Transcatheter Aortic Valve Implantation Impact on Clinical and Valve-Related Outcomes

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Background—Transcatheter aortic valve implantation is an alternative to open heart surgery in patients with aortic stenosis. However, long-term data on a programmatic approach to aortic valve implantation remain sparse.

Methods and Results—Transcatheter aortic valve implantation was performed in 168 patients (median age, 84 years) in the setting of severe aortic stenosis and high surgical risk. Access was transarterial (n=113) or, in the presence of small iliofemoral artery diameter, transapical (n=55). The overall success rate was 94.1% in this early experience. Intraprocedural mortality was 1.2%. Operative (30-day) mortality was 11.3%, lower in the transarterial group than the transapical group (8.0% versus 18.2%; P=0.07). Overall mortality fell from 14.3% in the initial half to 8.3% in the second half of the experience, from 12.3% to 3.6% (P=0.16) in transapical patients and from 25% to 11.1% (P=0.30) in transapical patients. Functional class improved over the 1-year postprocedure period (P<0.001). Survival at 1 year was 74%. The bulk of late readmission and mortality was not procedure or valve related but rather was due to comorbidities. Paravalvular regurgitation was common but generally mild and remained stable at late follow-up. At a maximum of >3 years and a median of 221 days, structural valve failure was not observed.

Conclusions—Transcatheter aortic valve implantation can result in early and sustained functional improvement in high-risk aortic stenosis patients. Late outcome is determined primarily by comorbidities unrelated to aortic valve disease. (Circulation. 2009;119:3009-3016.)

Key Words: aortic valve • aortic valve stenosis • catheters • prosthesis • valves • valvuloplasty

Since the initial demonstrations of the feasibility of percutaneous transvenous, transarterial, and transapical aortic valve implantation (AVI), this therapeutic option has rapidly gained credibility as a viable alternative to open heart surgery in high-risk patients with aortic stenosis. To date, reports of transcatheter AVI have focused primarily on procedural success, early mortality, and short-term clinical outcomes. However, long-term data on transcatheter AVI outcomes remain limited. In contrast, there is substantial literature demonstrating improved long-term survival in patients with symptomatic severe aortic stenosis undergoing surgical open heart AVI. Although current guidelines suggest surgical valve replacement for all such patients, a substantial number of individuals remain who do not undergo surgery because of comorbidities and the associated increased surgical risk of morbidity or mortality. Here, we report the short- and intermediate-term clinical outcomes in a large single-center experience using a collaborative approach of transarterial and transapical AVI in patients at high surgical risk.
the aortic annulus diameter was <18 or >26 mm, or if a reasonable quality or duration of life was unlikely. There were no other criteria for exclusion.

Procedures and Devices
Transarterial and transapical procedures were performed as previously described.2-6 Transarterial procedures were performed in a catheterization laboratory; transapical procedures were performed in an operating room. Transarterial access was gained by percutaneous puncture of the femoral artery, whereas transapical access was obtained by anterior minithoracotomy followed by direct needle puncture of the left ventricular apex. Balloon valvuloplasty was routinely performed before valve implantation. Burst rapid pacing was used to reduce cardiac output during prosthesis deployment.12 Early in the transarterial experience, the femoral access site was closed surgically, whereas later, percutaneous closure (Prostar XL, Abbott Inc, Chicago, Ill) was routinely used.

The balloon-expandable Cribier-Edwards equine valve5 was used early in the series, although the majority of procedures used the Edwards SAPIEN bovine valve (Edwards Lifesciences LLC, Irvine, Calif).6 More recently, a limited number of patients received the next-generation cobalt-chromium bovine valve (SAPIEN XT).13 Initial transarterial and transapical procedures were performed with the RetroFlex delivery catheter.6 This was subsequently replaced with the RetroFlex II transapical catheter incorporating a retractable nose cone13 and the Ascendra transapical catheter (all Edwards Lifesciences LLC).

Definitions and Data Collection
Patients were followed up as part of an ongoing prospective registry. Transthoracic echocardiograms were obtained at baseline, before discharge, and at 1, 6, and 12 months and yearly thereafter. Clinical follow-up occurred at similar intervals. All patients in whom valve implantation was attempted but in whom the procedure was not successful were followed up to 30 days. No patient was lost to follow-up.

