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 ± 18.6% (range: 11.4% to 70.4%), and 9.9 ± 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 challenging. 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 ± 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-
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.

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 valvar 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 the 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).

### 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

### Table 1 Baseline Pre-Operative Patient Characteristics

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<th>Patient #</th>
<th>Age, yrs</th>
<th>Sex</th>
<th>LVEF (%)</th>
<th>PASP (mm Hg)</th>
<th>STS Score</th>
<th>Logistic EuroSCORE</th>
<th>Past Cardiac Operation</th>
<th>Years Post-Operation</th>
<th>Redo Number</th>
<th>Prior PCI</th>
<th>Prior PPM</th>
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<th>Prior Stroke/TIA</th>
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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.
Mitral bioprostheses. All 3 patients with either bovine pericardial (Carpentier-Edwards Perimount valve) or porcine valves (Mosaic Valve, Medtronic) had the commissural strut protruding into the LVOT, which caused significant balloon displacement towards the aorta during inflation. All transapical AVI was successful despite the displacements (Fig. 3). One transfemoral AVI in a patient with a Mosaic bioprosthesis failed due to gross balloon shift during deployment, and valve embolization (Fig. 4). She returned for successful transapical AVI 4 years later (Fig. 5). A 26-mm SAPIEN valve was positioned more ventricular (60% of the stent in LVOT) in anticipation of the shift, and significant countertraction on both the valve catheter and delivery sheath was necessary to restrain the aortic shift.

Echocardiographic outcomes. Paravalvular AR was absent or mild in 8 of 10 patients. The possible causes of the

![Figure 1](https://example.com/figure1.png)

**Figure 1**  
**St. Jude Medical Mechanical Mitral Valve**  
(A) St. Jude Medical mechanical mitral valve. Arrow points to the mitral prosthetic ring (B). Root aortogram (C). Insignificant balloon shift aortic-ward during balloon aortic valvuloplasty, with reference to the red line. Arrow points to a nonmobile mitral prosthetic leaflet during balloon inflation (D and E). Completion aortogram with SAPIEN prosthesis in situ (F). No paravalvular leak (G).
moderate paravalvular AR in 2 patients are: 1) suboptimal position due to balloon displacement during deployment; and 2) insufficient oversizing of the selected transcatheter valve (26-mm valve into a 26- to 27-mm aortic annulus). The later patient did not have demonstrable paravalvular AR 6 months later. The mean transvalvular pressure gradient and effective orifice area improved from 40.0 mm Hg to 8.2 mm Hg, and 0.6 cm² to 1.3 cm², respectively (p < 0.0001) (Online Table 1). The mitral prosthetic function remained unaffected in all patients. At a mean echocardiographic follow-up of 13.9 ± 6.7 months (range: 6 to 27 months), there was no structural valve deterioration or displacement.

Clinical outcomes. The mean procedural time was 97.0 ± 11.8 min (range: 83 to 121 min), with no intraoperative mortality or complications. Two patients required subsequent left pleural drainage, 2 developed acute renal deterioration not requiring dialysis, and 1 was successfully treated for right heart failure. Post-procedural delirium was common (50%). The mean blood transfusion requirement was 0.8 ± 1.2 U (range: 0 to 3 U). Two of 4 patients without pacemakers pre-AVI required new pacemakers post-AVI for complete heart block.

There was no 30-day mortality, and patients improved, with 70% in NYHA functional class I to II (Online Table 1). At mean follow-up of 12.2 ± 10.4 months (range: 2 to 33 months), there were 4 nonvalve-related deaths (mean duration to demise was 407.0 ± 317.5 days [range: 144 to 861 days]), giving an overall survival of 60%. One patient died from a presumed ischemic bowel 2 years post-AVI, whereas another succumbed to sepsis and renal failure 1 year later. The third patient with initial moderate paravalvular AR died 8 months post-AVI from nonvalve-related pulmonary failure. The last patient died from a heparin-related bleeding complication during hip replacement 5 months post-AVI. Our longest surviving patient is now 2.5 years post-AVI.

Discussion

The technical concerns of implanting a SAPIEN valve in patients with prosthetic mitral valves evolve around the interaction between both the aortic and mitral prosthesis at the anatomic aortomitral continuity. Previous reports of patients with functioning mechanical mitral prostheses employed the percutaneous retrograde approach using the
CoreValve (CoreValve, Irvine, California) (6), and the transapical approach using the SAPIEN valve (7).

