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Main Risk Factors for Mortality After Cardiovascular Interventions in Newborns with Critical Congenital Heart Diseases

Kritik Konjenital Kalp Hastalıklı Yenidoğanlarda Kardiyak Girişim Sonrası Mortaliteyi Etkileyen Ana Risk Faktörleri

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ABSTRACT

Objective: It was aimed to define the main risk factors that affect mortality in infants with critical congenital heart disease (CHD).

Material and Methods: We analyzed data from 105 infants with critical CHD underwent cardiovascular intervention at a tertiary neonatal intensive care unit (NICU) between September 2010 and January 2012. Demographic data, clinical findings (before and after intervention), type of intervention, and intervention risk score according to Risk Adjustment in Congenital Heart Surgery (RACHS-1) classification were evaluated.

Results: The mean age at cardiovascular intervention was 15.2±11.8 days. Transcatheter interventions were performed in 29 patients (27.6%). Seventy-six patients (72.4%) underwent cardiovascular surgery. At post-interventional period, the rates of low cardiac output, pneumonia, and sepsis were significantly higher among patients underwent surgical intervention. Length of NICU stay was also longer among them. Overall mortality rate was 35.2% (n=37). Mortality was significantly lower in infants underwent transcatheter intervention. Univariate analyses showed that nonsurvivors differed from survivors in terms of gestational age, prematurity, the presence of associated disorder, pre-interventional need of mechanical ventilation, need of inotropic support, the presence of pulmonary hypertension and sepsis, requirement of cardiovascular surgery, age at intervention, and RACHS-1 score. Multivariate analysis showed that higher RACHS-1 score was associated with mortality (OR: 4.5, 95% CI (1.5-13.1), p=0.005) while higher gestational age was a preventive factor (OR: 0.6, 95% CI (0.5-0.9), p=0.01).

Conclusion: Our study indicates that lower gestational age and severity of the disease seem to be most possible risk factors for mortality among infants with critical CHD.

Key Words: Congenital heart disease, Newborn, Prematurity

ÖZET

Amaç: Kritik konjenital kalp hastalıklı (KKH) yenidoğanlarda girişim sonrası mortaliteyi etkileyen risk faktörlerinin belirlenmesi amaçlandı.

Gereç ve Yöntemler: Üçüncü düzey bir yenidoğan yoğun bakım ünitesinde (YYBÜ) Eylül 2010–Ocak 2012 tarihleri arasında izlenen ve girişim uygulanan kritik KKH tanılı 105 yenidoğan incelendi. Hastaların demografik verileri, girişim öncesi ve sonrası klinik bulguları, girişim tipi, Doğuştan Kalp Cerrahisi için Risk Ayarlanması sınıflamasına göre girişimsel risk skoru (Risk Adjustment in Congenital Heart Surgery; RACHS-1) ile ilgili veriler kaydedildi.

Bulgular: Kardiyak girişim sırasında ortalama yaş 15.2±11.8 gündü. Transkateter girişim 29 (%27.6) hastada uygulandı. Toplam 76 hastaya (%72.4) kardiyak cerrahi girişim yapıldı. Girişim sonrası dönemde düşük kardiyak debi, pnömoni ve sepsis görülme sıklığı cerrahi girişim yapılan olgularda daha yüksekti. Bu hastalarda YYBÜ kalış süresi de daha uzundu. Mortalite oranı %35.2 (n=37) olarak bulundu. Transkateter girişim yapılan hastalarda mortalite daha düşüktü. Univaryant analizde ölen hastalarda gebelik haftasının daha düşük, prematürite oranının daha fazla, eşlik eden hastalık sıklığının daha yüksek, girişim öncesi mekanik ventilatörde kalma oranı, inotrop desteği, pulmoner hipertansiyon ve sepsis oranının daha fazla, cerrahi girişim gereksiniminin daha çok, girişim sırasındaki yaş ve RACHS-1 skorunun daha yüksek olduğu saptandı. Çoklu regresyon analizinde RACHS-1 skorunun yüksek olmasının mortalite ile ilişkili olduğu (Odds oranı: 4.5, %95 GA (1.5-13.1), p=0.005), gebelik yaşının büyük olmasının ise koruyucu bir faktör olduğu dikkati çekti (Odds oranı: 0.6, GA(%95) (0.5-0.9), p = 0.01).

