Pros and cons of transcatheter aortic valve implantation (TAVI)

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Transcatheter aortic valve implantation (TAVI) or replacement (TAVR) was recently approved by the FDA for intermediate risk patients with severe aortic stenosis (AS). This technique was already worldwide adopted for inoperable and high-risk patients. Improved device technology, imaging analysis and operator expertise has reduced the initial worrisome higher complications rate associated with TAVR, making it comparable to surgical aortic valve replacement (SAVR). However, many answers need to be addressed before adoption in lower risk patients. This paper highlights the pros and cons of TAVI based mostly on randomized clinical trials involving the two device platforms approved in the United States. We focused our analysis on metrics that will play a key role in expanding TAVR indication in healthier individuals. We review the significance and gave a perspective on paravalvular leak (PVL), valve performance, valve durability, leaflet thrombosis, stroke and pacemaker requirement.

Keywords: Transcatheter aortic valve implantation (TAVI); transcatheter aortic valve replacement (TAVR); surgical aortic valve replacement (SAVR); review; paravalvular leak (PVL); paravalvular regurgitation; pacemaker; stroke; leaflet thrombosis

Introduction

Transcatheter aortic valve replacement (TAVR) for treatment of severe symptomatic aortic stenosis (AS) has become an accepted and even preferred alternative to surgical valve replacement (SAVR) for inoperable and high-risk patients, and has recently gained Food and Drug Administration (FDA) approval for intermediate risk patients. Current trials are evaluating the safety and feasibility of this technique in lower risk symptomatic patients and even patients who are asymptomatic, or with moderate AS and heart failure.

The growth of TAVR from an experimental technique to a highly reproducible procedure that has proliferated rapidly has been dependent on numerous key advancements: improved imaging with multi-detector computed tomography (CT), better device technology leading to easier implantation, and fewer major complications. These advancements have resulted in more transfemoral (TF) access route implantation, less paravalvular leak (PVL), fewer pacemakers (PPM), lower stroke rates (CVA), and less bleeding. However, major questions still remain regarding the use of TAVR in the wider population of AS patients, including long-term durability, acceptable PVL in active patients, optimal approach for patients without TF access, concomitant coronary artery disease and valve disease, and leaflet thrombosis. With close follow-up and careful investigation of patients, these questions will be answered. In this review, we describe the current advantages and disadvantages of TAVR with regards to key metrics affecting adoption into lower risk populations. The review is primarily limited to balloon-expandable and self-expanding systems available in the United States with commercial approval.

PVL and valve performance

PVL was shown to be a much frequent complication after TAVR than after SAVR with the first generation transcatheter devices. Early studies and meta-analysis

demonstrated that moderate to severe PVL is associated with worsened outcomes, including readmissions, congestive heart failure and one-year mortality, raising significant concern at the time (1,2). A French registry reported an incidence of any degree of PVL post TAVR as high as 60%, while most of the European registries correlated proportionally the degree of PVL with 1-year mortality (3,4). Efforts to recognize patients at a higher risk of PVL based on multi-imaging analysis have shown predictors of significant PVL to include: (I) valve undersizing; (II) device malpositioning; and (III) incomplete valve contact to the native aortic annulus, most often due to extensive and/or eccentric annular calcification (5-8). Interpretation of different trials and registries is difficult due to intra and inter-institutional variability in the timing, assessment and quantification of PVL. In 2015, Pibarot *et al.* proposed a unifying PVL five-class grading scheme that was accepted and progressively adopted (9) Recently, the Paravalvular Leak Academic Research Consortium recommended this scheme for use in clinical trials, in the setting of PVL closure after SAVR (10).

Intraprocedural strategies to diminish PVL have been refined, aiming for mild or less PVL after TAVR. After valve implantation, time is given to assess the degree of PVL by echocardiography. It is not unusual that small jets seen between the stent cells regress over the first 5–10 minutes post implantation. There are many different ways to treat more significant PVL. The first line of intraprocedural treatment is balloon valve post-dilatation, often by upsizing balloons. After balloon-expandable TAVR, the same delivery balloon can be used, that can be oversized by adding additional volume. After self-expandable TAVR, a separate post-dilatation balloon is usually sized by the smallest mean diameter of the annulus of the implanted valve on echocardiography.

