

Early Right Ventricular Function after Repair of Tetralogy Of Fallot: An Evidence-Based Study

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ABSTRACT

Background: Tetralogy of Fallot is a significant congenital heart disorder, and understanding its variants is crucial for pediatric cardiology management.

Objectives: This research aimed to compare different surgical techniques that can be used to address RVOT (Right Ventricular Outflow Tract) reconstruction in Fallot Tetralogy repair regarding their influence on Right Ventricular function and immediate postoperative outcome.

Methods: This is a prospective and evidence-based study; 60 children with TOF (Tetralogy of Fallot) were included. The main inclusion criteria are based on the children who undertook total repair between January 2019 and July 2021. Participants were assigned into three groups based on the surgical technique. In Group 1, no Transannular Patching was used; in Group 2A, Transannular Patching alone was used; and in Group 2B, Transannular Patching with mono-cusp construction was used. Moreover, preoperative and early postoperative assessments of Right Ventricular function were performed via pulse wave tissue Doppler imaging and conventional echocardiography. Assiut University's ethical committee granted ethical approval, and participants' informed consent was also obtained to maintain confidentiality and ethical principles.

Results: It was found that the three groups had no significant difference regarding mechanical ventilation time, inotrope duration, chest drain time, and total ICU stay. One month after surgery, RVSD (Right Ventricular Systolic Dysfunction) among Group 1 was observed in 6 patients (30%). Similarly, RVSD was found in Group 2A, with six patients (30%) and 10 patients (50%) in Group 2B. However, by the third month, none of the patients in any group exhibited RVSD. In contrast, RVDD (Right Ventricular Diastolic Dysfunction) was present in 10 patients (50%) in Group 1, 10 (50%) in Group 2A, and 18 (90%) in Group 2B at one month after surgery. In contrast, in the third month, no one in Groups 1 and 2A had RVDD, but it was persistent in eight patients (40%) in Group 2B. The severity of postoperative pulmonary regurgitation was generally increased in Group 2B ($P < 0.001$). IVA was negatively correlated with PRVCW/PVAD at one month ($r = -0.22$; $P = 0.02$) and three months ($r = -0.21$; $P = 0.03$) postoperatively. RV E/E' was positively correlated with PRVCW/PVAD at one month after surgery ($r = 0.61$; $P < 0.001$), while there was no significant correlation after three months.

Conclusions: In this study, pulmonary valve preservation and TAP alone with limited incision techniques had good results regarding RV function and competency of PV. In contrast, TAP had no added value with mono-cusp construction.

Keywords: Children, Echocardiography, Right Ventricular Function, Surgical Techniques, TOF (Tetralogy of Fallot).

1. INTRODUCTION

TOF (Tetralogy of Fallot) accounts for 7%–10% of the total prevalence of congenital heart diseases (CHDs). It is the cause of approximately one-third of CHD cases in individuals aged below 15 years^{1,2}. Typically, it is regarded as the most prevalent CHD, with an occurrence rate ranging from 23 to 63 cases per 100,000 births^{3,4}. However, surgical total repair remains the gold standard for treating TOF. Recent technological advancement plays a major role in enhancing surgical approaches and advances in anesthesia. The advancement and critical care resulted in higher survival rates after surgical correction. The postoperative mortality rate is currently below 2% in developed countries and around 3.6% in developing regions as a result

of these advancements^{5,6}. Moreover, it is essential to develop a comprehensive strategy for repairing TOF that is applicable across various age groups, effectively alleviating the obstruction in the RVOT (Right Ventricular Outflow Tract) to limit the progression of Right Ventricular (Rv) hypertrophy^{7,8}.

Furthermore, several preoperative characteristics can be linked to postoperative low cardiac output and mortality. These encompass anatomical irregularities marked by a diminutive Pulmonary Valve (PV) annulus, severe hypoplasia, or the absence of pulmonary stenosis. Intraoperative factors include the specific surgical approach employed for repair and myocardial oxygen deprivation during cardiopulmonary bypass. Conversely, postoperative factors include acute respiratory failure and chest infection^{9,10}. In addition, the type of surgical technique used for repair also influences RV function. In 1954, TOF surgical correction was reported successfully. Initially, a significant RV (right ventriculotomy) incision was performed, which is close to the VSD (Ventricular Septal Defect). Following that, a Transannular Patch (TAP) was used to expand the PV to relieve the obstruction of the RVOT¹¹. Subsequently, novel surgical approaches such as RVOT blockage reduction VSD transarterial repair without transarterial-transpulmonary and ventriculotomy repair. These techniques help to minimize ventriculotomy and RV function preservation at maximum level¹².

Moreover, it is essential to acknowledge that CMR imaging (Cardiac Magnetic Resonance) is often hailed as the benchmark for evaluating PR (Pulmonary Valve Regurgitation), Right Ventricular (RV) volumes, and RV function, its widespread application faces several glaring shortcomings. However, the exorbitant costs associated with CMR, the long image acquisition time, and post-processing limit its accessibility.¹³ The increasing patient population with repaired TOF (Tetralogy of Fallot) equipped with pacemakers and devices all serve as substantial stumbling blocks. As a result of these formidable challenges, echocardiography stubbornly retains its pivotal position in the ongoing monitoring of patients who have undergone TOF repairs. It not only continues to be an excellent substitute, but it also has the potential to reduce reliance on CMR and make it less necessary^{13,14}. Echocardiography is preferred over cardiac magnetic resonance (CMR) imaging since echocardiography requires less expense and easier access with better patient comfort. The modality is broadly accessible because it conducts noninvasive examinations for immediate visualization that does not require patients to take contrast agents or remain bound to scanners^{9,13,14}. The validation studies between echocardiography and CMR show powerful agreement between their ability to measure ventricular function with volumes, thereby showcasing the reliability of CMR. The observations from echocardiographic testing in specific patient groups provided affirmation to use this tool as an initial cardiac imaging strategy¹⁰.

Therefore, this study mainly focused on evaluating the influence of different types of surgical techniques employed in RVOT reconstruction during the surgical repair of TOF on early postoperative RV function outcomes at three-month follow-ups. This assessment was conducted using PW-TDI (Pulse Wave Tissue Doppler Imaging) and CE (Conventional Echocardiography) to evaluate RV function.

2. Materials and Methods

2.1. Study Design and Period

This study is based on a prospective approach as it helps to evaluate the effect of specific exposure. It was conducted at Assiut University Hospitals, near Assiut in Egypt, between January 2019 and July 2021. This research followed CONSORT principles to enhance reporting clarity and reproducibility of the design. However, clinical trial registration was not performed in the study.

2.2. Inclusion Criteria

In this study, 60 patients afflicted with TOF aged between 10 to 47 months were included. All the participants underwent total repair surgery, adhering to predetermined inclusion and exclusion criteria. Moreover, a surgeon and medical team executed surgical procedures. Additionally, DORV (double outlet right ventricle) with pulmonary stenosis (TOF variant) and TOF with pulmonary stenosis cases were included.

2.3. Exclusion Criteria

The study excluded cases with TOF accompanied by pulmonary atresia or absent pulmonary valve, a common atrioventricular canal, valved conduit repair by primary TOF, or TOF repair performed by other surgeons than the surgeons involved in the study to exclude the personal experience error.

2.4. Study Population

The participants were categorized into three different groups based on the approach employed for the management of the Right Ventricular Outflow Tact-Pulmonary Artery (RVOT-PA) pathway. Group 1 includes cases where no TAP was used. In Group 2A, only TAP intervention was employed. While in Group 2B, a mono-cusp TAP was specifically used as part of the treatment strategy. The surgical group selection depended on intraoperative pulmonary valve annulus Z-score measurements. Since randomization methods were not utilized, the clinical staff made surgical assignments using diagnostic measurements instead of random selection.

2.5. Ethical Approval

The study adhered to the ethical principles as per the Helsinki World Medical Association Declaration, specifically for medical research associated with human subjects. Furthermore, the Medical Ethical Committee of the Faculty of Medicine at Assiut University, Egypt (Study ID Number: 17200175) approved this study. The study protocol was explained to the parents of all participants, a study information sheet was shared with all participants to undertake participation decisions, and participants' informed content was also undertaken.

2.6. Clinical Evaluation

All the study participants underwent a comprehensive assessment, including a collection of demographic data through a detailed history-taking process. Additionally, all participants underwent a thorough clinical examination, with special emphasis on DBP (Diastolic Blood Pressure), SBP (Systolic Blood Pressure), BSA (Body Surface Area), and BMI (Body Mass Index).

The given formula used to calculate the participant's BMI¹⁵

$$\frac{\text{Weight(kg)}}{\text{Height (m}^2\text{)}}$$

Preoperative values of hemoglobin (Hb), hematocrit (HCT), and O₂ saturation were also recorded. Furthermore, a standard 12-lead resting ECG (Electrocardiogram) was conducted for all participants.

2.7. Surgical Technique

A single pediatric cardiac surgeon (Third Author) performed all surgical repairs. A median sternotomy was the standard incision. Afterward, systemic heparinization and aorto-bicaval cannulation CPB (Cardiopulmonary Bypass) was initiated at 30 °C for moderate hypothermia. The aorta underwent cross-clamping, and a cold-blood cardioplegia solution was administered via an antegrade cardioplegia cannula that was mainly inserted into the aortic root. The procedure involved making a right atriotomy, followed by a meticulous resection of any obstructing hypertrophied fibro-muscular bands in the RVOT. The majority of the resection in the RVOT was carried out by accessing it through the right atrium and tricuspid valve. However, in cases where required, additional resection was conducted through the pulmonary valve.

The glutaraldehyde-treated autologous pericardial patch was used to close VSD by using 5-0 polypropylene continuous sutures. Three different surgical approaches were employed for the reconstruction of the RVOT. In Group 1, the procedure did not involve the TAP, and the PV annulus was preserved. In Group 2A, the only intervention employed was TAP. Meanwhile, in Group 2B, TAP with mono-cusp construction was used. A transannular incision was performed during the surgical procedure. Moreover, the primary parameter guiding the decision between Pulmonary Valve Annulus (PVA) preservation and complete repair involving TAP utilization was the PVA Z-value in relation to the predicted norm for the patient's BSA^{16,17}.

