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Clinical consequences of the implementation of a weaning protocol

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Abstract *Objective*: To analyze the clinical and economic consequences of the implementation of a weaning protocol in patients mechanically ventilated (MV) for more than 48 h.
Design: Comparative study.
Setting: General intensive care unit (ICU) in a county hospital covering 360 000 inhabitants.
Patients: 51 patients weaned by a fixed protocol were studied prospectively and compared with 50 retrospective controls.
Measurements: The following variables were assessed: Acute Physiology and Chronic Health Evaluation (APACHE) II score, age, cause of respiratory failure, type of extubation (direct extubation or extubation using a weaning technique), number of days on MV before the weaning trial, weaning time, total duration of MV, complications (reintubations and tracheostomies), length of ICU stay, and mortality.
Results: The groups were comparable in terms of age, APACHE II score, and main cause of acute respiratory failure. Number of days on MV up to the weaning trial were similar in the two groups (8.4±7.7 in the protocol group vs 7.5±5.5 in the control group, NS). Most of the patients (80%) in the protocol group were directly extubated without a weaning technique, unlike the control group (10%) ($p<0.01$). When a weaning technique was used, the weaning time was similar in both groups (3.5±3.9 days vs 3.6±2.2 days in the control group). Duration of MV was shorter in the protocol group (10.4±11.6 days) than in the control group (14.4±10.3 days) ($p<0.05$). As a result, the ICU stay was reduced by using the weaning protocol (16.7±16.5 days vs 20.3±13.2 days in the control group, $p<0.05$). We found no differences in reintubation rate (17 vs 14% in the control group) and need for tracheostomies (2 vs 8% in the control group).
Conclusion: The implementation of a weaning protocol decreased the duration of MV and ICU stay by increasing the number of safe, direct extubations.

Key words Mechanical ventilation · Weaning · Weaning criteria · Weaning incidence · ICU stay

Introduction

The inability to tolerate discontinuation of mechanical ventilation (MV) or the need for reintubation has been reported in up to 20% of mechanically ventilated patients [1]. These difficult patients generate huge clinical, ethical, and economic problems [2]. In an attempt to reduce these problems, efforts have been made to improve weaning criteria and to design weaning indexes with better sensitivity and specificity. The most commonly used weaning criteria are vital capacity, maximal inspiratory pressure (PIMax), and minute ventilation [3]. Nevertheless, they have low predictive power and other weaning indexes have been suggested, such as occlusion pressure [4], rapid shallow breathing [1], PI/PIMax [5], and P0.1/PIMax [6, 7]. Although some have shown higher accuracy, the problem of predicting successful weaning remains. This uncertainty frequently leads to a lengthy weaning period.

Weaning time forms a large portion of the total ventilatory period. A national survey of Spanish hospitals [8] has recently shown that the time from initiation of weaning to disconnection of MV accounted for 41% of total ventilatory time. Therefore, measures that can reduce the weaning time will clearly decrease total ventilatory time.

The high economic cost of caring for critically ill patients is a matter of particular concern, as is the question of how to reduce the use of health care without reducing the quality of intensive care unit (ICU) services. Because of their poor outcome and long ICU stays, patients with respiratory failure generate the highest hospital costs among critically ill patients. These high costs are directly related to the duration of the MV period [9].

Additionally, Cohen et al. [10] found an improvement in the efficiency of ventilatory management in the ICU after forming an interdisciplinary ventilatory team. Their approach decreased arterial blood gas measurements and arterial catheter insertions, and more interestingly, also decreased ventilatory time, ICU stay, and hospital stay.

We hypothesized that the introduction of a weaning protocol could have a direct influence on the management of patients undergoing MV. Therefore, the objective of the present study was to analyze the clinical impact of the implementation of a weaning protocol, by comparing the outcome of a protocolized group with a historical control group.

Materials and methods

Protocol group

Fifty-one consecutive patients ventilated for more than 2 days in our ICU were weaned according to the Weaning Protocol of the Spanish Society of Intensive Care Medicine. All data from these patients are included in the recently published multicenter collaborative study of the Spanish Lung Failure Collaborative Group [11].

This weaning protocol included patients more than 15 years of age and mechanically ventilated for more than 2 days. Patients with a prognosis of home ventilation or with tracheostomies were excluded.

