Evolution of Transcatheter Aortic Valve Replacement | Review of Literature

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Abstract: Aortic valve stenosis is the most common primary valvular heart disease leading to either surgical or transcatheter valve replacement in the United States with its prevalence on the rise due to the elderly population. Over the recent years, the rise of transcatheter aortic valve replacement has been exponential due to technologic developments and randomized control trials. In this review article, we aim to review current literature on transcatheter aortic valve replacements. (Curr Probl Cardiol 2021;46:100600.)

Introduction

Aortic stenosis is the most common valvular disease in the elderly population and is associated with high mortality if symptomatic and is left untreated.[1,2] Aortic valve replacement alleviates the stenosis and prolong life, and traditionally, open heart surgery was the only therapeutic option.[3,4] The emergence of transcatheter aortic valve replacement (TAVR) in 2002[5] has not only served as alternative approach for those who were not surgical candidates, but also shown noninferiority and even superiority compared to surgical aortic valve replacement (SAVR) through a series of randomized control trials among patients

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of all spectrum of surgical risks. As a result, the number of TAVR procedures done each year continues to rise with phenomenal results.[6] The presence and severity of aortic stenosis is initially assessed via 2-dimensional transthoracic echocardiogram.[7] Additional imaging such as transesophageal echocardiogram, computed tomography, or magnetic resonance imaging may aid the diagnostic process. The echocardiographic criteria for severe aortic stenosis are $V_{max} \geq 4$ m/s, mean pressure gradient $>$ 40 mm Hg, and aortic valve area ≤ 1.0 cm^2 (or AVAi ≤ 0.6 cm^2/m^2) in patients without left ventricular dysfunction. Among those with reduced left ventricular ejection fraction, dobutamine stress echocardiography is performed to differentiate true-severe from pseudosevere aortic stenosis.[2] Valvular aortic stenosis can be classified in stages A through D corresponding to at risk, progressive, asymptomatic, and symptomatic. Asymptomatic aortic stenosis patients are subdivided into whether they have left ventricular dysfunction or not. Symptomatic severe aortic stenosis patients are subdivided into whether they have left ventricular dysfunction, mean pressure gradient, and the dobutamine stress echocardiography results.[8] However, emerging data suggest that the assessment for the presence of left ventricle flow reserve in the state of low-flow low-gradient clinical picture may no longer be required.[9] This article will summarize and discuss the latest available transcatheter aortic valves, the latest clinical data and trials on TAVR and the most recent guidelines on indications.

Current Literature Review

TAVR indications continue to expand with the development of newer valves and publication of prospective, multicenter, open-label, randomized control trials comparing TAVR against SAVR in symptomatic aortic stenosis patients with prohibitive, high, intermediate, and low surgical risks determined by Society of Thoracic Surgery Predicted Risk of Mortality (STS-PROM). For better understanding about the Landmark trials it is important first to know the commonly used valves.

Types of Valves Used

For vast majority of TAVR patients, any one of the commercially available valves can be used. There are currently 3 different commercially available valves that are approved in the Unites States. These include the balloon-expandable SAPIEN 3 and SAPIEN 3 Ultra manufactured by Edwards Lifesciences, the mechanically expandable LOTUS

Edge valve manufactured by Boston Scientific, and the self-expanding Evolut Pro+ manufactured by Medtronic.[10–12] In addition, the balloon-expandable Myval valve and the self-expanding ACURATE neo and portico valves are approved in Europe.[13,14]

The SAPIEN 3 Ultra valve received approval in August 2019 and is delivered by a 14F expandable sheath that enables low profile insertion and removal. It is advertised to have approximately 40% increased outer skirt height.[10] Even though SAPIEN 3 Ultra has not been published in randomized control trials at this time, available data suggest it is safe and effective. The SAPIEN 3 Ultra has relatively higher rate of left bundle branch block and should not be used in patients who do not tolerate blood thinning medications.[11,12]