Procedural success was defined as implantation of a functioning prosthetic valve within the aortic annulus and without intraprocedural mortality. Procedure-related events were defined as occurring during or as a direct result of the index procedure. Events that occurred before extubation were similarly classified as procedural. Outcome measures included procedural success, functional status (New York Heart Association [NYHA] class), major adverse cardiac and cerebrovascular events (MACEs) at 30 days, major adverse valve-related events (MACEs), and survival. MACEs included death, myocardial infarction, stroke, or aortic valve reintervention/operation. MACEs included valve-related mortality, valve-related morbidity, and need for new permanent pacemaker or defibrillator within 14 days after the procedure. Valve-related morbidity was defined as any structural deterioration or nonstructural prosthesis dysfunction, valve thrombosis, embolism, bleeding events, and prosthetic valve endocarditis.14,15

Frailty was defined according to the criteria of Fried et al.15 Renal failure was defined according to RIFLE (Risk, Injury, Failure, Loss, and End-stage kidney disease) criteria.16 Major vascular injury was defined as vascular rupture with fatal bleeding or need for urgent vascular surgery or dissection of the aorta.14

To allow comparison with the surgical literature, valve-related morbidity and events were reported in accordance with published reporting guidelines for valve surgery.14 Major bleeding was defined as any bleeding requiring transfusion, disabling or fatal.14 Nonstructural valve dysfunction was defined as major valve dysfunction (such as severe paravalvular regurgitation or late embolization) not occurring as a result of a structural problem, thrombosis, or infection.14

Statistical Analysis
Continuous variables are presented as mean±SD when normally distributed and as medians and first (Q1) and third quartiles (Q3) when not normally distributed. Categorical variables are given as frequencies and percentages. Normality was tested with the Shapiro-Wilks goodness-of-fit test. Continuous variables were tested for differences between procedure types with the Student t test or the Kruskal-Wallis test. Categorical variables were tested by the χ2 test or, when necessary, the Fisher exact test. For comparison of continuous variables before and after transcatheter AVI, differences were calculated and the l-sample Student t test or Wilcoxon signed-rank test was applied. Trends in functional class (NYHA class versus III) over time were analyzed with a logistic regression model adjusted for the baseline NYHA class and with general estimating equations methodology assuming compound symmetry to adjust for the correlation between repeated measurements from the same patient; results are presented as odds ratio with 95% confidence intervals (CIs). For comparison of procedural success over time, transarterial and transapical procedures were divided into 2 groups of consecutive patients. Thirty-day MACCE rates are given as percentages. Time-related events up to 2 years included survival, valve-related mortality, MACEs, and readmission; they are presented as Kaplan-Meier curves and were tested for procedural differences with the log-rank test. Patients with unsuccessful procedures were followed up for 30 days after the procedure. To identify predictors of death after transcatheter AVI, a Cox proportional-hazard model was applied, and results are reported as adjusted hazard ratios with 95% CIs. Testing was carried out as 2-sided tests with a significance level of 0.05. All analyses were conducted with SAS version 9.1 (SAS Institute Inc, Cary, NC).

The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

Results
Baseline Characteristics
A total of 168 patients underwent attempted transcatheter AVI, 113 transarterial and 55 transapical. Median age was 84 years (Q1 and Q3, 79 and 87 years). All patients had echocardiographically confirmed severe aortic stenosis with a median calculated aortic valve area of 0.6 cm2 (Q1 and Q3, 0.5 and 0.7 cm2). Baseline characteristics are shown in Table 1. Common comorbidities included the presence of coronary artery disease (67.9%), mitral regurgitation grade ≥3+ (39.9%), porcelain aorta (21.4%), frailty (25.9%), and a history of previous thoracotomy (39.9%).

All patients were at high risk for conventional surgery as reflected by a median logistic EuroSCORE of 28.6 (Q1 and Q3, 17.9 and 41.0) and a median Society of Thoracic Surgeons (STS) score of 9.1 (Q1 and Q3, 6.3 and 13.0). Standard estimates of surgical risk predicted a high operative mortality in 73.8% (STS >10% and/or logistic EuroSCORE >20%). In the remaining 26.2% of patients, surgeons identified specific conditions likely to contribute to excessive perioperative risk that were not reflected in EuroSCORE and STS risk scores. Specific conditions were surgical technical concerns (15.9%), age >90 years (13.6%), morbid obesity (body mass index >35; 9.1%), end-stage lung disease (9.1%), moderate to severe mitral regurgitation likely requiring double-valve surgery (9.1%), critical liver disease (6.8%), cancer (2.3%), and multiple debilitating comorbidities associated with frailty, cachexia, and immobility (34.1%). In particular, the presence of a porcelain aorta, a common reason for surgical refusal present in 21.4% of the entire cohort, was not accounted for by STS risk estimates.

