Rev Bras Cir Cardiovasc 2011;26(2):213-21

Effects of the use of mechanical ventilation weaning protocol in the Coronary Care Unit: randomized study

Efeitos da aplicação de protocolo de desmame de ventilação mecânica em Unidade Coronária: estudo randomizado

Raquel Ferrari PIOTTO[1], Lilia Nigro MAIA[2], Maurício de Nassau MACHADO[3], Suzana Perez ORRICO[4]

RBCCV 44205-1269

Abstract

Objective: **To compare mechanical ventilation weaning based on a protocol using the spontaneous breathing trial against mechanical ventilation weaning without a standardized protocol in heart patients.**

Methods: **Prospective, open, randomized study. In 2006, 36 patients undergoing mechanical ventilation for over 24 hours were randomized into two groups: control group - eighteen patients whose mechanical ventilation weaning was performed according to the different procedures adopted by the multidisciplinary team; and experimental group - eighteen patients weaned according to previously established protocol.**

Results: **Control group patients started the weaning process sooner than experimental group patients (74.7 ± 14.7 hours vs. 185.7 ± 22.9 hours, *P*=0.0004). However, after the experimental group patients were ready for weaning, the extubation was carried out more rapidly than in the control group (149.1 ± 3.6 min vs. 4179.1 ± 927.8 min, *P* < 0.0001) with significantly lower reintubation rates (16.7% vs. 66.7%, *P* = 0.005).**

Conclusion: **The use of a specific protocol based on the spontaneous breathing trial for mechanical ventilation weaning in heart patients had better outcomes than weaning carried out without a standardized protocol, with shorter weaning times and lower reintubation rates.**

Descriptors: **Cardiology. Intensive Care Units. Ventilator Weaning. Respiration, Artificial.**

Resumo

Objetivo: **Comparar o desmame da ventilação mecânica realizado segundo a aplicação de protocolo baseado no teste de respiração espontânea e o mesmo procedimento realizado sem padronização, em pacientes cardiopatas.**

Métodos: **Estudo prospectivo, aberto e randomizado. Em 2006, 36 pacientes em ventilação mecânica há mais de 24 horas foram randomizados em dois grupos: grupo controle:**

1. PhD; Supervision Center for Teaching and Research at Beneficencia Portuguesa Hospital, Sao Paulo, SP, Brazil.
2. PhD, Chief of the Coronary Unit at Base Hospital, Sao Jose do Rio Preto, SP, Brazil.
3. PhD, Chief of the Postoperative Cardiac Surgery at Base Hospital, Sao Jose do Rio Preto, SP, Brazil.
4. PhD, Pulmonologist at Base Hospital, Sao Jose do Rio Preto, SP, Brazil.

Study conducted at Base Hospital, Sao Jose do Rio Preto, SP, Brazil.

Correspondence address:
Raquel Ferrari Piotto
Av. 5544 Brigadeiro Faria Lima, Sao Jose do Rio Preto, SP, Brazil. Zipcode: 15090-000. 15090-000
E-mail: raquelfpiotto@yahoo.com.br

Article received on Wednesday, October 13, 2010
Article approved on Thursday, December 02, 2010

18 pacientes foram submetidos ao desmame da ventilação mecânica de acordo com os procedimentos adotados pela equipe multiprofissional e grupo experimental: 18 pacientes foram submetidos ao desmame de acordo com protocolo previamente estabelecido.

Resultados: **Os pacientes do grupo controle iniciaram o desmame precocemente em relação ao grupo experimental (74,7 ± 14,7 horas vs. 185,7 ± 22,9 horas; *P*=0,0004), Porém, após os pacientes do grupo experimental estarem aptos ao desmame, este foi realizado em um tempo mais curto em relação ao grupo controle (149,1 ± 3,6 min vs. 4179,1 ± 927,8 min; *P* < 0,0001) com taxas de reintubação significativamente menores (16,7% vs. 66,7%; *P* = 0,005).**

Conclusão: **O uso de um protocolo específico, baseado no Teste de Respiração Espontânea para desmame de ventilação mecânica, em pacientes cardiopatas, teve resultados melhores do que o desmame realizado sem um protocolo padronizado, com menor tempo de desmame e menores taxas de reintubação.**

Descritores: **Cardiologia. Unidades de Terapia Intensiva. Desmame do Respirador. Respiração Artificial.**

INTRODUCTION

Mechanical ventilation (MV) is a procedure widely used in intensive care units (ICUs) [1-3]. Recent studies show that 33% to 46% of patients admitted to these units use MV at some point during hospitalization [1-3]. Currently, most patients undergoing mechanical ventilatory support can be quickly removed from the ventilator, so that the condition responsible for establishing the MV has been treated and / or stabilized [4]. The unnecessary prolongation of this process can result in increased hospital costs and complications associated with MV [3].

