Original Study

Development of the Decannulation Prediction Tool in Patients With Dysphagia After Acquired Brain Injury

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ABSTRACT

Keywords:
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prediction

Objectives: Patients with acquired brain injuries (ABIs) often need tracheostomy because of dysphagia. However, many of them may recover over time and be eventually decannulated during post-acute rehabilitation. We developed the Decannulation Prediction Tool (DecaPreT) to identify, early in the post-acute course, patients with ABIs who can be safely decannulated.
Design: Nonconcurrent cohort study.
Setting and Participants: Patients with ABI, as well as with dysphagia and tracheostomy, were retrospectively selected from the database of a neurorehabilitation unit in Correggio, Reggio Emilia, Italy.
Measures: Potential bivariate predictors of decannulation were screened from variables collected on admission during clinical examination, conducted by an expert speech therapist. Multivariable prediction was then obtained in 2 separate random subsamples to develop and validate the logistic regression model of the DecaPreT.
Results: Of 463 patients with ABI (mean age 52.2 years) selected, 73.0% could be safely decannulated before discharge. After bivariate screening, multivariable predictors of decannulation were identified in the development subsample and confirmed in the validation subsample, each with its odds ratio and 95% confidence interval as follows: age tertile (1.77, 1.08–2.89; $P = .024$), no saliva aspiration (3.89, 1.73–8.64; $P = .001$), pathogenesis of ABI (trauma vs other causes vs stroke vs anoxia: 2.23, 1.41–3.54; $P = .001$), no vegetative status (8.47; 2.91–24.63; $P < .001$), and coughing score (voluntary and reflex vs voluntary vs reflex vs neither voluntary nor reflex cough: 2.62, 1.70–4.05; $P < .001$). In the validation subsample, the predicting equation obtained an area under the receiver operating characteristics curve of 0.836.
Implications: The DecaPreT predicts safe decannulation in patients with dysphagia and tracheostomy, using simple clinical variables detected early in the post-acute phase of ABI. The tool can help clinicians choose timing and intensity of rehabilitation interventions and plan discharge.

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Dysphagia represents a serious condition complicating a variety of acquired brain injuries (ABIs). Its incidence is particularly elevated following strokes in the vertebrobasilar territory or in multiple territories, as well as in the presence of extensive axonal injury, such as in post-traumatic hypoxia or intracranial hypertension. Regardless of the underlying ABI etiology, the presence of moderate to severe dysphagia can be predicted in the presence of at least 2 out of the following 6 clinical signs: loss of voluntary cough and gag reflex, dysphonia, dysarthria, coughing, or changes in the voice quality after swallowing.[1]

In patients with ABI, cuffed tracheostomy tube may be applied in intensive care units to allow airway management in patients who need long-term invasive mechanical ventilation, to facilitate aspiration of tracheal secretions, and to prevent aspiration pneumonia in the presence of dysphagia. Patients with ABI who remain severely dysphagic are often maintained on tracheostomy cannula even after discharge to a lower-care setting. However, severity of dysphagia may diminish over time and, fortunately, some patients may recover sufficient swallowing ability to consent for removal of tracheostomy.[2–4] The presence of a cannula may have a negative influence on the

rehabilitation process[5] and, therefore, decannulation is a primary goal in the rehabilitation of patients with ABI[2,4,6] because it improves quality of life, reduces the risk of complications related to the prolonged maintenance of the cannula, and simplifies care management, thereby facilitating patient's disposition toward home or lower-care settings.[7] Thus, early identification of patients with ABI in whom tracheostomy would eventually be removed may greatly facilitate their overall rehabilitative management. Previous studies, based on small and poorly comparable samples, reported that adequate level of consciousness, effective cough, and control of airway secretions predict effective decannulation.[3,4,6,8–11] Other factors, including presence of saliva aspiration or dysphagia severity, as documented by the Functional Oral Intake Scale (FOIS),[12,13] can also be expected to be associated with this outcome, but they have not been investigated as predictors of decannulation in current literature. Thus, early identification of patients suitable for decannulation remains an issue largely unexplored so far. To fill this knowledge gap, we performed this study on a large cohort of patients with ABI, all admitted to a rehabilitation unit with tracheostomy because of severe dysphagia, to identify factors that, detected on admission, would predict the ability to safely remove the cannula before discharge.