In Group 1, the meticulous excision of obstructing fibro-muscular bands in the RVOT, the partially fused commissures were divided to arterial wall back level. The tethered pulmonary valve leaflets were detached from the pulmonary artery wall via preserved annulus to facilitate maximum opening. Subsequent to repeated sizing using Hegar's dilators, if the PVA Z-value was equal to zero or exceeded, the annulus remained intact. Afterwards, a pericardial patch is used to close the pulmonary arteriotomy, relieving the supralvalvar obstruction to achieve the Main Pulmonary Artery (MPA) Z-value of zero. In Group 2, a TAP was used for patients with a PVA Z-value of < zero. From the point of main pulmonary artery bifurcation, a transannular incision was extended, traversing the annulus and continuing onto the infundibulum of the RV for a certain distance below the PVA to ensure the smooth passage of Hegar's dilator, as shown in (Figure 1).

Consequently, the patient's two subgroups in the study were made:

(a) Group 2A (TAP alone): In this group, a transannular patch was applied without mono-cusp construction, and the incision was extended into the infundibulum a few millimeters below the PVA. This extension aimed to maintain the integrity of the infundibulum and mitigate the adverse effects of PR, provided the RV/LV (Right Ventricle/Left Ventricle) ratio remained below 0.7 after repair.

(b) Group 2B (TAP with mono-cusp construction): In this group, the transannular incision was extended further into the infundibulum, addressing the whole extent of the hypoplastic region of the infundibulum. This extension was designed to counteract the adverse effects of resulting PR. The mono-cusp was constructed from a fresh autologous pericardial patch with suitable length and width¹⁶. Intraoperative variables were recorded, including ACC (Aortic Cross-Clamp) time, post-CPB invasive hemodynamic parameters, and CPB time. These parameters encompassed direct measurement of LV and RV pressures, the pressure ratio of RV-to-LV, pressure gradient across the RVOT, and MPA pressure. Furthermore, data on postoperative mechanical ventilation time, inotrope duration, chest drainage duration, and ICU (Intensive Care Unit) stay duration were also recorded.

2.8. Echocardiographic Evaluation

ECG tracing one month postoperatively and three months later. Three transthoracic echocardiographic examinations were performed on all participants. The assessments were performed with the participants positioned both supine and in the left lateral position. An ultrasound device (Esaote MyLab 40 Ultrasound System, Italy) with a PA122 probe (with a frequency range: 5-7.5 MHz Phased-Array Transducer) and a PA240 probe (with a frequency range: 1-4 MHz Phased-Array Transducer), was utilized in accordance to the ASE (American Society of Echocardiography) recommendations¹⁸.

All echocardiographic evaluations were conducted by a single professional pediatric echocardiographer (First Author) who was unaware of the clinical information related to participants. These evaluations encompassed conventional echocardiography and PW-TDI. These techniques served the purposes of diagnosing and quantifying the severity of TOF, measuring cardiac dimensions, and evaluating right ventricular function^{19,20}. The McGoon ratio is used to determine the extent of PA hypoplasia. Descending aorta diameter right above the diaphragm divided by the total of the diameters of the RPA (Right Pulmonary Artery) and LPA (Left Pulmonary Artery) just prior to their branching is known as the McGoon ratio. The McGoon ratio typically ranges from 2.0 to 2.5.²⁰ Using 2 D guided M-mode imaging, which recorded the tricuspid annular motion from apical perspectives, it was possible to estimate the TAPSE (Tricuspid Annular Plane Systolic Excursion). The difference between the end-diastolic and end-systolic locations of the tri-cuspid annulus was used to calculate TAPSE. To determine the RVFAC (right ventricular fractional area change), the difference between the end-systolic and RV end-diastolic areas in the apical 4-chamber image was used.²¹

Furthermore, Conventional Doppler echocardiography was employed to evaluate tricuspid inflow, including the measurement of (E) (peak early diastolic filling velocity), (A) (peak late diastolic filling velocity), the mean E/A ratio, and DT (Deceleration Time). Additionally, PW-DTI was utilized to assess (S') (lateral tricuspid peak systolic annular velocity), (E') (lateral tricuspid early diastolic annular velocity), (A') (lateral tricuspid late diastolic annular velocity), and the mean E/E' ratio in the apical 4-chamber view²². In addition, the RV-MPI (Right Ventricular Global Myocardial Performance Index) was determined using PW-DTI. It was evaluated as the sum of the IVCT (Isovolumic Contraction Time) and IVRT (Isovolumic Relaxation Time) divided by the ET (Ejection Time) within a cardiac cycle²³. However, RV-IVA was determined within the same cardiac cycle. Peak myocardial velocity ratio quantified during isovolumic contraction obtained from tissue Doppler imaging, divided by the AT (Acceleration Time).

In contrast, the RV contractile function quantitative assessment was performed by determining the IVA ratio, designed to remain uninfluenced by variations in RV geometry²⁴⁻²⁶. The postoperative evaluation of PR severity was conducted through color Doppler imaging, which considered parameters such as the proximal jet width (known as vena contracta width, VCW) and jet length as per ASE guidelines²⁷. A jet length of <10 mm is indicative of negligible PR, especially when the regurgitant flow is narrow at its point of origin²⁸. The VCW/PVAD ratio, which represents the ratio of the proximal jet width of PR to the PVA diameter, is a commonly employed semi-qualitative method in color Doppler assessment. This parameter demonstrates reduced dependence on driving pressures, offers simplicity, and exhibits higher reproducibility. When the VCW/PVAD ratio exceeds 0.5, it is associated with severe PR, while ratios ranging from 0.25 to 0.5 indicate moderate PR. Ratios less than 0.25 are indicative of mild PR, as assessed through CMR^{29,30}.

The study categorizes RVD into two types;

(i) (RVSD) and (ii) (RVDD)³¹. RVSD stands for Right ventricular systolic dysfunction, while RVSD stands for right ventricular diastolic dysfunction; RVSD is identified by specific criteria, such as a TAPSE measurement below 10mm, an S' wave velocity less than 10cm/s, an RVFAC value less than 35%, or an IVA value under 1.1 m/s²^{32,33}. The IVA parameter is applied to evaluate the systolic function of RV, as it does not affect due to the loading conditions geometry RV³⁴. RV diastolic dysfunction is assessed using the E/E' parameter³⁵ as an echocardiographic measure of diastolic dysfunction, particularly E/E'^{35,36}, which possesses high sensitivity also and specificity to identify elevated pressures at the right atrial side, which serves as reflections of RVDD^{37,38}.

Right ventricular function at an early stage after surgery was the main primary outcome variable using echocardiographic assessments of TAPSE, RVFAC, IVA, and RV MPI, which were measured at 1 month and 3 months postoperatively.

Right ventricular diastolic dysfunction (RVDD), systolic dysfunction (RVSD) incidence, postoperative pulmonary regurgitation (PR) severity, duration of mechanical ventilation, ICU stay, and residual RVOT gradient with pressure measurements were used as secondary outcome variables.

2.9. Statistical Analysis

SPSS software, particularly the specification of Statistical Package for the Social Sciences, version 20, IBM, Armonk, New York, was utilized for the analysis of collected data. ANOVA and paired t-tests were used to examine quantitative data. The two-tailed tests determined all p-values using a 95% confidence interval as the significance level. The use of two-tailed tests helped researchers examine possible differences existing in either direction between their studied groups. Meanwhile, the mean and standard deviation were calculated for the collected data. However, variables like Age, PV Z value, and others with non-normal distribution were reported via the interquartile range median (IQR) of the collected sample. Using the Chi-

squared (2) test, numbers (n) and percentages (%) of nominal data were calculated. The Pearson coefficient correlation was also applied to assess the association of the included variables. At p 0.05, the significance level was established.

3. Results

A total of 60 participants with TOF were diagnosed. According to their PVA Z-score, 20 (33.33%) participants underwent complete TOF repair with preservation of PV (Group 1), while another 20 (33.33%) received complete repair with the use of TAP (Group 2A). Additionally, 20 (33.33%) more participants had complete repair with a mono-cusp TAP (Group 2B). Importantly, none of these participants had undergone any previous shunt procedures. The progress of all participants in this study was monitored at one month and three months following their surgical procedures.

3.1. Characteristics of the Groups

Table 1 displays the demographic and preoperative data of participants who underwent surgical correction for TOF using three distinct surgical approaches to address the reconstruction of the RVOT. All groups were similar regarding clinical characteristics. A statistically significant difference in the PV Z- mean values was observed between Groups 2A and 2B in comparison to Group 1 (with values of -3.33 ± 1.61 , -4.11 ± 2.13 , and -1.39 ± 2.29 , respectively, $P < 0.05$). Moreover, the participants with PV preservation surgical procedure (Group 1) had a significantly higher mean McGoon's ratio as compared to those required TAP (Groups 2A and 2B; 2.85 ± 0.43 , 2.46 ± 0.38 , and 2.37 ± 0.39 , respectively $P < 0.05$)

Table 1 Demographic and preoperative data of children with tetralogy of Fallot included in the study						
Variables	Group 1 (n = 20)	Group 2A (n = 20)	Group 2B (n = 20)	P 1	P 2	P 3
Gender (male/female)	12 (60%)/8 (40%)	16 (80%)/4 (20%)	14 (70%)/6 (30%)	0.38	0.37	0.34
Age (months)	25.5 [18.3–33.8]	20.0 [12.0–30.0]	24.0 [15.0–31.5]	1.00	1.00	1.00
Weight (kg)	11.55 ± 2.25	10.52 ± 3.69	10.50 ± 2.48	0.72	0.69	1.00
Height (cm)	81.79 ± 7.21	75.40 ± 10.53	76.01 ± 9.31	0.09	0.15	1.00
BMI (kg/m ²)	17.34 ± 2.60	18.43 ± 3.20	18.26 ± 3.25	0.78	1.00	1.00
BSA (m ²)	0.51 ± 0.06	0.46 ± 0.09	0.46 ± 0.46	0.18	0.32	1.00
SBP (mmHg)	92.50 ± 5.64	92.50 ± 3.44	92 ± 6.56	0.06	0.45	0.40
DBP (mmHg)	59 ± 7.53	56.50 ± 4.61	59 ± 2.05	0.41	1.00	0.41
Hypercyanotic spells	10 (50%)	10 (50%)	11 (55%)	0.62	0.22	0.10
Hb (gm/dL)	12.73 ± 1.62	12.33 ± 1.41	12.67 ± 1.44	0.61	0.10	0.09
HCT (%)	39.05 ± 4.75	40.03 ± 3.55	40.09 ± 4.99	0.52	0.34	0.25
O ₂ Saturation (%)	89.60 ± 6.45	89.60 ± 8.09	87.50 ± 8.05	0.78	0.68	0.07
McGoon's ratio	2.85 ± 0.43	2.46 ± 0.38	2.37 ± 0.39	0.01*	< 0.001*	1.00
PVAD (mm)	11.77 ± 3.30	8.79 ± 1.64	8.29 ± 2.36	< 0.001*	< 0.001*	1.00
PV Z-value	-1.5 [-3.0 to 0.0]	-3.4 [-4.8 to -2.2]	-4.2 [-5.3 to -2.8]	0.01*	< 0.001*	0.68
Qualitative variables are expressed as n (%) and quantitative variables as mean \pm standard deviation, median [IQR] BMI: body mass index, BSA: body surface area, SBP: systolic blood pressure, DBP: diastolic blood pressure, Hb: hemoglobin, HCT: hematocrit, PV: pulmonary valve, PVAD: pulmonary valve annulus diameter P1 compares between Groups 1 and 2A, P2 compares between Groups 1 and 2B, P3 compares between Groups 2A and 2B * P < 0.05						

3.2. Operative and Immediate Postoperative Data

Table 2 presents the operative and immediate postoperative data for the study participants. A comparative analysis among the groups revealed that participants in Group 1 exhibited significantly lower ACC time, CPB time, RV pressure, RV/LV pressure ratio, MPA pressure, and PG mean across RVOT compared to Group 2A ($P < 0.05$). Furthermore, the total ACC and CPB times were significantly longer in Group 2B compared to Group 1 ($P < 0.05$). Group 2A presented significantly lower ACC times and significantly higher RV/LV pressure ratios in comparison to Group 2B ($P < 0.05$). Notably, no significant

differences in immediate postoperative data between groups were found.

