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Original Article

Interventional cardiac catheterization in neonates and premature infants with congenital heart disease: a single center experience

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ABSTRACT

Background. The increased survival of patients with congenital heart disease over the last three decades has been associated with improvements in diagnosis and treatment. This study aimed to evaluate therapeutic interventional catheterization, outcomes and complications of these procedures in neonates and premature infants.

Methods. In this study, therapeutic catheterization procedures performed on neonates and premature infants with congenital heart disease at a university hospital between February 2000 and October 2019 were retrospectively evaluated.

Results. A total of 322 procedures were performed on 279 neonates and 26 premature infants. Of the patients, 217 (67.4%) were male. The median age of the patients was 8 days (interquartile range [IQR] 2-20) and the median body weight was 3050 g (IQR 2900-3600). The most common procedures were balloon atrial septostomy, balloon aortic angioplasty, balloon pulmonary valvuloplasty and balloon aortic valvuloplasty (35.4%, 20.8%, 18.3% and 12.4% respectively). The most common diagnoses were transposition of the great arteries, coarctation of the aorta, pulmonary stenosis and aortic stenosis (26.7%, 19.3%, 15.2% and 11.5% respectively). Most procedures, 274 (85.1%), were successful. Complications were observed in 74 procedures (23%). Of these complications, 45 (14%) were minor and 29 (9%) were major. The most common complication was transient dysrhythmia (6.9%). There was no significant relationship between body weight, age and the rate of complications. However, longer procedure time and fluoroscopy time were associated with higher complication rates ($p<0.05$). Four procedure-related deaths were observed.

Conclusion. Procedure-related complications are higher in the neonatal period. Although the complication rate varies according to the type of procedure, longer fluoroscopy time and procedure duration are associated with an increased complication rate. Procedures performed with the right indications, appropriate equipment and by experienced teams will play a key role in reducing complication rates.

Key words: children, congenital heart disease, interventional cardiology, complications.

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Severe types of congenital heart disease (CHD) affect 2.5-3.0 per 1000 live births, with 25% of neonatal deaths attributable to severe congenital heart malformations.[1,2] Over the last 30 years, the progress made in the early diagnosis and treatment of CHD has resulted in noticeable improvements in patient survival rates.[3] Cardiac catheterization and angiocardiography have several uses in the preoperative assessment of cardiac diseases. These include determining the anatomy, assessing the presence and size of the shunt, measuring pulmonary vascular resistance, evaluating the response to vasodilator agents and oxygen, conducting postoperative follow-up of congenital cardiac diseases, performing a myocardial biopsy, conducting electrophysiological studies, transcatheter ablation and interventional cardiological treatment applications.[4] Transcatheter treatment methods offer various advantages, including shorter hospitalization duration, no requirement for thoracotomy, reduced need for blood transfusion and general anesthesia, facilitating surgical techniques for complex cardiac anomalies and enabling treatment without a second thoracotomy in postoperative residual anomalies. This study aims to retrospectively evaluate therapeutic interventional cardiologic procedures, their results and complications, carried out on neonates and premature infants and compare the findings with the literature.

Materials and Methods

Among the 10,374 diagnostic or interventional cardiac catheterizations carried out at the Pediatric Cardiology Department's cardiac catheterization laboratory at Hacettepe University hospital between 2000 and 2019 on neonates and preterm infants were included in the study. Age, gender, body weight, diagnosis, echocardiography findings, postoperative follow-up, details of operative complications and management of complications were extracted from the cardiac catheterization laboratory's medical records and patient files.