A portion of the cases, ranging from 5% to 30%, has difficulty in weaning, thus it is not possible to remove the fan in the first attempts. This fact occurs more commonly in patients with previous pulmonary diseases, cardiopathies, major abdominal or thoracic surgery, prolonged mechanical ventilation time, multiple organ dysfunction or even debilitating neurological diseases [4].

Several factors contribute to the weaning failure and return to the MV, such as retention of secretions, atelectasis, pulmonary congestion, myocardial ischemia, laryngeal edema and bronchoaspiration. The prolonged use of the fan can cause respiratory muscles atrophy and decrease performance of the diaphragm [4].

The weaning conducted properly reduces the number of reintubations, reduces hospital stay, reduces the risk of respiratory infections and improves survival of patients undergoing MV [50-10].

The effects of MV in patients with heart disease are complex and depend on a number of variables, especially the patient's volume status, the role of right and left ventricles, afterload, lungs functional status and chest and abdominal compliance [11.12].

Several studies have evaluated the weaning from MV in general ICU patients [10.13]. However, to the best of our knowledge, there is no study that has evaluated only cardiomyopathy patients (databases PUBMED and LILACS). These patients have characteristics that require special precautions for ventilatory, nutritional, hemodynamic and inotropic support. Many of these patients have ventricular dysfunction, pulmonary congestion, hemodynamic instability, myocardial ischemia or use of vasoactive drugs, and all of these conditions can contribute to the weaning failure and prolonged dependence on mechanical ventilator.

These conditions may already be present or triggered or aggravated by the MV and the weaning [11,12]. Although a significant number of cardiac patients admitted to coronary units remain in prolonged MV and present difficulties in the transition between mechanical and spontaneous ventilation, the different weaning modes were not tested in this population. Therefore, it is important to identify what type of weaning has the best results in this population.

The aim of this study was to evaluate the effects of the weaning protocol used in General Intensive Care in a population of cardiac patients admitted to the Coronary Care Unit (CCU).

METHODS

Selection of patients

From March to December 2006, 36 patients admitted to the CCU on MV for more than 24 hours were prospectively and consecutively included, with an median age of 59.5 ± 16.4 years, 58.3% male.

The inclusion criteria in the study were patients admitted to the CCV on MV for more than 24 hours; older than 18 years, both genders, patients who are able to

undergo spontaneous ventilation, patients with indication for weaning from MV. The study excluded patients who had at least one of the following: conditions and / or circumstances that could result in difficulty in understanding the informed consent form (psychiatric illness, alcohol or drug addiction, mental retardation), refusal of the patient's family to sign the informed consent; terminal illness and dependence on mechanical ventilation, in other words, patients who do not progress after weaning and often had to undergo tracheotomy.

Pilot Study

Before starting the study, a pilot study was conducted with a questionnaire answered by the professionals involved in weaning patients and collecting data related to this procedure. This pilot study identified the lack of standardization of the various stages of weaning and intense variation in the results obtained in this procedure with a high failure rate and high mortality of patients on prolonged mechanical ventilation.

The pilot study and the present study were approved by Local Research Ethics Committee (Notification No. 037/ 2006). (ClinicalTrials.govÉ

number NCT00557999).

Randomization

Patients were manually randomized into two groups. It was determined that the first patient would be from the experimental group, the next one from the control group and so on. In other words, odd patients were from the experimental group and even ones from the control group.

- **Experimental Group** Patients who underwent spontaneous breathing test (SBT) in accordance with its protocol, [4] without any modification;
- Control Group: Patients who underwent weaning without application of specific protocol and the criteria of the professional responsible for the procedure. The team consisted of doctors and therapists who had experience in mechanical ventilation. However, each one used their own weaning criteria, for example, they used: the gradual reduction of pressure support, in which the weaning is performed by gradually reducing the pressure support according to clinical parameters and SIMV (Synchronized Intermittent Mandatory Ventilation), in which the weaning is performed by gradually reducing the frequency of the mandatory artificial ventilator, without a specific protocol.

