

Journal of Clinical Cardiology and Cardiovascular Interventions

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Open Access Research Article

Tracheostomy in Infants after Cardiac Surgery: Indications, Timing and Outcomes

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Received Date: April 01, 2021; Accepted Date: May 12, 2021; Published Date: May 18, 2021

Citation: Ujjwal Kumar Chowdhury, Niwin George, Lakshmi Kumari Sankhyan, Suryalok Angadi, Suruchi Hasija, et al. (2021) Tracheostomy in Infants after Cardiac Surgery: Indications, Timing and Outcomes. *J. Clinical Cardiology and Cardiovascular Interventions*, 4(10); **Doi:**10.31579/2641-0419/164

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Abstract

Objective: There is little consensus on the indications and optimal timing of tracheostomy in the pediatric population. Our primary aim was to determine if early tracheostomy improves patient outcomes (between 10th and 15th postoperative day).

Methods: A retrospective review of 84 neonates and infants requiring tracheostomy after cardiac surgery between January 1997 and December 2019 was performed. Indications and timings for tracheostomy, and risk factors for mortality were analyzed using Cox regression analysis. The receiver operating characteristic curve analysis, Youden's index, sensitivity and specificity plot were performed to determine the optimal cut-off point of the timing of tracheostomy.

Results: Twenty-five (29.76%) neonates and 59 (70.23%) infants with a median weight 7.6 kg (IQR: 3.1-9.25 kg) were studied. Extubation failure and unsuccessful weaning from ventilator occurred in 45 (53.6%) and 39 (46.4%) patients respectively. The timing of tracheostomy of 15 days as the optimal cut-off point was associated with a sensitivity of 73% and a specificity of 84% and a Youden's index of 0.60. Early tracheostomy was associated with decreased mortality (p<0.001), morbidity (p<0.001), decreased duration of ventilation (p<0.001), ICU length of stay (p<0.001) and decreased time of decannulation (p<0.001).

The hazard of death was 5.26 times (95% CI: 1.47-20.36) higher in patients undergoing late tracheostomy. At a median follow-up of 166 (IQR: 82.5-216) months, the actuarial survival was $86.61\%\pm0.04\%$.

Conclusions: Early tracheostomy within 15th postoperative day was associated with lower perioperative and late mortality, morbidity and ICU stay compared with tracheostomy between 15-30 days, and confers significant long-term advantages.

Key words: congenital heart disease; diaphragmatic paralysis; mechanical ventilation; outcome assessment; trachcheostomy; tracheobronchomalacia

Running head: Tracheostomy in infants

Central Message

Early tracheostomy between 10th and 15th postoperative day in infants is associated with lower perioperative and late mortality and improves patient outcomes.

Perspective Statement

Early tracheostomy between 10th and 15th postoperative day in infants avoids mediastinitis, minimizes subglottic stenosis, and is associated with lower mortality compared with late tracheostomy.

Central Picture

Legend: Results of tracheostomy in infant after cardiac surgery

Abbreviations and Acronyms

CHD :Congenital heart diseases ECMO :Extracorporeal membrane

oxygenation

ICU :Intensive care unit IQR :Interquartile range

LVEF :Left ventricular ejection fraction

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Introduction

Tracheostomy is performed in 1.3% to 2.7% of pediatric patients following cardiac surgery due mainly to requirement for prolonged mechanical ventilation and various other reasons. [1-9] Children requiring tracheostomy have a higher risk of adverse events and mortality secondary to their comorbidities. [1-9]

Tracheostomy in pediatric patients has been shown to reduce total mechanical ventilation time, shorten intensive care unit and hospital stays, decrease the occurrence of lower respiratory tract infection (LRTI), improve oral and dental hygiene, reduce in-hospital mortality and hospital cost. [1-16] In addition, it decreases the number of self extubations and extubation-reintubation cycles, requirement of sedation, upper airway injury including vocal cord ulceration, dead space ventilation, airway resistance, and work of breathing, therefore facilitating separation from ventilator support in a steady manner. [11-19]

Literature is divided on the definition of early and late tracheostomy. Although tracheostomy is conventionally considered in patients who are ventilator dependent 2 weeks after cardiac surgery, the definition of early tracheostomy in published investigations ranged between 48 hours to 63 days. [1-11,19]

In this study, postoperative day 15 were selected as the upper limit of early tracheostomy and day 30 as the lower limit for the late group, because the likelihood of successful extubation after 30 days of translaryngeal intubation in pediatric cardiac surgery is low and risks of tracheal airway complications increases thereafter. [2,8,12-19]

All patients undergoing tracheostomy between 10th and 15th postoperative days have been grouped under early tracheostomy, and all undergoing tracheostomy between 15th and 30th postoperative days have been grouped under late tracheostomy. In pediatrics, available data on pediatric

tracheostomy are limited, and it is difficult to extrapolate data from other centers which practice prolonged mechanical ventilation. [1-19]

Although our institution is a tertiary level center, the socio-economic profile of the patients, and the lack of health insurance benefits in the developing world mandates reduction of duration of postoperative ventilation, and ICU stay, thereby attempting to reduce the cost of treatment. Tracheostomy if performed too early may be associated with increased risk of mediastinitis and if it is delayed, the number of extubation-reintubation cycle, risk of LRTI, and subglottic stenosis is increased. [11-19]

The primary objective of this study was to compare outcomes between early (within 15 days of primary operation) and late (between 15-30 days) tracheostomy. The secondary objectives were to: i) review the indications for tracheostomy in infants undergoing congenital heart surgeries requiring prolonged mechanical ventilation, and ii) evaluate the short- and long-term outcomes in terms of mortality and morbidity in these patients.

Patients and Methods

This retrospective study conforms to the principles outlined in the declaration of Helsinki and was approved by the Institutional Ethics Committee. Patients were enrolled in the study protocol after obtaining informed written consent from parents/guardians.

A 23-years (January 1997 to December 2019) retrospective review of medical records of all infants who underwent different types of closed and open heart surgical procedures (primary operation) at AIIMS, New Delhi, by the corresponding author, requiring prolonged postoperative ventilation (n=3900) were studied, and patients who underwent tracheostomy (n=84) postoperatively were identified and selected for further review. The six-monthly outpatient medical records were examined for follow-up data (**Figure 1**).

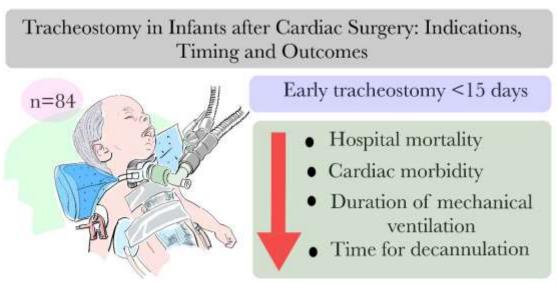


Figure 1: Graphic display (n=84) showing postoperative outcomes of early tracheostomy in neonates and infants following cardiac surgery

Criterions for selection of patients, indications and timings for tracheostomy

Decisions for extubation, reintubation, and tracheostomy and decannulation were indeed made collectively by a panel of reviewers comprising of the cardiac intensivist, cardiac surgeon, respiratory therapist and otolaryngologist and remained uniform through the study period. The timing of tracheostomy was tightly linked to patient condition which in turn was linked to postoperative outcome.

Inclusion criteria: In this study on postoperative cardiac surgical patients, the decision/indications of tracheostomy were: i) those requiring prolonged mechanical ventilation following cardiac surgery due to multifactorial reasons, ii) those following failed extubation, and iii) those following second failed extubation. A combination of three of more concerning issues among postcardiac surgical patients requiring prolonged mechanical ventilation was present in more than half of patients in this study (Definitions, **Tables 1-3**).

