

## Evolving strategies for preserving the pulmonary valve during early repair of tetralogy of Fallot: Mid-term results

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**Background:** The aim of the study was to evaluate our results with pulmonary valve (PV) preservation in selected patients with tetralogy of Fallot (TOF).

**Methods:** From January 2007, 69 patients who underwent early transatrial TOF repair were enrolled in the study. The patients were divided into 2 groups: PV preservation by PV annulus balloon dilation (group 1) and PV cusp reconstruction after annular incision (group 2).

**Results:** Thirty-four patients underwent a successful PV annular preservation (49%). Median age at surgery was 113 days (range, 36-521 days) (group-1 vs group-2,  $P =$  not significant). Median preoperative PV Z score was  $-3.15$  (range,  $-0.95$  to  $-5.62$ ) (group-1 vs group-2,  $P = .03$ ). Median intensive care unit and hospital stays were 3 and 10 days, respectively (group 1 vs group 2,  $P =$  not significant). Median follow-up time was 580 days (range, 189-1940 days) (group 1 vs group 2,  $P = .08$ ). Two patients were reoperated for residual right ventricular outflow tract (RVOT) obstruction (1 in group 1 and 1 in group 2). The remaining patients are alive and well. Median peak RVOT gradient was 25 mm Hg (range, 8-60 mm Hg) (group 1 vs group 2,  $P =$  not significant). The degree of PV regurgitation in group 1 was none/mild in 24 patients (80%) and moderate in 6 (20%) and was none/mild in 8 patients (25%), moderate in 11 (34.4%), and severe in 13 (28.6%) in group 2 ( $P = .001$ ). Median right ventricular fractional area change was 55% (range, 42%-70%) in group 1 and 50% (range, 40%-63%) in group 2 ( $P = .003$ ).

**Conclusions:** The integrity and function of the PV can be preserved in selected patients during early repair of TOF by concomitant balloon dilation, leading to a better mid-term right ventricular function. (*J Thorac Cardiovasc Surg* 2014;147:687-96)

Tetralogy of Fallot (TOF) repair is now routine practice and can be achieved with low surgical risk in many pediatric cardiac centers. Correction via a right ventriculotomy with transannular right ventricular outflow tract (RVOT) patch reconstruction is still the most frequent approach.<sup>1</sup>

More recently, a transatrial approach has become the preferred procedure and it yields excellent early and mid-term results.<sup>2-10</sup> The objective of a transatrial repair is to avoid (or minimize) structural damage to the subpulmonary pump, which has proved to be the Achilles' heel in the long term.

However, use of a transannular patch, although necessary in some cases, often results in pulmonary insufficiency with chronic right ventricular volume overload, leading inevitably to progressive right ventricular dilation and dysfunction that is associated with impaired functional capacity.<sup>1-5,8,9</sup> Augmentation plasty of the pulmonary valve (PV) leaflets can avoid PV regurgitation early postoperatively, improving the short-term clinical outcome.<sup>3</sup> Nonetheless, leaflet function often deteriorates over time resulting in progressive PV regurgitation.<sup>11-19</sup>

The interest in preserving PV function has stimulated surgeons to devise valve-sparing techniques for TOF repair.<sup>20-27</sup> In recent years, we have combined, in selected cases, our routine early transatrial transpulmonary repair with intraoperative balloon dilation of the hypoplastic pulmonary annulus.<sup>22</sup>

The aim of this study is to evaluate the early and mid-term results of this approach to early repair of TOF, focusing on PV and right ventricular function in comparison with our standard transatrial/transpulmonary repair technique.

### METHODS

Review of medical records and computerized hospital data was approved by the Clinical Investigation Committee from the University Hospital of Padua, and the procedures followed were in accordance with the institutional guidelines for retrospective record review and protection

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Disclosures: Authors have nothing to disclose with regard to commercial support.

Read at the 93rd Annual Meeting of The American Association for Thoracic Surgery, Minneapolis, Minnesota, May 4-8, 2013.

Received for publication May 2, 2013; revisions received Aug 30, 2013; accepted for publication Oct 11, 2013; available ahead of print Dec 5, 2013.

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0022-5223/\$36.00

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<http://dx.doi.org/10.1016/j.jtcvs.2013.10.029>

**Abbreviations and Acronyms**

PV	= pulmonary valve
RCA	= right coronary artery
RV	= right ventricular
RVFAC	= right ventricle fraction of area change
RVOT	= right ventricular outflow tract
TOF	= tetralogy of Fallot
VSD	= ventricular septal defect

of patient confidentiality. Individual consent was not obtained by patients enrolled in this study. Patients are not identified, and the chairperson of the Ethics Committee of our institution consented to publication of their data.

From June 2007, all patients who underwent repair of TOF at our institution were enrolled in the study. Patients with mild forms of TOF who did not require surgical manipulation of the PV, TOF with severe pulmonary valve stenosis and diminutive pulmonary artery branches with aortopulmonary collaterals who were treated by right ventricle–pulmonary artery conduit interposition, TOF with absent PV, double-outlet right ventricle, and adult patients undergoing repair of TOF were excluded.