Complications that arise during the catheterization and angiography or within 24 hours after the procedure are defined as procedure-related complications. Major complications were defined as life-threatening events including death, permanent rhythm abnormalities, bleeding requiring transfusion, respiratory arrest and cardiac perforation. Minor complications included non-life-threatening events such as transient circulatory and rhythm disturbances, bleeding from the surgical site not requiring transfusion, seizures, balloon rupture, etc. Mortality was categorized as either cardiac (procedural or post-procedural) or extra-cardiac (due to other causes, even if potentially aggravated by the cardiac procedure). Mortality resulting from electively planned surgery following a palliative percutaneous procedure was excluded, whereas deaths arising from the surgical rescue of complications or unsuccessful transcatheter intervention were considered procedure-related.[4,5]

Success criteria for procedures

Balloon atrial septostomy (BAS) or atrial septoplasty operations can result in improved arterial oxygen saturation, decreased pressure differences between the atria and an increase in the detectable diameter of the defect or flow with echocardiography.

Valvular pulmonary stenosis (PS): decrease in left ventricular/right ventricular systolic pressure ratio, increase in flow through the valve, or decrease in the need for prostaglandin E1 infusion.[6,7]

Valvular aortic stenosis (AS): 40% or more decrease in peak systolic pressure gradient, lower than 50 mmHg a residual peak gradient in patients with normal cardiac flow rate, decrease in left ventricular end-diastolic pressure, increase in output flow from the valve, increase in oxygen saturation in the lower extremities and decrease in the need for prostaglandin E1 or inotropic support.[8-10]

Coarctation of the aorta (CoA): a systolic gradient of 20 mmHg or less, a higher than 50% increase in the diameter of the coarcted segment or interruption of prostaglandin E1 infusion.[11-13]

Procedures that did not meet the above criteria were considered unsuccessful, while procedures that partially met the criteria were considered partially successful.

IBM SPSS Statistics 23.0 (SPSS Inc., Chicago, IL, USA) was used for statistical evaluation. Frequency distributions were expressed as numbers and percentages and continuous variables (measurements) were evaluated as median (interquartile range [IQR]). The Shapiro-Wilk test was used to determine whether the data were normally distributed. For statistical evaluation, the independent samples t-test was used to compare paired groups for normally distributed data and the Mann-Whitney U test for non-normally distributed data. This study was approved by the Ethics Committee of Hacettepe University dated decision number LUT 12/42-28.

Results

A review of 10,374 cardiac catheterization procedures was conducted, of which 322 (6.4%) were performed for the treatment and diagnosis of 279 neonates and 26 preterm infants (Table I). Recurrent procedures were performed during the neonatal period; 13 patients (4.2%) underwent catheterization twice and 2 patients (0.7%) three times. Of all patients, 217 (67.4%) were male and 88 (27.3%) were female. The patients' median age was 8 days (IQR 2-20 days), with a median body weight of 3050 g (IQR 2900-3600 g).

BAS was the most frequently performed procedure, accounting for 35.4% (Table I). Transposition of the great arteries (TGA) was the most common diagnosis, followed by CoA, PS and AS (26.7%, 19.3%, 15.2% and 11.5%, respectively) (Table II). CoA was accompanied by AS in 5 patients and isthmus hypoplasia in 9 patients. The procedure lasted for a median of 60 minutes (6-90 minutes) and the median fluoroscopy duration was 12 minutes (7.2-21 minutes). The success rate was 85.1% (274 procedures), while 6.8% (22 procedures) were unsuccessful and 8.1% (26 procedures) were partially successful.

Interventional procedures

One hundred and fourteen BAS procedures were carried out. Two patients received BAS twice, one patient received concurrent aortic

Table I. List of procedures.

Procedure	N:322	%
Balloon atrial septostomy	114	35.5
Balloon aortic angioplasty	67	20.8
Balloon pulmonary valvuloplasty	59	18.3
Balloon aortic valvuloplasty	40	12.5
Ductal stenting	20	6.2
Perforation of pulmonary valve, pulmonary valvuloplasty	12	3.7
Stenting of the right ventricular outflow tract and pulmonary artery	4	1.2
Fistula closure	3	0.9
Closure of major aortopulmonary collateral artery	2	0.6
Balloon pulmonary angioplasty	1	0.3

Table II. List of procedures.

