Section: Otorhinolaryngology

Original Research Article

A COMPARATIVE STUDY ON THE OUTCOME OF EARLY VERSUS LATE TRACHEOSTOMY IN PATIENTS UNDERGOING MECHANICAL VENTILATION

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Abstract

Background: Tracheostomy is commonly performed in critically ill patients who require prolonged mechanical ventilation. The optimal timing of tracheostomy remains debatable, with early tracheostomy potentially reducing ventilator dependency and hospital stay, whereas late tracheostomy may allow for better patient selection. This study compared the outcomes of early versus late tracheostomy in mechanically ventilated patients. **Materials and Methods:** A prospective randomised controlled trial was conducted on 80 patients who required mechanical ventilation at a tertiary care hospital. Patients were randomly assigned to the early (≤3 days post-intubation, n=40) or late tracheostomy group (>3 days post-intubation, n=40). Clinical outcomes, including the duration of mechanical ventilation, ICU stay, hospital stay, and mortality rates, were analysed. **Result:** The mean ICU stay was significantly shorter in the early tracheostomy group (19.18±10.94 days) than in the late tracheostomy group (25.80±8.90 days, p=0.04). The total hospital stay was also reduced in the early tracheostomy group (37.03±17.57 days) compared to that in the late tracheostomy group (47.98±19.50 days, p=0.01). The duration of mechanical ventilation was significantly lower in the early group (16.98±8.46 days) than in the late group (33.38±12.45 days, p<0.001). Additionally, the early tracheostomy group had a longer ventilator-free period (25.35±10.10 days) than the late group (13.43±5.03 days, p<0.001). There was no significant difference in PaO_2/FiO_2 ratios between the groups (p=0.8). Hospital mortality was lower in patients who underwent early tracheostomy (25.0%) than in those who underwent late tracheostomy (52.5%, p=0.012). **Conclusion:** Early tracheostomy is associated with shorter ICU stay, reduced duration of mechanical ventilation, and lower mortality. These findings suggest the potential benefits of early tracheostomy in improving outcomes in mechanically ventilated patients.

INTRODUCTION

Tracheostomy is a common surgical procedure performed in patients with critical illness who require continuous mechanical ventilation. The process of creating an artificial external tracheal opening is known as tracheostomy. This operation can be performed in an operating room as a standard surgical procedure or as an emergency procedure at the patient's bedside. Up to one-third of patients who require extended mechanical ventilation now undergo tracheostomy owing to the growing utilisation of this surgery, notably after the advent of a practicable bedside tracheostomy technique in 1985.[1] Tracheostomy has been proposed to shorten the length of stay in the intensive care unit (ICU), decrease the duration of mechanical ventilation, and lower the incidence of ventilator-associated pneumonia (VAP).

Compared to an endotracheal tube, tracheostomy is considered more comfortable for patients, requires less sedation, and provides a more stable airway, making it a beneficial option for patients requiring prolonged mechanical ventilation. Although tracheostomy is life-saving, it is frequently associated with complications. Its extended use raises the risk of VAP by bypassing and weakening laryngeal barriers, allowing oropharyngeal contamination of the

bronchial tree and lungs. Some studies have demonstrated that airway colonisation, tracheobronchitis, and pneumonia are also prevalent in patients who undergo tracheostomy.[2] The timing of tracheostomy remains a topic of debate in critical care medicine. Conventionally, the tracheostomy done within 10 days of intubation was referred to as early tracheostomy and beyond that was referred to as late tracheostomy.[3]

Early tracheostomy has been associated with potential benefits such as reduced ventilator-associated pneumonia, shorter ICU stays, and improved patient comfort.4 Other patient groups may benefit from early tracheostomy, particularly those who require little or no assistance from mechanical ventilation but still require airway protection or pulmonary toilet. Trauma and neurological damage from stroke, head injury, and spinal cord injury (SCI) represent a subset of patients for whom the benefits of early tracheostomy have been proven. Conversely, late tracheostomy is often preferred to allow time to assess the potential for extubation, thereby avoiding unnecessary surgical intervention. However, delayed tracheostomy may increase the risk of prolonged ventilator dependency and complications related to prolonged endotracheal intubation. The timing of tracheostomy is influenced by various factors, such as illness severity, clinician preference, hospital resources, treatment protocols, and predicted survival.

Several studies have attempted to determine the impact of early versus late tracheostomy on clinical outcomes; however, the results remain inconclusive. This study aimed to compare the outcomes of early and late tracheostomy in patients undergoing mechanical ventilation. Key parameters, such as duration of ventilation, ICU stay, incidence of complications, and mortality rates, were analysed. This study aimed to provide evidence-based insights for optimising tracheostomy timing. These findings may contribute to improving patient management strategies and guide clinical decision-making in critically ill patients requiring prolonged respiratory support.