Different anatomic and patient characteristics need to be considered before post-dilatation. There should be a higher threshold to post-dilate patients with anatomic risk for aorto-valvar injury or coronary obstruction, unless moderate or worse PVL is noted. This holds true especially if the patient was initially deemed inoperable. On the other hand, a younger less comorbid patient should be treated aggressively, aiming for a perfect result, or tolerating up to mild PVL. The role of echocardiography is crucial in determining the risk of aortic injury while post-dilatating, and may guide to a more conservative or aggressive inflation, by identifying menacing calcific lesions deforming the aortic wall (11). When repeated post-dilatations are insufficient or generate an unaffordable risk, a second line of treatment is represented by retrograde transcatheter PVL closure with plug devices or the use of a second transcatheter valve (12). The decision depends on the morphology and localization of the PVL, as well as the type of valve used.

Given the association with mortality, the industry has focused on modifying valve systems to decrease the rate of PVL. The Edwards Sapien 3 was innovated with an outer sealing skirt of polyethylene terephthalate (PET) and modified its frame design to achieve better circularity. Medtronic has improved the radial force of its Evolut R valve and expanded its larger valve size to treat a broader group of patients, by reducing undersizing. Evolut Pro system is the new optional platform of the Medtronic valve, which has a thin pericardial sealing skirt that showed excellent results with absence of moderate or severe PVL in a small pre-approval clinical study.

Hemodynamic performance has been consistently superior with TAVR when compared to SAVR in most studies. The SURTAVI trial showed a clear advantage for TAVR, having both a larger EOA (2.1 *vs.* 1.8 cm^2, P<0.001) and lower mean aortic gradients (8.9 *vs.* 12.4 mmHg, P<0.001) that persisted after two years of follow-up. Moreover, at 2 years, only 2.6% and 0.3% of patients undergoing TAVR had EOA <0.9 cm^2 and mean AV gradients higher than 20 mmHg, interpreted as valve deterioration. In the SAVR group 11.2 % had EOA <0.9 cm^2 and 6.6% had mean gradients larger than 20 mmHg (13). PARTNER 2A also demonstrate much better valve performance with the Sapien XT valve, reaching statistical significance in aortic valve area (1.7 *vs.* 1.5 cm^2, P<0.001) and aortic mean gradients (9.7 *vs.* 10.9 mmHg, P<0.001), both maintained at 2-year follow up (14). A recent study showed that intraoperative valve sizing can result in smaller aortic annular diameter compared with sizing on systolic phase multidetector computerized tomography (MDCT) imaging. As a result, the potential geometric orifice area could be between 25% and 40% larger in TAVR (15). In addition, Mooney *et al.* reclassified patient-prosthesis mismatch by comparing the indexed effective orifice area (EOAi), using left ventricular outflow tract measured from computed tomography (EOAi$_{CT}$) instead of conventional echocardiogram measurements (EOAi$_{TTE}$). The incidence of PPM was much lower with CT measurements (45% *vs.* 24%), it was not associated with mortality, rehospitalization or less ventricular mass regression 1 year after TAVR. However, EOAi$_{TTE}$ was associated with left ventricular mass

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regression (16).

Permanent pacemaker

Permanent pacemaker implantation (PPI) and heart conduction disturbances are the most common complications of TAVR. PPI frequency varies dramatically in relation with the valve type used. In the early PARTNER and PARTNER 2B (high risk and inoperable), the rate of PPI was below 7% (Sapien/Sapien XT) (17,18), rising to 8.5% (Sapien XT valve) in the later PARTNER 2A (15). The contemporary Sapien 3 valve, with its innovative skirt to reduce significant PVL, worsened the rate of PPI, reaching 13% in an intermediate and high-risk registry (19). In self-expanding valve trials patients had a rate of PPI of 19.3% (CoreValve High Risk Study) (20), rising to 25.9% in the SURTAVI intermediate risk trial (14). The newer Evolut pro platform showed a decrease to 10% in a small pre-approval US study (21).

Several predictors of PPI after TAVR have been consistently identified. The most important is history of right bundle branch block (RBBB) with an odds ratio of 3.7 to 8 according to different studies (22-24). Besides advanced age, the predictors can be differentiated in three groups: (I) EKG—RBBB, left anterior fascicular block (LAFB), QRS duration; (II) anatomic—degree of annulus calcification and location, left ventricular end-diastolic dimension LVEDd; and (III) procedural—depth of implantation, degree of oversizing, balloon aortic valvuloplasty (BAV) or use of Medtronic CoreValve valve. The depth of implantation of CoreValve 6 mm below the annulus showed to be a very strong predictor when combined with presence of RBBB (25).

