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MINI-REVIEW

Transcatheter Aortic Valve Replacement Programs: Clinical Outcomes and Developments

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ABSTRACT: Transcatheter aortic valve replacement is a relatively recent revolutionary treatment that has now become a standard procedure for treating severe aortic stenosis. In this article, the authors review the clinical history of transcatheter aortic valve replacement, summarize the major clinical trials, and describe the evolution of the technique over time. In doing so, the authors hope to provide a clear and concise review of the history and clinical evidence behind transcatheter aortic valve replacement.

Key Words: aortic valve replacement ■ clinical trial ■ complication ■ outcome ■ transcatheter aortic valve implantation

Aortic stenosis (AS) has an estimated prevalence of 12% to 13% for all AS and 2% to 4% for severe AS in patients ≥75 years of age in the Western world, making it one of the most common structural heart diseases affecting the elderly.[1,2] Severe AS is defined as an aortic valve area ≤1.0 cm^2 with mean aortic valve pressure gradient of ≥40 mm Hg or aortic maximum velocity of ≥4 m/s, and is an indication for aortic valve replacement based on the most recent professional society guidelines.[3]

Historically, severe AS was treated by surgical aortic valve replacement (SAVR) or medical management (which includes balloon valvuloplasty, a temporizing measure with notable complication risks).[4] These options were limited, because the Euro Heart Survey showed up to 30% of patients were not receiving surgery for severe symptomatic AS because of a high surgical risk.[5]

In 1989, the Danish cardiologist Henning Rud Andersen performed the first animal implantation of what is now known as a transcatheter aortic valve replacement (TAVR), resulting in a patent filed in 1990 that was granted in 1995.[6] Initially, there was skepticism and low enthusiasm for this innovation, leading to slow adoption and research. In 2002, the first human TAVR was performed on a 57-year-old man, which opened the doors to a new interventional era.[7] A standardized scoring tool for calculating the surgical risk of aortic valve replacement was subsequently established by the Society of Thoracic Surgeons (STS).[8]

The clinical benefit of TAVR compared with SAVR in inoperable and high surgical risk patients with severe AS was first established with the PARTNER (Placement of Aortic Transcatheter Valve Trial) series of trials.[9,10] In 2011, the US Food and Drug Administration approved the Edwards SAPIEN TAVR valve for patients with severe AS who were inoperable and not eligible for open heart surgery. This indication has since been expanded to cover high-risk, intermediate-risk, and recently low-risk AS patients through multiple vascular approaches for different manufactured valves.[11–19] Table 1 summarizes the major TAVR studies and their results.

In inoperable patients, TAVR was associated with an absolute 20% risk reduction in all-cause death at 1-year postoperation, compared with standard medical therapy with or without balloon valvuloplasty.[9] As

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Table 1. Summary of Major TAVR Clinical Trials

