Using Routinely Gathered Clinical Data to Develop a Prognostic Online Tool for Decannulation in Subjects With Acquired Brain Injury

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BACKGROUND: Clinicians are often required to provide a qualified guess on the probability of decannulation in estimating patients’ rehabilitation potential and relaying information about prognosis to patients and next of kin. The objective of this study was to use routinely gathered clinical data to develop a prognostic model of time to decannulation in subjects with acquired brain injury, for direct implementation in clinical practice. METHODS: Data from a large cohort including 574 tracheostomized subjects admitted for neurorehabilitation were analyzed using discrete time-to-event analysis with logit-link. Within this model, a reference hazard function was modeled using restricted cubic splines, and estimates were presented using odds ratios (95% CIs). RESULTS: A total of 411 subjects (72%) were decannulated within a median of 27 d (interquartile range 16–49) at the rehabilitation hospital. The prognostic model for decannulation included age, diagnosis, days from injury until admission for rehabilitation, swallowing, and overall functional level measured with the Early Functional Abilities score. Among these, the strongest predictors for decannulation were age and a combination of overall functional abilities combined with swallowing ability. CONCLUSIONS: A prognostic model for decannulation was developed using routinely gathered clinical data. Based on the model, an online graphical user interface was applied, in which the probability of decannulation within $x$ days is calculated along with the statistical uncertainty of the probability. Furthermore, a layman’s interpretation is provided. The online tool was directly implemented in clinical practice at the rehabilitation hospital, and is available through this link: (http://www.hospalsenhedmidt.dk/regionshospitalet-hammel/research-unit/Prognosissoftware/). Key words: cerebrovascular disease/stroke; information technology; prognosis; development; dysphagia; decannulation; tracheostomy; implementation. [Respir Care 0;0(0):1–.* © 0 Daedalus Enterprises]

Introduction

In patients with acquired brain injury, decannulation from a tracheostomy tube is an important marker of the rehabilitation potential. Therefore, patients and next of kin may often approach clinicians with questions about the timeframe for decannulation.1 Being able to present an evidence-based prognosis for decannulation is a valuable supplement for health care professionals working with tracheostomized patients, both in clinical decision-making and in the involvement of patients and next of kin.2

The ideal approach for making a prognostic model for decannulation would be to gather the best evidence from clinical factors associated with decannulation and then conduct an observational study on a large population of subjects, in which data are observed over time, to see if and when subjects are decannulated.3 However, conducting such studies may be cumbersome and may include predictors that are not routinely gathered in clinical practice, thus making the prognostic model less relevant and feasible for clinical practice.3

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By using clinical data, which are routinely gathered as part of everyday practice, it is possible to develop prognostic models that can be implemented directly into clinical practice because they do not require any changes in practice or the purchase of new medical equipment. Several small studies have reported that swallowing capability, coughing, and early rehabilitation were predictors of decannulation in subjects with acquired brain injury. However, these studies are of poor quality and do not provide an applicable prognostic tool. A recent multi-center study from Germany used routinely gathered clinical data to identify practicable predictors of decannulation in subjects with primarily neurological diseases. However, no prognostic model was developed from the analyses, and no internal validation of the predictors was reported. In a recent study from Italy, a decannulation prediction tool for subjects with acquired brain injury was developed based on routinely gathered clinical data. Internal validation of the prognostic model was analyzed by splitting the population into a development sample and a validation sample, and an algorithm on how to use the prediction tool was provided. However, the statistical uncertainty of the prediction was not provided and no interpretation in layman’s term was presented. For clinical decision-making and for communicating with patients and next of kin, the confidence interval of the prediction along with an easily interpreted likelihood are needed, in order to emphasize the uncertainty of such predictions and to avoid creating false hopes. A further limitation in the above studies is that they investigated predictors of decannulation at discharge from rehabilitation units, without considering the time to decannulation regardless of continued hospitalization. To be of greater use in clinical practice, a prognostic model that presents a likelihood of decannulation within a specific period (e.g., 30 d) is warranted.

