Tracheostomy before 14 Days: Is It Associated with Better Outcomes in Pediatric Patients on Prolonged Mechanical Ventilation?

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Abstract

Introduction: With the advancement of pediatric critical care services across India, many children require prolonged mechanical ventilation (MV), and tracheostomy is recommended to them. However, many pediatric intensivists have concerns regarding the safety, feasibility, and outcome of tracheostomy.

We aimed to analyze clinical characteristics, indication, duration, and outcome of tracheostomized children with respect to timing of tracheostomy.

Materials and methods: We conducted a retrospective study from the hospital clinical database of consecutive patients below 12 years who had undergone tracheostomy after admission into the pediatric intensive care unit (PICU) for prolonged ventilation (≥96 hours) from January 2015 to December 2019. The study was approved by the Institutional Ethics Committee. Patients were divided into two groups: tracheostomies done within 14 days of MV (early tracheostomy) and patients with tracheostomies performed after 14 days (late tracheostomy). Patients' age, sex, indications, complications, decannulation rate, length of MV, PICU, and hospital stay were analyzed.

Results: Of the 1,425 patients on invasive MV, 87 (6.1%) patients required tracheostomy after a mean 13.37 days of MV. The most common indication was encephalopathy 32 (36.7%) followed by acute respiratory distress syndrome 20 (22.9%). Factors like higher pediatric logistic organ dysfunction score, vasoactive inotrop score, incidence of pretracheostomy ventilator-associated pneumonia, and difficulty in obtaining parental consent were associated with late tracheostomy. The early tracheostomy group had a higher decannulation rate (odds ratio, 5.17; *p*, 0.01) and weaning rate (odds ratio, 5.94; *p*, 0.032). The late tracheostomy group needed a longer duration of MV, PICU, and hospital stay. Complications of tracheostomy were less in the early tracheostomy patients (odds ratio, 2.95; *p*, 0.03).

Conclusion: Early tracheostomy was associated with lower complications, higher successful weaning rates, and less utilization of intensive care facilities in patients receiving prolonged MV.

Clinical significance: In the context of scarcity of data on the timing of tracheostomy in children with prolonged ventilation (≥96 hours) the study shows that early (<14 days) tracheostomy is associated with a better outcome.

Keywords: Mechanical ventilation, Outcome, Pediatric intensive care, Tracheostomy.

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Introduction

Irrespective of the underlying disease process, mechanical ventilation (MV) is an important supportive treatment modality in the pediatric intensive care unit (PICU). Due to the nature of the disease process or complication of MV, such as ventilator-associated lung injury and pneumonia, a cohort of critically ill patients requires prolonged MV. Estimated 2.5–3% of the population admitted to pediatric ICUs require prolonged ventilation[1] and generally have a tracheotomy in place.[2] The authors considered a requirement of invasive mechanical ventilation (IMV) ≥96 hours as prolonged MV.[1]

There is no consensus on the timing of tracheostomy in children. A questionnaire-based multicenter study from the UK showed that most respondents considered timing on an individual basis.[3] A multisite, clinical PICU database from the USA revealed time range to insertion of a tracheostomy tube was from 7.4 to 25.7 days.[4] An important indication for tracheostomy was difficult extubation.[3] Tracheostomy was performed most often in children who had an airway obstruction, or those who required prolonged MV due to respiratory failure associated with chronic conditions such as neuromuscular disease or bronchopulmonary dysfunction.[5]

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Several advantages of tracheostomy over endotracheal intubation have been studied in patients undergoing prolonged MV, such as the promotion of oral hygiene and pulmonary toilet, improved patient comfort, reduced airway resistance, faster weaning from MV,[6] the ability to transfer ventilator-dependent patients from the ICU to step-down facilities[7] and a reduced risk of developing ventilator-associated pneumonia (VAP).[8]

Several risks and complications may be associated with tracheostomy, like the safety of the procedure and probable anticipation of complication, difficulty to decannulation of tracheostomy tube. Till date, clear evidence regarding the chances of such complications is not very clear in the pediatric population. Hence, addressing parental concerns regarding the safety of the procedure becomes very difficult. Meticulous selection of patients, advanced monitoring, and adherence to standard technique by an experienced surgeon are keys to a better outcome.[9] Well-timed tracheostomy could possibly avoid these complications.

