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Trans-Catheter Palliation in Tetralogy of Fallot Patients: Complications & Challenges

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ABSTRACT

Objective: To identify the complications of Transcatheter palliation in Tetralogy of Fallot patients.
Study Design: Analytical Cross-sectional study.
Place and Duration of Study: Paediatric Cardiology Department, AFIC/NIHD, Rawalpindi Pakistan, from Jul to Dec 2022.
Methodology: This Analytical Cross-sectional study was conducted in n=54 patients of Tetralogy of Fallot (TOF) who underwent Transcatheter palliation procedure. Cases were selected by using non-probability consecutive sampling. Patients with isolated pulmonary stenosis, complex congenital heart and Tetralogy of Fallot with pulmonary atresia were excluded from the study. Data was entered and analyzed by using SPSS version-24:00. In descriptive statistics, Mean±SD were calculated for continuous variables while frequency (%) for categorical variables. To find out the association between categorical variables, Chi-square test was used. *p*-value of <0.05 was taken as statistically significant.
Results: Out of 54 patients, 32(59.3%) were males and females were 22(40.7%). Mean age was 11.87±7.34 months. Right ventricular outflow tract ballooning was done in 39(72.2%) and right ventricular outflow tract stenting was done in 15(27.8%) patients. Transient arrhythmias 28(51.9%) were the most commonly encountered complications.
Conclusion: Transcatheter palliation is becoming the first line of management in Tetralogy of Fallot patients because of better outcomes, ease of performance and safety profile. Working professionally can yield a safe invasive procedure of balloon pulmonary valvotomy and stenting in these patients.

Keywords: Complications, Pulmonary ballooning, Stenting, Tetralogy of Fallot.

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INTRODUCTION

Tetralogy of Fallot (TOF) is the most common cyanotic congenital heart disease.[1-3] Many of these patients become symptomatic at a young age and the treatment options range from early complete repair, surgical palliation, in the form of modified Blalock-Taussig (BT) shunt and Transcatheter palliation in the form of Balloon Pulmonary Valvotomy (BPV) and Right Ventricular Outflow Tract (RVOT) stenting.[4,5] Different centers have different approach for these patients and it depends upon the availability of resources, skill and personal experience.[6] However, palliation is required in certain patients who don't have surgically correctable anatomy or there is a delay in surgery.[7,8]

Transcatheter palliation includes BPV, RVOT stenting and ductal stenting. BPV was introduced in 1980s for the first time in TOF patients.[1] First successful RVOT stenting was reported in 1990s.[2]

Transcatheter palliation has been promising in the management of TOF patients for providing the optimal interim care.[9] Certain complications have been described in association with these procedures.[10] Most of the complications are minor ones, and can be managed easily. Transient arrhythmias, cyanotic spells, bleeding from the puncture site are the minor complications. Major complications include sepsis, endocarditis, perforation, complete heart block and stent fracture or embolization. Many patients are not the candidates for early total surgical correction and there are multiple factors responsible for that. Transcatheter palliation carries significant importance in the management of these patients.[10]

Since the procedure is done quite routinely, we wanted to share our experience about the safety profile and complications encountered in these interventions.

METHODOLOGY

This Analytical Cross-sectional study was conducted at Paediatric Cardiology Department, Tertiary Cardiac Care Center Rawalpindi, from July to December 2022 after the approval from Institutional Ethical Review Board under letter no. (IERB 9/2/R&D /2022/213). Study was conducted by selecting patients from the Paediatric database using non-probability consecutive sampling.

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Sample size of 54 was calculated using WHO sample size calculator by taking 3.4% prevalence of Congenital Heart Defects out of 10,000 live births, at 95%Confidence level and 5% Margin of error.[12]

Inclusion Criteria: Patients of TOF of any age requiring palliation for RVOT stenosis.

Exclusion Criteria: Patients with isolated pulmonary stenosis, complex congenital heart diseases including pulmonary stenosis with other diagnosis and TOF with pulmonary atresia.

Tetralogy of Fallot, which includes ventricular septal defect, overriding of aorta, pulmonary stenosis and right ventricular hypertrophy. Transcatheter palliation procedure includes pulmonary valve, ballooning and right ventricular outflow stenting. Complications include mortality and morbidity (like thrombosis, sepsis, bleeding).[1]

Study was conducted on consecutive patients who met inclusion criteria after getting the consent. Anonymity of the patients was maintained and patient's data was kept confidential.

Patients with TOF who underwent catheter-based intervention in the form of balloon dilatation or stenting of RVOT. All patients were admitted in the hospital and underwent complete evaluation with detailed echocardiography, ECG, blood tests for the anesthesia fitness. Families were counselled and informed about the procedure, risks and possible complications and outcomes.

Patients were accessed through femoral vein to inferior vena cava to right atrium and right ventricle. Right heart catheter with guide wire was used to access the RVOT. Pulmonary balloon size was estimated with the help of pulmonary valve annulus. Balloon sizes were taken in the range of 1.4-1.6:1 ratio of pulmonary valve. RVOT stenting was done in patients with infundibular stenosis. Surgical backup was available for any possible intervention to deal with the complications.

