



## BRITISH CARDIOVASCULAR INTERVENTION SOCIETY

### Service Specification for Transcatheter Aortic Valve Implantation (TAVI)

#### Recommendations of the British Cardiovascular Intervention Society (BCIS) - updated July 2019

##### 1. Introduction

Severe aortic stenosis (sAS) is the most common primary valve disease leading to surgery or catheter intervention in Europe and North America, with a growing prevalence due to the ageing population.<sup>1</sup> It is a degenerative condition where the outflow of blood from the heart is restricted by progressive narrowing of the aortic valve. This leads to symptoms of breathlessness, exertional chest pain or blackouts. Untreated, the condition causes left ventricular failure and death, with up to 40% of patients dying within 1 year of symptom onset. No medical therapy can improve outcome for this condition and therefore valve intervention is the only treatment option which alters prognosis. The standard of care for this condition has historically been surgical Aortic Valve Replacement (sAVR), but around 1/3 of patients are ineligible for sAVR due to a combination of age and comorbidities.

TAVI is a transformational technology which is a much less invasive approach than sAVR and involves implantation of a new valve without the need for complex surgery or the use of a heart-lung bypass machine. This is most commonly done via the femoral arteries (transfemoral or TF approach) but may also be accomplished via the subclavian arteries or via minimally invasive access using the cardiac apex between the ribs, directly into the aorta through a small incision. Less common approaches via the carotid arteries, axillary artery and the femoral veins / abdominal aorta have also been described. Therefore, for the majority of patients undergoing TAVI, the procedure is performed via the femoral artery, under local anaesthesia/ conscious sedation in a catheter laboratory. This results in quicker patient recovery, shorter hospital stay and reduced use of expensive and limited resources such as cardiac operating theatres and intensive care unit beds, as well as post-operative nursing care.

A number of different valve designs are available, including balloon-expandable and self-expandable devices. Each has different performance characteristics, which may be tailored to specific anatomical or patient-specific features.

TAVI has been proven to be superior to medical therapy for inoperable patients and superior to sAVR in patients who are high risk for sAVR (Society of Thoracic Surgeons (STS) or Euroscore II  $\geq 8\%$ ).<sup>2-4</sup> Trials have also shown that patients with intermediate surgical risk (STS or Euroscore II  $\geq 4\%$ ) who are eligible for a transfemoral approach have superior outcomes with TAVI.<sup>5-7</sup> Moreover, randomised trials have shown TAVI

to be superior to sAVR in patients classified as 'low risk' (STS<4) with outcome data so far published to 12 months <sup>8,9</sup>

## **2. Entry to Care pathway**

Indications for aortic intervention by means of TAVI or sAVR include severe Aortic Stenosis (sAS) and any of the following:

1. Symptoms related to sAS
2. Left ventricular dysfunction related to sAS
3. Evidence of very severe AS, or rapid increase in echo severity
4. Abnormal exercise test or elevated cardiac biomarkers (BNP)
5. Severe bioprosthetic valve failure

After appropriate investigations including (but not limited to) transthoracic echocardiography and cardiac / peripheral CT scanning, patients should be discussed by an appropriately constituted Multidisciplinary Heart Team (MDT – the Heart Team) as per BCS/ SCTS/ BCIS guidelines – see below<sup>10</sup>. After taking into account age, frailty and comorbidities, MDT outcome will be:

1. sAVR
2. TAVI
3. Conservative/medical management

Recommendations 1 or 2 will be made by taking into account the cardiac and extracardiac characteristics of the patient, the individual risk of surgery, which is assessed by the judgement of the Heart Team, in addition to risk scoring and the technical and anatomical feasibility of TAVI.

Validated calculators of conventional surgical risk (e.g. Euroscore 2 or STS score) have several limitations in selecting patients to undergo TAVI and are now generally not used clinically. Specifically, they do not assess frailty, degree of disability, echocardiographic/anatomical features or important comorbidities. Therefore, patient selection for TAVI requires consideration of the whole patient as well as several prognostic variables.

Technical aspects which may favour TAVI or sAVR should be assessed by detailed review of all investigations. Technical factors for potential TAVI should include suitability for transfemoral access (which is associated with the lowest risk) and risk factors for adverse events such as coronary occlusion, annular trauma and paravalvar leak. Additional adverse features for sAVR which are not represented in surgical calculators should be noted. These include presence of severe aortic calcification, liver disease, chest wall deformity and previous thoracic radiotherapy.

