



Intracardiac Repair for TOF Below 1 Year of Age-Outcome Analysis and Review of Literature

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Abstract

Introduction: Most of the advanced centers perform intracardiac repair for tetralogy of fallot between 3-6 months. We had done this thesis to analyze outcome of TOF operated at 1 year or below in our institute.

Materials method: All patients underwent intracardiac repair for TOF below one year of age between 2020 Jan to 2021 June were included in our study. TOF with other associated anomalies and patients not willing to participate in the study were excluded from our study. Ethical clearance was taken from our institutional ethics committee. After history taking and physical examination CXR, ECG and 2 D echocardiography were done in all patients. All patients underwent intracardiac repair according to standard procedure. Immediately after the operation, vasoactive inotropic score, hours of ventilation, hours of inotropic support, intensive care unit stay, hospital stay, and in-hospital mortality was collected. All patients were followed up at 15 days intervals for the first two months, then once monthly for six months, then six monthly forever.

Result: Total 16 patients of tetralogy of Fallot were operated below one year of age. Mean age was 8.69 months and mean weight of the patients was 3.22 kg. Most common presenting symptom was cyanosis (100%) On echocardiography TOF with PS, TOF with PA and TOF with APV was present in 87.5%, 6.25% and 6.25% of the patients. 68.75% of the patients underwent TAP. Median VIS score, hours of ventilation, hours of inotropic support, NIV requirement were 25.5, 84 hours, 100 hours, and 72 hours consecutively. Mean ICU and hospital stay were 11.81 days and 19.29 days consecutively. Median follow up duration were 9 months and functional status of most of the patients were ROSS I.

Conclusion: Cardiopulmonary bypass time, aortic cross clamp time, intensive care unit stay and significant residual lesion, which is one of the major determinant of outcome of paediatric cardiac surgery was absent in all our patients. We have to wisely choose the optimal age of repair for accepted outcome.

Keywords: Tetralogy of Fallot; Intracardiac repair; Infant; Neonate

Abbreviations

AVSD: Atrio ventricular septal defect

BSA: Body surface area

B T Shunt: Blalock Taussig Shunt

CPB: Cardiopulmonary bypass

CT: Computed tomography

CTVS: Cardiothoracic vascular surgery

CXR: Chest x-ray

DORV: Double outlet right ventricle

ECG: Electrocardiography

ECHO: Echocardiography

ICR: Intracardiac repair

ICU: Intensive care unit

LPA: Left pulmonary artery

LSVC: Left superior venae cava

MPA: Main pulmonary artery

OPD: Outpatient department

PA: Pulmonary artery

PA: Pulmonary Atresia

PD: Peritoneal dialysis

PGIMER: Post graduate institute of medical science and research

POD: Postoperative day

PR: Pulmonary regurgitation

PTFE: Polytetra fluoro ethylene

RPA: Right pulmonary artery

RV: Right ventricle

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RVOT: Right ventricular outflow tract

SLNO: Serial number

TAP: Transannular patch

TEE: Transesophageal echocardiography

TOF: Tetralogy of fallot

VSD: Ventricular septal defect

Introduction

“Tetralogy of Fallot” is the commonly encountered “cyanotic congenital heart defect” [1]. Our published data had shown that in TOF fibrosis develops in the infundibular muscle and it increases with age [2]. In addition to the risk of operation and cost, there is chance of pulmonary artery distortion, shunt-related complications, and the development of “pulmonary vascular disease” in children undergoing BT shunt. Challenges in “intra cardiac repair in infants and neonates” are technical difficulties during arterial and central line insertion, cardiopulmonary bypass management, and myocardial protection, stormy postoperative course due to increased “pulmonary vascular resistance”, “low cardiac output syndrome”, “respiratory complication” and “acute kidney injury”. A highly trained and dedicated team is required for management. Need for transannular patch is more common in neonates and infants undergoing intra cardiac repair with respect to older age group.

