Use of transcatheter heart valves for a valve-in-valve implantation in patients with degenerated aortic bioprosthesis: Technical considerations and results

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Objective: Transcatheter aortic valve implantation has been used to treat high-risk patients with bioprosthetic valve degeneration (valve-in-valve). We report our experience with transcatheter aortic valve implantation in the treatment of degenerated biologic aortic valve prostheses and discuss factors that can influence the outcome.

Methods: From February 2009 to October 2011, 278 patients underwent transcatheter aortic valve implantation, of whom 23 underwent a valve-in-valve procedure with the Edwards Sapien valve to treat a failing bioprostheses in the aortic position. Eight of these valves were stentless bioprostheses. Thirteen patients had valve failure resulting predominantly from stenosis, and the remaining resulting from regurgitation.

Results: Mean age was 76.9 ± 14.4 years. The mean logistic EuroSCORE was 31.8% ± 20.3% and the Society of Thoracic Surgeons score was 7.6% ± 5.4%. All patients were New York Heart Association class III or IV. The majority of the operations (21/23) were performed via the transapical route. Procedural success was 100%, although 1 patient with a degenerated homograft needed immediate placement of a second valve because of low placement of the first. The reduction in the mean gradient was 31.2 ± 17.06 mm Hg to 9.13 ± 4.9 mm Hg. In those patients with predominant aortic regurgitation (9/23), reduction in aortic regurgitation was achieved in all. The median length of stay was 11.7 days (range, 3-44 days). In-hospital and/or 30-day mortality was 0%.

Conclusions: Valve-in-valve is a safe and feasible alternative to treat high-risk patients with failing aortic bioprostheses. The early results are excellent, with improvement seen in hemodynamics. (J Thorac Cardiovasc Surg 2012;144:1372-80)

Transcatheter aortic valve implantation (TAVI) has emerged as a viable treatment modality for patients with severe native aortic valve stenosis and multiple comorbidities that would typically preclude them from surgery.[1-3] The ''on-label'' indication for TAVI using the Edwards Sapien device (Edwards Lifesciences, Irvine, Calif) is native calcific aortic stenosis in a tricuspid aortic valve in absence of any other prosthesis in the heart.[2,3] Novel applications of TAVI, such as use in aortic stenosis in a bicuspid valve,[4] TAVI in the presence of mitral prosthesis,[5] and valve-in-valve (VIV),[6-16] have gathered momentum as a result of clinical need. Although small in number when compared with the number of TAVI implants, the number of VIV procedures has increased rapidly in 2011. In addition to the case reports, a few case series from single institutions and collaborative series' from multiple institutions have demonstrated feasibility and acceptable early results in selected patients.[6-16] The majority of the experience in VIV has been in the treatment of failing stented bioprosthetic aortic valves and, to date, there are only isolated reports of the use of TAVI in the setting of a failing stentless bioprostheses.[9,10,13]

The concept and initial results have been encouraging. VIV procedures are currently undertaken if the conventional redo operation is deemed high risk. We present our VIV experience in 23 consecutive patients using the Edwards transcatheter valve (Sapien and Sapien XT). We also discuss the technical considerations and current limitations of the VIV procedure.

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METHODS

Patient Characteristics

Between February 2009 and October 2011 we performed 23 VIV TAVI procedures for aortic bioprosthetic degeneration using the Edwards Sapien and Sapien XT valve. Mean patient age was 76.9 ± 14.4 years (range, 29-92 years). The male-to-female ratio was 1.3:1. The mode of presentation was either severe aortic valve regurgitation (n = 9) or stenosis (n = 14). The mean logistic EuroSCORE (LES) was 31.8% ± 20.3% and the mean Society of Thoracic Surgeons score was 7.6% ± 5.4%. Patients were discussed in a multidisciplinary team meeting (MDT) comprised of 2 cardiac surgeons, 2 intervention cardiologists, 1 noninvasive cardiologist, and 1

Abbreviations and Acronyms
BAV = balloon aortic valvuloplasty
CT = computed tomographic
LES = logistics Euroscore
MDT = multidisciplinary team meeting
TA = transapical
TAVI = transcatheter aortic valve implantation
TEE = transesophageal echocardiogram
TF = transfemoral
VIV = valve-in-valve

cardiac anesthetist. Patients were also discussed with a respiratory physician and a geriatrician when indicated. These patients were thought to be at high risk for conventional open aortic valve replacement and hence were accepted for TAVI. Patients' baseline characteristics are listed in Table 1. Of these 23 patients, 15 patients had a stented bioprosthesis and 8 patients had a stentless aortic bioprosthesis. The mean length of time from the previous aortic valve procedure for stented valves and stentless valves was 9.4 ± 3.86 years (range, 4-19 years) and 14 ± 6.21 years, respectively. Details of various degenerated bioprostheses are listed in Table 2.

