

Evaluation of the Outcomes of Cardiac Catheterization in Newborns

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What is known on this subject?

Pediatric cardiac catheterization in newborns is highly risky. Procedures must be performed with caution.

What this study adds?

Cardiac catheterization and angiography procedures can be safely and effectively performed in experienced centers for neonatal cases. The presence of experienced staff and the support of the surgical team during the procedures are crucial in overcoming the complications that may occur during and/or after the procedure.

ABSTRACT

Objective: Cardiac catheterization and angiography can be performed for diagnostic or interventional purposes in patients with congenital heart diseases. This study aimed to evaluate the outcomes of cardiac catheterization in neonates as a newly established unit.

Material and Methods: Records of neonates (under 28 days), who underwent cardiac catheterization and angiography procedures in our clinic between October 2020 and July 2021, were retrospectively reviewed. The demographic data of patients, echocardiographic diagnosis, cardiac catheterization, and angiography indications, and their outcomes were evaluated.

Results: A total of 76 cardiac catheterization and angiography sessions were performed in 66 neonates (34 males and 32 females), and this number constituted 22% of all angiography procedures performed in our hospital during childhood. Patients' median age and weight were 9 days (range, 1-28) and 3.1 kg (range, 1.7-4.3), respectively. Of the sessions, 88% (67/76) were performed for interventional purposes and 12% (9/76) for diagnostic. In 67 interventional angiography sessions, 74 interventional procedures were performed. The most common interventional procedures were patent ductus arteriosus stenting (n=47/74, 64%); balloon atrial septostomy (n=16/74, 22%); and pulmonary balloon valvuloplasty (n=5/74, 7%). Among the diagnostic procedures, 5 were for post-operative patient evaluation, wherein 3 patients were on extracorporeal membrane oxygenation (ECMO) support. The median procedure and fluoroscopy time were 37 min (range, 9-137) and 468 s (range, 66-2490), respectively. No complications were observed in 64/76 procedures (84%). Hence, complications were observed in 12/76 (16%) procedures, whereas major complications were observed in 8 and minor in 4 procedures. Two patients needed ECMO support in the catheterization



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ABSTRACT

laboratory during the procedure. No case died within the first 24 h. One of the two patients, under ECMO, was successfully discharged.

Conclusion: With the advancement in technological amenities, cardiac catheterization procedures, especially interventional procedures, could be performed with low mortality and high success rates in newborns. Diagnostic catheterizations should be performed for highlighting the underlying problems after cardiac surgery, where other diagnostic tools are insufficient.

Keywords: Neonate, cardiac catheterization, angiography, pediatric cardiology

Introduction

Heart diseases may be seen as congenital or acquired causes. Congenital heart diseases (CHDs) are one of the most leading causes of mortality and morbidity in childhood, especially among newborns. CHDs are heterogeneous diseases constituted by various subgroups with an incidence of 1% in all live births. On-time, accurate diagnosis, and appropriate treatment approaches are crucial to increase the survival rates of patients with CHD (1,2). A case-specific approach should be applied in neonates with CHD due to the variation in hemodynamics and clinical findings, depending on the patient's age and nature of the disease.

Physical examination, telerradiography, electrocardiography (ECG), and echocardiography are frequently used in evaluating and diagnosing cardiac diseases in children as initial tests. The specificity and sensitivity of these methods vary. In cases where these tests are insufficient, computed tomography (CT), magnetic resonance angiography (MRA), and cardiac catheterization and angiography can be performed (3).

Cardiac catheterization and angiography procedures in neonates require more attention, caution, and experience due to their characteristics and risk of high complications rates during the procedure. Catheterization procedures can be performed for interventional purposes, such as electrophysiological study and ablation, balloon atrial septostomy, balloon valvuloplasty (aortic or pulmonary), and stent implantation in the ductus arteriosus, and/or diagnostic purposes, such as revelation before/after surgery and evaluation of anatomical shunt presence and size in different interventional and/or complex heart diseases. Recently, echocardiography and other imaging methods have replaced catheter angiography for diagnostic purposes. Cardiac catheterization has been performed only for interventional procedures in most patients, especially for neonates (4,5).

This study aimed to evaluate neonatal cases who underwent cardiac catheterization and angiography in a newly established unit.

