Transcatheter Aortic Valve Implantation

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Abstract: There has been significant improvement in device designs, operative techniques, and early clinical outcomes in <5 years. Presently, there are two catheter-based bioprostheses (balloon expandable or self-expandable), which have been widely used in humans and are undergoing clinical investigations. Three approaches, including transvenous, transarterial, and transapical have been used for delivery of the catheter-based bioprostheses, and transarterial and transapical approaches have been adopted by cardiologists and cardiac surgeons worldwide. The most recent clinical results have been very encouraging and promising. With experience, 30-day operative mortality with either balloon-expandable or self-expandable bioprosthesis was reduced significantly to approximately 10% in high-risk patients. In vivo long-term durability of catheter-based bioprostheses remains unknown, and presently transcatheter procedure is limited to the cohort of high-risk patients. Expanding this new technology to low-risk patients should be done with extreme caution because conventional aortic valve replacement still provides the best long-term outcome with minimal operative mortality and morbidity in low-risk patients. Ongoing clinical trials will address many unanswered questions, such as patient selection, long-term in vivo durability, preoperative assessment, and the role of the procedures in management of valvular diseases.

Key Words: Transcatheter, Aortic valve implantation, Aortic valve replacement, Aortic stenosis, Stented bioprosthesis.

Conventional aortic valve replacement (AVR) with cardiopulmonary bypass (CPB) has been the only treatment that offers both the 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 Surgical intervention is based on standardized guidelines, which have resulted in excellent outcomes using conventional surgical AVR, especially in patients with a relatively low-risk profile.2–4 Even in octogenarians, recently published data indicates good patient outcomes.5–7 However, because a considerable number of elderly patients with symptomatic severe aortic stenosis have significant co-morbidities, conventional AVR with CPB can be associated with an unacceptable perioperative mortality and morbidity risk. A significant number of patients with aortic stenosis may not ever be referred for surgical assessment because of advanced age and other significant comorbidities.8,9 Therapeutic options for these patients are limited, and neither medical therapy nor balloon valvuloplasty offers survival benefit.9 Therefore, alternative minimally invasive AVR needs to be further investigated, developed, and evaluated to increase the safety of the procedure in these very high-risk patients. Over the past several years, the development of minimally invasive transcatheter valve implantation has been explored.10–16 A percutaneous alternative was first developed in an animal model by Andersen et al.17 Subsequently, a number of groups pursued various approaches to transcatheter aortic valve implantation (AVI).10,17–20 However, it was not until a decade after it was initially proposed that the feasibility of percutaneous AVI was demonstrated in humans by Cribier et al12,21 using a transvenous, transseptal approach. Subsequently, we described a retrograde procedure using percutaneous femoral artery access for transcatheter AVI.14 We then further reported the first successful transcatheter, transapical AVI through a left minithoracotomy and the apex of the left ventricle without CPB in humans in 2006,15,16 and our accumulated experience of transapical transcatheter AVI without CPB.22–24

Historical Perspectives in Development of Transcatheter AVI

The concept of transcatheter valve implantation for the treatment of aortic valve disease was proposed by Davies25 in 1965 and then by Andersen et al in 1992.17 Thereafter, transcatheter AVI was evaluated in various animal models.17–19 The first successful human percutaneous transcatheter implantation of a stented valve in a pulmonary position was performed by Bonhoeffer et al26 in 2000. The first successful catheter-based human AVI with a balloon-expandable stented tissue valve using transvenous approach was described by Cribier et al in 2002.21 The transcatheter valve procedure was not widely accepted until 2006 when the retrograde approach through a femoral artery (transarterial approach) for successful transcatheter AVI was reported by Webb et al24 at our center. The transarterial approach requires peripheral arterial access, which might not be available in elderly patients with significant peripheral vascular and aortic disease. Therefore, an alternative approach through the left ventricular (LV) apex (transapical approach) was explored.
for transcather AVI and was successfully performed in a human at our center in 2005,\textsuperscript{15,16} which further energized transcatheter valve procedures.

