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Original Research Article

A PROSPECTIVE STUDY OF EARLY AND MIDTERM SURGICAL OUTCOMES IN TETRALOGY OF FALLOT BEYOND 12 YEARS OF AGE

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ABSTRACT

Background: The aim of this study is to analyse and describe the early and midterm outcomes of patients in repaired TOF beyond 12 years of age at 3 months, 1 year and 3year follow-up. The primary objective is to assess early and midterm outcomes with respect to all-cause mortality, MACE and Sudden Cardiac Death at follow up periods of 3 months, 1 year and 3 years, in various groups as mentioned below.

Materials and Methods: It was a prospective observational study. The study was conducted at CTVS department of Government General Hospital, Guntur. A total of 50 consecutive patients with diagnosis of TOF beyond 12 years of age, requiring surgical correction were studied. Detailed clinical history was taken. All patients underwent routine blood investigations including investigations pertaining to coagulation. The patients underwent the following investigations at different intervals.

Results: In our study, the mean ICU stay & hospital stay were 6.91+/- 5.05 & 10.15 +/- 6.61days respectively. At 3 year follow up, the incidence of atrial arrhythmias was 8% and ventricular arrhythmias was 6%.However, the incidence of severe PR was highest (86.60%) in group-1b that is TOF without monocusp augmentation of PV, followed by 61.53% in group-1a that is TOF with TAP with monocusp augmentation and least (13.6%) in group-2 that is TOF correction without TAP. There was a gradual increase in the RVEDV and RVESV in all the groups over 3 years with highest in group-1b that is TOF correction with TAP without monocusp augmentation measuring 114.69 +/- 24.51 ml and RVESV 74.08+/-24.46mlrespectively. The lowest value was measured in TOF without TAP (group-2) that is RVEDV of 79.86 +/- 27.56 ml and RVESV of 35.95+/-16.70ml. However, there was significant improvement in clinical status of the patients following TOF repair in all groups.

Conclusion: The present study concluded that, TOF repair with TAP &monocusp augmentation has excellent results with reduced occurrence of severe PR upto 1 year. But at 3 years, the severity of PR is comparable with that of TOF repair with TAP without monocusp augmentation of pulmonary valve. Hence the durability of monocusp augmentation seems to be short lived. However, TOF repair without TAP has overall the best results with least incidence of PR, TR, RV dysfunction & post-operative arrhythmias. Hence it should be preferred wherever it is possible.

Keywords: TOF, TAP, RVESV, RVEDV, Ventricular arrhythmias.

INTRODUCTION

Tetralogy of Fallot (TOF) is the most common cyanotic congenital heart defect in all age groups, constituting approximately 8% of all congenital heart defects. It occurs in nearly 0.19 to 0.26 in 1000 live births, with a prevalence of about 3.9 per 10,000 live births in the United States.[1] The first complete description of TOF is credited to the French physician Etienne Louis Arthur Fallot, who published his findings in 1888. The four heart defects associated with TOF are, an interventricular communication or Ventricular Septal Defect (VSD), overriding of aorta over the muscular ventricular septum, obstruction of the Right Ventricular Outflow Tract (RVOT) and Right Ventricular Hypertrophy (RVH). (2The deletion of human TBX1 appears to be the basis for the 15% of TOF attributable to chromosome 22q11.[2] micro deletion, although TBX1 mutations in non-deleted TOF patients remain to be identified.[3,4]The exact cause of TOF is unknown, but several risk factors have been associated with the condition. These include maternal alcoholism, diabetes, poor prenatal diet and maternal age beyond 40 years. The genes causing TOF in trisomy 21, 18, and 13, which together account for 10% of TOF cases are yet to be identified. Thus, in approximately 70% of TOF patients, a genetic etiology remains to be determined. The embryological basis of the combination of lesions is antero-cephalad deviation of the developing outlet ventricular septum. The symptoms of TOF starts after few months of birth. They include, cyanosis of skin and mucous membrane, clubbing of nails, easy fatiguability, cyanotic spells and developmental delays. Associated anomalies are Ostium Secundum Atrial Septal Defect (OSASD), right aortic arch (25%), Major Aorto-Pulmonary Collateral Arteries (MAPCAs), Complete Atrio Ventricular Canal Defect (AVCD), anomaly of coronary arteries with e.g. anomalous Left Anterior Descending artery (LAD) from Right Coronary Artery (RCA) crossing the RVOT (5%).[5] The first surgical treatment for TOF was performed by Alfred Blalock at Johns Hopkins University in 1945.[6] Several innovative systemic-to-pulmonary shunt procedures were soon developed,[7,8] followed by the first successful intracardiac repair using human cross-circulation by Lillehei and Varco at the University of Minnesota in 1954.[9] Complete repair provides prompt relief of the volume and pressure overload on the Right Ventricle (RV), minimises cyanosis, decreases parental anxiety and eliminates the theoretical risk of stenosis occurring in a Pulmonary Artery (PA) due to a palliative procedure. Patients who undergo a successful complete repair during the neonatal period will be unlikely to require more than one intervention in the first year of life but are not free from re-intervention. Patches placed across the ventriculo-pulmonary junction, so-called Trans Annular Patches (TAP), create a state of chronic Pulmonary Regurgitation (PR), which increases morbidity in young adults, producing exercise intolerance and ventricular arrhythmias. If left untreated, this increases the risk of Sudden Cardiac Death (SCD).[10,11] The 10-year survival in patients of untreated TOF is 24% only,[12] and morbidity in adult survivors of TOF without surgery is high. The chronic hypoxemia results in exercise of intolerance and excessive erythrocytosis with an increased risk of thrombosis. Cerebral abscesses are frequent since infectious agents can easily reach the brain via right to left shunting on ventricular level. However medium-term survival of repaired Tetralogy of Fallot (repaired TOF) has been documented to be good, with 20-year survival rates at or above 90%.[13,14] Despite improvement in medical and surgical management of this disease, adults with repaired TOF remain at risk for cardiovascular morbidity and mortality.[10,15] The proposed risk factors include patient demographics such as age at time of TOF repair, left and right ventricular dysfunction, RV fibrosis, RVH, ventricular arrhythmia and increased Left Ventricular End-Diastolic Pressure (LVEDP).[15,16] Early definitive repair of TOF is now advocated, with an actuarial survival rate of almost 90% at 30 years.[17] The primary aim of this study is to analyse and describe the early and midterm outcomes of patients in repaired TOF beyond 12 years of age at 3 months, 1 year and 3 year follow up.

Aim and Objectives

Aim: The aim of this study is to analyse and describe the early and midterm outcomes of patients in repaired TOF beyond 12 years of age at 3 months, 1 year and 3 year follow-up.

Primary objectives: To assess early and midterm outcomes with respect to all-cause mortality, MACE and (SCD)Sudden Cardiac Death at follow up periods of 3 months, 1 year and 3 years, in various groups as mentioned below.

- Group-1a: TOF with TAP and monocusp reconstruction of PV.
- Group-1b: TOF with TAP without any reconstruction of PV.
- Group-2: Total correction of TOF without TAP (PV spared).

Secondary objectives:

- To observe morbidities and quality of life post-operatively in various groups which are mentioned above.

MATERIALS AND METHODS

Study Site: CTVS department of Government General Hospital, Guntur.

Study Population: Patients beyond 12 years of age coming to CTVS-PG diagnosed as TOF.

Study Design: A prospective, observational study.

Sample Size: 50 patients beyond 12 years of age undergoing TOF repair.

Time frame to address the study:4 Years (April 2021 to March 2025).

Inclusion criteria:

- Patients with diagnosis of TOF or Pentalogy of Fallot.
- Patients aged beyond 12 years.
- Patients undergoing total correction of TOF even with history of previous palliative shunt surgeries.
- Patients who are willing to give consent for participation in the study.

Exclusion Criteria

- Patients with Pulmonary Atresia.
- Patients with associated complex congenital cardiac anomalies.
- Patients with multi organ disease (eg. Renal or Neurocognitive dysfunction etc).

Data Collection Methods

- Perusal of case records.
- Follow up of cases.

All the risk factors, clinical values etc. will be measured according to standard cut off values.

Methodology: A total of 50 consecutive patients with diagnosis of TOF beyond 12 years of age, requiring surgical correction were studied. Detailed clinical history was taken. All patients underwent routine blood investigations including investigations pertaining to coagulation. The patients underwent the following investigations at different intervals.

Pre-operative: ECG, chest X-ray, 2D ECHO, Cardiac catheterization study in all patients. CT scan was done in 20 patients to look for peripheral branch PA status and MAPCAs.

Intra-operative: Cardiopulmonary bypass time, Aortic cross clamp time, and Intra-operative Trans oesophageal echocardiography.

ImmediatePost-operative: Duration of ventilation, duration of Oxygen requirement, duration of ICD bleeding in the first post-operative day, duration of inotropic support, duration of ICD, duration of ICU stay, heart rate and rhythm, occurrence of complications [MACE etc], requirement of blood and blood products, 2D ECHO for VSD patch, RVOT gradient, PR status and biventricular function.

Post-operative follow-up at 3 months, 1 year, 3 years: Clinical assessment, ECG to look for heart rate, rhythm and chamber hypertrophy, 2D ECHO to look for VSD patch status, RVOT gradient, PR and TR status, RVEDV, RVESV, RV function, FAC of RV and LVEF.

