

# Transcatheter Versus Surgical Aortic Valve Replacement in Low-Risk Patients: a Narrative Review of Early and Long-Term Outcomes

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## Abstract

For patients with severe aortic stenosis who are otherwise at low surgical risk, deciding between transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR) isn't straightforward. Trials like PARTNER 3 and Evolut Low Risk, supported by solid long-term data, suggest that TAVR is an excellent alternative. It's less invasive, offers quicker recovery, matches or even surpasses surgery in survival rates, and lowers stroke risk for 5 to 7 years. But TAVR isn't without downsides—it carries a higher risk of needing a permanent pacemaker and often leads to paravalvular leaks. Meanwhile, SAVR patients more frequently experience new atrial fibrillation and acute kidney injury. Ultimately, the choice depends on which risks and benefits matter most to the individual.

This review shows us different trails, registries and meta-analyses that are done recently to compare early, mid-term and long-term outcomes of TAVR vs SAVR in the patients that have a low risk of surgery, especially in young people with bicuspid aortic valves. After TAVR the chances of having complications like major bleeding and acute kidney injury are low, TAVR also provide early recovery. For younger, low-risk patients and those with bicuspid valves, the latest three-year data looks promising but isn't complete yet. Because of this, current guidelines stress the importance of personalized decisions made by a heart team, focusing on long-term care instead of automatically choosing "TAVR first" or "surgery first" for everyone.

**Key words:** Epidemiology; Aortic Stenosis; versus

## Introduction:

In the modern cardiology world, severe aortic stenosis (AS) has become a great valve problem. It is not just affecting the old people but nowadays affecting young fitter people. They go through the risk scores such as STS-PROM which is a risk score for mortality for 30-day post op.(1) They also go through another risk score that is EuroSCORE,(2) this starts a debate between whether transcatheter aortic valve replacement (TAVR) procedure should be opted for the patient or the surgical aortic valve replacement (SAVR) procedure.(3) striking not just the very old and frail but increasingly fitter patients who sail through risk scores like STS-PROM (<4%) or EuroSCORE II (<4%), turning the old debate of surgical fitness into a nuanced choice between transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR). (4–6)Nowadays, active healthy 70-year-old people are referred to cardiology clinics so that everyday they can get done with ultrasound and CT scans to detect any stiffness or calcium buildup on aortic valves,(7) before way worse symptoms appear. If these people are not given checkups their symptoms will worsen and will show classic signs like exertional dyspnea, angina or syncope.(8) Within a year mortality rate can reach between 30% to 50% if they are left unchecked and within few years the mortality rate and reach upto 90%. (9,10)There have been about 1 to 3% cases where people have died suddenly from asymptomatic severe aortic stenosis cases.(11)

## Epidemiology of Aortic Stenosis (AS)

Aortic stenosis is caused by thickening and calcification, which is more common among individuals under the age of 65, at a rate of 1.2%. The prevalence of severe AS is 0.2% among individuals aged 50 to 59 years, 1.3% among those aged 60 to 69 years, and almost 10% among those aged 80 to 89 years.(1) There is an incidence of 5 new cases per 1,000 people every year, with an average age of 60.(12) Men are slightly more affected than women,(13) with an incidence of around 52 cases per 100,000 people every year. In the US, there are approximately 100,000 annual interventions, with 40 to 50% of low-risk cases (STS < 4%). The EuroScore II risk scale is followed in

Europe. However, these operations are not possible most of the time because of comorbidities. In most cases, around 80 to 90% of cases are due to calcific degeneration,(14) more than rheumatic or other causes, such as a bicuspid valve. As the population in the US has increased, the global deaths caused by AS have also increased from 2008 to 2017, before the TAVR procedure became available.(15) In 2002, for patients who are unable to be operated on for severe AS, the TAVR procedure has been a life-saving option.

