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Gómez-Cardona, Efraín Antonio; Díaz-Hernández, Daniela; Borré-Naranjo, Diana Patricia; Dueñas-Castell, Carmelo; Lozada-Martínez, Iván David; Picón-Jaimes, Yelson Alejandro; Muñoz-Murillo, Katherine Lizeth

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Original Article

Relationship Between Tracheostomization and Survival in Mechanically Ventilated Patients with Respiratory Symptoms Suggestive of COVID-19 in Cartagena, Colombia

Relación entre traqueostomización y supervivencia en pacientes sometidos a ventilación mecánica con sintomatología respiratoria sugestiva de COVID-19 en Cartagena, Colombia

Relação entre traqueostomização e sobrevivência em pacientes submetidos à ventilação mecânica com sintomas respiratórios sugestivos de COVID-19 em Cartagena, Colômbia

Efraín Antonio Gómez-Cardona, MD., Sp.[1], *Daniela Díaz-Hernández, MD.*[2], *Diana Patricia Borré-Naranjo, MD., Sp.*[3], *Carmelo Dueñas-Castell, MD., Sp.*[4], *Iván David Lozada-Martínez, St.*[5], *Yelson Alejandro Picón-Jaimes, MD., Sp., Mg.*[6], *Katherine Lizeth Muñoz-Murillo, MD.*[7]

1. Physician, Specialist in General Surgery. Surgical Department, Universidad de Cartagena. Cartagena, Bolívar, Colombia.
2. Physician. Critical Care and Obstetrics Research Group, Hospital Naval de Cartagena. Cartagena, Bolívar, Colombia.
3. Physician, Specialist in General Medicine and Critical Care. Critical Care and Obstetrics Research Group, Centro Hospitalario Serena del Mar. Cartagena, Bolívar, Colombia.
4. Physician, Specialist in Pneumology and Critical Care, Professor. Critical Care and Obstetrics Research Group, Department of Critical Care, Universidad de Cartagena. Cartagena, Bolívar, Colombia.
5. Medical Student, Vice President of Future Surgeons Chapter. Asociación Colombiana de Cirugía, Prometheus and Biomedicine Applied to Clinical Sciences Group, School of Medicine, Universidad de Cartagena. Cartagena, Bolívar, Colombia.
6. Physician, Specialist in Bioethics Applied to the Experimental Field and Master in Bioethics. Centro de Investigaciones Médico-Quirúrgicas, Future Surgeons Chapter, Asociación Colombiana de Cirugía. Santiago, Metropolitan Region of Santiago, Chile.
7. Physician. Medical Department, Universidad del Quindío. Armenia, Quindío, Colombia.

Correspondence. Iván David Lozada Martínez. Universidad de Cartagena, Health Science Campus. Prometheus and Biomedicine Applied to Clinical Sciences Group. Cartagena, Bolívar, Colombia. **Email.** ilozadam@unicartagena.edu.co

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ABSTRACT

Introduction. COVID-19 has generated one of the highest disease burdens in the 21st century. To date, there are more than 280 million estimated cases globally. Many aspects of this condition are still unknown, which causes controversy in how to approach critically ill patients. Tracheostomy is an intervention that has been shown to be beneficial in the management of respiratory disease, however, there is an evidence gap on the effectiveness and safety of this intervention in critically ill COVID-19 patients. Consequently, the aim of this study was to relate the time elapsed from the onset of the clinical condition, during intubation and days of mechanical ventilation, to performing the tracheostomy, with the survival of patients with symptoms suggestive of COVID-19. **Methodology.** Retrospective cross-sectional study, conducted between March 2020 and February 2021 in two fourth-level hospitals in the city of Cartagena, Colombia. It included patients older than 18 years who were admitted to the intensive care unit due to the need for invasive mechanical ventilation for viral respiratory symptoms. Those with incomplete medical records and hospitalized for other respiratory causes were excluded. **Results.** A total of 122 patients were included in the study with a median age of 63 years (IQR 22; 20-89), with 66.4% (n = 81) being male. No significant correlation was found between the number of days from the onset of the clinical condition to the performance of tracheostomy (p = 0.12), nor between the time elapsed from endotracheal intubation to the performance of tracheostomy, with respect to survival (p = 0.53). However, there was a relationship between the number of days of invasive mechanical ventilation and the final outcome (p = 0.02). **Discussion.** Although it has been reported that tracheostomy is one of the riskiest procedures in the management of patients with severe respiratory symptoms, during the COVID-19 pandemic the literature describes that this intervention increases survival, decreases the time required for mechanical ventilation and reduces the length of stay in the intensive care unit. The number of complications is very low in comparison to the benefit it confers, and it was observed that the local behavior is very similar to that reported in the literature. **Conclusions.** Time from symptom onset or endotracheal intubation to the performance of tracheostomy does not correlate with survival in patients with respiratory symptomatology suggestive of COVID-19 who are mechanically ventilated and tracheostomized.

