Review

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Advances in transcatheter aortic valve replacement

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Abstract

Evidence in transcatheter aortic valve replacement (TAVR) has accumulated rapidly over the last few years and its application to clinical decision making are becoming more important. In this review, we discuss the advances in TAVR for patient selection, expanding indications, complications, and emerging technologies.

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Keywords: Aortic stenosis; Periprocedural complications; Surgical risk; Transcatheter aortic valve replacement

1 Introduction

Surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR) are the two therapeutic interventions for patients with severe native calcific aortic valve stenosis (AS) with an indication for valve replacement. TAVR is a rapidly evolving technique with several randomized control trials suggesting non-inferiority or even superiority compared with SAVR in extreme, high, intermediate and low surgical risk patients. Patient selection plays a crucial role to achieve the best benefit-risk ratio in those undergoing TAVR. Patients with severe AS and indications for invasive treatment should be first evaluated by a multidisciplinary heart valve team (including an interventional cardiologist and cardiothoracic surgeon) to assess patient's anticipated life expectancy and also the expected outcomes after the intervention. There are three main considerations in evaluating severe AS patients for TAVR: (1) what is the surgical risk? (2) TAVR or surgical aortic valve replacement (SAVR)? and (3) would the patient benefit from TAVR? In this review we will summarize the most recent evidence on patient selection, complications and emerging concepts in the field of TAVR.

2 Patient selection

2.1 Surgical risk

Assessment of the surgical risk of TAVR is outlined in

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the American College of Cardiology/American Heart Association Valvular Heart Disease guideline.^[1] Accordingly, surgical risks are categorized into low, intermediate, high, and prohibitive risk based on Society of Thoracic Surgeon Predicted Risk of Mortality score, frailty, major organ system compromise, and procedure-specific impediments (i.e., tracheostomy present, porcelain aorta, chest malformation, radiation damage, and arterial coronary graft adherent to posterior chest wall). Because the indication of TAVR is significantly different in each surgical risk (no indication for low risk, class IIa for intermediate risk, and class I for high and prohibitive surgical risk), this is an essential process in determining the candidacy of a patient for TAVR. Other markers such as gait speed, late gadolinium enhancement on cardiac magnetic resonance, C-reactive protein, and brain natriuretic peptide have shown to be useful variables to further risk-stratify TAVR candidates.^[2-5]

2.2 TAVR or SAVR?

Aside from the prohibitive and low surgical risk cohort where either TAVR or SAVR is definitely indicated more than the other, whether to perform TAVR of SAVR becomes complex as both have a high class of recommendation in intermediate and high surgical risk patients. Results of major randomized trials comparing TAVR *vs.* SAVR are summarized in Table 1. In this regard, two materials are especially helpful for guidance, the European guidelines for the management of valvular heart disease and the appropriate use criteria for the treatment of patients with severe aortic stenosis.^[6,7] Appropriate use criteria assign three categories, "appropriate", "may be appropriate", or "rarely appropriate" for treatment options to various clinical scenarios. Important factors to be considered when TAVR is preferred

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Author/Initial publica- tion, year	PAR	INER	U.S. Co	reValve	NOT	TION	PART	NER 2	SUR	TAVI	
Study period	5/2007-	5/2007-8/2009		2/2011-9/2012		12/2009-4/2013		12/2011-11/2013		6/2012-6/2016	
Follow-up duration	5	5 yrs		5 yrs		5 yrs		2 yrs		2 yrs	
Used valves	SAPIEI valve	SAPIEN heart- valve system		CoreValve		CoreValve		Sapien XT valve system		CoreValve (84%) Evolut R (16%)	
Procedure	TAVI	SAVR	TAVI	SAVR	TAVI	SAVR	TAVI	SAVR	TAVI	SAVR	
Cohort number	348	351	390	357	145	135	1011	1021	864	796	
Age, yrs	83.6 ± 6.8	84.5 ± 6.4	83.1 ± 7.1	83.2 ± 6.4	79.2 ± 4.9	79.0 ± 4.7	81.5 ± 6.7	81.7 ± 6.7	79.9 ± 6.2	79.7 ± 6.1	
STS score, %	11.8 ± 3.3	11.7 ± 3.5	7.3 ± 3.0	7.5 ± 3.4	2.9 ± 1.6	3.1 ± 1.7	5.8 ± 2.1	5.8 ± 1.9	4.4 ± 1.5	4.5 ± 1.6	
All-cause mortality at maximum follow up, %	67.8	62.4	55.3	55.4	27.7	27.7	16.7	18.0	11.4	11.6	
Stroke, %	10.4	11.3	12.3	13.2	10.5	8.2	*6.2	*6.4	*2.6	*4.5	

