INTRODUCTION

Coronavirus disease 2019 (COVID-19), causing severe acute respiratory syndrome (SARS-CoV-2), has spread rapidly around the world with critical outbreaks in several countries\(^1\). During the stay in the nursing unit of the Intensive Care Units (ICUs), it is important to consider the need for a tracheostomy in a patient with COVID-19, evaluating its risks and benefits\(^2\). The exact timing of tracheostomy in patients with COVID-19 is unclear. The first recommendations given by national and international societies suggest a 14 to 21 days intubation window in order to avoid clinically useless procedures and unnecessary exposure risks for healthcare workers\(^3,\)\(^4\). Therefore, it seems it makes sense to wait until the prognosis is clear before performing a useless procedure for the patient with a high risk of contagion for the staff\(^5\). A report of 21 critically ill patients from Washington state re-
ported that 67% of patients died within 12 to 26 days after infection\textsuperscript{7}. Tracheostomy should only be considered in this group if the endotracheal tube is proving to be insufficient to provide adequate ventilation\textsuperscript{8}. Authors such as Dong et al. stated that the procedure does not increase the benefits in invasive mechanical ventilation for COVID-19 pneumonia; therefore, the procedure is not routinely recommended for patients with severe coronavirus pneumonia\textsuperscript{9}. Elective tracheotomies in this setting can be risky for patients due to severe hypoxemia, and for the healthcare team, due to the high potential for viral transmission during this aerosol-generating procedure\textsuperscript{5,10,11}.

It is clear that tracheostomy allows a more practical mobilization of patients, reduces the incidence of unplanned extubation, reduces the need for administration of sedative drugs, and facilitates attempts of ventilatory weaning. On the other hand, it is known that prolonged intubation can lead to several complications, including tracheomalacia, stenosis, fistulas, and ventilator-associated pneumonia\textsuperscript{6}.

Health workers are especially vulnerable due to their high rate of exposure. Among physicians, otolaryngologists have been identified as the specialists most at risk of contracting COVID-19. The challenge of protecting healthcare workers is compounded by the limited resources of personal protective equipment (PPE) and the limited availability of COVID-19 tests to universally apply and repeat for those patients who require it\textsuperscript{7}. Within the preventive measures, it is suggested to perform the standard technique: intensive hand hygiene with hydro-alcoholic solution, full personal protective equipment (including the N95 mask), the use of double gloves, goggles or eye protection, face shield. Apron, gown, glasses and mask are recommended to care for all suspect or positive patients\textsuperscript{5}.

However, prolonged use can lead to fogging, carbon dioxide retention, especially when combined with a N95 mouth mask, in addition to generating communication problems\textsuperscript{12}. Authors such as Mecham et al. indicate that relative contraindications for tracheostomy from the point of view of anaesthesia include positive pressure at the end of expiration (PEEP) > 18 cmH\textsubscript{2}O, airway pressure > 45 cm and FiO\textsubscript{2} > 80%\textsuperscript{13}.

The estimated incidence of ARDS (acute respiratory distress syndrome) in hospitalized patients with COVID-19 ranges from 17\% to 29\%\textsuperscript{14}. Yang et al. reported that among critically ill patients with COVID-19, non-survivors had a higher rate of development of ARDS (81\% vs. 45\% of survivors) and need for mechanical ventilation (94\% vs. 35\%). In COVID-19 patients who required mechanical ventilation, the mean duration of ventilation was 17 days; however, after 28 days, 81\% of the patients with mechanical ventilation had died\textsuperscript{15}. Therefore, it is very prudent in patients with COVID-19 to make a considerably adequate selection of candidates to perform the surgical procedure.

Variations in the percutaneous versus open surgical technique have not found a significant difference as to which is safer, so it is suggested to be performed according to the faculty and resources of each institution\textsuperscript{16}. However, some authors recommend open over percutaneous tracheostomy due to the lower risk of aerosolization\textsuperscript{17} and others, inversely, recommend percutaneous tracheostomy, as agreed by the French Societies of Anesthesia & Intensive Care Medicine (SFAR) and of Otorhinolaryngology and Head and Neck Surgery (SFORL)\textsuperscript{18}.

