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High-Flow Oxygen with Capping or Suctioning for Tracheostomy Decannulation

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ABSTRACT

BACKGROUND

When patients with a tracheostomy tube reach a stage in their care at which decannulation appears to be possible, it is common practice to cap the tracheostomy tube for 24 hours to see whether they can breathe on their own. Whether this approach to establishing patient readiness for decannulation leads to better outcomes than one based on the frequency of airway suctioning is unclear.

METHODS

In five intensive care units (ICUs), we enrolled conscious, critically ill adults who had a tracheostomy tube; patients were eligible after weaning from mechanical ventilation. In this unblinded trial, patients were randomly assigned either to undergo a 24-hour capping trial plus intermittent high-flow oxygen therapy (control group) or to receive continuous high-flow oxygen therapy with frequency of suctioning being the indicator of readiness for decannulation (intervention group). The primary outcome was the time to decannulation, compared by means of the log-rank test. Secondary outcomes included decannulation failure, weaning failure, respiratory infections, sepsis, multiorgan failure, durations of stay in the ICU and hospital, and deaths in the ICU and hospital.

RESULTS

The trial included 330 patients; the mean (±SD) age of the patients was 58.3±15.1 years, and 68.2% of the patients were men. A total of 161 patients were assigned to the control group and 169 to the intervention group. The time to decannulation was shorter in the intervention group than in the control group (median, 6 days [interquartile range, 5 to 7] vs. 13 days [interquartile range, 11 to 14]; absolute difference, 7 days [95% confidence interval, 5 to 9]). The incidence of pneumonia and tracheobronchitis was lower, and the duration of stay in the hospital shorter, in the intervention group than in the control group. Other secondary outcomes were similar in the two groups.

CONCLUSIONS

Basing the decision to decannulate on suctioning frequency plus continuous high-flow oxygen therapy rather than on 24-hour capping trials plus intermittent high-flow oxygen therapy reduced the time to decannulation, with no evidence of a between-group difference in the incidence of decannulation failure. (REDECAP ClinicalTrials.gov number, NCT02512744.)

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Approximately 15% of patients undergoing mechanical ventilation receive a tracheostomy as part of their care,[1,2] but experimental data regarding readiness for decannulation are limited. Evidence of decannulation readiness has been limited to expert opinion,[3-5] survey studies,[6-8] single-center experience,[9,10] unvalidated scores to predict decannulation success,[11-13] and a few randomized trials that have focused on organizational concerns such as intensivist-led tracheostomy teams or the effects of specific decisions on outcomes such as dysphagia or sleep quality.[14-17]

A commonly used test to determine whether a critically ill patient with a tracheostomy tube is ready for decannulation is a capping trial, in which a cap is placed over the tracheostomy tube for a period of time to see whether the patient is able to breathe around the tracheostomy tube (or through a fenestration in the tube) through the nose and mouth.[3,4,7] Protocol-based capping trials have led to readiness criteria with high specificity and a positive predictive value for successful decannulation,[18] but their conservative nature can delay decannulation — that is, patients who do not meet the trial criteria for decannulation may still be able to undergo decannulation successfully.[13,18] An alternative approach to assessing readiness for decannulation is to measure the number of times that secretions are suctioned from a patient's airway over a given period of time, with fewer episodes of suctioning considered to be a positive indicator of potentially successful decannulation.[13]

In the Reducing Decannulation Time Limiting Capping (REDECAP) trial, we compared an assessment of readiness for decannulation that was based on suctioning frequency with an assessment that was based on tracheostomy capping. All the patients received high-flow oxygen therapy when they could respire through their tracheostomy tube.

Methods

Trial Design and Oversight

We conducted this randomized trial at five intensive care units (ICUs) in Spain. The ethics committee at each center and the departments of health of the regional governments with which these hospitals are affiliated (Madrid, Catalonia, and Castilla–La Mancha) approved the protocol (available with the full text of this article at NEJM.org). All the patients or their relatives provided written informed consent. The only commercial support for this trial was that Fisher and Paykel Healthcare paid for writing assistance with the manuscript, but it had no role in the design or conduct of the trial or in the decision to submit the manuscript for publication.

