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FOCUS ISSUE: VALVULAR HEART DISEASE

Extended Application of Percutaneous Pulmonary Valve Implantation

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Objectives This study was designed to report a novel indication for percutaneous pulmonary valve implantation in patients with previous right ventricular outflow tract (RVOT) patch.

Background Current indications for percutaneous pulmonary valve implantation are limited to patients who had pulmonary valve stenosis and/or regurgitation in a right ventricle-to-pulmonary artery conduit. Percutaneous pulmonary valve implantation has not been previously reported in patients with severe pulmonary valve regurgitation following repair of tetralogy of Fallot (TOF) using RVOT patch.

Methods After assessment of the RVOT patch in multiple projections, a catheter was placed in a distal pulmonary artery branch. In patients with an RVOT patch, sizing of the narrowest diameter of the RVOT patch by manual inflation of a sizing balloon was performed; a stent was placed into the RVOT patch at the level of the narrowest area to anchor the stent and to create an artificial conduit to place the Melody valve. The percutaneous valve was then implanted.

Results Seven females and 6 males with a mean age of 14.3 years and mean body weight 45 kg had successful percutaneous implantation of the Melody valve. Four patients had previous repair of TOF using RVOT patch. All patients were discharged within 2 days after the procedure without complications. After a mean of 4 months follow-up all patients were alive and well. Transthoracic echocardiography showed competent pulmonary valve. Chest X-ray showed no stent migration or fracture.

Conclusions Percutaneous pulmonary valve implantation can be performed in patients with pulmonary valve regurgitation, including those with previous RVOT patch using pre-stenting techniques, with satisfactory results. (J Am Coll Cardiol 2009;53:1859–63) © 2009 by the American College of Cardiology Foundation

Recent reports suggest that pulmonary valve replacement for chronic pulmonary valve regurgitation (PVR) should be considered before impairment of right ventricular (RV) function (1). This is particularly true for patients who have had chronic PVR following a right ventricular outflow tract (RVOT) patch for tetralogy of Fallot (TOF) repair. However, the invasive nature of redo PVR with its attendant risk may deter patients and their physicians from considering earlier valve replacement. The introduction of percutaneous pulmonary valve implantation (PPVI) to the clinical arena may quickly enable the reversal of this thinking process. To date, there is no report of use of this novel technology in patients who have had previous TOF repair using the RVOT patch (2,3). Moreover, the RVOT patch was considered a relative contraindication to PPVI in the early experience of Khambadkone et al. (2,3). We report PPVI in 13 patients, including 4 patients with pulmonary valve regurgitation after previous TOF repair using an RVOT patch.

Methods

Between September 2007 and March 2008, a total of 15 patients were referred for pulmonary valve implantation. Two patients were excluded from the study for technical reasons. The demographics of the 13 patients who had the complete procedure are summarized in Table 1.

All procedures were performed under general anesthesia. Cardiac catheterization was performed via percutaneous puncture of the right femoral vein. The femoral artery was also percutaneously accessed for monitoring and simultaneous coronary angiogram to rule out any potential compression on the coronary arteries by the newly implanted valve.

After assessment of the RVOT in multiple projections, a super-stiff exchange guidewire (Back-up Meier, Boston Scien-

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Abbreviations and Acronyms

PA = pulmonary artery
PPVI = percutaneous pulmonary valve implantation
PVR = pulmonary valve regurgitation
RV = right ventricular
RVOT = right ventricular outflow tract
TOF = tetralogy of Fallot

tific, Miami, Florida) was positioned in a distal pulmonary artery (PA) branch using a right coronary catheter. This was followed by sizing of the narrowest diameter of the outflow tract by manual inflation of a 24-mm sizing balloon (AGA Medical Corporation, Golden Valley, Minnesota), to determine its suitability for PPVI. In patients with previous conduits, the annulus size was determined by the original size of conduit. In patients with an RVOT patch, the mean size of annulus was 18 mm, and the stretch diameter was 20 mm.

Five of 6 patients with an RVOT patch had the RVOT patch extending into the main PAs (i.e., transannular patch); in these patients, a stent was placed into the RVOT at the level of the narrowest area to anchor the stent to create what we call an artificial conduit.

