Structural Heart Disease

Percutaneous Tricuspid Valve Implantation
Two-Center Experience With Midterm Results

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Background—Severe tricuspid valve (TV) dysfunction may lead to surgical TV replacement with a biological valve prosthesis in patients with congenital heart disease. To expand the lifetime of this valve and reduce the number of surgeries, percutaneous TV implantation (PTVI) may be an effective alternative to repeated surgery. We report on our 2-center experience with PTVI.

Methods and Results—Between 2008 and 2014, 17 percutaneous valves were implanted in 16 patients with TV bioprosthesis dysfunction (9 females) from 2 centers. Median age and weight were 31.3 years (5–77.2) and 65.2 kg (17.7–107); 14 patients had congenital heart disease (univentricular heart with a right atrial to right ventricle bioprosthesis in 3, Ebstein’s anomaly of the TV in 5, and other in 6), and 2 had acquired TV dysfunction. All procedures were successful (Melody n=7, Sapien 26 mm valve n=4, Sapien XT 29 mm valve n=6). One valve showed early dysfunction. It was replaced surgically and shortly after that a repeated PTVI was performed. The median duration of follow-up was 2.1 years (3 days to 6.3 years). The percutaneous valve was performing well in 15 of 16 patients.

Conclusions—PTVI was safe and effectively improved TV function in all but 1 patient at midterm follow-up. We think that PTVI is a good alternative to repeated surgical TV replacements and that it may reduce the total number of open heart surgeries in these patients. (Circ Cardiovasc Interv. 2015;8:e002155. DOI: 10.1161/CIRCINTERVENTIONS.114.002155.)

Key Words: percutaneous tricuspid valve implantation ▪ tricuspid bioprosthesis dysfunction

Patients with severe tricuspid valve (TV) dysfunction may develop signs of right ventricular (RV) failure and hence require treatment. The initial treatment option is TV surgery. If surgical valveplasty is not feasible or the result of this operation is not satisfactory, TV replacement has to be performed. In most of these patients, a bioprosthesis is implanted in TV position. With elapsing time, biological valves undergo degeneration, leading to TV regurgitation and stenosis, right atrial (RA) enlargement, onset of clinical deterioration, atrial dysrythmias, and signs of right heart failure. Then, these valves need to be replaced again.

Since the advent of percutaneous valve implantation in the year 2000, many patients have been treated successfully with a percutaneously implanted valve in the aortic or pulmonic position. The failing bioprosthesis usually is an ideal landing zone for a percutaneously implanted valve, if the dimensions are well defined and valve size is adequate. To date, only a few patients have been treated with percutaneous TV implantation (PTVI), and in most of these only short-term follow-up was reported. Most bioprostheses in the TV position are nondistensible valves, and if the metallic frame of the bioprosthesis is visible, this is an excellent land mark during valve implantation.

To avoid repeated open heart surgery with its known risks and comorbidities and to reduce the total number of surgical procedures during a patient’s life, PTVI is an alternative treatment option. We report on our 2-center PTVI experience with midterm term follow-up.

Methods

A retrospective analysis was performed on all patients with severe dysfunction of a bioprosthesis in the tricuspid position who were treated with PTVI at the German Heart Centers Munich (n=9) and Berlin (n=7) between July 2008 and May 2014. A total of 16 patients (female 9) were treated with 17 percutaneous valves at a median age of 31.3 years (5–77.2 years) and a median weight of 65.2 kg (17.7–107 kg). Fourteen patients had congenital heart disease (functionally univentricular heart with a RA to RV bioprosthesis in 3, Ebstein’s anomaly in 5, and other in 5; Table 1) and 2 patients had acquired TV disease and dysfunction of a surgically implanted bioprosthesis. Most patients (9/16) were in New York Heart Association (NYHA) functional class III (Table 1).
WHAT IS KNOWN

- Surgically implanted bioprostheses in tricuspid position have a limited durability and need to be replaced.
- Frequent open heart surgeries are necessary if the first tricuspid valve was replaced in a young patient with congenital heart disease.
- Until today, the only therapy available was repeated surgical valve replacement.

WHAT THE STUDY ADDS

- Percutaneous tricuspid valve implantation is technically feasible and safe and may expand the durability of a surgically implanted biological valve.
- This may result in less open heart surgeries during a patient’s life.