The objective of this study was to use routinely gathered clinical data to develop a prognostic model and an online tool for calculating the probability of time to decannulation in subjects with acquired brain injury, for direct implementation in clinical practice.

Methods

Study Population

The study population included tracheostomized patients with acquired brain injury admitted to Hammel Neurorehabilitation Centre and University Research Clinic, from March 2011 to the end of 2018. The inclusion criterion was that subjects should be registered in the medical record as tracheostomized within 3 d of admission. From a population of 609 tracheostomized patients, 574 subjects (94%) met this inclusion criterion. The 35 excluded patients did not differ from the study population regarding demographic factors. Data from electronic medical records have been routinely transferred to a clinical database for administrative, organizational, economic reporting, and research purposes. Data handling for this study was approved by the Danish Patient Safety Authority (ID: 3-3013-2832/1), and approval for storing data were granted by the Data Protection Agency in the Central Region of Denmark (ID: 1-16-02-35-19). In Denmark, no ethical approval is needed for research using only register-based data.

Rehabilitation Setting

At Hammel Neurorehabilitation Centre and University Research Clinic, neurorehabilitation is provided for patients with acquired brain injury who have complex rehabilitation needs. The hospital has a nationwide catchment area, and patients may be admitted once the neurosurgical treatment of the primary and secondary injuries is completed, to such a degree that complications are deemed unlikely. Rehabilitation starts at early levels of recovery and is provided by interdisciplinary teams of occupational therapists, physiotherapists, nurses, and auxiliary nurses, with close involvement from physicians, neuropsychologists, speech language therapists, and dieticians. In Denmark, dysphagia, and therefore decannulation of patients suffering from severe dysphagia, is primarily managed by occupational therapists, in close collaboration with physicians and the rest of the multidisciplinary team.

QUICK LOOK

Current knowledge

Previous studies have investigated predictors of decannulation in subjects with acquired brain injury and other critical illnesses. A simple algorithm for calculating the probability of decannulation of patients discharged from rehabilitation has also been published. Being able to present an evidence-based prognosis for decannulation would be a valuable tool in clinical decision-making, and in the involvement of patients and their next of kin.

What this paper contributes to our knowledge

A prognostic model and online tool for evaluating time to decannulation in subjects with acquired brain injury was developed. The online tool was directly implemented in clinical practice, as it required no change in practice or the purchase of equipment. Several interpretations of the probability of decannulation are provided along with the statistical uncertainty, which is essential information in relaying information about prognosis to patients and next of kin. The online tool has been made publicly available.
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#### Decannulation

The study outcome was time to first attempt of decannulation from any type of tracheostomy tube (cuffed or non-cuffed), and decannulation from a cuffed tube specifically. In Figure 1, examples A and B illustrate the most common courses of tube management leading to decannulation. However, as seen in example C, patients sometimes have more complex courses leading to decannulation, showing that it is not always a straightforward process.

Decannulation is attempted when the physician and the interdisciplinary team determine that the patient has sufficient respiratory capacity and is able to protect his or her airways. This is done through a combination of clinical assessments and observations, endoscopic evaluation of swallowing, systematic registrations of saliva above the cuff, coughing, and sometimes blue dye. In addition, the patient should have tolerated at least 24 h with a capped tube. The protocol for decannulation remained the same throughout the study period.

