SURGERY OF TETRALOGY OF FALLOT-15 YEAR EXPERIENCE AT AFIC-NIHD RAWALPINDI

Syed Shahid Nafees Zaidi, Inamullah Khan, Nausheen Bakht*, Syeda Aliza Shahid**, Khurram Akhtar, Hajira Akbar, Amjad Mahmood, Intisar Ul Haq, Nadeem Sadiq, Dawood Kamal, Hafsa Khalil

Armed Forces Institute of Cardiology/National Institute of Heart Disease (AFIC/NIHD)/National University of Medical Sciences (NUMS) Rawalpindi Pakistan, *Armed Forces Post Graduate Medical Institute/National University of Medical Sciences (NUMS) Rawalpindi Pakistan, **CMH Lahore Medical College, Lahore/National University of Medical Sciences (NUMS) Pakistan

ABSTRACT

Objective: To compare trans-atrial/Trans-pulmonary and trans-annular/trans-ventricular techniques of surgical correction of tetralogy of fallot.

Study Design: Descriptive cross sectional study.

Place and Duration of Study: AFIC-NIHD Rawalpindi, from Jan 2005 to Jan 2020.

Methodology: Pre-op variables included age, gender, weight, SaO2 and any previous operation (like Modified Blalock Taussig Shunt.) Operative variables were any previous Blalock Taussig Shunts and if present, then their takedown, Cardiopulmonary Bypass Time, Aortic Clamp Time, any Right Ventricle - Pulmonary Artery conduit, Main Pulmonary Artery patch-plasty, Left Pulmonary Artery/ Right Pulmonary Artery patch-plasty, dosage of inotropes and pacing started during weaning off CPB. Post-op variables were mechanical ventilation time (hrs), ventilation time >72 hrs, dosage and duration of inotropes, pacing >24 hrs, renal complications, neurological complications, sepsis, low cardiac output, re-ventilation, tachyarrythmias, any re-opening surgery, mean intensive care unit stay (hrs), overall hospital stay (days) and overall all-cause mortality.

Results: A total of 1271 TOF patients were operated. In (38.6%) cases Trans-atrial / Trans-pulmonary approach was used while in 780 (61.3%) correction was done by TAP/TV technique. In both techniques, male patients were 365 (66.4%) vs. 73 (64.1%) females. Mean age was 5 ± 2.3 vs. 4 ± 2.5 years, MPA patch-plasty was 190 ± 5 (38.6%) vs. 780 ± 8 (100%) (*p*-0.058), RPA/LPA Patch Plasty was 25 ± 6 (5%) vs. 180 ± 10 (23%) (*p*-0.025), In ICU, Ventilation hours was 25 ± 8 and 30 ± 12 , Ventilation >72 Hrs was 15 (3%) vs. 65 (8.3%) (*p*-0.015), Inotrope duration >72 Hours was 90 (18.3%) vs. 400 (51.2%) (*p*-0.338), pacing >24 hours was 30 (6.1%) vs. 150 (19.2%) (*p*-0.0001), renal complications were 10 (2.3%) vs. 35 (4.4%) (*p*-0.285), Neurological complications were 7 (1.4%) vs. 15 (1.9%) (*p*-0.553), Sepsis was 11 (2.2%) vs. 47 (6%) (*p*-0.33), Low cardiac output was 15 (3%) vs. 66 (8.4%) (*p*- 1.000), re-ventilation was 10 (2%) vs. 110 (14%) (*p*- 0.41), Tachy-arrhythmia was 25 (5%) vs. 108 \pm 10, Mortality was 35 (7.1%) vs. 75 (9.6%) (*p*-0.094), Mean hospital stay (Days) was 12.2 ± 2.5 vs. 15.8 ± 4.9 .

Conclusion: Fifteen years' experience of Tetralogy of fallot corrections at AFIC-NIHD indicates that Trans-atrial / Trans-pulmonary approach is more beneficial to patients due to high survival rate, less morbidity, less hospital stay and an early discharge. This ultimately translates into less financial burden on the patients, hospital, society and the country at large.

Keywords: Tetralogy of fallot, Trans-atrial/trans-pulmonary repair, Trans-annular patch/trans-venrticular repair, Total correction of tetralogy of fallot.

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INTRODUCTION

Tetralogy of Fallot (TOF) is the commonest type of cyanotic congenital heart disease having an incidence of 3/1000 live births¹. Its classical tetrad comprises of right ventricular outflow tract obstruction (RVOTO), ventricular septal defect (VSD), overriding aorta, and RV hypertrophy.

This anomaly was first mentioned in 1673 by Bishop & Steno but it was extensively elaborated upon by Fallot in 1888 ². The etiology of TOF is largely unknown but is said to be associated with environmental factors and genetic disorders and in one study chromosomal alterations were found in 30% patients³.

