Outcomes of newborns with tracheostomy: single center experience

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ABSTRACT

Background. Babies with severe bronchopulmonary dysplasia (BPD) are discharged with the support of a home-type mechanical ventilator, after opening a tracheostomy. In addition, although rare, tracheostomy is required in the neonatal period in congenital airway malformations. Early tracheostomy is appropriate to prevent complications due to prolonged intubation.

We aimed to find the appropriate time for tracheostomy by examining the tracheostomy opening and closing times, complications and demographic characteristics of the patients, who were hospitalized and underwent tracheostomy in our neonatal intensive care unit.

Methods. This retrospective study involved infants admitted to the neonatal intensive care unit between January 2014 and 2019 and discharged following tracheostomy. Information acquired from hospital data was enrolled. The protocol was registered with ClinicalTrials.gov identifier NCT04497740.

Results. Twenty-six neonates with median 27.5 weeks gestational age and birth weight 885 gr were enrolled in the study. The mean opening time for tracheostomy was 54 ± 24 days, and the postmenstrual age (PMA) was 36 ± 3 weeks. The mean time to closure of tracheostomy in newborns with a tracheostomy was 387 ± 164 days. The duration of accidental decannulation developed as an early complication in 8 patients was mean 11 ± 8 days. Aspiration pneumonia in 2, subglottic stenosis in 5, accidental decannulation in 2, suprastomal collapse in 7, tracheocutaneous fistula in 8 and granulation tissue in 2 patients were found to be late complications, which occurred within median 90 days.

Conclusions. If there is no evidence that breathing has improved and the patient is still using a mechanical ventilator at high pressures and high oxygen concentration, a tracheostomy placement should be considered within two months.

Key words: newborn, neonatal tracheostomy, extremely low birth, premature, congenital airway malformations.
in the neck or neuromuscular diseases need long term ventilation. Even if these babies have minimal ventilatory needs, tracheostomy plays a vital role to ensure airway patency in many of these conditions.\textsuperscript{5} Moreover, tracheostomy enables long-term, stable delivery of adequate positive airway pressure that may reduce breathing and promote growth. The minimization of agitation and airway injury caused by conventional endotracheal tubes, greater ease of movement, oral feeding and safer participation in developmental therapy may be additional benefits of a tracheostomy.\textsuperscript{6}

Several studies focus on the surgical indications, complications, and techniques used for pediatric tracheostomy whereas few studies focus on the complications and long-term clinical outcomes for infants that require tracheostomy placement and prolonged mechanical ventilation.\textsuperscript{7-9} However, the studies in the literature regarding tracheostomy timing and decannulation procedure in newborns or infants are limited.\textsuperscript{4,10,11} In addition, the opening time of a tracheostomy varies between NICUs. Rather, it depends on the clinician’s decision.

We aimed to find the appropriate time for tracheostomy by examining opening and closing times, complications and demographic characteristics of the patients who were hospitalized and underwent tracheostomy in our neonatal intensive care unit (NICU).

**Material and Methods**

This study was designed as a retrospective study. The records of all newborns admitted to the NICU and underwent a tracheostomy at our hospital between January 2014 and 2019 were reviewed. This study was approved by the Hacettepe University Non-Interventional Ethical Committee (2020/11-28). Premature newborns with a severe BPD and term newborns diagnosed with congenital airway malformations or different kind of diseases requiring tracheostomy were involved in our study. The National Institute of Child Health and Human Development (NICHD), NHLBI and Office of Rare Diseases (ORD) proposed the current (NIH consensus) definition of BPD, “Infants born <32 weeks, who require supplemental oxygen for at least 28 days and at 36 weeks postmenstrual age (PMA)”. The definition further stratified the disease into mild (breathing room air at 36 weeks PMA or discharge, whichever comes first), moderate (need for <30% oxygen at 36 weeks PMA or discharge, whichever comes first), severe (need for ≥30% oxygen and /or positive pressure [positive pressure ventilation (PPV) or nasal continuous positive airway pressure (NCPAP)] at 36 weeks PMA or discharge, whichever comes first).\textsuperscript{1} The NICHD Neonatal Research Network has proposed a severe BPD definition using a severity scale that is based on the use of positive pressure at 36 weeks PMA instead of supplemental oxygen. Infants were classified as no BPD (no support), grade 1 (nasal cannula ≤2 L/min), grade 2 (nasal cannula >2 L/min or non-invasive positive airway pressure), or grade 3 (invasive mechanical ventilation).\textsuperscript{2} Patients’ demographic information such as antenatal follow-up data, maternal diseases, birth weight, gestational age, delivery type, as well as invasive or non-invasive mechanical ventilation times during hospitalization in our unit were recorded. In addition, tracheostomy opening time and tracheostomy closure time at follow-up were added.

