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HEAD AND NECK

Tracheostomy in patients with COVID-19: predictors and clinical features

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Abstract

Background Around 20% of patients hospitalized for COVID-19 need mechanical ventilation (MV). MV may be prolonged, thus warranting tracheostomy.

Methods Observational cohort study enrolling patients admitted due to COVID-19. Demographic and clinical data at hospital and ICU admission were collected. The primary endpoint was to identify parameters associated with a need for tracheostomy; secondary endpoints were to analyze the clinical course of patients who needed tracheostomy.

Results 118 patients were enrolled; 37 patients (31.5%) were transferred to ICU, of which 11 (29.72%) needed a tracheostomy due to prolonged MV. Sequential Organ Failure Assessment (SOFA) score at ICU admission (OR 0.65, 95% CI 0.47–0.92, p 0.015) was the only variable found to be associated with increased risk of the need for tracheostomy, with a cut-off point of 4.5 (sensitivity 0.72, specificity 0.73, positive predictive value 0.57 and negative predictive value 0.85). The main complications were nosocomial infection (100%), supraventricular cardiac arrhythmia (45.5%), agitation (54.5%), pulmonary thromboembolism (9.1%) and depression (9.1%). All patients presented with hypoalbuminemia and significant critical illness polyneuropathy.

Conclusion SOFA at ICU admission is associated with an increased risk of tracheostomy in patients with COVID-19. Moreover, they present clinical features similar to those with chronic critical illness and suffer SARS-CoV-2-related complications.

Keywords COVID-19 · Tracheostomy · Prolonged mechanical ventilation · Respiratory failure

Abbreviations

95% CI	95% Confidence interval
ADRS	Acute respiratory distress syndrome
AUC	Area under curve
CCI	Chronic critical illness
CIPM	Critical illness polyneuropathy and myopathy
COVID-19	Coronavirus disease 2019
Covid19-CXRScore	Covid-19 chest X-ray severity score
ER	Emergency department
ICU	Intensive care unit
IQR	Interquartile ranges
MRC	Medical research council
MV	Mechanical ventilation
OR	Odds ratio
PMV	Prolonged mechanical ventilation
RCU	Respiratory care unit
ROC	Receiver operating characteristics
RW	Respiratory ward
SARS-CoV-2	Severe acute respiratory syndrome coronavirus-2
SOFA	Sequential organ failure assessment

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Introduction

On March 11 2020, coronavirus disease 2019 (COVID-19), caused by novel coronavirus SARS-CoV-2, was declared a global health emergency and pandemic by the World Health Organization [1]. The clinical spectrum of COVID-19 appears broad and can present as asymptomatic infection,

mild upper respiratory tract illness or severe bilateral pneumonia 1 or 2 weeks after primary infection, which may progress to acute respiratory distress syndrome (ARDS) [2]. Under these circumstances, around 20% of hospitalized patients may need respiratory support and admittance to an intensive care unit (ICU) [2].

Published data on the need for invasive mechanical ventilation (MV) in COVID-19 indicate that it is required in 3–17% of hospitalized patients [2–4]. Time from disease onset to MV has been established at 14.5 days [4]. Duration of MV is prolonged in some cases, sometimes exceeding 20 days [5]. Tracheostomy is recommended in patients with prolonged mechanical ventilation (PMV) [6] as it facilitates weaning from ventilation and potentially increases ICU bed availability if these patients are transferred to specialized areas such as Respiratory Care Units (RCU). Turri-Manzone et al. recently reported that around 32% of patients with COVID-19-related MV underwent elective tracheostomy due to PMV [5]. PMV is one of the principal factors determining the transition from acute critical process to chronic critical illness (CCI). A CCI patient is defined as having survived acute illness or injury but not yet recovered to the point of liberation from life-sustaining therapies [7].

The aim of our study is to identify which factors may predict the need for tracheostomy in patients with PMV due to COVID-19 and describe their clinical course and prognosis.

Methods

Type of study

Observational cohort study with patients admitted to both the Respiratory Medicine Department and ICU of a tertiary university hospital with a diagnosis of SARS-CoV-2.

Population

All patients admitted to our hospital for COVID-19 from February 27 to May 20 were included in a general registry. COVID-19 diagnosis was made according to WHO interim guidance [8] by real-time reverse-transcription polymerase chain reaction assay for nasal and pharyngeal swab specimens. Exclusion criteria were age under 18 years and refusal to participate in the study. All patients were managed according to the protocol set by Spanish health authorities (Ministerio de Sanidad, Consumo y Bienestar Social) [9]. Treatment of any disease produced by SARS-CoV-2, related complications and criteria for ICU admission followed the same guidelines [9]. ARDS was diagnosed according to the Berlin definition [10].

