

Outcomes of tracheostomies performed in COVID-19 positive patients at Hospital Central del Estado Chihuahua, Mexico

Resultados de traqueostomías realizadas en pacientes COVID-19 positivos en el Hospital Central del Estado Chihuahua, México

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Abstract

Objective. Provide a description of clinical characteristics, associated factors and outcome of tracheostomies performed in Patients with COVID-19. **Method.** Observational prospective study of 14 patients who underwent tracheostomy. 10 of them were diagnosed with COVID 19, confirmed with RT-PCR test of nasopharyngeal exudate and compatible tomographic findings. **Results.** Of the 10 patients, five were discharged and five died. The average age of the patients who died was 66.6 years; of those who were discharged, it was 60.4 years. Ventilatory parameters cut was taken as $FiO_2 \leq 40\%$ and $PEEP \leq 8$; of the patients discharged, four met both criteria. On the other hand, of the patients who died, neither met both. Of the latter, an average of APACHE II of 16.4 and SOFA 7.4 were documented, while in discharged patients an average of 12.6 and 4.6 were observed, respectively. **Conclusions.** Tracheostomy performed in patients with specific criteria, such as low ventilatory parameters, age, or low score in severity scales, may have a better prognosis.

Keywords: Tracheostomy. COVID-19. Prognosis. PEEP. Oxygen. APACHE.

Resumen

Objetivo. Realizar una descripción de las características clínicas, los factores asociados y el desenlace de las traqueostomías realizadas en pacientes con COVID-19. **Método.** Estudio retrospectivo observacional de 14 pacientes a quienes se realizó traqueostomía. Diez de ellos se encontraban diagnosticados con COVID-19, confirmada con prueba RT-PCR de exudado nasofaríngeo y hallazgos tomográficos compatibles. **Resultados.** De los 10 pacientes, cinco fueron dados de alta y cinco fallecieron. La edad promedio de los pacientes que fallecieron fue de 66.6 años, y la de los que fueron dados de alta fue de 60.4 años. De los parámetros ventilatorios, se tomó como corte una $FiO_2 \leq 40\%$ y una $PEEP \leq 8$; entre los pacientes dados de alta, cuatro cumplían con ambos criterios. En cambio, de los pacientes que fallecieron, ninguno los cumplió. En estos últimos se documentó un promedio de APACHE II de 16.4 y un SOFA de 7.4, mientras que en los pacientes dados de alta se observó un promedio de 12.6 y 4.6, respectivamente. **Conclusiones.** La traqueostomía realizada en pacientes con criterios específicos, como parámetros ventilatorios bajos, edad o puntuación baja en las escalas de gravedad, pueden llegar a tener mejor pronóstico.

Palabras clave: Traqueostomía. COVID-19. Pronóstico. PEEP. Oxígeno. APACHE.

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Introduction

During the current COVID-19 pandemic, the incidence of acute respiratory failure in hospitalized patients has been on the rise¹. It has been reported that 5% to 15% of the patients with COVID-19 develop severe illness that requires mechanical ventilation¹⁻⁶, and that the mortality rate of these patients can be up to a 50%⁷. Therefore, tracheostomy becomes important as it is performed to help the patient tolerate weaning from mechanical ventilation, reduce resistance, dead space, and secretions, as well as to improve mobility, comfort, and oral hygiene^{1,4,7-11}.

There is still no consensus on the timing of tracheostomies, as different studies¹²⁻¹³ have discussed various factors, including: 1) the timing after intubation, with a window of 10 to 21 days considered¹⁴⁻¹⁷, while taking into account that viral load decreases 10 days after symptom onset¹⁸; 2) the clinical characteristics of the patients, such as associated comorbidities; 3) prognosis¹⁹; 4) the risk-benefit ratio^{7,8}; 5) the procedural site; 6) the recommended technique: open with protective measures to minimize viral aerosolization⁹, or percutaneous, which depends on the current budget of the entire health care system².