Table 2 Operative and immediate postoperative data of children with tetralogy of Fallot included in the study						
Variables	Group 1 (n = 20)	Group 2A (n = 20)	Group 2B (n = 20)	P 1	P 2	P 3
ACC time(minute)	79.50 ± 13.70	94.90 ± 12.43	108.60 ± 8.09	< 0.001*	< 0.001*	< 0.001*
CPB time (minute)	142.30 ± 28.11	162.20 ± 25.19	164.60 ± 21.97	0.04*	0.02*	1.00
RV pressure(mmHg)	29.70 ± 6.47	40.70 ± 10.61	35.10 ± 7.92	< 0.001*	0.14	0.12
LV pressure(mmHg)	64.10 ± 7.99	61.50 ± 9.70	65.60 ± 7.28	0.99	1.00	0.38
RV/LV pressure ratio	0.46 ± 0.09	0.66 ± 0.19	0.54 ± 0.15	< 0.001*	0.27	0.03*
MPA pressure(mmHg)	23 ± 3.89	27.60 ± 6.76	26.10 ± 5.93	0.03*	0.26	0.100
PG mean across RVOT(mmHg)	6.0 [3.0–9.0]	12.0 [6.0–19.0]	8.0 [4.0–13.0]	0.04*	1.00	0.34
Ventilation time(hour)	11.30 ± 9.34	12.80 ± 6.78	21.30 ± 6.78	0.81	0.11	0.16
Inotrope duration (hour)	62.10 ± 18.54	66.20 ± 18.81	77.30 ± 25.08	0.54	0.02	0.10
Drain time(hour)	58.80 ± 17.31	62.20 ± 17.35	66.30 ± 18.08	0.54	0.18	0.46
ICU stay(days)	4.0 [3.0–5.0]	4.0 [4.0–5.0]	5.0 [4.0–7.0]	0.32	0.05	0.32
All measures are expressed as mean ± standard deviation, median [IQR] ACC: aortic cross-clamp, CPB: cardiopulmonary bypass, RV: right ventricle, LV: left ventricle, MPA: main pulmonary artery, PG: pressure gradient, RVOT: right ventricular outflow tract, ICU: intensive care unite P1 compares between Groups 1 and 2A, P2 compares between Groups 1 and 2B, P3 compares between Groups 2A and 2B * P < 0.05						

3.3. Echocardiographic Parameters of the RV (Right Ventricle) in the Study Group

Table 3 shows echocardiographic measurements of RV between groups that underwent complete TOF repair, regardless of the surgical approach used to address RVOT reconstruction. Comparisons of preoperative and postoperative follow-up measurements at different times detected a number of significant differences. Moreover, comparisons of TOF preoperative and TOF first month postoperative RV-MPI, tricuspid E velocity, tricuspid E/A ratio, DT, tricuspid E/E' ratio, IVCT, and IVRT were all significantly lower in the TOF preoperative group compared with the other group. However, TAPSE, RVFAC, lateral tricuspid S' velocity, lateral tricuspid E' velocity, lateral tricuspid A' velocity, IVV, IVA, and PVPSV were significantly higher among the TOF preoperative group ($P < 0.05$). A mild-to-moderate degree of PR was detected after one month of surgery (PRVCW/PVAD ratio = 0.27 ± 0.15).

Table 3 Echocardiographic parameters of the right ventricle in the study group						
Variables	Preoperative	1 st month postoperative	3 rd month postoperative	P 1	P 2	P 3
RVD (mm)	10.39 ± 2.21	10.51 ± 2.17	11.45 ± 2.56	0.78	0.01*	0.02*
MPI	0.28 ± 0.04	0.50 ± 0.08	0.43 ± 0.10	< 0.001*	< 0.001*	< 0.001*
TAPSE (mm)	19.30 ± 2.66	13.70 ± 2.74	15.23 ± 2.11	< 0.001*	< 0.001*	< 0.001*

RVFAC (%)	46.75 ± 6.27	34.82 ± 7.27	40.70 ± 6.96	< 0.001*	< 0.001*	< 0.001*
S' (cm/sec)	11.97 ± 1.06	9.20 ± 1.94	10.70 ± 1.64	< 0.001*	< 0.001*	< 0.001*
E (cm/sec)	77.87 ± 15.24	103.43 ± 21.25	95.50 ± 23.56	< 0.001*	0.03*	< 0.001*
A (cm/sec)	70.63 ± 19.29	76.37 ± 19.70	74.23 ± 21.24	0.18	0.32	0.56
E/A	1.17 ± 0.36	1.42 ± 0.39	1.36 ± 0.37	< 0.001*	0.01*	0.34
DT (ms)	95.17 ± 17.84	118.87 ± 17.33	108.17 ± 21.74	< 0.001*	< 0.001*	< 0.001*
E' (cm/sec)	17.13 ± 5.04	12.53 ± 4.22	16.17 ± 4.33	< 0.001*	0.24	< 0.001*
A' (cm/sec)	15 ± 3.87	9.70 ± 3.19	10.17 ± 3.30	< 0.001*	< 0.001*	0.46
E'/A'	1.11 [0.83–1.42]	1.26 [1.00–1.70]	1.49 [1.20–1.90]	0.06	< 0.001*	0.03*
E/E'	4.50 [4.00–5.00]	8.00 [6.00–12.50]	6.00 [5.00–7.00]	< 0.001*	< 0.001*	< 0.001*
IVV (cm/sec)	4.87 ± 0.61	2.55 ± 0.61	3.78 ± 0.56	< 0.001*	< 0.001*	< 0.001*
IVA (m/s ²)	2.68 ± 0.39	1.09 ± 0.29	2.15 ± 0.37	< 0.001*	< 0.001*	< 0.001*
IVCT (ms)	48.47 ± 4.30	61.33 ± 9.05	55.90 ± 7.36	< 0.001*	< 0.001*	< 0.001*
IVRT (ms)	52.33 ± 7.69	63.33 ± 11.38	60.23 ± 10.73	< 0.001*	0.01*	0.09
PVPSV (cm/sec)	438.20 ± 18.60	230.30 ± 56.16	206.90 ± 53.94	< 0.001*	< 0.001*	< 0.001*
PRVCW/PVAD		0.26 [0.15–0.36]	0.30 [0.20–0.49]			0.17
All measures are expressed as mean ± standard deviation, median [IQR]						
RVD: right ventricular diameter, MPI: myocardial performance index, TAPSE: tricuspid annular plane systolic excursion, RVFAC: right ventricular fractional area change, S': lateral tricuspid peak systolic velocity, E: tricuspid peak early diastolic filling velocity. A: tricuspid peak late diastolic filling velocity, DT: deceleration time, E': lateral tricuspid early diastolic velocity, A': lateral tricuspid late diastolic velocity, IVV: peak isovolumic myocardial velocity, IVA: isovolumic myocardial acceleration, IVCT: isovolumic contraction time, IVRT: isovolumic relaxation time, PV: pulmonary valve, PSV: peak systolic velocity, PG: pressure gradient, PR: pulmonary regurgitation, VCW: vena contracta width, PVAD: pulmonary valve annulus diameter P1 compares preoperative and first-month postoperative parameters, P2 compares preoperative and third-month postoperative parameters, P3 compares between 1 st month postoperative and third-month postoperative parameters * P < 0.05						

Consequently, a comparison between TOF preoperative and third-month postoperative outcomes in the groups clarified that RVD, RV MPI, tricuspid E velocity, tricuspid E/A ratio, DT, tricuspid E'/A' ratio, tricuspid E/E' ratio, IVCT, and IVRT were significantly lower in the TOF preoperative group. In contrast, TAPSE, RVFAC, lateral tricuspid S' velocity, lateral tricuspid A' velocity, IVV, IVA, and PVPSV were significantly higher ($P < 0.05$). A moderate degree of PR was detected three months after surgery (PRVCW/PVAD ratio = 0.32 ± 0.24). Furthermore, a comparison of TOF in the first month and third month postoperatively among the groups showed that RVD, TAPSE, RVFAC, lateral tricuspid S' velocity, lateral tricuspid E'

velocity, lateral tricuspid E'/A' ratio, IVV, and IVA were all significantly lower in the TOF in one month postoperatively. In contrast, RV MPI, tricuspid E velocity, DT, tricuspid E/E' ratio, IVCT, and PVPSV were significantly higher ($P < 0.05$). The indices of systolic and diastolic RV function exhibited a general deterioration at the first follow-up, which occurred one month after the operation. Subsequently, these indices showed signs of improvement during the second follow-up three months after operation.

Table 4 shows a comparative analysis of RV echocardiographic measurements among the different groups regarding the surgical approach used to address RVOT reconstruction one month after TOF repair. Notably, Group 1 exhibited significantly lower RV MPI, TAPSE, DT, and IVV while also evaluated significantly higher tricuspid A velocity and PVPSV compared to Group 2A ($P < 0.05$). Contradictory, significantly lower RV MPI, DT, tricuspid E/E' ratio, and PRVCW/PVAD were found in Group 1, and significantly higher lateral tricuspid E' velocity, lateral tricuspid E'/A' ratio, and PVPSV compared to Group 2B ($P < 0.05$). In addition, Group 2A reported a significantly lower tricuspid A velocity, tricuspid E velocity, tricuspid E/E' ratio, and PRVCW/PVAD, and a significantly higher TAPSE and lateral tricuspid E'/A' ratio when compared to Group 2B ($P < 0.05$).

