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Comparison of the Mid-term Results of Pulmonary Valve-sparing Strategy and Transannular Patch Repair in Tetralogy of Fallot

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Abstract

Background: Between January 2006 and October 2009, 148 patients underwent total repair of tetralogy of Fallot (TOF). In 13 patients, palliative procedures were performed before total repair, while total correction was the initial and definitive procedure in 135 patients.

Materials and methods: Patients who underwent total repair of TOF were evaluated retrospectively. They were assigned to one of two groups based on the right ventricular outflow tract (RVOT) reconstruction technique used: the transannular patch (TAP) group or the pulmonary valve-sparing strategy group. The two groups were compared with regard to age, weight, gender, annular structure, intraoperative right ventricular to left ventricular (RV/LV) pressure ratio, residual RVOT systolic gradient, RV diastolic parasternal long axis wall thickness, age-specific dilation, mortality, and morbidity during follow-up.

Results: The percentage of patients with RV diastolic dilation (age specific) was significantly higher in the TAP group (88.9%) than in the pulmonary valve-sparing group (4.8%; $p = 0.0009$). The mid-term results of the pulmonary valve-sparing strategy were significantly superior to TAP repair in terms of preservation of right ventricular function.

Conclusion: In order to preserve pulmonary valve function, TAP repair should be avoided when possible. The pulmonary valve-sparing strategy seems to result in less perioperative and long-term morbidity, and better preservation of RV function in the long-term, when compared to TAP repair.

Key words: tetralogy of Fallot, transatrial, transpulmonary, transannular.

Streszczenie

Wprowadzenie: Pomiędzy styczniem 2006 roku a październikiem 2009 roku 148 pacjentów zostało poddanych całkowitej korekcji tetralogii Fallota (TOF). U 13 pacjentów przed całkowitą korekcją przeprowadzono zabiegi paliatywne, natomiast u pozostałych 135 pacjentów całkowita korekcja była pierwszym i definitywnym zabiegiem.

Materiał i metody: Pacjenci po zabiegu całkowitej korekcji tetralogii Fallota zostali poddani retrospektywnej ewaluacji. Przypisano ich do jednej z dwóch grup, w zależności od tego, czy zastosowano u nich łatę przezpierścieniową (*transannular patch* – TAP), czy strategie oszczędzające zastawkę pnia płucnego (*pulmonary valve-sparing* – PVS). Grupy porównano w zakresie wieku, wagi, płci, struktury pierścieni, śródoperacyjnego stosunku ciśnienia prawej komory do ciśnienia lewej komory (RV/LV) oraz resztkowego gradientu skurczowego RVOT, rozkurczowej grubości ściany prawej komory w osi przymostkowej długiej, związanej z wiekiem dylatacji, śmiertelności i zachorowalności w czasie obserwacji.

Wyniki: Liczba pacjentów z (zależną od wieku) rozkurczową dylatacją prawej komory była znacząco większa w grupie TAP (88,9%) niż w grupie PVS (4,8%; $p = 0,0009$). Średnio odległe wyniki stosowania strategii oszczędzającej zastawkę pnia płucnego były znacząco lepsze od wyników stosowania łat przezpierścieniowych w zakresie ochrony funkcji prawej komory.

Wnioski: Aby chronić funkcję zastawki pnia płucnego, należy w miarę możliwości unikać korekcji TAP. Strategia oszczędzająca zastawkę pnia płucnego wydaje się skutkować mniejszą okołooperacyjną i odległą zachorowalnością oraz zapewniać lepszą długoterminową ochronę funkcji prawej komory w porównaniu z korekcją TAP.

Słowa kluczowe: tetralogia Fallota, przezpierścieniowy.

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Introduction

Tetralogy of Fallot (TOF) is the most common cause of cyanotic congenital heart disease. Improved operative techniques resulting in reduced operative mortality and the chance of surgical repair in early childhood prior to the development of cardiac compromise from chronic hypoxia have both contributed to improved survival. In this study, early postoperative and mid-term results of two techniques (transannular patch versus pulmonary valve-sparing strategy) for total repair of TOF were compared.

Material and methods

Screening of operative protocols, patient records, and the department database revealed a total of 148 surgically treated patients with TOF without pulmonary atresia from January 2006 to October 2009. All patients (n = 148) were evaluated in the Department of Pediatric Cardiology and echocardiography was performed in all patients. In addition to echocardiography, angiography was done in 140 patients before surgery.