Trial	Year	Patient Population	n	% Male	Mean Age (y)	Follow-up (y)	Short-Term Outcomes	Long-Term Outcomes
PARTNER 1[9]	2010	Inoperable patients	n=358 179 TAVR 179 standard therapy	46%	83	1.6	At 30 d, TAVR vs standard of care: • All-cause death (5% vs 2.8%, nss) • Repeat hospitalization (5.6% vs 10.1%, nss) • Major strokes (5.0% vs 1.1%, nss) • Major vascular complications (16.2% vs 1.1%, ss) • Major bleeding (16.8% vs 3.9%, ss)	At 1 y, TAVR vs standard of care: • All-cause death (30.7% vs 49.7%, ss) • Repeat hospitalization (22.3% vs 44.1%, ss) • Major stroke (7.8% vs 3.9%, nss) • Major vascular complications (16.8% vs 2.2%, ss) • Major bleeding (22.3% vs 11.2%, ss)
PARTNER 1[10]	2011	High surgical risk patients (STS ≥10%)	n=699 348 TAVR 351 SAVR	58%	84	1.4	At 30 d, TAVR vs SAVR: • All-cause death (3.4% vs 6.5%, nss) • Major stroke (3.8% vs 2.1%, nss) • Major vascular complications (11.0% vs 3.2%, ss) • Major bleeding (9.3% vs 19.5%, ss) • New-onset atrial fibrillation (8.6% vs 16.0%, ss)	At 1 y, TAVR vs SAVR: • All-cause death (24.2 vs 26.8%, nss) • Major stroke (5.1% vs 2.4%, nss) • Major vascular complications (11.3% vs 3.5%, ss) • Major bleeding (14.7% vs 25.7%, ss) • New-onset atrial fibrillation (12.1% vs 17.1%, nss)
CoreValve[13]	2014	Inoperable (≥50% 30-d risk of mortality or irreversible morbidity)	N=489 489 TAVR compared with meta-analysis data	48%	83	1	At 30 d, TAVR • All-cause death or major stroke (9.8%) • Major stroke (2.3%) • Major vascular complications (8.2%) • Major/life-threatening bleeding (36.7%)	At 1 y, TAVR • All-cause death or major stroke (26.0%) • Major stroke (4.3%) • Major vascular complications (8.4%) • Major/life-threatening bleeding (42.8%)
CoreValve[14]	2014	High surgical risk patients (STS ≥15%)	n=747 390 TAVR 357 SAVR	53%	83	1	At 30 d, TAVR vs SAVR: • All-cause death (3.3% vs 4.5%, nss) • Major stroke (3.9% vs 3.1%, nss) • Major vascular complications (5.9% vs 1.7%, ss) • Major/life-threatening bleeding (41.7% vs 69.5%, ss) • New-onset atrial fibrillation (11.7% vs 30.5%, ss) • Permanent pacemaker (19.8% vs 7.1%, ss)	At 1 y, TAVR vs SAVR: • All-cause death (14.2% vs 19.1%, ss) • Major stroke (5.8% vs 7.0%, nss) • Major vascular complications (6.2% vs 2.0%, ss) • Major/life-threatening bleeding (46.1% vs 75.1%, ss) • New-onset atrial fibrillation (15.9% vs 32.7%, ss) • Permanent pacemaker (22.3% vs 11.3%, ss)
PARTNER 2[15]	2016	Intermediate surgical risk patients (STS 4–8%)	n=2032 1011 TAVR 1021 SAVR	55%	82	2	At 30 d, TAVR vs SAVR: • All-cause death or disabling stroke (6.1% vs 8.0%, nss) • Major vascular complications (7.9% vs 5.0%, ss) • Major bleeding (10.4% vs 43.4%, ss) • Acute kidney injury (1.3% vs 3.1%, ss) • New atrial fibrillation (9.1% vs 26.4%, ss)	At 2 y, TAVR vs SAVR: • All-cause death or disabling stroke (19.3% vs 21.1%, nss) • Major vascular complications (8.6% vs 5.5%, ss) • Major bleeding (17.3% vs 47%, ss)
SURTAVI[16]	2017	Intermediate surgical risk patients (STS 3–15%)	n=1660 864 TAVR 796 SAVR	56%	80	2	At 30 d, TAVR vs SAVR: • All-cause death or disabling stroke (2.8% vs 3.9%, nss) • Rehospitalization (AVR-related disease) (2.9% vs 4.2%, nss) • Major bleeding (12.2% vs 9.3%, nss) • Acute kidney injury (1.7% vs 4.4%, ss) • Major vascular complication (6% vs 1.1%, ss) • Permanent pacemaker implantation (25.9% vs 6.6%, ss) • Atrial fibrillation (12.9% vs 43.4%, ss)	At 2 y, TAVR vs SAVR: • All-cause death or disabling stroke (12.6% vs 14%, nss) • Rehospitalization (13.2% vs 9.7%, ss) • Aortic valve reintervention (2.8% vs 0.7%, ss)

(*Continued*)