MATERIALS AND METHODS

This prospective randomised controlled trial was conducted on a population of patients admitted to the hospital who required tracheostomy for 18 months, from November 2022 to April 2024, at Government Mahatma Gandhi Memorial Medical College Hospital, Trichy, Tamilnadu.

Inclusion Criteria

The inclusion criteria for the study were as follows: patients aged between 18 and 70 years, those expected to require prolonged mechanical ventilation, and seronegative patients.

Exclusion Criteria

Patients were excluded if they had anatomical anomalies of the neck, such as tracheal stenosis, which could impair the tracheostomy procedure; a history of previous tracheostomy; soft tissue infections of the neck; coagulation disturbances, such as thrombocytopenia; were paediatric patients; or were unwilling to provide informed consent.

Sample Calculation

According to Chong et al. study,5 considering the mean and standard deviation of Length of stay in ICU in early tracheostomy as 23.18 ± 10.13, mean and standard deviation of Length of stay in ICU in Late tracheostomy as 30.51 ± 13.36 at 95% confidence interval with 80% power, the sample size is calculated as

$N = (Z\ 1-\alpha/2 + Z\ 1-\beta)2x\ 2\ x\ \sigma2/\ (\mu1 - \mu2)2$

$N = (1.96 + 0.84)\ 2x\ 2\ x\ (11.745)2/\ (23.18 - 30.51)2$

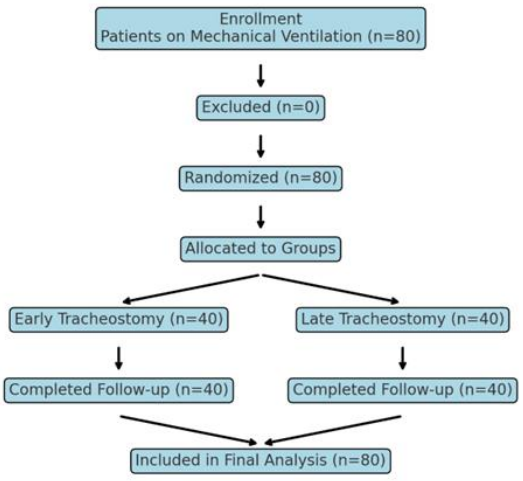
$N = 40.3$

Thus, the sample size required for each group was 40, and the total sample size was 80.

Methods

By convenient sampling, patients on mechanical ventilation who were admitted to the Emergency Department and met the inclusion criteria were selected for this study. This was performed daily until the desired sample size was achieved.

A semi-structured validated questionnaire was used to collect the socio-demographic details, symptoms, past medical history, mode of presentation, and treatment history. Vital signs were recorded, and a complete physical and systemic examination was performed. A total of 80 participants were enrolled and randomly assigned to the two groups. Group A (n=40) included patients who underwent early tracheostomy (<3 days), and Group B (n=40) included patients who underwent late tracheostomy (>3 days).



CONSORT Flow Diagram

The Acute Physiology and Chronic Health Evaluation II (APACHE II) score, measured post-tracheostomy, evaluates patient conditions using a point-based system derived from 12 routine physiological parameters: body temperature (in degrees Celsius), mean arterial pressure (mmHg), heart rate, respiratory rate, PaO_2, arterial pH or HCO_3, serum potassium (mEq/L), serum creatinine,

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haematocrit, white blood cell count (10^3/µl), Glasgow Coma Score (ranging from 3 to 15), and age (years). The scores were interpreted as follows: 0–10 indicated low risk, 11–20 corresponded to moderate risk, 21–30 signified high risk, and a score of 31 or above reflected a very high risk of adverse outcomes. The Sequential Organ Failure Assessment (SOFA) score was used to assess the risk of ICU mortality in patients with tracheostomies, with scores ranging from 0 to 24 (higher scores reflecting greater dysfunction). The SOFA score evaluates six organ systems: respiratory, cardiovascular, hepatic, coagulation, renal, and central nervous systems. Mortality rates correlated with score severity: 7.7% for scores ≤3 (lowest risk), 22.6% for scores between 3 and 9 (moderate risk), and 41.9% for scores >9 (highest risk), underscoring the association between escalating organ dysfunction and increased mortality risk.

Statistical analysis: All data collected were entered in Microsoft Excel and Statistical analysis was performed using SPSS 23.0 software. Continuous variables are presented as mean and standard deviation. Categorical variables are presented as frequencies and percentages. The chi-square test, Student's t-test, and Mann–Whitney U test were used to compare the outcome variables. Statistical significance was set at $p < 0.05$.

Ethical Considerations: This study was approved by the Institutional Ethics Committee (IEC) of the Government Mahatma Gandhi Memorial Medical College Hospital, Trichy. The study participants and attendees were informed about the purpose of the study. The participants were assured that the data they provided would remain completely confidential.