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Sonuç: Bu çalışmada cerrahi girişim gereken kritik KKH'lı yenidoğanlar arasında mortalitenin yüksek olduğu, özellikle gebelik haftasının düşük, RACHS-1 skorunun ise yüksek olmasının mortalite riskini artırdığı sonucuna varıldı.

Anahtar Sözcükler: Konjenital kalp hastalığı, Yenidoğan, Prematürite

INTRODUCTION

The reported total congenital heart disease (CHD) birth prevalence has increased substantially over time, from 0.6 per 1.000 live births in 1930 to 9.1 per 1,000 live births after 1995 (1). The recent incidence of CHD in the neonatal intensive care unit (NICU) has been reported as 3.7% in full-term and 6.8% in pre-term infants (2). In Turkey, every year 12,000 babies born with CHD and the prevalence rate is comparable to developed countries (7.7%) (3). Nearly half (48.1%) of deaths due to CHD occur during infancy (4).

Significant technologic advances have improved outcomes in neonatal cardiac surgery over the past three decades. However, outcomes might be different in developing countries because of the infrastructure limitations (5). Many factors such as late presentation of cases, associated co-morbid conditions, understaffing of units and limited resources contribute to suboptimal outcome in neonates with CHD who undergo cardiac intervention (6).

With advance in preoperative, surgical, and postoperative care, cardiac interventions for critical CHD have been more performed on infants to restore normal hemodynamic stability during this period. However, these interventions may result in many complications even mortality (7,8).

In this study, it was aimed to present our preliminary results of neonatal cardiovascular interventions and to discuss the risk factors that affect mortality.

MATERIAL and METHODS

We analyzed data from 105 patients with critical CHD, less than 45 days, underwent cardiovascular intervention at a tertiary neonatal intensive care unit (NICU) of a reference hospital between September 2010 and January 2012. In our NICU, the patients with CHD have been followed-up in consultation of pediatric cardiologists and cardiovascular surgeons. Most of our patients are referred to us from other hospitals, although around a quarter are inborn. Sometimes cardiovascular interventions may be performed on beyond one month of age because of wrong/late diagnosis of CHD in another center, delayed transfer of the patients, understaffing of the departments, and clinical condition of the patients.

Critical CHD is defined as a CHD requiring surgical or transcatheter cardiac intervention (9). Patent ductus arteriosus ligation and pacemaker placement were excluded. Data were obtained from the computerized patient record system of the hospital.

Demographic data of each patient (gestational age, birthweight, gender, age at diagnosis, echocardiography assessment, the presence of heterotaxy syndrome and chromosomal abnormality) were noted. The clinical findings before surgical or transcatheter cardiac intervention (the need for mechanical ventilation, inotropic support, and presence of pulmonary hypertension, arrhythmia, sepsis, kidney and liver dysfunction) were also receorded. Age at intervention, type of intervention (surgical or transcatheter), and intervention risk score according to Risk Adjustment in Congenital Heart Surgery (RACHS-1) classification were evaluated. RACHS-1 is a validated risk adjustment method that groups cardiac surgical procedures with similar expected in-hospital mortality rates into six predefined risk categories, in which category 1 has the lowest risk for death (e.g., secundum atrial defect closure), and category 6 has the highest risk for death (e.g., stage 1 Norwood surgery) (10). The primary outcome variable was in-hospital mortality for patients undergoing surgical or transcatheter cardiac intervention. Complications after surgical or transcatheter cardiac intervention were evaluated as secondary outcome.

Informed consent has been obtained from the parents of the patients both prior to hospitalization and before any interventions in our unit. This was not an experimental study and approved by Ethics Review Committee.

Data were recorded by using SPSS 15.0 (Chicago, IL, USA). Descriptive analyses were performed. Mean (SD) or Median (IQR) values were given according to distribution of the data. Differences among the groups were tested using Student's t test or Mann Whitney U test, as appropriate. Chi-square test was used for categorical data. Multivariate analysis was used to define the factors associated with higher mortality risk in infants underwent cardiac intervention. Gestational age, age at diagnosis of CHD, the need of mechanical ventilation, the presence of sepsis at pre-interventional period, age at intervention, the type of intervention, RACHS-1 score, and development of low cardiac output at post interventional period were assigned as independent variables. The level of significance was set at 0.05 in all comparisons.

