


Surgical Tracheostomies in COVID-19 Patients: Indications, Technique, and Results in a Second-Level Spanish Hospital

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Abstract

Objective. The main purpose of this work is to describe the sociodemographic and clinical characteristics of intensive care unit (ICU) patients in a second-level hospital in Madrid, Spain, focusing in those who underwent surgical tracheostomy during the coronavirus disease 2019 (COVID-19) pandemic. The surgical technique and associated complications are also detailed.

Study Design. Observational and historical cohort.

Setting. Single center.

Methods. Eighty-three intubated COVID-19 patients were analyzed. Thirty bedside surgical tracheostomies had been performed following our safety protocol.

Results. Data from 83 patients admitted to the ICU in Infanta Leonor University Hospital were collected; 74.7% were male. The average age was 59.7 years. The main comorbidities found were hypertension in 51.8%, diabetes mellitus in 25.3%, asthma in 7.2%, and chronic obstructive pulmonary disease in 3.6%. A surgical tracheostomy was carried out in 36.1% of patients who needed a prolonged intubation. The most frequent complication of the surgical procedure, bleeding, occurred in 30%, but the majority were mild and ceased with compression only. The most relevant complication was local infection, which occurred in 26.7% of patients. There were statistically significant differences in the time from the beginning of mechanical ventilation until weaning between tracheostomized and nontracheostomized patients. The mortality rate of patients who underwent tracheostomy was 56.7%. Despite severe acute respiratory syndrome coronavirus 2 being highly contagious and tracheostomy

being considered a high-risk procedure, our rate of infected ear, nose, and throat specialists was only 11.8%.

Conclusion. In our experience, bedside surgical tracheostomy is a safe procedure in COVID-19 patients when safety protocols are followed.

Keywords

COVID-19, SARS-CoV-2, coronavirus disease, surgical tracheostomy, intensive care unit, ICU, intubation

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Introduction

COVID in Context

Coronavirus disease 2019 (COVID-19), caused by a highly contagious virus (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]) was first identified in Wuhan, China, in December 2019¹ but has rapidly spread all over the world, being declared a pandemic by the World Health Organization (WHO) in March 2020.² It is causing a huge medical and socioeconomic impact worldwide.

Clinical presentation, severity, and mortality vary according to published series. In China, in a big series of 44,672 patients, 81% were reported as experiencing mild disease, 14% had severe disease, and 5% needed critical care.³ In other series in China, the percentage of patients requiring critical care ranged from 9.8% to 15%,^{3,4} while in Italy, the intensive care unit (ICU) admission rates went up to 12%.^{5,6} The largest study published to date in Europe and carried out in La Paz University Hospital, Spain, reported an ICU admission rate of 3.4%. The mortality rate in this study among hospitalized patients was 20.7%.⁷

Role of Tracheostomy in Intubated Patients

Tracheostomy is one of the most common procedures performed in critical patients. It is mainly indicated in patients undergoing prolonged intubation as it favors oral hygiene and management of respiratory secretions. It also allows decreasing the level of relaxation and sedation drugs,⁸ favoring weaning of mechanical ventilation, and reducing the average stay in the ICU in about 10 days.⁹ Moreover, prolonged intubation is a risk factor for development of subglottic stenosis, laryngeal granulomas, and dysphonia.¹⁰

Tracheostomies in COVID-19 Patients: What Do We Know?

The American Academy of Otolaryngology–Head and Neck Surgery does not recommend performing tracheostomies in COVID-19 patients before 25 days of intubation.⁸ The main reasons are the lack of evidence in these patients regarding the benefit of early tracheostomy in contrast with the possible complications and the potential high risk of infection in health workers involved in the technique.

These recommendations are based on severe acute respiratory syndrome coronavirus 1 (SARS-CoV-1) experience. The time from the beginning of symptoms to death was 27 days, so the benefits of tracheostomy were very low.¹¹ In SARS-CoV-1, the need for mechanical ventilation was associated with a 46% mortality.¹²

A Chinese study performed in Wuhan states that 67% of the 201 patients who required orotracheal intubation died.¹³ Thus, identifying the role of tracheostomy in COVID-19 patients remains a challenge, especially the role of early tracheostomy. Given the lack of information on this topic, all available knowledge should be shared to improve decision making and patient management.

