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Outcomes of Patent Ductus Arteriosus Stenting to Retrain Regressed Left Ventricle in Transposition of Great Arteries with Intact Ventricular Septum

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ABSTRACT

Objective: To assess the outcomes of Patent Ductus Arteriosus (PDA) stenting to retrain regressed Left Ventricle (LV) in Transposition of Great Arteries with Intact Ventricular Septum (TGA-IVS).

Study Design: Quasi-experimental study

Place and Duration of Study: Paediatric Cardiology Department, Armed Forces Institute of Cardiology & National Institute of Heart Diseases, Rawalpindi Pakistan from July-Dec 2023

Methodology: Thirty pediatric patients aged < 2 months who underwent PDA stenting with TGA-IVS having regressed LV were included using non probability consecutive sampling. Prior to PDA stenting, echocardiography was performed in all TGA-IVS patients to evaluate the effectiveness of LV retraining.The Mosteller formula was used to relate LV mass to body surface area. Echocardiographic LV assessment was repeated at 1st and 2nd week after PDA stenting. Post stenting angiogram was carried out to confirm optimum placement and adequate blood flow to branch pulmonary arteries.

Results: Among 30 participants, 19(63.3%) patients were males and 11(36.7%) were females with composite median age of 10.00(6.50-32.50) days. LV retraining using PDA stenting was found to be successful in 27(90.0%) patients and unsuccessful in 3(10.0%) patients. Successful patients exhibited high LV mass index [Pre stenting vs. post stenting: 33.00(32.00-34.00) g/m^2 vs. 63.00(61.00-65.00) g/m^2; p=0.005] and improved LV geometry after PDA stenting. However, the unsuccessful patients did not show an appropriate response because of large interatrial communication.

Conclusions: PDA stenting significantly improved both left ventricular mass index and LV geometry. Moreover, transcatheter ductal stenting was an effective and safe method to retrain the regressed LV in late presenters of TGA-IVS.

Keywords: Intact Ventricular Septum, Modified Blalock-Taussig Shunt, Patent Ductus Arteriosus, Regressed left ventricle, Transposition of Great Arteries

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INTRODUCTION

Transposition of great arteries (TGA) is a common cyanotic heart disease, majority of cases detected in newborn period, which accounts 5% to 7% of all congenital heart diseases (CHDs)[1] and has a prevalence estimate of 0.2 per 1000 live births.[2] It is more common in males than in females (male-to-female ratio of 3:1). Infants diagnosed with transposition of great arteries with intact ventricular septum (TGA-IVS) having regressed left ventricle, who present beyond first few weeks of age require LV retraining before the Arterial Switch Operation (ASO), because the LV's capacity to sustain systemic circulation after ASO is compromised which greatly impacts early survival in these late presenters.[3,4]

On echocardiography, the regressed left ventricle appeared as banana shaped, squashed chamber with interventricular septum bowing into LV cavity and having decreased LV mass, volume and posterior free wall thickness.[5] Multiple approaches are used for LV retraining including surgical and transcatheter techniques. Surgical retraining is carried out by pulmonary artery banding (PAB) and modified Blalock-Taussig (BT) shunt.[6,7] With its main benefits being the avoidance of thoracotomy, banding-induced neo-aortic valve regurgitation and pulmonary artery distortion, ductal stenting is a less morbid form of left ventricular retraining in transposition of the great arteries with regressed left ventricle.[8,9]

ASO is usually administered to the majority of patients worldwide within the first one to two weeks of life if they have Dextro-Transposition of the Great Arteries (D-TGA) and an intact septum with suitable anatomy. Nevertheless, we frequently find it difficult to handle the large number of these cases in our

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setting. Recent years have seen the emergence of transcatheter stenting of the patent ductus arteriosus (PDA) as a nonsurgical technique for retraining the left ventricle in patients with TGA-IVS.[10] As a result, in patients with regressed LV at the time of presentation, PDA stenting gained significant importance in our setup to offer ASO in these patients.

