Use of balloon expandable transcatheter valves for valve-in-valve implantation in patients with degenerative stentless aortic bioprostheses: Technical considerations and results

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Objective: Transcatheter valve-in-valve is an accepted treatment in high-risk patients with degenerative stented bioprostheses in the aortic position. Experience in treating stentless valves is, however, limited. Our aim was to determine the feasibility and single-center outcome of balloon expandable SAPIEN valve placement in degenerated stentless aortic valve bioprostheses.

Methods: From February 2010 to January 2014, 10 patients with failing stentless bioprostheses underwent transcatheter aortic valve implantation using the Edwards SAPIEN transcatheter heart valve (SAPIEN, SAPIEN XT, and SAPIEN 3) at our institution. Seven patients had valve failure due to regurgitation and three to stenosis. The mean age was 73.3 ± 15.0 years. The mean logistic EuroSCORE was 31.8 ± 20.3, and the Society of Thoracic Surgeons score was 7.6 ± 5.4.

Results: Technical success was achieved in 9 of 10 patients. One patient required immediate placement of a second valve owing to low placement of the first. Two intraoperative complications developed that needed additional procedures. One patient underwent immediate repair of a right ventricular perforation from a pacing lead, the other, reexploration for epicardial bleeding. No deaths occurred. The median length of stay was 8.5 days (range, 3-44). The mean follow-up was 8.1 months (range, 1-21). No late reoperations or reinterventions were required.

Conclusions: Transcatheter aortic valve implantation after previous stentless aortic valve replacement is technically demanding but a safe and feasible approach. The early results were excellent, with consistent improvement in hemodynamics. Prospective long-term follow-up in larger series is needed to evaluate this technique further. (J Thorac Cardiovasc Surg 2014;148:917-24)

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.[1,2] The expanding indications have led to the use of transcatheter heart valves (THVs) to treat stented bioprosthetic aortic valves that are failing owing to either stenosis or regurgitation.[3,4]

During a valve-in-valve (VIV) procedure with a stented bioprosthesis, the sewing ring and frame provide an anchor for the THV; hence, the procedure can be performed with relative ease.[5,6] In stentless valves, the lack of a stent frame and sewing ring results in the absence of radiopaque markers to allow VIV positioning. Moreover, different sewing techniques and the proximity to the coronary ostia can make the VIV procedure challenging.[7] Furthermore, the mechanism of failure of this valve type has typically been cusp perforation or prolapse leading to regurgitation, which could make locating the annular plane for correct positioning difficult.[7-9] These factors can amount to a greater incidence of malposition, embolization, and coronary obstruction during VIV compared with the VIV procedure in the stented bioprosthesis.[9] Choosing the correct type and size of the THV device is also important. THVs are available either as balloon expandable or self-expandable valves. There is currently a stronger inclination to use the self-expandable THV with a nitinol frame when performing VIV in a stentless bioprosthesis.

We report the feasibility of implanting a balloon expandable THV, the successful early outcomes of VIV for degenerated stentless biological aortic valve prostheses, and discuss the technical considerations in planning and performing such cases.

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Abbreviations and Acronyms
ID = internal diameter
TA = transapical
TAVI = transcatheter aortic valve implantation
TEE = transesophageal echocardiography
THV = transcatheter heart valve
VIV = valve-in-valve

METHODS

Patients

From February 2010 to January 2014, we performed 33 VIV procedures for aortic bioprosthetic degeneration using the Edwards SAPIEN valve (Edwards Lifesciences, Irvine, Calif). Of these 33 patients, 10 (30%) had previously undergone placement of a stentless aortic bioprosthesis: 6 homografts, 1 Toronto SPV (St Jude Medical, St Paul, Minn), 1 Freestyle root (Medtronic Inc, Minneapolis, Minn), 1 O'Brien (Cryolife, Kennesaw, Ga), and 1 Pericarbon Freedom stentless valve (Sorin, Saluggia, Italy; Table 1). The mean patient age was 73.3 ± 14.0 years (range, 43-90). Of the 10 patients, 7 were men and 3 were women. The mode of presentation was either severe aortic valve regurgitation (n = 7) or stenosis (n = 3). Six patients presented in New York Heart Association class IV. The mean interval from the previous aortic valve procedure was 14.1 ± 6.4 years (range, 7-27). Two patients had undergone >1 previous valve replacement. The mean logistic EuroSCORE and Society of Thoracic Surgeons score were calculated. The logistic EuroSCORE was 31.2 ± 19.0, and the mean Society of Thoracic Surgeons score was 7.0 ± 5.2. The risk of conventional open aortic valve replacement was evaluated by a multidisciplinary team comprised of cardiac surgeons and cardiologists.

