

Transcatheter valve-in-valve implantation for aortic bioprosthetic valve dysfunction

Interventional procedures guidance

Published: 26 September 2014

[nice.org.uk/guidance/ipg504](https://www.nice.org.uk/guidance/ipg504)

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. However, 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.

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.

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.

1 Recommendations

- 1.1 For patients with aortic bioprosthetic valve dysfunction for whom surgical aortic valve replacement (SAVR) is considered to be unsuitable (see section 1.6), the evidence on the safety and efficacy of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) is adequate. For these patients, ViV-TAVI may be

used with normal arrangements for clinical governance, consent and audit. Details of all patients should be entered into the [UK Central Cardiac Audit Database](#).

1.2 For patients with aortic bioprosthetic valve dysfunction for whom surgical aortic valve replacement (SAVR) is considered to be suitable but to pose a high risk (see sections 1.4, 1.5 and 1.6), the evidence on the safety and efficacy of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) is inadequate. For these patients, ViV-TAVI should only be used with special arrangements for clinical governance, consent and data collection or research. Details of all patients should be entered into the [UK Central Cardiac Audit Database](#).

1.3 For patients with aortic bioprosthetic valve dysfunction for whom surgical aortic valve replacement (SAVR) is considered to be suitable and not to pose a high risk (see sections 1.5 and 1.6), the evidence on the safety and efficacy of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) is inadequate. For these patients, ViV-TAVI should only be used in the context of research. In addition, details of all patients should be entered into the [UK Central Cardiac Audit Database](#).

1.4 Clinicians wishing to carry out valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) for patients with aortic bioprosthetic dysfunction for whom surgical aortic valve replacement (SAVR) is considered to be suitable but to pose a high risk (see section 1.2) should take the following actions:

Inform the clinical governance leads in their NHS trusts.

- Ensure that patients understand the risk of death, and the uncertainty about the procedure's efficacy in the long term.
- Provide them with clear written information.

In addition, the use of NICE's [information for the public](#) is recommended.

Patient selection should be carried out by a multidisciplinary team including interventional cardiologists, cardiac surgeons, a cardiac anaesthetist and an expert in cardiac imaging. The multidisciplinary team should determine the risk level for each patient.

- 1.5 Valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) is a technically challenging procedure that should only be done by clinicians and teams with special training and experience in complex endovascular cardiac interventions, including regular experience in the use of TAVI. Units doing this procedure should have both cardiac and vascular surgical support for emergency treatment of complications.
- 1.6 NICE encourages further research into valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) for aortic bioprosthetic dysfunction. Comparative studies between ViV-TAVI and surgical aortic valve replacement (SAVR) for patients who are judged to have a low risk from SAVR should describe patient selection clearly and should report fully on complications and valve durability in the short and long term.
- 1.7 NICE may review this procedure on publication of further evidence.

2 Indications and current treatments

- 2.1 The 2 main indications for aortic valve replacement are aortic stenosis and aortic regurgitation. Symptoms of aortic stenosis and regurgitation typically include shortness of breath and chest pain on exertion. The increased cardiac workload can lead to heart failure.
- 2.2 Surgical aortic valve replacement with an artificial prosthesis (biological or mechanical) is the conventional treatment for patients with severe aortic valve dysfunction who are well enough for open heart surgery. 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 repeat open heart surgery, with a further valve replacement. Re-operative surgery is associated with significant morbidity and a higher risk of mortality than primary surgery. Valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) has been developed as a less invasive alternative treatment that avoids the need for cardiopulmonary bypass. It can be used for the treatment of failed bioprosthetic aortic valves originally placed either by TAVI or by open heart surgery. In particular, it has been used for rescue of suboptimal TAVI.