Clinical evaluation

After resolution of the cause leading to the creation of MV, patients in both groups were subjected to daily clinical evaluation in the morning in order to determine whether they were able to be weaned from mechanical ventilation, according to the clinical criteria of SBT listed below:

1) Cause of MV: resolution of the cause and alteration that led to MV;

2) Neurological Stability: patient awake, with no infusion or with little infusion of sedative / narcotics, with effective cough and Glasgow Coma Scale (GCS ≥ 9);

3) Cardiovascular Stability: mean arterial pressure (MAP) ≥ 60 mm Hg without vasopressors or in low doses, heart rate (HR) ≥ 140 / min, hemoglobin (Hb) ≥ 8.0 to 10.0 g / L, partial pressure of arterial oxygen (PaO 2) ≥ 60 mm Hg with inspired oxygen fraction (FiO 2) ≤ 0.4, oxygenation index (PaO 2 / FiO 2) ≥ 150 to 300 without significant respiratory acidosis;

4) Metabolic stability, Temperature <37.8 ° C and absence of electrolyte disturbances. K +, Na +, Mg +, Ca +2, P +4 + that can impair ventilatory muscle function.

Experimental Group

In the experimental group, after completion of all clinical criteria, SBT was applied for 120 minutes with the fan set to the following parameters: respiratory rate (RR) - 1 rpm, pressure support (PS) - 7 cm H2O, positive end-expiratory pressure (PEEP) - 5 cmH2O and FiO2 - 0.4. The patient was monitored and if at the end of 120 minutes his oxygen saturation (SaO2) was greater than or equal to 90%, RR ≤ 35 bpm, systolic blood pressure (SBP) ≥ 90 mmHg and ≤ 180 mmHg, and HR ≤ 140 bpm, without severe agitation or decreased level of consciousness, extubation was performed. If the patient failed the test, the parameters of MV used before were reestablished, and, after a rest period of 24 hours, the test would be performed again, and so on, until extubation.

Control Group

In the control group, during weaning, the patient was evaluated for the parameters of SBT, but the test result was not communicated to the doctor assistant, leaving it to his discretion the moment for extubation.

Clinical Data

Clinical and demographic data of the patients were collected from both groups, previous diseases, admission diagnosis, date and reason for intubation and ventilatory parameters at the beginning of the weaning.

Objective

The study objective was to compare weaning from mechanical ventilation performed according to the application of SBT protocol and the same procedure performed without standardization, in cardiac patients admitted to the Coronary Care Unit.

For this comparison, the following parameters were used: 1) Primary Objective: reintubations frequency during the

hospitalization period; 2) Secondary objectives: time spent in Coronary Care Unit, time between intubation and beginning of the weaning; time between the beginning of the weaning and extubation, time elapsed between SBT and extubation ; occurrence of respiratory infection in patients who required reintubation, mortality of patients who required reintubation.

Definition of terms

Weaning: The term weaning refers to the process of transition from spontaneous to artificial ventilation in patients who remained on invasive mechanical ventilation (IMV) for more than 24 hours [4]; successful weaning: maintenance of spontaneous ventilation for at least 48 hours after discontinuation of artificial ventilation [4]; unsuccessful weaning: return to MV for a period less than 48 hours [4], reintubation, necessity to reestablish the artificial area via. The reintubation was considered premature when it occurs in less than 48 hours after extubation [4], respiratory infection: culture positive result (106 CFU) of tracheal aspirate in patients on MV for more than 24 hours [4], hospital mortality: death within the hospitalization period in which the patient remained on MV.

Statistical analysis

The sample size calculation was based on the comparison of proportions of independent cohort study, with 80% power and type I error of 5% based on the reintubation expectation of 15% in the experimental group and 60% in the control one, totaling a minimum of 17 individuals per group, according to a preliminary assessment made in the pilot study.

Categorical data are presented in absolute numbers and percentages, and continuous variables in mean ± standard error (SE). Continuous variables were compared by the nonparametric Mann-Whitney test (non-Gaussian distribution). Fisher's exact test was used to compare categorical variables. *P* values <0.05 were considered statistically significant (two-tailed). Analyses were carried out with the intention to treat.

The software used for statistical analysis were GraphPad Instat v. 3.0 and Stats Direct Statistics Software v. 2.6.2.