Ethical issues

This study was approved by the Ethics Research Committee of our institution (HCUV-INCLIVA, project 2020/115). Written informed consent and use of de-identified retrospective data were waived owing to the severity of the situation. However, verbal authorization from the patient or caregiver was required.

Data collection

Clinical, demographic and outcome data of hospitalized patients were extracted from electronic medical records in our center.

A Covid-19 chest X-ray severity score as adapted by Wong et al. [11] here termed Covid19-CXRScore, was used to radiologically determine severity. This radiological scale of lung involvement has a score varying between 0 and 8, with 8 indicating the highest degree of involvement. The Sequential Organ Failure Assessment score (SOFA) was used to assess the severity of SARS-CoV-2 infection [12].

Tracheostomy patient management

Patients on MV for more than 14 days underwent a percutaneous dilatational tracheostomy, as per recommendations. Criteria used for tracheostomy were: $PaO_2/FiO_2 > 200$ mmHg and signs of clinical improvement to avoid a futile procedure. After tracheostomy, sedation was reduced progressively and a weaning protocol was implemented based on progressive reduction in pressure support [13]. Once the weaning process was completed and the patient was able to maintain spontaneous ventilation for 48 h, the tracheostomy tube was replaced by an uncuffed, fenestrated one, placing a heat and moisture exchange filter with supplementary oxygen therapy at the top of the tracheostomy tube. During subsequent days a cap was placed at the top of the tracheostomy tube during progressively longer periods of time. The tube was removed and the tracheostomy was closed when the patient was able to maintain adequate ventilation by himself with the capped tracheostomy tube and was able to expel respiratory secretions by coughing. Tracheostomy care was performed daily; chlorhexidine was applied frequently in the skin around the stoma and respiratory secretions were suctioned when required with a closed suction system; no saline instillation through tracheostomy tubes was made.

Patients were continuously cardio-respiratory monitored during the entire process, first at ICU then, when the patient was in a more stable condition ($FiO_2 < 40\%$, no need for vasopressor drugs to maintain hemodynamic

stability, renal replacement therapy or sedation, combined with improvement in clinical and laboratory COVID-19 features) at the RCU of the Respiratory Medicine Department which have negative pressure rooms. All patients were included in a rehabilitation program to recover from critical illness polyneuropathy and myopathy (CIPM). To assess CIPM severity we used a score adapted from the Medical Research Council scale (MRC-muscle scale), ranging from 0 (paralysis) to 60 (normal strength) [14]. To ensure minimal exposure and risk, the healthcare team managing tracheostomized patients used full personal protective equipment for aerosol-generating procedures, including FFP3 mask, eye protection, fluid-repellent gown, and gloves.

Endpoints

The primary endpoint was to establish parameters at the hospital or at ICU admission associated with a need for tracheostomy in COVID-19 patients.

Secondary endpoints were to analyze demographics, clinical course, and prognosis of patients needing a tracheostomy due to COVID-19. Parameters collected were demographic variables, complications (pneumonia, sepsis, hemoptysis, embolic events), need for MV, duration of MV, length of UCI stay, time to decannulation, length of hospitalization, and all-cause mortality.

Statistical analysis

We followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for reporting observational studies [15]. Binary and categorical variables were summarized using frequency counts and percentages. Continuously distributed variables were expressed as mean ± SD or median and interquartile ranges (IQR). Data comparisons were performed using Student's t-test and paired Wilcoxon test. Dichotomous variables were compared using the chi-square test. Time from intubation to tracheostomy and survival was assessed with Kaplan–Meier charts. Forward stepwise logistic regression analysis was used to determine variables at hospital admission and ICU admission that were independently associated with need for tracheostomy in COVID-19 patients. The multivariate analysis model included variables that exhibited a significant association in the univariate model. Receiver operating characteristics (ROC) curves were used to identify a cut-off point in the variables that best predicted the need for tracheostomy in logistic regression. Statistical significance was set at $p < 0.05$.