Aims and Objectives

To assess the indications, clinical characteristics, rate of decannulation, and complications in pediatric tracheostomy.

Secondary objective was to compare the outcome in the form of duration of post-tracheostomy ventilation, days taken before decannulation, PICU and hospital stay and death between early (after <14 days of ventilation) vs late (after ≥14 days of ventilation) tracheostomies in PICU.

Materials and Methods

Clinical database of pediatric patients below 12 years of age who were admitted to the PICU of a tertiary care teaching hospital of Eastern India and have undergone tracheostomy for prolonged or anticipated prolonged ventilation over a period of 5 years (January 2015 to December 2019) was recorded from computerized hospital patient registry. Prolonged MV was defined as requirement of IMV for ≥96 hours in our study.[1] This study was approved by the Institutional Ethics Committee, which waived the need for informed consent.

Consecutive patients below 12 years of age, who had undergone tracheostomy in this period, were included in the study. Patients who required emergency tracheostomy due to fixed airway obstruction and patients with a tracheostomy tube already in place at the time of admission were excluded.

Study Design

This was a retrospective cohort study. Anonymized information concerning patients who had undergone tracheostomy was extracted from the database. These patients were divided into two groups: those with tracheostomies done within 14 days of MV (early tracheostomy group) and patients with tracheostomies performed after 14 days of MV (late tracheostomy group). In adults, early tracheostomy is defined as tracheostomy performed within or equal to 7 days of ventilation and late tracheostomy as any tracheostomy performed beyond 7 days.

Unfortunately, no pediatric consensus guideline is available on timing of tracheostomy. A pediatric multicenter retrospective study in the USA found the average days of ventilation before tracheostomy to be 14.4 days, though it varied significantly in different units (4.3–30.4 days).[4] We have adapted 14 days as the cutoff based on this evidence.

Variables

Data were obtained on patients with tracheostomy collecting all of the required data fields like age, gender, primary diagnosis, pediatric logistic organ dysfunction score (PELODS-2) to assess the severity of illness and organ dysfunction; highest score was taken for statistical analysis, comorbidities (neurological impairment—congenital and acquired, congenital or acquired heart disease, bronchopulmonary dysplasia, bronchiolitis obliterans, congenital malformation of airway, chronic renal disorder), surgery, trauma, VAP before tracheostomy, number of translaryngeal tracheal tube insertions, vasoactive inotrop score (VIS), incidence of cardiac arrest, need of renal replacement therapy, duration of MV, indication of tracheostomy, MV days prior to first tracheostomy. A patient was considered postsurgical if he/she had surgery within 24 hours before or after admission to the PICU. To calculate the numbers of reintubations one was subtracted from total number of translaryngeal tracheal tube insertions.

Outcome Variables

Date were recorded on length of MV before and after tracheostomies, day of PICU stay when tracheostomy performed, cause of weaning failure, immediate postoperative complication of tracheostomy, late complication of tracheostomy, incidence of VAP, and tracheitis before and after tracheostomies, need of sedation, comfort score, length of PICU stay, day of decannulation, length of hospital stay, survival to discharge.

Procedure

As a hospital policy decision on timing to perform tracheostomy was at the PICU physician's discretion depending on primary disease, secondary complications, and stability of the patient to withstand the procedure. All tracheostomies were formed surgically by an otorhinolaryngologist at the bed site under sedation and paralysis. Cuffed silicon tracheostomy tubes of appropriate size were introduced in all patients. Informed consent had been obtained from the patient, their next of kin, or their legal representative. A postoperative window of 48 hours after tracheostomy was examined for incidence of immediate complications. Decannulation was done by downgrading the size of tracheostomy tube. Bronchoscopy was done in all cases of difficult and failed decannulation.

