Review Article

2022 SASCI/SCTSSA joint consensus statement and guideline on transcatheter aortic valve implantation (TAVI) in South Africa

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Abstract

Patients with severe symptomatic aortic stenosis (AS) have traditionally been treated with surgical aortic valve replacement (sAVR). Transcatheter aortic valve implantation is a percutaneous option that has been shown to be at least as effective as sAVR in numerous subgroups of patients with severe AS. This is an update on the previous joint consensus statement and guideline on transcatheter aortic valve implantation (TAVI) in South Africa, published in 2016. It provides guidance on which patients should preferably be offered TAVI over sAVR, with special consideration of the resource-constrained environment in South Africa.

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The South African Society of Cardiovascular Intervention (SASCI) and the Society of Cardiothoracic Surgeons of South Africa (SCTSSA) published the most recent joint consensus statement and guidelines on transcatheter aortic valve implantation (TAVI) in South Africa in 2016.[1]

Over the last 10 years, TAVI has become an established therapy in South Africa for many patients with aortic stenosis. Based on clinical trial evidence that has become available since then, the TAVI indications have expanded and this treatment modality can now be offered to a broader patient population. In addition to this, the TAVI technology has improved and the implantation technique has been streamlined. This has resulted in excellent procedural outcomes and reduced hospital stays.[2] Furthermore, TAVI has been shown to be cost-effective and this is of relevance in the South African resource-constrained environment.

The European Society of Cardiology in conjunction with the European Association for Cardio-Thoracic Surgery has recently published the 2021 guidelines for the management of valvular heart disease.[3] This consensus statement by SASCI and SCTSSA aims to update the South African guidelines previously published to align them with what is currently considered best clinical practice. This will guide both treating physicians and funders to provide the best therapy for patients.

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Consensus guidelines on TAVI

The decision to proceed to TAVI as opposed to surgical aortic valve replacement (sAVR) must be made in a multidisciplinary heart team (MDT).[4] There are numerous factors guiding this decision, which the MDT must weigh up in each individual patient to advise on the optimal intervention.

Requirements and structure of the MDT

- The performance of TAVI should be restricted to a limited number of high-volume centres, which have both cardiology and cardiac surgery departments on site, with expertise in structural heart disease and high-risk valvular surgery. Additionally, as most complications of TAVI are related to vascular injury, it is important to have clinicians skilled in treating these available on-site.
- It is recommended that all TAVI teams aim to perform more than 10 implants per year.
- TAVI is reserved for patients who, after evaluation by the MDT, are found to have a risk/benefit analysis favouring TAVI over sAVR.
- The MDT should include at least a cardiologist, cardiac surgeon, imaging specialist and, if general anaesthesia is anticipated, a cardiac anaesthetist. Its composition is however dynamic and can also include a geriatrician and neurologist as well as other members as the MDT sees fit.

Patient selection

- Patients must have symptomatic severe aortic stenosis (AS).
- The patient must be evaluated by an MDT.

Indications for TAVI

- TAVI is indicated in patients where there are concerns regarding the technical difficulties of sAVR. Possible procedure-specific impediments are:
  - Porcelain aorta
  - Severe atherosclerosis of the aorta
  - Hostile chest (irradiation or previous sternotomy)
  - Potential damage to existing coronary artery grafts in the setting of a previous CABG.
- Frailty
  - Patients deemed to be too frail for sAVR should be considered for TAVI. This is often a subjective clinical assessment and the use of validated frailty scores can be helpful to obtain a more objective measure of the extent of a patient's frailty. There are numerous scores available, but a practically useful assessment tool is the essential frailty toolset (EFT) score, which correlates with one-year mortality[5] (see Table 1).
- Major organ compromise of two or more organ systems. Patients must be evaluated carefully for co-morbidities and the estimated survival related to these should be longer than one year. The severity of these co-morbidities should not be such that it limits the expected clinical improvement after TAVI (see Contra-indication below). Examples of significant co-morbidities include:
  - Cardiac: severe left ventricular (LV) or right ventricular (RV) dysfunction, severe pulmonary hypertension
  - Respiratory dysfunction: forced exhaled volume in 1 sec (FEV_1) or diffusing capacity for CO_2 ($DLCO_2$) < 50% predicted
  - Neurological: dementia, Alzheimer's disease, Parkinson's disease
  - Gastrointestinal tract: ulcerative colitis, Chron's disease
  - Hepatic: cirrhosis
  - Oncological concerns (but with expected survival of at least one year).

Table 1. EFT score for frailty.
(Adapted from Afilalo *et al. J Am Coll Cardiol* 2017; **70**(6): 689–700.)