The transannular patch causes free pulmonary regurgitation and right ventricular volume overload, which causes right ventricular dilatation and dysfunction. These patients will need “percutaneous pulmonary valve implantation” or “surgical pulmonary valve replacement” in the long term. Pulmonary vascular resistance is more at least up to 3 months and it may contribute development of right ventricular dysfunction which might prolong inotropic support and ventilation. TOF cases are operated around 3-6 months of age with a good outcome in developed countries with good outcomes. The advantages of early operation are to prevent the damaging effect of chronic hypoxia in the heart, brain, lungs, and other organ systems and relieve the family's psychological, emotional, and financial stress. It avoids initial palliative operation, cyanotic spells, and its related neurological complications, which can happen while awaiting operation [3].

Materials and Method

Study site: The study was carried out in the department of CTVS of PGIMER Chandigarh.

Study Population: Children were undergoing ICR for TOF at one year or below.

Inclusion criteria: All patients were undergoing ICR for TOF at one year or below.

Exclusion criteria

1. TOF with other associated anomalies.
2. Patients not willing to participate in the study.

Study design: Prospective observational studies.

Sample size: Patient of TOF treated with intracardiac repair below one year of age in PGIMER from January 2020 to July 2021.

Method: Cases operated by three surgeons were selected as

they adopt the same protocol. All preoperative, intraoperative, and postoperative parameters were taken as follows.

Preoperative workup: Apart from history and physical examination, CXR and ECG were done in all patients. Detailed 2D echocardiography was done in all patients. CT angiography was done in all patients for better delineation of pulmonary artery anatomy and major aortopulmonary collaterals. Perioperative transesophageal echocardiography was done in all patients.

Induction of anesthesia and ET tube insertion: Ketamine, Fentanyl, Vecuronium

Maintenance of anesthesia and analgesia: Isoflurane/Sevoflurane, intermittent Fentanyl, and Vecuronium.

Cardiopulmonary bypass: Ascending aorta and bicaval cannulation. Oxygenators (Kids/Sorin 100, Medos 1000) were used. The left heart was vented through RSVP or PFO and cooled to 32°C.

Myocardial protection: Delnido cardioplegia 30ml/kg followed by 20 ml/kg every 60 minute.

Surgical approach to the patient: Median sternotomy, Thymus was sub totally excised. Hemostasis was secured. A rectangular patch of the pericardium was harvested and treated with 0.6% glutaraldehyde for 6 minutes. After inspection of cardiac morphology, pulmonary arteries were dissected free from the aorta and PDA dissected, and MAPCA (major aortopulmonary collateral artery) was dissected and clipped, and the patient was heparinised and CPB established, PDA divided between hemoclips, heart arrested and protected with Delnido cardioplegia. RA was opened close and parallel to the RA RV groove, and if necessary, a sump sucker was placed through patent foramen ovale in addition to left ventricular vent through right superior pulmonary vein. Septum tricuspid leaflet and anterior tricuspid leaflet of tricuspid valve was retracted, and VSD identified. Approachability of all the borders was noted. Infundibular bands in RVOT were identified. These bands were divided /excised if necessary, and PV inspected.

If necessary, a longitudinal limited infundibular incision was made between two 6-0 prolene stay sutures on either side; additional infundibular muscle incision or excision was done through this infundibulotomy. The pulmonary annulus and valvular opening were sized with a Hegar dilator through infundibulotomy. If the valve is restrictive, a longitudinal incision in the MPA was made between stay suture of 6-0 prolene and commissurotomy, and if needed, the release of tethering was done, and once again, pulmonary annulus was sized. If the annulus is small in comparison to the nomogram, MPA incision and infundibulotomy incision were joined by cutting across the annulus, and a transannular patch with the pericardial patch was done. If the width of the patch is considerable in the case of a very small annulus, a PTFE membrane monocusp was inserted in the patch. This patch was done after the closure of VSD with continuous 6-0 prolene suture using either pericardium or PTFE patch.

In the case of separate MPA and infundibular incisions, those were closed with pericardial patches separately.