S.No.	Number of	Age at operation	Diagnosis	Operation
	patients			
1.	5	9 months, 10 months, 10 months, 12 months	Symptomatic tetralogy of Fallot	Intracardiac repair
2.	2	9 months, 10 months	Tetralogy of Fallot, absent pulmonary valve	Intracardiac repair
3.	9	2 months, 3 months, 3½ months, 4 months, 4 months, 6 months, 8 months, 8 months, 8 months	Tetralogy of Fallot with pulmonary stenosis/hypoplastic pulmonary arteries/atresia, univentricular heart with pulmonary stenosis/atresia, atrioventricular septal defect with pulmonary atresia	Right-sided modified Blalock- Taussig's shunt/UKC shunt
4.	1	5 months	Severe pulmonary stenosis with atrial septal defect	Pulmonary valvotomy and atrial septal defect closure (patch)
5.	8	1 month, 1 month, 2 months, 2 months, 2 months 1 month, 4 months, 1 month	Tricuspid atresia/univentricular heart, multiple ventricular septal defect/unbalanced atrioventricular septal defect with increased pulmonary blood flow, failure to thrive, on preoperative ventilation	Pulmonary artery banding
6.	4	9 months, 10 months, 11 months, 11 months	Tricuspid atresia/univentricular heart with pulmonary stenosis	Bidirectional Glenn with anterior flow open
7.	3	10 months, 11 months, 11 months	Univentricular heart with excessive pulmonary blood flow operation	Bidirectional Glenn with pulmonary artery banding
8.	9	20 days, 20 days, 12 days, 19 days, 20 days, 1 month, 18 days, 19 days, 2 months	Transposition of the great arteries	Arterial switch operation
9.	2	3 months, 5 months	Transposition of the great arteries (late presentation)	Senning's operation
10.	1	2 months	Aortopulmonary window	Johanson's repair
11.	2	2 months, 5 months	Anomalous origin of left coronary artery from pulmonary artery	Anatomical restoration
12.	7	3½ months, 4 months, 6 months, 8 months, 8 months, 10 months, 11 months	Ventricular septal defect (multiple ventricular septal defect/prematurity/ preoperative ventilation/malnutrition)	Ventricular septal defect closure
13.	2	1 month, 1 month	Coarctation of aorta with patent ductus arteriosus	Resection and end-to-end anastomosis, division of patent ductus arteriosus
14.	3	30 days, 35 days, 20 days	Coarctation of aorta with ventricular septal defect on ventilator (2 kg, 2.5 kg)	Pulmonary artery banding, repair of coarctation
15.	1	2 months	Interrupted aortic arch	Restoration of aorta
16.	2	9 months, 11 months	Previous pulmonary artery band due to multiple muscular ventricular septal defects	Debanding pulmonary artery, VSD closure, pulmonary arterioplasty
17.	2	2 months, 3 months	Atrioventricular septal defect	Two-patch repair
18.	3	3 months, 5 months, 6 months	Heterotaxy with univentricular heart, pulmonary stenosis, decreased pulmonary blood flow	Bidirectional Glenn
19.	3	20 days, 1 month, 1 month	Heterotaxy with totally anomalous pulmonary venous connection	Rechanneling of totally anomalous pulmonary venous connection
20.	3	5 days, 15 days, 7 days	Totally anomalous pulmonary venous connection (infracardiac) on preoperative ventilator	Rechanneling of totally anomalous pulmonary venous connection

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21.	8	39 days, 2 months, 2 months, 3 months, 3 months, 3 months, 5 months, 9 months	Totally anomalous pulmonary venous connection (supracardiac)	Rechanneling of totally anomalous pulmonary venous connection
22.	4	1 month, 2 months,	Mixed totally anomalous pulmonary	Rechanneling of totally anomalous
		2 months, 1 month	venous connection	pulmonary venous connection

Table 1: Age at primary operation, diagnosis, type of operation of all patients in the study group undergoing tracheostomy (n=84)

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Variables	Number (%)
Hospital death	9 (10.7%)
Late death	2 (2.7%)
Lost to follow-up	1 (1.4%)
Number of patients followed-up	72 (98.6%)

Table 2: Demographics of the patients in the study population (n=84)

Postoperative issues	No. (%)
Cardiac (Congestive heart failure, poor biventricular function, unstable hemodynamics)	35 (41.66%)
Cardiac cachexia, low body mass, malnourishment, unstable hemodynamics (preoperative)	39 (46.4%)
Persistent lobar collapse, pulmonary infection, sepsis (pretracheostomy)	19 (22.6%)
Severe pulmonary artery hypertension (cardiac related)	39 (46.4%)
Renal failure requiring peritoneal dialysis (pretracheostomy)	17 (20.2%)
Unilateral diaphragmatic paralysis	6 (7.1%)
Preoperative neurological event (Hypoxic, hydrocephalus)	5 (5.9%)
Postoperative new onset neurological event (Hypoxic, intracerebral bleed, subdural hematoma)	8 (8.3%)
Craniofacial syndromes and upper airway problems, glossoptosis	10 (11.9%)
Excessive pulmonary secretions (pretracheostomy)	37 (44%)
Chylothorax requiring surgical intervention	4 (4.7%)
Postoperative extracorporeal membrane oxygenation	3 (3.6%)
Subglottic stenosis	3 (3.6%)
Tracheobronchomalacia	3 (3.6%)
Cardiac + Renal	36 (42.8%)
Cardiac and subglottic stenosis	13 (15.5%)
Cardiac + Tracheobronchomalacia + suprastomal collapse	13 (15.5%)
Cardiac + Diaphragmatic paralysis	14 (16.6%)
Cardiac + Neurological event	30 (35.7%)
3 or more of (1-11)	49 (58.3%)

Table 3: Reasons for prolonged ventilation of all patients in the study group undergoing tracheostomy (n=84)

Exclusion criteria: Infants with tracheostomy preoperatively, and those requiring prolonged mechanical ventilation but not tracheostomized were excluded. Due to variable surgical and postcardiac surgical practices, patients operated by other surgeons were excluded.

Tracheostomy was performed in the operating room using the open technique in all patients. Postoperative day 15 was selected as the upper

limit for early tracheostomy based on the evidences available in the literature, and an increased incidence of postoperative sepsis in the developing world, and to decrease the hospital cost. [1-11] Day 30 was selected as the lower limit for the late group in this study.

Data collection

In addition to baseline characteristics, intraoperative and postoperative findings (table 1), the following mechanical ventilation-related parameters were recorded: i) duration of respiratory support before surgery, ii) the duration of ventilation before tracheostomy, iii) the

duration of ventilation after tracheostomy, and iv) time interval between tracheostomy and decannulation or death. The number of attempts at extubation, timing of decannulation (failed or successful), recannulation of tracheostomy, patient's outcome (decannulation/death) were noted for each patient. The indication(s) for tracheostomy, complications of tracheostomy, decannulation, and their outcomes were also recorded. [20]

Patients were classified with an airway anomaly if they had any major upper airway or laryngotracheobronchial abnormality confirmed by an otolaryngologist, using bedside bronchoscopy and laryngoscopy when clinically suspected. All tracheostomy were done surgically in operation room. Snuggly fitting tracheostomy tube with inflatable cuff was preferred on insertion and later changed to uncuffed tube after one week.

Decannulation was considered when patients had: i) stable hemodynamics with reduced/nil requirement of inotropes; ii) no requirement of ventilator support for a period of 7 days; iii) minimal requirement for suctioning; iv) no pulmonary atelectasis/lobar collapse vi) no diaphragmatic paresis/paralysis; vi) normal kidney function; vii)

patent upper airway, ascertained with laryngoscopy vii) removal of any obstructing suprastomal granulation tissue; and viii) no comorbidities necessitating tracheostomy.

Definitions

Primary operation: In this study, we have used the term "primary" operation or procedure to refer to cardiac operation necessitating the period of postoperative ventilation leading to tracheostomy.