RESULTS

Baseline characteristics of the study groups are presented in two tables, the first concerning the clinical and demographic data, and the second one regarding the respiratory variables recorded at the time the patient began to be weaned from MV. Regarding the admission diagnosis, there was no statistical significance between the two groups: myocardial revascularization 11.1% in the experimental group and 22.2% in the control group - (P = 0.658); valve surgery 16.7% in the experimental group and 16 7% in the control group - (*P*> 0.999), ACS with supra11.1% in the experimental group and 11.1% in the control group - (*P*> 0.999); ACS without supra 11.1% in the experimental group and 5,6% in the control group - (*P*> 0.999), CHF in the experimental group 16.7% and 5.6% in the control group - (*P* = 0.602), PTE 11.1% in the experimental group and 5.6% in control group - (*P*> 0.999).

There was no statistically significant difference between the groups, including the relation to the Apache II score applied prior to randomization (15 ± 0.0 vs. 14.3 vs. 0.4; *P* = 0,220) (Table1).

There was no statistically significant difference between groups in relation to ventilatory parameters at the beginning of the weaning, as shown in Table 2. The groups were comparable in relation to all assessed physiological variables.

Concerning the primary objective of the study, the experimental group had significantly lower rates of reintubation than the control group (16.7% vs. 66.7%; *P* = 0.005). In the control group, out of the 18 patients included, 16 of them (88.8%) were extubated and two (11.1%) remained on MV.

Eleven individuals (68.7%) of the 16 extubated patients failed the SBT conducted by the investigator and all were re-intubated in less than 48 hours after extubation. Out of the 5 patients approved by the SBT, only one (20%) was re-intubated after a week from complications of the underlying disease.

Regarding the experimental group, all the 18 patients included underwent the SBT, and 11 (61.1%) were approved and extubated. Concerning the 11 extubated patients, three (27.3%) required reintubation, two of them in less than 48 hours. The reintubation causes were the heart failure decompensation requiring the use of vasoactive drugs and complications in the immediate post-operative period of valve surgery associated with atrial septoplasty. The third patient remained extubated for more than a week, requiring reintubation due to a lung infection.

Patients in the experimental group had delayed onset of weaning in relation to the control group (185.7 ± 22.9 hours vs. 74.7 ± 14.7 horas; *P* = 0.0004). However, after being able to be weaned, it was performed in a much shorter time compared to the control group (149.1 ± 3.6 min vs. 4179.1 ± 927.8 min, *P* <0.0001), showing also a shorter period between the end of SBT and extubation (29.1 ± 3.6 min vs. 1493.0 ± 1216 min; *P* = 0.0005).

Pertaining to the other secondary objectives, the incidence of respiratory infection was higher in re-intubated patients in the control group [seven (58.3%) of 12 patients who were reintubated] compared to the experimental group [one (33.3%) of three patients reintubated], and this difference was not significant (P = 0.569) (Table 3).

Table 1. Baseline characteristics of patients undergoing weaning from mechanical ventilation (n = 36).

Baseline characteristics	Experimental Group n =18	Control Group n=18	*P Value*
Demographic data			
Men [n(%)]	10 (55.6)	11 (61.1)	*P* >0.999
Women [n(%)]	8 (44.4)	7 (38.9)	*P* >0.999
Age (mean ± SE)	59.3 ± 4.3	59.8 ± 3.5	0.820
Cause of current hospitalization			
Myocardial revascularization [n(%)]	2 (11.1)	4 (22.2)	0.658
Valve Surgery [n (%)]	3 (16.7)	3 (16.7)	*P* >0.999
ACS with Supra [n (%)]	2 (11.1)	2 (11.1)	*P* >0.999
ACS without Supra [n (%)]	2 (11.1)	1 (5.6)	*P* >0.999
CHF n(%)	3 (16.7)	1 (5.6)	0.602
PTE n(%)	2 (11.1)	1 (5.6)	*P* >0.999
Personal History			
History of diabetes [n (%)]	5 (27.8)	4 (22.2)	*P* >0.999
Smoking [n(%)]	7 (38.9)	5 (27.8)	0.724
COPD n(%)	1 (5.6)	2 (11.1)	*P* >0.999
SAH n(%)	10 (55.6)	10 (55.6)	*P* >0.999
Prior AMI (%)	7 (38.9)	3 (16.7)	0.264
Apache II Prognostic Score			
Apache II (mean ± SE)	15 ± 0.0	14.3 ± 0.4	0.220
Approximate mortality (mean ± SE)	21.2 ± 3.0	17.6 ± 2.0	0.530

n - number of patients,% - percentage of patients, SE - standard error; ACS - acute coronary syndrome; HF-heart failure; PTE - pulmonary thromboembolism, COPD - chronic obstructive pulmonary disease, SAH - systemic arterial hypertension; AMI - acute myocardial infarction

Table 2. Physiological variables of patients undergoing weaning from mechanical ventilation (n = 36).