Medical management may be recommended when comorbidities and frailty are so severe that no improvement in quality of life or prognosis is expected from intervention ie. Intervention is thought to be futile. Therefore, the MDT should refer to reports from other specialists with regard to prognosis and severity of other conditions. This may include memory clinic assessments for patients with cognitive impairment as significant dementia is likely to negate any benefit from intervention.

The table shown in Figure 1 is taken from the latest European guidelines but is already outdated. However, it illustrates a list of patient features which should be considered by the Heart Team in deciding whether SAVR or TAVI is appropriate in individual cases.

**Figure 1: Aspects to be considered by the Heart Team for the decision between SAVR and TAVI in patients at increased surgical risk<sup>1</sup>**

	Favours TAVI	Favours SAVR
<b>Clinical characteristics</b>		
STS/EuroSCORE II <4% (logistic EuroSCORE I <10%) <sup>a</sup>		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%) <sup>a</sup>	+	
Presence of severe comorbidity (not adequately reflected by scores)	+	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	+	
Frailty <sup>b</sup>	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+	
Suspicion of endocarditis		+
<b>Anatomical and technical aspects</b>		
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+
Sequelae of chest radiation	+	
Porcelain aorta	+	
Presence of intact coronary bypass grafts at risk when sternotomy is performed	+	
Expected patient–prosthesis mismatch	+	
Severe chest deformation 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 (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+
Presence of thrombi in aorta or LV		+
<b>Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention</b>		
Severe CAD requiring revascularization by CABG		+
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+

The MDT should refer to up to date guidelines on valve intervention (e.g. NICE, ESC / EACTS 2017 Guidelines for the management of valvular heart disease<sup>1</sup>) in order to inform decision-making. This is especially important, as this is a rapidly evolving literature and there are several trials in different patient groups underway which will further advance the evidence base for therapy.

Given the time dependency of treatment in the outcome of patients with sAS, it is vital that after MDT discussion, recommended therapy should be offered promptly – see

section 8a below. AS has an extremely poor prognosis and patients will die on the waiting list for treatment. BCIS recommends that regular review of mortality of patients on waiting lists is performed by all TAVI centres. The absolute maximum waiting time from point of referral to the definitive valve procedure should be 18 weeks.

### 3. MDT structure

Each MDT should involve a minimum of one TAVI interventionist, one cardiac surgeon, one imaging/general cardiologist and should have appropriate administrative support.<sup>10</sup> Direct MDT input from other specialties (Elderly Care medicine, anaesthetics) will be required for some patients and local pathways should be developed for this input to be available quickly. MDT meetings should occur at least weekly sufficiently frequently to ensure that unnecessary delays do not occur. Arrangements should also be put in place for ad hoc MDT discussion of urgent patients who may present between formal MDT meetings. Adequate documentation with dissemination of decisions should be prioritised.

Several studies have demonstrated the importance of the TAVI Clinical Nurse Specialist/Co-ordinator which BCIS considers a mandatory component of the Heart Team (MDT) and every TAVI centre.

### 4. Follow-up post-intervention

Following TAVI and at the point of discharge, the implanting team should document the recommended medical therapy and set out arrangements for further follow up. First follow up visit should be within 6-8 weeks in order to assess any possible adverse effects of treatment. This will usually be with the implanting centre. Subsequent follow up arrangements should be according to guidelines for bioprosthetic valve intervention – usually annually with echocardiographic assessment.<sup>1</sup> Patients can be followed up by their local Cardiology service after the first review at the TAVI centre.

### 5. Interdependence with other Services

BCIS recommends that a *TAVI centre* should fulfil the following criteria:

Essential on-site services:

- a. **MDT.** Constituted as above (see section 3).
- b. **Imaging.** A sophisticated echo and CT service is essential for procedural planning, vascular access assessment and valve sizing. At least one Consultant should be assigned to the Heart Team to lead the imaging aspect of the service.
- c. **ITU.** An on-site ITU is mandatory in order to manage multi-system dependence or complications of the procedure. In this regard, on-site access to renal replacement therapy is required.
- d. **Cardiac surgery.** Emergency cardiac surgery for complications is uncommon during transfemoral TAVI, with the latest registry data of 27,760 patients in Europe suggesting an incidence of <1%<sup>11</sup>. Although infrequent, the commonest complications requiring emergency surgical bailout include left ventricular perforation by guide wire and annular rupture, which are immediately life

threatening and can only be successfully treated with immediate surgery. Therefore, on site cardiac surgery is an absolute requirement to support a TAVI service and is recommended by ESC / EACTS and North American guidelines.<sup>12</sup> TAVI via thoracic approaches (e.g. transapical, direct aortic) are led by cardiac surgeons.