Results

During the study, 118 patients with a confirmed diagnosis of COVID-19 were hospitalized (108 admitted to the Respiratory Ward and 10 directly admitted to ICU from the Emergency Department). Of patients who entered the Respiratory Medicine Department 27 (25%) were transferred to ICU due to worsening clinical condition (mean time from hospital admission to ICU admission 3.87 ± 2.89 days) (Fig. 1). Time from symptoms onset to hospital admission was 8.20 ± 4.78 days. The most common symptoms of COVID-19 were fever (85.6%), cough (78.0%), dyspnea (50.8%) and general discomfort (46.6%). Patients' demographic and clinical characteristics at hospital admission are shown in Table 1. Thirty-seven patients (31.4%) were admitted to ICU, and 30 (81.1%) of these were intubated and mechanically ventilated, with a median UCI stay of 8.50 days (IQR, 3.75–21.50 days). Eighteen patients (15.3%) died during hospitalization, 10 patients in the Respiratory ward (12.3%) and 8 patients in ICU (mortality at ICU 21.6%); 62.5% of ICU mortality occurred during the first 14 days of ICU stay (Fig. 2).

Tracheostomy due to PMV was performed in 11 patients (36.7% of those on MV), and the time from orotracheal intubation to tracheostomy was 15.55 ± 4.84 days (Fig. 3). All patients presented COVID-19-related ARDS, thus protective lung maneuvers such as prone position were applied during MV. In tracheostomy patients length of time on MV was 27.70 ± 9.79 days and the mean time from tracheostomy to decannulation was 20.50 ± 7.76 days. Duration of hospitalization was 51.40 ± 10.96 days (30.91 ± 10.24 days at ICU). Compared with patients with no tracheostomy, the former were older and presented more criteria of severity at hospital admission (Table 1). Table 2 shows differences in clinical parameters at ICU admission between patients who needed a tracheostomy and those who did not. Univariate analysis revealed the variables at hospital admission (Table 3) and at ICU admission (Table 4) that were independently associated with the need for tracheostomy in COVID-19 patients, while a multivariable logistic regression model found no variable at hospital admission correlated with the need for tracheostomy. This same model found SOFA (OR 0.65, 95% CI 0.47–0.92, p 0.015) at ICU admission to be predictive of tracheostomy. In ROC curve analysis SOFA at ICU admission presented AUC = 0.779, 95% CI 0.59–0.96, $p = 0.009$, with a cut-off point of 4.5 (sensitivity 0.72, specificity 0.73, positive predictive value 0.57 and negative predictive value 0.85) (Fig. 4).

Regarding COVID-19-associated complications and long-term hospitalization, five patients (45.5%) presented supraventricular cardiac arrhythmias, six patients (54.5%) suffered agitation and confusion, one (9.1%) pulmonary

