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Transcatheter aortic valve implantation in patients with severe symptomatic aortic stenosis and low surgical risk

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Take-home messages

- TAVI is well established in the treatment of severe symptomatic AS and in patients considered to be at high risk or immediate risk for surgery and it is also an alternative to SAVR in low surgical risk patients with severe symptomatic AS, as demonstrated in well-designed clinical trials
- TAVI is MBS funded for all patients with symptomatic severe native calcific AS, including those at low surgical risk
- Patients with symptomatic AS should be involved in an evidence-based, shared-decision making discussion between the Heart Team and the patient around their care based on the various benefits and risks associated with either TAVI or SAVR

Introduction

Aortic stenosis (AS) is one of the most common cardiac conditions that affects the progressively aging populations of high-income countries such as Australia.[1, 2] AS may be due to congenital valve abnormalities, rheumatic heart disease, or calcium deposits.[3] In the elderly, AS largely occurs by calcific degeneration of the aortic valve leaflets leading to obstruction of blood flow from narrowing of the aortic orifice.[3-5] Severe AS leads to an increase in afterload, causing progressive hypertrophy of the left ventricle, and a decrease in systemic and coronary blood flow.[4, 6]

Approximately 97,000 Australians are estimated to be living with severe AS.[2] The prevalence of severe AS increases with age, with the point prevalence of severe AS in Australia estimated to be 7727 in individuals aged 55-59 years and increasing to 25,699 in those aged 75-79 years (**Figure 1**).[2] Modelling has suggested that over the 5-year period of 2020-2024, an estimated additional 9300 Australians aged ≥60 years will develop severe AS (approximately 6300 of whom will experience concurrent symptoms) each year.[2]

AUSTRALIA

- 55-59 yrs – **7727** [4018 females / 3709 males]
- 60-64 yrs – **6942** [3645 females / 3297 males]
- 65-69 yrs – **8573** [4501 females / 4072 males]
- 70-74 yrs – **12,695** [6601 females / 6094 males]
- 75-79 yrs – **25,699** [14,006 females / 11,689 males]
- 80-85 yrs – **17,694** [10,705 females / 6989 males]
- 85+ yrs – **18,050** [14,350 females / 3700 males]

Figure 1. Estimated point prevalence of severe aortic stenosis in Australia[2]

AS may be asymptomatic for many years, with symptoms appearing later in life after decades of gradual progressive narrowing of the aortic valve.[7, 8] The onset of symptoms may be gradual or abrupt. Clinical manifestations of severe AS include angina, dyspnoea, decreased exercise tolerance, syncope, and heart failure.[5, 9] Without timely intervention, symptomatic severe AS is associated with a very poor prognosis and sudden death may occur without warning.[1, 5, 10] Five-year survival rates for patients with newly diagnosed symptomatic AS have been shown to be 32%, with concomitant pharmacotherapy having no impact on survival.[11]

Because symptomatic severe AS has such a poor prognosis, early intervention is strongly recommended in all patients.[1, 9]

Patients with severe symptomatic AS have traditionally been treated with surgical aortic valve replacement (SAVR).[9] However, many patients deemed excessively high risk for an open surgical procedure, such as old and fragile patients or those with significant comorbidities, were left untreated.[12] In more recent years, transcatheter aortic valve implantation (TAVI), also called transcatheter aortic valve replacement (TAVR), has emerged as a less invasive alternative to isolated SAVR.[13-28]

During the TAVI procedure, a new aortic valve is inserted through a catheter into the heart, with the patient under general anaesthesia (or using local anaesthesia with sedation).[4] The new valve is positioned within the existing diseased aortic valve and is immediately functional. The faulty valve is not cut or removed. TAVI is commonly performed via the transfemoral approach (into the femoral artery) or via another approach, e.g., transapical, for patients in whom the transfemoral approach is not suitable.[29-31] The TAVI procedure can be performed using either a self-expandable, mechanically expandable, or a balloon-expandable device.[31]

Recent changes to Medicare-funding have expanded access to TAVI to include patients with severe symptomatic AS at low-, intermediate-, and high-risk of mortality from surgery. These changes will be discussed in this Educational review, along with clinical advantages of TAVI compared with SAVR, and the clinical evidence that supports the expanded funding to now include patients with severe symptomatic AS at low surgical risk.

Expert comment

AS is a common valvular disorder with preventable morbidity and mortality if diagnosed in a timely fashion. Mild to moderate AS must be followed up and there are active research projects looking at artificial intelligence in identifying AS from echocardiography and establishing follow up reminders (e.g., texts/emails) for patients. Most patients with severe AS do develop symptoms eventually and it is important symptoms attributable to AS are followed up. Not all shortness of breath is due to lung disease and this is very important for GPs and physicians to be aware of.

