

Outcomes in Post-ICU Mechanical Ventilation*

A Therapist-Implemented Weaning Protocol

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Background: Therapist-implemented protocols have been used to extubate or wean patients in the ICU setting. Barlow Respiratory Hospital (BRH) functions as a center for weaning patients from prolonged mechanical ventilation (PMV) in the post-ICU setting of a long-term acute-care (LTAC) facility. A therapist-implemented patient-specific (TIPS) weaning protocol was developed at BRH to standardize weaning from PMV.

Study design: Prospective cohort study with historical control.

Methods: A weaning protocol incorporating the procedures and pace of LTAC weaning was developed using available scientific evidence and expert consensus. After training of staff, collection and analysis of pilot data, and revisions and refinement of the protocol, the TIPS protocol was implemented hospital-wide. It was monitored for outcome, variance, and respiratory care practitioner (RCP) and physician compliance.

Results: Forty-six RCPs worked with eight pulmonologists treating 271 consecutive patients admitted for weaning from PMV during an 18-month period. Nineteen patients were excluded from weaning attempts by any method after initial physician evaluation. The remaining 252 patients (9,135 total ventilator days) were compared with a group of 238 patients treated by the same physicians in the 2 years before instituting protocol weaning. Median time to wean declined significantly from 29 days in historical control subjects to 17 days for TIPS protocol patients ($p < 0.001$). Outcomes (scored at discharge) were comparable for the two groups (TIPS group vs control group): weaned, 54.7% vs 58.4%; ventilator-dependent, 17.9% vs 10.9%; died, 27.4% vs 30.7% ($p = 0.10$). Variances incurred by physicians and RCPs were 324 and 136, respectively, for the 9,135 ventilator days.

Conclusions: Patients weaned from PMV using a new therapist-implemented protocol at BRH, an LTAC facility specializing in weaning, had significantly shorter time to weaning than historical control subjects, with comparable outcomes. The weaning outcome data collected after the implementation of the TIPS protocol are in fact attributable to its use, as we found a high degree of compliance with the protocol. (CHEST 2001; 119:236-242)

Key words: compliance; long-term acute care; outcome; prolonged mechanical ventilation; protocol; respiratory care practitioner; therapist-implemented; time to wean; variance; weaning

Abbreviations: ABG = arterial blood gas; APACHE = acute physiology and chronic health evaluation; BRH = Barlow Respiratory Hospital; DE = daily evaluation; LOS = length of stay; LTAC = long-term acute care; PMV = prolonged mechanical ventilation; PSV = pressure-support ventilation; RCP = respiratory care practitioner; RSBI = rapid shallow breathing index; SBT = self-breathing trial; SIMV = synchronized intermittent mandatory ventilation; TIPS = therapist-implemented patient-specific; WA = weaning assessment

Therapist-implemented protocols have been used to extubate patients or wean patients, as appropriate, in the ICU setting. Two recent randomized, controlled trials have shown that the time to both

outcomes for patients can be safely shortened by the use of such protocols.^{1,2} Barlow Respiratory Hospital (BRH), a 49-bed long-term acute-care (LTAC) facility, has functioned as a center for weaning patients

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from prolonged mechanical ventilation (PMV). With PMV defined as > 21 days of ventilator dependency, BRH has reported 56% weaning success in 1,123 patients during an 8-year period.³ Weaning was

physician-ordered on a daily, or as needed, basis while outcome data were accumulated. During the 2 years after that report, a therapist-implemented patient-specific (TIPS) weaning protocol was developed and put into practice. Compliance with TIPS, and the outcome of use of the protocol in weaning patients from PMV is herein reported.

