Prognostic variables and decannulation of tracheostomy in the long term acute care environment: A case for clinician driven decision making

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Abstract

Purpose

Tracheostomy is a necessary procedure required for prolonged mechanical ventilation in long-term acute care hospitals (LTACH). Many factors influence successful decannulation, or tracheostomy removal, and it is unclear what factors are essential for determining decannulation. The purpose of this study was to determine retrospective performance of single prognostic variables for successful decannulation, like peak expiratory flow measurement, overnight oximetry testing, and blood gas analysis.

Methods

A retrospective analysis of a three-year period to investigate the association between peak flow (PF) measurements ≥160 L/min, successful overnight oximetry (ONO), sex, and decannulation success. Average PF measurements, arterial blood gas (ABG), days on mechanical ventilation, LTACH length of stay (LOS), and age were also investigated.

Results

We examined the records of 135 patients, 127 of which were successfully decannulated. PF measurements ≥160 L/min (P 0.16), sex (P <0.05) and passing ONO (P <0.05) were significantly different between successfully and unsuccessfully decannulated patients; mean ABG (PH, $PaCO_2$, PaO_2), mechanical ventilation days, LOS, and age were not significantly different (P >0.05).

Conclusions

These results suggest no single prognostic variable can predict decannulation outcomes. Rather, clinical judgment of experienced medical professionals appears sufficient to achieve a 94% decannulation success rate. Additional investigation is required to determine what metrics are necessary, or if clinical judgment alone can predict decannulation success.

Key Words: Tracheostomy decannulation, long-term acute care facility, peak expiratory flow measurement

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Quick Look

There are multiple factors that influence successful decannulation which make it difficult to predict who will successfully be decannulated. The utility of a simple, single-valued test, such as peak expiratory flow measurements, to aid with the decision-making process to decannulate has been called into question. Peak flow measurements greater than or equal to 160 L/min is commonly believed to be associated with successful decannulation

Introduction

Tracheostomy is often used in cases of prolonged mechanical ventilation to prevent long-term complications of endotracheal tube intubation. Tubes for invasive ventilation are generally used to maintain airway protection and provide a means for invasive mechanical ventilation and/or airway clearance. These tubes are often capped for a period of time prior to decannulation as a means of screening subjects for potential success or failure of tracheal tube removal. [1]

There are multiple factors that influence successful decannulation [2] which make it difficult to predict who will successfully be decannulated and who will not be. For the past 25 years these findings have evolved into the belief that an elevated peak cough threshold is amongst the most important prognostic indicators of successful decannulation of tracheostomy. [3] In other words, PF has become the sole variable some use to determine decannulation readiness, causing prolonged times of ventilation as medical professionals wait for a threshold peak value to be reached when this may not be necessary. As a result, the prolonged time on ventilation could be causing more harm to the patient than good. This is based on evidence that subjects with neuromuscular disease who can spontaneously mount an peak cough expiratory flow of 180L/min or greater can successfully transition from intermittent positive pressure ventilation to non-invasive ventilatory support. [4, 5] There have also been multiple studies investigating invasive or assistive devices augmenting peak cough to improve chances for successful decannulation. [5-7] The literature suggests that decannulation may be possible at lower values, [3, 8] or based upon a combination of clinical assessments. [9]

In support of this we have seen evidence in our institution that suggests physician-directed decisions to decannulate based on clinical judgment amongst other clinical data beyond peak cough expiratory flow may be better prognostic predictors of decannulation success. These factors include things such as ONO and ABG measurements following a 24-hour capping trial.

In this effort, we investigated the association between PF measurements greater than or equal to 160 L/min[13] and the likelihood of a subject successfully decannulating prior to discharge from a LTACH over a three-year period. We also analyzed the rate of successful decannulation and the likelihood of successful decannulation with respect to ONO trials and ABG measurements following capping trials. The goal of this study was to determine the retrospective performance of the peak expiratory flow measurement, ONO, and ABG data compared to the clinician-driven method of decannulation in the long-term acute care environment. The expectation hope is to apply the findings of this study to populations of individuals who suffer from prolonged mechanical ventilation at the time of their transfer to LTACH's.