This present series demonstrates that the transapical AVI of a balloon expandable valve is feasible and safe in patients with both mechanical and bioprosthetic mitral prostheses. Technical challenges however exist in patients with mitral bioprostheses. Special procedural considerations are elaborated.

Type of mitral prosthesis. Mechanical valves have a rigid housing cage, with or without protruding pivot guards (Online Fig. 2). The St. Jude Medical valve has a narrow housing cage. The CarboMedics valve has “hidden” pivot guards within the solid housing. Both, however, have a small degree of rigid cage protruding into their ventricular aspect that may extend into the LVOT and cause balloon displacement. In contrast, the On-X mechanical valve (On-X Life Technologies, Austin, Texas) has a high, rigid housing cage without protruding pivot guards. Foreseeably, this may interfere with transapical AVI. Balloon valvuloplasty is mandatory to assess the degree of balloon displacement if the transfemoral approach is considered. The transapical approach is better and safer should significant displacement occur.

Bioprostheses have more prominent commissural struts and are invariably impinging on the LVOT. This causes balloon displacement toward the aorta during inflation, with resultant valve malposition or embolization (Fig. 4). The transapical approach is best suited for these patients (Fig. 5).

Relationship between the aortic annulus and the mitral prosthetic housing or bioprosthetic strut. Echocardiographic assessment is crucial to determine: 1) the extent of prosthetic housing/strut protrusion into the LVOT; 2) the distance between the protruding rigid structure and the aortic annulus; and 3) the location of the rigid housing in relation to the mitral annulus. The short distance between the protruding prosthetic housing/strut and the aortic annulus increases the risk of balloon displacement. The mechanical prostheses are generally less problematic because of the absence of commissural struts. However, its housing cage may be seated below the mitral annulus (within the ventricle), due to an inverting suture technique. This predisposes to balloon displacement, usually at the end of balloon inflation (Fig. 2).

Balloon valvuloplasty. Balloon valvuloplasty allows for observation of balloon “shifts” due to the rigid mitral prosthetic housing or strut. Using a balloon similar to that for subsequent prosthesis deployment provides the best prediction of the degree of balloon shift during actual
deployment. Subsequent slow balloon inflation usually minimizes balloon displacement.

**Valve positioning.** Valve positioning should be adjusted according to the degree of balloon displacement observed during valvuloplasty. Generally, in patients without mitral prostheses, the transapical valve is positioned at the aortic annulus with 40% to 50% of its stent below the annulus. In patients with mechanical mitral prostheses, the valve is positioned more ventricular (50% to 60% of stent below the annulus) to compensate for aortic displacement when valvuloplasty balloon shift is noted. With mitral bioprostheses, balloon displacement always occurs despite excellent transapical stabilization. If gross aortic shift is anticipated, the valve is positioned even more ventricular (60% of stent in LVOT).

**Valve stabilization and deployment.** The transapical operator can firmly stabilize both the delivery sheath and catheter when anticipating aortic displacement. Slow balloon inflation minimizes the displacement and also allows an experienced operator to actively pull back the valve at the earliest sign of balloon shift. The latter, however, also risks malposition and is not recommended for inexperienced operators.

**Other considerations.** Aortic annulus measurement, valve sizing, and other principles for SAPIEN transcatheter AVI are similar to those previously described (1,4,8). Aggressive valve oversizing may worsen deployment shifts. Redilation for paravalvular leaks should be avoided because it may displace the valve, and overdilation of the outflow stent aggravates transvalvular regurgitation. We do not think that there is an increased risk of coronary obstruction in these patients, if these rules are heeded.

The 50% new pacemaker rate (2 of 4 patients without pacemakers pre-AVI) appears high compared with patients without mitral prosthesis, but the numbers are too small to draw any conclusions. The overall survival of 60% at mean duration of 12.2 ± 10.4 months in this cohort is relatively lower compared with our published 12-month survival rate of 71.9 ± 5.5% (9).

**Conclusions**

Various degrees of balloon displacement occur due to impingement on the housing cage and pivot guards of mechanical mitral valves and on the bioprosthetic struts. Optimal valve position is achievable with experience and technical modifications. The high-risk patients have a bioprosthetic mitral valve, mechanical valve cage seating below the mitral annulus, and/or valvuloplasty shifts. The transapical approach is safe, with good outcomes in patients with mitral prostheses.
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REFERENCES


Key Words: aortic valve • catheter • prosthetic valves • surgery.

APPENDIX

For supplemental figures and a table, please see the online version of this article.