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Highlights:

- Swallowing dysfunction after extubation is frequent after prolonged invasive ventilation
- Except for stroke patients, a bedside screening tool is still needed in the ICU setting
- We developed a new bedside accurate tool to detect swallowing dysfunction
- Our test could be a useful screening test in ICU to avoid unnecessary examination
- A negative test would allow to resume oral feeding earlier in critically ill survivors

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Fiberoptic endoscopic validation of a clinical screening test of swallowing function in critically ill patients performed within 24 hours after extubation.

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Declarations

Ethics approval

This study was approved by the Rennes University hospital's ethical committee (no. 16.143) and written informed consent was obtained from all subjects participating in the study.

Conflicts of interest statement

The authors have no conflicts of interest to declare that are relevant to the content of this article.

Data availability statement:

The data that support the findings of this study are available from the corresponding author, AM, upon reasonable request.

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Authors' contributions

AM conceptualized the study and participated in its design, data acquisition and analysis, literature research, and manuscript drafting. VP participated in the literature research, data acquisition and analysis, and the drafting of the manuscript. EP participated in data acquisition. EG conceptualized the study, participated in data acquisition and analysis and manuscript

1 drafting. PB and AF participated in data acquisition, data analysis and manuscript drafting. YLT
2 participated in revising the article for important intellectual content and manuscript drafting. FJ
3
4 participated in the literature research. JMT and AG conceptualized the study and participated
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6 in its design, data analysis, and manuscript drafting and revision for important intellectual
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8 content. All authors read and approved the final manuscript.
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Abstract

Background: A bedside screening tool of swallowing dysfunction (SD) (BSSD) after extubation would be useful to identify patients who are at risk of SD. We aimed to evaluate the accuracy of our BSSD in comparison with fiberoptic endoscopic evaluation of swallowing (FEES) in critically ill patients after extubation.

Methods: We conducted a 1-year prospective monocentric study to evaluate the accuracy of our BSSD to diagnose SD following endotracheal intubation in comparison with FEES (gold standard). Patients intubated for longer than 48 hours were included. Both tests were assessed within 24 hours after extubation. Primary endpoint was the accuracy of the BSSD. Secondary endpoint was to assess risk factors of SD.

Results: Seventy-nine patients were included in the study. Thirty-three patients (42%) presented with a SD. The BSSD showed a sensitivity of 88% (95% CI 0.72-0.97) and a specificity of 91% (95% CI 0.79-0.98), a positive predictive value of 88% (95% CI 0.72-0.97) and a negative predictive value of 91% (95% CI 0.79-0.97). The AUC reached 0.83 (95% CI 0.74-0.92).

Conclusion: Our study describes an accurate clinical screening tool to detect SD after extubation in critically ill patients. Screening-positive cases should be confirmed by instrumental tests, ideally using FEES.

Keywords: Swallowing dysfunction, fiberoptic endoscopy, extubation, aspiration, pneumonia, endotracheal intubation.

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Introduction

Swallowing dysfunction (SD) is a major issue in post-extubated patients as it can lead to aspiration, acute respiratory failure, health-care associated pneumonia, reintubation, and, consequently, prolonged intensive care unit (ICU) and hospital length of stay[1–3]. Moreover, delayed enteral feeding after extubation could expose these patients to underfeeding[4], or the use of nasogastric tube feeding to laryngeal injury[5].

Several risks factors for SD have been identified, such as preexisting dysphagia (cancer, surgery and irradiation of the neck), stroke[6] and neuromuscular diseases, or critical illness polyneuromyopathy[7]. Nevertheless, the association between SD and critical illness polyneuromyopathy must be handled with great caution, and as highlighted by Beduneau et al., the underlying mechanisms contributing to dysphagia in ICU patients remain incompletely understood. [6,7]. Patients known to have pre-existing swallowing dysfunction will be cautiously re-fed after extubation because they are at risk of aspiration[8,9]. Nonetheless, a large proportion of patients without any pre-existing swallowing dysfunction may be at risk for aspiration after extubation in the ICU. Along these lines, prolonged or multiple tracheal intubation are known risk factors for laryngeal injuries ~~and SD~~ which can be responsible for extubation failure[10]. Among these risk factors, the duration of mechanical ventilation has been associated with the occurrence of swallowing disorders. Endoscopic studies have found that swallowing dysfunction leading to aspiration in critically ill patients intubated for longer than 48 hours are frequent, up to 80%[11–16]. These studies also demonstrated that expected clinical signs of aspiration such as cough, wheeze, stridor, tachypnea, cyanosis with feeds, oxygen desaturations, and noisy or wet breathing were not present in extubated patients with SD. Therefore, these patients should be considered as silent aspirators[17].