Keywords:
Tracheostomy; Respiration, Artificial; Coronavirus Infections; Respiratory Tract Diseases; Colombia; COVID-19.

RESUMEN

Introducción. La COVID-19 ha sido una de las enfermedades que ha generado mayor carga de enfermedad en el siglo XXI. A la fecha, se estiman más de 280 millones de casos a nivel global. Aún se desconocen muchos aspectos de esta condición, lo que ocasiona controversias sobre el abordaje de pacientes críticamente enfermos. La traqueostomía es una intervención que ha demostrado ser beneficiosa en el manejo de enfermedades respiratorias, sin embargo, existe un vacío en la evidencia sobre la efectividad y seguridad de esta intervención en pacientes críticamente enfermos de COVID-19. Por lo anterior, el objetivo de este estudio consistió en relacionar el tiempo transcurrido desde el inicio del cuadro clínico, durante la intubación y los días de ventilación mecánica, hasta la realización de la traqueostomía, con la supervivencia de pacientes con síntomas sugestivos de COVID-19. **Metodología.** Estudio retrospectivo de corte transversal, realizado entre marzo del año 2020 y febrero del año 2021 en dos centros hospitalarios de cuarto nivel de la ciudad de Cartagena, Colombia. Incluyó pacientes mayores de 18 años que ingresaron a la unidad de cuidados intensivos por requerimiento de ventilación mecánica invasiva por sintomatología respiratoria viral. Se excluyeron aquellos con historias clínicas incompletas e internados por otras causas respiratorias. **Resultados.** Un total de 122 pacientes fueron incluidos en el estudio con una mediana de edad de 63 años (RIQ 22; 20-89), siendo el 66.4% (n=81) hombres. No se encontró una correlación significativa entre el número de días desde el inicio del cuadro clínico hasta realización de la traqueostomía (p=0.12), ni entre el tiempo transcurrido desde la intubación endotraqueal hasta la realización de la traqueostomía, con respecto a la supervivencia (p=0.53). Pero sí entre el número de días de ventilación mecánica invasiva y el desenlace final (p=0.02). **Discusión.** Aunque se ha reportado que la traqueostomía es uno de los procedimientos que

acarrea mayores riesgos en el manejo del paciente con sintomatología respiratoria severa, durante la pandemia por COVID-19 la literatura describe que esta intervención aumenta la supervivencia, disminuye el tiempo de requerimiento de ventilación mecánica y reduce la estancia en unidad de cuidados intensivos. El número de complicaciones es muy bajo en comparación al beneficio que otorga y se observó que el comportamiento local es muy similar al reportado en la literatura. **Conclusiones.** El tiempo desde el inicio de los síntomas o de la intubación endotraqueal hasta la realización de traqueostomía no se correlaciona con la supervivencia de pacientes con sintomatología respiratoria sugestiva de COVID-19 que se encuentran bajo ventilación mecánica y traqueostomizados.

Palabras clave:
Traqueostomía; Respiración Artificial; Infecciones por Coronavirus; Enfermedades Respiratorias; Colombia; COVID-19..