All the cases were done under general anesthesia. All the procedural details were noted down. Complications were taken into account and addressed according to the institutional protocols. Patients were monitored in the post catheterization ICU for any complications and course of recovery. Vital signs, oxygen saturation, catheter site, limb perfusion, blood gas analysis, x-rays and echocardiography were continuously monitored.

Data was entered and analyzed by using Statistical Package for the Social Sciences (SPSS) version 24:00. For descriptive statistics, Mean±SD were calculated for continuous variables while frequency (%) for categorical variables. To find out the association between categorical variables, Chi-square test was applied. *p*-value of ≤0.05 was taken as statistically significant.

RESULTS

Out of 54 patients who underwent RVOT palliation, 32(59.3%) were males and 22(40.7%) were females. Mean age and hospital stay of the study participants was 11.87±7.34 months and 31.75±14.19 hours, respectively. RVOT ballooning was done in 39(72.2%) of the patients while 15(27.8%) patients underwent RVOT stenting. 36(66.7%) patients had hospital stay between 9-30 hours, 15(27.8%) had 31-50 hours, 3(5.6%) had 71-90 hours (Table-I).

Table-I: Demographics and Procedural Parameters of Study Participants (n=54)

Variables		Frequency(%)
Age (months/year) Mean±SD		11.87±7.34
Gender	Male	32(59.3)
	Female	22(40.7)
ITC Stay (hours) Mean±SD		31.75±14.19
Procedure	RVOT Ballooning	39(72.2)
	RVOT Stenting	15(27.8)
Hospital Stay (Hours)	9-30	36(66.7)
	31-50	15(27.8)
	51-70	0(0)
	71-90	3(5.6)

Complications were divided into minor and major. Perforation, death, stent displacement, pulmonary edema and sepsis were considered as major complications and others as minor complications. Out of minor complications, transient arrhythmias 28 (51.9%) were the most prevalent, while pulmonary edema 6(11.1%), cyanotic spell 5(9.3%) and sepsis 5(9.3%) were the most prevalent major complications. Fever occurred in 12(22.2%) of patients and responded to simple management. Increased bleeding from the catheter site was observed in 7(13.0%) of patients. Venous thrombosis was observed in 6(11.1%) of patients. More than one complications were observed in study participants (Table-II).

2(66.7%) patients developed fever of longer duration and were found to have evidence of infection, in the form of increased CRP and WBC count. These patients had prolonged duration of admission but responded to broad spectrum antibiotics (Table-III). Cyanotic spell during the procedure was improved with adequate ventilation, IV fluids and bicarbonate

therapy. One of the patients had displacement of the RVOT stent and could not be retrieved even with surgical exploration. One patient required second intervention in the form of RVOT stenting after inadequate ballooning. One patient had stent dislocation into the right pulmonary artery (RPA) but was eventually retrieved and brought back into the RVOT and was placed successfully with the help of larger sized balloon. One patient died of accompanying sepsis. None of the patients developed pericardial effusion or perforation.

Table-II: Frequency of Post-Procedural Complications

	Complications	Frequency (%)
Minor	Bradycardia	15(27.8)
	Tachycardia	13(24.1)
	Fever	12(22.2)
	Bleeding	7(13.0)
	Thrombosis	6(11.1)
Major	Pulmonary edema	6(11.1)
	Sepsis	5(9.3)
	Cyanotic spell	5(9.3)
	Stent displacement	1(1.9)
	Death	1(1.9)
	Perforation/Pericardial effusion	0(0)

Table-III depicts relationship of complications with in-hospital stay and it didn't show any significant association of In-hospital stay with minor or major complications (p>0.05).

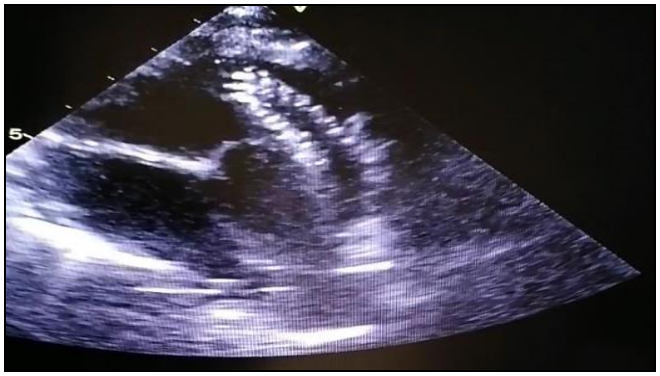
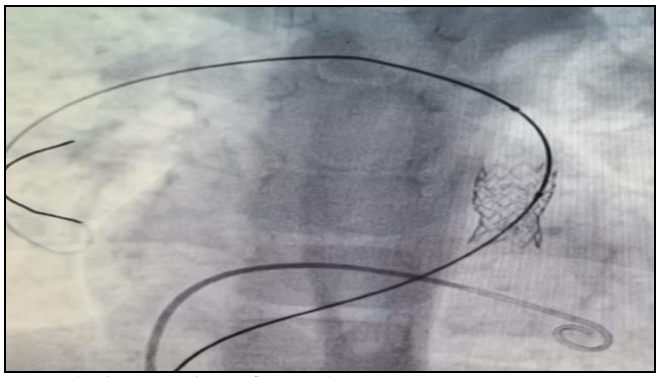


