

# Early right ventricular function following trans-right atrial versus trans-right atrial, trans-right ventricular repair of Tetralogy of Fallot: Results of a prospective randomized study

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## ABSTRACT

- Objective** : We compared the pre- and post-operative right ventricular (RV) function by tricuspid annular plane systolic excursion (TAPSE) between trans-right atrial (t-RA) versus t-RA/RV (RA/RV) approach for the repair of Tetralogy of Fallot (TOF).
- Patients and Methods** : Fifty consecutive patients, 1–15 years of age, undergoing intracardiac repair of TOF between September 2015 and June 2016 were randomized into two groups based on the approach for repair as follows: t-RA or t-RA/RV approach. TAPSE was used for the assessment of pre- and post-operative RV function.
- Results** : Age, body surface area, preoperative saturation, cardiopulmonary bypass and aortic cross-clamp times, inotropic score, postoperative intensive care unit, and hospital stay were similar in both the groups. However, t-RA/RV group had significant mediastinal drainage ( $169 \pm 163$  ml vs.  $90.6 \pm 58.7$  ml,  $P < 0.05$ ) and pleural effusions (8 vs. 2 patients,  $P < 0.05$ ), but had better relief of RV outflow tract gradients. The mean follow-up was  $23 \pm 6.7$  (median 26, range 21–29) months. There were no differences in arrhythmias in either group up to the 1<sup>st</sup> month and at last follow-up. Preoperative TAPSE for t-RA and t-RA/RV was similar ( $1.49 \pm 0.29$  vs.  $1.66 \pm 0.34$ ,  $P > 0.05$ ) and so was the post-operative TAPSE at discharge ( $1.52 \pm 0.30$  vs.  $1.43 \pm 0.32$ ,  $P > 0.05$ ), at 1 month ( $1.6 \pm 0.27$  vs.  $1.43 \pm 0.032$ ,  $P > 0.05$ ) and at last follow-up ( $1.79 \pm 0.15$ , median 1.8 vs.  $1.72 \pm 0.17$ , median 1.7  $P > 0.05$ ).
- Conclusion** : Both t-RA and t-RA/RV approaches provide safe palliation for patients with TOF. A limited right ventriculotomy neither leads to deleterious effects on early RV function nor does it increase the incidence of arrhythmias at early follow-up. Larger studies with longer follow-up are needed to further address these issues.
- Keywords** : Approaches, Tetralogy of Fallot, transatrial repair

## INTRODUCTION

Tetralogy of Fallot (TOF) is the most common cyanotic congenital cardiac anomaly.<sup>[1]</sup> The first repairs of TOF were undertaken through a right ventriculotomy with or without placement of a transannular patch.<sup>[2,3]</sup> Later with increasing experience of infundibular resection and

closure of the ventricular septal defect (VSD) through the transatrial route, intracardiac repair for TOF was advocated through a trans-right atrial (t-RA) approach.<sup>[4]</sup>

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Subsequently, the isolated transpulmonary artery route and/or a combination of approaches were reported with good results.<sup>[5]</sup> The trans-right ventricular (t-RV) approach was considered to increase the incidence of RV dysfunction, arrhythmias, and sudden death. The t-RA approach was purported to have a longer learning curve and was thought to leave residual RV outflow tract obstruction as compared to a t-RV approach.<sup>[6]</sup> Currently, both the approaches are popular depending on the anatomical subset and surgeon preference and experience.

Although there are numerous studies assessing the long-term functional outcome of the RV after repair of TOF, comparative data on the immediate and early postoperative RV function using either approach is sparse.<sup>[7]</sup> An assessment of the RV function is difficult in view of the more complicated anatomy of the RV and failure to trace its endocardial surface completely.<sup>[8]</sup> Tricuspid annular plane systolic excursion (TAPSE) is a simple measure of RV ejection fraction that can be assessed at the bedside by two-dimensional echocardiography. It has been validated by various studies as a reliable measure of systolic function of the RV.<sup>[9]</sup> This study aims to compare the immediate pre- and post-operative RV function between t-RA versus t-RA/RV approach for TOF repair using the TAPSE.