Methods

Study Design and Sample Selection

A nonconcurrent cohort study design was conducted, following STROBE guidelines.[14] Participants were selected from the database of patients admitted with dysphagia to the neurorehabilitation unit of the San Sebastiano Community Hospital in Correggio, Reggio Emilia, Italy, from November 1, 2003 through 31 December 2016. Inclusion criteria were admission diagnosis of severe ABI, age 16+ years, dysphagia, and presence of tracheostomy cannula on hospital admission. Exclusion criteria were diagnosis of esophageal or non-neurologic oropharyngeal dysphagia, invasive or noninvasive mechanical ventilation, peripheral oxygen saturation <89% on admission, and medical or neurosurgical instability, defined following the 2000 Modena Consensus Conference.[15]

Data Collection

Within 1 week from admission, each patient was evaluated by a speech therapist with at least 10 years of experience who applied a standardized assessment protocol.[6,16] Data collected included demographics, brain lesion date of onset and pathogenesis (classified as anoxia, stroke, trauma, and other causes), and presence of vegetative status or minimal consciousness state.[6] Saliva aspiration and voluntary and reflex cough, which are frequently associated with dysphagia[17,18] and may be expected to predict decannulation,[3,4,6,10,11] were recorded. Saliva aspiration was assessed using the blue dye test.[6,19,20] Severity of dysphagia was assessed on admission and at discharge with the Italian version of the FOIS,[12] the validation of which has been recently published.[13] This tool assigns scores of 1 (nothing by mouth), 2, or 3 (tube-dependent) to patients who cannot be fed orally, 4 or 5 to those with milder forms of dysphagia who may consent cautious oral feeding with a modified diet, and 6 to those who may be maintained on a normal diet with only minor attentions, whereas patients with a fully preserved deglutition are assigned a score of 7.

Study endpoint was represented by recovery of adequate swallowing, consenting to safe decannulation, before discharge. In agreement with the standard definition,[10,11] decannulation was considered safe when it was not followed by aspiration or need for new application of tracheal cannula within 48 to 96 hours.

The study was approved by the Institutional Review Board of Reggio Emilia Health District (n. 2017/0006124). Data were processed according to the Italian regulation on protection of personal data.

Analytic Procedures

Data were entered in an electronic form, where logic and range controls had been set to minimize input errors, and then imported for analysis into IBM SPSS software v 25 (IBM Corp., Armonk, NY). Interval variables are reported as mean ± standard error of the mean or, in case of non-normal distribution, median [interquartile range (IQR)]; categorical variables are given as percent frequencies. Scores were assigned to dichotomous and ordinal variables so that greater values would express increasing chances to achieve decannulation. Thus, presence/absence of vegetative status, focal lesions, and saliva aspiration were assigned scores of 0/1, respectively, whereas scores of 0, 1, 2, and 3 were assigned when neither voluntary nor reflex cough, only reflex cough, only voluntary cough, and both voluntary and reflex cough were present, respectively. Similarly, age was modeled as an ordinal variable, with scores of 0, 1, and 2 assigned to participants in the third, second, and first tertile, and also categories of brain lesion pathogenesis were ranked, a posteriori, based on their increasing bivariate association with the decannulation endpoint, being therefore scored as anoxia = 0, stroke = 1, others = 2, and trauma = 3. Values of the non-normally distributed FOIS score on admission were compared with those obtained at discharge using the Wilcoxon test for related samples. Potential predictors of tracheostomy removal were identified by comparing, between participants who could and those who could not be decannulated, mean values of interval variables with Student t test (or, for the FOIS score, with Mann-Whitney U test), and percent frequencies of categorical or ordinal variables with χ^2 test, taking into account trends as appropriate. Variables associated with the endpoint in preliminary, bivariate analyses were considered as candidates for multivariable analysis. For this purpose, the original sample was randomly and evenly split into a development and a validation subsample. The comparability of the characteristics of the 2 subsamples was preliminarily ascertained with appropriate testing. Logistic regression was applied in the development subsample, to identify independent predictors of decannulation. Variables remaining in the final parsimonious model, obtained with backward deletion of redundant variables (P out = .10), were then tested in the validation subsample; the resulting equation represented the Decannulation Prediction Tool (DecaPreT). Odds ratios (OR) with corresponding 95% confidence intervals (CI) were calculated from b coefficients and their standard errors. The goodness-of-fit of the logistic models was checked using the Hosmer-Lemershow test. Receiver operating characteristic (ROC) curves were obtained, and their corresponding areas under the curve (AUC) were calculated, to assess the discriminant ability of the predicted probability of decannulation from the entire logistic regression model of the DecaPreT; by comparison, the ROC AUC of the FOIS score was also calculated.

Because stroke was the most frequent underlying etiology of ABI, additional analyses were conducted to test the model in this subsample. For this purpose, variables contributing to the DecaPreT (with the exclusion of brain lesion pathogenesis) were entered in a logistic regression model predicting decannulation, and the ROC AUC of the DecaPreT was calculated, in the 246 participants with stroke.