Table 4
Comparison of right ventricular echocardiographic measurements between the different groups one month after TOF repair

Variables	Group 1 (n = 20)	Group 2A (n = 20)	Group 2B (n = 20)	P 1	P 2	P 3
RVD (mm)	9.92 ± 1.82	10.69 ± 1.97	10.92 ± 2.69	0.26	0.14	0.73
MPI	0.46 ± 0.06	0.54 ± 0.08	0.52 ± 0.09	< 0.001*	0.02*	0.31
TAPSE (mm)	12.85 ± 2.05	15.24 ± 3.06	13.02 ± 2.57	< 0.001*	0.83	< 0.001*
RVFAC (%)	36.40 ± 7.85	33.25 ± 6.10	34.80 ± 8.12	0.17	0.48	0.50
S' (cm/sec)	9.60 ± 2.01	9.40 ± 2.37	8.60 ± 1.35	0.74	0.10	0.18
E (cm/sec)	105.30 ± 26.49	94.50 ± 15.57	110.50 ± 19.07	0.09	0.42	0.01*
A (cm/sec)	81.90 ± 20.34	66 ± 13.76	81.20 ± 21.65	< 0.001*	0.90	0.01*
E/A	1.33 ± 0.31	1.47 ± 0.30	1.46 ± 0.55	0.25	0.29	0.93
DT (ms)	107.70 ± 18.02	123.90 ± 15.19	125 ± 14.27	< 0.001*	< 0.001*	0.82
E' (cm/sec)	14.30 ± 4.87	13.40 ± 3.66	9.90 ± 2.88	0.45	< 0.001*	< 0.001*
A' (cm/sec)	8.80 ± 2.34	10.20 ± 3.65	10.10 ± 3.57	0.16	0.19	0.92
E'/A'	1.59 ± 0.51	1.42 ± 0.50	1.09 ± 0.46	0.23	< 0.001*	0.03*
E/E'	8.07 ± 3.63	7.73 ± 3.12	12.33 ± 5.10	0.78	< 0.001*	< 0.001*
IVV (cm/sec)	2.31 ± 0.50	2.84 ± 0.39	2.50 ± 0.80	< 0.001*	0.30	0.07
IVA (m/s ²)	1.11 ± 0.37	1.14 ± 0.22	1.03 ± 0.26	0.76	0.33	0.20
IVCT (ms)	61.50 ± 7.53	61.40 ± 8.51	61.10 ± 11.61	0.97	0.88	0.91
IVRT (ms)	60 ± 8.55	63.60 ± 10.79	66.40 ± 14.32	0.31	0.07	0.43
PVPSV (cm/sec)	262.10 ± 62.96	224.50 ± 54.49	204.30 ± 36.27	0.02*	< 0.001*	0.21
PRVCW/PVAD	0.21 [0.20–0.23]	0.23 [0.20–0.25]	0.32 [0.24–0.49]	0.85	< 0.001*	< 0.001*

All measures are expressed as mean ± standard deviation, median [IQR]

RVD: right ventricular diameter, **MPI:** myocardial performance index, **TAPSE:** tricuspid annular plane systolic excursion, **RVFAC:** right ventricular fractional area change, **S':** lateral tricuspid peak systolic velocity, **E:** tricuspid peak early diastolic filling velocity, **A:** tricuspid peak late diastolic filling velocity, **DT:** deceleration time, **E':** lateral tricuspid early diastolic velocity, **A':** lateral tricuspid late diastolic velocity, **IVV:** peak isovolumic myocardial velocity, **IVA:** isovolumic myocardial acceleration, **IVCT:** isovolumic contraction time, **IVRT:** isovolumic relaxation time, **PV:** pulmonary valve, **PSV:** peak systolic velocity, **PG:**

pressure gradient, **PR**; pulmonary regurgitation, **VCW**; vena contracta width, **PVAD**; pulmonary valve annulus diameter
P1 compares between Groups 1 and 2A, **P2** compares between Groups 1 and 2B, **P3** compares between Groups 2A and 2B
*** P < 0.05**

Table 5 provides a comprehensive comparison of RV echocardiographic measurements among the different groups at the second postoperative follow-up, which occurred three months after the surgical repair. Group 1 showed significantly lower RVD, RV MPI, DT, lateral tricuspid E'/A' ratio, and IVV and significantly higher PVPSV compared to Group 2A ($P < 0.05$). Conversely, Group 1 exhibited a significantly lower RV diastolic dysfunction (RVDD), RV MPI, DT, tricuspid E/E' ratio, IVCT, and PRVCW/PVAD, and significantly higher lateral tricuspid E' velocity, IVA, and PVPSV comparison with Group 2B ($P < 0.05$). Furthermore, Group 2A presented a significantly lower tricuspid E/E' ratio, IVRT, and PRVCW/PVAD, and significantly higher lateral E' velocity, lateral tricuspid E'/A' ratio, and IVA when comparison was done with Group 2B ($P < 0.05$).

Table 5 Comparison of right ventricular echocardiographic measurements between the different groups 3 months after TOF repair						
Variables	Group 1 (n = 20)	Group 2A (n = 20)	Group 2B (n = 20)	P 1	P 2	P 3
RVD (mm)	10.13 ± 1.32	12.29 ± 2.78	11.93 ± 2.94	< 0.001*	0.01*	0.63
MPI	0.37 ± 0.08	0.48 ± 0.08	0.45 ± 0.09	< 0.001*	0.01*	0.21
TAPSE (mm)	14.75 ± 1.51	15.50 ± 2.27	15.90 ± 2.47	0.64	0.08	0.10
RVFAC (%)	40.80 ± 8.31	40.60 ± 8.49	40.70 ± 3.91	0.92	0.96	0.96
S' (cm/sec)	11 ± 1.63	10.70 ± 1.56	10.40 ± 1.84	0.56	0.25	0.56
E (cm/sec)	93.20 ± 19.19	102.30 ± 29.19	91 ± 22.11	0.22	0.76	0.13
A (cm/sec)	67.70 ± 16.12	75.70 ± 19.59	79.30 ± 27.05	0.23	0.08	0.58
E/A	1.42 ± 0.33	1.40 ± 0.37	1.25 ± 0.40	0.81	0.13	0.19
DT (ms)	92.40 ± 21.47	115.60 ± 15.01	116.50 ± 20.52	< 0.001*	< 0.001*	0.88
E' (cm/sec)	16.70 ± 3.47	18.40 ± 4.65	13.40 ± 3.56	0.16	< 0.001*	< 0.001*
A' (cm/sec)	10.70 ± 2.35	9 ± 1.63	10.80 ± 4.96	0.10	0.92	0.08
E'/A'	1.29 ± 0.37	2.01 ± 0.66	1.49 ± 0.96	< 0.001*	0.37	0.02*
E/E'	5.61 ± 0.55	5.55 ± 0.54	7.49 ± 3.91	0.92	0.01*	< 0.001*
IVV (cm/sec)	3.56 ± 0.50	3.99 ± 0.56	3.80 ± 0.57	0.01*	0.14	0.28
IVA (m/s ²)	2.28 ± 0.32	2.26 ± 0.40	1.92 ± 0.32	0.84	< 0.001*	< 0.001*
IVCT (ms)	52.40 ± 5.46	56 ± 6.09	59.30 ± 9.01	0.10	< 0.001*	0.13
IVRT (ms)	59 ± 9.10	57.40 ± 6.09	64.30 ± 14.58	0.62	0.11	0.04*
PVPSV (cm/sec)	242.10 ± 56.24	198.30 ± 48.38	180.30 ± 40.33	< 0.001*	< 0.001*	0.23
PRVCW/PVAD	0.21 [0.20–0.23]	0.22 [0.20–0.25]	0.45 [0.32–0.71]	0.96	< 0.001*	< 0.001*
All measures are expressed as mean ± standard deviation, median [IQR] RVD : right ventricular diameter, MPI : myocardial performance index, TAPSE : tricuspid annular plane systolic excursion, RVFAC : right ventricular fractional area change, S' : lateral tricuspid peak systolic velocity, E : tricuspid peak early diastolic filling velocity, A : tricuspid peak late diastolic filling velocity, DT : deceleration time, E' : lateral tricuspid early diastolic velocity, A' : lateral tricuspid late diastolic velocity, IVV : peak isovolumic myocardial velocity, IVA : isovolumic myocardial acceleration, IVCT : isovolumic contraction time, IVRT : isovolumic relaxation time, PV : pulmonary valve, PSV : peak systolic velocity, PG :						

pressure gradient, **PR**; pulmonary regurgitation, **VCW**; vena contracta width, **PVAD**; pulmonary valve annulus diameter

P1 compares between Groups 1 and 2A, **P2** compares between Groups 1 and 2B, **P3** compares between Groups 2A and 2B

* **P < 0.05**

Consequently, Figures 2 and 3 show the correlations between IVA and PRVCW/PVAD after TOF repair at one month and three months, respectively. IVA was negatively correlated with PRVCW/PVAD at one month ($r = -0.22$; $P = 0.02$) and three months ($r = -0.21$; $P = 0.03$) after TOF surgical repair. In contrast, the correlation analysis of tricuspid E/E' with PRVCW/PVAD after TOF repair at one month and three months revealed a positive correlation at one month ($r = 0.61$; $P < 0.001$) and no significant correlation at three months ($r = 0.07$; $P = 0.56$) as shown in Figure 4.