Operative procedure: Out of 50 patients, 26% (n=13) underwent TOF with TAP and monocusp reconstruction of PV, 30% (n=15) underwent TOF with TAP without any reconstruction of PV and 44% (n=22) underwent TOF without TAP (PV spared). After median sternotomy, pericardium was opened towards the right and stays were taken. After systemic heparanisation total CPB was established by aortic and bicaval cannulation. Antegrade cardioplegia cannula inserted proximal to the aortic cannula. Aortic cross clamp was applied and antegrade cardioplegia (Del Nido 20ml/kg) was given. Moderate hypothermia was induced. The MPA was dissected from the aorta. After satisfactory arrest, SVC and IVC were snugged, RA opened, and LV vented through PFO. The RVOT was inspected through the TV. The RVOT bundles were resected and sized with Hegars dilator according to PV normogram. (54) The VSD was closed through the RA using a Dacron patch with interrupted pledgetted 4-0 or 5-0 prolene sutures. If required, to construct adequate sized RVOT, pulmonary valvotomy/valvectomy through PA was done and it was augmented with autologous pericardial TAP in cases who persisted to have inadequate PV annulus. Monocusp reconstruction of pulmonary valve was done in some cases. TV was tested, and after deairing the left heart PFO was closed directly with prolene suture. Patient was rewarmed and aorta was declamped. RA was closed directly on beating heart with 5-0 prolene. After coming off bypass, Inotropes started, TEE was done to rule out any residual VSD, residual RVOT gradient, PR status and biventricular function. Heparin was reversed, hemostasis was achieved, pericardium was closed over the aorta, chest was closed in layers and shifted to ICU in stable condition.

Statistical analysis: Data collected was entered in excel format and analysed with SPSS version 22.For mean, standard deviation and repeated measures, ANOVA (analysis of variance) was used.

Ethical Consideration

- Ethical clearance was taken from the Ethics committee.
- Informed consent was taken from every patient for participation in the study.

RESULTS

Table 1: Age distribution in study groups

	Study Groups	N	Mean	SD	Min	Max
Age	1a	13	17.92	4.06	12	24
	1b	15	19.54	4.20	14	29
	2	22	20.73	7.31	12	35

In group1a (n=13), the mean age was 17.92 +/- 4.06 years, ranging from minimum age of 12 to maximum age of 24 years. Whereas in group-1b (n=15), the mean age was 19.54 +/-4.20 years, ranging from minimum age of 14 to maximum age of 29 years. Similarly, in group-2 (n=22), the mean age was 20.73 +/-7.31 years, ranging from minimum age of 12 to maximum 35 years of the age [Table1].

Table 2: Gender distribution in study groups

Sex	Group			Total
	1a	1b	2	
Female	3	7	5	15
	23.0%	46.7%	22.7%	30.0%
Male	10	8	17	35
	77.0%	53.3%	77.3%	70.0%

Among the patient belonging to group-1a (n=13), 10 were male patients (77.0%) and 3 were female patients (23.0%) with a total of 13 patients. Whereas in group-1b (n=15), 8 were male patients (53.3%) and 7 were female patients (46.7%) with a total of 15 patients. Similarly, in group-2 (n=22), 17 were male patients (77.3%) and 5 were female patients (22.7%) with a total of 22 patients [Table2].

McGoon's ratio in study groups (CATH study):

Table 3: Comparison of McGoon's Ratio in the study Groups

CATH Study	Study Groups	N	Mean	SD	Min	Max	ANOVA	
							F	p-value
McGoon's Ratio	1a	13	1.64	0.34	1.06	2.50	0.86	0.43(NS)
	1b	15	1.51	0.32	1.01	2.21		
	2	22	1.65	0.33	1.20	2.30		

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

In group-1a (n=13), the mean McGoon's ratio was 1.64 +/-0.34, ranging from minimum of 1.06 to maximum of 2.50. Whereas in group-1b (n=15), it was 1.51+/-0.32, ranging from minimum of 1.01 to maximum of 2.21. Similarly, in group-2 (n=22), the mean McGoon's ratio was 1.65+/-0.33, ranging from minimum of 1.20 to maximum of 2.30 with P value of 0.43, which was statistically not-significant (Table-3).

Major Aorto-Pulmonary Collateral Arteries (MAPCAs) in study groups:

Table 4: Number of MAPCAs in study groups

Study Group	N	Mean (SD)	Range	Median (Q1-Q3)	Kruskal Wallis Test	
					Chi Square value	p-value
1a	13	0.92 (1.00)	0 – 3	1 (0 - 1.75)	0.71	0.70(NS)
1b	15	1.23 (1.24)	0 – 4	1 (0 – 2)		
2	22	0.86 (0.94)	0 – 3	1 (0 – 2)		

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

The mean number of MAPCAs in group-1a (n=13) was 0.92 +/-1.00, ranging from 0 to 3 and in group-1b (n=15), it was 1.23 +/- 1.24, ranging from 0 to 4. Whereas in group-2 (n=22), the mean number of MAPCAs was 0.86 +/- 0.94, ranging from 0 to 3 with P value of0.70 which was non-significant (Table-4).

Intra-operative data:CPB and Aortic Cross Clamp times in study groups:

Table 5a: Comparison of Intra Operative CPB Time and Aortic Cross Clamp Time in study Groups

Intra Op	Study Groups	N	Mean	SD	Min	Max	ANOVA	
							F	p-value
CPB Time	1a	13	142.58	50.76	88	264	7.54	0.002*
	1b	15	186.77	59.64	97	320		
	2	22	116.73	46.77	48	203		
Aortic Cross Clamp Time:	1a	13	115.92	51.47	72	240	5.45	0.008*
	1b	15	141.00	44.51	60	190		
	2	22	89.59	41.52	31	176		

*p<0.05 statistically significant, p>0.05 Non-Significant, NS

In group-1a (n=13), the mean CPB time was 142.48 +/-50.76 minutes, ranging between 88 minutes to 264 minutes, in group1b (n=15) it was 186.77 +/- 59.64 minutes, ranging between 97 minutes to 320 minutes and in group-2 (n=22) it was 116.73 +/- 46.77 minutes, ranging between 48 minutes to 203 minutes with P value of 0.002 which was statistically significant. In group-1a (n=13), the mean aortic cross clamp time was 115.92 +/-51.47 minutes, ranging between 72 minutes to 240 minutes in group-1b (n=15) it was 141.00 +/- 44.51 minutes, ranging between 60 minutes to 190 minutes and in group-2 (n=22) it was 89.59 +/- 41.52 minutes, ranging between 48 minutes to 203 minutes with P value of 0.008 which was statistically significant

Table 5b: Pairwise comparison of Intra Operative CPB Time and Aortic Cross Clamp Time in study Groups

Intra Op	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Boun d
CPBTime	1a	1b	-44.19	20.64	0.09(NS)	-94.25	5.87
		2	25.86	18.50	0.35(NS)	-19.02	70.73
	1b	2	70.04	18.04	0.001*	26.30	113.79
Aortic Cross ClampTime	1a	1b	-25.08	18.02	0.35(NS)	-68.78	18.61
		2	26.33	16.15	0.24(NS)	-12.85	65.50
	1b	2	51.41	15.74	0.006*	13.22	89.60

Tukey Post Hoc Test *p<0.05 statistically significant, p>0.05 NonSignificant, NS

We observed that, there was a statistically significant difference in CPB and aortic cross clamp time between group-1b and group-2 with P values of 0.001 and 0.006 respectively as shown in [Table5b].

Table 6: Comparison of post-operative ventilator duration and O2 requirement in study groups

	Study Group	N	Mean (SD)	Range	Kruskal Wallis Test	
					Chi Squarevalue	p-value
Ventilation Duration (Hours)	1a	13	38.42 (62.13)	5 – 210	2.49	0.29(NS)
	1b	15	29.00 (62.69)	5- 237		
	2	22	11.73 (7.19)	4 – 33		
O2 requirement (Hours)	1a	13	25.25 (29.37)	3 – 86	0.12	0.94(NS)
	1b	15	21.08 (24.46)	4- 96		
	2	22	22.32 (23.00)	3 – 78		

*p<0.05 statistically significant, p>0.05 Non Significant, NS

The mean ventilator duration [Table6] in group1a (n=13) was 38.42 hours, ranging between 5 hours to 210 hours, 29.00 hours in group-1b (n=15), ranging between 5 hours to 237 hours and 11.73 hours in group-2 (n=22), ranging between 4 hours to 33 hours with P value of 2.49 (non-significant). Similarly the mean O2 requirement in group1a (n=13) was 25.25 hours, ranging between 3 hours to 86 hours, 21.08 hours in group-1b (n=15), ranging between 4 hours to 96 hours and 22.32 hours in group-2 (n=22), ranging between 3 hours to 78 hours with P value of 0.12 (non-significant)

Table 7a: Comparison of duration (hours) of Inotropes taken during post-operative period in study groups

Duration (Hours)	Study Group	N	Mean (SD)	Range	Kruskal Wallis Test	
					Chi Square value	p-value
DOPA	1a	13	61.67 (44.32)	0 - 124	2.23	0.33(NS)
	1b	15	43.69 (61.40)	0 – 213		
	2	22	55.86 (39.78)	0 – 136		
DOBUTA	1a	13	13.92 (27.69)	0 – 76	2.07	0.36(NS)
	1b	15	19.46 (33.12)	0 – 96		
	2	22	5.59 (13.84)	0 – 53		
ADR	1a	13	28.08 (50.07)	0 – 164	1.12	0.57(NS)
	1b	15	9.31 (19.32)	0 – 60		
	2	22	12.55 (28.54)	0 – 100		
NORADR	1a	13	21.17 (50.96)	0 – 156	3.08	0.22(NS)
	1b	15	49.92 (68.43)	0 – 188		
	2	22	18.45 (38.70)	0 – 116		
Milrinone	1a	13	0 (0)	0 – 0	2.62	0.27(NS)
	1b	15	1.85 (6.66)	0 – 24		
	2	22	0.00 (0.00)	0 – 0		