1 As emphasized in recent reviews, a simple and reproducible bedside assessment of swallowing
2 function after extubation in the ICU setting is still lacking. Bedside swallowing assessments are
3
4 inaccurate in detecting aspiration when compared to flexible endoscopic evaluation of swallow
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6 (FEES) or videofluoroscopic swallow study[18,19] which are the gold standard for the
7
8 diagnosis of SD. These procedures require manpower and equipment supply. Furthermore, a
9
10 recent study focused on acute respiratory failure survivors requiring mechanical ventilation and
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12 intubation longer than 48 hours. ~~and~~ They successfully developed a decision-tree algorithm[20].
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15 However, the authors concluded that their bedside swallowing evaluation demonstrated
16
17 variable accuracy to identify patients at high risk for aspiration and required further validation.
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19 Therefore, the development of effective screening strategies using bedside and reproducible
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21 assessments is crucial. Herein, we developed a new clinical bedside screening tool of
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23 swallowing dysfunction (BSSD) after extubation of critically ill patients. We aimed to
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25 prospectively assess the accuracy of our BSSD in comparison with FEES as a gold standard in
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27 critically ill patients requiring mechanical ventilation for more than 48 hours. ~~at risk to develop~~
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29 ~~swallowing dysfunction following endotracheal intubation.~~
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Methods

This study was approved by the Rennes University hospital's ethical committee (no. 16.143) and written informed consent was obtained from all subjects participating in the study.

Study design

We performed a prospective study over a 1-year period in our mixed 30-bed Intensive Care Unit at the Rennes University Hospital, a tertiary teaching hospital. This study complied with the STARD guidelines on reporting accuracy studies[21].

Patient eligibility

Criteria for inclusion were as follows: intubation for more than 48 h; extubation after a successful weaning trial of 1 h through a T-piece~~[10]~~; ability to maintain a sitting position and remain seated in an upright position for at least 5 minutes prior to the test; Glasgow coma scale after extubation of 15.

Exclusion criteria were a known laryngeal pathology, a preexisting swallowing dysfunction and an admission for stroke. We also excluded all patients for whom we were unable to perform the FEES within the first 24 hours following extubation because of the unavailability of the otorhinolaryngologists, and all patients who refused FEES.

All patients were orally intubated with soft, high-volume, low-pressure cuffed endotracheal tube (ETT) (Mallinckrodt Medical, Athlone, Ireland). All intubations were performed by experienced intensivists or emergency medicine physicians. During the ICU stay, cuff pressures were checked every 4 h to maintain a pressure < 25 cmH₂O.

Data collection

We prospectively collected the following parameters: age, sex, body mass index (BMI), severity of illness at admission according to the simplified acute physiological score[22] (SAPS II) and the sequential organ failure assessment score[23] (SOFA) at admission, main indication for intubation (neurologic failure, acute respiratory failure, hemodynamic failure and surgery), intubation characteristics (emergency or planned for surgery), use of sedation or myorelaxant drugs for intubation, the duration of intubation, ETT diameter (expressed in millimeters) and patient's height/ETT diameter ratio[10], history of self-extubation, and the number of intubations during ICU stay before inclusion. We also recorded if patients developed shock (defined as the need for dobutamine, epinephrine, or norepinephrine treatment during intubation period), if they received steroids prior to extubation (at least 50 mg equivalent of methylprednisolone per day during the period of intubation) and their SOFA score at the day of extubation[23].

After extubation, the patients were monitored for 28 days and the following parameters were recorded: extubation failure (defined as the need to reintubate the patient in the first week following extubation[24], regardless of cause), the development of pneumonia within 28 days after extubation[25], ICU length of stay, and vital status within 28 days after extubation.

Extubation procedure

Extubation was decided by the patient's attending physician after a successful 1h spontaneous breathing trial. A spontaneous breathing trial was considered as successful according to the following criteria: absence of development during the spontaneous breathing trial of any of the following events including respiratory rate > 35 breaths/min, increased accessory muscle activity, SpO₂ persistently below 90% despite increasing FiO₂, heart rate persistently above 140

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beats/min, systolic blood pressure < 90 or > 180 mmHg, or appearance of cyanosis or mottling, depressed mental status or agitation. Planned extubations were performed by a nurse and a respiratory therapist under the control of a physician, as previously reported[10]. The decision to resume oral feeding following extubation was left at the discretion of the attending physician, with the knowledge of the FEES result. Consequently, none of the patients with abnormal FEES was refed.

