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"Triple Testing" as a Tool to Detect Non-Reintubation in Weaning from Mechanical Ventilation in Critically Ill Patients from the Intensive Care Unit, IPSU, Medellin, Colombia- Cross Sectional and Diagnostic Research Study

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Abstract

Introduction: Weaning from mechanical ventilation still consumes many medical efforts. In addition to the numerical parameters in mechanical ventilation weaning decisions, some clinical decisions must be explored in more depth. The clinical extubation score should be combined with the spontaneous breathing test protocol and the superficial respiration index. This "triple test" should be utilised in daily clinical work.

Objective: Predict NON-reintubation based on combining the clinical extubation score (NRS), to the spontaneous ventilation test (SBT), and the superficial respiration index (IRS).

Materials & Methods: A prevalence research study and diagnostic tests were carried out. Measurements: The study is the demonstration of the "triple test" (TT) (Valencia, 2010) for the extubation of critically ill intubated patients. The study was carried out in the intensive care unit of IPS Universitaria between 2018 and 2019. For the clinical demonstration, 1,170 critically ill patients with the most common pathologies found in our city were used. This included those with: septic shock, community-acquired pneumonia, decompensated emphysema, secondary peritonitis, postoperative heart surgery and postoperative brain tumor resection surgery. Statistics: For the measurements, a sensitivity and specificity calculations analysis was performed with a statistical program of SPSS-25.

Results: One thousand one hundred and seventy patients were studied (1,170). 666 (56.9%) were men and 504 (43%) were women. The average age was 61.06 + 17.2 years. Score obtained from MPM-II: 43.59 + 25.9. The overall mortality rate of the patients intubated in the intensive care unit was 36.1% and the mortality rate of the reintubated patients was 36.3%. Mortality associated with the use of mechanical ventilation was a third higher than the overall mortality rate (24.1%). The prevalence of reintubation was 5.73% with the use of the "triple test". The triple test in the extubation of critically ill patients showed a sensitivity of 1.49% (0.08-9.14%); specificity of 99.9% (99.4%-100%); with a positive predictive value (PPV) of 50% (2.67%-97.3%) and a Negative Predictive Value (NPV) of 94.3% (92.8%-95.57%), with a positive probability ratio (CPP) of 16.4 (1.04-260.3) and a negative probability ratio (CPN) of 0.99 (0.96-1.02).

Conclusion: The spontaneous ventilation test combined with the superficial respiration index <55 and the release score interpreted in the form of a serial

statistical test, the "triple test", is an effective tool for identifying patients who can be safely extubated, with a very low risk of reintubation. In addition, the high specificity and high negative probability ratio make it easier to determine who is NOT reintubatable among the intubates. The combination of tests is not carried out with the aim of detecting candidate patients to extubate. The increase in specificity created by combining the three criteria, in relation to the need to reintubate, allows the decision to extubate to be safer. Traditional extubation of mechanical ventilation, based on only one parameter, does not seem to be justified.

Keywords: SBT (Spontaneous Breathing Trial), NRS (NON-Reintubation Score), Mechanical Ventilation, Reintubation.

Abbreviations: NRS- NON-Reintubation Score; LOS- Length of Hospital Stay; SBT- Spontaneous Breathing Trial; ROC- Receiving Operating Characteristic; PPV- Positive predicting value; NPV- Negative predicting value; LR- Likelihood Ratio; SRI- Spontaneous Breathing Index; PEEP- Positive end-expiratory pressure; CPAP- Continuous Positive Airway Pressure; PS- Pressure Support.

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Introduction

Patients are generally intubated and placed on mechanical ventilators when their own ventilator and/or gas exchange capabilities are outstripped by the demands placed on them by a variety of diseases. Mechanical ventilation is also required when the respiratory drive is incapable of initiating ventilator activity either due to disease process or the effect of drugs [1]. Weaning from mechanical ventilation remains a major challenge for critical-care physicians. Weaning can be defined as the process of abruptly or gradually withdrawing mechanical ventilation support when the cause of the acute respiratory failure is being resolved [2,3]. Weaning patients from mechanical ventilation in the Intensive Care Unit (ICU) is a difficult task, because subjective criteria for extubation are inaccurate [4,5]. Objective measurements consisting of clinical criteria and physiologic tests have been used to facilitate decision-making [5,6].

