Transapical transcatheter aortic valve implantation: 1-year outcome in 26 patients

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Background: We reported the first case of successful transapical transcatheter aortic valve implantation in a human subject in 2005 and have now completed a 12-month follow-up on our first 26 patients. This is, to date, the longest follow-up of patients undergoing transapical aortic valve implantation.

Methods: Between October 2005 and January 2007, 26 patients (13 female) underwent transcatheter transapical aortic valve implantation with either 23- or 26-mm Edwards Lifesciences transcatheter bioprostheses. All patients with symptomatic aortic stenosis were declined for conventional aortic valve replacement because of unacceptable operative risks and were not candidates for transfemoral aortic valve implantation because of poor arterial access. Clinical and echocardiographic follow-up was performed before discharge and at 1, 6, and 12 months. Data from the 17 patients who survived over 12 months were used for comparisons of the baseline and follow-up results.

Results: The mean age was 80 ± 9 years, and the predicted operative mortality was $37\% \pm 20\%$ by using logistic EuroSCORE and $11\% \pm 6\%$ by using the Society of Thoracic Surgeons Risk Calculator. Valves were successfully implanted in all patients. Six patients died within 30 days (30-day mortality, 23%), and 3 patients died from noncardiovascular causes after 30 days (late mortality, 12%). Among patients who survived at least 30 days, 12-month survival was 85%. There were no late valve-related complications. New York Heart Association functional class improved significantly. The aortic valve area and mean gradient remained stable at 12 months ($1.6 \pm 0.3 \text{ cm}^2$ and $9.6 \pm 4.8 \text{ mm Hg}$, respectively).

Conclusion: Our 1-year clinical and echocardiographic outcomes suggest that transapical transcatheter aortic valve implantation is a viable alternative to conventional aortic valve replacement in selected high-risk patients.

Aortic valve replacement (AVR) with cardiopulmonary bypass (CPB) has been the only treatment that offers both symptomatic relief and the potential for improved long-term survival and hence is the treatment of choice for patients with symptomatic severe degenerative aortic stenosis.¹ However, because a considerable number of elderly patients with symptomatic severe aortic stenosis have significant comorbidities, open-heart AVR with CPB can be associated with an unacceptable perioperative mortality and morbidity. Therapeutic options for these patients are limited, and neither medical therapy nor balloon valvuloplasty offers survival benefit. Over the past several years, the development of minimally invasive transcatheter valve implantation

has been explored.²⁻¹³ A percutaneous alternative was first developed in an animal model by Andersen and colleagues.^{2,14} Subsequently, a number of groups pursued various approaches to transcatheter aortic valve implantation (AVI).^{2-5,14-18} It was not until a decade after it was initially proposed that the feasibility of percutaneous AVI was demonstrated in human subjects by Cribier and associates^{7,8} using a transvenous transseptal approach. Subsequently, we described a retrograde procedure using percutaneous femoral artery access.¹⁰ We reported the first successful transcatheter transapical AVI through a left minithoracotomy and the apex of the left ventricle without CPB in human subjects in 2006^{11,12} and then our initial experience of transapical transcatheter AVI without CPB in our first 10 patients.^{19,20} We have now completed a 12-month clinical and echocardiographic follow-up in our first 26 patients who underwent transapical transcatheter AVI without CPB.

MATERIALS AND METHODS

The transapical procedure was approved by the Therapeutic Products Directorate, Department of Health and Welfare, Ottawa, Canada, for compassionate clinical use in patients with symptomatic severe aortic stenosis deemed not to be candidates for routine open-heart AVR and unsuitable for percutaneous transfemoral AVI. All patients were assessed independently by at least 2 cardiologists and 2 cardiac surgeons and accepted for the procedure based on the consensus that conventional surgical intervention was excessively high risk in terms of anticipated mortality and

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Abbreviations and Acronyms

AVI	= aortic valve implantation
AVR	= aortic valve replacement
CPB	= cardiopulmonary bypass
NYHA	= New York Heart Association
STS	= Society of Thoracic Surgeons
TEE	= transesophageal echocardiography

morbidity. Patient or physician preference alone was not considered adequate. Written informed consent was obtained.