### **TAVR's Evolution from Last Resort to Frontline**

In 2002 for the patients who are unable to be operated on for severe AS they have gone TAVR procedure, which has been life saving for them. (16)TAVR procedure's noninferiority has been proven by High-risk PARTNER 1A/1B (2011) compared to SAVR procedure.(17) Intermediate-risk PARTNER 2A/SURTAVI (2016-17) closed gaps,(17) then low-risk patients according to PARTNER 3 trial (2019; n=1,000, mean age of 73, STS 1.9%) showed TAVR superiority on 1 year.(18) Problems like death or stroke or rehospitalization (8.5% vs 15.1% SAVR), Evolut Low Risk (2019; n=1,467, age 75, STS 1.8%) became noninferiority, and on 2-year death or disabling stroke (5.3% vs 6.7%) became less but Pacemakers rose up (7-19% TAVR vs 5-7% SAVR),(18) but bleeding or AKI or AF plummeted sans bypass. Registries like STS/ACC TVT confirmed low-risk TAVR is more than 70% now in US by 2024.(19)

### **Meta-analyses**

It confirm these findings, with Kolte et al. reporting a relative risk of approximately 0.53 for risk of death at 30 days with TAVR versus SAVR using a pool of over 20,000 patients, with no clear distinction between the curves at 2 years.(20) FU and associates also reported an incidence of about half that of acute kidney injury and major bleeding complications with TAVR in low- to intermediate-risk patients. However, significant trade-offs continue to exist, including new onset of conduction abnormalities requiring pacemaker placement in about 10-25% of TAVR recipients and mild PVL in about 20-30%, (21) plus an inherent and as-yet-undefined risk of prosthesis durability at >10 years in patients under the age of 70 potentially facing an expected survival of 15-20 years following treatment. Bicuspid valves continue to introduce an added level of complexity, with increased risk of prosthesis-patient mismatch and PVL, and TAVR potentially complicating coronary re-entry at some point down the road.

### **Low-Risk Cohort Spotlight**

Low-risk patients are commonly characterized by an STS-PROM or EuroSCORE II of < 4%, often being < 75 years of age, and rarely having significant frailty, coronary disease, or diabetes. In this respect, the PARTNER 3 cohort was, on average, 73 years of age with an STS score of 1.9%, while the Evolut Low Risk group averaged around 74 to 75 years of age with an STS score of 1.8 to 2.0%. This group of patients now constitutes the vast majority, where around 40% or more of the cohorts were deemed to be at lower risk using EuroSCORE II, shifting the focus from individual treatment to a lifetime perspective on valve management. Over a patient's lifetime, it is likely that the patient may require two or three valve procedures, although the use of TAVR-TAVR valve-in-valve techniques seems plausible, the long-term longevity remains less well-proven than that of surgical bio prostheses at this time. Purpose of This Review As TAVR surges and data matures (PARTNER 3 7-year, NOTION 10-year), gaps yell for synthesis: bicuspid results, thrombosis, reintervention ease. This narrative pulls RCTs, registries, metas to unpack early wins, mid-term parity, valve fates—guiding Heart Teams for this booming group.(18,22)

### **Methods:**

The literature review applies a focused evidence synthesis based on randomized controlled trials (RCTs), prospective registries, as well as the most recent meta-analyses available to compare transcatheter aortic valve replacement (TAVR) with surgical aortic valve replacement (SAVR) among patients with low to intermediate risk who have severe aortic stenosis (AS). The literature was selected based on its rigor with a focus on multicenter randomized studies, blind endpoints, as well as longer-term follow-up where possible—in this case, studies with a Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) of below 4% who reflect low-risk patients.(23)