Bedside screening test of swallowing dysfunction (BSSD)

A bedside evaluation was conducted according to a standardized protocol within 24 h after extubation by two physiotherapists and, importantly, before the FEES procedure. The BSSD comprised a clinical evaluation of eight items as shown in Table 1[25]. SD was suspected if the patients did not check all the criteria summarized in the Table 1. Post-extubation stridor was defined as an audible inspiratory wheeze after extubation[26]; clear voice was defined as the absence of signs of wet-sounding voice and the absence of whispers; mobility of the tongue was defined as the ability to stick out the tongue and move it; voluntary coughing was defined as the ability to cough when asked for; the ability to maintain head lifted was defined as the ability to lift the head against gravity in a horizontal position for a few seconds; the oral praxis skills were defined as the ability to voluntarily move the facial muscles (ie. close the lips, puff out the cheeks, smile); salivary stasis was defined as the inability to keep the mouth clean and/or the absence of saliva control (ie. anterior leaking)- The potential items were identified based on data acquired during a study evaluating post-intubation laryngeal injuries[10]. Then, a descendant stepwise logistic regression analysis was performed to assess the independent variables with p=0.20 for enter. Then, the final variables were chosen for their ability to explore the first phases of normal swallowing[27]. Thus, the oral praxis skills, salivary stasis and

1 mobility of the tongue explore the oral phase; tone of the flexor muscles of the neck and ability
2 to maintain head lifted explore the pharyngeal phase; voluntary coughing and clear voice
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4 explore the signs of aspiration; and the post-extubation stridor explore the presence of laryngeal
5 injuries. A pass/fail response was assigned to each item so that failure on any item constitutes
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7 a positive screen result and therefore an increased risk for swallowing dysfunction. Importantly,
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9 BSSD was performed by two trained physiotherapists and inter reliability was assessed. To
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11 ensure blindness between the physiotherapists, the two BSSDs were made separately within the
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13 hour. Neither the attending physician nor the physiotherapists were aware of the results.
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23 **Endoscopic evaluation and definition of swallowing dysfunction**

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27 A laryngeal nasofibroscope was performed within 24 h after extubation by two experienced
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29 otolaryngologists. The FEES procedure was performed in the ICU in accordance with
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31 previously published studies[17]. We carried out the examination in a bed or on a chair for all
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33 patients with the back elevated to at least 75°. A fiberoptic laryngoscope (Karl Storz
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35 Endoskope™ 11101SP, Tuttlingen, Germany, 30 cm long and of 3.5 mm diameter was used
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37 with a Karl Storz™ 11301 DF cold light supply for illumination) was passed transnasally to the
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39 nasopharynx, oropharynx, and supraglottic area to allow adequate visualization of the structures
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41 involved in swallowing. No topical anesthetic or other preparation was used before placing the
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43 scope in the nose. Gastric tube, if it was present, was not removed during the procedure. Ten
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45 milliliter of stained liquid (International Dysphagia Diet Standardization Initiative consistency
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47 (IDDSI) of 0) and semi-liquid boluses (IDDSI = 4) were then given. Otolaryngologists assessed
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49 the ability to protect the airway and to uphold airway protection, the capability to clear the bolus
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51 during deglutition, the presence of pooling and residual material in the hypopharynx.
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2 To diagnose swallowing dysfunction, the Penetration Aspiration Scale (PAS) was used[28]
3 (**Supplementary Table 1**). The PAS allows describing all penetration and aspiration events in
4 the same scale and in an ordinal way. A score of 1 is considered as normal. We defined
5 swallowing dysfunction as a Penetration Aspiration Scale (PAS) > 1. Penetration is scored
6 either 2 or 3 if residue remains above the vocal folds and 4 or 5 if material crosses to the level
7 of the vocal folds. Finally, aspiration is scored 6, 7 or 8. Two boluses were used to explore
8 swallowing function and the highest PAS score was taken into account.
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18 The FEES was performed after BSSD, without knowledge of the BSSD result.
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24 **Endpoints**

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27 The primary endpoint was the accuracy of the BSSD compared to the FEES procedure.
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29 Secondary endpoints were: to identify risk factors for SD, to evaluate the incidence of SD,
30 pneumonia and death occurrence within the 28 first days following extubation.
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39 **Statistical analysis**

