

Safety profile of fast-track extubation in pediatric congenital heart disease surgery patients in a tertiary care hospital of a developing country: An observational prospective study

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Abstract

Background and Aims:: Early extubation after cardiac operations is an important aspect of fast-track cardiac anesthesia. In order to reduce or eliminate the adverse effects of prolonged ventilation in pediatric congenital heart disease (CHD) surgical patients, the concept of early extubation has been analyzed at our tertiary care hospital. The current study was carried out to record the data to validate the importance and safety of fast-track extubation (FTE) with evidence.

Materials and Methods: A total of 71 patients, including male and female aged 6 months to 18 years belonging to risk adjustment for congenital heart surgery-1 category 1, 2, and 3 were included in this study. All patients were anesthetized with a standardized technique and surgery performed by the same surgeon. At the end of operation, the included patients were assessed for FTE and standard extubation criteria were used for decision making.

Results: Of the total 71 patients included in the study, 26 patients (36.62%) were extubated in the operating room, 29 (40.85%) were extubated within 6 h of arrival in cardiovascular intensive care unit and 16 (22.54%) were unable to get extubated within 6 h due to multiple reasons. Hence, overall success rate was 77.47%. The reasons for delayed extubation were significant bleeding in 5 (31.3%) cases, hemodynamic instability (low cardiac output syndrome) in 4 (25%) cases, respiratory complication in 2 (12.5%), bleeding plus hemodynamic instability in 2 (12.5) cases, hemodynamic instability, and respiratory complication in 2 (12.5%) cases and triad of hemodynamic instability, bleeding and respiratory complication in 1 (6.5%) case. There was no reintubation in the FTE cases.

Conclusion: On the basis of the current study results, it is recommended to use FTE in pediatric CHD surgical patients safely with multidisciplinary approach.

Key words: Cardiopulmonary bypass, Congenital heart disease, Fast-track extubation, Operating room, Pediatric, Risk adjustment for congenital heart surgery.

Introduction

Changes in healthcare delivery have influenced all aspects of medical practice, including the field of congenital cardiac surgery. Fast-tracking in cardiac surgery refers to the concept

of early extubation, mobilization and hospital discharge in an effort to reduce the cost and perioperative morbidity.^[1,2] Economic concerns such as significant increases in overall medical expenses and the accumulating data that patient's care is not jeopardized, have made the concept of fast-tracking attractive for practitioners involved in the care of children with congenital heart disease (CHD).^[3]

Potential advantages of fast-tracking following surgery for CHD are: Reduced ventilator associated complications, reduced requirements of sedatives (and associated hemodynamic compromise), more rapid patient mobilization, earlier intensive care unit (ICU) discharges, decreased length of hospital stay and reduced patient or parental stress. Patient and parent satisfaction is increased in children who are extubated in the operating room (OR) or soon after ICU arrival. Early extubation allows earlier mobilization and verbal communication

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Access this article online	
Quick Response Code:	Website: www.joacp.org
	DOI: 10.4103/0970-9185.137267

between the child, parents and hospital staff involved. Prolonged mechanical ventilation in children can be one of the most distressing experiences for the patient and parents.^[4] The reported rate of reintubation following early extubation in patients undergoing CHD corrective or palliative surgery is typically very low, and rates <2-3% are usually reported.^[5,6]

At our hospital before the institution of an early extubation protocol, patient extubation after CHD surgery was determined by factors other than objective patient-focused parameters. The majority of patients were sedated and not extubated until the following day. Consequently, discharge from the ICU (and hospital) was unnecessarily delayed.

The current study was done to record the data to validate the importance and safety of fast-track extubation (FTE) with evidence. In the current study, our aim was to determine the success rate of FTE in CHD surgery patients at our set up to analyze the reasons for delayed extubation and also the rate of reintubation within 24 h in patients extubated on fast-track mode.

Materials and Methods

After taking informed consent from the patients or their parents and approval from ethical review committee (approval no: 2523-Ane-ERC-12 PI), the study was conducted in the cardiac ORs and cardiac intensive care of a tertiary care hospital on the pediatric CHD surgery patients fulfilling the inclusion criteria, for the period of 8 months from January 2013 to August 2013.