The indication for PTVI corresponded to patient selection for TV surgery.4,13 The decision for treatment was made after a detailed cardiac evaluation, including patient and medical history, review of the surgical reports, clinical examination, ECG with Holter, transthoracic and transesophageal (TEE) echocardiography with Doppler interrogation of the TV, chest x-ray, and an exercise test with the assessment of peak oxygen consumption (VO2 peak). Informed consent was obtained from all patients or their guardians.

Technique of PTVI

The techniques for PTVI into a failing bioprosthesis have been described previously.16-18 Patients were catheterized under conscious sedation or general anesthesia. A TEE was performed for the assessment of valve regurgitation and the inflow gradient across the TV. Vascular access (vein and artery) was achieved in the groin. RA and RV pressures were recorded, and the mean gradient across the TV was calculated. Most bioprostheses in the TV position are nondistensible and hence an ideal landing zone for a percutaneous valve. An RV angiogram was performed to assess RV function and to confirm and grade the degree of TV regurgitation. Because accurate valve delivery requires coaxial positioning within the bioprosthesis, the x-ray system was rotated so that the imaging plane was aligned parallel to the radiopaque valve ring in the anteroposterior camera. A 0.035-inch Super Stiff guidewire (Meier Wire Boston Scientific Natick, MA; Lunderquist Wire, Cook Medical, Bloomington, IN; or Amplatz Ultra-Stiff, Cook Medical) was placed distally into 1 pulmonary artery. This position was selected in part, to provide additional safety during valve delivery because a guidewire position in the RV is less stable and may cause severe ventricular arrhythmia. In this series, a balloon larger than the expected internal diameter of the bioprosthesis was inflated within the valve to determine the exact internal valve diameter in most patients. Most patients had nondistensible bioprosthetic valves in TV position. In these patients, a balloon test to rule out coronary compression may not be necessary. We always performed a balloon test with an aortogram in patients with a distensible bioprosthetic valve diameter because only the Melody valve was available (maximal external valve diameter 24 mm). Covered stent implantation (covered Cheatham Platinum stents) reduces the internal valve diameter by 1 mm. Second, prestenenting was thought to be necessary for the creation of a safe valve landing zone. Later on, however, if the internal diameter of the bioprosthesis was at least 2 mm less than the expanded external diameter of the selected percutaneous valve, prestenenting was not performed any more to leave the internal valve diameter as large as possible, especially in nondistensible bioprostheses. Once the Sapien 26-mm and, subsequently, the Sapien 29-mm valves became available, downsizing with a covered stent was not necessary. The Melody valve was mounted in the same orientation as for percutaneous pulmonary valve implantation.19 The Sapien 26-mm and XT 29-mm valves were crimped onto the balloon in reverse orientation for aortic valve delivery to account for the antegrade delivery to the TV, which is opposite to the usual retrograde delivery for aortic valve implantation. The Sapien 26-mm valve was mounted on the Retroflex 3 catheter system, which was introduced through a 24F hydrophilic sheath into the inferior vena cava. The Sapien XT 29 mm valve was mounted on the shaft of the NovaFlex+ transfemoral system, which was introduced via the eSheath (20F). Once the system was advanced to the inferior vena cava, the valve was positioned onto the delivery balloon against the direction of the valve leaflets (off label use). Deployment was similar for all 3 types of valves (Sapien 29 XT valve; Figure A–D). The valve was advanced slowly on the stiff guidewire until it reached the desired position within the TV prosthesis. Slow balloon inflation enabled readjustment of the implanted valve to avoid delivery in an angulated position. Readjustment during valve implantation can be achieved by gentle pulling or pushing during inflation as long as the valve does not have contact with the bioprosthesis. The valve was positioned as perpendicular to the plane of the bioprosthesis as possible. Stable distal wire position in the pulmonary artery allowed fine adjustments of the valve position during delivery. Strict perpendicular positioning of the x-ray system enabled alignment of the transcatheter valve so that the proximal struts just protruded out of the bioprosthesis into the RA clearly across the rigid valve ring. Positioning too far into the bioprosthesis, distal to the rigid valve ring, may increase the risk of embolization into the RV. Pressure measurements in the RV and RA, an RV angiogram, and a TEE examination were performed after valve implantation to confirm the result of the intervention.

