

Joint consensus statement and guideline on transcatheter aortic valve implantation (TAVI) in South Africa - October 2016

A report of the South African Heart Association developed by the South African Society of Cardiovascular Intervention (SASCI) and the Society of Cardiothoracic Surgeons of South Africa (SCTSSA)

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BACKGROUND

The South African Heart Association (SA Heart), together with 2 of its special interest groups, South African Society of Cardiovascular Intervention (SASCI) and Society of Cardiothoracic Surgeons of South Africa (SCTSSA) represent the scientific, educational, socio-economic, ethical and professional interests of South African cardiac specialists, with a combined membership of over 200 members. We are the only national organisations exclusively representing practicing cardiologists and cardiothoracic surgeons. SASCI and SCTSSA are dedicated to maintaining the highest standards of specialist practice and the highest quality of patient care. As a result, SASCI and SCTSSA seek to serve as a knowledge resource for patients, and funders, in matters related to new technology used in the cardiac interventional and surgical disciplines.

The introduction of new technology is a constant in modern medicine. While authorities in the U.S.A. and European Union, such as the Food and Drug Administration (FDA) and Conformite Europeenne (CE) provide regulatory clearance on safety and effectiveness, practicing medical

practitioners require scientific evidence on net health outcomes before offering new procedures to their patients. In addition, to meet clinical expectations of practicing specialists, new technology must stay consistent with fundamental medical and surgical principles.

Transcatheter Aortic Valve Implantation (TAVI) is considered a feasible technique, which may be used as an alternative to standard surgical aortic valve replacement in selected cases. The procedure is performed on the beating heart without the need for a sternotomy or cardiopulmonary bypass. There are currently 2 devices available in South Africa that are CE marked and approved by the FDA. The procedure may be performed via the trans-femoral, trans-subclavian and trans-apical approaches or via a mini sternotomy (trans-aortic approach).

SA Heart and the respective boards of the SASCI and SCTSSA by consensus hereby adopt the TAVI procedure for aortic stenosis in line with the principles of evidence-based medicine⁽¹⁾ after considering the various multinational society position statements and guidelines concerning TAVI and the most recently published evidence, including the

2014 AHA/ACC guideline for the management of patients with valvular heart disease,⁽¹⁾ the 2012 ESC/EACTS guidelines on the management of valvular heart disease,⁽²⁾ and the updated standardised endpoint definitions for TAVI (VARC-2 consensus document).⁽³⁾

CONSENSUS GUIDELINES ON TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

Members of the SA Heart Association, SASCI and SCTSSA (special interest groups of SA Heart Association) with experience in the technique and knowledge of the TAVI literature have agreed to the following consensus statement:

1. Requirements and structure of the Multidisciplinary Heart Team (MDT)

- a. The performance of TAVI, ab initio, 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 intervention and high-risk valvular surgery. Interventional cardiologists should be experienced in catheter based valvular interventions, and peripheral access using large devices. Cardiac surgeons should be experienced in valve surgery and the management of complex cases. It is recommended that all TAVI teams aim to perform more than 10 implants per year.
- b. TAVI should currently be reserved for patients who, after evaluation by a multidisciplinary heart team (MDT) are found to have a risk/benefit ratio favouring TAVI, rather than open heart surgery. The heart team should include (at least) a cardiologist, cardiac surgeon and imaging specialist. Its composition is however dynamic and can also include a cardiac anaesthetist, geriatrician and neurologist, as well as other members, as the MDT sees fit.
- c. Patients should be screened into a TAVI programme by a MDT (as defined above) and not by an individual specialist.
- d. Formal training of the implanting team should include:
 - i. Didactic theoretical training.
 - ii. Simulator training where available.

- iii. A visit to an experienced centre to observe TAVI cases.

- iv. Support for the initial cases at any site by a proctor until the proctor has certified the centre to be independent.

2. Patient selection/mandatory prerequisites

- a. Proof of severe symptomatic aortic valve stenosis.
- b. Patient evaluation by a MDT.

3. Indications for TAVI

- a. TAVI is recommended in patients who are, according to the MDT, considered unsuitable for conventional surgery because of severe comorbidities. These include:
 - i. Possible procedure specific impediment, e.g.
 1. Porcelain aorta or severely atherosclerotic aorta.
 2. Hostile chest.
 3. Patent coronary artery bypass grafts crossing the midline and/or adherent to the posterior table of the sternum.

OR

- ii. Frailty:

In the absence of validated frailty scores, this remains the opinion of an experienced physician. We recommend that it is the opinion of at least 2 physicians of which 1 should be a cardiac surgeon experienced in aortic valve replacement surgery.

OR

- iii. Major organ compromise of ≥ 2 organ systems.

Examples include:

1. Cardiac – severe LV or RV dysfunction, severe pulmonary hypertension.
2. Pulmonary dysfunction (FEV1 or DLCO2 <50% predicted).

3. CNS dysfunction (dementia; Alzheimer's disease, Parkinson's disease) (See section 4c regarding contra-indications).

4. GI dysfunction (Chron's disease, Ulcerative colitis).

5. Liver cirrhosis, variceal bleeding.

b. TAVI is recommended in patients who are, according to the MDT, considered to be at high risk for conventional surgery. In line with other guidelines, the evaluation of surgical risk should rely on the clinical judgement of a MDT rather than quantitative risk scores as these have not been well validated in this population. These risk scores may be used in addition, with cut-off values of an STS risk score >4 (4) or a log EuroSCORE >20 recommended. It must be emphasised that risk scores should not be used in isolation to determine whether a patient qualifies to undergo a TAVI procedure. Growing evidence supports the efficacy of TAVI in "intermediate risk group" patients.⁽⁴⁾ The final recommendation therefore remains with the MDT.

4. Contra-indications

a. Absence of a MDT and no cardiac surgery on site.

b. Patients whose life expectancy is expected to be <1 year.

c. Predicted lack of clinical improvement in quality of life after TAVI limited by co-morbidities. This may be especially relevant if the indication for TAVI is major organ compromise as outlined in 3.a.iii above.

d. Anatomical factors

i. Inadequate annulus size.

ii. Active endocarditis.

iii. Inadequate access site.

e. Significant other valve lesions or coronary artery disease which requires additional valve or coronary artery bypass surgery.

f. Relative contra-indications

i. LVEF <20%.

ii. Haemodynamic instability.

5. Establishing a TAVI programme

a. The centre should be sufficiently equipped to perform trans catheter procedures safely.⁽¹⁻³⁾

b. Minimum infrastructure requirements include:

i. The ability to set up an MDT (as above).

ii. Immediate availability of trans-thoracic and trans-oesophageal echocardiography.

iii. Availability of a dedicated cardiac catheterisation laboratory or hybrid theatre (a theatre with "C" arm screening facilities is generally not appropriate for TAVI procedures).

iv. CT scanning facilities.

v. Immediate availability of perfusion services in case emergency femoro-femoral bypass becomes necessary.

vi. On-site availability of a surgical recovery area and intensive care with staff experienced in looking after patients following surgical aortic valve replacement.

vii. Facilities for immediate renal support if necessary.

viii. Immediate access to vascular surgery and interventional radiology to deal with peripheral vascular complications.

ix. The above requirements determine that this procedure should only be performed in a unit currently carrying out surgical aortic valve replacement.

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