MATERIALS AND METHODS

Patients who were ventilator-dependent and transferred to BRH for attempted weaning from PMV were eligible for entry into the protocol. The TIPS protocol was therefore designed and then codified to use the modes of weaning and the steps of withdrawing ventilator support that had been used with safety and good outcomes during the prior decade. The protocol comprises 19 steps, in which the patient moves one step each day from full ventilator support to 24 h of spontaneous, unassisted breathing (Fig 1). This can be summarized as gradual reduction in support components to approximately "half-ventilator-supported," first reducing synchronized intermittent mandatory ventilation (SIMV), and then reducing pressure-support ventilation (PSV). At this level of half-support, self-breathing trials (SBT) with a Venturi tracheostomy mask were begun, gradually increasing in duration, returning the patient to the half-supported ventilator level between the SBT. Finally, 24 h of SBTs would end weaning efforts by protocol, with the patient liberated from ventilatory support. Failure to wean was a physician-directed decision in both the TIPS protocol patients and historical control subjects. Outcome (weaned, ventilator-dependent, or died) was scored as in the historical control period, at discharge from BRH.

A physician's order, written after admission evaluation by one of our pulmonologists, would allow a patient to begin the TIPS protocol. Note that the ratio of respiratory care practitioners (RCPs) to ventilator patients, one to seven, was not modified when the protocol was implemented. Objective screens applied daily by the RCPs assessed patients for readiness and tolerance to decrease ventilator support. The first screen to measure general stability and safety was called the daily evaluation (DE), and the screen for baseline tolerance of the level of respiratory support and then its reduction was called the weaning assessment (WA). Cutoff points used in these screens were commonly accepted values, and these are similar to cutoff points used in large multicenter ICU weaning trials.^{4,5} If patients passed the screens, ventilator support was withdrawn by the RCP in steps that again simulated the gradual pace that was used in our physician-directed weaning. When there was intolerance of reduction of ventilator support, the RCP increased support stepwise, until patient distress was relieved.

To give patients the opportunity to progress in weaning as fast as possible, three "acceleration" steps were incorporated into the protocol. At each of the following steps, a patient could progress faster than one step daily: (1) allowed reduction of SIMV to its lowest level in one step, if PSV breaths were adequate in volume (TIPS footnote "c"); (2) the rapid shallow breathing index (RSBI) measurement, if ≤ 80 (before step 1), allowed moving directly to the first SBT; and (3) a patient tolerating any of the SBTs was allowed to extend the trial through the duration of the next step (TIPS footnote "e").

During an 8-month pilot period, the protocol was introduced with both formal and informal education of RCPs, physicians, nurses, and other caregivers. A "frequently asked questions" file was created to make consistent responses readily available. Experienced senior RCPs (lead RCPs) met each weekday morn-

ing with the investigators to allow for problem solving and provide feedback for protocol revision. During the subsequent 18 months of protocol use, the following procedure was used to collect data and as an audit tool to measure compliance: The patient's RCP documented the results of the screens (DE and WA) on the patient's respiratory care flow sheet, the subsequent action taken, and its outcome. An investigator made rounds with the lead RCP daily to be sure that all data were recorded accurately; the lead RCP transferred this information to a data collection form. The database created was analyzed to score patients' weaning progress and variances from the protocol by physicians and RCPs, creating a weaning history for each patient. TIPS protocol outcome monitors were adopted by the hospital Organization Performance Review Committee and routinely reviewed. Statistical tests used to compare TIPS patients and those of the 2-year historical control included the following: χ^2 test for weaning outcomes; Mann-Whitney test of two independent groups for comparison of age, acute physiology score of the acute physiology and chronic health evaluation (APACHE) III, prior ventilator time in the ICU, and length of stay (LOS) and time to wean at BRH. Median values are reported.

RESULTS

Consecutively, 271 ventilator-dependent patients were transferred to BRH between April 1998 and September 1999 with the potential for entry into the TIPS protocol. Nineteen patients were excluded after initial physician evaluation determined that no withdrawal of ventilator support should be attempted by any method. One patient had advanced amyotrophic lateral sclerosis; one had severe Becker's muscular dystrophy. Fourteen were too medically unstable on admission to consider weaning; of these, 11 died and 3 were transferred to other acute-care facilities for surgical intervention and died subsequently. Finally, three patients would have qualified for TIPS, but were not enrolled, as the attending physicians ordered SBTs rather than TIPS on admission.