## PATIENTS AND METHODS

### Patients

Fifty consecutive pediatric patients between 1–15 years of age undergoing intracardiac repair of TOF between September 2015 and June 2016 by t-RA or t-RA/RV (t-RA/RV) approach without a transannular patch were enrolled in this single-surgeon study. Informed consent was obtained from the parents of all patients, and the study protocol was approved by the Ethics Committee of our institute (IEC/NP-263/10.7.2015 and RP-08/2015-10.9.2015). The trial was duly registered with the clinical trials registry of India (CTRI/2015/12/010387), that is housed in the National Institute of Medical Statistics of the Indian Council of Medical Research, New Delhi, India.

Preoperative echocardiography, cineangiography, or computed tomography angiography were used to assess the suitability for a nontransannular patch repair, and this was confirmed at intraoperative transesophageal echocardiography. Exclusion criteria included emergency surgery, prior systemic to pulmonary artery shunts (volume overloaded ventricle), patients requiring a transannular patch, and those requiring concomitant pulmonary artery patching. The primary outcome parameter was TAPSE. Secondary outcomes were duration of mechanical ventilation (hours), mediastinal drainage, pleural effusion, arrhythmia, inotropic score (see below),

intensive care unit (ICU), and hospital stay. Objectively assessed secondary parameters were gradients across the RV outflow tract and RV ejection fraction.

### Sample size calculation

The study was designed to detect RV function using a two-sided test with 5% alpha error and 80% power. For this purpose, 50 patients were needed; 25 in each group. The randomization list was generated using the nQuery Advisor version 7.0 (Statistical Solutions, Saugus, MA, USA) with a variable block size. This randomization sequence was transferred to sealed envelopes which were opened after opening the pericardium and confirming suitability for either approach.

### Surgical procedure

Surgery was performed by a single surgeon in a standard manner. Anesthesia was induced and maintained by weight-related doses of thiopental, fentanyl, midazolam, and pancuronium. Cardiopulmonary bypass (CPB) was carried out using a nonpulsatile roller pump, membrane oxygenators, and standard (uncoated) extracorporeal circuits under mild hypothermia (32°C). The circuit was primed with appropriate amounts of Plasmalyte-A solution, mannitol, and sodium bicarbonate. Blood was added as required.

For both groups of patients, aorto-bicaval cannulation, cold blood root cardioplegia (del Nido solution), and closure of VSD using a Dacron patch (C. R. Bard, Inc., Billerica, MA, US) was carried out through the right atrium. The only difference was in the technique of infundibular resection using either t-RA or t-RA/RV approach. In the t-RA group, the VSD closure as well as the infundibular resection and pulmonary valvotomy were performed through the right atrium, while in the t-RA/RV group, the VSD closure was performed through the RA following which a limited ventriculotomy was made in the in RV outflow tract starting 0.5 cm below the annulus and extending for a length of 1–2 cm group through which infundibular resection and pulmonary valvotomy was carried out. Pulmonary valve stenosis was managed by commissurotomy if commissural fusion was present or release of tethering and also by dilating the pulmonary valve using an appropriate-sized Hegar dilator. The ventriculotomy was then closed using a primary RV outflow tract patch using autologous glutaraldehyde-fixed pericardium. Care was taken not to cross the pulmonary annulus. From either route, the assessment of the pulmonary annulus was made by passing a Hegar dilator expected for that weight. Overzealous sizing of the annulus was not performed.

### Intra- and post-operative data

Per-operative data included data with respect to CPB and aortic cross-clamp times. Following completion of the repair, pRV/pLV was measured in all patients.

A value  $<0.8$  was accepted if there was no gradient between the RV and the pulmonary artery and if the hemodynamics were stable. Intraoperative transesophageal echocardiography was performed in all patients to assess the adequacy of repair and to assess biventricular function.

Parameters assessed postoperatively were hemodynamic status with special reference to central venous pressure, stability of cardiac rhythm, time to peripheral warming, and attainment of negative fluid balance. The need for inotropes was assessed by calculating the inotropic score using the formula:

$$\text{Inotropic score} = \text{dopamine dose (mcg/kg/min)} + \text{dobutamine dose (mcg/kg/min)} + 100 \times \text{epinephrine dose (mcg/kg/min)} + 10 \times \text{milrinone dose (mcg/kg/min)} + 10,000 \times \text{vasopressin dose (U/kg/min)} + 100 \times \text{nor-epinephrine dose (mcg/kg/min)}^{[10]}$$

The patients were managed by the ICU team that was blinded to the approach. The surgical team was, however, aware of the patient group.