The stents were selected to cover most of the RVOT. The stents were deployed so that one-third of the stent fell below the RVOT narrowest diameter, with the intent to keep the upper end of the stent 5 to 10 mm below the bifurcation of the main PA (Fig. 1). Three of 4 patients had a 34-mm-long CP stent (NuMED, Inc., Hopkinton, New York). In 1 patient, a 36-mm intrastent LD max (ev3 Inc., Plymouth, Minnesota) was used. All were pre-mounted on a 22 × 40 mm balloon-in-balloon catheter (NuMED, Inc.).

The Melody valve (Medtronic Inc., Minneapolis, Minnesota) was prepared using the ensemble delivery system as previously described (2,4). In summary, the Melody valve was withdrawn fully into a protective sheath on the delivery system. The whole assembly was then passed over the guidewire and advanced into the pre-stented RVOT patch or the stenotic conduit. Once in an acceptable position, the covering sheath was withdrawn to expose the Melody valve that was previously crimped on the balloon. The inner and outer balloons were sequentially inflated, thus deploying the Melody valve. Thereafter, both balloons were rapidly deflated and removed, leaving the guidewire in place. Angiographic and hemodynamic evaluations were repeated before the guidewire was finally removed.

The procedure could not be completed in the 2 patients who proved to be unsuitable for the procedure because their RVOT patch stretch diameter was >22 mm, which was larger than the size of the Melody valve available.

Patients were assessed on day 1, as well as 1, 3, and 6 months after the procedure. Assessment included physical examination, 12-lead electrocardiography, chest X-rays (posterior anterior and lateral views), and cross-sectional echocardiography with color Doppler.

Statistical analysis. Descriptive data are presented as mean ± SD. A paired Student *t* test was used to compare the before- and after-PPVI data. A p value of <0.05 was considered significant, and statistical analysis was performed using SPSS (SPSS Inc., Chicago, Illinois).

Results

Seven females and 6 males, age range 10 to 23 years (mean 14.3 years), weight range 30 to 84 kg (mean 45 kg), had successful PPVI (Table 1). Most of the patients had variant TOF, and the majority of them were treated with RV-to-PA valve conduits. Only 4 patients (numbers 1, 7, 8, and 13 in Table 1) had a previous surgical repair using an RVOT patch. The median procedure time was 102 min from puncture to sheath removal (range 67 to 124 min), and median fluoroscopy time was 21 min (range 11 to 36 min).

After valve implantation, the RV systolic pressure dropped from 61.2 ± 14.9 mm Hg to 37.6 ± 6.7 mm Hg ($p < 0.05$). The outflow (RV-PA) pressure gradient was also reduced from 39.6 ± 15.1 mm Hg to 12.1 ± 9 mm

Table 1 Patient Demographics and Diagnoses

Patient #	Sex	Age (yrs)	Weight (kg)	Height (cm)	Body Surface Area (m^2)	Diagnosis
1	Female	15	75	160	1.6	Pulmonary atresia with VSD, repaired with RVOT patch with transannular patch
2	Female	17	61	157	1.61	Truncus arteriousus, post–re-do conduit replacement with 20-mm Hancook valved conduit
3	Male	19	49	176	1.60	Pulmonary atresia with VSD, repaired with 20-mm Hancook valved conduit
4	Male	12	34	157	1.21	TOF, post repaired with 18-mm Hancook valved conduit
5	Female	12	34	130	1.11	Pulmonary atresia with VSD, repaired with 22-mm Hancook valved conduit
6	Female	10	37	138	1.19	TOF, repaired with 22-mm Hancook valved conduit
7	Male	17	60	156	1.6	TOF, repaired with RVOT patch with pulmonary valvotomy
8	Female	11	30	133	1.05	TOF, repaired with RVOT patch with transannular patch
9	Female	13	49	148	1.40	TOF, repaired with 21-mm Hancook valved conduit
10	Male	11	40	141	1.25	D-transposition of the great arteries post-Rastelli operation with RV-PA Hancook 20-mm valved conduit
11	Male	11	36	148	1.24	Pulmonary atresia with VSD, repaired with 19-mm valved conduit
12	Female	23	30	145	1.12	TOF, repaired with Hancook 18-mm valved conduit
13	Male	15	84	166	1.92	TOF, repaired with RVOT patch with transannular patch

RVOT = right ventricular outflow tract; RV-PA = right ventricle-pulmonary artery; TOF = tetralogy of Fallot; VSD = ventricular septal defect.