Protocol Outcome

Two hundred fifty-two patients entered the protocol, incurring a total of 9,135 ventilator days. The individual patients' weaning histories, and the medical records of all patients who died were reviewed, with no evidence found that reduction of ventilator support by protocol step contributed to any patient death. Outcomes were as follows: 138 patients were weaned, 45 patients failed to wean, and 69 patients died. The historical control subjects consisted of 238 patients admitted for weaning in the 2 years before institution of the TIPS protocol, after similar exclusion criteria were applied. Comparisons to historical control subjects, with outcomes expressed as percentage, are shown in Table 1. Differences in time to wean and LOS achieved statistical significance. The most dramatic finding is the shortened time to wean,

| TIPS[®] Protocol | WEANING STEPS |
|---|--|
| <p>INITIAL VENTILATOR SETTING For initial flow/volume setting, see footnote a For patient admitted on SIMV/PS: If SIMV >10 or PSV ≥ 20 → change to A/C If SIMV ≤10 and PSV ≤ 20 → no change but begin TIPS with footnote b or footnote c</p> <p>DAILY EVALUATION (DE) Do NOT wean if any ONE is present:</p> <ol style="list-style-type: none"> Hemodynamic instability: <ul style="list-style-type: none"> Dopamine infusion >5 mcg/kg/min Systolic blood pressure < 90 mmHg Pulse < 50 or > 130 bpm Temp >100.4 FiO₂ > 0.5 or PEEP > 8 Other (record reason) <p>WEANING ASSESSMENT (WA) Do NOT wean if any ONE is present:</p> <ol style="list-style-type: none"> Respiratory rate > 35 Spontaneous tidal volume < 0.3 L O₂ saturation < 90% Pulse > 130 or increase from baseline > 20 Prominent accessory muscle use <p>Do RSBI after first successful WA; if RSBI ≤ 80 start weaning at Step 10</p> <p>WEANING</p> <ol style="list-style-type: none"> Chart baseline WA, then advance TIPS step. Chart WA 5' after weaning step. If patient fails step, chart WA and record time; reverse steps until tolerated by patient. Notify MD if patient moved back ≥ 3 steps. If patient fails next step 3 consecutive days, report to MD. <p style="text-align: right;">(continued)</p> | <p>Reduction of SIMV</p> <ol style="list-style-type: none"> SIMV 10 / PS 20 (footnote c) SIMV 8 / PS 20 SIMV 6 / PS 20 SIMV 4 / PS 20 <p>Reduction of PSV</p> <ol style="list-style-type: none"> SIMV 4 / PS 18 SIMV 4 / PS 16 SIMV 4 / PS 14 SIMV 4 / PS 12 SIMV 4 / PS 10 <p>SBTs (footnotes d & e)</p> <ol style="list-style-type: none"> 1 hour 2 hours (draw ABG, result to MD) 4 hours 6 hours 8 hours 10 hours 12 hours 16 hours (footnote f) 20 hours 24 hours <p>Footnotes</p> <p>a) Set flow rate between 70 and 100, decelerating flow. Set V_T to 9ml/kg up to 900ml. If plateau pressure > 35, titrate tidal volume downward to 7ml/kg.</p> <p>b) If PSV breaths < 9ml/kg → increase PSV to 20, then footnote c.</p> <p>c) If PSV breaths > 9ml/kg → change SIMV to 4 in one step. Reduce PSV until spontaneous breaths approximate 8-9 ml/kg.</p> <p>d) Return to SIMV 4, PSV 10 at end of trial.</p> <p>e) If at the end of the SBT patient is comfortable and wishes to continue, trial may be continued one more step.</p> <p>f) Add EKG telemetry when SBT is to extend beyond 10 p.m.</p> |

FIGURE 1. TIPS protocol for weaning patients from PMV at BRH FIO₂ = fraction of inspired oxygen; PEEP = positive end-expiratory pressure; V_T = tidal volume. (Copyright 2000, Barlow Respiratory Hospital; may be reproduced for educational purposes without permission.)

from 29 to 17 days ($p < 0.001$), along with a reduced interquartile range, from 30 to 19 days (Fig 2). Fifty-two patients (38% of those who were weaned; 20.6% of all patients) progressed straight through the protocol without interruption or backtracking; average time to wean for this group was 11.3 ± 4.3 days. The effect on LOS for the three outcome groups is as follows (median, TIPS group vs control group): weaned, 38 vs 50 days; ventilator-dependent, 53 vs

87 days; died, 45 vs 39 days. Overall median LOS at the LTAC was 42.5 days for TIPS protocol patients and 49 days for control subjects ($p < 0.05$).

