RESEARCH ARTICLE

Tracheostomy in critically ill patients with SARS 2 COVID-19 infection: a prospective observational multi-center study of short- and long-term outcomes

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Background: We report the characteristics, timing, and factors related to the decision to perform a tracheostomy in patients with confirmed COVID-19 infection admitted to eight Italian intensive care units (ICUs).

Materials and methods: Prospective observational cohort study of patients with COVID-19 disease on mechanical ventilation. Long-term functional impairment (up to 180 days' post-hospital discharge) was assessed using the Karnofsky scale. Kaplan–Meier analysis assessed differences in survival and freedom from tracheostomy in relation to ICU stay. Cox regression model was used to assess which variables impacted on tracheostomy as a categorical outcome.

Results: A total of 248 patients were recruited in the eight participating ICUs. Patients undergoing tracheostomy (n = 128) had longer ICU (25 (18–36) vs. 10 (7–16), P = 0.001) and hospital (37 (26.5–50) vs. 19 (8.5–34.5) P = 0.02) stays. ICU and hospital mortality of patients tracheostomized was 34% and 37%, respectively. Cumulative survival Kaplan–Meier analysis documented improved survival rates in patients undergoing tracheostomy (Log-Rank, Mantel–Cox = 4.8, P = 0.028). Median Karnofsky scale values improved over time but were similar between survivors receiving or not receiving tracheostomy. No healthcare worker involved in the tracheostomy procedure developed COVID-19 infection during the study period.

Conclusions: Patients with COVID-19 infection who underwent tracheostomy had a better cumulative survival but similar long-term functional outcomes at 30, 60, and 180 days after hospital discharge.

Key Words: *COVID-19; critically ill patients; tracheostomy; Karnofsky; mechanical ventilation*

INTRODUCTION

Most people infected with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) develop mild or uncomplicated disease; approximately 14% progress to a more serious disease that requires hospitalization with oxygen therapy [1]. Up to one-third of these hospitalized patients with COVID-19 disease require intensive care unit (ICU) admission for complications such as acute respiratory distress syndrome (ARDS) and, less commonly, multi-organ failure, in particular renal and cardiac involvement dysfunction [1–5].

Tracheostomy is a common procedure in critically ill patients who require an extended period of time on mechanical ventilation [6, 7]. Use of tracheostomy can facilitate weaning from ventilation and may increase the availability of ICU beds. Tracheostomy may also be required for unsuccessful extubation due to weakness, poor cough, tenacious secretions, or a combination of these factors. Indications for tracheostomy during the COVID-19 pandemic were based mainly on existing standards of practice, although the evidence base for optimal timing is not particularly strong [8–12]. Moreover, as tracheostomy is considered an aerosol-generating procedure, healthcare workers are at potentially increased risk of infection during insertion and subsequent care, and this may have deterred or delayed the procedure.

This prospective observational study aimed to describe the characteristics of patients with confirmed COVID-19 infection admitted to eight Italian ICUs from February to May 2020 who underwent

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Published online at https://www.cjrt.ca on 30 September 2022

tracheostomy. It was performed to identify factors involved in performing the procedure, to assess the impact on short- and long-term outcomes.

METHODS

This multi-center prospective observational study was performed in eight Italian ICUs over a six-month period commencing on 21 February 2020.

The following variables (dates, categorical, and discrete) were collected through an interactive electronic database:

- demographic variables: age, sex, therapeutic diagnostic path before admission to ICU (date of admission to hospital and subsequent hospitalizations before admission to ICU);
- co-morbidities: namely hypertension, heart disease, chronic obstructive airways disease, neoplasm, insulin dependent/independent diabetes mellitus, chronic renal failure, chronic vascular disease, chronic pathological or iatrogenic immunosuppression;
- date of onset and characteristics of the first SARS COV-2 related symptoms;
- interstitial pulmonary alveolar involvement; development of ARDS;
- start date of non-invasive ventilation (NIV); date of hospitalization in ICU; and date of intubation;
- Simplified Acute Physiology Score (SAPS 2);
- Sequential Organ Failure Assessment (SOFA) score on admission and highest score reached during ICU stay;
- duration of mechanical ventilation; use of pronation;
- if performed, type and timing of tracheostomy (surgical or percutaneous techniques);
- identification of major pulmonary embolism;
- use and duration of renal replacement therapy;
- echocardiographic signs of cardiomyopathy and myocardial failure;
- hepatic dysfunction (alteration of liver enzymes and cholestatic indices);
- ICU and hospital outcomes;
- Karnofsky performance status scale [13] was determined at 30, 60, and 180 days after hospital discharge date to assess quality of life and recommencement of normal activities (including return to work) of patients undergoing tracheostomy or not during their ICU stay.