Methods

This was a single-center retrospective study of electronic medical records to record PF measurements, ONO and ABG prior to decannulation from tracheostomy, and the success rate of decannulation as defined by removal of tracheostomy tube without need for re-insertion or mechanical ventilation by other means for at least 48 hours or the remainder of the subject's admission, whichever was longer. This study was approved by Gaylord Hospital's Institutional Review Board. Informed

consent was obtained from all individual participants included in the study.

This study used medical record data from subjects admitted to Gaylord Hospital between 1 January 2016 and 1 January 2019. Specifically, we reviewed the records of subjects who experienced prolonged mechanical ventilation, defined as requiring mechanical ventilation for 21 days or more without uncapping, from time of initial intubation prior to or after LTACH admission, or determination by the admitting facility that the subject was "unable to wean from vent". Subjects were excluded from review if they were on dialysis, presented with stage III or greater chronic kidney disease (estimated GFR <30 mL/min/1.73 m^2), or were transferred in-house from within one section of the LTACH to another for more acute care.

As shown in Figure 1, Gaylord Hospital's decannulation protocol comprises several steps, including: the decision to initiate a trial based on clinical stability; the ability to tolerate a speaking valve; no evidence of tracheal obstruction; peak cough flow ≥160 L/min; and a 48-hour capping trial with passing ONO and ABG tests. [13] A peak flow measurement is taken using the Medline Portable Peak Flow Meter, with the patient either sitting or standing. PF is measured through the mouth with the tracheostomy tube capped. The patient is asked to breathe in as deeply as possible and then to breathe out as quickly and hard as they can into the meter using their mouth. This is done three times and the highest of these values is recorded as the peak flow value reading. The physicians supervising the decannulation protocol and making the decision to decannulate are experienced pulmonologists with greater than 20 years average experience. The respiratory therapists executing the protocol are seasoned therapists with decades of experience in the LTACH environment. Following decannulation, all subjects are monitored with pulse oximetry for the first 24 hours post decannulation with vital signs monitored every four hours. If clinically stable the subject may be discharged 48 hours after decannulation.

The association of categorical variables (PF measurements >160 L/min, successful ONO, and sex) with successful decannulation were analyzed using student's t-test. [13] A Fischer's Exact Test was used to analyze continuous variables (PF measurements, ABG values (PH, $PaCO_2$, and PaO_2), number of days on vent at the LTACH and length of stay at the LTACH) with respect to successful decannulation. Analyses were performed using R version 4.1.

Results

We reviewed the electronic medical records of 235 subjects, 135 of whom met our enrollment criteria and had sufficient data to perform the analysis. As shown in Figure 2, 94.1% (127/135) of these subjects were successfully decannulated.

Statistical analyses of categorical and continuous variables with respect to decannulation are shown in Table 1. We found a significant difference in the proportions of patients for whom decannulation failed when comparing sex (P <0.05) and those who passed ONO (P <0.05). There was no significant difference in the proportion of patients for whom decannulation failed when comparing those whose PF measurements were ≥160 L/min (P 0.16). In fact, of the 135 total patients evaluated, 74/135 (54.8%) had PF values ≥160, but a total of 127/135 (94.1%) patients successfully decannulated overall.

The positive predictive value (PPV) of the PF level (i.e. the percentage of people who were decannulated after achieving a PF level ≥160 L/min) was PPV = 71/74 or 95.9% (95% CI lower level, upper level= 91.4% - 100%). The negative predictive value (NPV) of PF <160 L/min was NPV = 5/61 or 8.2% (95% CI lower level, upper level = 1.3%-15.0%). The false negative (FN) rate, defined as [100%– sensitivity], which in this case is 100% - 62.5% or 37.5%. The false positive (FP) rate, defined as [100% – specificity], was 100% - 55.9% or 44.1%.

