**Title: Comparison of different pulmonary valve reconstruction techniques during transannular repair of Tetralogy of Fallot**

**Short Title: Pulmonary valve reconstruction techniques**

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**Abstract:**

**Background**: Transannular patch, which results pulmonary insufficiency (PI), is usually required during repair of Tetralogy of Fallot (TOF). In this study, we compared 3 types of pulmonary valve reconstruction techniques during transannular repair of TOF.

**Methods:** Between February 2014 and January 2018, 50 patients with TOF underwent total repair with transannular patch. These patients were divided into three groups. In group 1, (n= 15), a single gluteraldehyde treated autologous pericardial monocusp (standard method) was reconstructed. In group 2, (n= 16) Nunn’s bileaflet pulmonary valve reconstruction technique was used with autologous pericardial patch. In group 3, (n= 19), Nunn’s bileaflet technique was performed with expanded polytetrafluoroethylene (e-PTFE) membrane. Outcomes of the patients with early and mid-term competency of the pulmonary valves were analyzed.

**Results:** All three pulmonary valve reconstruction techniques were significantly effective in early postoperative period. Freedom from moderate to severe PI were 73.3%; 100% and 89.4% respectively. Mortality, duration of intensive care unit and hospital stay were similar between the groups. The mean follow-up period was 17.5±13.0 (3 to 57) months. Freedom from moderate to severe PI decreased to 40%; 81.2% and 73.7% respectively at the end of the follow-up period. Presence of moderate to severe PI was significantly higher in group 1 (p: 0,018 between group 1 and 2, p: 0,048 between group 1 and grup 3).

**Conclusions**: All three pulmonary valve reconstruction techniques provided competent pulmonary valves. Nunn’s bileaflet technique had better outcome at midterm. This technique has a potential to delay right ventricular dysfunction at long-term.

**Keywords:** cardiac valve annuloplasty, congenital heart defects, pulmonary regurgitation, pulmonary valve, pulmonary valve stenosis, Tetralogy of Fallot

**Introduction:**

Tetralogy of Fallot is the most common cyanotic congenital heart defect [1]. There is a wide variety of clinical and morphological spectrum, which affects surgical approaches. Although pulmonary valve sparing techniques gained acceptance in last decades, transannular patch (TAP) repair is still required in more than 50% of cases according to the STS database [2]. TAP repair alone inevitably causes severe pulmonary insufficiency which may lead to right ventricle systolic and diastolic dysfunction, septal motion abnormality, electrical dyssynchrony, dysrhythmias, eventual left ventricle dysfunction and sudden cardiac death [3,4,5]. Although pulmonary valve reconstruction techniques have gained increased popularity recently, they are far from being used in common practice because of a big concern about the fate of the reconstructed pulmonary valve functions in the mid to long term [6,7]. Nevertheless there is no consensus about which pulmonary valve reconstruction techniques have better results.

In this study, we aimed to present the early and mid-term results of three different types of pulmonary valve reconstruction techniques during total repair of TOF with transannular patch.

**Material and Methods**:

Between February 2014 and January 2018, a total of 161 patients with TOF underwent total repair. Fifty of them (31%) needed transannular patch to relieve right ventricle outflow tract (RVOT) obstruction. Pulmonary valve reconstruction was performed during operations for all those patients and three different techniques were used. Transthoracic echocardiography (TTE) and cardiac catheterization were performed to all patients before operations. Eleven of them had pulmonary balloon angioplasty and 5 had systemic to pulmonary shunt operation as a palliative intervention before total repair. Angiographically estimated Mc Goon index > 1.6 was used to decide total repair. TAP implantation was decided during operation, when the patients had PV annulus Z-value of ≤−2.

Approval for the study was obtained from the university ethics committee. Written concent was taken from all patients’s families. TTE examinations were performed in early postoperative period, before discharge and at the last outpatient clinic visit.

All operations were performed with median sternotomy and cardiopulmonary bypass (CPB) under moderate hypothermia. Aortic and bicaval cannulation were done. Previous shunts were ligated if present. The heart was arrested with intermittant antegrade tepid blood cardioplegia. VSD was closed with interrupted sutures with teflon pledgets via right atriotomy using a dacron patch. The patients were divided into 3 groups according to the pulmonary valve reconstruction techniques.