Outcome measures: Operative mortality (all cause) was defined as death either in ICU or prior to hospital discharge or within 30 days of the date of surgery according to the congenital heart surgery outcome measures endorsed by the Society of Thoracic Surgeons. [20] Short-term survival was defined as survival to hospital discharge. Long-term survival was defined as survival to most recent follow-up. Intubation time was defined as time in hours from the time of intubation either in the preoperative period or on the day of surgery to discontinuation of mechanical ventilation. Records were reviewed to determine whether patients had been successfully decannulated and if so, to document the time from the date of tracheostomy to decannulation, the length of stay in intensive care unit after surgery, and the need for surgical reintervention, when required.

Extubation failure: Extubation failure was defined as reintubation within 48 hours after extubation. For patients who failed extubation, reintubation was determined according to the following criteria: (i) hemodynamic instability; (ii) respiratory dysfunction (significant hypoxia, worsening hypercarbia, significant respiratory effort, respiratory fatigue, and massive atelectasis); (iii) airway obstruction; (iv) deteriorating level of consciousness; (v) major bleeding; and (vi) cardiac arrest. The decisions for extubation and reintubation were made by attending intensivist, cardiac surgeon and cardiac anaesthetist.

Suboptimal hemodynamics/low cardiac output syndrome: Suboptimal hemodynamic state/low cardiac output syndrome was defined as moderate or severe ventricular dysfunction requiring inotropic support

epinephrine at 0.01-0.1 μ g/[kg/min], milrinone at 50 μ g/kg intravenous bolus followed by 0.375-0.75 μ g/[kg/min]), either isolated or in combination with or without mechanical circulatory assistance in the operating room or in the intensive care unit, to maintain stable hemodynamics in the absence of residual structural lesions and mechanical external compression after correction of all electrolytes or blood gas abnormalities and after adjustment of the preload to its optimal value. Low-output syndrome was also diagnosed if there was an increasing requirement of the previously mentioned inotropes along with afterload reduction with sodium nitroprusside.

Tracheostomy-related complications: Early complications were defined as those occurring within the first postoperative week. At one week, the tracheostomy has usually matured, and the first tube change is performed. Late complications were defined as those occurring after the first 1st week.

Morbidities: Cardiac morbidity was defined as low cardiac output state with or without the requirement for extracorporeal membrane oxygenation. Renal morbidity was defined as oliguria (<0.5 ml/kg/hr) or anuria with rising blood urea and serum creatinine and/or starting hemodialysis or peritoneal dialysis. Culture proven pneumonia, mediastinitis, wound infection and bacteremia were diagnosed by clinical findings and microbiological cultures, and lab results.

Statistical Analysis

Statistical analysis was performed using STATA 14.0 Software (College Station, Texas, USA). Continuous and interval-related data were presented as mean±SD or median (minimum-maximum), whereas categorical variables were presented as frequency distribution and percentages. Qualitative data were analysed by using \square^2 / Fisher's exact test to establish the association.

The receiver operating characteristic curve analysis was performed on the timing of tracheostomy and mortality to establish the cut-off point (days) for the early and late tracheostomy (**Figure 2**).

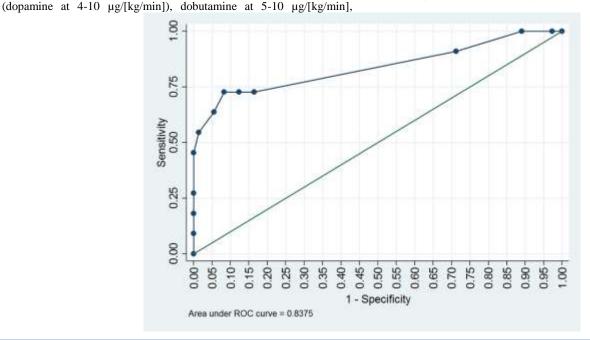


Figure 2: The receiver operating characteristic curve (ROC) of patients undergoing early and late tracheostomy following congenital heart surgeries in this study.

Youden's index was calculated to determine the optimal cut-off point of the timing of tracheostomy, which was also represented by a sensitivity and specificity plot (**Figure 3**).

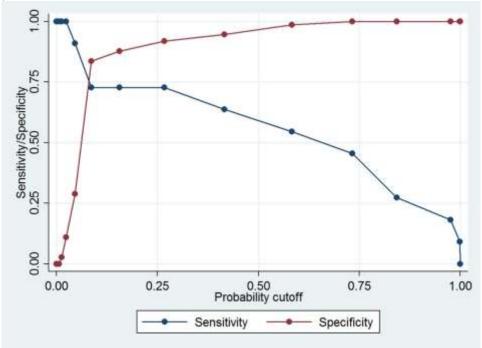


Figure 3: Probability cut-off point of timing of tracheostomy of patients in this study based on sensitivity and specificity.

Predictors of 0- to 23-year mortality were identified by univariate cox proportional hazards analysis initially performed on candidate variables (including the timing of tracheostomy as a potential explanatory variable). Stepwise multivariable Cox regression analysis was performed on the clinically important variables and the independent variables having the probability of <0.15 in univariate analysis.

Mortality rates were calculated depending on the total number of years of follow-up for each patient. The survival probability with 95% confidence intervals was reported at various time intervals with the Kaplan-Meier technique (**Figure 4**).

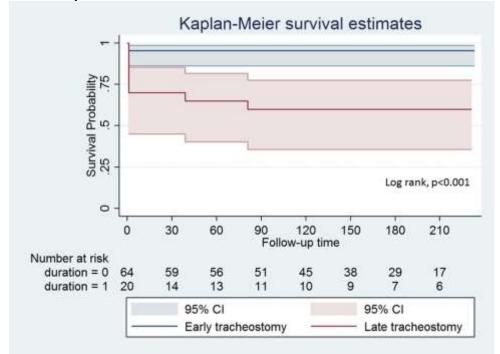


Figure 4: Survival probability from Kaplan-Meier curve of patients (early tracheostomy, n=64; late tracheostomy, n=20)) undergoing congenital

heart surgeries requiring prolonged mechanical ventilation who required tracheostomy (log rank p<0.001).

Results

Study population

The median age of patients at operation was 4 months (IQR: 23 days-9 months). Twenty-five (29.8%) patients were younger than 1 month, and 59 (70.2%) were between 1 and 12 months. Thirty (35.7%) infants in this

study population were premature and thirty-nine (46.4%) weighed less than 50th percentile of predicted weight by national standards. [21] Twenty-nine (34.5%) patients required preoperative ventilator support. A combination of three or more risk factors for requiring prolonged mechanical ventilation was present in 58.3% (n=49) of patients (Tables 1-4).

Variables	No. of patients	Hazard ratio (95% Confidence Interval)	p value
Age			
- <1 month	25	8.78 (2.09-36.84)	0.003
- >1 month	59		
Prematurity (<37 weeks)			
- Yes	30	11.14 (2.22-55.95)	0.003
- No	54		
Low birth weight (<2.5 kg)			
- Yes	39	6.45 (1.30-31.99)	0.02
- No	65		
Preoperative ventilation			
- Yes	29	6.60 (1.59-27.32)	0.009
- No	55		
Genetic syndromes			
- Yes	10	3.53 (0.75-16.47)	0.1
- No	74		
Preoperative lung infection/lobar collapse			
- Yes	19	2.20 (0.57-8.55)	0.25
- No	65	,	
Upper airway problems			
- Yes	16	1.73 (0.40-7.42)	0.46
- No	68	1.73 (0.10 7.12)	0.10
Unstable hemodynamics (on preoperative inotropes)			
- Yes	39	2.24 (0.60-8.33)	0.22
- No	65	2.24 (0.00-0.33)	0.22
Non-cardiac comorbidities	03		
- Yes	6	1.36 (0.14-12.86)	0.78
- No	78	1.30 (0.14-12.80)	0.78
Preoperative central neurological event	70	+	
- Yes	5	5 19 (0.76 25 22)	0.09
- Tes - No		5.18 (0.76-35.33)	0.09
	19		
Preoperative sepsis	10	2.51 (0.02.12.17)	0.06
- Yes	19	3.51 (0.93-13.17)	0.06
- No	65		
Surgery Before 2011	40	1.42 (0.38, 18)	0.49
After 2011	44	` , ,	
Types of surgical procedures			
- Univentricular type of repairs including pulmonary artery	19		
banding, systemic-pulmonary artery shunt		1.58 (0.32-7.99)	0.57
- Biventricular repair including systemic-pulmonary artery shunt,			
pulmonary artery banding, coarctation of aorta	65		
Cardiopulmonary bypass time			
- >120 minutes	35	1.82 (0.50-6.52)	0.36
- <120 minutes	49		
Aortic cross-clamp time (minutes)			
- >60 minutes	27	2.97 (0.82-10.79)	0.09
- <60 minutes	57		
Unstable hemodynamics on inotropes (postoperative)			
- Yes	39	1.45 (0.41-5.19)	0.56
- No	45	, , , , , ,	
Timing of tracheostomy after surgery			
- 15-30 days	20	13.55 (3.13-58.61)	< 0.001