The aim of this study was to assess the outcome of PDA stenting to retrain regressed LV in TGA-IVS patients. Patients with TGA-IVS frequently have regressed left ventricles at presentation, which complicates the use of standard surgical LV retraining. When compared to traditional surgical procedures, transcatheter PDA stenting offers a safer and more effective less intrusive solution for retraining the left ventricle.

METHODOLOGY

This Quasi-experimental study was conducted at Paediatric Cardiology Department, Armed Forces Institute of Cardiology & National Institute of Heart Diseases, Rawalpindi from July-Dec 2023 after the approval from Institutional Ethical Review Board (IERB Ltr.no 9/2/R&D /2023/278; Dated; 14th, July-2023). Non probability consecutive sampling was employed to collect data from patients.

A sample size of 30 was calculated using non probability consecutive sampling technique by taking 0.2% prevalence estimate of TGA-IVS out of 1000 live births with a confidence level of 95%, and 5% margin of error.[11]

Inclusion Criteria: All patients with TGA-IVS having regressed LV and aged < 2 months were included.

Exclusion Criteria: Patients with complex congenital heart disorders and TGA with accompanying anomalies other than intact ventricular septum were excluded.

After taking informed consent from patient's parents or guardian, data was collected. Prior to PDA stenting, echocardiography was performed in all TGA-IVS patients to evaluate the effectiveness of LV retraining.

LV indices of interest included, LV ejection fraction measured on M mode, LV posterior wall thickness measured at end diastole at the mid cavity level, LV dimensions obtained from the parasternal long axis view in end diastole.LV mass calculated using formula 0.8 [1.04 * (LVID +IVSd+PWd)3LVID3]+0.6g,where

LVID = Left Ventricle Internal Diameter in diastole. IVSd = Interventricular Septal Thickness,

PWd is Posterior Wall Thickness in diastole, 1.04 is the myocardium's specific gravity, and 0.8 is the correction factor.[12] The Mosteller formula was used to relate LV mass to body surface area.[13] Figure-1 demonstrated the entire process from patient selection till outcome assessment.

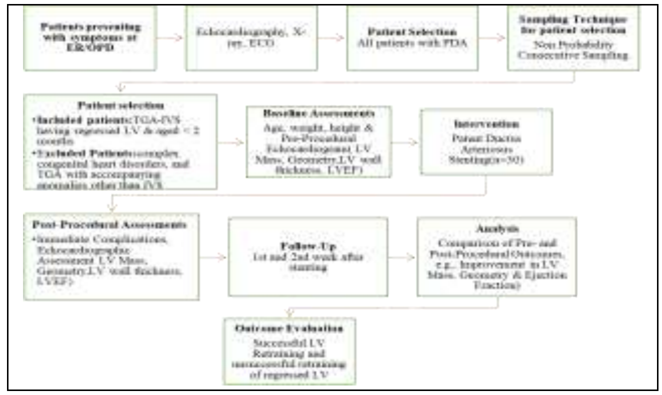

Figure.1 Quasi-Experimental Study Design with Single Group Approach

In order to characterize the degree of LV involution, the geometry of the LV was subjectively categorized as "satisfactory," "D-shaped," and "ellipsoid" on the basis of IVS location in end-systole.[14] General anesthesia was used in all procedures of PDA stenting. An aortogram was performed in lateral view to roadmap the position and the course of PDA. If a flow-restrictive PDA was found, using a 4F Judkins right catheter, the ductus arteriosus ampulla was engaged, and 0.014 inches angioplasty wire was advanced deeply into the branch pulmonary artery to secure parking. Measurements were made by checking angiogram after straightening the PDA by angioplasty wire and bare-metal coronary stent 3.5-4 mm was deployed to cover the whole length of PDA. Post stenting angiogram was carried out to confirm optimum placement and adequate blood flow to branch pulmonary arteries. In cases of obliterated ductal patency, the ductal ampulla was probed with a 0.014-inch BMW/ BHW guidewire to gain entry into the Pulmonary artery (PA) through the PDA, and then PDA was stented as described above (Figure-2). All these patients were given dual antiplatelets (aspirin and clopidogrel) after stenting and heparin 100 IU/kg bolus followed by 20 U/kg/h infusions for at least 24 hours.

Figure-2: PDA Stent in-situ Angiographic Image in LAO 90.