EFT score for frailty	*Points*
Five chair rises < 15 seconds	0
Five chair rises > 15 seconds	1
Unable to complete	2
No cognitive impairment	0
Cognitive impairment	1
Haemoglobin > 13 g/dl male and > 12 g/dl female	0
Haemoglobin < 13 g/dl male and < 12 g/dl female	1
Serum albumin > 3.5 g/dl	0
Serum albumin < 3.5 g/dl	1

	1-year mortality	
EFT score	*TAVI, %*	*sAVR, %*
0–1	6	3
2	15	7
3	28	16
4	30	38
5	65	50

EFT, essential frailty toolset; TAVI, transcatheter aortic valve implantation; sAVR, surgical aortic valve replacement.

- TAVI should be considered as the primary procedure for all patients deemed to be at high[6] or intermediate risk for sAVR.[7,8] The primary assessment of surgical risk resides with the MDT rather than formal quantitative risk scores such as the log EuroSCORE or the Society of Thoracic Surgeons (STS) risk score. Risk scores are however useful as an addition to the clinical assessment to assist the MDT to determine the best intervention for a patient. An STS risk score of > 4 generally indicates at least intermediate risk for adverse periprocedural outcomes with sAVR.
- TAVI should be considered in low-risk patients (STS score < 4) older than 75 years of age, if a transfemoral access option is feasible.[9-11] As there is still considerable uncertainty regarding the long-term durability of transcatheter valves, sAVR remains the first option in younger patients at low surgical risk, particularly in the setting of bicuspid or rheumatic aortic valve disease.
- The factors considered to choose the optimal aortic valve intervention are summarised in Table 2.[3]

Contra-indications

- Absence of MDT and no cardiac surgery on site.
- Patients whose life-expectancy is less than one year.

Table 2. Factors considered to choose the optimal aortic valve intervention.
(Adapted from Vahanian *et al. Eur J Cardio-Thorac Surg* 2021; **60**: 727–800.)

Variables	*Favours TAVI*	*Favours sAVR*
Clinical characteristics		
Lower surgical risk		+
Higher surgical risk	+	
Presence of severe co-morbidity (not reflected by risk score)	+	
Younger age		+
Older age	+	
Previous cardiac surgery	+	
Frailty	+	
Restricted mobility that may affect rehabilitation after the procedure	+	
Suspicion of endocarditis		+
Anatomical and technical aspects		
Favourable access for transfemoral TAVI	+	
Femoral access challenging or impossible		+
Sequelae of chest radiation	+	
Porcelain aorta	+	
Expected patient-prosthesis mismatch	+	
Severe chest deformity or scoliosis	+	
Short distance between coronary ostia and aortic valve annulus		+
Size of aortic valve annulus out of range for TAVI		+
Aortic root morphology unfavourable for TAVI		+
Valve morphology unfavourable for TAVI (bicuspid, degree of calcification and calcification pattern)		+
Presence of thrombi in aorta or left ventricle		+
Cardiac conditions in addition to AS that require consideration for concomitant intervention		
Severe CAD requiring revascularisation by CABG		+
Severe primary mitral valve disease		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta or significant aortic root dilatation		+
Septal hypertrophy requiring myomectomy		+

TAVI, transcatheter aortic valve implantation; sAVR, surgical aortic valve replacement; CAD, coronary artery disease; CAGB, coronary artery bypass graft.

- Predicted lack of clinical improvement after TAVI due to co-morbidities. While it can be difficult to discern to what extent AS is contributing to a patient's symptoms as opposed to underlying co-morbidities, it is important to carefully assess this, to avoid a futile TAVI procedure.
- Anatomical factors:
  - Unsuitable annulus size
  - Active endocarditis
  - Inadequate vascular access.
- Significant other valve lesions.
- Relative contra-indications:
  - LV ejection fraction < 20%
  - Haemodynamic instability
  - Presence of coronary artery disease that requires coronary artery bypass graft.

Cost-effectiveness studies for TAVI

Numerous cost-effectiveness studies in various clinical environments have shown that TAVI is cost effective with a better yield in terms of cost per quality-of-life years gained compared to sAVR.[12-15] This is particularly the case if the procedure is performed under local anaesthetic via the transfemoral approach with a short hospital length of stay.

Conclusion

TAVI has become the established therapy for severe AS in patients with technical contra-indications for sAVR, frail patients, patients with significant co-morbidity and patients at high and intermediate surgical risk. Recent evidence supports TAVI in older low-risk patients. Concerns regarding the long-term structural integrity of transcatheter valves remain, although there is no signal to date that the outcomes are any worse compared to sAVR with a bioprosthesis.

The decision regarding the choice of aortic valve intervention and/or medical therapy alone should be individualised and must be made by the MDT after weighing up all factors that affect the short-, medium- and long-term outcome of a patient with symptomatic severe AS.

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