

Transapical Transcatheter Aortic Valve Implantation in the Presence of a Mitral Prosthesis

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- Objectives** We review our experience with transapical transcatheter aortic valve implantation (AVI) in patients with functioning mitral prostheses, and describe the technical considerations.
- Background** Transcatheter AVI for aortic stenosis in patients with mitral prostheses is technically challenging.
- Methods** Ten patients (7 mechanical and 3 bioprosthetic mitral valves) received the Edwards SAPIEN balloon-expandable valve (Edwards Lifesciences, Irvine, California) during 2006 to 2010. All patients were declined conventional surgery and prospectively followed. The mean patient age was 77.6 ± 7.1 years (range: 67 to 88 years). The logistic EuroSCORE and the Society of Thoracic Surgeons–predicted operative mortality were $30.3 \pm 18.6\%$ (range: 11.4% to 70.4%), and $9.9 \pm 4.8\%$ (range: 4.6% to 18.7%), respectively.
- Results** All valves were successfully implanted, with no 30-day mortality or mitral prosthetic dysfunction. Nine patients had none to mild residual aortic paravalvular leak. The overall survival was 60% at a mean follow-up of 12.2 ± 10.4 months (range: 2 to 33 months), with 4 nonvalve-related deaths. Seven patients improved to New York Heart Association functional class I to II. The mean transvalvular gradient and effective orifice area improved from 40.0 ± 17.4 mm Hg to 8.2 ± 2.1 mm Hg, and 0.6 ± 0.1 cm² to 1.3 ± 0.2 cm², respectively ($p < 0.0001$). The mitral bioprosthetic strut predisposes to device “shift” during deployment. An “unfavorable” mechanical mitral prosthetic cage or pivot strut can also cause shifts. Balloon shifts during valvuloplasty warn of a high likelihood of prosthesis shift.
- Conclusions** This report details the technical lessons learned thus far from our first 10 patients. Excellent procedural success and early outcomes in patients with functioning mitral prosthesis can be achieved. (*J Am Coll Cardiol* 2011;58:715–21) © 2011 by the American College of Cardiology Foundation

Transapical transcatheter aortic valve implantation (AVI) for aortic stenosis and transcatheter valve-in-valve implantation for failed aortic bioprostheses have been described using the Edwards SAPIEN balloon expandable valve (Edwards Lifesciences) (1,2). The PARTNER (Placement of AoRTic TraNscathetER Valves) trial demonstrated significantly reduced mortality, rehospitalization rates and symptoms, in nonsurgical patients undergoing transfemoral AVI, despite the higher incidence of major strokes and vascular events (3). Transcatheter AVI may also be beneficial in the elderly with previous coronary bypass and mitral valve replacement. The latter is, however, technically chal-

lenging. We report our transapical AVI experience in patients with functioning mitral prosthesis and highlight the technical considerations learned.

Methods

Ten patients with functioning mitral prostheses underwent transapical AVI for severe symptomatic aortic stenosis using the SAPIEN balloon-expandable bioprosthesis between June 2006 and July 2010. The prosthesis was approved for compassionate use by the department of Health and Welfare, Ottawa, Canada, in consenting patients declined for conventional reoperative surgery. All patients were prospectively followed. Statistical analysis was performed using SPSS version 18.0 for Windows (SPSS, Chicago, Illinois). Paired Student *t* test was used to analyze continuous data, and values were expressed as mean \pm SD.

The transapical AVI performed through a 4- to 5-cm left anterolateral mini-thoracotomy has been previously described (4,5). Rapid ventricular pacing (160 to 200 beats/min) was used during balloon valvuloplasty and valve deployment. Bal-

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Abbreviations and Acronyms

- AR** = aortic regurgitation
- AVI** = aortic valve implantation
- LVEF** = left ventricular ejection fraction
- LVOT** = left ventricular outflow tract
- NYHA** = New York Heart Association

loon valvuloplasty has the additional role to assess the degree of balloon contact with the mitral prosthetic cage or struts; and to observe balloon displacement during inflation. A shorter 3-cm valvuloplasty balloon similar to the Ascendra balloon catheter (Edwards Lifesciences) is used to simulate and predict balloon displacement during valve deployment.

Results

The mean patient age was 77.6 ± 7.1 years (range 67 to 88 years). Seven patients were female. Table 1 summarizes the baseline characteristics of all patients. Three patients had undergone 2 previous operations: 1) subaortic myomectomy 2 years before concomitant mitral valve replacement and coronary bypass; 2) mitral paravalvular leak repair following mitral valve replacement; and 3) mitral valve re-replacement 6-years post-initial operation, respectively. The mean interval between AVI and the most recent operation was 11.7 ± 4.2 years (range: 4 to 19 years). The mean transmitral prosthetic gradient was 5.7 ± 2.5 mm Hg (range: 2 to 10 mm Hg).

Three patients were morbidly obese (body mass index >30 kg/m²). The mean pre-procedural pulmonary artery systolic pressure was 54.8 ± 18.8 mm Hg (range: 33 to 100 mm Hg), with 4 patients having pulmonary hypertension (≥60 mm Hg). Six patients had permanent pacemakers pre-AVI. Two patients had coronary angioplasty within 30 days of AVI, 1 for acute coronary syndrome during the same admission. One patient required short-term dialysis following screening angiography, and another had survived a failed attempt at transfemoral AVI with distal valve embolization 4 years earlier.