Variables	No. of patients	Hazard ratio (95% Confidence Interval)	p value
- 10-15 days	64		
Reoperations for residual lesions			
- Yes	15	3.83 (0.61-23.99)	0.15
- No	69		
Unilateral diaphragmatic paralysis			
- Yes	7	1.36 (0.14-12.86)	0.78
- No	78		
Postoperative lung infection/persistent lobar collapse			
- Yes	19	2.20 (0.57-8.55)	0.25
- No	65		
Severe pulmonary arterial hypertension, use of nitric oxide, postoperative			
pulmonary hypertensive crisis		0.62 (0.16.2.20)	0.47
- Yes	39	0.62 (0.16-2.30)	0.47
- No	45		
Postoperative new onset central neurological event			
- Yes	6	3.83 (1.61-23.99)	0.01
- No	78	, in the second of the second	
Subglottic stenosis / tracheobronchomalacia			
- Yes	3	1 (omitted)	-
- No	81	` ,	
Postoperative sepsis			
- Yes	19	15.03 (3.44-65.61)	< 0.001
- No	65	` '	
Renal failure requiring peritoneal dialysis and/or hemodialysis			
- Yes	17	18.96 (4.23-84.91)	< 0.001
- No	67		
Postoperative extracorporeal membrane oxygenation support			
- Yes	3	3.55 (1.29-42.82)	0.01
- No	81	, in the second of the second	
Delayed sternal closure/open sternum			
- Yes	11	2.09 (0.37-11.68)	0.39
- No	73	, in the second of the second	
Perioperative supraventricular/ventricular arrhythmias			
- Yes	13	0.50 (0.05-4.34)	0.53
- No	71	,,	
Poor systemic ventricular function/low ejection fraction			
- Yes	39	2.45 (1.40-5.19)	< 0.001
- No	45		
Excessive pulmonary secretions	<u> </u>		
- Yes	37	0.43 (0.10-1.75)	0.23
- No	47	0.15 (0.15 1.75)	0.20

Table 4: Univariate predictors of 0-to 23-year mortality by Cox proportional hazard regression analysis after tracheostomy in infants following surgery for congenital heart disease in this study (n=84)

Patient related variables	Early tracheostomy (n=64)	Late tracheostomy (n=20)	P value
Age (≤1 months)	18 (4.7%)	7 (35%)	0.37
Prematurity	19 (28.1%)	11 (55%)	0.03
Low birth weight	27 (42.2%)	12 (60%)	0.2
Preoperative ventilation	18 (28.1%)	11 (55%)	0.02
Genetic syndrome (yes)	8 (12.5%)	2 (10%)	0.76
Preoperative lung infection/lobar collapse	15 (23.4%)	4 (20%)	1.0
Upper airway problem	12 (18.7%)	4 (20%)	1.0
Non-cardiac comorbidities	6 (9.4%)	0 (0%)	0.15

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Preoperative central neurological event	3 (4.7%)	2 (10%)	0.38
Preoperative sepsis	14 (21.8%)	5 (25%)	0.76
Indications for tracheostomy	25 (39.1%)	20 (100%)	<0.001
Reoperation	1 (1.6%)	5 (25%)	0.003
Unilateral diaphragmatic paralysis	1 (1.6%)	5 (25%)	0.003
Preoperative lung infection	9 (14.1%)	10 (50%)	0.001
Presence of pulmonary arterial hypertension	33 (51.5%)	6 (30%)	0.12
Cerebral hemorrhage	2 (3.1%)	4 (20%)	0.02
Tracheobronchomalacia	1 (1.6%)	2 (10%)	0.14
Renal dysfunction requiring peritoneal/hemodialysis	6 (9.4%)	11 (55%)	<0.001
Postoperative extracorporeal membrane oxygenation support	0	3 (15%)	0.012
Delayed sternal closure / open sternum	3 (4.7%)	8 (40%)	0.002
Perioperative supraventricular/ ventricular arrhythmias	9 (14.1%)	4 (20%)	0.49
Poor systemic ventricular function/ low ejection fraction	26 (40.1%)	13 (65%)	0.07
Excessive pulmonary secretions	26 (40.1%)	11 (55%)	0.30
Unstable hemodynamics on preoperative inotropes	28 (43.7%)	11 (55%)	0.37
Postoperative unstable hemodynamics	21 (32.8%)	18 (90%)	<0.001
Aortic cross-clamp time >60 minutes	9 (14.1%)	18 (90%)	<0.001
Cardiopulmonary bypass time >120 minutes	25 (39.1%)	10 (50%)	0.38
Mortality	3 (4.7%)	8 (40%)	<0.001

ICU-Intensive care unit

Table 5: Preoperative and intraoperative variables examined in each surgical group

A total of 10 (11.9%) patients had a genetic syndrome. Common genetic syndromes included trisomy 21 (n=3), DiGeoerge syndrome (n=2), congenital rubella syndrome (n=2), Pierre Robin syndrome (Glossoptosis, n=1), and VACTERL (vertebral abnormalities, anal atresia, cardiac abnormalities, tracheoesophageal fistula and/or esophageal atresia, renal agenesis and dysplasia, and limb defects, n=2). These patients had significant neurodevelopmental impairment in combination with chromosomal abnormalities. The underlying cardiac diagnoses for patients requiring tracheostomy are shown in Table 1 and 2. (Definitions). In this study, 64 (76.2%) patients underwent tracheostomy between 10th-15th postoperative day and 20 (23.8%) patients underwent tracheostomy between 15-30 days following "primary operation" (Video Presentation).

In order to understand/analyze the outcome difference between early and late tracheostomy, the preoperative (pre-tracheostomy) status difference between two groups were analyzed. Descriptive characteristics and underlying cardiac diagnoses are summarized in table 1. The groups did not differ significantly in regard to age, sex, low birth weight, genetic syndrome, upper airway problems, preoperative lung infection/lobar collapse, sepsis, central neurological event, presence of excessive pulmonary secretions, poor systemic ventricular function, and unstable hemodynamics on preoperative inotropes (**Table 5**).

Variables	Early tracheostomy	Late tracheostomy	P value
Discharge mortality	2 (2.4%)	7 (8.3%)	< 0.001
ICU length of stay (days)	18±12	42±25	< 0.001
Mean±SD, median (range)	12 (8-22)	(37 28-74)	
Duration of mechanical ventilation from the time	13±11	31±15	< 0.001
of primary operation (days)	9 (7-15)	25 (17-58)	
Mean±SD, median (range)			
Time of decanulation (days)	14±9	29±14	< 0.001
	11 (8-19)	20 (17-34)	
Postoperative sepsis	6 (7.1%)	13 (15.4%)	< 0.001
Lower respiratory tract infection / lobar collapse	7 (8.3%)	12 (14.3%)	< 0.001
Cardiac morbidity	10 (11.9%)	19 (22.6%)	< 0.001
Subglottic stenosis / tracheobronchomalacia	0	3 (3.6%)	< 0.001

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Table 6: Mortality and morbidity between early and late tracheostomy in patients undergoing surgery for congenital heart diseases in the study (n=84)

There were significant differences between groups in regard to prematurity (p=0.03), preoperative ventilation (p=0.02), preoperative lung infection (p=0.001), renal dysfunction requiring peritoneal/hemodialysis (p<0.001), requirement of postoperative extracorporeal membrane oxygenation (p=0.012), delayed sternal closure/open sternum (p=0.002), cerebral hemorrhage (p=0.02), unilateral diaphragmatic paralysis requiring diaphragmatic plication (p=0.003), postoperative unstable hemodynamics (p<0.001), prolonged aortic crossclamp time (p=<0.001), and requirement of reoperation (p=0.003) (Table 5).

