

IMPACT OF A VENTILATORY WEANING PROTOCOL IN AN INTENSIVE CARE UNIT FOR ADULTS

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ABSTRACT

Objective: to evaluate the impact of a ventilatory weaning protocol on the weaning quality and on the outcomes of the patients.

Method: a quasi-experimental quantitative study, consisting of comparing a prospective study with a retrospective study. Data was collected through a weaning log sheet applied between September and December 2015 at an intensive care unit in northern Portugal following the implementation of a weaning protocol and compared with a base-line constituted in the year preceding the implementation of the ventilatory weaning protocol.

Results: the experimental group had a score mean of higher overall quality of weaning, with a reduction in the timing for initiating the weaning in 27.3% and the weaning time in 36.6%.

Conclusion: the implementation of the ventilatory weaning protocol improved the overall quality of the weaning, facilitating the identification of patients with criteria to initiate the process, starting earlier, resulting in a reduction in ventilatory weaning time.

DESCRIPTORS: Intensive care units. Artificial breathing. Mechanical ventilator weaning. Ventilatory weaning protocol. Critical care nursing.

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IMPACTO DE UM PROTOCOLO DE DESMAME VENTILATÓRIO EM UNIDADE DE CUIDADOS INTENSIVOS PARA ADULTOS

RESUMO

Objetivo: avaliar o impacto de um protocolo de desmame ventilatório na qualidade do desmame e nos *outcomes* dos doentes.

Método: estudo quantitativo quase-experimental, composto pela comparação de um estudo prospectivo com um estudo retrospectivo. Os dados foram recolhidos através de uma folha de registo de desmame aplicada entre setembro e dezembro de 2015, em uma unidade de terapia intensiva do norte de Portugal, após a implementação de um protocolo de desmame, sendo comparados com uma *base-line* constituída no ano anterior à implementação do protocolo de desmame ventilatório.

Resultados: o grupo experimental teve uma média de *score* de qualidade global do desmame superior, verificando-se uma redução do *timing* de início do desmame em 27,3% e do tempo de desmame em 36,6%.

Conclusão: a implementação do protocolo de desmame ventilatório melhorou a qualidade global do desmame, facilitando a identificação dos doentes com critérios para iniciar o processo, iniciando o mesmo mais precocemente, resultando numa diminuição do tempo de desmame ventilatório.

DESCRITORES: Unidades de terapia intensiva. Respiração artificial. Desmame do respirador. Protocolo de desmame ventilatório. Enfermagem de cuidados críticos.

EL EFECTO DE UN PROTOCOLO DE INTERRUPCIÓN DE LA VENTILACIÓN MECÁNICA EN UNA UNIDAD DE CUIDADOS INTENSIVOS PARA ADULTOS

RESUMEN

Objetivo: evaluar el efecto de un protocolo de interrupción de la ventilación mecánica sobre la calidad de dicha interrupción y sobre los resultados de los pacientes.

Método: estudio cuantitativo cuasi-experimental conformado por la comparación de un estudio prospectivo con uno retrospectivo. Los datos se recibieron a través de una planilla de registro de interrupción de la ventilación mecánica aplicada entre septiembre y diciembre de 2015 en una unidad de cuidados intensivos del norte de Portugal, después de implementarse un protocolo de interrupción de la ventilación mecánica, y se los comparó con una línea de referencia constituída el año anterior a la implementación del protocolo de interrupción de la ventilación mecánica.

Resultados: en el grupo experimental se obtuvo un puntaje medio de calidad global de la interrupción de la ventilación mecánica superior, con lo que se verificó una reducción del 27,3% en el *timing* de inicio de dicha interrupción y del 36,6% en el tiempo de ese proceso.

Conclusión: implementar el protocolo de interrupción de la ventilación mecánica mejoró la calidad global de la interrupción de la ventilación mecánica, facilitando así la identificación de los pacientes que presentaban criterios para iniciar el proceso, comenzarlo más tempranamente y con una disminución resultante en el tiempo de la interrupción de la ventilación mecánica.