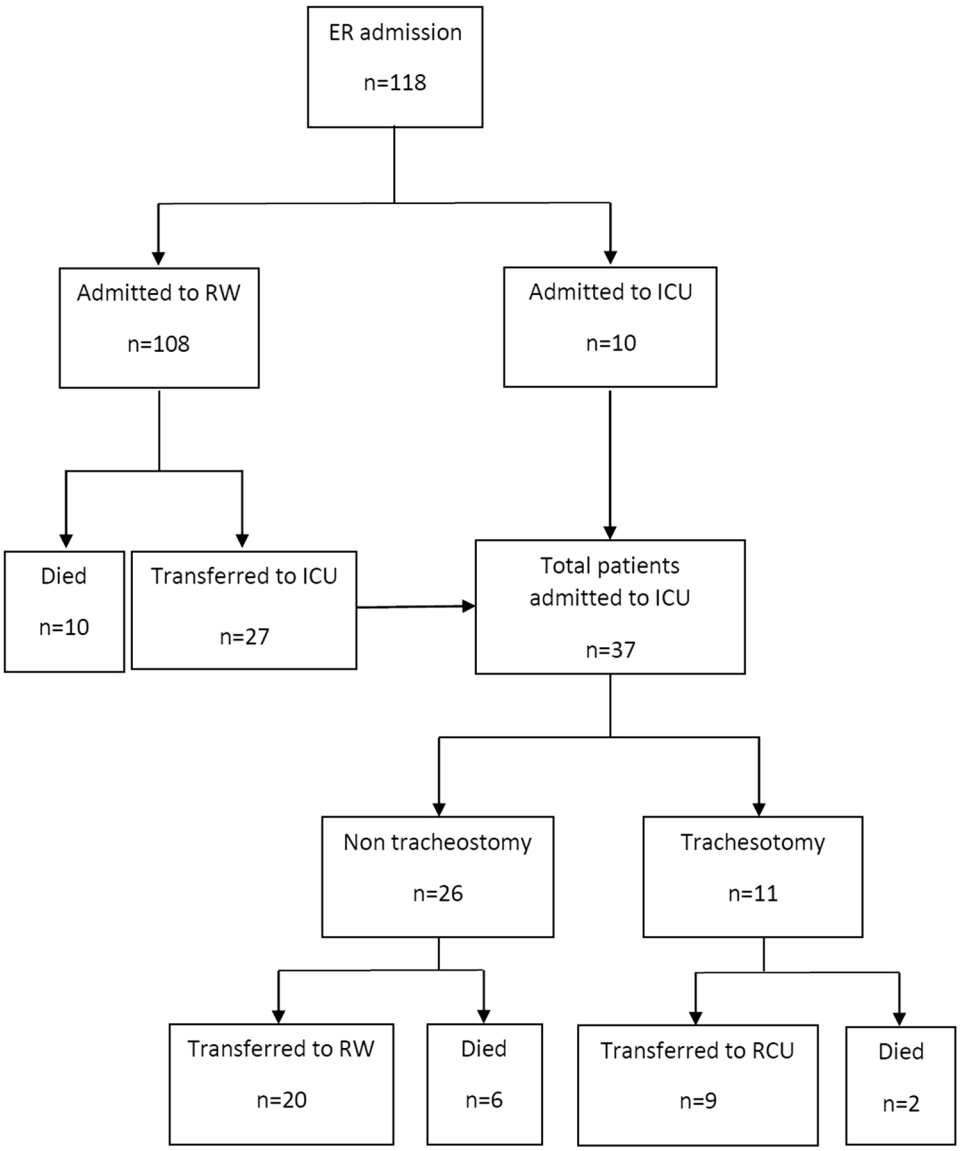

Fig. 1 Study flowchart. *ER* Emergency Department, *ICU* intensive care unit, *RCU* respiratory care unit, *RW* respiratory ward

thromboembolism, and another one (9.1%) depression. Nosocomial infection was detected in all patients (72.7% respiratory, 18.2% urinary, catheter 9.1%) with no predominant germ.

In patients admitted to RCU after ICU stay all patients presented hypoalbuminemia (2.90 ± 0.45 g/dL), increased D-dimmer (1074.11 ± 608 mg/mL), IL-6 (161.14 ± 126.64 pg/mL) and LDH (601.66 ± 152.10 U/L) and major CIPM (MRC-sumscore 34.22 ± 14.08); two patients (18.2%) had pressure ulcers and another two (18.2%) showed swallowing dysfunction. All patients with tracheostomy were liberated from MV and tracheostomy was successfully closed, except for two who died during ICU stay due to severe ARDS (mortality in tracheostomized patients 18.18%), in this way successfully weaning was achieved in 81.8% and decannulation in 81.8% patients. At hospital discharge swallowing dysfunction was resolved and CIPM improved after daily rehabilitation sessions (MRC-muscle score 51.50 ± 4.62, $p = 0.011$). None of the healthcare team responsible for patients with tracheostomy were infected with SARS-CoV-2.

Discussion

The findings of our observational study show that SOFA at ICU admission is associated with an increased risk of tracheostomy in patients with COVID-19 and MV. Moreover, these patients present clinical features similar to those with CCI and suffer complications related to SARS-CoV-2.

In patients with critical illness secondary to SARS-CoV-2 requiring MV, Hur et al. [16] reported that around

