ramr
Revista Americana de Medicina Respiratoria

RAMR 2017;1:25-37
ISSN 1852 - 236X

DecanulAR. Predictors of Decannulation Difficulty. A Multicenter Cohort Study

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Received: 10.24.2016
Accepted: 01.18.2017

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Abstract

Introduction: Tracheostomy (TQT) is perhaps the most common surgical intervention in the ICU. A prolonged use of a TQT cannula may subject patients to an increased risk of complications. Decannulation time in tracheostomies is becoming increasingly important during the recovery process after critical illnesses. At present, there is no prospective, multicenter study in our country that assesses tracheostomized patients as the population of the study. In addition, factors associated with decannulation difficulty are not usually analyzed.

Objective: To describe the epidemiological characteristics of the study population, to report the rate of decannulation failure, to analyze the existence of independent risk factors associated with the impossibility of decannulation and to evaluate time-related mortality while achieving decannulation.

Method: A prospective, multicenter cohort study that included patients who were tracheostomized at Intensive Care Units (ICUs) and patients who were admitted to Mechanical Ventilation Weaning and Rehabilitation Centers (MVWRCs) with TQTs. Epidemiological variables were recorded prior and during their hospitalization. The total duration of the study was one year. A sample size of 200 patients was calculated in order to draw a 5% rate (expected value for decannulation failure), determining the possibility to incur in a 5% alpha error and in a 20% beta error.

Results: Initially, 48 centers from different cities around the country were recruited, and 36 centers contributed patients (31 from ICUs and 5 from MVWRCs). Five hundred and seventy-six patients were included, of whom 238 were removed since they could not be weaned from mechanical ventilation. The average age was 55 years (SD± 18.3), with a median of 58 years (IQR 43-70). There were more male patients (59%; 95% CI 53.8 - 64.2). One hundred and ninety-three patients who were weaned could be decannulated (57%; 95% CI 51.7-62.2). Cumulative incidence regarding decannulation failure was 3.1% in 7 months (95% CI 1.4 - 6.6).

In the multivariate logistic regression analysis, the age group of patients over 70 years old (OR 3.40; 95% CI 1.51-7.66) and TQTs connected to surgical procedures (OR 1.74; 95% CI 1.08-2.79) were found as independent predictors contraindicating decannulation. Additionally, being a patient from an ICU versus being a patient from a MVWRC acted as a protective factor (OR 0.29; 95% CI 0.15-0.56).

Likewise, the 90-day mortality rate was assessed using the Kaplan-Meier survival curve and a significant difference was observed (log-rank $p<0.05$) in the group of patients who were not decannulated compared to those who could be decannulated.

Conclusion: The number of patients who achieved decannulation is similar to that described in the bibliography and the same happened with recannulation. Age was a predictor contraindicating decannulation, which is potentially connected with a worse general condition of the patient. There were no comorbidities linked to contraindications for decannulation. It is important to remove the tracheostomy cannula since decannulated patients are more likely to be discharged home than those who did not undergo decannulation. Although it is not possible to confirm that decannulation is a key factor for discharges or if it is part of a better general condition of the patient, it constitutes a relevant milestone in the patient's prognosis.

Key words: Tracheostomy; Decannulation; Intensive Care Unit; Mortality

Introduction

Mechanical ventilation is frequently used in patients admitted to Intensive Care Units (ICUs) and tracheostomies (TQTs) are performed in approximately 10% of the patients who receive mechanical ventilation[1-4] and up to 34% of the patients who need mechanical ventilation for over 48 hours[5]. This percentage is higher in patients with prolonged mechanical ventilation (PMV)[6, 7] whether it is to better handle patients or to refer them to other hospital departments or to Mechanical Ventilation Weaning and Rehabilitation Centers (MVWRCs). Tracheostomy has perhaps become the most common surgical intervention in the ICU[8].

A prolonged use of a TQT cannula can subject patients to an increased risk of late complications, including tracheal stenosis, tracheomalacia, granulomas, bleeding, fistulas, infections and aspiration[9-13]. Likewise, psychological consequences can be major in patients who experience body image perception disorders[14].

A permanent removal of a TQT cannula, known as decannulation, is a significant step towards recovering from a prolonged critical illness[15].