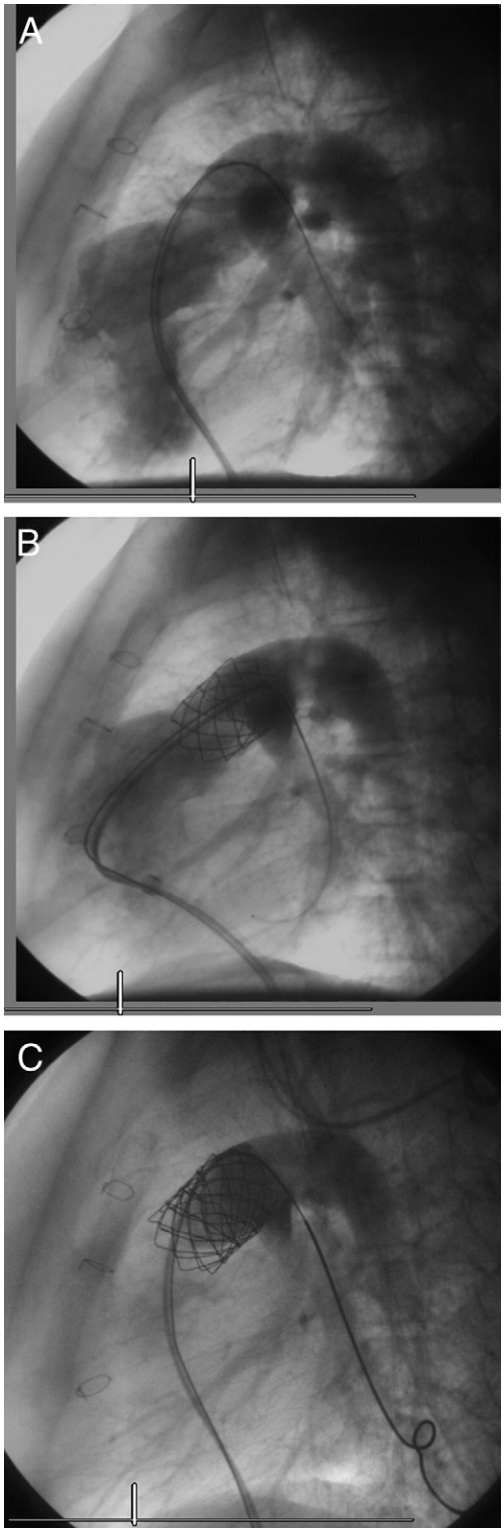

Figure 1 Lateral View of the RV Outflow Patch

(A) Lateral view of a still-frame angiogram of the right ventricular (RV) outflow patch with severe pulmonary regurgitation. **(B)** As in **A** after pre-stenting. **(C)** Same patient shown in **A** and **B** following percutaneous pulmonary valve implantation, showing a competent valve.