Table 1 Demographic and clinical characteristics at hospital admission

	Total population	No tracheostomy	Tracheostomy	*p*
Sample size (*n*)	118	107	11	
Sex (male/female)	78/40	69/38	9/2	0.248
Comorbidity (*n*, %)				
Smoker	11 (9.32)	11 (10.28)	0 (0)	0.171
HTA	47 (39.83)	40 (37.38)	7 (63.63)	0.090
DM	24 (20.33)	21 (19.62)	3 (27.27)	0.549
Cardiopathy	11 (9.32)	10 (9.34)	1 (9.09)	0.978
COPD	5 (4.23)	4 (3.73)	1 (9.09)	0.401
Asthma	6 (5.08)	6 (5.60)	0 (0)	0.420
Cancer	15 (12.71)	13 (12.14)	2 (18.18)	0.567
BMI > 30	20 (16.94)	16 (14.95)	4 (36.36)	0.078
Age (Years)	60.01 ± 13.97	59.27 ± 14.33	67.18 ± 6.63	0.004
Lymphocytes ($\times 10^9$/L)	1.80 ± 6.16	1.89 ± 6.44	0.81 ± 0.36	0.600
Platelets ($\times 10^9$/L)	207.50 ± 105.96	204.97 ± 10,504	105.04 ± 118.54	0.404
Neutrophils/Lymphocytes	6.39 ± 5.37	5.57 ± 4.10	16.00 ± 8.72	0.007
AST (U/L)	76.61 ± 222.40	77.68 ± 232.75	65.55 ± 36.47	0.877
ALT (U/L)	60.41 ± 85.47	62.01 ± 89.22	45.40 ± 32.71	0.562
Urea (mg/dL)	35.58 ± 19.62	33.87 ± 17.79	52.90 ± 28.66	0.003
Creatinine (mg/dL)	1.00 ± 0.50	0.98 ± 0.50	1.22 ± 0.49	0.146
LDH (U/L)	674.00 ± 373.08	647.93 ± 371.04	957.88 ± 275.76	0.016
CRP (mg/L)	104.17 ± 101.98	87.17 ± 77.32	284.31 ± 153.89	0.003
IL-6 (pg/mL)	217.93 ± 408.78	111.90 ± 136.95	562.51 ± 919.40	0.209
D-dimer (mg/mL)	1174.61 ± 2864.70	1170.31 ± 2988.02	1217.00 ± 1121.17	0.961
PaO_2/FiO_2	292.44 ± 106.39	297.29 ± 87.66	247.91 ± 215.37	0.468
SOFA	1.83 ± 2.05	1.53 ± 1.55	4.90 ± 3.66	0.018
Covid19-CXRScore	3.11 ± 1.96	2.94 ± 1.83	4.90 ± 2.55	0.002
Mortality (%)	15.30	14.95	18.18	0.777

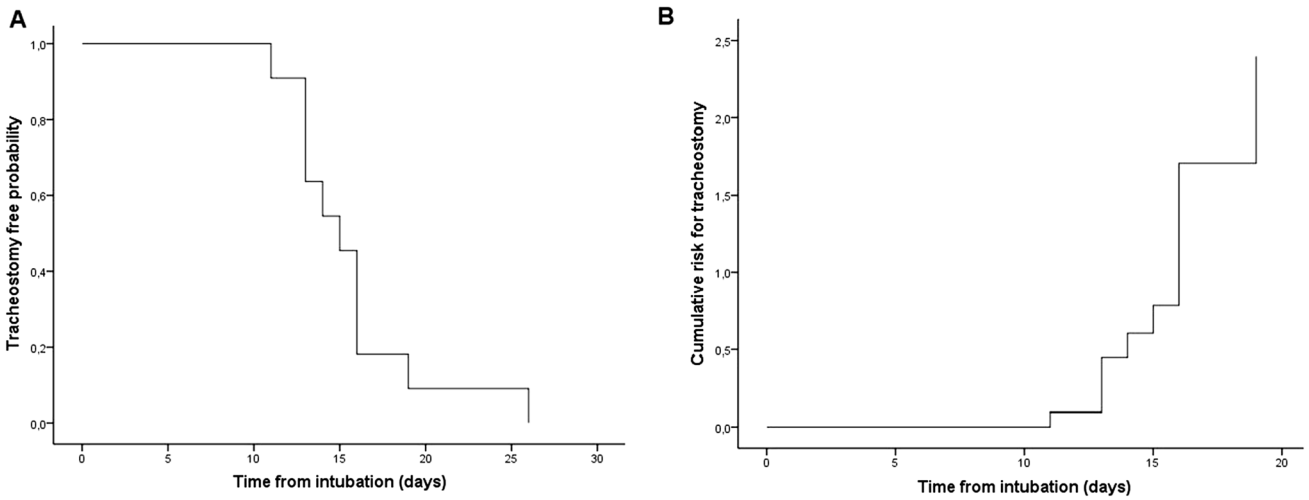

Fig. 2 **a** Probability of being tracheostomy-free after intubation. **b** Risk of tracheostomy after intubation

64% remained intubated for more than 14 days. In those requiring MV the percentage of patients in whom tracheostomy was performed ranges from 11 to 38%. [5, 16–19] Our findings showed that tracheostomy was performed in 36.7% of patients with MV. Tracheostomy confers advantages in patients with PMV that could also be applicable