Study Goals

The main goals of this work are describing the sociodemographic and clinical characteristics of ICU patients in Infanta Leonor University Hospital in Madrid, highlighting those who required tracheostomy, and detailing the surgical technique as well as the advantages, disadvantages, and complications during surgery and in the postoperative time.

Material and Methods

Patients and Study Design

This is an observational and historical cohort study. To carry out this work, we considered the 83 patients admitted to the ICU of the Infanta Leonor University Hospital in Madrid between March 5 and May 15, 2020. Patients admitted to the ICU without positive polymerase chain reaction (PCR) for SARS-CoV-2 were excluded from the study, as well as PCR-positive patients who had to be transferred to other hospitals due to the huge health care burden and those who were admitted to the ICU but did not need endotracheal intubation.

Data Collection and Analysis

Data were collected from electronic health records. The information was treated confidentially, with protection and anonymity.

A descriptive and comparative analysis of the sample was carried out based on the development of the different complications associated with tracheostomies. Continuous variables are presented as mean and standard deviation. Categorical variables are expressed as absolute and relative frequencies. The statistical significance of the comparison of proportions was determined using the χ^2 test or Fisher exact test for contingency tables. The statistical significance of the comparison of continuous variables was established using the Student *t* test. Statistical significance was considered for $P < .05$. Statistical analysis was performed using IBM SPSS Statistics 24 software (SPSS, Inc).

Ethical Considerations

Our work has been approved by the Ethical Committee of Infanta Leonor University Hospital in Madrid. Since it was an observational and historical cohort study in which patients did not receive a specific intervention when they were included in it, informed consent was not obtained. The ethical committee approved our study and the exemption from informed consent.

To respect confidentiality and preserve anonymity, each patient was coded and researchers were kept blinded during data analysis.

Surgical Technique

All surgeries were bedside tracheostomies in the ICU. Surgeons always used the correct personal protective equipment (PPE)¹⁴ with modified full-face snorkeling masks with antiviral filters and a microphone, 3 pairs of gloves, and a waterproof gown.

Table 1. Sociodemographic Characteristics and Main Comorbidities.

Variable	Total ICU patients (n = 83)	Nontracheostomized patients (n = 53)	Tracheostomized patients (n = 30)	P value
Age, mean (SD), y	59.6 (11.931)	59.04 (13.556)	60.8 (8.427)	.47
Sex, No. (%)				
Male	62 (74.7)	40 (75.5)	22 (73.3)	.83
Female	21 (25.3)	13 (24.5)	8 (26.7)	
Nationality, No. (%)				
Spanish	58 (69.9)	38 (71.7)	20 (66.7)	.79
Other Europeans	2 (2.4)	1 (1.9)	1 (3.3)	
Latin American	22 (26.5)	13 (24.5)	9 (30)	
African	1 (1.2)	1 (1.9)	0 (0)	
Comorbidities, at least 1, No. (%)	66 (79)	41 (77.4)	25 (83.3)	.51
Arterial hypertension	43 (51.8)	28 (52.8)	15 (50)	.80
Diabetes mellitus	21 (25.3)	14 (26.4)	7 (23.3)	.75
Dyslipidemia	45 (54.2)	30 (56.6)	15 (50)	.56
OSA	10 (12)	7 (13.2)	3 (10)	.66
Asthma	6 (7.2)	3 (5.7)	3 (10)	.46
COPD	3 (3.6)	3 (5.7)	0 (0)	.18

Abbreviations: COPD, chronic obstructive pulmonary disease; ICU, intensive care unit; OSA, obstructive sleep apnea.

Low molecular weight heparin was discontinued the previous day.

Prior to the procedure, the cuff was inflated slightly over the ideal level and adequate preoxygenation was performed. Patients were sufficiently relaxed to avoid coughing or any other movements that could hamper the procedure. The patients lay in a supine position with cervical hyperextension.

Local anesthesia was infiltrated (10 mL lidocaine 2% + 0.1% adrenaline). Using a cold scalpel, an approximately 4-cm-long horizontal skin incision was carried out about 2 cm above the suprasternal notch through the platysma muscle, which was dissected using Metzenbaum scissors. Upper and lower skin flaps were retracted with a Weitlaner retractor. The fascia and strap muscles were separated in the midline using a cold technique and Farabeuf retractors, exposing the thyroid isthmus. The thyroid isthmus was retracted from the trachea, and 2 curved clamps were inserted laterally. It was transected, and both ends were ligated with an absorbable, braided suture.

