ORIGINAL ARTICLE

A prospective observational study of paediatric cardiac surgery outcomes in a postoperative intensive care unit in Iran

Shahla Roodpeyma, Manuchehr Hekmat, Maryam Dordkhar, Sima Rafieyian, Arash Hashemi

Abstract

Objective: To evaluate the incidence of complications, morbidity and mortality, and the associated risk factors with mortality at a Paediatric Cardiology Intensiv Care Unit of a developing country.

Methods: The prospective observational study was conducted at Shahid Modarres Hospital, Tehran, Iran, from August 2009 to July 2010. A total of 202 patients were monitored from the time they entered the Paediatric Cardiology Intensive Care Unit till their final discharge. SPSS 16 was used for statistical analysis and $p \leq 0.05$ was considered statistically significant.

Results: Of the total, 107 (53%) were male and 95 (47%) were female. The mean age of the patients was 4.5 ± 4.9 years (range: 2 days to 18 years). Among the patients 59 (29.2%) had complications and 25 (12.37%) of them died. A total of 177 (87.6%) survived and were discharged. Infants ($p = 0.012$), cyanotic congenital heart disease ($p = 0.002$), longer duration of cardiopulmonary bypass ($p=0.027$), longer aortic cross-clamp time ($p=0.038$), longer mechanical ventilation time ($p < 0.006$), and early post-operative period ($p = 0.05$) were associated factors for mortality. According to regression analysis, cyanotic congenital heart disease, longer intubation time, and early post-operative period were major factors for mortality ($p = 0.01$, $p < 0.001$, and $p = 0.001$) respectively.

Conclusion: Critically ill cyanotic young infants in the first 24 hours after operation experienced high mortality. Prolonged mechanical ventilation was also associated with high mortality.

Keywords: Cardiac surgery, Children, Complication, Intensive care, Associated factors, Mortality. (JPMA 63: 55; 2013)

Introduction

Recent improvements in facilities in paediatric intensive care units (ICUs) have increased the survival rates among children suffering from congenital heart diseases (CHD), including those suffering from the more complex conditions.[1] The patient's course after a successful heart surgery depends on such diverse factors as the severity of the CHD, age and condition of the patient before surgery, events in the operating room, and the quality of post-operative care.[2] Ideal post-operative care following either corrective or palliative operations requires a thorough understanding and systemic evaluation of the underlying anatomic defect, the patho-physiology of pre-operative state, the anaesthetic regime used during surgery, the cardiopulmonary bypass (CPB), and the details of operative procedures.[3] The post-operative myocardium that has been exposed to the effects of CPB, aortic cross-clamping, deep hypothermia, or myocardial ischaemic damage may be incapable of increasing stroke volume to confront an acute increase in after-load following surgical procedures. This is especially true if myocardial performance is weakened by ventriculotomy as required for repair of a variety of CHDs.[3] Complete correction of the intracardiac defect and adequate intraoperative myocardial protection generally result in good cardiac function after the operation. Children who undergo an uncomplicated cardiac surgery, with good intraoperative care should need little post-operative management for a smooth recovery.[4]

In developing countries, several other factors affect the outcome of the paediatric cardiac surgery. Some of these factors depend on the condition of the patients or their parents such as, high incidence of malnutrition in children,[5,6] financial constraints of the parents, lack of awareness about signs and symptoms of heart disease and late presentation of the cases.[5]

There are other factors related to limitations in healthcare facilities of these countries, such as limited human and material resources for corrective heart surgery in early neonatal period and young infants, inadequate facilities for paediatric cardiac anaesthesia, non-existence of paediatric cardiac surgery anaesthesiologist, insufficiently trained staff in paediatric cardiology ICU (PCICU), poor health infrastructure and referral systems.[7,8] Iran is a developing country with a relatively well-established healthcare system. However, there are still insufficient facilities for corrective cardiac surgery in neonates and specialists for cardiac surgery anaesthesia. In review of the literature no local reference was found on the study

Department of Paediatric Cardiology and Paediatric Cardiac Surgery, Shahid Modarres Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran.
Correspondence: Shahla Roodpeyma. Email: roodpeyma_shahla@yahoo.com

subject. The current study was undertaken to determine the frequency of complications in different organ systems, the rate of mortality and morbidity and its associated factors in children with CHD who underwent cardiac surgery and were hospitalised in the PCICU of a university hospital in Tehran, Iran.