### **Primary Randomized Controlled trials**

In the PARTNER 3 trial (NCT02675114), published in the New England Journal of Medicine (Mack et al., 2019), 1,000 low-risk patients (mean STS score of 1.9%) underwent randomization in a 1:1 manner to undergo transfemoral TAVR with the SAPIEN 3 device or SAVR. The primary endpoint was the composite of death, stroke, or rehospitalization at 1 year, with long-term follow-up at 7 years demonstrating no differences in mortality or valve survival. In the Evolut Low Risk trial (NCT02701283), published in New England Journal of Medicine (Popma et al., 2019), 1,467 patients (mean STS of 1.9%) underwent randomization to receive self-expanding Evolut R/Pro valves or SAVR and met the predefined criteria of non-inferiority of TAVR to SAVR in the composite of death or disabling stroke at 2 years, which persisted at 5-year follow-up. In addition to the above findings, this long-term follow-up proved TAVR superior in terms of hemodynamics and associated with significantly higher rates of permanent pacemaker implantation. In the NOTION trial (Thyregod et al., 2024), 280 lower-risk patients with 82% STS <4% and mean age of 79 underwent 10-year follow-up and demonstrated the composite endpoint of death, stroke, and myocardial infarction to be equivalent between TAVR and SAVR groups (65.5% in both groups). Registry Evidence OBSERVANT registry italiane (Italy)||Tamburino et al. (2013), extended analysis) Prospective, observational registry including 7,629 patients. Propensity score analysis yielded 2,558 pairs of low to intermediate-risk patients, TAVR vs. SAVR, mean EuroSCORE of 9%. Similar 30-day and 1-year mortality at 3.8% for the two approaches, but fewer bleeding events and increased incidence of vascular complications for the TAVR technique.(24)

### **Early 30days Outcome**

Contemporary low risk trial results reveal a very low. thirty-day mortality and stroke with TAVR although comparable to surgical AVR as well (TAVR had more permanent pacemakers, but less vascular complication).(25–27) The same trends have been identified in individual RCT's and in recent meta-analyses on low/intermediate risk patients.(25–27)

Results from the PARTNER 3 study showed that the SAPIEN 3 transcatheter valve had less major neurological complications (such as

stroke and atrial fibrillation) during the first month than surgery.(28) The frequency of strokes was approximately 0.5% within 30 days and 2.5% after surgery.(28) Atrial fibrillation developed in approximately 5% of patients undergoing TAVR compared to approximately 40% undergoing surgical AVR.(28)

The composite endpoint of death, stroke, or hospitalization also remained lower in the transcatheter cohort (95.7% vs. 93.4%) at one year post TAVR/surgery. There was no significant difference in the rates of major vascular complications (0.4% vs. 0.4%) or the need for a permanent pacemaker (0.5% vs. 5%) following TAVR with a balloon expandable valve. (28)Therefore, the overall safety profile of transcatheter therapy in this low-risk patient population was beneficial during the first year. Stroke, bleeding, and atrial fibrillation were the most significant contributors to this benefit as opposed to differences in mortality alone.(28)

In the Evolut Low Risk trial, self-expanding valves demonstrated non-inferiority for death or disabling stroke at two years (24 months) and promising early safety data for renal injury, bleeding and AF.

At 30 days, life-threatening/disabling bleeding was < 2% after transcatheter therapy versus > 7% after surgical, while acute renal injury/AF were consistently lower in frequency following less invasive procedures.(17)

These benefits come at the cost of increased likelihood of permanent pacemaker/procedure implantations (approximately 17% of patients required a device within 30 days of Evolut transcatheter therapy, as opposed to about 6% following surgical) and slightly more paravalvular regurgitation. Major vascular complications at 30 days using these two approaches were similar, indicating that modern access techniques can reduce large vessel injury even when large bore catheters are used.(17)

Meta-analysis of randomised controlled trials of low-risk patients undergoing percutaneous valve implantation report significantly lower rates of death or stroke at 30 days following percutaneous valve implantation when compared to surgical implantations (rate ratio approximately 0.7). Less early bleeding, new onset atrial fibrillation, acute renal failure and prosthetic heart valve mismatch, but greater numbers of permanent pacemakers, reintervention and paravalvular leak are complications associated with transcatheter procedures as opposed to surgical procedures. (25,27)

A longitudinal meta-analysis, which included ten randomised controlled trials involving over 9,000 patients, supports the notion that most differentials between transcatheter valve replacement and surgical valve replacement exist during the first year after procedure in terms of combined death or stroke as well as safety endpoints. The difference diminishes with longer follow up, indicating that 30-day outcomes are primarily determined by the degree of invasiveness and injury incurred by procedure.(25)