TAVI has revolutionised the treatment of AS. Since the first-in-human case in April 2002 by Prof Alain Cribier, more than 2 million TAVIs have been performed around the world. TAVI is now offered in many countries around the world as an alternative to SAVR, with the intrinsic benefits of a less invasive approach – shorter recovery, earlier discharge, lower stroke and mortality, lower atrial fibrillation, and lower kidney injury risk amongst many other benefits. The science and evidence base behind TAVI has been one of the more scrutinised entities in cardiology; its rollout is supported by multiple carefully designed and adjudicated multicentre, randomised, controlled studies. It has also been a shining example of partnerships between different and competing societies (i.e., cardiologists and surgeons) in allowing a technology to replace an older gold standard that was SAVR and in doing so improving the most important unit in the whole equation – patient outcome.

Approval and funding of TAVI devices in Australia

Initially, TAVI was used as an alternative treatment to SAVR in patients with severe AS and multiple comorbidities considered non-operable or at high risk for surgical complications.[14-16] Subsequently, the safety and efficacy of TAVI has been established in randomised, controlled trials (RCTs) in both intermediate-risk and low-risk patients with severe AS.[17-28]

Given the evidence from these RCTs, as from July 1 2022, TAVI is to be funded on the Medical Benefits Scheme (MBS) for all patients with symptomatic severe native calcific AS, including those at low surgical risk (MBS item 38522).[32]

High-risk patients (38495) and intermediate-risk patients (38514) will continue to have access to TAVI procedures, but low surgical risk patients will also gain access to TAVI as an alternative to SAVR.[32] The changes to funding reflect modern clinical practice and will enable all patients with severe AS to receive a rebate for TAVI if it is deemed clinically appropriate.[32] It is expected that patient access to the new TAVI low-risk population service will complement the already established high- and intermediate-risk population MBS services.

TAVI devices which have TGA approval for patients with severe symptomatic AS (all surgical risk categories) include the Edwards Lifesciences SAPIEN 3 TAVI systems,[33, 34] Medtronic's CoreValve Evolut R,[35] and Medtronic's CoreValve Evolut PRO.[36]

These funding changes are expected to improve physical and emotional functioning of the patients with severe AS across all surgical risk groups (see **Advantages section** below), including those with low surgical risk (see outcomes from the PARTNER 3 trial in the **Clinical trials** section),[17] with an associated reduction in all-cause mortality, stroke, and rehospitalisation.[32]

Multidisciplinary Heart Team

Funding for TAVI requires that a case conference is undertaken by the Multidisciplinary Heart Team to determine and document that the patient is suitable for TAVI.[32]

The TAVI suitability case conference is to include an assessment of:[32]

- the patient's risk and technical suitability for a SAVR; and
- the patient's cognitive function and frailty.

TAVI should be performed at a hospital that is accredited by the TAVI Accreditation Committee by an interventional cardiologist or cardiothoracic surgeon who has been accredited by the TAVI Accreditation Committee.[32]

A TAVI suitability case conference must comprise a team of three or more participants including a cardiothoracic surgeon, an interventional cardiologist, and a specialist or consultant physician who does not perform the TAVI procedure for the patient being assessed.[32] A Multidisciplinary Heart Team includes a broad range of health professionals with all the necessary skills and expertise to adequately assess patients who are potential TAVI candidates. By sharing the decision-making process and providing balanced clinical judgment, the team can determine the most appropriate procedure for each patient. If the patient is deemed suitable for TAVI, the team can guide and perform a TAVI, and support the patient peri-procedurally. Assessment by a Multidisciplinary Heart Team, rather than just one member of that team (e.g., the surgeon), thus optimises the clinical outcomes for each individual patient.

Expert comment

The reimbursement for TAVI in low surgical risk patients in Australia has allowed the heart team and the clinician to lead an important patient-centric approach rather than limiting the technology to higher risk patients. Nevertheless, it was very important to differentiate a low-risk patient from a "young" patient. A low-risk patient aged 80 years is entirely different to a low-risk patient aged 65 years. Issues relating to patient's anatomy, likelihood of future challenges such as coronary access, and the ability to have a TAVI-in-TAVI, must be carefully canvassed. A patient aged 65 years having a TAVI now then needing surgical explantation of the TAVI at the age of 75 years may not be sound. A patient aged 65 years having SAVR but who ends up having too small a surgical bioprosthesis which makes it very challenging to perform a TAVI-in-SAVR is also not a good outcome.

In short, the reimbursement of TAVI in low-risk patients is a significant milestone in improving the care of AS patients in Australia but it is more important than ever that the patient's anatomy is carefully analysed in detail with regards to both TAVI and SAVR options.