Material and Methods

This study was conducted in the pediatric cardiology department of our newly established hospital. Neonates who underwent diagnostic or interventional cardiac catheterization between October 1, 2020, and July 1, 2021, were retrospectively analyzed. Electrophysiological studies and ablation procedures were excluded. Institutional review board approval was obtained from the University of Health Sciences Turkey, Başakşehir Çam and Sakura City Hospital Ethical Committee (2021-09-221).

The detailed history and physical examinations of patients were performed during the hospital stay, as well as ECG, echocardiography, and chest X-ray. Cardiac catheterization decisions were evaluated in the pediatric cardiology and cardiac surgery council. The parents of neonates were informed about the procedure and its complications. A proper written and informed consent was taken from all parents of neonates. Complete blood count, basic biochemistry analysis, and bleeding parameters of patients are evaluated. If required, CT or MRA was performed before the procedure to increase the prediction of the catheterization procedure and reduce the amount of contrast agent and the duration of fluoroscopy.

All procedures are performed in the pediatric cardiac catheterization laboratory, using the Philips Biplane Azurion 7 B12/12 (Philips Medical Systems International B.V., Best, Netherlands) device. All procedures were conducted under general anesthesia (Laryngeal mask or intubation). The femoral vein and/or artery (depending on the procedure type) were used for vascular access. In addition, axillary or carotid artery access was used when necessary. Since the beginning of 2021, all arterial or venous punctures were performed with ultrasound guidance.

The study was planned following the Helsinki Declaration and approved by the local ethical committee. A study form, that includes age, gender, body weight, physical examination findings, and transthoracic echocardiography and angiography findings of each case, was created.

Life-threatening complications were considered as major, and those not life-threatening as minor complications. Death, permanent rhythm problems, bleeding that requires blood transfusion, respiratory arrest, cardiac perforation, stent embolization, and postprocedural extracorporeal membrane oxygenation (ECMO) requirement were major complications. In addition, temporary circulatory and rhythm disturbances, bleeding that does not require a blood transfusion, seizure, balloon rupture, etc., were minor complications. The deaths that occurred within the first 24 h after cardiac catheterization and angiocardiology were considered procedure-related deaths.

Statistical Analysis

In the study, the distribution of variables was classified in the computer, and descriptive results were obtained using Statistical Package for the Social Sciences version 15 (Statistical Package for the Social Sciences for Windows). Descriptive statistics were evaluated as median (range) and percent-percentile.

Results

During the study period, 76 cardiac catheterizations were performed on 66 patients (34 males and 32 females), wherein, 88% (67/76) were performed for interventional purposes, whereas 12% (9/76) for diagnostic. In 67 interventional angiography sessions, 74 interventional procedures were performed. The general characteristic of patients, demographic data, and cardiac catheterization outcomes were summarized in Table 1.

The most common diagnoses were pulmonary atresia in 22/66 (33%) and hypoplastic left heart syndrome (HLHS) in 16/66 (24%). These diagnoses were followed by complete transposition of the great arteries, interrupted aortic arch, and critical pulmonary stenosis. Additionally, five patients

had atrial isomerism and two had dextrocardia. Detailed information about the diagnoses of patients is listed in Table 2.

Four patients had a definitive genetic anomaly that was diagnosed before the procedure, whereas 11 had suspected genetic anomalies.

Sixty-seven (88%) of 76 procedures were interventional and 9 were diagnostic sessions. Patent ductus arteriosus (PDA) stenting was the most common interventional procedure. Forty PDA stenting procedures were performed as a sole procedure and seven were performed in the same session with a different interventional procedure. The second most frequently performed interventional procedure was balloon atrial septostomy. A total of 16 balloon atrial septostomy procedures were performed (10 as a sole procedure and 6 were simultaneously performed with PDA stenting). The interventional procedures are listed in Table 3. In addition, figures related to the procedures given for hybrid PDA stenting for duct-dependent systemic flow are presented in Figure 1, pulmonary balloon valvuloplasty in Figure 2, and PDA stenting for duct-dependent pulmonary flow in Figure 3.