RESULTS

During the study period, a total of 105 patients underwent surgical or transcatheter cardiac intervention. Most were out-born and transferred from another health service. The demographical and clinical characteristics of the subjects are summarized in Table I.

The most common diagnoses were coarctation of aorta (AoC), pulmonary atresia (PA) and transposition of great arteries (TGA). Types of the CHDs are shown in Table II.

Congenital heart pathologies were associated with situs anomalies in 15 patients. These were right atrial isomerism (n=12), left atrial isomerism (n=1), and situs inversus totalis (n=2). Eight cases had major genetic disorders including Trisomy 21 (n=4), Trisomy 18 (n=2), and Di George syndrome (n=2).

Prostaglandin E1 (PGE1) was needed in 79 cases (75.2%) at pre-interventional period. The mean age at surgical or transcatheter cardiac intervention was 15.2±11.8 days. The most common reasons of delay for surgical or transcatheter cardiac interventions were the presence of sepsis on admission, delayed transportation of the patients, and inadequate staffing.

Transcatheter interventions were performed in 29 patients (27.6%); none of them needed surgery. Seventy-six patients (72.4%) underwent cardiovascular surgery. The most common surgeries were modified Blalock Taussig shunt (mod B-T shunt), coarctation repair, and pulmonary banding (Table III).

The most common complications observed at post-interventional period were listed in Table IV. The rates of low cardiac output, pneumonia, and sepsis were significantly higher among patients underwent surgery. Length of NICU stay was longer among them [surgery: 30 (18-38.5) days vs. transcatheter: 15 (12-18.5) days, p=0.001].

Table I: The demographical and clinical characteristics of the study patients.

Patient Characteristics	n=105
Prenatal diagnosis of CHD. n (%)	7 (6.6)
Out-born patients, n (%)	90 (85.7)
Gestational age (weeks), mean ± SD	38.8±2.0
Prematurity (<37 weeks of gestational age)	15 (14.2)
Birth weight (g), mean ± SD	3002±571
Male sex, n (%)	65 (61.9)
Age at diagnosis of CHD (d), median (IQR)	4 (2-11)
UyuClinical variables at pre-interventional period	
Need of mechanical ventilation, n (%)	25 (23.8)
Need of inotropic support, n (%)	14 (13.3)
Pulmonary hypertension, n (%)	41 (39)
Arrhythmias, n (%)	13 (12.4)
Renal failure, n (%)	5 (4.7)
Peritoneal dialysis	3 (2.8)
Clinical/proven sepsis, n (%)	12 (11.4)
Liver dysfunction, n (%)	13 (12.4)
Associated disorders	
Situs anomalies	15 (14.2)
Major genetic disorders	7 (6.6)
Length of hospital stay (days), median (IQR)	21(15-34.5)
Mortality, n (%)	37 (35.2)

*****Congenital heart disease*

Table II: The types of congenital heart diseases in study patients.

	n=105	%
Left heart obstruction		
Coarctation of aorta	35	33,3
Aortic interruption	5	4,7
Aortic valve stenosis	4	3,8
Hypoplastic left heart syndrome	3	2,8
Mitral valve atresia	1	0,9
Left ventricle hypoplasia	1	0,9
Right heart obstruction		
Pulmonary atresia	19	18
Critical pulmonary stenosis	9	8,5
Fallot type pulmoner atresia	4	3,8
Tricuspid atresia	4	3,8
Mixing pathology		
Transposition of great arteries	14	13,3
Truncus arteriosus	4	3,9
Double outlet right ventricle	1	0,9
Other		
Ventricular septal defect	1	0,9

Table III: The types of cardiac interventions and intervention-specific hospital mortality for the study patients.