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

The mean duration of Inj. Dopamine [Table7a] used in group-1a (n=13) was 61.67 +/- 44.32 hours, in group-1b (n=15) it was 43.69 +/- 61.40 hours and in group-2 (n=22) it was 55.86+/- 39.78 hours with p value of 0.33, which was statistically not-significant. Similarly the mean dose of Inj. Dobutamine in group-1a (n=13) was 13.92 +/- 27.69 hours, in group-1b (n=15) it was 19.46 +/- 33.12 hours and in group-2 (n=22) it was 5.59 +/- 13.84 hours with p value of 0.36, which was not-significant. The mean dose of Inj. Adrenaline used in group-1a (n=13) was 28.08 +/- 50.07 hours, in group-1b (n=15) it was 9.31 +/-19.32 hours and in group-2 (n=22) it was 12.55 +/- 28.54 hours with p value of 1.12, which was statisticallynot-significant. Similarly, the mean dose of Inj. Nor-Adrenaline in group-1a (n=13) was21.17 +/- 50.96 hours, in group-1b (n=15) it was 49.92 +/- 68.43 hours and in group-2 (n=22) it was 18.45 +/- 38.70 hours with p value of 3.08, which was not-significant. The mean dose of Inj. Milrinone used in group-1b (n=15) was 1.85 +/-6.66 hours

Table 7b: Pairwise comparison of Inj. Dopamine taken during post-operative period in study groups

DOPA	Mann Whitney U Test	
	U statistic	p-value
1a vs 1b	33.0	0.01*
1a vs 2	103.0	0.25(NS)
1b vs 2	85.0	0.04*

*p<0.05 statistically significant, p>0.05 Non-Significant, NS

We found there was a significant difference in mean dose (mcg/kg/min) of Inj. Dopamine between group-1a and group-1b and between group-1b and group-2 with P value of 0.001 and 0.04 respectively [Table7b], that being more requirement was there in group-1 than group-2.

Table 8: Comparison of Post-operative ICD (OP day) and ICD duration in the study groups

	Study Group	N	Mean (SD)	Range	Kruskal Wallis Test	
					Chi Square value	p-value
Drainage OP-day (ml)	1a	13	495.83 (419.30)	90 – 1540	1.90	0.39(NS)
	1b	15	342.31 (229.53)	70 – 830		
	2	22	381.36 (435.53)	30 – 1800		
ICD duration (Days)	1a	13	7.42 (5.66)	3 - 20	0.14	0.93(NS)
	1b	15	6.92 (6.05)	2 – 24		
	2	22	5.73 (3.04)	2 – 12		

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

The mean ICD tube duration was 7.42 +/- 5.66 days in group-1a (n=13), 6.92 +/- 6.05 days in group-1b (n=15) and 5.73 +/-3.04 days in group-2 (n=22) with P value of 0.93 (non- significant) [Table8].

Table 9: Post-operative re-exploration in study groups

		Group			Total	Fisher's ExactTest
		1a	1b	2		p-value
Re- exploration for bleeding	No	11	15	19	45	0.42(NS)
		84.6%	100.0%	86.36%	90.0%	
	Yes	2	0	3	5	
		15.4%	0.0%	13.64%	10.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

In our study, two patients (15.4%) in group-1a (n=13) and 3 patients (13.64%) in group-2 (n=22) underwent re-exploration for first post-operative bleeding. There was no statistically significant difference found in re-exploration for post-operative bleeding among study groups (p=0.42) [Table9].

Post-operative blood and blood products used in study groups:

Table 10: Comparison of post-operative blood and blood products used in the study groups

	Study Group	N	Mean (SD)	Range	Kruskal Wallis Test	
					Chi Square value	p-value
Blood (Units)	1a	13	3.17 (3.01)	0 - 11	0.21	0.90(NS)
	1b	15	2.38 (0.87)	1 – 4		
	2	22	2.68 (2.32)	0 – 8		
FFP (Units)	1a	13	3.42 (1.68)	0 – 6	2.25	0.32(NS)
	1b	15	2.46 (1.71)	0 – 4		
	2	22	2.68 (2.08)	0 – 7		

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

Post-operatively, the mean number of blood units used in group-1a (n=13) were 3.17 +/ - 3.01units, ranging between 0 units to 11 units, 2.38 + /- 0.87 units in group-1b (n=15), ranging between 1 unit to 4 units and 2.68 +/- 2.32 units in group-2 (n=22), ranging between 0 units to 8 units with P value of 0.90 (non-significant). Similarly the mean number of Fresh frozen plasma (FFP) units used in group-1a (n=13) were 3.42 +/ -1.68 units ranging between 0 units to 6 units, 2.46 + /- 1.71 units in group-1b (n=15), ranging between 0 unit to 4 units and 2.68 +/- 2.08 units in group-2 (n=22), ranging between 0 units to 7 units with P value of2.25 (non-significant) [Table10].

Table 11: Incidence of ICD tube re-insertion in study groups

		Group			Total	Fisher's Exact Test
		1a	1b	2		p-value
Re insertion of ICD tube for pleuraleffusion	No	12	14	18	44	0.63(NS)
		92.3%	93.3%	81.8%	88.0%	
	Yes	1	1	4	6	

		7.7%	6.7%	18.2%	12.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

In our study, in view of pleural effusion ICD tube re-inserted for one patient (7.7%) in group-1a (n=13), for 1 patient (6.7%) in group-1b (n=15) and for 4 patients in group-2 (n=22). There was no significant difference found in re-insertion of ICD for pleural effusion among study groups (p=0.63) [Table11].

CATH lab interventions:

1)MAPCAs embolization

2)PPI insertion

In view of prolonged oxygen (O2) requirement and ICD drainage, 3 patients underwent MAPCAs coil embolization in cardiac catheterization lab, which accounted to 6.0%. Similarly, in view of CHB post operatively, 2 patients underwent PPI insertion in cardiac catheterization lab and which accounted to 4.0%.

Hospital and ICU stay in study population: In our study, the mean ICU stay was 6.91+/- 5.05 days & hospital stay was 10.15 +/- 6.61days.

Table 12: Comparison of Hospital and ICU stay in study groups

	Study Group	N	Mean (SD)	Rang e	Kruskal Wallis Test	
					Chi Square value	p-value
Hospital stay (Days)	1a	13	10.83 (6.90)	4- 24	0.51	0.77(NS)
	1b	15	11.00 (8.21)	4 – 28		
	2	22	8.64 (4.74)	4 – 22		
ICU stay (Days)	1a	12	8.08 (6.08)	3- 21	0.66	0.72(NS)
	1b	13	6.92 (6.05)	2 – 24		
	2	22	5.73 (3.04)	2 – 12		

*p<0.05 statistically significant, p>0.05 Non Significant, NS

The mean hospital stay [Table12] of group-1a patients (n=13) was 10.83 +/- 6.90 days, ranging between 4 days to 24 days and the mean ICU stay was 8.08 +/-6.08 days, ranging from 3 days to 21 days. Whereas in group-1b (n=15), it was 11.00 +/- 8.21 days, ranging from 4 days to 28 days and the mean ICU stay was 6.92 +/-6.05 days, ranging from 2 days to 24 days. Similarly, in group-2 (n=22), the mean hospital stay was 8.64 +/-4.74 days, ranging from 4 days to 22 days and ICU stay was 5.73 +/- 3.04 days, ranging from 2 days to 12 days. The p values by Kruskal Wallis Test were 0.77 and 0.72 for hospital stay and ICU stay respectively, which were not-significant.

Table 13: Comparison of DOE - NYHA Class in study groups at follow up.

	DOE - NYHA Class	Group			Total	Fisher'sExactTest
		1a	1b	2		p-value
3Months	1	9	10	20	39	0.09(NS)
		69.3%	66.7%	90.9%	78.0%	
	2	4	5	2	11	
		30.7%	33.3%	9.1%	22.0%	
1 Year	1	8	8	17	33	
		61.6%	53.4%	77.3%	66.0%	
	2	4	7	5	16	0.26(NS)
		30.7%	46.6%	22.7%	32.0%	
	3	1	0	0	1	
		7.7%	0.0%	0.0%	2.0%	
3 Year	1	7	7	16	30	
		53.8%	46.7%	72.7%	60.0%	
	2	5	6	6	17	0.45(NS)
		38.5%	40.0%	27.3%	34.0%	
	3	1	2	0	3	
		7.7%	13.3%	0.0%	6.0%	

At 3 months follow up: In group-1a (n=13), 69.3% of patients (n=9) were in DOE NYHA class I and 30.7% (n=4) were in DOE NYHA class II symptoms. In group-1b (n=15), 66.7% of patients (n=10) were in DOE NYHA class I symptoms and 33.3% (n=5) were in DOE NYHA class II symptoms. Similarly, in group-2 (n=22), 90.9% of patients (n=20) were in DOE NYHA class I symptoms and 9.1% (n=2) were in DOE NYHA class II symptoms with P value of 0.09 (non-significant).

At 1 year follow up: In group-1a (n=13), 61.6% of patients (n=8) were in DOE NYHA class I, 30.7% (n=4) were in DOE NYHA class II symptoms and 7.7% (n=1) was in DOE NYHA class III symptoms. In group-1b (n=15), 53.4% of patients (n=8) were in DOE NYHA class I symptoms and 46.6% (n=7) were in DOE NYHA class II symptoms. Similarly, in group-2 (n=22), 77.3% of patients (n=17) were in DOE NYHA class I symptoms and 22.7% (n=5) were in DOE NYHA class II symptoms with P value of 0.26 (non-significant).

