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HEAD AND NECK

Outcomes and survival of tracheostomised patients during the COVID-19 pandemic in a third level hospital

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Abstract

Purpose Analyse the evolution and outcomes of COVID-19 tracheostomised patients. Clarify if this cohort presents an increased risk of haemorrhagic complications and verify the correlation between some risk factors with increased mortality.

Methods A retrospective single-centre observational study of a prospective cohort of all COVID-19 patients admitted to our centre between March and April 2020. A control group was obtained from a historical cohort of patients who required tracheostomy due to prolonged invasive mechanical ventilation (IMV) before 2020.

Results A total of 1768 patients were included: 67 tracheostomised non-COVID-19 patients (historic cohort), 1371 COVID-19 patients that did not require ICU admission, 266 non-tracheostomised COVID-19 patients and 64 tracheostomised COVID-19 patients. Comparing the obesity prevalence, 54.69% of the tracheostomised COVID-19 patients were obese and 10.53% of the non-tracheostomised COVID-19 patients ($p < 0.001$). The median of ICU admission days was lower ($p < 0.001$) in the non-tracheostomised cohort (12.5 days) compared with the COVID-19 tracheostomised cohort (34 days). The incidence of haemorrhagic complications was significantly higher in tracheostomised COVID-19 patients (20.31%) compared with tracheostomised non-COVID-19 patients (5.97%) and presented a higher percentage of obesity, hypertension, diabetes and smoking, significantly different from the historic cohort ($p < 0.001$). A Cox model showed that tracheostomy had no statistically significant effect on mortality in COVID-19 patients.

Conclusion Obesity and smoking may be risk factors for tracheostomy in COVID-19 patients, tracheostomised COVID-19 patients present a higher risk of bleeding complications than those admitted for other reasons and an elevated LDH and INR on ICU admission may be associated with increased mortality.

Keywords Tracheostomy · COVID-19 · Obesity · Smoking · Haemorrhagic complications

Introduction

Coronavirus 2019 (COVID-19) pandemic generated a high impact in the healthcare system all over the world, overloading the hospitals and especially the intensive care units (ICUs).

Most of the cases of pneumonia produced by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) presented acute severe respiratory failure that required a prolonged invasive mechanical ventilation (IMV) and the performance of a tracheostomy.

Due to the SARS-CoV-2 transmission characteristics, the airway manipulation involves an aerosol generation, implying a risk of viral infection to health care staff.

At the beginning of the pandemic, these facts posed a dilemma in the management and the performance of a tracheostomy in these patients: should we act as always and perform early tracheostomy or should we avoid, if possible, the aerosol-generating procedures? [1].

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According to the limited data available at that time, our department and the ICUs developed a protocol in February 2020 to perform elective tracheostomies in those COVID-19 patients who required prolonged IMV.

According to our protocol, the tracheostomies would be surgical, performed by otolaryngology staff equipped with personal protective equipment (PPE) by bedside approach in the patient's room, following the global guidelines recommendations [2–6].

During this pandemic, several studies have been published describing some risk factors that may be associated with increased mortality in COVID-19 patients, such as previous heart disease, lactate dehydrogenase (LDH) levels, age [7], obesity [8] and smoking [9].

This study aims to review the evolution and outcomes of these COVID-19 tracheostomised patients in a third-level university hospital. The secondary aim is to study if these patients have a higher risk of clinically relevant surgical complications than patients tracheostomised for other reasons.

Materials and methods

Retrospective single-centre observational study of a prospective cohort of all COVID-19 tracheostomised patients between March and April 2020.

A control group was obtained from a historical cohort of respiratory patients who required surgical tracheostomy due to prolonged IMV admitted in ICU before 2020 in our centre.

Hypothesis

- Tracheostomised COVID-19 patients presented a higher mortality rate than tracheostomised patients for other causes.
- Tracheostomised COVID-19 patients presented a higher risk of surgical complications of the tracheostomy than tracheostomised patients for other causes.
- Tracheostomised COVID-19 patients with one or more risk factors (obesity, smoking, heart disease, LDH $\geq$ 345 IU/L at admission, age $\geq$ 65 years) presented a higher mortality rate than those patients who did not present these factors.