RA was closed, leaving a 3 mm opening in the patent foramen ovale. After deairing cross-clamp was taken off and weaned from CPB at 36.50c, which is usually about 15 minutes after cross-clamp removal while rewarming was already started. After coming off bypass routine, Transesophageal echocardiography was done to detect residual VSD, gradient across right ventricular outflow tract, and biventricular function in addition to tricuspid regurgitation, aortic regurgitation and

any additional ventricular septal defect.

Postoperative outcome and follow-up: Immediately after the operation, vasoactive inotropic score, hours of ventilation, hours of inotropic support, intensive care unit stay, hospital stay, and in-hospital mortality was collected. Pre discharge, 2D echocardiography, was done in all patients. All patients were followed up at 15 days intervals for the first two months, then once monthly for six months, then six monthly forever. After history and clinical examination, 2D echocardiography was done at three months in all patients.

Data collection and follow up: All preoperative, intraoperative, and postoperative data will be collected as per the proforma attached.

Statistical Analysis

Data were expressed as “mean, sensitivity, specificity, positive predictive value, negative predictive value” when indicated. Statistical analyses will be performed using the “chi-square test” and the “Wilcoxon rank-sum test” for nonparametric variables. A “paired t-test” was used for continuous variables. The results were presented as the “mean +- the standard deviation”. All statistical analyses were performed using the SAS (statistical analysis system) program.

Result

During the study period of 18 months (Jan 2020-june 2021) total 84 patients of TOF were operated out of which 18 patients were of age of 1 year or less. Out of this 18, two patients were excluded from our study because they underwent modified B-T shunt. Mean age of the patients was 8.69 months and standard deviation was 3.54 kg. All patients had cyanosis and squatting was a common presentation (43.75). None of the patients had stroke or haemoptysis. Feeding difficulties, excessive crying, sweating and rapid breathing were present in 16(100%), 8(50%), 9(56.25%) and 10(62.5%) respectively. Preoperative Propranolol, Digoxin, Furoped were given to 8(50%), 3(81.25%), 4(25%) patients. None of the patients had underwent previous thoracic surgery and significant family history of congenital heart disease was absent in all patients.

On echocardiography situs solitus, levocardia was present in all patients and superior vena cava and inferior vena cava were drained into right atrium and none of the patients had left superior vena cava. Patent ductus arteriosus was present in 15(93.75%) patients. In 1(6.25%) left anterior descending artery was crossing right ventricular outflow tract. In 14(87.5%) patients valvular and infundibular pulmonary stenosis was present and pulmonary atresia and absent pulmonary valve were present in 1(6.25%), 1(6.25%) patients consecutively. Confluent branch pulmonary artery was present in 15(93.5%) and left pulmonary artery was absent in 1(6.25%) patients. Types of ventricular septal defect were sub aortic in 15(93.75%) and perimembranous in 1(6.25%). Mean size of ventricular septal defect was 9.75+-2.52 mm. Major aortopulmonary collaterals were present in 4(25%) patients. Aortic arch was right sided in 7(43.75%) patients and left sided in 9(56.25%) patients (Table 1).

Trans right atrial, right ventricular outflow tract and transpulmonary approach was used in all patients. Trans annular patch was done in 11 (68.75%) patients pulmonary valve preserving 2 patch technique was done in 3(13.75%). Right ventricle pulmonary artery conduit and left pulmonary artery and right pulmonary artery plasty were done in 1(6.25%),1(6.25%) patients consecutively. Mean cardiopulmonary bypass and aortic cross clamp time were 136.44+-20.22 minute, 111.38+-13.51 minute. Ratio of right ventricular systolic pressure and left ventricular pressure were less than 50% in 1(6.25%)

Table 1: Echocardiography.