Early Outcomes
Intraprocedural mortality was 1.2%. A 23-mm-diameter transcatheter valve was successfully implanted in 59 patients,
and a 26-mm valve was implanted in 100 patients. With transcatheter AVI, the echocardiographic median aortic valve area increased from 0.6 cm² (Q1 and Q3, 0.5 and 0.7 cm²) to 1.6 cm² (Q1 and Q3, 1.3 and 1.9 cm²) (P < 0.001). Median hospital stay was 6 days (Q1 and Q3, 4 and 10 days).

Procedural success was 94.1%, increasing from 89.3% to 98.8% from the initial half to the second half of the experience (P < 0.01). Mortality at 30 days was 11.3% overall, decreasing from 14.3% in the initial half to 8.3% in the second half (P = 0.22) (Figure 1). Logistic EuroSCORE and STS estimates of surgical risk were not significantly different between the first and second halves of the experience.

In the first half of the experience, 4 patients had unsuccessful transfemoral procedures. Three went on to have successful transapical procedures, and 1 had a successful repeat transfemoral procedure. Results are based on the initial 168 procedures, with unsuccessful procedures followed up for 30 days after the procedure.

In-hospital and 30-day adverse outcomes are detailed in Table 2. The most common complications observed were the need for transfusion (11.5%), major vascular surgery (6.6%), or a pacemaker (5.4%); renal failure (6.0%); and pneumonia (4.8%). The rate of combined MACCEs at 30 days was 14.9% (Figure 2). MACCEs were accounted for primarily by mortality in that no patient underwent repeat valve intervention, myocardial infarction was infrequent, and stroke was generally a fatal event. Only 1 patient surviving to 30 days...
was left with a disabling stroke (0.6%). The causes and times of death occurring within 30 days of the procedure are detailed in Table 3.

**Procedure Type**

Patients selected for a transapical procedure as opposed to a transarterial procedure were more likely to have peripheral vascular disease (76.4% versus 15.9; \( P < 0.0001 \)), have prior myocardial infarction (83.6% versus 68.1%; \( P = 0.03 \)), be female (60.0% versus 42.5%; \( P = 0.03 \)), have a lower body mass index (23.4 kg/m\(^2\) [Q1 and Q3, 21.6 and 26.8 kg/m\(^2\)] versus 25.7 kg/m\(^2\) [Q1 and Q3, 22.3 and 28.3 kg/m\(^2\)]; \( P = 0.02 \)), and be in NYHA class I or II (23.6% versus 8.8%; \( P = 0.01 \)). Transapical patients were at higher risk for conventional surgery as predicted by both a higher STS score (10.3% [Q1 and Q3, 6.8% and 17.7%] versus 8.7% [Q1 and Q3, 6.0 and 12.1%]; \( P < 0.03 \)) and logistic EuroSCORE (35.0% [Q1 and Q3, 20.0 and 50.3%] versus 25.0% [Q1 and Q3, 16.0 and 37.0%]; \( P = 0.01 \)).

**Table 2. Adverse Outcomes at Hospital Discharge and 30 Days for All Patients Combined and Separated by Procedure Type**