Table 1. Continued

Trial	Year	Patient Population	n	% Male	Mean Age (y)	Follow-up (y)	Short-Term Outcomes	Long-Term Outcomes
PARTNER 3[17]	2019	Low surgical risk patients (STS <4%)	n=950 496 TAVR 454 SAVR	69%	73	1	At 30 d, TAVR vs SAVR: • All-cause death, stroke, or rehospitalization (4.2% vs 9.3%, ss) • All-cause death (0.4% vs 1.1%, nss) • All strokes (driven primarily by nondisabling stroke) (0.6% vs 2.4%, ss) • Rehospitalization (for AVR-related disease) (3.4% vs 6.5%, ss) • Major bleed (3.6% vs 24.5%, ss) • Major vascular complications (2.2% vs 1.5%, nss) • New permanent pacemaker (6.5% vs 4%, nss) • New-onset atrial fibrillation (5% vs 39.5%, ss)	At 1 y, TAVR vs SAVR: • All-cause death, stroke, or rehospitalization (8.5% vs 15.1%, ss) • All-cause death (1.0% vs 2.5%, nss) • All strokes (1.2% vs 3.1%, nss) • Rehospitalization (7.3% vs 11%, nss) • Major bleed (7.7% vs 25.9%, ss)
Medtronic Evolut Transcatheter Aortic Valve Replacement in Low Risk Patients[18]	2019	Low surgical risk patients (STS <3%)	n=1403 725 TAVR 678 SAVR	65%	74	1.1	At 30 d, TAVR vs SAVR: • All-cause death or disabling stroke (0.8% vs 2.6%, ss) • All-cause death (0.5% vs 1.3%, nss) • Disabling stroke (0.5% vs 1.7%, ss) • Major bleed (2.4% vs 7.5%, ss) • New permanent pacemaker (17.4% vs 6.1%, ss) • New-onset atrial fibrillation (7.7% vs 35.4%, ss) • Major vascular complications (3.8% vs 3.2%, nss)	At 1 y, TAVR vs SAVR: • All-cause death or disabling stroke (2.9% vs 4.6%, nss) • All-cause death (2.4% vs 3%, nss) • Disabling stroke (0.8% vs 2.4%, ss) • Major bleed (3.2% vs 8.9%, ss) • New permanent pacemaker (19.4% vs 6.7%, ss) • New-onset atrial fibrillation (9.8% vs 38.3%, ss)

nss indicates not statistically significant; PARTNER, Placement of Aortic Transcatheter Valve Trial; SAVR, surgical aortic valve replacement; ss, statistically significant; STS, Society of Thoracic Surgeons; SURTAVI, Surgical Replacement and Transcatheter Aortic Valve Implantation; and TAVR, transcatheter aortic valve replacement.

this population represents up to 30% of the total severe AS population, this new proof of benefit led to TAVR rapidly becoming the standard of care in these patients.

In the 2011 PARTNER trial, it was found that in high-risk patients, defined as STS score ≥8%, there was a similar rate of death and stroke in the TAVR group compared with the surgical group at 30 days and 1 year.[10] However, in the TAVR population, there were higher rates of major vascular complications with a lower frequency of major bleeding and new-onset atrial fibrillation. There was no statistically significant difference between the groups at 1 year regarding symptoms.[10] Since the procedure was less invasive and had a shorter length of stay in the hospital, this outcome further reinforced the benefits of this new technique. Similar results were found in the trials studying the Medtronic CoreValve in inoperable[13] and high-risk[14] TAVR. These early valves have long-term outcomes and durability data available.

By 2015, the 5-year outcomes from both PARNTER 1 trials had emerged. PARTNER 1 study for inoperable patients demonstrated a significantly reduced risk of all-cause mortality in the TAVR versus standard therapy group (71.8% versus 93.6%, $P<0.0001$).[20] Of note, the mortality in these inoperable patients remains high, and this specific study is limited by low sample size in the follow-up.

The 5-year follow-up from the PARTNER 1 study for high-risk patients demonstrated no difference between TAVR and SAVR with regard to all-cause mortality, repeat hospital admission, stroke, myocardial infarction, or endocarditis, but a higher risk of moderate/severe aortic regurgitation (14% versus 1%, $P<0.0001$).[21] This is particularly important since valve regurgitation is a marker of long-term valve durability. Of note, this study used the SAPIEN valve, which is no longer used, as the newer generation SAPIEN XT, SAPIEN 3, and SAPIEN 3 Ultra valves have since been developed.