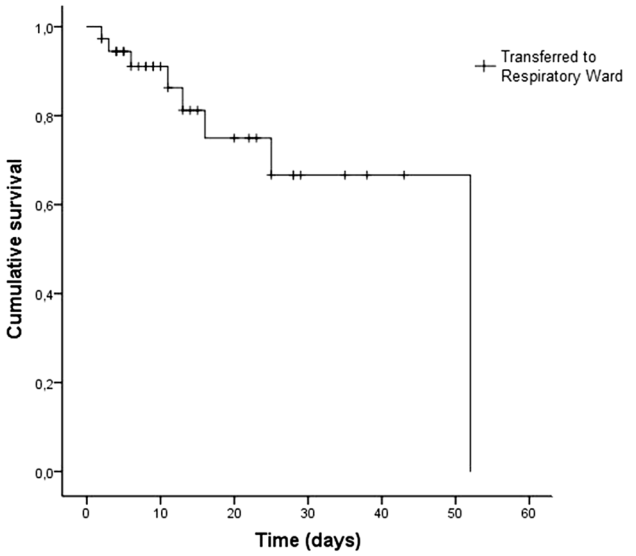

Fig. 3 Mortality in ICU patients admitted due to COVID-19

Table 2 Demographic and clinical characteristics at ICU admission

	No tracheostomy	Tracheostomy	*p*
Sample size (*n*)	26	11	
Sex (male/female)	20/6	9/2	0.741
Comorbidity (*n*, %)			
Smoker	4 (15.38)	0 (0)	0.111
HTA	12 (46.15)	7 (63.63)	0.331
DM	6 (23.07)	3 (27.27)	0.786
Cardiopathy	5 (19.23)	1 (9.09)	0.444
COPD	1 (3.84)	1 (9.09)	0.519
Asthma	1 (3.84)	0 (0)	0.510
Cancer	6 (23.07)	2 (18.18)	0.741
BMI > 30	6 (23.07)	4 (36.36)	0.446
Age (Years)	66.38 ± 8.51	67.18 ± 6.63	0.874
Lymphocytes ($\times 10^9$/L)	3.80 ± 13.46	0.81 ± 0.30	0.492
Platelets ($\times 10^9$/L)	200.53 ± 86.97	235.88 ± 118.54	0.354
Neutrophils/Lymphocytes	7.16 ± 5.06	16.00 ± 8.72	0.001
AST (U/L)	71.20 ± 5.06	65.55 ± 36.47	0.796
ALT (U/L)	52.85 ± 41.00	45.40 ± 32.71	0.622
Urea (mg/dL)	38.87 ± 22.45	45.40 ± 32.71	0.136
Creatinine (mg/dL)	1.09 ± 0.48	1.22 ± 0.49	0.502
LDH (U/L)	843.26 ± 301.56	957.88 ± 275.76	0.331
CRP (mg/L)	122.77 ± 81.21	284.31 ± 153.89	0.009
IL-6 (pg/mL)	176.51 ± 194.92	562.51 ± 919.40	0.298
D-dimer (mg/mL)	1429.95 ± 1344.62	1217 ± 1121.17	0.665
PaO_2/FiO_2	24,825 ± 83.16	247.91 ± 215.37	0.995
SOFA	2.59 ± 1.65	4.90 ± 3.66	0.041
Covid19-CXRScore	3.96 ± 1.64	4.90 ± 2.55	0.303
Mortality (%)	23.07	18.18	0.741

Table 3 Univariate analysis of factors at hospital admission associated with the need for tracheostomy

	OR	95% CI	*p*
Gender	0.40	0.08–1.96	0.261
Comorbidity			
Smoker	2.47	0.70–8.75	0.159
HTA	0.34	0.09–1.23	0.102
DM	0.65	0.15–2.66	0.551
Cardiopathy	1.03	0.11–8.90	0.978
COPD	0.38	0.04–3.81	0.417
Asthma	–	–	–
Cancer	0.62	0.12–3.20	0.570
BMI > 30	0.31	0.082–1.20	0.090
Age	0.94	0.893–1.00	0.080
Lymphocytes	1.00	1.00–1.00	0.280
Platelets	1.00	1.00–1.00	0.404
Neutrophils/Lymphocytes	0.76	0.66–0.88	0.000
AST	1.00	0.99–1.00	0.887
ALT	1.00	0.99–1.01	0.566
Urea	0.96	0.94–0.99	0.010
Creatinine	0.54	0.22–1.33	0.18
LDH	0.99	0.99–1.00	0.059
CRP	0.98	0.97–0.99	0.000
IL-6	0.99	0.99–1.00	0.126
D-dimer	1.000	1.00–1.00	0.960
PaO_2/FiO_2	1.00	0.99–1.01	0.133
SOFA	0.59	0.44–0.79	0.000
Covid19-CXRScore	0.63	0.46–0.87	0.005