After exposure of the anterior part of the trachea, mechanical ventilation had to be ceased before proceeding to open the trachea.

Swift tracheostomy was performed on the second tracheal ring by cutting a window with cold scissors. After cutting the window, the trachea was fixed to the lower skin flap with a nonabsorbable, braided suture.

The endotracheal tube was quickly retracted, the nonfenestrated tracheostomy tube inserted, the cuff inflated slightly over the limit, and the tracheostomy tube connected to mechanical ventilation to restart ventilation.

Once mechanical ventilation and hemodynamic stability of the patient were ensured, the incision was closed with an absorbable, braided suture, and hemostatic packing was

placed around the tracheostomy tube. Hemostasis was achieved with compression and eventually bipolar cautery. Electrocautery was avoided whenever possible because it is an aerosol-generating technique that produces small particles that may act as vehicles for the virus.

If suction was required during the procedure, it was performed whenever possible with a closed suction system.

The hemostatic packing and dressings were changed and appropriate skin care was performed daily. Chlorhexidine and a protective skin spray were applied frequently. A silver alginate dressing was placed around the stoma when exudates were present.

Tracheostomy tubes were usually first replaced after 3 weeks according to current guidelines^{8,15}; nonetheless, this timing was adapted to the individual situation of each patient.

Results

Data from the 83 patients admitted to the ICU in Infanta Leonor University Hospital in Madrid from March 5 to May 15, 2020, who met inclusion criteria, were analyzed.

On one hand, general data (sex, age), sociodemographic and clinical characteristics, and main comorbidities of these ICU patients were collected (**Table 1**). The individual situation of each patient was reviewed on May 15, 2020 (**Table 2**). We also calculated the time from beginning of mechanical ventilation with intubation until weaning in survivors (**Table 3**). During the analyzed time, 30 patients had had a surgical tracheostomy performed. On the other hand, post-surgical complications of patients who underwent a tracheostomy were gathered (**Table 4**).

Most of the patients were male (74.7%) with an average age of 59.6 years. There was no age difference between the

Table 2. Situation on May 15, 2020 (Submission Day).

Situation on May 15, 2020	Total ICU patients (n = 83), No. (%)	Nontracheostomized patients (n = 53), No. (%)	Tracheostomized patients (n = 30), No. (%)	P value
Discharged	18 (21.7)	16 (30.2)	2 (6.7)	.001
Still in ICU	8 (9.6)	1 (1.9)	7 (23.3)	
Still in hospitalization ward	7 (8.4)	3 (5.7)	4 (13.3)	
Dead	50 (60.2)	33 (62.3)	17 (56.7)	

Abbreviation: ICU, intensive care unit.

Table 3. Days From Intubation to Weaning.^a

Variable	Survivor on May 15 (n = 26)	Nontracheostomized patients (n = 19)	Tracheostomized patients (n = 7)	P value
From intubation to weaning, d	11.73 ± 11.95	5.68 ± 4.51	28.14 ± 10.19	.001

^aValues are presented as mean ± SD. Survivors who continued with mechanical ventilation were excluded.

Table 4. Postsurgical Complications.

Postsurgical complication	Tracheostomized patients (n = 30), No. (%)
Immediate bleeding, <24 hours	6 (20)
Early and late bleeding, >24 hours	3 (10)
Local infection	8 (26.7)
Mucous plug	1 (3.33)
No complications	12 (40)

group of tracheostomized patients and the nontracheostomized patients. The most common comorbidity was hypertension (HT) in 51.8% of the patients. We performed 30 tracheostomies, which corresponded to 36.1% of the patients. Bleeding in different severity grades was the most common complication in 30%, with mild bleeding the most frequent one.

There was a statistically significant difference in the duration of mechanical ventilation between nontracheostomized and tracheostomized patients ($P = .001$), with nontracheostomized patients having less time on mechanical ventilation.

The mortality rate in the tracheostomized group was 56.7%. Until the submission date of this article, 17 patients had died, 7 had been discharged from the ICU, and 6 are still in the ICU. One of these 6 patients is progressing adequately and will be discharged soon, whereas the other 5 are still in a critical condition and on mechanical ventilation.

