

Tracheotomy and high flow oxygen intake in severe patients

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Abstract

Objective: Purpose of this study is to find out the effects of tracheotomy in patients who are severely ill and if it has any different consequences in patients who are in ICU regarding their recovery procedure.

Method: 350 patients who were already in ICUs were chosen for this study. The patients were severely sick adults and who had issues in breathing. The purpose was to see if tracheotomy will result in early discharge and improved breathing in the sick adults. The data was taken in Nanjing Drum Tower Hospital from January 2012 to December 2019. and it was made sure that their consent has been taken for the experiment and the data was kept confidential and to be remained for the study purpose. The patients were divided into two groups i.e. control group and intervention group. The trial was kept blinded and patients assigned into control group had to undergo 24 hours intermittent high flow oxygen whereas on the other hand, patients assigned into intervention had to undergo 24 hours high flow of continuous oxygen therapy alongside with frequency of suctioning was held the indicator for the readiness for decannulation. Primary and secondary outcomes were kept in mind out from this trial. In primary outcome the time of decannulation was compared by means of log-rank test and the secondary outcome included multiple organ failure, decannulation failure, respiratory infections, weaning failure, sepsis, duration of stay in hospital as well as ICU and deaths.

Results: during this study 350 patients were involved and the mean/SD *(Standard Deviation) age of the patients was 58.3±15.1 years, whereas 68.2% of the patients were women. In intervention group, 200 patients were assigned and in control group 150 patients were assigned. The time for decannulation was shorter in intervention group as compared to the control group. Also, the incidents of pneumonia and other infections such as tracheobronchitis was lower as well as the stay of patients in hospital was also found lower in the intervention group as compared to control group. It means that high flow of continuous oxygen through tracheostomy results beneficial in severe ill people and can result in improved and better treatment as compared to people with intermittent high flow of oxygen.

Conclusion: Based on the results from this study, it has been concluded that decannulation on suctioning frequency alongside with 24 hours continuous high flow oxygen therapy as per the intervention group, its highly beneficial for patients to undergo it rather than being introduced to 24 hours intermittent high flow oxygen therapy.

Keywords: ICU, tracheotomy, high flow oxygen therapy

Introduction

According to Abe T. et al., (2018), around 15-20% patients who are going under mechanical ventilation are supposedly to go under tracheotomy too as a part of their medical procedure. However, very limited data was

available to testify the readiness for decannulation amongst the experts. It has been strictly limited towards the opinions of experts (Mitchell et al., 2018; Mc Grath et al., 2020) and further survey studies have been done too alongside with single-center experiences which invalidates to predict the success of decannulation procedure. Furthermore, there have been done few randomized trails that were based on specific decisions outcomes such as

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dysphagia or sleep quality (Tobin & Santamaria, 2008). Amongst all the tests the most successful trial to determine if the severely ill patient with tracheotomy is ready for decannulation or not has resulted to be capping. In this technique a cap is introduced to tracheotomy and placed over it to see if the patient can survive without tracheotomy tube and breathe on its own or not. The cap is placed for a shorter span of time and once it results positively only then the tube is removed which is called as decannulation. With the help of this procedure many patients who seem to be not eligible for decannulation are found to be eligible when the cap is placed on the tracheostomy tube. However, capping is not the only procedure to see if the patient is ready for decannulation there is an alternative procedure used where the number of times the secretions of patient's airway are suctioned are measured over a given period of time. The lesser the number of times the secretions are suctioned through the airways, the more it is considered a positive indication for a successful decannulation (Stelfox et al., 2008). In this study, the Reducing Decannulation Time Limiting Capping (REDECAO) was introduced where the assessment of readiness for decannulation was compared basing on the suctioning frequency with another assessment that was based on tracheotomy capping. Moreover, all the patients received high flow oxygen therapy when they could breathe in through tracheotomy tube.