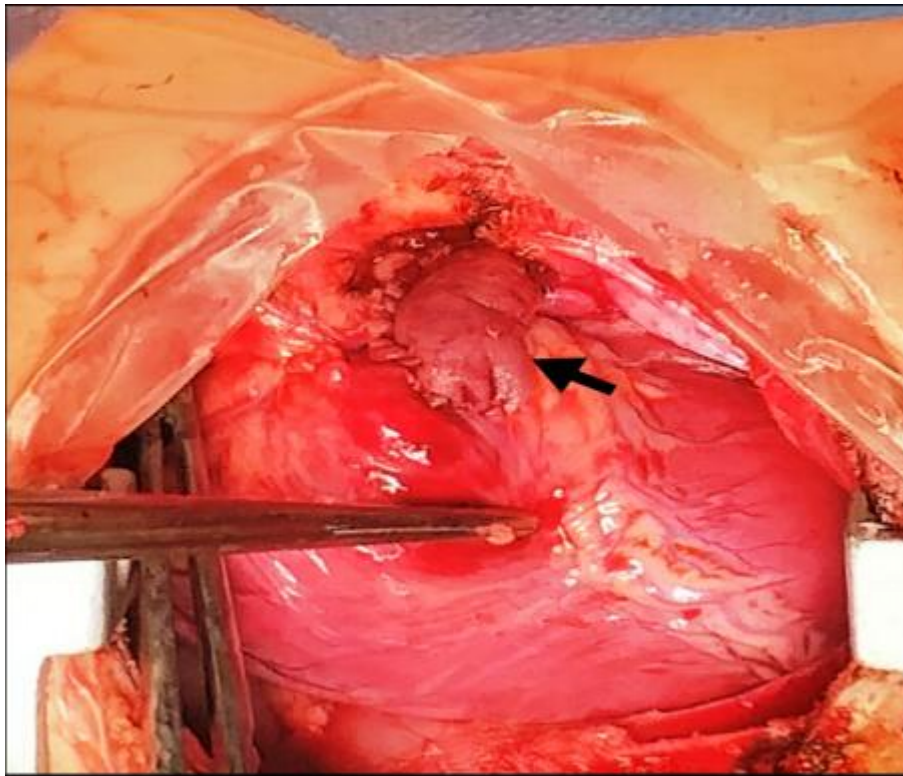


Figure 1. Intraoperative image of one of our cases in which we enlarged the right ventricular outflow tract by transannular patch (Group 2).

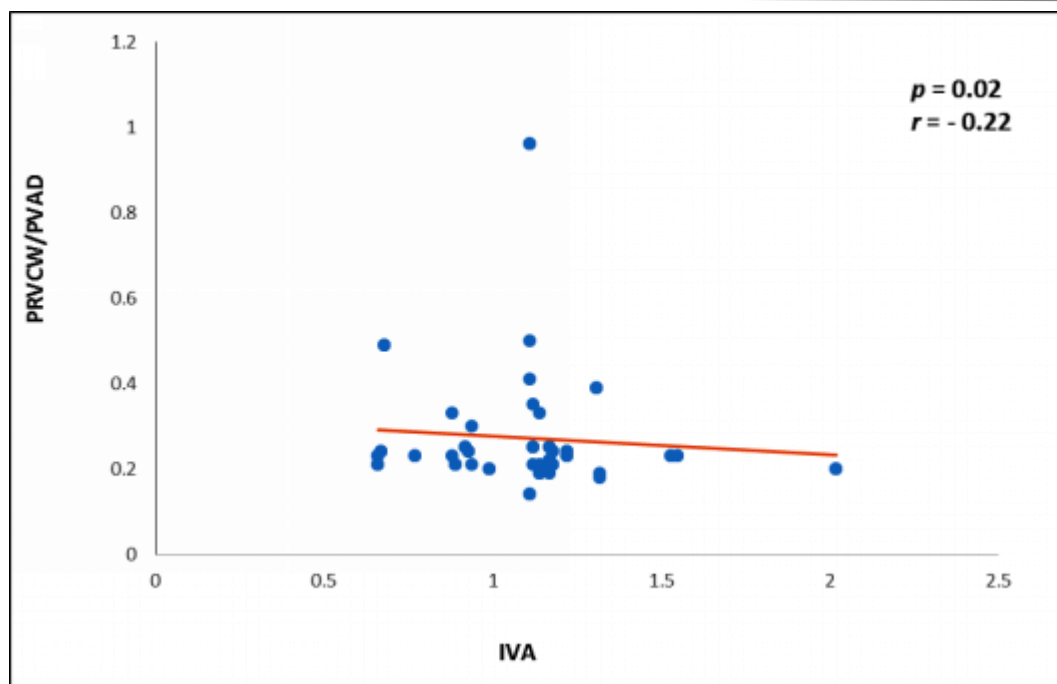


Figure 2. Correlation coefficient showing the negative relation between RV IVA and PRVCW/PVAD ratio at one-month postoperative follow-up.

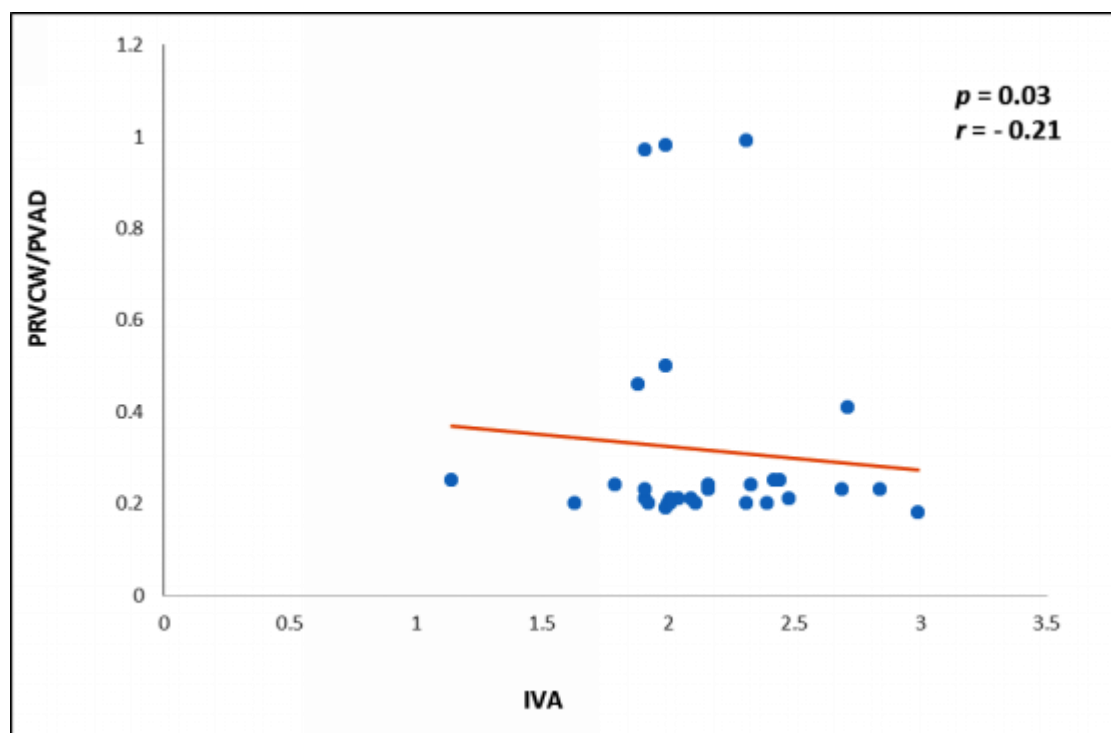


Figure 3. Correlation coefficient showing the negative relation between RV IVA and PRVCW/PVAD ratio at three months postoperative follow-up.

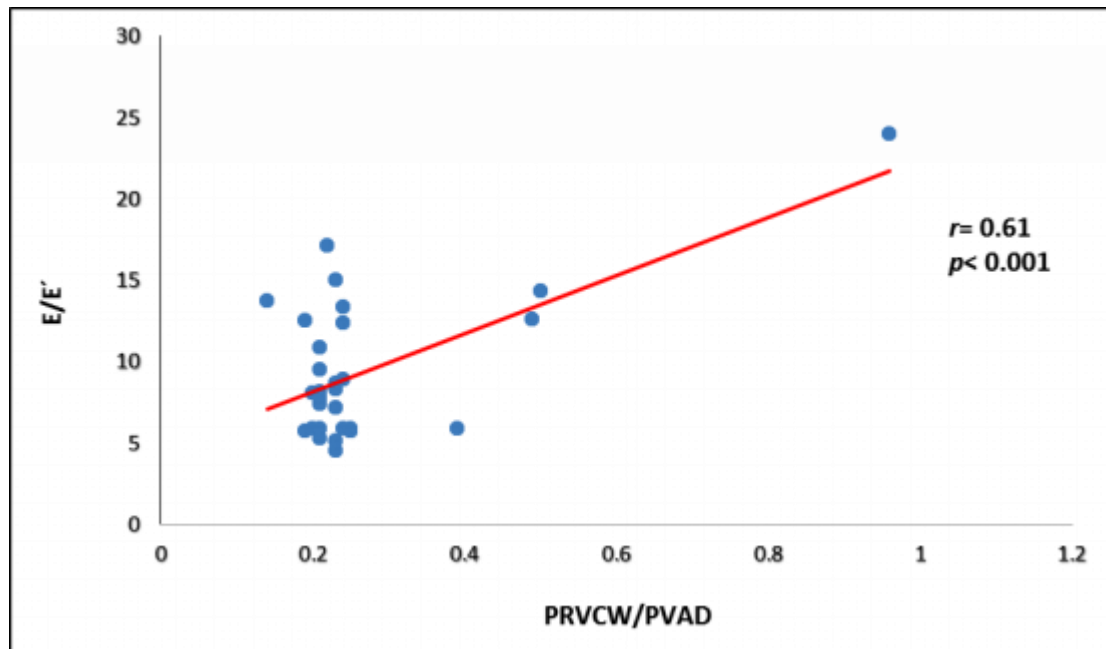


Figure 4. Correlation coefficient showing the positive relation between RV E/E' ratio and PRVCW/PVAD ratio at one month postoperative follow-up

3.4. Right Ventricular Dysfunction in Children in the Study Group

Consequently, Figure 5 illustrates that in the one-month follow-up after surgery, 6 out of 20 (30%) participants in Group 1, 6 out of 20 (30%) in Group 2A, and 10 out of 20 (50%) in Group 2B exhibited RVSD. However, by the third month after surgery, none of the participants in Groups 1 and 2A showed RVSD. Figure 6 shows that 10 out of 20 (50%) participants in Groups 1 and 2A and 18 out of 20 (90%) participants in Group 2B exhibited RVDD in one month after surgery. However, at the third-month follow-up, none of the participants in Groups 1 and 2A reported RVDD, whereas 8 out of 20 (40%) in Group 2B still reported RVDD.