Patients

Patients who were accepted for transcatheter AVI were initially assessed for suitability for percutaneous transfemoral AVI. Patients underwent preoperative work-up, including coronary and aortofemoral angiography and transthoracic echocardiography (TTE). Transesophageal echocardiography (TEE) was performed when the diameter of the aortic annulus could not be easily measured from the TTE images or a more accurate measurement was required. Transapical AVI was recommended if aortofemoral angiographic analysis revealed unfavorable anatomy of the aorta, iliofemoral arteries, or both for the transfemoral approach.

Prosthetic Valve Implantation

The procedure of transapical transcatheter AVI was described in detail in our previous publications.^{11,19,20} Briefly, the procedure was performed after achievement of general anesthesia in an operating room. The apex of the left ventricle was identified by using a portable C-arm fluoroscopy and exposed through an approximately 5-cm anterolateral minithoracotomy and a small pericardial incision. Two paired orthogonal U-shaped sutures with pledgets were placed into the myocardium and passed through tensioning tourniquets. Epicardial pacing wires were used for rapid ventricular pacing during aortic valvuloplasty and deployment of the prosthesis.

Heparin was administered to achieve an activated clotting time of greater than 250 seconds. Using fluoroscopic, aortographic, and TEE imaging, balloon valvuloplasty and then deployment of the bioprosthesis were performed during rapid ventricular pacing to minimize ventricular ejection without CPB (Figure 1). We used balloon-expandable transcatheter bioprostheses (SAPIENTM THV; Edwards Lifesciences, Inc, Irvine, Calif). Twenty-three-millimeter bioprostheses were used in 6 patients, and 26-mm bioprostheses were used in 20 patients. CPB was not used in any patient. Patients were maintained on aspirin indefinitely and clopidogrel for at least 1 month. Warfarin was initially used in some patients who underwent transapical AVI, but this was abandoned because of the frequency of bleeding intolerance in these elderly patients.

Follow-up and Data Collection

All patients were carefully followed by both cardiac surgeons and cardiologists. Clinical follow-up and echocardiographic results were obtained before discharge from the hospital and at 1, 6, and 12 months. We have completed 12 months of follow-up in our first 26 patients. We present data from the 17 patients who survived more than 12 months for comparisons of preoperative baseline and 1-, 6-, and 12-month follow-up clinical and echocardiographic results.

Echocardiograms were reviewed by our senior echocardiographers. Intraoperative and immediate postoperative acute myocardial infarction was defined by electrocardiographic criteria, whereas acute myocardial infarction during follow-up was defined as an increase of troponin T levels associated with clinical symptoms, electrocardiographic evidence of infarction, or both. Procedure-related major bleeding is defined as significant blood

FIGURE 1. Three major components of the transapical aortic valve implantation: balloon valvuloplasty, deployment, and assessment of the prosthetic valve. TEE, Transesophageal echocardiography.

loss caused by a difficult apical hemostasis and a requirement for blood transfusion intraoperatively. Postoperative bleeding was defined as any significant blood loss requiring surgical intervention, significant blood transfusion (>2 units), or both.

Statistical Analysis

Data are presented as the mean $\pm$ standard deviation. All echocardiographic parameters and New York Heart Association (NYHA) class were matched data from 17 patients who survived for longer than 12 months. The 2-way analysis of variance model was used to compare echocardiographic parameters (aortic valve area, mean transaortic pressure gradient, aortic insufficiency, left ventricular ejection fraction, and mitral regurgitation) and NYHA class between different time points. The paired *t* test was used to compare the left ventricular mass index at the baseline level and at 6 to 12 months after the procedure. The Kaplan–Meier method was used to generate survival curves. The statistical analyses were performed with the SAS (version 9.1.3) statistical software package.

RESULTS

Patients

The baseline characteristics of the 26 patients are shown in Table 1. Significant comorbidities include severe peripheral vascular disease (77%), coronary artery disease (69%), prior cardiac surgery (50%), moderate or severe mitral regurgitation (43%), porcelain ascending aorta (42%), and severe lung disease (27%). EuroSCORE, Logistic EuroSCORE, and Society of Thoracic Surgeons (STS) estimates of operative mortality were $12\% \pm 4\%$, $37\% \pm 20\%$, and $11\% \pm 6\%$, respectively. Several patients were not accepted for conventional AVR despite low estimates of operative mortality because of porcelain ascending aorta, severe lung disease, poor general condition, or end-stage liver cirrhosis.

