Parameters Influencing Tracheostomy Decannulation in Patients Undergoing Rehabilitation after severe Acquired Brain Injury (sABI)

Cecilia Perin¹  Roberto Meroni¹  Vincenzo Rega²  Giacomo Braghetto¹  Cesare Giuseppe Cerri¹

¹Medicina e Chirurgia, Università degli Studi di Milano-Bicocca Ringgold Standard Institution, Milano, Italy
²Riabilitazione Neurologica, Gruppo Ospedaliero San Donato Ringgold Standard Institution, Milano, Lombardia, Italy

Address for correspondence  Cecilia Perin, MD, Medicina e Chirurgia, Università degli Studi di Milano-Bicocca, Via Cadore 48, Milano 20126, Italy (e-mail: cecilia.perin@unimib.it).


Abstract

Introduction  Tracheostomy weaning in patients who suffered a severe acquired brain injury is often a challenge and decannulation failures are not uncommon.

Objective  Our study objective is to describe the decannulation failure rate in patients undergoing rehabilitation following a severe acquired brain injury (sABI); to describe the factors associated with a successful tube weaning.

Methods  We conduct a retrospective analysis of charts, consecutively retrieved considering a 3-year window. Variables analyzed were: age, sex, body mass index (BMI), Glasgow Coma Scale (GCS), cause of hospitalization (stroke, trauma, cardiac arrest), date of the pathological event, gap between the index event and the first day of hospitalization, duration of Neurorehabilitation Ward hospitalization, comorbidities, chest morphological alteration, kind of tracheostomy tube used (overall dimension, cap, fenestration), SpO2, presentation and quantification of pulmonary secretion, maximal inspiratory pressure (MIP) and maximal expiratory pressure (MEP), respiratory frequency and pattern, cardiac frequency, presence of spontaneous cough, cough strength, and blood gas analysis.

Results  We analyzed 45 tracheostomised sABI patients following stroke, trauma, or cardiac arrest. The weaning success percentage was higher in Head Trauma patients and in patients presenting positive spontaneous cough. Failures seem to be associated with presence of secretions and anoxic brain damage. GCS seemed not related to the decannulation outcome.

Conclusions  Parameters that could be used as positive predictors of weaning are: maximal expiratory pressure, presence of spontaneous cough, and cough strength. Provoked cough and GCS were not predictive of weaning success.

Keywords
► tracheostomy
► weaning
► severe acquired brain injury
► vegetative state
Introduction

After severe brain injuries – which are often the consequence of severe traumatic brain injury, a stroke (both ischemic and hemorrhagic), and anoxic brain damage – patients with tracheostomies are hospitalized in a Neurologic Rehabilitation Unit.

A tracheostomy tube is usually inserted in patients with acquired brain injuries (severe ABI-sABI) in the Intensive Care Unit (ICU) when a relevant impairment of consciousness is observed. The GCS has to be reported as <9 on the seventh day after the injury, in association with the patient’s prolonged inability to breath or protect their airway sufficiently. This maneuver permits the airflow to bypass an eventual superior respiratory tract obstruction, avoiding damage to the larynx and superior respiratory tract, which is linked to a prolonged trans-laryngeal intubation (decubitus), and guarantees a way in the inferior respiratory tract for secretions’ suction.1–3

The incidence of tracheostomy in sABI patients is reported to be from 50% to 70%; which indicates the seriousness of the issue.4

The tracheostomy is removed if and when clinical conditions allow it. According to published papers, decannulation can be performed in ICU,1–6 in neurosurgical units,7 in long-term care hospitals,8–10 and, less frequently, in rehabilitation medicine units.11–13 The papers also suggest that the possibility of performing the removal for sABI patients in a neurorehabilitation ward (NW) is rated as variable.12–15

The tube removal in the NW is justified because of the possibility of complications due to the length of time the tube is inserted in the patient: respiratory complications, infections, and problems due to abundant secretions complicate the rehabilitation treatment. Major complications connected with the lengthy permanence of the tube are bleeding, abscess in the trachea, tracheal stenosis, dehiscence and, occasionally, the death of the patient.1–3,16 The tube is also a factor which slows down two of the main rehabilitative goals: vocal and swallowing recovery.