When patients were clinically stable and their attending physicians considered them ready to be weaned from the ventilator, the weaning criteria were evaluated after disconnecting the patient from the ventilator as follows: (1) partial pressure of oxygen in arterial blood >60 mmHg with a fractional inspired oxygen <0.4; (2) PIMax <–20 cmH_2O; (3) respiratory rate (RR) <35 breathes per min; (4) tidal volume >5 ml/kg.

Patients who did not meet three of the four criteria remained in assist-control mode ventilation for 24-h and then weaning criteria were reevaluated. Patients who met at least three of the four criteria underwent a weaning trial consisting of a 2-h period of spontaneous breathing on 5 cmH_2O of continuous positive airway pressure. Tolerance criteria were described as follows: (1) RR <35 breathes/min, or an increment <50% of their basal RR; (2) heart rate <140 beats/min, or an increment <20%; (3) arterial pH >7.30; (4) absence of altered mentation, agitation, and diaphoresis; (5) arterial pressure >80 or <160 mmHg.

Patients who tolerated the weaning trial were extubated (so-called "direct extubation"). Patients who did not tolerate the weaning trial underwent a randomized weaning technique [T-piece, pressure support ventilation or synchronized intermittent mandatory ventilation (SIMV)] with progressive reduction of support as previously described [11] until extubation (so-called "extubation with a weaning technique").

Control group

The historical control group was composed of 50 patients weaned in our ICU in the 13-month period before the implementation of the weaning protocol. The inclusion and exclusion criteria were the same as for the protocol group. The patient was considered "directly extubated" when extubation was performed just after the assist-control ventilation period and without any weaning technique. Patients were considered under weaning: (1) when a T-tube technique was initiated; (2) if the ventilatory mode was SIMV when the ventilator rate was initially set at half or less the frequency used during assist-control ventilation; (3) if pressure-support ventilation was used when the pressure level was lower than 20 cmH_2O.

The following variables were assessed in both groups: (1) Acute Physiology and Chronic Health Evaluation (APACHE) II score [12] and mortality probability models (MPM) [13] on admission to the ICU, as indexes of severity of illness; (2) age; (3) type of extubation: direct extubation or extubation with a weaning technique; (4) duration of MV before the weaning trial in the protocol group and at the beginning of the weaning technique or direct extubation in the control group; (5) duration of weaning time when a weaning technique was used; (6) total duration of MV; (7) number of reintubations and tracheostomies; (8) length of stay in the ICU; and (9) mortality.

Data analysis

The results are expressed as mean ± standard deviation. The distribution of the populations was analyzed using the Kolmogorov-Smirnov test. Quantitative variables showing a normal distribution were analyzed with Student's *t*-test and those without a normal distribution with the Mann-Whitney U test. Qualitative variables were analyzed with the chi-square test. A p value of 0.05 was considered the limit of significance.

Results

Table 1 shows the baseline characteristics of patients in both groups. As Table 1 shows, the control and protocol groups were comparable concerning age, APACHE II score, distribution of the population with the MPM score, and diagnosis. Moreover, the number of days on MV before weaning was started, or before direct extubation, were similar in both groups.

Table 1 Patients' baseline characteristics in both groups (*APACHE* Acute Physiology and Chronic Health Evaluation, *MPM* mortality probability models, *MV* mechanical ventilation)

	Protocol group	Control group	*p*-value
Age (years)	62.5±17	60.2±15	NS
Index of severity of illness			
APACHE II score	21 ± 9	18 ± 8.9	NS
MPM 0–25%	20	22	NS
MPM 25–50%	12	14	NS
MPM 50–75%	7	5	NS
MPM 75–100%	12	9	NS
Diagnosis:			
Acute respiratory failure	39 (76%)	34 (68%)	NS
Chronic obstructive pulmonary disease	11 (22%)	14 (28%)	NS
Neurologic	1 (2%)	1 (2%)	NS
Duration of MV at the weaning trial (days)	8.4±7.7	7.5±5.5	NS

The main results of the present study are given in Table 2. Interestingly, the "direct extubation" rate was higher in the protocol group than in the control group (41 patients vs 5 patients; $p<0.01$). Consequently, only 5 patients in the protocol group were extubated with a weaning technique ($p<0.01$). The rest of the patients in both groups (5 in the protocol group, 4 in the control group) could not be extubated either because they died during the weaning period or because they underwent a tracheostomy.