Protocol Variance

Eight pulmonologists worked with 46 RCPs in the hospital-wide implementation of the protocol. Physician and RCP variances from the protocol were

Table 1—Patient Characteristics and Weaning Outcome*

| | TIPS (n = 252) | Control (n = 238) | p Value |
|----------------------|-------------------|----------------------|---------|
| Age, yr | 73 | 71 | 0.27 |
| APS [†] | 37 | 33.5 | 0.28 |
| PVT, d [†] | 31 | 30 | 0.91 |
| Outcome, % | | | |
| Weaned | 54.7 | 58.4 | |
| Ventilator-dependent | 17.9 | 10.9 | 0.10 |
| Died | 27.4 | 30.7 | |
| LOS, d | 42.5 | 49 | < 0.05 |
| Time to wean, d | 17 | 29 | < 0.001 |

*APS = median acute physiology score of APACHE III; PVT = prior ventilator time (in ICU).

[†]Information not available for 30 TIPS patients treated in a satellite unit.

monitored during the 9,135 ventilator days. Results are summarized in Tables 2 and 3. Of the 324 physician variances, 199 involved holding or halting TIPS. Physician variances varied greatly among the three outcome groups, with preponderance in the died and ventilator-dependent groups (Table 4). In 39 patients (15.5%), there were more than two physician variances, and they collectively accounted for 48% of all variances. Certain variances were prompted by specific circumstances. One patient refused to be reconnected to the ventilator on the second day of SBT. Pulse oximetry was impossible to perform in two patients because of severe peripheral

Table 2—Summary of Physician Variance

| Variance | No. (Total, 324) | Rationale |
|-------------------------------|---------------------|---|
| Ventilator orders | 26 | Perceived need to select level of support |
| Orders for specific TIPS step | 57 | Perceived need to select level of support |
| Altering protocol step | 34 | Perceived need to specify pace of withdrawal |
| Altering DE/WA | 8 | Perceived need to tailor readiness/tolerance criteria |
| Hold order—later resumed | 124 | Acute medical/surgical problems; days held per episode, 7.7 days (mean) |
| Hold order—never resumed | 75 | Unweanable; modified goal; anticipated death |

vascular disease. Telemetry units were temporarily unavailable, delaying some overnight SBTs during periods of high utilization.

A trend to reduced number of variances over time was noted (Fig 3), as heightened awareness and familiarity with the TIPS protocol were fostered through repeat in-services and continued compliance monitoring.

RSBI to Accelerate Weaning

Sixty-nine patients had an RSBI of ≤ 80 . Sixty-one performed a 1-h SBT per protocol, of whom 54 (89%) successfully completed the trial. Of the seven patients who failed, five developed distress during the SBT and two failed because of oxygen desaturation.