The LOTUS Edge recently received approval in April 2019 and it uses 18F or 20F sheath for delivery and its valves are available in 23 mm, 25 mm, and 27 mm.[12] The LOTUS Edge is 100% repositionable and allows the operator to assess the valve position and function after deployment, and reposition if needed.[15] The 2-year follow-up for REPRISE III trial comparing mechanical expanded valve to self-expanding valve showed that mortality and all stroke were not significantly different. Disabling strokes were more frequent with CoreValve (self-expanding) compared to LOTUS (4.7% Lotus vs 8.6% CoreValve; Hazard ratio (HR), 0.53; 95% confidence interval (CI), 0.31-0.93; $P = .02$). The need for a new permanent pacemaker was higher for LOTUS (41.7% vs 26.1%; HR, 1.87; 95% CI, 1.41-2.49; $P < .01$) and the incidence of valve thrombosis was higher for LOTUS compared to CoreValve (3.0% vs 0.0%; $P < .01$).[16]

The CoreValve Evolut Pro+ was approved in August 2019 and it uses 14F or 18F sheath for delivery and it has a self-expanding bioprosthesis in 23 mm, 26 mm, 29 mm, and 34 mm.[17] The advertised advantage of the Evolut Pro+ is its wide available sizing range, low delivery profile, and it can treat annulus range up to 30 mm in diameter, which is the widest among commercially available valves. It also boasts an external pericardial wrap which was designed to reduce paravalvular leak (PVL).[18] Latest available data showed that Evolut Pro+ has reduced PVLs compared to its previous generations.[19]

Landmark Trials

The PARTNER B trial (Placement of Aortic Transcatheter Valves B trial) randomly assigned 358 symptomatic patients with severe aortic stenosis who are at prohibitive surgical risk to receive TAVR or standard therapy (including balloon aortic dilation). The SAPIEN heart valve

system was used in this trial and all the valves were deployed via femoral access. The group that received TAVR had significantly reduced all-cause mortality, repeat hospitalization for valve or procedure-related deterioration when compared to standard therapy at the risk of higher incidence of stroke and major vascular events.[20] As a result, TAVR should strongly be considered for prohibitive surgical risk patients for whom an aortic valve replacement will improve their quality of life; this is reflected in the 2014 AHA/ACC Guidelines.[2,13,21]

The PARTNER A trial randomly assigned 699 symptomatic patients with severe aortic stenosis who were deemed to be high-risk surgical candidates to receive TAVR or SAVR. The SAPIEN heart valve system was used in this trial. Transfemoral approach was preferred while transapical access was also used in this study. TAVR was associated with similar all-cause mortality compared SAVR at 1-year mark.[22] This trial had several limitations. Both TAVR and SAVR group had unexpected number of patients withdraw from the trial. The study did not have sufficient statistical power to analyze the outcomes of specific subgroups of patients such as transfemoral versus transapical approach. Lastly, the durability of the valves was questioned. The 5-year follow-up result of PARTNER A trial published in 2015 continued to show no mortality difference between TAVR and SAVR. The valve deterioration was found to be insignificant via echocardiography showing consistent mean pressure gradient and valve area. However, there was a 10% increase in prevalence of severe aortic regurgitation in the TAVR arm.[23] Of note, the first-generation SAPIEN heart valve system was used in this trial, it was an initial experience for most centers that participated in the trial, and CT was not commonly used to size the annulus at the time. With the newest generation of SAPIEN 3 and SAPIEN 3 Ultra and more operator experience, the PVLs and aortic regurgitation maybe improved. As a result of this trial, TAVR was accepted as a reasonable alternative to SAVR in patients at high risk for operative complications.