Methods

The preoperative diagnostic workup and routine postoperative care have been previously described in detail.[10] The previous operative notes were consulted when available to obtain details of the type of valve implanted, valve size, and surgical technique used. A preoperative transesophageal echocardiogram (TEE) was performed in all patients to determine the exact aortic annular diameter. A noncontrast-enhanced computed tomography scan was used to identify and determine the presence of calcification in the aortic annulus. A single valve type, the Edwards SAPIEN heart valve (Edwards Lifesciences), was used in our series. The SAPIEN valve is a balloon expandable THV. We have used all 3 iterations of this device, depending on availability (ie, SAPIEN [steel frame], SAPIEN XT [cobalt chromium frame], and, recently, SAPIEN 3 [cobalt chromium frame]). Depending on the pre- and intraoperative measurements, either a 23-mm or 26-mm device was implanted. The procedures were all performed in a cardiac catheterization laboratory by a combined team of cardiac surgeons, cardiologists, and anesthesiologists. A perfusionist was always present with a primed cardiopulmonary bypass machine. The approach for TAVI was either transfemoral or transapical (TA). The approach chosen was dependent on the team's preference after a review of the preoperative workup findings. The TA approach was preferred when the size of the femoral arteries was not suitable for transfemoral access. In 1 case, a TA approach was preferred because the patient had a previously placed mechanical mitral prosthesis. The techniques for both approaches have been previously described in detail.[11,12] The size of the new valve to be implanted was determined according to the internal diameter (ID) of the annulus measured using transthoracic echocardiography and intraoperative TEE. In valves other than homografts, the ID of the prosthesis available from published charts was also used as a guide.[13] A size 23-mm SAPIEN valve was used if the ID of the annulus was 18 to 20 mm, and a 26-mm valve was used for a 22- to 24-mm annulus. In the case of a borderline annulus, such as one with an ID of 21 mm, a larger prosthesis (26-mm SAPIEN) was preferred if the leaflets were not bulky and circumferential annular calcification was minimal. Simultaneous fluoroscopic, angiographic, and TEE imaging was routinely used to guide the precise level for valve deployment. Balloon dilatation of the degenerated valve before insertion of the prosthesis was not undertaken. Slow, gradual inflation of the valve balloon was undertaken in contrast to the rapid valve deployment sometimes seen. Implantation was performed during a short run of ventricular rapid pacing. In 3 cases, a guidewire was placed in the left main stem ostium to provide a landmark during deployment, because it was impossible to determine the correct level of the aortic annulus owing to severe regurgitation (Figure 1, *A*). Aortography and TEE assessment were used to determine the correct placement and function of the SAPIEN valve immediately after implantation (Figure 1, *B*). Special attention was also given to the patency of the coronary arteries. The patients were followed up closely postoperatively in accordance with the requirements of our on-site registry. This included patient interviews, clinical examination, and follow-up echocardiography. The complications are presented in accordance with the Valve Academic Research Consortium-2 criteria.[14]

Statistical Analysis

Continuous variables are presented as the mean ± standard deviation and dichotomous or nominal variables as numbers and percentages. Student's *t* test was used to determine statistical significance, with an α of 0.05 for the parametric data set. Statistical analyses were performed using the Statistical Package for Social Sciences, version 17.0, for Windows (SPSS Inc, Chicago, Ill).

RESULTS

Operative Course

Of the 10 patients, 9 required only 1 device implantation, with 1 patient requiring an immediate second SAPIEN implant after low placement of the first valve. The low placement had resulted owing to difficulty visualizing the level of the annulus using angiography because of severe aortic regurgitation (Figure 1, *C-E*). One intraoperative complication that required an additional procedure. The patient experienced a right ventricular perforation from the transvenous pacing wire used during the procedure. This was immediately diagnosed as pericardial effusion using TEE and was repaired without the use of cardiopulmonary bypass. This happened during a TA procedure in a patient with minimal intrapericardial adhesions. In 5 patients, a SAPIEN size 26-mm valve was implanted and in 5, a size 23-mm valve was implanted. The first-iteration SAPIEN valve was used in 3 patients, the SAPIEN XT in 6 patients, and the SAPIEN 3 in 1 patient. The mean procedure time was 86.7 ± 27.6 minutes (range, 44-135). The mean fluoroscopy time was 11.1 ± 4.7 minutes (range, 5.5-18). The mean volume of contrast medium used during the procedure was 148 mL (range, 80-260). After valve implantation, the TEE-measured peak transvalvular gradient had decreased from 33.6 ± 17.6 mm Hg to 11.3 ± 4.4 mm Hg ($P < .05$). The TEE-measured mean transvalvular gradient had decreased from 16 ± 9.8 mm Hg to 8.0 ± 4.8 mm Hg ($P = .077$). Of the 10 patients, 4 had grade I paravalvular aortic regurgitation after implantation and 6 had either