The tracheostomy team comprised anesthesiologists and nursing staff with or without ear, nose, and throat (ENT) surgeons. All procedures were performed using personal protective equipment for aerosol-generating procedures, as defined by local hospital guidelines (FFP3 masks with fluid-repellent gowns, gloves, and eye protection). No powered respirators were worn by the tracheostomy team. Tracheostomy technique was both percutaneous and surgical. The tracheostomy team was tested with antibody testing 2 weeks after procedure.

The primary endpoints were the occurrence and timing of tracheostomy. Secondary endpoints assessed differences for all collected variables between tracheostomized and non-tracheostomized groups of patients.

We also registered differences in survival and the patients' functional outcome status assessed by the Karnofsky performance status scale between the two groups at days 30, 60, and 180 post-hospital discharge.

For statistical analysis, Student's *t* test was used for quantitative discrete variables and Mann–Whitney non-parametric U test for non-normal distributions. For categorical variables the χ^2 test was applied to assess differences in proportions with Fisher's test correction for expected values <5. Under the conditional independence assumption, Cochran's statistic was applied to assess the Mantel–Haenszel common odds ratio estimate (OR).

A Kaplan–Meier analysis (limit product method) was used to assess differences in survival and freedom from tracheostomy in relation to ICU stay. The log rank method was used to assess differences in the stratification groups for the Kaplan–Meier analysis. Linear regression was performed to assess differences in terms of ICU and post-ICU length of stay between the two groups. A Cox regression model was fitted to assess which variables could impact on tracheostomy as a categorical outcome. We assumed and demonstrated that proportions of hazards in relation to time were respected for each categorical and quantitative variable. Variables were entered into the model if univariate analysis confirmed their statistical significance. Otherwise, if a variable was considered important for a clinical outcome, it was also forced into the model.

RESULTS

During the study period, 248 patients were recruited in the eight participating ICUs of whom 128 (51.6%) underwent tracheostomy. Table 1 shows the main quantitative and categorical characteristics of all patients after stratification by receipt or not of tracheostomy.

Tracheostomy was performed after a median of 11 days of recovery. Patients undergoing tracheostomy had longer ICU, post-ICU, and hospital stays. They also required longer pronation cycles, more days receiving neuromuscular blockade, more days on mechanical ventilation, and a longer duration of vasoactive drug infusion, and sedative drug use. Diabetics, smokers, and vasculopathic patients were more likely to undergo tracheostomy. Non-tracheostomized patients had a higher incidence of COVID-2019 related gastro-intestinal symptoms but were less likely to receive specific anti-COVID-2019 therapies. Tracheostomy was more likely to be performed in patients experiencing both acute renal and acute liver failure who need vasoactive drugs. Severe infections, particularly ventilator-associated pneumonia (VAP), complicated tracheostomized patients more frequently. A significantly higher percentage of this group was prescribed antibiotics (Table 1).

Use of pronation reduced the likelihood of patients undergoing a tracheostomy by half, with a corresponding shorter duration of mechanical ventilation and ICU length of stay.

Multivariate Cox regression modelling (Table 2) showed that a higher SAPS II score in the first 24 h of ICU admission, a higher SOFA score during their ICU stay, and development of acute heart failure impacted negatively on outcomes following tracheostomy.

Figure 1 shows the relationship between ICU- and post-ICU length of stay. Patients undergoing tracheostomy were likely to have a relatively longer stay in ICU, whereas the opposite was seen for non-tracheostomized patients. The post-ICU to ICU length of stay ratio was higher in non-tracheostomized patients (median (IQR) ratio 1.5 (0.9–2.1) vs. 0.7 (0.3–1.1), $P = 0.001$).

No significant differences in ICU and hospital mortality were recorded between the two groups of patients (Table 1b). In terms of cumulative survival, the Kaplan–Meier analysis revealed a significantly better survival in patients undergoing tracheostomy (Log Rank, Mantel–Cox 4.8; $P = 0.028$) (Figure 2).