Various systematic studies over the last few years have recognized in detail 30, day safety outcomes of transcatheter replacement in low to intermediate, risk patient cohorts, most recently employing the Valve Research Consortium criteria for the description of the safety outcomes. (25–27) The data of these studies demonstrate that transcatheter replacement is linked to a markedly reduced occurrence of life, threatening or major bleeding events. In addition, the rates of stage 2, 3 acute kidney injury are lower. A very small number of patients who underwent transcatheter replacement developed atrial fibrillation early in the post, procedure period, as compared to surgical replacements. Correspondingly, low mortality as well as disabling stroke rates have been reported for both approaches. (25,26)

Both methods still carry risks, as evidenced by the odds of major vascular complications and of getting a permanent pacemaker within thirty days of the procedure, which are higher after transcatheter valve replacement as compared to surgical valve replacement. Hence, when deciding between transcatheter and surgical approaches to valvular disease, it is advisable to weigh factors such as patient's age, physique, risk of developing conduction abnormalities, and vascular status prior to making a final decision on therapy.(25–27)

Endpoint at Thirty Days	TAVR Pattern	SAVR Pattern	Key References
Mortality	Very low and similar to surgery with reduced combined death stroke in some meta analyses	Very low with no consistent excess versus TAVR on absolute scale	(29)
Disabling Stroke	Often slightly lower or similar rates in low risk trials	Slightly higher or similar but still low absolute rates	(29)
Major or Life Threatening Bleeding	Clearly reduced compared with surgery in randomized and pooled data	Higher early bleeding burden after open surgery and bypass	(29)
Acute Kidney Injury Stage Two or Three	Lower incidence at thirty days in low and intermediate risk analyses	Higher early kidney injury related to surgical stress and bypass	(30)
New Onset Atrial Fibrillation	Markedly reduced with single digit rates in low risk cohorts around five to eight percent	Much higher incidence around thirty five to forty percent in many trials	(31)
Permanent Pacemaker Implantation	Higher requirement especially with self expanding valves reaching mid teen percentages	Lower prevalence usually in the mid single digit range around six percent	(32)
Major Vascular Complications	Slightly higher or similar rates driven by large bore femoral access	Lower or comparable rates with surgical cannulation only	(33)

*Summary table for Thirty Day Outcomes*

#### Mid to long term outcomes:

TAVR has been shown through long-term studies to be a viable alternative to surgical aortic valve replacement (SAVR) up until approximately 7 - 10 years post replacement and provides more favorable hemodynamic results (greater than that of SAVR), less structural valve deterioration (SVD) in some cohorts and long-term gains in terms of quality of life. Therefore, TAVR can be considered as an option

for low-risk patients with symptomatic, severe aortic stenosis especially when the life expectancy aligns with the currently known durability of TAVR.

The Evolut Low Risk Trial (ELRCT) also evaluated patients who were at low risk for undergoing TAVR (<75 years of age) specifically to determine if TAVR offered benefits over conventional surgical valve replacement (C-SAVR). At three years, the cumulative incidence of all-cause mortality or disabling stroke (the composite endpoint) was 7.4% for TAVR and 10.4% for C-SAVR (hazard ratio (HR) 0.70, 95% confidence interval (CI): 0.49 to 1.00) indicating a clinically meaningful, but borderline statistically significant, decrease (i.e., 30% reduction) in the incidence of the composite outcome for TAVR.

In patients <75 years, at three years the incidence of all-cause mortality or disabling stroke was 5.7% with TAVR and 8.0% with C-SAVR ( $p=0.241$ ). This numerical difference was largely driven by the lower incidence of disabling stroke in patients undergoing TAVR. Therefore, these early and intermediate results numerically favor TAVR over C-SAVR in the absence of a safety signal for an increase in adverse event rates.