DESCRITORES: Unidades de cuidados intensivos. Respiración artificial. Interrupción de la ventilación mecánica. Protocolo de interrupción de la ventilación mecánica. Enfermería de cuidados críticos.

INTRODUCTION

Invasive Mechanical Ventilation (IMV) is a form of artificial ventilatory assistance used to promote oxygenation and ventilation in patients with respiratory failure, and is a supportive measure commonly used in the context of intensive care.¹ Approximately two-thirds of the adults admitted to Intensive Care Units (ICUs) require invasive ventilatory support.²⁻⁶ However, IMV is not risk-free and is associated with numerous physiological^{1,3-6} and psychological complications,⁷⁻⁸ entailing high economic costs for the institutions.⁹⁻¹⁰ From this perspective, its undue prolongation worsens the outcomes^{1,3-6} of the patients, being a reason why it should be discontinued as soon as spontaneous breathing is restored.^{3-4,11} However, it is noteworthy that the very early withdrawal of IMV also carries risks for patients, as re-intubation is associated with an increased incidence of Ventilation-Associated Pneumonia (VAP), prolonging the period of ICU admission and increasing the mortality rate.^{6,12-13}

Thus, identifying the ideal time to stop IMV is critical. The term commonly used to describe IMV discontinuation is ventilatory weaning, which is the process of transitioning from artificial ventilation to spontaneous breathing in patients who have been undergoing IMV for 24 hours or more.¹⁴ Planning should begin from admission to the ICU and involves treating the cause of the respiratory failure, identifying the criteria for weaning, performing Spontaneous Breathing Training (SBTs), and the extubation.¹⁵⁻¹⁷ It is important to highlight that ventilatory weaning is a process under medical and nursing responsibility, and nurses should actively participate in identifying the patients with criteria to initiate the weaning process, facilitating it.¹⁸

In the last decade, this theme has been the target of several international investigations (United States of America, United Kingdom, France, Spain, Germany, South Africa, South Korea), and ways to optimize ventilatory weaning have been studied, helping to a paradigm shift that transitions from a decision based on the clinical judgment to a more consistent *praxis*. Currently, the literature is increasingly emphasizing the use of ventilatory weaning protocols to standardize weaning criteria and methods, making them popular among the intensive care community, and is already used in 56% to 69% of the ICUs in Europe,^{2,11,19} with positive results in decreasing ventilatory weaning time, IMV and ICU stay, as well as reducing the incidence of VAP.^{4,20-26} In Portugal and in the nursing area, no studies on this theme were found.

In order to improve ventilatory weaning quality, an investigative study was conducted in an adult ICU in northern Portugal to assess the impact of a ventilatory weaning protocol on the weaning quality and on the outcomes of the patients.

METHOD

The investigation respected all the ethical precepts in accordance with the Helsinki rules.

This is a quasi-experimental quantitative approach study, consisting of comparing a prospective study with a retrospective study. In order to meet the proposed objectives, the study was designed in two phases. The first phase corresponded to the prospective study and included the following: (i) elaboration of a ventilatory weaning protocol in the light of the current guidelines¹ and their respective submission to the opinion of the clinical staff of the service where it was applied; ii) creation of a record sheet; iii) development and execution of a training program for applying the protocol, directed to the multidisciplinary team; iv) application of the weaning protocol; and v) data collect through the record sheet prepared between September 1st and December 31st, 2015, by the nursing staff, thus obtaining the Experimental Group (EG). The second phase (retrospective study) consisted of collecting the same data on ventilatory weaning by the investigators in a period prior to the implementation of the protocol (between September 1st and December 31st, 2014), thus constituting a base-line, corresponding to the Control Group (CG).

The study included all adult patients who underwent IMV for a period of 24 hours or more, meeting criteria for initiating the ventilatory weaning during the ICU stay. The defined exclusion criteria were as follows: patients in T-piece and/or tracheostomized for the admission in the ICU; patients who died or were transferred before meeting the criteria for initiating the weaning or before completing the ventilatory weaning; patients who were extubated directly for spontaneous ventilation by medical decision; and lastly, patients in whom ventilatory weaning was not a clinical objective.