Objectives

- Study which factors can impact the survival and development of complications in tracheostomised COVID-19 patients.
- Compare the mortality of the cohort of the tracheostomized COVID-19 patients with the historic cohort and study the related risk factors.
- Compare the surgical complications rate between both cohorts.
- Review the meantime of ICU admission in tracheostomized COVID-19 patients.
- Review the meantime between IMV and decannulation in tracheostomized COVID-19 patients.

Setting/tracheostomy performance protocol during COVID-19 pandemic in our centre

When ICU specialists decided that a patient requiring prolonged IMV needed a tracheostomy, they communicated it to the Otolaryngology Department. It was taken into account the patient's clinical condition, prognosis, evolution and weaning progression.

A protocol for COVID-19 tracheostomies was established. We would wait at least 10 days after IMV. It would be performed in the patient's room by bedside approach, equipped with personal protective equipment (PPE) and following the global guidelines recommendations [2–4, 11]. All tracheostomies will be surgical and subthyroid if possible. The use of electrocautery, in conjunction with a smoke evacuator, was considered to be appropriate because, although it has been shown to create aerosols, it allowed a reduction in operative and exposure time [12, 13].

Study variables

- The patient's following variables were collected from medical records:
- Demographics: age, gender
- Background: smoking, comorbidities, anthropomorphic data
- First day of symptoms
- Incoming date
- IMV date
- Outcoming date
- Tracheostomy date
- Evolution and complications
- Decannulation time
- Laboratory test data

Follow-up

The follow-up of the COVID-19 tracheostomised patient cohort was performed between February 2020 until March 2021, a total of thirteen months.

Statistical analysis

According to variable type, a descriptive baseline analysis has been done: for continuous variables, through mean,

standard deviation, median and interquartile range (IQR); for categorical variables, through the number of observations and total percentages.

Hypothesis tests were applied: T-test for means comparison, Wilcoxon–Mann–Whitney *U* test for medians comparison, Chi-squared test for the association between categorical variables.

Statistical significance applied on hypothesis tests has been fixed at a level of 5%.

Survival analysis methods have been used to compare days of hospitalisation until death, between different groups of patients: COVID-19 ICU patients and COVID-19 non-critical patients, COVID-19 tracheostomised patients and COVID-19 non-tracheostomised patients, and tracheostomised COVID-19 patients and a historical cohort of non-COVID-19 tracheostomised patients.

For patients who were admitted to ICU after a period of immortal time (non-ICU exposure) and patients who undergone a tracheostomy after a period of immortal time (non-TQT exposure), the immortal time bias has been controlled when describing the number of days from hospital admission to death with non-parametric Kaplan–Meier function and when estimating the effect of ICU admission, tracheostomy undergone and COVID-19 on time until death with Cox model regression, adjusting by potential prognostic factors: age, sex, obesity, smoke, LDH ≥ 345 and cardiac insufficiency.

To analyse associated factors to death, between groups, logistic regression analysis has been done, adjusting by variables Age and Sex.

The data management and data analysis were done through R-free software, using 3.6.3 version.

Results

Between February and April 2020, a total of 1701 patients diagnosed with Sars-CoV-2 infection were admitted to our centre. Of these, 19.4% ($n=330$) required admission to ICU and intubation for VMI. Surgical tracheostomy was performed by the Otolaryngology Department in 19.4% ($n=64$) of ICU patients, a 3.75% of the total of hospitalised COVID-19 patients (Fig. 1).

We also obtained a historical cohort of 67 patients who underwent surgical tracheostomy by the Otolaryngology Department at our centre between 2017 and 2019 to compare it with the cohort of patients tracheostomised during the 2020 pandemic. We decided to include only surgical tracheostomies and not percutaneous tracheostomies so that the groups would be as homogeneous as possible.