Type of intervention	Study patients (n=105)	Mortality (n=37)
Transcatheter intervention (n=29), %		
Balloon dilatation of coarctation of aorta	9 (8.5)	3 (8.1)
Atrial septostomy	7 (6.6)	0 (0)
Balloon dilatation of aortic valve	4 (3.8)	0 (0)
Balloon dilatation of pulmonary valve	4 (3.8)	0 (0)
Cardiovascular surgery (n=76), %		
Modified Blalock-Taussig shunt	29 (27.6)	10 (27)
Coarctation repair + pulmonary banding	16 (15.2)	8 (21.6)
Coarctation repair	10 (9.5)	2 (5.4)
Arterial switch	6 (5.7)	3 (8.1)
Norwood surgery-Stage 1	3 (2.8)	3 (8.1)
Aortic interruption repair	4 (3.8)	3 (8.1)
Repair of truncus arteriosus	4 (3.8)	4 (10.8)
Pulmonary banding	4 (3.8)	1 (2.7)

Table IV: Complications observed at post-interventional period.

Complication	Catheterization n=29 (%)	Cardiovascular surgery n=76 (%)	P value
Low cardiac output syndrome	2 (6.9)	20 (26.3)	0.03
Pneumonia/ventilator associated pneumonia	2 (6.9)	25 (32.9)	0.01
Clinical/proven sepsis	1 (3.4)	17 (22.4)	0.02
Renal failure	4 (13.7)	12 (15.8)	0.68
Peritoneal dialysis	1 (3.4)	6 (7.9)	0.70
Liver dysfunction	3 (10.3)	14 (18.4)	0.47
Thrombosis	5 (17.2)	10 (13.2)	0.75
Intracranial hemorrhage (>grade 2)	0 (0)	8 (10.5)	0.06
Heart failure	1 (3.4)	12 (15.8)	0.10
Arrythmias	0 (0)	5 (6.6)	0.31

Overall mortality rate was 35.2% (n=37). Intervention specific hospital mortality rates are listed in Table III. Mortality was significantly lower in infants treated with transcatheter intervention (Table V). Three of 29 patients (10.3%) who underwent balloon dilatation of AoC died. One of them was a 32 weeks of gestational age premature baby with AoC along with isthmus hypoplasia, left ventricular dysfunction and partial pulmonary venous connection abnormality. Other two patients were term newborns with AoC, severe isthmus hypoplasia and pulmonary hypertension. Twenty four of them (64.8%) died due to acute postoperative complications such as low cardiac output syndrome (n=20) and sudden cardiac arrest (n=4) within the first 48 hours of the surgical intervention. At follow-up, heart failure (n=5), respiratory insufficiency (n=4), and sepsis (n=4) were the causes of mortality.

Univariate analyses showed that there were significant differences between the survivors and nonsurvivors according to gestational age, prematurity, the presence of associated disorder, pre-interventional need of mechanical ventilator, use inotropic support, presence of pulmonary hypertension and sepsis, undergoing cardiovascular surgery, age at intervention, and RACHS-1 score.

Multivariate analysis was used to define the risk factors associated with mortality. It was found that higher RACHS-1 score was associated with mortality (OR: 4.5, 95% CI (1.5-13.1), p=0.005). Higher gestational age was a preventive factor for it (OR: 0.6, 95% CI (0.5-0.9), p = 0.01).

DISCUSSION

In this article, we report the early outcomes of cardiac interventions in a cohort of 105 consecutive neonates with critical CHD. The infrastructure limitations that exist in our NICU are typical of centers performing neonatal cardiac interventions in the developing world.

Delay in performing intervention puts the CHD infants at a greater risk for infections and organ dysfunction (11). Finally, these infants are more likely to develop problems, in addition to their cardiac diseases. In our study, post-interventional complications and mortality were evaluated as outcomes. The rates of pre and post-interventional problems were higher among nonsurvivors. Probably, pre-interventional problems caused to delay for intervention in these infants.

It was reported that transcatheter intervention had mortality rate less than 1% in experienced institutions. It could be as high 3.7- 7.7% and associated cardiac pathologies might increase mortality (12,13). Ergul et al. (14) showed that isthmus hypoplasia and pulmonary hypertension were risk factors for AoC dilatation during neonatal period. The newborns, especially premature babies, undergoing balloon dilatation of AoC were at high risk for mortality (15). Our study showed that the number of complications were lower in infants who underwent transcatheter intervention. As expected NICU stay was also shorter among them and a similar trend was hence obtained in mortality.