Current Transcatheter Aortic Valves

Cribier-Edwards Valve

The Cribier-Edwards valve (Edwards Lifesciences Inc., Irvine, CA) was the earliest generation of a balloon-expandable aortic equine pericardial tissue valve mounted on stainless steel stent (Fig. 1A). One third to half of the ventricular end of the stent is covered with a fabric sealing cuff, which is proposed to be approximated and anchored to the aortic annulus and reduce the potential for paravalvular regurgitation. This was successfully implanted in humans during our early clinical experience with transarterial and transapical AVI.\textsuperscript{14,15,23} It was suggested that the narrow fabric sealing cuff covering less than half of the stent might be inadequate to eliminate paravalvular leaks. Therefore, a wider fabric sealing cuff was used in the next generation of balloon-expandable aortic tissue valves.

SAPIEN\textsuperscript{™} Valve

The SAPIEN\textsuperscript{™} valve (Edwards Lifesciences Inc., Irvine, CA) is the current generation of balloon-expandable aortic tissue valves (Fig. 1B). The differences between the SAPIEN\textsuperscript{™} valve and the Cribier-Edwards valve are the material of the leaflets and the width of the fabric sealing cuff. In the SAPIEN\textsuperscript{™} valves, the leaflets are bovine pericardial tissue, rather than equine, the same as the materials used for the most recent generation of Edwards’ surgical bioprostheses. Therefore, the SAPIEN\textsuperscript{™} valve is hoped to have similar good durability. In the SAPIEN\textsuperscript{™} valve, the width of the fabric cuff covers two thirds of the ventricular end of the stent, which potentially will reduce paravalvular leaks even further. The valve is presently available in two sizes with external diameters of 23 and 26 mm. A 29-mm diameter is in development.

CoreValve ReValving\textsuperscript{™} System

The CoreValve ReValving\textsuperscript{™} system (CoreValve Inc., Irvine, CA) includes a self-expandable tissue valve that is constructed of a nitinol frame with trileaflet porcine pericardial tissue valve and a catheter delivery system (Fig. 2). The complete support frame of the valve is 45 mm in axial length. The upper portion of the frame anchors in the aorta above the coronary sinuses, the middle portion with a sealing cuff contains the tissue leaflets, and the lower portion is implanted in the subannular region. The lower portion of the prosthesis has high radial force to expand and displace the calcified leaflets and to prevent recoil. The prosthesis exists in two sizes according to the ascending aortic diameter (<23 mm and <45mm). Therefore, the ascending aorta diameter must be <45 mm. The catheter delivery system is now reduced to 18Fr (third generation) (Fig. 2), which is currently considerably smaller than the delivery catheter for balloon-expandable tissue valve, a major advantage for the transarterial approach.

Approaches for Aortic Valve Implantation

Transvenous Transseptal Approach

This approach was used during the initial AVI described by Cribier and coworkers.\textsuperscript{21,27} This approach was used for several reasons: (1) it allows the percutaneous insertion of the large 24F sheath through the femoral vein, with no need for surgical cut down; (2) it decreases the risk of vascular complications; (3) during valve delivery, the blood and the delivery catheter move in the same direction, antegrade across the aortic valve, facilitating the accurate positioning of the device within the native aortic valve. The technique is similar to the one used for Percutaneous Mitral Commissurotomy. The prosthetic valve is advanced through the femoral vein, inferior vena cava, right atrium, across the atrial septum, through the mitral valve, and left ventricle, to
With this approach, there is potential for trauma to the mitral valve that is made both stenotic and regurgitant during the procedure in already hemodynamically compromised patients. Although this has been successfully used in human transcatheter AVI, it is technically quite complex and therefore less transferable.