Table 1.Summary of included studies.

*Disabling stroke. NOTION: nordic aortic valve intervention; PARTNER: placement of aortic transcatheter valve; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement.

are higher age or frail, previous cardiac surgery or radiation history, porcelain aorta, and chest deformation while SAVR is preferred when patient has low coronary ostia, very large aortic annulus, bicuspid aortic valve (BAV), or concomitant cardiac conditions fulfilling concomitant non-SAVR operation (i.e., severe mitral or tricuspid lesion, aortopathy, severe coronary artery disease, and septal hypertrophy requiring myomectomy) criteria.^[6] In the appropriate use criteria document, similar consideration was given to factors, specifically, concomitant coronary artery disease, the presence of aortopathy, and non-aortic valvular disease. In high or prohibitive surgical risk patients, across the various scenarios, TAVR mostly had higher score compared with SAVR whereas SAVR mostly had higher score compared with TAVR when a concomitant severe non-aortic valvular lesion, aortopathy, or significant coronary artery disease were present. It should be noted that there is not vet evidencebased recommendation level to choose whether TAVR or SAVR is better compared to the other (except for low and prohibitive surgical risk) and appropriate use criteria also do not mandate clinicians to select either TAVR or SAVR in scenarios it presented. Given the significantly different invasive nature of TAVR and SAVR as well as peri-operative risks associated with each procedure, certain groups with specific comorbidities had better short-term outcomes in TAVR such as those with chronic obstructive lung disease, pulmonary hypertension, and chronic kidney disease.[8-11] These specific comorbidities also should be discussed within the heart team to choose TAVR or SAVR in a given patient. Recently studies have demonstrated similar or even better durability in TAVR compared with SAVR and support the expansion of TAVR to lower risk and younger populations.^[12,13]

2.3 Benefit of TAVR

The main outcome goal and benefit of TAVR, especially for those at high or inoperable risk cohort, is more of the improvement in the quality of life rather than increasing one's life-span because in these cohorts, even after TAVR or SAVR, long-term mortality remains very high.[14-16] A risk model to predict poor outcome (defined as death, Kansas City Cardiomyopathy Questionnaire-Overall Summary Scale < 45, or ≥ 10 -point decrease compared with baseline) at 6 months was reported by Arnold, et al.^[17] Poor outcome was observed in 32.9% and variables such as oxygen-dependent lung disease, chronic kidney disease, poor cognition, decreased 6-min walk test distance, and higher mean aortic valve gradient was identified as associated with poor outcomes. In patients with these risk factors, a shared decision making with the patient as well as within the heart team would be very important.

2.4 Timing of TAVR

During the waiting period, once the patient is determined to be an appropriate candidate for TAVR, the patient continues to be at risk for sudden cardiac death, especially high-surgical-risk patients. A population-based study from Canada reported that during a waiting period of 80-days, mortality and admission for heart failure was approximately 2% and 12%, respectively.^[18] These numbers are non-negligible and even in the United States where waiting time presumably are shorter, it would be important to minimize the waiting period. TAVR outcomes were worse after nonelective admissions and patients at high risk for non-elective admissions such as those with pulmonary circulatory disorder, anemia, congestive heart failure, and chronic kidney disease may benefit from an expedition of TAVR to avoid death or non-elective admission while awaiting for TAVR.^[19] Patients who refused the initial TAVR and had a median of 5.5 months after for worsening congestive heart failure had worse short and long-term mortality further highlighting the adverse impact of prolonging TAVR after once deemed for an appropriate candidate.^[20] The principal rule of timing to perform TAVR is, therefore, "as soon as possible".