Even though TQT is commonly used to manage patients with mechanical ventilation, there is a lack of knowledge and little evidence as to when and how the TQT cannula should be removed[16]. Uncontrolled pilot studies[17-20], expert guides[21] and surveys[22, 23] have suggested that decannulation can be contemplated in patients who no longer need mechanical ventilation or if the patient is used to noninvasive mechanical ventilation (NIV), if there is no upper airway obstruction or if it has been solved, if the patient has an adequate state of consciousness, good respiratory secretion management and if his/her swallowing has been assessed.

Decannulation time in tracheostomies is becoming increasingly important during the recovery process after critical illnesses, since there is increasing evidence that tracheostomized patients have a higher risk when they are assisted in general hospital wards but, at the same time, delayed discharges from the ICU are an extremely costly alternative from an economic point of view, both for public health and for private and public medical insurance providers[19].

Previous endeavors to develop a predictive model have had limited success to explain the prognosis of critical tracheostomized patients[23, 24]. A potential explanation for this is the high number of variables involved in the final result of the prognosis and the high level of heterogeneity of tracheostomized patients[19].

In our country, there is a retrospective report[20] where decannulation failure (known as the impossibility to decannulate) was associated with 6 variables in the univariate analysis: male gender, respiratory history, cardiovascular history, level of albumin at the moment of admission to the MVWRC, days of hospitalization at the MVWRC and days of hospitalization at the ICU + MVWRC. In the logistic regression analysis, the male gender and the respiratory history variables were found to be independent predictors. Decannulation acted as a protective factor for survival during hospitalizations at MVWRCs.

At present, there is no prospective, multicenter study in our country that assesses tracheostomized patients as the population of the study. In addition, factors associated with decannulation difficulty are not usually analyzed. Therefore, we developed

this study aiming to describe the epidemiological characteristics of the study population, to report the rate of decannulation failure, to analyze the existence of independent risk factors associated with the impossibility of decannulation and to evaluate time-related mortality while achieving decannulation.

Materials and method

A prospective, multicenter study that included 31 ICUs and 5 MVWRCs, performed in the Argentine Republic from June 1st, 2014 to January 31st, 2015. Patients who needed a tracheostomy during their hospitalization at the acute care facility or who were admitted to the MVWRC with a tracheostomy cannula were included. Prior to recruiting patients, all the centers sent the protocol to the corresponding teaching and research committees and ethics committees.

Participating centers received the protocol and the study operations manual two months before beginning with recruitment. Each center only had one leader (coordinator) in charge of sending forms to the person responsible for the creation of the computerized database. Three authors of the protocol were in charge of the database and of verifying the information entered.

The study did not require or request amendments to the decannulation protocols of the participating institutions (research centers). If the recruited centers did not perform any of the measurements requested in the protocol, they were not included (it was entered as missing data) and research centers were encouraged to not make changes in their follow-up and evaluation methods for tracheostomized patients as of their participation in the study, with the purpose of not modifying the usual management of the centers involved and to be able to reflect more irrefutably the characteristics of the study population with the least influence possible due to the descriptive nature of our investigation.

Consecutively, all patients > 18 years of age who might have been tracheostomized during their hospitalization at the ICU or who might have been admitted to the MVWRC with a TQT were included. The patients who 1-received a TQT due to a known airway lesion (e.g. tumor), 2-who received a TQT due to a known swallowing disorder (e.g. neuromuscular disease), 3-every patient who did not give their oral or written consent (only for those research centers where the ethics committee deemed necessary the use of a written informed consent form to enter the patient's data) were excluded. The patients who did not achieve MV weaning were removed.

The previous history of patients admitted to the ICU was documented at the moment of admission to the ICU; as well as their gender, age, ICU admission category (clinical, emergency surgery, programmed surgery, trauma, trauma + traumatic brain injury), admission diagnosis/reason for ICU admission, Charlson Index Score[25], Glasgow Coma Scale (GCS) at ICU admission. Likewise, the number of days with MV and successful MV weaning experiences were recorded (it was considered successful weaning when the patient did not require invasive or non-invasive ventilatory support for at least 120 hours/5 consecutive days). Date the TQT was performed, type of TQT (surgical or percutaneous). Reason for the TQT (suspected prolonged weaning, prolonged mechanical ventilation, extubation failures, emergency TQT)[26], decannulation success, number of days with TQT. Need for recannulation, days to recannulation. Reason for the recannulation (poor secretion management, respiratory failure, upper airway obstruction). Reason decannulation was contraindicated (if the patient cannot achieve decannulation, the center can specify why based on the unit's criteria). Number of days hospitalized. Discharge condition (deceased, alive to a MVWRC, alive to another hospital/clinic, alive to his/her home).