Physiological variables*	Experimental Group n=18	Control Group n=18	*P Value*
PEEP	5.0 ± 0.0	5.0 ± 0.0	*P* >0.999
Maximal inspiratory pressure	19.3 ± 0.6	19.2 ± 0.8	0.220
Respiratory rate	25.7 ± 1.1	25.2 ± 1.1	0.640
Tidal volume (ml)	505.5 ± 5.6	490.0 ± 16.9	0.580
Tobin Index	51.1 ± 2.3	53.2 ± 3.5	*P* >0.999
Pressure support	13.4 ± 0.7	12.8 ± 0.5	0.810
FiO_2	0.4 ± 0.0	0.4 ± 0.0	*P* >0.999
PaO_2	108.6 ± 6.3	108.8 ± 5.4	0.910
Oxygenation index (PaO2/FiO2)	271.5 ± 15.8	271.9 ± 13.4	0.910
Heart rate	80.5 ± 3.1	80.8 ± 3.0	0.990
Systolic blood pressure	127.0 ± 4.0	130.8 ± 3.1	0.500
Diastolic blood pressure	78.2 ± 3.3	81.8 ± 2.2	0.530
Arterial oxygen saturation	97.3 ± 0.3	97.3 ± 0.5	0.500
Body temperature (° C)	36.9 ± 0.1	36.9 ± 0.1	0.980
Hemoglobin	10.6 ± 0.2	10.5 ± 0.3	0.800
Glasgow Coma Scale	11 ± 0.4	11 ± 0.5	0.510

**Mean ± SE, n - number of patients, SE - standard error; PEEP - positive end-expiratory pressure; FiO2 - fraction of inspired oxygen, PaO 2 = partial pressure of oxygen in arterial blood*

Table 3. Secondary Objectives: weaning from mechanical ventilation (n = 36).

Mechanical ventilation*	Experimental Group n 18	Control Group n 18	*P Value*
Length of ICU stay (days)	23.1 ± 4.5	23.5 ± 3.7	0.77
Time between intubation and beginning of weaning (hours)	185.7 ± 22.9	74.7 ± 14.7	0.0004
Time between beginning of weaning and extubation (min)	149.1 ± 3.6	4179 ± 927.8	< 0.0001
Time between SBT and extubation (min)	29.1 ± 3.6	1493.0 ± 1216.0	0.0005

** Mean ± SE, n - number of patients, SE - standard error; ICU - Intensive Care Unit; min - minutes; SBT - spontaneous breathing test*

Concerning mortality, in the experimental group of three patients who underwent reintubation, two (66.6%) died, while in the control group of 12 patients who were re-intubated, eight (66.6%) died ($P > 0.999$).

DISCUSSION

Removing the patient from MV can be harder than keeping them on it. The withdrawal process of the ventilatory support takes about 40% of the total time of MV. Some authors describe the weaning as the "shadow area of intensive care" and, even in experienced hands, it can be considered a mixture of art and science [14,15].

In our study, the patients' baseline characteristics (Table 1) and physiological variables at the beginning of the weaning (Table 2) were similar. The process of randomization favored a balance between the two groups, making them comparable.

Despite the weaning of patients in the control group was too early initiated, the time elapsed between the beginning of this process and extubation was significantly shorter in the experimental group. This fact can be explained as follows: in the experimental group, the decision to initiate the procedure was made based on the approval of the spontaneous breathing test, which depended on the completion of a series of clinical, hemodynamic and ventilatory criteria. Meanwhile, in the control group, the onset of weaning was faster, because it did not depend on tests of independence and formal pre-established criteria.

On the other hand, in the experimental group, after the patients were able to be weaned, the same was done in a much shorter time. In the control group, the absence of well-established criteria that would ensure that the patient would be able to keep them on spontaneous ventilation, made the decision for extubation were invariably delayed. Thus, the total duration of weaning was significantly higher when compared to the experimental group.

These data are consistent with what was described in several studies of patients admitted to general intensive care units. In these studies, the non-use of protocol has made the time of extubation become inaccurate, resulting in early extubation and unnecessary prolongation of the duration of the weaning process [5,6,13,16-27].

According to the International Guidelines for weaning from MV [4] and the last Brazilian Consensus on Mechanical Ventilator, the recommended way to wean is based on the spontaneous breathing test (SBT). Therefore, this method was chosen to be used in our study.

