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Research Article

Role of Balloon Pulmonary Valvuloplasty in Symptomatic Infants with Tetralogy of Fallot Awaiting Intracardiac Repair

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Abstract

Background and aim: Mortality risk in tetralogy of Fallot (TOF) is highest in infancy, predominantly due to hypercyanotic spells. Timing of corrective surgery is centre/expertise dependent and surgical shunt procedures carry high mortality risk. We tried to study the efficacy and feasibility of balloon pulmonary valvuloplasty (BPV) in TOF physiology children, as an alternative to surgical shunt, in those infants who were severely cyanosed (saturation < 75%) or having recurrent spells and who were still awaiting intracardiac repair (ICR). The primary objective was to assess the following parameters pre and post BPV: resting saturation, Z score of pulmonary annuli by 2D Echocardiography, right ventricular outflow tract (RVOT) gradient, hypercyanotic spell frequency. Secondarily we looked at the modified Nakata index (MNI), any procedural complications, requirement of early shunt or ICR (within study period).

Materials and Methods: This was a single arm interventional study done over a period of one year. Values pre and post intervention were compared using Wilcoxon matched pair signed rank test and Chi-square test for categorical variables as appropriate. Independent groups were compared using Mann Whitney U test. The children were followed up for a period of 6 months post procedure.

Results: After enrolling 10 infants, data could be studied in 9 of them. 1 child was lost to follow up. Significant improvement was noted in saturation, size of PA annulus, RVOT gradient, MNI (p value < 0.05 each). 2 patients had access site thrombosis which resolved with heparin. 1 had transient complete heart block which resolved within 24 hrs but required temporary pacing. There was no mortality and none had more than mild pulmonary regurgitation. Out of 5 children who presented with recurrent spells, 2 were completely free of spells after BPV, 2 had spells with reduced frequency/duration, 1 continued to have spells needing surgical intervention. (p = 0.36). Apart from this child who needed surgery, one other patient remained severely cyanotic and had to undergo a shunt procedure.

Conclusion: To conclude, BPV seems like a safe and cost-effective alternative to high-risk surgical shunt palliation in symptomatic TOF infants, in resource constrained regions.

Keywords: tetralogy of fallot, cyanosis, hypercyanotic spells, balloon pulmonary valvuloplasty

Introduction

Tetralogy of Fallot (TOF) is the commonest cyanotic congenital heart disease (CHD). Modern surgery in congenital paediatric cardiology, has its roots in palliation and correction of this defect. Over the past five decades, there has been a notable improvement in our understanding of the anatomy of TOF and advancements in surgical facilities. As a result, there has been a significant shift towards performing total correction of the condition at an earlier age. In developed countries, medical centres routinely carry out repairs during the neonatal period. According to the Society for Thoracic Surgeons (STS) database, 89 Percent sign (of patients underwent intervention before their first year of life. Among these procedures, systemic-to-pulmonary artery (PA) shunts accounted for 9.5 Percent sign (of total TOF procedures, with 87.7 Percent sign (of these shunts performed before the age of three months [1]. In contrast, a study conducted by the International Quality Improvement Collaborative

for Congenital Heart Disease (IQIC), which collects data from 22 low- and middle-income countries (LMICs) including India, revealed that 54 Percent sign of patients underwent surgery after their first year of life. Systemic-to-PA shunts were performed in 9.2 Percent sign of patients, with only 17 Percent sign of these shunts performed before three months of age. The median age at which shunt surgery was done was 1.2 years [2]. Therefore, there is a significant disparity in the quality of care provided. The systemic to PA shunt is a surgery notorious for its stormy post operative course with mortality around 8 Percent sign as per the IQIC data and 7.5 Percent sign according to STS data [1-2]. In our centre, it is somewhere around 12-15 Percent sign (unpublished data as per 2022 internal census).

The American Association for Thoracic Surgery 2022 consensus statement suggests asymptomatic infants may be operated between 3 and 6 months, at an age which has shown to reduce hospital stays, lower rate of adverse events, and less need for a transannular patch. For symptomatic neonates, both palliation and primary complete surgical correction are considered viable treatment options [3].