There are approximately 1000 births per year in our center and there are perinatology, pediatric surgery and many other surgical branches. In addition to high-level surgical procedures, we have a fourth-level neonatal intensive care unit that can perform extracorporeal membrane oxygenation (ECMO). Tracheostomy procedures are performed especially by physicians specialized in pediatric and neonatal ear, nose and throat surgery (ENT).

All tracheostomies were performed through an endotracheal tube in the operating room by experienced otolaryngologists. All surgeons followed the same surgical technique. Patients were positioned with a shoulder roll and annular
head support in place. Cervical landmarks were identified and a midline horizontal incision was made with a knife along the skin. Colorado-tipped electrocautery was used to remove subcutaneous and perimuscular fat and dissect down to the anterior trachea in the midline. Lateral dissection was avoided. A skin hook was placed under the cricoid cartilage to elevate the trachea. A vertical incision was made between the second and third tracheal rings with an 11-blade scalpel. Bilateral stop sutures were placed through a vertical incision. The addition of maturation sutures from skin to trachea forms a mature stoma which, in conjunction with the use of stay sutures, allows easier replacement of the tube if accidentally displaced. The appropriately sized tracheostomy tube was then placed. The anesthesiologist then controlled for significant air leaks, even air intake and whether adequate oxygenation and ventilation could be maintained. The tracheostomy tube was then fixed in place with nylon sutures and tracheal ties. All patients underwent postoperative chest radiographs to evaluate tracheostomy tube placement and to determine whether there were any changes in the lungs after the procedure. Tracheostomy tubes were changed in the NICU by an otolaryngologist between postoperative days 5 and 7.

In addition, early and late complications encountered in the follow-up of patients with tracheostomy were also recorded in our study.

Before decannulation, airway examination via laryngo-bronchoscopy is the standard of care.

Data were analyzed using “Statistical Package for Social Sciences for Windows 27.0.” and were tested for normality with the Shapiro Wilk W-test; they were expressed as mean (SD) and median (minimum-maximum) as appropriate. In the analysis, p values less than 0.05 were accepted as statistically significant. The protocol was registered with ClinicalTrials.gov identifier NCT04497740.

Results
A total of 26 newborn infants who underwent a tracheostomy between January 2014 and 2019 were enrolled in our study. Demographic data such as gestational age, birth weight, gender, and maternal diseases are listed in Table I.

20 of the newborns who underwent tracheostomy were followed up with the diagnosis of bronchopulmonary dysplasia. The newborns median gestational ages were 26 (24-32) weeks and median birth weights were 790 grams (420-1500). 12 (60%) of these newborns used antenatal steroids.

Table I. Demographic data (n=26).

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD) or Median (Min-Max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age, weeks*</td>
<td>27.5 (24-39)</td>
</tr>
<tr>
<td>Birth weight, gram*</td>
<td>885 (420-3160)</td>
</tr>
<tr>
<td>Weight for gestational age (AGA/SGA/LGA)</td>
<td>23 (88.5) / 3 (11.5) / 0</td>
</tr>
<tr>
<td>APGAR 1./5. min*</td>
<td>6 (2-8) / 7 (4-9)</td>
</tr>
<tr>
<td>Delivery type (Cesarean section)</td>
<td>23 (88.5)</td>
</tr>
<tr>
<td>Gender (male)</td>
<td>17 (65)</td>
</tr>
<tr>
<td>Antenatal steroid</td>
<td>13 (50)</td>
</tr>
<tr>
<td>Mother’s diseases</td>
<td></td>
</tr>
<tr>
<td>Gestational diabetes</td>
<td>2 (8)</td>
</tr>
<tr>
<td>Preeclampsia</td>
<td>8 (31)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Chorioamnionitis</td>
<td>1 (4)</td>
</tr>
</tbody>
</table>

Expressed as n (%) unless indicated otherwise. * Median (min-max)
The diagnoses of the patients are listed in Table II. The hospitalization period was 89 ± 31 days. Twenty-two (85%) patients were discharged; however, 4 (15%) patients died.

