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Timing and predictors of tracheostomy decannulation in COVID-19 and non-COVID-19 ARDS: A real-world study

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ABSTRACT

Background: Tracheostomy is a commonly performed procedure in patients requiring prolonged mechanical ventilation (MV) in Intensive Care Units (ICUs), including COVID-19-related ARDS. However, limited data exist on the timing and predictors of decannulation.

Aim: To compare time to decannulation between COVID-19 and non-COVID-19 ARDS patients and to identify predictive factors.

Methods: A retrospective study including 96 COVID-19 ARDS and 32 non-COVID-19 ARDS tracheostomized patients admitted to step-down units after ICU stay from March 2020 to May 2021. Clinical, demographic data and comorbidities were analysed as well as predictors for decannulation delay.

Results: Timing of decannulation was similar between the two groups. Multivariate analysis identified limb weakness assessed by the Medical Research Council (MRC) scale, duration of steroids therapy, clinical complications, PaO_2/FiO_2 ratio and smoking history as independent predictors of decannulation timing.

Conclusions: COVID-19 did not affect timing of decannulation compared to non-COVID-19 ARDS. ICU-acquired weakness, assessed through the MRC scale, was the strongest predictor of delayed decannulation.

Key words: ARDS, COVID-19, tracheostomy decannulation, Stepdown Unit, Intensive Care Unit

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Consent for publication: Informed consent was obtained from all subjects involved in this study .

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Introduction

Invasive mechanical ventilation (IMV) is indicated for the treatment of acute respiratory failure (ARF) when noninvasive respiratory support, such as high flow oxygen therapy (HFOT) or noninvasive ventilation (NIMV), is contraindicated or fails, particularly for *de novo* respiratory failure [1]. Approximately 23.4% of patients admitted to the Intensive Care Unit (ICU) require IMV, with 10.4% of them being affected by acute respiratory distress syndrome (ARDS) [2]. Tracheostomy may be performed in cases of prolonged weaning from IMV, which occurs in about 10% of patients [3], and is among the most commonly performed procedures in ICUs [4]. Approximately 13% of patients with ARDS undergo tracheostomy after an average of 14 days on IMV [5]. Since February 2020, the landscape has changed dramatically due to the Coronavirus-19 (COVID-19) pneumonia [6] outbreak, which has led to an increase in ARDS cases. During the COVID-19 pandemic, tracheostomy became widely used to facilitate early discharges from ICUs to step-down units or other care settings, given the high demand for ICU beds. However, no standardized protocols for the decannulation process were available before the COVID-19 pandemic [7]. The existing decision-making algorithms are derived from retrospective studies or surveys [8] and pertain to heterogeneous populations [9]. Given this context, the present study aimed to compare the timing of decannulation between patients with COVID-19-related ARDS and those with non-COVID-19 ARDS, with a secondary objective of identifying potential predictive factors influencing the decannulation process.

Methods

Study design

We conducted a retrospective analysis of 329 medical records from patients admitted to five different Stepdown Units (SUs) in Italy following an ICU stay. This study was approved by the Ethics Committee of the participating institutions (2440 CE). The study included adult subjects (age >18 years old) with ARDS, as defined by the Berlin definition [10], who underwent tracheostomy for prolonged weaning from IMV. Exclusion criteria included tracheostomy for causes other than ARDS (e.g., neuromuscular or neurological disease, COPD exacerbation, trauma, surgery), pregnancy, pre-existing tracheostomy, or home ventilation before admission.

Patient selection

Our study population included patients with COVID-19 ARDS and an historical group of patients who underwent tracheostomy for non-COVID-19 ARDS (NC-ARDS) from January 2018 to December 2019. Patients were matched based on age, sex, the ratio between the partial pressure of oxygen and the fraction of inspired oxygen (PaO_2/FiO_2) at admission and pneumonia as the primary cause of ARDS, in a 1:1 ratio to ensure homogeneity in lung injury severity and etiology across groups. COVID-19 ARDS group was further divided into two groups according to the hospitalization period: during the first outbreak (C-I-ARDS) from March to June 2020 and during the second outbreak (C-II-ARDS) between October 2020 and May 2021.