P values of <.05 were considered as statistically significant.

Results

General Characteristics of Participants

From November 1, 2003 through December 31, 2016, 473 patients fulfilling the selection criteria were admitted to the neurorehabilitation

unit of the San Sebastiano Community Hospital in Correggio. Of the patients, 8 died in the hospital and 2 had incomplete data, leaving 463 participants (men: 314, 67.8%) available for the present study. Mean age was 52.2 ± 0.7 years, in a range between 16 and 85; 163, 151, and 149 participants were in the first, second, and third age tertile, identified by the cut-offs of <47, 48–61, and 62+ years. Median (IQR) time interval from ABI onset and admission to the neurorehabilitation unit was 52 (35–84) days. Other baseline characteristics are reported in Table 1. Stroke was by far the most frequent cause of brain lesion; accordingly, neuroimaging showed focal lesions in more than one-half of the participants. Vegetative status was present in slightly more than 1 out of 10 participants. Of the participants, 1 out of 3 aspirated saliva at baseline evaluation; almost 1 out of 4 had preserved reflex and voluntary cough and, at the opposite end, 27.6% had neither. As per inclusion criteria, all participants had dysphagia on admission, which was severe in the majority of cases, as indicated by a FOIS score of 1 or 2, with a median (IQR) value of 1 (1–2); on the other hand, the FOIS score increased significantly from admission to discharge, to reach a median (IQR) of 5 (2–7) (Table 2). As many as 338 participants (73.0%) could be decannulated before discharge; none of them had aspiration or needed recannulation within 48 hours. Discharge from the rehabilitation facility occurred after a median (IQR) stay of 96 (49–164) days.

Bivariate Predictors of Decannulation

Decannulation was achieved in 136 out of the 163 participants (83.4%) in the first age tertile, in 107/151 (70.9%) of those in the second tertile, and in 95/149 (63.8%) of those in the third tertile (P for trend <.001); the proportion of participants who could be decannulated was similar in men (227/314, 72.3%) and women (111/149, 74.5%; P = .618). Participants achieving decannulation were 19/35 (54.3%) among those with anoxic brain lesion, 162/245 (66.1%) of those with stroke, 31/38 (81.6%) of those with miscellaneous causes of ABI, and 126/145 (86.9%) of those with trauma (P for trend <.001). Other baseline conditions associated with an increased probability of being decannulated were absence of focal lesions at neuroimaging (161/203, 79.3% vs 177/260, 68.1%; P = .007), of vegetative status (316/411, 76.9% vs 22/52, 42.3%; P <.001), and of saliva aspiration (188/223, 84.3% vs 150/240, 62.5%; P < .001). The proportion of participants achieving decannulation was 57.0% (73/128), 71.0% (130/183), 81.8% (36/44), and 91.7% (99/198) when neither voluntary nor reflex cough, only reflex cough, only voluntary cough, or both were detected at baseline, respectively (P for trend <.001).

Table 1
Baseline Characteristics of the 464 Participants

Variables	Mean ± SEM or n (%)
Age, y	52.2 ± 0.7
Men	314 (67.8)
Pathogenesis of ABI	
Anoxia	35 (7.6)
Stroke	245 (52.9)
Others*	38 (8.2)
Trauma	145 (31.3)
Focal lesions	260 (56.2)
Vegetative status	52 (11.2)
Saliva aspiration	223 (48.2)
Coughing	
Neither voluntary nor reflex	128 (27.6)
Reflex only	183 (39.5)
Voluntary only	44 (9.5)
Voluntary and reflex	108 (23.3)

SEM, standard error of the mean.
  *Infection: n = 20; neurosurgery: n = 18.

Table 2
Distribution of the Functional Oral Intake Scale for Dysphagia Score on Admission and Discharge in 463 Participants

Scores	Admission N (%)	Discharge N (%)	P Value*
1	0 (0.0)	140 (30.2)	<.001
2	1 (0.2)	81 (17.5)	
3	28 (6.0)	57 (12.3)	
4	15 (3.2)	16 (3.5)	
5	16 (3.5)	11 (2.4)	
6	139 (30.0)	68 (14.7)	
7	264 (57.0)	90 (19.4)	

*Wilcoxon test.

Multivariable Predictors of Decannulation

To obtain a multivariable predicting equation, the original study sample was randomly split, with a 1:1 ratio, in a development and a validation subsample. Demographics and clinical characteristics (pathogenesis of brain lesion, FOIS score, proportion of focal lesions, vegetative status, saliva aspiration, voluntary cough, reflex cough, and decannulation) were comparable between the 242 and 221 participants in the 2 subsamples (Appendix: Supplemental Table 1).