Postinterventional Treatment and Follow-Up

Periprocedural treatment included antibiotic prophylaxis with a second-generation cephalosporine (cefuroxime 100 mg/kg per day, divided in 3 doses or 3x1.5 g in adults). Aspirin (100 mg/d or 3–5 mg/kg) was administered for 6 months. After 6 months, a TEE, a cardiac magnetic resonance imaging, an exercise test, and a clinical examination were scheduled.

Results

Procedure

The existing bioprosthetic valve was a Carpentier-Edwards valve in 7 patients (Edwards Lifesciences Corp), a Hancock valve (Medtronic Inc) in 2, a homograft valved conduit in 2, a Medtronic Mosaic valve in 1, and a Russian biolab valve in 1; in 3 foreign patients, the bioprosthesis in the TV position was unknown (Table 2). The primary mode of TV bioprosthesis dysfunction was stenosis in 1, regurgitation in 3, and a combination of stenosis and regurgitation in the rest (Table 2). Half of the cohort had undergone at least 3 prior cardiac surgical procedures.

A balloon test for sizing of the internal TV valve diameter was done in 13 patients. According to this test, or the available manufacturer information, a Melody valve on a 22-mm delivery system was selected in 7 patients, and an Edwards Sapien 26 in 4, and an Edwards Sapien XT 29 in 6. Prestenenting was performed in 5 patients, with a bare stent only in 2 (Max LD 36 mm length, EV3 Europe, Paris, France), a covered stent only in 3 (covered Cheatham Platinum stent; NuMed Inc, Hopkinton, NY). The intervention was successfully performed in all 16 patients. One patient (patient 10) was subsequently
treated with 2 percutaneous valves. Hence, 17 valves were implanted percutaneously in 16 patients. The median fluoroscopy time was 16.1 minutes (range, 7.9–57.4 minutes), and the median hospital stay was 3 days (2–33 days).

Adverse Events

The youngest and smallest patient in this series (5 years, 17.7 kg) developed femoral vein injury during retrieval of the Melody Ensemble delivery system. A segment of the femoral vein was torn off during removal of the delivery catheter. The patient did not experience major bleeding, and an ultrasound evaluation before discharge revealed a patent femoral vein. No other periprocedural complications occurred.

One patient had a significant perivalvular leak around the surgical valve before PTVI in addition to severe bioprosthetic valve regurgitation. He was treated with a Sapien XT 29 mm valve. An Amplatzer perivalvular leak occluder was placed at a later catheterization. The perivalvular shunt was diminished but not completely abolished, and there was no residual regurgitation of the percutaneous valve.

Follow-Up

At hospital discharge, all patients had absent to mild TV regurgitation and a mean TV gradient <4 mm Hg by echocardiographic evaluation. Follow-up information was available in 12 of 16 patients; of the other 4, 1 underwent the procedure recently and 3 patients were from abroad and lost to follow-up. Median follow-up time was 2.1 years (3 days to 6.3 years). One patient (patient 10) required a reoperation because of significant regurgitation of the implanted Melody valve 22 months after initial PTVI. Surgical replacement of the TV prosthesis was complicated by aortic dissection and quadriplegia because of spinal cord ischemia, with subsequent requirement of permanent home ventilation. The explanted Melody valve showed a central coaptation deficiency and degenerated thickened valve leaflets. Histologically, there were neither signs of degeneration nor any atypical pattern of tissue arrangement in this explanted Melody valve. Within several months after valve implantation, the newly implanted 31-mm Carpentier-Edwards bioprosthesis developed severe regurgitation, and the patient was in a poor clinical condition with effusions and reduced cardiac function. Six months after the operation, a 29-mm Sapien XT valve was inserted into the failing bioprosthesis and the cardiac function improved. On TEE 18 months after re-PTVI, the Sapien valve had evidence of moderate TV regurgitation. All other patients have absent or mild tricuspid regurgitation.