Patient Population

All critically ill adult patients in whom a first tracheostomy was created during an ICU stay underwent screening after being weaned from mechanical ventilation, which was defined as freedom from mechanical ventilation for 24 consecutive hours. Exclusion criteria were a contraindication for decannulation at randomization (unconsciousness, severe swallowing dysfunction, an airway patency problem, neuromuscular disease other than ICU-acquired weakness, or tracheostomy for airway control), an age of less than 18 years, or an expectation (according to the Sabadell score, which is a measure of the risk of death) that death would occur before hospital discharge.[19]

The following variables that were recorded at inclusion were age, sex, and body-mass index (BMI; the weight in kilograms divided by the square of the height in meters); the Acute Physiology and Chronic Health Evaluation (APACHE) II score in the first 24 hours after admission as assessed on the basis of 17 variables (scores range from 0 to 71, with higher scores indicating more severe disease); coexisting conditions, which were categorized according to the Charlson comorbidity index, on which 22 clinical conditions are scored with regard to the risk of death (with higher scores indicating a higher risk of death); and the primary diagnosis. The variables that were recorded on the day tracheostomy was performed were the indication for tracheostomy, tracheostomy technique, cannula characteristics, and the APACHE II score. The variables that were recorded at randomization were the APACHE II score, results of a swallowing test, and suctioning frequency. The following variables were recorded until discharge from the hospital: the date of decannulation, the date on which the criteria for decannulation were met, infectious complications, weaning failure or decannulation failure, reasons for capping-trial failure or delayed progression to decannulation,

ICU readmission, and duration of stay in the ICU and the hospital; and death in the ICU and in the hospital.

MECHANICAL-VENTILATION WEANING AND DECANNULATION PROTOCOLS

Patients were weaned from mechanical ventilation according to the following protocol[20]: Patients with a tracheostomy tube underwent screening daily in order to determine readiness for weaning according to prespecified criteria. To avoid prolonged cuff deflation in patients at high risk for aspiration, we assessed the risk of aspiration by checking swallowing with a drink test involving 50 ml of water with the cuff deflated for a short period of time. After the drink test, we performed a tracheostomy-tube occlusion test to rule out tracheal airflow obstruction. In brief, we occluded the opening of the cannula with the tracheal cuff deflated for 5 minutes. Patients who had any sign that was suggestive of airflow obstruction underwent diagnostic bronchoscopy.

Patients underwent progressive weaning from mechanical ventilation according to a protocol that was based on intermittent trials of spontaneous breathing of progressively longer duration through the tracheostomy tube. Between the trials, assist-controlled ventilation was reinstituted in order to allow patients to rest. Spontaneous breathing trials were attempted twice a day, with at least 2 hours of ventilatory support between trials. The attending physician stopped the trial if the patient had any sign of respiratory distress. When no signs of respiratory distress were present, the trial was continued for 12 consecutive hours. When patients were able to sustain spontaneous breathing for more than 12 consecutive hours on 2 consecutive days, they were switched to continuous high-flow oxygen therapy through their tracheostomy tube. The cuff was deflated and respiratory secretions were aspirated; the cuff remained deflated only during the periods of spontaneous breathing.