Tracheostomy is a frequently performed surgical procedure, indicated for patients in the intensive care unit (ICU) on mechanical ventilation^{3,8}. Its primary purpose is to prevent laryngeal damage from prolonged intubation, reduce the course of mechanical ventilation, shorten the ICU stay, and minimize the risk of hospital-acquired infections^{2,19}. Indications for tracheostomy include extended periods of mechanical ventilation (> 14 days)^{8,9}, and preventing complications associated with prolonged intubation (such as subglottic stenosis), airway obstruction such as laryngeal edema, unsuccessful extubation, excessive secretions, or a combination of the above^{1,15}. The ventilators, ICU capacity, and personal protective equipment availability should also be taken into consideration^{2-4,15,16}, since hospitals may face material and personnel shortages⁹. Contraindications may include the patient's advance directive rejecting the procedure, end-of-life status, uncontrolled septic shock, multiple organ dysfunction, and a high mortality risk^{2,9}.

Our center is one of the facilities designated exclusively to take care of patients with COVID-19. Therefore, a preoperative, intraoperative, and postoperative protocol was established based on the experiences of countries with a higher number of tracheostomies²⁰⁻²².

The aim was to standardize indications and reduce the risk of contagion for surgeons and the surgical team.

The primary endpoint of this article is to describe the utility of tracheostomies in patients with COVID-19 at our hospital and their prognosis related to comorbidity, respiratory patterns, and intubation duration. Additionally, it seeks to establish a systematic and specific protocol to perform the procedure in patients with COVID-19, as there is currently no consensus in our country. At the same time, it provides insights into the success and complications of the procedure among the Mexican population, specifically addressing open tracheostomies since our hospital lacks the financial and technological resources to perform percutaneous tracheostomies.

As a secondary endpoint, the article describes whether there were complications associated with the technique used and the infection rate among surgical staff following the established protocol.

Method

This was a retrospective and observational trial was conducted on 14 mechanically ventilated patients who underwent open tracheostomy from April 27 through September 11, 2020, at Hospital Central del Estado de Chihuahua, Mexico. Ten out of these 14 patients had a confirmed diagnosis of COVID-19 through a positive result in the reverse transcriptase-polymerase chain reaction (RT-PCR) test from nasopharyngeal swabs, or compatible findings in the thoracic computed tomography (CT) scans.

An experienced team of surgeons and anesthesiologists was put together to perform the surgical procedures. A specific protocol was developed, and the surgical team received training to minimize exposure and limit viral transmission to the health care workers.

Data were collected by reviewing the electronic health records of the patients who had undergone tracheostomy and with a diagnosis of COVID-19, images and lab test results. The collected baseline characteristics included gender, age, relevant medical history, admission dates, intubation, surgery, and discharge, or death, if applicable. In addition, the Acute Physiology and Chronic Health Evaluation II (APACHE II) and the Sequential Organ Failure Assessment Score (SOFA) scales, as well as preoperative ventilatory parameters (positive end-expiratory pressure [PEEP] and fraction of inspired oxygen [FiO₂]), were collected. These scales and ventilatory parameters were selected for analysis due to their availability and comparability with similar studies worldwide.

All tracheostomies were elective procedures. For the purposes of this study, a “favorable prognosis” means patients who were discharged from the hospital, while an “unfavorable prognosis” indicates patients who ended up dying. The surgical technique used, complications, and follow-up of symptomatic cases among the health care team involved were also analyzed.

Indications

Tracheostomy was performed after assessing the patients and based on the following indications (Table 1): prolonged intubation of, at least, 20 days, hemodynamically stable patients (mean arterial pressure > 70 mmHg, regardless of vasoactive amines), lack of multiple organ failure, availability of surgical equipment and operating room time, and informed consent form duly filled out by a responsible family member.