Considering that the same period of the previous year was chosen to minimize the impact of seasonal variations on medical diagnoses, causes of respiratory failure underlying the need for IMV, and severity indexes upon ICU admission.

After applying the inclusion and exclusion criteria, a total of 122 patients were included in the sample, subdivided into EG (n=60) and CG (n=62).

The implementation of the ventilatory weaning protocol began after two in-service training sessions addressed to the multidisciplinary team during August 2015, and its official application started in September, together with the implementation of the completed weaning registration sheet filled out daily by the nursing staff during the morning and afternoon shifts. Subsequently, a brainstorming session was performed at the beginning of November to recall concepts and clarify doubts.

A database was built for data processing in the Statistical Program for data processing in Social Sciences (SPSS, version 22), where they were edited. Data were analyzed using descriptive statistics by calculating the absolute and relative frequencies for all the variables and measures of central tendency and dispersion for the ratio measurement level variables. In addition, inferential statistics were performed using the Student t test for independent samples to compare the means of the following dependent variables: number of days of ICU stay, of IMV, of ventilatory weaning, of timing of weaning onset and of the number of SBT attempts between the EG and the CG. The χ^2 test was used to test and compare between the study groups the frequency with which: the SBTs were performed at night and/or continuously; the need for rescue non-invasive ventilation (NIV); re-intubations; tracheostomies and VAP. The "Student" t test was also used to compare the mean scores of the Global Weaning Quality variable, in the EG and CG. Finally, the *Mann-Whitney* test was used to compare the mean ordering of the overall weaning quality categories across the study groups. The significance level adopted was 5%.

The operationalization and categorization of the study variables also made it possible to create a new variable to assess the overall quality of weaning based on the sum of the scores attributed to the following variables: IMV time, number of SBT attempts, period of the SBTs day, ventilatory weaning time, rescue NIV and reintubations, as shown in Table 1. In the good quality weaning were considered of excellent quality, situations with scores: 9-11.

Table 1 – Global quality of ventilatory weaning. Vila Real, Portugal, 2015

Dependent variables	Ventilatory Weaning Quality			
	Poor		Mean	Good
1- Invasive Mechanical Ventilation time	0	-	1	2
2- Number of Spontaneous Breathing Training	0	-	1	2
3- Period of Spontaneous Breathing Training day	0	1	2	3
4- Ventilatory weaning time	0	-	1	2
5- Rescue non-invasive ventilation	0	-	-	1
6- Re-intubations	0	-	-	1
Score	0-1		2-5	6-11

RESULTS

The EG was characterized by the equality between the proportion of both genders (30, 50%) and the majority of the patients (43, 71.7%) belonged to the age group of 65-90 years old (elderly), the mean age being 69.08±13.5 years old, (Δ 39-90). In the CG, female patients predominated (42, 67.7%), maintaining the prevalence of the same age group (33, 53.2%), but not as markedly as in the EG. The mean age was 63.68±14.85 years old ($\pm\Delta$ 21-87). The most prevalent diagnostic category in the sample and in both groups was medical. Both groups had severity scores and high nursing workloads, the EG with an APACHE II mean value of 19.55±10.6, a SAPS II mean value of 43.53±10.9 and a TISS 28 mean value 34.82±5.91. For the same indicators, the CG had a mean value of 18.52±6.1, 43.97±11.12 and 32.81±3.8, respectively (Table 2).

The descriptive statistics revealed that in the EG weaning started on average at 4.47±4.35 days of IMV, while in the CG, on average, it started at 6.16±2.9 days of IMV. In addition, the EG took, on average, 2.1±3.25 days to complete ventilatory weaning, in contrast to the CG, which required, on average, 3.31±3.41 days. No statistically significant differences were observed between the study groups with respect to the mean length of stays in hospital, IMV time and number of SBT attempts (Table 3).

In the EG, it was observed that only five patients underwent continuous SBT (8.3%), no testing occurred during the night period; while in the CG, 15 (24.2%) participants performed SBT continuously and 12 (19.4%) overnight. It was also found that the weaning mean overall quality was higher in the EG (8.47) than in the CG (6.79) (Table 4).