We found no significant difference in the mean values of continuous variables measured in patients for whom decannulation failed compared to those who were successfully decannulated, including ABG values [PH (P 0.96), $PaCO_2$ (P 0.16), PaO_2 (P 0.65)], number of days on mechanical ventilation (P 0.50), length of stay (LOS) at LTACH (P 0.37), and age (P 0.65). The mean PF values of patients who were successfully decannulated were higher than those who were not successfully decannulated, 178 L/min (SD) and 120 L/min (SD), respectively, but not significant (P 0.14).

Table 1: Results for Decannulated and Non-Decannulated subjects

	Decannulated	Not decannulated	P
	Freq (%)	Freq (%)	
Total (N = 135)	N= 127 (94.1%)	N= 8 (5.9%)	
Sex			< 0.05
Male	88/127 (69.2%)	3/8 (37.5%)	
Female	39/127 (30.7%)	5/8 (62.5%)	
Overnight Oximetry			< 0.05
Passed	125/127 (98.4%)	1/8 (12.5%)	
Failed	2/127 (1.6%)	7/8 (88.5%)	
Peak flow < 160 L/min			0.16
Yes	56 (44.1%)	5 (62.5%)	
No	71 (55.9%)	3 (37.5)	
	Mean (SD)	**Mean (SD)**	
Peak Flow L/min	178 (83)	120 (89)	0.14
ABG PH	7.45 (0.05)	7.45 (0.03)	0.96
ABG $PaCO_2$ mmHg	42 (7.8)	57 (11.9)	0.16
ABG PaO_2 mmHg	82 (22)	76 (20)	0.65
Days on Vent days	17 (20)	26 (19)	0.50
Length of Stay days	39 (19)	32 (21)	0.37
Age years	62 (15)	64 (10)	0.65