Follow-up of surviving patients at 30, 60, and 180 days after hospital discharge found a similar improvement in median Karnofsky scale values over time in tracheostomized and non-tracheostomized groups (using General Linear Models for repeated measures) (Figure 3).

During the study period no healthcare workers involved in the tracheostomy procedure developed clinical or laboratory evidence of COVID-19 infection.

DISCUSSION

To our knowledge, this prospective study is the most extensive prospective assessment to date of short and long-term outcomes in tracheostomized and non-tracheostomized COVID-19 patients. Our main findings are that tracheostomy was commonly performed across all eight ICUs and most frequently undertaken after the first week of ICU admission. The likelihood of undergoing tracheostomy increased significantly in patients with a higher first 24 h SAPS-2 score or a higher SOFA score recorded during their ICU stay. Although these patients have longer ICU, post-ICU, and hospital stays, cumulative survival using Kaplan–Meier analysis documented a significantly better survival in patients

TABLE 1
Main characteristics of all patients stratified according to the occurrence or not of tracheostomy
1a: Quantitative variables.

Variable	All patients, *n* = 248 (range)	Patients with tracheostomy, *n* = 128 (range)	Patients without tracheostomy, *n* = 120 (range)	*P*
Age	66 (58–72)	67 (58–72)	66 (58–72)	0.843
Body mass index	27 (25–31)	28 (26–31)	26 (24–28)	0.071
First 24 h SAPS-2 score	37 (31–49)	37 (31–46)	37 (31–50)	0.488
	7 (5–9)	6 (5–8)	7 (5–9)	0.087
Worst recorded SOFA score	8 (6–10)	8 (7–10)	8 (6–10)	0.870
COVID-19				
Symptom onset days to hospital	6 (5–8)	6 (5–9)	6 (5–7)	0.213
Therapy days	8 (5–13)	9 (5–14)	7 (5–10)	0.014
CRP_{max}	160 (51–298)	161 (51–304)	148 (51–270)	0.719
CRP_{min}	7.5 (1.5–27)	6 (0.8–25)	8 (2–39)	0.250
PCT_{max}	1.9 (0.5–5.8)	1.9 (1–14)	1.85 (1.7–2)	0.399
PCT_{min}	0.12 (0.05–0.56)	0.12 (0.05–0.6)	0.1 (0.07–0.5)	0.148
pre-ICU – LOS	3 (1–5)	3 (2–5)	3 (1–7)	0.477
ICU – LOS	17 (12–26)	25 (18–36)	10 (7–16)	0.001
post-ICU-LOS	13 (8–21)	12.5 (7.5–21)	13 (7–18)	0.840
Hospital-LOS	28.5 (8.5–43)	37 (26.5–50)	19 (8.5–34.5)	0.024
NIPPV days	1 (0–2) (22 of pts.)	1 (0–2) (24 of pts.)	1 (0–2) (19 of pts.)	n.a.
CPAP days	1 (0–2) (21 of pts.)	0.5 (0–1) (23 of pts.)	1 (0–2) (18 of pts.)	n.a.
PaO_2/FiO_2 ratio pre-intubation	100 (69–150)	100 (70–150)	100 (69–150)	0.950
PaO_2/FiO_2 ratio post-intubation	147 (100–197)	147 (100–197)	147 (100–197)	0.890
Pronation cycles	1 (0–2)	2 (0–3)	1 (0–1)	0.048
Days of neuromuscular blockade	5 (2–8)	5 (2–11)	3 (2–5)	0.001
IPPV total duration	19 (11–26)	5 (20–37)	12 (6–17)	0.001
	21 (13–31)	28 (22–41)	13 (8–17)	0.001
Days to PSV trial from onset of IPPV	—	—	9 (5–12)	—
Days to spontaneous breathing trial from commencement of PSV	—	—	4 (2–8)	—
PaO_2/FiO_2 ratio pre-tracheostomy	—	127.5 (125–200)	—	—
Intubation to tracheostomy time	—	11 (7–14)	—	—
Tracheostomy to spontaneous breathing time	—	14 (8–24.5)	—	—
Decannulation time	—	14 (8–24.5)	—	—
CRRT days	13 (6–25)	19.5 (10.5–30)	5 (3–11.5)	0.003
Vasoactive drugs days	9 (5–19)	11 (6–19.5)	6 (5–10)	0.001
Sedation length	18 (11–24)	23 (12–25)	16 (11–24)	0.028

1b: categorical variables.

