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Long-term follow-up after trans-catheter tricuspid valve-in-valve replacement with balloon–expandable aortic valves

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ABSTRACT

Background: Transcatheter tricuspid VIV replacement has been proposed as a feasible option for high-risk patients with previous tricuspid valve replacement that undergo valve degeneration causing refractory heart failure. However, little is known about the long-term outcome of patients treated with transcatheter tricuspid VIV. We evaluate the safety of transcatheter tricuspid valve-in-valve (VIV) replacement by using balloon–expandable aortic valve stents and the long-term follow-up.

Methods and results: From January 2013 to March 2016, 4 patients underwent transcatheter tricuspid VIV in our center using balloon-expandable Edwards Sapien-XT and Sapien-3 valves. In all cases the procedure succeeded with significant improvement of the tricuspid valve area (from 0.98 ± 0.29 cm^2 to 3.1 ± 0.45 cm^2, $p = 0.005$), right atrial pressure (from 21 ± 7.78 mmHg to 8.5 ± 2.51 mmHg, $p = 0.025$) and mean trans-valvular gradient (from 11.5 ± 4 mmHg to 3.32 ± 1.28 mmHg, $p = 0.02$).

Three out of 4 patients presented a follow up longer than 2.5 years. At median follow up of 32 months (range 9–47 months) all patients were alive and presented with NYHA class I-II. Only one patient, who presented impaired right ventricular function at baseline, experienced re-hospitalization during the follow-up time. Echocardiographic assessment at long-term disclosed a well-maintained hemodynamic performance with low trans-valvular gradients and no significant valvular regurgitation in all cases.

Conclusions: In our experience, trans-catheter tricuspid VIV demonstrated good long-term results in terms of valve performance and functional class improvement at 32 months from intervention.

1. Introduction

Patients treated for tricuspid valve disease usually present multi-valvular involvement from rheumatic disease, endocarditis or congenital heart disease. Surgical tricuspid valve replacement (TVR) is the main indication for the treatment of severe tricuspid regurgitation (TR), tricuspid stenosis (TS) or mixed steno-insufficiency. However, the reported TVR longevity is often limited and around 40% of TVR patients need re-intervention within 5 to 15 years from surgery [1,2].

Tricuspid valve dysfunction, and especially severe TR, is associated with increased mortality [3] independently from other established prognostic indexes such as left ventricle ejection fraction or pulmonary hypertension [4]. Nevertheless, repeated TVR are associated with increased risk of mortality and poor clinical outcome [5].

Recently, percutaneous tricuspid valve-in-valve (VIV) replacement has been demonstrated to be a feasible treatment for high-risk patients with previous TVR that undergo valve degeneration and develop refractory heart failure [6]. However, at present only few data on mid-and-long-term follow-up after trans-catheter tricuspid VIV replacement is available [7].

The purpose of this analysis is to report clinical and echocardiographic long-term follow-up of patients treated with trans-femoral tricuspid VIV in our center, not included in the recent publication of the International Tricuspid VIV Registry [7].

2. Methods

Procedural and clinical in-hospital outcome data was collected from our institutional registry. Long-term follow-up was assessed with transthoracic echocardiography and outpatient clinic visits as part of our standard care program.

All the procedures were performed using Edwards Sapient-XT valves (Edwards Lifesciences Inc., Irvine, CA, USA), except for the last case that received an Edwards Sapien-3 (S3) aortic valve.