| | | | |
|----------------------------------|------------------------|----|--------|
| Situs | Solitus | 16 | 100% |
| | Inversus | 0 | 0% |
| | Ambiguous | 0 | 0% |
| Cardia | Levocardia | 16 | 100% |
| | Dextrocardia | 0 | 0% |
| | Mesocardia | 0 | 0% |
| LSVC | | 0 | 0% |
| PDA | Yes | 15 | 93.75% |
| | No | 1 | 6.25% |
| Type of VSD | PM VSD | 1 | 6.25% |
| | SA VSD | 15 | 93.75% |
| Infundibular and valvular lesion | Stenosis | 14 | 87.50% |
| | Atresia | 1 | 6.25% |
| | Absent pulmonary valve | 1 | 6.25% |
| LAD crossing RVOT | Yes | 1 | 6.25% |
| Confluent branch PA | Yes | 15 | 93.75% |
| MAPCA | Yes | 4 | 25% |
| Arch | Right | 7 | 43.75% |
| | Left | 9 | 56.25% |

patients, 50-60% in 4(25%) patients, more than 60% in 11(68.75%) patients. Complete heart block was not present in any patients. On post cardiopulmonary bypass transesophageal echocardiography residual gradient of 60 was present in 1 patient and on second time went into cardiopulmonary bypass and transannular patch was applied. In another patient second time went into cardiopulmonary bypass to close a rent in left atrium caused by vent. Postoperative mild, moderate and severe right ventricular dysfunction were present in 8(50%), 6(37.5%), 2(12.5%) patients consecutively. Postoperative left ventricular function was normal in 7(43.75%) patients. Postoperative mild, moderate left ventricular dysfunction were present in 8(50%), 1(6.25%) patients consecutively (Table 2).

Four patients were shifted to ICU with open sternum due to significant ventricular dysfunction. In perioperative period there is myocardial tissue edema due to prolong bypass time which subside within 48hrs. Myocardial edema due to prolong cardiopulmonary bypass time cause low cardiac output which is usual in first 48hrs. Sternum was closed in second postoperative days. Postoperative median VIS score, hours of ventilation, hours of inotropic support, NIV requirement were 25.5(13-35), 84(66-96), 100(84-117), 72(48-84) consecutively. Mean intensive care unit and hospital stay were 11.81+-6.61 days and 19.29+-9.3 days. There were four in hospital mortality two were due to hypoxic brain injury and sepsis and another two were due to low cardiac output with severe biventricular dysfunction. During discharge functional status of the patients was ROSS I in 1(7.14%) patients and ROSS II in 13 (92.86%) patients.

Median duration of follow up was 9 months (6-11 months). There was no mortality, surgical intervention or catheter guided intervention during follow up. No episodes of arrhythmia in any patients during follow up. Functional status of the patients during follows up were ROSS I in 10 (71.43%) patients and ROSS II in 4 (28.57%) patients. No cases of right ventricular dilatation were found in any patients (Table 3).

Discussion

Surgical management of TOF has evolved from Blalock Taussig shunt in 1945 through intracardiac repair with controlled cross circulation by Lillehei et al. in 1955 into primary repair in infant.

Table 2: Intraoperative findings.

| | | | |
|---------------------------|-----------------------------|----|--------|
| Operation | TAP | 11 | 68.75% |
| | PV preserving | 3 | 18.75% |
| | RV PA conduit | 1 | 6.25% |
| | LPA/RPA Plasty | 1 | 6.25% |
| AXC Time | Mean+-SD (111.88+-13.51) | | |
| CPB Time | Mean +- SD (136.44+-20.22) | | |
| RV/LV pressure | <50% | 1 | 6.25% |
| | 50-60% | 4 | 25% |
| | >60% ^s | 11 | 68.75% |
| Residual lesion on TEE | No | 15 | 93.75% |
| | Residual VSD | 0 | 0% |
| | Residual gradient across PV | 1 | 6.25% |
| Postoperative rhythm | NSR-16 (100%) | 16 | 100% |
| | Complete heart block | 0 | 0% |
| Postoperative RV function | Normal | 0 | 0% |
| | Mild dysfunction | 8 | 50% |
| | Moderate dysfunction | 6 | 37.5% |
| | Severe dysfunction | 2 | 12.5% |
| Postoperative LV function | Normal | 7 | 43.75% |
| | Mild dysfunction | 8 | 50% |
| | Moderate dysfunction | 1 | 6.25% |
| | Severe dysfunction | 0 | 0% |

Table 3: Postoperative findings.