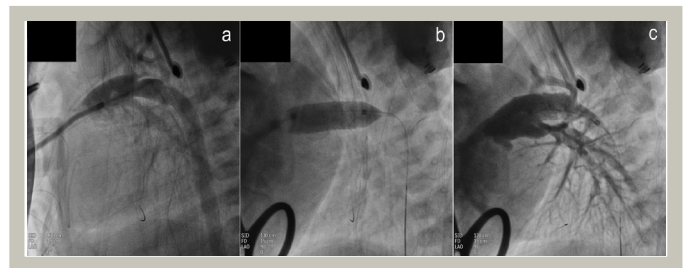


Figure 1. Seven-day-old newborn's cardiac catheterization diagnosed with hypoplastic left heart syndrome (subgroup aortic atresia and mitral hypoplasia). Hybrid patent ductus arteriosus procedure. a) Lateral angiogram showing narrowed ductus, b) stent implantation into the ductus, c) lateral angiogram after stent implantation showing the proper position of the stent and adequate retrograde aortic flow

Table 1. Demographic characteristics of patients and cardiac catheterization information

	Median	Range
Age (days)	9	1-28
Weight (kg)	3.1	1.7-4.3
Height (cm)	49	41-52
Procedure time (minutes)	37.5	9-137
Scopy time (seconds)	468	66-2490
Radiation dose (air kerma, mGy)	59	2.4-450
Radiation dose (DAP, cmGy/cm ²)	3.153	0.3-22.731
Contrast agent (cc)	25	0-40

DAP: Dose area product

Nine of the procedures were diagnostic, wherein five were post-operative patients. Three of the procedures aimed to determine the cause of ECMO requirement after the surgery. These patients were transferred to the catheterization laboratory under ECMO support. The remaining two post-operative patients underwent catheterization to reveal

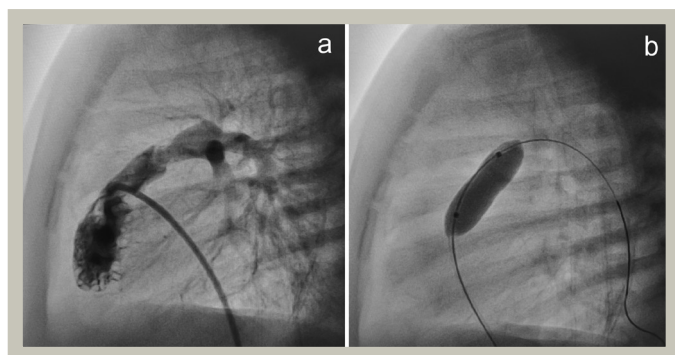


Figure 2. Eleven-day-old newborn's cardiac catheterization diagnosed with valvular pulmonary stenosis. a) Lateral right ventricular angiogram showing pulmonary stenosis, b) lateral angiogram during balloon pulmonary valvuloplasty

Table 2. Diagnoses of patients who underwent cardiac catheterization

	N	%
Pulmonary atresia	22	33.3
PA-VSD	17	-
Tricuspid atresia with PA	3	-
PA-IVS	2	-
HLHS	16	24.2
TGA	7	10.6
IAA	5	7.6
Critical pulmonary stenosis	3	4.5
Tetralogy of Fallot	3	4.5
Pulmonary stenosis	2	3.0
Tetralogy of Fallot with absent pulmonary valve	2	3.0
Coarctation of the aorta	1	1.5
Valvular aortic stenosis	1	1.5
Borderline left ventricle	1	1.5
Scimitar syndrome	1	1.5
Shone complex - aortic stenosis	1	1.5
Taussig bing anomaly	1	1.5
Total	66	100

PA-VSD: Ventricular septal defect pulmonary atresia, PA-IVS: Pulmonary atresia with intact ventricular septum, HLHS: Hypoplastic left heart syndrome, TGA: Transposition of the great arteries, IAA: Interrupted aortic arch

the hemodynamic/anatomical problems following cardiac surgery. In two patients, PDA stenting was terminated as the patients' PDA anatomies were not suitable. Details of the diagnostic procedure data are given in Table 4.

Two patients needed ECMO support during the procedure. In a patient diagnosed with pulmonary atresia with ventricular septal defect, the PDA stent was distally milked and the guidewire position was lost. The stent occluded the PDA, and the oxygen saturation dropped to 20%. ECMO support was urgently initiated in the catheterization laboratory. Then, the patient underwent central shunt surgery. This patient was weaned from ECMO and discharged without any sequela. The other patient had HLHS. He was taken to the catheterization laboratory for a hybrid stage-1 HLHS palliation operation. PDA stenting after balloon atrial septostomy was planned.