Correspondence: Dr Syed Shahid Nafees Zaidi, Peads Cardio Surgery, AFIC/NIHD Pakistan

The only definitive treatment for TOF is total surgical correction which has consistently impro-ed since the first surgical repair in 1954. Transatrial/trans-pulmonary (TA/TP) and transannular patch/trans-ventricular (TAP/TV) repair are two well-known surgical techniques for total correction of TOF. Improved treatment strategies have resulted in excellent long-term survival (30-year survival ranges from 68.5%-90.5%)⁴.

The selection of techniques depends upon case presentation and anatomical defects. Both techniques have their pros and cons. Advantages of TA/TP approach include shorter cardiopulmonary bypass (CPB) and aortic clamp time (ACT), smoother separation from CPB, minimal use of inotropes, lesser post-operative bleeding, lesser blood products transfusion, lesser reopening rate, smoother course in ICU, earlier extubation, minimal pleural drainage, minimal ICU and hospital stay, lesser mortality, an earlier hospital discharge⁵ and low rate of repeat sternotomy for right ventricular outflow tract (RVOT) reconstruction⁶.

TAP/TV correction is done to get the required RVOT dimension when the pulmonary valve is either hypoplastic/severely stenosed along with a ver tight infundibular stenosis. Although short term advantages of TAP/TV are fewer, but its long term prognosis and functional capacity is not shown to be significantly inferior to TA/TP approach⁷.

METHODOLOGY

Armed Forces Institute of Cardiology-National Institute of Heart Diseases (AFIC-NIHD) Rawalpindi, Pakistan, Cardiac Surgery database was analyzed from January 2005 to January 2020. Institutional Review Board of the hospital approved the study. Inclusion Criteria were operations done for TOF in the last 15 years. Exclusion Criteria included double outlet right ventricle (DORV) with aortic override >80%, and TOF with other associated anomalies like complete and partial anomalous pulmonary venous drainage (TAPVR/PAPVR), one and half ventricle repairs, pulmonary atresia (PA), atrioventricular septal defect (AVSD) and absent pulmonary valve syndrome (APVS). Pre-op variables included age, gender, weight, SaO2 in air and history of any previous operation like Modified Blalock Taussig Shunt (MBTS).

Operative variables were take-down of MBTS if present, cardiopulmonary bypass time (CPB), aortic clamp time (ACT), right ventricle pulmonary artery (RV-PA) conduit insertion, main pulmonary artery (MPA) patch-plasty, right pulmonary artery/left pulmonary artery (RPA/LPA) patch-plasty, inotropes dosage given (low/moderate/high) and initiation of pacing during weaning off CPB.

Post-op variables included mechanical ventilation time (hours), ventilation time >72 hours, inotropes dosage given (low/ moderate /high), duration of inotropes >72 hours, pacing continuation >24 hours, renal complications, neurological complications, sepsis, low cardiac output failure, re-ventilation, tachyarrythmias, any reopening surgery, mean ICU stay (hrs), overall hospital stay (days) and overall all-cause mortality.

Surgical Technique

All operations were done on standard cardiopulmonary bypass with aortic and bi-caval cannulation, moderate hypothermia of 32 C and warm blood cardio-plegia. Topical cooling with slush/cold saline was used for better myocardial protection.

Both techniques needed relief of RVOTO and VSD closure. In TA/TP correction, RVOTO was relieved by resecting infundibular bands transatrially and pulmonary valvular stenosis was relieved by mechanical Hegar's dilatation ± pulmonary valve commissurotmy.

The ultimate target was to achieve a pulmonary valve annulus of size $z \pm 1-3$ score. In TAP/TV correction, severe RVOTO needed either a right ventriculotomy and/or pulmonary valve incision (sacrificing its leaflet) to achieve a pulmonary valve annulur size $z \pm 1-3$ score. Pulmonary and ventricular patch was either bovine/autologous pericardium, depending upon surgeon's choice. In both techniques, VSD closure was done by Dacron patch stitched in place with interrupted pledgetted sutures.

Statistical Analysis

Data was analyzed using SPSS version 22. Mean and standard deviation (SD) was used for quantitative variables while frequencies and percentage were used for description of qualitative variables. Independent sample's t-test was used for comparison of quantitative variables. Chi-square test was used for comparison of qualitative variables between different groups. A two-tailed p<0.05 was considered statistically significant.

RESULTS

From 2005 to 2020 total 1271 TOF patients were operated. In 491 (38.6%) cases TA/TP app-

DISCUSSION

Keeping the anatomy of the defect in view, 780 (61.3%) of TOF corrections were operated via TAP/TV technique while in 491 (38.6%) TA/TP technique was done. However, other studies have shown a higher number of TA/TP techniques than TAP/TV technique⁸. Male patients were more in number in both techniques of corrections. A similar gender ratio has been exhibited in other studies as well⁹.