to COVID-19 patients, such as less need for deeper sedation, shorter weaning time, and shorter ICU and hospital stay [20]. Median weaning time after tracheostomy in our patients was 9.00 days (IQR 4.00–14.00) with a mean duration of MV of 27.70 days that is in range with previously published data [19, 21–23]. 81.8% of our patients achieved successfully weaning. This data contrast with the results of the study [23] with more patients included ($n = 1890$) which found that at 30 days of follow-up, liberation from MV was achieved only in 52% of the patients. However, Long et al. report similar rates of weaning success to our results [24].

The key factors in managing COVID-19 patients under PMV are correctly pinpointing patients who might benefit from a tracheostomy and optimal timing of the procedure. It has been reported that around 85% of deaths in patients with COVID-19-related MV occur within 2 weeks of intubation [16]. Our study reflects similar results, with 62.5% of deaths in patients with MV produced during the first 14 days after intubation. Safety for healthcare workers from viral exposure during aerosol-generating procedures such as tracheostomy is another important issue to take into consideration regarding timing of tracheostomy in COVID-19 patients, in which

Table 4 Univariate analysis of factors at ICU admission associated with the need for tracheostomy

	OR	95% CI	*p*
Sex	0.74	0.12–4.40	0.742
Comorbidity			
Smoker	3.20	0.70–14.52	0.132
HTA	0.49	0.11–2.08	0.355
DM	0.80	0.16–4.00	0.786
Cardiopathy	2.38	0.24–23.16	0.455
COPD	0.40	0.02–7.03	0.531
Asthma	–	–	–
Cancer	1.35	0.27–8.03	0.742
BMI > 30	0.55	0.11–2.56	0.448
Age	0.98	0.90–1.08	0.777
Lymphocytes	1.00	0.99–1.00	0.547
Platelets	1.00	1.00–1.00	0.759
Neutrophils/Lymphocytes	0.94	0.88–1.01	0.108
AST	1.00	0.99–1.02	0.340
ALT	1.01	0.99–1.03	0.204
Urea	0.98	0.96–1.01	0.369
Creatinine	0.57	0.17–1.87	0.361
LDH	0.99	0.99–1.00	0.275
CRP	0.99	0.98–1.00	0.036
IL-6	1.00	0.99–1.00	0.946
D-dimer	1.00	1.00–1.00	0.861
PaO_2/FiO_2	0.99	0.99–1.00	0.353
SOFA	0.65	0.46–0.91	0.013
Covid19-CXRScore	0.66	0.39–1.11	0.123

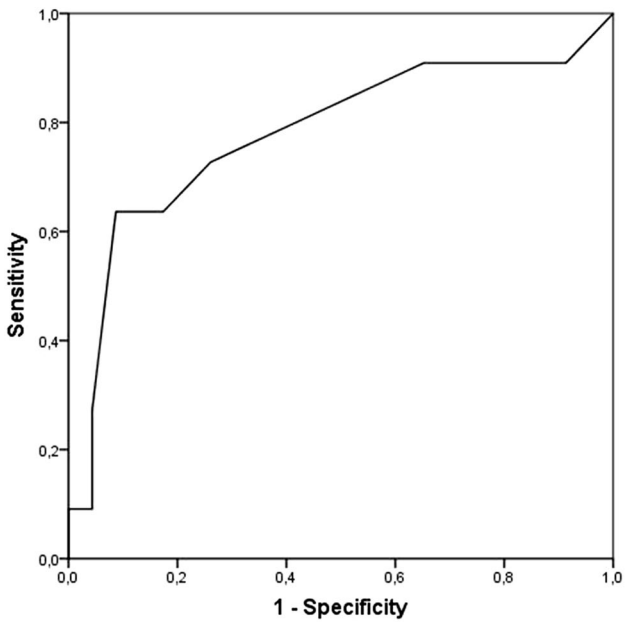

Fig. 4 Receiver operating characteristics curves. Sequential Organ Failure Assessment score (SOFA) at ICU admission (area under curve 0.779, 95% confidence interval 0.59–0.96, $p = 0.009$)

regard decreasing infectivity has been found beyond 10 days after symptoms onset [25]. In light of this, different international guidelines [6, 26–28] recommend that tracheostomy in COVID-19 patients should be delayed until 14 days of intubation and MV should be considered only in patients with stable pulmonary status, appropriate ventilator requirements, showing signs of clinical improvement and with a clear prognosis.