3 Expanding indications

Recently, because of its low invasive nature and high utility, TAVR has been performed in several "off-label" use. According to the Transcatheter Valve Therapy registry, approximately 10% (2,272/21,575) of TAVR performed in the United States between November, 2011 and September, 2014 were off-label, including bicuspid aortic valve (BAV), severe mitral regurgitation or aortic insufficiency (AI), moderate aortic stenosis, and sub-aortic stenosis.^[21] Among these reported categories of off-label use, severe stenosis of the bicuspid aortic valve and aortic regurgitation are studied more in detail.

3.1 Bicuspid aortic valve

Most rapidly evolving off-label use of TAVR is BAV. BAV accounted for 1.8%-2.5% of TAVR cases in large, multicenter registries.^[21,22] The main concern for TAVR in BAV is the under-expansion of the transcatheter valve due to the often, eccentric calcification of BAV and non-circular shape of the aortic annulus. Early multi-center, experience raised the concern of high percentage (28.4%) for residual of more than moderate AI, which was mitigated by multislice computed tomography-based valve sizing.^[23] Two large multicenter trials studying outcomes of TAVR in BAV versus tricuspid aortic valve and early versus new-generation valves in BAV patients were published in recently and have shed a light in these major clinical questions for TAVR in BAV. In a propensity-matched cohort of 546 patients in each arm (BAV and tricuspid aortic valve), although there was a higher rate of second TAVR, aortic root injury, conversion to surgery, and \geq moderate AI, the post-TAVR gradient was similar as well as new pacemaker rate. The 2-year mortality rate was similar between the two groups (17.2% vs. 19.4%, P = 0.28).^[24] When new-generation valves were used, the rate of \geq moderate AI significantly decreased but other peri-procedural outcomes were largely similar.^[24,25]

Currently, new-generation valves are routinely used and based on these results, if severe aortic stenosis with BAV has favorable anatomy such as an absence of concomitant severe aortopathy or low coronary ostium height, TAVR appears to be a reasonable option. However, no large studies are yet available on the outcome of TAVR compared with SAVR in BAV. In addition, because there is no longer-term follow-up on the performance of transcatheter bioprosthesis in BAV, the candidate of TAVR in BAV should be cautiously selected for now with regular echocardiography surveillance for valve function.

3.2 Aortic insufficiency

Not commonly as observed as aortic stenosis but TAVR for AI has been reported in several studies. According to the Euro Heart Survey on valvular heart disease, aortic regurgitation accounted for 18.9% of SAVR and half of the underlying cause being degenerative.^[26] Challenges of TAVR in aortic regurgitation are the degree of aortic root dilation, lack of calcification, and absence of dedicated transcatheter valve. The former two factors pose an increased risk of significant residual aortic regurgitation and valve embolization. Recently, a multinational study from Europe, North America, and Asia-Pacific centers reported the outcomes of TAVR in consecutive 331 native aortic valve regurgitation patients.^[27] In this study, the mean age of 74.4 years old, 52% were men, and mean Society of Thoracic Surgeon score of 6.7. Various types of valves were deployed (11 types), and a transfemoral approach was 70.4%. There were significantly higher device implantation success rate and lower peri-procedural complications with second-generation valves, which replicate the experience with TAVR in severe aortic stenosis. The one-year over-all mortality was 24.1% and relatively high and no difference was observed between early and new-generation valves, cardiovascular mortality was significantly lower with the use of new-generation valves (9.6% vs. 23.6%, P = 0.008). There were no differences in procedural outcomes and aortic root dilation when new-generation valves were used.^[27] A J-Valve (JieCheng Medical Technology Co., Ltd., Suzhou, China) has a unique design that allows the valve to be implanted in two stages with precise positioning and secure anchoring in predominantly AI patients with minimal aortic root calcification.[28,29] There has been no report that compared TAVR vs. SAVR in aortic regurgitation to date.