Advantages of TAVI vs SAVR

Across patients with severe symptomatic AS of all risk categories, TAVI, compared with SAVR, has been associated with a:

- less invasive procedure;[37]
- shorter procedure;[38, 39]
- shorter time in recovery;[39, 40]
- shorter hospital stay;[39, 41]
- more rapid improvement in quality of life;[40] and
- greater cost effectiveness.[42, 43]

A meta-analysis of clinical trials in patients with severe symptomatic AS across all surgical risk categories indicated that TAVI, compared with SAVR, was associated with a lower mortality rate (hazard ratio [HR] of 0.88; 95% CI 0.78, 0.99; p=0 0.03), an effect that was consistent across the entire spectrum of surgical risk (p-for-interaction = 0.410) and irrespective of type of transcatheter heart valve system (p-for-interaction = 0.674).[44] TAVI was also associated with a lower risk for stroke (HR 0.81; 95% CI 0.68, 0.98; p=0.028), a lower risk of major bleeding (HR 0.46; 95% CI 0.31, 0.69; p<0.001), and a lower risk of new onset atrial fibrillation (HR 0.34, 95% 0.23, 0.51).[44] However, SAVR was associated with lower rates of vascular complications (HR 1.99; 95% CI 1.34, 2.93), p=0.001) and permanent pacemaker implantation (HR 2.27; 95% CI 1.47, 3.64, p<0.001).[44]

Clinical trials: TAVI in AS patients at low surgical risk

TAVI was first investigated in randomised clinical trials (RCTs) involving severe symptomatic AS patients who were at high surgical risk.[14, 15] Subsequently, TAVI devices were investigated in RCTs in patients with severe symptomatic AS with an intermediate surgical risk,[22] such as in the PARTNER 2 trial.[18, 21] In the PARTNER 2 trial, there was no significant difference in the incidence of death or disabling stroke at 5 years after TAVI compared with SAVR.[21]

TAVI trials in patients at low risk of surgical mortality have been conducted and include the PARTNER 3 trial,[17] the NOTION trial,[24-27] and the EVOLUT trial.[23]

Outcomes from these trials are briefly described below.

PARTNER 3 trial

In the multicentre, randomised PARTNER 3 trial,[17] TAVI was compared with standard SAVR in patients with AS. Included patients had symptomatic severe AS, had to be eligible for transfemoral placement of the balloon expandable SAPIEN 3 system, and had a low risk of death with surgery (Society of Thoracic Surgeons Predicted Risk of Mortality [STS-PROM] score <4.0%).[17] Patients in the TAVI group received aspirin and clopidogrel 300 mg prior to the procedure and dual antiplatelet therapy for ≥1 month after the procedure. The primary endpoint was a composite of death from any cause, stroke, or rehospitalisation at 1 year after the procedure.[17] The patients enrolled in the PARTNER 3 trial[17] were younger (mean age 73 years), included more men (69.3%), had lower STS-PROM scores (mean score 1.9%), and had fewer coexisting conditions than patients enrolled in previous randomised trials of TAVI.[14, 15, 18, 21] The assigned procedure was performed in 950 patients (496 in the TAVI group and 454 in the surgery group).[17]

The primary outcome (all-cause mortality, stroke, or rehospitalisation) at 1 year occurred in 8.5% of the TAVI group compared with 15.1% of the SAVR group (absolute difference −6.6 percentage points; 95% CI −10.8, −2.5; p<0.001 for noninferiority; HR 0.54; 95% CI 0.37, 0.79; p=0.001 for superiority; **Figure 2**).[17]

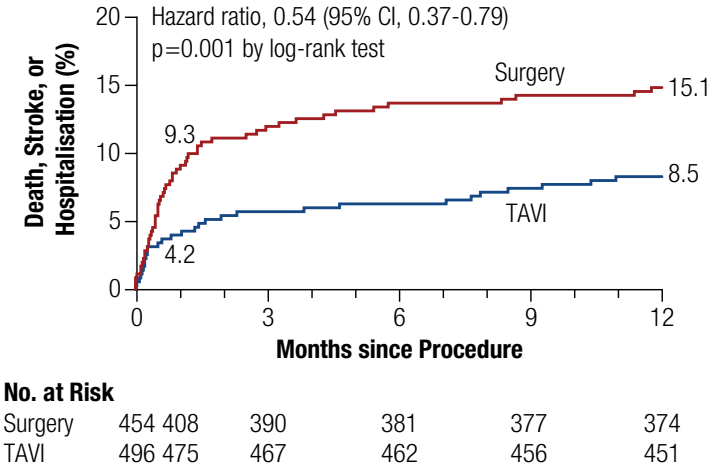

Figure 2. Kaplan–Meier estimates of the rate of the primary composite endpoint (all-cause mortality, stroke, or rehospitalisation) at 1 year[17]

At 30 days, fewer patients treated with TAVI, compared with SAVR, had a stroke (0.6% vs 2.4%; p=0.02), had died or had a stroke (1.0% vs 3.3%; p=0.01), had new-onset atrial fibrillation (5.0% vs 39.5%; p<0.001), or had a poor treatment outcome (death or a low Kansas City Cardiomyopathy Questionnaire score; 3.9% vs 30.6%; p<0.001).[17] TAVI, compared with SAVR, also resulted in a shorter index hospitalisation than surgery (median 3 vs 7 days; p<0.001).[17]

There were no significant between-group differences in the incidence of major vascular complications, new permanent pacemaker insertions, or moderate or severe paravalvular regurgitation.[17]

The researchers noted that a limitation of the PARTNER 3 trial[17] was that the results reflect only 1-year outcomes and do not address the problem of long-term structural valve deterioration.[17] They also noted that conclusions regarding the advantages and disadvantages of TAVI as compared with surgery (with either bioprosthetic or mechanical valves) will depend on long-term follow-up.[17]

