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Transfemoral Implantation of Transcatheter Heart Valves After Deterioration of Mitral Bioprosthesis or Previous Ring Annuloplasty

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ABSTRACT

OBJECTIVES This study sought to evaluate the feasibility of transfemoral transcatheter heart valve (THV) implantation in failed mitral bioprostheses and ring annuloplasties.

BACKGROUND Redo mitral surgery may be high risk or contraindicated due to comorbidity. THV implantation has been recently reported in this setting.

METHODS Transfemoral implantation of Edwards Sapien prosthesis was performed in 17 patients for degenerated mitral bioprosthesis or previous ring annuloplasty (6 bioprostheses, 11 ring annuloplasties). The procedure was elective for 14 patients and attempted as a rescue in 3 patients. Mean age was 61 ± 24 years. All patients were in New York Heart Association class ≥III, and the surgical risk was high (EuroSCORE [European System for Cardiac Operative Risk Evaluation]: 37 ± 29%, Society of Thoracic Surgeons score: 18 ± 22%).

RESULTS Procedure was successful in 14 patients (82%). Two complications occurred during rescue procedures: 1 procedural death and 1 THV migration. One patient had moderate paraprosthetic regurgitation following the procedure, whereas residual regurgitation was trace or less in 11 patients (69%) and mild in 4 patients (25%). Mean gradient decreased from 12 ± 6 mm Hg to 8 ± 3 mm Hg. During a mean follow-up of 22 months, 4 patients died, 3 from cardiac cause. The 18-month survival was 68 ± 14% in the overall population and 78 ± 14% for patients with elective procedure. One patient underwent mitral valve replacement due to periprosthetic mitral regurgitation. At last follow-up, 12 patients were in New York Heart Association class ≤II (75%) and 4 in class III (25%).

CONCLUSIONS This single-center series suggests that transfemoral THV implantation for deterioration of mitral bioprosthesis or surgical repair is feasible in selected patients and improves early hemodynamic and midterm functional status. (J Am Coll Cardiol Intv 2015;8:83–91) © 2015 by the American College of Cardiology Foundation.

Despite the major progress achieved over the past few decades, a significant proportion of patients who undergo mitral valve surgery require reoperation during follow-up. During the 10 years following mitral valve replacement or repair, reoperation is needed in 20% to 35% of patients (1). Whereas redo surgery is the treatment of choice after bioprosthesis (BP) or ring annuloplasty (RA) failure, it may be associated with significant early mortality (5% to 12%),

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ABBREVIATIONS AND ACRONYMS

BP = bioprosthesis

CT = computed tomography

MVIVI = mitral valve-in-valve implantation

NYHA = New York Heart Association

RA = ring annuloplasty

TEE = transesophageal echocardiography

THV = transcatheter heart valve

especially in patients with concurrent comorbidities (2,3).

Following the first description of transcatheter heart valve (THV) implantation for native aortic valve stenosis (4), treatment of failed aortic BP with THV implantation has emerged as a promising alternative to redo surgery in high-risk patients (5,6). Recently, THV implantation has also been reported for treatment of failed mitral BP or RA, mainly through the transapical approach (7–15).

We sought to evaluate the immediate and midterm results of transfemoral implantation of balloon-expandable Sapien XT valves (Edwards Lifesciences, Irvine, California) for failed mitral surgical valves in highly selected patients.

METHODS

POPULATION. The population consisted of symptomatic patients who underwent transfemoral implantation of a THV in mitral position for failing BP or RA at our institution from March 2, 2011 to August 16, 2013. No transapical approaches were performed during the same period. The decision to perform the intervention was based on a consensual agreement between the members of the heart team in patients considered at high risk for redo surgery. Informed consent for the procedure was obtained from all patients.

PROCEDURE. Prosthesis/annulus measurements. The choice of the THV size was based on an integrative approach taking into account manufacturer's inner diameters, and also the mean diameter determined from the long and short diameter measurements as assessed by computed tomography (CT), 3-dimensional transesophageal echocardiography (TEE), and fluoroscopy.

THV implantation procedures. The technique for THV implantation in mitral position through a transfemoral approach has been described previously (8,16,17). All procedures were performed under general anesthesia and TEE guidance, with the exception of 1, which was done under local anesthesia and fluoroscopic guidance due to impossible tracheal intubation. Bilateral femoral venous access was used. A temporary pacemaker lead was placed in the right ventricle as used during transcatheter aortic valve implantation. Transseptal puncture was performed under TEE guidance in a "high "and "posterior" position similar to that used during MitraClip (Abbott Vascular, Santa Clara, California) implantation. After placing a Mullins sheath (Medtronic, Minneapolis, Minnesota) in the left atrium, a bolus of heparin (70 IU/kg) was administered with the aim of achieving an activated clotting time between 250 and 300 s. Then the mitral valve was crossed with a Judkins right 5-F catheter advanced on a standard 0.035-inch guidewire or a 7-F balloon wedge pressure catheter (Arrow International, Reading, Pennsylvania). Then, a 0.035-inch Amplatz Super Stiff or Lunderquist guidewire (Cook Medical, Bloomington, Indiana) with a "J" curve at the end was placed in the apex of the left ventricle (**Figure 1A**). The atrial septum was dilated using 12- to 14-mm peripheral balloons. Although pre-dilation should generally be avoided, it was performed in 3 cases due to anticipated difficulties in crossing highly stenotic bioprostheses. In addition, 1 procedure was performed immediately after failed balloon valvuloplasty in a case of restenosis after open-heart commissurotomy with annuloplasty. Then the Sapien XT valve, mounted for antegrade implantation (similar to the position in transapical aortic valve procedures) on a NovaFlex catheter (Edwards Lifesciences), was advanced through the atrial septum. The THV was orientated toward the mitral valve and positioned using maximal flexion of the NovaFlex catheter. Implantation was performed by slow balloon inflation under rapid ventricular pacing (160 to 200 beats/min) (**Figure 1B**). Post-dilation was performed in 3 cases of moderate paravalvular regurgitation. The final result of implantation was assessed by echocardiography and fluoroscopy in the catheterization lab (**Figures 1C and 1D**) and CT before discharge (**Figures 1E and 1F**). Contrast medium was not used during mitral implantation, except in 1 case for positioning of a cerebral protection device (Embrella, Edwards Lifesciences) during mitral valve-in-valve implantation (MVIVI) within a severely calcified and stenotic BP.

The femoral veins were closed by manual compression or suture.

DEFINITIONS. Complications were reported according to the VARC-2 (Valve Academic Research Consortium Procedural) criteria (18). Device success was defined as the absence of procedural mortality, the correct positioning of a single THV, and the absence of residual moderate or severe prosthetic regurgitation. Prosthetic function was assessed before discharge according to current guidelines, using the integration of qualitative and quantitative parameters obtained by echocardiography and adapted to prostheses in mitral position (18–20). THV regurgitation was graded as absent, trace, mild, moderate, or severe.

FOLLOW-UP. Clinical evaluation and echocardiography (transthoracic and transesophageal) were