RESULTS

The mean age of patients in the early tracheostomy group was 58.28±11.32 years, while in the late tracheostomy group, it was 60.58±12.34 years, with no significant difference (p = 0.39). Males constituted 55% (22/40) of the early tracheostomy group and 77.5% (31/40) of the late tracheostomy group, with borderline significance (p = 0.06). The prevalence of diabetes was higher in the early tracheostomy group (60%) than in the late group (42.5%), although the difference was not significant (p = 0.18). Similarly, hypertension was present in 50% (20/40) of early and 57.5% (23/40) of late tracheostomy patients (p = 0.65).

The SOFA score, which assesses organ dysfunction, was slightly lower in the early tracheostomy group (10.16±1.29) than in the late tracheostomy group (10.9±1.45), but this difference was not significant (p = 0.29). The APACHE II score, a severity-of-illness classification system, was also lower in early tracheostomy patients (25.90±3.47 and 27.55±4.27, respectively), with borderline significance (p = 0.06). The most significant difference was observed in the mean day of tracheostomy, which was performed significantly earlier in the early tracheostomy group (6.38±3.66 days) than in the late tracheostomy group (16.58±4.31 days, p < 0.001) [Table 1].

Table 1: Distribution of demographic variables among study participants.

Demographic characteristics	Early Tracheostomy (n = 40)	Late Tracheostomy (n = 40)	P-value
Age (years), Mean ± SD	58.28 ± 11.32	60.58 ± 12.34	0.39
Male sex, n (%)	22 (55)	31 (77.5)	0.06
Diabetes, n (%)	24 (60)	17 (42.5)	0.18
Hypertension, n (%)	20 (50)	23 (57.5)	0.65
SOFA Score, Mean ± SD	10.16 ± 1.29	10.90 ± 1.45	0.29
APACHE II Score, Mean ± SD	25.90 ± 3.47	27.55 ± 4.27	0.06
Mean day of tracheostomy done, Mean ± SD	6.38 ± 3.66	16.58 ± 4.31	<0.001

The mean duration of ICU stay was significantly lower in the early tracheostomy group (19.18±10.94 days) than in the late tracheostomy group (25.80±8.90 days, p = 0.04). Similarly, the total hospital stay was significantly shorter in the early (37.03±17.57 days) than in the late (47.98 ± 19.50 days, p = 0.01) tracheostomy group, indicating a faster overall recovery. The duration of mechanical ventilation was notably reduced in early tracheostomy patients (16.98±8.46 days) than in those who underwent late tracheostomy (33.38±12.45 days, p < 0.001).

Conversely, the duration of mechanical ventilation was significantly longer in the early tracheostomy group (25.35±10.10 days) than in the late tracheostomy group (25.35 ± 10.10 vs.13.43±5.03 days, p < 0.001). However, the PaO2/FiO2 ratio, a marker of oxygenation status, showed no significant difference between the two groups (240.73±46.54 vs. 243.53±51.79, p = 0.8) [Table 2].

Table 2: Comparison of outcome variables among both groups

Outcome variables	Early Tracheostomy (n = 40)	Late Tracheostomy (n = 40)	P value
Duration of stay in ICU	19.18±10.94	25.80±8.90	0.04
Duration of stay in hospital	37.03±17.57	47.98±19.50	0.01
Time on Mechanical ventilation	16.98±8.46	33.38±12.45	0
Time off Mechanical ventilation	25.35±10.10	13.43±5.03	0
Pa02/Fi02 ratio	240.73±46.54	243.53±51.79	0.8

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In the ICU, the early tracheostomy group had a lower mortality rate (17.5%, 7/40) than the late tracheostomy group, in which 30% (12/40) of patients died (p = 0.009), indicating a statistically significant reduction in ICU mortality with early tracheostomy. Similarly, in the hospital setting, the early tracheostomy group had a lower overall mortality rate (25%, 10/40) than the late tracheostomy group (52.5%, 21/40) of patients who died (p = 0.012), also showing a significant survival benefit. These findings suggest that early tracheostomy is associated with a significantly lower mortality rate in the ICU and during the overall hospital stay, reinforcing the potential benefits of early intervention in critically ill patients.