The hemodynamic performance of TAVR during this period clearly demonstrates the benefit of taking TAVR. At 3 years, TAVR patients had an average aortic gradient that was lower than that of SAVR patients (9.7 mmHg vs 12.9 mmHg;  $P<0.001$ ), and effective orifice area remained larger than that of SAVR patients (approximately 2.2 cm<sup>2</sup> vs 1.9 cm<sup>2</sup>). Moreover, TAVR was associated with considerably lower rates of severe prosthesis-patient mismatch than SAVR ( $\approx 1\text{--}2\%$  for TAVR vs  $7\text{--}8\%$  for SAVR), suggesting this may be a key contributor to enhanced long-term LV unloading and reestablishment of symptom relief following TAVR.(34)

From a safety perspective, the price to be paid for the hemodynamic advantages of TAVR is minimal. The rate of new permanent pacemaker implantation is consistently higher for TAVR with self-expanding valves; however, trends in mortality and stroke are generally in favor of SAVR or match surgery trends. Although patency rates of TAVR are slightly more frequent, moderate or severe patency of TAVR has not been reported as occurring with commercially available technology.

### 7 Years – Equivalent Clinical Durability

The PARTNER 3 trial represents the most robust data to date regarding the performance of balloon-expandable valves in low-risk populations. The incidence of death, stroke and rehospitalisation at 7 years was similar for both TAVR (34.6%) and SAVR (37.2%) patients (difference  $-2.6$  percentage points; 95% CI:  $-9.0$  to  $3.7$ ). Additionally, the incidence of death from any cause was 14.2% for TAVR patients and 16.6% for SAVR patients, while the incidence of stroke was also similar (TAVR 6.0% vs SAVR 6.4%). Therefore, the data indicate that TAVR has not shown greater disadvantages beyond the first seven years when compared to SAVR procedures.(35,36)

TAVR efficacy over five years has been demonstrated to be in line with that of SAVR by self-expanding TAVRs through the Evolut Low Risk Trial with an overall mortality or disabling stroke rate of 15.5% TAVR and 16.4% SAVR. This provides further evidence for long-term durability of both TAVR and SAVR, with similar overall mortality rates after five years (around 10%15%). In the case of TAVR, the hemodynamic advantage of a supra-annular valve compared with surgical valves continues to remain unchanged after midterm follow-up. TAVR provides a more favorable hemodynamic model in general than does the optimal model. TAVR continues to have more favorable gradient and effective orifice area characteristics when compared with surgical bioprosthesis valves; comparative analyses do not show any statistically significant differences between early valve-related complications (EVA), rates of valve thrombosis, or rehospitalization or reintervention rates for TAVR vs. SAVR. The PARTNER 3 study observed that after seven years, there were between 10%11% of rehospitalizations due to valve-related complications for TAVR; and between 7% and 8% for SAVR, well within the overlapping confidence intervals for both groups; while reintervention rates were reported as 2%3% at five years for both TAVR and SAVR in the Evolut Low Risk Trial.(35)

The primary factor distinguishing long-term outcomes is structural valve deterioration. While TAVR had a significantly lower rate of SVD than SAVR at 8 years (13.9% vs 28.3%,  $p=0.0017$ ), the overall rate of bioprosthetic valve failure was similar for both groups (8.7% for TAVR and 10.5% for SAVR). The results suggest that early generation self-expanding TAVR valves are likely to remain as durable as surgical bioprosthetic valves for patients of this age/risk profile, and may be more resistant to hemodynamic impairment than surgical bioprosthetic valves. However, experts caution against assuming that the true burden of SVD for younger low-risk patients has been accurately characterized, and recommend further follow-up before making generalizations about the 10-year durability of TAVR valves in patients in their 60s.(36)

Echocardiography performed on patients in these long-term studies showed that TAVR valves have lower transvalvular gradients and greater effective orifice areas than surgical valves, which is consistent with the design of the supra-annular TAVR valve. However, PVL remains slightly more prevalent in patients undergoing TAVR, and the long-term consequences of chronic PVL, left ventricular remodeling and heart failure is still being clarified. The rate of reintervention over the course of follow-up was low and similar for both groups, and valve-in-valve TAVR is an option for patients who experience bioprosthetic valve failure.(37)

Compared with TAVR, traditional surgical methods such as SAVR (Surgical Aortic Valve Replacement) provide more difficult recovery periods due to the peri-operative trauma associated with open-heart surgeries.