Discussion

The COVID-19 pandemic has affected a large number of patients all over the world, with Spain the ninth country with the most infected patients to date.¹⁶ These large numbers of infected patients have completely changed the health

care system in Spain and in many other countries. Most of the hospitals have been transformed into only COVID-19 hospitals, discontinuing the rest of health care activity. New field hospitals have been built in record time in order to hospitalize the large number of infected patients. The effort of health care workers has been amazing. In certain places in Spain, such as the Community of Madrid, it has been necessary to increase the number of available beds, both in the hospitalization wards as well as in the ICUs. Specifically, in the Infanta Leonor University Hospital, a second-level hospital, the care burden has been tremendous. More than 2000 patients infected with COVID-19 have been treated in the emergency department, over 700 patients have been hospitalized, and the number of beds for critically ill patients has tripled.

Data from the 83 patients admitted to the ICU who met the inclusion criteria during the pandemic were analyzed. Thirty surgical tracheostomies were performed by the Department of Otorhinolaryngology–Head and Neck Surgery, corresponding to 36.1% of the ICU patients. As far as we know, this is the largest series published to date.

Taking into account the few published studies, the indication for early tracheostomy in COVID-19 patients is not clear compared to indication for early tracheostomy in other patients who require prolonged intubation. For example, the New York Head and Neck Society recommends performing a tracheostomy only after at least 3 weeks of intubation.¹⁵ In our experience, tracheostomy should be carried out in these critically ill patients with an individualizing approach, considering clinical aspects of each patient and including criteria from intensivists and otorhinolaryngologists.

The main criteria we established for the indication of elective, surgical tracheostomy were patients in whom prolonged intubation (more than 15 days) was expected and bacterial superinfection with increased bronchial secretions. Only 1 was performed in an urgent approach because

endotracheal intubation was not feasible. The average time from intubation until surgery was 10.1 days, ranging from 5 to 15 days.

Regarding the surgical technique, no major complications were observed. Twenty percent of patients presented with immediate postoperative bleeding and 10% had presented with bleeding after 24 hours. Most bleedings were self-limiting and ceased after compression with hemostatic packing. Only 2 patients required revision and bipolar electrocautery.

Postoperative local infections were described in 8 patients (26.7%), a significantly higher rate than the reported infection rate in previous literature, which usually is about 7%.¹⁷ This could be related to the pronation-supination maneuvers that these patients required for ventilatory management. Those maneuvers might have caused more ulcerous skin lesions. Due to the high number of infections, the products used for skin care were changed to 3M Cavilon and silver alginate.

Focusing on sociodemographic and epidemiological factors, no differences between tracheotomy and nontracheotomy patients were found. The average age of COVID-19 patients admitted to the ICU was 59.7 years, and most were male (74.7%). This high number of males could be related to the worse prognosis described for them in recent publications.¹⁸ In our sample, 70% of the patients were Spanish, whereas a strikingly high percentage (26.5%) belonged to Latin American ethnic groups. We could not find any references describing risk factors among Latin American ethnic groups.

Differences in comorbidities between our groups were not found. The most frequent comorbidity in our series was HT, found in 51.8% of patients. This datum is similar to the one reported in Vitoria's hospital in the north of Spain, with a rate of 44% of patients with high blood pressure.¹⁹ The prevalence of diabetes mellitus reached 25.3%, asthma 7.2%, and chronic obstructive pulmonary disease 3.6%. These prevalence rates were lower than the ones reported in literature in other hospitals.¹⁹ In contrast to other published series, 44% of our patients did not present with any comorbidity.²⁰

We observed that the average time from beginning of mechanical ventilation until weaning in patients who had progressed favorably was 11.7 days. The difference between nontracheostomy patients (5.7 days) and tracheotomy patients (28.1 days) was, in this regard, statistically significant ($P = .001$). This evidence highlights the fact that tracheostomies were performed in our hospital mainly in patients in whom a prolonged intubation was foreseen, avoiding the procedure to those patients who were predictably not going to benefit from it, limiting aggressive treatments and unneeded exposure of surgeons and health care workers to infection through aerosol-generating procedures.