In the first group (group 1, n: 15), a gluteraldehyde treated autologous pericardial patch was used for creation of a monocusp valve (standard method) [6]. The length of the patch was the distance from the apex of the RVOT incision to the pulmonary annulus level. The width of the free edge of the monocusp was equal to the circumference of the native annulus. The superior margin of the monocusp is positioned at the level of the commissures and was attached to the both sides of the pulmonary valve incision and the inferior margin was attached to the apex of the RVOT incision at three points. Monocusp was covered with a second pericardial patch which was sutured together with the remnants of the pericardial monocusp to close the transannular incision. In the second group (group 2, n: 16) Nunn’s bileaflet valve technique was used with gluteraldehyde treated autologous pericardial patch, which was prepared as the same fashion, but its free margin was at least 1.5 times larger than the standard technique [8]. Mid point of the free margin was sutured to the posterior wall of the pulmonary annulus first. Both ends were sutured to the both sides of the pulmonary trunk incision. Apex of the patch was sutured to the apex of the right ventriculotomy incision. Transannular patch was sutured over the created bileaflet valve to secure the remnants of the valve and to close the transannular incision. In the third group (group 3, n: 19), Nunn’s bileaflet valve technique was used with 0.1-mm expanded polytetrafluoroethylene (e-PTFE) membrane.

Nunn’s bileaflet valve technique creates two outflows for the right ventricle and outflow orifices should be large enough to prevent obstruction. Valve reconstructions were made with three or four single sutures and usually lasts no more than 5 minutes. A small fenestration of 2-3 mm in size in atrial septum was usually left. After weaning from cardiopulmonary bypass, RV/LV pressure ratio was measured. If RV/LV pressure ratio is >0,75, revision of the repair was considered. All patients had a dose of 5 mg/kg acetyl salicylic acid treatment for 3 months.

***Statistical Analysis****:* Statistical analysis was performed using SPSS software version. The conformity of variables to normal distribution was analyzed by visual (histogram and probability graphs) and analytical methods (Kolmogorovz-Simirnov / Shapiro-Wilk tests). Descriptive analyzes were performed using the frequency tables for categorical variables using mean and standard deviations for normally distributed variables. For the variables not normally distributed, the median and minimal - maximum values were given. For the comparison of inter-group variables, Kruskal Wallis test and Mc Nemar test was used. Fisher Freman Halton test, Pearson chi-square test was used for categorical variables. P values <0.05 were considered as statistically significant.

**Results:**

The mean age of the patients was 16.2±11.9 (range from 7 months to 6 years) months (Table 1). (M/F: 28/22 ). There was no significant difference in cardiopulmonary bypass and cross clamp times between the groups.Mean Cardiopulmonary bypass times were103.7±19.5, 111.8±29 and97.1±35 respectively (p: 0,11). Mean cross clamp times were 71±16.4, 74.1±15.6 and 68.5±12.4 respectively (p: 0,70). Total mortality was 6% (3 patients). One patient in group 1 needed ECMO support due to low cardiac output and couldn’t wean from ECMO because of multiorgan failure and gastrointestinal bleeding. Other two patients in Group 1 and 2 died of sepsis and MOF. No statistical difference was present in terms of mortality and morbidity between the groups. Postoperative complications are presented in Table 2. The median duration of intensive care unit stay (ICU) was 3 (2-90) days. The median time of ventilation was 1 (1-20) days. Nine patients (18%) needed long duration of mechanical ventilation (> 7 days). Of these, 4 patients (8%) needed tracheostomy. The median duration of hospital stay was 10 (5-108) days. The degree of pulmonary insufficiency was evaluated with TTE and was quantified as none, mild, moderate and severe (Figure 1-2). All three pulmonary valve reconstruction techniques were mostly effective in the early postoperative period. Freedom from moderate to severe pulmonary valve insufficiency were 73.3%; 100% and 89.4% respectively.

All patients were followed up for mean 17.5±13.0 (ranged 3 to 57) months. In group 1, mean follow-up time was statistically longer than the other groups (p: 0,01).

No late mortality was observed. All patients had normal growth and development without symptoms. Freedom from moderate to severe pulmonary valve insufficiency decreased to 40%; 81.2% and 73.7% respectively at the end of the follow-up period (Graphic 1). Presence of moderate to severe pulmonary insufficiency (PI) were significantly higher in group 1 (p: 0,018 between group 1 and 2, p: 0,048 between group 1 and grup 3). Pulmonary valve competency significantly worsened in group 1 than the others (p: 0.050) (table 3). The postoperative right ventricular outflow tract gradients were between 0-30 mmHg. Peripheral pulmonary artery stenosis was observed in 2 patients in groups 1 and 2 and pulmonary balloon valvuloplasty was performed successfully during follow-up period.

**Discussion:**

The prevailing method of Tetralogy of Fallot repair is, if possible, the protection of the pulmonary annulus and valve. In the presence of severe hypoplasia of pulmonary annulus, the integrity of the pulmonary annulus is impaired during repair and a transanular patch is inevitable. TAP leads to PI which is usually well-tolerated [9]. But the absence of pulmonary valve and pulmonary valve regurgitation after TAP repair are associated with postoperative right ventricle (RV) dysfuncion and RV dilatation [10-11] and some of the patients will eventually experience decreased exercise capacity and RV dysfunction [12]. This situation may cause the need for pulmonary valve replacement.

