

## Transcatheter Aortic Valve Implantation: British Cardiovascular Intervention Society Position Statement

David Hildick-Smith,<sup>1</sup> Daniel J Blackman,<sup>2</sup> Jonathan Byrne,<sup>3</sup> Simon Redwood,<sup>4</sup> Clare Appleby,<sup>5</sup> Faisal Khan,<sup>6</sup> Rajesh Kharbanda,<sup>7,8,9</sup> Stephen H Dorman,<sup>10</sup> Sagar N Doshi,<sup>11</sup> Richard A Anderson,<sup>12</sup> Stuart Watkins,<sup>13,14</sup> Michael J Mullen,<sup>15</sup> Philip A MacCarthy,<sup>3</sup> Christopher John Malkin,<sup>16</sup> Ghada W Mikhail,<sup>17</sup> Saib S Khogali,<sup>18</sup> Douglas F Muir,<sup>19</sup> Ganesh Manoharan,<sup>20</sup> James D Newton<sup>21</sup> and Adrian P Banning<sup>22</sup>

1. Sussex Cardiac Centre, University Hospitals Sussex, UK; 2. Leeds Teaching Hospitals NHS Trust, Leeds, UK; 3. King's College Hospital, London, UK; 4. Guy's and St Thomas' NHS Foundation Trust, London, UK; 5. Liverpool Heart and Chest Hospital, Liverpool, UK; 6. St George's Hospital, St George's, Epsom and St Helier Hospital Group, London, UK; 7. Oxford University Hospitals NHS Trust, Oxford, UK; 8. Department of Cardiovascular Medicine, University of Oxford, Oxford, UK; 9. Oxford Biomedical Research Centre, Oxford, UK; 10. Bristol Heart Institute, Bristol, UK; 11. Queen Elizabeth Hospital, Birmingham, UK; 12. Cardiff and Vale University Health Board, Cardiff Metropolitan University, Cardiff, Wales, UK; 13. Golden Jubilee University National Hospital, Glasgow, Scotland, UK; 14. University of Glasgow, Glasgow, Scotland, UK; 15. St Bartholomew's Hospital, Barts Health NHS Trust, London, UK; 16. Leeds Teaching Hospitals, Leeds, UK; 17. Imperial College Healthcare NHS Trust, London, UK; 18. Royal Brompton and Harefield & St Thomas' Hospitals, Guy's and St Thomas' NHS Foundation Trust, London, UK; 19. James Cook University Hospital, Middlesbrough, UK; 20. Belfast Health and Social Care Trust, Belfast, Northern Ireland, UK; 21. John Radcliffe Hospital, Oxford, UK; 22. Oxford Heart Centre, Oxford University Hospitals, Oxford, UK

### Keywords

Aortic valve, transcatheter valve, percutaneous valve

**Received:** 14 October 2025 **Accepted:** 16 October 2025 **Citation:** *Interventional Cardiology* 2026;21:e02. **DOI:** <https://doi.org/10.15420/icr.2025.50>

**Disclosure:** DHS has served as an advisor/proctor for Edwards Lifesciences, Meril, Abbott, Medtronic and Boston Scientific. DJB has served as a consultant and speaker for Abbott Vascular, Edwards Lifesciences, JenaValve Technologies and Medtronic, and has received institutional grant funding from Medtronic. JB has received proctor fees and served on advisory boards for Abbott and Edwards Lifesciences. SR has received proctor and speaker fees from Edwards Lifesciences. CA has received speaker fees from Edwards Lifesciences, Medtronic, Boston Scientific and Abbott. FK has served as a proctor for Medtronic and an advisor for Shockwave. SHD has received honoraria and consulting fees from Edwards Lifesciences, Medtronic and Meril, and support for attending meetings from Boston Scientific and Biosensors. SND has been a proctor for Edwards Lifesciences and Medtronic and has received speaker fees from Edwards Lifesciences, Medtronic, Meril Life Sciences and Biosensors. SW has received an educational grant and speaker fees from Medtronic, and consulting fees from Biosensors International. MJM has received payments for teaching and research support from Edwards Lifesciences and Abbott Vascular. PAM has received speaker fees and conference support from Abbott, and an educational grant from Edwards Lifesciences. CJM has served as a proctor for Medtronic, Abbott and Edwards Lifesciences. GWM has received honoraria from Medtronic and Abbott, and is director of the Imperial Valve and Cardiovascular Course. DFM has served as a proctor for Edwards Lifesciences and Abbott Vascular. GM has served as a proctor for Medtronic and Abbott Medical. JB is on the *Interventional Cardiology* editorial board; this did not influence acceptance. All other authors have no conflicts of interest to declare.