The duration of weaning in patients in whom a weaning technique was used was similar in both groups (3.5±3.9 days in the protocol group and 3.6±2.2 days in the control group, NS).

The total duration of MV was shorter in the protocol group (10.4±11.6 vs 14.4±10.3 days, $p<0.05$). As a result, ICU stay was also reduced in the protocol group (16.7±16.5 vs. 20.3±13.2 days, $p<0.05$).

Table 2 The outcome of weaning in both groups

	Protocol group	Control group	*p*-value
Direct extubations	41 (80%)	5 (10%)	<0.01
Extubations with a weaning technique	5 (10%)	41 (82%)	<0.01
Weaning time (days)	3.5± 3.9	3.6± 2.2	NS
Total duration of MV (days)	10.4±11.6	14.4±10.3	<0.05
Reintubations	9 (17%)	7 (14%)	NS
Tracheostomies	1 (2%)	4 (8%)	NS
ICU stay (days)	16.7±16.5	20.3±13.2	<0.05
Mortality	4 (8%)	8 (16%)	NS

We found no significant differences in the reintubation rate (17% in the protocol group vs 14% in the control group). The causes of extubation failure in the control group were inability to cough in 3 cases, nosocomial pneumonia in 2, and bronchospasm in 2; while in the protocol group they were inability to cough in 4, bronchospasm in 2, atelectasis in 1, sepsis in 1, and emergency surgical procedure in 1. There were no fatalities because of the need for reintubation.

On the other hand, differences in the number of tracheostomies and in mortality did not achieve statistical significance (Table 2). Death was mostly attributable to nosocomial pneumonia (7 patients), followed by cardiogenic shock and multisystem organ failure.

The hemodynamic data and blood gases at the time of extubation and at the time of reintubation are summarized in Table 3. We found no differences between groups in these variables independent of the method of weaning.

Discussion

This study shows that the implementation of a weaning protocol reduced the duration of MV and the stay in the

Table 3 Blood gases and hemodynamic data obtained at the time of extubation (direct extubation *DExt* or extubation with a weaning technique *WExt*) and at the time of reintubation (*PaO_2* partial pressure of oxygen in arterial blood, *$PaCO_2$* partial pressure of carbon dioxide in arterial blood)

	Protocol group			Control group		
	DExt (*n*=41)	WExt (*n*=5)	Reintubation (*n*=9)	DExt (*n*=5)	WExt (*n*=41)	Reintubation (n=7)
PaO_2 (FIO_2) (mmHg)	268 ±67	305 ±73	174 ±106	301 ±108	266 ±68	157 ±193
$PaCO_2$ (mmHg)	39 ± 8	40 ±11	58 ± 28	45 ± 14	44 ± 9	56 ± 37
pH	7.44± 0.50	7.44± 0.04	7.29± 0.13	7.41± 0.2	7.42± 0.05	7.39± 0.15
Mean arterial pressure	110 ±16	108 ± 8	111 ± 36	117 ± 6	108 ±16	110 ± 45
Heart rate (min^{-1})	103 ±14	107 ±15	99 ± 42	100 ±22	97 ±15	127 ± 6
Respiratory rate (min^{-1})	25 ± 3	24 ± 5	36 ± 4	21 ± 4	25 ± 5	39 ± 5

ICU for critically ill patients. The major reason was the greater number of patients extubated without any weaning technique.

The study of different weaning criteria and techniques has been the endpoint of many studies that have investigated whether these indexes could help to shorten weaning time. Only a few studies have had the same objectives as this one, using other adjuncts to weaning. Biofeedback during weaning was useful in reducing the time on MV for the difficult-to-wean patients in the study of Holliday and Hyers [14]. It was associated with improved respiratory drive, respiratory muscle efficiency, and reduced anxiety. A computer-controlled ventilator weaning system has also been successfully used in postoperative patients resulting in direct extubation [15]. Nevertheless, the reduction in time ranged only from 30 to 60 min for a total duration of 90 min. In our study, we used a similar approach by assuming that many weaning decisions are based on objective data. Therefore, these decisions can be directly managed either with a computer-controlled system or by applying a weaning protocol as we did in the present investigation. Both studies tried to reduce the time in the clinical decision process, without increasing complications. Similarly, Tong [16] used a microcomputer knowledge-based system approach and found a significant reduction in the number of arterial blood gas determinations needed to wean patients from MV. This reduction leads to a significant decrease in the economic cost of weaning, but Tong did not provide data about the duration of the weaning process.