In order to prevent pulmonary valve insufficiency during TAP repair, pulmonary valve reconstruction techniques with various methods may be used, but they are not generally accepted because of the lack of proven advantages in the mid-long term follow-up. However, most of the authors agree that monocusp pulmonar valves are effective in early postoperative period. Turrentine et al [6]; stated that monucusp valves reduces early postoperative and midterm PI. It is also shown that pulmonary monocusp creation may shortens ICU stay and reduces postoperative mortality and morbidity [6,8,13,14]. Some authors support that leaving mild residual RVOT obstruction helps to protect the right ventricle by limiting pulmonary regurgitation [15]. In a study of 171 operated TOF patients mild residual PS independently reduced the risk of pulmonary valve replacement as compared with patients without PS and moderate-to-severe PS [16].

In our recent report [17] a total of 64 TOF patients underwent total correction and pulmonary valve-sparing techniques were performed in 29 patients (Group 2), while transannular patch was applied in the remaining 35 patients (Group 1). Pericardial monocusp valve was constructed in 15 patients in Group 1. Total postoperative morbidity rate was significantly higher in Group 1 (51.4% vs. 6.8%) (p=0.0001). Morbidity rate was significantly lower in patients with pulmonary monocusp insertion than patients in the same group without a monocusp (p=0.0176). Twelve (80%) of the patients in Group 1 who had monocusp insertion were followed up. Only two of these patients had free pulmonary regurgitation (16.6%). The rest of them had mild (n=6) or mild-moderate pulmonary regurgitation (n=4). After this study, we started routine use of pulmonary valve reconstruction in TOF patients who need TAP during repair.

In this report, we compared 3 types of pulmonary monocusp creation techniques to delineate the most effective one in early and mid-term period. All three techniques were effective in early postoperative period. There was no significant difference in postoperative complications and ICU or hospital stay between the groups. Patients who underwent pulmonary valve reconstruction with Nunn technique had better results in the mid-term follow-up.

As described by Nunn, attaching the free central portion of the patch to the posterior of the pulmonary artery with a single suture enables a bileaflet formation of the valve [8]. In Brown’s study hand-sewn valves constructed from 0.1-mm PTFE have not shown structural deterioration or calcification [13]. The valves fashioned as monocusps have lost their competence (88%) in almost all cases. The valves fashioned as bicuspid valves using the same 0.1-mm PTFE membrane have retained their competence (93%) in most cases, and there has not been a deterioration in their function in the period of mean follow-up time for 4.9± 3.1 years. Gil-Juarena and associates [18] treated 21 patients of TOF with 0,1 mm PTFE monocusp valve using posterior fixation and right after the operation, pulmonary regurgitation was mild in 19 cases and moderate in two. Posterior fixation of the valve enables leaflet motion and coaptation without prolapse [8]. Also, it serves as an anchor point to optimize the closure mechanism [8,18]. Quintessenza et al [19] created PTFE bicuspid pulmonary valves (A surgically prepared 0.6 mm PTFE bicuspid valve with opposing attached leaflets that are shaped like a bishop’s hat) in 41 patients and stated that it is a durable and effective technique and appropriate oversizing of the patch minimizes outflow tract obstruction while maximizing competence.

Monocusp repair can be done with autogenous pericardium, bovine or porcine pericardium or e-PTFE patch. Autogenous pericardial and heterograft pericardial materials are claimed to be degenerated in the early period and valve functions are impaired [20]. The 0.1 mm PTFE membrane is a synthetic, inert material and it is suggested that this material can maintain its function for a very long time [13]. 0,1 mm thick ePTFE has micropores that are 1 𝝻m in diameter that might prevent cellular infiltation, calcification and maintains flexibility. It has good biocompatibility and its surface exerts anti-thrombogenic effects by electrically repelling platelets [21,22]. The histopathological analysis of explanted ePTFE valved patches/conduits showed that the surface of vascular grafts was covered in thin fibrous collagenous tissue predominantly comprising fibroblasts, even with partial endothelialization, whereas the valvular leaflet remained free of any attached matter [23]. Sasikumar and collegues [14] reported that the factors that effect PI progression are, fibrocollagenous incorporation of the monocusp valve, lack of proper frame for the valve, residual stenotic lesions in pulmonary vasculature, size of branch pulmonary arteries, and mobility of the monocusp. One study in Japan assessed the outcomes of ePTFE valved patches and conduits in 469 and 325 patients, respectively, based on clinical data collected from 52 institutions [21]. The follow-up rate was 100 % over a period of 43.62 ± 26.4 (range, 1.1–120) months. No patch or conduit-related deaths were reported, and 10-year rates of freedom from reoperation were 92.3 and 95.4 % in patients with patches and conduits, respectively. No evidence of thrombus or pannus formation was found in any of the patients.