At 3 year follow up: In group-1a (n=13), 53.8% of patients (n=7) were in DOE NYHA class I, 38.5% (n=5) were in DOE NYHA class II symptoms and 7.7% (n=1) was in DOE NYHA class III symptoms. In group-1b (n=15), 46.7% of patients (n=7) were in DOE NYHA class I
symptoms, 40.0% (n=6) were in DOE NYHA class II symptoms and 13.3% (n=2) was in DOE NYHA class III symptoms. Similarly in group-2 (n=22), 72.7% of patients (n=16) were in DOE NYHA class I symptoms and 27.3% (n=6) were in DOE NYHA class II symptoms with P value of 0.45 (non-significant) [Table13]

12 lead ECG findings at follow up periods in study groups:

Table 14: Comparison of heart rate (ECG) in study groups at each time interval

Rate ECG	Study Group	N	Mean	SD	Min	Max	ANOVA	
							F	p-value
3 Months	1a	13	83.92	14.68	54	104	0.02	0.99(NS)
	1b	15	84.15	11.52	67	103		
	2	22	83.50	8.30	70	100		
1 Year	1a	13	84.00	13.79	55	104	0.09	0.92(NS)
	1b	15	83.77	14.48	60	105		
	2	22	82.50	7.81	68	98		
3 Year	1a	13	83.75	15.82	52	112	0.04	0.96(NS)
	1b	15	84.69	13.43	67	105		
	2	22	83.50	9.22	65	100		

*p<0.05 Statistically Significant, p>0.05 Non-Significant, NS

At 3 months follow up, the mean heart rate was 83.92 +/- 14.68 beats/minute in group-1a (n=13), ranging between 54 beats/minute to 104 beats /minute, 84.15 +/- 11.52 beats /minute in group-1b (n=15), ranging between 67beats/minute to 103 beats/minute and in group-2 (n=22), it was 83.50 +/- 8.30 beats /minute, ranging between 70 beats/minute to 100 beats/minute with P value of 0.99 (non-significant).

At 1 year follow up, the mean heart rate was 84.00 +/- 13.79 beats/minute in group-1a (n=13), ranging between 55 beats/minute to 104 beats /minute, 83.77+/- 14.48 beats/minute in group-1b (n=15), ranging between 60 beats/minute to 105 beats/minute and in group-2 (n=22), it was 82.50 +/- 7.81beats /minute, ranging between 68 beats/minute to 98 beats/minute with P value of 0.92 (non-significant).

At 3 year follow up, the mean heart rate was 83.75+/- 15.82 beats/minute in group-1a (n=13), ranging between 52 beats/minute to 112 beats /minute, 84.69+/- 13.43 beats /minute in group-1b (n=15), ranging between 67 beats/minute to 105 beats/minute and in group-2 (n=22), it was 83.50+/- 9.22 beats /minute, ranging between 65 beats/minute to 100 beats/minute with P value of 0.96 (non-significant) [Table14]

Post-operative rhythm (ECG) at different follow up intervals in each study group:

Table 15a: Comparison of rhythm in study groups at 3 months follow up

	Rhythm	Group			Total	Fisher'sExact Test
		1a	1b	2		p-value
3 months	SR	12	10	21	43	0.20(NS)
		92.3%	66.7%	95.5%	86.0%	
	AF	0	2	0	2	
		0.0%	13.2%	0.0%	4.0%	
	AV-block First degree	0	1	1	2	
		0.0%	6.7%	4.5%	4.0%	
	CHB	1	1	0	2	
		7.7%	6.7%	0.0%	4.0%	
	Sinus Tachycardia	0	1	0	1	
		0.0%	6.7%	0.0%	2.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

At 3 months follow-up, patients were evaluated with 12 lead ECG. It was found that most of group-1a patients (n=13) were in SR, which accounted to 92.3%and one patient (7.7%) had CHB. In patients included in group-1b (n=15), 10 patients (66.7%) were in SR, one patient (6.7%) had sinus tachycardia, one patient (6.7%) had CHB, one patient (6.7%) had first degree AV block and two patients (13.2%) had AF. Similarly, among the patients included in group-2 (n=22), 21 patients (95.5%) were in SR and one patient (4.5%) had first degree AV block (p=0.20) [Table15a]

Table 15b: Comparison of rhythm in study groups at 1 year follow up

	Rhythm	Group			Total	Fisher'sExact Test
		1a	1b	2		p-value
	SR	10	9	21	40	
		76.92%	60.0%	95.5%	80.0%	

1 year	AF	2	2	0	4	0.05(NS)
		15.38%	13.2%	0.0%	8.0%	
	AV-block First degree	0	1	1	2	
		0.0%	6.7%	4.5%	4.0%	
	CHB	1	1	0	2	
		7.7%	6.7%	0.0%	4.0%	
	Sinus Tachycardia	0	1	0	1	
		0.0%	6.7%	0.0%	2.0%	
	VPC	0	1	0	1	
		0.0%	6.7%	0.0%	2.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

At 1 year follow-up, patients were evaluated with 12 lead ECG. It was found that most of group-1a patients (n=10) were in SR, which accounted to 76.92%, one patient (7.7%) had CHB and 2 patients were developed AF (15.38%). In patients included in group-1b (n=15), 9 patients (60.0%) were in SR, one patient (6.7%) had sinus tachycardia, one patient (6.7%) had CHB, one patient (6.7%) had first degree AV block, two patients (13.2%) had AF and one patient (6.7%) had VPC's. Similarly, among the patients included in group-2 (n=22), 21 patients (95.5%) were in SR and one patient (4.5%) had first degree AV block (p=0.05) [Table15b].

Table 15c: Comparison of rhythm in study groups at 3 year follow up

	Rhythm	**Group**			**Total**	**Fisher'sExact Test**
		1a	**1b**	**2**		**p-value**
3 year	SR	8	10	21	39	0.04*
		61.53%	66.8%	95.5%	78.0%	
	AF	2	2	0	4	
		15.38%	13.2%	0.0%	8.0%	
	AV-block First degree	0	1	1	2	
		0.0%	6.7%	4.5%	4.0%	
	CHB	1	1	0	2	
		7.7%	6.7%	0.0%	4.0%	
	Sinus Tachycardia	1	1	0	2	
		7.7%	6.7%	0.0%	4.0%	
	SVT	1	0	0	1	
		7.7%	0.0%	0.0%	2.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

At 3 year follow-up, patients were evaluated with 12 lead ECG. It was found that most of group-1a patients (n=8) were in SR, which accounted to 61.53%, One patient (7.7%) had sinus tachycardia, one patient (7.7%) had CHB, 2 patients (15.38%) had AF and one patient (7.7%) had SVT. In patients included in group-1b (n=15), 10 patients (66.8%) were in SR, one patient (6.7%) had sinus tachycardia, one patient (6.7%) had CHB, one patient (6.7%) had first degree AV block and two patients (13.2%) had AF. Similarly, among the patients included in group-2 (n=22), 21 patients (95.5%) were in SR and one patient (4.5%) had first degree AV block (p=0.04) [Table15c].

Table 16: Comparison of QRS duration at different time interval in each study group

Group	**QRS duration-ECG**	**N**	**Mean**	**SD**	**Repeated Measures ANOVA**	
					F	**p-value**
1a	3 Months	13	110.17	13.01	22.51	<0.001*
	1 Year	13	112.67	15.90		
	3 Year	13	131.50	19.67		
1b	3 Months	15	107.54	26.97	6.01	0.008*
	1 Year	15	111.46	28.04		
	3 Year	15	119.15	27.03		
2	3 Months	22	89.86	11.30	24.14	<0.001*
	1 Year	22	97.00	14.27		
	3 Year	22	110.27	22.04		

*p<0.05 Statistically Significant, p>0.05 Non-Significant, NS

The mean QRS duration (in milli seconds) in group-1a (n=13) was 110.17 +/- 13.01ms at 3 months, 112.67 +/- 15.90ms at 1 year and 131.50 +/-19.67ms at 3 year follow up with P value of <0.001 (significant). In group-1b (n=15), it was 107.54+/- 26.97ms at 3 months, 111.46+/- 28.04ms at 1 year and 119.15 +/-27.03ms at 3 year follow up with P value of 0.008 (significant). Similarly, in group-2 (n=22), it was 89.86+/- 11.30ms at 3 months, 97.00+/-14.27ms at 1 year and 110.27 +/-22.04ms at 3 year follow up with P value of <0.001 (significant). So we observed that, there was gradually increase in the mean QRS duration as time progressed with irrespective of type of surgery done [Table16].

Table 17: Comparison of RVH (ECG) in study groups at different intervals

ECG	RVH	Group			Total	Fisher's Exact Test
		1a	1b	2		p-value
3 Months	No	5	6	13	24	0.51(NS)
		38.46%	40.0%	59.1%	48.0%	
	Yes	8	9	9	26	
		61.54%	60.0%	40.9%	52.0%	
1 Year	No	8	9	17	34	0.44(NS)
		61.54%	60.0%	77.3%	68.0%	
	Yes	5	6	5	16	
		38.46%	40.0%	22.7%	32.0%	
3 Year	No	9	9	17	35	0.60(NS)
		69.24%	60.0%	77.3%	70.0%	
	Yes	4	6	5	15	
		30.76%	40.0%	22.7%	30.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

In our study, we observed that the RVH in ECG of study population (n=50), 52.0% (n=26) at 3 months, 32.0% (n=16) at 1 year follow up and 30.0% (n=15) at 3 year follow up. There was gradual decrease in RVH in all groups as time progressed. Especially there was a significant reduction of RVH from 3 months to 1 year follow up period [Table17].

Post-operative 2D ECHO findings at follow up periods in study groups: VSD patch status at follow up periods: In our study, VSD patch was intact in most of the patients at immediate post op, 3 months, 1 year and 3 year follow up in all groups. Only one patient in group-1a (n=13) had very tiny leak at upper end of the patch at all follow up intervals. Similarly, one patient in group-2 (n=15) had very tiny leak at upper end of the patch at immediate post-operative period. So, there is no significant difference in VSD patch status in study groups at each follow up period.