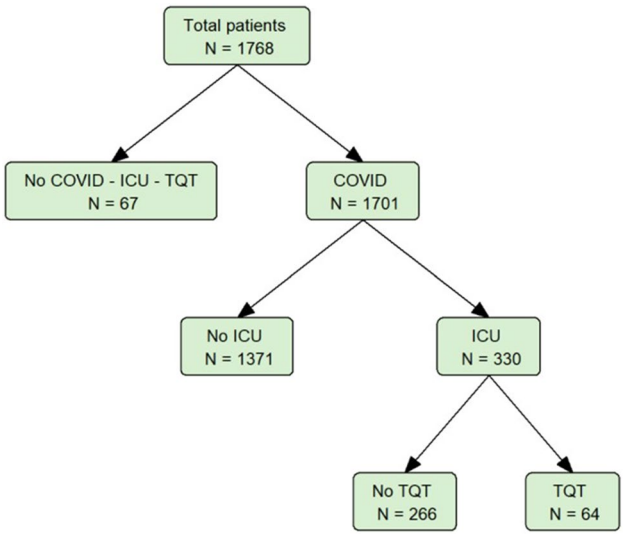

Fig. 1 Study flow chart

Tracheostomised COVID-19 patients cohort

A total of 64 tracheostomies were performed in COVID-19 patients admitted to the ICU. A 70.3% ($n=45$) of these patients were male. The mean age of the operated patients was 62.55 years (SD 9.4). An 87.5% presented some comorbidities ($n=56$) and a 54.7% ($n=35$) of the patients had a BMI greater than 30. All patients were receiving anticoagulation therapy at the time of tracheostomy.

The median of intubation days before tracheostomy was 13 days (interquartile range 11; 18). Patients required mechanical ventilation for a median of 32.5 days (25; 42). Tracheostomy tubes were required for a median of 33.5 days (28.75; 51), excluding those patients who died during admission. The median length of stay was 53 days [35; 75.25].

The group was divided into two groups: early (performed before 11 days of IMV) and late tracheostomies [14]. After analysis, it was determined that no statistically significant differences were found in survival between both groups (Log-rank test p-value was 0.78) (Table 1; Fig. 2).

Ventilatory, inflammatory and coagulation parameters of these patients were determined at the moment of tracheostomy. The following table describes the median of the analysed parameters. The PEEP Positive End-Expiratory Pressure (PEEP) value on day 7 of ICU admission, inflammatory parameter values as DDimer, Ferritin, Lactate Dehydrogenase (LDH), leukocytosis, lymphocytosis, C-Reactive Protein (PCR) and International Normalised Ratio (INR) values were included (Table 2).

According to statistical analysis, it was determined that LDH and INR were related to mortality. Higher LDH and INR values lead to higher mortality. A unit increase in LDH increases the risk of mortality by 47% ($p=0.005$). A

Table 1 Survival analysis of COVID-19 tracheostomised patient cohort, comparing early and late tracheostomies

	[ALL] *N* = 64	Early TQT *N* = 14	Lately TQT *N* = 50	OR	*P*. overall	*N*
Exitus, N (%):					0.716	64
No	37 (57.8%)	7 (50.0%)	30 (60.0%)	Ref		
Yes	27 (42.2%)	7 (50.0%)	20 (40.0%)	0.67 [0.20;2.29]		
Days from TQT to exitus, median [Q1;Q3]	11.0 [6.00;21.5]	13.0 [7.50;30.5]	10.0 [4.75;17.5]	0.98 [0.95;1.01]	0.346	27