The 5-year outcomes from the Medtronic CoreValve studies in high-risk patients who underwent TAVR versus SAVR demonstrated similar survival rates and stroke rates, but worse rates of aortic regurgitation (50% versus 23.9%), excluding deceased patients.[22]

In the 2016 PARTNER 2 trial, it was found that in intermediate-risk patients, defined as STS score 4% to 8%, there was a similar rate of death and disabling stroke in the TAVR group compared with the SAVR group at 2 years, though transfemoral TAVR demonstrated better outcomes than SAVR (hazard ratio of 0.79, $P=0.05$) and transapical TAVR had similar outcomes to SAVR.[15] Compared with SAVR, TAVR with the Sapien XT valve resulted in lower rates of severe bleeding, atrial fibrillation, and acute kidney injury, but higher rates of major vascular complications and paravalvular aortic regurgitation. In 2017, the SURTAVI (Surgical Replacement and Transcatheter Aortic Valve Implantation) trial for intermediate-risk patients (defined as a 30-day mortality risk of 3–15%) demonstrated that the CoreValve, a self-expanding bioprosthetic valve, had similar all-cause mortality and disabling stroke results as in PARTNER 2.[16]

The 5-year outcomes from the PARTNER 2 trial resulted in similar rates of all-cause death, strokes, and myocardial infarction, but had a higher rehospitalization rate and paravalvular aortic regurgitation.[23] The subsequent SAPIEN 3 valves were designed to minimize this risk through the use of a sealing skirt.

In the 2019 PARTNER 3 prospective randomized trial, it was found that in low-risk patients (defined as STS ≤4%) there was a lower risk of the composite outcome of death, stroke, and rehospitalization at 1 year, compared with surgical management.[17] Moreover, it was found that there was a lower risk of stroke and shorter hospitalization (3 days versus 7 days, $P<0.001$) with TAVR compared with surgery.[17] In addition, the 2019 Medtronic Evolut Transcatheter Aortic Valve Replacement in Low Risk Patients trial demonstrated noninferiority for composite all-cause death and stroke, as well as a statistically significant decrease in the rate of atrial fibrillation, acute kidney injury, and life-threatening bleeds compared with SAVR at 30 days postprocedure, though there was an increased rate of permanent pacemaker implantation.[18] Based on the PARTNER 3 and Medtronic results, the US Food and Drug Administration has expanded the TAVR indication in August 2019 to include low surgical risk patients. There are not yet any data on the long-term outcomes with the SAPIEN 3 or Evolut valves.

Beyond the proven medical outcomes and benefits, the high costs associated with TAVR programs have led some hospitals to modify the TAVR protocol to reduce length of stay, resource utilization, and complication rates.

CLINICAL OUTCOMES OVERVIEW

AS is a disease of the elderly, which is reflected in the fact that 90% of TAVRs are paid for by Medicare, according to the National Inpatient Sample Database.[24] With this advanced age comes several comorbidities, which would also be present in the SAVR population. However, TAVR patients usually have more advanced disease and have higher mortality risk since TAVRs are performed in high surgical risk and inoperable patients. This gap in surgical risk between the TAVR and SAVR patients is expected to reduce over time because of the new inclusion of low surgical risk AS patients in the TAVR population. Since TAVR has a lower risk-adjusted

reimbursement compared with SAVR, hospitals are working to modify elements of the procedure to improve clinical outcomes and improve economics of TAVR.[25]

Increase in TAVR Programs

The acceptance of TAVR as an important new therapy is evident by the proliferation of TAVR-performing institutions in the United States, rising 3-fold since 2012 to >600 programs in 2019.[26,27] This corresponds to a sharp increase in national TAVR cases (>4-fold since 2012) and a minimal change in SAVR, which is largely because of the expansion of the overall AVR patient pool to include nonoperative and high-risk candidates who now can undergo TAVR, with a corresponding proliferation of TAVR programs.[26,28,29] This AVR growth rate has increased with the results of the PARTNER 3 trial, and Edwards Lifesciences has already posted 26% growth in TAVR sales in Q3 2019 compared with Q3 2018, with continued increase in projected sales.[30] Moreover, it is likely that this expansion of TAVR into intermediate- and low-risk populations will now result in fewer SAVRs annually, though there is currently no definitive evidence for this in the literature to date.