However, in a developing nation like ours, there are several factors that contribute to the delay in primary repair. These include the late recognition of the defect or referral, financial constraints, and the overwhelming number of surgical cases that burden the operating facilities. Currently, the Indian guidelines recommend total repair between 6-12 months of age or earlier for stable or minimally cyanosed patients. For symptomatic children under 6 months of age with spells or severe hypoxemia despite therapy, palliation including balloon pulmonary valvuloplasty (BPV) carries a Class I indication [4]. The American Heart Association considers BPV a Class IIb indication for palliation in TOF [5]. In our institution, complete repair has shown favourable outcomes in children above 6 months of age and weighing at least 10kgs.

For this study, we considered a child with resting saturation of less than 75 Percent sign or having recurrent spells to be symptomatic, and who needs immediate palliation.

Materials and Methods:

Study design: Single arm interventional study carried out in a tertiary care centre of north India, conducted over a period of one year (January to December 2023)

Aim: To investigate the role of balloon pulmonary valvuloplasty (BPV) in symptomatic infants with TOF physiology awaiting intracardiac repair.

Primary objective: To compare the following data pre-BPV, immediate post-BPV and at 6 months follow up:

a) Saturation by pulse oximetry

b) Z score of pulmonary annulus diameter (by Echocardiography)

c) Right ventricle outflow tract (RVOT) gradient (by Echocardiography)

d) Hypercyanotic spell frequency

Secondary objective**:** Branch pulmonary artery size assessment by the modified Nakata index (MNI) on follow up, any complications of the procedure, the need for emergency surgery/ intra cardiac repair (ICR) within the 6 month follow up period.

Eligibility criteria:

Any child diagnosed with TOF having:

i. Age less than 6 months or weight less than 10kg and

ii. RVOT obstruction (RVOTO) with thickened pulmonary valves and a pulmonary annulus diameter greater than -3z on echocardiography and demonstrable antegrade flow across the valve and

iii. Presenting resting saturation of < 75 Percent sign or history of at least one episode of hypercyanotic spell despite being on maximum propranolol prophylaxis (4mg/kg/day or greater) and

iv. Who has not been offered ICR in the next 6 months

Exclusion criteria:

i. Predominant infundibular RVOTO with normal appearing pulmonary valves on echo

ii. Ventricular dysfunction

iii. Pulmonary annulus hypoplasia (z score < -4z)

iv. Active infection or high risk for cardiac anaesthesia

v. Coagulopathy or thrombocytopenia Less-than sign 50,000/cumm

Consent and ethical justification: Informed written consent was taken from parents of all children. The study was approved by the institutional ethics committee.

Sample size: Since the study was targeted at a rare cohort of cyanotic CHD, the sample size was taken as 10.

Statistical analysis: Values were expressed as median and range by Interquartile range, (IQR). Statistical analysis was performed using the analysis tool pack of Microsoft Office Excel™ and IBM SPSS ver. 26 software. Since the sample size was small, nonparametric tests of significance were applied. Values pre and post intervention were compared using Wilcoxon matched pair signed rank test and Chi-square test for categorical variables as appropriate. Independent groups were compared using Mann Whitney U test. P values Less-than sign 0.05 were considered as statistically significant

Procedure:

1. Saturation was recorded in the right upper limb using an FDA approved portable pulse oximeter in a sleeping/ non agitated child.

2. Weight was recorded in kilogram (Kg) using a weighing scale accurate to one hundredth of a gram and length was taken in the lying position using an infantometer and recorded in centimetre (cm). The body surface area (BSA) was calculated using the Mosteller formula [BSA = {length(cm) x weight(kg)/3600}1/2] and mentioned in m^2.

3. Echocardiography was done on a Philips EPIQ 7C machine with a phased array 8MHz/ 12 MHz probe. The echocardiographer was blinded to the interventional procedure details and to the baseline values while recording follow up values. The children were sedated with oral melatonin agonist, triclofos. The measurements were made in systole from leading edge to leading edge in the suprasternal short axis view in the case of the right pulmonary artery (RPA) and the suprasternal left anterior oblique view angling to the left in the case of the left pulmonary artery (LPA). Both sizes were recorded at the widest pre-hilar area. The modified parasternal long axis (PLAX) view i.e. by tilting the probe towards the pulmonary artery from a standard PLAX view was employed for the pulmonary valve annulus and was calculated in a similar manner at the lower most level of the pulmonary valve hinge point. The RVOT gradient was measured using a continuous wave Doppler in the same view [12]. The Z scores for all the values were obtained from Boston Children's Hospital z score calculator (https://zscore.chboston.org/)

4. The modified Nakata index (MNI) was calculated as per the formula [π (RPA^2 + LPA^2)/4]/BSA; LPA and RPA diameter being in mm and BSA in m^2 [11].