Patients and Methods

The Paediatric Cardiology Department at the Shahid Modarres Hospital consists of 18 beds in the ward and six beds in the PCICU. The department receives CHD patients (adults and children) referred by hospitals affiliated with Shahid Beheshti University. All patients admitted to the paediatric cardiology ward, first undergo a thorough evaluation and upon diagnosis, if required, are referred to the cardiac surgeon. After surgery, they are bought to PCICU for post-op management. Upon discharge from the PCICU, they return to the paediatric cardiology ward for complete recovery prior to final discharge from the hospital.

During the period of this prospective opservational study - from August 2009 to July 2010 - 234 patients underwent operation at the department. Six critically ill, intubated newborns died on the operating table and were excluded from the study. Besides, 16 adult patients (more than 18 years old) with CHD were operated upon and were admitted to the PCICU afterwards. they were also excluded. The remaining 202 paediatric patients who were admitted to the PCICU, and received intensive care were included in the study. Each case was enrolled only once. The study was approved by the Ethical Review Board of the institution. All our patients had CHD, except two who suffered from cardiac tumour. All the patients had a complete medical record containing demographic characteristics, past and present medical history, physical examination, diagnostic evaluation, and operation notes. The monitoring devices to be used in the PCICU were placed in the operating room, usually with the help of the anaesthesiologist. The PCICU care was provided by a team of trained ICU nurses, paediatric cardiologists, anaesthesiologists, cardiac surgeons, and in some cases by necessary paediatric subspecialists. The cardiac surgeons were responsible for the patient's course of care, including interactions with the other services. The post-operative course of each patient from entering the PCICU until being discharged from it was carefully monitored and the following data was collected: age, gender, type of cardiac malformation, type of cardiac surgery, complexity score of the surgical procedure, history of previous cardiac surgery, if applicable, pump time, cross-clamp time, intubation time, ICU-stay time, type of complication, and outcome.

The primary operation was defined as the first cardiac surgery, while secondary operation was defined as the second cardiac surgery at a different session. Complexity level was defined according to the Aristotle basic complexity[9] score and categorised at four levels: simple procedures were defined as level 1 or 2, and complex procedures were defined as level 3 or 4. If interventions involved two or more procedures during the same operating time, the procedure having the highest complexity level was chosen.

Ten major post-op complications were defined as: low cardiac output syndrome (state); cardio-respiratory insufficiency requiring re-intubation; bleeding or residual defect requiring re-operation; new onset seizure; complete atrioventricular (AV) block requiring permanent pacemaker; acute renal failure requiring temporary dialysis; pericardial effusion requiring drainage; pleural effusion requiring drainage; pneumothorax requiring insertion of chest tube; and chylothorax.

Categorical data was expressed as frequencies and percentage and tested with chi square test or Fisher's exact test. Quantitative variables were expressed as mean ± standard deviation (SD) and analysed with student's t tests. Logistic regression analysis (backward: logistic regression) was used to determine the factors associated with mortality. The data was analysed using the SPSS 16, and $p = \leq 0.05$ was considered statistically significant.

Results

Of the 202 patients, 107 (53%) were male and 95(47%) were female. The average age of the patients was 4.5 ± 4.9 years, ranging between 2 days and 18 years. The median age of the group was 3 years. Among the participants, 13

Table-1: The association between categorised variables and mortality.