**Correspondence:** David Hildick-Smith, Sussex Cardiac Centre, Royal Sussex County Hospital University Hospitals Sussex, Eastern Rd, Brighton BN2 5BE, UK.  
E: david.hildick-smith@nhs.net

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Transcatheter aortic valve implantation (TAVI) is a procedure that has evolved from being a niche treatment for inoperable patients to a standard therapy for most patients with severe symptomatic aortic stenosis. The first UK cases of TAVI were performed in 2007, and since then, the national volume has increased to 10,000 cases per year across 35 centres. The vast majority of TAVI procedures are for native severe aortic stenosis, with a smaller volume of cases for native aortic regurgitation or for failure of bioprostheses.

### Evidence

TAVI has an extremely robust evidence base. Patients have been systematically studied in the inoperable, high-, medium- and low-surgical risk categories in a sequential manner.<sup>1–5</sup> At every stage, TAVI has proved to be at least clinically equivalent to surgical valve replacement. Wider commissioning of TAVI has been held back by the

high price of valves, but patient preference for a less invasive procedure with equivalent or better outcomes is a strong driving force. Although the average patient age in the UK remains 81 years, increasingly, patients aged ≥70 years are being considered for TAVI as a primary strategy in preference to surgery, because of decreasing procedural risks and a short recovery time.

### Preprocedure Investigations

Aortic stenosis is usually diagnosed clinically, and then confirmed by echocardiography, but may be diagnosed unsuspected by echocardiography alone. Patients being considered for TAVI should have a gated contrast CT scan performed, preferably in the referring hospital, including a non-contrast component to allow Agatston scoring of the aortic valve. The scan should be reviewed and analysed by the implanting physician and by the multidisciplinary team (MDT). CT analysis is a core

skill for TAVI operators, and relying on others' interpretations of CT scans is strongly discouraged. The CT scan can either be assessed via multiplanar reconstruction or after importing into bespoke analytical software. Key anatomical features to assess include the degree of calcification of the aortic valve annulus and leaflets, anatomy of the leaflets (bicuspid, functionally bicuspid or tricuspid), perimeter and area of the annulus, calcification of the left ventricular outflow tract, and risk of coronary obstruction. Vascular access to the heart should be assessed for vessel calibre, calcification and tortuosity.

Most patients do not need an invasive coronary angiogram. If, however, on the TAVI CT there is strong suspicion of proximal coronary disease, and the patient has predominant angina, an invasive angiogram may be indicated, especially if the aortic stenosis itself is not unequivocally severe. As the average age of patients undergoing TAVI reduces, a higher proportion may undergo additional coronary assessment.

The resting ECG predicts risk of pacemaker implantation. Patients with pre-existing right bundle branch block may be considered for preprocedure pacing.<sup>6</sup> Transoesophageal echocardiography and dobutamine stress echocardiography are sometimes performed, but are not often highly discriminatory.

### Indications

TAVI is indicated for patients (usually aged  $\geq 70$  years) with severe symptomatic aortic stenosis in whom equivalent or superior outcomes to surgery can be expected.<sup>7</sup> Patients who have significant immobility (e.g. necessitating a walking frame), are moderately frail (physically or mentally) or who have significantly impaired cognition usually will not benefit from TAVI. Outcomes in these groups are disappointing.<sup>8</sup> The success of TAVI means that often patients who are in poor clinical condition (who would not normally be considered for a coronary angiogram, for example) are referred for TAVI.

Mortality on waiting lists for surgical or transcatheter treatment of aortic stenosis exceeds mortality on waiting lists for coronary artery bypass grafting or angioplasty. It is therefore important to ensure that those who have the most to gain have the shortest wait for the procedure. In liaison with Getting It Right First Time, fast-track referral of patients at greatest need has been proposed.<sup>9</sup> Patients with severe symptomatic aortic stenosis should be seen urgently and treated urgently if they have the following characteristics:

- peak flow velocity of  $\geq 5$  m/s;
- peak flow velocity of  $\geq 4$  m/s and impairment of left ventricular function ( $\leq 40\%$ ); or
- peak flow velocity of  $\geq 4$  m/s across, or severe aortic regurgitation of, a bioprosthesis.

However, these features should be combined with an absence of any of the following:

- severe immobility (3-wheel frame or higher-grade support);
- significant frailty (Rockwood score  $\geq 5$ ); or
- impaired cognitive function.

Other patients should be referred and treated on a non-fast-track basis. Urgent referrals should ideally be seen within 2 weeks and treated within 8 weeks. Patient (non-cardiac) life expectancy should be a minimum of 2 years.