In patients admitted to MVWRCs, invasive or non-invasive MV requirements were documented. Type of TQT cannula at admission. Successful MV weaning (tolerated 120 hours without any type of ventilatory support). Requirement of new MV cycles (needed ventilatory support for over 48 hours). Achieved decannulation. Successful decannulation. Number of days with TQT. Need for recannulation, days and hours to recannulation. Reason for the recannulation (poor secretion management, respiratory failure, upper airway obstruction). Reason decannulation was contraindicated (just as with acute care facilities, if the patient cannot achieve decannulation, the center can specify why based on the unit's criteria). Number of days hospitalized. MVWRC discharge condition (deceased, alive to an ICU due to acute exacerbations or new event, alive to his/her home, other).

In ATTACHMENT 1 all variables are explained, along with their operational definitions, the measurement scale and the potential values.

In the event that the patient might have required any surgical intervention to solve an abnormal airway function and/or to place any type of endoprosthesis (stent, Y-prosthesis, Montgomery, etc.), for the study, he/she was considered decannulated the day of the intervention. Likewise, if the patient had required a placement of a silicone stopper, for the study, he/she was not considered decannulated until it was removed.

The patient was considered "weaned from MV" when he/she did not require ventilatory support for 120 hours.

Once the patient had reached 120 days after being weaned from MV, he/she was considered "not able to undergo decannulation" and his/her follow-up was concluded for the purposes of this study. Patients in this condition concluded the study under the category "follow-up completion", follow-up activities were finalized and the patient's data were sent for analysis.

Once patient recruitment was over, we continued with a 120-day follow-up period (period in which the last enrolled patient was considered not able to undergo decannulation), then the cases were considered concluded and the information was sent to the people in charge of loading it.

An 8-month study period was established estimating to achieve an "n" of 200 patients. This number was obtained calculating a sample size for a 5% rate (expected value for decannulation failure), determining the possibility to incur in a 5% alpha error and in a 20% beta error (80% power to recreate this value within our population)

Statistical analysis

Continuous variables with normal distribution were presented as mean ± standard deviation (SD), whereas the ones with abnormal distribution were presented as median ± interquartile range (IQR). Categorical variables were presented as percentages.

Cumulative incidence regarding decannulation failure was calculated in tracheostomized patients who were decannulated and for some reason had to be recannulated, this incidence was estimated over a 7-month period.

To establish a link between impossibility of decannulation and numerical variables with normal distribution, we used Student's T-test and Mann–Whitney's U test; for categorical dichotomous variables, we used Fisher's exact test; and for dichotomous variables with more than two categories, we used the Chi^2 test; should this be significant, we used the column proportions test implementing the Bonferroni method to establish which categories showed significant differences. Variables that could constitute explanatory factors for the impossibility of decannulation and that, in addition, revealed certain degree of relevance ($p=0.1$) in the univariate comparison, were included in a binary multivariate logistic regression analysis where the factor to be compared was impossibility of decannulation. The Wald stepwise removal method was used, and the least relevant variable was removed in each step to individualize independent factors that hindered decannulation. The calibration and discrimination of the logistic regression model were assessed using the Hosmer–Lemeshow test and the analysis of the area under the curve (AUC) [27].

In addition, a survival analysis was included using the Kaplan-Meier method where the event analyzed was the 90-day mortality rate after the tracheostomy. The difference between the group of patients successfully decannulated and those who could not be decannulated was compared using the log-rank test. In two-tailed tests, a $p < 0.05$ value was considered significant. The statistical analysis of the data and the creation of charts were performed using the R software 3.1.1[28].

Results

Initially, 48 centers from different cities around the country were recruited and 36 centers contributed patients, 31 corresponding to ICUs and 5 to MVWRCs (the reference for each center is described in ATTACHMENT 2). Five hundred and seventy-six patients were included, of whom 238 were removed since they could not be weaned from MV (Fig. 1).