3.3 Aortic insufficiency in left ventricular assist device recipients

Continuous flow left ventricular assist device is now used widely for both destination and bridge to transplant for endstage heart failure. With more patients living longer with the assist device, AI has started to become a clinical issue in up

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to approximately 50% of patients and it negatively affects the efficiency of the support.^[30] Because of the often high or extreme risk of open-heart surgery in this cohort, TAVR is an attractive measure in this clinical scenario. However, additional clinical concerns arise such as the optimal valve design (self-expandable or balloon-expandable), appropriate oversizing of the valve to achieve adequate anchoring, and the existence of inflow cannula could potentially interfere with the valve positioning. There are currently only a small case series or case reports available with promising outcomes, however, these issues still remain to be addressed on a case basis by the heart team.^[31–33]

3.4 Moderate aortic stenosis

Transcatheter Aortic Valve Replacement to UNload the Left ventricle in patients with ADvanced Heart failure (TAVR UNLOAD) trial (NCT02661451)^[34] was designed to test the hypothesis that for those with moderate aortic stenosis and reduced left ventricular ejection fraction (< 50%) on optimal medical therapy for heart failure, TAVR would have incremental clinical benefit to optimal medical therapy. Depending on the results, it would open a substantial expansion of TAVR indication.

4 Complications

Outcomes of TAVR have seen a constant improvement since its introduction largely owing to improved transcatheter bioprosthesis design, smaller sheath diameter, and operator/institution experiences. A meta-analysis that compared new-generation (Acurate, Evolut R, Sapien 3, direct flow medical, or Lotus) with early-generation (Sapien/Sapien XT or CoreValve) transcatheter bioprosthesis showed a significant decrease in bleeding, significant paravalvular regurgitation, and acute kidney injury while the rate of stroke and pacemaker (PPM) were similar.^[35] Learning curve, like other invasive procedures, was reproduced in TAVR. From a large United State TAVR registry, mortality, vascular complications, and bleeding decreased significantly with increase in site volume.^[36] In the recent multi-center trial that assessed the short-term outcome of TAVR in low risk (Society of Thoracic Surgeon Predicted Risk of Mortality score ≤ 3 without major comorbidity) patient, there was no death, stage 3 acute kidney injury, stroke, and myocardial infarction reported with very low major vascular complications and life-threatening or major bleeding rate (2.5% each). New pacemaker implantation was 5.0% (10/200). The patient enrollment was from February 2016 to February 2018, predominantly used the new-generation valves, all patients had transfemoral-TAVR, and roughly 75% had moderate

sedation for the procedure.^[37] These superb outcomes represent the evolution of the device and the accumulation of experience.

4.1 Stroke

While many complications have seen a dramatic decrease, the rate of stroke and new PPM insertion has remained relatively the same. Approximately half of the clinically relevant strokes occur within 24 hours post-TAVR, implicating that the underlying etiology is embolization of calcium and debris at the time of pre or post balloon valvuloplasty and valve deployment.^[38] The clinical and economic impact of major stroke is substantial. Major stroke was associated with a substantial increase in the risk of 30-day (OR = 7.43, 95% CI: 2.45-22.53) and late mortality (hazard ratio 1.75, 95% CI: 1.01-3.04) as well as adding 31,030 U.S. dollars and additional 7.0 hospital stay per event.^[38,39] Several randomized controlled trials have evaluated the efficacy of cerebral embolic protection device. While the study that used TriGuard device showed lower new ischemic lesions, less neurological deficit, and improved cognitive function, a larger trial using the Sentinel device did not demonstrate a reduction in new brain lesion and neurocognitive function remained the same.^[40,41] However, in both trials, the debris was captured in the majority (about 90%) of the cases showing its efficacy. In a patient-level meta-analysis, dual-filter cerebral embolic protection device demonstrated a significantly lower rate of procedural all-stroke (relative risk reduction 65%) but this finding was not from a randomized trial.^[42] Currently, cerebral protection devices should be used for those at high-risk for strokes such as female sex and chronic kidney disease^[43] rather than routinely given the conflicting results of evidence and uncertainty of cost-effectiveness. Recently, a model was developed to predict in-hospital stroke from the largest United States registry including 97,600 TAVR patients and could assist in identifying those who would have the best cost-effectiveness from embolic protection devise.^[44]