The variables found to be bivariate predictors of decannulation were tested in the development subsample, using multivariable logistic regression. Age tertile, absence of vegetative state and of saliva aspiration, pathogenesis of brain lesion, and coughing score remained as independent predictors, whereas FOIS score and presence of focal lesions were backward deleted as redundant (Table 3). From the 5 variables retained in the final parsimonious logistic model, the probability of decannulation (DecaPreT) was calculated as reported in Figure 1. The goodness-of-fit of the model was satisfactory (P = .190). When the predictive equation was used to draw a ROC curve, the corresponding AUC was 0.792 (Figure 2, A). In this subsample, the FOIS score alone achieved a ROC AUC of 0.692.

In the validation subsample, the same variables were confirmed as independent predictors, with parameter estimates comparable to those from the development subsample: the multivariable ORs (95% CI) for achieving decannulation were indeed 1.77 (1.08–2.89) for age tertiles from third to first (P = .024), 3.89 (1.73–8.64) for no saliva aspiration (P = .001), 2.23 (1.41–3.54) per each point increase in the brain lesion pathogenesis score (P = .001), 8.47 (2.91–24.63) for absence of vegetative status (P < .001), and 2.62 (1.70–4.05) per each point increase in the coughing score (P < .001). The goodness-of-fit of the model was again satisfactory (P = .683). The corresponding ROC AUC of the DecaPreT was 0.836 (Figure 2, B), whereas in this validation subsample the FOIS score alone achieved a ROC AUC of 0.726.

Supplemental Analyses in Participants with Stroke

In the logistic regression model restricted to the 245 participants with stroke, the multivariable ORs (95% CI) for achieving decannulation were 1.94 (1.28–2.93) for age tertiles from third to first (P = .002), 3.29 (1.75–6.20) for no saliva aspiration (P < .001), 10.22 (2.98–35.13) for absence of vegetative status (P < .001), and 1.71 (1.26–2.33) per each point increase in the coughing score (P = .001). The goodness-of-fit of the model was acceptable (P = .134). The corresponding ROC AUC of the DecaPreT was 0.773, to be compared with the 0.691 ROC AUC of the FOIS score alone.

Discussion

This study shows that almost 3 out of 4 patients receiving tracheostomy cannula because of dysphagia after severe ABI can be safely decannulated at the end of rehabilitation. It also identifies predictors

Table 3

Independent Predictors of Decannulation, Detected at Baseline in 242 Participants of the Development Subsample. Multivariable Logistic Regression With Backward Deletion of Redundant Variables

Variables	OR (95% CI)	P Value
Age tertile	1.84 (1.19–2.83)	.006
Saliva aspiration (no vs yes)	3.22 (1.63–6.38)	.001
Pathogenesis of brain lesion	1.70 (1.20–2.43)	.003
Vegetative status (no vs yes)	4.45 (1.61–12.34)	.004
Coughing	1.56 (1.14–2.15)	.006

Multivariable logistic regression with backward deletion of redundant variables. Scores of 0, 1, and 2 were assigned to the third, second, and first age tertile, respectively. In the variable "pathogenesis of brain lesion," scores of 0, 1, 2, and 3 were assigned to anoxia, stroke, other causes, and trauma, respectively. In the variable "coughing," scores of 0, 1, 2, and 3 were assigned in the presence of neither voluntary nor reflex cough, reflex cough only, voluntary cough only, and both voluntary and reflex cough, respectively.

FOIS score and presence of focal lesions backward were deleted as redundant from the final parsimonious model.

of decannulation, the combination of which into the DecaPreT provides a multivariable equation to estimate the probability of safe decannulation. The small set of variables included in the tool (age, pathogenesis of ABI, saliva aspiration, voluntary and reflex cough, and consciousness level) can be easily collected, early in the post-acute phase, at the bedside by an expert speech therapist, with no need for instrumented evaluations. The calibration of the tool was more than satisfactory in the randomly selected participants in the validation subsample, which supports external validity of our findings. Furthermore, the DecaPreT was able to predict decannulation also in the subset of participants with stroke, which represented the most common etiology of ABI.