Figure-1: RVOT Stent Echocardiographic Image
RVOT (Right Ventricular Outflow Tract)



RVOT (Right Ventricular Outflow Tract)
Figure-2: RVOT Stent in-situ Angiographic Image

DISCUSSION

TOF being the most common cyanotic CHD is frequently seen in clinical practice. Since there are certain limitations for the early complete repair, we

Table-III: Relationship of in-Hospital stay with Complications (n=54)

Complications		In-Hospital Stay (Hours)			
		9-30 (n=36) Frequency (%)	31-50 (n=15) Frequency (%)	71-90 (n=3) Frequency (%)	p-value
Bradycardia	No	25(69.4)	12(80.0)	2(66.7)	0.72
	Yes	11(30.6)	3(20.0)	1(33.3)	
Tachycardia	No	28(77.8)	12(80.0)	1(33.3)	0.20
	Yes	8(22.2)	3(20.0)	2(66.7)	
Cyanotic spell	No	33(91.7)	14(93.3)	2(66.7)	0.32
	Yes	3(8.3)	1(6.7)	1(33.3)	
Sepsis	No	33(91.7)	13(86.7)	3(100.0)	0.72
	Yes	3(8.3)	2(13.3)	0(0)	
Thrombosis	No	32(88.9)	13(86.7)	3(100.0)	0.79
	Yes	4(11.1)	2(13.3)	0(0)	
Pulmonary edema	No	32(88.9)	14(93.3)	2(66.7)	0.40
	Yes	4(11.1)	1(6.7)	1(33.3)	
Fever	No	28(77.8)	12(80.0)	2(66.7)	0.87
	Yes	8(22.2)	3(20.0)	1(33.3)	
Stent Displacement	No	35(97.2)	15(100.0)	3(100.0)	0.77
	Yes	1(2.8)	0(0)	0(0)	
Bleeding	No	31(86.1)	14(93.3)	2(66.7)	0.43
	Yes	5(13.9)	1(6.7)	1(33.3)	

encountered these patients with indications of early palliation. We are not in practice of doing the surgical BT shunt commonly in our setup and Transcatheter intervention is the preferred approach to address these patients. Many local institutions are performing the Transcatheter palliation in TOF cases but there are limited published studies on this subject. We found in our study that some patients had complications and most of them were minor complications, and only few had major complications.

Our study included 54 patients while another study in our institution had 301 patients and included all the TOF cases for diagnostic and interventional angiography.[11] Transient arrhythmias were the most common unwanted event in our study seen in 28(51.9%), while the blood flow abnormalities were the most common events in that study.[11] Transient arrhythmias were reported in small number of patients in other studies as well.[1,10]

Fever and sepsis were seen in small number of patients in our patients which is in accordance to previous studies as well.[10] Pulmonary edema was noted in 6(11.1%) of our patients which is more than the previously reported.[9] All of these patients improved with immediate measures which included use of diuretics, steroids, fluid restriction and respiratory management.

Bleeding and thrombosis were seen in 7(13.0%) and 6(11.1%) of cases respectively which were reported earlier in our institution.[13]

Cyanotic spells were noted in 5(9.3%) of cases, which correlates with earlier studies.[14-16] Stent displacement and death were the least encountered complications, which was similar to the previous studies.[16-18] We didn't encounter perforation or pericardial effusion in our subset of patients, which was reported by other studies.

In general, we found statistically insignificant proportion of complications in our patients. Previous work in this field also enlightens us about the safety of the procedures in skilled and well equipped institutions. Many institutions consider Transcatheter palliation as a first line for such subset of patients.

LIMITATIONS OF STUDY

We did not include the patients of PDA stenting in our subset and we did not have the control group in our study. This study has some limitations such as it was conducted in just one center and it was Cross-sectional study.

CONCLUSION

Transcatheter palliation is becoming the first line of management in the patients of TOF like physiology because of better outcomes, ease of performance and safety profile. Working professionally can yield a safe invasive procedure of balloon pulmonary valvotomy and stenting in TOF patients.

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Conflict of Interest: None.

Authors' contribution

Following authors have made substantial contributions to the manuscript:

MAF & NS: Study concept, Study design, Manuscript writing, Proof reading

AS & A: Data analysis, Critical review, Study concept, Data collection, approval of the final version to be published.

AA: Manuscript writing, Data collection, Proof reading, 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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