Data collection and outcome measure

Demographic and anthropometric data were collected at SUs admission. Comorbidities were assessed using the Cumulative Illness Rating Scale (CIRS) [11]; the Simplified Acute Physiology Score (SAPS II) and the Sequential Organ Failure Assessment score (SOFA) were used to define the severity of the disease [12-13]. The ratio between the partial pressure of oxygen and the fraction of inspired oxygen (PaO_2/FiO_2) was utilized to assess the severity of respiratory failure, irrespective of the initial respiratory support employed (IMV, HFOT, standard oxygen therapy (SOT)). Furthermore, data regarding limb weakness were evaluated using a simplified Medical Research Council scale (MRC) [14]. Dysphagia was identified based on speech therapist assessment and/or a modified blue dye test. Clinically relevant delirium needing pharmacological treatment and neuropathy, diagnosed with peripheral electromyography, were also documented.

The following data about tracheostomy management were also collected: time to tracheostomy (defined as the number of days from intubation to tracheostomy), total duration of tracheostomy (number of days from placement to removal), time to decannulation (expressed as the number of days from admission to SUs until decannulation), respiratory supports used for managing tracheostomized patients (IMV, HFOT, SOT), availability of Physiotherapy (PT) (defined as at least 20 minutes per patient, four days per week), and tracheostomy complications (granuloma, stenosis, bleeding, paralysis of the vocal cords or tracheomalacia). Hospitalization data were also collected: ICU length of stay, total days of IMV (from intubation to definitive disconnection from IMV), total days of IMV in SUs (total days from admission to SUs until weaning from IMV), duration of corticosteroid therapy (total days from ICUs to SUs), administration of sedative drugs in the SUs (expressed in days) and clinical complications (defined as at least one event that prolonged the clinical course: respiratory infection, pneumothorax, pulmonary embolism, acute coronary syndrome, arrhythmia, sepsis or urinary infection, abdominal complications, major bleeding or stroke). Lastly, we reported the failure rate of decannulation (the inability to remove the tracheostomy tube during the SUs stay), the in-hospital mortality rate, and the total hospital length of stay (THLS), encompassing the combined ICU and SUs stay.

Statistical analysis

Values are expressed as median and interquartile ranges (IQR) or absolute numbers and percentages (%). The normality of data distribution was assessed using the Shapiro–Wilk test. Differences between categorical variables were analyzed using the χ^2 test. The Kruskal-Wallis one-way ANOVA test was used to analyze the between-group variance. Multivariate linear regression analysis evaluated potential independent predictors of on-ward decannulation time. The multilinear model included the following independent variables: sex, age, BMI, smoking status, presence of respiratory diseases or clinical complications, CIRS, PaO_2/FiO_2 ratio, delirium onset, days of steroid therapy and/or intravenous sedation. β coefficients and their corresponding significance values obtained from the models are reported. A significance level of $p < 0.05$ was considered statistically significant. Statistical analyses were performed using SPSS version 23.0 (Somers, NY, USA).

Results

A total of 96 tracheostomized patients with C-ARDS discharged from the ICU and transferred to the SUs were included: 45 patients in the C-I-ARDS group and 51 patients in the C-II-ARDS. These patients were compared with a historical group of 32 patients with NC-COVID ARDS (Figure 1). Table 1 shows the demographic and clinical characteristics upon admission to the SUs. There was no difference in gender distribution or BMI among the three groups, although patients in the C-I-ARDS group were significantly younger. Patients in the NC-ARDS group had a higher prevalence of smoking and COPD, along with a significantly higher prevalence of heart disease, corresponding to a significantly higher comorbidity index (CIRS). SOFA scores were similar across groups, whereas SAPS II scores were lower in the C-I-ARDS group. The prevalence of neuropathy was higher in the C-ARDS overall and significantly higher in the C-I-ARDS, while the MRC score was significantly lower in C-II-ARDS compared with C-I-ARDS. Approximately 80% of C-ARDS patients and over 50% of NC-ARDS patients were transferred to neurorehabilitation units. Dysphagia was significantly lower in the C-I-ARDS, while delirium was more frequent in C-ARDS, with a significantly higher prevalence in the C-II-ARDS subgroup. However, its incidence might have been underestimated, as it was defined only on a clinical basis.

