



Joint Statement on clinical selection for Trans-catheter Aortic Valve Implantation (TAVI)

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On behalf of BCS, SCTS and BCIS

1. Introduction

Intervention for aortic stenosis (AS) is evolving rapidly. Trans-catheter aortic valve implantation (TAVI) is a minimally invasive alternative to surgical aortic valve replacement (SAVR). The evidence base for use of TAVI as an alternative to either medical therapy or SAVR has expanded. This statement summarises the views of the British Cardiovascular Society (BCS), Society for Cardiothoracic Surgery (SCTS), and the British Cardiovascular Intervention Society (BCIS) on how patients with aortic valve disease should be treated and which patients are best suited to TAVI, on the basis of current evidence.

2. Current UK practice

The UK TAVI Registry data show that there has been a 31% growth in the number of TAVI procedures performed from 2015 (2473 cases) to 2016 (3250 cases). Notably, UK figures remain lower than many EU countries (37.5 TAVIs performed per million population in the UK in 2015 vs 104 in France and 164 in Germany), although the optimal rate is not known.

3. Changing evidence base

When TAVI was first introduced, the mortality risk was substantial - approximately 10%. However, morbidity and mortality have improved significantly, particularly in the last 3 years; with more sophisticated delivery systems and devices, increased operator/centre experience, and better patient selection by MDTs. The UK TAVI registry demonstrates a contemporary 30-day mortality of around 4%, with little change in the risk profile of the treated patients.

The majority of TAVIs are now percutaneous, trans-femoral (TF) procedures (88.6% of TAVIs were TF in 2015). An increasing proportion of cases are being performed without general anaesthesia (conscious sedation or local anaesthesia only) which has reduced the need for ITU (level 3) beds, in

association with which the median length of stay has also decreased substantially.

The evidence base for the use of TAVI in inoperable (extreme risk) patients is well-established. A number of randomised controlled trials (RCTs)'s have also shown that TF TAVI has superior outcomes to SAVR in high-risk patient cohorts; these findings were collated in a major meta-analysis published in December 2016 demonstrating a significant survival advantage with TF TAVI over SAVR.

More recent evidence has studied the use of TAVI in patients deemed to be at intermediate risk. The PARTNER 2A study (published in 2016) has demonstrated a survival advantage for TF TAVI over conventional SAVR in patients deemed to be at intermediate risk from surgery by a multidisciplinary heart team, with a guideline STS (Society of Thoracic Surgeons) predicted risk of mortality score of 4-8%. In 2017 the SURTAVI trial reported equivalent mortality but reduced risk of stroke with TAVI compared to SAVR in intermediate-risk patients. The UK-TAVI trial is currently randomising intermediate-risk patients in a similar RCT of TAVI vs SAVR, and is expected to complete recruitment in late 2017.

Patients at lower risk are now also being studied: The PARTNER 3 study and Evolut R Low-risk trials are currently recruiting patients with an STS score of <4% and <3% respectively in randomised comparisons of SAVR and TAVI with the SAPIEN 3 and Evolut R valves.

4. The TAVI Heart Team

TAVI should only be undertaken following documented discussion of the patient within a Cardiothoracic Surgical centre multidisciplinary TAVI Heart team consisting of a minimum of:-

- At least one interventional cardiologist with a specialist interest in TAVI
- At least one cardiac surgeon with a specialist interest in TAVI and SAVR
- An imaging cardiologist (specialising in echo/CT)
- A general cardiologist

Other clinical specialists should be members of the broader TAVI Heart Team, and available when needed to assess and/or review specific patients. These should include:-

- A Care of the Elderly physician
- A vascular surgeon
- A vascular radiologist
- A cardiac anaesthetist

Practicalities will dictate the members of the team present on a day-to-day basis and it is unrealistic to expect all members to present at all meetings. However, all patients undergoing TAVI must undergo formal documented discussion/review by at least one named cardiac surgeon and 2 cardiologists before device implantation.

Work-up investigations have become more streamlined in recent years and variability exists across centres as to the preferred work-up set required. Tests which will help determine the suitability and risk of the patient include:

- Trans-thoracic echocardiography - mandatory
- TAVI CT of aortic valve complex ± access vessels - strongly recommended
- Coronary angiogram (invasive or CT)
- Trans-oesophageal echocardiography - in specific cases
- Stress echocardiography - in specific cases

Heart Team meetings will be formally held, with written documentation of specialists in attendance, decisions made and suggested treatment strategies.

5. Which patients should be considered for TAVI?

Patients with symptomatic aortic stenosis who are at low surgical risk should be referred directly to the cardiac surgical service for consideration of SAVR.

Patients who are intermediate, high or extreme risk should be referred to the relevant TAVI Heart Team for consideration of the most appropriate aortic intervention.

TAVI should currently be considered if :

- The patient has a confirmed diagnosis of severe, symptomatic aortic stenosis.
AND
- The patient has been discussed at the TAVI Heart team MDT.
AND
- The patient is considered **extreme risk** for SAVR (owing to age, frailty and comorbidities)
OR
- The patient is **high risk** for SAVR (owing to age, frailty and comorbidities)
OR
- The patient is **intermediate risk** but has other risk factors that make TAVI preferable to SAVR
OR
- There are anatomical limitations to surgery e.g. extensive aortic calcification (“porcelain aorta”) and/or previous chest radiotherapy
OR
- The patient has undergone previous CABG and has patent coronary grafts and the cardiac surgeon believes that TAVI represents a lower risk procedure when compared to conventional SAVR
OR
- The patient currently has a biological prosthesis in-situ that is now failing and requires re-implanting (valve-in-valve prosthesis) and a surgeon believes that TAVI represents a lower risk procedure when compared to conventional

SAVR.

6. Assessment of Risk

Classification of patients as extreme, high, intermediate, or low-risk is dependent on multiple factors, including age, co-morbidity, and frailty. Surgical risk scores including STS-score, Logistic EuroSCORE, and EuroSCORE-II may be used. However, none of the existing surgical risk scores has been validated in TAVI, and all omit important clinical variables, including frailty.

It is therefore recommended that risk status and optimal treatment modality is determined by the MDT after considering all relevant clinical information.

7. When is TAVI not appropriate/futile?

TAVI should **not** be performed if thought to be 'futile' i.e.

- where the patient has a limited life expectancy (less than two years), possibly linked to other co-morbidities (such as malignancy or advanced airways disease)
- in patients with established dementia as diagnosed by an appropriate specialist (eg. Care of the Elderly physician, neurologist)
- in patients with such a burden of co-morbidities that no symptomatic benefit is likely and the patient is unlikely to be able to care for themselves in the community after a TAVI procedure.

Comorbidities:

- Interplay of various comorbidities will be determined by the MDT to assess likelihood of significant improvement in quality of life and life expectancy for a given patient.
- Comorbidities that may incline an MDT away from intervention include: cognitive impairment, poor mobility, poor respiratory function, poor renal function, severe additional valvular disease (regurgitation or stenosis), impaired right or left ventricular function and severe pulmonary hypertension.

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