Statistical Analysis

SPSS (Statistical Packages for the Social Sciences) version 23 software was used for statistical analysis of data of this study. Patients were categorized into an early tracheostomy group and late tracheostomy group. Continuous variables were expressed as the mean ± standard deviation (SD), or the median and interquartile range. Categorical variables were expressed as frequencies and proportions (%). Continuous variables were compared with Student's *t* test or the Mann–Whitney *U* test (for skewed data); categorical variables were compared with the Chi–square test or Fisher's exact test, as necessary. Levels of significance are expressed as *p* values; $p < 0.05$ was considered significant.

Results

During the study period, out of 2,395 PICU patients, 1,425 patients required IMV in the unit of which 87 (6.1%) patients had tracheostomy tubes inserted after admission in PICU. Five patients admitted with tracheostomy were excluded. Tracheostomy was done before 14 days of IMV in 48 (55.2%) patients (early tracheostomy) and after 14 days in 39 (44.8%) patients (late tracheostomy) (Flowchart 1).

The mean age of the patients who had tracheostomy during PICU admission was 6.83 years. The distribution of age and sex

Flowchart 1: Flow diagram of the study population

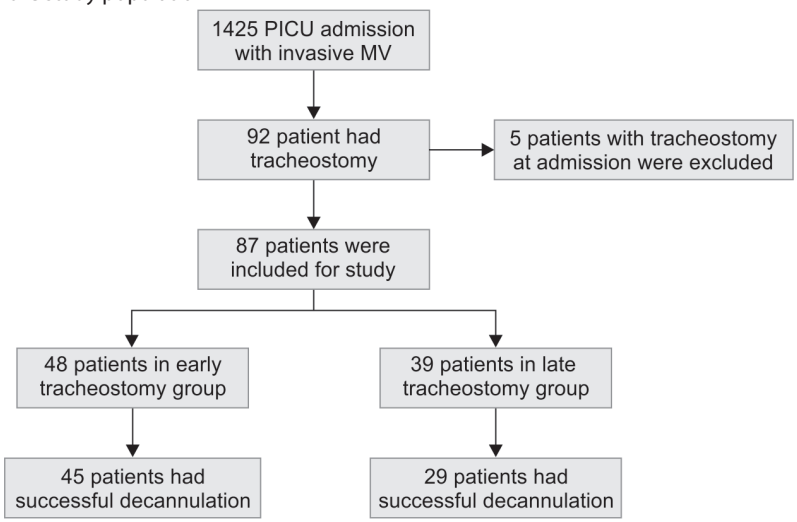

Table 1: Comparison of demographic and clinical characteristics of children between early and late tracheostomy groups

Characteristics	*Number of patients (87)*	*Early tracheostomy N = 48*	*Late tracheostomy N = 39*	*Odds ratio (95% CI)*	*p value*
Age year (mean ± SD)	6.83 ± 2.9	7.06 ± 3.3	6.56 ± 2.34		0.43
Sex, male *n*(%)	57 (65.5)	30 (62.5)	27 (69.2)	0.74 (0.27–1.98)	0.65
Primary diagnosis					
Encephalopathy *n*(%)	32 (36.78)	15 (37.5)	17 (35.9)	1.07 (0.45–2.55)	0.97
GB syndrome *n*(%)	17 (19.54)	14 (29.1)	03 (7.7)	4.94 (1.33–18.42)	0.01
ARDS *n*(%)	20 (22.98)	03 (6.2)	17 (43.5)	7.56 (2.32–25.22)	0.001
Acute airway obstruction *n*(%)	04 (4.59)	04 (2)	00 (7.7)		
Congenital airway malformation *n*(%)	10 (11.49)	08 (16.6)	02 (5.1)	3.09 (0.97–14.08)	0.15
Trauma *n*(%)	03 (3.44)	03 (6.2)	00		
Postsurgical *n*(%)	01 (1.14)	01 (2)	00		
Comorbidities *n*(%)	62 (71.26)				
Congenital or acquired chronic neurological impairment *n*(%)	26 (29.8)	11 (22.9)	15 (38.5)	0.48 (0.19–1.20)	0.14
Chronic lung disease *n*(%)	16 (18.39	5 (10.4)	11 (28.2)	3.38 (1.07–10.63)	0.04
Chronic heart disease *n*(%)	08 (9.19)	05 (10.4)	03 (7.7)	1.05 (0.32–6.13)	0.72
Chronic renal disease *n*(%)	04 (4.59	01 (2.2)	03 (7.7)	0.26 (0.03–2.49)	0.32
Neuromuscular disorder *n*(%)	08 (9.19)	07 (14.6)	01 (2.6)	6.49 (0.78–53.7)	0.03