Some recent research demonstrated both improved survival and reduced morbidity in prenatally diagnosed infants presenting to cardiac intensive care units compared to those with a postnatal diagnosis (16,17). However, Lim et al. (18) reported that prenatal diagnosis did not affect overall survival despite facilitated care in patients with isomerism. In our study, of 105 patients, only seven had prenatal diagnosis. Mortality rate was not lower in these patients compared to others without prenatal diagnosis. However, it is fact that prenatal diagnosis can be useful for better management of CHD patients.

It is well known that preterm delivery is associated with adverse outcomes. Pappas et al. (19) assessed the mortality, morbidity, and early childhood outcomes of <1000g infants with isolated CHD compared with infants with no congenital defects. The authors showed that adjusted risks of other short-term neonatal morbidities associated with prematurity were not significantly

different. Risk of death or neurodevelopmental impairment (NDI) was greater for <1000g infants with CHD. Cheng et al. (17) showed that delivery at 37 to 38 completed weeks of gestation was associated with more than twofold greater adjusted odds of patient hospital mortality and significantly greater morbidity compared with delivery at 39 to 40 completed weeks among neonates with CHD. Similarly, Costello et al. (20) reported that gestational age lower than 39 week is associated with mortality. In the current study, higher gestational age was a preventive factor for mortality.

Magliola et al. (9) reported a mortality rate of 19% in neonatal cardiac surgery from Argentina in 5 year period. We found a high mortality rate in cardiac interventions (35.2%). However,

Table V: Clinical characteristics of the patients related to the mortality.

Variables	Nonsurvivors Nonsurvivors n=37. (%)	Survivors	P value n=68. (%)
Prenatal diagnosis of CHD, n (%)	2 (5.4)	5 (7.4)	0.7
Gestational age (wk), mean ±SD	37.8±2.2	39.8±1.8	0.006
Prematurity, n (%)	9 (24.3)	6 (8.8)	0.03
Birth weight (g), mean ±SD	2930±609	3041±550	0.3
Male sex, n (%)	23 (62.1)	42 (61.7)	0.4
Age at diagnosis of CHD, median (IQR)	5 (2-13)	3 (2-11)	0.11
Clinical variables at pre-interventional period, n (%)			
Need of mechanical ventilation	14 (37.8)	11 (16.2)	0.01
Need of inotropic support	9 (27.3)	5 (9.3)	0.02
Pulmonary hypertension	21 (56.8)	20 (29.4)	0.006
Arrythmias	1 (2.7)	1 (1.5)	1.0
Renal failure	7 (18.9)	6 (8.8)	0.1
Clinical/proven sepsis		4 (5.9)	0.01
Liver dysfunction	7 (18.9)	6 (8.8)	0.1
Complications at post-interventional period, n (%)			
Low cardiac output syndrome	16 (43.2)	6 (8.8)	0.001
Pneumonia	8 (21.6)	19 (27.9)	0.63
Clinical/proven sepsis	8 (21.6)	10 (14.7)	0.53
Renal failure	9 (24.3)	6 (8.8)	0.06
Liver dysfunction	10 (27)	7 (10.3)	0.05
Thrombosis	8 (21.6)	7 (10.3)	0.19
Intracranial hemorrhage (>grade 2)	3 (8.1)	5 (7.4)	1.0
Heart failure	11 (29.7)	2 (2.9)	0,001
Arrythmias	2 (5.4)	3 (4.4)	1.0
Associated disorders			
Situs anomalie, n (%)	10 (27)	5 (7.4)	0.006
Chromosomal abnormality, n (%)	5 (13.5)	2 (2.9)	0.03
Age at intervention (days), median (IQR)	15 (10-28)	11 (11-19)	0.001
The type of intervention			
Catheterization	3 (8.1)	26 (38.2)	
Cardiovascular surgery	34 (91.8)	42 (61.7)	0.003
RACHS-1 category			
1-2	5 (13.5)	34 (50)	0.0001
3	13 (35.1)	26 (38.2)	
4	16 (43.2)	8 (11.7)	
5-6	3 (8.1)	0	
Length of neonatal intensive care unit stay (d), median (IQR)	18 (11.5-35.5)	25.5 (17-34.2)	0.09

in Magliola et al.'s study (9), experience in cardiac surgery and advanced care (e.g., extracorporeal membrane oxygenation use) should be noticed. In another study from a developing country, Bakshi et al. (21) reported their mortality for all neonatal corrective and palliative cardiac surgical procedures as 8.8%. In our study, mortality was particularly striking for corrective operations and this rate was higher than that of reported from the Bakshi et al.'s study. We should note that the authors excluded the patients with highly complex lesions, such as hypoplastic left heart syndrome and severe Ebstein anomaly. Excluding them will be expected to improve the outcomes reported in their study, as they also emphasized. Management of CHD with appropriate surgeries at proper time in developing countries is still a major challenge.