Categorised variables		Mortality (%)	P-value
Gender	Male	12 of 107(11)	0.67
	Female	13 of 95(14)	
Type of CHD	Acyanotic	10 of 138(7)	0.002
	Cyanotic	15 of 64(23)	
Type of operation	Open heart surgery	21 of 143(15)	0.16
	Close heart surgery	4 of 59(7)	
Order of operation	First operation	19 of 159(12)	0.79
	Second operation	6 of 43(14)	
Age groups	Neonates	7 of 13(54)	0.001
	Infants	10 of 86(12)	
	Children	8 of 103(8)	
Complication	Yes	5 of 59(9)	0.35
	No	20 of 143(14)	
Complexity	Yes	3 of 46(7)	0.21
	No	22 of 156(14)	

CHD: Congenital heart disease.

Table-2: Association between continuous variables and mortality.

Variable	Mortality (mean ± SD)	Survival (mean ± SD)	P-value
Age (year)	2.5 ± 3.9	4.8 ± 5	0.012
Intubation time (hr)	71.2 ± 78.3	17.8 ± 36	0.006
ICU-stay time (day)	3.5 ± 3.2	5.1 ± 4.1	0.05
Aortic cross-clamp time (minute)	70.2 ± 36.6	47.1 ± 27.8	0.038
CPB time (minute)	104.5 ± 60.9	70.1 ± 36.9	0.027

ICU: Intensive Care Unit. CPB: Cardiopulmonary bypass.

Table-3: Logistic regression analysis for risk factors associated with mortality.

Variable	OR	95% c.1.	P-value
Age (year)	0.91	0.59-1.4	0.67
Cyanotic CHD	395.8	1.1-1.41*105	0.046
Open heart surgery	1.77	0.12-253.4	0.8
Second operation	0.08	0.16-7.8	0.33
Intubation time (hr)	1.12	1.04-1.2	0.002
ICU-stay time (day)	0.06	0.008-0.41	0.005
Complication	0.64	0.02-20.4	0.8
Complexity	0.02	0-2.9	0.13
Cross-clamp time(min)	0.98	0.87-1.1	0.78
Pump time(min)	1.04	0.96-1.1	0.38
After deleting non significant variables			
Cyanotic CHD	68.9	1.7-1.7*103	0.01
Intubation time (hr)	1.1	1.05 - 1.17	0.001
ICU stay time (day)	0.084	0.02-0.32	0.001
Complexity	0.61	0.001-2.5	0.14
Pump time (min)	1.02	0.99-1.04	0.1

CHD: Congenital heart disease. ICU: Intensive care unit.

(6.4%) were newborns; 86 (42.6%) infants <2 years; and 103 (51%) ≥ 2 to 18 years, 8 of which were 16 to 18 years old. There were 138 (68.3%) acyanotic patients and 64 (31.7%) cyanotic cases. Acyanotic heart lesions consisted of 98 (71%) different types of left-to-right shunts; 26 (18.8%) valvular disease; 12 (8.7%) coarctation of aorta ± patent ductus arteriosus (PDA); and 2 (1.4%) tumour of the heart. Cyanotic heart lesions consisted of 30 (46.8%) tetralogy of Fallot; 22 (34.3%) different combinations of transposition of great arteries (TGA); and 12 (18.75%) miscellaneous. Of the total, 143 (70.8%) patients underwent open heart surgery. Types of open operative procedures included 76 (53.14%) repair of left-to-right shunts; 30 (21%) total correction of tetralogy of Fallot; 26 (18.18%) valvular repair or replacement; 4 (2.8%) Fontan operation; 3 (2%) Rastelli operation; 2 (1.4%) Senning operation; and 2 (1.4%) Glenn shunt. Besides, 59 (29.2%) underwent closed heart surgery. Types of closed surgeries included 22 (37.28%) ductus arteriosus ligation; 13 (22%) modified Blalock-Taussig shunt; 12 (20.3%) PDA ligation + pulmonary artery banding; and 12 (20.3%) coarctation of Aorta repair ± PDA ligation. Basic complexity level included: level one 50 (24.6%); level two 106 (52.4%); level three 43 (21.2%), and level four 3 (1.8%). The total number of simple procedures (level 1 and 2) was 156 (77.2%) and complex procedures (level 3 and 4) were 46 (22.8%).