The mean opening postnatal time for tracheostomy was 54 ± 24 days, and the postmenstrual age (PMA) was 36 ± 3 weeks. The mean time to closure of tracheostomy in the newborns was 387 ± 164 days.

However, when we evaluated only patients with bronchopulmonary dysplasia, the mean opening postnatal time for tracheostomy and the postmenstrual age was 63 ± 16 days and 35 ± 3 weeks, respectively. Moreover, the mean time of closure of tracheostomy in the newborns with tracheostomy was found to be 382 ± 159 days.

While the mean time to open tracheostomy was 63±16 days in patients with BPD, the median was 24.5 (0- 63) days in patients without BPD (p=0.03).

The duration of accidental decannulation developed as an early complication in 8 patients was mean 11 ± 8 days. Aspiration pneumonia in 2, subglottic stenosis in 5, accidental decannulation in 2, tracheocutaneous fistula in 8, suprastomal collapse in 7 and granulation tissue in 2 patients were found to be late complications, which occurred within 90 (IQR: 51- 345) days. Laryngotratcheal reconstruction (LTR) was required in 4 patients in the late period after grade 3 subglottic stenosis.

**Discussion**

This present study provides information about 26 newborns with tracheostomy for a duration of five years in our NICU. We aimed to find the appropriate time for tracheostomy by examining opening and closing times, complications and demographic characteristics of the patients who were hospitalized and underwent a tracheostomy in our NICU.

Tracheostomy has become a routine clinical intervention in adult critical care, performed in 10–24% of ventilated adult patients. Tracheostomy placement in adults occurred at a median of 9 days (interquartile range 5–14 d) after ICU admission. Improved neonatal intensive care with increased survival of premature infants has changed the management of the neonatal airway. The most important indication of tracheostomy is long-term adherence to mechanical ventilators and the other indication was upper airway obstruction. One of the pediatric tracheostomy studies in which 95 patients with mean age of 5.2 years were involved, revealed non-anatomical [preemie and chronic respiratory diseases (BPD)] and anatomical (vocal cord paralysis, airway stenosis, and syndromic) indications of tracheostomy.

A retrospective analysis of 917 children who underwent tracheotomy from 36 children’s hospitals found that the median age of tracheotomy was 0.5 years (inter-quartile range: 0.2–6.3 years). All patients under eighteen years were enrolled in the study in question. In our study, however, we enrolled infants who were admitted to our NICU. Their diagnosis for tracheostomy was similar to our study group.

While most of the published studies on tracheostomy were conducted in the pediatric period, we especially evaluated newborns and infants hospitalized in the infant period.

The timings for the placement of tracheostomy are not specific across many centers. In the Upadhyay et al.’s study, 41 infants required tracheostomy due to prolonged mechanical ventilator because of BPD. Their median age of tracheostomy placement was 168 days (108–197 IQR), and median PMA was 48 weeks (40–56
IQR). On the other hand, in Mandy et al.’s study, the mean age of tracheostomy placement was 177 ± 74 days and the PMA at receipt of tracheostomy was 51±10 weeks. In the present study, the mean opening time for tracheostomy was 54 ± 24 days, and the postmenstrual age was 36 ± 3 weeks. Tracheostomy opening time was found later in babies with severe BPD compared to babies with congenital anomalies. However, in this study, it was determined that tracheostomy was performed earlier than the literature.

A multicenter, retrospective study conducted in the year 2015 suggested that babies do better neurodevelopmentally, with early tracheostomy opening. However, the study did not show evidence of an overall attenuation of poor neurodevelopmental outcomes. Furthermore, Luo’s retrospective study (n = 72) found a positive significant improvement in linear growth, weight gain, and head circumference in severe BPD patients after tracheostomy. In addition, earlier tracheostomy may give a chance for physical and occupational therapies to start earlier as well as speech/language therapy.

