Extended Statement by the British Cardiovascular Intervention Society President Regarding Transcatheter Aortic Valve Implantation

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Disclosures: The authors have no conflicts of interest to declare.
Received: 18 December 2020 **Accepted:** 6 January 2021 **Citation:** *Interventional Cardiology Review* 2021;16:e03. **DOI:** https://doi.org/10.15420/icr.2021.02
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Transcatheter aortic valve implantation (TAVI) has now become the default intervention for severe, symptomatic aortic stenosis (AS) in inoperable and high-risk patients and patients at intermediate risk who are anatomically suitable for the transfemoral approach, under the guidance of a multidisciplinary heart team. Evidence is building for the use of TAVI in low-risk patients and as a result, the number of TAVI procedures in all developed nations is increasing dramatically. The number of TAVI procedures exceeded the number of isolated surgical aortic valve replacements in the US in 2015 and all surgical aortic valve replacements in 2018 according to the latest Transcatheter Valve Therapy Registry data.[1] Although the UK is lagging behind most of these nations, the numbers of TAVI procedures is nevertheless increasing year by year.

The British Cardiovascular Intervention Society (BCIS) has issued guidance as to how patients with AS should be managed and a service specification as to how TAVI should be performed.[2] We hope this will go some way to standardising care across the UK for patients with AS but we are aware that much more needs to be done. BCIS is collaborating with the Valve for Life campaign to analyse inequities in TAVI provision in the UK and we hope to work with NHS commissioners to address this, and to encourage new centres to provide TAVI where local provision is inadequate or impossible with current facilities. The following document forms the basis of what will be a prolonged effort to improve TAVI provision in the UK and standardise its delivery.

1. Introduction

Service Specification for TAVI: Recommendations of the British Cardiovascular Intervention Society – Updated July 2019

Severe AS (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.[3] It is a degenerative condition in which 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 that alters prognosis. The standard of care for this condition has historically been surgical aortic valve replacement (sAVR), but around one-third of patients are ineligible for sAVR due to a combination of age and comorbidities.

TAVI is a transformational technology; it 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 it 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 or abdominal aorta have also been described. Therefore, for most patients undergoing TAVI, the procedure is performed via the femoral artery, under local anaesthesia or conscious sedation in a catheter laboratory. This results in quicker patient recovery, a shorter hospital stay and reduced use of expensive and limited resources such as cardiac operating theatres and intensive care unit beds, as well as postoperative 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 >8%).[4–6] Trials have also shown that patients with intermediate surgical risk (STS or Euroscore II >4%) who are eligible for a TF approach have superior outcomes with TAVI.[7–9] 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.[10,11]

2. Entry to Care Pathway

Indications for aortic intervention by means of TAVI or sAVR include 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 (B-type natriuretic peptide);
5. severe bioprosthetic valve failure.

After appropriate investigations including (but not limited to) transthoracic echocardiography and cardiac–peripheral CT, patients should be discussed by an appropriately constituted multidisciplinary heart team (MDT; the Heart Team) as per the British Cardiovascular Society (BCS), and Society for Cardiothoracic Surgery (SCTS) and BCIS guidelines.[12] 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, and 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 II or STS score) have several limitations in selecting patients for TAVI and are now generally not used clinically.[4] Specifically, they do not assess frailty, degree of disability, echocardiographic and anatomical features or important comorbidities. Therefore, patient selection for TAVI requires consideration of the whole patient as well as several prognostic variables.

Technical aspects that may favour TAVI or sAVR should be assessed by detailed review of all investigations. Technical factors for potential TAVI should include suitability for TF access (which is associated with the lowest risk) and risk factors for adverse events, such as coronary occlusion, annular trauma and paravalvular leak. Additional adverse features for sAVR that 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, i.e. 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, given that significant dementia is likely to negate any benefit from intervention.