Transarterial Approach

This familiar approach is similar to that used for coronary angiography, LV angiography, and aortic valvuloplasty using a retrograde femoral arterial access. With this approach, a balloon-expandable stent tissue valve is advanced retrogradely through the femoral artery, iliac artery, and aorta and deployed retrogradely across the aortic valve (Fig. 1C). Compared with the transvenous approach, the approach has several advantages including a less complex and familiar direct route, easier positioning and stabilization during deployment, potential for retrieval of the stent tissue valve if embolized into the aorta, and generally less technically demanding. However, the disadvantages include retrograde crossing of aortic valve, increased intra-aortic manipulation, which may be a potential risk factor for stroke particularly in patients with severe artheromatic disease in the ascending aorta or aortic arch, and access limitation because of small iliofemoral arteries, excessive iliofemoral stenosis, calcification, or aortoiliac tortuosity. With continuous improvement in the device and the delivery systems, these disadvantages will likely become of less concern. This approach is suitable for implantation of both balloon-expandable and self-expandable stent tissue valves, which has been successfully adopted worldwide over the past 3 years.

Transapical Approach

The transapical approach was used previously by surgeons for closed mitral valvuloplasty for rheumatic mitral valve stenosis. In the present era, this approach is used to deliver a stent tissue valve antegradely across the aortic valve, position and deploy the stented valve at the aortic annulus through the apex of the left ventricle, which is exposed via a left anterior or anterolateral minithoracotomy (approximately 5 cm) (Fig. 3). Ye et al reported the first successful human transapical transcatheter AVI for severe aortic stenosis, and the transapical approach has now been adopted by many surgeons worldwide with reproducible results. Currently, with this approach, general anesthesia and surgical closure of the apex are necessary. Relative to other approaches, the major advantages of the transapical approach include independence of the size and the disease of the iliofemoral arteries, no limitations on valve and delivery sheath sizes, less intraaortic manipulation, a short straight route, and better positioning/stabilization. Because of accuracy of positioning, this approach is most suitable and the only one used by our group for transcatheter aortic or mitral valve-in-valve implantation for failed previously implanted bioprosthetic valves.

Defining High-Risk Patients

Despite the interest in the procedure, transcatheter AVI remains a clinical investigational procedure. The general agreement is that the new procedure should be initially reserved for patients who meet standard indications with surgical AVR, but are defined as “high risk or unacceptable risk” for operative mortality and morbidity for conventional open heart AVR. However, it is difficult to arrive at a clear or agreeable definition of high risk or unacceptable risk among cardiac surgeons and cardiologists at which level a patient is contraindicated for conventional open heart AVR and justified for the investigational treatment. To minimize the significant dispute in determining high-risk patients, several predictive risk models developed from large surgical data-
bases have been used to ascribe objective quantitative risks of operative mortality and morbidity for patient selection. The two most commonly used risk models are the European System for Cardiac Operative Risk Evaluation (EuroSCORE),31 which was also validated in North America,32 and the STS Risk Calculator.33 It has been generally agreed that logistic EuroSCORE greater than 20% or STS score higher than 10% is considered high risk for conventional open heart AVR. However, these risk models are not precise or entirely consistent, particularly in the elderly. In our experience, we feel that the logistic EuroSCORE most likely overestimates operative risks, whereas the STS Risk Calculator probably underestimates surgical risks. These predictive models are based on retrospective analysis of patients who have undergone conventional open heart surgery and contains few patients with risk profiles similar to the cohort of “nonoperative” patients or patients with unacceptably high risk that would be candidates for transcatheter valve procedures. Many risk factors that have been observed in nonoperative patients are not well reflected by these scoring systems, such as end-stage liver disease, prolonged preoperative hospital stay, general deconditioning, frailty, immobility because of other medical conditions, degree of obesity, significant abnormalities of other valves, severity of peripheral vascular and aortic disease, previous chest wall radiation, previous infected sternotomy, and end-stage lung disease. On the other hand, patients with high logistic EuroSCORE (>20%) or STS score (>10) may still be reasonable candidates for conventional AVR. We believe that a combination of objective quantitative predictive risk models and subjective assessments by experienced surgeons is the best way to characterize individual risks.