Fast-track extubation was defined as extubation within 6 h after arrival at cardiac ICU. On table extubation was termed as ultra-FTE. Both male and female patients aged 6 months to 18 years undergoing elective CHD surgical procedures under risk adjustment for congenital heart surgery (RACHS)-1^[7] category 1, 2 and 3 on cardiopulmonary bypass (CPB) or off pump were included in the study. RACHS-1 risk category (4, 5 and 6), emergency procedures, redo cases, and preoperative intubated patients were excluded from the study.

Extubation criteria were fully awake normothermic patients (core temperature 36°C) with regular breathing and tidal volume of 5-7 ml/kg, normal pre-extubation arterial blood gas (ABG) analysis on FIO₂ of 0.4, optimal hemoglobin with no metabolic acidosis, stable hemodynamics with minimal inotropic support, minimal chest tube drainage and normal per-operative postrepair transesophageal echocardiogram.

A total of 71 patients were included in this study on the basis of previous study in which the success rate of FTE in CHD

pediatric surgical patients was 65-88%.^[8] Success rate of FTE in CHD pediatric patients ($P = 76\%$) was estimated with 10% of the true proportion (error) with 95% confidence interval.

All patients were premedicated with midazolam. Inhalational induction with sevoflurane 8% in 100% O₂ was done in patients with no intravenous (I/V) line. For those with I/V access, midazolam 0.1 mg/kg plus fentanyl 2-3 µg/kg were used for induction. Tracheal intubation was done with atracurium 0.5 mg/kg I/V. For those with allergic asthma, rocuronium 0.9 mg/kg I/V was used. Maintenance anesthesia consisted of isoflurane titrated to the patient's response (minimum alveolar concentration [MAC] of 1).

Invasive blood pressure (radial or femoral) and central venous pressure monitoring through internal jugular vein or femoral vein was done apart from standard American Society of Anesthesiologists (ASA) recommended monitoring (pulse rate, electrocardiogram, noninvasive blood pressure, SPO₂, ETCO₂, nasopharyngeal temperature and urine output). Arterial blood gases with Hemoglobin, electrolytes (baseline, after CPB and preextubation), blood sugar (baseline, during CPB half hourly) and activated clotting time (ACT) (baseline and postprotamine reversal) were also monitored. Monitoring during CPB included mean arterial pressure (MAP), urine output, systemic venous O₂ saturation, half hourly ABGs and ACT.

During CPB, fentanyl infusion at 5 µg/kg/h plus 1% isoflurane through CPB fitted vapourizer were administered. Patients with off pump surgery were maintained with 2-3 µg/kg/h of fentanyl infusion with 1 MAC of isoflurane in 50% oxygen and air.

Atracurium was the primary muscle relaxant being run in infusion at 0.4 mg/kg/h until the start of sternal wiring. In patients with history of allergic asthma, 0.25 mg/kg I/V boluses of Rocuronium were used. For analgesia adjuvants, paracetamol 15 mg/kg I/V and ketorolac 0.5 mg/kg I/V were administered before chest closure. At skin closure, bupivacaine 2.5 mg/kg diluted in saline was infiltrated at the wound and drain sites. Neostigmine (40 µg/kg) and glycopyrolate (10 µg/kg) was administered as a reversal after assessment with the train of four stimulus response (TOF ratio >0.9). Standard pediatric extubation criteria were used to determine the suitability for immediate extubation.

The patients undergoing atrial septal defect (ASD), ventricular septal defect (VSD), Blalock-Taussig (BT) shunt, Glenn shunt and patent ductus arteriosus closure were assessed to be extubated on ultra-fast track mode. The

patients undergoing other procedures mentioned under RACHS-1 category 1, 2 and 3 were assessed for extubation and extubated within 6 h of arrival in the cardiovascular intensive care unit (CICU).

All statistical analyses were performed using Statistical Packages for Social Science version 19 (SPSS Inc., Chicago, IL). Age, weight, gender, success rate of FTE, reasons for delayed extubation and reintubation were analyzed. Frequency and percentage were computed for categorical variables and mean and standard deviation estimated for quantitative observations. Chi-square test was applied to compare the success rate between gender and age groups. $P \leq 0.05$ was considered as statistically significant.

Results

In the current study, there were 49 (69%) males and 22 (31%) females. Surgical procedures included 25 VSD closures (35.2%), 17 tetralogy of fallot (TOF) total corrections (23.9%), 14 (19.7%) ASD closures, 4 Glenn shunts (5.6%) and 4 BT shunts (5.6%). Other procedures (including pulmonary artery banding, pulmonary valve replacement/repair, coarctation of aorta repair, aortic valve, and mitral valve replacement) were 7 (9.9%) as shown in Table 1.