The average age of the 338 patients included in the analysis was 55 years (SD ± 18.3) with a median of 58 years (IQR 43-70). Two hundred patients out of the total population of the sample were males (59%; 95% CI 53.8 - 64.2).

Among admissions due to pathologies, the 5 categories with the highest rates were strokes (73 patients, 21.6%); multiple trauma with traumatic

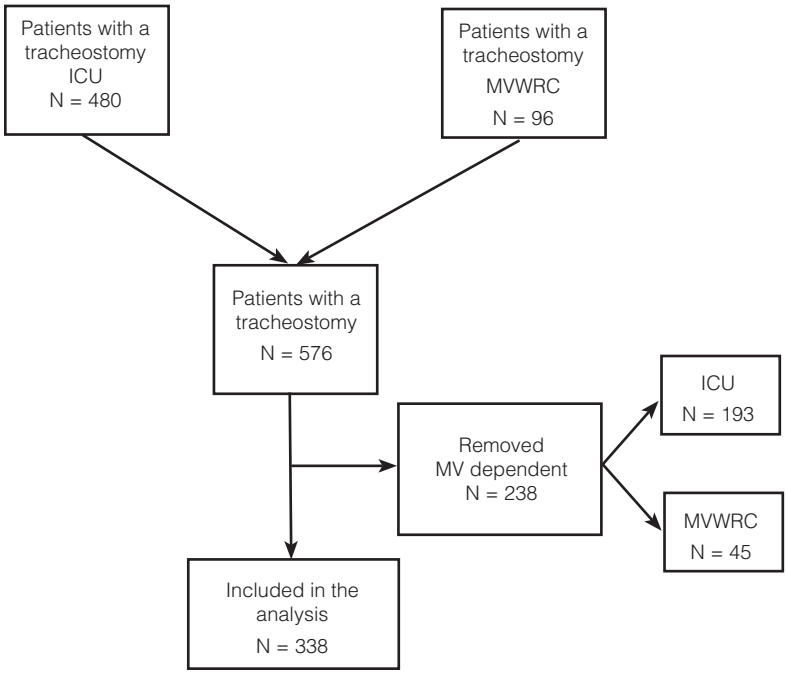

Figure 1. Screening - Flowchart of patients included in the analysis

brain injury (TBI) (36 patients, 10.7%; TBI only (32 patients, 9.5%); pneumonia (16 patients, 4.7%); septic shock (12 patients, 3.6%).

One hundred and ninety-three patients could be decannulated (57%; 95% CI 51.7-62.2). Table 1 shows a comparison between the groups of patients who achieved decannulation and those who could not be decannulated.

Cumulative incidence regarding decannulation failure was 3.1% in 7 months (95% CI 1.4 - 6.6). This percentage accounts for 6 patients out of 193 who achieved decannulation (displayed). It should be noted that out of these 6 patients who failed, 3 of them achieved decannulation in the second attempt. The other 3 could not be decannulated during the follow-up period.

In the univariate analysis among decannulated and non-decannulated patients there were statistically significant differences between age variables, patients referred from ICUs, patients referred from MVWRCs, the Charlson comorbidity score at admission, the number of days with a TQT cannula, the amount of deceased patients and the amount of patients discharged home within the different groups.

The variables that had an a priori association with the impossibility to achieve decannulation and that, in addition, had a p value below 0.1 in the univariate analysis, were included in a binary multivariate logistic regression analysis where the dependant variable was whether decannulation was achieved or not.

The multivariate analysis defined as independent predictors contraindicating decannulation the age group of patients over the age of 70, (OR 3.40; 95% CI 1.51-7.66) and tracheostomies due to surgical procedures (OR 1.74; 95% CI 1.08-2.79); on the other hand, being a patient from an ICU acted as a protective factor for decannulation difficulty (OR 0.29; 95% CI 0.15-0.56) (table 2). Calibration and discrimination of the logistic regression model were regular (Hosmer-Lemeshow 0.88; AUC 0.66).

Mortality was higher in the group of non-decannulated patients than in the group of decannulated patients ($p < 0.001$), the assessment of survival at Day 90 showed significant differences between the group of decannulated patients and those who could not be decannulated ($p < 0.05$ in the log-rank test); the Kaplan-Meier survival curve showed that among the patients who did not achieve decannulation, only 64.5% (95% CI; 56-71%) remained alive at Day 90, whereas in the group of decannulated patients 94.1% (95% CI; 89 -96%) remained alive at Day 90 (Fig. 2).