Clinical decision-making during weaning from mechanical ventilation consists of three stages. The first stage is for the clinician to decide whether or not a ventilator-supported patient has a reasonable likelihood of being able to breathe on their own [5-7]. The decision on patient readiness is typically guided by the measurement of physiological variables, known as 'weaning predictors' [4,5,6]. If the variables predict a clear chance of weaning success, clinicians move on to the second stage. The second stage consists of either a gradual reduction in the level of ventilator assistance, as with pressure support, or an abrupt decrease in mechanical ventilation, as with spontaneous breathing trials [8,9,10]. Finally, this is followed by an extubation trial (third stage) [11].

Several recent randomized trials and prospective case series have found that "protocol-directed weaning" by respiratory care staff can expedite the discontinuation of mechanical ventilation [10]. Therefore, mechanical ventilation requires intensive therapy care. These findings can improve both patient outcomes and resource use. Patients receiving mechanical ventilation incur significant morbidity, mortality, and costs. It has also been demonstrated that both premature and delayed weaning can cause harm. To avoid damage and reintubation many kinds of weaning predictors and weaning procedures had been developed: spontaneous breathing index (SRI) [4,6], esophageal pressure monitoring [5], spontaneous breathing trial (SBT) [9], computer-driven protocolized weaning [12], adaptive support ventilation [13], hypnosis [14], and clinical parameters [15,16].

The reasons for using a score for weaning from mechanical ventilation are as follows: A) The test includes two international demonstration tests, namely the spontaneous ventilation test [9] and the rate of shallow breathing [4], along with a clinical score from Colombian patients during a spontaneous ventilation test at the moment of mechanical ventilation release [15,17]. B) The test includes a clinical component. This is required for the management of mechanical ventilation release [15,17]. C) This test is done on Colombian patients [16]. D) The triple test demonstrated a well-performed statistical calculation with a specificity of 92.2% of NON reintubation, when performing a serial statistical test was developed. The aim of that statistic test was to increase specificity and reduce sensitivity. E) The triple test is a test to ensure that you do not have to reintubate a patient again after they have been extubated.

In the present study, it was hypothesized that the addition of a "NON Reintubation Score" (NRS) to the spontaneous breathing trial during weaning from mechanical ventilation allows this to be used as a setting point to reduce the percentage of reintubation. Accordingly, the main goal was to determine a score built of clinical variables taken during the spontaneous breathing test that developed for extubation and with suitable sensitivity and

specificity, creating a lower patient reintubation rate.

Materials and Methods

Patients: The study population comprised patients in the mixed intensive care unit who were admitted to our 44-bed university medical center between September 2018 and December 2019. During the study period, 1,170 calculated patients were enrolled in this cross-sectional study. An age of under 18 years and a lack of informed consent were the exclusion criteria. The number of patients was calculated according to the formula used for "n" detection, based on sensibility, specificity and relation of probability derived from a previous published weaning intervention diagnostic test [17].

Study Protocol: The study protocol was approved by the hospital's institutional review board. The intervention was a strategy of combined management incorporating daily screening of respiratory function, clinical extubation score measurements and a "spontaneous breathing trial". Only patients who had been on mechanical ventilation for at least 24 hours were included. All decisions on approaches to weaning, discontinuation of mechanical ventilation, reinstituting mechanical ventilation, and discharge from the intensive care unit were made by the patients' attending physicians, who were experienced intensivists. When a patient who remained extubated for 48 h after the first weaning score evaluation required reintubation for a different cause from the first time, it could be evaluated with the protocol as a new extubation case. The standard mode of mechanical ventilation at the unit was controlled mechanical ventilation.