The PARTNER 2 trial[24] randomly assigned 2032 symptomatic patients with severe aortic stenosis who were deemed to be intermediate-risk (4%-8% STS-PROM score) surgical candidates to receive TAVR (n = 1011) or SAVR (1021). The primary endpoint was all cause mortality or disabling stroke. The SAPIEN XT heart valve system was used in this trial through Transfemoral approach in 76.4% of the patients while the rest were used transthoracic approach. TAVR was found to be noninferior to SAVR with respect to all-cause mortality and disabling strokes at 2 years (TAVR vs SAVR: 19.3% vs 21.1%, $P = 0.001$ for noninferiority, $P = 0.33$ for superiority. Transfemoral TAVR appeared superior to TAVR, and

provided symptomatic benefits per patient's perspective at 2 years. At 30 days, vascular complications were higher in TAVR, while acute kidney injury (AKI), new onset atrial fibrillation (Afib), and bleeding were higher in the SAVR group. At the 5-year follow-up of PARTNER 2 trial (with the name of PARTNER 2A trial)[14] published on Feb 27, 2020, the primary endpoint was maintained, aortic valve area nor the mean gradient deteriorated over that time, indicating good durability. The PVL was significantly higher in the TAVR arm at 2-year and 5-year follow-up. However, the second-generation SAPIEN XT valves were used in this study, and the third-generation SAPIEN (S3) valves that have increased skirt height around the valve frame designed to reduce this complication were not used as long-term data are still lacking. Further data from the third-generation system are still pending.

The SURTAVI Study (Safety and Efficacy Study of the Medtronic Corevalve System in the Treatment of Severe, Symptomatic Aortic Stenosis in Intermediate Risk subjects Who Need Aortic Valve Replacement)[25] randomly assigned 1746 symptomatic patients with severe aortic stenosis who were deemed to be intermediate-risk surgical candidates to receive TAVR or SAVR. The primary endpoint was all cause mortality or disabling stroke at 24 months. The CoreValve bioprosthesis was used in 84% patients while Evolut R bioprosthesis was used in 16%. Transfemoral access was preferred, while subclavian or direct aortic approaches were used in patients with difficult anatomy. TAVR was found to be noninferior with respect to all-cause mortality and disabling strokes at 2 years. SAVR was associated with higher AKI, Afib, and transfusions requirements, whereas TAVR had higher PVL and permanent pacemaker need. The secondary outcome analysis showed that SAVR was associated with higher perioperative stroke rate while TAVR was associated with higher rate of hospitalization for aortic valve disease. High frequency of withdrawal from the study was noticed in the SAVR group, and the vast majority received the CoreValve bioprosthesis newer Evolut R bioprosthesis. Long-term follow-up and analysis will be needed as data become available. The current guidelines continue to favor SAVR to be class I indication for intermediate-risk group. With the results of these randomized multicenter trials: PARTNER 2 and SURTAVI showing promising noninferiority primary endpoints and cost effectiveness as well, this should lead to changes in guidelines.

The PARTNER 3 trial[26] randomly assigned 1000 symptomatic patients with severe aortic stenosis who were deemed to be low-risk surgical candidates to receive TAVR (n = 503) or SAVR (n = 497). The primary endpoint was composite of death, stroke, or rehospitalization at 12 months.

Both superiority and noninferiority testing were performed as well. The SAPIEN 3 heart valve system was used in this trial. Transfemoral access was utilized for all patients. TAVR was found to be superior to SAVR in death from any cause, stroke, or rehospitalization at 1 year. The TAVR group had significantly better quality of life compared to SAVR group assessed via Kansas City Cardiomyopathy Questionnaire score at 30 day, and surprisingly also at 1-year mark. It was also associated with a lower incidence of Afib, stroke, AKI, and shorter length of hospital stay. Since this is the 1-year analysis, long-term follow-up data are pending.

The Evolut Low Risk trial[26] randomly assigned 1468 symptomatic patients with severe aortic stenosis who were deemed to be low-risk surgical candidates to receive TAVR (n = 725) or SAVR (n = 678). The primary endpoint was all cause mortality or disabling stroke at 2 years. A mixture of CoreValve (3.6%), Evolut R (74.1%), and Evolut Pro (22.3%) from Medtronic were used in this study. Transfemoral access was used in 99% of the cases. TAVR was found to be noninferior to SAVR with respect to the composite end point of death or disabling stroke at 24 months. The secondary outcome analysis showed that hospitalization for heart failure was less significant in the TAVR arm compared to SAVR at 12 months. The most important limitation of this study is that the analysis was performed when 850 patients reached the 1-year mark, and long-term follow-up data await.