Diagnosis	N:305	%
Transposition of the great arteries	86	28.2
Coarctation of aorta	62	20.3
Pulmonary stenosis	49	16.1
Aortic stenosis	37	12.1
Pulmonary atresia with intact ventricular septum	15	4.9
Hypoplastic left heart syndrome	12	3.9
Pulmonary atresia	10	3.3
Tricuspid atresia	8	2.6
Double outlet right ventricle	6	2.0
Tetralogy of Fallot	6	2.0
Functional single ventricle	5	1.6
Other (coronary artery fistula, pulmonary arteriovenous fistula, interrupted aortic arch, aortic stenosis with coarctation of aorta)	9	3.0

balloon angioplasty and two patients received concurrent stent implantation of PDA with BAS. TGA was the most common diagnosis among patients who underwent BAS, accounting for 86 (76.7%) cases. Other diagnoses comprised hypoplastic left heart syndrome in eight patients (7.2%), tricuspid atresia (TA) in six patients (5.4%), double outlet right ventricle with a restrictive ventricular septal defect (VSD) in six patients (5.4%), pulmonary atresia with an intact ventricular septum in two patients (1.8%), aortic interruption in two patients (1.8%) and single functional ventricle in two patients (1.8%). Out of a total of 114 procedures, 99 (86.8%) were considered successful and 31 (27.2%) were accompanied by complications (Table III).

Sixty-seven aortic angioplasty procedures were performed and three of these were combined with aortic valvuloplasty procedures. Of the remaining 58 procedures (86.6%), the outcomes were successful, while three procedures (4.5%) were unsuccessful due to aortic hypoplasia. Fourteen (20.9%) procedures had complications (Table III). No aneurysms were present at the coarctation site after the procedures. Recoarctation occurred in 34 patients (50.7%), with recurrent angioplasty being performed in seven patients (10.4%). 27 patients (40.3%) survived without requiring surgery.

Fifty-nine procedures for pulmonary valvuloplasty were conducted, with a success rate of 91.5% (n=54) and partial success in four procedures (6.8%). Only one procedure was considered unsuccessful (1.7%), but ten patients (16.9%) had complications (Table III). Of the procedures, 54 (91.5%) were successful, four procedures (6.8%) were partially successful and one procedure (1.7%) was unsuccessful. Subsequently, eight patients needed further balloon valvuloplasty and five patients had surgery for stenosis (giving a total restenosis rate of 23.5%).

Of the 40 procedures carried out for AS using balloon aortic valvuloplasty, 29 (72.5%) were considered successful, one (5%) was

Table III. Distribution of the procedures according to age, body weight, duration of the procedure, duration of fluoroscopy, complications and success rate.

	Balloon atrial septostomy N:114	Balloon aortic angioplasty N:67	Balloon pulmonary valvuloplasty N:59	Balloon aortic valvuloplasty N:40	Stent implantation of patent ductus arteriosus N:20	Perforation of the atretic pulmonary valve and Balloon pulmonary valvuloplasty N:12	p
Age (day)	11.09 (12.46)	15.28(10.76)	14.83 (13.55)	12.60 (12.09)	8.40 (8.98)	2.17 (0.94)*	0.002
Body weight (g)	3188 (581.70)	3352 (637.60)	3119 (838.90)	3249 (755.30)	3045 (537.50)	3042 (264.40)	0.269
Procedure duration (min)	72.36 (30.07)	67.12 (30.15)	74.15 (28.86)	79.25 (31.49)	101.50 (43.71)**	131.25 (59.01)**	<0.001
Fluoroscopy duration (min)	15.48 (12.52)	11.01 (11.74)	16.07 (8.87)	16.52 (12.07)	21.26 (13.50)	38.97 (18.07)	<0.001
Complication	31 (27.20)	14 (20.90)	10 (16.90)	10 (25.00)	3 (15.00)	5 (41.70)	0.260
Success	99 (86.80)	58 (86.60)	54 (91.50)	29 (72.50)	17 (85.00)	8 (66.70)+	0.008

Complications and success are given as n (%) and other variables are given as mean (standard deviation).
*: The statistically significant difference is due to the low mean age of neonates in the marked procedure.
**: The statistically significant difference is due to longer mean fluoroscopy times in marked procedures.
+: The statistically significant difference is due to lower success rate in marked.

unsuccessful and the rest were considered partially successful. In three cases, AS was accompanied by aortic coarctation. However, complications were observed in 10 patients (%25) (Table III) and 11 patients required surgery during follow-up.

