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Retrospective Cohort Study

Clinical characteristics of COVID-19 patients who underwent tracheostomy and its effect on outcome: A retrospective observational study

Singh Y *et al.* Tracheostomy in COVID-19 patients

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Abstract

BACKGROUND

The exponential rise in the Coronavirus disease (COVID-19) cases has resulted in an increased number of patients requiring prolonged ventilatory support and subsequent tracheostomy. With the limited availability of literature regarding the outcomes of COVID-19 patients with tracheostomy, we attempted to study the clinical characteristics and multiple parameters affecting the outcomes in these patients.

AIM

To determine all-cause mortality following tracheostomy and its association with various risk factors in COVID-19 patients.

METHODS

This retrospective study included 73 adult COVID-19 patients admitted to the ICU between 1 April, 2020 and 30 September, 2021 who underwent tracheostomy as a result of acute respiratory failure due to COVID-19. The Data collected included

demographics (age, sex), comorbidities, type of oxygen support at admission, severity of COVID-19, complications, and other parameters such as admission to tracheostomy, intubation to tracheostomy, ICU stay, hospital stay, and outcome.

RESULTS

This study included 73 adult patients with an average age of 52 ± 16.67 years, of which 52% were men. The average time for admission to tracheostomy was 18.12 ± 12.98 days while intubation to tracheostomy was 11.97 ± 9 days. The mortality rate was 71.2% and 28.8 % were discharged alive. The mean duration of ICU and hospital stay was 25 ± 11 days and 28.21 ± 11.60 days respectively. Higher age, severe COVID-19, mechanical ventilation, shock and acute kidney injury were associated with poor prognosis; however, early tracheostomy in intubated patients resulted in better outcomes.

CONCLUSION

Patients with severe COVID-19 requiring mechanical ventilation have a poor prognosis but patients with early tracheostomy may benefit with no added risk. We recommend that the timing of tracheostomy be decided on a case -to- case basis and a well designed randomised control trial should be performed to elucidate the potential benefit of early tracheostomy in such patients.

Key Words: COVID-19; Intubation; Mechanical ventilation; ICU; Tracheostomy; Oxygen therapy

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Core Tip: Tracheostomies are commonly performed in critically ill patients who require mechanical ventilation for prolonged duration. Various recommendation and guidelines have been published regarding the safety of tracheostomy in Coronavirus disease (COVID-19) patients but literature with respect to indication, timing and outcome of tracheostomy in COVID-19 patients is still lacking. Therefore, in this study we aimed to describe the clinical characteristics of patients who underwent elective tracheostomies and multiple parameters affecting the outcomes in these patients. We found that patient with severe COVID-19 requiring mechanical ventilation has poor prognosis but patients with early tracheostomy may also benefit from this procedure.

INTRODUCTION

The Coronavirus disease (COVID-19) pandemic has resulted in extreme stress in healthcare establishments worldwide. Various studies have shown that 5%-15% of the patients with COVID-19 will develop severe disease requiring endotracheal intubation and mechanical ventilation^[1,2]. Some patients may require prolonged ventilatory support. Tracheostomies are commonly performed in critically ill patients who require prolonged mechanical ventilation^[3]. Compared with the orotracheal tube, the tracheostomy tube bypasses the mouth and pharynx resulting in better patient comfort and sedation requirement^[4]. Other benefits of tracheostomy include a reduced incidence of ventilator-associated pneumonia, reduction in anatomical dead space leading to less work of breathing, easy airway suctioning and toileting, and facilitation of weaning from mechanical ventilation^[5]. During the pandemic, tracheostomy will help in early transition of the patients from ICU care to ward care, thus helping to create a much-needed ICU bed that is always scarce in resource-limited countries with limited manpower. Tracheostomy will also help reduce the generation of highly infectious aerosols that are associated with the use of high flow oxygen devices or non-invasive ventilation^[6].

Various guidelines have been published regarding the safety of tracheostomy in COVID-19 patients; however, literature regarding the indications, timing, and outcomes

of tracheostomy in COVID-19 patients is lacking^[7,8]. Some authors suggest ¹ that tracheostomy should be delayed for at least 14 days after endotracheal intubation to obtain better information regarding patient prognosis along with reduced viral load^[9-13]. Early tracheostomy is advised so that patients can be weaned from the ventilator and transferred to ward care sparing the ICU bed^[14]. However, these recommendations are based on expert opinions and a well-designed study is needed to provide a high level of evidence. ¹ In this study, we aimed to describe the clinical characteristics of patients who underwent elective tracheostomies and to study multiple parameters affecting the outcomes of these patients.