Application of tracheostomy cannula may be mandatory in patients with severe dysphagia after ABI to prevent aspiration pneumonia. However, the presence of the cannula may seriously impact clinical and rehabilitation management of patients with ABI,[21] as it may increase the risk of respiratory complications and mortality,[5,6,22] reduce the chances of discharge at home,[7] and worsen quality of life.[23] Thus, decannulation should be pursued intensively after ABI and, for this purpose, patients potentially able to achieve this goal should be identified early during their clinical course. Several studies reported that, in patients with stroke or degenerative disease, dysphagia with aspiration is associated with poor voluntary cough, abnormal vomiting reflex, dysphonia, and dysarthria.[1,17] However, because physiology of swallowing is different after tracheostomy,[24–26] these prognostic indices cannot be directly applied to patients with tracheostomy cannula, and no previous studies suggested how to predict the probability of decannulation in patients with dysphagia and tracheostomy after severe ABI.[21] Therefore, our study fills an important knowledge gap.

Following recommendations issued by the Italian Consensus Conference on ABI,[27] our study included a large study sample with a broad range of ABIs. The DecaPreT is based on a limited number of simple clinical variables, easily obtainable by an expert speech therapist at the bedside soon after admission to a rehabilitation facility.[2,19,20,28] This overcomes the difficulties with instrumented techniques for the assessment of dysphagia, such as videofluoroscopy and fiberoptic endoscopic evaluation of swallowing, which are rarely available in post-acute settings and may be difficult to apply in cognitively compromised, poorly collaborating patients with ABI. Moreover, one of the important elements for decannulation is management of saliva,[2] which, as our findings show, does have a substantial prognostic impact and can be hardly evaluated with videofluoroscopy and fiberoptic endoscopic evaluation of swallowing.

One of the most used tools for evaluating dysphagia is the FOIS.[12,13,23] Although in our study the FOIS, used alone, had a fair to moderate ability to predict decannulation, with AUC of 0.692 to 0.726, it was backward deleted from the multivariable model, suggesting that, overall, its prognostic value is limited in comparison with other clinical variables.
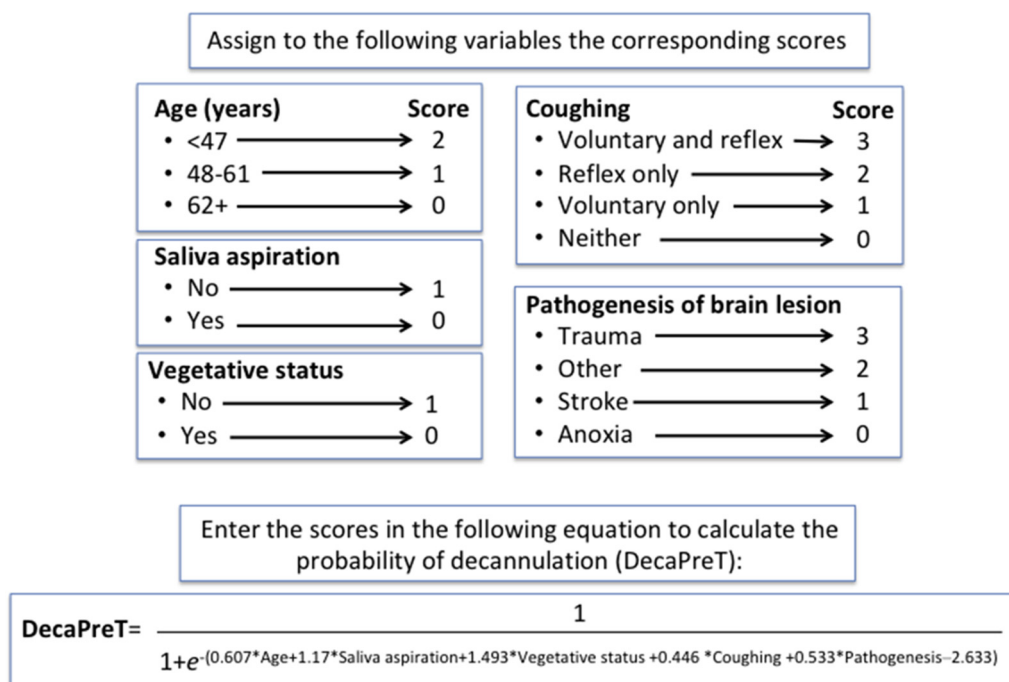
How to calculate the DecaPreT

Assign to the following variables the corresponding scores

Age (years)	Score
• <47 →	2
• 48-61 →	1
• 62+ →	0

Saliva aspiration	
• No →	1
• Yes →	0

Vegetative status	
• No →	1
• Yes →	0

Coughing	Score
• Voluntary and reflex →	3
• Reflex only →	2
• Voluntary only →	1
• Neither →	0

Pathogenesis of brain lesion	
• Trauma →	3
• Other →	2
• Stroke →	1
• Anoxia →	0

Enter the scores in the following equation to calculate the probability of decannulation (DecaPreT):

$$DecaPreT = \frac{1}{1+e^{-(0.607*Age+1.17*Saliva\ aspiration+1.493*Vegetative\ status+0.446*Coughing+0.533*Pathogenesis-2.633)}}$$