5. The child was admitted one day prior/ at clinical indication and routine hemogram, renal function tests and coagulogram were performed as per standard pre-anaesthesia checkup requirements.

6. BPV was performed under IV sedation and with general anaesthesia back up. The child was sedated with a combination of intravenous ketamine and midazolam.

7. Both right femoral artery and vein access were taken. A 4 Fr sheath was used for the artery and a 5 Fr sheath for the vein. Unfractionated heparin was given at a dose of 100IU/kg to keep the activated clotting time > 200s. A 5 Fr Judkins right 3.5R guiding catheter was placed in the right ventricle for hemodynamic measurements and angiography using hand contrast injection.

8. A coronary floppy tipped 0.014''wire was then passed across the stenotic pulmonary valve and parked distally in the left pulmonary artery. An appropriate size balloon was then chosen, which was approximately 100-140% of the measured pulmonary annulus diameter (measured on echocardiography). In case of severe stenosis graded dilatation was performed initially with smaller coronary non-compliant balloons followed by calculated, size appropriate Tyshak mini balloon.

9. Improvement in saturation was noted immediate post procedure and on 6 month follow up. Modified Nakata index (MNI), RVOT gradient, pulmonary annulus growth and growth of pulmonary artery and its branches in terms of z score and frequency of hypercyanotic spells were recorded at 6 month follow up.

Results:

A total of 10 patients were taken up as part of the study, in order of presentation, to the out-patient department. The data was recorded in a pre-determined proforma. Demographic details are as per **Table 1.**

Ser no.	Age (months)	Sex	Weight (kg)	Length (cm)	BSA (m^2)
Pt 1	9	Male	6	69	0.34
Pt 2	2	Female	3.7	56	0.24
Pt 3	7	Male	4.5	63	0.28
Pt 4	9	Male	5	65	0.3
Pt 5	12	Male	8	80	0.42
Pt 6	8	Female	5	65	0.3
Pt 7	8	Male	6.5	72	0.36
Pt 8	7	Female	5.2	62	0.3
Pt 9	6	Male	7	74	0.38
Pt 10	8	Male	4.5	62	0.28

Table 1: Demographic profile of the patients

The age ranged from 2 months to 12 months and there were a total of 7 male and 3 female infants enrolled in the study. The median weight was 5.1 kg (IQR 4.5Kg - 6.125Kg), length 65 cm (IQR 62 cm– 72.5 cm) and BSA 0.3 m2(IQR 0.28 m2 - 0.365 m2).8 patients were having classical TOF as the cardiac morphology, 2 had TOF like physiology with one infant having dextro-transposed great arteries (D-TGA), VSD, PS (Pt 4) and the other having double outlet right ventricle (DORV), VSD, PS (Pt 10). The median and IQR values of study characteristics are as per **Table 2.**

Ser no.	Diagnosis	Spell frequency	Pre-BPV saturation (%)	RVOT gradient (mmHg)	PA annulus (Z score)	MNI (mm^2/m^2)
Pt 1	TOF	Daily	58	90	-2.3	58
Pt 2	TOF	Daily	70	85	-3	44
Pt 3	TOF	Nil	65	72	-3.1	90
Pt 4	D-TGA, VSD, PS	Nil	58	65	-2.5	188
Pt 5	TOF	Daily	60	85	-2.7	152
Pt 6	TOF	Daily	63	95	-1	283
Pt 7	TOF	Nil	58	88	-2.4	127
Pt 8	TOF	Nil	60	68	-2.7	97
Pt 9	TOF	Nil	62	72	-2	217
Pt 10	DORV, VSD, PS	Weekly	62	75	-2.1	158
			Median= 61 IQR = 58 to 63.5	Median = 80 IQR = 71 to 88.5	Median= -2.3 IQR = -2.7 to -1.8	Median=139.5 IQR = 82 to 192.25

Table 2: Baseline values of study characteristics

BPV was performed either directly with Tyshak mini/ Tyshak II balloons (6 patients) or, in a graded fashion, with coronary noncompliant balloon initially followed by Tyshak balloons (4 patients). The median balloon size used in the study was 120% of the PA annulus estimated on echocardiography.