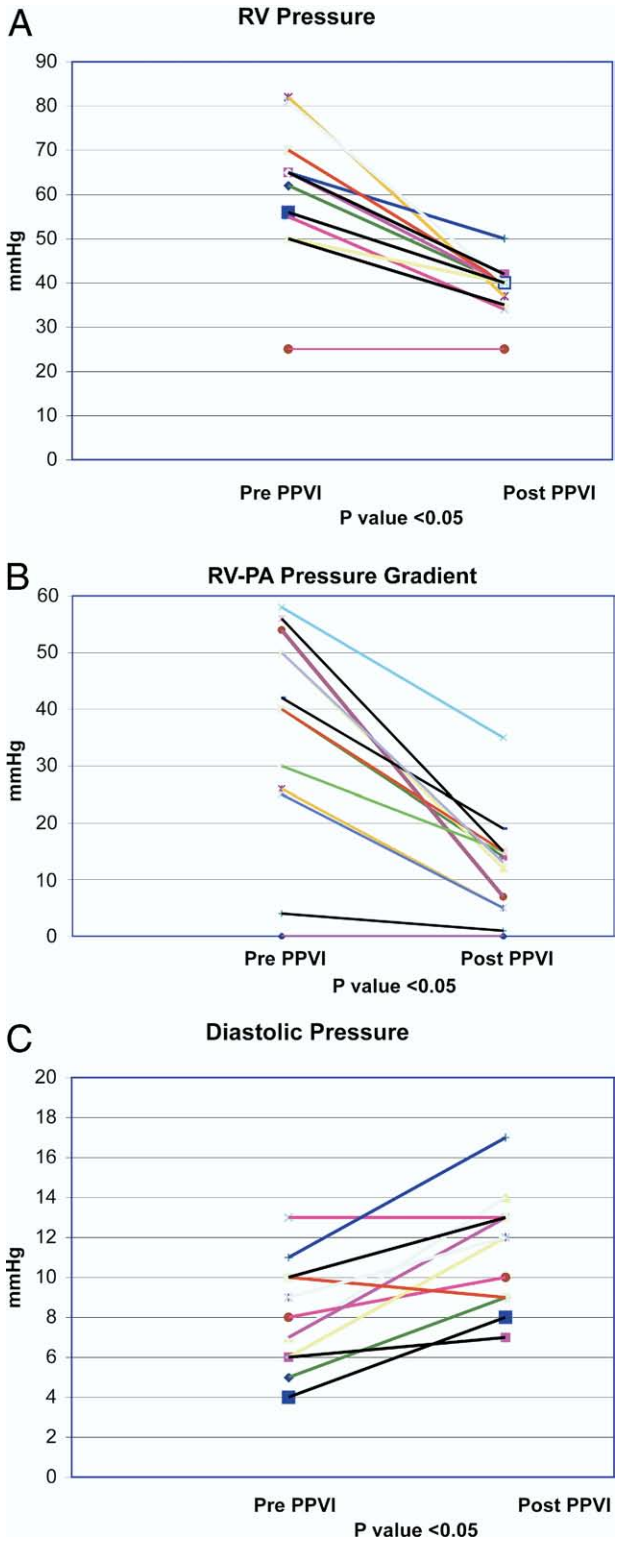

Figure 2 Changes in Ventricular Systolic Pressure, Pulmonary Valve Gradient, and PA Diastolic Pressure

Changes in **(A)** right ventricular (RV) systolic pressure, **(B)** pulmonary valve gradient, and **(C)** pulmonary artery (PA) diastolic pressure before and after percutaneous pulmonary valve implantation (PPVI).

Hg ($p < 0.05$). PA diastolic pressure increased from 8.1 ± 2.6 mm Hg to 11.5 ± 2.8 mm Hg ($p < 0.05$) (Fig. 2). Immediately after implantation, angiography showed no patient with more than mild regurgitation. Furthermore, there was a trend toward reduction in the RV end-diastolic pressure; however, this did not reach statistical significance (data not shown).

Echocardiography performed 24 h after the PPVI showed a reduction in RV systolic pressure as estimated from tricuspid valve regurgitation velocity and RVOT gradient. There was also a reduction in the PVR grade, and all patients had no or trace PVR after the procedure (Fig. 3).

All patients were discharged within 2 days after the procedure. The mean follow-up was 4 months, and all patients were alive and well. There were no immediate or late complications.

During follow-up, serial echocardiography showed that an early decrease in the RVOT gradient was sustained at the latest follow-up. Chest X-rays, posterior-anterior and lateral views, showed no stent migration or fracture.

Discussion

We have shown that PPVI can be used in patients with chronic PVR in the presence of an RVOT patch. However,