Twelve of the fifteen patients with an intact ventricular septum and pulmonary atresia (IVS-PA) underwent pulmonary valvular perforation and balloon pulmonary valvuloplasty, one patient also underwent concomitant pulmonary angioplasty and two patients underwent concomitant stent implantation in the PDA. Eight procedures (66.7%) were successful and four were unsuccessful (33.3%). While three of the unsuccessful procedures were due to technical reasons and the inability to maintain the proper position of the catheter, one procedure was due to right ventricular outflow tract (RVOT) perforation. Complications developed in 5 patients (41.7%). While minor complications were observed in two patients (transient circulatory disorders of the extremity and transient dysrhythmia), major complications were observed in three patients. Bleeding occurred at the intervention site in two patients. The procedures requiring pulmonary valve perforation and balloon pulmonary valvuloplasty had the highest rates of unsuccessful operations, longest operation and fluoroscopy time, and lowest age ($p<0.05$) (Table III).

Complications

Complications were observed in 74 (23%) procedures. Of these, 45 (14%) were minor complications and 29 (9%) were major complications (Table IV). The most common complication was transient arrhythmia (6.9%), mostly transient bradycardia (Table IV). Dysrhythmia was the most common complication in BAS (59%). A transient circulatory disturbance was seen in 11 patients and improved with elevation and warming of the extremity. Heparin infusion therapy was initiated in 5 patients due to the detection of a thrombus in the vascular access site (one femoral arterial and four femoral venous thrombi). All thrombi were resolved with medical therapy. Packed red cell transfusion was required in 6.5% of neonates due to bleeding from the access site during or after the procedure. Dissection of the aortic arch was observed in one patient with hypoplastic left heart syndrome after BAS and ductal stenting. There were no problems in the follow-up of the patient, who had no hemodynamic instability.

One patient had respiratory arrest, requiring short-term positive pressure ventilation without intubation. A 22-day-old neonate with a double outlet right ventricle developed pulseless ventricular fibrillation when the catheter entered the left ventricle during the procedure and responded to defibrillation. The procedure was considered unsuccessful and the patient was taken for emergency surgery. The patient who developed postoperative hemodynamic

Table IV. List of complications during the procedures.

Complications	N:248	%
Minor	45	14.0
Transient dysrhythmia	22	6.9
Bradycardia	8	2.5
Complete atrioventricular block	6	1.9
Atrial flutter	5	1.6
Atrial fibrillation	2	0.6
Tachycardia	1	0.3
Transient circulatory disorders of extremity/extremities in the intervention site	11	3.4
Thrombus	5	1.6
Balloon rupture	4	1.2
Apnea	2	0.6
Convulsion	1	0.3
Major	29	9.0
Bleeding in the insertion site	21	6.5
Vascular injury	3	0.9
Respiratory arrest during the procedure	2	0.6
Massive pulmonary hemorrhage	1	0.3
Perforation of right ventricular outflow tract	1	0.3
Ventricular fibrillation	1	0.3

instability died of cardiac arrest four days after the procedure. A total of 4 procedure-associated mortalities were noted. There was a case of massive pulmonary hemorrhage after ductal stenting in a patient with tricuspid atresia, who died due to cardiopulmonary arrest 48 hours later. A patient with TGA, who underwent BAS, had respiratory arrest in the catheterization room after the successful termination of the procedure and did not respond to resuscitation. There was massive pulmonary hemorrhage after ductal stenting in a patient with tricuspid atresia, who died due to cardiopulmonary arrest 48 hours later. One patient suffered from RVOT perforation during a pulmonary valve perforation and underwent RVOT repair, but died post-operatively. Another patient with hypoplastic left heart syndrome suffered from femoral vein dissection following ductal stenting. Following anticoagulant therapy, the patient's thrombosed femoral vein resolved completely. A neonate weighing 1200 g with IVS-PA experienced femoral vein avulsion during the removal of the 4 Fr sheath after a successful procedure. The patient was sent for surgical repair but suffered cardiac arrest during the operation and did not respond to cardiopulmonary resuscitation.