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version-27. The normality of continuous variables (age, weight, height, oxygen saturation, LV mass, LV free wall thickness, and EF) was explored using the Shapiro-Wilk test. The results indicated that the data were not normally distributed therefore, the median and interquartile range (IQR) were reported for these variables. Percentages and frequencies were reported to describe qualitative variables (gender, immediate complications, PDA recanalization, septostomy, and LV geometry). The Mann-Whitney U test was performed to compare the median differences in oxygen saturation and echocardiographic parameters between patients with unsuccessful and LV successful retraining. The Wilcoxon signed-rank test was applied to assess the changes in echocardiographic parameters before and after PDA stenting

RESULTS

Out of 30 pediatric patients, 19(63.3%) were males and 11(36.7%) were females with median age of 10.00(6.50-32.50) days. The Right Femoral Artery (RFA) approach was used in most of the patients 27(90.0%). Pulmonary edema observed in 3(10.0%) patients who were managed conservatively with Continuous positive airway pressure, Intra-venous diuretics and supportive care. However, 1(3.3%) patient required mechanical ventilation for 24 hours. One (3.3%) patient developed sepsis with raised C-reactive protein and White blood cell count and had prolonged hospital stay, however responded well to antibiotics. 3(10.0%) patients developed partial stent thrombosis with decreased flow across stent, 2(66.7%) of them were successfully managed with heparin infusion, and 1(33.3%) needed balloon angioplasty with drug eluting balloon. 2(6.7%) patients underwent Balloon Atrial Septostomy at median age of 10 days. PDA recanalization was done in 2(6.70%) patients due to functionally closed ductus arteriosus. In this study fewer immediate post procedural complications were seen. All patients with successful LV retraining had an ellipsoid LV geometry prior to stenting and improved to satisfactory after stenting. (Table-I)

Table-I: Baseline Characteristics, Left Ventricular geometry and Post stenting Immediate Complications of study Participants (n=30)

Variables			Median(IQR)
Demographics			
Age(days)			10.00(6.50-32.50)
Weight (kg)			2.50(2.30-3.35)
Height(cm)			50.00(49.00-53.00)
			Frequency (%)
Gender	Male		19(63.3%)
	Female		11(36.7%)
Approach	RFA		27(90.0%)
	LFA		3(10.0%)
Immediate Complications			Frequency (%)
Pulmonary Edema			3(10.0%)
Sepsis			1(3.30%)
Partial Stent Thrombosis			3(10.0%)
PDA Recanalization			2(6.7%)
Septostomy			2(6.7%)
PDA stent size			Median (IQR)
Length(mm)			12.00(10.25-15.00)
Width(mm)			3.75(3.00-4.00)
			Frequency (%)
Left Ventricular geometry	Pre stenting	Ellipsoid	30(100.0%)
	Post stenting		
	1st week	D-shaped	28(93.3%)
		Satisfactory	2(6.7%)
	2nd week	D-shaped	3(10.0%)
		Satisfactory	27(90.0%)

RFA=Right Femoral Artery; LFA= Left Femoral Artery; PDA=Patent Ductus Arteriosus

Significant improvements were observed in clinical and echocardiographic parameters following ductal stenting. Oxygen saturation improved from a median of 50.0(40.00–55.00%) before stenting to 90.00% (86.00–92.00%) within a second week (p<0.001). LV free wall thickness showed a noticeable increase [pre stenting vs. post-stenting; 3.00 (3.00–3.23) mm vs. 4.15 (4.00–4.30) mm; p<0.001]. Additionally, EF also showed statistically significant progression (p<0.001). These findings highlighted the effectiveness of ductal stenting in improving oxygenation and LV remodeling. (Table-II)

The changes in various indicators pre and post Ductal stenting in patients with successful and unsuccessful retraining is shown in Table -III. LV

Table II: Echocardiography Parameters Pre and Post PDA Stenting (n=30)