RVOT gradient in study groups at follow up periods:

Table 18: Comparison of RVOT gradient in study groups at each time interval

RVOTgradient (mmHg)	Study Group	N	Mean (SD)	Range	Kruskal Wallis Test	
					Chi Squarevalue	p-value
Pre Op	1a	13	81.67(20.39)	55 – 130	6.28	0.04*
	1b	15	101.46(19.47)	70 – 130		
	2	22	88.50(17.30)	60 – 124		
Post Op	1a	13	18.83 (9.60)	6 – 38	3.86	0.15(NS)
	1b	15	18.23 (10.08)	5 – 35		
	2	22	26.00 (14.64)	10 - 60		
3 Months	1a	13	20.75 (13.93)	8 – 50	5.17	0.08(NS)
	1b	15	18.00 (8.72)	4 – 35		
	2	22	26.77 (13.38)	10 – 63		
1 Year	1a	12	19.58 (10.00)	10 - 45	7.81	0.02*
	1b	15	15.54 (9.13)	4 – 38		
	2	22	26.82 (13.38)	8 – 58		
3 Year	1a	13	22.92 (11.53)	8 – 48	0.67	0.72(NS)
	1b	15	21.85 (11.50)	4 – 46		
	2	22	23.41 (8.85)	10 – 46		

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

There was a significant reduction of RVOT gradient from pre-operative period to post- operative follow up periods. At 3 months follow up period the mean RVOT gradient was20.75 +/-13.93 mmHg in group1a (n=13), 18.00 +/- 8.72 mmHg in group-1b (n=15) and26.77 +/-13.38 mmHg in group-2 (n=22) with P value of 0.08 (non-significant). At 1 year follow up, the mean RVOT gradient was 19.58 +/- 10.00 mmHg in group1a (n=132), 15.54+/- 9.13 mmHg in group-1b (n=15) and 26.82 +/-13.38 mmHg in group-2 (n=22) with P value of 0.02(significant). Similarly at 3 year follow up, the mean RVOT gradient was22.92 +/- 11.53 mmHg in group1a (n=13), 21.85 +/- 11.50 mmHg in group-1b (n=15) and23.41 +/-8.85 mmHg in group-2 (n=22) with P value of 0.67 (non-significant) [Table18].

Post-operative PR status in study groups at follow up periods:

Table 19a: Comparison of PR in study groups at immediate post-operative follow up

Echo	PR	Group			Total	Fisher's Exact Test
		1a	1b	2		p-value
	No	3	3	5	11	
		23.0%	20.0%	22.7%	22.0%	
	Trivial	1	3	5	9	
		7.7%	20.0%	22.7%	18.0%	
	Mild	6	4	10	20	

Post - Op		46.22%	26.7%	45.5%	40.0%	0.38(NS)
	Moderate	1	0	0	1	
		7.7%	0.0%	0.0%	2.0%	
	Severe	2	5	2	9	
		15.38%	33.3%	9.1%	18.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

At immediate post-operative period, one patient (7.7%) had trivial PR, 6 patients (46.22%) had mild PR, one patient (7.7%) had moderate PR and 2 patients had severe PR (15.38%) in group-1a (n=13). Whereas in group-1b (n=15), 3 patients (20.0%) had trivial PR, 4 patients (26.7%) had mild PR and 5 patients (33.3%) had severe PR. Similarly in group-2 (n=22), 5 patients (22.7%) had trivial PR, 10 patients (45.5%) had mild PR and 2 patients (9.1%) hadsevere PR with P value of 0.39, which was statistically not-significant [Table19a].

Table 19b: Comparison of PR in study groups at 3 months follow up.

Echo	PR	Group			Total	Fisher's Exact Test
		1a	1b	2		p-value
3Months	No	0	0	1	1	<0.001*
		0.0%	0.0%	4.5%	2.0%	
	Trivial	4	0	6	10	
		30.82%	0.0%	27.3%	20.0%	
	Mild	6	2	14	22	
		46.1%	13.3%	63.6%	44.0%	
	Moderate	1	4	1	6	
		7.7%	26.7%	4.5%	12.0%	
	Severe	2	9	0	11	
		15.38%	60.0%	0.0%	22.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

At 3 months follow up, 4 patients (30.82%) had trivial PR, 6 patients (46.1%) had mild PR, one patient (7.7%) had moderate PR and 2 patients (15.38%) had severe PR in group-1a (n=13). Whereas in group-1b (n=15), 2 patients (13.3%) had mild PR, 4 patients (26.7%) had moderate PR and 9 patients (60.0%) had severe PR. Similarly in group-2 (n=22), 6 patients 27.3%) had trivial PR, 14 patients (63.6%) had mild PR and one patient (4.5%) had moderate PR with P value of <0.001, which was statistically significant [Table-19b].

Table 19c: Comparison of PR in study groups at 1 year follow up

Echo	PR	Group			Total	Fisher's Exact Test
		1a	1b	2		p-value
1Year	No	0	0	1	1	
		0.0%	0.0%	4.5%	2.0%	
	Trivial	0	0	2	2	
		0.0%	0.0%	9.1%	4.0%	
	Mild	6	2	15	23	
		46.20%	13.4%	68.2%	46.0%	
	Moderate	5	2	3	10	
		38.4%	13.4%	13.6%	20.0%	<0.001*
	Severe	2	11	1	14	
		15.4%	73.2%	4.5%	28.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

At 1 year follow up, 6 patients (46.2 0%) had mild PR, 5 patients (38.4%) had moderate PR and 2 patients (15.4%) had severe PR in group-1a (n=13). Whereas in group-1b (n=15), 2 patient (7.7%) had mild PR, 2 patients (13.4%) had moderate PR and 11 patients (73.2%) had severe PR were found. Similarly in group-2 (n=22), 2 patients (9.1%) had trivial PR, 15 patients (68.2%) had mild PR, 3 patients (13.6%) had moderate PR and one patient (4.5%) had severe PR with P value of <0.001, which was statistically significant [Table19c].

Table 19d: Comparison of PR in study groups at 3 year follow up

Echo	PR	Group			Total	Fisher's Exact Test
		1a	1b	2		p-value
3Year	Trivial	0	0	2	2	<0.001*
		0.0%	0.0%	9.1%	4.0%	
	Mild	2	0	11	13	
		15.38%	0.0%	50.0%	26.0%	
	Moderate	3	2	6	11	
		23.09%	13.4%	27.3%	22.0%	

	Severe	8	13	3	24	
		61.53%	86.60%	13.6%	48.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

At 3 year follow up, 2 patients (15.38%) had mild PR, 3 patients (23.09%) had moderate PR and 8 patients (61.53%) had severe PR in group-1a (n=13). Whereas in group-1b (n=15), 2 patient (13.4%) had moderate PR and 13 patients (86.60%) had severe PR were found. Similarly, in group-2 (n=22), 2 patients (9.1%) had trivial PR, 11 patients (50.0%) had mild PR, 6 patients (27.3%) had moderate PR and 3 patients (13.6%) had severe PR with P value of <0.001, which was statistically significant
[Table19d].

Table 20a: Comparison of TR in study groups at immediate post-operative follow up

	TR	Group			Total	Fisher'sExact Test
		1a	1b	2		p-value
Post - Op	No	5	4	3	12	0.61(NS)
		38.5%	26.7%	13.6%	24.0%	
	Trivial	5	7	12	24	
		38.5%	46.6%	54.5%	48.0%	
	Mild	3	4	6	13	
		23.0%	26.7%	27.3%	26.0%	
	Moderate	0	0	1	1	
		0.0%	0.0%	4.5%	2.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

At immediate post-operative period, 4 patients (38.5%) had trivial TR and 3 patients (23.0%) had mild TR in group-1a (n=13). Whereas in group-1b (n=15), 7 patients (46.6%) had trivial TR and 4 patients (26.7%) had mild TR. Similarly in group-2 (n=22), 12 patients (54.5%) had trivial TR, 6 patients (27.3%) had mild TR and 1 patient (4.5%) had moderate TR with P value of 0.61, which was statistically non-significant [Table20a].

Table 20b: Comparison of TR in study groups at 3 months follow up

	TR	Group			Total	Fisher's Exact Test
		1a	1b	2		p-value
3 Months	No	3	3	6	12	0.73(NS)
		23.0%	20.0%	27.3%	24.0%	
	Trivial	4	4	9	17	
		30.8%	26.6%	40.9%	34.0%	
	Mild	5	7	7	19	
		38.5%	46.7%	31.8%	38.0%	
	Moderate	1	1	0	2	
		7.7%	6.7%	0.0%	4.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

At 3 months follow up period, 4 patients (30.8%) had trivial TR, 5 patients (38.5%) had mild TR and one patient (7.7%) had moderate TR in group-1a (n=13). Whereas in group- 1b (n=15), 4 patients (26.6%) had trivial TR, 7 patients (46.7%) had mild TR and one patient (6.7%) had moderate TR. Similarly, in group-2 n=22), 9 patients (40.9%) had trivial TR and 7 patients (31.8%) with moderate TR with P value of 0.73, which was statistically non-significant [Table20b].