RESUMO

Introdução. A COVID-19 tem sido uma das doenças que gerou a maior carga de doenças no século XXI. Até o momento, mais de 280 milhões de casos são estimados globalmente. Muitos aspectos dessa condição ainda são desconhecidos, o que gera controvérsias sobre a abordagem de pacientes gravemente doentes. A traqueostomia é uma intervenção que tem se mostrado benéfica no manejo de doenças respiratórias, porém, há uma lacuna nas evidências sobre a eficácia e segurança dessa intervenção em pacientes críticos com COVID-19. Portanto, o objetivo deste estudo foi relacionar o tempo decorrido desde o início do quadro clínico, durante a intubação e os dias de ventilação mecânica, até a realização da traqueostomia, com a sobrevivência de pacientes com sintomas sugestivos de COVID-19. **Metodologia.** Estudo transversal retrospectivo, realizado entre março de 2020 e fevereiro de 2021 em dois hospitais de quarto nível na cidade de Cartagena, Colômbia. Foram incluídos pacientes maiores de 18 anos que foram admitidos na unidade de terapia intensiva por necessidade de ventilação mecânica invasiva devido a sintomas respiratórios virais. Foram excluídos aqueles com historial clínico incompleto e internados por outras causas respiratórias. **Resultados.** Um total de 122 pacientes foram incluídos no estudo com idade média de 63 anos (IQR 22; 20-89), sendo 66.4% (n=81) homens. Não foi encontrada correlação significativa entre o número de dias desde o início do quadro clínico até a traqueostomia (p=0.12), ou entre o tempo decorrido da intubação endotraqueal até a traqueostomia, com relação à sobrevivência (p=0.53). Mas sim entre o número de dias de ventilação mecânica invasiva e o desfecho final (p=0.02). **Discussão.** Embora tenha sido relatado que a traqueostomia é um dos procedimentos de maior risco no manejo de pacientes com sintomas respiratórios graves, durante a pandemia de COVID-19 a literatura descreve que essa intervenção aumenta a sobrevivência, diminui o tempo necessário para a ventilação mecânica e reduz a permanência na unidade de terapia intensiva. O número de complicações é muito baixo em relação ao benefício que proporciona e observou-se que o comportamento local é muito semelhante ao relatado na literatura. **Conclusões.** O tempo desde o início dos sintomas ou intubação endotraqueal até a realização de uma traqueostomia não se correlaciona com a sobrevivência de pacientes com sintomas respiratórios sugestivos de COVID-19 que estão sob ventilação mecânica e traqueostomizados.

Palavras-chave:
Traqueostomia; Respiração Artificial; Infecções por Coronavirus; Doenças Respiratórias; Colômbia; COVID-19.

Introduction

Beginning December 2019, a new coronavirus (SARS-CoV-2) generated an international outbreak for the pandemic coronavirus disease 2019 (COVID-19) (1). As of December 28, 2021, there were 281,591,352 infections and 5,410,218 deaths around the world (2), with Colombia (5,127,971) among the countries with the highest number of infections, after Brazil and Argentina, Latin American countries with similar impact (2).

So far, there are no specific drugs to cure COVID-19 disease (3). In some patients hospitalized for

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respiratory symptomatology who develop the severe COVID-19 phenotype, endotracheal intubation and mechanical ventilation are common and indispensable life-saving treatments (4). Among these, those who remain under endotracheal intubation and mechanical ventilation for a long duration may be candidates for tracheostomy (5). The benefits of the latter include decreased sedation, a reduction in intensive care stay and in the time required for mechanical ventilation, as well as a decrease in the risk of ventilator-associated pneumonia (6).

However, there is controversy surrounding this treatment because many authors consider that tracheostomy should be avoided if possible due to the risk involved, not only during the procedure, but also during post-tracheostomy care and additional interventions (7). A prolonged duration of tracheostomy may delay the patient's discharge from the Intensive Care Unit (ICU) (8). In addition, changes in tracheostomy care after insertion have been recommended to minimize transmission of COVID-19 by healthcare personnel (8-10). This may limit rehabilitation, detailed patient assessment and ultimately delay weaning (11).

The decannulation process is complex and depends on the coordination of pharyngolaryngeal stimulation, airway protection, among other factors (7). Therefore, the duration of time under respiratory support, the functional outcome and the survival of these patients is unpredictable.

Several international clinical practice guidelines (5,7,12) have raised the need to develop work aimed at understanding and explaining cultural differences, the factors that lead to divergence of guidelines, and to evaluate the impact of these guidelines during the management of critically ill patients with COVID-19 (5,7,12). Depending on the sociocultural and economic context of each region, studies should be designed in response to the behavior of the emerging disease to determine how the recommendations are used in practice and to what extent they meet the needs of physicians and managers (5,7,12). Consequently, the aim of this study was to relate the time elapsed from the onset of the clinical condition, through intubation and days of mechanical ventilation, to the performance of tracheostomy, with the survival of patients with mechanically ventilated with respiratory symptoms suggestive of COVID-19.

Methodology

Retrospective cross-sectional study that included data from the clinical history of patients with respiratory symptomatology suggestive of COVID-19 who were admitted to the ICU, required invasive mechanical ventilation and eventually required tracheostomy. The study was conducted during the period from March 2020 to February 2021 in two fourth level hospitals in Cartagena, Colombia. This study was based exclusively on data extracted from the medical record and, therefore, no questionnaires were used or validated. The sampling was non-probabilistic, census-type and included all patients who met the inclusion criteria during the assessment period.