We agree with the idea of trying to preserve integrity of pulmonary annulus and competency of the valve in all patients with TOF during repair. But it is not always possible. In our practice 31% of patients need transannular patch. This ratio is around 50% according to STS database [2]. Our study shows that all types of pulmonary valve reconstruction techniques were effective, but Nunn bileaflet technique with e-PTFE is our current choice because of the mid-term advantages. The implantation technique of monocusp valves is simple and not time consuming. Our study is important as it is one of the few reports that compares different reconstruction techniques of hand-sewn valves with different materials.

Limitations of the study are its retrospective nature and limited number of the cases.

**Conclusion:** In patients with TOF, who need transannular patch during total repair, pulmonary monocusp reconstruction may be easily performed and the results are promising. This technique has a potential to delay right ventricular dysfunction at long-term. Studies with large number of patients and long-term results are needed to reveal the efficacy of pulmonary valve reconstruction techniques.

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Table 1: Clinical data between groups.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Clinical data** | **Group 1 (n:15)** | **Group 2 (n:16)** | **Group 3 (n:19)** | **P value** |
| Age (months) | 13.3±6.8 | 19.1±18.7 | 15.9±6.8 | 0.29 |
| CC time (min) | 71±16.4 | 74.1±15.6 | 68.5±12.4 | 0.70 |
| CPB time (min) | 103.7±19.5 | 111.8±29 | 97.1±35 | 0.11 |
| ICU stay days | 9.7(3/2-58) | 9.2(2.5/2-90) | 6.9(2/2-55) | 0.32 |
| Hospital stay mean, range | 17±14.1 | 18.6(9.5/5-108) | 15.7(10/6-96) | 0.83 |
| Mechanical ventilation time (median/ min-max) | 1/1-15 | 1/1-20 | 1/1-12 | 0.81 |
| Follow-up (month) | 26.7±17.2 (6-57)\* | 17.0±10.1 (3-30) | 10.6±5.3 (3-22) | 0.01\* |

CC: Cross clamp

CPB: Cardiopulmonary bypass time

ICU: Intensive care unit

Table 2: Postoperative complications

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Postoperative Data** | **Group 1 (n:15)** | **Group 2 (n:16)** | **Group 3 (n:19)** | **P değeri** |
| Mortality n(%) | 2 (%13.3) | 1 (%6.3) | 0 | 0.27 |
| ECMO n (%) | 1 (%6.7) | 0 | 0 | 0.30 |
| Prolonged ventilation (>7 days) | 4 (%26.7) | 2 (%12.5) | 3 (%15.8) | 0.56 |
| Tracheostomy | 2 (%13.3) | 1 (%6.3) | 1 (%5.3) | 0.66 |
| Minor neurological event | 1 (%6.7) | 1 (%6.3) | 0 | 0.53 |
| Sepsis | 1 (%6.7) | 1 (%6.3) | 0 | 0.53 |

ECMO: extracorporeal membrane oxygenation

Table 3: Pulmonary valve functions

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Data** | **Group 1 (n:15)** | **Group 2 (n:16)** | **Group 3**  **(n:19)** | **P value** |
| **Early postop** | No PI | 1 (%6.7) | 3 (%18.8) | 9 (%47.4)\* | 0.02\* |
|  | Mild PI | 10 (%66.7) | 13 (%81.3) | 8 (%42.1) | 0.054 |
|  | Moderate PI | 1 (%6.7) | 0 | 1 (%5.3) | 0.59 |
|  | Severe PI | 3 (%20) | 0 | 1 (%5.3) | 0.1 |
| **Mid-term** | PI (-) | 1 (%6.7) | 3 (%18.8) | 9 (%47.4)\* | 0.02\* |
|  | Mild PI | 5 (%33.3) | 10 (%62.5) | 5 (%26.3) | 0.08 |
|  | Moderate PI | 5 (%33.3) | 2 (%12.5) | 3 (%15.8) | 0.31 |
|  | Severe PI | 4 (%26.7) | 1 (%6.3) | 2 (%10.5) | 0.24 |
| P value |  | 0,050\* | N/A | 0,135 |  |

PI:Pulmonary insufficiency

Graphic 1: Freedom from moderate to severe PI in early and mid-term postoperative period.

PI:Pulmonary insufficiency

Figure 1: Postoperative Echocardiography image of the bileaflet valve

Figure 2: Postoperative echocardiography image of mild regurgitation of the reconstructed pulmonary valve