Table 20c: Comparison of TR in study groups at 1 year follow up

	TR	Group			Total	Fisher's Exact Test
		1a	1b	2		p-value
1Year	No	0	1	3	4	0.47(NS)
		0.0%	6.7%	13.6%	8.0%	
	Trivial	6	4	10	20	
		46.15%	26.6%	45.5%	40.0%	
	Mild	6	9	9	24	
		46.15%	60.0%	40.9%	48.0%	
	Moderate	1	1	0	2	
		7.7%	6.7%	0.0%	4.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

At 1 year follow up, 6 patients (46.15%) had trivial TR, 6 patients (46.15%) had mild TR and one patient (7.7%had moderate TR in group-1a (n=13). Whereas in group-1b (n=15), 4 patients (26.6%) had trivial TR, 9 patients (60.0%) had mild TR and one patient (6.7%) had moderate TR. Similarly, in group-2 (n=22), 10 patients (45.5%) had trivial TR and 9 patients(40.9%) had moderate TR with P

value of 0.47, which was statistically non-significant [Table20c].

Table 20d: Comparison of TR in study groups at 3 year follow up

	TR	Group			Total	Fisher'sExactTest
		1a	1b	2		p-value
3Year	Trivial	0	0	4	4	<0.001*
		0.0%	0.0%	18.2%	8.0%	
	Mild	7	8	18	33	
		53.8%	53.3%	81.8%	66.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

At 3 year follow up, 7 patients (53.8%) had mild TR and 6 patients (46.2%) had moderate TR in group-1a (n=13). Whereas in group-1b (n=15), 8 patients (53.3%) had mild TR and 7 patient (46.7%) had moderate TR. Similarly, in group-2 (n=22) 4 patients (18.2%) had trivial TR and 18 patients (81.8%) had mild TR with P value of <0.001, which was statistically significant [Table20d].

The RVEDV and RVESV at follow up periods:

Table21a: Comparison of RVEDV in study groups at each time interval

RVEDV (ml)	Study Group	N	Mean	SD	Min	Max	ANOVA	
							F	p-value
3 Months	1a	13	80.67	21.11	44	105	2.90	0.07(NS)
	1b	15	90.23	12.76	56	106		
	2	22	73.68	22.02	27	110		
1 Year	1a	13	91.50	19.68	55	112	5.48	0.007*
	1b	15	100.92	15.44	58	117		
	2	22	76.82	24.99	28	112		
3 Year	1a	13	106.33	15.28	80	124	9.88	<0.001*
	1b	15	114.69	24.51	56	145		
	2	22	79.86	27.56	30	143		

*p<0.05 Statistically Significant, p>0.05 Non-Significant, NS

The mean Right Ventricular End Diastolic Volume (RVEDV) at 3 months follow up period, 80.67+/-21.11 ml in group-1a (n=13), 90.23 +/-12.76 ml in group-1b (n=15) and 73.68 +/-22.02 ml in group-2(n=22) with P value of 0.07, which was statistically not-significant. At 1 year follow up, it was 91.50+/-19.68 ml in group-1a (n=13), 100.92 +/-15.44 ml in group- 1b (n=15) and 76.82+/-24.99 ml in group-2 (n=22) with P value of 0.007, which was statistically significant. Similarly at 3 year follow up, the mean RVEDV was 106.33+/-15.28 ml in group-1a (n=13), 114.69 +/-24.51 ml in group-1b (n=15) and 79.86+/-27.56 ml in group-2 (n=22) with P value of <0.001, which was statistically significant [Table21a].

Table 21b: Pairwise comparison of RVEDV in study groups at each time interval

RVEDV (ml)	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						LowerBound	UpperBound
1 Year	1a	1b	-9.42	8.58	0.52(NS)	-30.24	11.40
		2	14.68	7.69	0.15(NS)	-3.98	33.34
	1b	2	24.11	7.50	0.007*	5.91	42.30
3 Year	1a	1b	-8.36	9.68	0.67(NS)	-31.84	15.12
		2	26.47	8.68	0.01*	5.42	47.52
	1b	2	34.83	8.46	<0.001*	14.31	55.34

Tukey Post Hoc Test *p<0.05 Statistically Significant, p>0.05 Non-Significant, NS

There was a mean difference of RVEDV between group-1b and group-2 at 1 year follow up with P value of 0.007 (significant) that being RVEDV was less in group-2. Similarly at 3 year follow up, there was a significant mean difference in RVEDV found between group-1a and group-2 (P=0.01) and between group-1b and group-2 that being RVEDV was less in group-2 (P=<0.001) [Table21b].

Table 21c: Comparison of RVEDV between different time intervals in each study group.

Group	RVEDV (ml)	N	Mean	Std. Deviation	Repeated measures ANOVA	
					F	p-value
1a	3 Months	13	80.67	21.11	13.44	<0.001*
	1 Year	13	91.50	19.68		
	3 Year	13	106.33	15.28		
1b	3 Months	15	90.23	12.76	25.04	<0.001*
	1 Year	15	100.92	15.44		
	3 Year	15	114.69	24.51		

2	3 Months	22	73.68	22.02	18.05	<0.001*
	1 Year	22	76.82	24.99		
	3 Year	22	79.86	27.56		

*p<0.05 Statistically Significant, p>0.05 Non-Significant, NS

The mean RVEDV in group-1a (n=13), 80.67 +/ - 21.11ml at 3 months, 91.50 +/-19.68 ml at 1 year and 106.33 +/ - 15.28 ml at 3 year follow up period with P value of <0.001, which wasstatistically significant. In Group-1b, it was (n=15), 90.23 +/- 12.76 ml at 3 months, 100.92+/-15.44 ml at 1 year and 114.69 +/ - 24.51 ml at 3 year follow up period with P value of<0.001, which was statistically significant. Similarly the mean RVEDV in group-2 (n=22),73.68+/- 22.02 ml at 3 months, 76.82 +/- 24.99 ml at 1 year and 79.86 +/ - 27.56 ml at 3 year follow up period with P value of <0.001, which was statistically significant [Table21c].

Table 22a: Comparison of RVESV in study groups at each time interval

RVESV (ml)	Study Group	N	Mean	SD	Min	Max	ANOVA	
							F	p-value
3 Months	1a	13	37.67	13.07	20	69	2.34	0.11(NS)
	1b	15	39.00	8.52	24	54		
	2	22	30.82	13.13	10	66		
1 Year	1a	13	50.67	18.78	26	80	5.46	0.008*
	1b	15	54.00	19.88	20	86		
	2	22	34.91	17.00	12	68		
3 Year	1a	13	55.83	23.68	0	82	13.94	<0.001*
	1b	15	74.08	24.46	24	99		
	2	22	35.95	16.70	13	75		

*p<0.05 Statistically Significant, p>0.05 Non-Significant, NS

The mean Right Ventricular End Systolic Volume (RVESV) at 3 months follow up period, 37.67+/- 13.07 ml in group-1a (n=13), 39.00+/-8.52 ml in group-1b (n=15) and 30.82 +/-13.13 ml in group-2 (n=22) with P value of 0.11, which was statistically not-significant. At 1 year follow up, it was 50.67 +/- 18.78 ml in group-1a (n=13), 54.00 +/-19.88 ml in group-1b (n=15) and 34.91+/-17.00 ml in group-2 (n=22) with P value of 0.008, which was statistically significant. Similarly at 3 year follow up, the mean RVESV, 55.83+/-23.68 ml in group-1a (n=13), 74.08 +/-24.46 ml in group-1b (n=15) and 35.95+/- 16.70 ml in group- 2(n=22) with P value of <0.001, which was statistically significant [Table22a].

Table 22b: Pairwise comparison of RVESV in study groups at each time interval

RVESV (ml)	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	p-value	95% CI	
						Lower Bound	Upper Bound
1 Year	1a	1b	-3.33	7.32	0.89(NS)	-21.08	14.41
		2	15.76	6.56	0.05(NS)	-0.15	31.67
	1b	2	19.09	6.39	0.01*	3.58	34.60
3 Year	1a	1b	-18.24	8.36	0.09(NS)	-38.53	2.04
		2	19.88	7.50	0.03*	1.70	38.06
	1b	2	38.12	7.31	<0.001*	20.40	55.85

*p<0.05 Statistically Significant, p>0.05 Non-Significant, NS

There was a difference in mean's of RVESV between group-1b and group-2 at 1 year follow up with P value of 0.01(significant) that being RVESV was less in group-2. Similarly at 3 year follow up, there was a significant difference in mean's in RVESV found between group-1a and group-2 (P=0.03) and between group-1b and group-2 that being RVESV was less in group-2 (P= <0.001) [Table22b].

Table 22c: Comparison of RVESV between different time intervals in each study group.

Group	RVESV(ml)	N	Mean	SD	Repeated measures ANOVA	
					F	p-value
1a	3 Months	13	37.67	13.07	7.92	<0.001*
	1 Year	13	50.67	18.78		
	3 Year	13	55.83	23.68		
1b	3 Months	15	39.00	8.52	21.99	<0.001*
	1 Year	15	54.00	19.88		
	3 Year	15	74.08	24.46		
2	3 Months	22	30.82	13.13	17.06	<0.001*
	1 Year	22	34.91	17.00		
	3 Year	22	35.95	16.70		

*p<0.05 Statistically Significant, p>0.05 Non-Significant, NS

The mean RVESV in group-1a (n=13), 37.67 +/ - 13.07 ml at 3 months, 50.67 +/-18.78 ml at1 year and 55.83 +/ - 23.68 ml at 3 year follow up period with P value of <0.001, which is statistically significant. In Group-1b (n=15), it was 39.00 +/- 8.52 ml at 3 months, 54.00 +/19.88 ml at 1 year and 74.08 +/ - 24.46 ml at 3 year follow up period with P value of <0.001, which is statistically significant. Similarly the mean RVESV in group-2 (n=22), 30.82+/-13.13 ml at 3 months, 34.91 +/-17.00 ml at 1 year and 35.95 +/ - 16.70 ml at 3 year follow up period with P value of <0.001, which is statistically significant [Table22c].