Developments in TAVR Valves

A major development in TAVR is the expected increase in the number of valves available on the market. As of 2019, 3 companies have US Food and Drug Administration–approved TAVR valves: Edwards Lifesciences (SAPIEN, SAPIEN XT, SAPIEN 3, and SAPIEN 3 Ultra), Medtronic (CoreValve, Evolut R, Evolut PRO, Evolut PRO+), and Boston Scientific (LOTUS Edge). Moreover, there are numerous additional valve manufacturers that have had success internationally and are in the process of seeking US Food and Drug Administration approval in the United States. Unfortunately, there are little clear comparative data among the valves, since the valves are continuously evolving. While many studies try to compare balloon-expandable and self-expanding valves, the evolution in these valves makes it difficult to compare which category is better. As such, the studies below name the specific valves that are being compared in order to give a better indication of which generation of valve was used for the comparison.

The 2014 CHOICE (Comparison of Transcatheter Heart Valves in High Risk Patients With Severe Aortic Stenosis: Medtronic CoreValve versus Edwards SAPIEN XT) trial was a relatively small investigator-initiated trial in high-risk patients that compared outcomes between the Edwards SAPIEN XT and the Medtronic CoreValve from 2012 to 2013.[31] The valves were found to have similar rates of mortality and bleeding/vascular complications, though balloon-expandable valves (Edwards SAPIEN XT) were more often successfully placed (95.9% versus 77.5%, $P<0.001$) and had lower rates of permanent pacemaker placement (17.3% versus 37.6%, $P=0.001$) compared with the Medtronic CoreValve. Of note, this study highlighted the importance of developing newer valves that can be recaptured and repositioned to minimize the risk of device failure. As such, the CoreValve is being slowly phased out as the Evolut R, Evolut PRO, and Evolut PRO+ valves were developed with this additional feature. At 1-year follow-up, the rates of all-cause death, stroke, and repeat hospitalization from heart failure were similar between the 2 groups.[32] Five-year follow-up data were presented at EuroPCR and it was found that compared with the CoreValve, SAPIEN had similar rates of all-cause mortality, lower rates of myocardial infarction, and lower rates of new pacemaker placement, but higher mean transprosthesis gradient, smaller effective orifice area (EOA), higher structural valve deterioration, and higher rates of valve thrombosis.[33] This follow-up was limited by low population size for both valves.

After the initial CHOICE trial, the CHOICE-Extend registry was generated, which is an ongoing registry of nonrandomized patients at a single center in Germany undergoing transfemoral TAVR with the Edwards SAPIEN 3 and the Medtronic Evolut R.[34] A trial using the CHOICE-Extend registry found that the Evolut R had a significantly larger effective orifice area index, lower patient–prosthesis mismatch, and lower transvalvular peak gradients at 30 days postprocedure than SAPIEN 3, regardless of annulus size.[34] However, this study was limited by the fact that the SAPIEN 3 valve was used at least 3-fold more often than the Evolut R valve, and that the Evolut R valves were consistently at least 3 mm larger than the corresponding SAPIEN 3 valve for the given small-, medium-, and large-valve categories, likely contributing to the lower rates of severe prosthesis-patient mismatch (PPM) in the Evolut R valves.

A separate study from the FRANCE-TAVI registry comparing propensity-matched patients from 2013 to 2015 who underwent TAVR with SAPIEN XT or SAPIEN 3 versus CoreValve found that the CoreValve has higher rates of in-hospital mortality, permanent pacemaker implantation, moderate/severe paravalvular regurgitation, and 2-year mortality.[35] The elevated 2-year mortality appears to be driven primarily by the early mortality in the first 3 months after TAVR with the CoreValve.