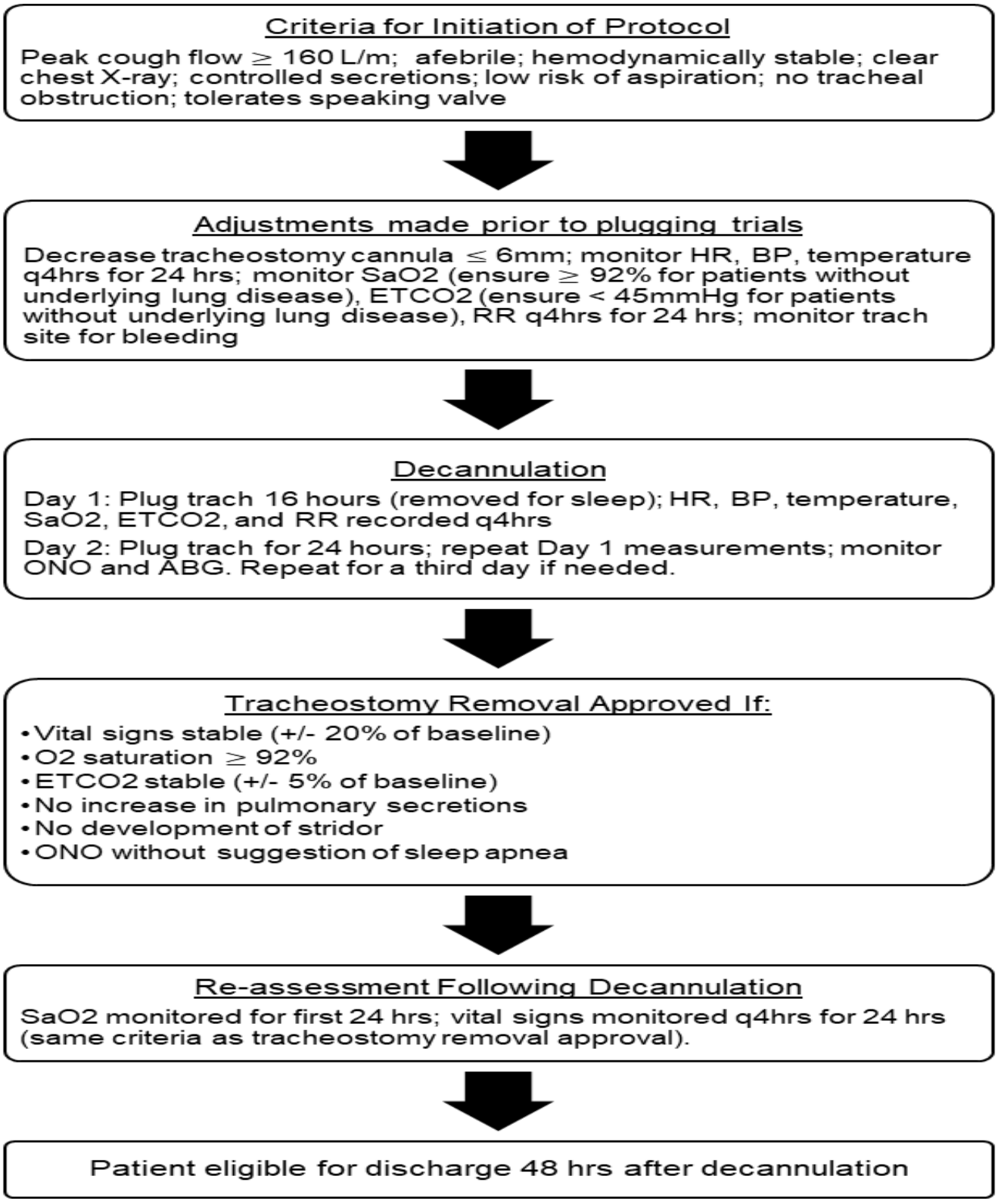

Figure 1: Decannulation protocol for Gaylord Hospital
HR: Heart Rate; BP: Blood Pressure; q4hrs: Every 4 hours; SaO_2: Oxygen saturation of arterial blood; $ETCO_2$: End-tidal CO_2; RR: Respiratory Rate; ONO: Overnight Oximetry; ABG: Arterial Blood Gas