TABLE 1. Univariate comparisons between decannulated and non-decannulated.

Variable*	Decannulation result: Decannulated patients at the end of follow-up N = 193		Decannulation result: NON-decannulated patients at the end of follow-up N = 145		p
Males	119	(61)	80	(56)	0.62†
Age	56	(40-66.5)	62	(48.5-74)	< 0.001‡
Group under the age of 34	39	(20.3)	18	(12.4)	< 0.001¶
Group between the age of 35 and 54	51	(26.5)	25	(17.2)	
Group between the age of 55 and 74	83	(43.2)	67	(46.2)	
Group over the age of 75	20	(10.4)	35	(24.1)	
Patients referred from ICUs	176	(91.7)	110	(75.9)	< 0.001†
Patients referred from MVWRCs	17	(8.3)	35	(24.1)	< 0.001†
GCS at admission	10	(4.7-15)	9.5	(6-15)	0.82 ‡
Charlson Score at admission	2	(1-3)	3	(1-4)	0.03‡
Respiratory history	36	(18.6)	25	(17.2)	0.77†
Obstructive	27	(13.9)	17	(11.7)	0.72†
Restrictive	4	(2.0)	4	(2.7)	0.62†
Tuberculosis	3	(1.5)	1	(0.6)	0.63†
Cardiovascular history	91	(47.1)	69	(47.5)	> 0.99†
HTN	73	(37.8)	60	(41.3)	0.57†
Panvascular	6	(3.1)	2	(1.3)	0.47†
CHF	6	(3.1)	7	(4.8)	0.57†
Cardiovascular postoperative period	11	(5.6)	8	(5.5)	0.51†
Neurological history	32	(16.5)	29	(20.0)	0.47†
Stroke	13	(6.7)	14	(9.6)	0.41†
Medullary lesion	2	(1.0)	1	(0.6)	> 0.99†
Extrapyramidal disorder	4	(2.0)	2	(1.3)	0.70†
Neuromuscular disease	2	(1.0)	1	(0.6)	0.99†
Metabolic history	62	(32.1)	54	(37.2)	0.35†
Obesity	18	(9.3)	31	(21.3)	0.35†
Hypothyroidism	9	(4.6)	13	(8.9)	0.12†
Diabetes	24	(12.4)	16	(11.0)	0.73†
Psychiatric history	11	(5.6)	12	(8.2)	0.39†
Oncological history	16	(8.2)	14	(9.6)	0.70†
Smoker before admission	59	(30.5)	31	(21.3)	0.06†
Previous home oxygen therapy	1	(0.5)	5	(3.4)	0.08†
Reason for admission to ICU					0.34¶
Clinical	81	(24.0)	67	(19.9)	
Emergency surgery	43	(12.8)	32	(9.5)	
Programmed surgery	26	(7.7)	12	(3.6)	
Trauma	4	(1.2)	7	(2.1)	
Trauma with TBI	39	(11.6)	26	(7.7)	
TQT due to surgical procedure	105	(54.4)	94	(45.6)	0.058†
Reason for TQT					0.60¶
Premature	74	(38.3)	47	(32.4)	
Prolonged weaning	49	(25.3)	31	(21.3)	
Prolonged mechanical ventilation	37	(19.1)	27	(18.6)	
Extubation failures	22	(11.3)	11	(7.7)	
Airway obstruction	8	(4.1)	16	(11.0)	
Days at ICU	40.5	(27-70)	41	(27-64)	0.97‡
Days at MVWRC	63.5	(53.5-114.7)	90.5	(25.7-107)	> 0.99‡
Days at general ward	16	(9 - 35)	12	(5-32.7)	0.20‡
Total number of days hospitalized in follow-up care	63	(38.5 -89.5)	61	(39-114.2)	0.35‡
Duration of mechanical ventilation	25	(15-36)	23	(13-34.2)	0.66‡
Number of days with tracheostomy	29	(17-47)	43	(21.5 -77.5)	< 0.001‡
Discharge condition or condition at the end of follow-up					
Deceased	7	(3.6)	45	(31.0)	< 0.001†
Alive referred to MVWRC	20	(10.3)	31	(21.4)	0.006†
Alive referred to ICU	29	(15.0)	26	(17.9)	0.45†
Alive discharged home	109	(56.4)	17	(11.7)	< 0.001†
Alive at the end of follow-up	28	(14.5)	26	(17.9)	0.45†
Recannulation	3	(1.5)	3	(2)	> 0.99†

