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ORIGINAL ARTICLE

Feasibility of Pulmonary Valve Balloon Dilation as Palliative Procedure in Children With Symptomatic Tetralogy of Fallot

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Abstract

Background/Aim: Tetralogy of Fallot (TOF) is the most prevalent cyanotic congenital heart disease, for which surgical correction remains the definitive treatment. Balloon dilatation of the pulmonary artery provides recognised immediate palliative benefits in selected TOF patients. Nonetheless, optimal patient selection and midterm outcomes remain subjects of ongoing debate. This study aimed to assess midterm results following pulmonary valvoplasty at 6 months period in children with TOF focusing on defining factors that affect response to palliative therapy.
Methods: A retrospective study assessed 25 children with TOF who underwent transcatheter balloon dilatation of pulmonary valve over 5 years period. Three parameters were used to assess the palliative effect of the procedure including: oxygen saturation, pulmonary artery size and body weight, all of which measured before and 6-month post Cath. Besides, the effect of patients age, sex and presentation on palliative effects was done.
Results: Of the 25 children who subjected to palliative procedure, three patients died within 24 hours. At 6 months follow-up remnant 22 children demonstrate significant improvements in oxygen saturation, pulmonary size and body weight ($p < 0.001$). Children older than one year had significantly higher weight and pulmonary size than infants ($p = 0.002$, $p = 0.001$), respectively. Children with spells and cerebrovascular accident (CVA) had significantly higher weight than those with spells only ($p = 0.040$).
Conclusion: Transcatheter balloon valvuloplasty is an effective palliative intervention for children with TOF with excellent midterm outcomes for those who survived the first day. Older children and presentation with CVA indicated higher response.

Key words: Pulmonary valve; Dilatation; Cyanotic spells; Tetralogy of Fallot.

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Introduction

Tetralogy of Fallot (TOF) remains the most prevalent cyanotic cardiac defect with right ventricle outflow tract (RVOT) and pulmonary valve (PV) pathology largely defines its clinical course.[1, 2] Corrective surgery remains the definite therapy for patients with TOF that are usually implemented at 6-9 months with majority of younger children offered palliative intervention in advance to surgery with stenting of patent ductus arteriosus, RVOT or dilatation of PV.[3] These transcatheter approaches aim to reduce gradients across the RVOT, augment forward pulmonary flow and

raise systemic oxygen saturations while avoiding or delaying surgical shunts or early complete repair.[4, 5]

Pulmonary valve valvoplasty (PVV) is predominantly offered when obstruction is valvular which results in short term symptoms relieved.[6] However, it carries inherent risks of complications including cyanotic spells, arrhythmias, RVOT perforation and death.[7] With recent advances in cardiac transcatheter interventions in low resource countries, PVV is increasingly offered to children with TOF as palliative relief for valvular pulmonary stenosis.[8, 9] Although the procedure has been attempted since 1987 with historical and contemporary series show immediate improvement, large debate exists regarding midterm and long-term efficacy, safety and related complications.[6]

This study aimed to assess midterm results following pulmonary valvoplasty at 6 months period in children with TOF focusing on defining factors that affect response to palliative therapy.

Methods

A retrospective study included children with symptomatic TOF who were subjected to transcatheter balloon dilation of PV as palliative procedure. The study was conducted at the Iraqi Centre for Cardiac Diseases, Medical City Complex Baghdad-Iraq over 5 years period from March 2019 till April 2024.

The inclusion criteria included: (1) children presented with cyanotic spells not responding to medical therapy and/or (2) developing severe polycythaemia with a complication of stroke and (3) in families who refused the corrective surgery.

All included children were subjected to echocardiographic assessment before, during and after intervention to assess the degree of stenosis, PV annulus before the intervention and for residual pressure gradient and degree of PV regurgitation after intervention and for any complication and using echocardiographic for follow up as the PV annulus. In addition, the oxygen saturation of patients in pre- and post-balloon dilation.

