ORIGINAL ARTICLE

Early postoperative evolution of patients operated for total correction of Tetralogy of Fallot with transannular patch and monocuspid valve placement.

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Objective. **Tetralogy of Fallot is one of the most frequent causes of congenital heart disease, ranking fourth in frequency of all congenital heart diseases worldwide. At the Hospital Infantil de Mexico, 272 cases had been operated on until 1996. Of the patients operated with the transannular patch technique, 53% progressed from moderate to severe pulmonary insufficiency. The aim of this study is to document the immediate postoperative evolution in those patients who underwent total correction and monocuspid valve placement in the immediate postoperative period.** ***Material.*** **A comparative, descriptive, prospective, observational, prospective study was carried out, in which 16 patients who underwent total correction of Tetralogy of Fallot and transannular patch placement were studied. During the period going from March 1, 2013 to March 31, 2015, a total of 40 total corrections of tetralogy of Fallot were reported, of which 18 of them were corrected with transannular patch. Two groups were analyzed, the first one made up of 9 patients who underwent monocuspid valve placement, and the second group made up of those individuals who did not undergo monocuspid valve placement.** ***Results.*** **The results suggest a clinical improvement in the immediate postoperative evolution, a shorter stay in the postoperative Intensive Care Unit (p=0.2), a tendency towards a decrease in the need for inotropic support (p=0.3), as well as a decrease in ventilation (p=0.7) and other morbidity variables that are not specifically analyzed. The length of hospital stay indirectly reflects the recovery and stability of the patient. The statistical analysis performed did not show significant differences in the variables analyzed, probably due to the number of patients included and the associated complications.** ***Conclusions.*** **Transannular patch implantation with modified monocuspid valve in right ventricle outflow tract reconstruction for total correction of Tetralogy of Fallot is actually simple and reproductible.**

Key words: **Congenital heart disease; Monocuspid Valve; Tetralogy of Fallot; Pulmonary Valve Insufficiency.**

Objetivo. **La tetralogía de Fallot es una de las causas más frecuentes de cardiopatías congénitas, ocupando el cuarto lugar en frecuencia de todas las cardiopatías congénitas a nivel mundial. En el Hospital Infantil de México se habían operado 272 casos hasta 1996. De los pacientes operados con la técnica del parche transanular, el 53% progresó de insuficiencia pulmonar moderada a severa. El objetivo de este estudio es documentar la evolución postoperatoria inmediata en aquellos pacientes a los que se les realizó corrección total y colocación de válvula monocúspide en el postoperatorio inmediato.** ***Material.*** **Se realizó un estudio comparativo, descriptivo, prospectivo, observacional, en el que se estudiaron 16 pacientes a los que se les realizó corrección total de Tetralogía de Fallot y colocación de parche transanular. Durante el período comprendido entre el 1 de marzo de 2013 y el 31 de marzo de 2015, se reportaron un total de 40 correcciones totales de Tetralogía de Fallot, de las cuales 18 de ellas fueron corregidas con parche transanular. Se analizaron dos grupos, el primero conformado por 9 pacientes a los que se les colocó válvula monocúspide, y el segundo grupo conformado por aquellos individuos a los que no se les colocó válvula monocúspide.** ***Resultados.*** **Los resultados sugieren una mejoría clínica en la evolución del posoperatorio inmediato, una menor estancia en la Unidad de Cuidados Intensivos (p=0,2), una tendencia a la disminución de la necesidad de soporte inotrópico (p=0,3), así como una disminución de la ventilación mecánica (p=0,7) y otras variables de morbilidad que no se analizaron específicamente. La duración de la estancia hospitalaria refleja indirectamente la recuperación y la estabilidad del paciente. El análisis estadístico realizado no mostró diferencias significativas en las variables analizadas, probablemente por el número de pacientes incluidos y las complicaciones asociadas.** ***Conclusiones.*** **La implantación del parche transanular con válvula monocúspide modificada en la reconstrucción del tracto de salida del ventrículo derecho para la corrección total de la Tetralogía de Fallot es realmente simple y reproducible.**

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Palabras clave: **Cardiopatía congénita; Válvula monocúspide; Tetralogía de Fallot; Insuficiencia de la válvula pulmonar.**

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Tetralogy of Fallot is the most frequent of the complex heart diseases, understood as those in which more than one lesion is associated. It was described in detail by Fallot in 1888, although it was known at least 200 years earlier.