Mortality has not been increased in patients undergoing SAVR or TAVR that required a PPI. However, having a PPI is far from benign. It increases the duration of hospitalization and the rate of rehospitalization (7.3 vs. 6.2 days, P=0.001) (22). Possible complications include pocket hematoma, pneumothorax, pocket erosion, lead infection, endocarditis, lead failure, lead-induced tricuspid regurgitation and right ventricular (RV) perforation (26). Long-time effects on left ventricular function is also something to bear in mind. Moreover, pacemakers need to be replaced every ten years, exposing the patient to new surgeries and subsequent risk of complications.

PPI after TAVR has significant financial implications. Firstly, most of the time the pacemaker implantation is performed in the same hospitalization, increasing not only total length of stay (LOS) but also the intensive care unit (ICU) LOS. The hospital final reimbursement for TAVR decreases significantly after subtracting the cost of the device and electrophysiology services. Patients with temporal venous pacemaker (TVP) are mostly bed bound until pacemaker implantation. It is common that the elderly meet difficulties in going back home independently after the deconditioning generated by the prolonged inactivity, requiring referral to rehabilitation centers, which also penalizes the US hospital by decreasing the total TAVR reimbursement.

In conclusion, PPI continues to be the most common complication of TAVR. While some physicians may advocate that this complication does not increase mortality and is "part of the procedure", we cannot ignore the long-term implications or complications of having a permanent pacemaker, particularly in the younger population. A concerted effort should be made to recognize patients at risk, evolve devices, and perfect deployment techniques to decrease this important complication.

Stroke

Stroke is one of the most devastating and meaningful complications associated with aortic valve replacement, not only due to the increased mortality, but most importantly due to the associated worsening quality of life and disability. Recent studies identified balloon post-dilatation and valve dislodgement as acute stroke predictors, while new onset atrial fibrillation (AF) was identified as subacute stroke predictor and age, chronic AF, history of stroke, TIA and peripheral vascular disease or coronary artery disease as late stroke predictors (27-30). The recently presented Sentinel Trial proved that MRI baseline FLAIR Volumes is a strong predictor of a new lesion volume after TAVR (31).

In the high-risk cohort of the PARTNER trial, stroke incidence for TAVR was shown to be worse than SAVR with 5.4% vs. 2.4 % and 8.3% vs. 4.3% at 30-day and 1-year follow up. Major strokes after TAVR were 3.8% vs. 2.1% (P=0.20) at 30-day but 5.1% vs. 2.4% (P=0.07) at 1-year follow-up, in comparison to SAVR (18). Later, the high-risk trial using Medtronic CoreValve system inverted the prior relationship, with TAVR becoming superior to SAVR with a stroke rate of 4.9% vs. 6.2% (P=0.46) at 30-day and 8.8% vs. 12.6% (P=0.10) at 1-year follow-up, in comparison to SAVR. Moreover, this trial was the first to prove lower rate of death from any cause in TAVR at 1 year, which was the primary end point (14.2% vs. 19.1%), representing

an absolute risk reduction of 4.9% [upper boundary of the 95% confidence interval (CI), –0.4; P<0.001 for non-inferiority; P=0.04 for superiority] (20). Even between contemporary randomized trials, the stroke rate was dissimilar, probably due to differences between population treated. In newer trials, a trend towards lower stroke in TAVR was corroborated. PARTNER 2A, evaluating Sapien XT in an intermediate risk group, confirmed a similar frequency of stroke between the transcatheter group and the surgery group. In the TF access cohort, TAVR resulted in a lower rate of death from any cause or disabling stroke than surgery (hazard ratio in the intention-to-treat analysis, 0.79; 95% CI, 0.62 to 1.00; P=0.05; hazard ratio in the as-treated analysis, 0.78; 95% CI, 0.61 to 0.99; P=0.04) (14). This year, the SURTAVI trial similarly evaluated an intermediate risk group of patients, proving the superiority of TAVR in terms of rate of stroke. On this occasion, all stroke and TIA was 3.4% *vs.* 5.3% (95% CI: –3.9 to 0.1) in favor of TAVR at 30-day follow-up, a non-significant difference that persisted at 2-year follow up (10% *vs.* 11%, 95% CI: –4.1 to 2.3). Finally, disabling stroke was half (1.1% *vs.* 2.2 %, 95% CI: –2.3 to 0.2) in the transcatheter group at 30-day follow-up and almost got superiority at 2 years follow-up (2.6% *vs.* 4.6%, 95% CI: –4.0 to 0.0). Of note, patients in this trial were younger and have lower STS risk in comparison to PARTNER 2A patients, explaining the better results of both SAVR and TAVR in the later trial (13).