#### Clinical Predictors

The predictors included in the prognostic model were chosen by a panel of clinical experts working with tracheostomized patients in collaboration with a statistician, and selection was based on clinical relevance for the probability of decannulation, along with availability in the medical records. Clinically meaningful predictors that were statistically significantly associated with the probability of decannulation in the multivariate model were included in the final model. The predictors included were: age (age groups: < 18, 18–40, 41–65, and > 65 y); diagnosis of acquired brain injury categorized as stroke (ischemic or hemorrhagic), traumatic brain injury, subarachnoid hemorrhage, encaphalopathic brain injury, and other injuries; weeks from injury to admission to rehabilitation (grouped as unknown, 0–2, 2–4, 4–8, and > 8 weeks); and the Early Functional Abilities (EFA) score. The EFA is an interdisciplinary score developed to assess functional abilities during rehabilitation in patients with severe acquired brain injury. The EFA is an appropriate assessment tool for functional level in patients with severe disabilities because it is more sensitive to changes in these subjects than the Functional Independence Measure, which is more appropriate for patients with moderate to mild disabilities. The EFA was scored within 72 h from admission to rehabilitation and every fourth week by an interdisciplinary team consisting of occupational therapists, physiotherapists, nurses, and auxiliary nurses. Additionally, a newly published English version of the EFA has made its use in other countries possible. The scale includes 20 items merged into 4 overarching dimensions: vegetative functions, oro-facial functions, sensorimotor abilities, and cognitive abilities. All items are scored on a 5-point Likert scale (1: no function; 2: severe disturbance; 3: moderate disturbance; 4: slight disturbance; 5: normal), with a total score ranging from 20 to 100. This score, along with the item score for swallowing function (ie, swallowing function vs no swallowing function), were included in the prognostic model, with the following categories: (1) EFA 20–40 + no swallowing function, (2) EFA 20–40 + swallowing function, (3) EFA 41–60 + no swallowing function, (4) EFA 41–60 + swallowing function, (5) EFA 61–100 + no swallowing function, (6) EFA 61–100 + swallowing function, and (7) missing. The region from which the subject was referred was also included as a predictor, because the likelihood of being discharged with a tracheostomy tube was reduced in subjects from central Jutland (for organizational reasons) compared with the 4 other regions in Denmark, thus introducing systematically different right-censoring mechanisms of event times between regions. For international usage, this predictor has

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**Fig. 1.** Process from admission at neurorehabilitation until decannulation from a tracheostomy tube. A: Common process for a subject admitted with a cuffed tube. B: Common process for a subject admitted with a non-cuffed tube. C: Process for a non-cuffed subject with aspiration risk detected at admission for rehabilitation.
been removed in the English version of the online templates, by fixating the region variable to central Jutland.

Statistical Analysis

A prognostic model was developed based on clinical predictors from the first week following admission to the rehabilitation hospital. The prognostic model can be applied to calculate the probability of decannulation in newly admitted patients, which is based on evidence from “patients like me.”

We applied discrete time-to-event analysis with logit-link to calculate time to decannulation. In this model, a reference hazard function was analyzed, expressed as

\[ h(t) = P(T = t | T \geq t) \]

using restricted cubic splines with 4 knots. This function represents the daily likelihood of decannulation, given that it has not occurred yet. The prognostic factors included modify the reference hazard function as seen in an ordinary logistic regression. A time-to-event analysis was applied, in which subjects may be right-censored due to discharge from the hospital before decannulation. Hence, time to decannulation can be modeled and predicted despite the possibility that subjects may be discharged with a tracheostomy tube. The associations between the predictors and probability of decannulation are presented as odds ratios (95% CI) in a multiple adjusted model. Missing values were seen in weeks from injury until admission and in EFA scores. These missing values were treated as independent categories in the analytical model. The model was validated using standard methods. For illustrative purposes, figures showing the hazard function for decannulation for different subgroups of subjects are presented. The R statistical software was used for all analyses.

Results

Two thirds of the tracheostomized subjects were men, and one third were diagnosed with an ischemic or hemorrhagic stroke. The second largest diagnostic group was traumatic brain injury. See Table 1 for further baseline characteristics of the study population. Of the 574 tracheostomized subjects, 411 (72%) were decannulated within a median of 27 (interquartile range 16–49) d at the rehabilitation hospital. Nine (2%) failed decannulation and had a tracheal tube re-inserted during stay at the rehabilitation hospital. Multiple adjusted odds ratios for each predictor included in the model are displayed in Table 2. The strongest predictors of decannulation from any tracheostomy tube were age and functional level: subjects < 18 y were 4.23 times (95% CI 2.36–7.52) more likely to be decannulated during stay at the hospital compared with those > 65 y old, and subjects with an EFA score of 61–100 with swallowing function at admission were 4.67 times (95% CI 2.96–7.38) more likely to be decannulated compared with those who had an EFA score of 20–40 and no swallowing function.

