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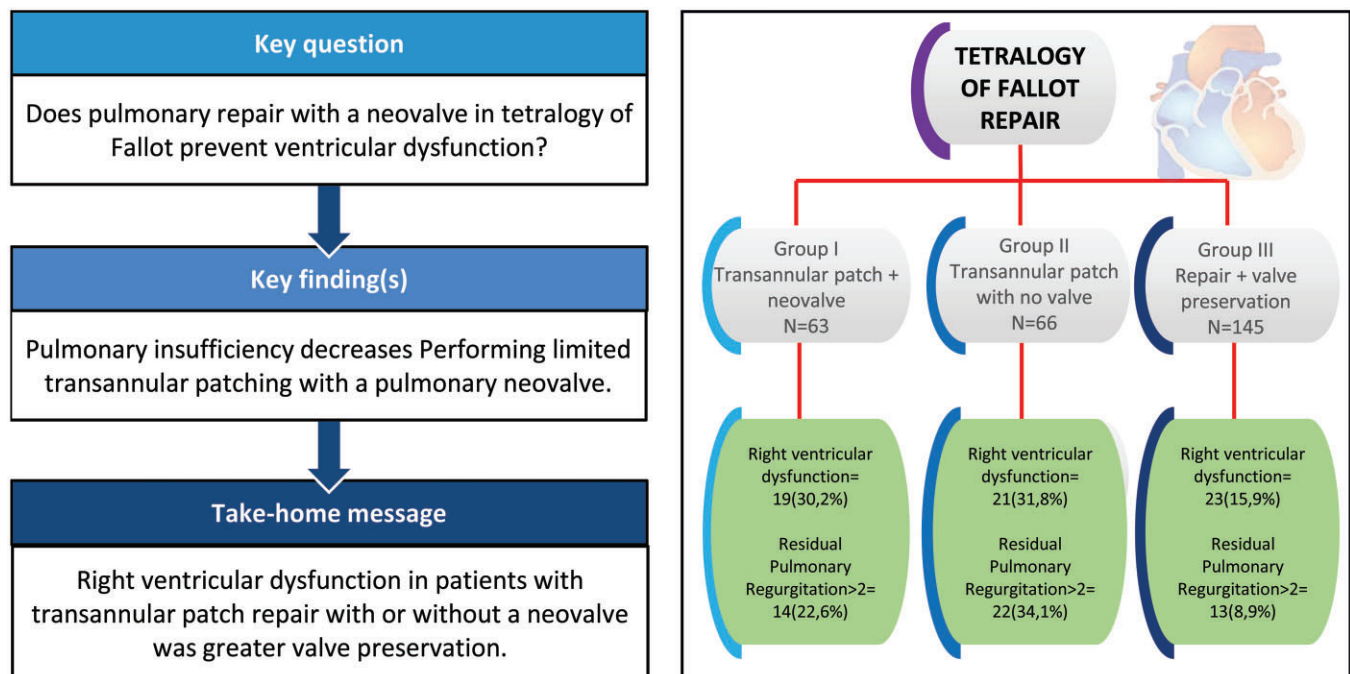
Repair with a pulmonary neovalve in tetralogy of Fallot: does this avoid ventricular dysfunction?

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Abstract

OBJECTIVES: Given the anatomical variations of tetralogy of Fallot (TOF), different surgical techniques can be used to achieve correction. Transannular patches (TAPs) are the most commonly used technique; they are associated with right ventricular dysfunction, the incidence of which can be reduced through pulmonary valve preservation.

METHODS: Between January 2010 and July 2019, we performed 274 surgical corrections of tetralogy of Fallot at Fundación Cardioinfantil; 63 patients (23%) underwent repair with a TAP in addition to a pulmonary neovalve (Group I), 66 patients (24.1%) received a TAP without a pulmonary valve (Group II) and 145 patients (52.9%) had a repair with valve preservation (Group III). We analysed patient's characteristics before, during and after surgery at a 30-day follow-up.