Variable	All patients, *n* = 248	Patients with tracheostomy, *n* = 128	Patients without tracheostomy, *n* = 120	OR 95% (CI)	*P*-values
Male: Female (ratio)	3.5:1	3:1	94:26 (3.6:1)	1.2 (0.6–2.1)	0.552
Past medical history					
Smoking	49 (19.80)	35 (27.3)	18 (15)	2.1 (1.1–4)	0.02
Diabetes	54 (23.2)	30 (23.4)	22 (18.3)	1.3 (0.7–2.5)	0.252
Hypertension	117 (47.20)	74 (57.8)	55 (45.8)	1.1 (0.6–2.9)	0.075
Coronary artery disease	26 (11.2)	21 (16.4)	18 (15)	1.1 (0.6–2.2)	0.827
Vasculopathy	34 (14.5)	25 (19.5)	10 (8.3)	2.7 (1.2–5.8)	0.017
Chronic obstructive airways disease	29 (12.5)	18 (14.1)	10 (8.3)	1.8 (0.8–4.1)	0.166
Neoplasia	14 (6)	8 (6.3)	8 (6.7)	0.9 (0.3–2.1)	1
Chronic renal failure	13 (5.6)	10 (7.8)	11 (9.2)	0.8 (0.3–2.1)	0.822
Immunosuppression	9 (3.6)	4 (3.9)	5 (4.2)	0.7 (0.2–2.8)	0.743
SARS-COV-2 symptoms					
Fever	216 (90)	116 (90.6)	108 (90)	0.5 (0.2–1.1)	0.086
Gut symptoms	29 (11.7)	20 (23.4)	49 (40.8)	0.4 (0.3–0.8)	0.004
SARS-COV-2 therapy					
Lopinavir–ritonavir	181 (73.1)	79 (78.4)	102 (69.2)	1.6 (0.9–3)	0.153
Tocilizumab	71 (28.6)	53 (41.4)	9 (7.5)	2.1 (1.1–4)	0.020
Hydroxychloroquine	205 (82.8)	114 (89.1)	78 (65.1)	4.3 (2.2–8.6)	0.001
Acute organ failures					
Renal failure	34 (16.6)	24 (18.8)	10 (8.3)	2.5 (1.1–5.6)	0.026
Cardiac failure	12 (5.7)	7 (5.5)	5 (4.2)	1.3 (0.4–4.3)	0.770
Liver failure	47 (18.9)	28 (21.9)	10 (8.3)	3 (1.4–6.7)	0.004
Vasoactive drug use	151 (60.9)	105 (82)	46 (38.3)	7.3 (4–13.1)	0.001
Pulmonary embolism	5 (3.2)	6 (4.7)	6 (5)	0.9 (0.2–3)	0.570

(Continues)

1b: categorical variables.

Variable	All patients, *n* = 248	Patients with tracheostomy, *n* = 128	Patients without tracheostomy, *n* = 120	OR 95%(CI)	*P*-values
Respiratory management					
NIPPV	140 (56.3)	15 (11.7)	12 (10)	1.2 (0.5–2.7)	0.570
CPAP		8 (6.3)	7 (5.8)	1.1 (0.4–3.1)	0.552
Pronation cycles	51 (20.0)	86 (67.2)	54 (45)	2.5 (1.5–4.2)	0.001
Neuromuscular blockade	128 (51.6)	116 (90.6)	101 (84.2)	1.8 (0.3–3.9)	0.130
Re-intubation	13 (5.2)	9 (7)	4 (3.3)	2.2 (0.7–7.3)	0.470
Decannulation	—	68 (53.1)	—	2.2 (0.7–7.3)	0.257
Infectious complications					
Severe infection	101 (40.7)	63 (49.2)	38 (36.7)	2 (1.2–3.5)	0.007
Bacteremia	37 (14.9)	23 (18)	14 (11.7)	1.7 (0.8–3.4)	0.212
Ventilator-associated pneumonia	62 (25)	38 (29.7)	24 (20)	1.7 (0.9–3)	0.081
Urinary tract infection	21 (8.5)	12 (9.4)	9 (7.5)	1.3 (0.5–3.1)	0.653
>1 infection type	9 (3.6)	3 (2.3)	4 (3.3)	07 (0.2–3.1)	0.715
On antibiotics		106 (82.8)	55 (45.8)	5.7 (3–10.1)	0.001
On antifungals	30 (12.1)	23 (18)	7 (5.8)	3.5 (1.5–6.6)	0.003
ICU survival	158 (63.7)	81 (65.6)	74 (61.7)	1.2 (0.7–2.1)	0.597
Hospital survival	142 (57.3)	62 (63.3)	61 (50.8)	1.7 (1–2.8)	0.054