The MDT should refer to up-to-date guidelines on valve intervention (e.g. National Institute for Health and Care Excellence [NICE], European Society of Cardiology and European Association for Cardio-Thoracic Surgery [ESC/EACTS] 2017 guidelines for the management of valvular heart disease) in order to inform decision-making.[3] This is especially important, given that this is a rapidly evolving literature, and that there are several trials in different patient groups underway that 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 (section 8a). 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 and one imaging or general cardiologist and should have appropriate administrative support.[13] Direct MDT input from other specialties (elderly care medicine, anaesthetics) will be required for some patients, and local pathways should be developed to ensure that this input is available quickly. MDT meetings should occur at least weekly or 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/coordinator, 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. The 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).[4] Patients can be followed up by their local cardiology service after the first review at the TAVI centre.

5. Interdependence with Other Services

The BCIS recommends that TAVI centre essential on-site services should fulfil the following criteria:

a. MDT. Constituted as above (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 TF TAVI, with the latest registry data of 27,760 patients in Europe suggesting an incidence of <1%.[14] Although infrequent, the commonest complications requiring emergency surgical bailout include left ventricular perforation by guidewire 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.[15] 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 TF TAVI,

therefore robust emergency arrangements are needed to deal with these. Vascular bailout may be performed by open surgery or percutaneous techniques. Vascular interventional radiology and vascular surgery expertise should be immediately available, with 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 for these clinical events to ensure that emergencies are managed effectively and that systems are reviewed and updated frequently.

f. TAVI clinical nurse specialist and administrative support. BCIS considers a coordinating TAVI clinical nurse specialist an essential component of the TAVI team. Administrative support should also be provided for an effective MDM (section 3).

6. Expected Significant Future Demographic Changes

In keeping with the degenerative nature of the condition, the ageing population will require an increase in TAVI implantation rates. In addition, newer data suggest the efficacy of TAVI (versus sAVR) across the spectrum of risk in patients with AS, including studies in patients at low surgical risk who currently undergo sAVR.[11,12]

7. Current Evidence Base for TAVI in Treating Severe Aortic Stenosis

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

- Inoperable or extreme-risk patients: TAVI superior to medical therapy (PARTNER 1B trial).[5]
- High-risk patients (mortality risk >8%): TF TAVI non-inferior or superior to sAVR (CoreValve high-risk study, PARTNER A trial).[6,7,16]
- Intermediate-risk patients (mortality risk >4% and <8%): TF TAVI non-inferior or superior to sAVR (PARTNER 2 trial, SURTAVI, NOTION).[7–9]
- Low risk: TF TAVI superior to sAVR in patients at low risk (STS < 4; PARTNER 3 follow-up to 12 months to date[10] or equivalent in this patient population; Evolut low-risk trial).[11] These data have been reviewed extensively in the production of the updated ESC/EACTS 2017 guidelines,but unfortunately several more trials have been published since the guidelines publication, rendering them already out of date.[3]

8. British Cardiovascular Intervention Society TAVI Pathway Recommendations

The goal of therapy is 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 <6 weeks;
- clinic to investigations and MDT discussion <6 weeks;
- MDT decision to TAVI <6 weeks.

Regular local audit of service performance should be performed, including quality improvement projects and waiting list surveillance.

b. TAVI volume per centre and operator: there is now published evidence to support improved outcomes with TAVI centre and operator volume:[15]

- new centres should aim for 50 cases per year for two operators during their learning curve;
- the aim of every centre should be for at least 100 cases/year – that is, 50 cases/operator done as first in established centres to ensure volume experience and skill in more than one device;
- the TAVI procedure should be performed by two appropriately trained TAVI operators.

c. General anaesthesia versus non-general anaesthesia: 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. TAVI data submission: the full UK TAVI dataset for all TAVI procedures should be submitted to the National Institute for Cardiovascular Outcomes Research (NICOR) at least every quarter, with data for one quarter to be submitted by the end of the following quarter. Thirty-day mortality, stroke rate and vascular complications (as per VARC [Valve Academic Research Consortium] criteria) will be monitored (observed versus 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 are 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 complications 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/ European Standards