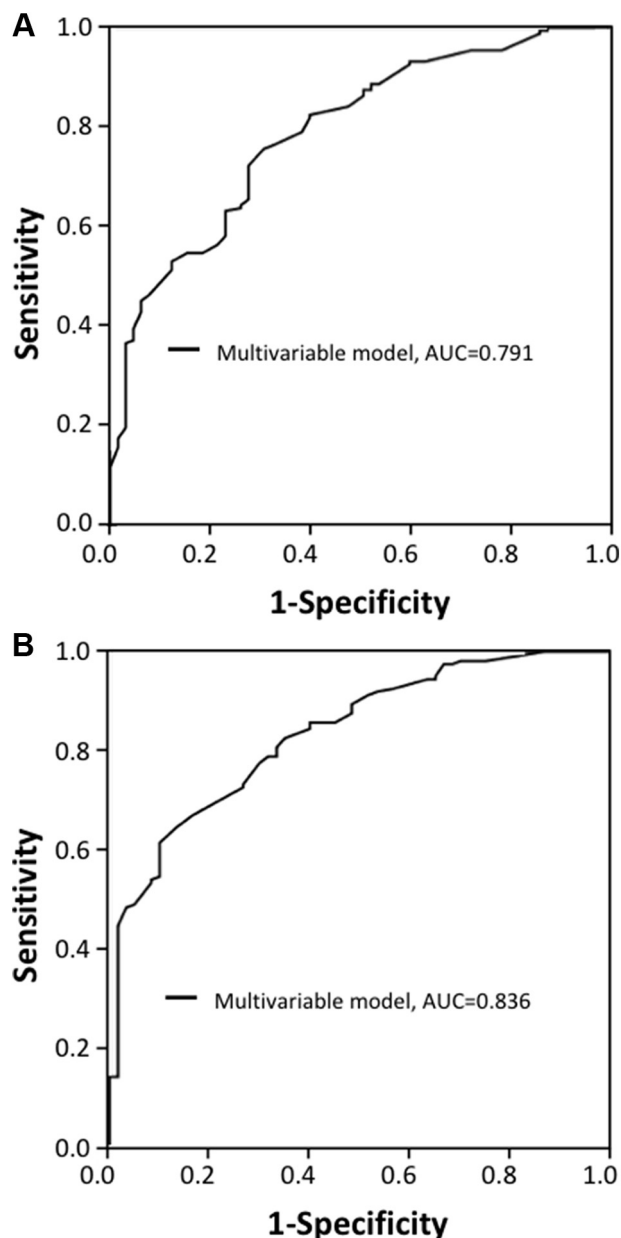**Fig. 1.** Algorithm to calculate the DecaPreT.

Fig. 2. ROC curves for the prediction of decannulation, based on the multivariable model shown in Table 3, separately in the 242 participants of the development (A) and in the 221 of the validation subsamples (B).

There is a general consensus that voluntary cough should be present to achieve safe decannulation.[8–10,29] However, owing to an altered state of consciousness or presence of facial buccal apraxia, most patients with ABI are unable to perform voluntary cough,[4] although they may maintain effective reflex cough during blue dye swallowing test.[4,19,20] Preserved reflex cough, even in the absence of voluntary cough, is commonly considered to be permissive toward decannulation.[3,4,6] Our study provides evidence to support these consensus-based recommendations, as detection of reflex cough was a predictor of safe decannulation even after controlling for a severely compromised consciousness, as in the presence of vegetative state. Another strength of the DecaPreT is that it does not consider global functional status, which is often very poor following ABI and, therefore, may not provide a relevant contribution because of a floor effect. It should be also noted that, according to our findings, anoxic

vegetative state, in spite of its negative prognostic role in terms of state of consciousness,[30] may not definitively hinder decannulation.

Implications of the DecaPreT on global care management of patients with ABI should be emphasized. First, early prediction of decannulation may orient timing and intensity of targeted rehabilitation interventions, thus supporting clinicians' choices in their decision-making process. Furthermore, when decannulation is unlikely, home discharge cannot usually be obtained and the patient must be maintained in facilities with an adequate level of skill in the management of tracheostomy. However, the number of beds in such facilities is limited, at least in Italy, and their availability should be checked as early as possible in the clinical course, when chances to obtain decannulation are deemed to be poor. All of these are important features impacting patients, their families, providers, and healthcare services managers.

As previously highlighted, the DecaPreT was developed in a post-acute setting and serves to the scopes of this level of care. However, its potential for more precocious application in intensive care units might be foreseen, yet it should be tested in future studies.