Inclusion criteria were defined as: all patients over 18 years of age admitted to the ICU with respiratory symptoms suggestive of COVID-19 requiring mechanical ventilation and eventually undergoing tracheostomy. Patients who did not have a complete medical history, who were transferred to another care unit and the outcome was not known, and who, during the course of their stay, it was determined that the respiratory disease was due to a condition other than viral pneumonia were excluded.

The following data were collected: gender, age, date of symptom onset, date of mechanical ventilation onset, date of tracheostomy, days of hospital stay, days of mechanical ventilation, final outcome, comorbidities, indication for tracheostomy, D-dimer, PCR or antigen test result for SARS-CoV-2 infection, performance of Chest Computed Tomography (CT), site of tracheostomy performance, need for tube change, complications of tracheostomy, CHARLSON index and SOFA index.

The CHARLSON comorbidity index is a ten-year life expectancy assessment scale that assigns scores according to the individual's age and comorbidities; the higher the score obtained, the lower the life expectancy of the subject being evaluated (13,14).

The SOFA index is a mechanism for the evaluation of multisystemic failure in the Intensive Care Unit, using the assessments by systems and the use of vasoactive medications: the higher the score, the greater the degree of organ dysfunction (15).

Statistical analysis was performed using the IBM SPSS (Chicago, IL) version 25 statistical package. Nominal and ordinal variables were expressed as percentages, while discrete and continuous variables were expressed as median and interquartile range (IQR) since they did not have a normal distribution. In addition, correlation analyses were performed using the Chi-square test

and Fisher's exact test (in cases where the box counts were less than 5), the p-value was also expressed and the intensity of the correlation was measured using Cramér's V test, since at least one of the variables was qualitative (nominal). Intensity was considered low if Cramér's V was less than 0.3; moderate intensity from 0.3 to 0.6, and high intensity if Cramér's V had a value greater than 0.6. Where possible, the directional relationship of the association was measured using the Lambda test. Kaplan-Meier survival analysis was also performed. Confidence intervals of 95% and a p-value <0.05 were considered significant.

This study received ethical approval from the corresponding hospital and according to article 11 of Resolution 8430 of 1993 of the Colombian Ministry of Health (16), this research is classified as risk-free. In addition, in compliance with the Helsinki Declaration, paragraph 11, and in accordance with the provisions of the World Medical Association (17), the dignity, integrity, privacy and confidentiality of the personal information of the persons included in this research were protected.

Results

A total of 122 patients were included in the study with a median age of 63 years (IQR 22; 20-89), as pertains to gender distribution, 66.4% (n = 81) being male. According to patient comorbidities, 74.6% (n = 91) suffered from at least one underlying pathology. Of these, arterial hypertension (AHT) was the most prevalent (n = 62; 68.1%), followed by type 2 diabetes mellitus (T2DM) (n = 32; 35.2%) and obesity (n = 11; 12%) (Table 1). However, patients with only one comorbidity (discarding those with more than one pathology) were distributed as follows: patients with only AHT accounted for 25.3% (n = 23), patients with only T2DM accounted for 8.8% (n = 8) and patients with only obesity accounted for 2.2% (n = 2).

With respect to days of ICU stay, the median was 25.5 days (IQR 18; 4-97). The number of days from symptom onset to completion of tracheostomy had a median of 23 (IQR 13; 3-76) (Figure 1) and the number of days from intubation to performance of tracheostomy had a median of 13 (IQR 7.25; 0-34). No statistically significant correlation was found between the number of days from the onset of symptoms to the performance of tracheostomy (p 0.12), nor between the time elapsed from endotracheal intubation to the performance of tracheostomy and survival (p 0.53). The median number of days of total mechanical ventilation was 23 days (IQR 18; 4-95), with a median of 9 days (IQR 13.25; 0-77) of mechanical ventilation since the tracheostomy was performed. A statistically significant relationship was found between the number of ventilation days and survival (p 0.02) (Figure 2).

Table 1. Clinical and sociodemographic characterization of the study population.