The subject has been, and still is, debated in relation to the following issues:

• Which parameters and criteria are necessary to proceed to removal of the tube?4,8,17–23
• Which parameters are associated with, or predict, the success of the decannulation procedure?6,9,10,12,14,16,18,22–24

Several authors concur on the good management of secretions and reactive cough as the main factor in the phenomenon analysis,4,6,8,10,12,16,18,21–29 while others underline the importance of the ability to tolerate tracheostomy tube capping.6,8,16,17,23,28 In addition, other studies report an adequate consciousness status and absence of psychiatric diseases4,19,20 as an important factor in the process.

Although conscience level is not applicable, the majority of other criteria is still useful (stable arterial blood gases, absence of distress, hemodynamic stability, absence of fever and infection, PaCO2 < 60 mm Hg, normal endoscopic examination or revealing stenotic lesion occupying <30% of the airway, and ability to expectorate).19

Other literature underlines that spontaneous or induced peak cough flow (PCF)16,18 and cough peak flow rate (CPFR)24 are valid predictors of successful decannulation. Mean expiratory pressure (MEP)3,16,30 and lung vital capacity18 are other parameters associated with success in the tube removal procedure.

Other variables that seem to be linked to a positive outcome are: GCS1,9,24,29,31,32 and the cause of the sABI (Head Trauma).9,10,33 In addition, Christopher,5 and Coplin29 further explored the concept of the safety of extubation in patients with a depressed mental status, and their results stated that there is still a possibility of tube removal, even in patients with a low GCS score.

This study covered a cohort of sABI patients who were hospitalized in a neurorehabilitation ward. The purpose was to analyze the percentage of success/unsuccess of decannulation, in addition to the study of factors revealed to be linked with both success and failure. The following is an observational retrospective pilot monocentric study, based on patients from an intensive neurorehabilitation ward for sABI. We collected all the data from patients having a tracheostomy tube since their first day of hospitalization.

The aims of the study are:

- to describe the decannulation failure rate in sABI during the rehabilitative process;
- to identify the factors associated with the outcome of tube removal.

We analyzed the following parameters to study the patients’ response: the neurological cause of hospitalization and its features, respiratory parameters, the time of permanence of the tracheostomy tube, the tube’s own special features, and the anamnestic records for cardiac and respiratory problems.

The ward selected for the study is an intensive rehabilitation ward for sABI short and mid-term consequences, where patients go after their time in ICU. According to national law, patients can stay in this kind of ward for a maximum of six months.

Methods

The population observed was composed of patients hospitalized from 2011 to January 2014 after they had suffered a sABI. They all had a tracheostomy tube inserted when they were in the ICU. The patients involved in the study had been undergoing treatment for physical and respiratory rehabilitation.

Data used in the retrospective study were eased by a standard data collection form.

The first part of the survey contained the patient’s features: age, sex, BMI, GCS, the cause of hospitalization (e.g., stroke, trauma, cardiac arrest), the date of the pathological event, the gap between the index event and the first day of hospitalization, the duration of NW hospitalization, any comorbidities, the chest morphologic alteration, and the diagnostic test performed.
The second part of the study involved collecting the following information regarding the respiratory tract: type of tracheostomy tube used (overall dimension, cap, fenestration), SpO2, quantification and presentation of pulmonary secretion, MIP and MEP, respiratory frequency and pattern, cardiac frequency, presence of a spontaneous or valid cough, and blood gas (Fig. 1).

The use of this form was approved by the institution’s Quality Control board in accordance with the Declaration of Helsinki.

The data used were obtained from the first form, compiled during the first week of NW hospitalization.

The decision tree used to determine when to approach to tracheostomy tube removal are shown below in Fig. 2.

The variables analyzed were: age, sex, BMI, GCS, cause of hospitalization (stroke, trauma, cardiac arrest), date of the pathological event, gap between the index event and the first day of hospitalization, duration of NW hospitalization, any comorbidities, chest morphologic alteration, type of tracheostomy tube used (overall dimension, cap, fenestration), SpO2, quantification and presentation of pulmonary secretion, MIP and MEP, respiratory frequency and pattern, cardiac frequency, presence of a spontaneous cough, cough strength, and blood gas analysis.