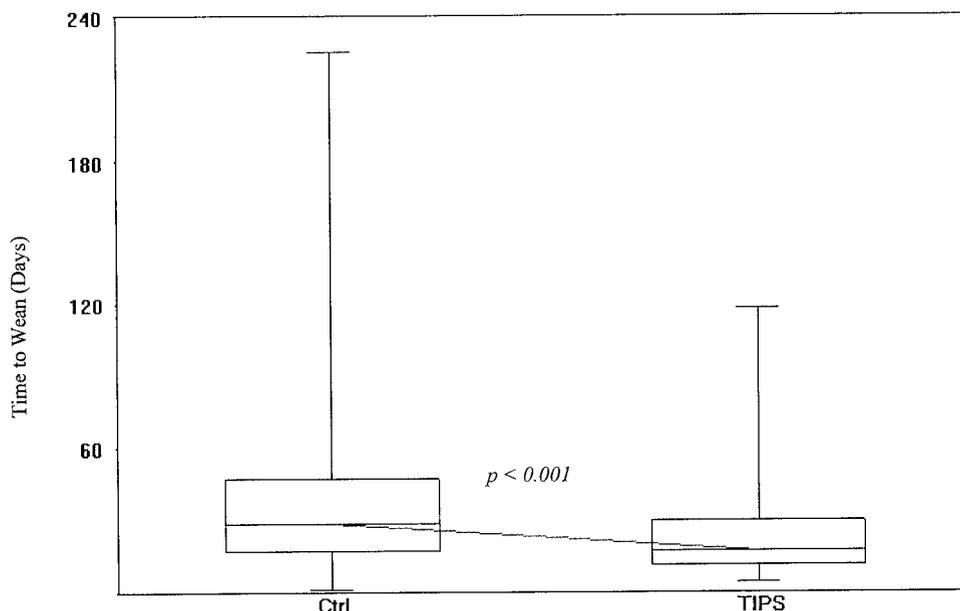


FIGURE 2. Difference between control subjects and TIPS protocol patients in time to wean, from 29 to 17 days ($p < 0.001$), along with a reduced interquartile range, from 30 to 19 days. Ctrl = control.

Table 3—Summary of RCP Variance

| Variance | No. (Total, 136) | Rationale |
|------------------------------|---------------------|----------------------------------|
| Steps not followed | 41 | Familiarity with protocol |
| RSBI not done | 35 | Compliance and monitoring issues |
| ABG not done | 18 | Compliance and monitoring issues |
| Telemetry not done | 4 | Compliance and monitoring issues |
| Documentation omission/error | 38 | Attention to details |

Utility of Routine Arterial Blood Gas

The utility of a routine arterial blood gas (ABG) test after the first 2 h of SBT was analyzed. One hundred sixty-five ABG tests were performed. Of these, only 17 (10.3%) prompted actions. Findings included unexpected hypoxemia ($PO_2 < 50$ mm Hg) in seven patients, hyperoxia ($PO_2 > 170$ mm Hg) in four patients, and acidemia ($pH < 7.30$) caused by hypercarbia in six patients.

DISCUSSION

Protocols (from the Greek “prot + kollan,” to glue together⁶) are rigid codes of procedure, which in medical treatment follow the mantra: assessment → intervention → assessment. The outcomes of weaning patients from PMV presented above were attained with a new therapist-implemented protocol, and in the setting of an LTAC. Gluck⁷ forecast the possibility of success in this when he said that protocols “allow some part of the expertise of physicians to be present at the bedside of weaning patients continuously.” In this manner, the TIPS protocol imposed organization and standardization of the weaning process combined with the 24-h availability of a team of caregivers attending to each patient.

Compliance

Scoring of compliance is essential to the analysis of protocol results to assure outcomes are the result of protocol use, not variance from the protocol, or a combination of the two. Ely and coworkers⁸ recently analyzed compliance with a large clinical therapist-

implemented weaning protocol, dissecting compliance barriers and demonstrating the importance of educational reinforcement in improving implementation. As shown in Table 2, variance from the TIPS protocol by physician order occurred in very few of the TIPS protocol steps in > 9,000 ventilator days. The majority of the physician variance episodes involved halting the weaning process (mean time, 7.7 days) because of patient medical status worsening, which impacted tolerance of weaning, or was expected to do so. These were appropriate interventions in patient care, after which a recovering patient went on to outcome in the protocol. In some of these instances, it became clear that the daily screens would have automatically held the protocol and that physician “hold” and then “resume” orders were not necessary. On the other hand, in nearly 25% of these variances, patients became too ill to ever resume weaning efforts, remaining ventilator-dependent or dying.