### Echocardiographic assessment

Echocardiographic assessment was performed by a single echocardiographer who was blinded to the approach used for surgical repair. TAPSE was taken as a surrogate for RV function and was calculated in the apical four-chamber view using M-Mode echocardiography. The longitudinal excursion of the lateral annulus of the tricuspid valve toward the apex (TAPSE) has been found to have good correlation with isotopic derived RV ejection fraction.<sup>[11]</sup> This was recorded for each patient in peak systole. It was recorded preoperatively, in the postoperative period after weaning off the inotropes, at the time of discharge from the hospital, and subsequently at 1 month of follow-up. The patients were subsequently followed up in the outpatient clinic at 3 months, 6 months, and yearly intervals. Similar measurements were made at the last follow-up which was a mean of  $23 \pm 6.7$  (median 26, range 21–29) months.

### Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics software for Windows, version 23 (IBM Corp., Armonk, NY, USA) by a qualified biostatistician who was blinded to the approach used for surgical repair. Data are presented as mean  $\pm$  standard deviation for continuous variables among the two groups. Nonparametric Mann-Whitney U test was used to compare baseline and postintervention numerical variables. Chi-square test was used to compare ordinal and categorical variables.  $P < 0.05$  was considered statistically significant.

## RESULTS

There were 25 patients in each arm designated as Group 1 (operated through t-RA route) and

Group 2 (Operated through combined t-RA/RV approach). Patient demographics are shown in Table 1. There were no differences between the two groups with respect to demographics, preoperative RVOT gradient, and RV function. The patients in each group were subjected to surgery by a single surgeon (ST) operating in a reproducible manner, and any given patient was deemed suitable for intracardiac repair by either approach without a transannular patch on preoperative evaluation and after opening the pericardium. The pulmonary artery annulus of each patient was sized preoperatively as described above and a Z-value of the pulmonary annulus up to  $-3$  was accepted to avoid a transannular patch.

Intra- and post-operative results are detailed in Table 2. The two groups had comparable CPB and aortic cross-clamp times. There were no early deaths in either group. There were no significant differences between the two groups with respect to the duration of mechanical ventilation, inotropic score, ICU, and hospital stay. However, a significant number of patients in Group 2 had pleural effusion, and the quantity of mediastinal drain in the same group was significantly higher leading to increased number of reexplorations. Three patients from group two were reexplored for bleeding, and the bleeding site was found to be from the patch in one and from retrosternal tissue in the other two.

In Group 1, only two patients had postoperative sinus tachycardia that resolved spontaneously. In Group 2, four patients had postoperative arrhythmias. Two of these had sinus tachycardia that resolved spontaneously, and two had junctional ectopic tachycardia that was controlled with core cooling, reduction in catecholamine support, and amiodarone.

**Table 1: Preoperative details of patients**

	Group 1 (trans RA)	Group 2 (trans RA/RV)	P
n	25	25	
Age (years)			
Mean age	5.8 $\pm$ 4.8	5.2 $\pm$ 4.2	0.623
Median age	4	4	
Minimum	1	1	
Maximum	15	15	
Weight (kg)			
Mean weight	17.6 $\pm$ 11.2	16.7 $\pm$ 12.8	0.8
Median weight	14	11	
BSA (m <sup>2</sup> )			
Mean $\pm$ SD	0.70 $\pm$ 0.30	0.69 $\pm$ 0.33	0.895
Minimum	0.35	0.34	
Maximum	1.43	1.63	
Median	0.63	0.54	
Sex			
Male:female	23:2	18:7	0.06
Preoperative saturation (%)	67	65	0.363

SD: Standard deviation, BSA: Body surface area, RA: Right atrial, RV: Right ventricular