Variables	Pre stenting	Post stenting (1st week)	*p-value	Post stenting (2nd week)	**p-value
O2 Saturation (%)	50.00(40.00-55.00)	90.00(85.00-92.00)	<0.001	90.00(86.00-92.00)	<0.001
LV Mass (g/m^2)	33.00(31.75-34.00)	53.50(50.00-55.00)	<0.001	60.00(62.50-65.00)	<0.001
LV Free Wall Thickness (mm)	3.00(3.00-3.23)	3.80(3.60-3.93)	<0.001	4.15(4.00-4.30)	<0.001
EF (%)	43.00(40.00-45.00)	53.00(52.00-55.00)	<0.001	60.00(58.00-60.00)	<0.001

*LV=left ventricular; EF=Ejection Fraction*p= pre vs .post stenting1st week; **p= pre vs.post stenting 2nd week*

Table III: Comparison of Oxygen Saturation and Dimensions with Left Ventricular Retraining Status (n=30)

Variables		Successful LV Retraining Yes (n=27)	Successful LV Retraining No (n=03)	*p*-value
		Median(IQR)		
O2 Saturation (%)	Pre-stenting	50.00(40.00-55.00)	40.00(31.0-45.00)	0.08
	Post stenting			
	1st week	90.00(87.00-92.00)	85.00(80.00-85.00)	0.01
	2nd week	90.00(86.00-92.00)	85.00(81.00-85.00)	0.01
LV Mass g/m^2	Pre-stenting	33.00(32.00-34.00)	26.00(22.00-28.00)	0.004
	Post stenting			
	1st week	54.00(51.00-55.00)	33.00(28.00-33.00)	0.005
	2nd week	63.00(61.00-65.00)	34.00(33.00-35.00)	0.005
LV Free Wall Thickness (mm)	Pre-stenting	3.00(3.00-3.00)	3.00(2.00-3.00)	0.006
	Post stenting			
	1st week	4.00(4.00-4.00)	3.00(3.00-3.00)	0.004
	2nd week	4.00(4.00-4.00)	3.00(3.00-3.00)	0.005
LVEF (%)	Pre-stenting	43.00(40.00-45.00)	41.00(40.00-42.00)	0.18
	Post stenting			
	1st week	53.00(53.00-55.00)	48.00(47.00-50.00)	0.004
	2nd week	60.00(58.00-60.00)	55.00(54.00-56.00)	0.005

LVEF=Left ventricular ejection fraction

retraining through ductal stenting was found to be successful in 27(90.0%) patients and unsuccessful in 3(10.0%) patients. Successful patients exhibited high LV mass index [Pre-stenting vs. post stenting; 33.00(32.00-34.00) g/m^2 vs. 63.00(61.00-65.00) g/m^2]. Moreover, posterior free wall thickness was increased in successful retraining patients [pre-stenting vs. post-stenting; 3.00(3.00-3.00) mm vs. 4.00(4.00-4.00) mm] patients whereas unsuccessful patients did not show similar improvements.

DISCUSSION

Current study demonstrated successful LV retraining using transcatheter ductal stenting in 27(90.0%) out of 30 patients in the form of LV mass, LV geometry and LV posterior wall thickness (p=0.001), with fewer immediate post procedural complications. Leong *et al.*, reported the successful LV retraining in 7(63.6%) out of 11 patients with PDA stenting.[5] This study showed noticeable improvement in LV mass index from 33.00(32.00-34.00) g/m^2 to 63.00(61.00-65.00) g//m^2 (p=0.001) and all patients had improved LV geometry. Comparable results were reported by the previous study with LV mass index improving from 45.14±17.91 to 81.86±33.11g/m^2(p=0.023) and improved LV geometry.[5]

In this study, PDA recanalization was done in 2(6.7%) out of 30 patients due to functionally closed Ductus Arteriosus. 3(10.0%) patients developed partial stent thrombosis, 2(66.7%) of them were managed with IV heparin infusion and one (33.3%) needed re-intervention in the form of stent ballooning. 3(10.0%) patients developed pulmonary edema which was managed with supportive care and 1(3.3%) patient developed sepsis which responded well to broad spectrum antibiotics. Previous research documented 2(11.1%) out of 17 cases of acute stent thrombosis and other 2(11.1%) patients reported stent dislodgment.[12]