ARDS, acute respiratory distress syndrome; GB syndrome, Guillain–Barré syndrome

did not differ between the early and late tracheostomy groups. Encephalopathy (36.78%), acute respiratory distress syndrome (ARDS) (22.98%), Guillain–Barré (GB) syndrome (19.54%), and congenital airway malformation (11.49%) were major primary diagnosis of patients necessitating tracheostomy. It was observed that a significant proportion of GB syndrome patients required early tracheostomy (odds ratio, 4.94; *p*, 0.01), while significantly more ARDS patients underwent late tracheostomy (odds ratio, 7.56; *p*, 0.001) (Table 1). Reintubation was associated with late tracheostomy. The mean time of tracheostomy was 13.25 ± 6.03 days from the start of MV. A significant difference was noted between the groups regarding timing of tracheostomy (10.47 ± 2.2 vs 17.04 ± 3.1, *p* <0.001). Factors like higher PELOD-2 score, VIS, incidence of pretracheostomy VAP, and difficulty in obtaining parental consent were associated with late tracheostomy (Table 2).

Fifteen patients (17.2%) had early (within 48 hours of procedure) complications (Table 3). Majority of them were obstruction of tracheostomy tube by a clot which was relieved by suctioning. Other minor complications were hemorrhage, accidental decannulation, and subcutaneous emphysema. Late complications were observed in 21 (24.13%) patients. There was an overlap of complications in individual patients. Tracheomalacia and tracheitis were found in 10.3 and 9.19% of patients of the whole cohort, respectively. Complications that required further interventions like suprastomal, stomal, infrastomal granulations, and subglottic stenosis were found in a small proportion of patients. Other complications like pneumothorax, trachea-esophageal fistula, and trachea-innominate fistula were not observed.

Patient outcome was measured in the form of total MV days, pediatric ICU stay, hospital length stay, total sedation day and

Table 2: Comparison of severity of disease and complication, in children before tracheostomy between early and late tracheostomy groups

Characteristics	*Number of patients (87)*	*Early tracheostomy N = 48*	*Late tracheostomy N = 39*	*Odds ratio (95% CI)*	*p value*
Number of reintubation					
0 *n*(%)	38 (43.67)	34 (70.8)	4 (10.3)	21.2 (6.45–70.02)	<0.001
1 *n*(%)	42 (48.27)	13 (27)	29 (74.3)	7.81 (3.02–20.16)	<0.001
2 *n*(%)	07 (8.04)	01 (2.2)	06 (15.4)	5.91 (1.26–27.70)	0.04
Timing of tracheostomy (mean ± SD)	13.25 ± 6.03	10.47 ± 2.2	17.04 ± 3.1		<0.001
VAP before tracheostomy *n*(%)	21 (24.1)	06 (12.5)	15 (38.46)	4.38 (1.52-12.62)	0.006
Cardiac arrest *n*(%)	4 (4.59)	1 (2.2)	3 (7.7)	3.9 (0.40–8.25)	0.32
PELODS-2 maximum (mean ± SD)	14.45 ± 5.59	12.23 ± 3.55	20 ± 4.56		0.03
VIS maximum (mean ± SD)	16.2 ± 1.8	14.6 ± 1.6	20.5 ± 2.3		0.07
Difficult to obtain parental consent *n*(%)	21	5 (10.4)	16 (41)	5.98 (1.97–18.19)	0.001
Successful decannulation *n*(%)	74 (85.05)	45 (93.7)	29 (74.3)	5.17 (1.33–20.1)	0.01