Potential Candidates for Transcatheter AVI

The indications for conventional open heart AVR are clearly stated in the American Heart Association/American College of Cardiology guideline. Conventional AVR has been the only treatment that offers both the symptomatic relief and the potential for improved long-term survival, and hence is the treatment of choice for patients with symptomatic severe aortic stenosis.1 It has also been demonstrated that patients of 80 years or older, who were candidates for conventional AVR, but refused to have surgery, had poor survival (~40%), compared with a similar group of patients who underwent AVR surgery (87% survival at 3 years). The group of patients, who were declined for AVR by surgeons, had dismal survival (19%).34 The EuroHeart Survey on Valvular Heart Disease showed 32% of patients with symptomatic aortic stenosis indicated for conventional AVR were declined for surgery and managed conservatively.8 The reasons given for declining surgery of these patients included advanced age, comorbidities, “end-stage” diseases, reduced symptoms after conservative treatment, and patient’s refusal. These reports lend support to the notion that lesser invasive interventional/surgical treatments need to be developed, such as transcatheter AVI, which would minimize operative mortality and morbidity while retaining the effectiveness of conventional AVR. Thereby, the group of patients who are at high risk for conventional AVR would benefit from the less invasive treatment. During early development of transcatheter AVI, the procedure was approved for compassionate use only in patients who were deemed to be nonsurgical candidates because of unacceptable operative risks of mortality and morbidity, which was assessed by at least two cardiologists.
and two cardiac surgeons. Subsequently, the combination of the EuroSCORE risk model and surgeons’ assessment was used to achieve more consistent agreement in selecting candidates for transcatheter AVI. As it is suggested that the logistic EuroSCORE risk model most likely overestimates operative risks in the elderly population, the STS Risk Calculator has been adopted to define high-risk patients who could benefit from the transcatheter procedure. Although operative mortality is one of the major factors in determining candidacy of patients for conventional AVR, evaluation of operative morbidity and potential for postoperative improvement in quality of life are probably more critical in defining high-risk patients in the elderly (>80 years old). The group of patients with more advanced age (>90 years old) could benefit from the transcatheter procedure even though the STS score is <10%. In the ongoing PARTNER trial, the criteria to determine potential candidates includes the combined risk of operative mortality and morbidity greater than 50% estimated by two surgeons (medical treatment versus transcatheter AVI), operative mortality >10% by the STS Risk Calculator (conventional AVR versus transcatheter AVI), or predicted operative mortality >15% estimated by three surgeons (conventional AVR versus transcatheter AVI). Patients with specific morbidities, such as porcelain aorta, liver failure, severe lung disease, previous sternotomy complicated by extensive mediastinitis, or other medical diseases limiting life expectancy, most likely would benefit from transcatheter AVI. With proof of effectiveness and durability of transcatheter tissue valve and minimization of operative risk, we believe that potential candidates for transcatheter AVI will inevitably include younger and less risky patients with symptomatic aortic valve disease in the future. Furthermore, our primary experience has indicated a great potential for repeat transcatheter valve-in-valve implantation after initial transcatheter AVI. The feasibility of valve-in-valve implantation would enlarge potential candidates involving younger patients, even if the in vivo durability of the transcatheter tissue valve is confirmed to be less than that of current surgical tissue valves. Furthermore, the proven ability to implant a transcatheter stented valve into a failed previously surgically implanted bioprosthesis will likely reduce the age for bioprosthetic valve choice over mechanical valves in the general population.