4.2 New pacemaker

New PPM is caused by direct mechanical injury to the conduction system because of its anatomical proximity to a valve landing zone. New PPM does not seem to negatively impact the 1-year mortality but did have lower improvement in left ventricular ejection fraction.^[45] In addition, each PPM insertion added 15,613 U.S. dollars and 3.6 extra days of hospital stay, which have substantial economical implication.^[39] Common risk factors of new PPM are right bundle branch block and self-expandable valves making the use of

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balloon-expandable valve more preferable for the patient at risk of new PPM.^[46,47] While several risk factors have been reported for new PPM, only a few are modifiable. Deployment of the device to a more ventricular side was associated with higher PPM risk and is a potentially modifiable factor by minimizing the risk of damage to the conduction system when deployed more to the aortic root. Meticulous preplanning of device deployment depth using the three-dimensional computed tomography printing may potentially have a role in determining the optimal depth of valve deployment lower the PPM rate. A small study suggested the potential effect of steroid to decrease PPM rate by mediating acute inflammation caused at the site of valve deployment and conduction system but this has to be evaluated in larger studies.^[48]

4.3 Delirium

Post-operative delirium has been less emphasized as post-TAVR complication compared with other procedural-related complications, however, considering the high mean age of patient undergoing TAVR, it is a clinically important complication. Delirium was associated with 20% higher hospital cost in the intensive unit care setting.^[49] It occurs in roughly 8.1% and three times more often in non-transfemoral (21.4%) than transfemoral (7.2%) approach.^[50] Major risk factors reported from a meta-analysis included acute kidney injury, transapical approach, and carotid artery disease.^[51] The short and long-term mortality rate in those who experienced post-TAVR delirium was significantly worse than those without delirium.^[52] Prevention measures could shorten the hospital and intensive care unit stay but because it is unknown whether delirium is the direct cause of worse prognosis or a mere maker of a frail cohort, the benefit of these measures are not yet determined. Because postoperative delirium could be a manifestation or early sign of post-TAVR complications such as stroke and infection, a physician in care should be well aware of common complications post-TAVR and investigate occult complications causing delirium as appropriate.

5 Emerging technology

Even with the technological improvements, there still remain challenging cases. To overcome some of the clinical challenges, several techniques and concepts have recently emerged.

5.1 Bioprosthetic valve fracture

The key concept of (bioprosthetic valve fracture) BVF is to achieve full expansion of the transcatheter bioprosthetic by fracturing the underlying surgical bioprosthetic causing significant aortic gradient with high-pressure balloon inflation either before or prior to valve-in-valve (ViV)-TAVR. ViV in aortic position has been reported as a feasible and efficacious procedure and even with better outcomes compared with TAVR to the native aortic valve.^[53,54] The drawback of ViV is residual stenosis, which mainly is caused by under-expansion of the second valve and is associated with increased adverse events.^[55] BVF was developed as a measure to solve this issue and the first case series of BVF was reported from nine institutions in the United States after the bench test showed promising results.^[56,57] In their report, 20 consecutive patients (mean age and Society of Thoracic Surgeons Predicted Risk of Mortality score was 76.4 years old and 8.4%, respectively) underwent BVF for various types of surgical bioprosthetic valves, ranging from 20 to 26 mm in size. The baseline mean gradient was 41.9 ± 11.2 mmHg and significantly decreased to 20.5 ± 7.4 post-ViV-TAVR (P < 0.001). Importantly, the gradient post-ViV-TAVR showed a further significant decline to 6.7 ± 3.7 mmHg post-BVF (P < 0.001 compared with post-ViV). One patient had a stroke but otherwise, patients were free from major complications including coronary occlusion, root rupture, valvular or paravalvular regurgitation, and PPM insertion.^[57] BVF has recently expanded its use for pulmonary, tricuspid, and mitral valve position.[58-60] Although the long-term effect remains uncertain, this new technique offers a promising result in those who have deterioration of their bioprosthesis at high risk for redo surgery.