Throughout the trial period, the same style of 7-mm inner-diameter tracheostomy tube with a fenestrated inner sleeve (TRACOE twist, TRACOE Medical) was used; the cuff was deflated for all capping trials. In patients who had a BMI greater than 45 or who had anatomical abnormalities of the airway, other tracheal cannulas were allowed. In the control group, the decision to decannulate was based on a 24-hour capping trial.[18]

Patients were considered to be ready to undergo a capping trial when they had had no more than one aspiration every 4 hours during a 12-hour period according to prespecified indications (see below). Failure on the capping trial was defined as decapping for any reason during the 24-hour period (see the protocol).[21] When a capping trial failed, a new capping trial was not allowed until the next day (i.e., ≥12 hours later in order to check criteria for eligibility). Patients in whom capping trials failed repeatedly could undergo decannulation outside the protocol on the basis of suctioning requirements if the attending physicians considered them to be ready for decannulation.

In the intervention group, the decision to decannulate was based on suctioning frequency. Patients underwent decannulation when they had had no more than two aspirations every 8 hours during a 24-hour period according to prespecified indications (see below). Patients in this group did not undergo capping trials.

Suctioning was performed when a patient presented with any of the following conditions: presence of rhonchi over the trachea, visible secretions in the airways, an inability to generate an effective spontaneous cough through the cannula despite repeated attempts, suspected aspiration of gastric or upper-airway secretions, acute respiratory distress, or deterioration of the oxygen saturation (to ≤92%) that was thought to be related to airway obstruction. When suctioning was performed, it was done according to guideline recommendations.[21] Aspirations that were performed only to obtain sputum specimens for analyses were not considered in the decannulation protocols.

Decannulation could be delayed in patients because of pending diagnostic or therapeutic procedures and in those with a limited level of consciousness who were considered by the clinicians to be at risk for neurologic deterioration. To rule out bias related to these delays, we performed an intention-to-treat analysis. Every week, reasons for delayed decannulation were classified.

All the patients received high-flow oxygen therapy (Airvo 2, Fisher and Paykel Healthcare) with a specific interface for tracheostomy tubes (OPT870, Fisher and Paykel Healthcare) when they were breathing through the tracheostomy tube. This setup meant that patients in the control group received intermittent high-flow oxygen

therapy while the tube was decapped and patients in the intervention group received continuous high-flow oxygen therapy until decannulation. High-flow oxygen therapy was targeted to a temperature of 37°C and a flow of 60 liters per minute, and the fraction of inspired oxygen was regularly adjusted to maintain an arterial oxygen saturation, as measured by pulse oximetry, of between 92% and 95%.

Patients could be discharged from the high-dependency unit (ICU or step-down unit) before decannulation if they met the safety criteria (see the protocol). All the patients who were discharged to a ward while they had a tracheostomy tube were followed up by intensivist-led teams and trained nurses.

Both groups of patients were treated by the same medical, nursing, and respiratory therapy staff and received similar medical treatment. Attending physicians were aware of the trial groups. Within 8 hours after weaning from mechanical ventilation, eligible patients underwent simple randomization to the control group or the intervention group by means of concealed assignment with a random-number generator through a call center.

END POINTS

The primary outcome was the time to decannulation, which was defined as the time from the completion of weaning from mechanical ventilation (24 consecutive hours disconnected from the ventilator) to actual decannulation (intention-to-treat analysis). Secondary outcomes were decannulation failure, which was defined according to prespecified criteria; weaning failure; respiratory infections (pneumonia and tracheobronchitis); sepsis; multiorgan failure; durations of stay in the ICU and hospital; ICU readmission; and in-ICU and in-hospital deaths.

STATISTICAL ANALYSIS

The sample size was calculated to detect a 3-day difference in the time to decannulation (primary outcome), assuming a mean (±SD) time of 13±11 days in the control group.[22] A sample of 165 patients per group was considered to be adequate for the trial to have 80% power, with an alpha level of 5% for two-sided tests and with no more than 15% of the patients withdrawing from the trial. All the outcomes were analyzed according to the intention-to-treat principle. The results for the primary outcome were also stratified according to center. Results for differences in days are reported in absolute values. Secondary and exploratory outcomes were not adjusted for multiplicity, and therefore these results should not be used to infer treatment effects.