**Patient Selection**

Currently, there are no standardized recommendations on selection of candidates for transcatheter AVI. At our center, patient selection requires multidisciplinary consultation involving cardiac surgeons, cardiologists, echocardiographers, radiologists, and anesthesiologists. Presently, transcatheter AVI is recommended only for patients with calcified aortic stenosis with or without regurgitation and is not offered in patients with pure aortic regurgitation. The process of patient selection involves several steps, including confirmation of severity of aortic stenosis and indications for AVR, evaluation of operative risk, and assessment of candidacy of conventional AVR and suitability of transcatheter AVI. The potential candidates for AVI must have severe aortic stenosis, which meet the indications for conventional AVR according to the American College of Cardiology/American Heart Association guidelines. Furthermore, these patients are at high risk, unacceptably high risk, or contraindicated for conventional AVR as described earlier. It is also recommended that the transcatheter AVI should be offered only to the candidates who have life expectancy of ≥1 year. The suitability for transcatheter AVI is assessed by our transcatheter team including cardiac surgeons and cardiologists who are performing the procedure. Certainly, the qualified candidates should also be assessed by anesthesiologists to confirm the suitability for general anesthesia. Conventional coronary angiography, conventional aortofemoral angiography, and transthoracic echocardiography are routinely performed. Computed tomography aortofemoral angiography is necessary when conventional angiography shows borderline sizes of iliofemoral arteries if transfemoral artery approach is considered. Transesophageal echocardiography is performed if the aortic annulus size is of borderline and more accurate measurements of the annulus are necessary before the procedure. We believe that transesophageal echocardiography gives the most accurate measurement of the aortic annulus if this is performed by experienced echocardiographers. Currently, general contraindications for transcatheter AVI include (1) aortic annulus size of <18 or >25 mm for balloon-expandable transcatheter valves, and <20 or >27 mm for self-expandable valves, (2) sinotubular junction dimension of >45 mm for self-expandable transcatheter valves, (3) LV thrombus, (4) critical and diffuse obstructive coronary artery disease that is not amenable to revascularization and would put the patient at risk during rapid ventricular pacing, (5) bulky calcification near one of the coronary ostia, and/or one of the coronary ostia located unusually low toward the annulus, and (6) endocarditis. Relative contraindications include (1) bicuspid aortic valve, (2) aortic annulus size of 25 to 26 mm with heavily calcified cusps, (3) severe LV dysfunction, particularly left ventricular ejection fraction <20%, (4) large mobile atheroma in the ascending aorta and/or aortic arch, (5) concomitant significant mitral stenosis with significant mitral annular calcification, and (6) obstruction of LV outflow tract. Regarding selection of balloon-expandable valve sizes, the general agreement at our center is that a 23-mm valve is appropriate for an annulus diameter of 18 to 22 mm, and a 26-mm valve for an annulus diameter of 22 to 25 mm. A 26-mm valve could be considered for an annulus diameter of 25 to 26 mm with severe calcification uniformly distributed in three native cusps.

**Clinical Experience**

**Transarterial Balloon-Expandable Valve**

Initial experience suggested transarterial AVI was feasible and reproducible in humans with encouraging clinical outcomes in a selected high-risk group of patients. Subsequently, we reported early outcomes in the initial 50 patients with transcatheter AVI with balloon-expandable stent valves using a retrograde femoral arterial approach. Valve implantation was successful in 86% of patients. With experience, procedural success improved from 76% in the first 25 patients to 96% in the second 25 patients. Intraprocedural mortality
was 2% and 30-day mortality 12% in patients in whom the logistic EuroSCORE was 28%. Echocardiographic aortic valve area increased from preprocedural 0.6 ± 0.2 cm² to 1.7 ± 0.4 cm², which was associated with significant improvement in heart failure symptoms. These improvements were maintained at 1 year after the procedure. Paravalvular leaks ranged from trivial to mild in the majority of patients, which proved to be clinically insignificant. Stroke rate was 4% in this initial cohort of patients. One-year survival after transfemoral AVR was about 80%. Now the overall mortality in the initial 114 patients decreased to 7.9% (logistic EuroSCORE 31% ± 9%, STS score 9% ± 4%) with 0% mortality in the last one third of patients (unpublished data). A similar early outcome was found in the multicenter REVIVAL II study with a 30-day mortality of 12.5% in selected high-risk patients who underwent transarterial AVI with balloon-expandable valves.