Other data collected were chest X-rays and blood test results.

### Parameter Collection

We analyzed the quantity of secretion and divided it into five categories: no secretions, very few, few, abundant, very abundant. The respiratory pattern could have been normal or abnormal (e.g., prolonged apnea or paradox breathing). We collected MIP, MEP, and cough strength pressures using of a manometer linked to the tracheostomy tube, which measured respiratory tract resistance during the two breathing phases. Cough evaluation – when not spontaneous – was performed by recording the patient’s response after a tracheal cannula touched the pharynx.

### Statistical Analysis

We analyzed the qualitative variables with contingency tables. We calculated the odds ratio in 2 x 2 tables, with a confidence interval of 95%. When tables presented more cells, we performed the chi-squared test. When the data contained in cells were not sufficient (n < 5) we used the Fisher exact test. All of the continuous variables results showed them as not parametrically distributed, so we further analyzed them with non-parametrical inferential statistics.

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**Fig. 1** Respiratory Evaluation Form in Patients with Severe Acute Brain Injury. Abbreviations: GCS, Glasgow coma scale; MIP, mean inspiratory pressure; MEP, mean expiratory pressure.
Results

We consecutively recruited total 45 patients (20 women and 25 men) for the study.

The mean age distribution was ~67 years with an interquartile range of 23 (17–84) (Table 1). We performed decannulation on 21 subjects (D) (46.7%), while in 24 cases the procedure was not possible (ND) (53.3%). The ND causes are reported in Table 2. Sex, age, and BMI distribution were not significantly different between D and ND patients.

Table 1 Population characteristics

<table>
<thead>
<tr>
<th>Variables</th>
<th>D (21 patients)</th>
<th>ND (24 patients)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Age (Interquartile Range)</td>
<td>69 (21)</td>
<td>63.5 (30)</td>
<td>0.793</td>
</tr>
<tr>
<td>Median GCS (Interquartile Range)</td>
<td>8 (1)</td>
<td>7.50 (2)</td>
<td>0.145</td>
</tr>
<tr>
<td>Median BMI (Interquartile Range)</td>
<td>23,23 (5,23)</td>
<td>22.5 (6.7)</td>
<td>0.796</td>
</tr>
<tr>
<td>Median SpO (Interquartile Range)</td>
<td>93 (3)</td>
<td>95 (4)</td>
<td>0.017*</td>
</tr>
<tr>
<td>Respiratory Rate (Interquartile Range)</td>
<td>22 (8)</td>
<td>24 (4)</td>
<td>0.075</td>
</tr>
<tr>
<td>Median MIP (Interquartile Range)</td>
<td>-8*10^-15</td>
<td>-10*15^-15</td>
<td>0.287</td>
</tr>
<tr>
<td>Median MEP (Interquartile Range)</td>
<td>5 (8)</td>
<td>8.50 (9)</td>
<td>0.044*</td>
</tr>
<tr>
<td>Decannulation – Admission Time</td>
<td>37 (16.5)</td>
<td>44 (39)</td>
<td>0.419</td>
</tr>
<tr>
<td>Treatment Length</td>
<td>43 (42)</td>
<td>58 (84)</td>
<td>0.432</td>
</tr>
<tr>
<td>Decannulation – End Treatment Time</td>
<td>89 (56)</td>
<td>107 (79)</td>
<td>0.162</td>
</tr>
</tbody>
</table>

Abbreviations: GCS, Glasgow coma scale; BMI, body mass index; SpO, saturation level of oxygen; MIP, mean inspiratory pressure; MEP, mean expiratory pressure.

* Mann Whitney test < 0.05.