Parameter	Median - IQR
Age, years	63 (22; 20-89)
Gender, male (%)	81 (66.4%)
Presence of comorbidity, n (%)	91 (74.6%)
High blood pressure	62 (68.1%)
Diabetes mellitus	32 (35.2%)
Obesity	11 (12%)
Chronic kidney disease	9 (9.9%)
Chronic obstructive pulmonary disease	6 (6.6%)
Stay in intensive care, days	25 (18; 4-97)
Time between symptom onset and tracheostomy, days	23 (13; 3–76)
Time between intubation and tracheostomy, days	13 (7.25; 0-34)
Total mechanical ventilation, days	23 (18; 4-95)
Mechanical ventilation during tracheostomy, days	9 (13.25; 0-77)
D-dimer, µg/L	587 (453; 50-4655)
COVID-19 test positivity, n/nT (%)	42/86 (48.9 %)
Tomography suggestive of COVID-19, n/nT (%)	59/80 (73.7%)
Indication for tracheostomy	
Prolonged intubation	110 (90.2%)
Laryngeal edema	7 (5.7%)
Failed extubation	3 (2.5%)
Tracheostomy site	
Intensive Care Unit	65 (53.3%)
Operating Room	57 (46.7%)
Tracheostomy tube change, n (%)	2 (1.6%)
Complications from tracheostomy, n (%)	2 (1.6%)
CHARLSON index	3 (3; 0-10)
Absence of comorbidity	38 (31.1%)
Low level of comorbidity	19 (15.6%)
High level of comorbidity, n (%)	65 (53.3%)
SOFA index	5 (4; 0-13)
Survival	43 (35.2%)

nT: total number of patients
Source: prepared by the authors

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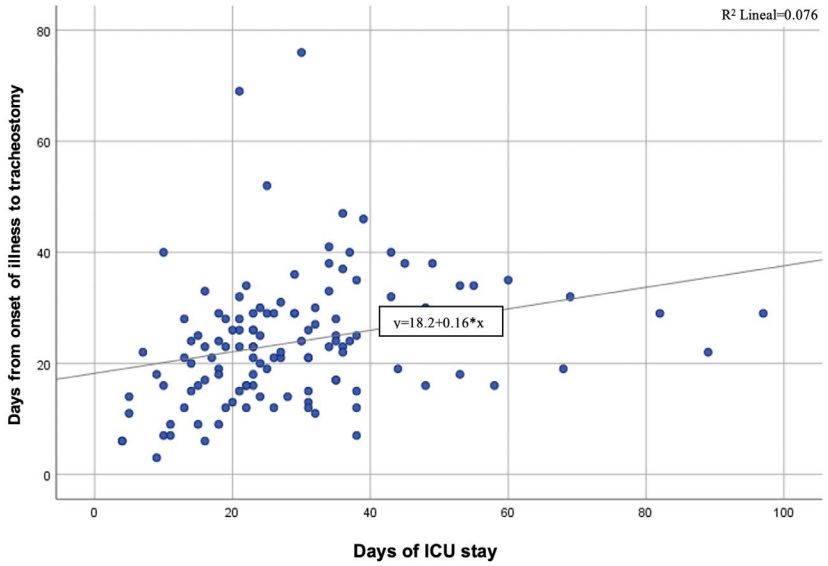

Figure 1. Scatter plot comparing days of intensive care unit stay vs. days from onset of illness to tracheostomy.
Source: prepared by the authors

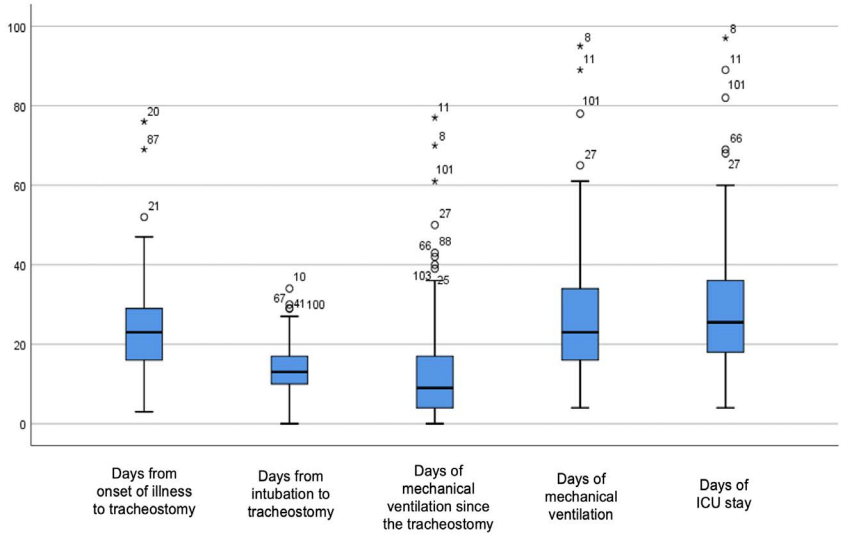

Figure 2. Boxplot representing the medians and ranges of the times evaluated in days. Values accompanied by an asterisk represent extreme data. The values accompanied by circles correspond to distant data.
Source: prepared by the authors