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2.1. Hemodynamic assessment

The invasive hemodynamic assessment was repeated before and after the tricuspid VIV replacement. Right heart catheterization was performed using a balloon-tipped Swan–Ganz catheter (Edwards Lifesciences, Irvine, California), which was inserted from the femoral vein. Pressures were recorded at end-expiration. The following hemodynamic variables were collected: systolic pulmonary arterial pressure (sPAP); diastolic pulmonary arterial pressure (dPAP); mPAP, calculated by (sPAP + 2 × dPAP)/3; right atrial pressure (RAP); pulmonary artery wedge pressure (PAWP); and pulmonary arterial pulse pressure (PP), calculated as PP = sPAP − dPAP. Cardiac output (CO) was determined using the Fick oxygen method in all the patients, since the thermodilution method might underestimate or overestimate the CO in presence of relevant TR [8–11]. Pulmonary vascular resistance (PVR) was calculated as: (mPAP-PAWP)/CO. Pulmonary arterial compliance (PAC) was calculated as the ratio between SV and PP.

2.2. Echocardiographic assessment

All the patients underwent comprehensive echocardiographic assessment, including 2-dimensional, pulsed-wave, continuous-wave (CW) and color-Doppler imaging. Echocardiographic examinations were performed by expert operators with commercially available ultrasound system (Philips HD7 or CX50, Philips Medical System, Andover, MA). The evaluation of the severity of the TR was based on a multiparametric approach.

The assessment of TR severity was made using with color-Doppler imaging, analyzing the color-flow TR jet. The jet density was then assessed with CW-Doppler. In presence of eccentric TR jet, given the difficulty to obtain adequate CW-Doppler signal, semi-quantitative parameters were applied. A vena contracta width > 7 mm and a proximal isovelocity surface area (PISA) radius > 9 mm were considered indicative of severe TR.

For TS, pressure gradient was measured with CW-Doppler aligned with flow. To minimize the respiratory variations of RV inflow, measurements were taken in end-expiratory apnea.

2.3. Tricuspid valve-in-valve procedure

The tricuspid VIV implantations were performed under general anesthesia for transesophageal echocardiographic guidance in the first two cases, while a mild conscious sedation without TEE was used for the others. In all cases the common femoral vein was percutaneously cannulated and prepared with 18 Fr dilators. The Edwards introducer has been then advanced over an extra-stiff guide-wire (Amplatz extra-stiff, Cook Medical, Bloomington, IN). After crossing the tricuspid valve, the extra-stiff guide-wire was advanced into one of the right pulmonary artery branches as distally as possible for optimal support. After reverse mounting on the Edwards NovaFlex system for adapting to the tricuspid position, the Edwards Sapien-XT or S3 prosthesis was advanced into the inferior vena cava and aligned with the balloon. The balloon expandable device (Sapien-XT or S3, Edwards LifeSciences, Irivine, CA) was then advanced across the degenerated tricuspid bioprosthesis, using fluoroscopy in a 40° right anterior oblique incidence that clearly disclosed the radiographic markers of the prosthetic valve as reference points (Fig. 1). The height of the 29 mm Sapien-XT valve is 19 mm when fully expanded, 3 mm less than its crimped height. Considering the 20 mm height of the 31 mm Perimount Magna bioprosthesis, with a very slow inflation, the 29 mm Sapien-XT valves fitted nicely within the surgical valves (Fig. 1). The Edwards Sapien-3 valve used in the 4th case, has a larger foreshortening, (crimped and expanded heights 31 and 22.5 mm respectively) this mainly occurring at the atrial side (i.e. the side of the outer sealing skirt) of the valve; therefore, the valve was slowly inflated starting with a "head to head" alignment at the ventricular edge. The 18 mm height Edwards Perimount 27 mm valve permitted an adequate (4 mm) protrusion of the stented valve in the right atrium after full deployment. Indeed, positioning the central marker closer to the atrial side of the surgical bioprosthesis is advised in order to compensate for the device foreshortening [12].

All the prostheses were inflated at nominal volume without need for previous balloon valvuoplasty, or rapid ventricular pacing.

Following deployment, the valve delivery system was removed and valve function was evaluated by transesophageal and/or transthoracic echocardiography.

2.4. Statistics

Continuous data are reported as mean ± standard deviation, whereas categorical variables are reported as frequencies (percentages). To assess variations in hemodynamic and echocardiographic data before and after the procedure a paired *t*-test has been performed. A *p*-value < 0.05 was considered statistical significant. All statistical analyses were performed using SPSS 20.0 (SPSS Inc. Chicago, IL).

