



Extubation Failure after Neonatal Cardiac Surgery: A Multicenter Analysis

Christopher W. Mastropietro, MD¹, Katherine Cashen, DO², Lisa M. Grimaldi, MD³, Keshava Murty Narayana Gowda, MBBS⁴, Kurt D. Piggott, MD⁵, Michael Wilhelm, MD⁶, Eleanor Gradidge, MD⁷, Elizabeth A. S. Moser, MS⁸, Brian D. Benneyworth, MD¹, and John M. Costello, MD⁹

Objectives To describe the epidemiology of extubation failure and identify risk factors for its occurrence in a multicenter population of neonates undergoing surgery for congenital heart disease.

Study design We conducted a prospective observational study of neonates ≤ 30 days of age who underwent cardiac surgery at 7 centers within the US in 2015. Extubation failure was defined as reintubation within 72 hours of the first planned extubation. Risk factors were identified with the use of multivariable logistic regression analysis and reported as OR with 95% CIs. Multivariable logistic regression analysis was conducted to examine the relationship between extubation failure and worse clinical outcome, defined as hospital length of stay in the upper 25% or operative mortality.

Results We enrolled 283 neonates, of whom 35 (12%) failed their first extubation at a median time of 7.5 hours (range 1-70 hours). In a multivariable model, use of uncuffed endotracheal tubes (OR 4.6; 95% CI 1.8-11.6) and open sternotomy of 4 days or more (OR 4.8; 95% CI 1.3-17.1) were associated independently with extubation failure. Accordingly, extubation failure was determined to be an independent risk factor for worse clinical outcome (OR 5.1; 95% CI 2-13).

Conclusions In this multicenter cohort of neonates who underwent surgery for congenital heart disease, extubation failure occurred in 12% of cases and was associated independently with worse clinical outcome. Use of uncuffed endotracheal tubes and prolonged open sternotomy were identified as independent and potentially modifiable risk factors for the occurrence of this precarious complication. (*J Pediatr* 2017;182:190-6).

As surgical techniques and perioperative management of neonates undergoing surgery for congenital heart disease continue to evolve, mechanical ventilation continues to be a necessary and important component of postoperative management.^{1,2} In a small but important number of neonates, initial attempts at extubation fail and reintubation is required. Reintubation of these fragile patients is a high-risk procedure with potential for life-threatening consequences such as profound hypoxemia, cardiovascular instability, and cardiopulmonary arrest. Following reintubation, these neonates are then committed to another course of mechanical ventilation, with its risks and exposures such as ventilator-associated infections, airway trauma, and the need for sedative infusions. In neonates and children undergoing cardiac surgery, extubation failure has been associated consistently with increased postoperative morbidity and mortality.³⁻⁷ Prevention of this important complication is therefore an essential part of optimizing clinical outcomes in this patient population.

Unfortunately, assessment of extubation readiness in critically ill neonates can be challenging.⁸ In many cases, despite reassuring respiratory and hemodynamic indices, extubation failure still occurs. Initial studies focused on extubation failure after surgery for congenital heart disease in neonates, although providing some valuable insight, have been restricted to small, single-center cohorts and thus have had limited generalizability.^{6,7,9} In a recent review of data from the Pediatric Cardiac Critical Care Consortium (PC4), only the presence of an underlying anatomic airway anomaly could be identified as an independent risk factor for extubation failure after neonatal cardiac surgery, but the analysis in this study was limited to the variables available within the registry.¹⁰ We aimed to describe the epidemiology of extubation failure in a large multicenter population of neonates undergoing surgery

From the ¹Department of Pediatrics, Division of Critical Care, Indiana University School of Medicine, Riley Hospital for Children, Indianapolis, IN; ²Division of Critical Care, Department of Pediatrics, Wayne State University School of Medicine, Children's Hospital of Michigan, Detroit, MI; ³Division of Cardiovascular Intensive Care, Phoenix Children's Hospital, Department of Child Health, University of Arizona, College of Medicine – Phoenix, Phoenix, AZ; ⁴Division of Pediatric Critical Care Medicine, Department of Pediatrics, Cleveland Clinic, Cleveland, OH; ⁵The Heart Center at Arnold Palmer Hospital for Children, Division of Pediatric Cardiac Intensive Care, Department of Pediatrics, University of Central Florida College of Medicine, Orlando, FL; ⁶Division of Pediatric Cardiac Intensive Care, Department of Pediatrics, University of Wisconsin, Madison, WI; ⁷Division of Critical Care at Phoenix Children's Hospital, Department of Child Health, University of Arizona, College of Medicine – Phoenix, Phoenix, AZ; ⁸Department of Biostatistics, Indiana University School of Medicine & Richard M. Fairbanks School of Public Health, Indianapolis, IN; and ⁹Divisions of Cardiology & Critical Care Medicine, Department of Pediatrics, Ann & Robert H. Lurie Children's Hospital of Chicago, Northwestern University Feinberg School of Medicine, Chicago, IL

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ICU	Intensive care unit
LOS	Length of stay
PC4	Pediatric Cardiac Critical Care Consortium
STAT Mortality Category	Society of Thoracic Surgeons-European Association for Cardiothoracic Surgery Society Congenital Heart Surgery Mortality Category

for congenital heart disease. From these data, we aimed to identify risk factors for extubation failure and determine its impact on clinical outcome.