Daily Screening: All patients enrolled in the study were screened each morning between 8 to 10 AM by the respiratory therapist at the unit. Mechanical ventilation measurements were obtained using the Galileo (Hamilton Medical, AG, Rhazuns, Switzerland). The therapist was not allowed to change the fraction of inspired oxygen or the level of positive end-expiratory pressure (PEEP). The results of the daily screening were not available to the physician caring for the study patients. The decision to extubate was made according to the intensivist analysis of the data from each patient. Meanwhile, the respiratory therapist developed a weaning score, keeping this information from the intensivist in order to avoid influencing their extubation judgment. In this way, the NRS (based on clinical parameters) could be evaluated as a tool to be added to the "*SBT*". We did not assay RSBI as an extubation criteria.

Spontaneous Breathing Trial (SBT): Before SBT started, all sedative drugs were stopped. The selection of NRS measurements was performed during the "*spontaneous breathing trial*" protocol. In that trial, the patient was allowed to breathe through a ventilator circuit using "flow triggering" (rather than pressure triggering) continuous positive airway pressure (CPAP) of 5 cm of water and pressure support (PS) of 5 cm of water. Automatic tube compensation was not used. No change was made in the fraction of inspired oxygen or level of PEEP. The "*spontaneous breathing trial*" was initiated and monitored by the respiratory therapist and the nurse caring for the patients, with electrocardiography and pulse oximetry throughout. SBT was terminated by the physician according to their own appreciation of clinical conditions and based on known protocols (a respiratory rate that exceeded 35 breaths per minute for five minutes or longer and arterial oxygen saturation below 90 percent, a heart rate that exceeded 140 beats per minute, sustained changes in the heart rate of 20 percent in either direction, and systolic blood pressure greater than 180 mmHg or less than 90 mmHg) (18). "SBT" was considered successful when the patient could breathe without mechanical ventilation for 60 minutes [18].

During "SBT", the respiratory therapist carried out the NRS assessments 10 minutes after initiation: every patient was interrogated in order to obtain 10 answers; every question was valued with 1 if it was positive and 0 if the answer was negative. The evaluated parameters were agitation, diaphoresis, retractions, somnolence, bad breathing pattern (abdominal contractions), secretions presence (yes/not, during SBT), cough incapability, patient rejection of extubation, nasal flaring (clinical observation), and head up inability; each of them with a value of 1 point. Information was kept and provided to the study's epidemiologist [16].

Ethical Standards: All human studies were approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. It must also be clearly stated that all persons gave their informed consent prior to their inclusion in the study or admission to the intensive care unit.

Outcomes: The following primary outcome was defined a priori: reintubation. Reintubation was defined as a case when the patient did not have the capacity to maintain a saturation of over 90 percent and acceptable clinical respiratory conditions. The secondary outcomes were frequency of complications, length of hospitalization, and death.

It must be borne in mind that our study evaluates "NON Reintubation", while many other weaning research studies were researching extubation criteria. Therefore, for us, high specificity was more important than high sensitivity. The other studies were looking for high sensitivity, looking for a criterion that would give them success when removing the tube. We were looking for parameters that would give us the success of not having to reinsert the tube. For this reason, the 3-parameter serial test is successful in improving specificity.

Statistical Analysis: General Approach: Sample size of 1,170 was calculated based on a sensitivity of 71% and specificity 89% to identify a score to detect reintubation, at a power of 80% with a two-tailed type I error of 0.05. Data are presented as averages. All categorical variables were analyzed with a chi-square test, except where a small size required the use of Fisher's exact test. After getting a cutoff point, patients were divided into two groups, and comparison of continuous variables among the two groups was done with Student's t test for variables with normal distribution, and with the Mann-Whitney U test for variables with non-normal distribution.

Diagnostic accuracy analysis: Standard formulas were used to calculate sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and likelihood ratios (LR) of the

primary outcome.