A complete whole chapter could be dedicated to cerebral protection devices (CPSs) during TAVR. Haussig *et al.* proved, in a single-center randomized trial, the benefit using a dual independent filter for embolic debris capture. Reduction in number of lesions and volume of lesions reached statistical significance (32). More recently, Sentinel trial, a multi-center randomized study evaluating the same CPS, concluded that the device profile is safe but failed to prove superiority by reducing median total new lesion volume, the primary MRI-based end-point. Giustino *et al.* presented a clinical event meta-analysis where the use of CPS had lower risk of death or stroke on relative (6.4% *vs.* 10.8%; P=0.04) and absolute terms (ARD: –4.4%; 95% CI: –9.0% to –0.1%; NNT =22) (33). The Sentinel device was recently approved by the FDA and is now commercially available. In contrast to the Sentinel CPS, which is deployed from radial approach and capture debris, many other deflectors devices are being tested. On one hand, these new devices, working as umbrellas, protect all the vessels of the Aortic arch. On the other hand, big emboli deflected downstream could generate distal vascular ischemic events

while the required femoral access may increase the risk of vascular complications. The cost of the Sentinel device will play a significant role in its wide adoption. Until more robust evidence supports its acceptance, the choice of using neuroprotection in TAVR requires an individualized risk-benefit analysis. CPS technology was not yet tested in surgical aortic valve replacement (SAVR).

There are also unanswered questions in regards of the pre- and post-aortic valve replacement medical management. A consistent evidence-based strategy to treat our patients after surgical AVR in view of ameliorating the incidence of new onset AF remains scarce. Recent randomized trials in intermediate risk patients SAVR showed a post procedural new onset AF incidence between 25% and 40%, that is, sustained at 1-year follow-up (13,14). Recommendations on antithrombotic therapy after TAVR are insufficient and based on weak data. This is a complex field, where numerous variables such as the presence of chronic or new onset AF, the risk of stroke, the risk of bleeding and prior coronary interventions interact in unpredictable way. Many ongoing clinical trials evaluating the use of single *vs.* dual antiplatelet therapy and the combination of new oral anticoagulant are enrolling patients at the moment (34-37). A better understanding of which regimen is better will be paramount to reduce the rate of stroke in the TAVR population. Most subacute or late strokes in patients undergoing SAVR with chronic or new onset AF are thought to be due to thrombus formation in the left atrium. In patients with non-valvular AF, more than 90% of thrombi develop in the left atrial appendage (LAA). Different LAA exclusion procedures have been and are currently being explored in view of avoiding life-long oral anticoagulation and reducing the stroke rate (38,39). In TAVR, percutaneous LAA occlusion proved to be safe and effective in patients with AF. The WATCH-TAVR trial will assess the efficacy and safety of staged or simultaneous percutaneous LAA closure and TAVR against current medical practice. Of note, the potential added cost of percutaneous LAA closure to TAVR may increase the economic differences between a transcatheter and a surgical strategy.

For the younger and lower risk patients requiring aortic valve replacement, subclinical leaflet thrombosis is a topic of current concern in the cardiovascular community. Makkar *et al.* initially reported hypo-attenuated leaflet thickening (HALT) and reduced leaflet motion (RLM) in transcatheter valves, evaluated by four-dimensional volume- rendered computer tomography (40). Recent registries reported an

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incidence of subclinical leaflet thrombosis in 12% of Sapien XT, S3 and Lotus, 8.3% in CoreValve and only 7.4% in SAVR. So far, the new imaging findings are not accompanied by increasing rates of death, myocardial infarction or stroke, but it was associated with higher rates of TIA and increase in the mean aortic gradient in ECHO (41). Again, registry based conclusion may underestimate the rate of neurologic events. Oral anticoagulants prevent subclinical thrombosis and also helped in its regression. These findings require careful longer and larger adequately powered studies in order to draw valid conclusions. PARTNER 3 trial includes a sub-study to evaluate this issue in a more controlled fashion. If new oral anticoagulants succeed in reducing the current rate of neurovascular events in non-AF patients in comparison to DAPT, valve thrombosis may be of more clinical significance than currently known.