Method

Trial Design

To conduct this research, a randomized trial was conducted in the ICU of Nanjing Drum Tower Hospital from January 2012 to December 2019. It was made sure that the ethics committee was informed and involved. The privacy of the data was kept confidential and to be used only for research purposes. The relatives of the patients were informed and a written consent was taken as an approval for the research protocol. The hospitals were involved in the collection of data however, the research has been solely designed by the researchers and there no other parties involved in the research besides the researchers themselves. The patients involved in this data collection were all severely ill patients in whom a first tracheotomy was already introduced in the ICU and underwent screening after they were weaned from the mechanical ventilation process which was determined as a freedom from mechanical ventilation for 24 consecutive hours. The areas that

were excluded from this study were a contraindication for decannulation at randomization such as unconsciousness, severe swallowing dysfunction, neuromuscular disease besides the ICU-acquired weaknesses, airway patency problems or tracheotomy for airway control. Also patients who are younger than 18 years were also excluded alongside with risks of death before the discharge. The variables that were involved in this study were age, sex, gender, BMI (Body Mass Index), the APACHE II (Acute Physiology and Chronic Health Evaluation) score right after the first 24 hours post admission as assessed as per the variables ranging from 0 to 71. The higher the score it indicates the severity of the disease; coexisting conditions which were categorized as per the Charlson comorbidity index. In this index, 22 clinical conditions are measured which tells the risk of death. Again higher the measurements or scores are, higher are the chances of death alongside with primary diagnosis in the patient. In this study, the variables that were recorded while performing the tracheotomy were the indications for tracheotomy, tracheotomy technique, APACHE II score, and cannula characteristics. However, the variables recorded for randomization were slightly different such as, APACHE II score, suctioning frequency, and results of swallowing test. Besides these variables, there were other variables introduced as well that were recorded and evaluated until the patient had been discharged and they were, date of decannulation, the date on which the criteria for decannulation was met, weaning failure, infectious complications, decannulation failure, reasons why capping trial failed, or delayed progress for decannulation or capping trial failure, number of stay in ICU, death in ICU or hospital, ICU readmission. Patients with mechanical-ventilation weaning or decannulation protocols were weaned from mechanical ventilation as per the protocol in previous studies done by Hernandez et al., (2013). Patients who have been introduced to tracheotomy tube were undergoing the screening on daily basis as per the pre decided criteria to determine whether if the patient was ready for weaning process or not. In order to prevent the prolonged cuff deflation in patients who were at high risk for aspiration, the researchers assessed the risk of aspiration through checking the swallowing which involved a drink test of 50 ml water alongside with the cuff deflated for a shorter span of time. After the drink test was done, another test i.e. a tracheotomy tube occlusion test was performed to see if there was blockage in the tracheal airflow, if not then it would be ruled out (Papathanakos,

Andrianopoulos, Zikou, Papathanasiou & Koulouras, 2020). Briefly, the researchers occluded or blocked the opening of the cannula with the tracheal cuff deflated for 5-7 minutes. Patients that showed signs for airflow blockage were sent for diagnostic bronchoscopy. Furthermore, there were many patients who did well whilst going under progressive weaning from mechanical ventilation according to the pre specified protocol that was determined on the basis of intermittent trials of spontaneous breathing of progressively longer span of time through the tracheotomy tube. However, while these trials were being done, assist-controlled ventilation was being reinstated to the patients so that they may take rest. Amidst these trials, spontaneous breathing trials were also introduced to the patients twice a day with a gap of two hours and meanwhile they would be on ventilator support trial. If any distresses seen in the patient the physician looking after would stop the trial. But when no signs of distress were seen then the trial would continue for consecutive twelve hours. And when progress was seen and patient could stay on spontaneous breathing for more than consecutive twelve hours for two consecutive days only then they were switched to high flow oxygen therapy via the tracheotomy tube. The respiration secretion was aspirated alongside with cuff being deflated and the cuff remained deflated only when then the spontaneous breathing procedure would be introduced. Through this trial tenure, the pattern was followed and 7-mm-diameter tracheotomy tube with a fenestrated inner sleeve was used whereas the cuff was deflated for all of the capping trials. For the patients who were overweighted as per the BMI criteria i.e. who had BMI greater than 45 or who might have anatomical abnormalities in their airways, then other tracheal cannulas were introduced.