Performing the tracheostomy in a conditioned area in the intensive care unit is the most reasonable thing to do, to reduce mobility and spread, or in an operating room with negative pressure. Establishing a specific COVID-19 airway team is essential prior to surgery. It is recommended to minimize or avoid the use of diathermy, bipolar or monopolar. A minimum staffing policy is suggested for each procedure\textsuperscript{19}. Often, a temporary operating room can be established in the ICU, ideally using a negative pressure room. If any of these circumstances is not available, the tracheostomy should be performed in an isolated room (i.e. doors and windows closed). The procedure requires precise planning over time and should be performed on an already intubated and sedated patient, with medication that decrease secretions as anticholinergics and muscle relaxants, in order to decrease the possibility of aerosol formation. Due to the risk-related procedure, the operating room should house only strictly necessary workers (i.e. surgeons, anaesthetists and nurses)\textsuperscript{18}. All team members will receive personal protective equipment\textsuperscript{19}.

**MATERIAL AND METHODS**

**Design and study population**

A prospective, longitudinal, descriptive study was carried out on a series of cases from two hospitals, one in Culiacán, Sinaloa and the other in Cd Obregón, Sonora, belonging to the Northwest region of Mexico. Variables were included, such as age, gender, days of tracheal intubation, risk factors for severe COVID-19, ventilatory parameters before and 72 hours after the procedure (positive pressure at the end of expiration (PEEP), inspiratory oxygen fraction (FiO\textsubscript{2}), oxygen saturation),
some gasometric parameters such as hydrogen potential (pH), partial pressure of carbon dioxide (PCO$_2$), oxygen pressure (PO$_2$), blood levels of bicarbonate (HCO$_3$). These variables were evaluated before and after tracheostomy. In the same way, the PaO$_2$ / FiO$_2$ ratio or Kirby index was calculated to evaluate the degree of severity and mortality.

We also included the number of deaths in our series and the time they were weaned from the ventilator after the tracheostomy. All patients underwent the open tracheostomy technique, under general anaesthesia and local anaesthetic infiltration in the ICU, some in their beds and another in an adapted operating room in the same ICU area. The staff who performed the procedures had the personal protective equipment, as well as the minimum number necessary to perform a safe procedure in the shortest possible time.

**Surgical technique**

All patients were prescribed a tracheostomy that was performed according to the specific recommendations of the Mexican Society of Otorhinolaryngology and Head and Neck Surgery for the performance of tracheostomies in patients infected with SARS-CoV-2. These recommendations can be summarized in the following way: use of appropriate protective measures and personal protective equipment (PPE); avoid the use of electrical or ultrasonic cutting and coagulation systems; complete muscle relaxation of the patient throughout the procedure to avoid coughing and aerosolization; adequate pre-oxygenation of the patient, short-term apnea for passive expiration with open adjustable pressure limiting valve or ventilator disconnection; tracheal incision, orotracheal tube removal, and cannulation of the tracheostomy. Position of the patient with hyperextended neck is necessary to facilitate the procedure. In all cases, attempts were made to place a viral filter on the tracheostomy tube when reconnecting it to the ventilator.

We consider, according to the indications by other authors$^{15,20}$, to establish at least three recommendations for tracheostomy in COVID-19 patients, which include:

1. Oro-tracheal intubation ≥21 days
2. Low ventilation settings (PEEP) <12 cm and FiO$_2$ 40% to 50%
3.Patient with hemodynamic stability without haemorrhagic diathesis or need for vasoressors.

**Statistical analysis**

Descriptive statistics with frequencies and percentages were used for the qualitative variables, for the numerical measures of central tendency as mean and median. The analysis was carried out with the statistical package SPSS version 21 in English.

**RESULTS**

From April to August 2020, approximately 71 patients were admitted to the ICU of the specialty Hospital No. 2, IMSS, Cd Obregón, of which 10 tracheotomies were performed (14%). In the Regional Hospital No 1 of Culiacán, a total of 63 were admitted, of which 4 procedures were performed (6.3%). A total of 134 cases with 14 (10.4%) surgeries were included in the present study.

Of the 14 patients, 13 patients (92.86%) were male and 1 (7.14%) female, with a mean age of 49.21 years (range 30 to 70), 12 with a positive test and 2 negative for COVID-19.