Limitations of the study are to be acknowledged. First, it is based on a retrospective analysis of data collected in a single center. However, only a few patients (10/473, 2.1%) who were potentially eligible were not enrolled, whereas assessment was conducted according to a rigorous, standardized protocol, so that selection and information biases are unlikely. No external validation could be performed, although the random split of the sample into 2 subsets for separately developing and validating the DecaPreT equation should reduce the risk of over-fitting of the model and improve its generalizability. We could not distinguish between patients with a vegetative state and those with minimal consciousness state. A recent study[31] showed that only 3% of patients in vegetative state achieve oral feeding, but it did not report data on patients with a minimal consciousness state. Future studies should take into account this issue, possibly by adding a standardized assessment of consciousness state, such as that provided by the Coma Recovery Scale Revised.[32] This would allow for a more accurate assessment of the possibility of decannulation between patients with different disorders of consciousness.[33] Finally, objection may be raised that instrumented evaluation provides sophisticated information on characteristics of swallowing, which could potentially improve prediction of decannulation, compared with the DecaPreT. On the other hand, instrumented evaluation is not always available and sometimes cannot even be performed in patients with ABI: therefore, a tool purely based on clinical data would be more extensively applied at the bedside to virtually all patients, leaving instrumented techniques for selected cases.

Conclusions

Our results show that the DecaPreT can valuably predict the possibility of decannulation in patients with severe dysphagia secondary to ABI. The tool, purely based on bedside clinical evaluation, can be applied by trained personnel in a few minutes in any post-acute setting, contributing to a better clinical management of patients with ABI.

Acknowledgments

References

1. Daniels SK, Ballo LA, Mahoney MC, et al. Clinical predictors of dysphagia and aspiration risk: Outcome measures in acute stroke patients. Arch Phys Med Rehabil 2000;81:1030–1033.