Compared to present study, Bilal *et al.*,[13] demonstrated successful LV retraining for regressed LV with cavopulmonary shunt and PA banding with left ventricular mass indices increased from 18-32 to 44-74 g/m^2 and found it useful in 4(66.7%) out of 6 patients. Cevik *et al.*, also demonstrated successful LV retraining with Cavopulmonary shunt and PA banding in patients presented after neonatal life with regressed LV.[14]

Anantharaj et al. reported a successful LV retraining in a 39 days old infant with LV mass increased from 37g/m^2 to 90g/m^2 and LV post wall thickness increased from 3.0 mm to 3.8 mm with a satisfactory shift in LV geometry, who then underwent successful ASO after 17 days of ductal stenting.15 The unsuccessful LV retraining group 3(10.0%) had a large interatrial communication might be the reason of failure. However, previous study also reported 4 patients desired results were not achieved because of large interatrial communication.[16] Compared to current study, Kothari *et al.,* showed successful LV retraining within 7-14 days with ductal stenting in 5(83.3%) out of 6 patients even with functionally closed ducts in which ducts were recanalized.[17]

Ductal stenting was a useful approach for retraining the regressed LV in TGA-IVS.[5] Aligning with the findings of our study where we depicted effectiveness of PDA stenting in retraining the regressed left ventricle, a previous study demonstrated PDA in 43 patients, with a success rate of 93%.[18] Similar results were found in this study, where 90% of patients had successful retraining of regressed left ventricle.

Sivakumar et al. in his study reported that ductal stenting in two 3-month-old patients improved indexed left ventricular mass from 18.9 to 108.5 g/m^2 and left ventricular free wall thickness from 2.5 to 4.8 mm, within three weeks.[19] This study showed noticeable improvement in LV mass index from 33.00(32.00-34.00) g/m^2 to 63.00(61.00-65.00) g//m^2 and left ventricular free wall thickness from 3.00(3.00-3.00) mm to 4.00(4.00-4.00) mm within 2 weeks.

TGA was typically identified at the newborn stage in developed nations. However, due to lack of diagnostic facilities in developing countries including our region Pakistan, Afghanistan and India these patients get delayed attention when the prime time of management has been passed. Because the risk of ASO rises significantly after first few weeks of age when the LV involutes, the best course of treatment for a patient presenting with TGA-IVS beyond that time is still up for debate. The prognosis for these patients, which depends on the LV's capacity to sustain systemic circulation after surgery, remains unclear.

Classically LV retraining was done by various surgical methods including Pulmonary artery banding and BT shunt/Cavopulmonary shunt. Due to risk and associated complications with redo surgery[20], including huge financial implications, prolonged hospital stay, trauma of surgery and significant interstage mortality, transcatheter palliation for LV retraining is becoming standard of care, because of less invasive, affordable, effective with short hospital stay compared to classical surgeries for LV retraining before ASO. In this way our study will play a significant role for optimal management of these late presenters for LV retraining before ASO.

In patients with TGA-IVS, this study assessed the effectiveness of PDA stenting in retraining the regressed left ventricle. In 90% patients, echo-cardiographic parameters had been significantly improved. The results emphasized transcatheter ductal stenting is a useful, an efficient and approach for LV retraining.

LIMITATIONS OF THE STUDY

This study was limited by small sample size, financial implications and limited resources which may have affected the generalizability of results. We did not include the course and outcome of ASO after ductal stenting. Future studies should address these aspects to provide a more comprehensive evaluation of PDA stenting in LV retraining.

CONCLUSION

Transcatheter ductal stenting was an effective and safe method to retrain the regressed LV in late presenters of TGA-IVS. Mostly patients had a favorable outcome after stenting, which improved left ventricular mass index and LV geometry significantly. Most notably, it is a nonsurgical, less intrusive technique with less turbulent post procedural course, which makes it a desirable substitute of traditional surgical LV retraining.

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Authors' Contribution

AU, NS & AM: Concept and Study design, data interpretation, drafting the manuscript, final approval of the version to be published.

MAF & MI: Critical Review, data acquisition and analysis, Drafting the manuscript, Data acquisition, Data interpretation, final approval of the version to be published.

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