The average of the days and tracheal intubation was 22.7 days (range 16 to 43). Within the risk factors: 4 presented only obesity, 3 obesity and hypertension, 2 only hypertension, 1 obesity and alcoholic cirrhosis, 1 diabetes and hypertension, 1 chronic obstructive pulmonary disease (COPD) and 1 asthma and 1 patient had none (Table 1).

In 6 of the 14 patients, the procedure was performed in bed, 4 in an appropriate ICU operating room and 4 in a standard operating room, following the standard disinfection techniques established for COVID-19.

The average values of the ventilatory parameters recorded before the procedure were PEEP = 7.28 cmH$_2$O, FiO$_2$ = 48.64%, O$_2$ saturation = 94.1%. Evaluating the same parameters after the surgical procedure, we found the following average values: PEEP = 7 cmH$_2$O, FiO$_2$ = 39.64%, O$_2$ saturation = 97.1%. The gasometric parameters before surgery were: pH = 7.39, PCO$_2$ = 43.9 mmHg, PO$_2$ = 77.35 mmHg, HCO$_3$ = 28.2 mEq/l, FiO$_2$ = 7.39%, while afterwards pH = 7.50 PCO$_2$ = 48.5 mmHg, PO$_2$ = 79.8 mmHg, HCO$_3$ = 28.9 mEq/l, FiO$_2$ = 7.47%. When determining the Kirby index mortality by acute respiratory distress syndrome (ARDS) with the Berlin definition, we found 2 mild (27% mortality), 8 moderate (32% mortality) and 4 severe (45% mortality).

Among the early complications, there were 2, a self-limited bleeding with pressure and partial occlusion by traction of the cannula. There were also 3 (21.4%) deaths associated with the underlying pathology.

After the tracheostomy, the average number of days to wean from the ventilator was 5.5 (range from 2 to 17).

Only one doctor developed symptoms of COVID-19 without complications, 2 weeks before starting the procedures. None of the other members had developed contagious symptoms for COVID-19 so far.
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Abbreviations:  F: Female;  M: Male  
Ventilatory Parameters  
COVID-19: Coronavirus disease  
IOT: Intubation  
DM: Diabetis mellitus  
HAS: Arterial hypertension  
OBE S: Obesity  
Gasometry  
PEEP: Positive end-expiratory pressure  
FiO2: Inspiratory oxygen fraction  
PCO2: Carbon dioxide blood pressure  
Pao2/FiO2: Oxygen saturation  
Pao2: Blood pressure of oxygen  
HCO3: Carbon dioxide  
FiO2: Oxygen fraction  

Table 1. Summary of 14 cases of patients operated on for tracheostomy for COVID-19. Source: "Lic. Luis Donaldo Coloso Murieta" Specialty Hospital No 2, IMSS, Cd Obregón, Sonora, and Hospital Regional No 1, Culliacán, Sinaloa.
DISCUSSIONS

Of the 14 patients included in the presented study, 13 patients (92.86%) were male and 1 (7.14%) female, different from what was found by Chong Cui in which 11 of 20 (55%) men and 9 were female. Prabhakaran reported in his study 14 (77.8%) male and 4 (22.2%) female. Our average age was 49.2 years (range 30 to 70), lower than that described by Chong Cui with 63 years (range, 32-72 years) and Prabhakaran, 61.7 years (range, 23–85). The results of the COVID-19 test were 12 positive and 2 negative, different from that reported by Prabhakaran, where all 18 patients were positive.

The average of the tracheal gold intubation days was 22.7 days (range 16 to 43), which proved to be greater than that described by Ferri et al. with an average of 14 (range 7-14), but similar to that recommended by Heyd et al. (more than 21 days). Among the associated risk factors, Cui et al. reported chronic diseases such as diabetes, hypertension and / or coronary artery disease. In our series, obesity prevailed as the most common comorbidity, alone or accompanied by another chronic disease such as diabetes, hypertension or alcoholic cirrhosis, similar to those reported by Prabhakaran. Two patients in the Prabhakaran series did not have any risk factor, similar to what was found in our series with 1 case without risk factors.