2. Checklin M, Etty-Leal M, Iseli TA, et al. Saliva management options for difficult-to-wean people with tracheostomy following severe acquired brain injury (ABI): A review of the literature. Brain Inj 2015;29:1–10.
3. Zanata Ide L, Santos RS, Hirata GC. Tracheal decannulation protocol in patients affected by traumatic brain injury. Int Arch Otorhinolaryngol 2014;18:108–114.
4. Enrichi C, Battel I, Zanetti C, et al. Clinical criteria for tracheostomy decannulation in subjects with acquired brain injury. Respir Care 2017;62:1255–1263.
5. Keren O, Cohen M, Lazar-Zweker, et al. Tracheotomy in severe TBI patients: Sequelae and relation to vocational outcome. Brain Inj 2001;15:531–536.
6. Garuti G, Reverberi C, Briganti A, et al. Swallowing disorders in tracheostomised patients: A multidisciplinary/multiprofessional approach in decannulation protocols. Multidiscip Respir Med 2014;9:36.
7. Zampolini M, Zaccaria B, Tolli V, et al. Rehabilitation of traumatic brain injury in Italy: A multi-centred study. Brain Inj 2012;26:27–35.
8. Perin C, Meroni R, Rega V, et al. Parameters influencing tracheostomy decannulation in patients undergoing rehabilitation after severe acquired brain injury (sABI). Int Arch Otorhinolaryngol 2017;21:382–389.
9. Santus P, Gramegna A, Radovanovic D, et al. A systematic review on tracheostomy decannulation: A proposal of a quantitative semiquantitative clinical score. BMC Pulm Med 2014;14:201.
10. Stelfox HT, Crimi C, Berra L, et al. Determinants of tracheostomy decannulation: An international survey. Crit Care 2008;12:R26.
11. Ceriana P, Carlucci A, Navalesi P, et al. Weaning from tracheotomy in long-term mechanically ventilated patients: Feasibility of a decisional flowchart and clinical outcome. Intensive Care Med 2003;29:845–848.
12. Crary MA, Carnaby Mann GD, Groher ME. Initial psychometric assessment of a functional oral intake scale for dysphagia in stroke patients. Arch Phys Med Rehabil 2005;86:1516–1520.
13. Battel I, Calvo I, Walshe E. Cross-cultural validation of the Italian version of the functional oral intake scale. Folia Phoniatr Logop 2018;70:117–123.
14. von Elm E, Altman DG, Egger M, et al. STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: Guidelines for reporting observational studies. J Clin Epidemiol 2008;61:344–349.
15. Taricco M, De Tanti A, Boldrini P, Gatta G. National Consensus Conference. The rehabilitation management of traumatic brain injury patients during the acute phase: Criteria for referral and transfer from intensive care units to rehabilitative facilities. Eur Medicophys 2006;42:73–84.
16. Bargellesi S, Reverberi C, De Tanti A, Pregno S. La gestione della cannula tracheostomica nelle persone con grave cerebrolesione acquisita: Consenso ad un protocollo condiviso. G Med Fis Riabil 2013;7:9–16.
17. Daniels SK, McAdam CP, Brailey K, Foundas AL. Clinical assessment of swallowing and prediction of dysphagia severity. Am J Speech Language Pathol 1997;6:17–23.
18. Ramsey D, Smithard D, Kalra L. Silent aspiration: What do we know? Dysphagia 2005;20:218–225.
19. O'Neil-Pirozzi TM, Lisiecki DJ, Momose KJ, et al. Simultaneous modified barium swallow and blue dye tests: A determination of the accuracy of blue dye test aspiration findings. Dysphagia 2003;18:32–38.
20. Béchet S, Hill F, Gilheaney Ó, Walshe M. Diagnostic accuracy of the modified Evan's Blue dye test in detecting aspiration in patients with tracheostomy: A systematic review of the evidence. Dysphagia 2016;31:721–729.
21. Scottish Intercollegiate Guidelines Network (SIGN). Brain injury rehabilitation in adults. Edinburgh: SIGN publication no. 130. Available at: http://www.sign.ac.uk. Accessed June 6, 2018.
22. Stauffer JL, Olson DE, Petty TL. Complications and consequences of endotracheal intubation and tracheotomy. Am J Med 1981;70:65–76.
23. Jones E, Speyer R, Kertscher B, et al. Health-related quality of life and oropharyngeal dysphagia: A systematic review. Dysphagia 2018;33:141–172.
24. Ding R, Logemann JA. Swallow physiology in patients with trach cuff inflated or deflated: A retrospective study. Head Neck 2005;27:809–813.
25. Terk AR, Leder SB, Burrell MI. Hyoid bone and laryngeal movement dependent upon presence of a tracheotomy tube. Dysphagia 2007;22:89–93.
26. Goldsmith T. Evaluation and treatment of swallowing disorders following endotracheal intubation and tracheotomy. Int Anesthesiol Clin 2000;38:219–242.
27. De Tanti A, Zampolini M, Pregno S. Recommendations of the jury of the third Italian Consensus Conference for treatment of severe brain injury. Ann Phys Rehabil Med 2014;57:e66.
28. McCullough GH, Martino R. Clinical evaluation of patients with dysphagia: Importance of history taking and physical exam. In: Shaker R, Easterling C, Belafsky PC, Postma GN, editors. Manual of Diagnostic and Therapeutic Techniques for Disorders of Deglutition. New York: Springer; 2013. p. 11–30.
29. O'Connor HH, White AC. Tracheostomy decannulation. Respir Care 2010;55:1076–1081.
30. The Multi-Society Task Force on PVS. Medical aspects of the persistent vegetative state (2). N Engl J Med 1994;330:1499–1508.
31. Mélotte E, Maudoux A, Delhalle S, et al. Is oral feeding compatible with an unresponsive wakefulness syndrome? J Neurol 2018;265:954–961.
32. Estraneo A, Moretta P, De Tanti A, et al. An Italian multicentre validation study of the coma recovery scale–revised. Eur J Phys Rehabil Med 2015;51:627–634.
33. Giacino JT, Katz DI, Schiff ND, et al. Practice guideline update recommendations summary. Disorders of consciousness Neurology 2018;91:450–460.

Supplemental Table 1
Comparison Between the Development and the Validation Subsamples

Variables	Development Subsample (n = 242)	Validation Subsample (n = 221)	P Value
Age, y	53.1 ± 1.0	51.2 ± 1.0	.191
Men	158 (65.3)	156 (70.6)	.223
Pathogenesis of ABI			
Anoxia	22 (9.1)	13 (5.9)	.219
Stroke	126 (52.1)	119 (53.8)	
Others	15 (6.2)	23 (10.4)	
Trauma	79 (32.6)	66 (29.9)	
Focal lesions	131 (54.1)	129 (58.4)	.359
Vegetative status	27 (11.2)	25 (11.3)	.958
Saliva aspiration	124 (51.2)	116 (52.5)	.788
Coughing			
Neither voluntary nor reflex	61 (25.2)	67 (30.3)	.503
Reflex only	103 (42.6)	81 (36.2)	
Voluntary only	23 (9.5)	21 (9.5)	
Voluntary and reflex	55 (22.7)	53 (24.0)	
Decannulation	177 (73.1)	161 (72.9)	.944

Values are mean ± standard error of mean or n (%).