Intraoperative Outcome

Transapical transcatheter AVI through a left minithoracotomy without CPB was successfully performed in all 26 patients. Twenty patients received 26-mm and 6 patients

TABLE 1. Baseline characteristics of 26 patients

Characteristics	No. of patients	%
Age (80.1 ± 9.1 y)*		
≥ 90 y	3	12
80–89 y	13	50
Female sex	13	50
Body mass index (kg/m^2 ; 22.8 ± 3.1)*		
$\geq 25 \text{ kg}/\text{m}^2$	7	27
Body surface area (m^2 ; 1.68 ± 0.22)* $\geq 1.8 \text{ m}^2$	9	35
New York Heart Association class		
II	5	19
III	17	65
IV	3	12
Hypertension	20	77
Diabetes	2	8
Coronary artery disease	18	69
Severe lung disease	7	27
Cerebral ischemic event	7	27
Peripheral vascular disease	20	77
Prior cardiac surgery	13	50
Estimated glomerular filtration rate $< 60 \text{ mL}/\text{min}$	12	46
Ejection fraction $< 50\%$	5	19
Mitral regurgitation		
III (moderate)	8	31
IV (severe)	3	12
Pulmonary hypertension (systolic pressure $> 60 \text{ mm Hg}$)	6	23
Porcelain aorta	11	42
Smoking	16	62
Severe carotid disease	5	19
Atrial fibrillation	11	43
Permanent pacemaker	4	15
Hemoglobin $< 120 \text{ mg}/\text{L}$	10	38

*Mean $\pm$ standard deviation.

received 23-mm prostheses. In 1 patient a second transcatheter bioprosthesis was implanted after the first transcatheter bioprosthesis was deployed too low within the left ventricular outflow tract. Four patients with moderate paravalvular regurgitation immediately after the deployment of bioprostheses underwent redilatation, with further expansion of the prosthesis and satisfactory reduction in paravalvular regurgitation in 3 patients. One patient died immediately after completion of the procedure in the operating room, probably as a result of obstruction of the left coronary ostium by a native bulky calcified aortic valve. This patient also had significant intraoperative bleeding caused by difficult hemostasis at the puncture site of the LV apex. There was no conversion to open-heart AVR. Procedural characteristics are shown in Table 2.

Early Clinical Outcome

Of the 26 patients, 20 were discharged from the hospital, and 6 died in the hospital or within 30 days after valve implantation. The 30-day mortality was 23%. The characteristics of the 6 patients and the causes of death are listed in

TABLE 2. Procedural characteristics

Characteristics	N = 26 patients	%
Aortic annulus diameter (mm)*	22 ± 2	
Aortic bioprosthesis		
23 mm	6	23
26 mm	20	77
Successful valvuloplasty	26	100
Successful valve implantation	26	100
Postdeployment redilatation	4	15
Fluoroscopic time (min)*	12 ± 3	

*Mean $\pm$ standard deviation.

Table 3. Five of the 6 patients had logistic EuroSCOREs of 20 or greater (20% to 58%), and 1 patient had a low logistic EuroSCORE (2%) despite end-stage liver disease. Twenty patients survived 30 days and had an average hospital stay of 9 ± 5 days. The delayed hospital discharge was mainly due to preoperative comorbidities and general debilitation. Early postoperative complications included major gastrointestinal bleeding from peptic ulcer disease, heart block, pneumonia/sepsis, thromboembolic event (ischemic bowel), and stroke (Table 4).

Late Clinical Outcomes

All procedures (26 patients) were performed 12 or more months before the last follow-up contact. Twenty patients survived for more than 30 days, and 3 additional deaths occurred between 30 days and 1 year (postoperative days 51, 85, and 89). These deaths were due to noncardiac causes, including cancer and pneumonia. Seventeen patients remained alive at the 12-month follow-up. Among 20 patients who survived for more than 30 days, 12-month survival was 85%. Figure 2 shows the Kaplan–Meier survival after transapical transcatheter AVI.

Late complications were uncommon in 20 survivors. One patient had gastrointestinal bleeding, requiring blood transfusion, and another patient needed chest tube drainage for pleural effusion. There were no other significant valve-related complications, such as stroke or transient ischemic attack, myocardial infarction, major arrhythmia, endocarditis, thromboembolic events, or valve structural deterioration/dysfunction during 12 months of follow-up.