Short-term outcomes

There were 9 (10.8%) perioperative deaths after tracheostomy while still ventilated through the tracheostomy within 30 days following surgery. A combination of three or more risk factors was responsible for death in all patients. In 7 neonates, the causes of mortality were prematurity with low birth weight requiring preoperative ventilator support, lung collapse and sepsis who developed renal failure requiring peritoneal dialysis/hemodialysis and ultimately died of multiorgan dysfunction. One patient died of diffusely hypoxic cerebral injury and another patient died of new onset postoperative intracranial haemorrhage and cerebral coning.

Discharge mortality (2.4% vs 8.3%, p <0.001) and cardiac morbidity (11.9% vs 22.6%, p <0.001) was lower in the early tracheostomy group.

Early tracheostomy was associated with decreased duration of mechanical ventilation (13 ± 11 vs 31 ± 15 days, p<0.001), ICU length of stay (18 ± 12 vs 42 ± 25 days, p<0.001) and decreased time of decannulation (14 ± 9 vs 29 ± 14 , p<0.001) days. The overall postoperative sepsis was lower in the early tracheostomy group (7.1% vs 15.4%, p<0.001). There were no cases of mediastinitis in either group (Table 6)

Neonates, prematurity (<37 weeks), low birth weight (<2.5 kg), preoperative ventilation, tracheostomy performed beyond 15 days of cardiac surgery, postoperative new onset cerebral hemorrhage, hypoxic cerebral injury, renal failure requiring peritoneal dialysis/hemodialysis, neonates requiring ECMO, LVEF (<0.40) and postoperative sepsis were significant negative factors for survival according to univariate analysis (Table 4).

Multivariate analysis identified six predictors for death after tracheostomy in this study group. The risk of death was 5.26 times higher (95% CI: 1.47, 20.36) in infants undergoing late tracheostomy (beyond 15 days) as compared to early tracheostomy (p=0.001). Neonates with renal failure requiring peritoneal dialysis/hemodialysis also exhibited 19.37 times (2.22-168.37) higher risk of death following surgery (p=0.007) (Table 7).

Variables (covariates adjusted)	Hazard ratio (95% confidence interval)	p value
Age (<1 month)*	6.09 (1.54, 24.02)	0.01
Preoperative requirement of ventilation*	5.21 (1.35, 20.15)	0.01
Renal failure requiring peritoneal dialysis and/or hemodialysis*	19.37 (2.22, 168.37)	0.007
Timing of tracheostomy after surgery (>15 days)*	5.26 (1.47, 20.36)	0.001
Postoperative sepsis*	6.72 (1.74, 25.93)	0.006
Postoperative new onset central neurological event	18.59 (1.61, 214.44)	0.01
(hemorrhage/hypoxic/embolism)*		

^{*}Variables with increased risk

Table 7: Predictors of 0- to 23-year mortality by Cox proportional hazard regression analysis applied to all 84 patients

Long-term outcomes

There were 2 (2.7%) late deaths 39 and 81 months after surgery due to renal failure (n=1) and cerebral thrombosis (n=1) respectively. One patient was lost to follow-up. Seventy-two patients (98.6%) were followed up for a period of 1-276 month and yielded 885.6 patient-years of data. At a median follow-up of 166 (IQR: 82.5-116) months, the actuarial survival was 86.61% (SE \pm 0.04%; 95% CI: 77.1, 92.3). The actuarial survival was significantly lower in patients undergoing late tracheostomy (log rank p<0.0001), (Figure 4).

Cohort of survivors

At the completion of the period of review, 73 children were known to be alive. Late follow-up data was not available for one patient. All survivors (n=72) were examined and studied between June 2019 and December 2019, which was the closing interval of the study. Postoperative evaluation consisted of six monthly clinical examination, electrocardiogram, chest radiograph, soft tissue x-ray of the neck and echocardiogram. The severity of congestive heart failure was assessed according to Ross clinical score. [22]

Preoperative respiratory insufficiency was present in 55 (65.5%) of 84 infants, of whom 29 (34.5%) were already intubated and ventilated, and

the remainder were not intubated but were oxygen dependent. The median total duration of mechanical ventilation before tracheostomy was 20 days (10-28 days). The interval between the primary operation and tracheostomy was 10 days in 23 (27.3%) infants, 15 days in 41 (48.8%) infants, and 30 days in 20 (23.8%) infants (Table 2).

Ventilation could not be weaned sufficiently to allow a trial of extubation in 39 (46.4%) patients. In 38 (45.2%) cases extubation had failed on single occasion and in 7 (8.3%) cases on two occasions. The reasons for prolonged ventilation were multifactorial for most patients. Cardiac cachexia, malnutrition, persistent postoperative pulmonary arterial hypertension, extremely poor body muscle reserves were other factors for requirement of prolonged ventilation in 39 (46.4%) infants (Table 3).

Neurological comorbidity was present in a total of 21 (25%) infants: six had experienced new insults, and five had pre-existing stroke, and 10 (11.9%) had major neurodevelopmental abnormalities. One infant had unilateral vocal cord palsy. Persistent chylothorax requiring prolonged intercostal drainage and reoperation affected four infants (Table 3).

Of the 84 children, 15 (17.8%) required cardiothoracic reoperations due to various causes. Two (2.4%) patients required revision of transannular patch. Two (2.4%) patients underwent tracheal operations for tracheal stenosis, 4 (4.7%) patients required ligation of the thoracic duct for

chylothorax, and 7 (8.3%) patients required unilateral diaphragmatic plication (before tracheostomy).

Decannulation was successful in all 72 infants. The median duration of mechanical ventilation after tracheostomy was 22 days (range 11-35 days) and the median total duration of ventilator support (before and after tracheostomy) was 37 days (20-48 days). The median duration of tracheostomy to decannulation in survivors was 31 days (30-52 days). Sixty-eight (94.4%) survivors were in Ross's clinical score of 2 and without antifailure cardiac medications. [22] There were no reoperations during this period.

Complications of tracheostomy

One infant with tracheobronchomalacia had local infection at the tracheostomy site and the tracheostomy was exchanged for a period of nasotracheal ventilation. After the infection had cleared, the tracheostomy wound was revised without any further complications. Two children with subglottic stenosis who were preoperatively ventilated for 15 and 20 days respectively underwent excision of subglottic membrane and cricoid splinting and were ventilated for a period of 3 weeks in two sessions. There were no other complications, directly related to tracheostomy.

Prolonged tracheostomy ventilation

Preoperative ventilation before the "primary operation", preoperative respiratory insufficiency, subglottic stenosis, tracheobronchomalacia, diaphragmatic paralysis, cardiac cachexia, and sepsis were associated with a longer period of tracheostomy ventilation. At the end of the follow-up, all survivors were successfully decannulated.

Analysis of the ROC curve, sensitivity and specificity plot

Tracheostomy performed between 12^{th} and 14^{th} postoperative day was associated with 100% sensitivity and 10.9% specificity in terms of superior clinical outcome. The timing of tracheostomy of 15 days as the optimal cut-off point was associated with a sensitivity of 73% and specificity of 84%, and at this time point, the Youden's index was 0.60. The results obtained from the area under the ROC curve indicate that 83% (SE ± 0.083 , 95% CI 67.4, 1.0) of the time, the clinical outcome of postoperative patients was superior when tracheostomy was performed between 12^{th} and 15^{th} postoperative days compared with those performed between 15^{th} and 30^{th} postoperative days. Analysis of the sensitivity and specificity plot revealed the timing of the tracheostomy with an optimal cut-off point <16 days, Youden's value of 0.64 and was associated with a sensitivity of 73% and specificity of 91% (Figures 2, 3).