Table 23: Comparison of RV dysfunction between the study groups

Echo	RV dysfunction	Group			Total	Fisher'sExact Test
		1a	1b	2		p-value
Post - Op	No	13	15	21	49	1.00(NS)
		100.0%	100.0%	95.5%	98.0%	
	Mild	0	0	1	1	
		0.0%	0.0%	4.5%	2.0%	
3 Months	No	12	15	22	50	
		100.0%	100.0%	100.0%	100.0%	
1 Year	No	12	15	22	50	
		100.0%	100.0%	100.0%	100.0%	
3 Year	No	11	9	21	41	0.05(NS)
		84.6%	60.0%	95.5%	82.0%	
	Mild	2	4	1	7	
		15.4%	26.7%	4.5%	14.0%	
	Moderate	0	2	0	2	
		0.0%	13.3%	0.0%	4.0%	

*p<0.05 statistically significant, ` p>0.05 Non-Significant, NS

At immediate post-operative period, one patient (4.5%) had mild RV dysfunction in group-2 (n=22) and there was no RV dysfunction at 3 months and 1 year follow up periods in all groups. Similarly at 3 year follow up, 2 patients (15.4%) had mild RV dysfunction group-1a (n=13), 4 patients (26.7%) had mild RV dysfunction, 2 patients (13.3%) had moderate RV dysfunction in group-1b (n=15) and one patient (4.5%) had mild RV dysfunction in group-2 (n=22) with P value of 0.05, which was statistically not-significant [Table23].

Fractional Area Change of Right Ventricle (FAC of RV) in study groups at follow up periods:

Table 24a: Comparison of FAC of RV in study groups at each time interval

FAC of RV	Study Group	N	Mean	SD	Min	Max	ANOVA	
							F	p-value
3 Months	1a	13	43.17	3.13	39	48	4.60	0.02*
	1b	15	42.62	4.59	38	50		
	2	22	46.91	5.15	36	56		
1 Year	1a	13	41.67	3.23	38	47	5.52	0.007*
	1b	15	40.77	3.83	36	48		
	2	22	45.86	5.95	30	60		
3 Year	1a	13	38.92	4.50	30	46	1.92	0.16(NS)
	1b	15	39.15	7.23	32	59		
	2	22	42.82	7.13	28	55		

*p<0.05 Statistically Significant, p>0.05 Non-Significant, NS

The mean FAC of RV at 3 months follow up period was 43.17+/-3.13 % in group-1a (n=13), 42.62 +/- 4.59 % in group-1b (n=15) and 46.91+/-5.15 % in group-2 (n=22) with P value of 0.02, which was statistically significant. At 1 year follow up, it was 41.67 +/-3.23% in group-1a (n=13), 40.77+/-3.83 % in group-1b (n=15) and 45.86 +/-5.95 % in group-2 (n=22) with P value of 0.007, which was statistically significant. Similarly at 3 year follow up, the mean FAC of RV was 38.92 +/-4.50 % in group-1a (n=13), 39.15 +/-7.23 % in group-1b (n=15) and 42.82 +/- 7.13 % in group-2 (n=22) with P value of 0.16, which was statistically not-significant [Table24a].

Table 24b: Pairwise comparison of FAC of RV in study groups at each time interval

FAC of RV	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	p-value	95% Confidence Interval	
						Lower Bound	Upper Bound
3Month s	1a	1b	0.55	1.83	0.95(NS)	-3.89	4.99
		2	-3.74	1.64	0.07(NS)	-7.72	0.23
	1b	2	-4.29	1.60	0.03*	-8.17	-0.42
1 Year	1a	1b	0.90	1.94	0.89(NS)	-3.81	5.60
		2	-4.20	1.74	0.05(NS)	-8.42	0.02

	1b	2	-5.09	1.70	0.01*	-9.21	-0.98

Tukey Post Hoc Test *p<0.05 Statistically Significant, p>0.05 Non-Significant, NS

There was a mean difference of FAC of RV between group-1b and group-2 at 3 months follow up with P value of 0.03 (significant). Similarly, at 1 year follow up, there was a significant difference of mean in FAC of RV found between group-1b and group-2 (P =<0.01) [Table24b].

LVEF in study groups at follow up periods:

Table 25a: Comparison of LVEF (%) in study groups at each time interval

LVEF (%)	Study Group	N	Mean	SD	Min	Max	ANOVA	
							F	p-value
3 Months	1a	13	60.83	1.80	58	64	0.94	0.40(NS)
	1b	15	60.39	2.63	55	66		
	2	22	61.32	1.59	60	64		
1 Year	1a	13	60.33	2.19	58	65	1.53	0.23(NS)
	1b	15	59.85	1.68	56	62		
	2	22	60.86	1.36	58	64		
3 Year	1a	13	59.00	2.49	56	64	0.87	0.43(NS)
	1b	15	59.62	3.38	56	66		
	2	22	60.18	1.87	55	64		

*p<0.05 Statistically Significant, p>0.05 Non-Significant, NS

The mean Left Ventricular Ejection Fraction (LVEF) at 3 months follow up period was,60.83 +/- 1.80 % in group-1a (n=13), 60.39 +/-2.63 % in group-1b (n=15) and 61.32 +/-1.59% in group-2 (n=22) with P value of 0.94, which was statistically non-significant. At 1 year follow up period, it was 60.33+/-2.19 % in group-1a (n=13), 59.85 +/-1.68 % in group-1b (n=15) and 60.86 +/-1.36 % in group-2 (n=22) with P value of 1.53, which was statistically non-significant. Similarly at 3 year follow up, the mean LVEF was, 59.00 +/-2.49 % in group-1a (n=13), 59.62 +/-3.38 % in group-1b (n=15) and 60.18 +/- 1.87 % in group-2 (n=22) with P value of 0.87, which was statistically non-significant [Table25a]

Table 25b: Comparison of LVEF (%) between different time intervals in each study group.

Group	LVEF (%)	N	Mean	SD	Repeated Measures ANOVA	
					F	p-value
1a	3 Months	13	60.83	1.80	2.24	0.07(NS)
	1 Year	13	60.33	2.19		
	3 Year	13	59.00	2.49		
1b	3 Months	15	60.39	2.63	0.68	0.57(NS)
	1 Year	15	59.85	1.68		
	3 Year	15	59.62	3.38		
2	3 Months	22	61.32	1.59	2.28	0.09(NS)
	1 Year	22	60.86	1.36		
	3 Year	22	60.18	1.87		

*p<0.05 Statistically Significant, p>0.05 Non-Significant, NS

The mean LVEF in group-1a (n=13) was 60.83 +/- 1.80 % at 3 months, 60.33 +/-2.19 % at 1 year and 59.00 +/ - 2.49 % at 3 year follow up period with P value of 0.07, which was statistically not-significant. In Group-1b (n=15), it was 60.39 +/- 2.63 % at 3 months, 59.85+/-1.68 % at 1 year and 59.62 +/ - 3.38 % at 3 year follow up period with P value of 0.57, which was statistically not-significant. Similarly the mean LVEF in group-2 (n=22) was61.32 +/- 1.59 % at 3 months, 60.86 +/-1.36 % at 1 year and 60.18 +/ - 1.87 % at 3 year follow up period with P value of 0.09, which was statistically non-significant (Table-25b).

DISCUSSION

TOF is the most common cyanotic congenital heart disease and is one of the most extensively studied entity among complex congenital heart diseases. Although the surgical outcomes of adult TOF patients are good,[17] the predominant trend in the timing of surgical procedure has been towards earlier intervention with elective repair within the first 4–6 months of life.

Pre-Operative data: In our study, the mean age at the time of presentation was 19.39 +/- 5.19 years. This was comparative to study done by Khan et al,[19] where the mean age was 21+/-0.21 years. Our study was not correlating to studies done by Ho KW et al,[20] in 2007, where the mean age was 32.2 +/- 12.4 years and Fernando A. et al,[21] in 2003, where the mean age group of 26.6 years in Brazil.

Our study included, 35 male patients (70%) and 15 female patients (30%), which were not comparable to similar studies conducted by Mark Dennis et al,[22] where 55% were males and 45% were females.

In our study, the associated anomalies with TOF were right aortic arch in 24% of patients (n=12), ASD / PFO in 12% of patients (n=6), PAPVC in one patient (2%) and severe TR in one patient (2%),

which was correlating to the study conducted by Anderson RH et al in 2014.[5]

In our study, 3 patients (6%) underwent prior palliative procedures, out of them one patient had undergone BT shunt at the age of 1 year and 2 patients had undergone central shunt at the age of 2 years and 1 ½ year respectively, which were not comparable to similar study performed by Khan et al, where 18.75% of our patients had undergone palliation procedures previously.[19]

In 2001 a similar study of adult TOF conducted by Navabi-Shirazi et al,[23] concluded that older patients generally do better with 2-stage repair because of improvement of oxygen saturation before correction and may improve outcome in selected group of adult patients. However comparative analysis of outcomes of such patients in our study is not feasible due to less number of patients.

Intra-operative period:CPB time and aortic cross clamp time were used to estimate the operative difficulty. The mean CPB time and aortic cross clamp time in our study were 186.67+/-52.39mins & 115.50+/-45.83mins respectively. We found that group-1(with TAP) patients had more CPB and aortic cross clamp time as compared to group-2 (without TAP) with P value of 0.002 and0.008 respectively. We did not find any impact of prolonged CPB and aortic cross clamp time on early and midterm outcomes. But study done by Yim D et al,[24] concluded that the aortic cross- clamp time can also impact long term outcome, as shown by an association with greater RV fibrosis burden 10 years after complete repair of TOF. Thus, there is a need for long term follow up to know the impact of prolonged CPB and aortic cross clamp time on RV fibrosis in our study.