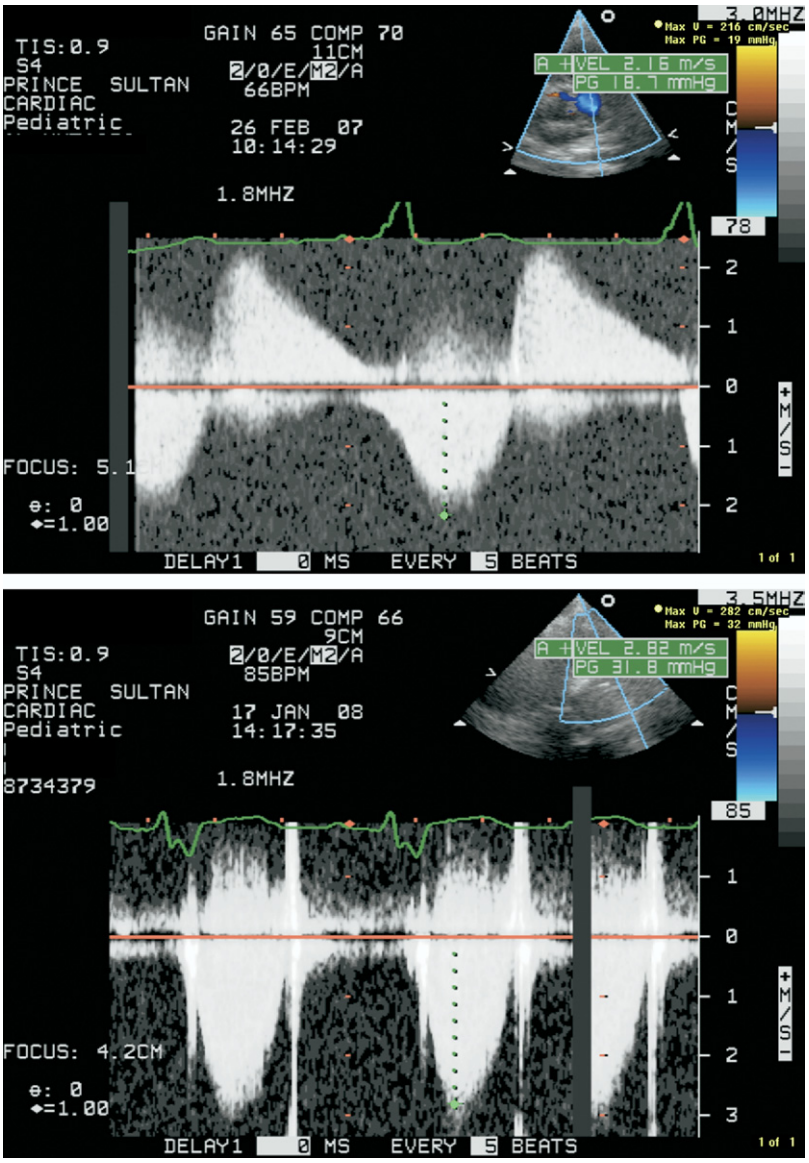

Figure 3 **Continuous-Wave Doppler Tracing of the Pulmonary Valve**

(Top) Pulmonary regurgitation before pulmonary valve implantation; **(bottom)** competent pulmonary valve following percutaneous pulmonary valve implantation.

this can only be accomplished by prior deployment of an intravascular stent as an artificial conduit that allows subsequent valve implantation.

Gibbs et al. (5) have previously described stenting of the RVOT as palliative for severe RV infundibular stenosis as an alternative to surgical ventricular outflow enlargement. We have modified this technique to allow the use of a stent as an artificial conduit to anchor the Melody valve.

This technique can be applied to patients with an RVOT dimension of <22 mm because the maximum available size of the Melody valve is 22 mm. We expect that the use of a longer stent in the RVOT will not only facilitate implanting the pulmonary valve but may also prevent stent fracture and/or migration of the newly implanted pulmonary valve.

Pre-dilation of the stenotic area is an important step for safety and effectiveness in pre-stenting an RVOT patch. Compliance of the RVOT patch is unpredictable, but balloon sizing allows for determination of the exact location of the waist. The presence of multiple waists may result in stent malposition. Furthermore, balloon sizing may predict potential coronary artery compression if performed with simultaneous coronary angiography. This potential complication has been previously described (6). Because the RVOT patch is relatively more distensible as compared to conduits, we elected to use the more compliant AGA balloon.

These preliminary results suggest that, in selected patients, pre-stenting and pulmonary valve implantation offers a less invasive alternative to re-do surgical operation in patients after TOF repair with an RVOT patch. However, further follow-up is required to study the long-term results of PPVI in this subset of patients.

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Key Words: percutaneous valve ■ pulmonary valve ■ tetralogy of Fallot ■ RVOT patch.