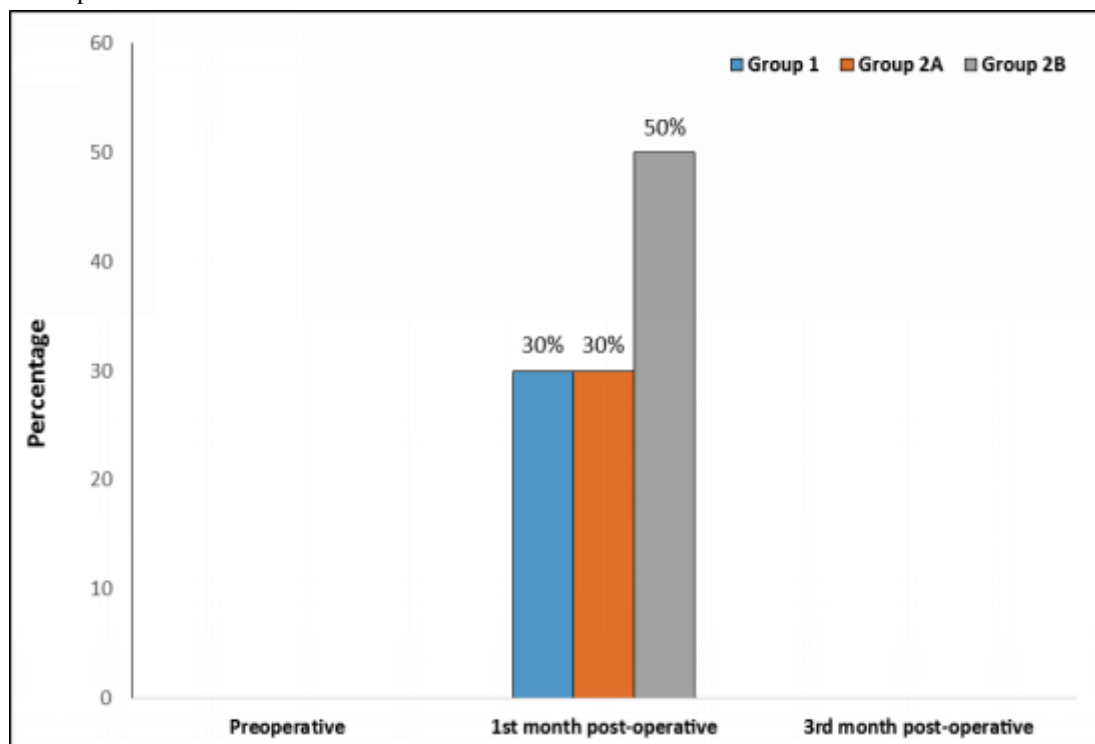


Figure 5. Frequency of right ventricular systolic dysfunction among the studied groups.

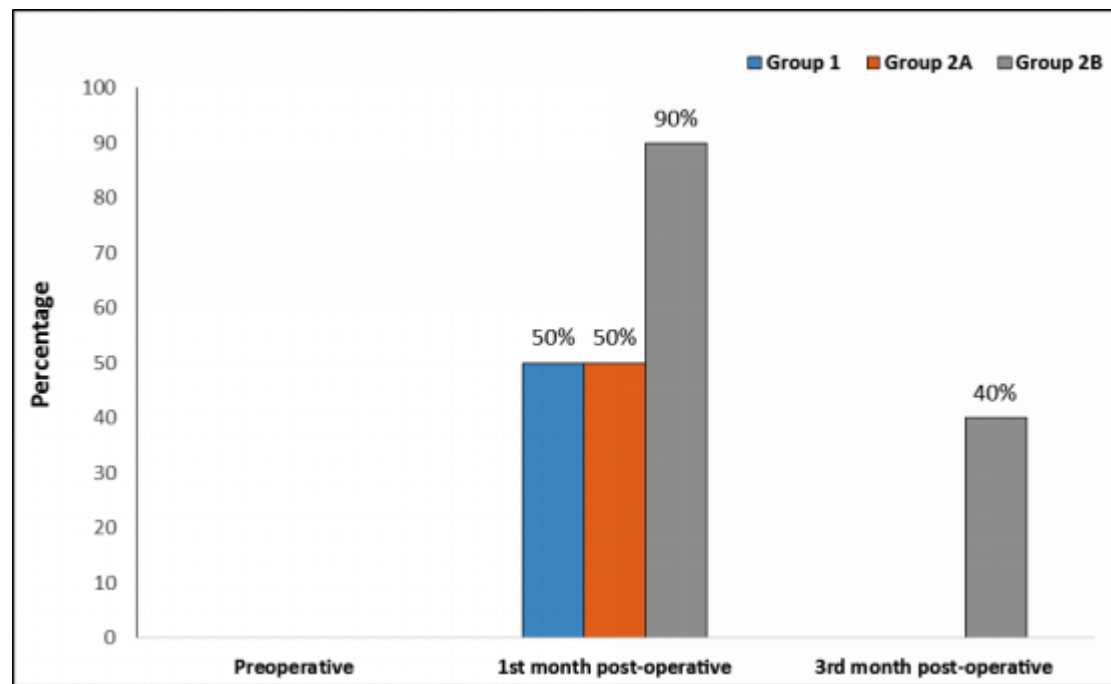


Figure 6. Frequency of right ventricular diastolic dysfunction among the studied groups.

3.5. Postoperative Pulmonary Regurgitation among the Studied Groups

Figures 7 and 8 depict the degree of postoperative PR among the studied groups that received different RVOT strategies for TOF repair. In Group 1, all the participants exhibited mild PR during follow-up after surgery in the first month or third month. Among participants in Group 2A, 18 out of 20 (90%) reported mild PR, while 2 out of 20 (10%) reported moderate PR during follow-up after surgery in the first month or third month. For Group 2B, in the first-month post-surgery, 4 out of 20 (20%) reported mild PR, 4 out of 20 (20%) showed moderate PR, and 2 out of 20 (10%) exhibited severe PR, respectively. While at the third month after surgery, 10 out of 20 (50%), 4 of 20 (20%), and 6 of 20 (30%) reported mild, moderate, and severe PR, respectively. Moreover, the severity of postoperative PR was generally increased among the participants in Group 2B, where a mono-cusp TAP was employed.

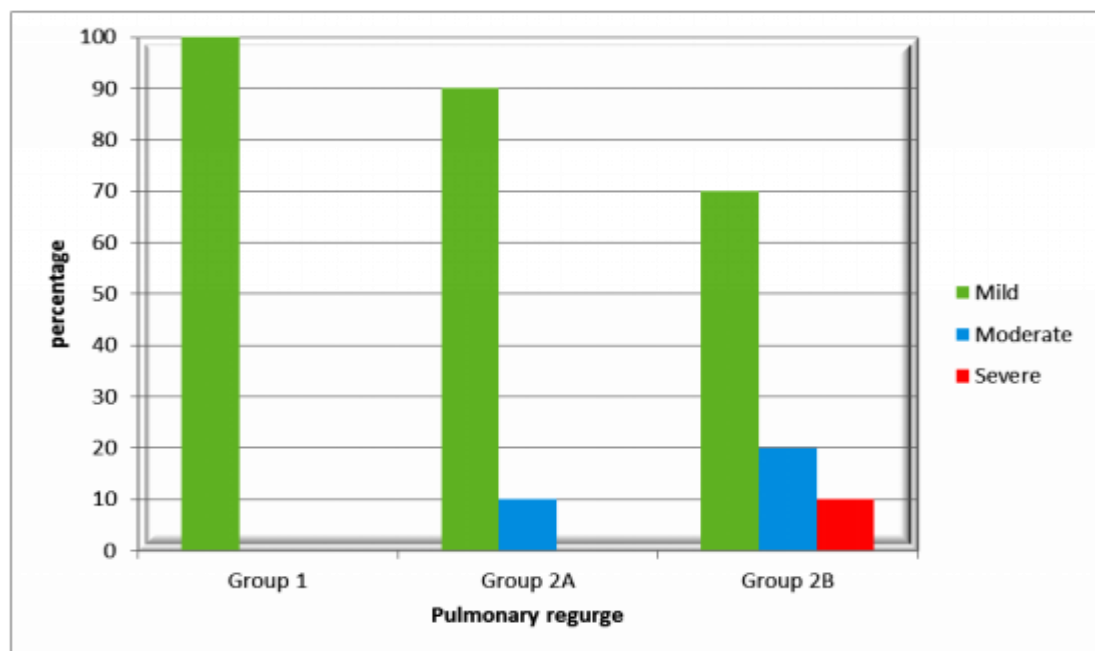


Figure 7. Frequency of pulmonary regurgitation among the studied groups at one month postoperative follow-up.

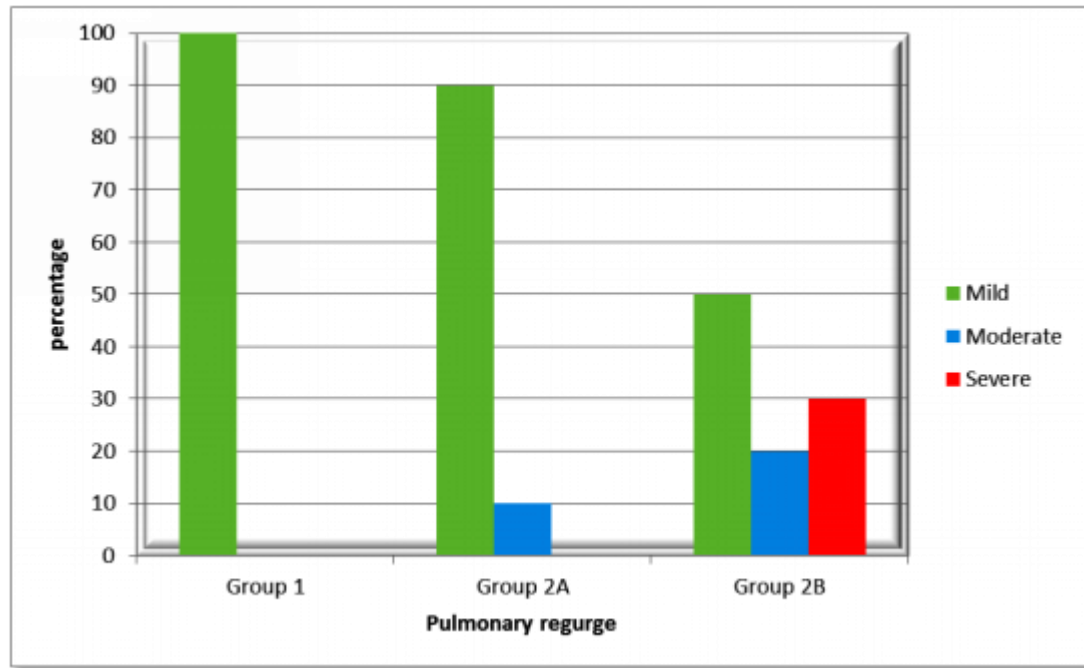


Figure 8. Frequency of pulmonary regurgitation among the studied groups at three months postoperative follow-up

3.6. Postoperative Residual RVOT Stenosis among the Studied Groups

Table 6 shows the degree of postoperative residual RVOT stenosis. Notably, Group 1 showed a significantly lower intraoperative maximum pressure gradient across the PV during the surgical procedure. However, it reported significantly higher values in the first and third months after surgery when comparison was done with Groups 2A and 2B ($P < 0.05$). Conversely, Groups 2A and 2B showed insignificant differences at different times of assessment.

