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Transcatheter Palliative Balloon Pulmonary Angioplasty in Symptomatic Patients with Tetralogy of Fallot and its Outcome at Tertiary Care Setting

Ahsan Ali Shaikh, Nadeem Sadiq, Muhammad Rashid Hasnain, Imrana Ata, Naseem Ullah, Saqlain Anwar

ABSTRACT

Objective: To analyze transcatheter palliative balloon angioplasty's safety, efficacy, and clinical outcomes by a single operator in symptomatic Tetralogy of Fallot (TOF) patients in tertiary care.

Study Design and Setting: This is a case series study. It was carried out at the Pediatric Cardiology Department PNS SHIFA Karachi and the Armed Forces Institute of Cardiology (AFIC/NIHD) Rawalpindi, Pakistan, from November 2022 to May 2024.

Methodology: This study selected patients from the pediatric database using non-probability consecutive sampling. A sample size of n=30 was taken. Symptomatic infants of TOF requiring palliation for (right ventricular outflow tract) RVOT obstruction were included and infants with predominant valvular narrowing and those not fulfilling the criteria of TOF were excluded. Data was entered and analyzed by using SPSS version-24:00. In descriptive statistics, Mean ± SD was calculated for continuous variables while frequency (%) for categorical variables. The Chi-square test was used to find out the association between categorical variables, p-value of <0.05 was taken as statistically significant.

Results: Out of 30 patients, 11(37%) were males and females were 19(63%). The median age was 24 months. Immediate improvement in saturation was noted in all patients and transient arrhythmias 5(16%) was the most encountered complication.

Conclusion: Transcatheter palliative balloon angioplasty is becoming the first line of treatment for patients with Tetralogy of Fallot due to its physiologic improvement in blood flow to the lungs and reciprocal increase in saturation. It is safe and requires much less hospital stay in a professionally sound environment.

Keywords: Balloon Angioplasty, Congenital Heart Disease, Palliative Treatment, Tetralogy of Fallot, Transcatheter Intervention.

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INTRODUCTION

Tetralogy of Fallot (TOF) is the most common cyanotic congenital heart disease accounting for 7-10% of all congenital heart diseases.[1] It includes ventricular septal defect (VSD), overriding of the aorta, pulmonary stenosis, and right ventricular hypertrophy.

Associations of TOF are with 22q11 microdeletions, trisomy 21, Alagille's syndrome, Cat Eye syndrome, or CHARGE and VATER associations. The severity of symptoms depends upon the right ventricular outflow tract (RVOT) obstruction. Many symptomatic young infants are treated by either the complete surgical repair or by the palliative methods early in their life. The mainstay of treatment for patients with TOF is complete surgical repair and it has long-term survival rates of more than 90% after 25 years of surgery.[2] Despite these impressive outcomes, access to timely surgical repair remains a challenge in resource-limited settings, highlighting the critical role of interim palliative measures. Early intervention can mitigate life-threatening hypoxemic spells and improve overall clinical stability in affected infants.[3]

As more patients with repaired Tetralogy of Fallot reach

adulthood, the long-term effects of isolated, surgically induced pulmonary valvular insufficiency or insufficiency and mild stenosis (as is more typical with smaller transannular patches) are still being defined. A to-and-fro murmur at the left sternal border is present in many patients following tetralogy repair and in all patients undergoing transannular patch repairs.[4] Patients with more severe or prolonged pulmonary valve insufficiency may also develop tricuspid regurgitation when the tricuspid valve annulus dilates. A holosystolic murmur at the lower left sternal boundary will occur in these patients. While smaller degrees of residual obstruction typically do not require reintervention, patients with a moderate to severe residual gradient (stenosis) across the right ventricular obstruction typically require surgery. The pulmonic listening post, located on the left upper sternal border, is the ideal place to hear the quiet, high-pitched, early diastolic decrescendo murmur caused by pulmonic regurgitation.[5]