Features of Neurological Disease (Table 3)

The patients were divided into three groups according to the neurological event: anoxic brain damage (A), stroke (S), and head trauma (TC). We observed a different prevalence of decannulated patients in the three groups. Decannulation was successful in 7.1% (1 out of 14) of A subjects, 60% in the S group (15 out of 25), and 83.3% in the TC group (5 out of 6). This difference in distribution was reported as significant using Fisher’s exact test = 14.319 with p = 0.0001.
Respiratory Features (Table 3)

The 80% of patients with an effective cough underwent tracheostomy tube removal (8 out of 10), and among patients with no appreciable cough, 37.1% of them were decannulated (13 out of 35). The presence of a cough seems to be associated with successful performance of the tracheostomy tube removal, with an OR of 6.769, and a CI of 95% or 1.244–36.848.

In addition, the presence of a spontaneous cough seems to be related to a favorable decannulation (OR: 10 - CI 95% 1,860–53,756). The 83.3% of patients with a spontaneous cough (10 out of 12) underwent the decannulation procedure. On the other hand, 33.3% of patients with a positive reflex cough had the tube removed (11 out of 33).

The respiratory parameters presenting a significant difference between the two groups were mainly SpO2 (p < 0.0.5) and MEP (p < 0.01) (Table 1). The evaluation of respiratory secretions showed no differences in quality and quantity between the D and ND groups of patients.

Table 2 Cause of non-decannulation

<table>
<thead>
<tr>
<th>Cause</th>
<th>N 24</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secretions</td>
<td>9</td>
<td>37.5%</td>
</tr>
<tr>
<td>Infections</td>
<td>7</td>
<td>29.16%</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>2</td>
<td>8.33%</td>
</tr>
<tr>
<td>Stridor</td>
<td>1</td>
<td>4.16%</td>
</tr>
<tr>
<td>Non-Pathological</td>
<td>1</td>
<td>4.16%</td>
</tr>
<tr>
<td>Anatomic features</td>
<td>1</td>
<td>4.16%</td>
</tr>
<tr>
<td>Regurgitation</td>
<td>1</td>
<td>4.16%</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>1</td>
<td>4.16%</td>
</tr>
<tr>
<td>Edema</td>
<td>1</td>
<td>4.16%</td>
</tr>
</tbody>
</table>

Table 3 Patient features

<table>
<thead>
<tr>
<th>N</th>
<th>Variables</th>
<th>%D</th>
<th>%ND</th>
<th>Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sex</td>
<td>45</td>
<td>55</td>
<td>OR =0.886 CI 95% (0.272–2.884)</td>
</tr>
<tr>
<td></td>
<td>m</td>
<td>48</td>
<td>52</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cause</td>
<td>71</td>
<td>29.9</td>
<td>FET = 14.319 p = 0.0001*</td>
</tr>
<tr>
<td></td>
<td>Anoxia</td>
<td>60</td>
<td>40</td>
<td>OR = 6.769 CI 95% (1.244–36.848)</td>
</tr>
<tr>
<td></td>
<td>Stroke</td>
<td>83.3</td>
<td>16.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Head Trauma</td>
<td>33.3</td>
<td>66.7</td>
<td>OR = 10 CI 95% (1.860–53,756)</td>
</tr>
<tr>
<td></td>
<td>Pattern</td>
<td>43.6</td>
<td>56.4</td>
<td>OR =0.386 CI 95% (0.063–2.364)</td>
</tr>
<tr>
<td></td>
<td>Normal</td>
<td>66.7</td>
<td>33.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Altered</td>
<td>33.3</td>
<td>66.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cough Strength (cmHO)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Positive</td>
<td>80</td>
<td>20</td>
<td>OR = 6.769 CI 95% (1.244–36.848)</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>37.1</td>
<td>62.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cough</td>
<td>83.3</td>
<td>16.7</td>
<td>OR = 10 CI 95% (1.860–53,756)</td>
</tr>
<tr>
<td></td>
<td>Spontaneous</td>
<td>33.3</td>
<td>66.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Provoked</td>
<td>42.9</td>
<td>57.1</td>
<td>OR =0.750 CI 95% (0.231–2.435)</td>
</tr>
<tr>
<td></td>
<td>Tube Cap</td>
<td>42.9</td>
<td>57.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No Cap</td>
<td>50</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tube Inner Caliber</td>
<td>4 mm</td>
<td>37.5</td>
<td>62.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 mm</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 mm</td>
<td>61.1</td>
<td>38.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7 mm</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8 mm</td>
<td>42.9</td>
<td>57.1</td>
</tr>
<tr>
<td></td>
<td>Cardiac Problems</td>
<td>Positive</td>
<td>38.1</td>
<td>61.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Negative</td>
<td>54.2</td>
<td>45.8</td>
</tr>
<tr>
<td></td>
<td>Respiratory Problems</td>
<td>Positive</td>
<td>28.6</td>
<td>71.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Negative</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>Secretions</td>
<td>Very abundant</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Abundant</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Few</td>
<td>62.5</td>
<td>37.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Very Few</td>
<td>37.5</td>
<td>62.5</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; f, female; m, male; D, decannulated; ND, non-decannulated; FET, Fisher’s Exact Test; OR, odds ratio.