Of the total 71 patients included in the study, 26 patients (36.62%) were extubated in the OR, 29 (40.85%) were extubated within 6 h of arrival in CICU and 16 (22.54%) failed to get extubated within 6 h demonstrated in bar graph. Hence overall, success rate was 77.47%. The reasons for delayed extubation were significant bleeding in 5 (31.3%) cases, hemodynamic instability (low cardiac output syndrome [LCOS]) in 4 (25%) cases, respiratory complication in 2 (12.5%), bleeding plus hemodynamic instability in 2 (12.5%) cases, hemodynamic instability and respiratory complication in 2 (12.5%) cases and triad of hemodynamic instability, bleeding and respiratory complication in 1 (6.5%) case as shown in Table 2. There was no reintubation in the FTE patients shown in Figure 1.

Success rate and delayed extubation according to age, weight and sex were also noted as shown in Table 3. In the age group < 1 year, patients extubated on the table were 21.4%, those extubated within 6 h were 28.6% and delayed extubation was noted in 50% of the cases. In the age group 1-5 years, on table extubation, extubation within 6 h and delayed extubation was 47%, 15% and 11% respectively. In the age group > 5 years it was 28.6, 47.6, and 23%, respectively. The mentioned percentages were clinically significant with $P = 0.042$. The

results of fast-track and delayed extubation calculated as percentages with respect to sex and weight were not clinically

Table 1: Demographic and clinical characteristic of patients

Variables	Results
Age (years)	3.08 (4.92)
Weight (kg)	11 (7.05)
Pump time (min)	62.5 (43)
Cross clamp time (min)	35 (33)
Gender (%)	
Male	49 (69)
Female	22 (31)
Procedure (%)	
VSD closure	25 (35.2)
TOF repair	17 (23.9)
ASD closure	14 (19.7)
Glenn shunt	4 (5.6)
BT shunt	4 (5.6)
Others	7 (9.9)
Inotropes/vasopressors (n=43) (%)	
Epinephrine	30 (61.22)
Milrinone	17 (34.6)
Dopamine	2 (4.08)

Table 2: Reasons for delayed extubation in the selected patients (n = 16)

Reasons	Count	Percentage
Significant bleeding: (12 ml/kg/h in 1 st h or 10 ml/kg/h in 1 st 2 h or 8 ml/kg/h in the 1 st 3 h) affecting the hemodynamics or reopening	5	31.3
Hemodynamic instability (LCOS)	4	25
Respiratory complication (RC)	2	12.5
Bleeding + hemodynamic instability	2	12.5
Hemodynamic instability + RC	2	12.5
Bleeding + hemodynamic instability + RC	1	6.2

Data are presented as number and percentage. LCOS=Low cardiac output syndrome

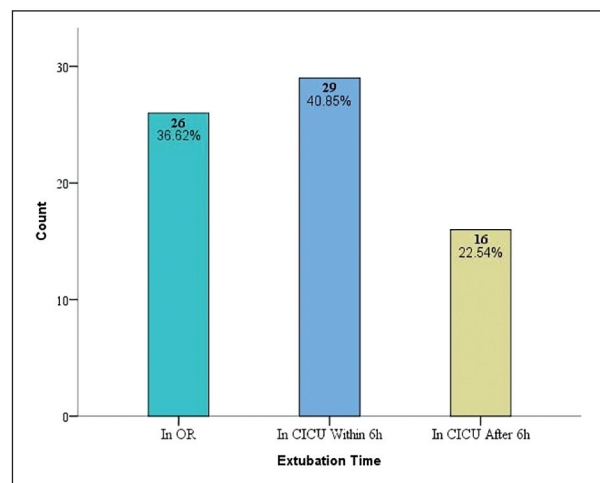


Figure 1: Success rate of fast-track extubation in congenital heart disease pediatric surgery patients. (OR=Operating room, CICU=Cardiac intensive care unit)

Table 3: Success rate of fast-track extubation according to age of the patients, weight and gender

Variables	In OR (%)	In ICU within 6 h (%)	In ICU after 6 h (%)	P value
Age (years)				
≤1 year	3 (21.4)	4 (28.6)	7 (50)	0.042*
1.1-5 years	17 (47.2)	15 (41.7)	4 (11.1)	
>5 years	6 (28.6)	10 (47.6)	5 (23.8)	
Weight (kg)				
<10 kg	10 (32.3)	11 (35.5)	10 (32.3)	0.27
10-20 kg	7 (30.4)	12 (52.2)	4 (17.4)	
>20 kg	9 (52.9)	6 (35.3)	2 (11.8)	
Gender				
Male	20 (40.8)	17 (34.7)	12 (24.5)	0.28
Female	6 (27.3)	12 (54.5)	4 (18.2)	

Data presented as the number and percentage. Row wise percentage is computed. Chi-square test applied; *P ≤ 0.05 showing statistical significance

significant. The results of the study validated the safety of FTE in pediatric CHD surgery patients at our pediatric cardiac surgery setup.