Palliative methods are kept reserved for those patients who are not fit for open surgery.[6] A study of the data showed that the most important element was the medicine dose rather than the patient's age. Results have improved so much over the last 60 years that with repair surgery, almost 95% of neonates with this condition should live to adulthood. As an alternative to the surgical technique of a modified Blalock-Taussig shunt to promote pulmonary artery growth in cyanotic children with tetralogy of Fallot, right ventricular outflow tract (RVOT) stenting has surfaced recently.[7] Palliative methods include surgical palliation in the form of modified Blalock Taussig BT-shunt and transcatheter palliation in the form of Balloon Pulmonary Angioplasty and RVOT stenting.[8] Transcatheter Balloon Pulmonary Angioplasty is the standard method of emergency treatment of RVOT obstruction and has decreased the postoperative hospital stay and shown good results of growth of pulmonary valve and arteries.[9-11] Balloon angioplasty facilitates the anterograde pulmonary blood flow and enhances oxygen saturation at its standards by promoting the growth of pulmonary arteries.[10] The procedure involved the use of a balloon inserted through a guide wire and the balloon is set at the narrowest portion of the pulmonary stenosis and is inflated by low pressure.[11]

However, every procedure has its side effects, so some are minor ones ranging from bleeding from a punctured site, arrhythmias (tachycardia and bradycardia), infundibular spasm, pulmonary edema, etc.[13] In experienced centers, careful patient selection and adherence to procedural guidelines have minimized the incidence of complications, reinforcing the value of balloon angioplasty as a viable palliative approach. We have routinely practiced balloon angioplasty in symptomatic young infants with TOF. This study aimed to assess the immediate results of percutaneous balloon angioplasty in symptomatic infants diagnosed with TOF in a tertiary-care setting.

METHODOLOGY

This case series study was conducted at the Pediatric Cardiology Department, Tertiary Cardiac Care Center PNS SHIFA/AFIC, from November 2022 to May 2024 by a single operator. The study was conducted by selecting patients from the pediatric database using non-probability consecutive sampling. Inclusion criteria included (1) Symptomatic TOF patients having frequent spells with specifically valvular narrowing, (2) Small Branch Pulmonary arteries, (3) Asymmetrical Pulmonary arteries, (4) Small Left Ventricle, (5) Multiple VSDs. Exclusion criteria included: Patients with predominant infundibular narrowing.

The study was conducted on consecutive patients who met inclusion criteria after approval of parents/ guardians and getting informed written consent. Patients were selected using non-probability consecutive sampling. All symptomatic patients with Tetralogy of Fallot meeting the inclusion criteria were enrolled in the study in the order they presented for treatment at the tertiary care center. No randomization was performed, and every eligible patient who sought medical attention within the study period was included until the sample size was reached.

The sample size of 30 was determined based on the availability of eligible patients within the study period, as well as feasibility constraints. Since this was a case series study, a formal sample size calculation was not performed. Instead, the number was chosen based on prior similar studies in the literature and the expected number of cases presenting to the tertiary care center during the study duration

The study was conducted following ethical guidelines, with approval from the hospital's Ethical review committee. Data and information of patients were kept confidential. All patients were admitted to the hospital after baseline investigations and 2D echocardiography. The procedure was explained in detail to the family with pros and cons. Interventions were performed at the discretion of the attending cardiologist. General criteria for intervening included discrete angiographic stenosis (as opposed to diffuse hypoplasia), typically with a pressure gradient across the stenotic vessel. Elevated central pulmonary artery pressure was a consideration in decision-making but was not necessarily present. Technical considerations, such as balloon type, size, inflation pressure, number of inflations, etc, were at the discretion of the interventional cardiologist. Because balloon inflation pressure was documented selectively, there was insufficient data for robust analysis. In general, our preference is to avoid pulmonary artery stents in this population, particularly in the peripheral branches.

