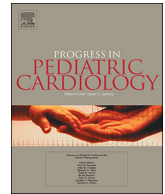




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## Risk factors and outcomes of tracheostomy after prolonged mechanical ventilation in pediatric patients with heart disease

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## ABSTRACT

The indications for tracheostomy after prolonged mechanical ventilation among pediatric patients with heart disease are multifactorial and difficult to determine; therefore, knowing the risk factors and outcomes of tracheostomy may be useful for selecting patients who require tracheostomy. The aim of this study was to identify the risk factors and outcomes of tracheostomy after prolonged mechanical ventilation in pediatric patients with heart disease. We performed a retrospective, single-center observational study in consecutive patients with heart disease aged  $\leq 18$  years admitted to a pediatric intensive care unit at a tertiary children's hospital between January 2010 and December 2016. Patients who required prolonged mechanical ventilation ( $\geq 14$  days) were included. Clinical characteristics and outcomes were compared between the patients with and without tracheostomy and the risk factors for receiving tracheostomy were assessed. Of the 85 patients who required prolonged mechanical ventilation, 20 (24%) underwent tracheostomy. The duration of mechanical ventilation before tracheostomy was 51 days, and pediatric intensive care unit lengths of stay in patients with and without tracheostomy were 83 and 34 days, respectively ( $P < 0.001$ ). Risk factors for tracheostomy were multiple ( $\geq 2$ ) surgeries and mean airway pressure  $\geq 10$  cmH<sub>2</sub>O after 14 days of mechanical ventilation. In patients with tracheostomy, six (30%) were successfully weaned from mechanical ventilation and two (10%) were de-cannulated. Tracheostomy complications included granulation tissue in three cases and airway obstruction in one. There was no difference in the survival rates of patients with and without tracheostomy (70% vs. 74%;  $P = 0.73$ ). Although the mortality rate of patients with and those without tracheostomy were not significantly different, the baseline illness severity might be different. Further studies that adjust for patient factors, such as disease severity, are needed to determine the effect of tracheostomy on patient outcomes; however, this was beyond the scope of our study.

### 1. Introduction

Approximately 10% of pediatric patients require mechanical ventilation for  $> 7$  days after cardiac surgery [1]. Prolonged mechanical ventilation is associated with respiratory complications [2], ventilator-associated pneumonia [3], prolonged sedation [4], an extended stay in the pediatric intensive care unit [5], and high mortality [6].

Tracheostomy may reduce mechanical ventilation time and the incidence of complications associated with prolonged mechanical ventilation [7] and improve outcomes for patients who require respiratory support [4]. Additionally, tracheostomy allows the transfer of patients who require prolonged mechanical ventilation from the pediatric intensive care unit to a general ward and from the hospital to their home, thereby improving their quality of life [5]. However, tracheostomy is

also associated with fatal complications including massive bleeding from a tracheoinnominate fistula and mechanical airway obstruction [5,8,9]. Therefore, the indications for tracheostomy should be carefully evaluated in each case.

Tracheostomy is considered when prolonged mechanical ventilation is required [4]. However, determining the need for and timing of tracheostomy is often difficult because multiple factors must be assessed, especially in pediatric patients with heart disease [10–12]. Knowing the risk factors for tracheostomy and outcomes in patients who did or did not undergo tracheostomy may facilitate patient selection for the procedure. However, previous studies only investigated patients who underwent tracheostomy and did not include those who were successfully extubated after prolonged mechanical ventilation [5,8,10–13]. Therefore, the differences in clinical features and outcomes between patients

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who underwent tracheostomy and those who did not have yet to be evaluated. The purpose of this study was to identify the risk factors and outcomes of tracheostomy after prolonged mechanical ventilation in pediatric patients with heart disease.

## 2. Materials and Methods

### 2.1. Design and Setting

We performed a retrospective observational study of pediatric patients with heart disease who underwent prolonged mechanical ventilation from January 2010 to December 2016 in the pediatric intensive care unit at the Osaka Women's and Children's Hospital in Osaka, Japan. The study was approved by the hospital's ethics committee, conformed with the 1964 Helsinki declaration and its later amendments or comparable ethical standards, and the need for informed consent was waived due to its retrospective nature. The pediatric intensive care unit had 6–12 beds for medical and surgical pediatric patients during the study period. The unit cared for 300–600 pediatric patients annually, and approximately 150–200 patients were admitted after cardiac surgery. Heart transplantation was not performed at the hospital.

### 2.2. Inclusion and Exclusion Criteria

We included all consecutive patients with heart disease aged 18 years or younger admitted to the pediatric intensive care unit and treated with prolonged mechanical ventilation. Prolonged mechanical ventilation was defined as the administration of invasive mechanical ventilation for 14 consecutive days or more. A previous study reported that the mean length of intubation before tracheostomy was 424 h [14]. Additionally, decreased survival was reported in patients intubated for > 10 days, and the mean time to a diagnosis of ventilator-associated pneumonia was reported as 17 days [3,15]. Therefore, we defined prolonged as 14 consecutive days or more. We included only the latest admission for patients who had two or more admissions with prolonged mechanical ventilation during the study period. We excluded patients who had received tracheostomy before admission to the pediatric intensive care unit and those who underwent tracheostomy before receiving 14 days of mechanical ventilation.