In addition to the status of pulmonary annulus and valvular structures and the clinical status of the patient, the McGoon ratio calculated from angiographic and echocardiographic measurements was used to establish the surgical indication and the need for a shunting operation. The McGoon ratio of the patients ranged from 1.7 to 2.4, with a mean value of 2.06. In patients with a McGoon ratio < 1.6, a Blalock-Taussig (BT) shunt was placed prior to total repair (n = 13), whereas in the remaining patients with a McGoon ratio ≥ 1.7, total repair was the initial procedure.

Selection of the right ventricular outflow tract (RVOT) reconstruction technique was based on preoperative angiocardiographic and echocardiographic data, as well as the assessment of pulmonary valve structure and body surface area-specific pulmonary annulus diameter during the operation. If a Hegar dilator with a diameter 2-3 mm larger than the normal body surface area-specific pulmonary annulus size could easily pass through the annulus, then the patient was accepted as a candidate for valve-sparing surgery. A transannular patch (TAP) was indicated for patients with a smaller annulus size, hypoplastic annulus, or inappropriate valve structure.

A TAP repair was performed in 127 patients (85.8%), and the pulmonary valve-sparing strategy was used in 21 patients (14.2%). None of the patients required re-operation for a residual ventricular septal defect (VSD) or residual RVOT systolic gradient. In all patients, resection of the infundibular muscle band and VSD closure were done using a transatrial-transpulmonary approach.

A pericardial infundibular patch was used for RVOT reconstruction in 16 of 21 patients who were operated on using the pulmonary valve-sparing strategy. In five patients from the valve-sparing group, pulmonary arterial stenosis was evident after band resection, which was treated with pulmonary artery patch reconstruction.

Echocardiographic evaluation of the right ventricle was done at postoperative 12 months and patients were followed for approximately 4 years. Patients with a > 30% increase in age-specific RV end-diastolic parasternal long axis (M-mode) wall thickness were considered to have a dilated RV due to pulmonary failure.

Surgical technique

A median sternotomy was done under general anesthesia to access the mediastinum. Previously created aorto-pulmonary shunts were identified and prepared for closure to prevent ventricular distension due to the flow from the systemic circulation to the pulmonary bed during the early periods of cardiopulmonary bypass. Pericardium that would be used in the reconstruction of the right ventricular outflow tract was removed and processed in 0.6% glutaraldehyde for 10 minutes.

Heparin was given at a dose of 3 mg/kg before a standard aortic and bicaval cannulation was done. The patient was cooled following the establishment of partial bypass. Simultaneously, if present, aorto-pulmonary shunt or patent ductus arteriosus was either ligated or a hemostatic clip was applied. The patient was cooled to 30°C and then a cross-clamp was placed to establish total bypass. Cardiac arrest was induced by injection of 20 mL/kg of blood cardioplegic solution from the aortic root. Cardioplegia was repeated every 15-20 minutes with a dose of 10 mL/kg. The VSD was explored and transatrial closure of the VSD was performed by gore-tex patch using a continuous suture technique. First, a transatrial septal and parietal band resection was performed. A ventriculotomy was performed using a vertical incision in the absence of a coronary anomaly crossing the right ventricular outlet, or an incision parallel to the coronary artery was made in the presence of such an anomaly. Septoparietal bands and VSD were explored. Following the septal and parietal band resections, the sizes of the main pulmonary artery and its branches were measured using Hegar dilators.

The pulmonary valve-sparing strategy was used in patients with a well-developed pulmonary valve annulus (n = 21). In order to eliminate pulmonary valve stenosis, if necessary, a pulmonary commissurotomy was performed through ventriculotomy incision. RVOT of 21 patients with a normal annulus diameter in whom valvular stenosis was relieved was reconstructed using a glutaraldehyde-treated pericardium. The pulmonary artery was reconstructed with pulmonary arteriotomy and a pericardial patch in five of these 21 patients. Intraoperative pressure measurements revealed that the RV/LV pressure ratio was < 0.7 in all patients.

In patients with a less developed pulmonary annulus (n = 127), transannular patch repair was done during RVOT reconstruction. When peripheral pulmonary stenosis was present, the patch was extended to the distal part of the stenosis unilaterally or in a T-shape extending the pulmonary arteries bilaterally, whichever was compatible with the anatomy. Intraoperative pressure measurements revealed that the RV/LV ratio was < 0.7 in all patients.

Additional cardiac repairs were carried out during the warming period. Hemofiltration was routinely performed for all patients during weaning from cardiopulmo-

nary bypass. Following de-airing through the left atrial and aortic cannula, the clamp was removed. Extracorporeal circulation was terminated after sufficient pump support.