RESULTS: We found that patients in Group III were older ($P=0.04$). Group II had the lowest level of O_2 saturation before surgery (82%, $P=0.001$). Cardiopulmonary bypass and aortic cross-clamp times were longer in Group I ($P < 0.001$). Right ventricular dysfunction was less frequent in Group III (15.9%, $P=0.011$). Severe residual pulmonary regurgitation was more common in Group II (21.9%, $P=0.001$).

CONCLUSIONS: Preservation of the pulmonary valve is an important factor for immediate postoperative management of tetralogy of Fallot. Patients who were repaired with a TAP with or without a pulmonary neovalve had a higher incidence of right ventricular dysfunction than those with pulmonary valve preservation.

Keywords: Tetralogy of Fallot • Transannular patch • Pulmonary neovalve • Pulmonary regurgitation

ABBREVIATIONS

TAP	Transannular patch
TOF	Tetralogy of Fallot

INTRODUCTION

Total repair of tetralogy of Fallot (TOF) is increasingly performed on neonates and infants. Often, the right ventricular outflow tract must be widened using a transannular patch (TAP), as described in 52% of cases in the Society of Thoracic Surgeons series, and in the European Association for Cardio-Thoracic Surgery studies in which it was the most frequently used technique in 57.5% [1, 2].

This technique is known to have significant ramifications not only postoperatively but also in the short, medium and long term, secondary to progressive dysfunction of the right ventricle [1–4]. The use of TAPs leads to free pulmonary regurgitation, which initially, and for a long time, is well tolerated by physiological mechanisms. At the time of repair, the right ventricle is hypertrophic and has low compliance, with hypoplastic or below normal diameters of both central pulmonary arteries, low capacitance and a high heart rate, which leads to a short diastole. Thus, despite having a wide pulmonary regurgitation aperture, the degree of insufficiency is limited [5]. Over time, the right ventricle dilates, ventricular reserve decreases, the functional class may deteriorate, and arrhythmia and right heart failure may develop [3, 6, 7]. In addition,

these patients with pulmonary insufficiency have been found to be more prone to needing late reinterventions and pulmonary valve replacement [8].

In some series, fewer than 50% of patients achieve correction with valve preservation [3, 8, 9]. Currently, the vast majority of centres try to preserve pulmonary competence to the greatest extent possible [10–14]. The combination of ventriculotomy and free pulmonary regurgitation leads to progressive deterioration of right ventricular function and the onset of arrhythmias [3]. To preserve pulmonary valve competence, various materials have been used in manufacturing neovalves including autologous pericardium, bovine pericardium, polytetrafluoroethylene and valved conduits [15, 16]. However, the biological nature of these materials predisposes them to future tissue degeneration, calcification and dysfunction, with the potential development of stenosis-insufficiency, leading to the need for multiple interventions [17].

A simple method for achieving pulmonary competence in cases requiring a TAP during surgical correction is the manufacturing of an autologous pericardial neovalve, which is usually always available and is cost-effective [18]. Its usefulness has been described in the immediate postoperative period, and in the short and medium term [19]. Since 2008, at Fundación Cardioinfantil, we have routinely used the technique described by Sung *et al.* [20, 21], seeking to preserve the pulmonary valve or reconstruct a pulmonary neovalve using autologous pericardium as an alternative to the TAP [22] (Fig. 1).

The objective of this study was to determine the early postoperative progression and right ventricular dysfunction of patients undergoing definitive correction of TOF.