Tracheostomy was mainly indicated for prolonged intubation (in 90.2% of cases n = 110), followed by laryngeal edema (in 5.7% of cases n = 7) and failed (in 2.5% of cases n = 3). Dividing the intervention times into two semesters (March 2020 - September 2020 and September 2020 - February 2021), in the first semester a median of 23 days was observed from the onset of symptoms to the performance of tracheostomy (IQR 11), the time elapsed from intubation to the performance of tracheostomy had a median of 14.5 days (IQR 9). Days on mechanical ventilation after the performance tracheostomy had a median of 9 days. In the second half of the year, a median of 23 days (IQR 13) was observed for the time from symptom onset to the performance of tracheostomy; a median of 13 days (IQR 7) for the time from intubation to tracheostomy; and a median of 8 days for days of mechanical ventilation after tracheostomy. The correlation between these variables was not significant (p>0.05).

D-dimer evaluation was performed in 33.6% (n = 41) of patients only. This paraclinic had a median value of 587 µg/L (IQR 453; 50-4655). Diagnostic tests for SARS-CoV-2 (RT-PCR or antigen) were performed in 70.5%

(n = 86) of patients and were positive in 48.9% (n = 42). Chest CT scans were performed in 65.6% (n = 80) of the patients and were suggestive in 73.7% (n = 59). An association was found between laboratory diagnostic test and CT diagnosis with a Chi-square of 137.2 (p = 0.00) and a Cramér's V with a value of 0.750 (p = 0.00), which means that the intensity of the correlation between the two variables is high. In addition, a symmetrical Lambda of 0.660 (p = 0.00) was found indicating that the directional relationship is high.

The most frequent site of tracheostomy was the ICU with 53.3% of the cases (n = 65), and the operating room in the remaining 46.7% (n = 57). Only two patients (1.6%) required tracheostomy tube change and only two patients (1.6%) had complications with the tracheostomy.

Correlation tests evidenced an association between tracheostomy tube change and the presence of complications with a Fisher's exact test with a p = 0.033, a Cramér's V of 0.492 (p = 0.00) indicating a moderate intensity of association and a Lambda of 0.00 evidencing a null directional relationship.

A correlation was also found between the site of tracheostomy performance and patient survival, with a Chi-square of 5.04 (p = 0.025) indicating a significant correlation and a low intensity of association evidenced by a Cramér's V of 0.203 (p = 0.025).

The CHARLSON index had a median of 3 (IQR 3; 0-10) and the SOFA index had a median of 5 (IQR 4; 0-13). Looking at the CHARLSON index, as scored, 53.3% (n = 65) of patients were found to have a high level of comorbidity.

Patient survival after ICU stay was 35.2% (n = 43). When comparing the time elapsed from the onset of symptoms to the performance of tracheostomy, with survival, we obtained a correlation given by a Chi-square equal to 46.664 with a p = 0.158, which was not significant. When comparing the CHARLSON index with survival, we obtained a Chi-square equal to 1.260 with a p = 0.533, which was also not significant. When attempting to compare the SOFA index with survival, we obtained a Chi-square equal to 12.748 with a p = 0.338, which was also not significant.

Finally, survival analysis using the Kaplan-Meier model showed that the longer the number of days spent in the ICU, the lower the survival rate. In the first 10 days survival was greater than 90%, while at 121 days survival was <5% (Figure 3).