NOTION trial

The NOTION trial (Nordic Aortic Valve Intervention) compared TAVI with SAVR in patients aged ≥70 years with isolated severe symptomatic AS.[24-27] This trial was an allcomers trial, but predominantly enrolled low-risk patients (82%). This trial used an older TAVI device that is no longer marketed in Australia; however, data from this trial have demonstrated the long-term efficacy of TAVI in low-risk symptomatic severe AS.[27] After 8 years of follow-up, there were no significant between-group differences in the risk for all-cause mortality, stroke, or myocardial infarction, as well as the risk of bioprosthetic valve failure after 8 years of follow-up.[27]

EVOLUT trial

The multicentre, randomised, noninferiority EVOLUT trial compared TAVI with a self-expanding supra-annular bioprosthesis with SAVR in 1468 patients who had severe AS and who were at low surgical risk.[23] The incidence of death or disabling stroke at 24 months (the primary endpoint) was 5.3% in the TAVI group and 6.7% in the surgery group, with the pre-specified criterion for non-inferiority being met.[23] At 30 days, patients treated with TAVI, compared with SAVR, had a lower incidence of disabling stroke (0.5% vs 1.7%), bleeding complications (2.4% vs 7.5%), acute kidney injury (0.9% vs 2.8%), and atrial fibrillation (7.7% vs 35.4%), but a higher incidence of moderate or severe aortic regurgitation (3.5% vs 0.5%) and permanent pacemaker (PPM) implantation (17.4% vs 6.1%).[23]

Vancouver 3M Clinical Pathway study

In a prospective clinical study that implemented the Vancouver 3M Clinical Pathway, 1400 patients with AS considered at increased surgical risk were screened by the Heart Team.[39] Of the screened patients, 411 were enrolled and received a SAPIEN XT (58.2%) or SAPIEN 3 (41.8%) valve.[39] The median age of the patients was 84 years, with a median STS PROM score of 4.9%.

The Vancouver 3M (Multidisciplinary, Multimodality, but Minimalist) Clinical Pathway focuses on next-day discharge, made possible by the use of objective screening criteria, as well as streamlined peri- and post-procedural management guidelines in patients undergoing balloon-expandable transfemoral TAVI.[39] The three key components of the Vancouver 3M TAVI Clinical Pathway are a minimalist peri-procedure approach, facilitated post-procedure recovery, and criteria-driven discharge (**Figure 3**).[39]

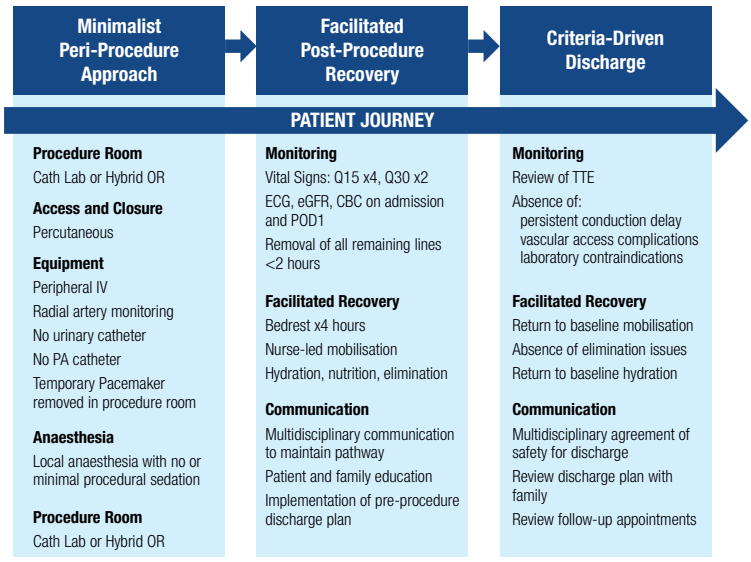

Figure 3. The Vancouver 3M TAVI Clinical Pathway[39]

CBC = complete blood count; **ECG** = electrocardiogram; **eGFR** = estimated glomerular filtration rate; **IV** = intravenous; **OR** = operating room; **PA** = pulmonary artery; **POD1** =post-operative day 1; **Q15** = every 15 min; **Q30** = every 30 min; **TTE** = transthoracic echocardiography.

Next-day discharge to home was achieved in 80.1% of patients, and within 48 hours in 89.5%. The composite of all-cause mortality or stroke by 30 days occurred in 2.9% of the patients (95% CI 1.7%, 5.1%).[39] Secondary outcomes at 30 days included major vascular complication (2.4% of patients), readmission (9.2%), cardiac readmission (5.7%), new PPM (5.7%), and >mild paravalvular regurgitation (3.8%).[39]

Expert comment

The NOTION trial was the first randomised, controlled trial using the first generation CoreValve self-expanding devices comparing this with SAVR. Initially, in its inception, there was significant controversy, as in the early days TAVI was mainly restricted to high surgical risk patients. It has now become an incredibly important study, with the longest duration of follow up in a carefully adjudicated dataset (RCT unlike registry data) providing significant reassurance regarding durability of transcatheter devices.