The decision of decannulation in the control group was based on 24 hours capping trial. In this procedure, patients were considered as ready to undergo a capping trial only when they had to not undergo more than one aspiration every four hours during a twelve-hour tenure as per the pre decided criteria. However, the premises for failure were defined as de-capping for any reason during the 24 hours' tenure. When one capping trial fails, the second one can only be introduced after giving a rest to the patient until the next day or twelve hours later to be minimum. If the capping trial fails multiple times, then the patient could undergo decannulation outside the protocol which was pre specified and on the basis of the requirements for suctioning and that only if the physician would

suggest that the patient is ready for the decannulation procedure. In the intervention group the decision when to decannulated was based on the frequency of suctioning of secretions through the airways. The patients were allowed to go under decannulation only twice after every eight hours in the total 24 hours' tenure as per the pre specified criteria. Patients of intervention group did not have to under capping trials. Also, suctioning would only be performed if the patients showed symptoms such as, visible secretions in the airways, presence of rhonchi over the trachea, an inability to produce an effective spontaneous cough through the cannula even when multiple attempts were made, acute respiratory distress, suspected aspiration of upper-way secretions or gastric, deterioration of oxygen saturation i.e. below 92% which is referred to be blockage to airway. When the suctioning procedure was being performed it was made sure that it was done as per the guidelines and recommendations.

Furthermore, aspiration that were being introduced only to gain sputum specimens for analyses purpose were not considered amongst the decannulation protocols. Decannulation at times can be delayed in patients due to the diagnostic pending or at times due to the therapeutic procedures as well. Also, patients who have limited level of consciousness were determined as risk for neurological deterioration were also considered as a part of delayed decannulation. In order to rule out the biasness to these delays, the researchers introduced an intention-to-treat analysis. Every week, there would be classifications of 'why there is a delay in decannulation'. All the patients would receive high flow oxygen therapy with a specified interface for tracheotomy tube whilst they were breathing through their tracheotomy tubes. This setup was based for patients who were undergoing intermittent high flow oxygen therapy in the control group meanwhile the tube was de-capped and the patients in the intervention group had been receiving continuous high flow oxygen therapy until the decannulation was performed. The targeted temperature for high flow oxygen therapy was to be 37°C along with the flow of 60 liters per every minute whereas, the fraction of inspired oxygen was being regularly adjusted to sustain an arterial saturation of the oxygen, as per the measurement by pulse oximetry, between 92% and 95%. In this procedure, the patient could be discharged from ICU or High Dependency Unit even before the decannulation if they met the pre specified after criteria as per the safety protocols. Patients who were later being transferred into wards with

tracheotomy tube were accompanied by highly trained nurses and intensive led teams. Both the intervention and control groups were being looked after the same medical, nursing and respiratory staff and were receiving the same medical treatment as per the safety protocols to see better if the results were different even when the medical team is similar but the treatment is being done differently. Attending physicians of these patients were highly informed and well aware on the trial groups and within eight hours after the weaning procedure was performed after mechanical ventilation, eligible patients (as per the pre specified criteria) had to undergo simple randomization to the control group or intervention group with referenced to concealed assignment with random number produced via a call center.

End Points

The basic primary outcome was the time of decannulation which was determined as the time from the completions of weaning procedure from mechanical ventilation to the actual decannulation procedure. Weaning from mechanical ventilation was designed to be the procedure of 24 consecutive hours' disconnection from the ventilator whereas the actual decannulation was designed to intention-to-treat analysis. Secondary outcomes were supposedly kept in consideration to be multiple organ failure, decannulation failure, respiratory infections, weaning failure, sepsis, duration of stay in hospital as well as ICU and deaths.

Statistical Analysis

The sample size for this study was 350 patients that were severely ill adults and it was calculated to detect on three-day difference in the time to decannulation i.e. the primary outcome. The mean or standard deviation was assumed time of 13 ± 11 days in the control group. A sample size of 85 patients per group was considered to be sufficient for this trail test to have 80-90% power within an alpha level ranging 5% for two-sided tests and which would have no more than 15-20% of the patients withdrawing from the trial. The outcomes of this study were all based and analyzed on the principle of intention-to-treat.

The results that were extracted from this were also stratified as per the center. Outcomes for differences in days were reported in absolute values with no errors. Secondary and exploratory outcomes from this study have not been adjusted for multiplicity and therefore the results should and must not be used to infer the effects of treatment.

In order to assess the time of decannulation, researcher had plotted Kaplan-Meier curved and on basis of that the researcher compared them using the log-rank test. Patients who could not undergo the decannulation were also included in the analysis and their data was purposely censored at the date of discharge, death or withdrawal from the trial. Confidence interval was also calculated for time-to-event outcomes buy using inference for linear function of median and the Newcombe and Wilson hybrid scored have been used in this study to calculate the interval examination to distinguish the difference between the proportions. Furthermore, the two-sided level of significance was determined to be 0.05. To do the analysis, SPSS software was used in order to do the statistical analysis.