To assess the time to decannulation, we plotted Kaplan–Meier curves and compared them using the log-rank test. Patients who did not undergo decannulation were included in the analysis and had their data censored at the date of hospital discharge, death, or withdrawal from the trial. Confidence intervals for time-to-event outcomes were calculated with the use of inference for linear function of medians,[23] and the Newcombe and Wilson hybrid score was used to calculate the interval estimation for the difference between proportions.[24] The two-sided level of significance was set at 0.05. We used SPSS software, version 13.0 (SPSS), for statistical analyses.

RESULTS

PATIENTS

From May 2016 through May 2018, we identified 799 patients with a tracheostomy tube; of these patients, 138 did not complete weaning from mechanical ventilation. Thus, 661 patients underwent screening for inclusion in the trial. A total of 330 patients (49.9% of those screened) underwent randomization: 161 patients were assigned to the control group (capping trial and receipt of intermittent high-flow oxygen therapy) and 169 were assigned to the intervention group (assessment of suctioning frequency and receipt of continuous high-flow oxygen therapy) (Fig. 1). Eight patients in each group did not undergo decannulation and had their data censored. Overall, the mean (±SD) age of the patients was 58.3±15.1 years, and 68.2% of the patients were men. The demographic and clinical characteristics of the patients were similar in the two groups (Table 1; and Table S1 in the Supplementary Appendix, available at NEJM.org). In the control group, 12 patients underwent decannulation without having met the decannulation criteria after they had repeated failures on capping trials; all these patients underwent decannulation successfully. Five patients had the cannula changed out of protocol for anatomical reasons. All the patients were followed to hospital discharge or death.