Last but not least, there were statistically significant differences between the tracheotomy and the nontracheotomy groups regarding the current situation of the patients at the

end of the follow-up ($P = .001$). There was a higher proportion of discharged home and deceased patients in the nontracheostomized group, whereas in the tracheostomized group, there was a higher proportion of patients still in the hospitalization ward or ICU. This could be explained by the fact that the patients who had not undergone a tracheostomy had progressed very favorably or their condition was so unfavorable that the intervention was not considered appropriate since there would be no benefit in it. In any case, tracheostomized patients progressed in a more uncertain and slower way.²¹

The mortality rate of our intubated, critically ill patients was 60.2%. This figure was 56.7% among tracheostomy patients and 62.4% among nontracheostomy patients. China published similar rates of alarmingly high mortality: 62% and 67%, respectively.²²

We should consider that SARS-CoV-2 is a highly contagious virus that presents a high infection risk among surgeons and health care workers involved in tracheostomies, as they are exposed to high levels of aerosolization. In our center, all the procedures were performed by the same 4 surgeons, all of them experienced otorhinolaryngologists wearing adequate PPE. The rest of the staff was involved with the wound management and general clinical care of the critically ill patients due to the high care burden in the hospital during the pandemic. Some publications have stated that otorhinolaryngologists are one of the health care workers with higher rates of infection.²³ To date, in our department, the infection rate of otorhinolaryngologists is 11.8% (2 of 17).

Performing bedside procedures with PPE in COVID-19 patients increased considerably the difficulty of the technique, causing heat, movement and vision limitation, inconvenient postures, and communication difficulties among professionals. That and avoidance of bipolar electrocautery were some of the obstacles we faced. Some difficulties could be overcome by using adapted full-face snorkeling masks with an antiviral filter and a microphone that allows communication (**Figure 1** and **Figure 2**).

Conclusions

COVID-19 requires an unbelievable effort to be able to attend to thousands of sick patients who need hospital care. Otorhinolaryngologists play an important role during the pandemic by performing surgical tracheostomies. Appropriate use of PPEs can prevent SARS-CoV-2 infection among exposed ear, nose, and throat surgeons and staff. In our experience, tracheostomy is a safe procedure. The risk of complications is low for patients and for professionals involved in the technique. COVID-19 patients under prolonged intubation should undergo a tracheostomy when indicated. More studies are needed to improve the evidence and design more adequate protocols, especially involving timing of tracheostomy.



Figure 1. Adapted full-face snorkeling masks with an antiviral filter.



Figure 2. Surgeon wearing adapted full-face snorkeling mask with an antiviral filter and a microphone that allows communication.

Author Contributions

Alejandro Zuazua-Gonzalez, study design, collected data, data analysis and interpretation, drafting, revised article, final approval, agrees to be accountable for all aspect of work; **Teresa Collazo-Lorduy**, study design, collected data, data analysis and interpretation, drafting, revised article, final approval, agrees to be accountable for all aspect of work; **Guadalupe Coello-Casariago**, study design, collected data, data analysis and interpretation, drafting, revised article, final approval, agrees to be accountable for all aspect of work; **Ana Collazo-Lorduy**, study design, collected data, data analysis and interpretation, drafting, revised article, final approval, agrees to be accountable for all aspect of work; **Elena Leon-Soriano**, study design, collected data, data analysis and interpretation, drafting, revised article, final approval, agrees to be accountable for all aspect of work; **Angel Torralba-Moron**, study design, collected data, data analysis and interpretation, drafting, revised article, final approval, agrees to be accountable for all aspect of work; **Tomas Onrubia-Parra**, study design, collected data, data analysis and interpretation, drafting, revised article, final approval, agrees to be accountable for all aspect of work; **Jose-M Gomez-Martin-Zarco**, study design, collected data, data analysis and interpretation, drafting, revised article, final approval, agrees to be accountable for all aspect of work; **Rosa Echarri-SanMartin**, study design, collected data, data analysis and interpretation, drafting, revised article, final approval, agrees to be accountable for all aspect of work; **Javier Ripolles-Melchor**, study design, collected data, data analysis and interpretation, drafting, revised article, final approval, agrees to be accountable for all aspect of work; **Amalia Martinez-De-la-Gandara**, study design, collected data, data analysis and interpretation, drafting, revised article, final approval, agrees to be accountable for all aspect of work; **Carlos Domingo-Carrasco**, study design, collected data, data analysis and interpretation, drafting, revised article, final approval, agrees to be accountable for all aspect of work.

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