MATERIALS AND METHODS

Study overview

This study was conducted by the Department of Anaesthesiology, Pain Medicine, and Critical care in a tertiary care centre. The retrospective data presented in a study is the part of the project titled-Post discharge outcomes of COVID-19 patients following admission to the intensive care unit, which was approved by the institute ethics committee (IEC-291/17.04.2020). Since the study was retrospective in nature, informed written consent from individual patients was waived off. The major databases like Pubmed, Embase, Scopus, Web of Science and Google scholar were searched for finding the latest literature. The search was strengthened by using a new tool called as Reference Citation Analysis (<https://www.referencecitationanalysis.com/>).

Inclusion criteria

The study included all confirmed COVID-19 adult patients admitted to ICU who underwent tracheostomy between 1st April 2020 to 30th September 2021.

Exclusion criteria

All patients with missing data or polytrauma cases who were incidentally COVID-19 positive were excluded from the study.

Data collection

Data were retrospectively collected using medical records and a computerized patient record system. Data collected included demographics (age, sex), comorbidities, type of oxygen support at admission, the severity of COVID-19, complications, and tracheostomy-related parameters like admission to tracheostomy, intubation to tracheostomy, ICU stay, hospital stay, and outcome. The timing of tracheostomy was classified as early (within 10 days of intubation) and late (more than 10 days of intubation).

Statistical analysis

The primary outcome of the study was to measure all-cause mortality following tracheostomy and its association with various risk factors. The secondary outcome included various tracheostomy-related parameters like the timing of tracheostomy, admission to tracheostomy, intubation to tracheostomy, ICU stay, and hospital stay. Continuous variables were expressed as mean \pm SD and categorical variables as number (percentage). Group comparison was performed using independent *t*-tests or Fischer's exact test. *P* values less than 0.05 were considered statistically significant.

RESULTS

During the study period, 113 mechanically ventilated patients with confirmed COVID-19 who underwent tracheostomy were screened for possible inclusion in the study. 73 patients satisfied the inclusion criteria. They were further subdivided into Survivors and Non-survivors.

Table 1 shows the patient's demographics, comorbidities, COVID-19 severity, initial respiratory support, and tracheostomy-related parameters. The average age of the patient was 52 years (SD- 16.67) and 52 % were male. Hypertension was the most common comorbidity (35.6%) followed by chronic kidney disease with superimposed acute kidney injury (34.3 %), diabetes (24.6%), cerebrovascular accident (15.1%), and

coronary artery disease (5.44%).² The most common oxygen therapy modality used at the time of ICU admission was mechanical ventilation (42.5%), followed by a non-rebreathing mask (19.2%), high flow nasal canula (10.9%), room air (12.3%), face mask (8.2%) and non-invasive ventilation (6.8%). Most of the patients who were admitted to ICU were suffering from severe COVID-19 (50.6%) followed by moderate (30.2%) and mild (19.2%) disease. The mortality rate was 71.2 % and 28.2 % were discharged alive. The mean duration of ICU and hospital stay was 25 ± 11 days and 28.21 ± 11.60 days respectively.

The average time for admission to tracheostomy was 18.12 ± 12.98 days while intubation to tracheostomy was 11.97 ± 9 days. Thirty-five (47.9%)² patients' tracheostomies were performed early i.e., within 10 days of intubation. Subgroup analysis among survivors and non-survivor showed that patients in the non-survivor group were older ($P = 0.02$), had severe COVID-19 ($P = 0.001$), and had a late tracheostomy ($P = 0.03$) as compared to the survivor. But, the number of days from admission to tracheostomy, duration of ICU, and, hospital stay showed no significance between survivors and non-survivors. (Table 2)

DISCUSSION

This retrospective study describes the effect of tracheostomy in COVID-19 patients suffering from acute respiratory failure in a tertiary care centre of northern India. In our cohort of tracheotomized patients with COVID-19 pneumonia, we found that the average time from intubation to tracheostomy was 12 days; tracheostomy was performed in 6.4% of the patient admitted to the ICU. This rate is slightly lower than the French COVID-ICU study which reported a rate of 9%^[15]. The patients in the non-survivor group were older and had severe COVID -19 and late tracheostomy.

The timing of tracheostomy in COVID-19 has been a matter of debate since the published studies have presented heterogeneous results^[8,16-19] and this debate is not going to settle as most of the studies on tracheostomy are retrospective in nature. Various researchers have demonstrated that early tracheostomy has the advantage of

rapid weaning from mechanical ventilation, decreased need for sedation, and shorter length of ICU stay^[20]. Other proposed advantage includes reduced risk of oropharyngeal and laryngeal damage as well as facilitation of oral feeding and oral care^[21].