A less frequent type of physician variance was one in which screens were modified, or steps were bypassed or modified. These reflect the fact that, because of patient diversity, even the most robust protocol cannot encompass all patients. A patient with restrictive lung disease, for example, may only be comfortable breathing at a respiratory rate > 35 breaths/min, outside of the WA screen; the physician then would modify that part of the screen to allow the patient to progress. Unsurprisingly, Table 4 shows that physician variance is patient-driven, in that patients who wean easily do not generate as many variances as those who do poorly. It also shows that modifying the protocol does not necessarily result in a successful outcome.

Table 3 shows that RCP variances were of two significant types: not following a step dictated by the protocol, and omitting an ancillary test or procedure dictated by the protocol. The number of episodes of noncompliance was very low, especially considering that in addition to procedures, there were 19 therapist-implemented weaning steps in the protocol. In comparison, the large study cited above, by Ely et al,⁸ had only two steps on which RCP compliance was scored. Omission of ancillary tests, of which there were few, and documentation errors accounted for the majority of the variances from our protocol. On the other hand, because not every protocol action was documented or verifiable, we were not able to monitor all aspects of RCP performance. RCP aggressiveness, communication skills, and, importantly, the weight of the therapist-implemented step in ICU studies (eg, “extubate patient”) impact RCP compliance greatly.⁹ Figure 3 shows how over time, with continued teaching and reinforcement, both physician and RCP compliance steadily improved.

Table 4—Physician Variance by Outcome Group

| Outcome | No. | Variances, No. | Per Patient |
|----------------------|-----|----------------|-------------|
| Weaned | 138 | 89 | 0.65 |
| Ventilator-dependent | 45 | 99 | 2.20 |
| Died | 69 | 121 | 1.75 |

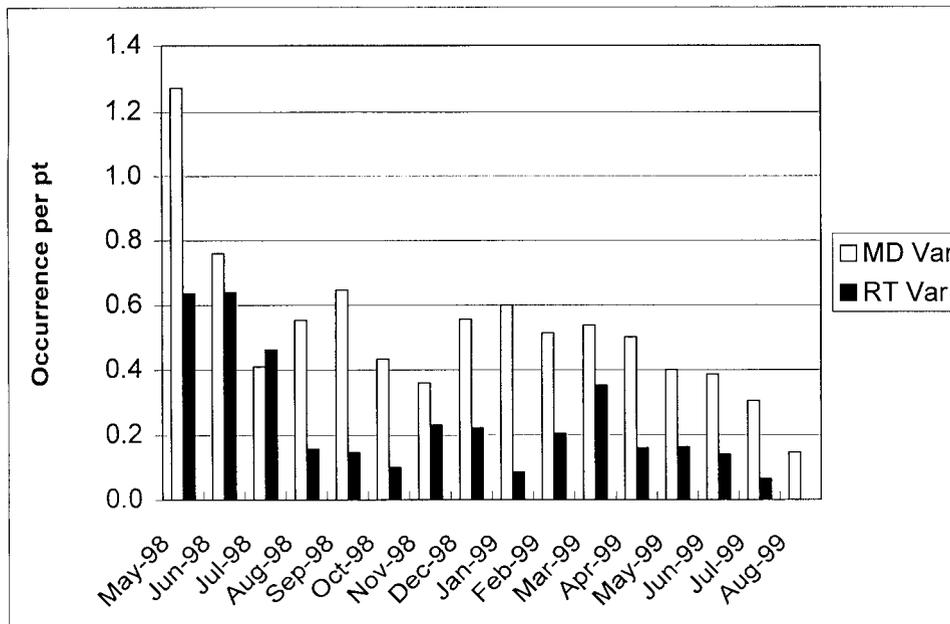


FIGURE 3. Variance from the TIPS protocol over time for both physicians and RCPs. RT = respiratory therapist.