**Assessment of right ventricular function**

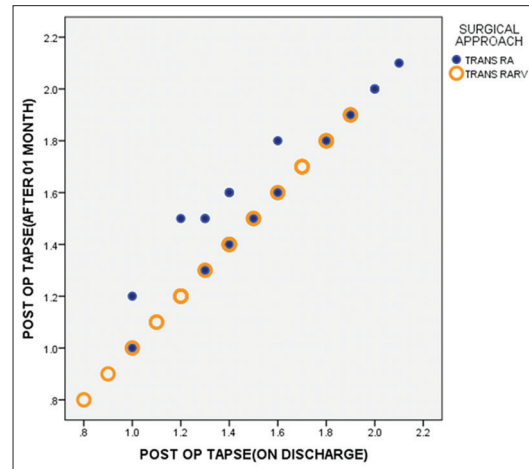
The mean pre-TAPSE for Group 1 was  $1.49 \pm 0.29$  cm and that for Group 2 was  $1.66 \pm 0.34$  cm, and the difference between the two groups was not significant [Table 3]. Age-wise normal TAPSE values for both the groups were evaluated and compared between the two groups, which revealed well-matched groups without any statistically significant differences. After TOF repair, there was a reduction in the mean TAPSE for both groups; however, the differences between the groups were not significant. At 1 month of follow-up, echocardiography revealed marginal improvement of TAPSE values in Group 1, while in Group 2, the TAPSE values remained static. However, this was not statistically significant. The linear correlation between the TAPSE values in immediate postoperative period and 1 month later in both groups is depicted in Figure 1. At a mean follow-up of  $23 \pm 6.7$  (median 26, range 21-29) months, TAPSE values improved to  $1.79 \pm 0.15$  (median 1.8) versus  $1.72 \pm 0.17$  (median 1.7) in Groups 1 and 2, respectively,  $P > 0.05$  [Figure 2].

The mean preoperative gradient across the RVOT in Group 1 was  $63.64 \pm 11.8$  mmHg, and in Group 2, it was  $65.36 \pm 11.36$  ( $P > 0.05$ ). After TOF repair, the mean gradients fell to  $16.96 \pm 8.06$  mmHg in Group 1 and to  $9.8 \pm 2.80$  mmHg in Group 2, and the difference between the groups was statistically significant ( $P = 0.02$ ). These gradients did not change significantly at follow-up.

The pre- and post-operative RV ejection fraction as measured echocardiographically by fractional area shortening showed only marginal and statistically insignificant differences between the two groups.

**DISCUSSION**

In the current era, the patients undergoing intracardiac repair of TOF are expected to have a long-term survival with good quality of life.<sup>[12]</sup> However, there is a definite learning curve to the operation, and multiple



**Figure 1: Linear correlation between TAPSE in immediate postoperative period and after 1 month. TAPSE: Tricuspid annular plane systolic excursion, RA: Trans-right atrial**

**Table 2: Perioperative details of the patient**

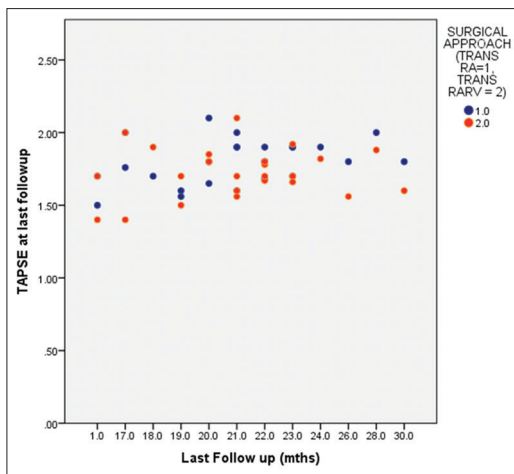
	Group 1 (trans RA) (n=25)	Group 2 (trans RA/RV) (n=25)	P
CPB time (min)	88.20±28.36	104.64±35.43	0.08
Aortic cross clamp time (min)	57.40±25.10	67.48±26.28	0.19
Mechanical ventilation (h)	8.96±4.1	8.60±3.2	0.98
Mediastinal drain quantity (ml)	90.6±58.7	169±163	<b>0.03</b>
Pleural effusion (number of patients)	2	8	<b>0.03</b>
Arrhythmia (number of patients)	2	4	0.38
Inotropic score	13.2±6.9	16.6±10.3	0.27
ICU stay (h)	50.28±22.1	50.6±20.8	0.69
Hospital stay (days)	5.64±1.03	6.6±2.5	0.21

