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

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 its major special interest groups, SASCI and SCTSSA represent the scientific, educational, socio-economic, ethical and professional interest of cardiac specialists, with a combined membership of over 200 members: We are the only national organisations exclusively representing practicing cardiologists and cardiothoracic surgeons. We are dedicated to maintain the highest standards of practice for our specialists and the highest quality of care for patients who require our care. As a result, we seek to serve as a knowledge resource for patients and funders in matters related to new technology used in our 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 Conformité Européenne (CE) respectively provide regulatory clearance on safety and effectiveness, practicing medical practitioners may 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 selective cases. The procedure is performed on the beating heart without the need for a sternotomy or cardio-pulmonary bypass. Currently, 2 devices are CE marked and one is approved by the FDA without restriction. The procedure may be performed via the transfemoral, subclavian and transapical approaches or via a mini sternotomy.

SA Heart and the respective boards of SASCI and SCTSSA, via this combined and most up-to-date consensus agreement, hereby adopt in line with the principles of evidence-based medicine, the TAVI procedure for aortic stenosis after considering the most recent published evidence and the various multinational society position statements and guidelines concerning TAVI.

LITERATURE REVIEW

This consensus guideline considers the literature reviewed, for the second time since June 2008, as at April 2011, by the National Institute for Health Clinical Excellence (NICE)[1] as significant new evidence has been published and much experience gained.

The European Society of Cardiology (ESC)[2] and the European Association of Cardiothoracic Surgeons (EACTS)[3] Guidelines as issued by respective bodies were also reviewed. The published PARTNER[4,5] cohort A and B which represent randomised data confirming clinical effectiveness of TAVI were also considered.

CONSENSUS GUIDELINES ON TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

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

Requirements and structure of the multidisciplinary team (MDT)

- 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, 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.
- TAVI should currently be reserved for patients who have been considered by a multidisciplinary team (MDT) (2 surgeons, 2 interventional cardiologists, 1 cardiac anaesthetist and cardiac imaging specialists) who consider the risk/benefit ratio of open heart surgery and TAVI to favour TAVI.
- Patients should be screened into a TAVI programme by this MDT team and not by any individual speciality.
- Formal training of the implanting team should include:
  - Didactic theoretical training;
  - Simulator training where available;
  - A visit to an experienced centre to observe TAVI cases; and
  - Support for the initial cases at any site by a proctor until the proctor has certified the centre to be independent.

Patient entry criteria/selection

- Mandatory pre-requisites for catheter-guided aortic valve replacement:
  - Proof of symptomatic, degenerative, severe aortic valve stenosis;
  - Evaluation of risk scores; and
  - Review of the possibilities of catheter-guided aortic valve replacement based on the valvular annular size by means of echocardiography.
- TAVI can be considered for patients in whom surgical heart valve procedures can only be performed with a high risk - if at all – for example:
  - Patients with severe malformation of the thorax or a porcelain aorta;
  - Previously operated patients with significant co-morbidity or patients with severe adhesion in the thorax due to radiation;
  - Older patients in whom a high surgical risk can be anticipated based on the STS or EuroSCORE; and

- Old or very old patients with a degenerated bio-prostheses.

- TAVI should be performed only in calcific aortic stenosis.

- TAVI should only be proposed in patients with symptoms that can definitely be attributed to valve disease.

- TAVI should currently be restricted to patients at high risk or with contra-indications for surgery. It is premature to consider using it in patients who are good surgical candidates. The EuroSCORE and STS score are not accurate predictors of mortality, since these scores are not validated for the high risk population. Recent peer-reviewed publications have demonstrated that logistic Euroscore is a severe overestimation of operative risk in the targeted patient population. Nevertheless since no more accurate scoring systems are available, and in the light of the position statement of the EACTS and ESC, a joint decision should be taken by a team of cardiac surgeons and cardiologists with a vast experience in heart valve surgery and percutaneous interventions for structural heart disease.

- Patients with a contra-indication for surgery and/or at least a logistic EuroSCORE >20% or STS score >10% might be eligible for the procedure.

- TAVI is seldom considered in patients <70 years of age. However, age alone is not sufficient for its use instead of surgery. TAVI should not be performed in patients whose life expectancy is <1 year, who should be managed conservatively.

- Preference of the patient is not sufficient to choose for a transcatheter heart valve procedure over conventional surgery, unless the patient has independently consulted with both a cardiological and a surgical member of the team.

- Other forms of aortic valve disease such as a failing aortic bioprostheses may be treated, where deemed appropriate.

Contra-indications

- Significant other valve lesions or coronary artery disease that requires coronary bypass surgery.

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

Establishing a TAVI programme

- The centre should be sufficiently equipped to perform transcatheter procedures safely.[2,3]

- Minimum infrastructure requirements include:

  - The ability to set up a MDT (as above);

  - Immediate availability of trans-thoracic and trans-oesophageal echocardiography;

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

  - CT scanning facilities;

  - Immediate availability of perfusion services in case of the need for emergency femora-femoral bypass;

  - On-site availability of a surgical recovery area and intensive care with staff experienced in the aftercare of patients who had surgical aortic valve replacement;

  - Facilities for immediate renal support if necessary; and

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

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

REFERENCES

1. National Institute for Health Clinical Excellence (NICE) Guideline - Interventional procedure overview of transcatheter aortic valve implantation for aortic stenosis http://guidance.nice.org.uk/nicemedia/live/11914/55669/55669.pdf.
2. European Society of Cardiology (ESC) Guidelines, in collaboration with the European Association of Percutaneous Interventions (EAPCI), European Heart Journal 2008;29:1463-1470.
3. European Association for Cardio-Thoracic Surgery (EACTS) Guidelines, European Journal of Cardio-Thoracic Surgery 2008;34:1-8.
4. PARTNER Trial, N Engl J Med 2011;364:2187-2198.
5. PARTNER Trial, N Engl J Med 2010;363:1597-1607.