NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transcatheter aortic valve implantation (TAVI) for native aortic valve regurgitation

The aortic valve controls the flow of blood out of the lower left chamber of the heart into the main artery (aorta). In aortic valve regurgitation, the aortic valve is unable to close properly and allows blood to leak back into the heart. This can cause fatigue, chest pain and shortness of breath, and may lead to heart failure.

In transcatheter aortic valve implantation (TAVI) a tube (catheter) is inserted into the heart through a large blood vessel, usually in the groin, or directly through the chest wall. A replacement valve is passed through this tube and inserted (implanted) inside the existing faulty valve (the native valve). The aim is to reduce symptoms and prolong life.

NICE is looking at transcatheter aortic valve implantation (TAVI) for native aortic valve regurgitation.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 3 March 2025

Target date for publication of guidance: June 2025

1 Draft recommendations

When SAVR is not suitable or is high risk

1.1 Transcatheter aortic valve implantation (TAVI) for native aortic valve regurgitation can be used in the NHS while more evidence is generated to treat native aortic valve regurgitation when surgical aortic valve replacement (SAVR) is not suitable or is high risk. It can only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wanting to do TAVI when SAVR is not suitable or is high risk should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.

- Regularly review data on outcomes and safety for this procedure.

When SAVR is suitable and is not high risk

1.4 More research is needed on TAVI for native aortic valve regurgitation when SAVR is suitable and is not high risk before it can be used in the NHS.

1.5 This procedure should only be done as part of a formal research study and a research ethics committee needs to have approved its use.

For everyone having TAVI for native aortic valve regurgitation

1.6 Patient selection should be done by an experienced multidisciplinary team, which must include:

- interventional cardiologists experienced in the procedure
- cardiac surgeons
- an expert in cardiac imaging, and
- when appropriate, a cardiac anaesthetist and a specialist in medicine for older people.

The multidisciplinary team should determine the risk level for each patient and the TAVI valve most suitable for them.

1.7 TAVI is a technically challenging procedure that should only be done in specialised centres and only by teams with specific training and experience in complex endovascular interventions. Units doing this procedure should have both cardiac and vascular surgical support for the emergency treatment of complications and subsequent care.

1.8 Enter details about everyone having TAVI for native aortic valve regurgitation into the UK TAVI registry, managed by the National Institute for Cardiovascular Outcomes Research. Contact nicor.auditenquiries@nhs.net for details.

What evidence generation and research is needed

1.9 Further evidence generation and research should be in the form of suitably powered randomised controlled trials and patient registries across all risk categories. The trials should report details of:

- patient selection
- comparisons between TAVI and SAVR or medical treatment
- comparisons between different TAVI prosthetic aortic valves
- long-term outcomes, including:
  - valve durability and reintervention rates
  - the need for a second TAVI valve-in-valve implantation
- safety outcomes, including embolisation, stroke and myocardial infarction.

Why the committee made these recommendations

Evidence on TAVI for native aortic regurgitation when SAVR is not suitable or is high risk shows well-recognised safety concerns. Evidence on short-term efficacy is limited and comes mainly from small observational studies or registries. So, when SAVR is not suitable or the person has a high risk of complications from surgery, the procedure can be used with special arrangements for clinical governance, consent, and audit or research.

There is not enough evidence on efficacy and safety when SAVR is suitable and is not high risk. So, for these people, the procedure should only be used in research.

2 The condition, current treatments and procedure

The condition

2.1 Aortic regurgitation (AR) is the leakage of blood backwards from the aorta into the left ventricle during diastole (when the heart relaxes and fills with blood). It develops when the aortic valve pathology prevents normal closure of the valve in diastole. AR is usually the result of leaflet degeneration, aortic root dilatation with aortic annulus enlargement, or both. People may remain asymptomatic for years but eventually they present symptoms, most often with shortness of breath. In severe cases this leads to heart failure.

Current treatments

2.2 For people with severe symptomatic AR who are well enough for surgery, surgical aortic valve replacement (SAVR) with a biological or mechanical prosthetic valve is standard treatment.

2.3 For some people, surgery is not an option. This can be because of medical comorbidities or technical considerations, such as a calcified aorta or scarring from previous cardiac surgery. For these people, the risks of SAVR outweigh the potential benefits, and so medical treatment is the standard treatment. But for some of these people, medical treatment is not effective.

The procedure

2.4 TAVI provides a less invasive alternative to open cardiac surgery for treating AR, avoiding the need for cardiopulmonary bypass and median sternotomy.

2.5 TAVI is usually done under local anaesthesia with sedation. Or it may be done under general anaesthesia. Imaging guidance, including transoesophageal echocardiography (if general anaesthesia is used), fluoroscopy or angiography is used to help with prosthetic valve size selection, valve positioning and assessing the implanted prosthetic valve post procedure. Prophylactic antibiotics and anticoagulation medication are administered before and during the procedure.

2.6 A bioprosthetic aortic valve is implanted within the damaged native aortic valve. Access to the aortic valve can be percutaneous, with entry to the circulation through the femoral artery (endovascular approach). Alternatively, subclavian access may be used if the anatomy of the femoral arteries is not suitable. Deciding how to achieve catheter access to the aortic valve may depend on a number of factors related to the person having the procedure, such as femoral artery anatomy and the presence of aortic calcification.

2.7 The new prosthetic valve is manipulated into position and deployed over a guide wire passed through the native aortic valve.

2.8 Rapid ventricular pacing is used to temporarily reduce cardiac motion and blood flow through the native aortic valve during placement of the new prosthetic aortic valve. The new valve may be mounted on a metal stent that is self-expanding. Or, it may be expanded by inflating a large balloon on which the stented valve has been crimped. Positioning the new valve obliterates the native aortic valve. The catheter is removed once the valve has been successfully placed.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 4 systematic review and meta-analyses, 1 prospective study, 1 retrospective propensity score-matched study and 2 retrospective studies. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be:

- symptomatic relief
- reduction in aortic regurgitation (AR)
- improvement in quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be:

- mortality
- stroke
- myocardial infarction
- major valvular complications, including:
  - embolisation
  - bleeding
  - residual AR
  - reintervention.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 Some of the evidence comes from prosthetic aortic valves that do not have regulatory approval for use in this indication. The evidence shows worse safety outcomes when valves not indicated for use in aortic valve regurgitation are used.

3.6 Bioprosthetic valves are made from porcine or bovine tissue. Some people may not want to have these.

3.7 This procedure may not be appropriate for people with significant aortic root dilatation.

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Chair, interventional procedures advisory committee
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