Discussion

Fast-tracking strategy is being followed all over the world in the cardiac surgery centers. FTE is an important component of fast-tracking strategy. The current study was carried out at cardiac ORs and ICU of a tertiary care hospital to assess the safety profile of this fast-tracking strategy in pediatric CHD surgical patients. A study was done in adult cardiac surgery patients to see the success and failure of FTE.^[9] A total of 614 patients underwent CABG surgery and 388 (63.19%) patients were planned for FTE. A total of 196 (49.5%) patients could be extubated within 6 h of arrival in the cardiac ICU. Common reasons for delayed extubation included deep sedation in 80 patients (46.5%), confusion in 44 (25%) cases, excessive bleeding in 20 (11.3%) and high inotropic support in 10 (5.68%) patients.

The concept of fast-tracking is popular due to its associated better patient outcome and resource saving advantages. It plays an important role in reducing the patient elective ventilation time, ICU and hospital stay and above all provides psychological relief to the patient and the parents.

On the basis of experience from the current study, all the mentioned advantages were achieved including better patient outcome and best possible resource utilization. There was an improvement in patient turn over from pediatric CICU and improved ability to treat more CHD patients.

Despite increasing evidence that fast-tracking in surgery for CHD can be achieved safely, there still remains

significant individual as well as institutional concerns about the safety of such an approach.^[10] Large series in adult cardiac surgery have shown that fast-tracking can be accomplished safely and may actually benefit the patient.^[11,12] In addition, early extubation can clearly benefit some patients, and it was demonstrated that early extubation (within 6 h) in children undergoing surgery for CHD had no negative affect on cardiac function.^[13] The rate of reintubation following early extubation with modern anesthetics is low and mostly unrelated to fast-tracking. We attribute this to improved surgical techniques, CPB refinements such as minimal priming volumes, the use of modified and conventional ultrafiltration technique and the availability of drugs with favorable pharmacokinetics (short plasma half-life) and pharmacodynamics. Our study had shown no incidence of reintubation in patients being extubated on fast-track or ultra-fast-track mode validating the safety profile of FTE in pediatric CHD surgical patients. Settings in surgery for CHD where fast-tracking cannot be considered safe include all patients who are hemodynamically unstable, coagulopathic patients or patients that do not meet generally accepted extubation criteria. In our study, the major factors that resulted in delayed extubation were age < 1 year, bleeding, hemodynamic instability and LCOS.

With the help of modern short acting opioids, fast-tracking of pediatric cardiac patients can be achieved safely. The short acting opioids allows for a “high-dose opioid” technique without the need for prolonged mechanical ventilation. The use of nonopioids in the postoperative period has been advocated.^[14] The use of acetaminophen and ketorolac for supplementary postoperative pain control has been reported.^[15] In our study, we also used opioid based technique with high-dose fentanyl (20-40 µg/kg). In the current study, I/V paracetamol, ketorolac and local infiltration of the wound and chest tube sites with bupivacaine were used to facilitate fast or ultra-fast-track pain free extubation.

Conclusions

On the basis of the current study, it is recommended to use FTE in pediatric CHD surgical patients safely with multidisciplinary approach involving the pediatric cardiac anesthesiologist, surgeon and intensivist.

Acknowledgement

Mr. Amir Raza and Ms. Feroza Nasir for their contribution in data analyses and formulation of study results.

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How to cite this article: Akhtar MI, Hamid M, Minai F, Wali AR, A, Aman-Ullah M, Ahsan K. Safety profile of fast-track extubation in pediatric congenital heart disease surgery patients in a tertiary care hospital of a developing country: An observational prospective study. *J Anaesthesiol Clin Pharmacol* 2014;30:355-9.
Source of Support: From Aga Khan University Hospital, Karachi, **Conflict of Interest:** None declared.

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