Note: BMI, Body Mass Index; SAPS-2, score Simplified Acute Physiology Score 2; SOFA score, Sequential [Sepsis-related] Organ Failure Assessment Score; CRP, C-reactive Protein; PCT, Procalcitonin; ICU, Intensive Care Unit; LOS, Length of Stay; NIPPV, Non-invasive positive pressure ventilation; C-PAP, Continuous Positive Airway Pressure; IPPV, Invasive Positive Pressure Ventilation; PSV, Pressure support ventilation; CRRT, Continuous Renal replacement therapies.

TABLE 2
Multivariate predictive model of tracheostomy: Cox's regression

Variables	Parameter β	*P*	Hazard ratio	(95% CI)
Age	–0.012	0.398	0.9	0.9–1.1
Gender	–0.46	0.129	0.6	0.3–1.1
Smoke	–0.213	0.600	0.8	0.4–1.8
Vasculopathy	0.487	0.300	1.7	0.7–4.1
Antiviral therapy (lopinavir/ritonavir)	0.833	0.230	2.3	0.9–4.9
Hidroxycloroquine	–0.669	0.215	0.5	0.2–1.5
SAPS2	0.04	0.017	1.1	1.1–1.9
SOFA at the admission time	–0.04	0.672	0.9	0.8–1.2
Worst SOFA during ICU stay	0.191	0.021	1.2	1.1–1.4
PaO2/FiO2 ratio before intubation	0.003	0.463	1.1	0.9–1.1
Pronation cycles	–0.755	0.011	0.5	0.3–0.8
NMB duration (days)	–0.012	0.697	0.9	0.9–1.1
Acute heart failure	–1.542	0.03	5	1.3–10
Acute kidney failure (in CRRT)	0.965	0.077	2.6	0.9–7.6
Acute liver failure	–0.252	0.509	0.8	0.4–1.6
Vasoactive drugs	–0.279	0.547	0.7	0.3–1.9
Severe infectious complication	–0.103	0.837	0.9	0.3–2.4
VAP	0.409	0.237	1.5	0.8–2.9
On antibiotic treatment	0.555	0.208	1.7	0.7–4.1
On antifungal treatment	–0.226	0.616	0.8	0.3–1.9

Note: SAPS-2 score, Simplified Acute Physiology Score 2; SOFA score, Sequential [Sepsis-related] Organ Failure Assessment Score; ICU, Intensive Care Unit; NMB, Neuromuscolar Blocking; VAP, Ventilator Acquired Pneumonia; CRRT, Continuous Renal replacement therapies.

undergoing tracheostomy. Post-discharge functional status assessed by the Karnofsky scale showed progressive functional improvement in survivors over 180 days, with no difference between those tracheostomized or not.

In non-Covid-19 patients requiring tracheostomy after an extended period of mechanical ventilation, at least half did not survive for more than 1 year, and fewer than 12% were at home and functionally independent [9]. In our study, patients with COVID-19 infection undergoing tracheostomy showed a better cumulative survival but equivalent functional status compared to non-tracheostomized patients. Of note, the median Karnofsky score at 30, 60, and 180 days post-hospital discharge was ≥80 for 73.1% of patients at 180 days; a score of 80 corresponds to a condition of normal activity and no special care needs. It is uncertain why long-term outcomes are so much better in COVID-19

FIGURE 1.

Linear regression representing comparison between ICU and post-ICU length of stay stratified according with tracheostomy or not.