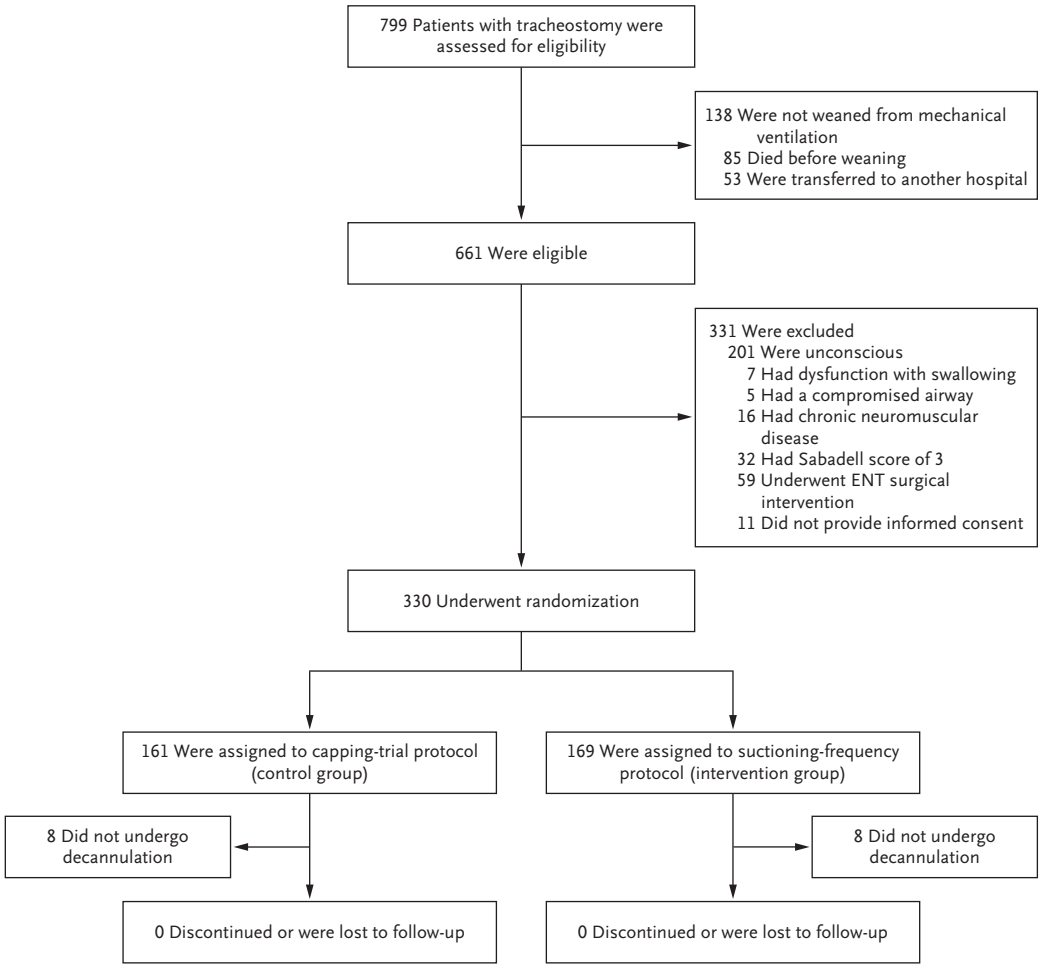


Figure 1. Randomization and Follow-up of the Patients.

Sabadell scores range from 0 to 3, with higher scores indicating a higher risk of death. ENT denotes ear, nose, and throat.

PRIMARY OUTCOME

Table 2 shows the results of the intention-to-treat analysis for the primary outcome. The median time to decannulation was shorter in the intervention group than in the control group (6 days [interquartile range, 5 to 7] vs. 13 days [interquartile range, 12 to 14]; absolute difference, 7 days [95% confidence interval {CI}, 5 to 9]) (Fig. 2 and Table S2).

SECONDARY OUTCOMES

Results regarding the secondary outcomes are shown in Table 2. Recannulation (i.e., decannulation failure) occurred in 9 patients (5.6%) in the control group and in 4 (2.4%) in the intervention group (difference, 3.2 percentage points; 95% CI, –1.2 to 8.1). Weaning failure occurred in 27 patients (16.7%) in the control group and in 11 (6.5%) in the intervention group (difference, 10.3 percentage points; 95% CI, 3.4 to 17.4). The causes of and reasons for weaning failure are presented in Table 2 and Figure S1.

Pneumonia occurred in 16 patients (9.9%) in the control group and in 7 (4.1%) in the intervention group (difference, 5.8 percentage points; 95% CI, 0.2 to 11.8). Tracheobronchitis occurred in 47 patients (29.2%) in the control group and in 32 (18.9%) in the intervention group (difference, 10.3 percentage points; 95% CI, 1.0 to 19.3). The median duration of stay in the hospi-

Table 1. Characteristics of the Patients.*

Characteristic	Control Group (N=161)	Intervention Group (N=169)
Age — yr	59.3±14.8	57.3±15.4
Male sex — no. (%)	108 (67.1)	117 (69.2)
APACHE II score†	10.8±3.7	11.6±4.1
Median duration of mechanical ventilation before tracheostomy (IQR) — days	13 (10–19)	13 (10–18)
Indication for tracheostomy — no. (%)		
Mechanical ventilation for >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 secretions	4 (2.5)	6 (3.6)
Airway-patency problems	20 (12.4)	18 (10.7)
Percutaneous tracheostomy	126 (78.3)	133 (78.7)
Out-of-protocol tracheal cannula	3 (1.9)	2 (1.2)
Coexisting conditions — no. (%)§		
Body-mass index >25¶	122 (75.8)	126 (74.6)
Heart disease	34 (21.1)	29 (17.2)
Neurologic disease	36 (22.4)	30 (17.8)
Chronic obstructive pulmonary disease	21 (13.0)	18 (10.7)
Type of diagnosis at admission — no. (%)‖		
Medical	128 (79.5)	133 (78.7)
Trauma	38 (23.6)	39 (23.1)
Surgical	94 (58.4)	90 (53.3)
Swallowing dysfunction at randomization — no. (%)**	63 (39.1)	52 (30.8)
Suctioning frequency at randomization — no. of events during 8 hr before randomization	1.9±1.2	2.0±1.1