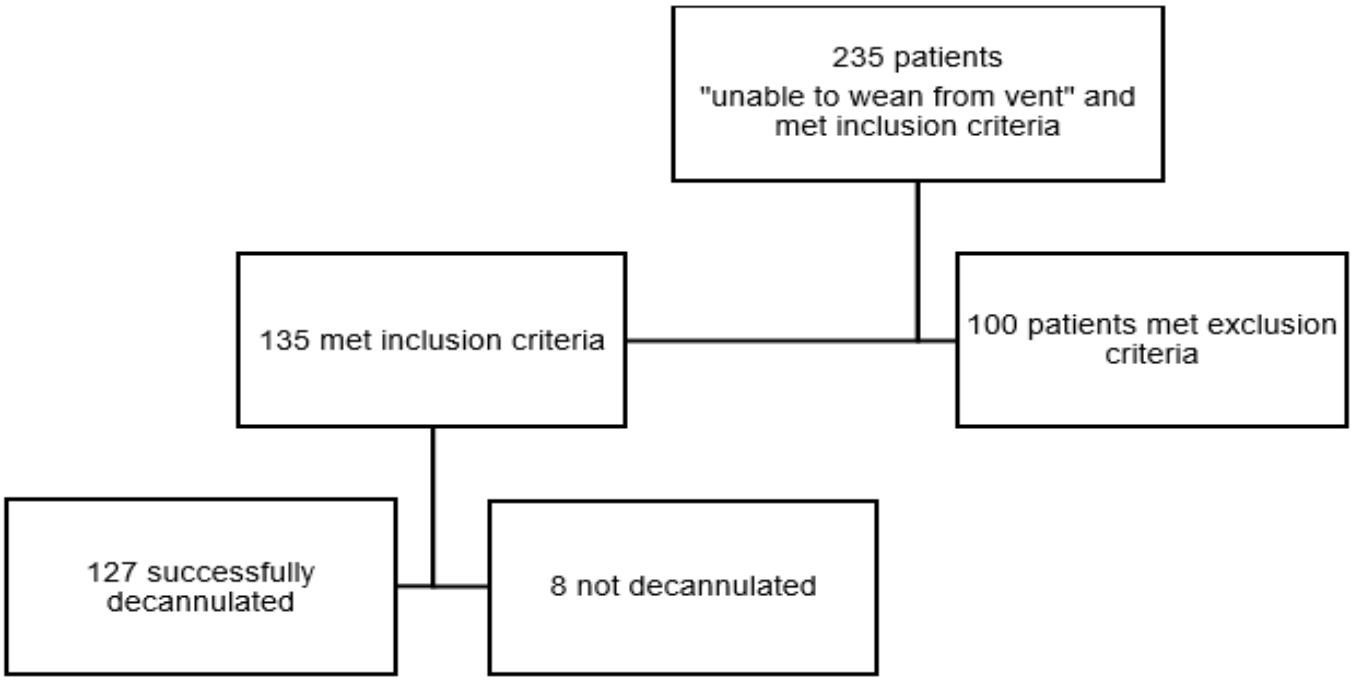

Figure 2: Patient Population Consort Diagram

Discussion

We found that a negative PF trial (PF expiration measurement <160 L/min) was not associated with failure to decannulate in our institution. No single prognostic variable (ABG, days on mechanical ventilation, LOS, and age) appeared to have predictive value. Physician-based clinical decision-making based on evaluation including ABG and ONO yielded over 94% successful decannulation rate in our population. Overall, we interpret this data to suggest that contrary to the common practice of basing decannulation on PF measurements alone, in our institution the PF measurements are not particularly helpful in determining which subjects are ready to be decannulated.

The ability to mount sufficient expiratory force to clear secretions is a critical factor to consider prior to decannulation. [10] However, it is one of many factors that determine someone's ability to maintain their airway. While some studies have demonstrated utility of a simple, single-valued test to aid with the decision-making process to decannulate subjects with tracheostomy, such as peak expiratory or inspiratory flow measurements, [8, 11] others have also found that relying solely on the peak expiratory flow

measurement to determine suitability for tracheostomy decannulation is questionable. [3, 9] Our study supports the latter. Factors other than PF measurements should be considered when predicting successful decannulation such as neurological status at time of decannulation, [3] patency of airways, and swallowing ability to prevent aspiration. [9, 12] It is important that literature shows the questionability and dangers of waiting on a sufficient peak expiratory flow measurement, since doing this can lead to multiple adverse patient outcomes and hospital costs.

Maintaining a tracheostomy tube can lead to inflammation, stenosis, lingering cough, tracheomalacia, and swallowing impairment which can lead to aspiration. Prolonged ventilation, and the adverse outcomes of this, are especially true for certain populations. For some patients, tracheostomy tubes will have to be maintained for long periods of time, and with most of the literature on decannulation protocols being designed for acute intensive care scenarios, these protocols need to be altered for long-term tracheostomy. Certain patient populations will have complications that also will affect their time on ventilation and their decannulation process. For example, patients with traumatic brain injury, or severe neurologic and cognitive impairments, can have altered motor control and longer stays on ventilation, the consequences of which will affect their success with decannulation and their continued recovery afterwards. [9] Further, during the acute phase of spinal cord injury the leading cause of death at all levels is respiratory compromise and illness.

This remains high due to impairment of voluntary control of muscles and contamination of devices like tracheostomies. These patients are expected to struggle with inhalation and exhalation, affecting their PF measures and increasing their time with tracheostomy and the probability of respiratory illnesses. [6] Thus relying solely on PF measurements for this population poses problems due to lack of functional ability, making PF measurement a barrier and potentially prolonging stay and increasing likelihood of complications.