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42 Based on the literature and a first unpublished cohort, we hypothesized a prevalence of SD of
43 0.30 and an expected sensitivity of our BSSD of 0.80 with a minimal lower confidence interval
44 of 0.6; these estimates allowed us to calculate a sample size of 76 patients[29].
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51 Normally distributed continuous variables are presented as the means (standard deviations),
52 whereas non-normally distributed data are presented as medians (Interquartile ranges).
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54 Categorical variables are presented as numbers (percentages). For between groups comparison,
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58 Mann-Whitney test for continuous variables and a χ^2 test or Fisher's exact test when more
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1 appropriate for categorical variables were used. The two groups (normal swallowing vs.
2 swallowing dysfunction) were compared using the Mann-Whitney test for continuous variables
3 and a χ^2 or Fisher's exact test when more appropriate for categorical variables. A descendant
4 stepwise logistic regression analysis was performed to assess the independent factors of
5 swallowing dysfunction with $p=0.20$ for enter. Among related factors (SAPS II at admission
6 and SOFA at intubation) only the most clinically relevant (SAPS II for severity) were included
7 in the multivariable analysis model to minimize the effect of collinearity. Thus, the variables
8 entered into the multivariable analysis were SAPS II at admission, hemodynamic failure,
9 intubation characteristics (emergency or planned for surgery), duration of intubation and main
10 indication for intubation.
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25 We identified potential items for our BSSD based on data acquired during a study evaluating
26 post-intubation laryngeal injuries[10] and their impact on extubation. Then, a descendant
27 stepwise logistic regression analysis was performed to assess the independent variables with
28 $p=0.20$ for enter. Because we aimed to develop a screening test, we wanted to focus on the
29 sensitivity and negative predictive values. We then assigned one point for each identified
30 variable. The novel BSSD (Table 1) was then assessed on these preliminary data, the results are
31 reported in the supplementary appendix 1.
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43 The FEES results were considered as the gold standard[20]. We calculated the accuracy,
44 sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of
45 the BSSD from 2 x 2 table. Ninety-five percent confidence intervals (95% CI) were calculated
46 as exact binomial confidence intervals. The accuracy of the BSSD was assessed by the mean of
47 receiver operating characteristics (ROC) curves and the area under curve (AUC). The threshold
48 value of the BSSD was then determined from analysis of the ROC curves as the value that led
49 to the best compromise between sensitivity and specificity. The reproducibility of the BSSD
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1 between the 2 physiotherapists was analyzed using the weighted Cohen's Kappa measure of
2 interrater reliability.
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5 Statistical analyses were performed using R 4.0.2 (R Foundation for Statistical Computing,
6 Vienna, Austria), and p values of less than 0.05 were considered significant.
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Results

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6 During the one-year study period, a total of 1026 patients were admitted to the ICU. Among
7 them, 554 were intubated, and 307 were intubated longer than 48 h. Ninety-five patients did not
8 met the inclusion criteria for the following reasons: 55 patients died before their extubation, 12
9 had a Glasgow coma scale < 15 and 28 were not able to maintain a sitting position. 79 patients
10 were included. Of note, althoughIn total, 212 patients were eligible for inclusion, and 133 were
11 excluded for the following reasons: 37 (17%) patients were reintubated before both evaluations,
12 2 died before both evaluations, and 8 were transferred to a different hospital before extubation.
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14 Importantly, unavailability of a FEES operator affected 74 (55.6%) patients. Finally, 12 patients
15 refused FEES examination before or at the beginning of the procedure. Thus, 79 patients were
16 included. Flow-chart is represented in the **Figure 1**. The time interval between extubation and
17 BSSD was 3.3 ± 2.1 h (mean \pm SD) and 6.8 ± 5.7 h between BSSD and FEES. There was no
18 clinical intervention between the two tests. Of note, no FEES complications were observed.

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Thirty-three patients were diagnosed as having SD according to the FEES. Their baseline characteristics are shown in **Table 2**. Of note, the SD frequency of FEES confirmed aspirators (PAS > 6) was 6% of all the patients and accounted for 15% of the SD patients (PAS > 2). Among the 59 patients who presented with shock, 51 (86%) presented with septic shock, 4 (7%) with hypovolemic or hemorrhagic shock and 4 (7%) with cardiogenic shock.

Test results

Thirty-three patients (42%) had swallowing dysfunction (FEES positive, using endoscopic criteria, **Figure 3**). BSSD was positive for 29/33-(37%) of them. Comparison of the results of

1 the fiberoptic endoscopic evaluation of swallowing (FEES) and bedside swallowing evaluation
2 (BSSD) is represented in Table 3. The BSSD showed a sensitivity of 88% (95% CI 0.72-0.97)
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4 and a specificity of 91% (95% CI 0.79-0.98), a PVV of 88% (95% CI 0.72-0.97) and a NPV of
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7 91% (95% CI 0.79-0.97). The accuracy of the BSSD is shown in **Figure 2**. The AUC reached
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9 0.83 (95% CI 0.74-0.92). The BSSD value of zero was determined from the ROC as the most
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11 accurate to detect a swallowing dysfunction.
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15 Based on weighted Cohen's kappa statistics, we found a high level of interrater agreement with
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17 $\kappa = 0.77$ (0.66-0.89) between the two physiotherapists.
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21 **Risk factors for swallowing dysfunction**

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24 The characteristics and comparison of patients with and without SD are shown in **Table 2**.
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26 Swallowing dysfunction was significantly associated with longer duration of mechanical
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28 ventilation, intubation for respiratory failure, and hemodynamic failure requiring vasopressor
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30 infusion. Using multivariable analysis, independent risk factors for SD were duration of
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32 intubation (OR=1.08; 95% CI 1.02-1.17, p=0.03) and hemodynamic failure requiring
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34 vasopressor infusion (OR=4.46; 95% CI 1.27-21, p=0.03).
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40 **28-Day follow-up**

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43 Among the study population, 10 (12.7%) patients developed pneumonia during the follow-up
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45 period. Five had SD assessed by FEES and 5 had no evidence of SD shown by FEES. Among
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47 these 10 patients, 4 died within the 28 first days.
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51 Among the 33 patients who presented with a swallowing dysfunction, 5 (15%) developed
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53 pneumonia and 3 (10%) died within the first 28 days after extubation.
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Discussion