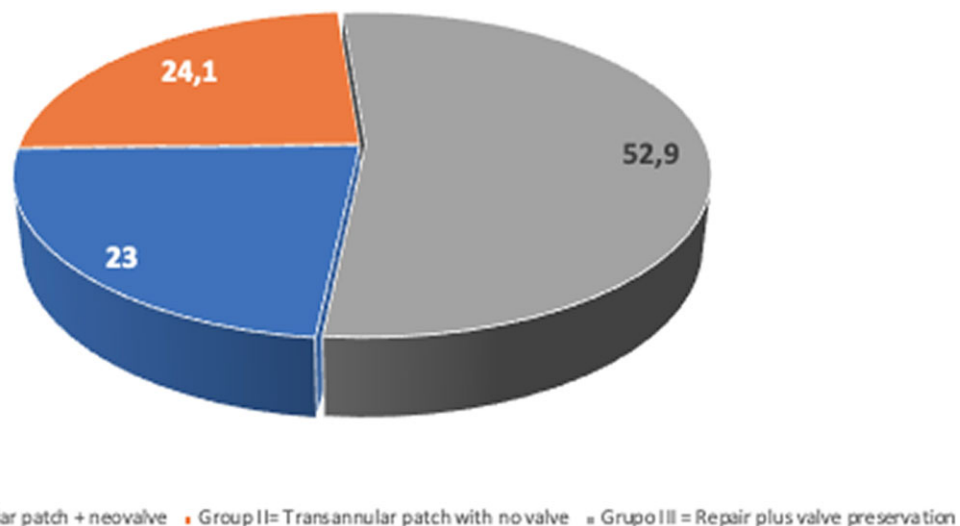


Figure 1: Tetralogy of Fallot repair technique.

MATERIALS AND METHODS

A historical cohort design was selected, all procedures of definitive correction of TOF were performed at Fundación Cardioinfantil–Instituto de Cardiología (FCI–IC) between January 2010 and June 2019. This study was approved by the ethics committee of Fundación Cardioinfantil (ID: CEIC-3059-2016) and need for individual consent was waived. The patients were found in the paediatric cardiovascular surgery database, which collects data prospectively, follows the variable definition and operationalization system of the International Quality Improvement Collaborative (IQIC) database guidelines and undergoes an annual external audit, which helps control information bias. All procedures were categorized into 3 groups according to the surgical repair technique employed, as follows:

- Group 1: correction using a TAP and neovalve creation
- Group 2: TAP with no valve
- Group 3: repair with valve preservation.

The surgical technique used was chosen by the surgeon considering the anatomy of the right ventricular outflow tract and the z-value of the pulmonary valve. In our surgical practice, patients with a z-value of the pulmonary valve <2 required intervention in the pulmonary annulus, with or without neovalve.

The surgical technique is illustrated in Fig. 2; an autologous pericardial patch is extracted and treated with 0.2% glutaraldehyde for 10 min. Extracorporeal circulation is begun with aortic and bicaval cannulation under mild hypothermia or normothermia. Cardiac arrest is induced using antegrade cardioplegia, the right atrium is incised longitudinally, and the left heart is drained through the foramen ovale, and the right atrium is prepared for exposure. The right ventricular outflow tract obstruction is located through the tricuspid valve, and the parietal extensions of the infundibular septum are sectioned, along with the muscle and fibre bands. The ventricular septal defect is closed through the tricuspid valve using a thin GORE-TEX patch with a continuous 5/0 polypropylene suture. Subsequently, if the artery and pulmonary ring must be enlarged, a longitudinal incision is made in the main pulmonary artery with limited extension to the pulmonary ring. Residual lesions requiring resection and the pulmonary valve are assessed in a retrograde fashion. Hegar dilators are

introduced according to the Z-value of the pulmonary ring, and, if the Z-value of the ring is less than -2 , the proximal incision is widened until an adequate diameter is achieved. An incision is made in the centre of the (bicuspid or tricuspid) pulmonary valve's most anterior leaflet, and the leaflet is widened using a section of autologous pericardium. A second autologous pericardial patch is used to enlarge and close the roof of the pulmonary artery and the right ventricular outflow tract. The competence of the tricuspid valve is checked, the chambers are closed in the usual manner and the patient is taken off bypass.

Primary and secondary endpoints

The primary endpoint of the study was postoperative right ventricular dysfunction. Secondary endpoints were residual pulmonary regurgitation, surgical site infection, stroke, jet, extracorporeal membrane oxygenation and mortality.

