

## Transcatheter Cardiac Interventions in Neonates with Congenital Heart Disease: A Single Centre Experience

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### ABSTRACT

**Objective:** To analyze the outcome among neonates undergoing transcatheter balloon atrial septostomy for various kinds of congenital heart diseases.

**Study Design:** Prospective longitudinal study.

**Place and Duration of Study:** National Institute of Cardiovascular Diseases, Karachi Pakistan, from Feb 2020 to May 2021.

**Methodology:** A total of 28 neonates of both genders with echocardiography proven diagnosis of Tricuspid Atresia with restrictive Patent Foramen Ovale, Dextro-Transposition of Great Arteries with Intact Ventricular Septum, complex cyanotic congenital heart disease with inadequate mixing or hypoplastic left heart syndrome with restrictive PFO and a non-significant Patent Ductus Arteriosus, undergoing transcatheter balloon atrial septostomy were included. Demographic data along with diagnosis, clinical presentation, echocardiographic findings, procedural outcome (successful/unsuccessful), duration of the procedure, complication (if any), post-procedural echocardiographic findings, duration of hospital stay, further treatment plan and 3-months follow up outcomes were recorded among all neonates.

**Results:** Most common diagnosis was Dextro-Transposition of the Great Arteries with IVS observed in 14(50.0%) neonates. Procedural outcome was found to be successful among 23(82.1%) neonates. There were 19(67.9%) neonates who did not show any post-procedure complication. At 3-months follow up, improvement in blood saturation and weight gain were reported among 12(42.9%) neonates each. Overall, mortality was noted in 7(25.0%) neonates, of whom 4(57.1%) neonates were having hypoplastic left heart syndrome.

**Conclusion:** Transcatheter atrial septostomy done in neonatal period was found to have positive outcomes. Mortality remains high among neonates undergoing transcatheter atrial septostomy having hypoplastic left heart syndrome.

**Keywords:** Atria, Echocardiography, Newborn, Transcatheter.

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### INTRODUCTION

Cardiac diseases among pediatric population are noted to contribute significantly to morbidity and mortality.<sup>1</sup> Congenital heart disease (CHD) is considered to form an important proportion of major congenital malformations and affects between 2-3% of newborns whereas incidence of CHD is 3 to 10 per 1000 live-births globally.<sup>2,3</sup> Pakistan is estimated to have 40000 newborns every year with CHD.<sup>4</sup> About 25% of all neonatal deaths because of congenital malformations are credited to CHD.<sup>5</sup>

Not all kinds of CHD need immediate post-natal interventions but some types of CHD need early surgery or catheterization during the neonatal period. Neonates having duct-dependent CHD require immediate administration of prostaglandin infusion that can save life until palliative or therapeutic

interventions can be planned.<sup>5</sup> CHD requiring early identification and intervention can cause serious forms of morbidity as well as mortality if left unidentified or untreated.<sup>6</sup>

Recent decades have seen lots of advancement in terms of interventional pediatric cardiology improving survival of affected pediatric population significantly.<sup>7</sup> Percutaneous cardiac catheterizations have been a topic of interest for diagnosis and therapeutic benefits especially among neonates. In neonatal age groups, less invasive interventions are favored as open heart surgeries are not doable at all clinical settings and are linked with significantly increased death rates especially among developing countries. Transcatheter atrial septostomy is one of the most frequently performed intervention done in the emergency setting at National Institute of Cardiovascular Diseases, Karachi Pakistan, and this study was planned to analyze the outcome among neonates undergoing transcatheter atrial septostomy for various kinds of

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CHDs. Owing to the importance of this topic, and a dearth of similar studies, our study aimed to demonstrate the outcome of transcatheter balloon atrial septostomy as a palliative procedure in few types of CHD in neonates.

### METHODOLOGY

The prospective longitudinal study was conducted from February 2020 to May 2021 at National Institute of Cardiovascular Diseases (NICVD), Karachi Pakistan, after approval from Institutional Ethical Committee (ERC 001/2021, dated: 07-05-2021). Written, informed consent was taken from parents/guardians of all study participants. Non-probability consecutive sampling technique was adopted.

**Inclusion Criteria:** Neonates of either gender with echocardiography proven tricuspid atresia with restrictive PFO, d-transposition of great vessels (d-TGA) with intact ventricular septum (IVS), complex cyanotic CHD with inadequate mixing and hypoplastic left heart syndrome with inadequate PFO, undergoing transcatheter balloon atrial septostomy were included.

**Exclusion Criteria:** Neonates with any kind of extra-cardiac congenital malformations, neonates having gestational age below 32 weeks and parents or guardians of neonates unwilling to give informed written consent were excluded.