Recently, Hur et al. [16] found that advanced age (> 65 years) and obesity (BMI > 30 kg/m^2) were strongly associated with time to extubation and therefore higher risk for prolonged intubation in intubating COVID-19 patients. However, the results of our study show that SOFA at ICU admission, with a cut-off point of 4.5, was the only variable associated with the need for tracheostomy due to PMV. Tornari et al. [29] found that higher FiO_2 (≥ 0.4) at tracheostomy and peak cough flow prior to tracheostomy were associated with delayed decannulation in COVID-19 patients. Different studies conducted in non-COVID-19 patients have been published assessing predictors of PMV, [30] showing that variables that evaluate the severity of critical illness, most of them included in the SOFA score, could predict the need for PMV and tracheostomy.

This is the first study to address the clinical course of tracheostomy in COVID-19 patients. All patients but the two who died (mortality 18.18%) could be liberated from MV and later decannulated and tracheostomy closed. They experienced prolonged hospital stays and suffered SARS-CoV-2-related complications. The agitation has been previously described as a primary neurologic feature in severe COVID-19, present in up to 67% of patients, and was observed in 54% of our tracheostomized patients [31]. 45% of our patients showed cardiac arrhythmias, in line with previously reported COVID-19-associated cardiac complications, in which arrhythmias occurred in 16.7% of patients hospitalized with SARS-CoV-2 pneumonia [32]. Evidence shows that severe COVID-19 can be complicated by coagulopathy that can manifest as pulmonary thromboembolism. It has been reported to occur in 21% of patients; [33] in our study 9.1% of patients presented pulmonary emboli. In addition to SARS-CoV-2 complications, our patients presented a collection of symptoms characteristic of CCI, such as nosocomial infections, hypoalbuminemia, skin breakdown, CIPM, depression, and increased inflammatory markers (mainly IL-6). CCI physiopathology is secondary to persistent inflammation, immunosuppression, and catabolism precipitated by dysregulated host immune responses to an initial insult [34]. The immune system clearly plays a key role in the host defense against SARS-CoV-2. The viruses induce inflammatory responses, mainly in the lungs, resulting in pneumonia. In susceptible patients, SARS-CoV-2 can cause a massive inflammatory response known as a cytokine storm, which in around 20% of patients results in severe

disease with ARDS due to diffuse alveolar damage and can lead to multi-organ failure [35]. Some patients who survive this acute critical phase may develop a chronic state known as CCI. This is defined as organ dysfunction that persists more than 14 days in ICU patients and is linked to persistent immune dysregulation [36]. This persistent inflammation is typically associated with significantly elevated levels of inflammatory mediators such as IL-6 (30). In fact, in COVID-19 IL-6 is a significant predictor of mortality [37]. Moreover, this state is also associated with T cell depletion and decreased activation leading to immune suppression [36].

The study has some limitations which must be taken into account when interpreting our findings. It was conducted at a single-center hospital, implying a small sample size; also, due to the exploratory nature of the study, not driven by formal hypotheses, the sample size was not calculated. International guidelines recommend that patients with tracheostomy secondary to COVID-19 need to be managed by experienced staff trained in tracheostomy care and management; [6] (6) in this regard, our Respiratory Care Unit has extensive experience in the management of patients with tracheostomy and patients with CCI [38].

In conclusion, our results suggest that the SOFA score measured at ICU admission, with a cut-off point of 4.5, is an independent risk factor for prolonged mechanical ventilation and the need for tracheostomy in patients with COVID-19. Moreover, COVID-19 patients with tracheostomy present clinical features similar to patients with chronic critical illness in addition to SARS-CoV-2-related complications.

Author contributions JS, SF, and JS-C conception and design of the study, acquisition of data, analysis, and interpretation of data, drafting the article and final approval of the submitted version. TP, EB, PB, LF-P, PR, MLB acquisition of data, drafting the article, and final approval of the submitted version. JS is responsible for the overall content of the manuscript as guarantor.

Compliance with ethical standards

Conflict of interest All the authors have no financial relationship with any commercial entity that has an interest in the subject of this manuscript.

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