Statistical analysis

Statistical analysis of data was done using SPSS 11.0 statistical software (SPSS Inc, Chicago, IL, USA). Descriptive data are presented as mean and standard deviation for continuous variables, and categorical data are presented as frequency and percentage. The Kolmogorov-Smirnov test was used to test the normality of distribution. The parametric Student-t test or non-parametric Mann-Whitney U test was used for inter-group comparison of continuous variables. Inter-group comparisons of categorical data were done using the chi-square test or Fisher exact test, where appropriate. A p value < 0.05 was considered as an indication of statistical significance.

Results

Of the 148 patients included in the study, the pulmonary valve-sparing strategy was used in 21 patients. A BT shunt was done in 13 of 148 patients before total repair (TAP or pulmonary valve-sparing strategy). Of these 13 patients, TAP was performed for 12 patients and pulmonary valve-sparing strategy was used for one patient. All 21 patients who were operated on using the valve-sparing strategy had a well-developed annulus.

Details of demographic and clinical characteristics of the patients are given in Table I. There was no significant difference between the two groups in terms of age. However, the mean weight in the valve-sparing group was significantly lower and in that group the male-to-female ratio was significantly higher. Regarding clinical data, hypoplastic annulus and RV diastolic dilatation (corrected for age, at follow-up) were more frequent among the patients in the TAP group. In addition, the follow-up residual RVOT systolic gradient was higher and the RV diastolic parasternal long axis wall thickness was shorter in the valve-sparing group, whereas groups did not differ with regard to intraoperative RV/LV pressure ratio. During follow-up, moderate-to-severe free pulmonary insufficiency occurred in 80% of the patients treated by TAP, whereas mild-to-moderate pulmonary insufficiency was present in 30% of the patients treated by the pulmonary valve-sparing strategy.

Five patients died in the TAP group (3.9%), whereas no deaths were recorded in the pulmonary valve-sparing group. However, the difference was not significant (p = 0.49). Detailed postoperative morbidity and mortality data are given in Table II.

Tab. I. Clinical and demographic characteristics of patients

	TAP group (n = 127)	Pulmonary valve sparing group (n = 21)	p
Age [years]	4.7 ±2.9	3.6 ±3.5	0.12
Weight [kg]	13.5 ±6.3	17.4 ±10.7	0.02
Male/female [n/n]	71/56	17/4	0.03
Hypoplastic annulus [n (%)]	121 (95.3%)	5 (23.8%)	0.0001
RV/LV pressure ratio (intraoperative)	0.50 ±0.56	0.53 ±0.53	0.05
Residual RVOT systolic gradient [mm Hg]*	4.6 ±10.6	18.8 ±6.6	0.0004
RV diastolic parasternal long axis wall thickness [mm]*	16.4 ±3.7	12.3 ±4.1	0.000008
RV diastolic dilation (adjusted for age) [n (%)]*	113 (88.9%)	1 (4.8%)	0.0009

Unless otherwise stated, data are presented as mean ± standard deviation. RV – right ventricle; LV – left ventricle; TAP – transannular patch; RVOT – right ventricular outflow tract. *These measurements were done at postoperative 12 months by echocardiography.

Discussion

The original surgical repair of TOF involves closure of the VSD through a large right ventriculotomy and enlargement of the RVOT with a large TAP [1]. Later, advanced techniques including transatrial closure of the VSD and resection of the RVOT [2-3], and transatrial-transpulmonary repair and enlargement of the pulmonary artery with a patch [4-5] were developed. The most promising techniques avoid ventriculotomy and adopt a pulmonary valve-sparing strategy. In addition, pre- and peri-operative evaluations together with the use of a Z-value, defined by Kirklin *et al.* [6], and the pulmonary index, introduced by Nakata [7], led to a significant reduction in mortality and morbidity rates, and offered the chance to perform early primary repair during infancy.

Although satisfactory results have been obtained by surgery performed in the neonatal period and infancy together

Tab. II. Postoperative mortality and morbidity data of the study population

Morbidity	TAP group (n = 127) n (%)	Pulmonary valve sparing group (n = 21) n (%)	Total n (%)
Permanent pacemaker for AV complete block	2 (1.6)	-	2 (1.4)
Peritoneal dialysis at p.o. day 1, died at p.o. day 3	1 (0.8)	-	1 (0.7)
Peritoneal dialysis at p.o. day 2, died at p.o. day 4	1 (0.8)	-	1 (0.7)
Cardiac arrest following respiratory arrest	1 (0.8)	-	1 (0.7)
Sternum left open followed by death at p.o. day 2	1 (0.8)	-	1 (0.7)
Incomplete VSD closure, died at p.o. day 1	1 (0.8)	-	1 (0.7)
No morbidity	120 (94.5)	21 (100.0)	141 (95.1)
Total	127 (100.0)	21 (100.0)	148 (100.0)