3 The procedure

- 3.1 The procedure is done with the patient under general or local anaesthesia, with imaging guidance using fluoroscopy and usually transoesophageal echocardiography. Prophylactic antibiotics and anticoagulant medication are given before and during the procedure. Temporary peripheral extracorporeal circulatory support (usually through the femoral vessels) is sometimes used.
- 3.2 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.
- 3.3 The procedure is technically similar to transcatheter aortic valve implantation for aortic stenosis into a native aortic valve (see [NICE interventional procedures guidance 421](#)), but some modifications to the technique have been reported. Instead of dilating the failed aortic bioprosthetic valve with a balloon, the new prosthetic valve is attached tightly into the orifice of the failed bioprosthetic valve, pushing the old valve leaflets aside. The important modification is slow, gradual valve deployment (without rapid inflation of the balloon) with angiography to enable accurate positioning of the valve. The old prosthesis is used as a guide for positioning the new valve. The size of the new valve is usually selected so that its external diameter matches or exceeds the internal diameter of the old valve.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

The evidence on efficacy is presented separately for 2 different indications: first for degenerated aortic surgical bioprostheses and second for rescue of suboptimal transcatheter aortic valve implantation (TAVI).

Transcatheter ViV implantation in degenerated aortic surgical bioprostheses

- 4.1 A register of 47 patients treated by valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) reported implantation success of 100% and short-term procedural success of 98% (46/47). Implantation success was defined as successful implantation into the failed surgical prosthesis (procedural success was not defined).
- 4.2 In a register of 459 patients who were treated by ViV-TAVI for degenerated bioprosthetic valves, the 1-year survival rate calculated using a Kaplan–Meier curve was 83% (228/459; 95% confidence interval [CI] 81.8 to 84.7%). Factors associated with mortality within 1 year included small size of the original surgical bioprosthesis (<21 mm; hazard ratio [HR] 2.04; 95% CI 1.14 to 3.67; $p=0.02$) and aortic stenosis before intervention (compared against regurgitation, HR 3.07; 95% CI 1.33 to 7.08; $p=0.008$).
- 4.3 The register of 459 patients treated by ViV-TAVI for degenerated bioprosthetic valves reported improvement in New York Heart Association (NYHA) functional class after the procedure. Before treatment, 8% (35/459) of patients were in class I/II, compared with 93% (313/459) at 30-day follow up. Before treatment 92% (424/459) of patients were class III/IV compared with 7% (25/338) at 30 days. These results were maintained at 1-year follow-up.
- 4.4 The register of 47 patients reported that there was an improvement in the mean transvalvular pressure gradient (from 38 ± 15 mmHg to 17 ± 10 mmHg, significance not reported) and an increase in mean aortic valve area (from 0.90 ± 0.42 cm² to 1.61 ± 0.47 cm², $p<0.001$) after ViV-TAVI implantation.

Transcatheter ViV implantation for rescue of suboptimal TAVI

- 4.5 A register of 663 patients, including 24 patients treated by transcatheter ViV for aortic bioprosthesis malposition reported procedural success in all patients treated by ViV-TAVI. For the 24 patients treated by ViV-TAVI, the register reported survival of 23 patients (96%) and an improvement in the mean

transaortic gradient in all 24 patients (from 45.4 ± 14.8 mmHg to 10.5 ± 5.2 mmHg, $p=0.83$) at 1-year follow-up.

- 4.6 The specialist advisers listed additional key efficacy outcomes as mid- and long-term survival, long-term durability and quality of life.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 A register of 459 patients treated by valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) for degenerated bioprostheses reported an all-cause mortality rate of 8% (35/459) at 30-day follow-up. Reasons for the deaths were not described.
- 5.2 Ostial coronary obstruction was reported in 2% (9/459) of patients in the register of 459 patients and was more frequent in the group of patients with aortic valve stenosis (4%; $p=0.02$) (further details were not reported).
- 5.3 Major adverse cerebrovascular and cardiac event rates of 0% and 5% were reported at 30-day and 1-year follow-up respectively, in 24 patients treated by ViV-TAVI in a register of 663 patients treated for aortic bioprosthesis malposition.
- 5.4 Major stroke within 30 days was reported in 2% (8/459) of patients in the register of 459 patients treated for degenerated bioprostheses.
- 5.5 Myocardial infarction was reported in 8% (2/25) of patients at 30-day follow-up in a case series of 25 patients (further details were not reported).
- 5.6 Conversion to surgical aortic valve replacement (SAVR) during the procedure was reported in 1 patient because of dislocation of the prosthesis into the ascending aorta twice during deployment, in a case series of 20 patients with degenerated bioprosthesis. A case report of 1 patient reported conversion to SAVR for sudden cardiogenic shock secondary to the migration of 2 prosthetic valves (bioprosthetic valve and ViV implanted to treat severe central aortic

regurgitation) into the left ventricular outflow tract. The patient died soon after the operation.