Most patients (n=159; 78.7%) experienced their first cardiac surgery and for 43(21.3%) cases, this was their second heart operation. Aortic cross-clamp time ranged from 4.4min to 156min with a mean of 49.7±29.7 minutes. CPB or pump time ranged from 15min to 240min with a mean of 75.1±42.7 minutes. The range of intubation time was 30min to 13 days with a mean of 23.5±45.5 hours. The range of ICU stay time was 2 hours to 28 days (4.9±4 days).

A total of 143 (70.8%) patients had a smooth and uncomplicated course in ICU and were discharged from the PCICU and subsequently from the hospital, while 59(29.2%) experienced some kind of complication. Of the 59 complicated cases, 25 (42.4%) died, and the remaining 34 (57.6%) cases recovered and were discharged from PCICU and the hospital, but 2 of these 34 (5.6%) required permanent pacemaker implantation. As such, a total of 177(87.6%) patients survived and 25(12.4%) died. The complications were as follows: 10 (17%) low cardiac output syndrome (2 were due to insufficiency of Blalock-Taussig [B-T] shunt); 10 (17%) cardio respiratory failure requiring re-intubation (7 were due to pulmonary hypertension crisis); 9 (15.25%) bleeding requiring re-operation (all of them were due to bleeding from suture lines); 7 (11.8%) new onset of seizure (5 were due to stroke; 2 were due to brain oedema); 6 (10.16%) pleural effusion requiring drainage (all of them were sterile effusion); 5 (8.5%) pneumothorax requiring chest tube insertion; 4 (6.8%) acute renal failure requiring temporary dialysis; 3 (5%) pericardial effusion requiring drainage; 3 (5%) chylothorax; and 2 (3.4%) complete AV block requiring permanent pacemaker. Complications in open heart surgery were 43 out of 143 cases, while complications in the closed surgery were 16 of 59 ($p = 0.74$). Complications in newborns were 4 of 13 cases versus complications in infants 23 of 86 ($p= 0.8$), and versus complications in children 32 of 103 ($p = 0.8$). Complications in simple procedures were 27 of 156 versus complications in complex procedures 22 of 46 ($p < 0.003$).

Mortality in complex surgeries was 5 of 59 versus mortality in simple surgeries 20 of 143 ($p = 0.35$). Mortality in open heart surgeries was 21 of 143 versus mortality in closed heart surgeries 4 of 59 ($p = 0.16$).

Cyanotic CHD had a higher mortality rate than acyanotic lesions ($p <0.002$), and in the neonate group, mortality was higher than other age groups ($p <0.001$) (Table-1).

Younger age, longer mechanical ventilation (intubation time), shorter ICU stay, longer aortic cross-clamp time, and longer pump time were associated with higher mortality and the differences were significant (Table-2). The CPB time and aortic cross-clamp time in closed heart surgeries were considered zero in logistic regression analysis. In the open heart surgery group, odds ratio for cross-clamp time and pump time were 0.98 (95%CI; 0.95-1.01) and 1.03 min (95%CI; 1.01-1.05) respectively (Table-3). Cyanotic heart disease, longer intubation time and shorter ICU stay were associated with higher mortality and their associations were significant ($p < 0.01$, $P < 0.001$, $P < 0.001$) respectively.