A retrospective Canadian study of transfemoral TAVRs from 2007 to 2013 comparing the SAPIEN or SAPIEN XT devices against the CoreValve demonstrated no difference in death or all-cause readmission, though the CoreValve had higher rates of in-hospital stroke, permanent pacemaker placement, and second valve placement while the 2 SAPIEN valves had higher vascular access complications.[36]

Another study in 2019 compared the Portico self-expanding valve (by Abbott Vascular) to the SAPIEN 3 valve in TAVR patients at a German hospital (average STS 3.9), and found that 30-day mortality, stroke, major bleeding, major vascular complications, and pacemaker implantation were not statistically different between the 2 valves.[37] A separate meta-analysis compared the ACURATE neo self-expanding valve (by Boston Scientific) to the SAPIEN 3 and found that the ACURATE neo had a slightly higher risk of paravalvular leak and 30-day mortality, but lower rates of patient–prosthesis mismatch and pacemaker implantation.[38] While the Portico and ACURATE neo valves are not accepted in the United States currently, this comparison demonstrates the scarcity of objective evidence for a difference in outcomes between the 2 categories of self-expanding and balloon-expandable valve.

All taken together, there is no clear superiority between any of the known valves that are currently being used, as CoreValve and SAPIEN are being retired. The data are limited because CoreValve was being compared with newer generations of SAPIEN, and now there are limited data that seem to slightly favor the newer generation of self-expanding valves. However, this remains a difficult topic to study since new valves are being developed, operator skill is improving, and hospitals make practice changes to reduce complications.

Moreover, there is some evidence that the long-term valve degeneration is minimal, with the most recent 2019 study by Blackman et al[39] on TAVR patients from 2007 to 2011 suggesting that >90% of patients remain free of clinically defined structural valve degeneration within the 5 to 10 years of valve implantation, with similar results in both balloon-expandable and self-expandable valves. More data are expected to be published on this in the upcoming years, as TAVR is still a relatively new technology and the true durability is not yet known.

Table 2. Unanswered Questions Regarding TAVR

Questions	Currently Available Data
Should TAVR be used in AR?	Multiple small observational studies demonstrate success with the use of TAVR for AR.[60]
Should TAVR be used in bicuspid aortic valves?	Observational studies indicate no difference in 1-y all-cause mortality.[61]
Should TAVR be performed in patients with aortic dissection?	Minimal data available.
Should TAVR be performed in prior SAVR prosthetic valves (aka valve-in-valve implantation)?	Observational studies indicate that valve-in-valve operations have similar outcome to redo SAVR.[62]
Should TAVR be performed in individuals >90-y-old?	Observational study shows worse outcomes than in younger patients.[63]
Should TAVR be performed in younger populations?	Observational studies show similar or worsened outcomes in younger populations.[64,65]
How should obstructive coronary artery disease be treated when a patient is being considered for TAVR?	Numerous studies exist without definitive data, though generally staging PCI and TAVR procedures is the most common strategy.[66]
Is there a head-to-head comparison of clinical outcomes between the different valve manufacturers?	Some evidence suggests that balloon-expandable TAVRs have better outcomes than self-expanding TAVR, though there are limitations to the data.[35]
Should TAVR be performed in patients with end stage renal disease?	Observational studies show worse outcomes.[67]
Should younger patients receive a mechanical SAVR or a TAVR?	Minimal data available.

AR indicates aortic regurgitation; PCI, percutaneous coronary intervention; SAVR, surgical aortic valve replacement; and TAVR, transcatheter aortic valve replacement.

Length of Stay

Part of the driving force for favorable clinical outcomes over the years has been the evolution in practice patterns. In the early days of TAVR, hybrid operating rooms that have the functionalities of both a cardiac catheterization laboratory and a cardiac operating room were commonly used because of the ability to rapidly convert the case into a surgical case in the event that the TAVR was unsuccessful or a catastrophic complication occurred, a complication that occurs <1.5% of the time.[40] TAVRs performed in hybrid operating rooms employed standard surgical practices of general anesthesia with endotracheal intubation, bladder catheterization, invasive hemodynamic monitoring, transesophageal echocardiography, and surgical cutdowns for femoral access and closure. It was standard practice to transfer patients to the intensive care unit for extubation and postoperative care.