Results

A total of 500 patients with tracheotomy tube were identified from Jan 2012 till Dec 2019 and out of these 500 patients 85 did not successfully attempt the weaning process through mechanical ventilation (Fig 1). Therefore, only 415 patients had to undergo screening to be included in the trial. However, 350 patients were selected for screening and underwent randomization. Among these 350 patients, 150 patients were assigned to the control group where they had to undergo the capping trial and then if succeeded they would be provided 24 hours intermittent high flow oxygen therapy whereas on the other hand, 200 patients were assigned to the intervention group where they would be assessed for the suctioning frequency and then would be provided with 24 hours high flow oxygen therapy. Total of 10 patients from both the group did not undergo decannulation and the researchers had to censor their data. Moreover, the overall mean or standard deviation (SD) was 58.3 ± 15.1 years, whereas 68.2% of the patients were women. The clinical characteristics and demographic of both the groups were same in most of the criteria. In the control group, 15 patients had to undergo decannulation without even meeting the criteria of decannulation after having multiple repeated failures on capping trials; all 15 of them underwent the procedure of decannulation successfully. Further, another five patients had to change their cannula due to protocol for anatomical reasons. All the patients were followed either for death or hospital discharge.

Primary Outcome

In the table, the researcher demonstrates the primary outcome and the results of intention to

treat analysis. In the table the median time of decannulation can be seen shorter in the intervention group as compared to the control group which is 4 days of interquartile range, 5 to 7 as compared to 13 days' interquartile range, 12 to 14. An absolute difference of approximately 7 days can be seen with a confidence interval (CI) of 95%. It can be seen in both figure 2 and table 2 as shown below.

Secondary Outcomes

In the secondary outcome as demonstrated in table 2, it can be seen that the procedure of recannulation (failure of decannulation process) has occurred nine times in the control group whereas on the other hand, it occurred only in four patients in the intervention group, again with confidence interval (CI) of 95%. Moving forward to the weaning procedure failure, the process was failed in 27 patients in the control group whereas only in 11 patients it was found failed in the intervention group. The causes and reasons for the failure of weaning process are also demonstrated in table number 2 for the reference. Also, pneumonia occurred in 16 patients in the control as compared to intervention group it was again found lower as there were only 7 patients who had pneumonia. Furthermore, tracheobronchitis was found in 49 patients in the control group and only in 32 patients in the intervention group.

The median for the number of stays in hospital in the control group was 62 days and the interquartile range was 38 to 105 whereas in the intervention group the number of stays in hospital was 48 days with the interquartile range of 33 to 71 days.

Discussion

As per the data collected and analysis done on this survey results have been concluded and the researchers clearly found that the severely ill patients with tracheotomy tube installed, the time duration of the treatment and decannulation was shorter in the intervention group (decanulation based upon suctioning frequency as well as use of continuous high flow oxygen therapy) as compared to those who were assigned to control group (patients who received standard care which included capping trial alongside with intermittent high flow oxygen therapy). The explanation for the failure of decannulation in control group could be given as being more in demand therefore, it delays the time of decannulation which reflects the high proportions of patients with capping trials that were failed alongside with patients with weaning

failure. Furthermore, due to the failure in decannulation it caused infections in the patients and weaning failure and a study suggested due to the failure in decannulation there are high chances of clinical deterioration in the patients (De-Miguel-Díez et al., 2020). In both the groups same tracheotomy tube was used so the differences are minimized with respect to patients' experiences. As per the protocol, the cannula used was 7 mm inner diameter, 9.7 mm external diameter and had multiple large fenestrae to complete weaning from mechanical ventilation.