Technique and procedure

The surgical procedures followed several stages:

- Preparation of the team: a checklist (Table 2) for the procedure and personal protective equipment (level 3) adapted to the available resources of our hospital (Table 3) was considered. It should abide by the global recommendations set forth on personal protection equipment vs COVID-19. Negative pressure and optimal viral filters were used in the operating room. The surgical procedure used an open tracheostomy tray with medium-sized spreaders and electrocautery. Tracheostomy tubes size 7-8, all with balloons, were selected based on the resources available at our center.
- Preparation of the medical staff: a team of surgeons, anesthesiologists, and specialized nursing staff trained and informed on the surgical protocol for contingency purposes was assembled (Table 4).
- Surgical procedure: procedures were performed in an operating room with an in-hospital COVID protocol, involving the minimum essential personnel in the surgical room wearing personal protective equipment (level 3). Sterile gowns and gloves were provided for the surgical team, including circulating personnel, and specific personnel for patient mobilization by placing the patient in a dorsal decubitus position with neck hyperextension.
- Surgical technique: conventional asepsis was applied, and the functionality of the tracheostomy

Table 1. Indications for tracheostomy

Negative COVID-19 RT-PCR test result
Prolonged intubation (> 20 days)
Hemodynamically stable patient (mean arterial pressure > 70 mmHg regardless of vasoactive amines)
No multiple organ failure
Size 7-8 tracheostomy tube with cuff and available surgical time
Consent for the procedure.

Table 2. Surgical procedure checklist

1. Verify with the anesthesiologist that the patient is adequately anesthetized.
2. Make sure that the patient is in the Rose position with arms together at the sides.
3. Verify that the equipment is ready, along with the nursing staff for the surgeon and his/her assistant to enter the operating room. Check for hypochlorite solution and surgical drapes in the field.
4. Are the surgeon and assistant properly dressed and wearing gloves in a proper way?
5. Notify when the drapes and surgical sheets are in place, as per the surgeon's instructions.
6. Is the tracheostomy tube ready, tested, with the syringe in place, the outlet occluded, and a replacement tube at hand?
7. Does the surgeon announce the start of the surgery?
8. Surgeon notifies when the trachea is exposed and ready to be opened.
9. Terminate preoxygenation by anesthesia.
10. Is the patient relaxed?
11. Is ventilation suspended?
12. Does the trachea open?
13. Has the new tracheostomy tube with cuff inflation been inserted?
14. Is the circuit connected, and the hypochlorite compress on the field?
15. Start ventilation by anesthesiology.
16. Provide a hypochlorite compress to the surgeon and assistant.
17. Notify the completion of the procedure and exit of the surgeon and assistant from the operating room.

The list will be announced by the circulating nurse in the operating room while the patient is undergoing the tracheostomy. Should the procedure not follow this order, a stop should be called for the safety of the entire surgical team, and the operating room supervisor should be notified at that exact time.

tube was verified before starting surgery. A vertical 2 cm to 3 cm incision above the sternal notch was performed, followed by dissection through layers until the tracheal rings were reached. At this point,

Table 3. Personal protective equipment used during surgery

Tyvek Suit

Non-sterile disposable gown

Sterile disposable gown

2 pairs of non-sterile nitrile gloves

1 pair of sterile latex gloves

N95 Mask

Goggles

Face shield

Non-sterile boots

Non-sterile caps.

Table 4. Personnel involved in the procedures

General surgeon/Lead surgeon

General surgeon/First assistant

Anesthesiologist/Lead anesthesiologist

Registered nurse/Instrumentalist

Registered nurse/scrub nurse

Registered nurse/External circulating nurse.

the anesthesiology service was instructed to perform preoxygenation before putting the patient in apnea. Once this was achieved, the surgeon opened the trachea between rings II and III, inserted the tracheostomy tube with immediate cuff inflation, and performed glove, gown, and field cleaning with gauzes soaked in 10% chlorine solution. Ventilation was resumed after the surgical field was covered with the gauze.

- Patient verification: the capnographic waveform was checked, the tracheostomy tube was secured to the skin, drapes were removed, surgeons exited, and the patient was moved by specific personnel.

A checklist was verbally reviewed by the circulating nursing staff at all times to minimize any possible technical errors associated with the staff safety (Table 2).

Follow-up

Patients discharged from the hospital were monitored through phone calls for 14 days. Also, symptoms of dyspnea or the need for supplemental oxygen after decannulation were also monitored.

The health care personnel involved in the procedures was monitored to rule out symptoms of fever, cough, dyspnea, and chest pain, and therefore, the possibility of contagion. RT-PCR and CT scans were not performed since no team member developed any suspicious symptoms.