The EVOLUT LR and PARTNER 3 studies were both RCTs involving low surgical risk patients and younger patients, using the Evolut and Edwards S3 platforms, respectively. Both trials demonstrated superiority over SAVR in short-term measures. Both trials were only short term when published/presented and, in younger patients, longer term outcomes are eagerly awaited and important. The results are largely as anticipated for a minimally invasive technique compared with an open surgical approach – lower stroke and lower mortality related to the procedure are expected. However, the higher PPM rate and severe paravalvular leak rate with Evolut R were of some concern.

The 3M pathway study has provided reassurance that a minimally invasive technology (i.e., TAVI) can allow safe early discharge compared with SAVR, with no increase in adverse cardiac events. This has led to the adoption of early discharge and mobilisation in many centres around the world.

2020 ACC/AHA guidelines

The 2020 ACC/AHA guidelines for the management of valvular heart disease have provided recommendations for the use of TAVI in patients with severe AS.[9, 45] In particular, the guidelines note that TAVI is a safe and effective procedure for treatment of severe symptomatic AS (see **Table 1** for definition) in all adults regardless of estimated surgical risk.[9]

Table 1. ACC/AHA definition of severe aortic stenosis (AS)[9]

Stage	Definition	Valve anatomy	Valve haemodynamics	Haemodynamic consequences
Symptomatic severe AS				
D1	Symptomatic severe high-gradient AS	Severe leaflet calcification/ fibrosis or congenital stenosis with severely reduced leaflet opening	Aortic V_{max} ≥4 m/s Mean ΔP ≥40 mm Hg AVA typically ≤1.0 cm^2 (or AVAi ≤0.6 cm^2/m^2) but may be larger with mixed AS/AR	LV diastolic dysfunction LV hypertrophy Pulmonary hypertension may be present
D2	Symptomatic severe low-flow, low-gradient AS with reduced LVEF	Severe leaflet calcification/ fibrosis with severely reduced leaflet motion	Aortic V_{max} <4 m/s Mean ΔP <40 mm Hg AVA ≤1.0 cm^2	LV diastolic dysfunction LV hypertrophy LVEF <50%
D3	Symptomatic severe low-gradient AS with normal LVEF or paradoxical low-flow severe AS	Severe leaflet calcification/ fibrosis with severely reduced leaflet motion	Aortic V_{max} <4 m/s Mean ΔP <40 mm Hg AVA ≤1.0 cm^2 (indexed AVA ≤0.6 cm^2/m^2) AND stroke volume index <35 mL/m^2*	Increased LV relative wall thickness Small LV chamber with low stroke volume Restrictive diastolic filling LVEF ≥50%

*Measured when patient is normotensive (systolic blood pressure <140 mm Hg)

AR = aortic regurgitation; **AS** = aortic stenosis; **AVA** = aortic valve area circulation; **AVAi** = AVA indexed to body surface area; **ΔP** = pressure gradient between the LV and aorta; **HF** = heart failure; **LV** = left ventricular; **LVEF** = left ventricular ejection fraction; **V_{max}** = maximum velocity.

The broad indications for TAVI are the result of multiple randomised trials of TAVI versus SAVR (e.g., the PARTNER trials).[9]

The 2020 ACC/AHA guidelines recommend that all patients with symptomatic severe heart disease be evaluated by a Multidisciplinary Heart Team when an intervention is being considered.[9] The ACC/AHA guidelines note that if SAVR and TAVI are being proposed as an option for patients with AS, then the limited data about TAVI durability should be considered. SAVR has been used for more than 50 years, with durability data available for specific valve types across different age groups.[9] Generally, robust long-term durability data for TAVI extend to only about 5 years.[9]

The 2020 ACC/AHA guidelines recommend that:[9, 45]

- For symptomatic and asymptomatic patients with severe AS and any indication for atrial valve replacement who are <65 years of age or have a life expectancy >20 years, SAVR is recommended (Class of recommendation 1: Level of evidence A).[9, 45]
- For symptomatic patients with severe AS who are 65 to 80 years of age and have no anatomic contraindication to transfemoral TAVI, either SAVR or transfemoral TAVI is recommended after shared decision-making about the balance between expected patient longevity and valve durability (Class of recommendation 1: Level of evidence A).[9, 45]

- For symptomatic patients with severe AS who are >80 years of age or for younger patients with a life expectancy <10 years and no anatomic contraindication to transfemoral TAVI, transfemoral TAVI is recommended in preference to SAVR (Class of recommendation 1: Level of evidence A).[9, 45]
- For symptomatic patients of any age with severe AS and a high or prohibitive surgical risk, TAVI is recommended if predicted post-TAVI survival is >12 months with an acceptable quality of life (Class of recommendation 1: Level of evidence A).[9, 45]