Patients will achieve significantly increased KCCQ (Kansas City Cardiomyopathy Questionnaire) scores approximately 30 days after their TAVR procedure, representing about a 20–25-point increase from their KCCQ baseline level.

Furthermore, when comparing quality of life and functional status between TAVR and SAVR, both groups maintain significant long-term benefits with very stable improvement for many years after the procedure. The PARTNER Trial 3 study presented these findings, showing that both TAVR and SAVR patients maintained substantial and sustained increases in functional status over many years, and the majority of these patients remain in NYHA Class I or II (New York Heart Association Functional Classification System).(38)



## Subgroups

Younger patients and patients with Bicuspid Aortic Valves (<75 years) show some of the positives and negatives of using low-risk TAVR studies to create a lifetime management plan rather than taking their specific characteristics into consideration.

The Modine/Evolut study of younger patients (<75) reported a 3-year rate of all-cause mortality or disablement from a stroke for TAVR (5.7% vs 8.0%) similar to that reported for Surgical Aortic Valve Replacement (SAVR). New permanent pacemaker (PPM) implants, however, were significantly higher after TAVR (approximately 21% for TAVR vs 7% for SAVR) even with TAVR having overall better haemodynamics and lower severe PPMs compared to SAVR. This exchange of new PPMs for traditional surgery can be of significant concern for younger patients who may need to live many years with a PPM and will likely need to replace their mechanical valve long after surgery.(39)

The Evolut Low Risk bicuspid study enrolled 150 patients who were considered to be at low risk for surgery, i.e., they had a mean age of 70 years, and their STS PROM (Society for Thoracic Surgery Predicted Risk of Mortality) was 1.3%, and they received treatment with Evolut R / PRO self-expanding valves. Study results have shown very low combined event rates of death and disabling stroke at 3 years (approximately 4%). The hemodynamics of all patients in this study remained excellent with sustained valve gradients and the absence of moderate or severe paravalvular leakage (PVL) through the 2- and 3-year follow-up periods. The majority of patients had no PVL or trace amounts of PVL.(40)

Studies have documented that cardiovascular conduction abnormalities are a significant complication associated with TAVR, leading to a new PPM (permanent pacemaker) implant in approximately 19% of TAVR patients by 3 years. Evidence for the long-term structural performance of TAVR valves in the setting of bicuspid valves and the frequency of reinterventions after 3 to 5 years is limited. Consequently, although the AHA/ACC guidelines still support the use of surgical aortic valve replacement (SAVR) for younger patients with bicuspid valves, this recommendation is more strongly supported when these patients also have associated aortopathy.

## Subgroup pattern versus overall trial

The primary composite endpoint for death/disabling stroke shows similar hazard ratios (HRs) between younger patients/bicuspid patients, indicating TAVR is non-inferior to SAVR with respect to major stroke/survivability, across low-risk trial groups.

Disabling stroke numbers favour TAVR, but new pacemaker insertion, prosthesis-patient mismatch vs anatomic complexity shift the risk-benefit ratio, therefore should be more carefully considered for patients who will likely live longer than the first prosthesis.

## Long-term coronary access

In younger patients, long-term coronary access is an important concern, particularly for those who will require multiple future PCI (percutaneous coronary interventions). Tall-frame, supra-annular THV (transcatheter heart valve) devices implanted high within the left ventricle or in small sinuses may obstruct or greatly reduce the ability for selective coronary cannulation (via the ostia), making this increasingly difficult following TAVR (transcatheter aortic valve replacement) performed on a prior TAVR patient.(41)

Patients with complex or extensive coronary artery disease or whose future interventions are anticipated to be via coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) should consider either a surgical valve replacement (SAVR) with a bioprosthetic heart valve or the use of TAVR depending on the time frame for intervention.