Focusing on the total MV process, Cohen et al. [10] showed an improvement in the efficiency of ventilatory care by developing an interdisciplinary ventilatory management team. This approach resulted in significant reductions in ventilatory time, ICU and hospital stay, arterial blood gas measurements, and the number of arterial catheters used. Nevertheless, these authors did not report data concerning the weaning period.

Nursing care is another important aspect during weaning. The effect of a common nursing intervention and nursing contact on the stress response to the weaning process was evaluated by Henneman [17], but he failed to prove any difference between patients treated with and without direct nursing contact. Recently, Thorens et al. [18] correlated the duration of MV with the lack of training in the nursing team. This problem was avoided in the present study because the composition of the attending team in both phases was comparable.

The design of the study also deserves mention. The use of controls to compare interventions must address specific aspects to avoid loss of statistical power. In analyzing the effect of the implementation of a weaning protocol and comparing the results with a historical control group, we explore the possible effect of some confounding factors. Both parts of the study were performed in the same ICU, with the same physicians and equivalent nursing teams during consecutive years; thus, the impact of "new treatments" (the so-called "time effect") is reduced. The distribution of both populations according to age, severity of illness scores, and the reason for MV were similar. Moreover, an important predictive factor for successful weaning, i.e., the duration of MV before weaning [1], was also comparable in both groups. Therefore, we can assume that the "management care" was no different in the two groups, except for the weaning approach. Nevertheless, randomized studies would have more power to establish conclusions.

Interestingly, the smaller proportion of patients needing a weaning technique in the protocol group was the main cause of the differences between the groups; this difference could be attributed to the different behaviour of physicians in choosing how to begin disconnection of MV. Aggressive approaches may result in early, failed extubations, while conservative approaches can result in excessive MV periods. In this scenario, without a weaning protocol, physicians frequently adopt a conservative strategy by reducing ventilatory support progressively, which lengthens the MV period. In this way, physicians are more concerned to avoid the need for reintubation than to reduce intubation time. The process of a gradual decrease of ventilatory support may serve, therefore, to prolong MV because the physician may not immediately recognize that the patient is able to breath spontaneously [19].

Because of the similar duration of the weaning time in both groups, the difference between the number of direct extubations remains the main difference between the two groups. Therefore, the smaller number of patients needing a weaning technique in the protocol group (5 vs 41 patients in the control group) determined the mean reduction in the total duration of MV and, consequently, in the ICU stay, of 4 days. Whether the weaning protocol would also reduce the time to extubation remains speculative because of the few patients weaned with a technique in the protocol group.

The similar reintubation rate observed in both groups suggests that the increase in the number of patients directly extubated was not attributable to premature extubations. In our patients, we were unable to find any clinical, hemodynamic, or blood gas parameters that might predict extubation failure. Interestingly, this aspect has been reinforced by the recent study of Epstein [20], who also found a 17% reintubation rate. Moreover, the incidence of this extubation failure ranged from 11 to 19% in some studies [21–24], while it was lower in others [25].

The incidence of tracheostomies was higher in the control group, but the difference was not statistically significant; thus, we cannot eliminate the possibility that a higher sample size may show differences. Nevertheless, it would be anticipated that patients with a longer duration of MV (control group) would be more likely to undergo tracheostomies.

Finally, an important effect of the reduction in the duration of MV was the shortening of the ICU stay. ICU resources are scarce and demand is high, and, when matching the two, it is necessary to consider how the available resources are used best. In this way, the present study reinforces the idea that the efficiency of some medical practices can be improved by using clinical protocols to guide the decision-making process.

We conclude that the implementation of a weaning protocol reduces the duration of MV by increasing the number of direct extubations without using a weaning technique. Moreover, it decreases the ICU stay, and probably the economic costs, without worsening the number of complications, the incidence of reintubation, and need for tracheostomies.

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