The assessment of NYHA functional class was possible in 9 patients from Munich. Apart from the previously mentioned patient, all other patients presented in NYHA class I or II (Table 3). Pre- and postinterventional exercise testing was possible in 4 patients. VO₂ max improved in 2 patients and remained unchanged in the other 2 (Table 3). Pre-/post-PTVI magnetic resonance imaging derived RVEDvol indices were acquired in 5 patients. In 4 patients, an magnetic resonance imaging was not possible (pacer n = 3, anxiety n = 1). RV volume indices decreased in 2 patients, remained unchanged in 2, and increased in 1 patient (Table 3). Stent fractures without clinical significance was diagnosed in 1 patient (patient 8), 6.3 years after Melody valve implantation (the early results of this patient were published as a case report⁸). Patients 1, 2, 7, 8, 9, and 10 were part of a previously published case series. Follow-up was updated in these patients.

Discussion

This series of patients, most with underlying congenital heart disease, shows that PTVI is technically feasible, safe, and effective in selected patients with dysfunction of surgical bioprostheses in TV position, using both Melody and
Sapien transcatheter valves. Overall, the population was at high risk for repeated surgery, with most in NYHA class III, and ≥3 prior cardiac operations in half. The intervention was straightforward and successful in all patients, and all but 2 (who had other problems) showed an improvement in their functional status. There were no major periprocedural complications.

PTVI durability cannot be assessed adequately from this study, but to date only 1 valve (Melody valve) has been exchanged, 1.5 years after PTVI for recurrent severe TV regurgitation. Histologically, the explanted Melody valve did not show any signs of valve infection or thrombosis, but the valve leaflets were thickened, with a central coaptation defect causing the valve regurgitation. The findings of this patient were published in a recent report by Benthem et al.19 Notably, this patient subsequently developed early regurgitation of the newly replaced surgical prosthesis and moderate regurgitation of a Sapien XT valve implanted within the bioprosthesis, suggesting that there was something about this patient’s physiology/anatomy that predisposed to TV prosthetic valve dysfunction. The reason for this recurrent dysfunction of various biological valves (ie, Mosaic, Melody, Perimount, and Sapien XT 29) implanted surgically and with different transcatheter methods remains speculative. Severe RV dysfunction was present, which leads to slow almost continuous blood flow through the TV, such that the valve did not open and close in the normal phasic fashion, and proper valve leaflet function was not achievable. This is similar to the physiological conditions after a Fontan procedure in which the initially suggested implantation of homograft valves proved to be unsuccessful.20 Another possible mechanism for this early recurrent valve dysfunction is an enhanced immunologic reaction.

The only other procedural complication was femoral vein injury in our smallest patient (17.7 kg) after Melody valve implantation, which did not result in serious clinical sequelae.

### Technical Considerations
To date, only 2 larger case series of PTVI have been reported.10,14 In both, the Melody valve was used exclusively. In the current series, a nondistensible valve prosthesis was present in 14 patients and a potentially distensible valve (valved homograft conduit) in 2. All valves were implanted via the femoral veins; however, successful valve delivery via a venous neck vessel has been described as well.21,22 Seven patients were treated with a Melody valve, 5 with a Sapien XT 29 mm valve, and 4 with a Sapien 26 mm valve. Initially, only the Melody valve was available for treatment. Crimped on a 22-mm delivery system and fully inflated, the external diameter of the Melody valve is 24.06 mm,23 which limits its use in larger diameter valves. The more recent availability of the Sapien 26 mm24 and XT 29 mm valves enables PTVI treatment of internal valve diameters ≤28 mm. In this series, a balloon waist of 25 to 27 mm was our general criterion for choosing a Sapien XT 29 mm valve. Pretenting of the bioprosthesis, which reduces the internal valve diameter and thus may contribute to a smaller orifice area that may be detrimental in the long-term, was performed in 5 patients early in our experience, with the primary aim of reducing the internal valve diameter using a covered stent or protecting the Melody valve stent against fracture with a bare stent. In our more recent experience, pretenting was no longer performed. However, balloon sizing was used to assess the internal bioprosthetic valve diameter for proper selection of a percutaneous valve. If the type of TV bioprosthesis is known beforehand, a balloon test may not be necessary to determine the actual inner diameter of the prosthesis.
although it may be beneficial for fully treating stenosis of the bioprosthetic valve.25

Follow-Up
Up to 6.3 years of follow-up information was available in 12 of the 16 patients. Eight patients were in NYHA class I or II. TV regurgitation was absent or mild in all but 1 patient, and there was no evidence of TV stenosis in any of the patients. In the pulmonic position, the Melody valve has demonstrated excellent competence.18,26 Currently, there is only short-term information available on the performance of the 23-mm and 26-mm Sapien valves in the pulmonic position,27,28 and there are no data on the Sapien XT 29-mm valve in the right side of the heart. The preliminary findings in this series suggest that