5.2 Non-femoral access

Secondary, we will discuss the emerging alternative access site, transaxillary, suprasternal, and transcaval approach. All approaches are an alternative for the transfemoral approach, which is currently the default for TAVR. The main advantages and disadvantages of each approach are summarized in Table 2.

The transaxillary approach has been also reported as an option for large-bore access in those requiring mechanical circulatory support for heart failure. It could be performed by surgical cut-down but also via a percutaneous approach. McCabe, *et al.*^[61] reported fully percutaneous insertion of Impella CP device, which requires 14 French size sheath but there were no neurovascular complications. In a large, 2 center single-arm study of 100 patients who had transaxillary TAVR, major and minor access site complication as well as life-threatening bleeding was observed in 0, 11%, and 3% and was low. However, 11 patients required covered stent implantation after sheath removal because of residual bleeding from the access site.^[62]

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Table 2. Su	mmary of	non-femora	l access.
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	Advantages	Disadvantages		
Transaxillary	Full percutaneous approach is possible			
	Axillary artery is often less tortuous and calcified compared with iliofemoral artery	In case of bleeding, manual compression is less effective		
	Artery size could be larger than 5.0 mm in those with iliofemoral diameter	and urgent surgical bailout may be necessary.		
	less than 5.0 mm (29314639)	No dedicated devices		
	Patient can ambulate	Lack of experience in many operators		
	Technically not demanding			
Transcaval		High technical expertise is required		
	Con account data lance size alterati	Offered only at limited institutions		
	Can accommodate large size sneath	Intra-abdominal procedural complications could result		
	Able to overcome severe periprieral arterial disease	in fatal consequences.		
		No dedicated closure device		
Suprasternal		Less clinical data available		
	Does not require a sternotomy	Could only be performed by surgeons with expertise.		

The suprasternal approach was first described in 2015 in 4 cases.^[63] To access through the suprasternal, a transverse incision 1 to 2 cm above the suprasternal notch is created. Through that incision, the operator accesses the brachiocephalic artery to perform TAVR.^[64] To date, clinical outcomes of suprasternal approach are limited with few studies and low cohorts. Single-center experience from the United States and France showed low peri-operative complication rates thus far but further experience should be accumulated to establish its role as a viable alternative to a transfemoral approach.^[64,65]

Transcaval access has been described in endovascular intervention preceding its application to TAVR.^[66] Large size sheath is introduced in the femoral vein and stiff guidewire will be inserted in an exchange with the microcatheter. The puncture hole of the abdominal aorta will be closed with an occluder device after completion of the procedure. It was first reported in those at prohibitive surgical risk in 19 patients. Subsequently, its feasibility and efficacy were confirmed in larger series and its outcomes were compared with transfemoral TAVR.^[67–69] Although the length of hospital stay was longer in transcaval compared with transfemoral access (4 days *vs.* 2 days), 1-year outcomes were similar (80% *vs.* 86% for transcaval and transfemoral, respectively).^[69]

These unique accesses require special skills and currently only performed at selected centers. Therefore, for those patients with the non-accessible femoral artery, it would be better to consult institutions capable of these accesses. It should be noted, however, that there are no prospective randomized trials comparing different non-femoral access and comparative evidence of clinical outcomes among different approaches are limited to observational data with a limited number of cohorts. Heart team discussion to determine the best access site is imperative in non-transfermoral TAVR cases.

6 Conclusions

Evidence of TAVR has accumulated tremendously in a short span. Advances in technology and accumulation in experiences have transformed TAVR into acceptable risk procedure with non-inferior benefit compared with SAVR in high and intermediate risk population. Complications such as PPM and stroke warrant further solution to decrease the incident. Long-term valve durability of TAVR compared with SAVR and more clarity whether TAVR or SAVR is beneficial compared to one another in certain sub-sets of population are areas where more evidence is warranted.

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