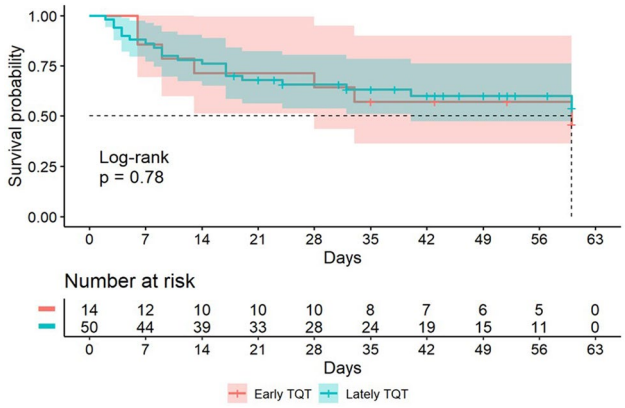

Fig. 2 Kaplan–Meier estimator according to tracheostomy moment

Table 2 Descriptive analysis of laboratory parameters

Laboratory parameter	Median [25%; 75%]
PEEP7 (MMHG)	10 [10; 12]
DDIMER (MG/L)	1127.5 [484; 2954.25]
Ferritina (MG/L)	1671.3 [1017; 2294]
LDH (U/L)	480.5 [383.25; 600.75]
LEUKOCYTES (X10^9/*L*)	10.1 [7.25; 13.83]
Lymphocytes (%)	5.95 [3.6; 8.22]
PCR (MG/L)	139.5 [64.25; 247.43]
INR	1.21 [1.09; 1.36]

unit increase in INR increases the risk of mortality by 52% ($p = 0.012$) (Table 3).

Complications in these patients were counted and divided into intraoperative and postoperative complications. A 37.5% ($n = 24$) of these patients presented some complications. A 20.31% ($n = 13$) of COVID-19 tracheostomised patients presented haemorrhagic complications (taking into account that one patient presented this type of complication during and after the procedure).

The relationship between laboratory parameters and complications was analysed and none of the inflammatory parameters were found to be related to haemorrhagic complications.

A 42.2% ($n = 27$) of COVID-19 patients tracheostomised died, with 25% of events occurring within 6 days since the tracheostomy.

This Kaplan-Meyer graph shows how the probability of death is higher during the first 20 days after tracheostomy and then stabilises (Fig. 3). In the first 30 days, 27 patients were censored or died. Censure refers to those patients who were discharged and are represented in the graph as vertical stripes.

During the follow-up of the surviving patients, a case of probable post-COVID-19 sudden hearing loss and a case of subglottic stenosis were detected.

Comparison with the historical cohort

A historical cohort of 67 patients who underwent surgical tracheostomy before 2020 was obtained.

The incidence of haemorrhagic complications was analysed.

In the historical cohort, only 5.97% ($n = 4$) of the total patients presented haemorrhagic complications. These data were compared with the 20.31% ($n = 13$) of COVID-19 tracheostomised patients who had haemorrhagic intraoperative and postoperative complications (Table 4). Statistically significant differences were found between both groups (p-value was 0.029). This could be explained by the fact that all patients in the COVID-19 tracheostomised cohort were receiving anticoagulation treatment.

The incidence of haemorrhagic complications was not associated with increased mortality of the affected patients (Table 5).

The survival of both groups was also compared and a log-rank test was performed with a p-value of 0.47, so the hypothesis that the survival curve is equal in both groups cannot be rejected (Fig. 4).

The median number of days in hospital was 55 days [37, 77.5]. No statistically significant differences were observed in the distribution of days in hospital between both groups.

Patients in the COVID-19 group presented a higher percentage of obesity, hypertension, diabetes and smoking, statistically significantly different from the NON-COVID-19 group ($p < 0.001$).

Table 3 INR and DDimer proportional hazards evaluation

	Days from TQT to exitus			Days from TQT to exitus		
	HR	CI	*p*	HR	CI	*p*
INR	1.52	[1.1–2.11]	0.011	1.63	[1.16–2.29]	0.005
Age				1.02	[0.97–1.07]	0.417
Sex [Male]				2.18	[0.82–5.77]	0.116
Number of observations	64			64		
	Days from TQT to exitus			Days from TQT to exitus		
	HR	CI	*p*	HR	CI	*p*
LDH	1.47	[1.04–2.06]	0.027	1.59	[1.11–2.29]	0.012
Age				1.04	[0.98–1.09]	0.18
Sex [Male]				1.99	[0.79–5.02]	0.144
Number of observations	64			64		