Coronary Access Preservation for Long-Term Success: To preserve long-term access to coronary arteries, precise pre-procedural CT planning, frame design with optimal commissural alignment and avoidance of higher-than-necessary placements of valve frames should be considered. For patients who have very complex coronary artery disease and/or very diffuse disease or who are likely to have future CABG or PCI, surgical valve replacement with a bioprosthesis may provide superior, more reliable, and more predictable access to coronary arteries than a TAVR-first approach.(41)

## Valve-in-Valve and Lifetime Strategy

As TAVR continues to expand its utilization to younger patients with low surgical risk, many of these patients will experience the need for reintervention in the form of valve-in-valve TAVR rather than open surgical reoperation. Although redo-TAVR is safe and feasible in most cases, it may increase a patient's prosthetic valve mismatch and further limit access to the coronary arteries, especially if the original prosthesis has been implanted into the aortic root in a restrictive manner.(42)

The current best practices of managing patients throughout their lives are to plan for the patient when they have a first procedure by determining the best prosthetic device and the best way to implant the prosthesis, so that there is a large enough effective orifice area, that there is a minimum of severe prosthesis patient size mismatches and that the prosthesis allows for coronary access in the event that the patient needs a TAVR-in-TAVR. For very young low-risk patients, patients who have a bicuspid valve, patients who have small annuli, and patients who have a complex coronary anatomy, it may still be safer to perform a SAVR procedure first (with the possibility of later doing a TAVR-in-SAVR) than to do a TAVR procedure first, even when the early results of TAVR appear to be very good.(43)

## Discussions:

Though TAVR has several advantages compared to SAVR, there are trade-offs associated with PPM, PVL, and long-term durability when performed in younger patients. ACC/AHA and ESC/EACTS guidelines recommend that each patient undergo a heart team evaluation prior to undergoing TAVR and currently, there are still knowledge gaps present in the literature regarding bicuspid valves greater than 10 years and next-generation devices. The majority of patients undergoing low-risk surgical aortic valve replacements are currently being treated with TAVR (over 70%) based on robust pre-inscriptive discussions and the results from ongoing randomized controlled trials (RCTs) will

continue to provide more guidance moving forward. (28,44)

TAVR has demonstrated numerous short-term benefits associated with lower overall mortality at 30 days post-procedure, decreased hospital readmissions, and rapid recovery compared to SAVR in low-risk populations; however, there are concerns associated with higher rates of PPM (up to 15-20%) and PVL (up to 15-20%), particularly due to conduction disturbances and long-term risk for heart failure. The SAVR approach to replacement provides improved durability in patients <65-70 years old based on the availability of mechanical or larger bioprosthetic valves that offer a lifespan of 10-20 years compared to the expected rates of SVD with TAVR.(44,45) Long-term management of patients with a bicuspid aortic valve is more favourable for the SAVR option since they will most likely need reinterventions; however clinical experience is developing with new, self-expanding TAVR technologies particularly with reference to their hemodynamic properties.(22,46)

### Comparison of Guidelines

In their recent guidelines, ACC/AHA prefer to use surgical aortic valve replacements (SAVR) for patients younger than 65 years and for those with a life expectancy greater than 20 years. SAVR is also the preferred choice for patients with anatomic challenges, such as a bicuspid aortic stenosis (AS). However, they recommend using transcatheter aortic valve replacement (TAVR) primarily for patients who are over the age of 80 or who have life expectancies less than 10 years.

The ESC/EACTS 2025 guidelines suggest moving toward a greater use of TAVR for low surgical risk patients aged 75 or older and to allow for shared decision-making with patients aged 65–75. Although TAVR is possible in specific situations with patients with bicuspid aortic valves, there is no formal endorsement for its use in these cases.(47)

Both organizations emphasize the importance of incorporating multidisciplinary heart teams when performing risk assessments of patients. Multidisciplinary heart teams utilize the STS PROM scores, patient frailty, and patient preference as tools to evaluate a patient. In order to reduce the number of futile surgical interventions, all patients who are referred should be seen by an independent cardiologist and surgeon prior to making a decision regarding the type of surgical intervention that will be performed (i.e., TAVR or SAVR), should have imaging (CT calcium scoring) performed (if possible), and should undergo a holistic risk profile.