| | | | |
|------------------------------------|--|----|--------|
| VIS Score | Median, Interquartile range-25.5 (13-35) | | |
| Hours of ventilation | Median, Interquartile range-84 (66-96) | | |
| Hours of inotropic support | Median, Interquartile range-100 (84-117) | | |
| NIV requirement | Median, Interquartile range-72 (48-84) | | |
| ICU stay | Mean+-SD-11.81+-6.61 | | |
| Functional status during discharge | Ross I | 1 | 7.14% |
| | Ross II | 13 | 92.86% |
| Hospital stay | Mean+-SD-19.29+-9.3 | | |
| Duration of follow up | Median, Interquartile range-9 (6-11) | | |
| Functional status during follow up | Ross I | 10 | 71.43% |
| | Ross II | 4 | 28.57% |

In well-developed centre early surgical total correction of TOF is commonly done. Two stage approaches is not preferred because of distortion of pulmonary arteries, pulmonary vascular disease and shunt related complications. Routine repair of TOF between 6-12 months of age is now recommended and in case of prostaglandin dependent patient with acceptable pulmonary artery size intra cardiac repair can be done even in neonatal age although chances of transannular patch application is more [4] Despite improvement in the management early repair is associated with significant morbidity with prolong intensive care unit stay [5] In our series of 16 patients mortality was 25%. There were four in hospital mortality two were due to hypoxic brain injury (one due to intraoperative hypotension after coming off from bypass and second due to persistent low cardiac output with one episode of cardiac arrest) and sepsis and another two were due to low cardiac output with severe biventricular dysfunction. Series by “Reddy et al and Touati et al” revealed that early surgical mortality in infant TOF is less than 3% a with slightly increased mortality in neonate [2, 6]. In hospital mortality from different study are described in the following table [7-16] (Table 4).

Median intensive care unit stay in our series was 11.61 days (Highest ICU stay-32 days, lowest ICU stay-6 days). Most common cause of prolong ICU stay in our case was due to postoperative right ventricular

Table 4: Comparison between mortality in different series.

| Name of the series | In hospital mortality (%) |
|---|---------------------------|
| Our series | 25% |
| Alassal M et al. [7] | 2.04% |
| Moraes Neto FR et al. [8] | 2.98% |
| Egbe AC et al. [9] | No mortality |
| Kantorova A et al. [10] | 1.6% |
| Park CS et al. [11] | No mortality in ICR group |
| Parry AJ et al. [12] | No mortality |
| Hirsch JC et al. (Only neonatal patient included in this series) [13] | 1.63% |
| Kanter KR et al. (Only neonatal patient included in this series) [14] | No mortality |
| Tamesberger MI et al. (Only less than 4 month of patients are included in this series) [15] | No mortality |
| Kirsch RE et al. (Only less than 6 month of patients are included in this series) [16] | No mortality |

Table 5: Comparison between ICU stays between different studies.

| Name of the series | Mean/Median ICU stay |
|---|--|
| Our series | 11.81+-6.61(Mean+-SD) |
| Egbe A C et al. [9] | 6(2-21) (Median, Interquartile range) |
| Park CS et al. [11] | 6(2-21) (Median, Interquartile range) |
| Parry AJ et al. [12] | 4(2-21) (Median, Interquartile range) |
| Hirsch JC et al. (Only neonatal patient included in this series) [13] | 9.1+-8 (Mean+-SD) |
| Kanter KR et al. (Only neonatal patient included in this series) [14] | 11.8+-12.1 (Mean+-SD) |
| Tamesberger MI et al. (Only less than 4 month of patients are included in this series) [15] | 6(1-77) (Median, Interquartile range) |
| Kirsch RE et al. (Only less than 6 month of patients are included in this series) [16] | 3(1-82) (Median, Interquartile range) |

dysfunction with high inotrope requirement and hospital acquired infection. High VIS score and prolong hours of ventilation and hours of inotropic support was due to right ventricular dysfunction. ICU stay of different series are described below

In our series 68.75% of the patients underwent transannular patch repair. TAP is associated with chronic pulmonary regurgitation followed by right ventricular dilatation. Mono cusp PTFE membrane valve is helpful to prevent perioperative pulmonary regurgitation but in case of infant feasibility of mono cusp is questionable due to mismatch between pulmonary artery and PTFE membrane size match after growth of pulmonary artery [17]. Incidences of TAP in different studies are described below [9, 11-16] (Table 5).