<table>
<thead>
<tr>
<th>Adverse Outcome</th>
<th>Combined (n=168), n (%)</th>
<th>Transarterial (n=113), n (%)</th>
<th>Transapical (n=55), n (%)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion ( \geq 5 ) packed cells</td>
<td>19 (11.5)</td>
<td>13 (11.6)</td>
<td>6 (11.1)</td>
<td>0.93</td>
</tr>
<tr>
<td>Cardiac tamponade</td>
<td>4 (2.4)</td>
<td>2 (1.8)</td>
<td>2 (3.6)</td>
<td>0.60</td>
</tr>
<tr>
<td>Major vascular injury</td>
<td>11 (6.6)</td>
<td>9 (8.0)</td>
<td>2 (3.6)</td>
<td>0.51</td>
</tr>
<tr>
<td>Cardiopulmonary bypass, emergent</td>
<td>4 (2.4)</td>
<td>1 (0.9)</td>
<td>3 (5.5)</td>
<td>0.19</td>
</tr>
<tr>
<td>Conversion to open heart surgery</td>
<td>1 (0.6)</td>
<td>0 (0)</td>
<td>1 (1.8)</td>
<td>0.72</td>
</tr>
<tr>
<td>Acute renal failure(^1)</td>
<td>10 (6.0)</td>
<td>5 (4.4)</td>
<td>5 (9.1)</td>
<td>0.30</td>
</tr>
<tr>
<td>Temporary hemodialysis</td>
<td>3 (1.8)</td>
<td>0 (0)</td>
<td>3 (5.5)</td>
<td>0.03*</td>
</tr>
<tr>
<td>Atrial fibrillation, new</td>
<td>7 (4.2)</td>
<td>0 (0)</td>
<td>7 (12.7)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Need for permanent pacemaker</td>
<td>9 (5.4)</td>
<td>5 (4.4)</td>
<td>4 (7.3)</td>
<td>0.48</td>
</tr>
<tr>
<td>Ventilation &gt;48 h</td>
<td>4 (2.4)</td>
<td>2 (1.8)</td>
<td>2 (3.6)</td>
<td>0.60</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>2 (1.2)</td>
<td>0 (0)</td>
<td>2 (3.6)</td>
<td>0.11</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>8 (4.8)</td>
<td>4 (3.5)</td>
<td>4 (7.3)</td>
<td>0.44</td>
</tr>
<tr>
<td>Local infection</td>
<td>4 (2.4)</td>
<td>3 (2.7)</td>
<td>1 (1.8)</td>
<td>1.00</td>
</tr>
<tr>
<td>Septicemia</td>
<td>5 (3.0)</td>
<td>3 (2.7)</td>
<td>2 (3.6)</td>
<td>0.66</td>
</tr>
<tr>
<td>Multiorgan failure</td>
<td>6 (3.6)</td>
<td>3 (2.7)</td>
<td>3 (5.5)</td>
<td>0.39</td>
</tr>
<tr>
<td>Hospital stay, median (Q1–Q3), d</td>
<td>6 (4–10)</td>
<td>5 (3–9)</td>
<td>7 (5–12)</td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Stroke</td>
<td>7 (4.2)</td>
<td>6 (5.3)</td>
<td>1 (1.8)</td>
<td>0.43</td>
</tr>
<tr>
<td>Mortality at 30 d</td>
<td>19 (11.3)</td>
<td>9 (8)</td>
<td>10 (18.2)</td>
<td>0.07</td>
</tr>
<tr>
<td>MACCEs at 30 d</td>
<td>25 (14.9)</td>
<td>14 (12.4)</td>
<td>11 (20.0)</td>
<td>0.19</td>
</tr>
</tbody>
</table>

Categorical variables are defined on the basis of the STS definitions unless noted otherwise. *Significant difference between procedural types.

**Figure 2.** MACCEs at 30 days as defined by current surgical standards.\(^1\)\(^4\) C indicates combined transapical and transarterial; F, femoral access; A, apical access; AMI, acute myocardial infarction; and Re-OP, subsequent cardiac surgery.
Early Outcomes

The high rate of procedural success is encouraging in this early experience. It appears that with careful screening,

Discussion

Late Outcomes

Survival at 1, 12, and 24 months was 88.7%, 73.8%, and 60.9%, respectively. The following variables were examined as possible predictors of death: age, gender, history of prior coronary artery bypass, poor left ventricular systolic function, chronic renal failure, moderate to severe mitral regurgitation at baseline, moderate to severe functional class impairment at baseline, logistic EuroSCORE ≥ 20%, STS score > 10%, presence of frailty, body mass index, and baseline creatinine. By multivariate analysis, only transapical access and chronic renal failure were significantly associated with increased mortality (hazard ratios, 1.85 [95% CI, 0.99 to 3.43] and 3.48 [95% CI, 1.78 to 6.83], respectively).