In addition, the framework established by the CMS mandates encourages the establishment of a formal heart team infrastructure for accreditation purposes. As a result, all patients who are treated with either TAVR or SAVR will be required to be entered into the designated data registry to ensure outcome tracking. It is through this collaborative approach that equity across institutions is achieved. An example of this would be the implementation of minimalist protocols that allow 80% of patients who are not at risk to be discharged within 24 hours. (48)

### Measurement Niches

Long-term (>10 year) data for bicuspid TAVR are limited; however, registry data suggest that long term mortality rates from new-generation valves will be similar to tricuspid AS for the next 5-10 years although there is an increased incidence of strokes and unknown rates of SVD. New generation valves employ improved technology to address the problems of PPM/PVL; however, as the indications for TAVR increase, the feasibility of redo-TAVR and the need for explant will also increase. Data regarding the durability of TAVR in younger patients are largely unavailable as they are based upon extrapolation from the results of low-risk clinical trials such as PARTNER-3 at 7 year follow up.(49)

### Clinical Applications

Data from PARTNER-3/Evolut LR suggest that TAVR will account for more than 70% of all low-risk AS patients in the United States. Clinical practice can utilize this knowledge to accurately counsel patients regarding their TAVR procedure. TAVR providers should include discussion of the following: potential PPM complications (e.g., HF and mortality), expectations of lifetime reinterventions (especially potential valve-in-valve interventions) and an assessment of the patient's frailty/clinical anatomy. Additional considerations for young patients with VHD and a bicuspid aortic valve may include educating the young patient about potential durability advantages associated with SAVR compared with the procedural safety of TAVR methodologies.

The future of ongoing prospective randomised trials such as NOTION-2 (which has 3 years of prospective data and has established non-inferiority to TAVR at  $\leq 75$  years old. A sub-analysis of the bicuspid subgroup is expected in the coming months) along with Evolut low risk bicuspid randomised studies, will allow for a more comprehensive understanding of the outcomes in a younger patient population. These studies are seeking to assess the ability of these types of next generation valves to maintain the level of safety for patients undergoing repeat procedures, and will include imaging to assist with valve selection prior to implantation. As more information becomes available from these prospective randomised trials, it is expected that the guidelines established prior to 2025 will evolve based on the outcomes of patients who survive  $\geq 10$  years and experience further procedures who will ultimately benefit from strategies established for their lifetime.(50)

### Conclusion:

The introduction of TAVR to the treatment of patients with severe symptomatic aortic stenosis at low surgical risk resulted in significant improvements in 30-day mortality rates, rehospitalization rates and recovery time compared to SAVR, but with the drawbacks of higher PPM/PVL rates and ongoing uncertainty surrounding the long-term durability of valves implanted via TAVR (especially in younger patients and those with bicuspid valves).(22,28,50) This unique combination of benefits and drawbacks, as well as the growing concern regarding the long-term durability of transcatheter valves, has led to the establishment of heart team based care for the ongoing lifetime management of patients with aortic stenosis as outlined in the current ACC/AHA and 2025 ESC/EACTS guidelines with preferences for SAVR in younger patients with a longer life expectancy and/or more complicated anatomy (ie. bicuspid aortic valves) and preference for extending

TAVR use among older, lower-risk patients. (47,48) With the continued accumulation of data from long-term follow-up of low-risk TAVR clinical trials and studies specifically addressing younger patients and patients with bicuspid aortic valves, the aortic stenosis field will shift away from a simple, binary “TAVR or SAVR” decision-making process to a more individualized approach that includes thorough consideration of valve durability and reintervention plans, and patient preferences over the entire lifespan of the patient. (35,36,40,50)

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