ICU: intensive care unit, MVWRC: mechanical ventilation weaning and rehabilitation center, GCS: Glasgow coma scale, HTN: hypertension, CHF: chronic heart failure, MVS: mechanical ventilatory support.

*Values presented as counts and percentages of the total sample unless otherwise stated.

†Fisher's exact test

‡Mann-Whitney's U test

¶X2 test

TABLE 2. Binary logistic regression.

Variable	OR	CI (95%)		p
AGE groups				0.012
Between the age of 18 and 34 (reference category)				
Between the age of 35 and 54	1.02	0.47	2.21	0.95
Between the age of 55 and 74	1.53	0.77	3.03	0.21
Over the age of 74	3.40	1.51	7.66	0.003
Smoker before admission	0.69	0.40	1.20	0.19
Chronic home oxygen therapy	4.44	0.46	42.31	0.19
Charlson Score at admission	0.92	0.79	1.08	0.33
Patients referred from ICUs	0.29	0.15	0.56	< 0.001
Type of surgical procedure	1.74	1.08	2.79	0.021

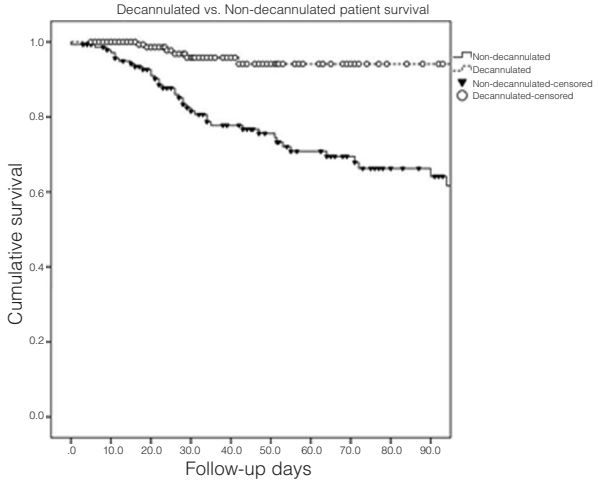

Figure 2. Kaplan-Meier survival curves between decannulated and non-decannulated patients.

Discussion

This multicenter study was the first of its kind and it was developed to attempt to clarify which factors were linked to the impossibility to decannulate patients.

A large sample of patients with TQTs was obtained, both from the private and public sector, from intensive care units and from Mechanical Ventilation Weaning and Rehabilitation Centers and, lastly, a significant participation of health centers was obtained from provinces throughout the country.

Patients who did not achieve MV weaning were removed from the sample since MV dependence disqualifies patients from undergoing the process of decannulation. In our area, it is uncommon to remove the TQT cannula in MV-dependant patients with the purpose of continuing with non-invasive ventilation methods. There were no decannulated patients who continued with non-invasive ventilation among the total of patients removed due to MV dependence (n = 238).

The total rate of decannulated patients was similar to that described in other studies where rates ranged from 31% to 44%. [20, 29-31]. Likewise, decannulated patients who were previously weaned from respiratory support reached rates similar to those described by many authors[20,31,32] However, these are among the lowest rates of successful decannulation. We think this finding stems from having a relatively short follow-up period (one year). Similarly, we should add to this the follow-up termination criterion, which defined patients who could not be decannulated 3 months after their tracheostomy as unable to undergo decannulation.

The number of days to decannulation was similar to that described in literature[20, 29, 33, 34] although it differed from Hernandez's[19] observations (median between 9 and 12 days depending on the groups under study). In our study, only patients from the ICU were included and the times established by decannulation protocols were usually more prolonged in MVWRCs than in ICUs.

Six patients required recannulation during the study, out of whom 3 attained successful decannulation and 3 could not be decannulated. This generated a 3.1% incidence rate, similar to that published by other authors[22, 23, 35, 36]. These values continue to demonstrate that once the patient meets certain criteria and is decannulated, failure rates and recannulation requirements are low.