* p significance < 0.05; absence of secretions was not reported in any patient observed.
Neurologic Condition Features (→ Table 1)
The Glasgow Coma Scale result was not significant between D group patients (median = 8, interquartile range = 1) and ND patients (median = 7.5, interquartile range = 2).

Tracheostomy Tube Features (→ Table 3)
The stratified data analysis performed on all sample patients (both D and ND) showed no significant differences related to the tube caliber and relative capping. Further analysis on hospitalization timing and treatment duration did not show any significant results either (→ Table 1).

Causes of Failure in Tracheostomy Weaning (→ Table 2)
Factors that have proven to be the cause of failure in tracheostomy weaning are the presence of abundant pulmonary secretions and infections, as shown in → Table 2.

Discussion
Weaning success is an outcome reported by numerous papers in the literature.4–7,9,11,12,16–18,22–24,25,31,34,35 For the most part, the authors reported successful weaning from the tracheostomy in the ICU context taking into account patients with different pathologies (neurological, cardiac, pulmonary). In this study, the percentage of successful D varies significantly from the 33% reported in a population with infratentorial damage to the 85–95% in populations with cardio-circulatory, pulmonary, neurological etiology.

Based on these premises, a comparison between the population enrolled in our study and what is reported in the literature is challenging, given that only a rough estimate is possible, describing the hospitalized regimen.

Upon examination of the percentage of success and failure data for sABI decannulation, our study shows that D = 46% seems to be lower than the results of De Lima Zanata et al 13 and Matesz,13 with D = 60%, whereas Klein et al 14 showed a lower percentage of success than the study referred to in our study, with D = 23.8% in a population of patients with Sub Arachnoid Hemorrhages (SAH) and Mackiewicz-Nartowicz 26 showed D = 31.5%. In sum, literature reports as fairly variable and high the percentage of sABI patients who did not undergo tracheostomy weaning.

None of the decannulated patients needed to regress to the previous condition of being tracheostomised throughout the observation period. We defined weaning failures according to the Stellfox definition. Stellfox guidelines outline that if any respiratory failure happens after 48/96 hours from the weaning attempt, a regression to the previous condition of being tracheostomised is needed.28 It is important to highlight that in several papers the definition for failures, unfortunately, is not univocal, ranging from 24 hours12 to one week,34 while other authors define a weaning failure as when the patient cannot tolerate an uncuffed fenestrated tube.21

Moreover, our study reports no differences regarding the kind of tracheostomy tube used versus the success rate of decannulation, contrary to Raees et al,21 which states that the cup tube carried a major ND risk.

Stroke (S) and head trauma (HT) patients underwent decannulation in more cases than patients hospitalized for anoxic episodes (A). According to Namen,9 O’Connor,10 and De Lima Zanata13 HT patients have the best prognosis for decannulation.

Weaning guidelines always refer to the state of consciousness as an important parameter.4,19,20 However, authors have also reported successful D in patients in a vegetative state.5–23 In most of the papers, the state of consciousness is related to the success of extubation. Since the population in the present study is composed by non-intubated and non-ventilated patients, we limited the comparison of the literature considering only studies that enrolled patients with neurological conditions with spontaneous breathing.