In Figure 2, the probability of decannulation for 3 sub-groups with traumatic brain injury, subarachnoid hemorrhage, and stroke are displayed, representing subjects with good, intermediate, and bad prognoses, respectively. As an example, for the subarachnoid hemorrhage subgroup (intermediate prognosis), the probability of being decannulated not later than 60 d from admission is 67%. In Figure 3, the probability is presented for additional subgroups, showing 2 subgroups with and without swallowing function in Figure 3A, 2 subgroups with traumatic brain injury and stroke in Figure 3B, and 2 subgroups with subarachnoid hemorrhage and stroke in Figure 3C.

The online prognostic tool is available online at (http://www.hospitalsenhedmidt.dk/regions hospitalet-hammel/research-unit/Prognosissoftware/). The instructions describe the purpose of the prognostic tool along with a layman’s interpretation of a good (green), intermediate (yellow), and bad prognosis (red). In addition, brief instructions for use are provided. In the prognostic template, the clinical characteristics of the subject are entered, and the probability (95% CI) is provided. In addition, prognosis for the 80% fractile is provided, stating that 80% of subjects (like her/him) were not decannulated within x days.

Discussion

In this study, we present an example of how routinely gathered clinical data can be used to develop a simple and feasible prognostic model, analyzing time to decannulation in subjects with acquired brain injury. Based on the prognostic model, an intuitive online tool was
developed for clinical application. In the online tool, clinically meaningful information acquired during the first week of admission for rehabilitation is entered, and a prognosis for decannulation is generated on the basis of data from “patients like me.” The prognosis is presented with both an estimate and a confidence interval, as well as a layman’s interpretation. Thus, the prognosis can be calculated, thus giving the prognostic model a more nuanced picture than a model calculating probability of decannulation at discharge.

Several previous studies have investigated predictors of decannulation in subjects with acquired brain injury. However, many studies are of poor quality (eg, small study populations, or the use of univariate analyses), and the prediction of decannulation by development of a prognostic model for decannulation in a large population of subjects with acquired brain injury, in which time to decannulation has been included in the model. By including time (eg, 30 d), the prognosis for decannulation can be calculated, thus giving the prognostic model a more nuanced picture than a model calculating probability of decannulation at discharge.

In the model, which included age, diagnosis, days until admission to rehabilitation, region, swallowing function, and functional ability after the injury, we found that age in particular and a combination of swallowing function and overall functional ability after the injury were highly associated with time to decannulation. Age as an inverse predictor of decannulation is in line with several previous studies investigating predictors of decannulation in either subjects with acquired brain injury or critically ill subjects in general, and swallowing function has also been reported as a predictor of decannulation.

For illustrative purposes, we have presented probability curves for subgroups, to show that the model is able to...
discriminate the probability of decannulation for these subgroups. Thus, a young man with a traumatic brain injury, a short hospitalization in acute care, good overall functional ability, and swallowing function has a far better prognosis than an elderly man with a stroke, a long hospitalization in acute care, lower overall functional ability, and no swallowing function. This finding corresponds well with an algorithm for probability of decannulation proposed by Reverberi et al., in which a higher probability for decannulation was calculated for younger subjects versus older subjects, no saliva aspiration versus saliva aspiration, and traumatic brain injury versus stroke. However, in the prognostic algorithm by Reverberi et al., the statistical uncertainty of the prognosis is not taken into account. In communicating a prognosis to patients and next of kin, it is necessary that the statistical uncertainty of the prognosis is provided because they may suffer further crisis reactions if their expectations are not met. In addition to providing confidence intervals for probabilities, the following statement is also provided: “80% of patients like her/him have been decannulated in x days,” thus taking into account the risk of statistical type II errors.