### 2.3. Data Collection

Data were retrospectively collected from medical records including patient demographic data, genetic studies, and diagnoses of cardiac lesions; the number of patients who underwent tracheostomy; and the indications for tracheostomy. We assessed the follow-up data for each patient including the duration of mechanical ventilation, pediatric intensive care unit stay, and hospitalization. We recorded pediatric intensive care unit, hospital, and post-discharge mortalities. The end of the follow-up period was November 2017. Additionally, we identified the number of patients weaned from mechanical ventilation, the number of patients de-cannulated, and tracheostomy complications including bronchial granulation, tracheoinnominate fistula, and airway obstruction. We also identified the causes of death in non-survivors after tracheostomy.

### 2.4. Risk Factors for Tracheostomy

We identified potential risk factors for tracheostomy based on the relevant literature and our experience and compared these between patients with and without tracheostomy. Our analysis included the following factors: age in days at the initiation of mechanical ventilation [16], sex, pediatric intensive care unit admission body weight, genetic abnormalities [16–18], cardiopulmonary resuscitation, central nervous system complications (including cerebral hemorrhage, cerebral infarction, hypoxic encephalopathy, and convulsions) [10], respiratory

complications (including upper airway obstruction, vocal cord paralysis, subglottic stenosis, tracheomalacia, bronchomalacia, phrenic nerve paralysis, pneumothorax, and episodes of pulmonary aspiration) [10–12,18], extubation failure (defined as reintubation within 48 h of a planned extubation), single ventricle anatomy [19], hypoplastic left heart syndrome and its variants, cardiac surgery, multiple ( $\geq 2$ ) surgeries before tracheostomy [13], use of extracorporeal membrane oxygenation [18], peak serum level of brain natriuretic peptide before tracheostomy [11,20], diagnosis of pulmonary hypertension (based on echocardiogram results or the use of nitric oxide inhalation or sildenafil citrate), chylothorax, diagnosed or suspected infection (defined by the use of antibiotics), pediatric index of mortality 2 score (a scale for predicting mortality in patients admitted to the pediatric intensive care unit) [21], fraction of inspired oxygen and mean airway pressure  $\geq 10$  cmH<sub>2</sub>O after 14 days of mechanical ventilation, and vasoactive-inotrope score after 14 days of mechanical ventilation [22,23].

### 2.5. Statistical Methods

Categorical variables were evaluated using the chi-square or Fisher's exact test as appropriate. Continuous variables were evaluated using the Mann-Whitney *U* test. Statistical significance was defined as  $P < 0.05$ . Individual potential risk factors for tracheostomy were assessed in bivariate analysis. Potential risk factors ( $P < 0.3$ ) in the bivariate analysis were included in multivariable logistic regression analysis. Survival curves were constructed using the Kaplan-Meier method and compared using the log-rank test. The statistical analyses were carried out using JMP, version 10.0 (SAS Institute Inc., Cary, NC, US).

## 3. Results

### 3.1. Patient Characteristics

During the study period, there were 90 patients (97 admissions) with heart disease who received prolonged mechanical ventilation. Seven admissions were excluded because these patients had two admissions with prolonged mechanical ventilation during the study period. Five patients who underwent tracheostomy were excluded before 14 days of mechanical ventilation. The remaining 85 patients were included in our analysis. Fig. 1 shows the study flowchart. Of the 85 patients enrolled in the study, 20 (24%) involved a tracheostomy after prolonged mechanical ventilation. The indications for tracheostomy in these 20 patients were heart failure ( $n = 12$ ), respiratory failure ( $n = 6$ ), and neurological complications ( $n = 2$ ). In the excluded patients, tracheostomy was performed for pulmonary aspiration ( $n = 2$ ), upper airway obstruction ( $n = 1$ ), pleural effusion ( $n = 1$ ), and airway bleeding ( $n = 1$ ). Two of the excluded patients subsequently died.

Of the 85 patients included in the study, 38 (45%) were male patients. The median age at mechanical ventilation initiation and pediatric intensive care unit admission body weight were 46 days (interquartile range, 2.5–293) and 3.5 kg (interquartile range, 2.9–5.8), respectively. Twenty-six patients (31%) had a genetic abnormality, including 9 cases of trisomy 21, 2 of the 22q11.2del syndrome, and 15 of another defect. Single ventricle anatomy was identified in 30 patients (35%). Table 1 shows the primary cardiac lesions in all patients and those treated with a tracheostomy.

### 3.2. Clinical Course and Patient Outcomes

The median follow-up period in survivors was 52 months (interquartile range, 29–69). The duration of mechanical ventilation before tracheostomy and extubation was 51 days (interquartile range, 25–87) and 22 days (interquartile range, 16–40), respectively ( $P < 0.001$ ). In patients with and those without tracheostomy, 16/20 (80%) and 53/65 (82%) survived to discharge from the pediatric intensive care unit,

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