In conclusion, TAVR and SAVR have shown similar stroke rates both in high and intermediate risk patients. The key point now is to determine how the stroke profile could be improved in both fields. In TAVR, this could be eventually achieved by protecting the aortic arch vessels with filters or deflectors, excluding the LAA or refining and tailoring the post procedural antithrombotic strategy. The first two may increase the procedural cost significantly, though. In SAVR, there is space to improvement in terms of prevention of new onset of AF, and there are research trials awaited to understand better the role of surgical LAA occlusion in this population.

Durability

After the initial excitement with PARTNER trial earlier this decade demonstrating proof-of-concept in inoperable and high-risk patients (18,19), the wish of expanding this technology to lower risk populations become stronger. The cardiovascular community became comfortable with short-term TAVR results in procedure mortality, stroke, PVL and vascular complications. The main attention is now directed to long term durability of the transcatheter valves.

Structural valve deterioration is defined as any change in valve function resulting from an intrinsic abnormality, generally presenting with a mean aortic valve gradient ≥20 mmHg, effective orifice area ≤0.9–1.1 cm^2 and/or dimensionless valve index <0.35 m/s, and/or moderate or severe prosthetic valve regurgitation (42). The term structural refers to changes like wear and tear, stress fracture, calcification, pannus and disruption. Most surgical aortic bio-prosthesis have a 10-year freedom from

reoperation that is above 97% (43). To bear in mind, most of the literature in surgical AVR failure is based on freedom of reoperation, so those patients with bioprosthetic failure that were deemed inoperable did not count in the statistics. Long-term survival free of structural degeneration is well-recognized for SAVR while still remains the biggest question mark for TAVR.

A recent report from 5-year follow-up from PARTNER I trial revealed excellent durability of Sapien valve, without significant SVD to 5 years. The echocardiographic evaluation showed early favorable changes immediately after implant followed by later mid-term stability out to 5 years. Abnormal hemodynamics suggestive of valve thrombosis or stenosis were rarely described (44). It is critical to understand the pathogenesis of THV failure, since treatment varies dramatically. While PVL could be treated with percutaneous closure, post-dilatation or valve-in-valve TAVR, early central aortic regurgitation should arouse the suspicion of endocarditis, a dysfunctional leaflet, maldeployment or malposition. An increase in valvular gradients should warrant imaging work up for valve thrombosis and eventually a period of anticoagulation, as described before in the stroke section. If anticoagulation is not effective, then THV degeneration should be suspected and the patient should be evaluated by the Heart Team for TAVR or SAVR (45).

Longer term durability becomes a primary point of discussion in any younger patient with a life-expectancy greater than 10 years when TAVR or SAVR options are considered. Given the limited durability information that is currently available for TAVR and based on the fact that the majority of intermediate risk data was gathered from elderly patients [the mean age for the intermediate risk trials was close to 82- and 79-year-old for PARTNER 2A (15) and SURTAVI (14) respectively], low-risk trials will continue to collect clinical data for 10-year follow-up. This data will provide key insight into the true durability and performance of TAVR in healthy patients expected to live to study completion.

Moreover, the concept of individualized anatomy is more relevant than ever in the field of aortic valve disease. Delineating the exact aorto-valvar complex is an important step in treating each patient with the appropriate treatment. There is a limited number of TAVR valve-in-valve procedures that a patient can undergo, especially with a small annulus, as well as a maximum number of repeat sternotomies a patient can undergo without extreme risk. Hence, it is important to know exact sizing and anatomic

limitations that will allow or exclude future interventions. It is therefore advantageous to place the largest SAVR or TAVR possible in any given patient to facilitate later valve-in-valve, in theory (15). Different strategies may be offered to different patients, depending on size, age, life expectancy, candidacy for valve-in-valve, personal preference, SAVR durability, and TAVR durability.