Two patients underwent late reoperation: one 4 months after an unsuccessful but uncomplicated transarterial attempt and a second who developed prosthetic endocarditis 1 year after a successful but uncomplicated transarterial attempt and a third who developed severe mitral regurgitation at 1 year after a successful transapical attempt. Aortic valve area increased from 0.6 cm² at baseline to 1.6 ± 0.4 cm² before discharge (P < 0.01); it subsequently decreased slightly to 1.5 ± 0.3 cm² at 1 year (P = 0.04). Paravalvular aortic regurgitation was a frequent finding at all time points but was trace to mild in the majority of cases; eg, immediately after the procedure, 84 (58%), 53 (37%), and 7 (5%) of the patients alive at 30 days showed grade 0/1+, 2+, and 3+ paravalvular aortic regurgitation, respectively (Figure 4). The degree of valvular regurgitation was even less, with 97 (77%) and 66 (67%) of the patients with actuarial follow-up at 6 and 12 months, respectively, showing only none/trace or mild valvular regurgitation. No severe aortic regurgitation was observed. A minority of patients showed moderate regurgitation, which remained unchanged over time. At a median follow-up of 221 days (Q1 and Q3, 49 and 401 days) and a maximum of 1111 days, structural valve deterioration was not observed.

NYHA Functional Class

For patients surviving to 1 year, there was an improving trend in the functional class over the year (P < 0.001); patients were less likely to be in class NYHA III/IV compared with NYHA I/II (odds ratio, 0.66; 95% CI, 0.55 to 0.78). After transcatheter AVI, substantial improvement was observed within the first month (Figure 3). At baseline, 2 (1%), 17 (12%), 88 (61%), and 37 (26%) of the 144 patients with successful transcatheter AVI and alive at 30 days were in NYHA class I, II, III, and IV, respectively; at the 30-day follow-up, 124 (86%) were in class I or II. The most improvement occurred in patients who were in class III and IV at baseline, of whom 78 (88.6%) and 37 (100%) had improved by at least 1 functional class. This increase in functional class was sustained over time, with 77 (78%) of the 99 patients with actuarial follow-up at 1 year being in class I or II.

Echocardiographic Valve Function

Transaortic mean gradient decreased from 46.1 ± 6.7 mm Hg at baseline to 10.0 ± 0.4 mm Hg before discharge (P < 0.01). Subsequently, the gradient increased slightly to 11.2 ± 4.9 mm Hg at 1 year (P = 0.07). Aortic valve area increased from 0.6 ± 0.2 cm² at baseline to 1.6 ± 0.4 cm² before discharge (P < 0.01); it subsequently decreased slightly to 1.5 ± 0.3 cm² at 1 year (P = 0.04). Paravalvular aortic regurgitation was a frequent finding at all time points but was trace to mild in the majority of cases; eg, immediately after the procedure, 84 (58%), 53 (37%), and 7 (5%) of the patients alive at 30 days showed grade 0/1+, 2+, and 3+ paravalvular aortic regurgitation, respectively (Figure 4). The degree of valvular regurgitation was even less, with 97 (77%) and 66 (67%) of the patients with actuarial follow-up at 6 and 12 months, respectively, showing only none/trace or mild valvular regurgitation. No severe aortic regurgitation was observed. A minority of patients showed moderate regurgitation, which remained unchanged over time. At a median follow-up of 221 days (Q1 and Q3, 49 and 401 days) and a maximum of 1111 days, structural valve deterioration was not observed.

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Two patients underwent late reoperation: one 4 months after an unsuccessful but uncomplicated transarterial attempt and a second who developed prosthetic endocarditis 1 year after successful AVI. Major bleeding (n = 9) was the predominant event; observed in the 29 patients experiencing MAVREs at the last follow-up (Table 4). The incidence of late valve-related events was low (Figure 5).

Discussion

Early Outcomes

The high rate of procedural success is encouraging in this early experience. It appears that with careful screening,
current techniques, and experience, short-term procedural success can be achieved in most patients in whom the procedure is attempted. Similarly, a 30-day mortality of 11.3% with a transcatheter approach in very-high-risk patients compares favorably with standard estimates of surgical mortality. In particular, the low mortality (3.6%) in the final half of the transarterial experience suggests that outcomes may further improve. An early learning curve is evident in the overall experience. The transapical experience probably benefited from lessons learned in the earlier transarterial experience. This learning curve has implications for dissemination of this technology.

**Late Outcomes**

At a follow-up with a median time of 7.4 months and a maximum of >3 years, the incidence of late adverse valve-related events\textsuperscript{14} was low. In particular, structural valve failure was not observed, and reoperation and endocarditis were rare. The most common late valve-related event was bleeding related to gastrointestinal disease, often seen in warfarin-treated patients receiving postprocedural dual antiplatelet therapy. Currently, we avoid combined antiplatelet and antithrombotic therapy in our elderly patients with comorbidities. Paravalvular regurgitation was common but generally mild and remained stable at late follow-up.