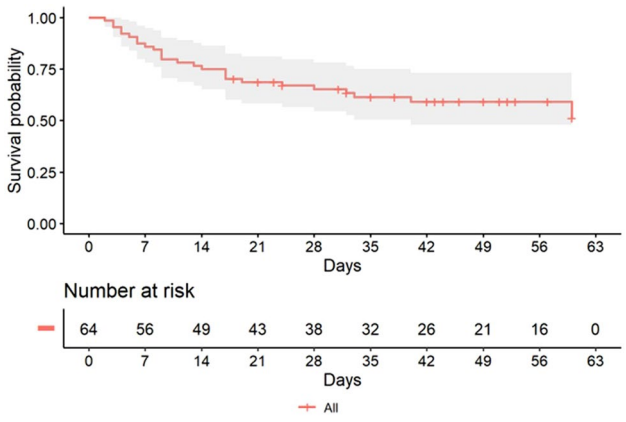

Fig. 3 Kaplan–Meier survival estimator of COVID-19 tracheostomised patients survival

Table 4 Complication rate comparing COVID-19 tracheostomised patients and non-COVID-19 tracheostomised patients

	COVID-ICU-TQT N = 64	Non-COVID TQT N = 67	*P* value
Bleeding complications, *N* (%):			0.029
No	51 (79.69%)	63 (94.03%)	
Yes	13 (20.31%)	4 (5.97%)	

Comparison between tracheostomised and non-tracheostomised COVID-19 patients

Mortality and survival were compared between both groups of COVID-19 patients, those who were admitted to the ICU and underwent tracheostomy ($n = 64$) and those who did not ($n = 266$).

Mortality was similar between both groups, without significant differences.

A Cox model showed that age had a statistically significant effect on mortality, with a one-unit increase in age implying a 6% increase in the risk of dying.

Both groups showed statistically significant differences in the percentage of obese patients. A 54.69% of the tracheostomised COVID-19 patients were obese compared with 10.53% of the non-tracheostomised COVID-19 patients ($p < 0.001$).

The distribution of ICU days was significantly different between both groups ($p < 0.001$). The median of days in ICU in the non-tracheostomised group was 12.5 [8, 18.75] whereas, the median in the tracheostomised group was 34 [16.25, 54].

A Cox model showed that tracheostomy has no statistically significant effect on mortality.

Risk factors for COVID-19 mortality in tracheostomised patients

We can affirm that, in our cohort of tracheostomised COVID-19 patients, LDH and INR were related to mortality. Higher LDH and INR values lead to higher mortality. A one-unit increase in LDH increases the risk of mortality by 47%. A one-unit increase in INR increases the risk of mortality by 52%.

Obesity, PEEP7, other inflammatory parameters at the time of tracheostomy (DDimer, Ferritin, leukocytosis, lymphocytosis, Protein C-Reactive), heart disease, diabetes, hypertension and smoking were not risk factors for mortality in these patients.

None of the inflammatory parameters were related to the increased risk of haemorrhagic complications.

Table 5 Mortality rate comparison between complicated and non-complicated patients

	Without bleeding complications	With bleeding complications	or	*P* value	*N*
	N = *114*	*N* = *17*			
Exitus				0.638	131
No	71 (62.3%)	9 (52.9%)	Ref		
Yes	43 (37.7%)	8 (47.1%)	1.47 [0.51;4.18]		
Days from TQT to exitus	20.2 (22.4)	32.6 (31.3)	1.02 [0.99;1.04]	0.314	51