Tetralogy of Fallot is one of the most frequent causes of congenital heart disease, with a prevalence ranging from 0.26 to 0.46 per 1000 live births. This pathology ranked fourth in frequency of all congenital heart diseases within and outside the country [1]. At the Hospital Infantil de México, 272 cases had been operated on up to 1996 with a surgical mortality of 18% [2]. From 2000 to 2009, 181 patients were operated, 125 of them (69%) with infundibular patch, 45 (24%) with transannular patch, 6 ventricular-pulmonary connections were carried out (3.3%), as well as 5 transatrial approaches (2.7%). Of the patients operated with transannular patch technique, 53 % progressed with moderate to severe pulmonary insufficiency distributed as follows: 6 patients without pulmonary insufficiency, 15 patients with mild insufficiency, 14 patients with moderate insufficiency, and 10 of them with severe insufficiency [2].

This is a defect in partitioning of the truncus and conus, i.e., belonging to the group characterized by defects in the outflow tracts, which includes others such as common truncus arteriosus, pulmonary atresia with ventricular septal defect and double outlet right ventricle. These last three pathologies share common features with tetralogy of Fallot, but have different clinical and surgical implications.

Without surgical intervention, survival is poor and inversely related to the degree of pulmonary obstruction. The trend has evolved toward performing total correction at younger ages and abandoning the original Blalock-Taussig fistula or modified as palliation. Early mortality of total correction reported by specialized centers in developed countries has been less than 3%. However, several hospitals, particularly in developing countries, maintain the strategy of performing a fistula in the first year of life or using interventional cardiology with balloon or stent as palliation to maintain patency of the RV outflow tract or keep the ductus arteriosus patent and then perform total correction at a latter stage. In cases requiring annular enlargement, the dilemma of pulmonary valve insufficiency arises. The combination of ventriculotomy and pulmonary regurgitation implies deterioration of right ventricular function and the appearance of arrhythmias in the long term. Different methods of valve implantation or valved conduits solve the problem of pulmonary insufficiency in the short or medium term, while resolving the right outflow obstruction. However, the biological nature of them anticipates their tissue degeneration and consequent stenosis or insufficiency over time. A simple method of obtaining pulmonary competence (in cases requiring a transannular patch during surgical correction) is the implantation of a monocuspid valve made up of expanded polytetrafluoroethylene (PTFE) membrane. During the immediate postoperative period, it facilitates recovery and its function may persist in the medium or long term [3].

Tetralogy of Fallot is the most common complex heart disease worldwide. Surgical correction can be performed using a transannular patch, 53% of which present severe pulmonary valve insufficiency. Among the most frequently presented post-surgical complications, right heart failure secondary to pulmonary insufficiency is described, prolonging the stay in intensive care by requiring longer mechanical ventilation and vasoactive drug support [4].

It has been described that the placement of a monocuspid valve in the right ventricular outflow tract could reduce the degree of pulmonary valvular insufficiency and thus reduce immediate post-surgical complications in intensive care [5].

Based on the descriptions of the authors abovementioned, the degree of pulmonary valvular insufficiency correlates with right heart failure, so that the monocuspid valve could prevent acute pulmonary valvular insufficiency and, therefore, favor a satisfactory early post-surgical evolution in intensive care in patients operated on for total correction of tetralogy of Fallot with transannular patch.

At Hospital Infantil de México "Federico Gómez", about 20 surgeries for correction of tetralogy of Fallot are yearly performed. Therefore, with this technique, we theoretically can favor the immediate post-surgical evolution in intensive care, thereby shorten the length of hospitalization with the consequent reduction of medical supplies and costs.