* Plus–minus values are means ±SD. IQR denotes interquartile range.
† The Acute Physiology and Chronic Health Evaluation (APACHE) II score was calculated on the basis of 17 variables on the day of admission to the intensive care unit. Scores range from 0 to 71 points, with higher scores indicating more severe disease.
‡ Prolonged weaning from mechanical ventilation was defined according to the Sixth International Consensus Conference in Intensive Care Medicine.[25]
§ Coexisting conditions were assessed according to the Charlson comorbidity index, on which 22 clinical conditions are scored with regard to the risk of death; scores range from 0 to 37, with higher scores indicating a higher risk of death.
¶ The body-mass index is the weight in kilograms divided by the square of the height in meters.
‖ Patients could have had more than one type of diagnosis at admission.
** Swallowing dysfunction was defined as an abnormal result on the 50-ml drink test. Patients with severe swallowing dysfunction were excluded from the trial. No patient's condition worsened from having an abnormal result on the drink test to having severe swallowing dysfunction during the trial period.

tal was 62 days (interquartile range, 38 to 105) in the control group and 48 days (interquartile range, 33 to 71) in the intervention group (absolute difference, 14 days; 95% CI, 9 to 33).

DISCUSSION

In conscious, critically ill adult patients with a tracheostomy tube, we found that the time to decannulation was shorter in those with decannulation based on suctioning frequency plus the use of continuous high-flow oxygen therapy than in those who received the standard of care including capping trials plus the use of intermittent high-flow oxygen therapy, with no significant difference in the incidence of recannulation. The most plausible explanation for this result is that capping trials are highly demand-

Table 2. Primary and Secondary Outcomes.*

Outcome	Control Group (N=161)	Intervention Group (N=169)	Difference (95% CI)
Primary outcome: median time to decannulation (IQR) — days†	13 (11 to 14)	6 (5 to 7)	7 (5 to 9)
Secondary outcomes			
Decannulation failure — no. (%)	9 (5.6)	4 (2.4)	3.2 (–1.2 to 8.1)
Weaning failure — no. (%)‡	27 (16.8)	11 (6.5)	10.3 (3.4 to 17.4)
Pneumonia — no. (%)	16 (9.9)	7 (4.1)	5.8 (0.2 to 11.8)
Tracheobronchitis — no. (%)	47 (29.2)	32 (18.9)	10.3 (1.0 to 19.3)
Median duration of stay (IQR) — days			
In the ICU§	35 (27 to 51)	32 (25 to 43)	3 (–1 to 11)
In the hospital	62 (38 to 105)	48 (33 to 71)	14 (9 to 33)
Death — no. (%)			
In the ICU	0	0	0 (–2.2 to 2.3)
In the hospital	8 (5.0)	4 (2.4)	2.6 (–1.7 to 7.4)
Sepsis — no. (%)	12 (7.5)	12 (7.1)	0.3 (–5.5 to 6.3)
Multiorgan failure — no. (%)	6 (3.7)	2 (1.2)	2.5 (–1.1 to 6.8)
Exploratory outcomes			
Decannulation before ICU discharge — no. (%)	104 (64.6)	139 (82.2)	–17.7 (–26.8 to –8.1)
Capping-trial failure — no. (%)¶	118 (73.3)	NA	NA
Median duration of stay (IQR) — days			
In the hospital after randomization	37 (20 to 66)	23 (14 to 36)	14 (10 to 31)
In the hospital after ICU discharge	27 (11 to 53)	16 (7 to 27)	11 (4 to 20)
ICU readmission — no. (%)	17 (10.6)	10 (5.9)	4.6 (–1.4 to 10.9)
Swallowing dysfunction at decannulation — no. (%)	16 (9.9)	15 (8.9)	1.1 (–5.4 to 7.6)

* Results for differences in days are reported in absolute values; durations in the intervention group were always shorter than those in the control group. Differences between percents are shown in percentage points and were calculated on the basis of unrounded data. The 95% confidence intervals (CIs) for the secondary and exploratory outcomes were not adjusted for multiplicity, and therefore these results should not be used to infer treatment effects. ICU denotes intensive care unit, and NA not applicable.