Figure 4 provides an algorithm proposed by the ACC/AHA regarding the choice of SAVR or TAVI when aortic valve replacement is indicated for valvular AS.[9] Importantly, every patient with symptomatic AS should be involved in an evidence-based, shared, decision-making discussion between the patient and the Heart Team around their care based on the various benefits and risks associated with either TAVI or SAVR.[9]

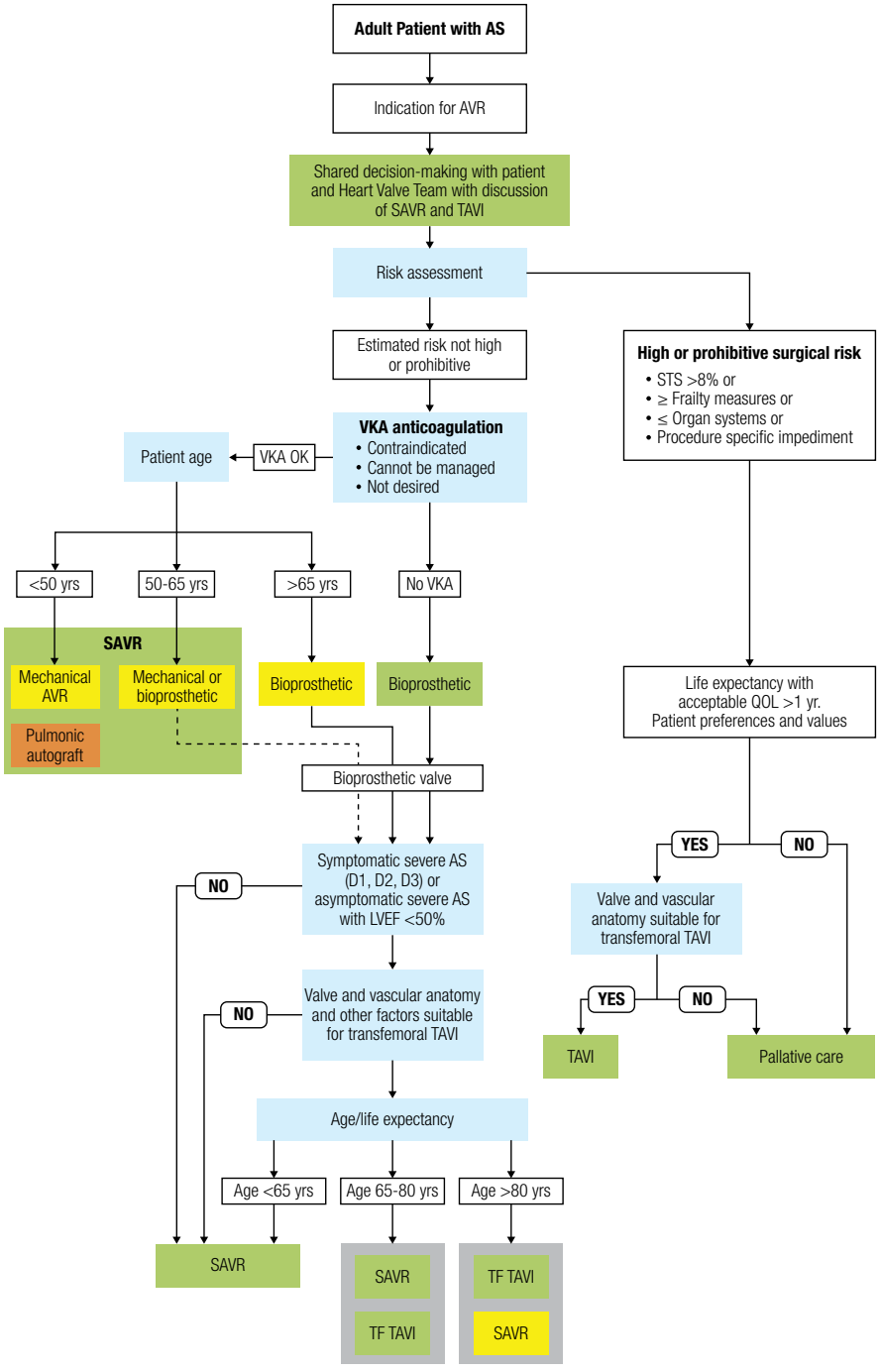

Figure 4. Choice of surgical aortic valve replacement (SAVR) versus transcatheter aortic valve implantation (TAVI) when aortic valve replacement (AVR) is indicated for valvular aortic stenosis (AS)[9]

Expert comment

The ACC/AHA guidelines have recommended the adoption of a transcatheter solution to AS for patients aged as young as 65 years compared to the ESC guideline which recommends the age of 75 years. This is a very forward looking and some would argue aggressive stance as both the low-risk TAVI trials included patients with an average age of 73 years. In Australia, the reimbursement for TAVI has no age limit and places significant responsibility on the heart team of each institution. As such, it is critically important that experienced TAVI operators are involved in the heart team meetings and multiple factors including patient preference, comorbidities, but more importantly feasibility of coronary artery access, future TAVI-in-TAVI feasibility, likely PPM risk, are all discussed. It is incredibly important that a convenient and expeditious solution that is TAVI, almost definitely favoured by the patient, is not chosen at the price of longer-term issues such as future coronary artery access and TAVI-in-TAVI.