Demographic data along with diagnosis, clinical presentation, echocardiographic findings, procedural outcome (successful/unsuccessful), duration of the procedure, complication (if any), post-procedural echocardiographic findings, duration of hospital stay and further treatment plan was recorded among all neonates. Transcatheter atrial septostomy was termed successful if post-procedure enlargement of patent foramen ovale (PFO) was more than 1/3rd of the total septal diameter, along with a minimum increase in blood O<sub>2</sub> saturation of at least 15-20 percent from the neonatal baseline saturation. Prior and post-intervention standard echocardiography was done among all enrolled neonates by a pediatric cardiologist with a minimum 3-year post-fellowship experience. At 3-months follow up, outcome in terms of improvement in blood saturation, weight gain, failure to thrive, deteriorating medical condition, any surgical procedure planned/attempted or mortality were recorded.

A specifically designed proforma was used for this study. Data was analyzed using SPSS version 26.0. Qualitative variables like gender, place of procedure (emergency or cardiac catheterization laboratory), prenatal/fetal diagnosis of CHD (yes/no), clinical presentation at the time of admission, pre-procedural diagnosis on 2-D echocardiography for which inter-vention was planned, any procedure related complications, procedure outcome (successful/unsuccessful), post-procedural 2-D echocardiographic findings, long term management plan and outcome at 3-months follow up were described as frequency and percentages. Quantitative variables like age at the time of admission (days), gestational age (in weeks), body weight at the time of admission (in grams), saturation on pulse oximeter at the time of admission (%), duration of procedure (minutes), post-procedure blood saturation on pulse oximeter (%) and duration of hospital stay (days) were represented as mean and standard deviation.

### RESULTS

Out of a total of 28 neonates, 16(57.1%) were male. Mean age at the time of admission was noted to be 11.43±6.02 days (ranging from 3 to 21 days) while 10(35.7%) presented within 7 days of life. Prenatal diagnosis of CHD was made in only 5(17.9%) neonates. Most frequent clinical presentation was bluish discoloration 20(71.4%) while sepsis was noted in 12(42.9%) neonates at the time of admission. Most common diagnosis was d-TGA with IVS observed in 14(50.0%) neonates. Table-I shows details of demographic and clinical characteristics among neonates who were enrolled to undergo transcatheter atrial septostomy.

Transcatheter atrial septostomy was done in the emergency room in 25(89.3%) neonates while remaining 3(10.7%) neonates had cardiac catheterization laboratory as the place of intervention (shifted to cath lab due to any technical difficulty after being attempted for septostomy in the emergency room). Table-II shows That procedural, post-procedural and outcome variables among all 28 neonates who underwent transcatheter atrial septostomy. Procedural outcome was found to be successful among 23(82.1%) neonates while 3 neonates reported cardiopulmonary arrest requiring resuscitation (and, consequently, abandonment of the procedure) while other 2 neonates were managed conservatively (the very restrictive PFO could not be crossed with septostomy balloon). There were

19(67.9%) neonates who did not show any postprocedure complication while cardiopulmonary arrest

**Table-I: Demographic and Clinical Characteristics of Neonates Undergoing Transcatheter Atrial Septostomy (n=28)**

Characteristics		n (%) / Mean+SD
Gender	Male	16(57.1%)
	Female	12(42.9%)
Age at the Time of Admission (days)		11.43+6.02
Body Weight at the Time of Admission (grams)		3716.07+630.70
Gestational Age (weeks)		36.36+1.62
Prenatal Diagnosis of Congenital Heart Disease		5(17.9%)
Frequency of Clinical Presentation at the Time of Admission	Respiratory Distress	7(25.0%)
	Bluish Discoloration	20(71.4%)
	Repeated Chest Infection	4(14.3%)
	Lethargy	15(53.6%)
	Reluctance to Feed	8(28.6%)
	Sepsis	12(42.9%)
O2 Saturation at the Time of Admission (%)		53.54+3.99
Diagnosis	Tricuspid Atresia with restrictive paten foramen ovale	5(17.9%)
	Dextro-Transposition of the Great Arteries with intact ventricular septum	14(50.0%)
	Hypoplastic Left Heart Syndrome with restrictive paten foramen ovale	5(17.9%)
	Complex Cyanotic congenital heart disease with inadequate mixing	4(14.3%)

requiring resuscitation was the most frequent complications seen in 3(10.7%) neonates. Regarding long term management plan, there were 5(17.9%) neonates who were planned to have modified BT shunt after 3 months of age, 7(25.0%) were planned for arterial switch in the upcoming next two weeks of septostomy, while 3(7.1%) were planned for Senning at nine months of age, as is the practice in our institute (as the LV morphology did not seem prepared for arterial switch). At 3-months follow up, improvement in blood saturation and weight gain were reported among 12(42.9%) neonates each. Failure to thrive was observed among 3(10.7%) neonates. Overall, mortality was noted in 7(25.0%) neonates. Four (57.1%) out of