Patients with asymptomatic aortic stenosis needing non-cardiac surgery are often referred for 'preoperative TAVI'. These requests should be discussed in the MDT. Preoperative TAVI is usually inappropriate unless the aortic stenosis is very severe (e.g.  $>5$  m/s), as the risks of TAVI usually outweigh the perceived perioperative benefits. Direct liaison with a cardiac anaesthetist can be very helpful. Other patients with asymptomatic severe aortic stenosis can join relevant clinical trials or await symptom development.<sup>10</sup>

Patients with severe aortic regurgitation may also be considered for TAVI if they are at high risk for surgical valve replacement and the aortic annulus falls within a dedicated range. Severe bioprosthetic aortic, mitral or tricuspid stenosis or regurgitation occurs at an accelerated degenerative rate, with sometimes acute presentation. Patients with severe bioprosthetic degeneration can be treated highly effectively at low risk with transcatheter valve implantation. The UK Commissioning Policy for TAVI from 2012 is currently being updated.

### Outpatient Assessment

Severe aortic stenosis often co-exists with other conditions of decline as patients approach the last years of their life. Face-to-face outpatient assessment is the best way to assess patient suitability for TAVI. Conversations about finite expectations can be stressful and may not align with the patient's or family's hopes. Assessment should take into account the patient's mental and physical frailty, mobility, and cognitive function.

### Inpatient Transfer for Transcatheter Aortic Valve Implantation

Referrals for inpatient TAVI now represent 25% of total TAVI volume. Admission of stable patients from echocardiography departments or outpatients because of very severe aortic stenosis should be avoided. Indications for inpatient transfer for TAVI should ideally be limited to acute pulmonary oedema presentations and true exertional cardiac syncope. Inpatients who are transferred for TAVI have often not met the implanting team and in this setting many borderline or worse candidates undergo TAVI from which they derive little benefit. Urgent outpatient assessment to address suitability for TAVI is preferable where possible.

### The Multidisciplinary Team

In the TAVI MDT meetings, the relative merits of surgery, TAVI or conservative therapy should be discussed. This does not take the place of direct patient assessment, but should be complementary.<sup>11</sup> Technical aspects of the procedure can be planned. For some patients, there is genuine potential equipoise between surgery and TAVI. For many patients, however, the preferred treatment is clinically clear, and in these cases, an MDT discussion of the patient's case should not be considered essential.

### The Transcatheter Aortic Valve Implantation Procedure

The TAVI procedure has evolved over the past decade and is now usually performed under local anaesthesia, with light sedation if desired. Femoral vascular access is made using vascular ultrasound and the procedure is usually completed under fluoroscopy alone, without temporary pacing wires. The implanting team may comprise two consultant operators (for more complex cases), a consultant and Fellow, or a consultant and an assistant. Management of sedation, analgesia and pressors is undertaken by a specialist nurse. A wide team is needed, including a physiologist adept at both rapid pacing on the left ventricular

wire and transthoracic echocardiography, a radiographer familiar with procedural flow, a nurse specialist to prepare the valve and catheter laboratory nurse specialists.

Most cases are transfemoral, with secondary radial access.<sup>12</sup> Centres should have an alternative arterial approach (e.g. transaxillary, transcaval), and should stock at least two different types of valve to ensure that all anatomies can be treated effectively. Valve type, size and implantation technique are decided by the implanting team and should be based on (their own) analysis of the CT scan.

After valve implantation, assessment of aortic regurgitation should be made by aortography with appropriate catheter placement, allied to haemodynamics and echocardiography where helpful. Relying solely on a high-ascending (sub-innominate) aortogram is not adequate. More than mild aortic regurgitation should usually prompt further intervention. Effectiveness of vascular closure should be assessed in the laboratory either with ultrasound or fluoroscopy, and action taken if necessary (see below). Patients should not leave the laboratory until concerns about valve haemodynamics, vascular closure or cardiac rhythm have been addressed.

### Complications

The commonest complications are vascular. TAVI operators should become familiar with the use of peripheral balloons, stents and covered stents. Although some stents are not recommended for use in the common femoral artery, these can be life-saving, and long-term complications are very rare.<sup>13</sup> An inventory of long peripheral balloons (for temporary femoral or iliac occlusion from the radial artery), stents and covered stents is necessary. Femoral complications can be managed by placement of additional closure devices, or by ipsilateral (via the superficial femoral artery) or contralateral (via the common femoral artery) delivery of covered stents, avoiding occlusion of the profunda femoris. Cardiologists should become familiar and comfortable with immediate management of vascular complications. Involvement of other specialties with expertise in this area (interventional radiology or vascular surgery) can be helpful, but should be rarely needed once a service is mature.

