

Valve-in-valve TAVI for aortic bioprosthetic valve dysfunction

Interventional procedures guidance

Published: 26 June 2019

www.nice.org.uk/guidance/ipg653

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG504.

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) for aortic bioprosthetic dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Details of all patients should be entered into the UK TAVI registry.
- 1.3 Device-related adverse events should be reported to the Medicines and Healthcare products Regulatory Agency.
- 1.4 Patient selection should be done by a 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 elderly medicine. The multidisciplinary team should determine the risk level for each patient and the device most suitable for them.
- 1.5 During the consent process, patients should be told about all treatment options, and their advantages and disadvantages.
- 1.6 ViV-TAVI is a technically challenging procedure that should only be done in specialised centres, and only by clinicians and teams with special 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 patient care.

2 The condition, current treatments and procedure

The condition

- 2.1 The 2 main indications for aortic valve replacement are aortic stenosis and aortic regurgitation. Symptoms of both conditions typically include shortness of breath and chest pain on exertion. The increased cardiac workload can lead to heart failure.

Current treatments

- 2.2 Aortic valve replacement with an artificial prosthesis (biological or mechanical) is the conventional treatment for patients with severe aortic valve dysfunction. Valves may be placed by either open heart surgery or using transcatheter aortic valve implantation (TAVI; see [NICE's interventional procedures guidance on TAVI](#)). Although bioprosthetic valves have some advantages over mechanical valves, they may degenerate and fail over time. The standard treatment for a failed bioprosthetic valve is open heart surgery, with a further valve replacement. Reoperative surgery is associated with significant morbidity and a higher risk of mortality than primary surgery.
- 2.3 Valve-in-valve (ViV) TAVI has been developed as a less invasive alternative treatment that avoids the need for cardiopulmonary bypass. It can be used for treating failed bioprosthetic aortic valves originally placed by either open heart surgery or TAVI.

The procedure

- 2.4 The procedure is done with the patient under general or local anaesthesia with sedation, using fluoroscopy. Prophylactic antibiotics and anticoagulant medication are used.
- 2.5 A new prosthetic valve is mounted within a stent, which is either self-expanding or expanded using balloon inflation. It is delivered by a catheter across the failed bioprosthetic aortic valve. Access to the aortic valve can be achieved transluminally, with entry to the circulation through the femoral or other large artery (sometimes known as a percutaneous or endovascular approach), or through apical puncture of the left ventricle (a transapical or transventricular approach). In the transluminal approach, surgical exposure and closure of the artery may be needed. How access to the aortic valve is achieved depends on whether there are factors that make the passage of a catheter through the circulation difficult, such as peripheral arterial disease.
- 2.6 The procedure is technically similar to [TAVI for aortic stenosis into a native aortic valve](#), but some modifications to the technique have been reported. The new prosthetic valve is placed tightly into the orifice of the failed bioprosthetic valve, pushing the old valve leaflets aside. Gradual valve deployment (without rapid inflation of the balloon) is done and angiography is used to ensure accurate positioning of the valve. The old prosthesis is also used as a guide for positioning the new valve. The external diameter of the new valve should usually match or exceed the internal diameter of the old valve. Anticoagulation or antiplatelet therapy may be continued after the procedure.

3 Committee considerations

The evidence

- 3.1 To inform the committee, 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 11 sources, which was discussed by the committee. The evidence included 3 systematic reviews and

meta-analysis and 8 case series, and is presented in [table 2 of the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.

- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: survival, haemodynamic improvement, symptom relief and improvement in quality of life.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: mortality, stroke, myocardial infarction and paravalvular leak.
- 3.4 Two commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

Committee comments

- 3.5 There is a move towards using sedation rather than general anaesthesia for this procedure.
- 3.6 The longer-term evidence for valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) is from earlier-generation TAVI devices and the technology is evolving. Longer-term evidence is needed and this should be taken into account by the multidisciplinary team.
- 3.7 The replacement valve used for ViV-TAVI can be smaller than the original, increasing the risk of aortic outflow obstruction.
- 3.8 There is a risk of patient–prosthesis mismatch.
- 3.9 Some of the patients having this procedure may have concomitant coronary artery disease, and this needs to be considered by the multidisciplinary team when planning treatment.

ISBN: 978-1-4731-3436-2

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).