Applicable Obligatory National Standards

NICE IPG586: Transcatheter aortic valve implantation for aortic stenosis. July 2017.[17]

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.[3] ❑

1. Carroll JD, Mack MJ, Vemulapalli S, et al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement. *J Am Coll Cardiol* 2020;76:2492–516. https://doi.org/10.1016/j.jacc.2020.09.595; PMID: 33213729.
2. BCIS. British Cardiovascular Intervention Society. Service Specification for Transcatheter Aortic Valve Implantation. 2020. https://www.bcis.org.uk/resources/bcis-guidance-documents/service-specification-for-transcatheter-aortic-valve-implantation-tavi (accessed 11 February 2021).
3. Baumgartner H, Falk V, Bax JJ, et al. 2017 ESC/EACTS guidelines for the management of valvular heart disease. *Eur Heart J* 2017;38:2739–91. https://doi.org/10.1093/eurheartj/ehx391; PMID: 28886619.
4. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010;363:1597–607. https://doi.org/10.1056/NEJMoa1008232; PMID: 20961243.
5. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011;364:2187–98. https://doi.org/10.1056/NEJMoa1103510; PMID: 21639811.
6. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med* 2014;370:1790–8. https://doi.org/10.1056/

NEJMc1408396; PMID: 25184874.
7. Thyregod HGH, Steinbrüchel DA, Ihlemann N, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic valve stenosis. 1-year results from the all-comers NOTION randomized clinical trial. *J Am Coll Cardiol* 2015;65:2184–94. https://doi.org/10.1016/j.jacc.2015.03.014; PMID: 25787196.
8. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med* 2016;374:1609–20. https://doi.org/10.1056/NEJMoa1514616; PMID: 27040324.
9. Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med* 2017;376:1321–31. https://doi.org/10.1056/NEJMoa1700456; PMID: 28304219.
10. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med* 2019;380:1695–705. https://doi.org/10.1056/NEJMoa1814052; PMID: 30883058.
11. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med* 2019;380:1706–15. https://doi.org/10.1056/NEJMoa1816885; PMID: 30883053.
12. Joint Statement on clinical selection for trans-catheter aortic valve implantation (TAVI) 1/8/2017 on behalf of BCS, SCTS and BCIS. https://www.bcis.org.uk/wp-content/uploads/2017/08/TAVI-commissioning-statement-final.pdf (accessed 11 February 2021).
13. Eggebrecht H, Vaquerizo B, Moris C, et al. Incidence and outcomes of emergent cardiac surgery during transfemoral transcatheter aortic valve implantation (TAVI): insights from the European Registry on Emergent Cardiac Surgery during TAVI (EuRECS-TAVI). *Eur Heart J* 2018;39:676–84. https://doi.org/10.1093/eurheartj/ehx713; PMID: 29253177.
14. Otto CM, Kumbhani DJ, Alexander KP, et al. 2017 ACC expert consensus decision pathway for transcatheter aortic valve replacement in the management of adults with aortic stenosis: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol* 2017;69:1313–46. https://doi.org/10.1016/j.jacc.2016.12.006; PMID: 28063810.
15. Vemulapalli S, Carroll J, Mack M, et al. Procedural volume and outcomes for transcatheter aortic valve replacement. *N Engl J Med* 2019;380:2541–50. https://doi.org/10.1056/NEJMsa1901109; PMID: 30946551.
16. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011;364:2187–98. https://doi.org/10.1056/NEJMoa1103510; PMID: 21639811.
17. National Institute for Health and Care Excellence. *Transcatheter aortic valve implantation for aortic stenosis: Interventional procedures guidance [IPG586].* London: NICE; 2017. https://www.nice.org.uk/guidance/ipg586 (accessed 11 February 2021).