In all cases, patients were admitted one day prior to procedure and kept on continuous intravenous fluids with at least 6 h of fasting. In Cath lab, two lines were inserted femoral artery and vein then five or sixth French pigtail in right ventricle and right ventricular (RV) angiogram was done with biplane view lateral and the anterior tube was 35 cranial angulation some time may need some right anterior oblique (RAO) and left anterior oblique (LAO) tilting for good pulmonary artery visualisation. Heparin was administered intravenously in dose 50-100 U/kg prior to RV angiogram.

Attempting was done to cross the PVV by either straight Teramo wire 0.35 mm or 21 straight guide wire after that 5 or 6 fr Judkin right catheter the exchange guidewire used. Choice of balloon according to PV annulus was made and best to be used was short balloon which was 20 mm in length to be away from the infundibulum and to inflate only the annulus. It was necessary to observe the saturation, electrocardiogram (ECG) and RV angiogram to look for response to balloon dilation and for early detection of spell. After completing the procedure, the child was referred to ward with close monitoring for all vital parameter for early detection of any complications.

Next day, patients were discharged home after echocardiographic assessment and establishing medical therapy as propranolol hydrochloride (*Inderal*) tablet and iron therapy according to weight with follow up after one month, 3 months and 6 months. Three parameters were evaluated on follow up of the patients at 6 months period following the procedure including peripheral oxygen saturation (SpO_2) (%), pulmonary artery (PA) size and body weight.

Results

A total of 25 patients were recruited to study after matching inclusion criteria. The age ranged from 15 days to 15 years with majority (48 %) were in the 1-5 years and the male to female ratio was 1.3:1. Most cases were presented with cyanotic spells only (68 %), with fewer having "Spell + cerebrovascular accident (CVA)" (32 %). The outcome was favourable in most cases, with survival documented in 88 % of patients (Table 1).

The majority (17 cases) had isolated small pulmonary artery, 6 cases had other cardiac pathology

Table 1: Clinical and demographical characteristics of the study sample (n = 25)

Variable	N	%
Age groups (years)		
< 1	4	16
1-5	12	48
> 5	9	36
Sex		
Female	11	44
Male	14	56
Condition		
Spell	17	68
Spell + CVA	8	32
Previous palliative surgery		
BT shunt	6	24
No previous intervention	19	76
Outcome		
Death	3	12
Survival	22	88
Total	**25**	**100**

CVA: cardiovascular accident; BT: Modified Blalock-Taussig-Thomas shunt;

together with small pulmonary artery including: two cases of obstructed a modified Blalock-Taussig-Thomas (BT) shunts, two cases with previous excision of right ventricle outflow tract (RVOT) and subsequent severe stenosis and one case for each of atrioventricular sepal defect (AVSD) and left pulmonary artery (LPA) osteal stenosis. Normal size PA for age was reported in 2 cases only, as seen in Figure 1.

Significant improvements were observed in all three parameters after 6 months. SpO_2 increased markedly from 47.91 to 88.77 (p = 0.0001), indicating improved oxygenation. Weight also increased significantly (from 16.85 to 20.25) and PA size increased from 10.33 to 11.81 (p < 0.001), reflecting both physical growth and likely positive clinical response to treatment or intervention (Table 2).

Table 2: Difference in peripheral oxygen saturation (SpO_2) (%), weight (kg) and pulmonary artery (PA) size (mm) before and after 6 months (n = 22)

Variable	Before	After 6 months	p-value
SpO_2 (%)	47.91 ± 7.18	88.77 ± 2.68	< 0.001
Weight (kg)	16.85 ± 15.69	20.25 ± 16.35	< 0.001
PA (mm)	10.33 ± 2.47	11.81 ± 2.63	< 0.001

Values are presented as mean ± standard deviation (SD); SpO_2: peripheral oxygen saturation; PA: pulmonary artery size;

Table 3: Gender-based comparison of study parameters at 6-months follow up

Variable	Male (n = 12)	Female (n = 10)	p-value
SpO_2 (%)	88.33 ± 3.42	89.30 ± 1.41	0.440
Weight (kg)	22.87 ± 19.11	17.10 ± 12.54	0.400
PA (mm)	12.45 ± 2.75	11.05 ± 2.40	0.200