Table 3: Comparison of mortality among both groups

		Early Tracheostomy (n = 40)	Late Tracheostomy (n = 40)	P-value
ICU	Death	7 (17.5)	12 (30)	0.009
	Survived	33 (82.5)	28 (70)	
Hospital	Death	10 (25)	21 (52.5)	0.012
	Survived	30 (75)	19 (47.5)	

DISCUSSION

Mechanical ventilation is a critical intervention for patients with severe respiratory failures. However, prolonged mechanical ventilation can lead to various complications, including ventilator-associated pneumonia, muscle weakness, and increased mortality rates. Tracheostomy, a surgical procedure to create an opening through the neck into the trachea, is often performed in patients who require extended mechanical ventilation. This procedure facilitates airway management, reduces the need for sedation, and improves patient comfort. The timing of tracheostomy, whether early or late during mechanical ventilation, remains a topic of debate among clinicians. Early tracheostomy is defined as the procedure performed within the first week of mechanical ventilation, whereas late tracheostomy is typically performed after more than a week. Proponents of early tracheostomy argue that it may reduce ventilator-associated complications, shorten ICU and hospital stays, and improve overall patient outcomes. Conversely, late tracheostomy is often favoured to avoid unnecessary procedures in patients who may recover without it.[6,7]

The study involved participants with a mean age of 58.28 and 60.58 years in both groups, respectively which did not differ significantly. This is similar to the study by Balushi et al. which included participants with a mean age of 53 (15.617) and 57.25 (15.474) years in both groups for a comparative study between early and late tracheostomy among ICU patients. Male sex was predominant in both the groups in our study which is similar to the study by Balushi et al.[8]

The SOFA scores between the groups were comparable without any statistical significance. This is similar to the study by Luo et al. which was conducted in groups with comparable SOFA scores. The APACHE II scores in the Early and Late groups were 25.90±3.47 and 27.55±4.27, respectively which were similar. This was also similar to Luo et al. study, in which a study was done with the groups where the APACHE scores were comparable in both groups.[9]

The mean duration of ICU stay was significantly lower in the early tracheostomy group (19.18±10.94 days) than in the late tracheostomy group (25.80±8.90 days), which is consistent with the findings of other studies. Ahmed et al. in their study among the head injury patients observed that patients in the early tracheostomy group spent far less time in the intensive care unit (19.0 ± 7.7 vs. 25.8 ± 11.8 days; p = 0.008) than those in the late group.[10] The observation was consistent with the findings of meta-analysis done by Deng et al. which emphasized the shorter duration of ICU stay in the early tracheostomy group.[11]

Similarly, the total hospital stay was significantly shorter in the early (37.03±17.57 days) than in the late (47.98 ± 19.50 days, p = 0.01) tracheostomy group, indicating a faster overall recovery. This is consistent with the systematic review and meta-analysis did by Qiu et al. which indicate that early tracheostomy in stroke-related patients is associated with a shorter duration of hospital stay compared to late tracheostomy, suggesting potential benefits in recovery and resource utilization.[12]

The duration of mechanical ventilation was shorter in early tracheostomy patients (16.98±8.46 days) than in those undergoing late tracheostomy (33.38±12.45 days, p < 0.001). Han et al. reported a similar observation that early tracheostomy significantly shortens the duration of mechanical ventilation compared to late tracheostomy, according to a meta-analysis of 21 randomised controlled trials involving patients receiving mechanical ventilation.[13] Conversely, the time on mechanical ventilation was significantly longer in the early tracheostomy group (25.35±10.10 days) than in the late tracheostomy group (13.43±5.03 days) in the study. This was similar to the finding of Morakami et al. which showed that the same was 25 ± 28 days and 21 ± 47 days in early and late tracheostomy groups respectively.[14]

In our study, the PaO2/FiO2 ratio, a marker of oxygenation status, showed no significant difference between the two groups (240.73±46.54 vs. 243.53±51.79, p = 0.8). However, a study by Tetaj et al. among COVID patients observed that early tracheostomy was associated with better improvements in the PaO2/FiO2 ratio compared to late tracheostomy.[15] In the ICU, the early

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tracheostomy group had a lower mortality rate (17.5%) compared to the late tracheostomy group, where 30% of patients died. This finding is consistent with the previous study.16 Similarly, in our study, in the hospital setting, the early tracheostomy group had a lower overall mortality rate (25%, 10/40) than the late tracheostomy group, where 52.5% (21/40) of patients died. Sarwari et al. also had a similar observation with 44% and 48% deaths among the early and late groups respectively.[16]

CONCLUSION

This study highlights that patients who underwent early tracheostomy had a significantly shorter ICU stay and reduced total hospital stay, suggesting that early intervention may facilitate faster recovery. Moreover, early tracheostomy was associated with a significantly shorter duration of mechanical ventilation and a longer time off mechanical ventilation, indicating improved ventilatory outcomes and respiratory recovery. Furthermore, early tracheostomy is associated with improved survival rates. In the ICU, the mortality rate was lower in the early tracheostomy group, and this trend continued in overall hospital outcomes, where the hospital mortality rate was significantly lower in patients who underwent early tracheostomy. These findings suggest that early tracheostomy may contribute to better clinical outcomes by reducing ventilator dependency, mortality rates, and hospital length of stay. Further large-scale studies are needed to validate these results and establish standardised guidelines for the optimal timing of tracheostomy in critically ill patients.

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