There were no significant differences in GCS between the D and ND groups. Therefore, it seems that the basal neurologic condition does not influence the success of tube weaning, which concurs with Chan et al 24 We further analyzed the decannulation maneuver within a database of tracheostomy patients5,16,19,34 and the results showed it is slightly more difficult for patients with a lower GCS, but this does not carry a significant difference in the D and ND ratios. Other authors1,3,11,12 have found divergent results. According to them, a low GCS is related to a strong possibility of ND. Coplin,29 moreover, claimed that a lower GCS is an independent predictor of failure in extubation from mechanical ventilation.

In summary, the data seems to concur that GCS does not influence the weaning process and overall procedure outcome.

Regarding the variables influencing D patients, the important associated factors are a valid cough and the presence of a spontaneous cough.

In particular, we found that decannulation success is more likely to happen with a valid and spontaneous cough.

The majority of the authors acknowledge the importance of a valid cough. In particular, such authors highlight that peak cough flow (PCF) is a crucial parameter.24 Unfortunately, this parameter is difficult to measure in our population, given that only a rough estimate is possible, describing the cough as “valid” or “reflex.”

While not enough comparable data was found for a spontaneous versus a provoked cough, a comparison is only possible with Duan’s26 identification of spontaneous cough peak flow as a positive predictor for D, compared with cough reflex. MEP was identified as another associated factor significant to D. The literature on the subject is not unisonous, as some authors concord,16 while others do not confirm.30

Regarding the principal causes of ND, the study showed that these are mainly the excessive quantity of secretions and the presence of infections (see → Table 2).

Although we did not find a statistically significant difference in the quantity of secretions between ND and D groups, we do believe that secretions management is crucial for the tracheostomy weaning process.

In particular, several authors recognize the negative impact of unsuccessful secretions management.31,32,35,36

Checklin37 suggests an endoscopic protocol, which is a treatment that mandatorily requires the patient’s compliance. Regarding the patients in the survey, an otorhinolaryngologist team evaluated all of the cases using a fiberscope and stated
that they found a problem in treating or managing secretions in 9 out of 24 subjects. Therefore, this point remains a failure due to the difficult and challenging nature of the treatment. 38

Other reported causes of failure were related to infections: difficulty in managing them, elevated relapse, and a selection of multi-drug resistance germs, indicating a complex situation of difficult treatment.

In this study, we used a standardized protocol. Based on our study results, we believe that the use of a standardized protocol is one of the key factors for decannulation success. Timing and parameters can improve the success rate, and other studies3,4,9,11,13,16,17,21,30,34,39–41 have determined its importance, although some authors from a Nepalese team42 did not find a concrete difference in an abrupt D versus a monitored path to decannulation. Ultimately, it is essential to consider that in a NW, especially in cases without the possibility of referral to an internal ICU, protocol use is highly recommended to avoid acute respiratory failure.

### Conclusion

In conclusion, this study highlights the NW decannulation as a valid possibility for sABI patients, even after ICU demission. A valid and non-provoked cough is again identified as a fundamental parameter for the road to successful decannulation, as it is for MEP. The decannulation outcome in the study was not influenced by initial GCS, although anoxic brain injury seems to be strictly related to weaning failure.

The main limitations of the study were the low number of participants examined and the absence of a proper follow-up after the six months spent in the operative unit.

Big samples are indeed a big challenge in neurorehabilitation. In our study, the sample included subjects with severe brain injury. Such patients undergo lengthy hospitalization (6 months) and turnover in the rehabilitation ward is low. Despite the small sample size, the characteristics of the tracheostomised subjects were similar to the characteristics reported in other studies.13,14,26,33

It was not possible further investigation of the patient’s outcome after demission, thus, some subjects could have been decannulated after a longer period without clinical problems. The less probable result seems to be that patients defined as D could have encountered problems that led to further tracheostomy tube replacement.

A longer follow-up period of more than six months is definitively a functional option to analyze the subject and monitor all of the subjects in more detail.

There are no actual or potential conflicts of interest for the author. Funding was solely provided by departmental resources.

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