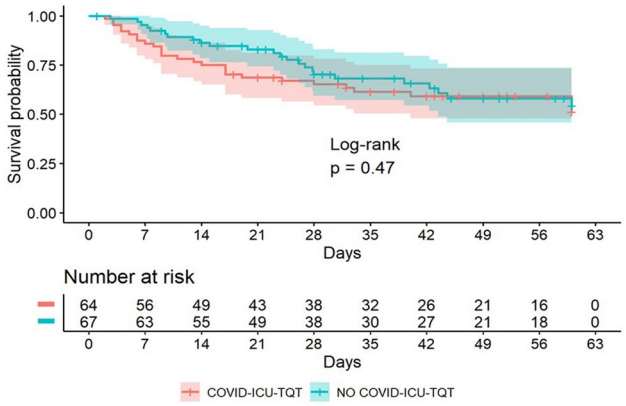

Fig. 4 Kaplan–Meier survival estimator of COVID-19 tracheostomised patients survival compared to an historic cohort

Risk factors of tracheostomy in COVID-19 patients

We decided to carry out an analysis to determine which factors could influence the performance of tracheostomy in COVID-19 patients. Obesity, smoking and heart failure were analysed. The results showed that smoking (odds ratio 2.68) and obesity (odds ratio 10.87) do have a statistically significant relationship with the performance of tracheostomy, so we can affirm that they are risk factors for the performance of tracheostomy in our cohort of COVID-19 patients (Table 6).

Discussion

The performance of tracheostomy in patients requiring prolonged IMV is widely used. In COVID-19 patients there are strong recommendations about how to proceed but the timing of the tracheostomy remains controversial. Some articles suggest avoiding the tracheostomy if possible [15] or wait until the prognosis is clear, between 14 to 20 days intubation [2, 3, 11, 16, 17], whereas, others suggest that an early tracheostomy may reduce de hospitalisation and ventilation time [14, 18]. All authors agree that the decision for tracheostomy needs to be made through a multidisciplinary evaluation considering the clinical situation of every patient [1, 2, 14, 19, 20].

This study describes a large cohort of tracheostomised patients with COVID-19 in Spain and, to the best of our knowledge, is the first to analyse the risk factors associated with tracheostomy and compare these patients with a historic cohort.

The rate of tracheostomies in ICU COVID-19 patients (19.4%) was similar to that reported in other large cohort studies [14, 20].

The mortality of tracheostomised COVID-19 patients in our cohort was 42%, higher than those described in other studies, such as Volo et al. that observed a mortality rate of 18% [21] or Martin-Villarés et al. that described a mortality rate of 23.7% [20], but we have to take into account that our follow-up was 9 months longer than these studies, a total of thirteen months.

Comparing both groups of COVID-19 patients, tracheostomised and non-tracheostomised, we cannot confirm that tracheostomy was related to mortality.

Length of stay in ICU was longer in tracheostomised COVID-19 patients in our cohort.

This study describes times of intubation days before tracheostomy (median 13 days (11;18)), days of mechanical ventilation (median 32.5 days (25;42)), time to decannulation (median 33.5 days (28.75;51)) and length of stay in hospital (median 53 days (35;75.25)) comparable with results described by Kwak et al. [22].

No statistically significant differences in survival were found between early and late tracheostomised COVID-19 patients.

The incidence of haemorrhagic complications was higher in the tracheostomised COVID-19 patients (20.3%) compared with the historic cohort (5.97%). The incidence of this complication in the bibliography is variable. Chao et al. described only a case of haemorrhagic complication (1.88%) [23], Avilés et al. described this complication in 12% of the tracheostomised COVID-19 patients [14] and Angel et al. described an incidence of 5.1% in a cohort of percutaneous tracheostomised COVID-19 patients [24].

Elderly, male gender and elevation of LDH levels were found to be risk factors of mortality in COVID-19 patients.