Values are presented as mean ± standard deviation (SD); SpO_2: peripheral oxygen saturation; PA: pulmonary artery size;

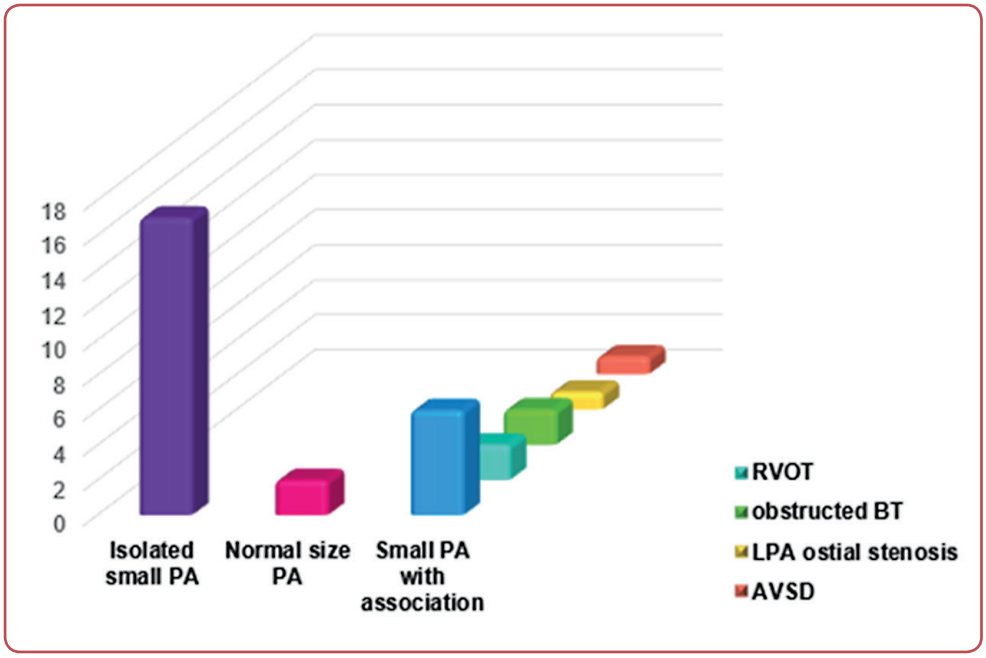

Figure 1: Distribution of pulmonary artery size and associated conditions
AVSD: atrioventricular sepal defect; BT: Blalock- Taussig shunt; LPA: left pulmonary artery; PA: pulmonary artery;

Table 4: Age -based comparison of study parameters at 6-months follow up

Variable	< 1 (n = 3)	1-5 (n = 11)	> 5 (n = 8)	p-value
SpO_2 (%)	88.33 ± 1.15	88.18 ± 3.02	89.75 ± 2.55	0.400
Weight (kg)	8.46 ± 1.80	12.73 ± 1.58	35.00 ± 20.02	0.002
PA (mm)	8.96 ± 0.65	10.90 ± 1.46	14.13 ± 2.60	0.001

< 1: younger than 1 year of age; Values are presented as mean ± standard deviation (SD); SpO_2: peripheral oxygen saturation; PA: pulmonary artery size;

There were no statistically significant sex-based differences in SpO_2 levels, weight, or PA size after 6 months. Although males showed slightly higher mean values in all three parameters that these differences were not significant (Table 3).

SpO_2 levels after intervention did not significantly differ among age groups (p = 0.400). However, significant differences were observed in both weight (p = 0.002) and PA size (p = 0.001) after 6 months. Older children (> 5 years) had notably higher mean weight and larger PA size compared to younger age groups, indicating age-related growth and vascular development (Table 4).