Table 3: Complications of tracheostomy

Complications	*Number of incidences*	*Percentage*
Early complication total	15	17.2
Obstruction by secretion	11	17.24
Hemorrhage	03	3.44
Accidental decannulation	03	3.44
Subcutaneous emphysema	02	2.29
Late complication	21	24.13
Tracheitis	08	9.19
Tracheomalacia	09	10.3
Tracheostomy site infection	06	6.89
Obstruction by cast	11	12.64
Suprastomal granulation	2	2.29
Stomal granulation	1	1.14
Infrastomal granulation	1	1.14
Subglottic stenosis	2	2.29

were significantly more among the late tracheostomy group, and decannulation was also more delayed among the late tracheostomy group. Weaning rate was significantly high in early tracheostomy group (odds ratio, 5.94; *p*, 0.032). Complication like VAP was less among the early tracheostomy group. In our study, decannulation rate among the surviving population was 85.05%. Significantly higher number of patients in the late tracheotomy group had to be discharged with a tracheostomy tube (10 vs 3, *p*. 0.016). Six patients in the late tracheostomy group had to be discharged with home ventilator support (Table 4).

Discussion

Tracheostomy is a well-accepted procedure in adult ICUs, but in children sometimes it becomes very difficult to take a timely decision due to less expertise in infants, difficulty in performing a bedside procedure, fear of side effects, presumed difficulty in extubation in the future, and concerns of the parents. This retrospective study was able to identify several demographic and clinical characteristics that were associated with tracheostomy and the difference in the distribution of these factors among early and late tracheostomy groups. We found that patients admitted for respiratory failure due to ARDS, high PELOD-2 score, VIS, and complications of MV like VAP were most likely associated with late tracheostomies. Moreover, in the late tracheostomy group, the duration of MV, PICU stays, and hospital stays were longer.

In our study, 6.1% of the patients necessitating MV in PICUs received tracheostomies, which is similar to the rate seen in other countries (2.05–6.6%). As such, our findings are consistent with other reports.[3,4]

Presence of comorbidities was found in 71.26% of children with tracheostomy in our study. Neurological comorbidity contributed the most (29.8%). A study conducted by Ishihara et al. in Japan found that 74% of tracheostomy patients had chronic conditions.[9] Wood et al. in a retrospective study observed that neuromuscular problems and chronic conditions influenced the decision to perform a tracheostomy.[3] Neurological impairment was noted in 48% of patients who had tracheostomy by Berry et al. at major children's hospitals.[10]

There is no fixed time frame in pediatric patients for tracheostomy. In Canada, the average number of days of ventilation before tracheostomy is 21, but in the USA it is 14.4 days, though it varied significantly in different units (4.3–30.4 days).[3,4] There are some studies comparing early and late tracheostomies in adult ICU ventilated patients (early is defined as within 7 days) and it was shown that though early tracheostomy has no effect on incidence of VAP,[11] it significantly reduced stay and chances of mortality.[12] In our unit, the average number of days of ventilation before tracheostomy was 13.37 days. Unlike adults, an established guideline regarding timing of tracheostomy in case of prolonged ventilation in pediatric ICU patients is not available. Individual units follow their own guideline according to expertise and experience. Multicenter randomized control trial regarding the timing of tracheostomy in prolonged ventilation in pediatric patients will help to establish evidence and guideline.