Finally, for the overall risk of reintubation a logistic regression analysis was undertaken to control for confounding variables and to identify independent risk factors for each item included in the score. The following variables were entered into the maximal model: agitation, diaphoresis, retractions, somnolence, bad breathing pattern, secretions presence, cough incapability, patient rejection of extubation, nasal flaring, and head up inability.

A combined measurement (serial combined testing) was developed to maximize specificity from two published tests: "Rapid shallow breathing index (RSBI)" [4,6], "spontaneous breathing trial" (SBT) [7]. The NON-reintubation score (NRS) is added to the serial combined testing analysis.

Test A (RSBI) + Test B (SBT) + Test C (NRS) = Increases specificity

Results

Demographic information and patient data regarding the severity of the illness are shown in **Table 1**. The cause of respiratory failure was diverse (**Table 1**). Acute lung injury/acute respiratory disease syndrome, sepsis/septic shock, COPD, trauma, and postoperative- and community-acquired pneumonia accounted for 90.6 percent of the cases of respiratory failure. At enrollment, a standard mode of mechanical ventilation was used; these parameters did not differ among patients.

A total of 1,170 patients were analyzed to look for an association between reintubation and the "triple test". Of the 1,170 patients extubated after entering mechanical ventilation with the protocol, only 67 required reintubation (5.72%) (odd ratio, 16.7; 95 percent confident interval, 1.03 to 269.9). Of those extubated, 1,103 (94.1%) were successful after using the triple test. Of the reintubated patients, only 1 patient (1.49%) required reintubation despite having passed all points of the triple test. In addition, of those who were successful in extubation, only 1 patient (0.090%) required reintubation due to causes unrelated to the failure of the "triple test". The most common reasons for reintubation were clinical signs of increased respiratory work, hypoxemia, and impaired clearance of secretions.

Combined measurements: Serial testing maximizes specificity and the positive predictive value but lowers sensitivity and the negative predictive value. Serial testing is particularly useful when none of the individual tests available to clinicians are highly specific. The sensitivity and specificity of SBT and RSBI were taken from published data [4,7]. Adding a weaning score to the combination of IRS and SBT at the moment of weaning with ***serial combined testing*** improved the weaning score specificity from 81.3% to 99.91% and LR+ from 0.21 to 16.46. The objective of this application of statistics with the "triple test" was to increase specificity, for which sensitivity should be sacrificed. Sensitivity with the "triple test" went from 3.9% to 1.49% in this clinical study. The reason that we searched for a test that enabled a high specificity to be achieved was because we were looking for something that would provide security. Something that indicated that the patient should NOT be reintubated. Therefore, with the "triple test" it was important to obtain tests that produced a high negative predictive value, because we were looking for specificity. It was NOT a screening test to determine whether we were removing the tube, as previous studies tried to determine, but rather it was an accuracy test for not putting the tube back in. With the "triple test" it was possible to go from a positive predictive value of 39.6% to 50%, and a negative predictive value of 21.1% to 94.35%.

Discussion

This study confirms that NRS is a clinical score value that is useful when added to protocols for weaning from mechanical ventilation. NRS is the first clinical weaning score applied to weaning from mechanical ventilation as it can be used as a tool to reduce reintubation, mainly when NRS is combined with SBT and SRI.

The objective with this clinical demonstration of the "triple test" was replication in clinical and day-to-day use in an intensive care unit, as demonstrated in epidemiological investigations. Valencia developed a ROC curve analysis (2010). The area under the ROC curve for an NRS **higher than 1** for the first 10 minutes of the "spontaneous breathing trial (SBT)" was 0.74 (0.67-0.80, 95% confidence intervals; p = 0.0001). The best cutoff values for NRS were > 1: sensibility 84% (63%-95%); specificity 56% (47%-64%); with a LR+ 1.91; LR- 0.29; PPV: 23.3 and NPV 95.7 (**Table 1**) [16].