There was no statistically significant relationship found between body weight, age and complication rate ($p>0.05$). Nevertheless, higher complication rates were associated with longer procedure times and greater fluoroscopy durations (p values 0.029, <0.001, respectively).

Prognosis

Nineteen post-procedural mortalities due to cardiac and respiratory problems occurred within one week of follow-up. Of the patients, 71 (23.3%) died during follow-up (extracardiac mortality), 118 patients (36.6%) were lost to follow-up, and 129 patients (40.1%) continued follow-up. Of the patients who were followed, 74 (57,4%) continued their lives without the need for surgery. In patients requiring surgery, the median follow-up time until the procedure was 62 days (IQR 7-158 days) for the whole patient group, 65 (IQR 36-112) days for aortic angioplasty, 9 (IQR 3-184) days for BAS, 122 (IQR 12-1167) days for balloon aortic valvuloplasty and 401 (IQR 42-708) days for balloon pulmonary valvuloplasty.

Discussion

In this study, interventional cardiac catheterizations for neonates and premature infants were evaluated in a tertiary referral hospital. In recent years, transcatheter interventions for CHD have gained popularity with improvements in technology, devices and pre- and post-intervention care in intensive care units. Catheter based therapies offer a good alternative to surgery for both initial palliation and treatment.[1,14] As shown in the present study, it has a wide profile similar to the literature in terms of procedural diversity.[15-17] In the literature, it has been reported that the mean duration of the procedure in interventional cardiac catheterizations is between 115-122 minutes, with a median fluoroscopy time of 22-35 minutes. Lower durations were observed in this study.[17,18]

In the presented study, the most common procedure was BAS, and it was frequently applied to TGA patients. TGA is the most common cyanotic congenital heart defect in neonates, with an estimated incidence of 1 in 3200 live births.[19] Current medical approaches are medical stabilization and correction of acidosis followed by early arterial switch surgery. Preoperative death in neonates with TGA is due to hypoxemia refractory to prostaglandin E initiation, restrictive atrial septum, persistent pulmonary hypertension, prematurity and very low birth weight.[19] Emergency BAS improves oxygenation until definitive surgical treatment. In another study presented by our center, Celiker et al. reported that patients with TGA, TA, and severe mitral stenosis showed improvement in their clinical status and increased oxygen saturation levels following atrial septostomy. Atrial septostomy is a life-saving and effective intervention.[20]

Although the complication rate in this study was 27.5% and the most common complication was transient arrhythmia, the complication rate for BAS was reported as 47% (the most common complication was a thrombus in the femoral vein) in the literature.[21]

Coarctation of the aorta comprises 5-8% of all CHD.[22] In recent years, aortic balloon angioplasty has become a method that can be preferred to surgery because of its good outcomes.[23] However, this issue is still controversial because of early recoarctation after balloon dilation in newborns. Restenosis rates in balloon angioplasty range from 5% to 33.7% and are higher in neonates.[22,24,25] Postoperative recoarctation rates are similarly 7-30% and are more common in newborns.[11,26] Galal et al. reported that the rate of recoarctation in neonates was 90%, while recoarctatation was seen less by age, respectively, 62% in 30-90 days, 21% in 3-6 months and 6% in 6-12 months of life.[25] Similar to the literature, the rate of recoarctation was found to be high (50.7%) in this study, as it was a study in which newborns were included.