As shown in Table 2, the decannulation time was similar among the three groups, while the failure rate was higher in NC-ARDS. None of the patients required recannulation after tracheostomy tube removal. Standard oxygen therapy (SOT) was more frequently used in the NC-ARDS and C-I-ARDS groups, whereas high-flow oxygen therapy (HFOT) was significantly more common in the C-II-ARDS group. The duration of IMV and total days of

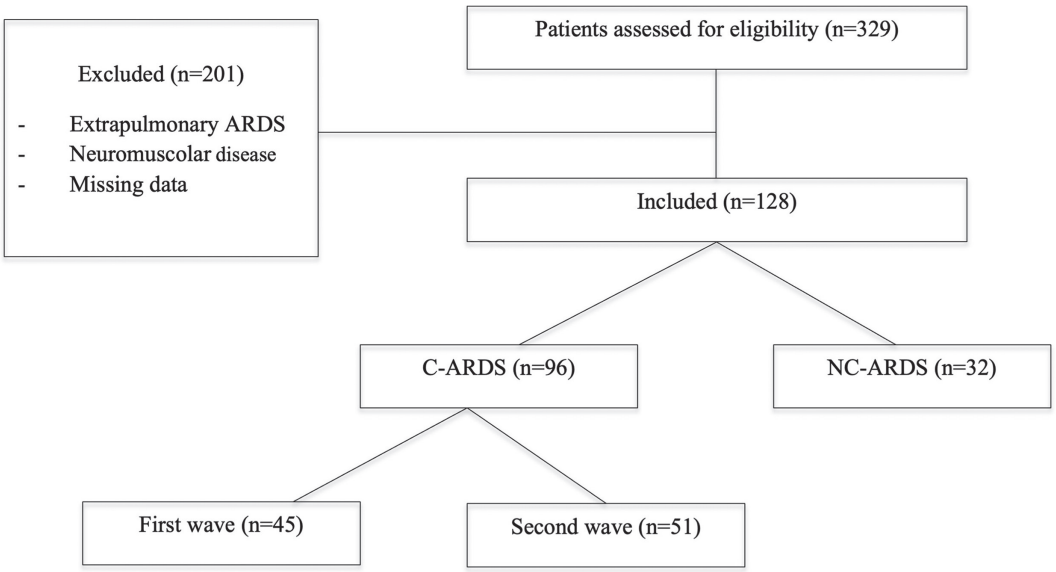

Figure 1. Population in study.
ARDS, acute respiratory distress syndrome; COVID-19, Coronavirus Disease 19; C-ARDS, patients tracheostomized for COVID-19 ARDS, NC-ARDS, patients tracheostomized for non-COVID-19 ARDS.

tracheostomy were higher in C-II-ARDS compared with C-I-ARDS, whereas no significant difference was observed when compared with NC-ARDS. At the SUs admission, about half of the patients in all groups were still dependent on IMV. However, all patients were successfully weaned from IMV, with no significant difference in weaning duration among the groups. The C-II-ARDS patients had a more extended ICU stay and longer THLS, whereas the time to tracheostomy was similar among the three groups. The length of sedative treatment for delirium management was similar in the three groups. A high percentage of patients underwent PT in all populations, without difference among the three groups. There were no differences in the prevalence of clinical complications nor the prevalence of tracheostomy complications among the three groups. In-hospital mortality was significantly higher in NC-ARDS. Table 3 presents the multivariate linear regression analysis for the entire cohort identifying the association between time to decannulation and key clinical variables, showing a strong correlation with the PaO_2/FiO_2 ratio, peripheral muscle weakness at admission to the SUs, smoking history, clinical complications and duration of steroid therapy.