Variables	Group 1 (n = 20)	Group 2A (n = 20)	Group 2B (n = 20)	P 1	P 2	P 3
Intraoperative (mmHg)	14.0 [8.0–23.0]	30.0 [18.0–49.0]	29.0 [28.0–32.0]	< 0.001*	0.01*	0.50
1 st month postoperative (mmHg)	26.0 [18.0–36.0]	18.0 [12.0–25.0]	15.0 [11.0–19.0]	0.02*	< 0.001*	0.20
3 rd month postoperative (mmHg)	22.0 [16.0–31.0]	13.0 [8.0–21.0]	12.0 [8.0–17.0]	< 0.001*	< 0.001*	0.48
All measures are expressed as median [IQR] P1 compares between Groups 1 and 2A, P2 compares between Groups 1 and 2B, P3 compares between Groups 2A and 2B * $P < 0.05$						

4. Discussion

This study compared the outcomes of different surgical techniques that were used to address RVOT reconstruction in TOF repair. Subsequently, different surgical procedures influenced RV function during the early postoperative period, as during a follow-up of three months and during the postoperative period. Tissue Doppler echocardiography imaging and conventional methods were utilized in this study. This is the first study on clinical assessment and comparison of RV functional changes with echocardiography in a group of children with TOF after complete surgical repair with three different surgical approaches to address RVOT obstruction.

The research used pulmonary valve (PV) preservation together with transannular patching (TAP) alone and TAP with mono-cusp construction for RVOT reconstruction. The surgeon who performed all procedures worked independently to minimize

procedural variations between subjects. The surgeons from Group 2B created cusp structures through autologous fresh pericardial patches that underwent no treatment before being shaped according to measured annular parameters during the procedure. The use of this material presents benefits through its availability and biocompatibility but fails to display the structural durability of synthetic PTFE, which clinicians frequently select because it makes cusp structures stronger and more resilient against deformation. Group 2B required a wide incision through the transannular region, which crossed into the infundibulum tissue for treating hypoplastic areas, which may have led to postoperative complications. The surgical approach of Group 2A used limited infundibular incision with TAP but did not create an artificial cusp to safeguard native RVOT anatomy, while Group 1 entirely maintained the PV annulus. The technical methods coupled with material selection influenced the measured PR severity and functional results in all three study groups.

The present study regarding operative findings showed that the ACC time was significant in Group 2B higher when a comparison was performed with other Groups ($P < 0.05$). Also, the Group 2B CPB time was found to be significantly longer as compared to Group 1 ($P < 0.05$) but did not reach a statistical significance level compared to Group 2A. These results align with the findings by Waqar et al.³⁹ and were expected because the construction of mono-cusp is technically time-consuming and also a challenging approach. The study found an excellent median RV/LV pressure ratio of 0.46 to 0.66 across all groups, indicating meticulous intraoperative precautions. Direct invasive measurements were conducted post-weaning to ensure the ratio did not exceed 0.75, consistent with results by Karl et al.⁴⁰. In another study, Warnes et al.⁴¹ recommended re-intervention when the RV pressure exceeds 2/3 times the pressure in the left ventricle. This cutoff value is significant because it shows the increased risk of progressive deterioration in RV function.

Furthermore, this study's findings were aligned with the findings reported by Sasson et al.⁴² where the median RV/LV pressure was between 0.47 and 0.5 among all groups. The study found that Group 2A had a higher mean Pressure Gradient (PG) across the RVOT and residual Pulmonary Stenosis (PS) compared to Group 1 ($P < 0.05$). Additionally, a higher PG was observed in Group 2A compared to Group 2B. However, this difference was found to be similar. This observation is attributed to the surgical technique employed in Group 2A, which used a TAP with a limited incision extension onto the infundibulum, extending a few millimeters below the PVA. This approach was used to preserve the infundibulum's integrity and mitigate the adverse effects of PR, especially when the RV/LV ratio was less than 0.7 after repair.

The outcomes of this research are also parallel with a study by Sasson et al.⁴², in which a significant increase was examined in PG across the RVOT patients from the TAP alone group compared to other groups. Their study emphasized that limiting the transannular incision length prevents PR while introducing mild stenosis as a trade-off⁴². The present study evaluated that the mean maximum PG across the RVOT ranged from 17.10 ± 16.63 to 33.20 ± 18.03 mmHg in participants with residual PS. This is mainly because post-repair residual RVOT obstruction when gradients exceed 40 mmHg is considered significant. Consequently, these results are considered valid and align with existing literature^{43,44}. The immediate postoperative course in the participants was generally well tolerated. The study did not find significant differences between the three groups regarding mechanical ventilation time, inotrope duration, chest drain time, and ICU stay. Ismail et al.⁴³ findings were also similar to the current research outcomes. However, other studies by Waqar et al.³⁹ and Sasson et al.^{39,42} reported that there were significantly longer postoperative mechanical ventilation times and total ICU stays in the TAP group compared to the PV preservation group ($P < 0.05$ and < 0.0001 , respectively).

Moreover, this study employed conventional echocardiography and tissue Doppler imaging to assess the RV in TOF patients. The results showed a significant improvement in RV diameter at the third month postoperatively compared to the first month and preoperative assessment ($P < 0.05$). This improvement was anticipated due to the excision of obstructing fibromuscular bands, which improved blood flow and hemodynamics through the right ventricle. Among the participants in this study, 22 out of 60 (36.66%) exhibited RVSD during the first-month follow-up after surgery. However, by the third month, no cases of RVSD were observed, indicating that RV systolic function was generally good following TOF repair during the early postoperative duration. These results align with findings reported by Cullen et al.⁴⁵, which evaluated that RV systolic function was qualitatively normal in all patients immediately after TOF repair.

Furthermore, it was noted that during the early postoperative period, biventricular systolic function among patients typically remains well⁴⁵. The present study observed that echocardiographic indices of systolic RV function (IVA, TAPSE, S', and RVFAC) deteriorated during the initial follow-up at one month after TOF repair but improved during the second follow-up at three months. In contrast, Farah et al.⁴⁶ reported a deterioration of RV systolic function (measured mainly by IVA and S') immediately postoperatively. They remained impaired at the third-month follow-up compared to preoperative measurements.

The results contradict some previous reports suggesting that RV systolic function among patients was found normal immediately in the postoperative period⁴⁵⁻⁴⁷. However, other studies revealed a negative correlation between RV systolic function, as assessed by IVA, and the postoperative PR severity measured by PRVCW/PVAD was identified²⁴⁻²⁶. In terms of the incidence of RVDD among the study participants, 38 out of 60 (63.33%) participants exhibited RVDD during the first-month follow-up after surgery. However, at the third-month follow-up, only 8 out of 60 (13.33%) participants exhibited RVDD. These results indicate a high prevalence of RVDD among study participants in the initial postoperative month. Hence, these findings are consistent when compared with other studies, which also reported a high prevalence of RVDD

immediately postoperatively after TOF repair.

Conversely, Singh et al.¹⁰ reported that among the 24 patients included in their study, RV functions in the immediate to postoperative period were assessed via echocardiography, and 13 (54.16%) patients exhibited signs of RV dysfunction. At four weeks of follow-up, persistent RVDD was found among 5 out of 13 patients with RV restrictive physiology examination¹⁰. However, at the 12-week follow-up, persistent abnormalities were found in only two patients, regardless of clinical improvement, and they continued to exhibit despite significant clinical improvement. Consequently, at 12 weeks, 61% (8 among 13 patients) showed transient restrictive physiology after surgical repair, while it persisted in two patients' cases. This study found a decline in the indices of RV diastolic function one month after the operation, followed by improvement during the second follow-up after a three-month postoperative period. This phenomenon was due to the relatively older ages of the patients in all study groups (average: 21-25 months, range: 10 to 47 months), with no significant differences observed among the study groups. The RV musculature of the 24-month-old TOF patient might be different from that of younger children as neonates or early infants in terms of RV hypertrophy. In addition, the study by Singh et al.¹⁰ assessed RV function immediately after surgical repair among patients and reported a high incidence (54.16%) of RV dysfunction¹⁰: (a) The use of a TAP in all patients^{9,48}; and (b) Combination 2D pulse Doppler with tissue Doppler for RV function assessment found more sensitive than 2D pulse Doppler^{49,50}. In contrast, Farah et al., 2010 also found a significant presence of restrictive ventricular physiology after the postoperative period immediately, 91%, while 39% after the third-month follow-up⁴⁶. The older age of the children may have already exhibited hypertrophied RV musculature at the time of TOF repair.

Similarly, Terol et al.⁵¹ findings are also similar to this research findings as they found that the RV E' and A' velocities were decreased, and the E/E' ratio was increased significantly after the first month of the post-operative period. These results suggest that early postoperative RV dysfunction may be attributed to factors such as limited RV protection via cold cardioplegia, damage of tissues, and the presence of pericardiotomy or pericardial adhesions. The present study observed a significant and positive correlation between RV diastolic function as reflected by tricuspid E/E' and the severity of postoperative PR as reflected by PRVCW/PVAD ($r = 0.61$; $P < 0.001$), while there was no significant correlation after three months. These findings are unique as the previous study did not focus on investigating the association between the RV E/E' ratio, an indicator that includes myocardial relaxation and trans-tricuspid. This also helps to understand RV filling pressures and the PRVCW/PVAD ratio. This parameter measures the severity of PR after TOF repair, which indicates that postoperative PR is associated with restrictive RV physiology.