It was also verified that the average ordering of the EG (71.50) is higher than that of the CG (51.82), inferring that the EG had a higher proportion of cases classified in the categories of good and excellent weaning quality than the CG (Table 5).

Table 2 – Demographic and clinical characterization of the sample. Vila Real, Portugal, 2015. (n=122)

Variable	Experimental Group		Control Group		P
	N	%	N	%	
Gender					
Female	30	50	42	67.7	
Adjusted residue	-2.0		2.0		0.065*
Male	30	50	20	32.3	
Adjusted residue	2.0		-2.0		
Age group					
21-64 years old adults	17	28.3	29	46.8	
Adjusted residue	-2.1		2.1		0.041*
65-90 years old elderly	43	71.7	33	53.2	
Adjusted residue	2.1		-2.1		
Diagnostic categories					
Medical	30	50	29	46.8	
Surgical	26	43.3	25	40.3	0.7†
Trauma	4	6.7	8	12.9	

χ^2 test * Fisher's Exact Test; †Pearson's chi-square test.

Table 3 – Differences between the mean length of stay in intensive care unit (ICU), invasive mechanical ventilation (IVM) time, ventilatory weaning and attempts at Spontaneous Breathing Training (SBT) according to the study group. Vila Real, Portugal, 2015. (n=122)

Variables	Study groups	Mean	Test value	DF*	p†
Stay time in ICU	Experimental Group	8.47	1.39	120	0.17
	Control Group	10.1			
IVM time	Experimental Group	6.95	1.61	120	0.109
	Control Group	8.69			
Ventilatory weaning time	Experimental Group	2.1	2	120	0.048
	Control Group	3.31			
Timing for initiating the weaning	Experimental Group	4.47	2.52	106.8	0.013
	Control Group	6.16			
No. of SBT attempts	Experimental Group	2.08	0.89	120	0.378
	Control Group	2.42			

Student t test; *DF: Degrees of Freedom; †p: Probability.

Table 4 – Mean overall weaning quality between the study groups, Vila Real, Portugal, 2015. (n=122)

Dependent variables	Study groups	Mean	Test value	DF*	p†
Overall weaning quality	Experimental Group	8.47	-3.914	120	0.000
	Control Group	6.79			

Student t test; *DF: Degrees of Freedom; †p: Probability.

Table 5 – Orderings for the overall weaning quality between the study groups. Vila Real, Portugal, 2015. (n=122)

Dependent variables	Study groups	N	Mean of the orders	Test value	P*
Overall weaning quality	Experimental group	60	71.50	1260	0.001
	Control Group	62	51.82		

Mann-Whitney test; *p: Probability.

DISCUSSION

Compared with other studies, this research allowed to characterize the ventilatory weaning, building up from scratch the concept on overall weaning quality, which does not only depend on its success, taking into account how it occurs, its onset, its duration as well as the resulting complications. Thus, it was found that the implementation of a ventilatory weaning protocol improved the overall weaning quality, allowing a reduction of 27.4% in the onset timing of the weaning and of 36.6% in the weaning time, values in line with the results obtained in other studies (70% of reduction in the weaning time, $p < 0.009$)²⁰. In addition, it allowed for a decrease in the proportion of patients who attempted SBT continuously and during the night. It is noteworthy that these data are new since they were not previously studied. Regarding the remaining dependent variables, there were no significant

differences between the study groups regarding IMV time, length of stay, number of SBT attempts, VAP incidence, rescue NIV, re-intubations and tracheostomy.

In other investigations on the theme it was found that the implementation of weaning protocols reduced the time of IMV (16.6 ± 13 days in the EG and 22.5 ± 21 days in the CG),²⁰ (71 hours in the EG and 96 hours in the CG, $p < 0.0001$),²³ (2 days in the EG and 4 days in the CG),²⁵ (25 hours in the EG and 35.5 hours in the CG, 95% IC 12.5),¹⁵ as well as the length of stay (21.6 ± 14.3 days in the EG and 27.6 ± 21.7 days in the CG),²⁰ (5 days in the EG and 7 days in the CG),²⁵ (0.96 days in the EG and 1.7 days in the CG, 95% IC 0.24),¹⁵ the incidence of VAP (35.1% in the EG and 52.4% in the CG, $p < 0.001$),²¹ and the incidence of re-intubations (3% in the EG and 12.7% in the CG, $p = 0.05$).²² The explanation for the fact that there were no significant differences between the study groups regarding the time of IMV and hospitalization may be related to the severity of the clinical situation of critically ill patients, which justified the need to prolong IMV and hospitalization in the ICU.