Discussion

In this study, we found no significant difference in the time to decannulation between tracheostomized patients with NC-ARDS and C-ARDS after ICU discharge. Early concerns that aerosol-related risks might delay decannulation, particularly in COVID-19 patients [15] were not supported by our findings. On the contrary, the availability of clinical experience likely led to a pragmatic, expedited approach to decannulation in COVID-19 patients, even in the absence of standardized protocols [16]. Although time to decannulation was similar across groups, the NC-ARDS cohort showed a significantly higher decannulation failure. This difference is likely due to older age, a greater number of comorbidities, as reflected by higher CIRS scores, and greater prevalence of COPD and smoking. These factors may have contributed to a more complex and prolonged recovery trajectory. On the contrary, all decannulated patients maintained airway stability and none required re-cannulation. Of note, the relatively low mortality rate likely reflects the characteristics of the patients transferred to SUs after ICU discharge, excluding those with the most severe or fatal course of ARDS.

Table 1. Demographics, anthropometric and clinical characteristics of patients.

Variables	NC-ARDS (n=32)	C-I-ARDS (n=45)	C-II-ARDS (n=51)	NC-ARDS vs C-I-ARDS (p-value)	NC-ARDS vs C-II-ARDS (p-value)	C-I-ARDS vs C-II-ARDS (p-value)
Age (y)	69.5 (60-77)	61 (55-66)	70 (63-72)	<**0.01**	0.42	<**0.01**
Male (%)	22 (68.8%)	38 (84.4%)	39 (76.5%)	0.10	0.44	0.33
BMI	26 (23-28)	28 (24-33)	28 (23-31)	0.08	0.09	0.78
Smoke (%)	18 (56.3%)	11 (24.4%)	22 (43.1%)	<**0.01**	0.24	0.06
Heart disease (%)	15 (46.9%)	10 (22.2%)	15 (29.4%)	**0.02**	0.11	0.42
Arterial Hypertension (%)	21 (65.6%)	22 (48.9%)	40 (78.4%)	0.15	0.20	<**0.01**
COPD (%)	13 (40.6%)	2 (4.4%)	6 (11.8%)	<**0.01**	**0.02**	0.19
OSAS (%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	-	0.43	0.35
Renal failure (%)	5 (15.6%)	3 (6.7%)	4 (7.8%)	0.20	0.27	0.82
Diabetes Mellitus (%)	14 (43.8%)	7 (15.6%)	16 (31.4%)	<**0.01**	0.25	0.07
CIRS	7 (3.5-8.5)	3 (0-5)	4 (2-6)	<**0.01**	**0.02**	0.06
SAPS II	32 (24-39)	24 (20-30)	32.5 (25-40.5)	**0.01**	0.49	<**0.01**
SOFA	3 (2-5)	3 (2-4)	2.5 (2-4)	0.54	0.12	0.31
PaO2/FiO2	240.5 (191-281)	246 (166-246)	233.5 (190-280)	0.58	0.23	0.68
MRC score	2 (1-3)	3 (2-4)	2 (2-3)	0.16	0.63	**0.03**
Neuropathy (%)*	17 (58.6%)	16 (94.1%)	33 (76.7%)	<**0.01**	0.10	0.12
Dysphagia (%)	13 (40.6%)	8 (17.8%)	22 (43.1%)	**0.02**	0.82	<**0.01**
Delirium (%)	8 (25.0%)	15 (33.3%)	26 (51.0%)	0.43	**0.01**	<**0.01**