TAP – transannular patch; p.o. – postoperative; VSD – ventricular septal defect. The results are not suitable for statistical analysis due to the low number of patients with morbidity; thus only descriptive data are provided.

with the use of TAP with well-tolerated free pulmonary insufficiency [8-12], some studies have demonstrated that free pulmonary insufficiency induced by the TAP procedure is not well tolerated; and RV dysfunction [13-14], low functional status [15], arrhythmia, and sudden death [16-17] have been reported in the long-term follow-up of these patients. Gatzoulis *et al.* reported that occurrence of free pulmonary insufficiency after TAP repair was associated with ventricular tachycardia and sudden death in the long-term follow-up period [17]. On the other hand, several long-term studies have demonstrated improvement in ventricular function and symptoms by placement of the pulmonary valve following TOF repair [18-19].

Several studies have compared TAP with other strategies. Bacha *et al.* evaluated the long-term results of 45 patients with TOF who were operated on in the infantile period and reported successful outcomes without any significant difference between the valve-sparing strategy and TAP in terms of functional status [10]. On the other hand, Kirklin *et al.* retrospectively evaluated 814 patients (aged between 2 months and 57 years) with TOF who had been treated by total repair [11]: 255 were treated by TAP, 538 by RVOT patch with or without pulmonary valvotomy, and 21 by valved conduit. The mortality rate was 4% in the TAP group, whereas it was 1.4% in the patients who did not undergo TAP. Based on their 20 years of experience and considering the potential RV dysfunction problems and pulmonary insufficiency in the early and late periods, Kirklin *et al.* recommended preservation of the pulmonary artery annulus in patients with TOF where possible and they suggested that TAP should be reserved for patients with an expected RV/LV pressure ratio > 0.65 after repair. In support of these suggestions, findings of this study were in favor of the pulmonary valve sparing strategy. During follow-up, the mean RV diastolic parasternal long axis wall thickness on echocardiography was significantly higher and RV diastolic dilation (corrected for age) was significantly more frequent in the TAP group, when compared to the valve-sparing strategy group. In addition, moderate-to-severe free pulmonary insufficiency was evident in a substantial proportion of patients (80%) in the TAP group.

None of the patients in this study required re-operation for residual VSD and/or RVOT obstruction during follow-up. Despite higher residual RVOT systolic gradient in the valve-sparing group, no significant difference was found between groups with regard to re-operation for residual RVOT gradient. Aggressive resection of the muscle bands within the right ventricle seems to account for the absence of re-operation requirement in either of the groups. Besides muscle band resection, commissurotomy was performed when pulmonary stenosis was present. If a residual gradient is suspected despite valvotomy, and there is obstruction in the RVOT and/or pulmonary artery and/or its distal parts, reconstruction should be performed with two separate patches preserving the annulus.

There was no significant difference between the TAP and pulmonary valve-sparing strategy groups in terms of the RV/LV pressure ratio, and the mean ratio was 0.5. Kirklin *et al.* and Katz *et al.* reported that the mortality risk was increased by 2.5 and the re-operation risk was increased by 7.3-fold when RV/LV pressure ratio is > 0.85 [11, 20]. Hirch *et al.* also reported that the re-operation risk is increased when the RV/LV pressure ratio is > 0.7 [21]. In the present study, we aimed to keep the RV/LV pressure ratio < 0.7 in both treatment groups. In our study, the valve type of 21 patients treated using the pulmonary valve-sparing strategy was tricuspid in 20 patients and bicuspid in one patient. Besides the annulus diameter, the presence of a tricuspid pulmonary valve is also an important determinant for the pulmonary valve-sparing strategy since the tricuspid pulmonary valve has been reported to be associated with a low post-operative RV/LV pressure ratio and reduced prevalence of pulmonary insufficiency [22-24].

Karl *et al.* treated 366 patients with TOF between 1980 and 1991. The transatrial-transpulmonary approach was used and the hospital mortality rate was 0.5%. The surgery was postponed until the infant was 6-8 months of age. A palliative shunt was performed in 37% of these patients [4]. In this study including 148 patients with TOF, the mean age of 127 patients treated with TAP was 4.7 years and the mean age of 21 patients treated using the pulmonary valve-sparing strategy was 3.6 years. We believe that as the experience with the pulmonary valve-sparing strategy increases, the age of patients will decrease to the infant age.

Conclusion

In total correction of TOF, the pulmonary valve-sparing strategy seems to result in less perioperative mortality/morbidity and better long-term preservation of RV function, when compared to TAP. Thus, it would be wise to recommend avoiding TAP, particularly in patients with well-developed pulmonary valves, and to preserve pulmonary valve functions. TAP should be reserved for patients with insufficient annulus diameter or insufficient relief of RVOT obstruction despite resection.

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