Follow up:

Out of the 10 children who underwent the procedure, one patient (Patient 2) was from a remote location of the country and could not report physically for follow up. 2 patients (Patients 4 & 5) were referred to the CTVS department and underwent surgical intervention because of continued severe cyanosis within one month of procedure. Hence, though data for analysis was available in the immediate post BPV period for all 10 children, only 7 could be analysed in the scheduled follow up at 6 months.

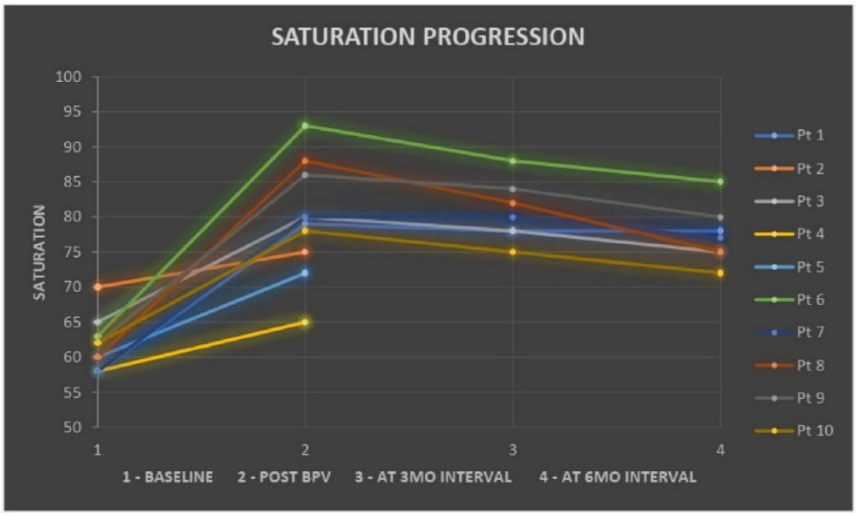
Saturation and RVOT gradient:

There was noted improvement in the saturation and RVOT gradient post BPV (recorded 24hrs after the procedure). The improvement was statistically significant with 2 tailed p values as shown in **Table 3.**

Name	Pre - BPV saturation (%)	Post – BPV Saturation (%)	P value	Saturation 6mo (%)	P value	Pre-RVOT gradient (mmHg)	Post-RVOT gradient (mmHg)	P value	RVOT gradient 6mo (mmHg)	P value
Pt 1	58	79		78		90	60		75	
Pt 2	70	75	***0.005***	LFU	***0.018***	85	70	***0.005***	LFU	***0.018***
Pt 3	65	80		75		72	62		70	
Pt 4	58	65		Sx		65	60		Sx	
Pt 5	60	72		Sx		85	70		Sx	
Pt 6	63	93		85		95	50		65	
Pt 7	58	80		77		88	50		69	
Pt 8	60	88		75		68	55		65	
Pt 9	62	86		80		72	50		64	
Pt 10	62	78		72		75	60		68	

Table 3: Saturation and RVOT gradient comparison after BPV (Sx – Surgery; LFU – Lost to follow up)

There was a gradual reduction in the saturation gained post procedure on follow up at 6 months (**Figure 1**). Similarly, the RVOT gradient was also noted to increase on subsequent visits **(Figure 2).**



(Note: - Pt 2, 4, 5 could not be evaluated on scheduled follow up)

Figure 1: Line diagram depicting the improvement in saturation post BPV followed by the gradual drop on follow up

