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 1998</td>
<td>90</td>
<td>94</td>
<td>92</td>
</tr>
<tr>
<td>December 1998</td>
<td>87</td>
<td>85</td>
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<td>January 1999</td>
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<tr>
<td>February 1999</td>
<td>97</td>
<td>94</td>
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<tr>
<td>March 1999</td>
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<td>April 1999</td>
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<td>May 1999</td>
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<td>June 1999</td>
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<td>August 1999</td>
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<tr>
<td>September 1999</td>
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<td>October 1999</td>
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<td>98</td>
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</tr>
<tr>
<td>November 1999</td>
<td>95</td>
<td>100</td>
<td>98</td>
</tr>
<tr>
<td>Average</td>
<td>91</td>
<td>90</td>
<td>91</td>
</tr>
</tbody>
</table>

Protocol utilization is becoming more common in the ICU. The purpose of these protocols is to facilitate care by standardizing ICU management. The goal is to decrease ventilator requirements and complications, ICU complications, and ICU length of stay. Two of the primary protocols are for sedation and weaning.

The sedation protocol is designed to improve patient pain control and to limit agitation and anxiety.\(^7\) Adequate sedation is essential to the care of a patient receiving ventilation. Not only is it important for patients to be comfortable to sufficiently oxygenate and ventilate, but strict control of sedation allows for ease of reversal. Multiple medication combinations have been studied to identify the most efficacious protocol. A task force of 40 experts in areas related to the use of analgesic and sedative agents in the ICU determined that morphine was the analgesic of choice.\(^8\) This recommendation was based on the extensive experience with its use and on its predictability and low cost. Studies\(^9\) comparing lorazepam with other sedatives concluded that lorazepam was preferable because it was inexpensive and efficacious. These 2 drugs were the primary medications used in our protocols. Strict titration guidelines allowed the nursing staff to adjust dosages based on sedation levels without requiring constant input from a physician.

The goal of a weaning protocol is to expedite extubation without increasing reintubation rates.\(^10,11\) Protocol options include intermittent mandatory ventilation weans, pressure support weans, and spontaneous respiration trials. Esteban et al\(^10\) and Ely et al\(^11\) studied the mode of weaning and found that the spontaneous breathing trial was the most efficient. Brochard et al\(^9\) performed a similar study and had the best results with a pressure support protocol. Volume-based weaning had consistently poorer results. Ely et al\(^11\) evaluated respiratory therapist-driven weaning protocols and found them to be a feasible method to increase the efficiency of the weaning process by eliminating the need for physician input at each step of the wean.

A pressure support protocol was used in this study, with respiratory therapists assisting in the surveillance of patient progress. Unless the patient was having difficulties on the ventilator, the interaction between the respiratory therapist and the physician was limited to daily rounds.

Self-extubation is a potentially lethal complication associated with mechanical ventilation. Boulin\(^12\) prospectively evaluated risk factors and complications of unplanned extubations and found that these events were not uncommon. Agitation was present in 61% of patients who self-extubated, and 39% of patients did not have to be reintubated. These findings suggest that more aggressive weaning policies may decrease the incidence of self-extubation, since 18 of 46 patients were able to remain unventilated. Mort\(^13\) further emphasized the gravity of this problem in a quality improvement audit. He found that 72% of patients who self-extubated had hemodynamic

### COMMENT

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changes and airway-related complications. One patient died secondary to an inability to reestablish an airway.

Unplanned extubations were examined because of the seriousness of this problem. We intended to identify risk factors and associated complications of self-extubation, but the small sample size prevented meaningful results. Only a small percentage of patients who self-extubated were identified before and after institution of the protocols. Although there was a decrease in the number of self-extubations after the protocols were initiated, it did not reach statistical significance because the total number of patients in this group was 10. These data were generated from quality assurance reports, which may have resulted in an underestimation because the staff had to self-report the errors that resulted in the inadvertent extubation.

No improvements were demonstrated in any area evaluated. One explanation for these results is that the protocols do not work. This ICU may already have had efficient ventilator management, so use of these protocols did not add substantially to patient care. Ely et al\(^1\) compared a protocol group and a nonprotocol control group. They demonstrated a significant decrease in ventilator length of stay by 2 days, but they used a spontaneous respiration protocol that was not used by the ICU in this study. Our pressure support weaning protocol was similar to that of Brochard et al,\(^3\) who found this method to be more effective. If another weaning method was used, such as spontaneous respiration trials,\(^10\) better results might have been realized. Differences between the groups may have been demonstrated by altering the medications used, although these drugs were selected based on literature support. Another possible explanation is that a combination of learning curve and compliance may have prevented us from experiencing improvements seen in other series. Although our staff was adequately trained in the use of the protocols, compliance mostly ranged from 85% to 95% during the first year of its use. A significant decrease in compliance was seen in August, which may be secondary to new residents. It is possible that improvements in protocol compliance may result in better outcomes. It is also not clear what impact, if any, the protocols had on each other. We believed that it was important to include both protocols since they were initiated at the same time, but the study's design did not allow for correlations between each protocol and outcome. A more sophisticated analysis may clarify the role and possible advantages of each protocol on a patient's ICU course. Further subgroup analysis may identify advantages to protocol use not seen in this study, such as decreased ventilator-associated pneumonia, morbidity, and mortality rates and increased physician satisfaction.

No improvements in specific areas of ICU outcomes were shown despite having adequate power to determine differences in ventilator length of stay. However, optimism regarding the use of protocols should be maintained. Protocols have not been found to interfere with resident education since these physicians are still learning principles of ventilator management in addition to contemporary protocol practice. Physicians are satisfied with their use primarily because they have more time to devote to other aspects of patient management. Before eliminating protocols from the ICU based on discouraging results, there should be continued research into their implementation and execution. Although not specifically studied, the institution of these protocols was not difficult. Therefore, continued use of these protocols is recommended to allow further evaluation of outcomes that may demonstrate benefits not identified in this study.

Accepted for publication March 9, 2002.

This study was presented at the American College of Surgeons Surgical Forum, Chicago, Ill, October 11, 2000.

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