- e. **Vascular/Interventional Radiology/Vascular surgery.** Vascular complications are the commonest adverse events during transfemoral TAVI, so robust arrangements are needed to deal with these emergently. Vascular bailout may be performed by open surgery or percutaneous techniques. Vascular interventional radiology/vascular surgery expertise should be immediately available allowing access to equipment and techniques for percutaneous management of complications (occlusion balloons, guidewires and peripheral stents) or open vascular surgery as needed. TAVI centres should have a local Standard Operating Policy SOP for these clinical events to ensure that emergencies are managed effectively and systems are reviewed and updated frequently.
- f. **TAVI clinical nurse specialist/admin support.** BCIS considers a co-ordinating TAVI Clinical Nurse Specialist an essential component of the TAVI team. Administrative support should also be provided for an effective MDM (see section 3 above).

## 6. Expected Significant Future Demographic Changes

In keeping with the degenerative nature of the condition, the ageing population will require a growth in TAVI implantation rates. In addition, newer data suggests efficacy of TAVI (vs sAVR) across the spectrum of risk in patients with AS, including studies in patients at low surgical risk who currently undergo sAVR<sup>8,9</sup>.

## 7. Current Evidence Base for TAVI in treating sAS

Several large randomised controlled trials (RCT) have been published, which may be briefly summarised as follows:

- **Inoperable / extreme risk patients:** TAVI superior to medical therapy. (PARTNER 1B trial)<sup>2</sup>
- **High risk patients** (mortality risk  $\geq 8\%$ ): TF TAVI non-inferior or superior to sAVR (high risk Corevalve trial, PARTNER A trial)<sup>3-4</sup>
- **Intermediate risk patients** (mortality risk  $\geq 4\%$ ;  $\leq 8\%$ ): TF TAVI non-inferior or superior to sAVR (NOTION trial, PARTNER 2 trial, SURTAVI trial)<sup>5-7</sup>
- **Low risk:** TF TAVI superior to sAVR in patients at low risk (STS $<4$ ; PARTNER 3 – follow-up to 12 months to date<sup>8</sup>) or equivalent in this patient population (Evolut low risk trial<sup>9</sup>)

These data have been reviewed extensively in the production of the updated ESC/EACTS 2017 guidelines<sup>1</sup> – but unfortunately, since the guideline publication, several more trials have been published, rendering them already out-of-date.

## 8. BCIS TAVI pathway recommendations

**Goal of therapy:** to offer eligible patients with sAS timely intervention to prevent premature death, improve symptoms and reduce hospitalisation, using a

transformational, minimally-invasive treatment allowing rapid return to improved quality of life.

BCIS proposes the following guidelines:

- a. **TAVI pathway** – maximum 18 weeks
  - Referral to clinic <6wks
  - Clinic to investigations/MDT discussion <6wks
  - Decision MDT to TAVI <6wksRegular local audit of service performance should be performed, including quality improvement projects/waiting list surveillance
- b. **TAVI volume per centre/operator** – there is now published evidence to support improved outcomes with TAVI centre/operator volume<sup>13</sup>
  - New centres should aim for 50 cases per year/2 operators
  - The aim should be for at least 100 cases/year i.e. 50 cases/operator in established centre to ensure volume experience and skill in more than one device
  - The TAVI procedure should be performed by 2 appropriately trained TAVI operators
- c. **GA vs non-GA**: Centres should aim for >90% cases non-GA
- d. **Length of Stay**: 1-5 days. Level 3 beds should be used only in exceptional cases
- e. **Submission of the full UK TAVI dataset for all TAVI procedures to NICOR** at least every quarter, with data for a quarter to be submitted by the end of the following quarter. 30-day mortality, stroke rate and vascular complications (as per VARC criteria) will be monitored (observed vs predicted) using the NICOR TAVI mortality model/funnel plots.

Details of all TAVI procedures and their outcomes are submitted to NICOR. Criteria for defining outlier performance is currently being agreed, but it is expected that the BCS Outlier policy will be used to implement Society advice. At present 30 day mortality and major complications including rate of vascular complication or stroke are used to measure safety. However other outcomes such as change in symptoms and quality of life may be used in the future.

Currently all departments receive performance outcomes adjusted for risk with funnel plots.

### **Applicable Obligatory National Standards**

*NICE IPG586: Transcatheter aortic valve implantation for aortic stenosis. July 2017*

### **Other Applicable Standards to be met by Commissioned Providers**

Adherence to *ESC / EACTS 2017 Guidelines for the management of valvular heart disease* or subsequent updates.

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