Ethical considerations

The authors declare that regarding this research, no experiments have been conducted on human beings or animals. Protocols on the publication of patient data were followed in full compliance with the General Health Act (*Ley General de Salud*), and authorization was obtained from the center research ethics committee on the use, analysis, and reporting of the obtained information.

Results

During the study period, we had 14 patients, only 10 of whom tested positive for COVID-19 on the RT-PCR and CT scans, therefore, suggestive of disease-related lung damage. Thus, a total of 4 patients were excluded. All patients underwent elective tracheostomy using an open technique.

Demographic and clinical characteristics are shown in table 5.

The patients' mean age was 63.5 years (standard deviation [SD], 10.66). A total of 5 patients, all men, with a mean age of 66.6 years (SD, 10.83), died, while the remaining ones were discharged on a mean age of 60.4 years (SD, 9.52), including 4 women and 1 man. Three of the patients discharged had a diagnosis of systemic arterial hypertension and type 2 diabetes mellitus, 2 had chronic ischemic heart disease, 1 had major depressive disorder, 1 had an ischemic stroke with cerebral edema, and 1 had bacterial pneumonia (unidentified pathogen). Only 1 of these patients had no diagnosed comorbidities.

On the other hand, 2 of the 5 patients who ended up dying had a diagnosis of systemic arterial hypertension, 2 had chronic ischemic heart disease, 2 had superimposed pneumonia (one with *Klebsiella pneumoniae* and the other with *Acinetobacter baumannii*), 1 had type 2 diabetes mellitus, 1 had obesity, and 1 had no comorbidities or overlapping diseases whatsoever.

All patients were intubated and put on mechanical ventilation before undergoing tracheostomy. Two of the patients discharged were intubated on the same day of admission, 2 were intubated the following, and 1 was intubated 32 days after admission. Three of the

Table 5. Patients' demographics and clinical characteristics

Patient	Gender	Age	APACHE II prior to surgery	SOFA prior to surgery	FiO ₂ prior to surgery	PEEP prior to surgery	Days from intubation to tracheostomy	Comorbidity	Days from tracheostomy to discharge, or death	Outcome
1	Woman	51	13	4	40	8	23	None	32	Discharged
2	Woman	53	10	6	35	5	19	Bacterial pneumonia (unrecognized agent)	26	Discharged
3	Man	67	23	10	65	10	22	Bacterial pneumonia due to <i>K. pneumoniae</i>	2	Deceased
4	Woman	60	16	4	55	6	23	SAH, DM2, obesity, ischemic stroke, cerebral edema	28	Discharged
5	Man	80	15	9	60	7	21	SAH, chronic ischemic heart disease	1	Deceased
6	Man	60	11	4	30	4	19	SAH, DM2, chronic ischemic heart disease	20	Discharged
7	Woman	78	13	5	35	6	20	SAH, DM2, chronic ischemic heart disease, major depressive disorder	30	Discharged
8	Man	74	18	5	45	6	20	None	2	Deceased
9	Man	48	14	6	65	7	36	SAH, DM2	22	Deceased
10	Man	64	12	7	65	12	18	DM2, obesity, bacterial pneumonia due to <i>A. baumannii</i>	1	Deceased

APACHE II: Acute Physiology and Chronic Health Evaluation II; DM2: diabetes mellitus type 2; FiO₂: fraction of inspired oxygen; PEEP: positive end-expiratory pressure; SAH: systemic arterial hypertension; SOFA: Sequential Organ Failure Assessment Score.

patients who ended up dying were intubated on the same day of admission, 1 the next day, and two of them 2 days later.

The days elapsed since intubation until tracheostomy were calculated, with a mean of 20.8 days (SD, 1.83). On the other hand, in those patients who ended up dying, the mean was 23.4 days (SD, 1.83).

Regarding ventilatory parameters FiO₂ and PEEP, with a cut-off value of $\leq 40\%$ and ≤ 8 , respectively (as minimum ventilation values), it was found that 4 of the patients discharged met both cut-off criteria, with mean FiO₂ of 35% (SD, 3.5) and a mean PEEP of 5.75 (SD, 1.5). In contrast, none of the patients who ended up dying met both criteria, and only 3 met the PEEP ≤ 8 criterion.