In the 17 survivors the majority of the patients (near 80%) had NYHA class III and IV heart failure symptoms before the procedure. Significant early improvement in functional class was achieved in most patients, and more than 80% had NYHA class I or II heart failure symptoms at the 1-month follow-up. Some continued improvement in functional class was observed during 6 to 12 months of follow-up (Figure 3, F).

Echocardiographic Follow-up

All echocardiographic data used for comparisons were obtained only from 17 matched survivors. PredischARGE

TABLE 3. Characteristics of 6 patients who died within 30 days and causes of early death

Characteristics	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6*
Age (y)/sex	91/M	58/M	71/F	91/M	82/F	81/M
Severe lung disease	Yes	No	Yes	No	No	Yes
CAD	Yes	No	No	Yes	No	Yes
Stroke/TIA	Yes	No	Yes	No	No	Yes
Severe PVD	Yes	No	Yes	Yes	Yes	No
GFR <60	No	No	Yes	Yes	No	Yes
Pulmonary HTN	Yes	No	No	Yes	Yes	No
LVEF (%)	40	70	60	60	35	65
NYHA class	4	3	4	2	3	3
Other significant morbidity	Recent CHF, feeding tube	End-stage liver disease	Severe COPD	Severe PVD	ESRD, long-term steroid	Severe COPD
EuroSCORE	16	2	14	11	14	10
Logistic EuroSCORE	58	2	51	20	44	20
STS estimates	14	1.6	9	10	24	11
Days to death	12	5	10	9	0	6
Causes of death	Aspiration pneumonia	Bleeding from chest tube insertion and coagulopathy	Ischemic colitis (embolism?)	Septic shock	Possible left coronary ostial obstruction	Stroke

CAD, Coronary artery disease; TIA, transient ischemic attack; PVD, peripheral vascular disease; GFR, glomerular filtration rate; HTN, hypertension; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; ESRD, end-stage renal disease; STS, Society of Thoracic Surgeons. *Underwent combined transapical aortic valve implantation and minimally invasive coronary artery bypass.

transthoracic echocardiographic analysis documented a significant increase in estimated aortic valve area from $0.5 \pm 0.1 \text{ cm}^2$ preoperatively to $1.7 \pm 0.5 \text{ cm}^2$ ($P < .0001$) and a significant reduction in transaortic mean gradient from 44.5 ± 13.7 to $8.9 \pm 5.0 \text{ mm Hg}$ ($P < .0001$). The prosthetic valve area and transvalvular pressure gradient remained stable during 1 to 12 months of follow-up (Figure 3, A and B). Echocardiography also documented excellent midterm prosthetic valve durability without structural or hemodynamic deterioration during 12 months of follow-up.

The left ventricular ejection fraction increased after AVI from a mean of $56\% \pm 13\%$ preoperatively to $63\% \pm 9\%$ at 12 months (Figure 3, E), although this was not statistically significant. The increase in ejection fraction was mainly as a result of an improvement in the patients with preoperative left ventricular dysfunction. Three patients with severe left ventricular dysfunction had more impressive improvement in ejection fraction from $33\% \pm 3\%$ preoperatively to $57\% \pm 10\%$ at 12 months of follow-up.

Moderate-to-severe mitral regurgitation was present at baseline in 59% of the 17 survivors. A reduction in mitral regurgitation was observed immediately after the procedure, and 23% of the 17 survivors had moderate or severe MR at 12 months (Figure 3, D).

Valvular or paravalvular aortic insufficiency was determined by means of echocardiography. No survivors had aortic insufficiency greater than mild (mild in 47% and trivial/none in 53% of survivors) at 1 month after the procedure. The degree of aortic insufficiency remained unchanged from 1 to 12 months (Figure 3, C). Clinical hemolysis was not observed.

In 9 survivors left ventricular mass indices were available at baseline and at 6 to 12 months of follow-up. In these

patients the left ventricular mass index decreased from $133 \pm 56 \text{ g/m}^2$ preoperatively to $104 \pm 32 \text{ g/m}^2$ at 6 to 12 months after the procedure, but there was no statistical difference ($P = .123$).