The study examined the impact of different surgical techniques on RVOT reconstruction and RV systolic function in patients. Results showed that 6 out of 20 (30%) in Group 1, 6 out of 20 (30%) in Group 2A, and 10 out of 20 (50%) in Group 2B exhibited RVSD at one-month follow-up in the postoperative period, whereas no significant difference found in this research among the three groups. None in all the groups experienced RVSD in the third month postoperatively. The study concluded that RV systolic function was not affected by the surgical technique used for RVOT reconstruction, and RV systolic function was generally well preserved in these patients^{45,47}. The study compared the frequency of RVDD in patients using different surgical techniques for RVOT reconstruction in Group 1 and Group 2 (both 2A and 2B groups), including TAP. The results showed that 10 out of 20 (50%) participants in Group 1 compared to 28 out of 40 (70%) participants in Group 2 exhibited RVDD one month after surgery, while no cases of RVDD in Group 1 compared to 8 out of 40 (20%) participants in Group 2 revealed RVDD at the third-month follow-up, indicating that the PV preservation technique was better than the TAP technique regarding RV function and that a PV preservation technique should be the first choice. This was expected as PV preservation preserves the annulus integrity, resulting in better RV function compared to the TAP technique.

Moreover, Norgård et al.⁴⁸ findings results are also similar to this research; they found that 16 out of 34 TOF patients after repair surgery had early RV restrictive physiology. TAP repair was found to be the only independent factor in predicting early RV restriction, as the odds ratio was 4.3 (1.1–47; $P < 0.05$)⁴⁸. In another study, Eroglu et al.⁵² found that restrictive RV physiology was present in 25 (57%) out of 44 patients with TOF who underwent TAP repair despite PV preservation. This restriction was observed in many patients at the mid-term follow-up after TAP repair. Other studies have also found that RVDD tends to be worse with the TAP technique, indicating a potential impact on the patient's overall health^{52,53}.

This study demonstrated that RVDD was higher in Group 2B in comparison to other groups during the first month or third month after surgery significantly ($P < 0.05$), while between Group 2A and Group 1, no significant difference was found. The study found that TAP with a mono-cusp construction technique was the worst technique for RV function, while the PV preservation technique and TAP alone technique revealed good results. This study aimed to preserve the infundibulum's integrity and mitigate the negative impact of PR resulting from TAP. In Group 2A, only TAP was used to preserve the infundibulum integrity and mitigate the negative impact of PR resulting from TAP (the RV/LV ratio was <0.7 after repair). However, in Group 2B (TAP with mono-cusp construction), the transannular incision was extended into the infundibulum to address the hypoplastic part of the infundibulum. However, this strategy had a negative effect on RV function postoperatively, making it the worst technique compared to other techniques. This may be due to the large transannular incision, which negatively affected RV function postoperatively.

Moreover, the large incisions on the infundibulum should be avoided due to their potential to make the infundibulum akinetic and dilate, leading to inefficient RV mechanics, which can reduce RV function in case of late follow-up. The constructed mono-cusp did not perform its intended function, leading to increased degrees of PR in Group 2B. Significant PR found a deleterious effect on RV function. They also found that among patients with surgically repaired TOF, RV function is an indicator of RV contractile dysfunction^{24,54,55}.

This study found that participants in Group 2B experienced a higher incidence of moderate and severe, in some cases, postoperative heart failure (PR) after surgery, possibly due to the malfunctioning mono-cusp. Additionally, Waqar et al.³⁹ compared the mono-cusp repair group to the PV repair group, finding a statistically significant incidence of moderate PR in the mono-cusp repair group with a P-value of 0.005. It was recommended that a PV repair strategy for RVOT repair of TOF be used, and it was noted that increasing experience could make a mono-cusp repair strategy a popular option. However, the long-term durability of a mono-cusp repair strategy remains a debate^{39,42}.

On the other hand, Sasson et al., 2013 found that the TAP with mono-cusp construction group and PV preservation group had good postoperative PR results, with 91% of patients having mild PR assessed by echocardiography at discharge. The TAP alone group showed bad results, with only 50% having mild PR, 16.7% having moderate PR, and 33.3% having severe PR. Ismail et al.⁵⁶ found that patients in the TAP with a mono-cuspid valve (Contegra) group had no evidence of PR or mild PR in the immediate postoperative period, while 22.91% had moderate PR and 77.08% had severe PR. The TAP alone technique had bad results, while a mono-cuspid TAP had good results in the early postoperative period.^{42,43} Despite initial positive results after valved TAP, long-term results remain uncertain due to limited durability in many studies. Only 14% of homograft mono-cusp TAP patients experienced competent valves within 24 months of surgery, and most observed PTFE valve function deteriorated within three years. Many groups abandoned mono-cusp use as they realized there was no significant advantage for their patients⁵⁶.

Similarly, another study found that most patients with a mono-cusp valve deteriorated within three years after repair, leading many groups to abandon the procedure⁵⁷. The poor outcomes of TAP with a mono-cusp valve strategy in this study could be due to different age groups, RV hypertrophy severity, surgical techniques, and materials used. Most studies reported good results with a 0.1-mm polytetrafluoroethylene (PTFE) membrane mono-cusp valve, but in this study, the untreated autologous fresh pericardial patch was used, which may be less stiff and less effective in decreasing PR. The study's findings may be influenced by the availability of PTFE membrane material in the Institute⁵⁸. In the present study, an untreated autologous fresh pericardial patch in constructing the mono-cusp, which may be less stiff and less effective than PTFE in decreasing the PR, was used.

Postoperative results in TOF repair depend highly on the choice of surgical patch material. The study employed autologous fresh pericardial patches because these biocompatible and easily accessible patches do not possess the same structural strength as synthetic materials do. PTFE (polytetrafluoroethylene) patches show better longevity along with reduced contraction that leads to improved long-term mono-cusp valve efficiency and diminished pulmonary regurgitation. PTFE raises potential concerns about calcification development, whereas it restricts its growth suitability, particularly for pediatric use. Multiple studies demonstrated that PTFE mono-cusps give better results for short-term valve competence, yet doubts persist about their long-term degradation potential⁵⁸. In this study, the unsatisfactory outcomes observed in Group 2B stem from limitations of fresh pericardium as a material due to its biomechanical deficiencies, which stress the need to evaluate material choices for achieving enduring results.

Autologous pericardial patches serve well for mono-cusp as they provide excellent biocompatibility and reduced immunogenic response with no risk of transmitting diseases. It is easily available during surgical procedures and easy to manipulate. During surgical procedures, these patches are easy to work with and readily available, which makes them suitable, especially in resource-constrained environments. The main drawbacks of autologous pericardial patches relate to structural weakening during use, while their flexibility and durability levels, and performance are below PTFE synthetic materials⁵⁹. The valve dysfunction due to these limitations tends to worsen with time until it results in elevated postoperative pulmonary regurgitation, according to Group 2B of this research. The long-term functionality of mono-cusp valves suffers from the untreated pericardium, which both shrinks and develops distorted tissue structures.

The consistency of surgical results between different healthcare facilities depends on standard operating procedures for all medical procedures. The surgical protocol must provide specific guidelines about transannular incision extent, together with mono-cusps building details and patch selection preferences. The guidelines need to provide recommended best practices that use patient-specific indicators such as PVA Z-scores and infundibular morphology. Standardized procedures enhance both intraoperative clinical decisions and enable researchers to perform optimal comparisons of study outcomes across different research centers⁶⁰. The application of standardized techniques with pre-treated autologous pericardium or PTFE and validated practices will minimize inconsistencies while improving data interpretation to enhance TOF repair evidence.

5. Conclusion

Considering the study results, it was concluded that the PV preservation technique and TAP with limited incision technique

showed good results for RV function and PV competency post-surgery. However, constructing a mono-cusp during TOF patients with TAP resulted in higher RVDD frequency and increased PR severity. However, the influence of these techniques on myocardial morphology function needs to be assessed for a longer follow-up period.

6. Summary/Impact

Different surgical techniques were used to address RV Outflow Tract reconstruction in the TOF (Tetralogy of Fallot).

Pulmonary valve preservation and transannular patching (TAP) alone, along with limited incision techniques, had better RV function and PV competency.

There was no added value of TAP with mono-cusp construction.

7. Strengths and Limitations

This study compared three surgical techniques for RVOT reconstruction in TOF repair.

A prospective study design was used to collect data and reduce bias.

All participants underwent an operation by a single surgeon.

A pediatric cardiologist did an echocardiography assessment.

However, the study has some limitations due to its single-center nature, small population, and short follow-up period.

The use of echocardiography over CMR for RV function and the unclear clinical relevance of diastolic function measurements in participants require longer follow-up periods.

Prior to the study researchers did not use power analysis for assessing their work but they used previous study patient numbers¹⁰ for determining this study's sample size. Future research studies must perform official power calculation processes.

8. Clinical Implications

Diastolic function assessments of patients suffering from Tetralogy of Fallot (ToF) matter clinically because heart relaxation and filling defects often develop before noticeable systolic dysfunction becomes apparent. A complete assessment of diastolic heart functions assists physicians in detecting myocardial dysfunction at its early stages and provides information to determine when to intervene and follow patient symptoms⁵⁷.

The clinical results in patients with repaired TOF show a strong relationship between E/E' ratio measurements during the diastolic phase. Higher E/E' ratios indicate increased filling pressure and reduced compliance which leads to decreased exercise tolerance and arrhythmias and poor quality of life. The observation of long-lasting right ventricular diastolic dysfunction (RVDD) particularly in patients undergoing mono-cusp TAP repairs resembles a continuous threat to adverse health results which emphasizes the need for individualized postoperative care.

Right ventricular diastolic dysfunction exists commonly in repaired Tetralogy of Fallot (ToF) patients and shows clear links to exercise difficulties as well as irregular heart rhythms and harmful clinical results. Medical management decisions, surveillance strategy planning derive from correct diastolic evaluations which determine optimal preload, and afterload control approaches⁵⁸. The incorporation of diastolic assessments into standard follow-up care helps healthcare providers identify risks, which leads to better outcomes for the long-term health and quality of life of ToF patients.

Declarations

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Conflicts of Interest/Competing Interests: The author(s) declare no competing interest.

Availability of Data and Materials: The datasets used or analyzed during the current study are available in the manuscript.

Ethics Approval: The study was carried out in accordance with the World Medical Association Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects. Moreover, the Medical Ethical Committee of the Faculty of Medicine at Assiut University (Study ID Number: 17200175) approved the study.

Consent to participate: Written informed consent was obtained from parents at the time of the participant's enrollment in the study.

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Authors' Contributions: All author(s) equally contributed to the study design and conception.

FA: Material preparation, data collection, analysis, review, writing, editing.

AMM: Material preparation, data collection, analysis, review, editing.

AG: Material preparation, data collection, analysis, review, editing, proofreading.

EZ: Material preparation, data collection, analysis, review, writing of first draft, editing.

AMN: Material preparation, data collection, analysis, revisions.

All authors read and approved the final version of the manuscript as submitted and agree to be accountable for all aspects of the work.

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