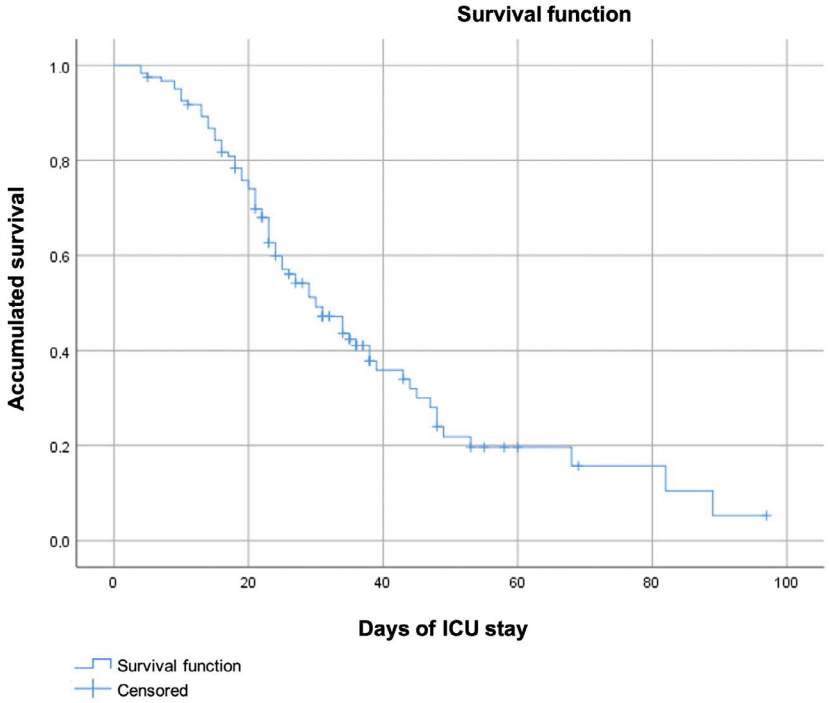

Figure 3. Kaplan-Meier survival model showing the distribution of the decrease in survival expressed in percent, with respect to the increase in days of intensive care unit stay. The crosses represent censored data and correspond to those patients who survived.
Source: prepared by the authors

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Discussion

Among the factors to consider that can modify the success and prognosis of tracheostomy in patients with respiratory symptoms suggestive of COVID-19 are the preparation of the physician who performs it, the type of tracheostomy, the technological and surgical team to be used, the post-tracheostomy care, the clinical context of the patient, the hospital infrastructure and the availability of supplies and medications (12,18,19).

Percutaneous dilatational tracheostomy is generally preferred as it is a minimally invasive method and can be performed at the bedside (20). However, some patients with unfavorable neck anatomy, such as short neck, enlarged thyroid, scar contracture of the neck, and others, represent a risk for the development of complications (20). In these circumstances, conventional tracheostomy is an unavoidable option for the surgeons who perform it (20). During conventional open tracheostomy, the opening of the airway is more prone to cause splashing of secretions that generate aerosols and may contribute to nosocomial spread of the virus from patients to operating room staff (8).

Although tracheostomy has been reported to be one of the riskiest procedures in the management of the COVID-19 patient with severe phenotype, studies with clear objectives evaluating this intervention are scarce and most of them come from high-income countries (21-23). Likewise, most of the existing systematic reviews synthesize information from clinical practice guidelines or consensus based on opinions (21-23). Meanwhile, the outcomes of this group of patients with respect to the timing of symptom onset and invasive interventions are a question about which not much is known at present, and resolving it is essential to determining whether early or late initiation of an intervention is more favorable.

Of the few published studies with similar objectives, one was performed by the Queen Elizabeth Hospital Birmingham COVID-19 airway team (24). In this prospective cohort study, 164 patients were evaluated; of these, 100 patients had a mean age of 55 years and underwent tracheostomy (24). Compared to the control group (the remaining 64 patients), despite similar APACHE-II scores, 30-day survival was higher (85%) in tracheostomized patients compared to (42%) non-tracheostomized patients (RR 3.9, 95% CI; 2.3-6.4, $p<0.0001$).

Sixty-eight percent of tracheostomized patients, with APACHE-II scores ≥17, survived, compared with 19% non-tracheostomized patients ($p<0.001$) (24). Tracheostomy within 14 days of intubation was associated with shorter duration of ventilation (mean difference: 6 days, 95% CI; 3.1-9.0, $p < 0.0001$) and ICU stay (mean difference: 6.7 days, CI 95%; 3.7-9.6, $p < 0.0001$) (24). This led to the conclusion that, regardless of the severity of critical illness by COVID-19, 30-day survival was longer, and ICU stay shorter in patients who received tracheostomy. Therefore, early tracheostomy appears to be safe in COVID-19. All the tracheostomies mentioned above were performed in specialized wards, unlike those in the present study which, due to the lack of available space, personnel and supplies, were performed, in at least 50% of the cases, in ICUs. This resulted in longer ventilation times and hospital stay.

Several studies have investigated the role of tracheostomy in the management of the patient with COVID-19 and have yielded interesting results in favor of this intervention. For example, Benito et al. (25) conducted a systematic review and meta-analysis evaluating the impact and outcomes of tracheostomy use in 3,234 patients with COVID-19. They found that 55% of patients were successfully weaned from mechanical ventilation (95% CI, 47.4%-62.2%), decannulation time was 18 (±5.7) days after tracheostomy, and mortality in COVID-19 tracheostomized patients was 13.1%, with a mean time of 13 (±4) days after tracheostomy (25).

Staibano et al. (26), carried out a study at the same level as the authors mentioned above, with the aim of determining the outcomes of patients tracheostomized by COVID-19 and the risk of contagion among health care workers. It was found that of the 4,669 patients included, the great majority were men averaging 60 years of age (26). They found that performing tracheostomy early is associated with a shorter intensive care stay (-6.17 days; 95% CI -11.30 to -1.30), but not with fewer weaning days (-2.99 days; 95% CI, -8.32 to 2.33) or decannulation (-3.12 days; 95% CI, -7.35 to 1.12) (26).