All procedures were done under general anesthesia, and a guide wire was accessed through the femoral vein to the inferior vena cava to the right atrium to the right ventricle to the pulmonary artery. The balloon size was taken by pulmonary valve annulus in the range of 1.5-2:1 ratio of the pulmonary valve. In 2 patients, MAPCAs coiling was also

done in the same setting, 2 patients had branch PAs stenosis as well, so balloon angioplasty of branch Pas was done, and 6 patients required two balloons as after first ballooning there was no substantial increase in flow to pulmonary arteries so larger size balloon was taken with good result. In patients with asymmetrical pulmonary arteries (Figure 1), the balloon angioplasty of the branch pulmonary artery was done (Figure 2,3) with good results. There is severe stenosis as shown in Figure 1. After successful balloon dilation, the waist is disappeared in Figure 2. Post-procedure angiogram image shows patent flow to the left pulmonary artery (LPA) as shown in Figure 3.

These patients otherwise require a modified BT shunt for the growth of pulmonary arteries. All the procedural details were noted down. After the procedure, all 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 was calculated for continuous variables while frequency (%) for categorical variables. To find out the association between categorical variables, the Chi-square test was applied. P-value of =0.05 was taken as statistically significant.

RESULTS

Out of 30 patients who underwent RVOT palliation balloon angioplasty, 11(37%) were males and 19(63%) were females. The median age and hospital stay of the study participants was 24 months (4 months-25 Years) and 24.3±6.2 hours, respectively (Table 1).

We encountered only transient arrhythmias (16%) and cyanotic spells (.06%) in our patients (Table 2). There were no major complications like perforation, pericardial effusion, pulmonary edema, and cardiac arrest during this study.

Table 1: Demographics and Procedural Parameters of Study Participants

Variables	**Frequency**	
Age (months/year) Median	24 months (4m-25yrs)	
Gender	Male	11(37%)
	Female	19(63%)
PICU Stay (hours) Mean±SD	24.3±6.2 hours	

Table 2 Frequency of Procedural Complications

Complications	**Frequency**
Bradycardia	3
Tachycardia	2
Cyanotic spell	2

Figure 1 Showing 2 wires parked in LPA with balloon angioplasty; there is severe stenosis as marked by the narrowing of the middle part of the balloon (waist).

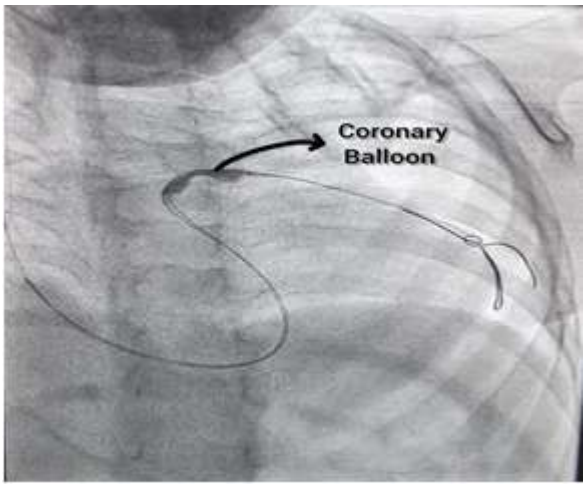


Figure 2 Angiogram showing dilation of balloon with disappearance of waist as it was significant in figure 1