Discussion

Indications

The need for prolonged mechanical ventilation was a result of multifactorial etiology in over half of our patient cohort (49, 58.3%), most common being suboptimal hemodynamics due to cardiac cause in conjunction with renal failure requiring peritoneal dialysis and sepsis. On individual basis, the leading causative factors were cardiac cachexia (46.4%), severe cardiac-related pulmonary arterial hypertension (46.4%), followed by unstable hemodynamics (41.6%), persistent pulmonary infection, lung collapse & sepsis (22.6%), renal failure requiring peritoneal dialysis/hemodialysis (20.2%), and craniofacial syndromes with upper airway problems (19%) (Table 2). A number of studies found no association between surgical complexity and cardiac diagnoses with extubation failure. [1-11,18,19] However, other studies reported a history of pulmonary hypertension, prolonged CPB duration, deep hypothermic circulatory arrest, chromosomal abnormalities, and a high dose of narcotics as risk factors for extubation failure. [1-11,18,19]

Tracheobronchomalacia has been reported in 4% to 12% of young infants with CHD. [23-25] Additionally, it is not uncommon for patients with CHD to have a dysmorphic upper airway and genetic disorders. In this study, one infant had tracheobronchomalacia and two infants had subglottic stenosis requiring excision of the subglottic membrane. Although our patient cohort was not specifically evaluated for ciliary dysfunctional status, it remains an important consideration in syndromic patients. [26] Although not demonstrated in our study group, children with CHD might be at high-risk for airway compression by virtue of the anatomic proximity of cardiac chambers and great vessels to the central airways. [1-10]

Diaphragmatic paresis/ paralysis is less well tolerated in infants and small children due to relative weakness of the intercostal muscles, greater compliance of the chest wall, horizontal orientation of the rib cage, and increased mediastinal mobility with shifting of the mediastinal contents to the contralateral side on inspiration. Additionally, the recumbent position of infants reduces the vital capacity and small calibre of the infant bronchial tree, facilitates retention of secretions and bronchial obstructive debris. [27,28] Unilateral diaphragmatic paralysis reduces pulmonary function by about 25% in older children and by up to 60% in infants. [27,28]

The causative factors include intraoperative use of iced saline, cautery-induced neuropraxia, neurotemesis, surgical dissection close to the phrenic nerve, and staged palliation for univentricular repairs. The reported prevalence in retrospective studies varies from 0.3% to 5.7%. [27,28] In prospective studies, the reported incidence varies from 1.9% to 23.8%, which may indicate increased surveillance in prospective studies to detect asymptomatic cases. [27,28] In our cohort, 7 (8.3%) patients underwent plication for unilateral diaphragmatic paresis, however, it was not a significant factor in mortality. The opinion on timing of diaphragmatic plication varies from immediate plication on diagnosis, to a waiting period of 1-6 weeks in anticipation of spontaneous recovery. [27,28] In general, an arbitrary figure of 2-3 weeks of symptomatic diaphragmatic paralysis is advocated for diaphragmatic plication. [27,28]

Outcomes

Children requiring tracheostomy after surgery for CHD are at significant risk of poor outcomes with less than half still alive at a median follow-up of 3.9 years. [2-11] Mastropietro analysed 606 tracheostomies in neonates and infants in the STS Congenital Heart Surgery database in 2016 and found an overall mortality rate of 25.2%. [6] Johnson and associates in a multi-institutional study on 1292 tracheostomies in children undergoing cardiac surgeries reported an overall mortality rate of 21.6% (range 0% to 50%). [1]

Our overall mortality of 10.7% are in accordance with the published investigations which documents a tracheostomy-related mortality rate between 3.2% and 25% after 1985. [1-11] If a patient could not be extubated, we tried to identify anatomic or physiologic causes that were potentially reversible, e.g. plication of a paralysed diaphragm, optimization of hemodynamics with inotropic support, and nutritional supplementation to alleviate chronic cardiac cachexia. The decision of tracheostomy was taken before attempting second extubation in 45.2 % (n=38) of infants, and following failed second extubation in 8.3 % (n=7) of infants. Ventilation could not be weaned sufficiently to allow a trial of extubation in 39 (46.4%) infants.

In our study, logistic regression analysis accounting for the effects of other factors demonstrated neonatal intervention, ventilation requirement in the preoperative period because of unstable hemodynamics, renal failure requiring peritoneal/ hemodialysis, postoperative sepsis, postoperative new-onset cerebral hemorrhage, hypoxic cerebral injury as significant negative factors for survival. The risk of death was 5.26 times

higher (95% CI: 1.47, 20.36) in infants undergoing tracheostomy beyond 15 days following surgery in comparison to those undergoing tracheostomy between 10 and 15 days following surgery (**Table 7**). All of our patients underwent open surgical procedure for tracheostomy. In this study, a midline vertical incision through the 2nd to 4th tracheal cartilages was used in all cases, thus minimizing incision of tracheal rings as few as possible.

Stomaplasty techniques described by Eliacher, Koltai and Bjork involves resection of tracheal cartilages and are recommended when longer duration of tracheostomy is expected.[17,29,30] We did not use any of these methods, since we expected our patients to be decannulated before discharge from hospital.

The reported incidence of tracheostomy-related complication is around 15% in adults and 15-19% in children. [1-11] Tracheitis was the most common complication in the reported literature followed by tracheostomy site breakdown. Other complications include tracheo-brachiocephalic artery fistulization, and mediastinitis. [31-35] Except for one infant who developed local infection at the site of tracheostomy, which was managed conservatively, and two children with subglottic stenosis, no other patients developed tracheostomy-related complications. We have a dedicated multidisciplinary team comprising of intensivists, tracheostomy nurses, chest physicians, ENT surgeons who carry out regular reassessments of all these patients while inpatient and after discharge. In our study population, we have been able to decannulate all infants prior to discharge. Due to lack of health care resources, hospital discharge with a tracheostomy or ventilator is not a viable option in India, therefore in-hospital decannulation is preferable in our setup.

We were particularly encouraged to find that there were no cases of mediastinitis in our group. Published reports on the incidence of mediastinitis following tracheostomy are varied from nil to significant risk by different investigators. [1-11,31-35] Some authors have demonstrated an increased risk of mediastinitis with tracheostomy following sternotomy in adult patients. [31,34] Percutaneous tracheostomy has been incriminated as a risk factor for mediastinitis by some investigators. [31,34,35] Two (2.4%) patients in this study developed spontaneous pneumothorax immediately following decannulation of the tracheostomy tube requiring intercostal drainage.

Five (6.8%) patients had superficial wound infection, which was managed conservatively. In case of clinical (fever, superficial wound infection, chest findings), laboratory (leukocytosis, elevated C-reative protein, procalcitonin), or radiological evidence (pneumonia), we begin broad spectrum antibiotics, and switch over to culture directed therapy on an individualized basis later on. The antibiotics were stopped when these features resolved.

Following placement of the tracheostomy tube, one of the concerns is the duration of time that the patient remains dependent on the device. In our study, all our patients were successfully weaned from positive pressure ventilation at a variable time period. Patients undergoing early tracheostomy were decannulated earlier than those undergoing late tracheostomy (mean, 14 ± 9 vs 29 ± 14 days; p<0.001).

Comparing outcomes in early and late tracheostomy

There is no consensus in the published literature on the indications and the duration a child should remain endotracheally intubated prior to tracheostomy and on the optimal pediatric decannulation protocol. [1-10]

Tracheostomy performed between 12th and 14th postoperative day was associated with 100% sensitivity and 10.9% specificity in terms of superior clinical outcome using the timing of tracheostomy of 15 days as the optimal cut-off point was associated with a sensitivity of 73% and specificity of 84%, and at this time point, the Youden's index was 0.60.