Similar to the presented study, the immediate success rate of balloon valvuloplasty in neonates varies between 87.5-100%. Technical problems and anatomical problems such as hypoplasia in the right ventricle, tricuspid valve and pulmonary valve may also affect this rate.[27, 28] Due to resistance to dilatation or subvalvular stenosis, surgery is required 5-10% of critical PS in neonates.[27,29,30] Karagöz et al.[15] showed that balloon dilatation was a safe and effective method for pulmonary valvular stenosis in neonates that weigh below 3000 gr, there was no procedure related mortality and only 30% of patients required reintervention at the 8th month of the procedure and 76% of patients did not require surgery during the 10-year follow-up. Loureiro et al.[27] showed that of the 24 neonates who underwent percutaneous balloon valvuloplasty, one died (4.17%), six (29.2%) had complications and reintervention rate was 42.9%. In the presented study, lower complication rates (16.9%) and restenosis (23.5%) were found compareble to the literature.

IVS-PA is a ductus-dependent heart disease. Although it has a high mortality rate without intervention, the percutaneous transcatheter approach, including pulmonary valve perforation (laser-assisted or radiofrequency-assisted) and balloon valvuloplasty, may preclude surgery. However, patients treated with the percutaneous approach have been shown to have a 5-25% procedural failure rate, 5-50% risk of cardiac perforation, 17% procedural mortality, 50% hospital mortality, and 76% risk of requiring surgical intervention.[31] This procedure had the lowest success rate, the highest complication rates and the longest procedure and fluoroscopy duration in the presented study. Although complications were common with this procedure the majority of them were hemorrhages requiring blood transfusion and transient dysrhythmia. We thought that this was related to the younger age of the patients, performing two procedures at the same time, and technical difficulties.

Complications range from resolving spontaneously without treatment to requiring open heart surgery. The risk for complications may be related to the age, weight, clinical status of the patient, the type of underlying disease and procedure (diagnostic or interventional), as well as the cardiologist's skills and experience.[32] Mori et al.[33] reported that the rate of complications was 14.7% in the cardiac catheterization of the pediatric age group and the most common complication was arrhythmias. Mehta et al.[16] revealed that the rate of complications was 7.3% and independent risk factors for complications were male gender and being under 6 months of age. In the presented study, no significant relationship was found between the development of complications and age, gender and body weight but procedure time and fluoroscopy duration were associated with higher complication rates. Sutton et al.[18] found that the complication rate was 57% in infants under 1500 g, and 56% in infants between 2000-3000 g. The most common complication was bleeding requiring a blood transfusion. In our study, the complication rate was 23%. The most common complication was transient dysrhythmia (6.9%) and among these dysrhythmias the most common was bradycardia. The most common major complication was transient bleeding at the insertion site.

This study has some limitations. The study was designed as a retrospective, single-center study. This study did not include long-term longitudinal follow-up data of the patients. Some of the patients were lost to follow-up. Therefore, mortality, restenosis, surgery and prognosis of the whole patient group could only be evaluated in the follow-up patient group. There is a need for prospective studies in which the outcomes of patients are also evaluated.

In conclusion, interventional cardiological procedures in neonates are life-saving and as well as bridging treatment to surgery in order to improve the clinical status of the patient before the operation. Complications related to the procedure are found to be higher in the neonatal period. Although the complication rate varies according to the procedure type, long fluoroscopy time and procedure duration are associated with an increase in the complication rate. Procedures performed with the right indications, appropriate equipment and by experienced teams will play a key role in reducing complication rates. Further prospective studies with a larger series are needed on interventional cardiac catheterization.

Ethical approval

The study was approved by the local ethics committee (no. LUT12, 42-28).

Author contribution

The authors confirm contribution to the paper as follows: study conception and design: UTN, KT, AE, AD, EI and CA; data collection: UTN, AHH and UYA; analysis and interpretation of results: UTN, KT and AHH UTN; draft manuscript preparation: UTN, AHH, KT. All authors reviewed the results and approved the final version of the manuscript.

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Conflict of interest

The authors declare that there is no conflict of interest.

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