However, due to the heterogeneity of the studies and risk of bias, it was not possible to determine the mortality or rate of complications derived from any type of tracheostomy. It was therefore concluded that the probability of contagion among health care workers due to tracheostomy is minimal and that performing tracheostomy early improves survival (26).

On the other hand, Shah et al. (27) asserted that the ideal place to perform this procedure is in an isolated room with negative pressure and without laminar flow

(27); however, the present study found that performing this procedure in the same ICU is related to a very low frequency of complications. However, these results are not consistent because of the difference between the groups. Considering that the literature is divergent, the provision of strict recommendations is not feasible, and this raises the debate between performing or not performing tracheostomy. However, given the difficulty of patient management under prolonged mechanical ventilation, with the risk of ventilator-associated pneumonia, it is imperative to lean towards the use of tracheostomy.

In the present study, the mean age was similar to that reported in the literature (63 years). Seventy-five percent of patients had at least one comorbidity, the median number of total mechanical ventilation days was above 20 days (23, IQR 18; 4-95), and with a median of 9 days (IQR 13.25; 0-77) of ventilation days since the tracheostomy was performed. When dividing tracheostomy times from symptom onset and duration of ventilation between the first half of the pandemic and the second half of the pandemic, no significant correlation was found. This suggests that, although there was no evidence regarding time management, the requirements and approach among patients showed a similar pattern. The indications for performing tracheostomy were similar to those reported in the studies cited (prolonged intubation and failed extubation) (23-28).

A large percentage of COVID-19 positive patients presented a tomographic pulmonary pattern compatible with ground glass $p = 0.001$. Only two patients required tube change and the same number had complications. Unlike what was found in studies with similar objectives, this one did not find correlations between SOFA ($p = 0.338$), CHARLSON ($p = 0.533$) and survival scores, as well as between the time of tracheostomy from the onset of the disease and survival ($p = 0.158$).

In this order of ideas, there were not many significant differences between the behavior of the disease, management times and survival among patients with respiratory symptoms suggestive of COVID-19, who were submitted to mechanical ventilation and eventually to tracheostomy. In addition, some statistically significant variables showed high intensity and directionality. However, the limitations of the study make it impossible to determine its significance with certainty.

Now, considering the context of Colombia, a country that experienced difficulties in managing the pandemic due to the limited number of intensive care beds compared to the number of its population, and the fact that there was no significant difference with respect to the intervention and outcome, it is possible to highlight the social impact that early tracheostomy would have on the adequate management of the flow of patients and thus avoid congestion or organizational destabilization in the health care institutions.

It is also important to mention the approach to patients with a clinical diagnosis of COVID-19 pneumonia with epidemiological link, but negative test. Only 42 patients had a positive test. However, the evolution of the disease, the clinical presentation and the radiological pattern suggestive of COVID-19, made it necessary to use the same approach for those with a positive test.

Recent evidence has included these two groups of patients in the study population (29-31), taking into account that RT-PCR has a sensitivity of 71-98%, giving a false negative rate of up to 29% (30). This is accompanied by estimated excess deaths and underreporting of epidemiological data (29-31). Considering these assertions, patients with both clinical diagnosis and confirmed by molecular tests were evaluated.

Limitations of this study included: insufficient sample size, lack of information on short- and medium-term follow-up of survivors, and the significant difference between subgroups, which did not allow significant correlations to be obtained. Although related information is scarce and there is the limitation of obtaining a representative sample, few studies have been published. In Colombia they are nonexistent, therefore, it is urgent to investigate the behavior and results of tracheostomized patients during the COVID-19 pandemic, which, at present, continues to claim a large number of lives daily and is unsustainable for the national health system.

Conclusions

The time from the onset of symptoms or endotracheal intubation to the performance of tracheostomy does not correlate with survival in patients with respiratory symptomatology suggestive of COVID-19, under mechanical ventilation and tracheostomized. However, the number of days under artificial respiration is directly related to survival.

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Conflicts of interest

The authors declare that there is no conflict of interest.

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Ethical responsibilities

Protection of persons and animals: this study is considered risk-free due to its nature. It was approved by the Institutional Ethics Committee.

Data confidentiality: the authors declare that they have followed their center's protocols on the publication of patient data.

Right to privacy and informed consent: the authors have obtained informed consent from the patients and subjects referred to in the article. This document is in the possession of the corresponding author referred to in the article.

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