The results obtained from the area analysis of ROC curve indicate that 83% of standard error (SE) ± 0.083 , 95% CI 67.4, 1.0) of the time, the clinical outcome postoperative patients was superior when tracheostomy was performed between 12th and 15th postoperative days compared with those performed between 15th and 30th postoperative days.

In this study, 22.6% (n=19) had postoperative sepsis and was associated with 6.72 times (1.74, 25.92) increased risk of death on logistic regression analysis (Table 7). We believe that early tracheostomy leads to a decreased need for sedation, allows a gradual increase in the volume of enteral/parenteral feeds, thus improving nutrition, allows gradual weaning of ventilatory support, improves hemodynamics, shortens ICU stay and improves pulmonary toilet. [1-11]

In our cohort, ICU mortality and cardiac morbidity was significantly lower in the early tracheostomy group. Early tracheostomy was associated with decreased duration of mechanical ventilation, length of ICU stay, and decreased time of decannulation days. The overall postoperative sepsis was lower in the early tracheostomy group. There were no cases of mediastinitis in either group. However, adverse outcomes like sepsis, low cardiac output syndrome/suboptimal hemodynamics, delayed sternal closure, cardiothoracic reoperations were responsible for delaying tracheostomy placement, and thus more likely the plausible reasons for the differences seen in mortality.

Study Limitations

This study has several limitations. The study spans 23 years over which almost all aspects of intensive care have changed. Given its retrospective design, there may have been unmeasured confounding factors that influenced the observed outcomes and a prospective randomized trial of tracheostomy timing would be challenging given the small number of pediatric cardiac surgical patients who require prolonged ventilation, the diversity of diagnoses, and associated congenital and developmental factors. Short of randomization, propensity matching is probably the best protection against confounding and selection bias. Despite this, there may be confounding factors even propensity matching cannot overcome.

As this was a single surgeon study, it may not be possible to directly extrapolate the reported findings to other clinical settings. For example, the ventilation weaning protocols and extubation readiness test can vary among ICUs. Center-to-center variations in indications for tracheostomy, the timing of tracheostomy, and post tracheostomy care could potentially influence the outcomes. The small number of patients in this study, and the large number of candidate predictors analyzed in this study also limit the validity of results.

The study institution likely has a referral bias for high-risk patients with complex CHD, prematurity, late presentation, a referral from outside the geographic area. Additionally, a large proportion of the group having biventricular or univentricular repair had genetic syndromes or significant noncardiac comorbidities, which may reflect referral bias as well. Despite the limitations as above, the prevalence of extubation failure and the airway diseases in this study were comparable with recently published studies including high-risk cardiac surgical patients. However, our outcomes and possible risk factors need to be confirmed by larger multicenter studies with further investigation.

Conclusions

Our study demonstrates the relatively high incidence and diverse etiologies of extubation failure in pediatric cardiac surgery. We conclude that tracheostomy in neonates and infants undergoing cardiac surgeries, requiring prolonged mechanical ventilation provide a stable airway with improved pulmonary toilet, secures airway control, allows patient mobilization, allows the adequate intake of nutrients, thus improving

cardiac cachexia and body mass, reduces work of breathing and allows gradual weaning from ventilation.

The timing of tracheostomy placement as it relates to the overall duration of positive pressure ventilation and survival between 10-15 days after surgery with the partially healed wound and mediastinal tissues appears safe. Early tracheostomy within 15th postoperative day was associated with decreased ICU mortality, decreased morbidity, and decreased ICU stay compared with tracheostomy between 15 and 30 days.

Conflict of interest: No potential conflicts exist

Source of funding: Nil

Informed consent and Patient identification release

Statement: Obtained from all patients

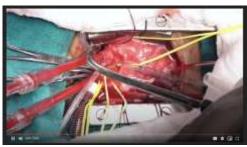
References

- Johnson JT, Marino BS, Klugman D, Shamszad P. Natioanl variation in the use of tracheostomy in patients with congenital heart disease. Pediatr Crit Care Med 2017; 18(10): 958-964
- Cotts T, Hirsch J, Thorne M, Gajarski R. Tracheostomy after pediatric cardiac surgery: frequency, indications, and outcomes. J Thorac Cardiovasc Surg. 2011;141 (2): 413-418.
- Hoskote A, Cohen G, Goldman A, Shekerdemian L. Tracheostomy in infants and children after cardiothoracic surgery: indications, associated risk factors, and timing. J Thorac Cardiovasc Surg. 2005;130 (4): 1086-1093.
- Polito A, Patorno E, Costello JM et al. Perioperative factors associated with prolonged mechanical ventilation after complex congenital heart surgery. Pediatr Crit Care Med 2012; 12: e122e126
- 5. Rosner E, Mastropietro CW. Prior cardiac surgery is independently associated with decreased survival following infant tracheostomy. Respir Care 2015;60: 47-55.
- 6. Mastropietro CW, Benneyworth BD, Turrentine M et al. Tracheostomy after operations for congenital heart disease: an analysis of the Society of Thoracic Surgeons congenital heart surgery database. Ann Thorac Surg 2016; 101: 2285–2292
- LoTempio MM, Shapiro NL. Tracheostomy tube placement in children following cardiothoracic surgery: indications and outcomes. Am J Otolaryngol. 2002; 23: 337-340.
- 8. Rossi AF, Fishberger S, Hannan RL, et al. Frequency and indications for tracheostomy and gastrostomy after congenital heart surgery. Pediatr Cardiol. 2009;30:225-231.
- 9. Berry J, Graham R, Roberson D, et al. Patient characteristics associated with in-hospital mortality in children following tracheotomy. Arch Dis Child 2010; 95: 703-710.
- Yavas S, Yagar S, Mavioglu L, et al. Tracheostomy: how and when should it be done in cardiovascular surgery ICU? J Card Surg 2009; 24: 11-18.
- Costello JP, Emerson DA, Shu MK, et al. Outcomes of tracheostomy following congenital heart surgery: A contemporary experience. Congenit Heart Dis. 2015; 10: E25–E29
- 12. Allen TH, Steven IM. Prolonged endotracheal intubation in infants and children. Br J Anaesth. 1998; 81: 473-481.
- 13. Benjamin B. Prolonged intubation injuries of the larynx: endoscopic diagnosis, classification, and treatment. Ann Otol Rhinol Laryngol Suppl. 1993; 160: 1-15.
- Hawkins DB. Glottic and subglottic stenosis from endotracheal intubation. Laryngoscope. 1977; 87: 339-346.
- Nicklaus PJ, Crysdale WS, Conley S, White AK, Sendi K, Forte V. Evaluation of neonatal subglottic stenosis: a 3-year prospective study. Laryngoscope. 1990; 100: 1185-1190.