Expert's concluding comments

The adoption of low-risk TAVI has been steadily increasing in Australia. This is perhaps reflective of the careful adoption and analysis of available data in the Australian cardiology community. It is likely that in the future the majority of AS patients will be treated with TAVIs in Australia like all around the world. Although caution must be exercised in hostile anatomy where surgery will almost certainly be more controlled and better than TAVI. Hostile anatomy includes hostile bicuspid anatomy, concomitant other valvular lesions requiring open surgery (e.g., complex mitral valve disease or complex coronary artery disease), and no femoral access for TAVI (i.e., subclavian or axillary TAVI).

As with a few examples in cardiology – e.g., coronary bypass surgery vs coronary stent – patients and referrers will likely enthusiastically favour a less invasive approach i.e., TAVI for AS. Nevertheless, perhaps as with coronary disease, some are clearly better treated with coronary artery bypass graft (e.g., multivessel disease or complex coronary artery disease) and, whilst stenting applies to the majority of patients, surgery will always have a place. When stenting was first pioneered 30 years ago, there was animosity and resistance from cardiac surgeons; now stenting and coronary bypass surgery co-exist allowing the best option to be offered to patients.

There are still lots of unresolved issues with TAVI but for the majority of patients, in experienced hands, TAVI can be offered with exceptional outcomes and with likely superior results to surgical aortic valve replacement.