MATERIAL

A comparative, descriptive, prospective, observational study was performed. During the period from March 1, 2013

Table 1. Characteristics and operative results

Variable	With Valve (n= 09)	Without Valve (n= 07)	p value
Age (years) (range)	3.3 (1-8)	4.4 (1-18)	NA
Gender (female:male)	5:4	6:1	NA
Weight (Kg)	14.14 (8.7-18.5)	18.91 (5.6-68)	NA
Aortic cross-clamping time (min)	105.78 (65-135)	80.71 (70-120)	0.0596
Pulmonary insufficiency	mild-moderate	mild-severe	0.0910
Mechanical ventilation (days)	2.33 (1-8)	2.71 (1-5)	0.7146
Lengh of stay in ICU (days)	5.67 (3-12)	7.29 (8-29)	0.5271
In-hospital lenght of stay	15 (3-22)	22 (9-45)	0.2579
Inotropic drugs (days)	3.4 (2-12)	3 (2-11)	0.3426

ICU: Intensive care unit; PI: Pulmonary insufficiency.

to March 31, 2015, a total of 40 total corrections of tetralogy of Fallot were reported, of which 16 of them were corrected with transannular patch. The clinical records were reviewed to include them in the statistical study. For the statistical analysis, measures of central tendency and dispersion were used in addition to inferential statistics with Student's t-test for unpaired samples and the X2 test with a confidence interval of 95% and with a margin of error of 0.05 ($p<0.05$).

RESULTS

Two groups were analyzed. The first group (series 1) consisted of 9 patients who received monocuspid valve placement represented 56% of the total, and the second group (series 2), who did not receive monocuspid valve placement, was composed by 44%. With a total of 16 patients, it was found a distribution by gender of 6 men (37.5 %) and 10 women (62.5 %), with an average weight of 16.2 kg, a weight ranging from 5.6 kg to 68 kg. Age at the time of surgery ranged from 1-year old to 18-years old, with an average age of 3.8-years old. Extracorporeal circulation time in patients who underwent monocuspid valve placement was of 145 minutes, while in those who did not undergo monocuspid valve placement was of 125 minutes. Aortic cross-clamping time was 105 minutes, and 80 minutes, respectively. The degree of pulmonary insufficiency in the immediate postoperative period assessed by echocardiography was predominantly mild in 55.5%, and moderate in 44.4%. At hospital discharge, the insufficiency progressed from moderate to severe in only one patient, while the rest did not show any changes. The intubation time in patients who received a monocuspid valve ranged from 1 to 8 days, with an average of 2.3 days. In patients who did not receive a monocuspid valve, it ranged from 1 to 5 days, with an average of 2.7 days. The average length of stay in pediatric intensive care was 5.6 days in patients with a monocuspid valve, while in patients without a monocuspid valve it was 7.2 days. Patients with a valve required less inotropic time with a mean of 3.4 days, while patients without a valve required a mean of 5 days of inotropic medication. Regarding in-hospital stay, patients with a monocuspid valve stayed an average of 15 days, while patients without a monocuspid valve stayed an average of 22 days. Concerning the total number of patients, the morbidity reported was as follows: in the first series, 3 patients presented pneumonia, 4 patients had sepsis, 1 patient had septic shock, and 1 patient had complete AV block requiring the placement of a permanent pacemaker. Of the second series, 2 patients presented pneumonia, one patient sepsis, one patient septic shock. During the analysis of the study, 2 deaths were reported, associated with septic shock and multiple organ failure with a prolonged stay in intensive care, not directly associated with the surgical procedure for total correction of tetralogy of Fallot, since the complications described are right heart failure and heart rhythm disorders. These patients were excluded from the analysis since the complications presented are not directly related to the placement or not of a monocuspid valve and have no relationship with the patient's hemodynamics (**Table 1**).

DISCUSSION

Currently, the immediate results of Fallot surgery are considered excellent, regardless of the timing and surgical technique. The expected in-hospital morbidity and mortality is < 2%. Immediate postoperative morbidity is related to low output, right ventricular diastolic dysfunction and arrhythmias. The long-term prognosis of typical Fallot is favorable. Overall survival is 90% at 30 years of age in NYHA functional class I or II. Late complications occur in 10-15% of operated cases after 20 years of follow-up, the most important of which are right ventricular failure caused by chronic IP, ventricular and supraventricular arrhythmias and sudden death in 1.5 out of 1,000 cases per year [4]. Risk factors predicting adverse outcomes are advanced age of repair, evidence of sustained ventricular tachycardia or longer QRS duration and hemodynamic compromise due to long-term pulmonary insufficiency with dilated right ventricle and biventricular dysfunction Transannular patch produces pulmonary valve insufficiency in virtually all cases. However, the actual degree of regurgitation is variable and depends on several factors related to VD afterload and the degree of distensibility of the right ventricle itself, also affected by the noncontractile area of the free wall corresponding to the ventricular portion of the patch. The consequent physiology is well tolerated for a long time in most patients, but some will eventually present right ventricular failure of varying degrees, and the abrupt change from pressure overload to volume overload associated with ventriculotomy can also have an acute effect in the immediate postoperative period. The interest in achieving a pulmonary valvular mechanism in the correction of tetralogy of Fallot is twofold: better recovery in the immediate postoperative period and, ideally, maintenance of valvular competence in the medium and long term.