Our standard institutional policy for TOF repair in early infancy since June 1991 (usually in patients  $\leq 3$  months of age) includes (1) the transatrial/transpulmonary approach to the subpulmonary outflow tract, (2) incision of the PV annulus with minimal right ventriculotomy (3–5 mm) when necessary, and (3) transatrial closure of the ventricular septal defect using an autologous pericardial patch.<sup>24</sup>

PV function is reestablished by the use of a pulmonary homograft monocusp patch, tailored at the annular level, to match the posterior natural leaflets (up to 2007) or by adding either a polytetrafluoroethylene (0.1 mm diameter) or CorMatrix ECM Technology (CorMatrix Cardiovascular Inc, Sunnyvale, Calif) leaflet under the RVOT enlargement patch.

Since 2007, we have attempted to preserve the PV annulus anatomy and function by intraoperative PV balloon dilation in selected patients. After a longitudinal pulmonary arteriotomy, the PV orifice was sized on the beating heart using a Hegar dilator (Table 1) to assess the effective diameter of the PV orifice. Valvular commissurotomy was routinely performed up to the sinutubular junction and the valve was sized again with a Hegar dilator to check the real annular diameter and to calculate the effective PV Z score.<sup>28</sup> After the subpulmonary muscular obstruction was relieved through the tricuspid valve up to the hinges of the PV leaflets, and the ventricular septal defect (VSD) was closed, a valvuloplasty balloon was then introduced through the tricuspid valve across the PV orifice and inflated under direct vision until the inner pressure reached 10 atmospheres. We chose short (2 cm), high-pressure (>10 atmospheres), noncompliant balloons,<sup>22</sup> sized according to the calculated size of the PV orifice relative to the body surface area of the patient. At the end of the procedure, the diameter of the PV was sized again with an appropriate Hegar dilator to check the results of the dilation, and the valve was carefully examined to exclude any possible iatrogenic lesion (Figures 1 and 2).

This new technique was initially used in selected patients with milder forms of TOF (Z score  $\geq -3$ ). The criteria for using this approach have recently evolved to include patients with a Z score of  $-4$  or lower. When dealing with a hypoplastic PV annulus (Z score between  $-3$  and  $-4$ ) after an initial PV commissurotomy followed by PV balloon dilation (up to the expected PV dimension for the body surface area), the PV leaflets, which have often been separated at the commissure level, are reconstructed by carefully delaminating the PV hinge point with a fine scalpel down to the right ventricular (RV) epicardium, thus extending the leaflet's coaptation area (Figures 1 and 2). Subsequently, the extended leaflets are resuspended at the level of the new PV commissure or further extended

by means of a small prosthetic (biological) patch and then resuspended. An appropriate Hegar dilator for the PV size (PV Z score = 0) is passed through the new PV annulus.

Particular care is taken to remove any possible RVOT obstruction up to the subannular level by combining transatrial, transtricuspid, muscle band resection and a further transpulmonary residual muscle band excision through the PV annulus, before and after balloon dilation.

**Clinical Data and Outcomes**

Transesophageal or epicardial echocardiography was used to monitor the immediate surgical results. Patients were evaluated by echocardiography (iE33 xMATRIX Echocardiography System, Philips Medical System, Andover, Mass) at hospital discharge and during outpatient follow-up.

Patients who were followed for less than 6 months after surgery were excluded from the analysis ( $n = 7$  patients, 4 of whom underwent PV preservation and 3 a standard TOF repair). Two patients who required a reoperation for residual RVOT obstruction after the initial repair were also excluded.

RVOT obstruction was quantified using Doppler echocardiography and classified as mild (<20 mm Hg), moderate (between 20 and 40 mm Hg), or severe (>40 mm Hg). Pulmonary regurgitation was quantified as (1) none-mild, (2) moderate, or (3) severe.<sup>29,30</sup> Right ventricular function was measured using the fractional area change (RVFAC).<sup>31,32</sup> The two-dimensional echo images were retrospectively reviewed in the echocardiography laboratory by a single staff pediatric cardiologist, who was blinded to the surgical procedure.

The primary outcome of this study was to assess the effectiveness of the PV preservation technique by focusing on mid-term PV and RV function. These results were compared with those of our standard transatrial repair with transannular patch (TAR-TAP) performed during the same time interval (including patients who had a failed PV preservation and who were converted to a standard TOF repair) (group 2).

Categorical variables are shown as absolute frequencies and percentages. Quantitative variables were summarized as the median and range. When quantitative variables were not normally distributed (assessed by the Shapiro-Wilk normality test), comparison between groups was done using the Kruskal-Wallis test. Categorical variables were compared using the  $\chi^2$  test or the Fisher exact test. Linear regression analysis was used to test the relationship between residual RVOT obstruction or PV regurgitation at follow-up and ventricular function. All reported *P* values are 2-sided. Statistical analysis was performed using Stata software (release 10.0 for Windows; Stata Corporation, College Station, Tex).

**RESULTS**

Sixty-nine patients were included in our study. Median age at surgery was 113 days (range, 36–521 days). In 39 patients, we attempted to preserve PV integrity. The remaining 30 patients, most of them at the beginning of our experience, underwent a standard transatrial/transpulmonary repair. In accordance with our policy of early repair, none of the patients had previously undergone a palliative procedure except for 1 patient from another institution in whom a stent had been placed in the patent ductus arteriosus at 1 month of age for severe arterial oxygen desaturation.

The median preoperative transcutaneous oxygen saturation was 93% (range, 80%–100%). Three patients (4.3%) had repeated cyanotic spells. The preoperative transcutaneous oxygen saturation was significantly higher ( $P = .03$ ) in patients who had preservation of the PV (Table 1).

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