Intra-operatively after coming off bypass, 70% of patients (n=35) regained SR spontaneously. 26% (n=13) came off in JR and (4%) (n=2) patients developed CHB, who were shifted to ICU with AV sequential epicardial pacing. During the ICU stay, most of the patients regained SR (90%), 3 patients remained in JR (6%) and 2 patients remained in CHB (group-1) (4%).

Post-Operative period: Post-operatively, the most common inotropic support used was Dopamine. The mean dose and duration of it was 5.63+/-3.73 mic/kg/min and 53.74+/-48.5 hrs respectively. We found significant difference in mean dose of Dopamine between group 1a and group 1b and between group 1b and group 2 with P value of 0.001 and 0.04 respectively that being higher dose was required in group-1 as compared to group-2. Whereas there was no significant difference in duration of Dopamine in all study groups. In our study, Dopamine was used in 76% of patients, Noradrenaline in 32% of patients, Dobutamine in 24% of patients, Adrenaline in 24% of patients, and Milrinone in 2 % of patients.

The mean first post-operative day bleeding was 406.5+/-361.45ml. Similarly, the mean number of blood and FFP used were 2.74+/-2.06 and 2.85+/-1.82 units respectively. The incidence of re-exploration for post-operative bleeding in our study was 10.6%, which was not correlating with Khan et al,[19] study, where the incidence of re-exploration for bleeding was 3.8%. In our study, the mean ICD tube duration was 6.69+/-4.92 days. The incidence of post-operative pleural effusion was 12.8%.

In view of prolonged ventilatory requirement and ICD drainage, 3 patients underwent MAPCAs coil embolization in cardiac catheterization lab, which accounted to 6%. In our study, the incidence of sternal wound infection and pneumothorax were 2% each. Post operatively one patient (2%) developed left upper limb paresis in group-1b (n=15), which recovered with physiotherapy. Two patients (4%) had new onset seizures post operatively, one patient belonged to group-1a (n=13) and another patient belonged to group-2 (n=22) and were treated medically.

ICU stay & hospital stay are other variables considered for measuring outcomes in congenital heart surgery and ICU stay of > 7 days was considered as a morbidity parameter as per Vasdev et al,[25] In our study, the mean ICU stay & hospital stay were 6.91+/- 5.05 &10.15 +/- 6.61days respectively. Our ICU stay was comparable to studies conducted by Hirsch et al, Kolcz et al,[26] and Tamesberger et al,[27] where the mean length of ICU stay of 9 days, 7 days and 6 days respectively. However, our study was not comparable to the study conducted by Vasdev et al,[25] where the mean ICU stay & hospital stay was 3.58 +/- 4.08 &7.04 +/- 4.24 days respectively. In our study, although statistical significance was found with the type of elective repair & CPB time & aortic cross clamp time, this did not translate with statistical significance when comparing the type of elective repair with that of mean ICU & hospital stay. In our study, out of 50 patients, 12 patients (24%) had ICU stay of > 7 days and 38 patients (76%) had ICU stay of < 7 days. This did not correlate with the study done by Lodin D et al,[28] and Mercer-Rosa et al,[29] where the mean ICU stay of > 7 days was 32.4% and 41% respectively.

Post-Operative follow up period:

At 3 years follow up, 60% of patients were in DOE NYHA class-I, 34.0% were in DOE NYHA class-II and 6% were in DOE NYHA class-III symptoms. We found that, there was no significant difference in NYHA class between TAP and valve-sparing approaches atfollow up periods, which was correlating to the studies conducted by Kirklin J.K et al.[30]

In our study, the incidence of atrial arrhythmias were 8% at 3 year follow up, which was correlating to the study conducted by Khan et al,[19] where the incidence was 5%. Our study also correlating to the studies conducted by Kirklin J.K et al.[30]where the incidence of atrial arrhythmias were 3.7% and 4% to 20% respectively.

In our study, there was a significant decrease in RVOT gradient from pre-operative period to post-

operative period in all study groups, but we did not find any significant increase in RVOT gradient at follow up periods in all study groups. The mean RVOT gradient at follow up periods were 25.92+/-11.82mmHg in group-1a, 24.85+/-9.78mmHg in group-1b and 25.66+/-11.87mmHg in group-2 with P value of 0.52, which was statistically insignificant.
In our study, of 56% patients who underwent TOF correction with TAP, 26% were with monocusp reconstruction (Group-1a) and 30% were without monocusp (Group-1b) reconstruction. It was correlating to the study conducted by Dittrich S et al,[32] where TAP was needed in approximately 40% of adult patients.
We compared PR status at immediate post-operative, 3 months, 1 year and at 3 year follow up periods in study groups and it was found that the incidence of severe PR was 15.3% in group-1a, 33.3% in group-1b and 9.1% in group-2 at immediate post-operative period (p=0.38) and 15.38% in group-1a, 60.0% in group-1b and 0.0% in group-2 at 3 months follow up period (p=<0.001). Whereas at 1 year follow up period, severe PR was 15.4% group-1a, 73.2% in group-1b and 4.5% in group-2 (p=<0.001). Similarly at 3 year follow up, it was 61.53% in group-1a, 86.60% in group-1b and 13.6% in group-2 with P value of p=<0.001.
So we observed that the patients who underwent TAP with monocusp (group-1a) had less incidence of PR till 1 year follow up as compared to patients without monocusp (group- 1b) reconstruction. But no statistical significance was found at 3 year follow up between group -1a and group-1b. As time progressed, the incidence of PR was gradually increasing in all study groups. At 3 year follow up, the incidence of severe PR in our study was 48.0% which was not correlating to studies conducted by Khan et al,[19] and Kirklin J.K et al,[30] where it was 25% and 7% respectively. We observed that patients with severe PR were asymptomatic at follow up periods, which was correlating with the observation of Roest.
In our study, 8.0% of patients had trivial TR, 66.0% had mild TR and 26.0% had moderate TR at 3 year follow up period. We noted that, the patients with moderate TR were belonging to group-1a and group-1b equally. Patients in group-2 had trivial to mild TR during all follow up periods.
O'Meagher S et al,[33] stated that MRI derived increased RV volumes, EDVi, have been considered a sign of prolonged high PR burden and thus a predictor of RV dysfunction. However, exercise capacity can be preserved even in severely dilated ventricles, demonstrating that compensatory mechanisms can still be adequate to maintain performance of large RV's.
As published in literature 2D ECHO also can be a good tool to measure RV volumes and correlates with functional status of the patients. Post operatively RVEDV were calculated by 2D ECHO in our study. At 3 year follow up period, the mean RVEDV in group-1a was 106.33 +/-15.28ml, 114.69+/-24.51ml in group1b and 79.86+/-27.56ml in group-2. Similarly the mean RVESV was 55.83+/-23.68ml in group-1a, 74.08+/-24.46ml in group1b and 35.95+/-16.70ml in group-2. We observed that the mean RVEDV and RVESV were increasing gradually as time progressed and it was more in group-1b and group-1a as compared to group-2. All patients were clinically stable. So, there is a need for long term follow up for the assessment of these indices on the patient's functional status clinically.
Giannopoulos NM et al,[34] and Gatzoulis MA et al,[35] stated that the extent of RV dysfunction was more in patients who needed a TAP and there was remarkable decrease in systolic wall motion velocity which occurred despite the presence of volume overload, because of the concomitant PR. In our study, 82.0% of patients had normal RV function, 14.0% had mild RV dysfunction and 4.0% had moderate RV dysfunction at 3 year follow up. Moderate RV dysfunction was found only in patients who underwent TAP without monocusp reconstruction (group-1b) which was correlating to studies conducted by Giannopoulos NM et al,[34] and Gatzoulis MA et al,[35] Thus progressive RV dilation is responsible for RV dysfunction in these patients. RV Fractional Area Change (FAC) of <32% correlates with RV dysfunction. Only 2 patients (4%) had FAC of RV <32% in group-1b of our study at 3 years follow up period. All patients had normal LVEF at follow up periods.
In our study, there were 3 deaths (6%) all of which belonged to group-1. One patient who belonged to group-1a died at 8th post-operative day due to severe RV dysfunction with septicaemia and multi organ failure. (SCD) Sudden Cardiac Death occurred in two patients belonging to group-1b at 4th and 8th month of discharge due to VT. The incidence of early death rate (6%) in our study was correlating with studies done by Khan et al (19) (8%), Dennis et al,[22] (6%) and was not correlating with studies conducted by Folino AF et al,[17] (<1%).

CONCLUSION

The population included in our study were older, more symptomatic and belonged to lower socioeconomic strata.The clinical outcome of elective repair in adult TOF is excellent irrespective of the type of surgery performed.Although the incidence of severity of PR, RV dysfunction & post-operative arrhythmias is more in patients who undergo TOF repair with TAP, no significant difference is found in late mortality, morbidity & quality of life assessment among the various groups during follow up.TOF repair with TAP &monocusp augmentation has excellent results with reduced occurrence of severe PR upto 1 year. But at 3 years, the severity of PR is comparable with that of TOF repair with TAP without monocusp augmentation of pulmonary valve. Hence the durability of monocusp

augmentation seems to be short lived. However, TOF repair without TAP has overall the best results with least incidence of PR, TR, RV dysfunction & post-operative arrhythmias. Hence it should be preferred wherever it is possible.

Limitations of the study:

- There are some limitations to our study. Firstly, our study is based on a relatively small sample size of patients from a single centre and so the strength for predicting operative mortality, morbidity & difficulty in TOF surgery could be biased, thus the results need to be further examined using a large number of patients across the multi- centre database.
- Late outcomes post TOF repair is as important as the early and midterm results because of chronic PR, progressive RV dilatation & failure especially in patients who underwent TAP. These patients are also prone for sudden cardiac arrhythmias & death. Hence need for long term analyses of TOF patients post repair is required.
- The surgeries performed in this study were not by single surgeon.

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