**Data available for 29 patients of NC-ARDS group, 17 patients of C-I-ARDS and 43 patients of C-II-ARDS group.*

BMI, body mass index; COPD, chronic obstructive respiratory disease; OSAS, obstructive sleep apnoea syndrome; CIRS, Cumulative Illness Rating Scale; SAPS II, Simplified Acute Physiology Score; SOFA, Sequential Organ Failure Assessment score; MRC score, Medical Research Council score; C-I-ARDS, patients tracheostomized for COVID-19 ARDS in first outbreak; C-II-ARDS, patients tracheostomized for COVID-19 ARDS in second outbreak; NC-ARDS, patients tracheostomized for non-COVID-19 ARDS; ns = not significant. Data are shown as median and interquartile ranges (IQR) or absolute numbers and percentages (%). $p < 0.05$ was considered statistically significant.

Importantly, we identified several independent predictors of delayed decannulation, with the MRC score emerging as the most consistent and strongest factor. The MRC scale is a simple and inexpensive bedside tool, although limited by inter-operator variability and moderate reproducibility. Previous studies have associated higher MRC scores with better readiness for spontaneous breathing, better cough effectiveness, and earlier decannulation [17-19]. Our data reinforce the role of MRC score specifically in predicting decannulation timing in both COVID-19 and non-COVID-19 ARDS patients. These findings support early, routine assessment of limb muscle strength to identify patients at risk of delayed decannulation and enable timely rehabilitation. Given its simplicity, the MRC scale could be feasibly implemented in step-down units as part of decannulation protocols.

Other variables associated with delayed decannulation included prolonged steroid therapy, clinical complications, lower PaO_2/FiO_2 ratio at SU admission, and smoking history. These findings are in line with existing literature but reinforce the complex interplay

Table 2. Tracheostomy management and hospitalization.

	NC-ARDS (n=32)	C-I-ARDS (n=45)	C-II-ARDS (n=51)	NC-ARDS vs C-I-ARDS (p-value)	NC-ARDS vs C-II-ARDS (p-value)	C-I-ARDS vs C-II-ARDS (p-value)
Hospitalization						
Time to decannulation (days)	14 (9-22)	13 (8-17.5)	13 (8.5-21)	0.38	0.69	0.61
Time to tracheostomy (days)	12.5 (10-14)	14 (9-19)	14 (10-18.5)	0.60	0.16	0.54
Total days of tracheostomy (ICU+SU)	28.5 (22-41)	27 (20-37)	41 (26-62)	0.59	0.09	**0.01**
Patients on IMV in SU (%)	21 (65.6%)	22 (48.9%)	25 (49.0%)	0.15	0.14	0.98
Patients weaned from IMV in SU (%)	21 (65.6%)	22 (48.9%)	25(49.0%)	0.15	0.14	0.98
Total days of IMV (ICU+SU)	35 (18-48)	28 (23-40)	43 (27-57)	0.41	0.29	<**0.01**
Total days of IMV in SU	3 (3-11)	0 (0-7)	0 (0-7)	0.06	0.06	1.00
THLS (days)	74.5 (58.7-98.2)	68 (51-85)	96 (71.5-114)	0.09	**0.01**	<**0.01**
ICU length of stay (days)	25.5 (17.5-39.5)	30 (18-41)	39 (30-56.5)	0.67	<**0.01**	<**0.01**
Respiratory support and therapies of interest						
Standard Oxygen Therapy (%)	23 (71.9%)	24 (53.3%)	17 (33.3%)	0.10	**0.01**	**0.04**
High-Flow Oxygen Therapy (%)	9 (28.1%)	21 (46.7%)	34 (66.7%)	0.10	**0.01**	**0.04**
Physiotherapy (%)	29 (90.6%)	39 (86.6%)	49 (96.1%)	0.59	0.31	0.10
Total days of steroid therapy (ICU+SU)	16 (3-30)	10 (2-24)	28 (17-40)	0.45	**0.01**	<**0.01**
Days of sedative therapy (SU)	0 (0-5)	0 (0-4)	0 (0-8)	0.93	0.27	0.27
Outcomes						
Clinical complications (%)	23 (71.9%)	27 (60.0%)	37 (72.5%)	0.28	0.95	0.19
Tracheostomy complications (%)	9 (28.1%)	7 (15.6%)	13 (25.5%)	0.18	0.79	0.23
Failure of decannulation at discharge (%)	12 (37.5%)	1 (2.2%)	4 (7.8%)	<**0.01**	<**0.01**	0.22
At discharge – Rehabilitation (%)*	17 (56.7%)	33 (84.6%)	37 (78.7%)	**0.01**	**0.03**	0.48
New admission in pulmonary wards (%)*	5 (16.7%)	0 (0.0%)	2 (4.3%)	<**0.02**	0.07	0.17
Mortality (%)*	4 (13.3%)	0 (0.0%)	1 (2.1%)	**0.01**	**0.05**	0.90
Home (%)*	3 (10.0%)	6 (15.4%)	7 (14.9%)	0.51	0.71	0.73