All patients undergoing surgery during the study period were included. Patients undergoing reintervention for Double Outlet Right Ventricle TOF type were excluded. All patients were followed up per protocol 45 days after hospital discharge. This follow-up included outpatient assessment and a telephone call to determine freedom from events such as death, reintervention, infections and readmission.

Statistical analysis

A descriptive analysis was performed of the preoperative and intraoperative variables, postoperative outcomes and ventricular function analyses. Quantitative variables were initially evaluated using the Shapiro–Wilk test to determine their distribution. Based on this result, they were analysed using mean and standard deviation for variables with a normal distribution and median and interquartile range for variables with a non-parametric distribution. Variables were analysed using relative and absolute frequencies. The Chi-squared or Fisher's exact test if the marginal absolute frequencies were <5 for categorical variables, and Kruskal–Wallis test for continuous non-parametric variables was used to determine the difference between groups. Differences were considered statistically significant if the *P*-value was <0.05 .

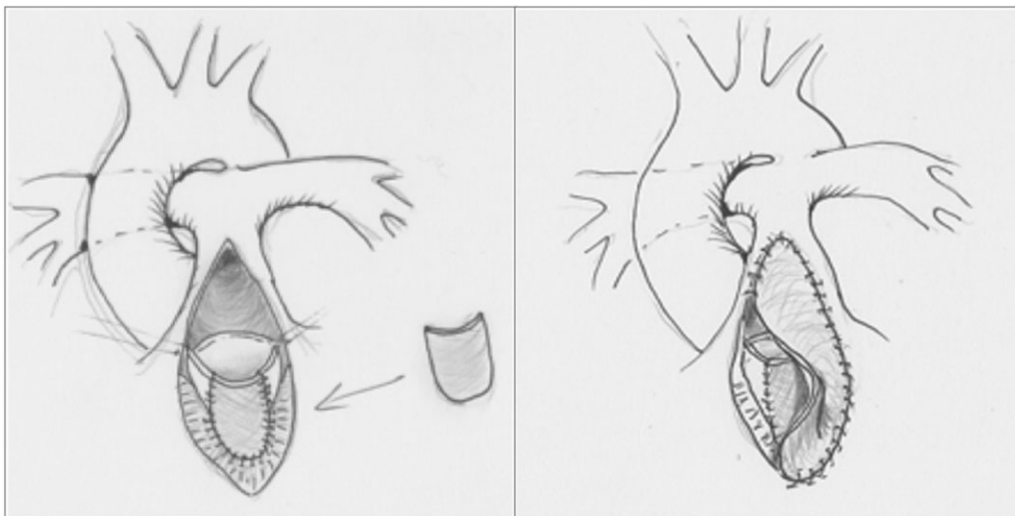


Figure 2: Pulmonary neovalve created with an autologous pericardial patch.

and post-hoc tests for adjusting the *P*-values for multiple comparisons as Bonferroni, or Tukey were performed. The data were analysed on STATA 15 (Stata Corp. 2017. Stata Statistical Software: Release 15. College Station, TX: Stata Corp LLC) for Windows.

The study was carried out within ethical norms and under the precepts of Resolution 8430 of 1993 of the Ministry of Health of the Republic of Colombia, and it was classified as a no-risk study. The authors guarantee the confidentiality of all the data used in this study.

RESULTS

During the study period, 274 patients met the inclusion criteria. On average, 27 TOF repair procedures were performed per year, with mortality reduced to zero in the last 3 years of the study (Fig. 3). The TAP plus pulmonary neovalve creation repair technique was used in 63 patients (23%) (Group I), (24.1%) a TAP with no valve was used in 66 patients (Group II) and 145 patients (52.9%) underwent correction with pulmonary valve preservation (Group III).

Regarding the preoperative characteristics, the median age was 18.8 months (11.4–48.9), most patients (56.9%) were male and the median LVEF was 72% (67–76). There were statistically significant differences between the groups in preoperative O₂ saturation, which was lower in Group II (*P*=0.001); haematocrit, which was higher in Group II 48 (*P*=0.019); and age, with those in Group III being older (*P*=0.04) (see Table 1).