In relation to the primary objective of the study, the experimental group had significantly lower rates of reintubation than the control group (16.7% vs. 66.7%; $P = 0.005$). It is worth emphasizing that in the control group, all patients re-intubated in less than 48 hours after extubation, 68.7% of the cases had no criteria for weaning, according to the SBT conducted by the investigator.

The reduction in reintubation rates found in the experimental group was the result of choosing the best time for extubation, determined by the SBT. Several authors have demonstrated the importance of this result in the evolution of patients [5,12,13,18-20,24,28]. When compared to the first intubation, reintubation increased eight times the risk of pneumonia and from 6 to 12 times the risk of death, being considered an independent predictor of mortality [13,14,19,29,30].

In the control group, the early weaning, without the use of standardized clinical and ventilatory criteria, made the patients take a longer time to be weaned, and re-intubated more frequently, which was a decisive factor for the weaning failure from MV.

The daily assessment of the weaning parameters held in the experimental group has been described in the literature as one of the factors responsible for good performance observed using the protocol of SBT [4,13,16-18,31].

Ely et al. [32] demonstrated that patients who underwent daily assessment of weaning parameters have been more successful during extubation (87% vs. 30%; $P = 0.0001$) and higher survival rates (74% vs. 29%; $P = 0.0001$) in relation to the control group.

The reduction of the weaning period in our study had great practical importance, since it is widely shown that prolonged mechanical ventilation is associated with increased length of stay in hospital and intensive care and

an increased risk of respiratory infection and death.

Several randomized controlled trials in hospitalized patients in general intensive care demonstrated reduction of the period in which patients used to be on mechanical ventilation, lower rates of reintubation and fewer complications when weaning from MV was performed according to specific protocol [5,6,13,16-23, 28].

A recent randomized multicenter trial comparing the weaning protocol with SBT to the weaning performed without standardization, evaluated 147 patients admitted to general ICU, 74 from the experimental group and 70 from the control group. When compared to the control group, the experimental group showed significant reduction of time spent on MV (7.5 vs. 12 days, P = 0.003), reintubation rates (23% vs. 46%; *P* = 0.4) and hospitalization period (74% vs. 15.5 days, *P*=0.02) [24].

However, these studies were performed in non-cardiac patients admitted to general intensive care units.

Although a significant number of cardiac patients admitted to coronary units remain on prolonged MV and present difficulties in the transition between mechanical and spontaneous ventilation, the different weaning modes were not tested in this population.

The presence of cardiopathy may contribute to weaning failure and prolong dependence on the ventilator due to several factors, including ventricular dysfunction and vasoactive drug addiction. During the weaning process, those patients with cardiopathies have higher risk of hemodynamic instability or acute myocardial ischemia [27.33-39].

The results of this study, with emphasis on reducing weaning time and risks of reintubation were similar to those already demonstrated in general ICU patients. These data suggest that the protocol based on the SBT was beneficial and safe in cardiac patients admitted to the Coronary Unit. The importance of the current study is the fact that it is the first study that randomly evaluated the use weaning protocol in cardiac patients, so there is no data in the literature. The rationale described in this paper tries to summarize the reasons why most units do not use coronary weaning protocol developed for general patients. These reasons do not have scientific proof and the study shows that the physiopathological changes caused by the cardiopathy did not prevent these patients to benefit from the use of a weaning standardized protocol from mechanical ventilation.

However, the number of patients included in this study was insufficient to accurately assess the secondary objectives in relation to clinical events (respiratory infection and mortality). The absence of significant differences is noted between the two groups, and it was useful to reinforce the obtained results, as the main objective according to the sample size calculation.

However, definitive conclusions can only be obtained by means of analysis of mortality. As the studies that accurately analyze morbidity and mortality require a large number of patients, the surrogate endpoints are often used, in the present study, weaning time and risks of reintubation. The analysis performed are useful in evaluating the procedures, provide a basis for future research, but the conclusions should be used as a guide, not as definitive information on clinical decision-making.

CONCLUSION

The application of specific protocol in cardiac patients admitted to the Coronary Unit based on SBT for weaning from MV was superior than the non-standardized weaning, with shorter weaning time and lower reintubaiton rates.

REFERENCES

1. Esteban A, Anzueto A, Alia I, Gordo F, Apezteguia C, Palizas F, et al. How is mechanical ventilation employed in the intensive care unit? An international utilization review. Am J Respir Crit Care Med. 2000;161(5):1450-8.