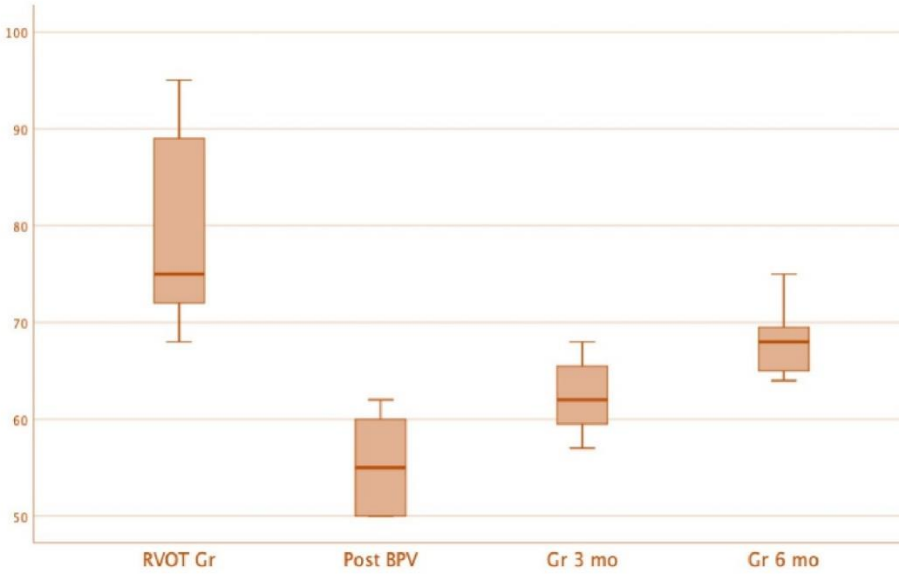


Figure 2: Box and whisker plot of RVOT gradient evolution with BPV

PA annulus, MPA and MNI:

The growth of PA annulus, diameter of MPA, RPA and LPA were monitored by echocardiography on follow up and the modified Nakata Index (MNI) was calculated as per body surface area (BSA). Both PA annulus and MNI achieved statistical significance at the end of 6 months follow up period **(Table 4).**

Name	PA annulus Z score	PA annulus Z score 6mo	P value	MNI (mm^2/m^2)	MNI (mm^2/m^2) 6mo	P value
Pt 1	-2.3	-2.1		58	164	
Pt 2	-3	LFU	*0.018*	44	LFU	*0.018*
Pt 3	-3.1	-3		90	193	
Pt 4	-2.5	Sx		188	Sx	
Pt 5	-2.7	Sx		152	Sx	
Pt 6	-1	-0.6		283	370	
Pt 7	-2.4	-1.9		127	154	
Pt 8	-2.7	-2.6		97	144	
Pt 9	-2	-1.8		217	246	
Pt 10	-2.1	-1.8		158	189	

Table 4: Growth of pulmonary annulus and branch pulmonary arteries (as calculated by MNI) (Sx – Surgery; LFU – Lost to follow up)

As mentioned earlier patients 2, 4 & 5 couldn't be evaluated on follow up and out of the 7 that were followed till the end of 6 months, only 1 (Patient 8) didn't achieve the theoretical target MNI of > 150 mm^2/m^2, which is a predictor of good outcome post corrective surgery **(Figure 3).**