As far as intraoperative characteristics, both cardiopulmonary bypass time and aortic cross-clamp time were found to be longer in Group I, with the differences being statistically significant (*P* < 0.001).

About postoperative events, there was greater mortality in Group II with 7.6% of the cases, although it was not a significant finding (*P*=0.18). Five patients (1.8%) required extracorporeal membrane oxygenation therapy, right ventricular dysfunction was more frequent in Group II with 31.8% of the cases and less frequent in Group III, with 15.9% (*P*=0.011). For pulmonary regurgitation, grade I residual pulmonary regurgitation was found to be more common in Group III (24.6%; *P*=0.008), grade II in Group I (41.9%; *P*=0.02) and grade III and IV in Group II, with 12.5% and 21.9% of cases, respectively (*P* < 0.05) (see Table 1).

DISCUSSION

The diagnosis and treatment of TOF in developing countries, where healthcare access is limited, occurs late; although the current tendency is towards total repair in early infancy [1, 3], the age of our patients ranged from 2 to 4 years, which is higher than what is reported in the literature. Nevertheless, it is similar to data reported by the International Quality Improvement Collaborative [22], in which 55.7% of 2164 patients underwent surgery after age one.

Neonatal correction can be performed with excellent early results, which can lead to the routine use of wide ventriculotomy and TAP repair in more than 70% [23]. If the patient has an adequate weight and favourable anatomy, we perform total correction. Preservation of the pulmonary ring is attempted during repair; if this is not possible, a limited ventriculotomy is performed which is reconstructed using a TAP or a TAP with a neovalve. With regard to the repair technique employed, our study showed that the pulmonary valve was able to be preserved in 53% of the cases, in patients with a median age of 21.3 months (interquartile range 12.6–65.5). We believe that this result could be related to the development of the tissues making the anatomy more favourable.

The pathophysiology of TOF creates compensatory mechanisms due to hypoxaemia, including increased haematocrit to optimize tissue oxygenation. This study shows statistically significant differences in data consistent with these mechanisms, whereby patients undergoing TAP repair with or without neovalves had low presurgical saturations and high haematocrits, as well as more prolonged intensive care unit stays, compared with the valve preservation group. These data are similar to those reported by Özbek *et al.* [24] who identified oxygen saturation and presurgical haematocrit as an independent risk factor for longer hospital stay.

Right ventricular dysfunction following surgical repair of TOF is caused by multiple factors such as limited myocardial protection of the right ventricle during aortic cross-clamping due to severe muscular hypertrophy, muscle band resection which may trigger arrhythmias and heart blocks, increased diastolic dysfunction, the need for high filling pressures and the length of the right ventriculotomy [25, 26]. Consequently, in our study, we found that patients undergoing TAP repair with or without neovalves had a greater proportion of right ventricular dysfunction (*P*=0.011) than those in whom the valve was preserved, along with a greater