Annular rupture is usually fatal. Pericardiocentesis with pericardio-venous return is usually required. Cardiac anaesthesia emergency support is critical if the patient is to survive. Interventional or surgical approaches may be taken to try to salvage the situation, depending on local expertise.

Patients with immediate and obvious postprocedure stroke should be considered for immediate neurovascular intervention. Unfortunately, debris is more usually calcific than thrombotic and results of intervention are therefore variable.

### Postprocedure

Post-TAVI, the main concerns relate to vascular access and cardiac rhythm. Patients should be monitored for 3–4 hours post-TAVI, at which point they can mobilise. Patients in sinus rhythm who have a narrow QRS complex can be considered for same-day discharge if there is home support. Most day-case TAVI patients receive a balloon-expandable valve, but this need not be exclusively the case.

Patients who remain in hospital overnight should usually be discharged the next morning. Echocardiography can be carried out as an outpatient; routine in-hospital postprocedure echocardiography slows down patient discharge. Occasional inpatients require longer stays, but avoidance of

package-of-care assessment helps to maintain throughput to the benefit of those on the waiting list.

### Standards

TAVI services should co-exist with cardiac surgical services. This allows formal and informal patient discussion, seamless transfer of patients between modalities, and optimum use of the skills and specialties of the wider regional hospital in and out of hours, and in the event of complications. Concentration of expertise and volume optimises outcomes. All surgical centres should offer TAVI as part of a comprehensive regional aortic valve interventional service. Centres should be commissioned by NHS England or its successor to undertake the procedure.

Expansion of TAVI services has required considerable investment in infrastructure, inventory and personnel in the regional centres. Regions should ensure that their TAVI services are rapidly responsive and are sufficiently flexible to take the volume of referred cases. TAVI services require a wider team than all other cardiology procedures, with additional need for nurse anaesthesia, consultant anaesthesia, nurse valve specialists, valve preparation specialists, radiographers, physiologists and scrub nurses, who are all familiar with TAVI and its possible complications, which, when they occur, require prompt co-ordinated efforts if the patient is to survive.

TAVI volumes in the UK are currently approximately 170 per million. This represents a low rate per million in comparison with other European countries. Given that aortic stenosis is a degenerative condition, there may, however, be a peak anticipated volume per million that is manageable by cardiothoracic centres performing up to 800 TAVI procedures per year. Cardiac centres should manage their anticipated volume, which currently occupies an average of only 100 days of a single catheter laboratory per year in a given centre.

Centres should aim to have a minimum of four TAVI operators, so that procedures can take place 5 days a week (as surgical services do) with a range of valves and vascular access routes. Centres should perform a minimum of 200 cases per year. Operators should aim to be involved in a minimum of 100 TAVI cases per year (as first or second operator interchangeably). Training in TAVI is likely to remain a post-Certificate of Completion of Training phenomenon for most trainees in the immediate future. A number of excellent fellowships exist in the UK for potential candidates.

### Structural Heart Nurse Specialists

All TAVI services in the UK should have at least one structural heart nurse specialist. In this role, a nurse will have many responsibilities. Preprocedurally, the nurse will commonly be the main point of contact for patients, co-ordinate the waiting list, co-ordinate the MDT and communicate results. They may also be involved in co-ordinating the availability of a wide TAVI-specific additional inventory, including preclosure devices, large-bore sheaths, specialist 0.035" wires, peripheral balloons, aortic balloons, valves, peripheral stents and snares. Procedurally, the nurse may, after training, act as nurse anaesthetist, prepare valves for implantation, act as expert scrub assistant or second operator and respond quickly in emergency settings. Postprocedure, the nurse specialist may review patients on the ward, and may arrange telephone and clinic follow-up. This is a highly specialised role that is integral to the successful delivery of a TAVI service. Services running a program offering >200 TAVIs per year will need more than one specialist nurse. Integration of a research practitioner allied to the TAVI team is also recommended.

## Governance

Procedural and outcome data should be entered into the National TAVI Registry housed by the National Institute for Cardiovascular Outcomes Research. Outcomes are linked to the Office for National Statistics, and funnel plots of validated 30-day survival will be made available to centres so that internal and external audits of results can be made and quality control examined. Centres are expected to have at least annual reviews of their TAVI activity, with discussion of morbidity and mortality outcomes, at departmental governance meetings.

## Conclusion

Transcatheter aortic valve implantation is a safe and effective treatment for patients with severe symptomatic aortic valve disease requiring intervention. Identification of the patients who are most likely to benefit is a key feature of a good TAVI service. Case volume should be manageable within existing cardiothoracic centres. Implementation of a fast-track pathway for the most deserving cases is warranted. All cardiac surgical centres should offer TAVI as part of a comprehensive aortic valve disease management strategy. 

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