We found that our BSSD was reproducible and presented a high accuracy and high negative predictive value to screen SD after extubation of critically ill patients ~~with SD after extubation.~~

This high NPV is important for diseases such as post-extubation SD where the risk of being undetected can lead to serious consequences of pneumonia, malnutrition and death. Since SD is frequent, its early identification can reduce the occurrence of pulmonary complications after extubation. For instance, Barquist reported the onset of aspiration pneumonia after extubation in 15% of patients[13], while others authors[11] found that up to 50% of patients had swallowing dysfunction after extubation. Contrarily, a recent study[7] evaluating the incidence of persistent SD after extubation showed clinical evidence of SD in 25% of patients ventilated for 7 days or more, but SD were not associated with an increased risk of pneumonia. Nevertheless, they focused in patients ventilated more than 7 days, and they acknowledged that the unblinded design might have contributed to the low number of complications related to SD. The largest prospective study to date on dysphagia frequency in a tertiary mixed medical-surgical ICU setting reported a lower incidence rate than in our study[30]. However, this incidence was likely underestimated due to exclusion of patients leaving the ICU alive with tracheostomy. Moreover, a recent study conducted by Moss et al. reported a prevalence of 33% of SD assessed by FEES[20], consistent with our results. The epidemiology of post-extubation SD is challenging, probably because of a high heterogeneity in its definition. The high probability and potential severity of aspiration pneumonia emphasize the need for the early screening of patients after extubation in ICU.

Our BSSD presented a high sensitivity (88%) and negative predictive value (91%) to identify high-risk critically ill survivors for swallowing dysfunction after extubation. Subsequently,

1 these high-risk patients could be rapidly diagnosed by an instrumental test using FEES and
2 referred to speech-language pathologists. Moreover, a negative BSSD would allow
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4 practitioners to resume oral feeding earlier in eligible patients and allow missing very few
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6 “aspirators”, thus avoiding unnecessary instrumented examination.
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10 Fiberoptic evaluation of swallowing is considered a gold standard test for the assessment of SD
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12 in recently extubated survivors of critical illness[31]. This technique has several advantages:
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14 first, it can be performed at the bedside and does not require patient transportation outside the
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16 ICU. Second, it allows direct visualization of the larynx and of the movement of the pharyngeal
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18 and glottic structures, including the vocal cords and the proximal trachea. However, FEES has
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20 several limitations. Although it can be considered as invasive and uncomfortable by some
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22 patients, equipment and otorhinolaryngologist availability are the most important barriers to the
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24 routine use of FEES. For example, a national survey in the US showed that endoscopy is
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26 available in only 41% of hospitals caring for recently extubated patients; furthermore, even
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28 when available, FEES is used only 15% of the time in university hospitals and 8% of the time
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30 in general hospitals[32]. A recent European survey reported that only 30% ICUs routinely
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32 assessed for dysphagia following extubation, and only 8% used instrumental assessments[33].
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34 Our study emphasizes this issue, as 74 (55% of the excluded patients) patients were excluded
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36 because of unavailability of FEES operator. Consequently, a simple clinical bedside swallowing
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38 screening test could be of benefit for intubated patients in the ICU. This evaluation is easy to
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40 implement, cost-effective and non-invasive, which could make it available in all ICUs.
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49 Additionally, a systematic and accurate method of detecting swallowing dysfunction might
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51 decrease aspiration pneumonia by allowing modifications of the care of these patients, such as
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53 implementing enteral feeding tube placement and providing rapid care by speech-language
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55 practitioners. Finally, it could allow rapid oral feeding in patients whose swallowing evaluation
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57 has been found normal. Indeed, caloric deficit has been reported to be associated with increased
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1 nosocomial infection rates, especially bloodstream infections[34] and pneumonia, as well as
2 higher mortality[35], longer ICU stays, and higher healthcare costs[36,37].
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5 Many studies have previously proposed bedside swallowing assessments, mainly in stroke
6 patients[37–40]. One study has been conducted to develop an accurate bedside assessment of
7 swallowing function after extubation in non-stroke patients. This study reported the
8 development of a decision-tree algorithm to identify aspiration risk in acute respiratory failure
9 survivors, but the tool developed showed variable accuracy[20] and the algorithm still needs a
10 future external validation since the evaluation was performed 25 hours after extubation and the
11 reproducibility was not assessed. In our study, we only excluded stroke patients for whom
12 several screening tools exist, and patients with a known preexisting laryngeal disorder.
13 Therefore, our screening test is intended to be complementary with existing tools and used in a
14 general ICU population.
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29 We found that duration of intubation and hemodynamic failure requiring vasopressor infusion
30 were risk factors independently associated with SD. In a monocentre study focused on elderly
31 patients, El Sohl et al. found that up to 50% of patients had swallowing dysfunction after
32 extubation. Among the risk factors, duration of intubation and hemodynamic failure requiring
33 vasopressor infusion were associated with SD. Duration of endotracheal intubation has
34 previously been associated with laryngeal injuries that can promote swallowing dysfunction
35 along with loss of muscle strength attributable to non-use during intubation and loss of
36 proprioception[18,41]. Recently, Beduneau et al. found that the presence of persistent SD was
37 associated with longer duration of ICU stay after extubation[7]. Furthermore, the association
38 between a need for vasopressor (i.e., hemodynamic failure) and swallowing dysfunction ~~might~~
39 ~~be explained by the effects of vasopressor therapy, which induces neuronal dysfunction that~~
40 ~~can diminish both the sensitivity and mobility of laryngeal and pharyngeal structures~~[40,41]. is
41 controversial. The Dynamics trial[30] found an association between SD and the number of days
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1 on adrenaline, but not with noradrenaline. As highlighted in a recent review[31], studies
2 focusing on risk factors for dysphagia following endotracheal intubation are scarce and provide
3 conflicting results. They either support or reject the identified risk factors, such as intubation
4 duration, cardiac failure, etc. Although we found such association, it remains unclear whether
5 hemodynamic failure is a risk factor of swallowing disorders following endotracheal intubation.