Relying on a single variable, such as PF, can have many limitations in itself. There is always the chance of human error in recording and consistency in taking measurements. A factor contributing to possibility of human error, as well as a patient's prolonged time on ventilation, is the multiple steps in the workflow of the decannulation protocol. Our hospital uses a decannulation protocol similar to many LTACH in the United States (Figure 1). The many steps in the protocol involves nurses, respiratory therapists, physicians, and multiple pieces of equipment requiring two to three days to complete. While three days may appear lengthy from an acute care perspective, in the context of a patient who has endured weeks of prolonged ventilation three days may not be excessive. Our current decannulation protocol was developed approximately 15 years ago at a time when there was a strongly held belief amongst the American LTACH community that elevated peak flow values were amongst the most important prognostic indicators of successful decannulation of tracheostomy. In general, there was a paucity of literature on the topic of decannulation then, and literature on this topic remains scarce. In-house quality control studies performed at our institution after the protocol was introduced suggested that our protocol reduced the number of days between liberation from mechanical ventilation and decannulation. Therefore, we routinely apply this protocol to all patients in our LTACH that meet criteria. While we associate our high rate of successful decannulations with this protocol, we also recognize that analyses such our current study are necessary to eliminate unnecessary work, unneeded procedures, and unnecessary prolongation of a tracheostomy for the patient. Ultimately, this reduces time of hospitalization and unnecessary costs.

Another mitigating factor that can also confound PF measurements may be that tracheostomy tubes cause significant airflow obstruction that is difficult to quantify for each subject and may alter flow measurements and capping trials. [1] Further, depending on the patient population, mounting a specific PF measurement may be unattainable due to their functional ability, and other factors may be just as important, if not more, for these populations. For example, literature has shown that stroke patients who showed functional improvement in swallowing or coughing were more likely to successfully decannulate. [12] For patients with spinal cord injury, surface functional electrical stimulation of abdominal muscles has shown potential in helping patients decannulate faster and more effectively by assisting with augmentation of cough. [6] However, this technology requires funding and sufficient medical professionals able to administer this treatment.

There are several limitations of this study which need to be considered. First, 94.1% of the subjects were decannulated prior to discharge. This decannulation success rate may be a higher than rates compared to other institutions and may limit the applicability or generalizability of our findings. There is a possibility that this high success rate may be due to the specific decannulation protocol, shown in Figure 1, used to determine a patient's fitness for extubating. However, as mentioned before, this protocol has multiple steps over multiple days. More research needs to be done to determine which steps, if any, could be eliminated. Second, the relatively few failed decannulations (8/135) resulted in unstable models from generalized linear regression analyses. A larger sample population is necessary to calculate odds ratios from prognostic values. Third, this study may also suffer from selection bias. This long-term acute care facility has the ability to screen which subjects will be admitted based on Medicare and insurance criteria for patients able to be discharged. It is possible that subjects who are more likely to wean from prolonged mechanical ventilation are unintentionally chosen for admission. This would limit the generalizability of this study to facilities that are able to select those subjects that they choose to admit to their facility rather than all referred patient all-comers. These limitations could be resolved by conducting a prospective randomized study where one group is randomized to PF measurements, ABG, ONO, and physician/therapist clinical judgment, and the other group is randomized to physician/therapist clinical judgment alone. However, even this model would have limitations including lack of a concrete definition of "physician/therapist clinical judgement alone." In other words, what metrics are used for "clinical judgement" can vary based on provider and medical facility location, so reproducibility and reliability of this as a metric would be challenging. With all institutions not using exactly the same protocol, including some

places like Australia and New Zealand not using a peak flow test, this also shows the need for research on creating a single best protocol for all institutions. Further, the question of the ethics of assigning one group to “clinical judgement” is questionable. Regardless, we suspect that such a study would yield no significant difference in the percentage of subjects that are successfully decannulated and time to decannulation, based on the results of our study.

Conclusion

Tracheostomy tube decannulation can result in complications that can compromise a subject’s airway, which is potentially life-threatening. The inability to decannulate is associated with a separate set of potential problems that are just as potentially harmful, if not more so. Therefore, the ability to predict which subjects can be successfully decannulated and which cannot is critical. Single-test algorithms can be helpful in aiding complex medical decisions in the acute care setting. However, when deciding to decannulate someone with a tracheotomy in a long-term acute care facility, our study suggests that an experienced physician’s clinical ability outperforms the predictive ability of the PF measurement with a threshold of 160 L/min and prognostic variables such as ABG values, number of days on mechanical ventilation, length of stay at the LTACH, and age.

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