The aim of this study is to demonstrate some difference in the immediate postoperative evolution in patients who have undergone total correction of tetralogy of Fallot with transannular patch, with or without placement of a monocuspid

valve. One of the advantages of the surgical material manufacture is the possibility of modifying it as required. In our case, this applies to the shape and dimensions of both the transannular patch and the PTFE (expanded polytetrafluroethlene) pulmonary neovalve. The PTFE material appears to retain a degree of functional durability beyond the immediate postoperative period and results in favorable VD (remodeling in patients undergoing surgery for tetralogy of Fallot). What is unknown is how long the monocuspid valve will continue to function and thus sustain this normalization of VD structure and function.

The statistical analysis performed did not show significant differences in the variables analyzed, probably due to the number of patients included and the associated complications. However, although the results of our study were not statistically significant, some considerations can be made.

As a result, many reports have described methods of creating a competent pulmonary valve in the right ventricular outflow tract as a means of improving this pathophysiological process and better evolution and early recovery from ventricular failure, although with results that are not always statistically significant. In 1967, the use of a homograft patch was first described, but unfortunately its use in children almost uniformly requires reintervention for structural valve failure or right ventricular outflow tract obstruction, often within a couple of years [6]. The use of homograft tissue has limitations as it is expensive and not readily available in all locations. This led some innovative surgeons to create methods of constructing a simple monocuspid pulmonary valve from autogenous and prosthetic material. Techniques using fresh autologous tissue and homograft from gluteraldehyde-treated pericardium, xenograft pericardium, and silastic membrane have been reported. Unfortunately, these materials document early degeneration and, in some cases, caused RV outflow obstruction, leading to variable clinical outcomes.

In 1993, Yamagishi et al. [7] and Oku et al. [8] independently introduced PTFE as a readily available material with good characteristics for monocuspid valve manufacture when compared to the other materials. In the study, carried out by Turrentine et al. [3] reported animal studies suggesting that PTFE-0.1 mm material performed better than fresh pericardium treated with gluteraldehyde.

In this study, the overall results suggest a clinical improvement in the immediate postoperative evolution, judging by the length of stay in the postoperative Intensive Care Unit, a tendency towards a decrease in the need for inotropic support as well as a decrease in ventilation and other morbidity variables that are not specifically analyzed. The length of hospital stay indirectly reflects the recovery and stability of the patient. As reported in the literature, our study suggested a beneficial effect of TSVD (reconstruction with a monocuspid valve). In our series of samples, TSVD reconstruction with a monocuspid valve has proven to be a simple and reproducible technique that demonstrates excellent early postoperative function by decreasing the degree of pulmonary insufficiency. However, TSVD growth or eventual incorporation of fibrocollagen into the leaflet is likely to limit long-term function. Therefore, at this time, and with this technique, only PTFE monocuspid valve placement should be indicated to maintain adequate function in the short and medium perioperative term. On the other hand, it would be interesting to perform a long-term follow-up of the degree of pulmonary insufficiency developed by patients who had a monocuspid valve placed, demonstrated by clinical symptoms of right failure and supported by echocardiogram and MRI studies. In addition to observing whether a certain degree of obstructive gradient appears in the TSVD secondary to the placement of the monocuspid valve. The implantation technique is simple and time consuming, no significant ischemia time difference is reported. Late follow-up of the series will confirm the duration of valve competence.

In conclusion, the transannular patch implantation with a modified monocuspid valve in the right ventricle outflow tract reconstruction for total correction of tetralogy of Fallot is simple and reproductible. Initial results are promising, in terms of mild regurgitation and low gradient, during immediate postoperative evolution. Medium and long-term follow-up is needed to confirm these results and compare them with those obtained through other techniques.

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