Although Valencia demonstrated that there were two variables in the most important clinical score for evaluating the risk of reintubation, this was not the objective of our study. However, due to the statistical validity of the data found in this previous publication [16], when all variables of the score remained constant, a patient with a positive bad respiratory pattern will be 7.1 times more likely to be reintubated (OR: 7.16; CI: 1.86 to 27.6; p = 0.004). Results of the complete model are showed in **Table 2**. Besides this, significant variables from the NRS were head up inability and retractions (odd ratio: 2.49; confidence interval:

Table 1 Specificity, Probability of Proportions Positive (PPP), Probability of Proportions Negative (PPN), Positive Predictive Value (PPV) and Negative Predictive Value (NPV) of Shallow Breathing Index (IRS), Spontaneous Breathing Test (SBT), and NO Reintubation Score (NRS) in combined test series (Valencia, 2010).

Parameter	Sensitivity (%)	Specificity (%)	PPP	PPN	PPV	NPV
IRS (Yank, 1991) *	92.1	22.2	1.18	0.36	83.3	40
SBT (Esteban 1995) *	30.4	76.1	1.27	0.91	24.1	81.4
IRS+SBT (Yank, 1991) (Esteban, 1995)	3.9	81.3	0.21	1.18	39.6	21.1
WS > 1	84	56	1.91	0.29	23.3	95.7
IRS + SBT + NRS (Valencia, 2010)	18.8	92.2	2.42	0.88	91.1	21.2

*IRS: Spontaneous Respiratory Index and SBT: Spontaneous Breathing Trial

Table 2 Logistic Regression Model Results.

Variables in the equation	β Coefficient Constant = -2.412	Wald	*P*	Exp (β) = OR
Nasal fin	-0.869	1.181	0.277	0.41 (0.087-2.010)
Bad Respiratory pattern	1.970	8.203	**0.004**	**7.16 (1.86-27.6)**
Retractions	-2.391	4.035	**0.045**	**0.09 (0.009-0.944)**
Diaphoresis	0.873	1.927	0.165	2.39 (0.69-8.21)
Drowsiness	-0.138	0.110	0.741	0.87 (0.38-1.96)
Agitation	-0.223	0.123	0.726	0.80 (0.23-2.78)
Secretions	0.257	0.525	0.469	1.29 (0.64-2.59)
Inability to cough	0.793	3.720	0.054	2.20 (0.98-4.94)
Inability to raise head	0.913	4.552	**0.033**	**2.49 (1.07-5.76)**
Rejection of the patient from extubation	0.554	1.085	0.298	1.74 (0.61-4.93)

1.07 to 5.76; p = 0.033; and odd ratio: 0.092; confidence interval: 0.009 to 0.944; p = 0.045; respectively). Altogether, muscle strength variables involved in the weaning score had more power in the total score to define reintubation. In this order of ideas, the clinical criteria of the inability to raise the head and a poor respiratory pattern are two clinical variables that intensivists always take into account in the clinical evaluation of patients.

Our findings are in agreement with those of Esteban and colleagues [9] who compared clinical outcomes after using "SBT" in patients weaned with the T-tube. They reported that in the short (30 min) and long (60 min) trial groups, 87.8% and 84.8% of patients completed the trial distress and were extubated, respectively, whereas 13.5% and 13.4% required reintubation within 48 hours. The proportion of successful extubation was better in our study as it was in the far larger investigation of the Spanish Lung Failure Collaborative Group (Esteban, 1999). Moreover, the rates of reintubation were significantly lower in the present investigation (5.73%).

To explain these differences, we can consider the reasons for the duration of mechanical ventilation (6.42 $\pm$ 6.8 days) and mean APACHE II value 15.2 $\pm$ 7. The case mix of our study populations was similar to that in the study by Esteban (1999), although ventilator support before SBT and SBT + NRS was shorter in our study (6.5 vs 6.42 days). In spite of a similar APACHE II value in our study (15.2 *vs* 15) we observed a longer ICU LOS (12.7 vs 11 days). Special points in our study protocol were the careful titration of the sedation to get a good evaluation of the NRS, taking into account that some weaning score variables evaluate sedation, agitation and answer the question of the rate of extubation rejection. We believe that shortening the ventilatory support prior to the final SBT + NRS reduced subsequent morbidity, therefore decreasing ICU mortality, and most likely decreasing the reintubation rate.