The results of the APACHE II and SOFA scores of the patients 24 hours prior to surgery revealed that patients discharged had mean scores of 12.6 (SD, 2.05) on the APACHE II scale and 4.6 (SD, 0.8) on the SOFA one. For those who died, the means were 16.4 (SD, 3.8) and 7.4 (SD, 1.85) on the APACHE II and SOFA scales, respectively.

Regarding the time elapsed between tracheostomy and the day patients were discharged, the mean was 27.2 days (SD, 4.11). Similarly, the time elapsed between the day of tracheostomy and the day patients died was 5.6 days (SD, 8.21).

Regarding the surgical procedure, none of the patients developed surgical site infections, postoperative bleeding, pneumothorax, or tracheoesophageal fistula. All surgeries were performed in the operating room, and none of the team members listed in table 2 exhibited symptoms of COVID-19 within 14 days after surgery. Maximum efforts were made to minimize the number of personnel inside the operating room, with a maximum of 5 people present at the same time: 1 anesthesiologist, 2 surgeons, 1 scrub nurse, and 1 circulating nurse.

Discussion

The COVID-19 pandemic presented various challenges to the health care community. Regarding the performance of tracheostomies, difficulties arose on the

indications for the procedure and the selection of the patients with COVID-19 and prolonged mechanical ventilation. Currently, there are no predictors of good or poor prognosis associated with the performance or non-performance of the procedure. However, it is known that patients admitted to the ICU requiring mechanical ventilation have a high mortality rate, around 70% to 80%³. Additionally, the procedure is considered an aerosol generator. Therefore, not only the patient's risk-benefit ratio is taken into consideration, but also exposure of the entire surgical team.

To date, there are no standardized clinical guidelines on how to perform tracheostomies in patients with COVID-19. However, several articles have been published with recommendations on patient selection criteria, techniques, materials, and protective equipment, as well as the minimum time required to reduce the patient's viral load and, thereby, the exposure of the health care workers.

Our hospital has faced these challenges by creating protocols and strategies aimed at maximizing patient benefits, and observations have been made regarding the outcomes. This article provides, for the first time, recommendations based on the experience of the staff working at our center.

The timing of tracheostomy in relation to symptom onset has been a matter of discussion. It is essential to consider the maximum benefit for the patient and the point at which the patient is less contagious. Former studies have suggested a reduction in viral transmission 8 days after symptom onset¹⁸, and it is recommended to perform tracheostomies in patients with COVID-19 who have been intubated for over 10 days with the potential for clinical improvement^{4,15,20}. However, other criteria may be considered before the 10-day mark if specific conditions are met^{10,23}. In this study, all patients had been intubated for over 18 days, thus guaranteeing a lower risk of disease transmission to the health care workers involved.

Similarly, studies have shown that patients who undergo tracheostomy have a successful decannulation rate of nearly 52%⁷. In this study, a similar success rate was observed (approximately 50%).

Regarding the time elapsed from intubation to tracheostomy, there is evidence suggesting that patients selected for tracheostomy before 21 days have a better prognosis. However, this needs further investigation, as several factors could influence the outcomes²¹. In our study, the results show a trend which is consistent with the idea that patients who were discharged had shorter intubation periods until tracheostomy

compared to those who passed away. However, several factors may influence the patients' outcomes. Ferri et al.⁸ mention that they did not see a better prognosis in patients with shorter intubation periods. Some studies^{14,24-28} support the notion that patients recover more quickly if tracheostomy is performed before the 21st day of intubation. This also holds true in our study, as 60% of the patients who underwent tracheostomy before day 21 survived, compared to a 40% survival rate in those who underwent tracheostomy after this deadline.

In other aspects related to the management of ventilation, former studies used criteria for tracheostomy, such as minimal ventilation configurations of $\text{FiO}_2 \leq 40\%$ and $\text{PEEP} \leq 8$, 24 hours prior to surgery. This resulted in better outcomes for patients meeting these criteria^{3,29}. In our study, 4 out of the 5 patients who were discharged met these criteria, while none of the patients who passed away did. Although our sample size is small to obtain statistically significant results, data are important because patients who met both criteria had better prognoses, which is clinically relevant.