References

1. Vahanian A, Beyersdorf F, Praz F, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2022;43(7):561-632.
2. Strange G, Scalia GM, Playford D, et al. Uncovering the treatable burden of severe aortic stenosis in Australia: current and future projections within an ageing population. BMC Health Serv Res. 2021;21(1):790.
3. Sverdlov AL, Ngo DT, Chapman MJ, et al. Pathogenesis of aortic stenosis: not just a matter of wear and tear. Am J Cardiovasc Dis. 2011;1(2):185-99.
4. Adams HSL, Ashokkumar S, Newcomb A, et al. Contemporary review of severe aortic stenosis. Intern Med J. 2019;49(3):297-305.
5. Carabello BA, Paulus WJ. Aortic stenosis. Lancet. 2009;373(9667):956-66.
6. Rana M. Aortic valve stenosis: Diagnostic approaches and recommendations of the 2021 ESC/EACTS Guidelines for the management of valvular heart disease - a review of the literature. Cardiol Cardiovasc Med. 2022;6(3):315-24.
7. Department of Health State Government of Victoria. Aortic stenosis. 2022. Available from: 'https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/aortic-stenosis'.
8. Das P, Pocock C, Chambers J. The patient with a systolic murmur: severe aortic stenosis may be missed during cardiovascular examination. QJM. 2000;93(10):685-8.
9. Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA Guideline for the management of patients with valvular heart disease: A report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. Circulation. 2021;143(5):e72-e227.
10. Strange G, Stewart S, Celermajer D, et al. Poor long-term survival in patients with moderate aortic stenosis. J Am Coll Cardiol. 2019;74(15):1851-63.
11. Varadarajan P, Kapoor N, Bansal RC, et al. Clinical profile and natural history of 453 nonsurgically managed patients with severe aortic stenosis. Ann Thorac Surg. 2006;82(6):2111-5.
12. Iung B, Cachier A, Baron G, et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? Eur Heart J. 2005;26(24):2714-20.
13. Boskovski MT, Nguyen TC, McCabe JM, et al. Outcomes of transcatheter aortic valve replacement in patients with severe aortic stenosis: A review of a disruptive technology in aortic valve surgery. JAMA Surg. 2020;155(1):69-77.
14. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010;363(17):1597-607.
15. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011;364(23):2187-98.
16. Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. Circulation. 2002;106(24):3006-8.
17. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019;380(18):1695-705.
18. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2016;374(17):1609-20.
19. Baron SJ, Arnold SV, Wang K, et al. Health status benefits of transcatheter vs surgical aortic valve replacement in patients with severe aortic stenosis at intermediate surgical risk: results from the PARTNER 2 randomized clinical trial. JAMA Cardiol. 2017;2(8):837-45.
20. ElGuindy A. PARTNER 2A & SAPIEN 3: TAVI for intermediate risk patients. Glob Cardiol Sci Pract. 2016;2016(4).
21. Makkar RR, Thourani VH, Mack MJ, et al. Five-year outcomes of transcatheter or surgical aortic-valve replacement. N Engl J Med. 2020;382(9):799-809.
22. Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2017;376(14):1321-31.
23. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. N Engl J Med. 2019;380(18):1706-15.
24. Thyregod HG, Steinbrüchel DA, Ihlemann N, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic valve stenosis: 1-year results from the all-comers NOTION randomized clinical trial. J Am Coll Cardiol. 2015;65(20):2184-94.
25. Thyregod HG, Søndergaard L, Ihlemann N, et al. The Nordic aortic valve intervention (NOTION) trial comparing transcatheter versus surgical valve implantation: study protocol for a randomised controlled trial. Trials. 2013;14:11.
26. Thyregod HGH, Ihlemann N, Jørgensen TH, et al. Five-year clinical and echocardiographic outcomes from the Nordic Aortic Valve Intervention (NOTION) randomized clinical trial in lower surgical risk patients. Circulation. 2019; Online ahead of print.
27. Jørgensen TH, Thyregod HGH, Ihlemann N, et al. Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement. Eur Heart J. 2021;42(30):2912-9.
28. Swift SL, Puehler T, Misso K, et al. Transcatheter aortic valve implantation versus surgical aortic valve replacement in patients with severe aortic stenosis: a systematic review and meta-analysis. BMJ Open. 2021;11(12):e054222.
29. Biasco L, Ferrari E, Pedrazzini G, et al. Access sites for TAVI: Patient selection criteria, technical aspects, and outcomes. Front Cardiovasc Med. 2018;5:88.
30. Toggweiler S, Leipsic J, Binder RK, et al. Management of vascular access in transcatheter aortic valve replacement: part 1: basic anatomy, imaging, sheaths, wires, and access routes. JACC Cardiovasc Interv. 2013;6(7):643-53.
31. Antony I, Mehari Abraha H, Hameed A, et al. A European update on transcatheter aortic valve implantation (TAVI) in the COVID era. J Anat. 2022; Online ahead of print.
32. Australian Government - Department of Health. New MBS item for Transcatheter Aortic Valve Implantation (TAVI) – low surgical risk 2022. Available from: 'http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/EE47A7D509AFC354CA2588410004083F/$File/QRG-TAVI-low-risk.06.06.22.pdf'.
33. Australian Government - Therapeutic Goods Administration. Edwards Lifesciences Pty Ltd - Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System - Valve-non-specific transcatheter heart valve bioprosthesis (343715). 2020. Available from: 'https://www.tga.gov.au/resources/artg/343715'.
34. Australian Government - Therapeutic Goods Administration. Edwards Lifesciences Pty Ltd - Edwards SAPIEN 3 Transcatheter Heart Valve System –Valve -non-specific transcatheter heart valve bioprosthesis (284496). 2017. Available from: 'https://www.tga.gov.au/resources/artg/284496'.
35. Australian Government - Therapeutic Goods Administration. Medtronic Australasia Pty Ltd - Medtronic CoreValve Evolut R System - Aortic transcatheter heart valve bioprosthesis, stent-like framework (284003). 2016. Available from: 'https://www.tga.gov.au/resources/artg/284003'.
36. Australian Government - Therapeutic Goods Administration. Medtronic Australasia Pty Ltd - CoreValve Evolut PRO system - Aortic transcatheter heart valve bioprosthesis, stent-like framework (319850). 2019. Available from: 'https://www.tga.gov.au/resources/artg/319850'.
37. Raiten JM, Gutsche JT, Horak J, et al. Critical care management of patients following transcatheter aortic valve replacement. F1000Res. 2013;2:62.
38. Hamm CW, Möllmann H, Holzhey D, et al. The German Aortic Valve Registry (GARY): in-hospital outcome. Eur Heart J. 2014;35(24):1588-98.
39. Wood DA, Lauck SB, Cairns JA, et al. The Vancouver 3M (multidisciplinary, multimodality, but minimalist) clinical pathway facilitates safe next-day discharge home at low-, medium-, and high-volume transfemoral transcatheter aortic valve replacement centers: The 3M TAVR study. JACC Cardiovasc Interv. 2019;12(5):459-69.
40. Reynolds MR, Magnuson EA, Wang K, et al. Health-related quality of life after transcatheter or surgical aortic valve replacement in high-risk patients with severe aortic stenosis: results from the PARTNER (Placement of AoRTic TraNscathetER Valve) Trial (Cohort A). J Am Coll Cardiol. 2012;60(6):548-58.
41. Minutello RM, Wong SC, Swaminathan RV, et al. Costs and in-hospital outcomes of transcatheter aortic valve implantation versus surgical aortic valve replacement in commercial cases using a propensity score matched model. Am J Cardiol. 2015;115(10):1443-7.
42. Mennini FS, Meucci F, Pesarini G, et al. Cost-effectiveness of transcatheter aortic valve implantation versus surgical aortic valve replacement in low surgical risk aortic stenosis patients. Int J Cardiol. 2022;357:26-32.
43. Zhou JY, Liew D, Duffy SJ, et al. Cost-effectiveness of transcatheter versus surgical aortic valve replacement in low-risk patients with severe aortic stenosis. Heart Lung Circ. 2021;30(4):547-54.
44. Siontis GCM, Overtchouk P, Cahill TJ, et al. Transcatheter aortic valve implantation vs. surgical aortic valve replacement for treatment of symptomatic severe aortic stenosis: an updated meta-analysis. Eur Heart J. 2019;40(38):3143-53.
45. Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA Guideline for the management of patients with valvular heart disease: Executive summary: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2021;143(5):e35-e71.

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