As per the findings of this study, when patients are introduced to prolong capping trials with limited respiratory functional reserve may overcome an excessive demanding ventilator workload. Whereas, patients in the intervention group were given benefit due to the continuous high flow oxygen therapy as compared to the patients in control group. According to a research done by Birk et al., it was examined that heated (37°C) humidified oxygen administered at 230 liters per every minute can enhance mucociliary transport and reduce the number of suctioning procedure in patients who have tracheotomy tube installed. However, the data is not enough to determine the clinical benefits with short term high flow oxygen therapy in patients who have tracheotomy tube installed. When the tracheotomy tube is introduced with a gas flow of 50 liters per every minute then high flow oxygen can result in improvised oxygenation. Previous studies that have been done on the similar topics have suggested that decannulation occurs in most of the patients (approximately 60% to 90%) depending upon the neurological condition of the patients who had been assigned (Trouillet et al., 2018). Moreover, most of the patients had to undergo decannulation procedure even before they were discharged from the ICU. As it can be seen in this study and the analysis that the number of infections in intervention group were lesser than in control group. Although there is no explanation for it yet but further researches can be done to determine if there is any scientific reason behind it. However, this information is noteworthy. Factors and variables that have played part in contribution towards this study are unclear and needs to be further distinguished. Another limitation in this study could be that the protocol decided and specified for both the trials was slightly different with respect to seeing the condition of the patient. There have been multiple incidents where the capping trial had to be stopped in the control as per the physician because of the condition of the

situation of the patient. It can be further studied to see if there is any difference if situation is different than this. The examiners have been excluded out of the analysis in this study as it might have made the analysis biased based upon their personal experiences. Therefore, as per the results tracheotomy tube with high flow of oxygen in severely ill patients can lead to better results and shorter the span of the treatment procedure as well as their stay in ICU and hospital.

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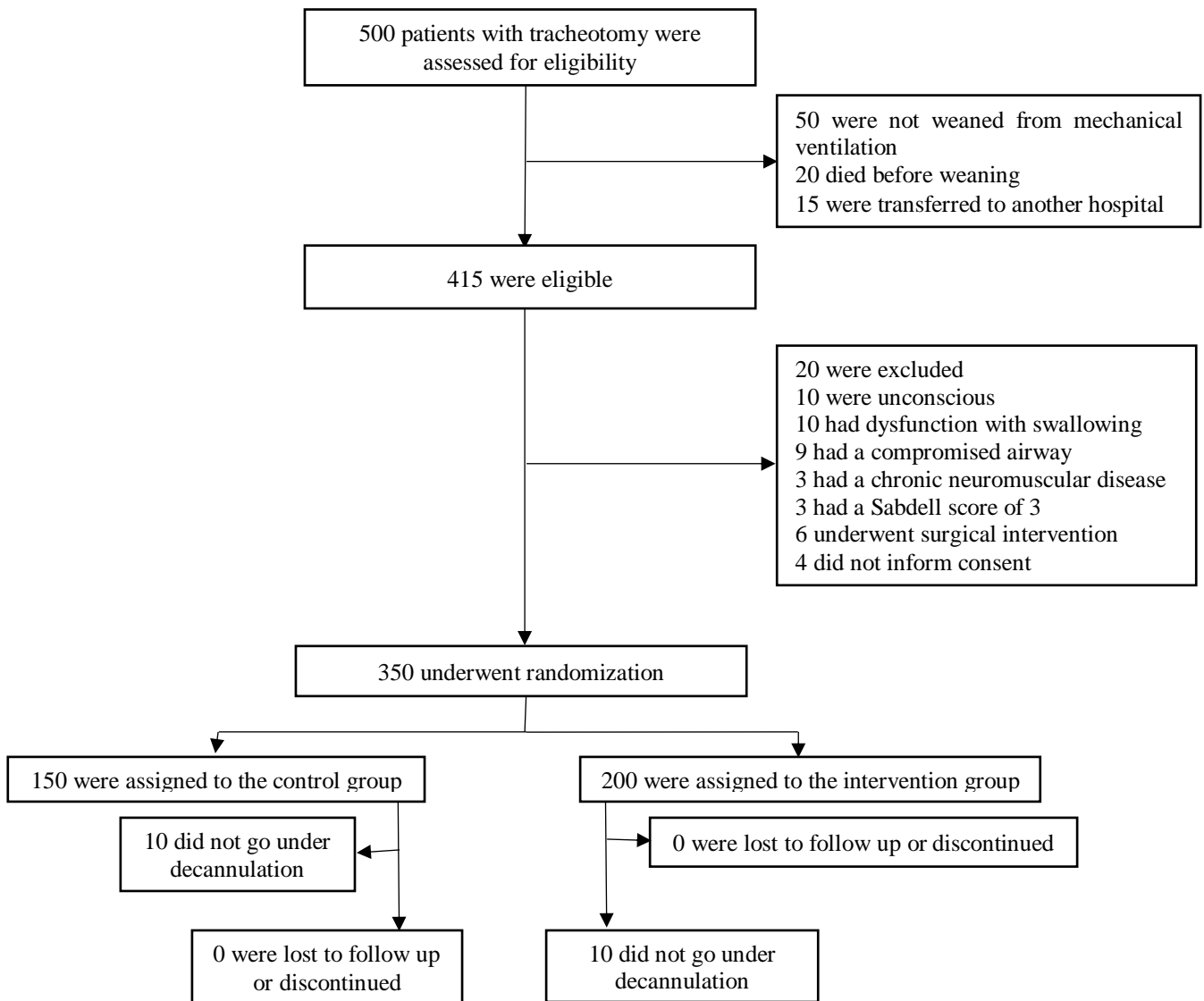