The majority were in New York Heart Association (NYHA) functional class IV (80%) (Online Table 1). The mean left ventricular ejection fraction (LVEF) was 50 ± 14.3% (range: 20% to 65%). The mean aortic valve area was 0.6 ± 0.1 cm² (range: 0.5 to 0.8 cm²), with a mean transaortic valvular pressure gradient of 38.5 ± 17.1 mm Hg (range: 20 to 70 mm Hg). Three patients had previous balloon aortic valvuloplasty.

The logistic EuroSCORE and the Society of Thoracic Surgeons predicted mortality were 30.3 ± 18.6% (range: 11.4% to 70.4%), and 9.9 ± 4.8% (range: 4.6% to 18.7%), respectively. All valves were successfully implanted. The first patient received a Cribier-Edwards valve (Edwards Lifesciences), whereas the others received the Edwards SAPIEN (9000TFX) valve. Table 2 summarizes the procedure and outcomes. The first patient had a functioning Björk-Shiley mechanical mitral prosthesis, whereas the following mitral prostheses are represented in the others.

CarboMedics bileaflet mechanical valve. The patient had a CarboMedics valve (Sorin, Milano, Italy) with rigid housing cage and pivot guards within the cage. Despite a bulky sewing cuff, the cuff was sewn above annulus, and the cage is distant to the left ventricular outflow tract (LVOT) and aortic annulus. Slight balloon displacement occurred during valvuloplasty, but none during deployment of the 23-mm SAPIEN valve. There was only trivial paravalvular aortic regurgitation (AR) (Online Fig. 1).

St. Jude Medical bileaflet mechanical valves. This mechanical valve (St. Jude Medical, Minneapolis, Minnesota) has a rigid housing cage with pivot guards rising above the cage. Four of 5 patients underwent uneventful AVI (Fig. 1). In 1 patient, a 3-mm aortic shift occurred at the end of balloon inflation during valve deployment, which resulted in mild paravalvular AR. Subsequent review revealed that the rigid housing cage sat below the mitral annulus and protruded into the LVOT (Fig. 2).

Table 1 Baseline Pre-Operative Patient Characteristics

| Patient # | Age, yrs | Sex | LVEF (%) | PASP (mm Hg) | STS Score | Logistic EuroSCORE | Past Cardiac Operation | Years Post-Operation | Redo Number | Prior PCI | Prior PPM | Prior BAV | Prior Stroke/TIA | Pre-Op AF/Flutter |
|-----------|----------|-----|----------|--------------|-----------|--------------------|-----------------------------------|----------------------|-------------|-----------|-----------|-----------|-------------------------------|-------------------|
| 1 | 86 | F | 60 | 61 | 18.7 | 70.43 | MVR + CABG + Subaortic myomectomy | 13 | 2 | No | Yes | Yes | Stroke/carotid endarterectomy | Yes |
| 2 | 82 | F | 60 | 48 | 13.8 | 30.53 | MVR | 9 | 1 | No | No | No | No | Yes |
| 3 | 78 | M | 40 | 63 | 5.0 | 32.62 | MVR + AF ablation | 13 | 2 | Yes* | Yes | No | No | Yes |
| 4 | 67 | M | 50 | 60 | 4.6 | 13.27 | MVR + CABG + TVA | 19 | 1 | Yes | No | Yes | No | Yes |
| 5 | 77 | F | 60 | 33 | 8.2 | 16.13 | MVR | 15 | 2 | No | Yes | No | No | Yes |
| 6 | 71 | F | 60 | 41 | 4.6 | 11.42 | MVR+TVA | 12 | 1 | No | No | No | TIA | Yes |
| 7 | 82 | F | 35 | 40 | 8.9 | 13.03 | MVR+TVR | 14 | 1 | No | Yes | No | No | Yes |
| 8 | 69 | F | 50 | 100 | 10.3 | 31.91 | MVR + CABG + TVA + AF ablation | 4 | 1 | No | Yes | Yes | Stroke | Yes |
| 9 | 76 | M | 20 | 55 | 15.5 | 38.75 | MVR + CABG | 8 | 1 | Yes | No | No | No | Yes |
| 10 | 88 | F | 65 | 47 | 9.8 | 28.59 | MVR + CABG + TVA | 10 | 1 | Yes* | Yes | No | No | No |

Patients 1-7: mechanical mitral prosthesis; patients 8-10: bioprosthetic mitral valve. *Within 30 days of transcatheter aortic valve implantation.

AF = atrial fibrillation; BAV = balloon aortic valvuloplasty; CABG = coronary artery bypass graft; LVEF = left ventricular ejection fraction; MVR = mitral valve replacement; PASP = pulmonary arterial systolic pressure; PCI = percutaneous coronary intervention; PPM = permanent pacemaker; Pre-Op = pre-operative; STS = Society of Thoracic Surgeons; TIA = transient ischemic attack; TVA = tricuspid valve annuloplasty; TVR = tricuspid valve replacement.

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