Other studies mention that considering critical score results could help identify patients with COVID-19 who are too ill to benefit from additional interventional procedures²⁷. In our study, we considered the APACHE II and SOFA scores 24 hours prior to surgery and saw that patients with APACHE II scores ≤ 13 and SOFA score ≤ 6 were the ones who were eventually discharged. There was one exception, a patient who met the SOFA score criteria but had an APACHE II score of 16 and was discharged. The remaining patients who did not meet any of these cut-off values died. Obtaining a more significant sample size would be interesting to determine if these criteria could become significant.

It has also been mentioned that comorbidity negatively impacts prognosis, regardless of intubation or tracheostomy time. Selecting patients with fewer comorbidities is advised to improve prognosis²⁶. In our sample, both good and poor outcomes were seen in patients with comorbidities. Further research is needed to identify the variables that made a difference in these cases.

As mentioned earlier, only open tracheostomies were performed because the hospital lacks the necessary equipment and supplies for the percutaneous technique. Therefore, the techniques could not be compared. However, we should mention that no patient experienced intraoperative or postoperative complications. Following protocols and striving to maintain a closed circuit for the trachea and ventilator has proven

to enhance the safety profile of health care workers^{3,19,22,25,29}. It is obvious that, to obtain better outcomes, the surgeon should choose the most suitable technique with the materials available in their respective centers¹⁵.

All procedures were performed in an operating room with negative pressure and viral filters, as recommended by various authors^{30,31}. Additionally, the patient was left in an apneic state from the time the trachea was opened until the cuff was inflated, after which ventilation was resumed. Some of these recommendations were published from the beginning of the pandemic based on the experience with SARS back in 2003^{17,19,24,32}. By attempting to follow these suggestions, we minimized the personnel present during the procedure while making sure that the necessary personal protective equipment was available (Table 3). Similar to what former studies showed^{21,26,29}, there were no symptomatic infections among the health care workers at our center. Several reports emphasize that, as long as the health care worker correctly uses his/her personal protective equipment, the likelihood of infection is reduced^{9,11,17,21,22,32-35}.

Finally, 3 out of the 5 patients discharged left with a functional tracheostomy. One was decannulated 13 days later, and the other one, 32 days after surgery. After being discharged and at the follow-up, only 1 patient reported mild symptoms and was referred to the hospital for evaluation.

Before concluding, it is essential to consider the limitations and advantages of this study. The most significant limitation is the small sample size ($n = 10$). Conducting a randomized clinical trial associated with the performance of the procedure is not possible for ethical considerations, along with a lack of resources to maintain all patients in optimal conditions during longer intubation periods or to perform tracheostomies earlier. However, this is the first study ever conducted in the current situation of our center and paves the way for further research that can increase the sample size, providing statistically significant information, while considering the criteria mentioned.

Conclusions

Based on the results obtained in this retrospective observational study, we can conclude that tracheostomy performed in patients with specific criteria, such as low ventilatory parameters ($\text{FiO}_2 \leq 40\%$ and $\text{PEEP} \leq 8$), age ≤ 60 years, or APACHE II ≤ 13 and SOFA ≤ 6 , 24 hours prior to surgery, may lead to better outcomes. This is of paramount importance because the goal of

the procedure is to help the patient tolerate weaning from mechanical ventilation, thereby increasing his/her chances of survival. Precisely defining parameters and criteria for treating patients with tracheostomy would reduce mortality and risk for both the patient and the health care personnel involved. Further studies with larger samples are necessary to compare results of the different criteria used, such as intubation time, in addition to those already mentioned.

We cannot determine whether infections occurred among the surgical staff because RT-PCR testing was not conducted on the personnel involved. Nevertheless, the absence of identified infections suggests that the pre- and intraoperative protocol is useful and effective.

This initial experience in our setting regarding tracheostomies in patients with COVID-19 contributes to improving surgical protocols to perform tracheostomies in patients with this disease, enhancing their survival, and safety of the health care personnel involved. It also provides tables with checklists that can serve as references for future procedures in Mexico and other countries.

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Conflicts of interest

None declared.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained approval from the Ethics Committee for analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective observational study.

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