Esteban (1999) [9] performed the weaning trial with the T-piece. Our patients were not disconnected from the ventilator and were finally weaned using the pressure support technique (5 cmH2O) plus the weaning score (NRS). The use of an inspiratory pressure support at the end of the weaning period is probably mainly needed to compensate for the resistance and the dead space of the ventilator circuit and not of the endotracheal tube. Moreover, pressure support improves oxygen consumption by the respiratory muscle during weaning [19]. Some variables of the weaning score were developed to evaluate the clinical manifestation of respiratory muscle failure: retractions, head up inability, cough incapability, and breathing pattern.

According to our results in this clinical research demonstration, an NRS value of ≤ 1 is suitable for achieving extubation in the large majority of patients. Moreover, NRS has an NPV of 94.35 percent, and may be more significant in the prediction of non-reintubation than the prediction of extubation. In our study, NRS showed a 94.27% confidence rate in relation to those people who would not be reintubated. Therefore, an NSR of ≤ 1 as a component of the "triple test" was considered to be a protector risk factor of reintubation (odd ratio: 16.69). Of the total ten variables used on NRS demonstrated by Valencia (2010), some have more influence on our results. However, these were not the aim of this clinical research study.

There are already some tests to evaluate patients during weaning from mechanical ventilation that attempt to get a low reintubation rate: "spontaneous respiratory index (SRI)" [4,6], "spontaneous breathing trial (SBT)" [9] and "simple criteria" had been used during weaning for a long time. The benefit of using NSR during weaning from mechanical ventilation as a component of the "triple test" could not be evaluated alone. Therefore, ***serial combined testing*** was used as it maximizes the specificity of SRI and SBT. This test decreased diagnostic sensitivity but increased specificity (reducing false positives: reintubated patients with a normal SRI and SBT). Based on our analysis, doing a weaning protocol taking into account IRS < 105 [4] on SBT [6] plus NRS > 1 at the first 10 minutes (triple test) would determine up to 94.2% of patients who would need reintubation.

Some investigations have shown that respiratory therapists using protocol guidance wean patients from mechanical ventilation safely and more quickly than a medical team following the traditional practice of physician-directed weaning [20,21]. In Colombia, ICUs are relatively closed units and specialized respiratory therapists have some autonomy in the strategy and handling of ventilatory support and weaning. Our therapist staff were involved in the study and autonomously guided the entire weaning period, including NRS, according to the "triple test" weaning protocol. The efficacy of respiratory therapists on directed-weaning protocol was not the target of this study. We do not have objective data on the efficacy or role of respiratory therapists in protocol-directed weaning scores. Further studies are required to investigate this interesting topic.

The main limitation of this study is that there is no comparison of data between the two groups. Nevertheless, some factors support the credibility of results obtained in the NRS study as a "triple test" tool for mechanical ventilation weaning. Firstly, the reintubation rate of 5.73 percent is better than the rates consistently found in the literature [7,8,9,21,22]. Secondly, as demonstrated by Esteban (1999) [9], NRS, like SBT, can be safely added to weaning protocols. Finally, Eptein (1995) and Yank and Tobin (1991) [4,6] established IRS as a value to be used when weaning from mechanical ventilation.

Conclusion

In conclusion, for this subset of patients our findings add the following information to the ongoing discussion about weaning strategies: SBT plus SRI measurements < 55 plus NRS ≤ 1 is an effective "TRIPLE TEST" tool for identifying patients who can be safely extubated with a low risk of reintubation. Considering that NRS as a first weaning clinical score is as effective as SRI and/or SBT alone to reduce reintubation, the traditional weaning from mechanical ventilation based on one parameter does not seem to be further justified.

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