Interim follow-up results from the precommercial transapical PARTNER EU registry, which included 54 transfemoral patients (logistic EuroSCORE 25.3%), showed a 30-day survival of 92% and a 6-month survival of 90%. The 30-day results from the postapproval commercial SOURCE registry including 303 cases (logistic EuroSCORE 26.4%) in 12 European countries showed a 30-day survival of 93.6% and a stroke rate of 3.4%. The preliminary outcomes of both PARTNER EU and SOURCE demonstrate very encouraging results (Heartwire at www.medscape.com).

Transapical Balloon-Expandable Valve

Transapical transcatheter AVI through a left minithoracotomy without CPB in a human was reported in 2006. This patient was hospitalized for severe congestive heart failure due to severe aortic stenosis before the procedure, and now has been living free of heart failure for > 3 years after the procedure. We then reported our early clinical experience22 and 6-month outcome,23 which confirmed the feasibility and reproducibility of the procedure, as well as encouraging early clinical outcomes. In this very initial cohort of high-risk patients who were deemed to be unsuitable for both open heart surgery, as assessed by at least two surgeons, and for the transarterial approach mainly because of severe peripheral vascular disease, there was no intraprocedural mortality and 30-day mortality was 14% (logistic EuroSCORE 31% ± 23%). Follow-up echocardiography demonstrated stable transcatheter valve size (1.5 ± 0.5 cm²) and mean gradient (11 ± 8 mm Hg) at 6 months. Clinical improvement in heart failure symptoms was maintained at 6 months. Recently, we reported 12-month follow-up on our first 26 patients. All patients with symptomatic aortic stenosis were declined for conventional AVR and were noncandidates for transfemoral AVI. Mean age was 80 ± 9 years and the predicted operative mortality was 37% ± 20% by logistic EuroSCORE and 11% ± 6% by STS Risk Calculator. Six patients died within 30 days (30-day mortality 23%), and three patients died of noncardiovascular causes after 30 days (late mortality 12%). One-year and 2-year survival were 64.8 ± 9.5 and 56.7% ± 11.2%, respectively. There were no valve-related complications up to 48-month follow-up. New York Heart Association functional class improved from preprocedural III–IV to I–II at 12 months after the procedure. The aortic valve area and mean gradient remained stable at 12 months (1.6 ± 0.3 cm² and 9.6 ± 4.8 mm Hg, respectively). Transvalvular or paravalvular aortic insufficiency remains in the range of zero to mild (mild in 47% and trivial/none in 53% survivors) at 12 months after the procedure. Excellent structural and hemodynamic stability of the bioprosthesis suggest that transapical transcatheter AVI is a viable alternative to conventional open heart AVR in selected high-risk patients with symptomatic severe aortic stenosis. Currently, this single center experience approaches 70 transapical cases (unpublished data), mortality remains 13.5% (EuroSCORE 34.9% ± 20.5%, STS 12.2% ± 8.0%) after our first 15 cases (30-day mortality 33.3%), which clearly indicates a significant learning curve for those institutions entertaining the introduction of this modality. Overall 3-year survival rate was 65.8% ± 6.2%. There was no evidence of structural valve deterioration beyond 3 years. The cohort of our patients for transapical AVI are the sickest patients who could be accepted for any interventional treatment for aortic stenosis because these patients were declined for conventional AVR and transarterial AVI. Severe peripheral vascular disease was diagnosed in > 70% of our patients.

In the United States feasibility study of transapical AVI in 40 patients (STS score 13.4%, logistic EuroSCORE 35.5%), 30-day mortality was 17.5% with a further 5% mortality before discharge at 42 and 72 days. There was no immediate postoperative stroke. The Kaplan-Meier survival was 81.8% ± 6.2% at 1 month and 71.7% ± 7.7% at 3 months. Similar findings were observed in European experiences in transapical AVI with 30-day mortality of 8% to 13.6% and survival of 71.4% at 1 year.28,29

Interim follow-up results from the precommercial transapical PARTNER EU registry including 67 transapical patients (logistic EuroSCORE 33.5%) showed a 30-day survival of 82% and a 6-month survival of 56%. A 30-day survival for transapically treated patients in SOURCEN was 88.4% (mean logistic EuroSCORE 30%)(Heartwire at www.medscape.com).