- Santos PM, Afrassiabi A, Weymuller EA Jr. Risk factors associated with prolonged intubation and laryngeal injury. Otolaryngol Head Neck Surg. 1994; 111: 453-459.
- Midwinter KI, Carrie S, Bull PD. Paediatric tracheostomy: Sheffield experience 1979-1999. J Laryngol Otol. 2002; 116: 532-535.
- Combes A, Luyt CE, Nieszkowska A. Is tracheostomy associated with better outcomes for patients requiring long-term mechanical ventilation? Crit Care Med. 2007;35 (3): 802-807.
- 19. Rodriguez JL, Steinberg SM, Luchetti FA, et al. Early tracheostomy for primary airway management in the surgical critical care setting. Surgery 1990; 108: 655-659.
- Jacobs JP, Mavroudis C, Jacobs ML, et al. What is operative mortality? Defining death in a surgical registry database: a report of the STS Congenital Database Taskforce and the Joint EACTS-STS Congenital Database Committee. Ann Thorac Surg. 2006;81 (5): 1937-1941.
- 21. World Health Organization. Global nutrition targets 2025: low birth weight policy brief (WHO/NMH/NHD/14.5). Geneva: World Health Organization, 2014.
- Ross RD, Bollinger RO, Pinsky WW. Grading the severity of congestive heart failure in infants. Pediatr Cardiol 1992; 13: 72-75
- 23. Gupta P, McDonald R, Gossett JM, et al. A single-center experience of extubation failure in infants undergoing the Norwood operation. Ann Thorac Surg 2012;94: 1262-1268.
- Bandla HP, Hopkins RL, Beckerman RC, Gozal D. Pulmonary risk factors compromising postoperative recovery after surgical repair for congenital heart disease. Chest. 1999;116: 740-747.
- 25. Kanter RK, Bove EL, Tobin JR, Zimmerman JJ. Prolonged mechanical ventilation of infants after open heart surgery. Crit Care Med. 1986;14 (3): 211-214.
- 26. Harden B, Tian X, Giese R, et al. Increased postoperative respiratory complications in heterotaxy congenital heart disease patients with respiratory ciliary dysfunction. J Thorac Cardiovasc Surg. 2014; 147 (4): 1291-1298.
- 27. Akay TH, Ozkan S, Gultekin B. Diaphragmatic paralysis after cardiac surgery in children: incidence, prognosis, and surgical management. Pediatr Surg Int. 2006; 22: 341-346.
- Mok Q, Ross-Russell R, Mulvey D, et al. Phrenic nerve injury in infants and children undergoing cardiac surgery. Br Heart J. 1991;65: 287-292.
- 29. Ruggiero FP, Carr MM. Infant tracheotomy: results of a survey regarding technique. Arch Otolaryngol Head Neck Surg 2008; 134(3): 263-267.
- 30. Koltai PJ. Starplasty: a new technique of pediatric tracheotomy. Arch Otolaryngol Head Neck Surg 1998; 124(10): 1105-1111.
- 31. Ryan DW, Kilner AJ. Another death after percutaneous dilational tracheostomy. Br J Anaesth. 2003; 91(6): 925-926.
- 32. Shlugman D, Satya-Krishna R, Loh L. Acute fatal haemorrhage during percutaneous dilatational tracheostomy. Br J Anaesth 2003; 90(4): 517-520.
- 33. Durbin CG Jr. Early complications of tracheostomy. Respir Care. 2005; 50 (4): 511-515.
- Curtis JJ, Clark NC, McKenney CA, et al. Tracheostomy: a risk factor for mediastinitis after cardiac operation. Ann Thorac Surg. 2001;72: 731-734.
- Stamenkovic SA, Morgan IS, Pontefract DR, Campanella C. Is early tracheostomy safe in cardiac patients with median sternotomy incisions? Ann Thorac Surg. 2000; 69(4): 1152-1154.
- Chowdhury UK, Kothari SS, Patel CD, et al. An alternative technique for transfer of anomalous left coronary artery from the

pulmonary trunk in children and adults using autogenous aortic and pulmonary arterial flaps. Cardiol Young 2008; 18: 165-176.

Video Presentation



A presentation of an alternative technique for transfer of anomalous origin of left coronary artery from the pulmonary trunk in a child using autogenous aortic and pulmonary arterial flaps who underwent subsequent tracheostomy.³⁶

Surgical planning and position

Following median sternotomy, the thymus was subtotally excised taking care not to expose the brachiocephalic vein. The pericardium was harvested using scissors about 1 cm infront of and parallel to the phrenic nerve, to avoid inadvertent cautery-induced ventricular fibrillation. Note the grossly dilated and tortuous coronary arteries. A continuous thrill is palpable at the root of the pulmonary trunk.

The operation was performed under moderately hypothermic cardiopulmonary bypass at 28°C using an angle venous cannula into the superior caval vein, a straight venous cannula into the inferior caval vein, and distal ascending aortic cannulation. Measures were taken to avoid excessive manipulation.

Dissection of the ascending aorta and pulmonary trunk

The pericardial reflection between the ascending and the pulmonary trunk was incised. The ascending aorta and pulmonary trunk were separated from each other. The persistent ductus arteriosus was interrupted using a liga clip (Johnson and Johnson Ltd., Ethicon, LLC, San Lorenzo, USA). The right and left pulmonary arteries were dissected and freed upto their first lobar branch.

Cross-clamping of the ascending aorta and pulmonary trunk, and administration of the cardioplegia

The aorta and pulmonary trunk were individually cross-clamped and cold hyperkalemic blood cardioplegic solution was infused simultaneously into both vessels at a pressure of 80 mmHg for 3 minutes to achieve optimal myocardial protection. This technique avoids run-off of the cardioplegic solution from the orifice of the proximal pulmonary trunk. A small right atriotomy was done for decompression of the right heart chambers due to the infused cardioplegic solution. The left heart was vented through the right superior pulmonary vein using a left heart DLP vent catheter (Medtronic Inc., Minneapolis, MN).

Transection of the distal pulmonary trunk and creation of a vertical pulmonary arterial flap

The pulmonary trunk was opened transversely in between stay sutures just below the bifurcation and completely transected. A DLP vent catheter was inserted into the distal end of the transected pulmonary artery to prevent flooding of the surgical field. A vertical flap of the pulmonary arterial wall was fashioned for preparation of a long arterial conduit to augment

the bridging aortic flap to the anomalous coronary artery. Note the orifice of the left coronary artery posterolaterally within the left posterior aortic sinus.

The vertical pulmonary arterial flap of the sinus of valsalva containing the left coronary artery at its buttom was mobilized avoiding injury to the pulmonary valve leaflets. The proximal part of the left coronary artery was mobilized over a distance of about 1 cm.

Creation of an anteriorly based aortic wall flap

An arteriorly based, obliquely directed, rectangular flap of the aortic wall was created, approximately 10-15mm above the sinutubular junction, starting from the posterior aspect towards the left lateral side and continuing to the anterior aspect of the aorta, thereby maintaining anterior continuity of the aortic flap.

While selecting the site of re-implantation of the anomalous coronary artery, precautions were taken not to damage or distort the aortic valve, to implant the anomalous left coronary artery in the appropriate sinus, to elongate the main stem of the artery by combining the obliquely positioned rectangular aortic flap with a vertical pulmonary artery flap so as to obtain a "trapdoor" effect, and avoiding narrowing, flattening, torsion, tension or saccule formation, to direct the extended main stem of the anomalous artery posterior to the pulmonary trunk in anatomical position without extrinsic compression. The neo tunnelled left coronary artery was implanted above the sinotubular junction to ensure absence of kinking and external wasting of the left coronary without any tension.

Creation of an elongated neo-aortic tube by trap door technique

The isolated segment of the pulmonary trunk containing the left coronary artery at its bottom was approximated to the neoaortic window. The right inferomedial margin of the pulmonary artery flap was sutured along the posterior lip of the neoaortic orifice. The next point of suturing starts on the left inferolateral portion of the pulmonary arterial flap. The two adjacent edges of the inferolateral margin of the pulmonary arterial flaps were sutured with each other with left coronary artery orifice at its fulcrum.

Subsequently, the redundant superior edge of the pulmonary arterial flap was folded anteriorly over the left coronary sinus. Finally, the anteriorly based, obliquely directed, small rectangular aortic flap was sutured over the residual flap to obtain a "trapdoor" effect. Thus, an obliquely positioned extended left main stem was created, maintaining a tubular confiruation with the orifice of the left coronary artery at its fulcrum. Note the absence of narrowing, flattening, kinking, wasting, tension, torsion or saccular configuration of the neoaortic site.

Reconstruction of the pulmonary trunk

The aortic cross clamp was released, restoring myocardial perfusion. The pulmonary trunk was repaired on a beating, perfused heart. The defect created in the pulmonary trunk and its sinus was repaired with an autogenous pericardial patch using 6-0 monofilament polypropylene suture. Thus, a neoaortic conduit of viable, endothelialized, antogenous arterial flaps was created for transfer of the anomalous left coronary artery with correct angling and length, avoiding injury to the aortic and pulmonary valvular apparatus, without tension, torsion, traction, or

saccular configuration, avoiding obstruction of right ventricular outflow tract.

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