Table 5: Clinical presentations-based comparison of study parameters at 6-months follow -up

Variable	Spell	Spell and CVA	p-value
SpO_2 (%)	88.50 ± 2.87	89.25 ± 2.43	0.500
Weight (kg)	14.93 ± 9.04	29.55 ± 22.24	0.040
PA (mm)	11.07 ± 1.95	13.11 ± 3.28	0.100

CVA: cardiovascular accident; Values are presented as mean ± standard deviation (SD); SpO_2: peripheral oxygen saturation; PA: pulmonary artery size;

Comparative analysis based on presentation reveals a significant difference in body weight after six months, with patients in the spell and CVA group demonstrating a higher mean weight (29.55 ± 22.24 kg) compared to those in the spell-only group (14.93 ± 9.04 kg) (p = 0.04), while there were no significant differences in SpO_2 (p = 0.500) and PA size (p = 0.100) after 6 months across the different clinical conditions (Table 5).

Discussion

The study demonstrated significant benefits of transcatheter balloon dilatation of pulmonary artery in TOF children, as on follow up at 6 months there was significant improvement of oxygenation, pulmonary artery size and weight of the patients. The improvement was affected by age and presentation of the patients as children older than 1 year had significantly higher improvement in body weight and PA size than infant. Children presented with spells and CVA had significantly higher improvement in body weight than children with spells only. The sex of the children did not affect the response to the procedure. Children suffering from cyanotic congenital heart disease with pulmonary oligemia including TOF were suggested as a candidate for palliative effect of balloon pulmonary dilatation to augment pulmonary blood flow with improving systemic hypoxaemia. However, it was recommended that only selected candidates should be offered this intervention including those unfit for total surgical correction.[10]

Although total corrective surgery is still the gold standard approach for children with TOF, many children die without surgical correction due to being unfit for open surgery, complex anatomy, or family refusal of surgery. Management with modified BT shunts was the most employed palliative procedure. Recently, it has been increasingly getting out of date with rising use of PA dilatation, RVOT and PDA stenting.[11] Transcatheter balloon dilatation of pulmonary artery is increasingly offered to those children with promising results documented all over the world. In addition, their short hospital stays and less complication rate makes it appealing choice for many centres.

Since 1980, several case series reported the use of pulmonary valvoplasty in children with TOF with variable success rates and outcomes.[5, 12] Although the average success rate is documented to be 60 to over 90 %, the definition of success varies among studies, with some adopting immediate reduction in pulmonary pressure across PV while others rely on long term outcomes mainly the need for corrective surgery.[13, 14] In the current study, 22 children out of 25 (88 %) who underwent the procedure showed significant improve-

ment in pulmonary artery size, oxygen saturation and body weight at 6-months follow up when compared to pre procedure period. This high success rate aligns with case series reported previously in other parts of the world.[13]

Three children died within 24 hours following the ballon valvoplasty that was attributed to resistant cyanotic spells. In literature, death following balloon dilatation of pulmonary artery had unclear aetiology and incidence. Acute lung injury was reported as a cause of death in adult patients,[15] while in children the mortality is attributed usually to resistant hyper-cyanotic spells, perforation of RVOT, sepsis, endocarditis, complete heart block.[16, 17] However, in high resource countries, the procedure carries excellent results with zero death rate even in infancy.[18]

Cyanotic spells following balloon valvoplasty has been a raising concern and largely attributed to infundibular spasm. This serious complication was behind recommendation to limit the procedure to paediatric cardiologist highly expertise in interventional catheterisation.[19] Despite advances, this complication remains largely unpredictable and resulted in death or needs for early corrective surgery 2.

The study is limited by small sample size and retrospective nature which subjects the results to possible bias. However, it adds to our knowledge about midterm outcomes of pulmonary balloon valvoplasty in low-middle income countries with Iraq as an example where limited resources can stand as an obstacle for early corrective surgery for children diagnosed with TOF.

Conclusion

Transcatheter balloon valvuloplasty is an effective palliative intervention for children with TOF with excellent midterm outcomes for those who survived the first day. At six-month follow-up, children with TOF subjected to this intervention showed a significant increase in body weight, arterial oxygen saturation and pulmonary artery dimensions.

Ethics

The Ethics Committee of Mustansiriyah University issued the study approval, decision No (IRB 91), dated 22 September 2025.

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None.

Conflicts of interest

The authors declare that there is no conflict of interest.

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Data access

The data that support the findings of this study are available from the corresponding author upon reasonable individual request.

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