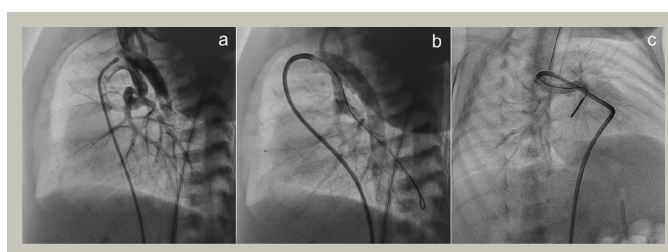


Figure 3. Five-day-old newborn's cardiac catheterization diagnosed with pulmonary atresia with a ventricular septal defect. Ductus arteriosus stenting via an antegrade approach through the femoral vein. a) Lateral angiogram showing vertical ductus. b) Lateral angiogram after two coronary stent implantation into the duct. c) 30LAO-30 cranial angiogram showing proper stent position

Table 3. Procedure types

Procedure	N	%
PDA stenting	40	52.6
Balloon atrial septostomy	10	13.2
Diagnostic cardiac catheterization	9	11.8
Balloon atrial septoplasty and PDA stenting	6	7.9
Balloon pulmonary valvuloplasty	4	5.3
Balloon aortic valvuloplasty	1	1.3
Arcus aorta stenting	1	1.3
Balloon angioplasty of aortic coarctation	1	1.3
Stent implantation of aortic coarctation	1	1.3
Pulmonary balloon valvuloplasty + PDA stenting	1	1.3
RVOT stenting	1	1.3
Sequestration artery embolization	1	1.3
Total	76	100

RVOT: Right ventricular outflow tract, PDA: Patent ductus arteriosus

Atrial and ventricular fibrillation was observed following balloon atrial septostomy. Meanwhile, extrapulmonary cardiopulmonary resuscitation was initiated. PDA stenting was performed under ECMO support. Unfortunately, this patient died during intensive care unit follow-up.

A total of 12/76 (16%) complications occurred, where in 8/76 (16%) were major complications as summarized in Table 5.

No deaths occurred either during or within the 24 h following the procedures. The detailed information about the patients who underwent catheterization under ECMO support was presented in Table 5.

Discussion

This study evaluated the results of cardiac catheterization of neonates in a newly established center. Most procedures

were performed for interventional purposes with an acceptable complication rate. This is one of the limited numbers of studies conducted in our country.

Both diagnostic and interventional procedures can be performed safely in neonates with various structural heart diseases. The interventional procedures are less invasive than surgery for neonates and had several advantages, such as decreased hospital stay and provision of palliation, and even definitive treatment in some cases. However, these procedures have some disadvantages, such as vascular complications, and unknown long-term follow-up results (5).

Recently, with the advancement in non-invasive imaging methods, such as CT and MR imaging, the rate of interventional procedures tends to exceed the diagnostic ones. Soylu (6) reported an interventional procedure rate of 30% in their series consisting of 2,265 cardiac catheterizations. Shim et al. (7) stated interventional procedure rate is more

Table 4. Characteristics of patients who underwent diagnostic cardiac catheterization

No	Post-op	Cardiac catheterization indication	Diagnosis
1	Yes	Post-op prolonged intubation	TGA patient after Jatzen operation
2	Yes	For coronary artery assessment	After central shunt palliation for PA-IVS, low cardiac output
3	Yes	Investigate the cause of ECMO	Tetralogy of Fallot with absent pulmonary valve
4	Yes	Investigate the cause of ECMO	TGA patient after Jatzen operation
5	Yes	Investigate the cause of ECMO	Aortic stenosis after aortic valve repair
6	No	PDA stenting	Ventricular septal defect pulmonary atresia
7	No	PDA stenting	Left isomerism, mitral atresia, aortic outlet right ventricle, pulmonary artery atresia
8	No	MAPCA and PA assessment	Ventricular septal defect pulmonary atresia
9	No	MAPCA and PA assessment	Right atrial isomerism, cAVSD, pulmonary atresia, TAPVC

ECMO: Extracorporeal membrane oxygenation, MAPCA: Major aortopulmonary collateral artery, PA: Pulmonary artery, TGA: Transposition of the great arteries, PA-IVS: Pulmonary atresia with intact ventricular septum, TAPVC: Total anomalous pulmonary venous connection, cAVSD: Complete atrioventricular septal defect

Table 5. Complications, treatments, and clinical outcomes

Major	N	Treatment	Outcome
Stent embolization 7 migration	6	The stent was snared and the procedure was continued. During the procedure, 2 stents were implanted into PDA (n=1)	Discharged
		Stent was secured with a second stent (n=4)	Discharged (n=3) Dead (n=1)
Arrhythmia	2	ECMO support was initiated (n=1)	Discharged after central shunt (n=1)
		ECMO support was initiated (n=1)	Dead (n=1)
Minor			
Arrhythmia	3	Resolved after catheter manipulation	
Bleeding	1	Blood transfusion	

CPR: Cardiopulmonary resuscitation, ECMO: Extracorporeal membrane oxygenator, HLHS: Hypoplastic left heart syndrome, PDA: Patent ductus arteriosus

than half in their series. In our study, the interventional procedure was performed in most cases (88%). In addition, the PDA stenting attempt was given up in two cases because of unsuitable anatomy.