Table 3. Follow-Up Data

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<th>Case No.</th>
<th>Follow-Up</th>
<th>TV Regurg. by Echo</th>
<th>NYHA Class</th>
<th>VO2pre, mO2/min/kg</th>
<th>VO2post, mO2/min/kg</th>
<th>RVEDvolpre, ml/m²</th>
<th>RVEDvolpost, ml/m²</th>
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<td>III</td>
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<td>...</td>
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<tr>
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<td>17.0</td>
<td>Not done</td>
<td>MRI not possible ddd-pm</td>
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ddd-pm indicates pace maker in DDD-mode; ICD, defibrillator; regurg., regurgitation; MRI, magnetic resonance imaging; NYHA, New York Heart Association; RVEDvol, right ventricular end-diastolic volume in MRI; TV, tricuspid valve; TTE, transthoracic echocardiography; and VO2 max, maximal oxygen uptake.

Figure. A–D (Patient 13; Ebstein’s anomaly with Carpentier-Edwards Perimount 31-mm prosthesis) A, Angiography into the right ventricle (p.a.) depicts severe tricuspid regurgitation. B, Balloon test with a 60 mm × 30 mm VACS II balloon (Dr. Osypka GmbH, Rheinfelden, Germany). Balloon waist at 25 to 27 mm. C, Implantation of a Sapien 29 XT directly into the bioprosthesis, p.a. view. The 2 plane x-ray system was rotated such that the p.a. plane shows the valve strictly from the side. The p.a. plane is used for valve delivery. Slow balloon inflated allows perfect positioning into the bioprosthesis. The proximal struts of the Sapien valve just protrude into the RA. D, Angiogram into the RV after PTVI shows no residual regurgitation. This was confirmed by transthoracic and transesophageal echocardiography. PTVI indicates percutaneous tricuspid valve implantation; RA, right atrium; and RV, right ventricle.
the Sapien valves perform similar to the Melody valve in this application, at least in the short- and intermediate-term.

Limitations of the Study
A retrospective 2-center analysis of a new treatment mode exhibits inherent limitations. Follow-up was not available for all foreign patients; hence, clinical follow-up was documented in only 11 of 16 patients, and the mean follow-up time of 2.1 years was rather short. During the 6-year enrollment period, new percutaneous valves were available and thinking about how to perform the intervention evolved as experience grew.

Conclusions
In this preliminary experience, PTVI was safe and it effectively improved hemodynamics and functional status in patients with a failing bioprosthesis in the tricuspid position, both acutely and in the short-term to midterm. Hence, in our series, PTVI was an effective means to expand the life span of a surgically implanted bioprosthesis in the tricuspid position. However, these results have to be veriﬁed in larger series with extended follow-up.

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Disclosures
Dr Berger serves as consultant to Medtronic and Edwards Lifesciences and is proctor for St. Jude Medical, the Melody valve implantation in “tricuspid position” after a Fontan Björk Roberts P
danous D, Nadeem SN, Mason X, Colman JM, Benson LN, Horlick ang HY, Kim KH, Kim KB, Ahn H. Propensity score matching analy-

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3. Hwang HY, Kim KH, Kim KB, Ahn H. Propensity score matching analy-

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/content/8/5/e000013.full.pdf

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On page 1, in the affiliations footnote, “Klinik für Herz-und Gefäschirurgie (S.S., F.B.), Deutsches Herzzentrum München, Technische Universität München, Munich, Germany; Klinik für Kinderkardiologie und angeborene Herzfehler, Deutsches Herzzentrum Berlin, Berlin, Germany (J. Hörer),” has been changed to read, “Klinik für Herz-und Gefäschirurgie (J. Hörer), Deutsches Herzzentrum München, Munich, Germany; Klinik für Kinderkardiologie und angeborene Herzfehler, Deutsches Herzzentrum Berlin, Berlin, Germany (S.S., F.B.).”

The authors regret the error.

This correction has been made to the online version of the article, which is available at http://circinterventions.ahajournals.org/content/8/4/e002155.