**Data available for 30 patients of NC-ARDS group, 39 patients of C-I-ARDS and 47 patients of C-II-ARDS group.*

ICU, intensive care unit; SU, stepdown unit; IMV, invasive mechanical ventilation; THLS, total hospital length of stay; C-I-ARDS, patients tracheostomized for COVID-19 ARDS in first outbreak; C-II-ARDS, patients tracheostomized for COVID-19 ARDS in second outbreak; NC-ARDS, patients tracheostomized for non-COVID-19 ARDS; ns = not significant. Data are shown as median and interquartile ranges (IQR) or absolute numbers and percentages (%). $p < 0.05$ was considered statistically significant.

among respiratory function, systemic inflammation, and functional recovery in patients with ARDS. Of note, although the role of steroids in ARDS remains debated [20,21], their use in COVID-19 ARDS is associated with improved survival [22,23] due to anti-inflammatory, antifibrotic and immunomodulatory effects [24]; however, prolonged steroid exposure has been linked to functional side effects [25-27]. In our

Table 3. Predictive factors influencing the decannulation time.

	All patients		COVID-19	
Variables	**Beta**	**p-value**	**Beta**	**p-value**
Age (years)	0.000	0.998	-0.014	0.887
Sex (M=0, F=1)	0.041	0.626	-0.068	0.476
BMI (kg/m^2)	0.157	0.085	0.148	0.153
ARDS aetiology	-0.134	0.128		
Smoke	**0.176**	**0.043**	**0.213**	**0.023**
Respiratory diseases	-0.136	0.111	-0.091	0.343
CIRS	0.006	0.944	-0.058	0.568
PaO2/FiO2 at admission to SUs	**-0.251**	**0.007**	**-0.224**	**0.029**
Duration of IMV (days)	-0.044	0.69	-0.004	0.69
MRC score at admission in SUs	**-0.326**	**<0.0001**	**-0.376**	**<0.0001**
Clinical complications	**0.275**	**0.004**	**0.246**	**0.023**
Tracheostomy complications	0.127	0.144	0.136	0.155
Delirium	0.132	0.222	0.179	0.130
Duration of steroid therapy (days)	**0.285**	**0.001**	**0.242**	**0.012**
Duration of sedative therapy (days)	0.117	0.259	0.065	0.566

BMI, body mass index; ARDS, acute respiratory distress syndrome; CIRS, Cumulative Illness Rating Scale; IMV, invasive mechanical ventilation; MRC score, Medical Research Council score, ns = not significant.

cohort, extended steroid use may have been associated with slower recovery of respiratory muscle function and a higher frequency of infections or delirium [28,29], potentially delaying recovery and contributing to longer decannulation times. Clinical complications during hospitalization, such as infections and sepsis, were also associated with prolonged decannulation, aligning with previous studies [30], underscoring the importance of vigilant prevention and prompt management of complications in post-ICU care.