Preoperative Investigations

Three patients had undergone at least 3 open surgical procedures. Other than routine investigations, the preoperative diagnostic workup included a transthoracic echocardiogram, coronary and peripheral angiography, a noncontrast computed tomographic (CT) scan of the aorta, a respiratory function test, and a carotid Doppler examination. In addition, a preoperative transesophageal echocardiogram (TEE) was carried out in all patients with a stentless aortic bioprosthesis to determine the exact aortic annular diameter. Infective endocarditis was ruled out in all patients, which is especially important when the mode of valve failure is regurgitation. Prior operative notes were consulted when available to obtain details of the type of valve implanted, the valve size, and the surgical technique used.

Operative Technique

The procedures were all performed in a cardiac catheterization laboratory by a combined team of cardiac surgeons, cardiologists, and anesthesiologists. A perfusionist was also always present with an assembled heart–lung machine. The approach for TAVI was either transfemoral (TF) or transapical (TA). The choice of the approach was dependent on the type of bioprosthesis in situ and the size of the femoral arteries. We preferred the TA approach in all cases of stented bioprostheses and when the size of the femoral arteries was not suitable for TF access in cases of stentless bioprostheses. The techniques for both approaches have been described in detail elsewhere.[17,18] For the TA approach, Ascendra 1 and Ascendra 2 delivery systems were used with Sapien and Sapien XT valves, respectively. For the TF approach, the Novoflex delivery system was used with the Sapien XT valve. All procedures were performed under fluoroscopic and TEE guidance.

In the case of stented bioprostheses, the size of the Sapien or Sapien XT valve to be implanted was determined according to the internal diameter of the degenerated prosthesis provided by the manufacturer. Valve design and fluoroscopic appearance of the degenerated bioprosthesis were studied for correct and secure placement of the Sapien valve. We have published elsewhere[19] the guidance on the design, fluoroscopic appearance, and dimensions of all bioprosthetic valves as well as the ideal position of a TAVI device during the VIV procedure. A size 23-mm Sapien valve was used if the internal diameter of the valve stent was <22 mm, a 26-mm prosthesis was used for an internal diameter of 23 to 25 mm, and a 29-mm prosthesis was used for an internal diameter of 26 to 28 mm.

In case of a stentless bioprosthesis, the size of the new valve to be implanted was determined according to the internal diameter of the aortic annulus as in a native aortic valve measured by preoperative chest CT scan and intraoperative TEE. Internal dimensions available from the valve literature and operative records in cases of homografts were consulted. The final decision, however, was based predominantly on the intraoperative TEE.

Simultaneous fluoroscopic, angiographic, and TEE imaging were used routinely to guide the precise level for valve deployment. Balloon aortic valvuloplasty (BAV) of the degenerated valve prior to insertion of the prosthesis was not undertaken. Also, slow and gradual implantation was performed during a short phase of ventricular rapid pacing (Figure 1).

It can be difficult to visualize the level of the annulus in stentless valves because they are not as calcified as native aortic valves, the mode of presentation is most likely to be regurgitation, and, unlike stented valves, they have no radiologic markers.[9,10] We have used 2 procedural modifications to achieve correct implantation in these cases, which are discussed subsequently.

Postimplant Assessment

Aortography and TEE assessment were used to determine the correct placement and function of the Sapien valve and patency of the coronary arteries. TEE assessment was used to identify and grade paravalvular leak (mild, moderate, and severe).

Discharge and Follow-up

Patients were monitored closely postoperatively per the requirements of our onsite registry, which includes patient interviews, clinical examination, and follow-up echocardiography. All patients were discharged on dual antiplatelet therapy for the first 3 months and a single agent thereafter unless contraindicated clinically.

Statistical Analyses

Continuous variables are described as mean ± standard deviation; dichotomous or nominal variables are described as numbers and percentages. Statistical analyses were performed using SPSS (version 17.0 for Windows, SPSS Inc, Chicago, Ill).

RESULTS

Intraoperative

The procedural success rate was 100%. One patient with a degenerated homograft had an immediate second VIV implant after low placement of the first valve resulting from difficulty in visualizing the level of the annulus. One patient had a right ventricular perforation from 1 of the transvenous pacing wires used during the procedure. This was diagnosed immediately as a pericardial effusion on the TEE and was repaired without the use of cardiopulmonary bypass. In 15 patients, a 23-mm Sapien valve was implanted (13 stented valves and 2 stentless valves), in 6 patients a 26-mm valve was implanted (2 stented valves and 4 stentless valves), and in 2 patients a 29-mm valve was implanted (both stented valves). The sizes of in situ bioprostheses and the Sapien valve used are listed in Tables 2 and 3. The mean procedure time was 89 ± 28.5 minutes (range, 44-135 minutes). The mean fluoroscopy time was 11.4 ± 4.9 minutes (range, 5.5-18 minutes). The mean volume of