Internationally, the trend is doing neonatal correction of TOF and some surgeons have even recommended performing the same on circulatory arrest. Some have shown good results¹⁰, however in one meta-analysis on 8 studies having 3858 patients, 19% neonatal repairs resulted in increased mortality, longer ICU and hospital stays¹¹. The minimum age of our patients was ≥1

Variables		TA/TP (n=491)	TAP/TV (n=780)	<i>p</i> -value
Age (years)		5 ± 2.3	4 ± 2.5	
Gender	Male	320 (65.1%)	520 (66.6%)	0.036
	Female	171 (34.8%)	260 (33.3%)	
Weight (Kg)		15 ± 3.5	13 ± 4.5	
SaO2 (Mean)		82.3 ± 1.3	65.2 ± 2.5	
MBTS		15 (3.05%)	50 (6.41%)	0.024
Table-II: Con	mparison of operati	ve variables of TA/TP and TA	P/TV techniques.	L.
Variable		TA/ TP	TAP/TV	<i>p</i> -value
MBTS take down		15 (3.05%)	50 (6.41%)	0.049
CPB time (Mean)		135 ± 6 Min	165 ± 8 Min	
ACT time (Mean)		90 ± 5Min	125 ± 8Min	
RV-PA conduit		-	14 (1.79%)	0.044
MPA patch-plasty		190 ± 5 (38.6%)	780 ± 8 (100%)	0.058
RPA/LPA patch-plasty		$25 \pm 6(5\%)$	$180 \pm 10(23\%)$	0.025
Inotropes	Mild	350 (71.2%)	250 (31.6%)	
	Moderate	100 (20.3%)	450 (57.6%)	0.031
	High	41 (8.3%)	80 (10.2%)	
Temporary pacing initiated (before CPB weaning off)		360 ± 10(73.3%)	760 ± 15(97.4%)	

Table-I: Pre-op variables of TA/TP and TAP/TV repairs for TOF.

roach was used while in 780 (61.3%) TAP/TV approach was employed. The details of pre-operative variables are shown in table-I. Results of the operative variables are depicted in table-II. Results of ICU variables are depicted in table-III. Incidental anatomical findings in patients undergoing TOF repairs are shown in table-IV.

year, because our institute neither recommends neonates for TOF surgery nor circulatory arrest during operation. Others suggest an optimum age of 3-11 months for TOF correction¹².

Parameters used by surgeons' while selecting the operative techniques include pre-operative SaO2, 2D-Echocardiography findings (like hypoplastic pulmonary annulus) and Cine angiography.

All MBTS were taken down during total corrections. This is quite a complex undertaking since it is done before establishing cardio-pulmosave LAD in all these cases, right ventricle to pulmonary artery (RV-PA) conduit (Contegra, Medtronic) of 16-20 mm size was implanted, while in TA/TP cases it was not needed (p=0.044). Others report similarly¹⁵.

Variable	TA/TP	TAP/TV	<i>p</i> -value
Ventilation (Hrs)	25 ± 8	30 ± 12	
Ventilation >72 Hrs	15 (3%)	65 (8.3%)	0.015
Inotropes dosage Mild	401 (81.6%)	400 (51.2%)	0.031
Moderate	70 (14.2%)	300 (38.4%)	
High	20 (4%)	80 (10.2%)	
Inotrope duration >72 Hrs	90 (18.3%)	400 (51.2%)	0.338
Pacing >24 hours	30 (6.1%)	150 (19.2%)	0.0001
Renal complications	10 (2.3%)	35 (4.4%)	0.285
Neurological complications	7 (1.4%)	15 (1.9%)	0.553
Sepsis	11 (2.2%)	47 (6%)	0.33
Low cardiac output	15 (3%)	66 (8.4%)	1.000
Re-ventilation	10 (2%)	110 (14%)	0.41
Tachy-arrhythmia	25 (5%)	150 (19.2%)	0.11
Re-openings	19 (3.8%)	65 (8.3%)	0.0003
ICU stay (Hours)	87 ± 8	108 ± 10	
Mortality	35 (7.1%)	75 (9.6%)	0.094
Mean hospital stay (Days)	12.2 ± 2.5	15.8 ± 4.9	

nary bypass and complications can happen during its take down. We also lost 2 patients due to tearing of lobar arteries and lung haemorrhage.

Presently MBTS has largely been surpassed by pulmonary artery ballooning and/or RVOT/ PDA stenting which is life saving for babies presenting with cyanotic spells, having a small McGoon Index and an unsuitable anatomy for total correction like very small size branch pulmonary arteries for an MBTS. Additionally, it also provides time for pulmonary vasculature to grow by increasing pulmonary blood¹³.