It has been reported that female gender is a predictor of decannulation. Gender was associated with the probability of decannulation in univariate analyses but not in multivariate analyses. In addition, there is no clinical rationale to justify the inclusion of gender as a predictor of decannulation, and it was therefore not included in the final model due to statistical elimination. FOIS is also scored systematically at the present rehabilitation hospital, but FOIS was not included as a predictor of decannulation because patients with cuffed tracheostomy tubes are restricted from oral intake of food due to the high risk of aspiration. Thus, patients with a cuffed tube will, by definition, have a FOIS score of 1, which will present a floor effect with no prognostic value. Therefore, we included the swallowing item in the EFA, which indicates whether the patient swallows spontaneously and whether there is risk of aspiration. Other functions that have been reported to predict decannulation, such as vegetative status and consciousness, are embedded in the EFA and are therefore taken into account in the EFA score. The Functional Independence Measure was also considered as a predictor of decannulation, but it was not included because the EFA has been reported to have superior value in describing the functional level in subjects with severe acquired brain injury, whereas the Functional Independence Measure is better in describing the functional level in subjects with moderate or mild acquired brain injury. The EFA was therefore included in the model. We acknowledge that EFA is not yet widely applied internationally in assessing the functional level of patients with acquired brain injury. However, with knowledge about the functional level of a particular patient and with the EFA manual, an EFA score can be calculated easily by an interdisciplinary team, making it possible for clinicians in other settings to assess the predictive value of the prognostic tool on their own patients. Results from clinical assessments such as blue dye and fiberoptic endoscopic evaluation of swallowing have

Fig. 2. Probability of decannulation according to days of rehabilitation in 3 subgroups with acquired brain injury; an early prognosis based on clinical data from the first week of admission for rehabilitation. TBI = traumatic brain injury, SAH = subarachnoid hemorrhage.
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Fig. 3. Probability of decannulation according to subject characteristics. A: Two women with SAH, with and without swallowing function (18–40 y old, 4–8 weeks from injury, EFA score 20–40). B: Two men with stroke or TBI and no swallowing function (41–65 y old, 2–4 weeks from injury, EFA score 20–40). C: Two women with SAH or stroke and no swallowing function (18–40 y old, 2–4 weeks from injury, EFA score 20–40). SAH = subarachnoid hemorrhage, EFA = early functional abilities, TBI = traumatic brain injury.
been proposed to be strong predictors of decannulation.\textsuperscript{5,32} These assessments are frequently carried out at the rehabilitation hospital, but they are not assessed systematically on every patient, and not within the first few days after admission. With the objective of developing a simple tool for direct implementation in clinical practice,\textsuperscript{7} predictors that were available within the initial 72 h after admission were chosen, in order to calculate an early prognosis for decannulation. Future research and development of the model could include clinical assessment throughout hospitalization to yield a weekly updated prognosis of the probability of decannulation within a certain timeframe. This would help clinicians set goals on a daily basis and ensure that evidence-based information can be relayed to patients and next of kin.

Conclusions

The objective of this study was to present an example of how routinely gathered clinical data from medical records can be used to develop a prognostic model to assess time to decannulation in subjects with acquired brain injury. Several important predictors of decannulation proposed in the research literature were therefore not included in the model due to a lack of availability in the medical records. Thus, clinicians should interpret the probability of decannulation by taking into account any further information they may have about important clinical predictors of decannulation.

Based on the model, we introduced an online tool that was directly applied in clinical practice to assist decision-making and to relay evidence-based information to patients and next of kin regarding prognosis for decannulation. The clinical tool for calculating early prognosis of time to decannulation is available online at (http://www.hospitalsenhedmidt.dk/regionshospitalet-hammel/research-unit/Prognosissoftware/), enabling clinicians in other settings to assess the predictive value of the prognostic model on their patients, considering that the prognostic tool was developed and validated on a selected population of subjects with acquired brain injury.

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REFERENCES