Functional class improved at 1 month and was sustained, with the majority of patients alive at 1 year being class I or II. Admittedly, NYHA functional class is a relatively insensitive and subjective measure. Future evaluation will require more detailed measures of functional status. Survival at 1, 12, and 24 months was 89%, 74%, and 61%, respectively. A 1-year survival of 74% in patients declined surgery compares favorably with other reports. By way of comparison, Kojodjojo et al\textsuperscript{17} reported a 1-year survival of 51% in elderly aortic stenosis patients who were not considered to be surgical candidates and 66% in elderly surgical candidates who declined surgery. Bach et al\textsuperscript{18} reported a 1-year survival of 62% in unoperated patients.

**Stroke**

Stroke occurred in 4.2% overall. Prior smaller studies report an incidence varying from 0% to 9%.\textsuperscript{6–8,19–22} Transcatheter AVI may carry an inherent risk of aortic atheroemboli and valvular calcific emboli. This concern may be greater with the retrograde approach to the aortic valve, a concept that is
consistent with the trend to a lower stroke rate with transapical access. Approaches to reducing this risk include preprocedural screening for friable aortic atheroma, more attention to a gentle passage of catheters through the aortic arch, and the use of embolic protection devices. The current trend to lower-profile and less traumatic transarterial catheters will likely reduce embolic risk.8,23,24 Importantly, major stroke was generally a fatal event and was largely accounted for in the overall mortality. Only 1 patient surviving to 30 days was left with a disabling stroke (0.6%).

Vascular Injury
Major vascular injury, primarily iliofemoral dissection or perforation, was the most common transarterial complication, occurring in 8% of patients. With improved screening, case selection, and experience, it appears that the incidence of vascular injury is falling. Still, given the large diameter of current transarterial catheters, the potential for arterial injury argues for transapical access in borderline cases. As with stroke, it is hoped that the development of lower-profile and less traumatic catheters will reduce the risk of vascular injury.8,23,24

Renal Failure
Even mild worsening of renal function after conventional cardiac surgery is associated with significant morbidity and short- and long-term mortality.25 Preexisting renal impairment was a common reason for referral for transcatheter AVI, and in this experience, renal impairment, even dialysis dependency, was not an exclusion criterion. Postprocedural acute renal failure was seen in 6%. Temporary hemodialysis was required in 1.8% of the entire group (0% transarterial, 5.5% transapical; P=0.03). By multivariate analysis, chronic renal failure was the strongest single predictor of mortality at late follow-up.

Estimates of Risk
Available predictors of surgical risk are often helpful. Nevertheless, many determinants of operative risk (such as porcelain aorta, frailty, planned multivalve surgery) are not incorporated into commonly used predictive models. Approximately one quarter of the patients in this experience would not be considered high risk by logistic EuroSCORE or STS risk estimates and yet were declined surgery because of such factors. Of note, neither model predicted transcatheter AVI mortality. Presumably, factors that determine risk with open heart surgery, sternotomy and cardiopulmonary bypass, cardioplegia, and aortic cross-clamping are different from those that predict risk with a transcatheter procedure.

Conclusions
Transcatheter AVI can result in early and sustained functional improvement in high-risk aortic stenosis patients. Early out-
comes compare favorably with high-risk surgery, and late outcome is determined primarily by comorbidities other than aortic valve disease. An early learning curve has implications for training and maintenance of competence.

**Source of Funding**

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**Disclosures**

Drs Cheung, Munt, and Webb are consultants to Edwards Life-sciences. The other authors report no conflicts.

**References**


**CLINICAL PERSPECTIVE**

Transcatheter aortic valve implantation was performed in 168 patients with severe aortic stenosis and high surgical risk in this transarterial (n=113) and off-pump transapical (n=55) single-center experience. Intraprocedural mortality was 1.2%. Operative (30-day) mortality was 11.3%, lower in the transarterial group than the transapical group (8.0% versus 18.2%). Mortality fell from the initial half to the second half of this experience, from 12.3% to 3.6% in transarterial patients and from 25% to 11.1% in transapical patients. There was early and sustained functional improvement. At a maximum of >3 years and a median of 221 days, structural valve failure was not observed. Paravalvular regurgitation was common but generally mild and remained stable at late follow-up. The bulk of late readmission and mortality was not procedure or valve related but rather due to comorbidities. Late outcome after transcatheter aortic valve implantation for aortic stenosis is determined primarily by comorbidities unrelated to aortic valve disease.
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