† The primary outcome was assessed in the intention-to-treat population and was calculated according to the day on which the patient underwent decannulation. In 81 patients who met the criteria for decannulation (30 in the control group vs. 51 in the intervention group), attending physicians delayed decannulation. The main reason for delay was therapeutic intervention in 28 patients (12 in the control group and 16 in the intervention group), expected diagnostic procedure in 24 patients (9 and 15, respectively), and fluctuating level of consciousness in 17 patients (6 and 11). The analysis according to the day on which the patients met decannulation criteria showed the following results: the median time to decannulation was 12 days (interquartile range, 7 to 12) in the control group and 4 (interquartile range, 3 to 8) in the intervention group (absolute difference, 8 days; 95% CI, 5 to 10).

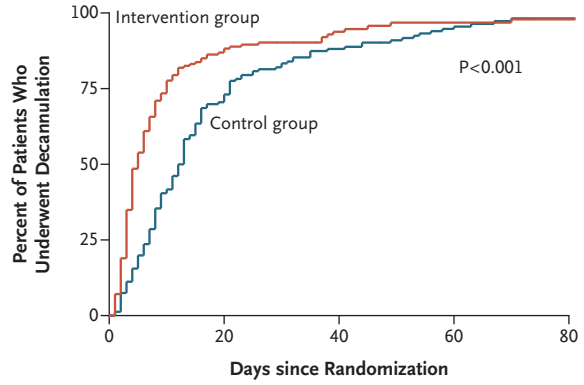
‡ The causes of weaning failure were related to respiratory acidosis (in 3 patients in the control group), decreased level of consciousness (in 1 patient in the intervention group), hypoxemia (in 2 patients in the intervention group and in 13 in the control group), tachypnea (in 3 and 2, respectively), and clinical signs suggestive of respiratory-muscle fatigue (in 5 and 9) (Fig. S1).

§ The median duration of stay in the ICU before randomization was 27 days (interquartile range, 17 to 36) in the control group and 24 days (interquartile range, 17 to 34) in the intervention group (difference, 3 days; 95% CI, –7 to 4).

¶ Of these 118 patients, 23 (19.5%) had the tracheostomy-tube cap removed because of deterioration in the oxygen saturation level (to ≤92%), because an increase in the fraction of inspired oxygen (F_{IO_2}) to at least 0.40 was warranted, or because an increase in the F_{IO_2} by at least 0.10 from the baseline value was warranted, and 95 patients (80.5%) had the tracheostomy-tube cap removed after the attending nursing staff considered it to be necessary in order to remove accumulated pulmonary secretions (see the protocol). The mean (±SD) number of failed capping trials per patient was 2.95±2.45.

ing, thus delaying the time to decannulation as reflected by the high proportions of patients with capping trials that failed and of patients with weaning failure. In addition, failure on capping trials preceded infection episodes and weaning failure, a finding that suggests that failure on capping trials could lead to a sequence of clinical deterioration (Fig. S1).

Capping-trial protocols usually call for downsizing the tracheal cannula or deflating the cuff and switching to a fenestrated or uncuffed cannula. In this trial, whenever possible, we used



No. of Patients					
Intervention group	169	20	7	3	1
Control group	161	46	17	7	1

Figure 2. Kaplan–Meier Analysis of the Time to Decannulation (Intention-to-Treat Population).