There are no studies with a published evidence-based decanulation algorithm that is for tracheostomy. The soonest indicator of readiness for decanulation is decreased reliance on mechanical ventilation. The most recent clinical consensus statement from the American Academy of Otolaryngology-Head and Neck Surgery discusses the key essentials in readiness for decanulation. Evaluation should involve rigid bronchoscopy and flexible laryngoscopy to ensure airway patency. Our preference is that the child should not have aspiration-type dysphagia and should be independent of the ventilator for the previous 2-4 months. Especially after the age of 2, there should be no need for a ventilator both day and night. This report highlights individualized medical decision making. A study about tracheostomy in which researchers have 12-year experience in the topic in question revealed that median time of decanulation exceeded 2 years. In our study we also used laryngo-bronchoscopy before decanulation, and the mean time of closure of tracheostomy in newborns was 387 ± 164 days (approximately 13 months). In contrast to the other studies, our study revealed that tracheostomy is opened and closed earlier in prolonged intubation. The reason may be that subglottic stenosis and the other complications occur less frequently. In this study, we found that we opened the tracheostomy early without subglottic stenosis. Its closure is also early, but one of the effective aspects is the elimination of the systemic problems that cause the tracheostomy to be opened. As the lung development of the patients accelerates, the tracheostomy closure time is shortened.

Tracheostomy complications are shown in the adult patients more than pediatric patients. Some reports suggest that 39% of preterm children with BPD develop tracheostomy complications. The complications comprise in accidental decannulation, tube plugging, tracheal stenosis, tracheocutaneous fistula, false passage creation, stomal cellulitis, suprastomal collapse and stomal granuloma or keloid formation. Suture abscess, pneumomediastinum, pneumothorax and innominate artery erosion have also been documented less frequently. Accidental decannulation in 8 (31%) patients was the early complication that we came across. On the other hand, aspiration pneumonia in 2 (%8), subglottic stenosis in 5 (19%), accidental decanulation in 2 (8%), suprastomal collapse in 7 (27%), tracheocutaneous fistula in 8 (31%) and granulation tissue in 2 (8%) patients were among the late complications we encountered. We haven’t seen the other complications like tube plugging, false passage creation, air leaks, artery erosion, and stomal cellulitis. The reason why we do not see the false passage in particular is that we put a maturation suture during the tracheostomy. In addition to this, good nursing care during intensive care follow-up and a scheduled cannula change are also effective.
Also, it was observed in this study that infants did not remain hypoxic with accidental decannulation.

Airway damage and stenosis may occur secondary to chronic trauma of the intubation cannula as well as mechanical ventilator-related lung injury in infants who have not yet completed their lung and airway development, and surgical operation (LTR, balloon dilatation) may be required in severe cases. Therefore, we think that an earlier tracheostomy decision may reduce the risk of airway damage in premature babies with increased susceptibility to injury. However, there is a need for prospective observational studies in which the risk of intubation trauma in the airway is directly observed and evaluated by bronchoscopy, and concrete criteria are developed in this regard. Although many late complications are not seen because the tracheostomy is opened early, suprastomal collapse can be seen in early tracheostomies. This was detected in the long-term follow-up in seven patients due to early tracheostomy.

One of the most important strengths of the study was that it presented the data obtained as a result of a 5-year observation in the NICU. Another strong point is that babies who were discharged with tracheostomy in the early period also had less complications developing after discharge.

The most important limitation of this study was that we did not evaluate polysomnography (PSG) meantime decannulation. PSG can be used prior to decannulation. While PSG does not significantly impact decannulation success rates, it is helpful for determining the presence or absence of central sleep apnea.\textsuperscript{24,25}

The limited number of patients included is also a limitation. Instead, a large number of patients should have been involved to evaluate complications.

In conclusion, there is no optimal timing and context for the placement of tracheostomy in infants. A reasonable approach which can be suggested by this report is that chronically ventilated infants should be assessed at approximately 2 months. If there is no evidence that breathing has improved and the patient is still using a mechanical ventilator at high pressures and high oxygen concentration, a tracheostomy placement should be considered within two months. But airway damage and stenosis may occur secondary to chronic trauma of the intubation cannula as well as mechanical ventilator-related lung injury in infants who have not yet completed their lung and airway development, and surgical operation (tracheoplasty, balloon dilatation) may be required in severe cases. Therefore, we think that an earlier tracheostomy decision may reduce the risk of airway damage in premature babies with increased susceptibility to injury. On the other hand, the data obtained from this study can be used in future studies to compare the lung prognosis of infants with early and late tracheostomy.

**Ethical approval**

Hacettepe University Non-Interventional Ethics Committee decision number: 2020/11-28.

**Author contribution**

The authors confirm contribution to the paper as follows: study conception and design: UAT, HTC; data collection: OD, UAT; analysis and interpretation of results: UAT, HTC; draft manuscript preparation: UAT, SY, HTC, ROG. All authors reviewed the results and approved the final version of the manuscript.

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**Conflict of interest**

The authors declare that there is no conflict of interest.
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