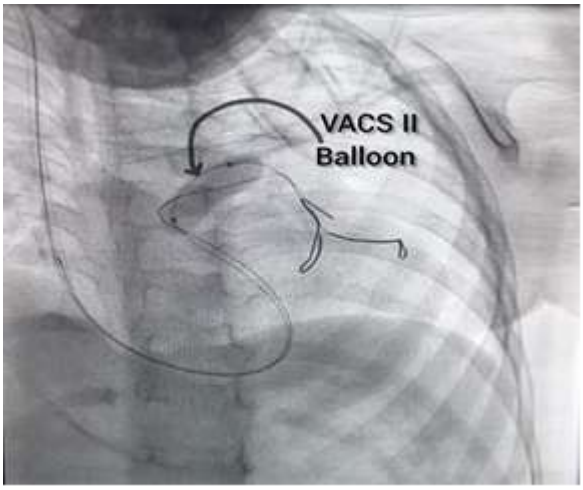
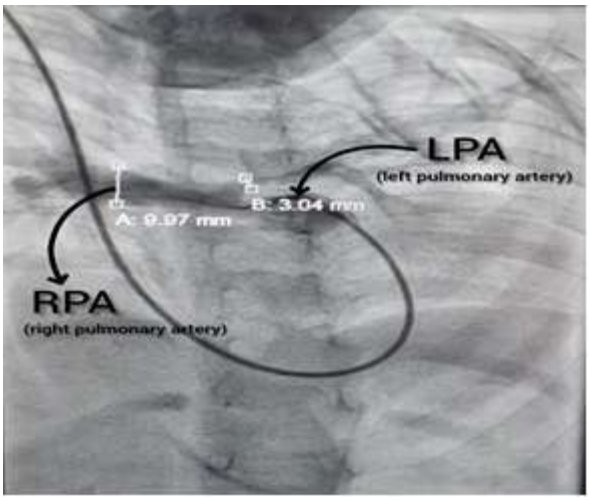


Figure 3 Post-ballooning Angiogram showing good flow to LPA



DISCUSSION:

TOF is commonly observed cyanotic congenital heart disease in clinical practice and surgical repair is done during infancy in most developed centers.[14] However, in our scenario where several reasons result in late surgeries including late diagnosis/referrals, financial constraints, a smaller number of centers/expert hands, etc. In several patients, the anatomy is considered unsuitable for complete repair, requiring palliation to improve the symptoms and underlying pathology as well. A portion of patients will experience symptoms early on and will either receive a full neonatal repair or staged palliation, even if the majority of individuals remain asymptomatic until surgical repair.

Historically, surgical phased palliation which dates back to the original Blalock-Taussig-Thomas (BTT) shunt—was carried out. Although other surgical palliations have been carried out, many patients now receive phased palliations in the catheterization lab before full surgical repair because of advancements in catheter-based technology and outcomes. Patients with TOF can benefit from three common treatments that enable stepwise palliation: patent ductus arteriosus (PDA) stenting, RVOT stenting, and balloon pulmonary valvuloplasty. Selecting an intervention is unique to each patient and institution. A minimally invasive surgery known as balloon valvuloplasty was initially reported for patients with valvar pulmonary stenosis, but it has also been extensively documented in patients with TOF.

Patients with pulmonary valve stenosis or severe narrowing who have TOF may benefit from this. The palliative procedure is usually offered in patients with small pulmonary arteries, neonates with frequent spells, small left ventricles, multiple VSDs, etc. In our centers, we preferred to have transcatheter palliation for these patients rather than going for the surgical option due to multiple reasons including length of hospital stay, financial issues, expert surgical hands, etc. The balloon angioplasty is the best out of all palliation as the immediate results are marvelous in our study with only fewer minor complications. A catheter with a deflated balloon at its tip is introduced into the femoral vein and guided to the location of the pulmonary valve during balloon valvuloplasty. The balloon is positioned and then inflated to widen the constricted valve, which enhances blood flow from the RV to the PA (pulmonary artery). It is usually advisable to have an angiography that displays the valve before proceeding with balloon sizing. The stenotic pulmonary valve's obstruction will be relieved through the treatment, improving blood flow to the lungs. This can help people with symptoms including dyspnea and cyanosis. The stenotic pulmonary valve's obstruction will be relieved through the treatment, improving blood flow to the lungs. In patients with TOF, this helps lessen symptoms including dyspnea and cyanosis. The anesthesia team and the operator need to be prepared for the possibility that the patient may experience a severe episode of hypercyanotic spell during balloon valvuloplasty. Although our team was vigilant and successfully managed such scenarios, we emphasize that pre-procedural planning and immediate access to emergency medications are critical for optimizing outcomes.[15] It is crucial to remember that the suitability of balloon valvuloplasty for patients with TOF depends on several variables, such as the degree of stenosis, the structure of the heart, and the patient's general health. These individuals frequently have other areas of stenosis (typically infundibular blockage), which makes balloon valvuloplasty ineffective in treating their condition.