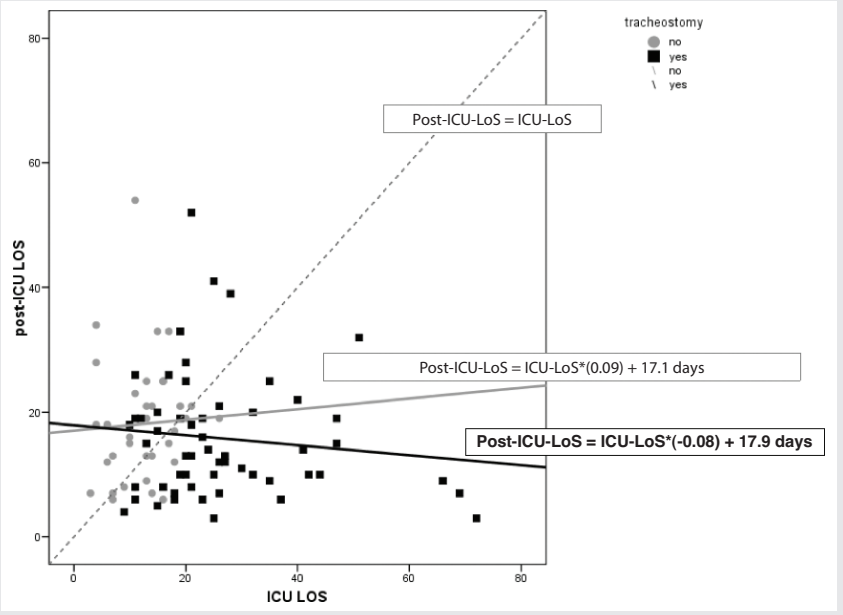


FIGURE 2.

Kaplan-Meier curves for cumulative survival stratified by patients tracheostomized and non-tracheostomized.

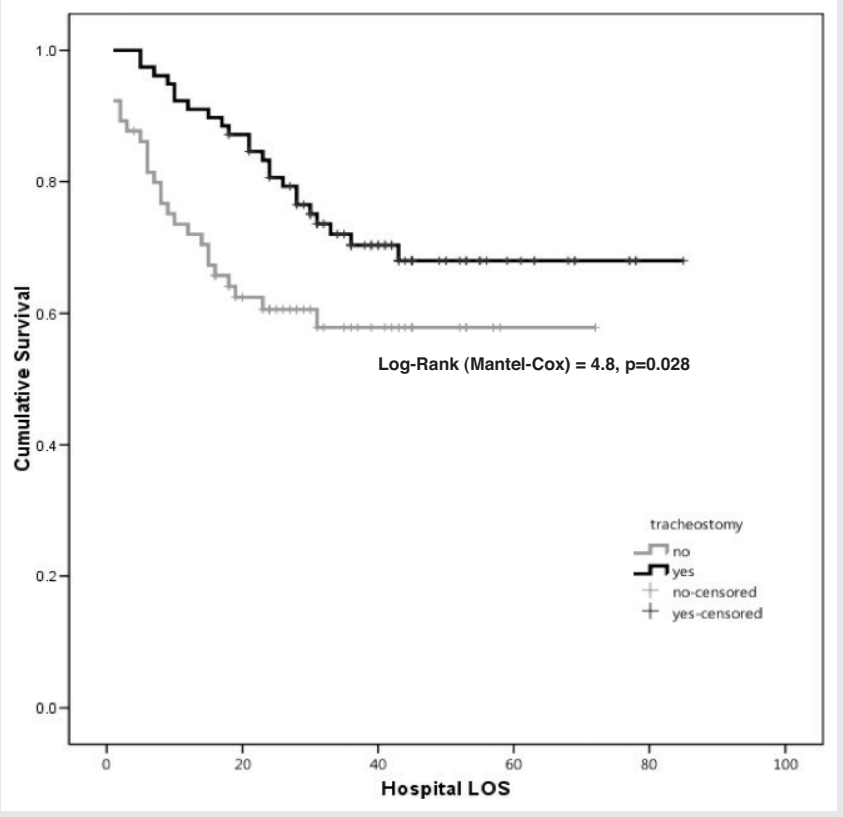
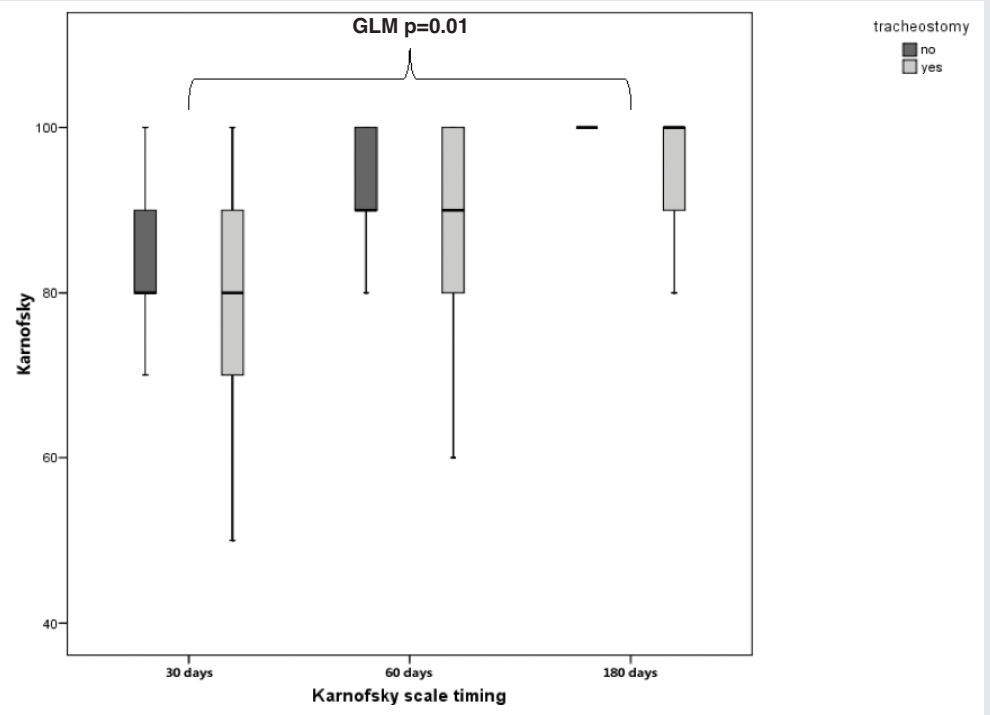