2. Esteban A, Anzueto A, Frutos F, Alia I, Brochard L, Stewart TE, et al; Mechanical Ventilation International Study Group. Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study. JAMA. 2002;287(3):345-55.

3. Knebel AR, Janson-Bjerklie SL, Malley JD, Wilson AG, Marini JJ. Comparison of breathing comfort during weaning with two ventilatory modes. Am J Respir Crit Care Med. 1994;149(1):14-8.

4. MacIntyre NR, Cook DJ, Ely EW Jr, Epstein SK, Fink JB, Heffner JE, et al; American College of Chest Physicians; American Association for Respiratory Care; American College of Critical Care Medicine. Evidence-based guidelines for weaning and discontinuing ventilatory support: a collective task force facilitated by the American College of Chest Physicians; the American Association for Respiratory Care; and the American College of Critical Care Medicine. Chest. 2001;120(6 Suppl):375S-95S.

5. Kollef MH, Shapiro SD, Silver P, St John RE, Prentice D, Sauer S, et al. A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation. Crit Care Med. 1997;25(4):567-74.

6. Ely EW, Bennett PA, Bowton DL, Murphy SM, Florance AM, Haponik EF. Large scale implementation of a respiratory therapist-driven protocol for ventilator weaning. Am J Respir Crit Care Med. 1999;159(2):439-46.

7. Epstein SK, Ciubotaru RL, Wong JB. Effect of failed extubation on the outcome of mechanical ventilation. Chest. 1997;112(1):186-92.

8. Epstein SK, Nevins ML, Chung J. Effect of unplanned extubation on outcome of mechanical ventilation. Am J Respir Crit Care Med. 2000;161(6):1912-6.

9. Esteban A, Alia I, Tobin MJ, Gil A, Gordo F, Vallverdú I, et al. Effect of spontaneous breathing trial duration on outcome of attempts to discontinue mechanical ventilation. Spanish Lung Failure Collaborative Group. Am J Respir Crit Care Med. 1999;159(2):512-8.

10. Esteban A, Alia I, Gordo F, Fernández R, Solsona JF, Vallverdú I, et al. Extubation outcome after spontaneous breathing trials with T-tube or pressure support ventilation. The Spanish Lung Failure Collaborative Group. Am J Respir Crit Care Med. 1997;156(2 Pt 1):459-65.

11. Laaban JP. Heart-lung interactions. Rev Mal Respir. 2003;20(6 Pt 3):S5-6.

12. Wood G, MacLeod B, Moffatt S. Weaning from mechanical ventilation: physician-directed vs a respiratory-therapist-directed protocol. Respir Care. 1995;40(3):219-24.

13. Tanios MA, Nevins ML, Hendra KP, Cardinal P, Allan JE, Naumova EN, et al. A randomized, controlled trial of the role of weaning predictors in clinical decision making. Crit Care Med. 2006;34(10):2530-5.

14. Tobin MJ. Remembrance of weaning past: the seminal papers. Intensive Care Med. 2006;32(10):1485-93.

15. Esteban A, Alia I, Ibañez J, Benito S, Tobin MJ. Modes of mechanical ventilation and weaning. A national survey of Spanish hospitals. The Spanish Lung Failure Collaborative Group. Chest. 1994;106(4):1188-93.

16. Esteban A, Frutos F, Tobin MJ, Alia I, Solsona JF, Valverdú I, et al. A comparison of four methods of weaning patients from mechanical ventilation. Spanish Lung Failure Collaborative Group. N Engl J Med. 1995;332(6):345-50.

17. Brochard L, Rauss A, Benito S, Conti G, Mancebo J, Rekik N, et al. Comparison of three methods of gradual withdrawal from ventilatory support during weaning from mechanical ventilation. Am J Respir Crit Care Med. 1994;150(4):896-903.

18. Krishnan JA, Moore D, Robeson C, Rand CS, Fessler HE. A prospective, controlled trial of a protocol-based strategy to discontinue mechanical ventilation. Am J Respir Crit Care Med. 2004;169(6):673-8.

19. McLean SE, Jensen LA, Schroeder DG, Gibney NR, Skjodt NM. Improving adherence to a mechanical ventilation weaning protocol for critically ill adults: outcomes after an implementation program. Am J Crit Care. 2006;15(3):299-309.

20. Ely EW, Baker AM, Dunagan DP, Burke HL, Smith AC, Kelly PT, et al. Effect on the duration of mechanical ventilation of identifying patients capable of breathing spontaneously. N Engl J Med. 1996;335(25):1864-9.