Table 6 Factors associated with tracheostomy performance

Obesity descriptive table according to tracheostomy								
	No	Yes		OR		*p*. overall		N
	N = 266	*N* = 64						
Obesity						< 0.001		330
No	238 (89.5%)	29 (45.3%)		Ref				
Yes	28 (10.5%)	35 (54.7%)		10.1 [5.43;19.3]				
	Tracheostomy				Tracheostomy			
Predictors	Odds ratios	Std. error	CI	*p*	Odds ratios	Std. error	CI	*p*
(Intercept)	0.12	0.02	0.08 – 0.18	< 0.001	0.05	0.04	0.01 – 0.29	0.002
Obesity [Yes]	10.26	3.29	5.52 – 19.47	< 0.001	10.87	3.58	5.76 – 21.05	< 0.001
Age					1.01	0.01	0.99 – 1.04	0.315
Sex [male]					1.10	0.38	0.57 – 2.22	0.777
Observations	330	330						
R^2 TJUR	0.197	0.202						
AIC	274.044	276.943						
Smoke descriptive table according to tracheostomy:								
	No	Yes	OR		*p*. overall	N		
	N = 266	*N* = 64						
Smoke:					0.003	330		
No	212 (79.7%)	39 (60.9%)	Ref					
Yes	54 (20.3%)	25 (39.1%)	2.51 [1.39;4.50]					
	Tracheostomy				Tracheostomy			
Predictors	Odds ratios	Std. error	CI	*p*	Odds ratios	Std. error	CI	*p*
(Intercept)	0.18	0.03	0.13 – 0.26	**< 0.001**	0.23	0.19	0.04 – 1.11	0.077
Smoke [Yes]	2.52	0.75	1.39 – 4.50	**0.002**	2.68	0.82	1.46 – 4.90	**0.001**
Age					1.00	0.01	0.98 – 1.02	0.971
Sex [Male]					0.72	0.23	0.39 – 1.37	0.310
Observations	330	330						
R^2 TJUR	0.030	0.033						
AIC	319.446	322.433						

In the multivariate analysis of our study, we found a positive association between mortality and levels of LDH and INR in COVID-19 tracheostomised patients. The association between high levels of LDH and worse prognosis in COVID-19 patients was described by Martos et al. [7].

Furthermore, obesity and smoking were significant risk factors predictive of tracheostomy performance in COVID-19 patients. Hur et al. described that obese patients are at higher risk for prolonged intubation [25], a fact that is consistent with the results of the present study.

Strengths and limitations

Our study presents several limitations. First, our study might have selection bias because it was a retrospective single-centre study. Second, it was not possible to carry out an analysis and comparison with percutaneous tracheostomies in that period because all the tracheostomies were surgical and bedside. Finally, it might be a bias in the comparison between the COVID-19 tracheostomised

patient's cohort and the historical cohort, because the conditions and protocol to perform COVID-19 patients were different.

The strengths of our study are the long follow-up of the COVID-19 tracheostomised patient's cohort and the comparison of this cohort with a historical cohort of tracheostomised patients before 2020.

Conclusions

According to the present study, elevated LDH and INR levels may be associated with increased mortality.

Obesity and smoking seem to be risk factors of tracheostomy in COVID-19 patients.

Although the risk of haemorrhagic complications is higher in COVID-19 patients, they do not seem to influence the survival of these patients.

Tracheostomy does not increase the survival in COVID-19 patients and does not reduce ICU stay in comparison with non-tracheostomised patients, so we should not rush the indication of tracheostomy and always perform it in an appropriate manner and take into account the risks that it may entail.

Further studies are required to evaluate the outcome of the tracheostomised COVID-19 patient's cohort and determine which risk factors worldwide clinicians need to take into account before performing a tracheotomy, considering the estimated survival of these patients, in a pandemic situation with limited health resources like the one we experienced in 2020.

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Availability of data and material Not applicable.

Code availability The data management and data analysis were done through R-free software, using 3.6.3 version.

Declarations

Conflicts of interest The authors declare no conflicts of interest.

Ethics approval All the data were compiled in a database where the anonymity of the patients was preserved without recording any data that could lead to their identification. Only the researchers had a list containing the number of the patient's history with restricted access. The study complied with the ethical guidelines of the Declaration of Helsinki [10] and was revised and approved by the Hospital Universitari de Bellvitge Ethics Committee (PR371/20). Given the retrospective nature of the present study, the fact that no personal data were available and could not have any impact on the evolution nor treatment of the patients, it was not considered necessary to obtain informed consent.

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