Figure 1. Randomization or Follow up Process

Table 1. Characteristics and Demographics of the Patients

Characteristics	Control Group N=150	Intervention Group N=200
Age	59.3±14.8	57.3±15.4
APACHE Score	10.8±3.7	11.6±4.1
Median (Duration of days of mechanical ventilation before undergoing tracheotomy)	13 (10–19)	13 (10–18)
Indication for tracheotomy		
Mechanical ventilation above 21 days	30 (18.6)	29 (17.2)
Prolonged weaning from mechanical ventilation	64 (39.8)	80 (47.3)
Low level of consciousness	43 (26.7)	37 (21.9)
Management of respiratory infections	4 (2.5)	6 (3.6)
Airway patency problems	20 (12.4)	18 (10.7)
Percutaneous tracheotomy	126 (78.3)	133 (78.7)
Out of protocol tracheal cannula	3 (1.9)	2 (1.2)
Co-existing conditions (no.) %		
BMI (Body Mass Index)	122 (75.8)	126 (74.6)
Heart disease	34 (21.1)	29 (17.2)
Neurological disease	36 (22.4)	30 (17.8)
Chronic Blockage disease	21 (13.0)	18 (10.7)
Types of diagnostics at the time of admission		
Medical	128 (79.5)	133 (78.7)
Trauma	38 (23.6)	39 (23.1)
Surgical	94 (58.4)	90 (53.3)
Swallowing disability at randomization (no.) %	63 (39.1)	52 (30.8)
Frequency of suctioning at randomization or no. of events during eight hours before randomization	1.9±1.2	2.0±1.1

Table 2. Primary and Secondary Outcome

Outcome	Control Group	Intervention Group	Difference
Primary Outcome: median time for decannulation	13 (11 to 14)	6 (5 to 7)	7 (5 to 9)
Secondary Outcomes:			
Failure of Decannulation Process	9 (5.6)	4 (2.4)	3.2 (-1.2 to 8.1)
Failure of Weaning Process	27 (16.8)	11 (6.5)	10.3 (3.4 to 17.4)
Pneumonia	16 (9.9)	7 (4.1)	5.8 (0.2 to 11.8)
Tracheobronchitis	47 (29.2)	32 (18.9)	10.3 (1.0 to 19.3)
Number of stays:			
ICU	35 (27 to 51)	32 (25 to 43)	3 (-1 to 11)
Hospital	62 (38 to 105)	48 (33 to 71)	14 (9 to 33)
Deaths:			
ICU	0	0	0 (-2.2 to 2.3)
Hospital	8 (5.0)	4 (2.4)	2.6 (-1.7 to 7.4)
Sepsis	12 (7.5)	12 (7.1)	0.3 (-5.5 to 6.3)
Multiple Organ Failure	6 (3.7)	2 (1.2)	2.5 (-1.1 to 6.8)
Exploratory Outcomes:			
Decannulation before discharge from ICU	104 (64.6)	139 (82.2)	-17.7 (-26.8 to -8.1)
Failure of Capping Trial	118 (73.3)	NA	NA
Number of Stays:			
Hospital (after randomization)	37 (20 to 66)	23 (14 to 36)	14 (10 to 31)
ICU (after discharge)	27 (11 to 53)	16 (7 to 27)	11 (4 to 20)
Readmission in ICU	17 (10.6)	10 (5.9)	4.6 (-1.4 to 10.9)
Swallowing disability at decannulation	16 (9.9)	15 (8.9)	1.1 (-5.4 to 7.6)