21. Foster GH, Conway WA, Pamulkov N, Lester JL, Magilligan DJ Jr. Early extubation after coronary artery bypass: brief report. Crit Care Med. 1984;12(11):994-6.

22. Grap MJ, Strickland D, Tormey L, Keane K, Lubin S, Emerson J, et al. Collaborative practice: development, implementation, and evaluation of a weaning protocol for patients receiving mechanical ventilation. Am J Crit Care. 2003;12(5):454-60.

23. Kollef MH, Levy NT, Ahrens TS, Schaiff R, Prentice D, Sherman G. The use of continuous i.v. sedation is associated with prolongation of mechanical ventilation. Chest. 1998;114(2):541-8.

24. Lellouche F, Mancebo J, Jolliet P, Roeseler J, Schortgen F, Dojat M, et al. A multicenter randomized trial of computer-driven protocolized weaning from mechanical ventilation. Am J Respir Crit Care Med. 2006;174(8):894-900.

25. Vitacca M, Vianello A, Colombo D, Clini E, Porta R, Bianchi L, et al. Comparison of two methods for weaning patients with chronic obstructive pulmonary disease requiring mechanical ventilation for more than 15 days. Am J Respir Crit Care Med. 2001;164(2):225-30.

26. Blackwood B, Alderdice F, Burns KE, Cardwell CR, Lavery G, O'Halloran P. Protocolized versus non-protocolized weaning for reducing the duration of mechanical ventilation in critically. J Med Assoc Thai. 2010;93(8):930-6.

27. Chaiwat O, Sarima N, Niyompanitpattana K, Komoltri C, Udomphorn Y, Kongsayreepong S. Protocol-directed vs. physician-directed weaning from ventilator in intra-abdominal surgical patients. J Med Assoc Thai. 2010;93(8):930-6.

28. Strickland JH Jr, Hasson JH. A computer-controlled ventilator weaning system. A clinical trial. Chest. 1993;103(4):1220-6.

29. Demling RH, Read T, Lind LJ, Flanagan HL. Incidence and morbidity of extubation failure in surgical intensive care patients. Crit Care Med. 1988;16(6):573-7.

30. Ely EW, Evans GW, Haponik EF. Mechanical ventilation in a cohort of elderly patients admitted to an intensive care unit. Ann Intern Med. 1999;131(2):96-104.

31. Ely EW, Baker AM, Evans GW, Haponik EF. The prognostic significance of passing a daily screen of weaning parameters. Intensive Care Med. 1999;25(6):581-7.

32. Ely EW, Meade MO, Haponik EF, Kollef MH, Cook DJ, Guyatt GH, et al. Mechanical ventilator weaning protocols driven by nonphysician health-care professionals: evidence-based clinical practice guidelines. Chest. 2001;120(6 Suppl):454S-63S.

33. Clochesy JM, Daly BJ, Montenegro HD. Weaning chronically critically ill adults from mechanical ventilatory support: a descriptive study. Am J Crit Care. 1995;4(2):93-9.

34. Hurford WE, Favorito F. Association of myocardial ischemia with failure to wean from mechanical ventilation. Crit Care Med. 1995;23(9):1475-80.

35. Srivastava S, Chatila W, Amoateng-Adjepong Y, Kanagasegar S, Jacob B, Zarich S, et al. Myocardial ischemia and weaning failure in patients with coronary artery disease: an update. Crit Care Med. 1999;27(10):2109-12.

36. Bryan-Brown CW. Blood flow to organs: parameters for function and survival in critical illness. Crit Care Med. 1988;16(2):170-8.

37. Kotanidou A, Armaganidis A, Zakynthinos S, Mavrommatis A, Roussos C. Changes in thoracopulmonary compliance and hemodynamic effects of positive end-expiratory pressure in patients with or without heart failure. J Crit Care. 1997;12(3):101-11.

38. Laizo A, Delgado F, Rocha G. Complicações que aumentam o tempo de permanência na unidade de terapia intensiva na cirurgia cardíaca. Rev Bras Cir Cardiovasc. 2010;25(2):166-71.

39. Arcêncio L, Souza M, Bortoloni B, Fernandes A, Rodrigues A, Evora P. Cuidados pré e pós-operatórios em cirurgia cardiotorácica: uma abordagem fisioterapêutica. Rev Bras Cir Cardiovasc. 2008;23(3):400-10.