Although it differs from the expected results for this study, this situation was also found by other investigators regarding the IMV time (14.4 days in the EG and 16.3 days in the CG, $p = 0.6$) and the length of stay (20.8 days in the EG and 21 days in the CG, $p = 0.9$).²⁶ The absence of significant differences between the study groups in the occurrence of adverse events is probably related to the reduced number of elements subject to such events, which has also been found in other studies regarding the incidence of VAP (20.2% in the EG and 31% in the CG, $p = 0.12$),¹⁹ (39% in the EG and 7% in the CG, $p = 0.37$),²⁵ unsuccessful extubations (31% in the EG and 35% in the CG, $p = 0.81$),¹⁹ incidence of re-intubation (8% in the EG and 10% in the CG, $p = 0.25$),²³ (9,8% in the EG and 10% in the CG, $p = 1$),²⁵ (10,7% in the EG and 16.7% in the CG, $p = 0,9$),²⁶ and tracheostomies (7% in the EG and 9% in the CG, $p = 0.51$).²³ It is noteworthy that these results suggest that applying ventilatory weaning protocols is safe.

The main limitations of this study seem to be related to the methodology, more precisely because the sampling was non-probabilistic, since it runs the risk of not being representative, being traditionally less reliable than the probabilistic alternative, regarding the generalization of the results.²⁷ In addition, the rational choice selection process may have reduced the number of participants in the sample as only a small proportion of patients admitted during the study periods met the inclusion and exclusion criteria of the study. On the other hand, implementing the ventilatory weaning protocol implied performing training sessions in order to standardize and systematize the performance of the multidisciplinary team, also facilitating the integration for new elements. Now, a formative process always has some behavioral change underlying it, which cannot be totally achieved in such a narrow time window. Finally, the fact that the research was confined to a single institution was also a limitation, so it is essential to replicate and extend the study in other health facilities, since the conclusions will be either more valid or more extended as the sample becomes more randomized.

Ideally, the weaning protocol should be implemented in conjunction with a sedation, analgesia, and rehabilitation protocol.^{15,28} In this perspective, in future studies, a sedation and analgesia protocol should be created to be implemented, in parallel to the weaning protocol, requiring the involvement of anesthesiologists and the collaboration/coordination of the entire multidisciplinary team.

CONCLUSION

The accomplishment of this study made it possible to elaborate a ventilatory weaning protocol and to apply it in an ICU, contributing to the uniformity of the practice regarding this process. This research also made it possible to introduce a new concept, the global weaning quality that includes the following variables: IMV time, number of SBT attempts, period of the SBTs day, ventilatory weaning time, rescue NIV incidence and re-intubations. The inferential analysis of the data showed that implementing the ventilatory weaning protocol improved its overall quality, facilitating the identification of the patients who met criteria to initiate the process, which enabled the early weaning to begin, resulting in a decreased ventilatory weaning time. On the other hand, implementing the protocol influenced the selection of the daytime period for performing the SBTs, resulting in reduced SBTs performed continuously and during the night, which reflects respect for the patient's circadian rhythm, allowing their rest at night, as preconized. It is noteworthy that these results were obtained without increasing the incidence of adverse events (VAP, tracheostomies, re-intubations, rescue NIV), suggesting that the application of ventilatory weaning protocols is safe.

Thus, the results of this investigation have implications for practicing critical patient care, as it has been found that the application of ICU ventilatory weaning protocols enables earlier identification of the patients with the ability to move from IMV to spontaneous breathing, reducing the weaning period and safely improving its quality for the patients.

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NOTES

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CONFLICT OF INTERESTS

There is no conflict of interest.

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