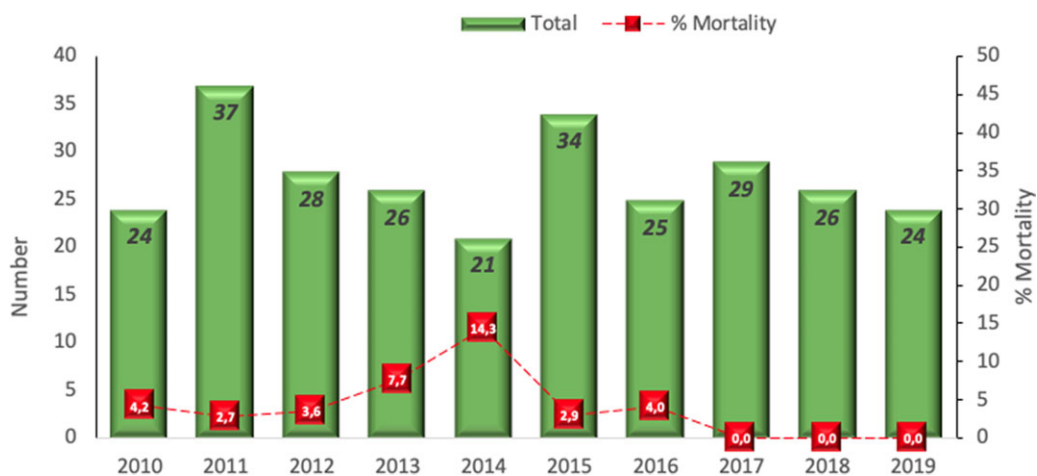


Figure 3: Annual volume of patients with tetralogy of Fallot repair, January 2010 to June 2019.

Table 1: Preoperative characteristics of patients undergoing tetralogy of Fallot repair, by surgical technique, January 2010 to June 2019

Variable	Total N = 274	Group I Transannular patch + valve creation N = 63	Group II Transannular patch N = 66	Group III Preservation valve repair N = 145	Valour P
Preoperative					
Age (months)	18.8 (11.4–48.9)	17.9 (10.4–41)	15.1 (9.5–35.2)	21.3 (12.6–65.5)	0.029 ^a
Male	156 (56.9)	37 (58.7)	37 (56.1)	82 (56.6)	0.96
Prematurity	47 (17.2)	7 (12.9)	15 (25.4)	25 (21)	0.247
Weight (kg)	9.5 (7.7–13)	9.2 (7.5–12.1)	9.1 (7.2–11.9)	9.8 (7.8–15)	0.103
Height (cm)	18.3 (71–95)	77.5 (69–94)	75.3 (68–87)	80 (72–99)	0.0556
Malnutrition	84 (30.7)	19 (30.2)	27 (40.9)	38 (26.2)	0.099
Oxygen saturation	86 (80–92)	85.5 (80–91)	82 (78–88)	89 (83–93)	0.003 ^a
Haematocrit (%)	44 (39–50)	43 (39–49)	48 (41–52)	43 (38–49)	0.1478
Left ventricular ejection fraction	72 (67–76)	71 (65–75)	74 (68–76)	72 (68–77)	0.4214
Chromosomal abnormalities	27 (9.9)	7 (11.1)	8 (12.1)	12 (8.3)	0.638
Non-congenital cardiac anatomic abnormality	31 (11.4)	9 (14.3)	8 (12.1)	14 (9.7)	0.589
Intraoperative					
CPB minutes	111 (86–141)	134 (108–158)	108 (89–130)	98 (74–133)	0.0001
Aortic cross-clamp minutes	82 (63–108)	107 (87–122)	79 (68–96)	73 (51–96)	0.0001
Commissurotomy	27 (9.9)	6 (9.5)	3 (4.6)	18 (12.4)	0.211
Postoperative					
Surgical infection	10 (3.6)	2 (3.2)	1 (1.5)	7 (4.8)	0.528
Mediastinitis	1 (0.4)	1 (1.6)	0	0	0.23
Low cardiac output	65 (23.7)	18 (28.6)	18 (27.3)	29 (20)	0.292
Stroke	3 (1.1)	1 (1.6)	0	2 (1.4)	0.797
Bleeding reoperation	14 (5.1)	3 (4.8)	4 (6.1)	7 (4.8)	0.934
ECMO	5 (1.8)	3 (4.8)	0	2 (1.4)	0.102
Mortality	10 (3.6)	2 (3.2)	5 (7.6)	3 (2.1)	0.18
Right ventricle dysfunction	63 (23)	19 (30.2)	21 (31.8)	23 (15.9)	0.011 ^b
Arrhythmia	48 (17.5)	11 (17.5)	16 (24.2)	21 (14.5)	0.224
JET	4 (8.3)		2 (12.5)	2 (9.5)	0.355
Atrioventricular block	5 (10.4)	1 (18.2)	1 (6.3)	2 (9.5)	0.719
Other	39 (81.3)	9 (81.8)	13 (81.3)	17 (81)	1.000
Degree of residual pulmonary insufficiency					
I	47 (17.8)	5 (8.1)	8 (12.5)	34 (24.6)	0.0077 ^b
II	73 (27.7)	26 (41.9)	15 (23.4)	32 (23.2)	0.0157 ^b
III	15 (5.7)	2 (3.2)	8 (12.5)	5 (3.6)	0.0252 ^b
IV	34 (12.9)	12 (19.4)	14 (21.9)	8 (5.8)	0.0013 ^b

Data are presented as median with the 25th to 75th percentile interval, or *n* (%).