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12 Our study has several limitations. ~~First, although FEES is considered as the gold standard test~~
13 ~~to assess SD for recently extubated survivors of critical illness, we cannot rule out missed~~
14 ~~diagnoses of SD.~~ First, 133 patients were excluded mainly due to a lack of availability
15 of otorhinolaryngologists to perform FEES. This fact emphasizes that FEES availability is the
16 most important barrier to its routine use[32]. Third, we did not assess the evolution of
17 swallowing dysfunction using a second FEES, which could have been of interest. Few studies
18 have focused on the duration of swallowing dysfunction in survivors of critical illness. El Solh
19 et al.[11] showed that at day 5 and day 14 after extubation, 40% and 14% of elderly patients
20 had endoscopically confirmed aspiration, respectively and another study showed an
21 improvement in swallowing delay in all patients at 7 days after extubation[41]. More recently,
22 a ~~retrospective-prospective~~ cohort showed persistent swallowing dysfunction in ~~35~~40% of SD
23 ~~patients at hospital discharge~~ within a maximum of 3 days after extubation[7]. Moreover, as we
24 aimed to develop a screening test, we wanted to focus on the sensitivity and negative predictive
25 value and assigned a pass/fail response to each item. Nevertheless, we cannot rule out that using
26 a different ponderation for some items could have enhanced the accuracy of our BSSD. Also,
27 we defined SD as a PAS > 1, which could be debatable, as it can overestimate the incidence
28 and mislead on clinically-relevant SD. Indeed, it is not clear if a patient with a PAS score of 2-
29 3 must not be fed. Finally, we designed our BSSD as a physical examination tool, and did not
30 include known risk factors of SDs such as mechanical ventilation duration[31] ~~and those~~
31 ~~identified in our study.~~ The combination of these parameters with the BSSD ~~might would have~~

1 ~~been interesting to~~ increase the accuracy of the tool. ~~Future studies could assess the accuracy~~
2 ~~of our BSSD in combination with known risk factors for SDs in critically ill survivors.~~

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5 This study presents a simple and accurate bedside swallow evaluation providing a previously
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12 ~~unreached level of sensitivity and specificity. Although still needing external validation, we~~
13 ~~believe that our BSSD could be a useful screening test in ICU.~~ ~~We believe that our BSSD could~~
14 ~~be a useful screening test.~~ A negative test would allow to resume oral feeding earlier in eligible
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survivors of critical illness with prolonged MV.

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Figure Legends

Figure 1: Diagram flowchart of patients included in the study. *Definition of abbreviations:* FE = fiberoptic endoscopy, SD = swallowing dysfunction.

Figure 2: Receiver-operating characteristics (ROC) plot of the cohort. True positive fraction is plotted on y-axis and the true-negative fraction is plotted on x-axis. The BSSD threshold value of 0 was determined as the most accurate to detect a SD

Figure 3: Fiberoptic endoscopic evaluation of swallowing after extubation before administration of semi-liquid bolus (A) and after administration (B): the material (dashed line) entered the airway, contacted the vocal folds (*), and was not ejected from the airway.