CPB: Cardiopulmonary bypass, ICU: Intensive care unit. Figures in bold represent statistically significant observations

**Table 3: Perioperative echocardiographic parameters of the patients**

	Group 1 (trans RA) (n=25)	Group 2 (trans RA/RV) (n=25)	P
Mean normal TAPSE (cm) for age	1.88±0.24	1.84±0.22	0.7
Preoperative TAPSE (cm)	1.49±0.29	1.66±0.34	0.06
Postoperative TAPSE (cm)	1.52±0.30	1.43±0.32	0.30
TAPSE at 1 month (cm)	1.6±0.27	1.43±0.032	0.46
Preoperative RVOT gradient (mmHg)	63.64±11.8	65.36±11.36	0.60
Postoperative RVOT gradient (mmHg)	16.96±8.06	9.8±2.80	0.01
Preoperative RVEF	0.51±0.05	0.51±0.03	0.85
Postoperative RVEF	0.51±0.04	0.52±0.03	0.59
RVEF at 1 month	0.51±0.04	0.52±0.03	0.59

RVOT: Right ventricular outflow tract, TAPSE: Tricuspid annular systolic plane excursion, RA: Right atrial, RV: Right ventricular, RVEF: Right ventricular ejection fraction



**Figure 2: TAPSE at last follow-up. RA-RV: Trans-right atrial trans-right ventricular approach, TAPSE: Tricuspid annular plane systolic excursion**

approaches to achieve a secure closure of the VSD and achieve optimal relief of RVOT obstruction have been described.<sup>[13,14]</sup>

The RA approach, first described by Hudspeth *et al.*, and Edmunds *et al.*<sup>[15,16]</sup> have gained popularity because it is thought by many to avoid the disadvantages of a ventriculotomy (with or without placement of a transannular patch). In addition, it has been claimed to prevent the deleterious long-term consequences of pulmonary regurgitation by virtue of better preservation of the pulmonary valve. In earlier studies from our center, we have reported acceptable mid-term results of the transatrial repair of TOF.<sup>[12,17]</sup> The other advantages of the RA approach include avoidance of injury to the ventricular branch of the right coronary artery and a purported decreased incidence of life-threatening arrhythmias at a later age.<sup>[18]</sup> However, some groups have reported a higher incidence of complete heart block and tricuspid insufficiency with a transatrial approach to TOF repair.<sup>[13]</sup> In addition, an earlier report has suggested that a significant number of patients undergoing t-RA repair have residual RVOT gradients necessitating reoperation in a significant subset of the patient.<sup>[6]</sup>

The transventricular route was used classically for the closure of the VSD and for the relief of RVOT gradient by infundibular resection. The ventriculotomy was then subsequently repaired along with simultaneous enlargement of the RV outflow using a patch that may be transannular or may not extend across the pulmonary valve annulus (primary RVOT patch). However, there have been concerns that a ventricular incision<sup>[13]</sup> leads to an increased incidence of ventricular scarring leading to late ventricular tachyarrhythmias and sudden death. The RV incision has been shown to produce significant disruption of RV geometry leading to late dysfunction.<sup>[19]</sup> However, in patients with a restrictive

pulmonary annulus, a right ventriculotomy incision with the placement of a transannular patch is still mandatory.

The trans-RA-RV approach probably combines the advantages of the two approaches, wherein the VSD is preferably approached from the right atrium, and the RVOT resection is performed through a small ventriculotomy that does not extend across the annulus. Closing the VSD from the right atrium helps to limit the size of the ventriculotomy and probably reduces the incidence of heart block by providing direct vision of the anatomical landmarks and also probably helps in a secure closure of the VSD with a reduced incidence of a residual shunt.<sup>[13]</sup> At the same time, performing the RVOT resection through a right ventriculotomy allows for a direct visualization of the obstructing bands and permits infundibular enlargement by placement of a nontransannular RVOT patch. The pulmonary valve exposure is also better as compared to the RA approach that may allow a more accurate pulmonary valvotomy without the need to open the pulmonary artery. As the ventriculotomy is small, it may avoid the complications of a long ventriculotomy as discussed above.