^aTukey–Kramer.

^bBonferroni/Fisher–Hayter.

CPB: cardiopulmonary bypass; JET: junctional ectopic tachycardia; ECMO: extracorporeal membrane oxygenation.

need for extracorporeal membrane oxygenation, associated with greater extracorporeal circulation and aortic cross-clamping times.

Many groups have described strategies for limiting the right ventriculotomy size and reducing the incidence of pulmonary insufficiency. Valved allografts and xenografts have been proposed as the most anatomic and physiologic way to repair the right ventricular outflow tract obstruction but, unfortunately, they must all be replaced due to patient growth and conduit deterioration [27]. The use of monocuspid valves made of pericardium, xenograft valve cusps, fascia latae, autologous pulmonary artery wall or polytetrafluoroethylene has shown decreased pulmonary insufficiency in the short term. However, they have limited durability [28]. Gundry reported that, at 24 months, only 14% of his patients with a monocuspid allograft had a competent pulmonary valve, despite the excellent short-term results [29]. At the University of Indiana, Turrentine *et al.* [30] showed that most patients had polytetrafluoroethylene monocuspid deterioration at 3 years. In our study, we found that patients undergoing TAP

repair with a neovalve and those with valve preservation had a smaller percentage of moderate to severe residual pulmonary insufficiency compared with those in the TAP group ($P=0.001$). These findings concur with those of Ducas *et al.* [8] who reported a high rate of pulmonary insufficiency in patients with TAPs (65.1% vs 16.3% in patients with a preserved pulmonary ring).

Limitations

Several limitations in our investigation deserve mention. First, it is single institution experience. Second, it is a retrospective, non-randomized cohort study in which selection criteria for each type of surgical technique were not established, which leads to bias. Third, due to socioeconomic conditions and lack of adequately medical access, we do not have for now long-term data on these patients, or late follow-up echocardiograms to evaluate the durability of the repair. We do not know what proportion of patients with TOF in our country die without having the defect repaired.

CONCLUSIONS

Performing limited transannular patching with a pulmonary neovalve, using an autologous pericardial patch, decreases the degree of pulmonary insufficiency immediately after surgery and at short-term follow-up. Right ventricular dysfunction in patients with TAP repair with or without a neovalve was greater than in those in whom valve preservation was possible. Prospective multicentre studies and long-term follow-up are needed to obtain conclusive results regarding the durability of the repair.

ETHICAL APPROVAL

All study procedures and data management were carried under national and local ethical standards. For this type of research, formal consent is not needed. Institutional review board: Comité de Ética en Investigación Clínica.

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Conflict of interest: none declared.

Data availability

Database collected in the study is available from the corresponding author on reasonable request. Data sharing is not applicable to this article as no data sets were generated or analysed during the current study.

Authors contributions

Albert Franz Guerrero: Conceptualization; Formal analysis; Supervision; Writing—original draft; Writing—review & editing. **Ivonne Gisel Pineda-Rodriguez:** Formal analysis; Methodology; Software; Supervision; Writing—review & editing. **Andres Mauricio Palacio:** Visualization; Writing—review & editing. **Carlos Eduardo Obando:** Investigation; Visualization; Writing—review & editing. **Tomas Chalela:** Validation; Visualization. **Jaime Camacho:** Supervision; Validation. **Carlos Villa:** Validation. **Juan Pablo Umaña:** Supervision; Validation; Visualization. **Nestor Fernando Sandoval-Reyes:** Conceptualization; Supervision; Validation; Visualization.

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