Methods

All neonates who underwent surgery for congenital heart disease at 7 tertiary care pediatric referral centers between January 1 and December 31, 2015, were considered for inclusion in the study. Patients were enrolled prospectively from the following institutions: Riley Hospital for Children, Indianapolis, Indiana (coordinating center); Children's Hospital of Michigan, Detroit, Michigan; Cleveland Clinic, Cleveland, Ohio; Arnold Palmer Hospital for Children, Orlando, Florida; Phoenix Children's Hospital, Phoenix, Arizona; Ann & Robert H. Lurie Children's Hospital of Chicago, Illinois; and American Family Children's Hospital, Madison, Wisconsin.

The study was approved by the institutional review boards at all participating centers and was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Because of the observational nature of the data collected, the need for informed consent was waived. Neonates <2.5 kg who underwent isolated ligation of patent ductus arteriosus, neonates with tracheostomy tubes in place at the time of cardiovascular surgery, and neonates who died or underwent tracheostomy without undergoing any planned extubation attempts were excluded from the analysis.

Postoperative management and the decision to extubate from mechanical ventilation was left to the discretion of the primary intensive care unit (ICU) teams at each institution. Postoperative management, assessment of extubation readiness, and assessment of endotracheal tube leak were determined by the standard practices of individual study centers and the clinical judgment of individual clinicians working in those centers.

Extubation failure was defined as the need for reintubation within 72 hours of first attempted extubation from mechanical ventilation.⁷ Patients who underwent endotracheal intubation and had another period of mechanical ventilation that was initiated after 72 hours from the first extubation attempt were considered successful initial extubations. A comprehensive list of variables collected and additional definitions are included in **Table I** (available at www.jpeds.com).¹¹⁻¹⁹

Statistical Analyses

Data are represented with the use of descriptive statistics as follows: means with SDs for continuous normally distributed variables, medians with 25th percentiles and 75th percentiles for continuous skewed variables, and absolute counts with percentages for categorical variables. To determine the risk factors associated with extubation failure, we performed a bivariate analysis by comparing variables in neonates who required reintubation within 72 hours with those who were extubated successfully on their first attempt using *t* tests, Mann-Whitney *U* tests, χ^2 tests, and Fisher exact test as appropriate for individual variables. All variables with *P* values < .2 on bivariate analysis were considered for inclusion in our multivariate

logistic regression model. The multivariable model also was analyzed as a mixed model with a random effect for center. Linearity in the logit was examined for continuous variables before model-building; those with evidence of nonlinearity were converted to categorical variables. Variables with *P* values < .05 after multivariable analysis were then identified as independent risk factors for extubation failure after neonatal cardiac surgery.

To determine whether extubation failure had an independent effect on clinical outcome, we dichotomized hospital length of stay (LOS) as upper 25% and lower 75% and then defined prolonged LOS as patients in the upper (worst) 25%. Patients with prolonged LOS and patients who died before the cut-off value were categorized as having worse clinical outcomes compared with the rest of the cohort. Stepwise multivariable regression modeling was then performed to determine whether extubation failure was associated independently with worse clinical outcomes. All statistical analyses were performed with Stata version 14 (StataCorp, College Station, Texas) and SAS version 9.4 (SAS Institute, Cary, North Carolina).

Results

We prospectively enrolled 293 neonates who underwent surgery for congenital or acquired heart disease in 2015. Ten patients died before any extubation attempts and were therefore not included in the analysis. Data were collected for the remaining 283 neonates, who were intubated endotracheally, received mechanical ventilation during their surgical repair or palliation, and had at least one extubation attempt. Median number of subjects enrolled at each institution was 30 (range 17-71). Four institutions were categorized as small-to-moderate volume centers (range 17-30 neonates), and 3 institutions were categorized as large volume (range 55-71 neonates). Primary surgical procedures are provided in **Table II** (available at www.jpeds.com), organized by Society of Thoracic Surgeons-European Association for Cardiothoracic Surgery Society Congenital Heart Surgery Mortality Category (STAT Mortality Category).^{11,13} The most common operations performed were the arterial switch procedure (*n* = 60) and the Norwood procedure (*n* = 47).

Thirty-five patients (12%) failed their first extubation attempt at a median time of 7.5 hours after the attempt (range 1-70 hours). The timing of extubation failure is summarized in **Figure 1**. Extubation failure ranged from 8% to 23% across the participating centers. Extubation failures were distributed broadly across STAT Mortality Categories and surgical procedures (**Table II**). The most common diagnosis implicated as the major contributor to extubation failure was cardiogenic shock (*n* = 11, 31%). Other clinical findings implicated as important contributors to the extubation failures were pulmonary edema (*n* = 7), apnea/hypopnea (*n* = 5), atelectasis (*n* = 3), chylothous effusion (*n* = 3), diaphragm paresis (*n* = 3), stridor (*n* = 2), and hypercarbia (*n* = 1). Vocal cord paresis did not contribute to any of the extubation failures in this cohort. Eight patients (23%) had residual cardiac lesions that were deemed to have possibly contributed to their extubation failures:

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