Bleeding and acute kidney injury (AKI)

Bleeding in SAVR has been historically inconsistently reported, with no clear criteria, timing or quantification of the bleeding. Murphy *et al.* described an incidence of at least 1 transfusion in 57% of patients undergoing SAVR, association with mortality between transfused and not transfused, and also mortality associated with the larger requirement of transfusion (46). Recently, the randomized British TITRe trial failed to associate mortality with number of transfusions, but the patients that had not been transfused showed a better outcome with decrease in mortality (47). In the PARTNER trial, SAVR doubled the major bleeding in comparison to TF TAVR (22.7% *vs.* 11.2%, P=0.0004), with major bleeding being a strong predictor of mortality at 1 year [HR 2.36 (95% CI: 1.68 to 3.31), P<0.0001]. Interestingly, major bleeding in SAVR was correlated with 40% mortality while having no statistical impact in mortality after TF TAVR. In PARTNER 2A trial, major bleeding was lower for TAVR at both 30-day and 2-year follow-up (10.4 *vs.* 43.4, P<0.001; 17.3 *vs.* 46, P<0.001) while in the SURTAVI trial there was no significant difference in the same time-range between SAVR and TAVR (12.1% *vs.* 9.3%, 95% CI, –0.19 to 5.78) (13,14,18).

There are several predictors of AKI in TAVR, such as bleeding/RBC transfusion, low ejection fraction, age, female sex, history of diabetes and hypertension, and prolonged hypotension (48,49). Predictors of AKI in SAVR are mainly BMI and intraprocedural transfusion (50). PARTNER, PARTNER 2A, and SURTAVI trials showed a marked lower rate of AKI in TAVR compared to SAVR at 30-day follow-up (1.3 *vs.* 3.1, P=0.006; 6 *vs.* 15.1, P<0.001 and 1.7 *vs.* 4.4, 95% CI: –4.4 to –1.0 respectively) that was maintained at 1 and 2-year follow-up (13,14,19). A meta-analysis confirmed the importance of AKI on survival, showing that patients with AKI have a 5-fold increase in 30-day mortality and 3-fold increase at 1-year post TAVR (51). In a propensity score analysis with SAVR, TAVR with Sapien 3 in intermediate risk patients showed

6-fold reduction in AKI (0.5% *vs.* 3.3%), a similar rate of major vascular complications (6.1% *vs.* 5.4%) and a strong difference in life-threatening/ disabling bleeding (4.6 *vs.* 46.7) and cardiac death (0.9% *vs.* 3.1%) (52). The improvement in the screening imaging of patients with CKD, the ability to use small amounts of dye, and the aid of 3D TEE guidance has made a difference in reducing contrast induced nephropathy in TAVR patients. The introduction of 14 Fr delivery sheath and the increased experience of the operators have been key in reducing both major vascular complications, major bleeding and subsequently AKI. Recognition of patients at risk of AKI and bleeding is paramount to improving clinical outcomes in TAVR.

Catastrophic complications

Complications involving the aorta (aortic dissection or perforation), aortic valvar complex (injury or rupture), or left ventricle (perforation) have become very rare (0.2% to 1.1%), but potentially catastrophic. Coronary obstruction after TAVR have become comparable to SAVR in randomized trials (0.4%) (13,14,18,20). These complications, in high risk or inoperable patients, present a unique management challenge, making open exploratory and repair unfeasible or inappropriate. The identification of anatomic predictors in CT have largely helped preventing or preparing for these complications (11).

Economics

Studies addressing the relative cost-effectiveness of SAVR compared with TAVR have reported conflicting results. McCarthy *et al.* compared the Medicare cost of transcatheter aortic valve implantation (TAVI) and SAVR during 2012, at similar surgical risk levels and after propensity score-matching. Not surprisingly, TAVR decreased the LOS, OR charges, and blood administrations charges, but index hospitalization costs for medical/surgical supplies and cardiology care were higher for TAVR (53). The median estimated hospital costs and contribution margins were USD 45.500 and USD 2,390 for SAVR and USD 50.200 and USD 3,380 for TAVR, respectively. New changes in TAVR clinical practice such as conscious sedation, expedited recovery without ICU, early discharge, and more judicious PPI may reduce overall TAVR costs further but does little to address the primary expenditure related to the valve itself. A more detailed analysis regarding

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hospital readmission and health care cost is in progress based on the two recently released intermediate risk trials, PARTNER 2A and SURTAVI trials (16,19).

Conclusions

TAVR in the current era offers patients an alternative method to treat AS that is now safe, reproducible, applicable to most patients, and effective. Multiple questions must be answered in the future regarding stroke, valve performance, durability, pacemaker requirement, and other key metrics before further expansion into lower risk populations can occur—this data will be forthcoming with low-risk randomized trials within the next 5 years. Understanding the advantages and disadvantages of this powerful technology will allow clinicians to treat patients using a toolbox consisting of both TAVR and SAVR in the correct time and correct place.

Acknowledgements

Footnote

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