Current Aortic Valve Stenosis Management Per 2017AHA/ACC Guidelines

The management of patients with aortic valve stenosis (AS) is rapid evolving due to advancement in diagnostic imaging and improvements of catheter-based interventions.

SAVR Versus TAVR?

Common indications for aortic valve replacement (surgical or transcatheter) are as follows:[27]

- Severe AS with symptoms(class I recommendation, level B evidence)
- Asymptomatic patients with severe AS and left ventricle ejection fraction < 50 (class I recommendation, level B evidence)
- Presence of severe AS when undergoing other cardiac surgery (class I recommendation, level B evidence)

- Asymptomatic severe AS and low surgical risk (class IIa recommendation, level B evidence)
- Symptomatic with low-flow/low-gradient severe AS (class IIa recommendation, level B evidence)
- Moderate AS when undergoing other cardiac surgery (class IIa recommendation, level C evidence).

First TAVR was initially approved in 2011 for severe AS with prohibitive risk, followed by its approval in patients at high surgical risk in 2012 and then valve-in valve procedure for failed surgical bioprosthetic valve in 2015 and most recently, the FDA-approved SAPIEN valve for those with severe AS at intermediate risk.

Once patient is deemed to have indication for aortic valve replacement based on above guidelines, choice between TAVR and SAVR needs to be made. This complex decision should involve the patient and the heart valve team, which typically include but not limited to interventional cardiologist with expertise in valvular heart disease, cardiothoracic surgeon, and cardiac anesthesiologist for the best outcome.[8] If the life expectancy with aortic valve replacement is less than 1 year, or quality of life is unlikely to improve with intervention, then palliative and medical management is recommended.[2] If the life expectancy of the patient exceed 1 year and quality of life will improve with aortic valve replacement, the heart valve team then should evaluate the morbidity and mortality with SAVR using STS-PROM calculator.[2,17]

For symptomatic patients with severe aortic stenosis, the approach to the choice of therapy is summarized in the flow chart below taken 2017 Guidelines for Aortic Valve Stenosis Management. For those with extreme surgical risk ($\geq$50% probability of death or irreversible complication), TAVR is the choice of therapy unless contraindicated. For high-risk surgical candidates (STS-PROM $>$8), TAVR is preferred if feasible. If not, the heart valve team should perform individualized risk-benefit analysis and evaluate based on that. For intermediate surgical risk candidates (STS-PROM 4-8), TAVR is the choice of therapy if transfemoral approach is feasible AND there is absence of high-risk anatomic features (severe left ventricular outflow tract calcification, adverse aortic root anatomy, low coronary ostial height, and severely calcified bicuspid aortic valve). If those criteria are not met, SAVR is recommended or individualized risk-benefit analysis can be performed to evaluate for alternative access site. The low (STS-PROM $<$4) surgical risk candidates should get TAVR only if the following 4 criteria are met: age $\geq$65 years, transfemoral approach is feasible, aortic valve is trileaflet, and the absence of adverse anatomic features. Even then, those criteria are topics of ongoing research and clinical trials.[8,28]

Taken from 2017 AHA/ACC Guidelines of Valvular Heart Disease Management.

Contraindications to TAVR?

TAVR feasibility is a crucial component of determining route of intervention and its indication continues to expand more clinical data come into light. Absolute contraindications to TAVR include life expectancy less than a year secondary to noncardiac condition, if TAVR will unlikely result in quality of life improvement, valvular disease other than severe aortic stenosis only treatable via surgery, and the presence of high-risk anatomic features and clinical diseases.[29,30] High-risk anatomic features that are absolute contraindications to TAVR include inadequate annulus size, active endocarditis, asymmetric valve calcification, low coronary ostia height, adverse aortic root in the form of small sinus of valsalva or small, calcified sinotubular junction.[29,30] Other contraindications include myocardial infarction in past 30 days, need for emergency surgery, left ventricular ejection fraction $<20\%$, severe pulmonary hypertension with right ventricular dysfunction, hypertrophic cardiomyopathy with or without outflow tract obstruction, severe mitral regurgitation, MRI confirmed stroke or transient ischemic attack within last 6 months, and elevated annular rupture risk.[31]