3. Results

From January 2013 to March 2016 four patients underwent transfemoral tricuspid VIV replacement at our institution. This represents the 2.8% of the total trans-catheter valve population treated during the same period.

3.1. Patient 1

The first patient has been previously reported as the first case performed by the trans-femoral route [13]. Briefly, He was a 60-year old man previously treated with TVR with 31 mm Edwards Perimount Magna valve in 2001 for severe steno-insufficiency secondary to rheumatic valvular disease. He had undergone also surgical aortic and mitral valve replacement with mechanic valves in 1995. He presented with multiple and severe comorbidities such as chronic obstructive pulmonary disease, atrial fibrillation, peripheral vascular disease, previous major strokes and patent foramen ovale. The severe tricuspid steno-insufficiency of the degenerated bioprosthesis had caused severe right heart congestion including hemodynamic liver and kidney insufficiency and massive ascites. He underwent trans-catheter tricuspid VIV with 29 mm Edward Sapien-XT in January 2013. The hemodynamic improvement was impressive, with >10 kg of weight loss during the week after the procedure and before discharge due to the reduction of edema.

3.2. Patient 2

The second patient was a 66-years old woman with a long history of rheumatic heart disease with multi-valvular involvement causing severe aortic steno-insufficiency, mitral stenosis and tricuspid steno-insufficiency. She was treated in 1982 with aortic (27 mm Carbomedics Sorin Biomedica, Saluggia, Italy) and mitral (23 mm Lillehei-kaster, Inner Grove Heights, MN, US) mechanic valves and tricuspid (31 mm Perimount Magna Edwards Lifesciences, Irvine, CA, US) bioprosthesis. She underwent tricuspid balloon valvuloplasty for severe prosthesis stenosis in 1997 and in 2010 with clinical improvements. In January 2014, when tricuspid VIV became an option, she underwent trans-femoral tricuspid VIV implantation with 29 mm Edward Sapien-XT valve for severe prosthesis degeneration presenting with re-stenosis causing severe right heart congestion and systemic hypo-perfusion.

3.3. Patient 3

The third patient was a 54-year old woman treated in 2006 with mitral (mechanic) and tricuspid bioprosthesis replacement for severe bivalvular steno-insufficiency secondary to rheumatic disease with 27 mm Carbomedics Sorin and 31 mm Carpenter Edwards valves respectively. After surgery, she developed advanced A-V block, and a permanent pacemaker was implanted with a catheter lead through the valve into the right ventricle. The patient presented with advances signs and symptoms of right heart insufficiency due to severe tricuspid prosthesis stenosis and mid-grade insufficiency 7 years after surgery. She underwent percutaneous tricuspid VIV implantation in June 2014 with a 29 mm Edwards Sapient-XT prosthesis.

3.4. Patient 4

The fourth case was a 40-year old man with an history of drug abuse and of multiple episodes of tricuspid endocarditis previously treated with surgical implantation of 27 mm Edwards Perimount in 2009. He presented with massive tricuspid regurgitation from bioprosthesis degeneration and underwent tricuspid VIV with implantation of a 29 mm Edwards Sapien-3 in March 2016.

Mean age and weight at baseline were 60.3 (54.3–66.6) years and 70 (54–89) kg. Time from surgical valve implantation to the VIV procedure ranged between 32 and 6 years. Procedure succeeded in all patients, with no intra-operatory or in-hospital complications. All patients were discharged on oral anti-coagulation (OAC). The first 3 patients had chronic atrial fibrillation, the last was on sinus rhythm. Hemodynamic and echocardiographic data at baseline, at hospital discharge and at long-term follow-up are shown in Table 1.

Acute angiographic and echocardiographic results were assessed to verify the position and functioning of the valve. Patient 1 had a patent