In our series 68.75% of the patients underwent transannular patch repair. TAP is associated with chronic pulmonary regurgitation followed by right ventricular dilatation. Monocusp PTFE membrane valve is helpful to prevent perioperative pulmonary regurgitation but in case of infant feasibility of monocusp is questionable due to mismatch between pulmonary artery and PTFE membrane size match after growth of pulmonary artery [17]. Incidences of TAP in different studies are described below [7, 8, 10-17] (Table 6).

Aortic cross-clamp time and cardiopulmonary bypass time are important determinant of postoperative outcome. “Aortic cross-clamp” time and “cardiopulmonary bypass” time from different study are compared in the following table [7-9, 11, 13-16] (Table 7).

Although intensive care unit stay and cardiopulmonary bypass

Table 6: Comparison between incidences of TAP in different studies.

| Name of the study | Incidence of TAP |
|---|------------------|
| Our series | 68.75% |
| Alassal M et al. [7] | 30.6% |
| Moraes Neto FR et al. [8] | 64.1% |
| Kantorova A et al. [10] | 73.1% |
| Kaulitz R et al. [17] | 63% |
| Park CS et al. [11] | 67% |
| Parry AJ et al. [12] | 24% |
| Hirsch JC et al. (Only neonatal patient included in this series) [13] | 80.32% |
| Kanter KR et al (Only neonatal patient included in this series) [14] | 100% |
| Tamesberger MI et al(Only less than 4 month of patients are included in this series) [15] | 65.55% |
| Kirsch RE et al(Only less than 6 month of patients are included in this series)[16] | 67.5% |

Table 7: "Aortic cross-clamp" time and "cardiopulmonary bypass" time in infant TOF repair.

| Study | Aortic cross clamp time | Cardiopulmonary bypass time |
|---|-------------------------|--------------------------------|
| Our study | 111.88+-13.51 min | 136.44+-20.22 min |
| Alassal M et al. [7] | 86.92+-27.15 min | 152.06+-45.71 min |
| Moraes Neto FR et al. [8] | 51.8+-15.6 min | 78.8+-21 min |
| Kanter KR et al. (Only neonatal patient included in this series) [14] | 55.5+-21.5 min | 120.9+-37.7 min |
| Tamesberger MI et al. (Only less than 4 month of patients are included in this series) [15] | Less than 28days child | 62+-13 min 132 (101-217) min |
| | More than 28 days child | 66+-13 min 131 (92-252) min |
| Kirsch RE et al. (Only less than 6 month of patients are included in this series) [16] | 35(14-111) min | 63(18-201) min |
| Hirsch JC et al. (Only neonatal patient included in this series) [13] | 45+-15 min | 71+-26 min |
| Park CS et al. [11] | 104 (70-157) min | 165 (103-236) min |
| Egbe A C et al. [9] | 61 (30-104) min | 114 (61-205) min |

time of our study is comparable with respect to most of the studies aortic cross clamp time is more in our series.

Conclusion

In our institute although the mortality of all age group undergoing ICR for TOF was 6.5%, in 16 patients at 1 year or below (mean age 8.69 months and mean body weight 3.2 kg) between Jan 2020 to June 2021, the mortality was 25%. Cardiopulmonary bypass time, aortic cross clamp time and intensive care unit stay were comparable with few other centers with low mortality. Significant residual lesion, which is one of the major determinant of outcome of Pediatric cardiac surgery was absent in all our patients. Institute has to strengthen man power and skill of the postoperative care team for better outcome. We have to wisely choose the optimal age of repair for accepted outcome.

Limitation of the study

Due to COVID pandemic less number of patients was operated during study period. Only emergency cases were operated during this study period. Emergency and semi emergency nature of the cases could be related to high mortality.

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