7 neonates who died were having diagnosis as hypoplastic left heart syndrome, while 2(28.6%) had d-TGA with IVS and 1(3.6%) complex cyanotic CHD

**Table-II: Procedural, Post-Procedural Study Variables and Outcome among Neonates who Underwent Transcatheter Atrial Septostomy (n=28)**

Study Variables		n (%) / Mean+SD
Duration of Procedure (minutes)		37.86+8.0
Post-Procedure O2 Saturation (%)		72.29+2.59
Procedure Outcome	Successful	23(82.1%)
	Unsuccessful	5(17.9%)
Frequency of Complications	None	19(67.9%)
	Transient AV Block	2(7.1%)
	Bradycardia	2(7.1%)
	Gangrene/Necrosis of Lower Limbs	2(7.1%)
	Cardiopulmonary Arrest Requiring Resuscitation	3(10.7%)
Post-Procedure Echocardiographic Findings	Adequate Sized paten foramen ovale with good mixing	25(89.3%)
	No Improvement	3(10.7%)
<b>Duration of Hospital Stay (days)</b>		<b>14.29+3.40</b>
Frequency of Outcome Findings at 3-months Follow up	Improving Blood O2 Saturation	12(42.9%)
	Weight Gain	12(42.9%)
	Failure to Thrive	3(10.7%)
	Mortality	7(25.0%)

with inadequate mixing. In 7 neonates who died, cardiopulmonary arrest was the cause of death in 3 (these were the neonates who expired in the hospital within a few days of the failed intervention) while recurrent chest infections and sepsis were the causes of death in 2 neonates each.

**DISCUSSION**

Not every child with CHD is suited to surgery or intervention, owing to conditions such as low birth weight, complex cardiac anatomy, poor general health condition or co-existing congenital anomalies.<sup>8</sup> Transcatheter interventions are among the most commonly adopted interventions among neonates because in comparison to surgery, they are not only less invasive but also associated with significantly lesser duration of hospitalization.<sup>9,10</sup>

A study done by Melekoglu *et al.* from Turkey evaluating percutaneous cardiac catheterization among neonates having CHD found 73.9% neonates to have successful outcome,<sup>11</sup> which was similar to our rate of successful immediate outcome at 82.1%. Not many studies have documented procedure related

complication among neonates undergoing transcatheter interventions. Melekoglu AN *et al.* reported overall complication rate with transcatheter interventions to be 28.3%<sup>11</sup> which is quite consistent with what was found in the present study at 32.1%. Vitiello *et al.* analyzing complications linked with cardiac catheterization found 14% neonates to have complications.<sup>12</sup> Some researchers have documented comparatively higher rates of complications among neonates which could be one of the reasons why relatively higher rates of complications were reported<sup>11,13</sup> in the present study. Another reason could be that prenatal diagnosis CHD was only made in 5(17.9%) neonates whereas 25(89.3%) neonates had transcatheter atrial septostomy done in the emergency room. Some other researchers have reported bleeding, hematomas, or venous thrombosis as complications following balloon atrial septostomy.<sup>12,14</sup> In this study, it is important to note that among 5 neonates with hypoplastic left heart syndrome, 4 died. Neonates with hypoplastic left heart syndrome have high rates of adverse outcomes and studies in past have shown significantly higher rates of mortality among neonates undergoing transcatheter atrial septostomy with hypoplastic left heart syndrome.<sup>15-17</sup>

Transcatheter cardiac interventions are found to have significantly lesser complications in comparison to open heart surgical procedures, and experts have advised individualization of catheter-based interventions considering variation in cardiac anatomy and defect size.<sup>11,18</sup>

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#### CONCLUSION

Transcatheter atrial septostomy done in neonatal period was found to have good outcomes. Mortality remains high among neonates undergoing transcatheter atrial septostomy having hypoplastic left heart.

**Conflict of Interest:** None.

#### Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

FUR: & MTA: Study design, drafting the manuscript, data interpretation, critical review, approval of the final version to be published.

MUR: & SA: Data acquisition, data analysis, approval of the final version to be published.

ASS: & VK: Critical review, concept, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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