The reported early survival seems less favorable in transapical patients than in transfemoral patients, but this is most likely due to the fact that the transapical patients are generally sicker and have more comorbidities, such as peripheral vascular disease, severe aortic disease, and previous mitral valve replacement, than the transfemoral patients.4,24 It has been demonstrated that patients with peripheral vascular disease have a greater risk of stroke and mortality after either conventional valve replacement or reoperative valve replacement.38 This probably results in negatively biased results with transapical AVI. Conclusions on this issue await a randomized trial.

CoreValve “ReValving™” Procedure

The first successful implantation of the CoreValve stent valve was reported by Grube et al in 2005. The initial largest clinical series of CoreValve implantation was reported in 2006, in which 25 patients with aortic stenosis underwent...
AVI using transarterial retrograde approach under the support of extracorporeal percutaneous femorofemoral bypass. Device success and procedural success were achieved in 88% and 84% of patients, respectively. In-hospital mortality was 20% (median logistic EuroSCORE 11.0%) and major inhospital cardiovascular and cerebral events occurred in 32% of patients. There were no incidence of valve migration and no cases of moderate or severe paravalvular leaks. Mean transvalvular pressure gradient was 12.4 ± 3.0 mm Hg. Subsequently, a multicenter experience including 86 patients was reported in which acute procedural success was 74% with overall 30-day mortality of 12% (Logistic EuroSCORE 21.7% ± 12.6%) and stroke rate of 10%.41

Since then, there has been significant improvement in device design, operative technique, and early clinical outcomes. The latest results from 1243 patients in the 18F ReValving™ postmarketing registry showed a procedural success rate of 98% and major complications including aortic dissection, major bleeding, cardiac tamponade, conversion to surgery, and access-site complications, of ≤2% (Heartwire at www.medscape.com). Recently, CoreValve announced that >1800 high-risk patients have been treated with its ReValving™ System for percutaneous AVI. The data from the CoreValve Registry showed 30-day survival of about 90% (logistic EuroSCORE 23%) (www.corevalve.com).

**Transcatheter AVI versus Medical Management**

In the recent study from Kojodjojo et al, three groups of patients of 80 years or greater were followed for 3 years to investigate the impact of patient’s choice of refusing conventional AVR on survival. The group of patients who were accepted for AVR, but refused the surgery has ~68% and ~48% survival at 1 and 2 years, respectively, which was significantly lower than the group of patients who were accepted for AVR and underwent the surgery (~89% and ~88% at 1 and 2 years, respectively). The group of patients who were declined by surgeons for conventional AVR had the lowest survival at 1 and 2 years (~50% and ~26%, respectively).34 The group of patients who were declined for surgery in Kojodjojo’s study are probably similar to the population of patients currently undergoing transcatheter AVI. Reported 1-year survivals after transcatheter AVI were at the range of 65% to 80% and 2-year survival was 57%. This suggests that transcatheter AVI probably improves survival in high-risk or nonoperative patients compared with conservative management, although no definite conclusions can be made at this time.

**Unique Complications**

**Paravalvular Leak**

Trivial-to-mild paravalvular leaks are common immediately after transcatheter AVI, but remained stable during follow-up.14,23,24,36 More significant paravalvular leaks are infrequent and most likely result from incomplete deployment or suboptimal positioning of the bioprostheses. Incomplete deployment of a valve can be corrected by repeating balloon dilatation in the majority of cases. Significant mal-positioning of a valve may require deployment of a second transcatheter bioprosthesis. Clinically important hemolysis has not been observed to date.14,36

**Stroke**

It was initially thought that deploying a tissue valve into a calcified native aortic valve would carry a high risk of stroke. However, cumulative experience does not support this concept. Reported incidences of stroke were approximately 4%,24,29,30,36 It has been suggested that the incidence of stroke may be lower with transapical approach because of less manipulation in the aortic arch compared with transarterial approach, but this remains to be confirmed by a randomized trial or with a large database. The cause of early stroke is most likely as a result of thromboembolism from the calcified native valve, diseased aortic arch/ascending aorta, clots on catheters, or air. The incidence of late stroke has been extremely rare, and there has been no evidence of valve thrombosis with current antiplatelet treatment only, and no evidence to support the use of warfarin after transcatheter AVI.