To the best of our knowledge, there are no studies that have compared the t-RA approach with the t-RA/RV approach in a prospective randomized fashion to assess early postoperative outcomes. This study is, therefore, unique in this respect, although it is limited to the assessment of early outcomes only.

RV function has been difficult to assess echocardiographically because the right ventricle does not conform to any geometrical shape. Cardiac magnetic resonance (CMR) imaging is thought to be the gold standard for calculating the RV ejection fraction<sup>[20]</sup> and to assess the timing of pulmonary valve replacement following transannular patch repair of patients with TOF. CMR is however not available universally, is expensive, takes longer time to perform, requires sedation, and most often endotracheal intubation, especially in younger infants and children. Hence, the closest alternatives are echocardiographic parameters, such as TAPSE, which is a preload-dependent assessment of longitudinal systolic motion of the lateral annulus of the tricuspid valve. It can be easily measured at the bedside and although not a gold standard, it is a practically easy useful tool for assessing RV function.<sup>[21-25]</sup> Another surrogate of RV ejection fraction is fractional area change of the right ventricle (RV FAC) on two-dimensional echocardiography on the four-chamber apical view. Some studies have validated its close correlation to angiographic standards in a small population of children.<sup>[21]</sup>

This study was a unique opportunity for us to compare the early results of the two approaches in a prospective randomized fashion. The randomized groups were well matched with respect to age, body surface area,

and cardiac anatomy. The consistency of the surgical procedure could be gauged easily from the uniform CPB and aortic cross-clamp times. Our unit favors early tracheal extubation, and none of the 50 patients in either group needed prolonged ventilatory support or required reinstatement of mechanical ventilatory support after extubation. The significant difference between the two groups was in the form of high mediastinal drainage necessitating reexploration in patients operated using t-RA/RV approach. However, this difference is likely to be more of a chance rather than being a truly statistically significant because the bleeding related to the RVOT patch was encountered only in one of the three patients in Group 2. The other significant difference was a higher amount and a longer duration of pleural effusion in patients in the t-RA/RV group. This entailed placement of chest tubes in the respective pleural cavities and led to a longer hospital stay in this group. However, statistically, this did not translate into longer ICU and hospital stay when the two groups were compared.

There was an overall decrease in RV function after intracardiac repair of TOF in both the groups with gradual recovery at the end of 1 month and at follow-up. The differences in the mean value of TAPSE were not significant at any point of time. Patients operated using t-RA/RV approach did have less mean TAPSE values than their counterparts operated using t-RA route, however, this did not translate into significant differences in the need for inotropes, ICU, or hospital stay. The fractional area shortening of the RV did correspond to decreasing of TAPSE values signifying some degree of RV dysfunction, marginally more so in t-RA/RV approach. However, their relation to TAPSE was weak and inconsistent with RV dysfunction.

The only other relevant finding in this study was that there was a significant decrease in the RVOT gradient when the infundibular dissection was carried out using a combined t-RA/RV approach. This relief of RVOT gradient through the ventriculotomy did not produce statistically significant arrhythmias and overt early RV dysfunction. Theoretically, this does offer an attractive choice of approach for infundibular resection and pulmonary valvotomy. Moreover, this approach may reduce the incidence of reoperations in the long-term because late reoperations following TOF repair are more often due to residual RVOT gradients than due to other factors.<sup>[26]</sup> However, the concerns of a ventriculotomy on the RV function in the long-term remain.

#### Study limitations

Our study was limited to a small number of patients operated by a single surgeon with a short duration of follow-up. However, such a study has not been performed earlier, and it does indicate the need for conducting larger prospective multicenter studies involving more

patients with a longer follow-up to assess differences in RV function, arrhythmias, need for late reoperation, and exercise capacity in either group. We also did not perform CMR in these patients because of financial constraints and relied on echocardiographic parameters of RV function.

## CONCLUSION

Both t-RA and t-RA/RV approaches provide a safe palliation for patients with TOF. A limited right ventriculotomy does not lead to deleterious effects on RV function or a higher incidence of arrhythmias at early follow-up. Larger studies are needed to further address these issues.

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Nil.

#### Conflicts of interest

There are no conflicts of interest.

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