DISCUSSION

Open-heart AVR remains the gold standard for the treatment of symptomatic severe aortic stenosis and is associated with minimal operative mortality and morbidity in the majority of patients. However, surgical mortality rates increase in the presence of comorbidities or the need for additional

TABLE 4. Early outcome after transapical aortic valve implantation in 26 patients

Outcome	No. of patients (total = 26)	%
Stroke or transient ischemic attack	1	4
Myocardial infarction	1	4
Procedure-related major bleeding	1	4
Postoperative bleeding	2	8
Atrioventricular block	3	12
Wound infection	0	0
Pneumonia/sepsis	2	8
Postoperative ventilation >10 h	2	8
Acute renal failure	0	0
Blood transfusion >2 units	3	12
Thromboembolic events	1	4
Ventilator time (h)*	6 ± 4	
Hospital stay for 20 patients surviving >30 d (d)*	9 ± 5	
30-d mortality	6	23
12-mo survival	17	65%

*Mean $\pm$ standard deviation.

FIGURE 2. Twelve-month follow-up of echocardiographic parameters and New York Heart Association (NYHA) functional class in 17 patients surviving more than 12 months (matched data). * $P < .0001$ versus preoperative baseline. MR, Mitral regurgitation; Pre-op, preoperative; Post-op, postoperative; AR, aortic regurgitation.

cardiac procedures.²¹⁻²⁸ A considerable number of potential surgical candidates have significant comorbid conditions, and cardiac surgery with CPB might pose risks that are unacceptable to them or their physicians.^{29,30} According to the STS database (1998–2001), surgical AVR carries a rate of serious complication or mortality of 16.8%. Although the mortality of selected octogenarians undergoing cardiac surgery compared with that of younger patients is only moderately increased, their morbidity is clearly higher. Reported mortality for septuagenarians and octogenarians undergoing primary isolated AVR ranges from 6.6% to 16.7%, whereas reported operative morbidity, including atrial fibrillation, in elderly patients (>70 years old) after AVR with or without coronary artery bypass was up to 64% to 76%.^{22,31,32}

Transcatheter AVI is an evolving surgical procedure developed in part to deal with an increasing preoperative risk profile of the patient population with symptomatic aortic valve disease. The clinical feasibility of the transapical transcatheter AVI has been well documented.^{11,12,19,20,33} This report represents the longest follow-up data on transapical transcatheter AVI in a relatively large number of patients

($n = 26$) being followed clinically and echocardiographically for at least 12 months. These patients were judged to be poor candidates for routine cardiac surgery by 2 independent surgeons because of an unacceptably high risk of operative mortality and particularly morbidity. These patients were also declined for transcatheter transfemoral AVI, mainly because of severe aortic or peripheral vascular

FIGURE 3. Kaplan-Meier survival. Pts, Patients.

disease, or had failed transfemoral AVI. The estimated operative mortality was $37\% \pm 20\%$ by using the logistic EuroSCORE and $11\% \pm 6\%$ by using the STS Risk Calculator. Our observed 30-day mortality in this initial cohort of patients was 23%, which is higher than STS estimates. However, the prediction models are based on retrospective analysis of patients who underwent conventional AVR, which contains a few patients with risk profiles similar to those of our patient cohort. Many risk factors that were observed in our patients are not well reflected by these scoring systems, such as end-stage liver disease, prolonged preoperative hospital stay, general deconditioning, immobility because of other medical conditions, significant abnormalities of other valves, severity of peripheral vascular and aortic disease, and end-stage lung disease. These risk factors are also the major contribution to the early and late mortality and morbidity after transapical transcatheter AVI, which would explain our relatively high 30-day operative mortality. Nine of our 26 patients had EuroSCOREs of greater than 50%, several patients had end-stage lung and liver diseases, and the majority of our patients had severe systemic vasculopathy. We believe that patient selection has a direct effect on operative mortality. Furthermore, the learning curve of the novel procedure would also have an effect on our operative mortality because the operative mortality in our last 30 patients decreased to 13% (unpublished data). Early major complications are observed in 9 patients, of whom 6 died within 30 days. Early operative mortality could be reduced significantly by preventing perioperative complications, such as bleeding and pneumonia, and appropriate patient selection. The causes of late mortality (11.5%) are noncardiac, including pneumonia in 2 patients and cancer in 1 patient. There were no late valve-related or procedure-related complications in this cohort of patients during the 12 months of follow-up.