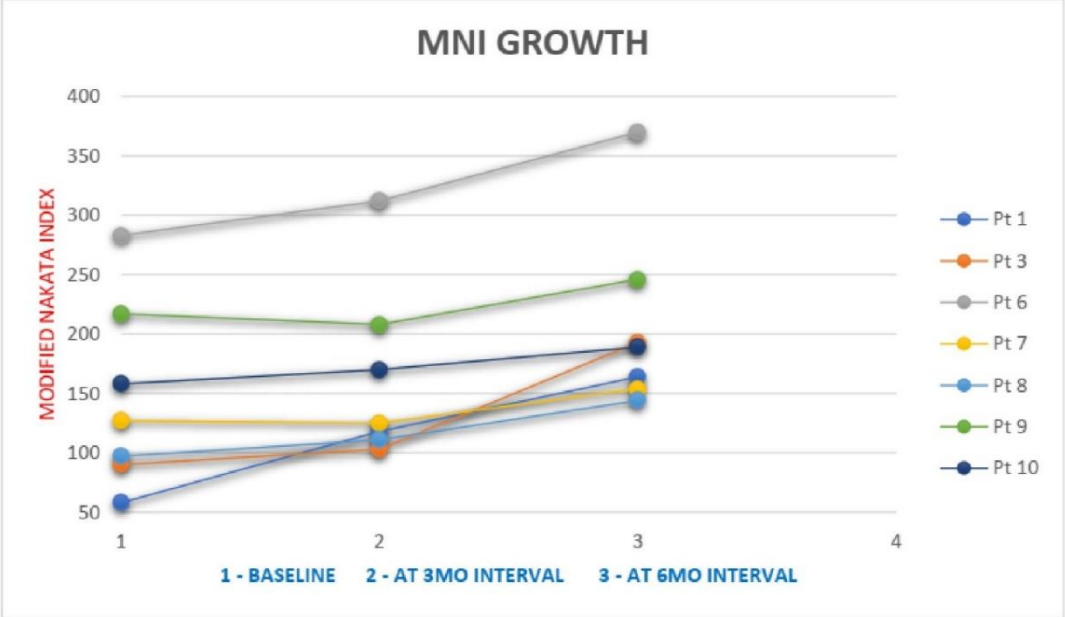


Figure 3: Line diagram of growth of branch pulmonary arteries as calculated by MNI over time

Hypercyanotic spells:

Out of the 10 patients enrolled in the study, 5 patients gave history of hypercyanotic spells (patients 1, 2, 5, 6, 10) despite being on propranolol prophylaxis at the maximum tolerated dose. Out of these, 2 patients (6, 10) were spell free at the end of 6 months follow up. Patients 1 & 2 reported a reduction in frequency of spells from multiple times daily to weekly once/ twice and lasting for a lesser duration than earlier (Patient 2 was telephonically followed up for reasons mentioned earlier). Patient 5 continued to have spells as usual and underwent surgical intervention. Considering termination of spells as the end point, the p value was not statistically significant (p = 0.36131).

Complications and adverse outcomes:

Of the 10 patients who underwent BPV, 3 had complications without any long-term effects (**Table 5**). None of the patients developed significant pulmonary regurgitation (PR) and there was no mortality in the study.

Patient	Complications	Therapy	Final outcome
Pt 1	Nil		
Pt 2	Nil		
Pt 3	Nil		
Pt 4	Nil		
Pt 5	Nil		
Pt 6	Nil		
Pt 7	Right femoral artery spasm	No drugs	Improvement in less than 24 hrs
Pt 8	Nil		
Pt 9	Transient complete heart block	Temporary pacing for 24hrs, steroids	Resolved in 24hrs
Pt 10	Thrombosis of right femoral artery	Low molecular weight heparin	Resolved in 72hrs

Table 5: Complications noted in the study

Discussion:

Our study showed significant improvement in saturation and RVOT gradient in the immediate post BPV period as well as at follow up of 6 months (p value Less-than sign 0.05 each). The findings are similarly evident in multiple studies, beginning with, Qureshi et al in 1988 where they found systemic arterial oxygen saturation improved from a mean value of 75 Percent sign to a mean of 87 Percent sign (p Less-than sign 0.05) after dilatation. The mean RVOT gradient also reduced from an earlier value of 70 mmHg to 64 mmHg [6]. Slyusmans T et al in 1995 in their publication in Circulation journal found that after balloon dilatation, systemic oxygen saturation increased from a mean value of 79 Percent sign to 90 Percent sign [7]. Similar statistical improvement in saturation were also noted by Remadevi et al, Wu E et al and Muneuchi J et al [8-10]. This goes to suggest that there is irrefutable evidence that BPV improves saturation in a case of TOF albeit for a temporary duration.