Ten (71.43%) tracheostomies were performed in the ICU, 6 (42.86%) in bed and 4 (28.57%) in an adequate ICU operating room. Only in 4 (28.57%) patients the procedure was performed in a standard operating room. The benefits of bedside tracheostomy include avoiding exposure to more healthcare workers during transfer to the operating room. Additionally, bedside tracheostomy may limit potential viral exposure time by decreasing procedure time and more effectively conserving scarce resources compared to tracheostomy in the operating room. Among the early complications, there were 2, a self-limited bleeding with pressure and a partial occlusion due to traction of the cannula. 3 (21.4%) deaths associated with patients’ base condition were reported, similar to Ferri et al. with 25%.

After tracheostomy, the average days to weaning from the ventilator was 5.5 (range 2 to 17). A meta-analysis performed by Koji Hosokawa et al. in critically ill patients not infected by COVID-19 suggest that tracheostomy has been associated with more ventilator-free days and shorter ICU stays. Rumbak et al. in a multicenter clinical study on 120 ICU patients, found that tracheostomy can reduce mortality by half and pneumonia by three-quarters, and there was, on average, a 10-day reduction in the need for ventilatory support. Our results in patients with COVID-19 suggest that tracheostomy facilitates weaning from the ventilator compared to oro-tracheal intubation, similar to the other cases of critically ill non-COVID-19 patients. The exact mechanism by which the tracheostomy produces a clinical improvement in respiratory function and the release of mechanical ventilation is unknown. One explanation can be the fact that the tracheostomy tube offers less resistance than the thermostable endotracheal tube, which can deform in the upper airway. Wright et al. demonstrated that the in vivo resistance of the endotracheal tubes exceeds the in vitro resistance, due to the thermolability of the materials and the tortuous trans-laryngeal trajectory. Sofi et al. describe that the tracheostomy reduces dead space, in comparison with the non-intubated state; even if this difference was small, the authors concluded that “the work of breathing through a tracheostomy tube may be less than through an endotracheal tube of the same internal diameter.”

Under normal circumstances, the larynx represents a small fraction of the total resistance to airflow. However, the transition from the oro-tracheal tube to the tracheostomy tube has a significant impact on the positive end-expiratory pressure (PEEP) and the measurement of respiratory mechanical work (WOB). These observations suggest that it is the reduction in the length of the airways that explains the observed variations.

In theory, tracheostomy should reduce dead space ventilation and improve lung mechanics, thus facilitating weaning from mechanical ventilation. Mohr et al. in an US study found no differences in lung mechanics before and after tracheostomy. Davis et al. suggested that a decreased airway resistance and intrinsic positive end-expiratory pressure (PEEP) play a partial role in releasing the patient.

CONCLUSIONS

The results of our study indicated that the male gender was the most common in our series with 13 cases and obesity was found as the most frequent risk factor. The average days of tracheal gold intubation was 22.7. All of our cases were operated on in the ICU. Among the early complications, there were cases of self-limited bleeding and partial occlusion of the cannula. After the tracheostomy, the average number of days after weaning from the ventilator was 5.5 days.

It is also necessary to emphasize that there were
changes in the mechanics of ventilation and arterial gases, before and after the intervention. Tracheostomy in COVID-19 patients should be a widely justified procedure, in which the benefits outweigh the risks, for the patient and the health personnel involved.

In our cases, all patients complied with the minimum recommendations for their intervention, which consisted in oro-tracheal intubation more than 21 days, low ventilation settings (PEEP) <12 cm and FiO₂ from 40% to 50%. In order to safely perform tracheostomy, we took into consideration patients with hemodynamic stability without hemorrhagic diathesis or need for vasopressors.

**Ethical Considerations:** Researchers have followed bioethical principles of human research. The identification data of deceased patients will not be disclosed and have been recoded to avoid recognition.

**Contribution of authors:** Laura Valle Soto and Eduardo González Quintana, surgeons of the Regional Hospital No. 1 in Culiacan, Sinaloa, operated and registered the cases of that headquarters in addition to reviewing and adapting the final manuscript. Oscar Said Rodríguez Quintana, Edwin Canché Martín, Roberto Reina, Alfonso Antonio Rubio Espinoza, surgeons of the “Lic. Luis Donaldo Coloso Murrieta” Specialty Hospital No 2 in Cd Obregón, Sonora, operated and registered the cases from that headquarters. Fernanda Verana Barragán Márquez: Literature search and review. Nohemí Sainz Fuentes: Review of the final manuscript. Juan Antonio Lugo-Machado: Preparation of the draft and descriptive analysis of the case series.

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**REFERENCES**