Different studies reported many types of procedures, such as balloon atrial septostomy, balloon angioplasty for aortic coarctation, balloon pulmonary and aortic valvuloplasty, PDA stent implantation, radiofrequency pulmonary valve perforation, and right ventricular outflow tract (RVOT) stenting, as therapeutic procedures in neonates (4,5,6,7,8).

Tekerek (9) reported that balloon atrial septostomy was the most common interventional procedure that was performed on newborns, with a frequency of 35%. Similarly, balloon atrial septostomy was the most common procedure followed by balloon valvuloplasty in Shim et al.'s (7) study. In our study, the most common interventional procedure was PDA stenting. This difference is because the majority of our neonatal cases were diagnosed with pulmonary atresia or HLHS that require PDA stenting. PDA stenting was preferred in patients with duct-dependent pulmonary or systemic circulation. In addition, our center is a referral center for complex heart diseases.

PDA patency is provided with medical methods, such as prostaglandin E1, in the early postnatal period and palliation can be achieved with PDA and RVOT stenting until the definitive surgery is performed (10,11). Akintuerk et al. (11) reported high success rates with the hybrid approach (bilateral pulmonary artery banding and PDA stenting \pm balloon atrial septostomy) in HLHS patients. Gibbs et al. (10) stated that most patients with PDA stent had pulmonary atresia with an intact ventricular septum. In the PDA stenting group, pulmonary atresia and HLHS cases were the majority of our patients, consistent with the literature.

Cardiac catheterization complications range from minor problems that do not end up with any sequelae to major problems that lead to emergency cardiac surgery, permanent sequelae, and/or death. The risk of complications may be related to the patient's age, weight, clinical condition at the time of intervention, the type of underlying disease, the purpose of catheter angiography procedure as diagnostic or interventional, and the skill and experience of the performing cardiologist and cardiac team (12). The literature reported that the complication rate after cardiac catheterization is 2-40% in pediatric patients (13). Booth et al. (14) reported that the complication rate was 24% in their series of 160 patients for balloon procedures with the most common complication

as vascular problems and 70% of all complications occurred in the neonatal patient group. Uysal (15) reported the complication rate as 5.8% and Tavli et al. (16) as 3.4% in their study. Tekerek (9) encountered a complication rate of 29% in 61 procedures, including 36 minor (17%) and 25 major (12%) complications in the neonatal group in their study consisting of 201 patients who underwent interventional procedures. Our study had a total of 12/76 (16%) complications during the procedures. The major complications were 8/76 (10%), whereas the minors were 4/76 (6%). No deaths occurred in the first 24 h after the procedure.

Study Limitations

The main limitation of this study include the single-center study with a limited number of patients, as well as insufficient experience of the healthcare team who perform the procedures (nurse, technicians, junior cardiologists, etc.) and its impact on the procedure time and success rates.

Conclusion

In conclusion, cardiac catheterization and angiography procedures can be safely and effectively performed in experienced centers for neonatal cases. The presence of experienced staff and support of the surgical team during the procedures are crucial to overcoming the complications that may occur during and/or after the procedure.

Ethics

Ethics Committee Approval: Institutional review board approval was obtained from the University of Health Sciences Turkey, Başakşehir Çam and Sakura City Hospital Ethical Committee (2021-09-221).

Informed Consent: A proper written and informed consent was taken from all parents of neonates.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: İ.C.T., H.D.Ö., S.S., A.G., K.Y., E.Ö., Concept: İ.C.T., E.Ö., Design: İ.C.T., E.Ö., Data Collection or Processing: H.D.Ö., S.S., A.G., K.Y., Analysis or Interpretation: İ.C.T., A.G., E.Ö., Literature Search: H.D.Ö., S.S., Writing: İ.C.T., E.Ö.

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