- 5.7 Conversion to SAVR after the procedure was reported in 1 patient in a register of 47 patients with degenerated bioprosthesis because of bleeding at the transapical site (further details were not reported). Conversion to SAVR after the procedure was reported in 1 patient for symptomatic heart failure and 'patient-prosthesis mismatch' after 426 days in a case series of 11 patients with degenerated bioprosthesis.
- 5.8 Pacemaker implantation was needed for atrioventricular block in 11% (5/47) of patients in the register of 47 patients. Arrhythmias after the procedure were also reported in 6% (3/47) of patients in this study (further details were not reported).
- 5.9 Endocarditis 3 months after the procedure was reported in 1 patient in a case series of 14 patients. This was successfully treated by inserting a new valve by open heart surgery.
- 5.10 Renal failure needing dialysis after the procedure was reported in 9% (4/47) of patients in the register of 47 patients (further details were not reported). Acute kidney injury was reported in 7% (34/459) of patients in the register of 459 patients (further details were not reported).
- 5.11 Paravalvular aortic regurgitation after the procedure was reported as none-to-trivial in 50% (10/19) of patients, mild in 30% (6/19) and mild-to-moderate in 10% (2/19) of patients in the case series of 20 patients (10 with stenosis, 9 with aortic regurgitation and 1 with a combination of both). Paraprosthetic leak (grade 2+ or more) was reported in 4% (1/24) of patients in the ViV group in the register of 663 patients.
- 5.12 Severe patient-prosthesis mismatch (clinical consequences not described) occurred in 32% of patients surviving a ViV procedure in a register of 459 patients. The incidence was lower in patients with bioprosthetic regurgitation before the procedure than in those with stenosis and combined valve dysfunction (19% compared against 36% and 36%; $p=0.03$).

- 5.13 Major bleeding was reported in 8% (37/459) of patients in the register of 459 patients (further details were not reported).
- 5.14 Vascular access-related complications were reported in 13% (6/47) of patients during the procedure in the register of 47 patients (further details were not reported).
- 5.15 The specialist advisers listed additional safety outcomes as cardiac tamponade, aortic dissection and 'left apical complications'.

6 Committee comments

- 6.1 The Committee noted that most of the evidence on the use of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) for patients with aortic bioprosthetic valve dysfunction was in older patients at high risk from surgery. It noted that there was no published evidence specific to patients judged to be at low risk from surgical aortic valve replacement, and it therefore considered that there is uncertainty about the balance of risks and benefits of ViV-TAVI for these patients. This uncertainty underpinned the recommendation that the procedure should only be used in the context of research for patients who are at low risk from surgical aortic valve replacement (see section 1.3).
- 6.2 The Committee was advised to consider patients having ViV-TAVI for rescue of suboptimal TAVI separately from those having the procedure for degenerated bioprosthetic valves, and the evidence for those 2 groups is presented separately. The Committee considered that the use of ViV-TAVI for rescue of suboptimal TAVI is covered by the recommendations set out in sections 1.1 and 1.2 of the guidance.
- 6.3 The Committee noted that survival was lower among patients with small bioprostheses and those who, before the procedure, had predominant stenosis rather than regurgitation of their surgically implanted valves.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).

Information for patients

NICE has produced information on this procedure for patients and carers ([Information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedures guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

This guidance was developed using the NICE [interventional procedures guidance process](#).

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence the guidance is based on is also [available](#).

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ISBN 978-1-4731-0744-1

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