Transcatheter balloon angioplasty provides a naturally increased pulsatile flow to branch pulmonary arteries with immediate improvement in saturation as in all patients the saturations rose from 40-50% to 80-90%.[16] RVOT stenting is a procedure that is increasingly being used for patients with TOF. The goal of RVOT stenting in patients with TOF is to relieve the obstruction by covering the valvar, supravalvular, and infundibular stenoses; this will all help to improve blood flow from the RV to the PA. After the patient has an RVOT stent placed, the obstruction to the pulmonary circulation is relieved, and it can be managed similarly to other patients with TOF until the full surgical repair is completed. Although RVOT stenting is another transcatheter palliation it has a higher rate of complications and requires antiplatelet therapy after the procedure.[17]

The balloon palliation is considered a more suitable option for patients of TOF as also supported by other published literature on this topic.[18] It not only improves oxygen saturation significantly but also promotes better pulmonary arterial growth, which facilitates later elective repair at low-risk age. Thus, short/medium-term palliation in RVOT ballooning should be considered as the first-line option in patients with TOF with valvular stenosis who are initially considered high risk or not suitable for total correction or those with late presentation as in developing countries. Furthermore, the role of balloon angioplasty in addressing long-term outcomes, such as improved exercise tolerance and reduced complications associated with hypoxic spells, underscores its utility in carefully selected cases.[19] In certain situations in which there is a disparity of branch pulmonary arteries and patients require palliation like BT shunt, we have done balloon angioplasty of selected pulmonary artery, as it can be a feasible option. In our investigation, we discovered that while some patients experienced serious complications the majority of them were minor issues like transient arrhythmias, accounting for 16%. While selecting a patient for balloon angioplasty one must keep in mind that the stenosis is at a valvular level as our patients all have valvular narrowing and the patient with infundibular narrowing do not respond to ballooning and it might be counterproductive in some cases and usually done with RVOT stenting as depicted by existing literature.[20-21]

A small percentage of patients can have a fever, sepsis,

thrombosis, bleeding, and cyanotic spells during balloon angioplasty but we did not have such minor complications in our patients. Other serious complications like pulmonary edema and pericardial effusion can occur during such procedures and patients with pulmonary edema should be managed promptly with diuretics, afterload-reducing agents, fluid restriction, and respiratory care.[22-23] We recommend integrating multidisciplinary teams in managing such complications to ensure swift decision-making and better patient outcomes. In some rare cases, death can be a dreadful complication, but we did not observe any death in our subset of patients.[24]

Despite potential risks, our findings reinforce that balloon angioplasty offers a highly favorable risk-benefit profile, making it a valuable option in resource-constrained settings.[25] We discovered a statistically negligible percentage of minor problems among our patients and overall balloon angioplasty can be considered as a palliative procedure in selected patients as being adapted as a first-line option in many institutions.[26]

CONCLUSION

Palliative balloon angioplasty emerges as a promising and safe intervention for symptomatic patients with Tetralogy of Fallot (TOF), particularly in resource-limited settings or when definitive surgical repair is delayed. Our study highlights its efficacy in improving oxygen saturation and pulmonary arterial growth, with minimal procedural complications, making it an excellent alternative to traditional surgical palliation. By offering immediate physiological improvement and reducing hospital stays, this technique not only stabilizes high-risk patients but also optimizes their candidacy for future corrective surgery. As advancements in interventional cardiology continue, palliative balloon angioplasty may establish itself as the first-line option for managing TOF patients with valvular stenosis, ensuring better short-term outcomes and paving the way for definitive repair at a more opportune time.

Authors Contribution:
Ahsan Ali Shaikh: Conceptualization of Study Design, Writing
Nadeem Sadiq: Research Supervision
Muhammad Rashid Hasnain: Data Analysis and Interpretation
Imrana Ata: Literature Search
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Saqlain Anwar: Data Collection and Analysis

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