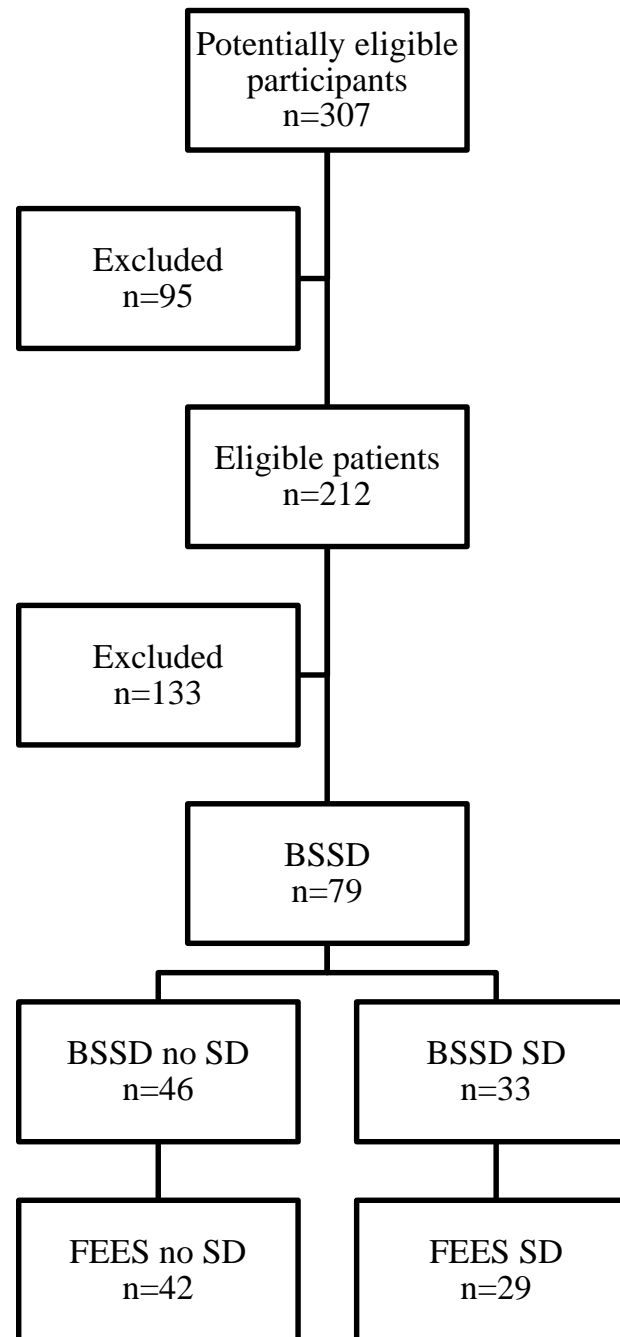


Figure 2

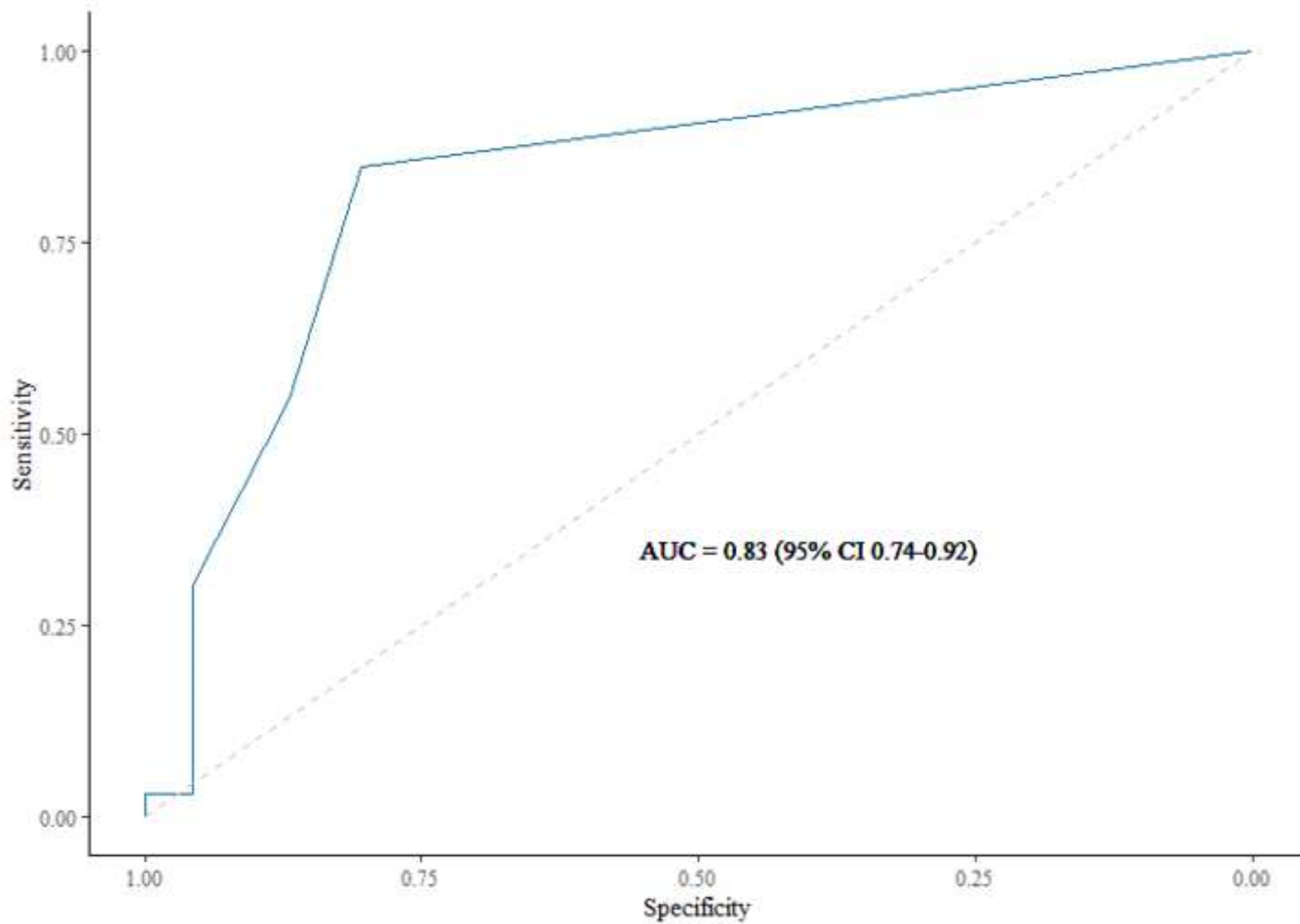


Table 2: Baseline characteristics of the patients and comparison between patients with and without swallowing disorder.

Characteristics	All population (n=79)	No swallowing disorder (n=46)	Swallowing disorder (n=33)	p value
Male	43 (54.4)	27 (58.7)	16 (48.5)	0.4
Age, years	64 [55-70]	63 [53.5-69]	65 [56-70]	0.41
BMI	25.9 [22.5-30.3]	24.5 [22.2-30.5]	26.9 [23.4-30.3]	0.5
Shock	59 (74.7)	29 (63)	30 (90.9)	0.01
SAPS II	52 [37-61.5]	49.5 [36.3-59.8]	57 [38-68]	0.14
SOFA at intubation	9 [6-12]	8 [6-11]	9 [8-12]	0.18
SOFA at extubation	2 [1-3.5]	2 [0-3.8]	2 [1-3]	0.48
Intubation				0.16
Emergency	71 (89.9)	39 (84.8)	32 (97)	
Planned	8 (10.1)	7 (15.2)	1 (3)	
Steroid therapy	35 (44.3)	21 (45.7)	14 (42.4)	0.8
Duration of intubation, days	8 [4.5-13]	6 [3.3-10.8]	11 [7-20]	0.001
History of self-extubation	3 (3.8)	2 (4.3)	1 (3)	0.8
Number of intubations	1 [1-1]	1 [1-1]	1 [1-2]	0.63
Height/ETT ratio	228.6 [220-235.7]	230 [221.3-236.9]	228.6 [217.9-235.5]	0.85
Setting of intubation				0.9
Pre-hospital	6 (7.6)	3 (6.5)	3 (9.1)	
Hospital	73 (92.4)	43 (93.5)	30 (90.9)	
Use during intubation				
Myorelaxant drug	77 (97.5)	46 (100)	31 (93.9)	0.9
Sedation	77 (97.5)	46 (100)	31 (93.9)	0.9
Main indication for intubation				0.04
Surgery	8 (10.1)	7 (15.2)	1 (3)	