The growth of PA annulus, MPA growth, branch PA growth in terms of z scores and modified Nakata index (MNI) showed similar trajectories. At the end of 6 months adequate growth was visualized with final dimensions achieving p value of Less-than sign 0.05 in each category. Out of the 7 patients that were followed up till 6 months, only 1 patient (patient 8 – 144 mm^2/m^2) didn't achieve an eventual value Greater-than sign 150 mm^2/m^2. As per Nakata et al's paper, an index of less than 150 mm^2/m^2 predicts higher rate of mortality in a post repair case of TOF [11]. Similar outcomes in terms of Z scores were obtained in the study by Remadevi et al where the Z score for the pulmonary annulus improved from -5.59 ±1.04 to - 4.31 ± 1.9 (p=0.018), mean Z score of hilar right pulmonary artery (RPA) increased (p = 0.001), mean Z score of hilar left

pulmonary artery (LPA) increased (p = 0.005) on a follow up period of around 2 years [8]. In a study of 23 neonates with TOF who underwent elective primary pulmonary valvuloplasty by M Leye et al in Montreal, Canada, they found that Nakata index increased from a mean of 115.12 ± 39.67 mm2/m2 to 174.51 ± 93.74 (p = 0.57) at the time of surgery [12]. In a study from Pusan National University Children's Hospital, Republic of Korea, Dr G Kim et al were able to compare outcomes of BPV with BT shunt and Infundibulectomy in TOF and their association with requirement of transannular patch (TAP) at surgery. They found that PV annulus growth was much greater in the BPV group and the infundibulectomy group compared to that in the BT shunt group and the BT shunt group was associated with a greater need of TAP than the other two groups [13]. In terms of hypercyanotic spells, though the end result was not statistically significant (p = 0.36), the eventual improvement in saturation as mentioned earlier could be an indicator of improved left to right shunt. The concern regarding spells has been addressed by Slyusmans et al in 1995, where they opined that BPV does not prevent cyanotic spells, and surgery is recommended if increasing cyanosis is not responding to propanolol therapy after the procedure [7].

We had one femoral artery spasm, one transient artery thrombosis and one transient heart block. None had permanent deleterious effects and none had more than mild PR. In the study by Godart F et al, 33 patients underwent BPV out of which 4 patients had transient arrhythmia during inflation (atrial tachycardia in 2; bradycardia in 1 and complete heart block in 1) [14]. In other studies complications like RVOT perforation and pericardial tamponade have been mentioned [8].

Limitations: To begin with, the sample size was small and statistical derivations are based on nonparametric tests. The study being a single arm interventional study has biases inherent to the design. Though the echocardiographer was blinded to the procedure, the echocardiographic values themselves are prone to lot of intra-observer variations. Nakata index being an angiographic determined value, echocardiographic derivatives are prone to errors.

Conclusion:

To conclude, BPV is a safe procedure for palliation in TOF children who are severely symptomatic and awaiting corrective surgery in a resource limited country like ours. This study, like others previously, has shown that BPV can yield satisfactory improvement in saturation of children with suitable anatomy and aid in growth of the pulmonary artery and its branches. This will definitely help in surgical outcomes later on. Whether a transannular patch can be prevented remains to be seen. The absolute number of patients being small in this study, it is difficult to assign a recommendation at this point of time. However, a larger dataset would have helped in better correlation of statistical outcomes. What this study lacked, was the follow up effect on quality of life these patients and their parents experienced post procedure. May be a questionnaire on the same would have brought out these invaluable aspects. But a, once irritable, severely cyanosed child, getting transformed into a cheerful infant is a sight to behold!

List of abbreviations

TOF – Tetralogy of Fallot

CHD – Congenital Heart Disease

STS – Society of Thoracic Surgeons

IQIC - International Quality Improvement Collaborative

LMIC – Low Middle Income Countries

BPV – Balloon Pulmonary Valvuloplasty

RVOT - Right Ventricular Outflow Tract

MNI – Modified Nakata Index

ICR – Intra Cardiac Repair

RVOTO – Right Ventricular Outflow Tract Obstruction

IQR – Interquartile Range

IBM – International Business Machine

SPSS – Statistical Package for the Social Sciences

FDA – Food and Drug Administration

BSA – Body Surface Area

RPA – Right Pulmonary Artery

LPA – Left Pulmonary Artery

PLAX – Parasternal Long Axis

Fr - French

D-TGA – Dextro-Transposition of Great Arteries

DORV – Double Outlet Right Ventricle

VSD – Ventricular Septal Defect

PS – Pulmonary Stenosis

CTVS – Cardio Thoracic and Vascular Surgery

TAP – Transannular Patch

PR - Pulmonary Regurgitation

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