While the predictive value of PaO_2/FiO_2 is debated [31], oxygenation remains a key clinical parameter in assessing readiness for weaning and decannulation [32]. The observed relationship between impaired oxygenation and delayed decannulation could reflect the impact of chronic airway inflammation, impaired gas exchange and reduced mucociliary clearance on respiratory recovery [33]. This association was evident even in patients without COPD, emphasizing the need for early smoking history documentation in tracheostomized patients. Interestingly, the etiology of ARDS (COVID *vs* non-COVID) did not influence decannulation timing, suggesting that COVID-related ARDS shares several pathophysiological features with classical ARDS in the post-ICU phase, including diffuse alveolar damage, microvascular thrombosis, and long-term pulmonary sequelae [34-36] and should be managed with similar ventilatory and rehabilitation strategies.

Finally, we observed a high prevalence of dysphagia, particularly in NC-ARDS and C-II-ARDS patients, potentially linked to older age and frailty. Although it did not independently affect decannulation timing, dysphagia remains clinically relevant in post-ICU rehabilitation. Recent studies support incorporating swallowing assessment into broader recovery planning, even if not as a strict criterion for decannulation [37].

Our study presents several limitations. First, its retrospective design may introduce selection and information bias, despite the multicenter approach. Second, due to the biological risk during the pandemic, dysphagia evaluation was often limited to bedside assessments, primarily using the modified blue dye test or a speech therapy approach. Despite their simplicity, these methods have shown good sensitivity and various advantages including cost-effectiveness and feasibility in clinical practice [38,39]. More objective tools, such as fiberoptic endoscopic evaluation of swallowing

(FEES) or videofluoroscopy, were not consistently available. Similarly, although ICU-acquired weakness was assessed using the MRC scale, without direct measurements of cough strength or diaphragmatic function—factors known to influence decannulation readiness. Moreover, the definition of delirium was extrapolated from medical records indicating pharmacological treatment, without the use of standardized screening tools, thus the incidence of delirium in the study population may be underestimated. Regarding steroid treatment, we only considered the duration of therapy, without accounting for dosage, administration route, or specific agents, which may also affect neuromuscular outcomes.

We did not evaluate other therapies used in C-ARDS, such as Interleukin-6 (IL-6) receptor antagonists, immunomodulators, anti-viral medications, or monoclonal antibodies; these therapies could influence our patients' outcomes. Finally, we lacked detailed data on the type, timing, and intensity of rehabilitation interventions across centers and did not collect follow-up information after discharge. However, the multicenter nature of the study enhances the external validity of the findings, as it reflects varied clinical practices across different institutions and regions, offering a unique perspective on real-world practices and provides actionable insights for clinicians managing post-ICU patients in step-down or rehab units.

Clinical implications

Our findings suggest that routine assessment of muscle strength using the MRC scale should be integrated into decannulation protocols, particularly in step-down or rehabilitation settings. Patients with low MRC scores may benefit from early, intensive physiotherapy or referral to specialized weaning units. The results also support a standardized, multidisciplinary approach to tracheostomy care that includes respiratory therapists, physiatrists, and speech therapists to address the multiple factors that influence decannulation readiness. Finally, decannulation protocols may be applied similarly to both COVID-19 and non-COVID-19 ARDS patients. Early recognition of ICU-acquired weakness using simple bedside tools like the MRC scale may help anticipate the need for prolonged tracheostomy and rehabilitation support. Future prospective studies with longer follow-up are needed to validate these predictors and explore additional tools to guide safe and timely decannulation.

Conclusions

Time to decannulation after tracheostomy did not differ between COVID-19 and non-COVID-19 ARDS patients. However, decannulation failure was more frequent in non-COVID patients, likely due to older age and greater comorbidities. ICU-acquired weakness measured by the MRC score emerged as the strongest predictor of delayed decannulation, highlighting the importance of assessing ICU-acquired weakness early in the recovery process. Other predictors included prolonged steroid use, clinical complications, impaired oxygenation, and smoking history. These findings provide insights into the integration of functional assessments, such as the MRC scale, into routine decannulation protocols.

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