CPB time was 30 minutes lesser in TA/TP than TAP/TV. The difference was however not statistically significant. ACT was 35 minutes lesser in TA/TP as compared to TAP/TV, This was not statistically significant. Longer CPB and ACT cause more likelihood of junctional ectopic tachy-cardia (JET) which in turn increases mortality¹⁴.

Left anterior descending artery (LAD) crossed RVOT in 14 (1.79%) of TAP/TV cases and to

Main pulmonary artery (MPA), right pulmonary artery/left pulmonary artery (RPA/LPA), patch plasty was done either by bovine or auto-

Table-IV: Incidental anatomical findings in patients undergoing TOF repairs.

Incidental anatomical findings	n=205	%
Atrial septal defect	70	5.5
Patent ductus arteriosus	50	3.9
Left superior vena cava	25	1.9
>1 ventricular septal defects	8	0.62
Sub-aortic membrane	7	0.55
Right aortic arch	45	3.5

logous pericardium. Branch pulmonary artery patch plasty was also done where MBTS had been taken down to address the stenosis at the shunt insertion site.

During weaning off CPB, TA/TP cases require smaller doses of inotropes while TAP/TV patients needed higher doses (p=0.031). Others have reported similarly¹⁶.

During ICU stay, ventilation time >72 hours was observed to be 15 (3%) in TA/TP vs. 65 (8.3%) in TAP/TV cases (p= 0.015). This increased ventilation time in TAP/TV cases is also reported by other studies¹⁷.

Re-opening for hemorrhage was 19 (3.8%) in TA/TP vs. 65 (8.3%) in TAP/TV (p=0.0003). 418 and 522 ml of blood products were transfused in TA/TP and TAP/TV respectively. On an average, more blood products were transfused in both techniques as compared to other studies¹⁸.

Mean pleural drainage was 180 ml in TA/TP vs. 580 ml in TAP/TV and the drainage duration was 2 ± 1 and 5 ± 3 days respectively. This increased amount of pleural effusion in TAP/TV. Other studies report similar results¹⁹. Mean ICU stay was 87.8 hours in TA/TP vs. 93.3 hours in TAP/TV. This ICU stay time was more in our study as compared to other studies²⁰.

An all-cause hospital mortality of 35 (7.1%) of TA/TP vs. 75 (9.6%) for TAP/TV patients, (p=0.094). Our mortality of TA/TP and in TAP/TV cases are more as compared to international studies²¹. The dismal situation is likely to improve by having a dedicated ECMO program, keeping nurse-bed ratio as per international recommendations and making services of a resident intensivist available.

An important cause of mortality is bypass time (BPT) and aortic clamp time (ACT). BPT and ACT were not statistically different in both techniques. Studies have shown that these longer durations lead to increase mortality²².

Arrythmia was another cause of mortality like SVT, Nodal and JET. JET is an important complication during the postoperative period as it increases ventilation time, inotropic support, and length of ICU and hospital stay. Its risk factors are younger age, longer aortic crossclamping/bypass times, calcium and magnesium deficiency. JET has been observed as a cause of mortality in other studies too²³. Another study showed a 12% incidence of arrhythmia in TOF patients leading to an approximate mortality between 11%-13%²⁴. Mortality in TAP/TV cases is also attributable to a post repair higher grade of pulmonary insufficiency. One of the techniques to reduce this risk of pulmonary insufficiency is to apply on RVOT, a monocusp patch of either PTFE membrane or autologous pericardium. It has shown good results in some studies. It was applied in 25 (21.9%) of our cases with acceptable results. In our study, TAP/TV TOF repair had a higher mortality than TP/TV repair but it was not statistically significant.

One study which compared 46 years of data showed that TAP/TV repair did cause late RV dysfunction but it did not led to mortality²⁴ Good long term outcome of TP/TV is also supported by other studies²⁵. The average hospital stay in TA/TP repair was 7 days vs. 10 days in TAP/TV repair.

To summarize, TA/TP corrections of TOF fare better than TAP/TV repair in terms of inotropes use, pacing requirement, ventilation hours, post-operative hemorrhage re-opening, ICU stay and total hospital stay. In our study, mortality with both techniques was not statistically different.

CONCLUSION

Fifteen years of TOF corrections at AFIC-NIHD reveal that TA/TP approach is beneficial for patients on account of fewer complications, shorter mean ICU stay and earlier hospital discharge. With this technique, the various advantages are: Lesser requirement of previous MBTS, Lesser number of taken down in definitive correction, Lesser requirement of RV-PA conduit placement, Lesser pacing requirement, Lesser amount of inotropes given, Fewer cases need ventilation >72 hours in ICU, Lesser re-opening for post-op bleeding, Lesser all-cause mortality. This ultimately translates into less financial burden on the patient, hospital, society and the country at large.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

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