Neurologic failure	23 (36.7)	20 (43.5)	9 (27.3)	
Acute respiratory failure	35 (44.3)	17 (37)	18 (54.5)	
Hemodynamic failure	7 (8.9)	2 (4.3)	5 (15.2)	
Aspirators (PAS > 6)	5 (6)	0 (0)	5 (15.2)	0.02

Definition of abbreviations: BMI = Body mass index, SAPS = Simplified Acute Physiologic Score, SOFA = Sequential Organ Failure Assessment, ETT = Endotracheal Tube, PAS = Penetration Aspiration Scale. Data are median [interquartile range] for continuous variables and number (%) for categorical variables.

Credit author statement

Adel Maamar: Conceptualization, Methodology, Formal analysis, Investigation, Writing - Original Draft, Writing - Review & Editing, Visualization. Valentine Parent: Conceptualization, Investigation, Writing - Original Draft. Emmanuelle Prudhomme: Investigation. Emmanuel Guérot: Conceptualization, Investigation, Formal analysis. Pauline Berneau: Investigation, Formal analysis. Aurélien Frérou: Investigation, Formal analysis. Yves Le Tulzo: Investigation. Franck Jégoux: Conceptualization. Arnaud Gacouin: Conceptualization, Methodology, Formal analysis, Investigation, Writing - Original Draft, Writing - Review & Editing, Visualization. Jean-Marc Tadié: Conceptualization, Methodology, Formal analysis, Investigation, Writing - Original Draft, Writing - Review & Editing, Supervision, Visualization.



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