Similar to the study by Scrigna et al.[20], the patients' age and the Charlson comorbidity score acted as predictors of decannulation difficulty. Additionally, in our study, age also acted as an inde-

pendent predictor of difficulty in the multivariate analysis. This finding, which is that populations over the age of 75 are associated with difficulties in decannulation, concurred with the observations from other studies[19, 20, 37].

Having found surgical procedures as predictors that contraindicated decannulation –as opposed to percutaneous procedures– was a finding less consistent with the current theory. The reason why these patients could not be decannulated was not documented, although in a subsequent analysis it was assessed whether groups with surgical procedures were similar in age to patients with percutaneous procedures, and no significant differences were found. Neither the type of pathology nor the reasons for admission were analyzed in these two groups, which could have created baseline differences within them.

Variables associated with the severity at the moment of admission to the ICU (APACHE example) or the progress during hospitalization (SOFA example) were not requested in the study protocol since most centers do not usually document them. Therefore, we could not assess if these types of variables are predictors that contraindicate decannulation. The Glasgow variable at ICU admission showed no significant differences when comparing patients who achieved decannulation versus those who did not.

The chances of patients referred from the ICU to not undergo decannulation were 29% lower than those referred from a MVWRC, that is to say, patients at an ICU were more likely to be decannulated than patients at a MVWRC. This could be explained by the fact that patients referred to this type of institution are precisely referred to be weaned from MV, decannulated or rehabilitated, as the main objectives. In conclusion, they are referred to improve their clinical condition and usually they have undergone several decannulation attempts, which could not be achieved for various reasons. Therefore, these patients are placed in a difficult decannulation category, even more difficult than those at an ICU.

There were no differences between the reasons for admission in patients who attained decannulation and those who did not. However, reasons for admission were only analyzed broadly, and they were defined as clinical, surgery, emergency surgery and trauma (with or without TBI). Admissions were not analyzed by pathology, for instance, in patients with exacerbated COPD as the medical reason, which was a predictor contraindicating decannulation in other studies[20].

When patient outcomes were analyzed comparing the decannulated group and the non-decannulated group, it was found that the first had a lower mortality rate and, conversely, a higher rate of discharges home than the non-decannulated group. A potential explanation to this finding could be that the state of the patients in the non-decannulated group was more severe and for this reason they could not be decannulated, which could have led to increased mortality rates. Hernández[35] reported a higher mortality rate in patients who left the ICU with a TQT compared to those who achieved decannulation in closed areas. In our country it is not common for tracheostomized patients to be discharged home. Even if they are in good clinical condition, they usually stay hospitalized until decannulation or another outcome has been achieved[20].

Among the limitations of this study, we can include the type of sampling selected, since a non-probability consecutive sampling was used. However, in spite of using this type of sampling, we avoided screening biases using broad inclusion criteria to include every tracheostomized patient who had the chance of being decannulated at some point. In addition, a special emphasis was placed on centers reporting negative events, such as decannulation failures, to avoid potential information biases. There was a second limitation related to the number of events of the outcome variable (no decannulation), which was lower than what is recommended for the amount of variables introduced in the model; this could have reduced the power of the study to detect the possibility of committing a type-II error, that is, taking the absence of differences as true when there would actually be differences but the study did not have enough power to detect them.

Conclusion

This multicenter study evidences that the number of decannulated patients is higher than what is described in the bibliography and is similar when it comes to recannulation. The importance of achieving decannulation should be left clear since these patients have a higher rate of home discharges. However, it is not possible to confirm

that decannulation is a key factor for discharges or if it is part of a better general condition of the patient. Age was a predictor contraindicating decannulation, which is potentially connected with a worse general condition of the patient. There were no comorbidities linked to contraindications for decannulation. Although TQTs performed due to surgical procedures were predictors of lower decannulation rates, we cannot confirm there is has a direct connection.

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Acknowledgments_ Gabinete de apoyo a la producción de información hospitalaria (GAPIH) from Hospital Nacional Prof. Alejandro Posadas.

Conflict of interest: The authors declare that there is no conflict of interest associated with this publication.