There are different advantages of tracheostomy over endotracheal tube in case of prolonged ventilation. Most important of them is patient's comfort. Patient can eat, oral hygiene can be maintained easily, patient can move easily, airway resistance is decreased, and a stable airway is maintained.[13,14] On the other hand, studies have shown to decrease the duration of ventilation and sometimes help in extubation in case of difficult extubation cases.[15] In our study, it was also found that early tracheostomy causes a significant reduction in ventilation days, PICU stay, hospital stay, and incidence of VAP but no mortality benefit was noted. There is no published data on early vs late tracheostomy in children to the best of our knowledge.

Table 4: Comparison of outcome variables between early and late tracheostomy groups

Variables	*Early tracheostomy N = 48*	*Late tracheostomy N = 39*	*Odds ratio (95% CI)*	*p value*
MV days total (mean ± SD)	17.5 ± 5.6	29.4 ± 10.5		0.001
Weaning rate *n*(%)	46 (95.8)	31 (79.48)	5.94 (1.20–29.32)	0.032
Length of PICU stay (mean ± SD)	30.3 ± 7.3	42.6 ± 15.1		0.001
Length of hospital stay (mean ± SD)	41.4 ± 6.5	55.4 ± 14.7		0.001
Incidence of VAP *n*(%)	16 (33.3)	23 (62.1)	2.79 (1.20–6.49)	0.01
Incidence of tracheitis *n*(%)	5 (10.41)	3 (7.69)	1.05 (0.19–7.28)	0.634
Late complication *n*(%)	8 (16.6)	13 (33.3)	2.95 (1.00–8.93)	0.03
Decannulation day (mean ± SD)	24.4 ± 5.8	36.7 ± 6.5		0.006
Total duration of sedation (mean ± SD)	14.4 ± 2.6	22.5 ± 5.2		0.017
Discharge with tracheostomy tube *n*(%)	3 (6.25)	10 (25.4)	5.17 (1.33–20.09	0.016
Discharge with home ventilation	0	6 (15.38)		
Death	2 (4.16)	5 (12.8)	3.38 (0.63–18.14)	0.254

Tracheostomy in pediatric patients has a higher complication rate as compared to when performed on adults.[16,17] Severe complications such as cardiopulmonary arrest and pneumothorax have been seen in 5–40%.[18,19] In our study, no perioperative mortality was noted but subcutaneous emphysema occurred in a few cases. Berry et al. used pooled data from 36 pediatric centers and followed 917 children from 2002 to 2007. Nearly 19% of this cohort experienced tracheostomy-related complications.[10] In our study, it was found that 24.1% patients had late complications and major late complications were tracheomalacia (10.3%), tracheitis (9.25%), granuloma, and subglottic stenosis in six patients.

Seven patients succumbed to death due to primary disease related causes. No cases of tracheoesophageal fistula or pneumothorax noted during surgery. While a few studies have showed that there is a low rate of decannulation (35–75%) after tracheostomy in pediatric patients,[19–22] our study found that the majority of patients were decannulated before discharge. Decannulation rate among the surviving population was 85.05%. The average time taken before decannulation was significantly less in early tracheostomy group.

Limitation

This was a single-center, retrospective analysis. Only an association among the available data could be described. The sample size was small. The data about tracheostomy were evaluated by univariate analysis, so careful interpretation of these results is needed.

Conclusion

Early tracheostomy was associated with reduced complications of tracheostomy and effective decannulation in the majority of the patients. Late tracheostomized patients had a longer duration of MV and length of PICU and hospital stays compared with patients in early tracheostomy group. Multicenter randomized control trial regarding the timing of tracheostomy in pediatric patients on prolonged ventilation will help to establish evidence and guideline.

Clinical Significance

In the context of scarcity of data on timing of tracheostomy in children with prolonged ventilation, the study proposes that early (<14 days) tracheostomy is associated with a better outcome.

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