Bottom line: Regardless of surgical risk, TAVR showed noninferiority if not superior to SAVR according to PARTNER and Evolute low-risk trials. TAVR group had better quality of life and shorter length of hospital stay and favorable cost-effectiveness in the long run. AKI, Afib, stroke, and transfusion were higher in SAVR, whereas PVL and the need for permanent pacemaker was higher in TAVR. Current guideline heavily favors SAVR in the low and some of the intermediate surgical risk groups. However, these data bring into question whether TAVR should be expanded into all groups given its safety profile. Due to this favorable outcome, this led to initiation of a new trial named, The ERLY TAVR trial which is a prospective, randomized, controlled, multicenter study that compares TAVR with clinical surveillance in asymptomatic patients with severe aortic stenosis, and primary results are expected by the end of 2021.[32]

Conclusion

TAVR has emerged as a striking approach for aortic valve replacement. Latest advancements in valve types as well as improved operator training lead to a promising future in transcatheter aortic valve replacements (Fig 1).

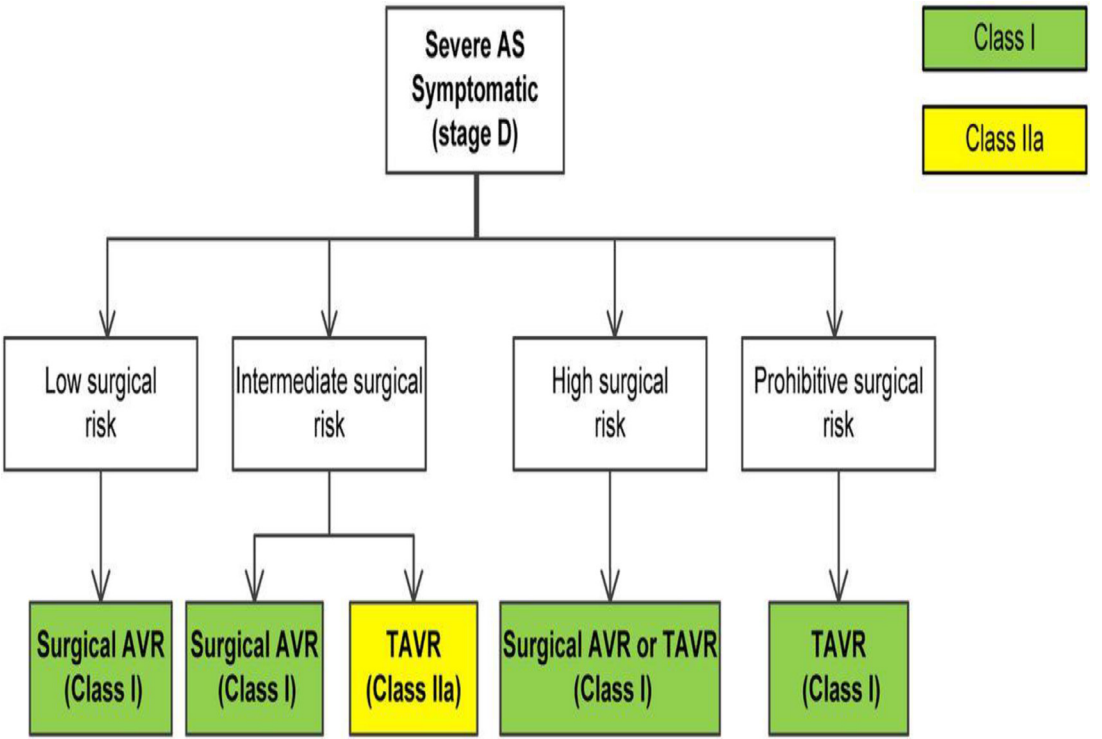

FIG 1. Approach to surgical versus transcatheter aortic valve replacement.

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