The analysis was truncated at 80 days. Patients who underwent decannulation after this time had their data censored. In the control group, one patient underwent decannulation at 83 days and one at 319 days; in the intervention group, one patient underwent decannulation at 142 days.

the same tracheostomy tube in both groups, thus minimizing the differences in this aspect of the patients' experience.

Our protocol included one change to a cannula with a 7-mm inner diameter, a 9.7-mm external diameter, and multiple large fenestrae in order to complete weaning from mechanical ventilation. Even under these conditions, 73.3% of the patients in the control group had at least one failure on the capping trial, and 12 patients had repeated failures on capping trials but nevertheless underwent decannulation successfully out of protocol. These results reinforce the hypothesis that prolonged capping trials require that patients with limited respiratory functional reserve overcome an excessively demanding ventilatory workload.

Patients in the intervention group may have benefited from receiving more continuous high-flow oxygen therapy than patients in the control group. Birk et al.[26] found that heated (37°C) humidification of oxygen administered at 30 liters per minute enhanced mucociliary transport and reduced the number of suctioning procedures in patients with a tracheostomy tube. Although data are lacking regarding clinical benefits with short-term high-flow oxygen therapy in patients with a tracheostomy tube,[27] when it is used with a gas flow of at least 50 liters per minute, high-flow oxygen therapy improves oxygenation, reduces the respiratory rate, and provides a small degree of positive airway expiratory pressure.[28]

Applying decannulation protocols on the basis of subjective criteria leads to an incidence of recannulation ranging from 2 to 5%.[6,29] Our objective criteria led to a similar incidence of recannulation (2.4% in the intervention group and 5.6% in the control group). However, these results must be interpreted in light of the high percentage of patients who underwent decannulation (95.2%). Previous studies have shown that decannulation occurs in 56%[12] to 88%[18] of patients, depending mainly on the number of patients included who had a neurocritical condition and the type of facility where decannulation was performed. Moreover, a high percentage of our patients underwent decannulation before ICU discharge.

The lower incidence of infection in the intervention group than in the control group, although not significant, is also noteworthy. The mechanisms that are involved in this difference are unclear. Factors that might have contributed to this finding include a shorter time with an invasive airway present and the continuous use of high-flow oxygen therapy until decannulation.[20]

One limitation of our trial is the criteria affecting the time to decannulation in the two protocols. In the control group, the cutoff to determine readiness for capping trials (≤1 aspiration every 4 hours for 12 hours) was based on safety results in another group.[18] It could be argued that this criterion was overly restrictive and thus prolonged the hospital course before the capping trial was started; however, the high proportion of patients in whom the capping trial failed (73.3%) seems to rebut this argument. Furthermore, 12 patients in the capping-trial protocol who had repeated failures on the capping trial underwent successful decannulation. In the intervention group, the cutoff to determine readiness for decannulation (≤2 aspirations every 8 hours for 24 hours) was based on the results of a different study that showed a hazard ratio ranging from 0.7 (95% CI, 0.54 to 0.91) to 0.81 (95% CI, 0.67 to 0.97) per aspiration in an 8-hour period.[13] Some patients who receive more frequent suctioning can undergo decannulation, but the identification of these patients would require a more complex protocol and expertise.[13] Both protocols included the use of high-flow oxygen therapy. However, the frac-

tion of time that the high-flow oxygen therapy was applied was much greater in the intervention group than in the control group. The role that the differential use of high-flow oxygen therapy had in our outcomes is not known. Finally, the attending teams were aware of the trial-group assignments. Although the investigators were excluded from participating in the clinical decisions, we cannot rule out the possibility that this bias may, at least in part, explain the results.

We found that in conscious, critically ill adults with a tracheostomy tube, a protocol that was based on suctioning frequency plus continuous high-flow oxygen therapy resulted in a shorter time to decannulation than capping trials plus intermittent high-flow oxygen therapy, with no significant difference in the incidence of recannulation.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

A data sharing statement provided by the authors is available with the full text of this article at NEJM.org.

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