Weaning From Mechanical Ventilation in Neurological Patients

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INTRODUCTION

A high percentage of patients with acute neurological disease require invasive mechanical ventilation (MV) to isolate the airway, to provide adequate oxygenation and to prevent aspiration of gastric content (1-3). During weaning from MV, a spontaneous breathing trial (SBT) is realized before extubation in order to assess patient's capacity to breath (4-6), and reducing the risk of extubation failure. The extubation failure is associated with a prolonged length of stay in the intensive care unit (ICU) and in the hospital, as well as, more risk of infections and higher mortality (7). In neurological patients, a successful SBT can not predict exactly the success of extubation (8-10). It is necessary both the assessment of muscle strength and the ability to keep the airway clearance capacity to ensure success of extubation (8-15).

The results obtained with the application of weaning protocols in neurological patients are not conclusive (16), with the exception of one clinical trial (17). A meta-analysis concluded that the establishment of weaning protocols in subjects in a medical-surgical unit reduced the duration of MV by 25%, weaning time by 78% and ICU stay by 10%. These results support the use of weaning protocols in patients undergoing MV (18).

In this study we try to demonstrate that the use of a protocol-directed weaning in neurological patients will reduce the rate of extubation failure and associated complications. The primary objective is to reduce the failure rate of extubation. As secondary objectives we are going to analyse the incidence of infections, need for tracheostomy, duration of MV, length of ICU and hospital stay, and mortality at ICU, hospital and 90 days.

MATERIAL AND METHODS

A prospective interventionist no randomized study will be conducted in a medical-surgical ICU. Patients 18 years or older with acute medical or surgical neurological disease [acute ischaemic or haemorrhagic stroke, acute subarachnoid haemorrhage, traumatic brain trauma, metabolic encephalopathy (toxic, infectious as encephalitis or meningitis), scheduled neurosurgical surgery with a prolonged MV, and status epileptics], will be included. Exclusion Criteria: scheduled neurosurgical surgery (duration of MV <24 hours), neuromuscular disease,

spinal cord injury, tracheostomized, inability to be evaluated, severe multiple traumatic injuries evaluated by the Injury Severity Score (19), direct extubation and self-extubation, patients who died during their ICU stay (without a trail of weaning), and patients transferred to another hospital.

At ICU admission, the following variables will be collected: age, sex, body mass index, comorbidities, prognosis severity scale by Simplified Acute Physiological Score (SAPS) 3, Organ failure by Sequential Organ Failure Assessment (SOFA) (at ICU admission and 5 days after admission), reason for MV, the level of consciousness by Glasgow Coma Scale (GCS) at the time of intubation and where it was performed. During the ICU stay, all neurological treatments and procedures such as treatment of intracranial hypertension (manitol or hypertonic saline, hyperventilation, decompressed craniotomy), cranial tomography (CT) scanner, external ventricular drainage, intracranial pressure sensor, cerebral arteriography, will be collected. The infectious complications (ventilator-associated pneumonia, tracheobronchitis, urinary tract infection, bacteraemia,) will be registered during the ICU stay.

To be included into study, subject undergoing mechanical ventilation will meet the following conditions: no or minimal sedation (propofol≤1mg/kg/h o midazolam≤0,1mg/kg/h), with spontaneous ventilatory stimulus, absence of intracranial hypertension, Glasgow Coma Score (GCS)> 9 (motor> 4 points), noradrenaline ≤ 0,2mcgr/kg/min, (fraction of inspired oxygen)FiO2 ≤ 0.5 (positive end-expiratory pressure) PEEP of 5cmH20, no intervention scheduled in the next 48 hours, maximal inspiratory pressure (MIP)< -20cmH20 (20), occlusion pressure (P0.1) >6mmHg with support pressure of 7cmH20 and 0 cmH20 of positive end-expiratory pressure (Z-PEEP).

Protocol study (study group). The subject will be connected to MV in a pressure support ventilation (PSV) mode, which will be gradually reduced (until a level de pressure support of 10 cmH20 above 5 cmH20 of PEEP). After, the subject will be disconnected from the ventilator and a SBT will begin through the connexion of the subject to a T-tube and a source of oxygen (21). Haemodynamic parameters [systolic blood pressure (SBP), heart rate (HR)], and respiratory parameters [respiratory rate (RR), partial pressure of carbon dioxide (paCO2), partial pressure of oxygen to fraction of inspired oxygen ratio (paO2/FiO2), and pH through blood gas analysis and saturation of oxyhemoglobin (SaO2) by pulse oximetry], and neurological parameters (means by GCS) will be collected during final period of pressure support ventilation (before disconnection) and at onset (5 minutes) and final (between 30 to 120 minutes) of SBT (22). A once daily SBT will be established in all the subjects until they

were extubated. A failure SBT will be considered with more than 2 criteria: paO2<50-60mmHg with FiO2 ≤ 0.5 (or SaO2 <90%), paCO2 > 50 mmHg, pH <7.35, RR > 35bpm, HR > 140 bpm, SBP > 180mmHg, cardiac arrhythmias during SBT, dyspnea, and increased use of accessory muscles (6). If the SBT fails, the subject will reconnect to MV. A successful SBT is defined as absence of whatever of variables above defined. *Airway clearance capacity.* Otherwise, if the SBT is successful, the ability to maintain airway will be analysed by the following variables: Number of aspirations of secretions/8-h nursing shift (No pass-0, 1 pass-1, 2 passes-2, ≥ 3 passes-3), cough capacity (strong -0, mild-1, weak-2, absent-3), appearance of secretions [viscosity (liquid-0, frothy-1, thick-2, dry-3) and colour of secretions (clear- 0, brown- 1, yellow-2, green-3), and finally, the presence of gag reflex (strong- 0, moderate- 1, weak- 2, absent- 3). A score ≤8 was considered as adequate to keep the permeability of airway (4). Then the subject will be extubated and connected to venturi mask with FiO2 of 0.4. In case of extubation failure, the patient will be reintubated. The use of non-invasive ventilation is not considered in this study (neither prevention of extubation failure nor in case of extubation failure).

Conventional weaning (control group). Subjects in the control group will receive weaning from MV according to the usual procedure, by reducing level of PSV. Then a SBT will be performed through a T-tube (the same parameters as protocol study will be collected) and subsequent extubation of the patient if there is a successful SBT. The criteria for SBT and for extubation failure are the same than in the study group. In case of extubation failure, non-invasive ventilation will be not considered, but it left to the discretion of the attending physician.

STATISTIC ANALYSIS. Based upon previous results (10), the authors considered that the need for an intubation could be reduced by 13% (6) [26% in the control group vs. 13% in the study group]. The estimated sample size was 109 patients in each group (confidence interval [1-α] = 95% (P=0.05) and power [1-β] = 80%). A comparative analysis was conducted by using the Student's t-test or the Mann-Whitney test for a comparison of the quantitative variables for the parametric and non-parametric characteristics, respectively. For the qualitative variables, we used the Chi-Square statistic or Fisher's exact test. A statistical significance was reached if P<0.05. The cumulative probability of survival was compared by using a Kaplan-Meier estimation of survival and a Log-Rank Test to compare both of the groups. Intention-to-treat

analysis will be realized. The data will be analysed with the aid of the statistical package SPSS 22.0.

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