Discussion

Cyanotic heart diseases are usually complex lesions which require difficult surgical techniques and longer operation time for correction. The technique difficulty, the case complexity, and the surgery duration have been reported to be associated with higher mortality and morbidity in previous reports.[1,10-13] In the present study, 40.8% of patients were less than 2 years old. The mean age of the patients who survived was significantly more than that of the patients who died ($p = 0.012$). Mortality in neonatal period was also higher than that in infancy and childhood ($p = 0.001$). The number of cyanotic CHD in our data was about half of the acyanotic lesions, but mortality in cyanotic patients was significantly more than that of acyanotic cases ($p < 0.002$). Critically ill cyanotic newborns suffering from complex heart lesions usually need emergency surgery. These patients usually suffer from severe metabolic acidosis and tissue hypoxaemia which predispose them to complications and death. The standard management for such patients is quick and safe transfer to a well-equipped, specialised ward and effective treatment by corrective surgeries.[2] The majority of our cyanotic newborns and young infants suffered from various combinations of TGA. The facilities and experience required for corrective surgery - arterial switch procedure - are not available in our ward. We performed emergency palliative surgery (atrial septectomy ± aortopulmonary shunt or pulmonary artery banding) for such patients. Because of the poor condition of our patients, even the above simple procedure was associated with complication and death. This may explain the increased post-operative mortality of closed heart surgery in our cases. Therefore, we did not find significant differences in mortality between open and closed heart surgeries and also between simple and complex procedures.

Higher mortality and morbidity such as central nervous system (CNS) problems in redo operation were reported in previous studies.[1,14] We did not find a significant difference between mortality of first operation, and mortality of second (re do) operation. The majority of our second operations were corrective surgeries after previous pulmonary artery banding or previous modified B-T shunts which usually are not associated with a high mortality rate.

Intraoperative support techniques, including CPB, can precipitate a complex systemic inflammatory response that impairs the function of multiple organs and results in more haemodynamic instability and early morbidity in newborns, more so than in infants and children.[15] In several previous reports, prolonged CPB and aortic cross-clamp times were cited as risk factors for major post-operative complications and increased mortality.[1,10,16] Of our patients, 143 underwent CPB. CPB and aortic cross-clamp times in patients who died were significantly longer than those in the survivors.

Longer mechanical ventilation is usually associated with longer ICU stay and both are associated with higher mortality.[17] The results of our series showed that the longer intubation time and shorter ICU stay were associated with higher mortality. Ten of the 25 deaths in our series occurred in young infants with complex cyanotic heart lesion who were in shock and/or were intubated before operation. They died due to low cardiac output state within the first several hours after surgery. These patients made up 40% of our mortality. Their short ICU stay was due to their poor condition in the early post-operative period.

The complication rate in our patients was 29.2% (59 of 202), and 25 of the 59 complications resulted in death. The overall mortality rate was 12.4%. In large paediatric cardiac centres in North America, post-operative mortality after complete repair of CHD in neonates was <5%.[15] One study looked at 184 consecutive CHD patients with a median age of 9 months (range, 10-165 months); 11 (5.9%) patients who required reintubation died.[18] In another study, 200 newborns younger than 45 days underwent cardiac surgery requiring CPB. The whole series mortality was 19% and fell to 14% within 5 years of experience.[19] In our series, the major complications which resulted in death were in young cyanotic infants with complex heart lesions who were affected by cardiovascular or CNS problems. Our patients with CNS problem had long duration of mechanical ventilation and ICU stay. Five of our cases had fatal CNS thromboembolic event. The frequency of vaso-occlusive stroke in children with CHD undergoing cardiac surgery is reported to vary from 0.5 to 10% in different studies.[14,20,21] Hypoperfusion, long CPB, re do operation, complex anomaly, and metabolic acidosis were reported as risk factors for stroke.

The same risk factors have been reported for fatal arrhythmias after CHD surgery.[22] We had no fatal arrhythmias in our study group.

We did not find a significant difference in complication rates between open and closed heart surgery, or in different age groups. However, complications in complex procedures were significantly higher. Logistic regression analysis showed that cyanosis, longer intubation time and shorter ICU stay were associated with higher mortality. The above findings are due to our high mortality rate of cyanotic young infants on the first operation day.

This study was conducted in a single tertiary cardiac surgery unit with limited number of cases. A multi-central study, with a larger cohort of patients is recommended.

Conclusion

In our setting, cyanotic young infants with emergency presentation had a higher rate of mortality on the first day after the operation. Prolonged mechanical ventilation was also associated with increased mortality.

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