Before the COVID-19 pandemic, a systematic review by Adly *et al*^[20] suggested that early tracheostomy *i.e.*, within 7 days, was associated with a reduced duration of mechanical ventilation, decreased mortality rate, and shorter length of ICU stay. A Cochrane review by Andriolo *et al*^[22] found that early tracheostomy was associated with lower mortality rates and a higher probability of discharge from the ICU at day 28. But meta-analysis by Griffiths *et al*^[23] and Siempos *et al*^[24] demonstrated that there was no survival benefit of early tracheostomy as compared to late tracheostomy. TracMan randomized controlled^[25] trial comparing early (within 4 days) vs late tracheostomy (after 10 days), demonstrated that there were no differences in 30-day mortality and 1- and 2-year survival or length of ICU stay between them.

During the COVID-19 pandemic, various studies have described different timing of tracheostomy. Kwak *et al*^[26], Queen Elizabeth Hospital Birmingham COVID-19 airway team^[27], Angel *et al*^[28], Chao *et al*^[10], Martin-Villares *et al*^[18], Hernandez-Gracia *et al*^[29] and Mario *et al*^[30] have reported a mean time from intubation to tracheostomy of 12.2 days, 13.9 days, 10.6 days, 19.7 days, 12 days, 17 and 15 days respectively. In our study, the mean intubation to open tracheostomy time was 11.97 days and in 47.9% ($n = 35$) COVID-19 patients' tracheotomies were performed within 10 days of intubation.

The subgroup analysis of tracheostomy among non-survivor and survivors showed that the mean age of non-survivor was higher than survivor. This poor outcome in older age with tracheostomies is consistent with many studies published on COVID-19^[1,18]. Similarly, non-survivor with tracheostomies were suffering from severe COVID-19, which was also consistent with the previously published research. Further, most of the non-survivor in our study had late tracheostomy demonstrating poor outcome in patients with late tracheostomy (beyond 10 days), which may be due to the worsening of the disease at later stages. But Tang Y *et al*^[16] suggested better outcomes in

tracheostomies done after 14 days whereas Aviles-Jurado *et al*^[31] in their prospective study on the safety of tracheostomy reported that early tracheostomy (< 10 days) had no association with mortality. Other parameters such as the number of days from admission to tracheostomy, duration of ICU, and hospital stay had no significance between survivors and non-survivors. The overall mortality in our study was 71.2%, which was consistent with other studies reporting > 50% mortality in COVID-19 patients on mechanical ventilation^[32,33].

Limitations

Our study had several limitations. First, it was a retrospective observational study with a relatively small sample size. Therefore, a well-designed multi centre randomized controlled trial with adequate sample size is needed to validate the findings in our study. Second, due to its retrospective nature, some key statistical tests could not be performed. Thirdly, the various scores used in the ICU in predicting the outcome were not analysed. Lastly, we were not able to retrieve and calculate the incidence of complications associated with a tracheostomy. The study may help the other clinician in designing the clinical trial for future research in pursuit of finding the best time of tracheostomy in critically ill mechanically ventilated patients.

CONCLUSION

Our study describes the clinical characteristics and outcome of a cohort of patients who underwent tracheostomy after intubation due to COVID-19. Our study showed that early tracheostomy (less than 10 days) was associated with reduced mortality. However, a well-designed randomized multicentre trial is needed to elucidate the potential benefit of early tracheostomy in mechanically ventilated COVID-19 patients. We also suggest that the timing of tracheostomy be decided on a case-to-case basis rather than following a strict rule.

ARTICLE HIGHLIGHTS

Research background

Rapid increase in Coronavirus disease (COVID-19) patients has resulted in increased number of patients with severe disease requiring prolonged ventilatory support and subsequently tracheostomy. Details regarding the timing, and safety of tracheostomy in the management of COVID-19 patients continue to evolve.

Research motivation

With the limited availability of literature regarding the outcomes of COVID-19 patients with tracheostomy, we attempted to study the clinical characteristics and multiple parameters affecting the outcomes in these patients.

Research objectives

Our research objective was to determine the all-cause mortality after tracheostomy and its relation with various risk factors in COVID-19 patients.

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Research methods

We conducted a retrospective observational study at a tertiary care hospital. The study included 73 adult COVID-19 patients admitted to the ICU between 1 April, 2020 and 30 September, 2021 who underwent tracheostomy as a result of acute respiratory failure due to COVID-19.

Research results

73 adult patients were included in the study with an average age of 52 ± 16.67 years, of which 52% were male. The average time for admission to tracheostomy was 18.12 ± 12.98 days while intubation to tracheostomy was 11.97 ± 9 days. The mortality rate was 71.2 % and only 28.8 % were discharged alive. Higher age, severe COVID-19, mechanical ventilation, presence of shock and acute kidney injury were associated with poor prognosis; however, early tracheostomy in intubated patients resulted in a better outcome.

Research conclusions

The study showed that early tracheostomy (less than 10 days) was associated with reduced mortality with no added risk to the patient. Further, the timing of tracheostomy be decided on a case-to-case basis rather than following a strict rule.

Research perspectives

A well designed randomised control trial should be performed to elucidate the potential benefit of early tracheostomy in COVID-19 patients.

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