**Coronary Obstruction**

Coronary obstruction is a fatal complication with transcatheter AVI. Fortunately, this complication is rare.14,24 This occurred in one of 70 transapical cases at our center, as a result of bulky native valve calcification displaced toward the left main ostium after deployment of the tissue valve. Immediate stent of the left main may be effective. Preoperative assessment of the bulkiness of the native valve calcification, distance from the coronary ostia to the annulus, and the ratio of the sinus valsalva and annulus diameters may be helpful in predicting the risk of this complication. If a bulky calcium load is seen to move toward the coronary ostium during valvuloplasty, the procedure should be abandoned.

**Valve Embolization**

Prosthetic embolization occurred mainly in the early experience with transcatheter, particularly transarterial, AVI.42-44 This complication is primarily because of malpositioning of a valve or incorrect selection of a valve size. With increased experience, this complication decreased significantly. We have not observed valve embolization in our 70 transapical patients. Relative to the transfemoral approach, transapical approach may carry less risk of this complication because of more accurate positioning and better catheter stabilization during valve deployment. The best management of an embolized bioprosthesis is to anchor it to the aorta preferably distal to the origins of arch vessels to avoid compromise of blood flow through the arch vessels.42 This is only possible if the guide wire remains in place to prevent the valve from flipping into a permanently closed position, and therefore the guide wire should not be removed until the end of the procedure. Embolization of a bioprosthesis into the left ventricle is very rare, but very challenging. Surgical removal is probably the only option.43
Apical Bleeding

Apical bleeding is a unique complication with transapical AVI and occurred mainly in our initial experience with the transapical procedure.²⁴ Massive apical bleeding is rare, but could be fatal. Temporary percutaneous femorofemoral bypass support may be required to control apical bleeding. The risk factors include friable tissue, fatty apex, chronic use of steroid, dilated LV with thin walls, and hypertension during removal of a valve delivery sheath. However, the most important risk factors are probably because of the inappropriate surgical techniques for the placement of purse-string sutures or two “U shape” orthogonal sutures in the apex, and a lack of initial experience in dealing with apical bleeding in an emergent situation.

Heart Block

As seen in conventional AVR, heart block also occurs after deployment of a transcatheter valve. This is probably as a result of displacement of calcification that causes permanent pressure on or injury to the atrioventricular conducting system. The ventricular end of the valve stent could also be responsible for injury to the conducting systems located in the ventricular septum. Reported incidences are at the range of 4% to 18%. Potential risk factors include aggressive oversizing, small LV outflow tract, subaortic calcification near the membranous septum, pre-existing atrioventricular block, and deployment of the valve too far below the aortic annulus.

CONCLUSION

Significant achievements in transcatheter valve implantation have been made within the last 5 years and the most recent results have been very encouraging and promising. Ongoing clinical trials will address many unanswered questions. Because in vivo durability of transcatheter valves remains unknown and there are some fatal complications related to this new valve procedure, expanding this new technology to low-risk patients should be done with extreme caution. Conventional AVR still provides the best long-term outcome with minimal operative mortality and morbidity in low-risk patients. This technology is currently at a very early stage of development and clinical applications and used only in selected high-risk patients. However, with continuous improvement in valve and delivery system devices, operating techniques, and clinical outcomes, this new evolving technology will inevitably become a part of standard management for valvular diseases in the future. With continuous breaking waves of new technologies, cardiac surgeons have to be adaptive, make significant adjustment, and remain flexible to the changes to well-established routine practice and so-called standard surgical techniques. We believe this new valve technology will no doubt be eagerly adopted by both the medical community and patients irrespective of any potential inferiority in initial outcomes or durability because both will be attracted by its considerably less invasive nature and rapid recovery.

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