FIGURE 3.
Karnofsky scale values over time in tracheostomized and non-tracheostomized groups.



patients. This may reflect a selection bias in that COVID-19 patients admitted to ICUs during periods of bed shortages likely had less underlying frailty and/or chronic severe co-morbidities.

Avoiding tracheostomy in COVID-19 disease in the first 10 days of intubation was proposed as a recommendation based on expert opinion [10, 14]. A recent systematic review and meta-analysis identified 39 articles reporting outcomes for a total of 3929 patients with weighted mean follow-up time of 42 ± 26 days post-tracheostomy [15]. Weaning from mechanical ventilation occurred in 61.2% (95% CI 52.6%–69.5%), 44.2% (95% CI 34.0%–54.7%] were decannulated, and cumulative mortality was 19.2% (95% CI 15.2%–23.6%) across the entire tracheostomy cohort. No differences were found in the mortality rates between early and late tracheostomy, and tracheostomy timing did not predict time to decannulation. It is unclear, however, if early tracheostomies were performed overall in a less sick patient subset.

Healthcare personnel safety influenced the development of tracheostomy guidelines with some authorities advocating a delay in tracheostomy to allow time for the viral load to reduce. In our study none of the clinicians involved in the tracheostomy team developed COVID-19 symptoms during the study period and antibody testing at two weeks was negative. In the meta-analysis cited above [15], there were 10 confirmed nosocomial staff infections reported from 1398 tracheostomies. Our study supports the assertion that tracheostomy can be performed with low risk to both COVID-19 patients and healthcare workers as recently reported by Murphy and colleagues [16].

CONCLUSIONS

Although we used robust statistical methods, the observational nature of our study only allows us to report associations and cannot test causal relationships between factors and tracheostomy practice. However, to our knowledge, this is the first multi-center observational study evaluating the role of tracheostomy in COVID-19 patients, indicating a significant higher cumulative survival and an equivalent 180-day functional status in COVID-19 patients undergoing tracheostomy. Further studies are warranted to confirm these findings.

DISCLOSURES

Funding
None.

Conflicts of interest
No conflicts of interest to declare.

Ethics approval
Local Institutional Review Boards approved the study.

Consent to participate
Informed consent was obtained from all individual participants enrolled in the study.

Availability of data and material
Data are available from the corresponding author, [VDS], upon reasonable request.

Authors' contributions
Concept and design: De Santis V., Corona A. Acquisition, analysis, or interpretation of data: De Santis V., Corona A., Singer M. Drafting of the manuscript: De Santis V., Corona A., Nencini C., Singer M.

Critical revision of the manuscript for important intellectual content: Singer M., Nencini C., Vitale D. Statistical analysis: Corona A. Administrative, technical, or material support: All authors.

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