In a study from a developed country, evaluating 174 infants undergoing cardiac intervention, the authors reported that independent risk factors for mortality were a 5 min Apgar score ≤ 7, need for pre-intervention mechanical ventilation, and RASCH-1 category ≥ 4 or not assignable (17). Bakshi et al. (21) stated that the earlier period of surgical intervention, age of less than 7 days, need for preoperative antibiotics, and requirement of exchange transfusion for postoperative sepsis were predictors of mortality. According to our results, univariate analyses showed that there were significant differences between the survivors and nonsurvivors for gestational age, the presence of associated disorder, pre-interventional need of mechanical ventilator and inotropic support, presence of pulmonary hypertension and sepsis, undergoing cardiovascular surgery, RACHS-1 score and post-interventional low cardiac output syndrome and heart failure. However, in multivariate analysis only higher RACHS-1 score was shown to be associated with mortality while higher gestational age was a preventive factor.

It has been reported that situs anomalies with complex cardiac defects and the presence of immunologic dysfunction increases the risk for mortality (18,22). We also observed that the rate of situs anomalies and chromosomal abnormality associated to CHD was higher among nonsurvivors. Major extra cardiac anomalies accompanied with chromosomal anomalies can explain higher mortality rate in this group.

The most reported other predictors of mortality in CHD patients are infectious complications (21). Although the rate of pre-interventional sepsis was higher among nonsurvivors, post-interventional sepsis rate did not differ between survivor and nonsurvivors.

There are some limitations resulting from the retrospective nature of our study. Furthermore, it is a single center based study, so a lot has to be taken into consideration before the results can be generalized. Another important limitation is the inclusion of all interventions such as interventional catheterization procedures; including these would be expected to improve the outcomes.

Our study indicates that currently our unit has a high mortality rate compared to other NICUs of different countries. The results of this study are of particular relevance to NICU staff planning to co-work with pediatric cardiovascular surgery on the road of being a newborn CHD center. Few published reports on the outcomes of NICU-CHD surgery are available from the developing world (6,21,23,24). Improvement in outcomes with growing experience has been reported by other centers and is associated with the initial learning curve of new programs (25). Because of infrastructure limitations and some logistic problems, there are many challenges to establishing and maintaining a NICU-CHD surgery program in these countries.

Neonatal mortality in Turkey has declined substantially over the past 10 years, 26/1000 in 1998 and 10/1000 in 2009 (26). This indicates that maternal and neonatal health interventions have played a major role in decreasing neonatal mortality rate in our country. As neonatal and infant mortality from readily preventable conditions decrease, CHDs are likely to require increasing attention.

Currently, in Turkey, a total of 23 centers (6 public, 4 private and 13 university hospitals) deal with pediatric cardiovascular surgery. However, neonatal cardiovascular surgery could be performed only in one third of them (27,28). On the other hand, there are geographic and socio-economic inequalities among people living in our country. Therefore, transportation of the CHD patients from a rural area to the cardiovascular surgery center can be problematic. In recent years, Ministry of Health of Turkey has taken important steps in increasing the number of the cardiovascular surgery centers and improving patient transport. However, there is still need to new well equipped cardiovascular surgery centers experienced in the management of neonatal CHD patients.

The common problems of the developing countries are inexperienced cardiac team, inadequate staffing, limited infrastructure and resources. These problems can only be solved by determined health policies and increased experience of the centers.

CONCLUSIONS

In this study, we reported our local data for the first year experience in neonatal cardiovascular surgical or transcatheter intervention and compared the results with other institutions. With increasing experience, neonatal cardiac surgery may be performed with better outcomes in developing countries that have limited infrastructure and resources.

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