Outcome

Review of the literature revealed only one protocol for weaning PMV patients at an LTAC, using invasive physiologic testing and specialized equipment, with 18% weaning success.¹⁰ This was deemed not practical for use at BRH. As shown in Table 1, the demographics, severity of illness, and prior ventilator-dependent time of the population were not significantly different from those of the control group. The finding that outcomes, scored at the conclusion of the hospital stay, were not significantly different from those scored during the historical control period is not surprising. Our protocol was designed to follow the modes and pace of weaning in the historical period, and the physician staff and referral patterns to BRH were essentially unchanged. The exclusion from the protocol of approximately 7% of patients who, although transferred to BRH for weaning attempts, were not ready or safely able to attempt weaning is consistent with physician judgment decisions during the historical control period.

Patients were always allowed to extend SBTs historically, if they were tolerating the trial and wished to continue. Addition of the other two acceleration steps, however, was new compared with historical practice, and may have contributed to faster weaning. The physiologically sound principle, namely, that if patient-supported PSV breaths are of sufficient volume, there is no need to reduce SIMV breaths stepwise, had been used for many years by

the physicians, but probably not with the consistency that the protocol dictated. The widespread adoption of some form of the RSBI of Yang and Tobin¹¹ as a measure of readiness for SBTs in the ICU setting made incorporation of its use attractive, with an intentionally conservative threshold value recalculated from the original data of Yang and Tobin to identify PMV patients ready for such a trial.¹² As an accelerant step with a threshold of 80 breaths/min/L, it allowed almost 90% of those who passed it to successfully skip to SBTs. Further study is warranted to see whether a higher threshold would allow more patients to safely skip ventilator-reduction steps. Retrospectively looked at as an outcome predictor, if the values were 80, 81 to 120, or > 120 breaths/min/L, then 72%, 57%, and 42%, respectively, of PMV patients went on to wean, again with weaning outcome scored at discharge from BRH.¹³ Only 10% of the single ABG determination picked up blood-gas or acid-base abnormalities requiring action. Because noninvasive capnography was not used, it remains a valuable safety net to identify patients with central hypoventilation not clinically identified.

Both patients weaned with the TIPS protocol, as well as those who remained ventilator-dependent, had fewer ventilator-dependent days and a shorter LOS in the LTAC hospital (Table 1). With the similarities of the TIPS and the control population noted above, these results in patients who weaned may be attributable largely to the organizational effects of the protocol. By this is meant the persistent

daily application of both readiness and tolerance screens, followed by therapist-implemented decrease in ventilator support, with follow-up of tolerance. Standardized ventilator-support reduction, imposed by the protocol, resulted in significantly less variability in time to wean as well (Fig 2). The availability of computerized weaning histories may be responsible for earlier transfer of ventilator-dependent patients from the LTAC to lower levels of care. It is more likely, however, that increased utilization review pressure, owing to cost concerns, resulted in this finding.

LOS is only affected indirectly by shorter time to wean, because after successful weaning, patients spend 2 to 4 weeks in inpatient pulmonary rehabilitation. This highly variable period of hospitalization depends on the physical status of the patient and their medical needs apart from ventilatory ones, nosocomial complications, what their third-party payer will allow, and placement problems at discharge.

Faster weaning for a greater percentage of patients reduced ventilator days in the weaned group by an average of 16.1 days, saving 1,112 ventilator days in 70 patients per year. In the patients who remained ventilator-dependent, the reduction, presumably occasioned by earlier identification of lack of progression, was 25.9 days, for a total of 570 ventilator days of hospitalization saved per year in 22 patients. Because prior time ventilated was the same as for the historical control patients, cost of treatment per protocol should be less for the entire episode of ventilator-dependent illness.

CONCLUSION

Patients weaned from PMV using a new therapist-implemented protocol, in the post-ICU setting of an LTAC specializing in weaning, had significantly shorter time to wean than historical control subjects, with comparable outcomes. Fewer days of ventilator-dependency should translate into greater safety for patients, who would be at less risk for ventilator-related nosocomial complications in the post-ICU period. We found a high degree of compliance with our TIPS protocol for weaning patients from PMV; weaning outcome data during the period after implementation of the TIPS protocol are in fact attrib-

utable to use of the protocol. It is clear that simple well-documented monitors are needed to ensure such compliance, and that continued education is needed to sustain good compliance, from both our experience and that of others.

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