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ATTACHMENT 1. Study variables

For all the patients enrolled in the study

Variable	Scale	Procedure	Values
Date of tracheostomy (TQT)	Continuous	Document the date in which the patient was tracheostomized	Date
Age	Continuous	Document data in medical record	Age in years
Gender	Nominal (dichotomous)	Patient's identification	Male or female
History prior admission to the intensive care unit (ICU)	Nominal (dichotomous)	Document all data required by the operations manual	Yes or no
ICU admission category	Nominal	Select one of the categories provided in the operations manual	clinical, emergency surgery, programmed surgery, trauma, trauma + traumatic brain injury
Diagnosis/Reason for admission to ICU	Nominal	Document the reason why the investigator thinks the patient was admitted to the ICU	Open variable
Charlson Score at ICU admission	Continuous	Calculate and document Charlson Score according to previous history and current diagnosis	Score values range from 0 to 39.
Glasgow Coma Scale (GCS) at admission	Ordinal	Calculate and document GCS	Scale values range from 3 to 15
Mechanical ventilation (MV) weaning success	Nominal (dichotomous)	Document if patient could be weaned (over 120 hours without support)	Yes or no
Amount of days with MV	Continuous	Count the number of days the patient was with MV once he/she is weaned	Discreet number of days
Type of TQT	Nominal	Document the type of procedure based on the surgical chart or the medical record	surgical or percutaneous
Reason for TQT	Nominal	Document according to the categories provided in the operations manual	suspected prolonged weaning; prolonged weaning; prolonged mechanical ventilation; extubation failures, emergency TQT
Successful decannulation	Nominal (dichotomous)	Document if patient could be decannulated	Yes or no
Number of days with TQT	Continuous	Count and document the number of days with TQT	Discreet number of days
Recannulation	Nominal (dichotomous)	Document if the patient required recannulation at the ICU	Yes or no
Days to recannulation	Continuous	Count and document the number of days to recannulation in patients who failed	Discreet number of days
Reason for recannulation	Nominal	Document according to the categories provided in the operations manual	poor secretion management, respiratory failure, upper airway obstruction
Reason decannulation is contraindicated	Nominal	Define and document the reason why the investigator thinks the patient could not be decannulated at the end of the follow-up period	Open variable
Number of days hospitalized	Continuous	Count and document the number of days the patient was hospitalized in follow-up care	Discreet number of days
Discharge condition	Nominal	Document according to the categories provided in the operations manual	Deceased; alive to MVWRC; alive to another hospital/clinic; alive to his/her home.

Continuation Annex 1

Variables only measured in patients referred from Mechanical Ventilation Weaning and Rehabilitation Centers (MVWRC)

Variable	Scale	Procedure	Values
Required respiratory support at MVWRC admission	Nominal (dichotomous)	Document if patient is admitted with ventilation support	Yes or no
Type of support at MVWRC admission	Nominal (dichotomous)	Document the type of ventilation support the patient is admitted with	Invasive MV or non-invasive MV
Type of TQT cannula at admission	Nominal	Document the type of cannula according to the categories provided in the operations manual	Type of cannula according to the operations manual
MV weaning success	Nominal (dichotomous)	Document if patient could be weaned (over 120 hours without support) from invasive or non-invasive mechanical ventilation	Yes or no.
Required new MV cycles	Nominal (dichotomous)	Document if a previously weaned patient had to be reconnected for over 48 hours	Yes or no
Successful decannulation	Nominal (dichotomous)	Document if patient could be decannulated at the MVWRC	Yes or no
Number of days with TQT	Continuous	Count and document the number of days with TQT	Discreet number of days
Required recannulation	Nominal (dichotomous)	Document if the patient required recannulation at the MVWRC	Yes or no
Days to recannulation	Continuous		
Reason for recannulation	Nominal	Document according to the categories provided in the operations manual	poor secretion management, respiratory failure, upper airway obstruction
Reason decannulation is contraindicated	Nominal	Define and document the reason why the investigator thinks the patient could not be decannulated at the end of the follow-up period	Open variable
Number of days hospitalized.	Continuous	Count and document the number of days the patient was hospitalized in follow-up care	Discreet number of days
MVWRC discharge condition	Nominal	Document according to the categories provided in the operations manual	Deceased; alive to MVWRC; alive to another hospital/clinic; alive to his/her home.

ANEXO 2. Center distribution