Many practices now utilize an optimized minimally invasive approach in a cardiac catheterization laboratory, utilizing only local anesthesia, conscious sedation, percutaneous access site entry, and transthoracic echocardiography, without urinary catheters or invasive hemodynamic monitoring.[41] Postprocedurally, patients are monitored on a telemetry unit, rather than an intensive care unit, emulating the percutaneous coronary intervention experience that is familiar to all catheterization laboratories. This optimized minimally invasive approach had similar mortality rates as standard hybrid operating room–based TAVRs, but had significant reductions in procedure room time, intensive care unit time, and length of hospital stay, which greatly reduced TAVR costs.[42]

TAVR patients have historically had lengths of stay that were 3 to 7 days long, though more recently are

<3 days,[43–46] while SAVR continues to require longer hospital stays (8–13 days). In 1 TAVR study, patients were discharged in <2 days with ambulatory heart rhythm monitoring for 30 days to detect delayed high-grade atrioventricular block after TAVR, and found 10% of patients developed this complication an average of 6 days postprocedure.[47] This reinforces the lack of added benefit to long stays in the hospital.

One method that has reduced hospital length of stay is the use of local anesthesia with conscious sedation instead of intubation, which has resulted in a shorter hospital stay, shorter procedure time, and lower complication rates (intubation trauma, dysphagia, postprocedural pneumonia, vasopressor support) without affecting the overall 30-day mortality.[48–50]

Another method of reducing hospital stay has been the transition to using percutaneous femoral artery access without surgical cutdowns, which has greatly reduced length of the hospital stay (by 1–3 days), increased home discharge rate (by up to 20%), and made no difference in major adverse events (vascular complications, wound infections, transfusion rates, and 30-day mortality).[43,51,52]

Complication Rate

A study for Medicare's Bundle Payment for Care Improvement Model 2 program from 2013 to 2015 indicates that there are similar 30-day readmission rates between TAVR (12.1%) and SAVR (9.9%), though there was a higher rate of late readmissions (30–90 day) in TAVR (15%) versus SAVR (6%) patients.[53] Of note, TAVR patients in this study were older with more comorbidities than the SAVR cohort, which may at least partially explain the higher late readmission.

There is no consistent literature that supports TAVR having a higher rate of any individual complication compared with SAVR, though this may reflect the natural evolution of this new technique regarding procedural protocol, postprocedural care, and operator skill. The most common concerning complications after any AVR include heart block requiring pacemaker placement, stroke, paravalvular leak, and vascular complications.[54–58] These complications lead to elevated length of stay, postoperative care, and healthcare costs.[40] Certain risk factors for late mortality have been identified: chronic obstructive pulmonary disease, chronic kidney disease, frailty, and chronic atrial fibrillation.[59] As TAVR patients are typically very sick elderly patients with multiple comorbidities, it is important to recognize that efforts to further reduce these complications and poor outcomes may be inherently limited.

Long-Term Prospects

The long-term viability of TAVR is dependent on continued excellent clinical outcomes as well as long-term financial sustainability. The overall clinical outcomes are likely to improve as the procedure becomes more popular and low surgical risk populations begin receiving TAVRs, and the financial sustainability will also improve as further optimizations are made to the procedural and postprocedural protocols. There remain several unanswered questions regarding the clinical applications of TAVR that have been touched upon by studies but require more detailed study to properly understand the scope of therapy (Table 2).[35,60–67]

CONCLUSIONS

TAVR is a relatively new technology that has revolutionized aortic stenosis treatment. In this review, we present a concise review of the clinical history, major clinical trials, procedural evolution, and unanswered questions of TAVR. There will be continued improvements in the field as more valves enter the market and more studies take place.

ARTICLE INFORMATION

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