The transapical approach for transcatheter AVI is reliable, with acceptable operative risks and favorable clinical and echocardiographic outcomes in the majority of these very high-risk patients. Postoperative recovery, length of hospital stay, and late survival are largely dependent on preoperative comorbidities and general health conditions. The procedure provides immediate relief of symptoms related to aortic stenosis, such as angina, presyncope, or syncope, and continued improvement in heart failure symptoms during the 12 months of follow-up. The majority of survivors (94%) had NYHA class I or II heart failure symptoms at 12 months after the procedure. Most of the survivors were very satisfied with their cardiac conditions and living independently at follow-up.

Transcatheter bioprosthetic valve function appeared excellent, without evidence of structural valve deterioration/dysfunction or inadequate fixation at 12 months after implantation. Trivial-to-mild paravalvular regurgitation was common immediately after deployment of the prostheses but remained stable at 12 months. More significant paravalvular

regurgitation resulting from incomplete deployment of the bioprosthesis can be effectively reduced by repeat balloon dilation.³⁴ This has been demonstrated in 2 patients. However, repeat balloon dilation is not effective in reducing significant paravalvular regurgitation caused by suboptimal positioning of the bioprosthesis, which was seen in 1 patient.

Concomitant severe mitral regurgitation or significant coronary artery disease in the presence of severe aortic stenosis is generally considered an indication for a combined surgical procedure with an attendant increase in operative mortality and morbidity, particularly in patients with advanced age and significant comorbid conditions. In the present series 59% of patients had moderate-to-severe mitral regurgitation. A decrease in mitral valve regurgitation and an increase in left ventricular function after transapical AVI suggest that a conservative approach to coexisting mitral valve regurgitation might be a reasonable approach in selected patients.

Coronary artery disease was present in 69% of patients. Although prior coronary artery grafting and angioplasty had been performed in the distant past in 31% and 19%, respectively, many patients had residual nonrevascularized coronary disease. One patient underwent prophylactic preprocedural angioplasty, and 1 patient had a combined minimally invasive coronary artery bypass and transapical AVI. No early and late myocardial infarction in this cohort of patients was observed during 12 months of follow-up, which suggests that aggressive interventions for moderate coronary artery disease before the transapical procedure might not routinely be necessary.

The risk of perioperative stroke appeared low because it was observed only in 1 (3.8%) patient during 12 months of follow-up. The low incidence of stroke, particularly with the transapical approach, is likely a result of (1) avoidance of passing a large catheter through the aortic arch and ascending aorta, as occurs during transfemoral retrograde AVI; (2) an antegrade, rather than retrograde, approach to the calcified aortic valve; or both. Obstruction of the coronary ostium by a bulky calcified native valve, the transcatheter bioprosthesis, or both has been documented, but the incidence appears infrequent.¹⁰ We observed this complication in 1 patient in this series. Preoperative assessment of the amount of the calcification, location of the bulky calcification, location of the coronary ostia, and anatomy of the aortic root might reduce the risk of this fatal complication.

Device embolization is a documented complication³⁵ but was not observed during early and late follow-up in this cohort undergoing transapical AVI. Theoretically, better coaxial positioning and stabilization of the device during deployment can be achieved with the transapical approach because of a short straight line from the apex to the annulus, relative to the transfemoral approach. Given the small numbers treated to date, this remains to be evaluated. We believe that the experience of surgeons, interventional cardiologists,

and echocardiographers plays a major role in avoiding this complication.

In summary, our 12-month clinical and echocardiographic outcomes suggest that transapical transcatheter AVI is a viable alternative to conventional open-heart AVR in selected high-risk patients with symptomatic severe aortic stenosis. Although excellent structural and hemodynamic stability of the bioprosthesis is demonstrated at 12 months of follow-up, in vivo long-term durability of the transcatheter bioprosthesis remains to be determined. Both the technology and techniques in transapical transcatheter AVI continue to evolve, and we are all in a process of learning who will be the most appropriate candidates. Conventional open-heart AVR remains the first-line therapy for symptomatic severe aortic stenosis.

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