

Transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis

Interventional procedures guidance

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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

These recommendations apply only to patients for whom open surgical valve implantation is unsuitable.

- 1.1 The current evidence on the safety of transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis shows the potential for serious complications. However, this is in patients for whom open surgical valve implantation is unsuitable, who have severe symptoms and a high risk of death. The evidence on efficacy shows generally good symptom relief in the short term, but is based on very small numbers of patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to do transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis should:
- Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy in the long term, and provide them with clear written information. In addition, the use of NICE's [information for the public](#) is recommended.
 - Enter details about all patients having transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis onto the [National Institute for Cardiovascular Outcomes Research database \(NICOR\)](#) and review local clinical outcomes.
- 1.3 Patient selection should be done 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 and review their suitability for alternative medical or surgical treatments.
- 1.4 Transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis should only be done by clinicians and teams with special training and experience in complex endovascular cardiac interventions, including regular experience in transcatheter valve implantation procedures. Units doing these procedures should have both cardiac and

vascular surgical support for emergency treatment of complications.

- 1.5 NICE encourages further research into transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis. This may include prospective observational studies. Studies should include details on patient selection, functional outcomes, quality of life, survival and complications. Studies should report long-term follow-up of clinical outcomes and valve durability. NICE may update this guidance on publication of further evidence.

2 Indications and current treatments

- 2.1 Mitral valve replacement is done for severe mitral valve stenosis, mitral regurgitation or a combination of both. Symptoms of severe mitral valve disease typically include shortness of breath, fatigue and palpitations (arising from atrial fibrillation).
- 2.2 If symptoms of mitral valve disease are sufficiently severe, valve replacement with an artificial prosthesis (bioprosthetic or mechanical) may be done by open heart surgery in patients who are well enough for this kind of operation. Bioprosthetic valves have some advantages over mechanical valves, but they are more likely to degenerate and fail over time. This can result in severe stenosis or regurgitation, needing replacement of the bioprosthetic valve.
- 2.3 The standard treatment for a failed bioprosthetic valve is repeat open heart surgery to replace the valve. Repeat open heart surgery is associated with a higher risk of morbidity and mortality than primary surgery. Transapical transcatheter mitral valve-in-valve implantation is a less invasive alternative when repeat open heart surgery is considered to have a high risk. It avoids the need for cardiopulmonary bypass and can be used to treat failed bioprosthetic mitral valves originally placed during open heart surgery.

3 The procedure

- 3.1 The procedure is done with the patient under general anaesthesia and using imaging guidance including fluoroscopy, angiography and transoesophageal echocardiography. Prophylactic antibiotics and anticoagulants are given before

and during the procedure. Temporary peripheral extracorporeal circulatory support (usually through the femoral vessels) is sometimes used.

- 3.2 The mitral valve is accessed surgically via apical puncture of the left ventricle using an anterior or left lateral minithoracotomy (transapical approach). A guidewire is placed across the existing mitral prosthetic valve and into a pulmonary vein. A balloon catheter delivery system is then advanced over the guidewire. When there is severe prosthetic mitral valve stenosis, a balloon valvuloplasty may be done first. The inner diameter of the degenerated valve is measured using transoesophageal echocardiography to establish the size of new bioprosthetic valve needed. Using the delivery system, the new bioprosthetic valve is then introduced, manipulated into position and slowly deployed within the degenerated mitral valve under fluoroscopic and echocardiographic guidance. Often, rapid ventricular pacing is used to reduce movement of the heart. After valve deployment, the catheter delivery system, guidewires and pacing wires are removed and the chest wound is closed. Valve performance is then assessed using echocardiography and fluoroscopy.

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](#).

- 4.1 In a case series of 23 patients treated by transapical transcatheter mitral valve-in-valve implantation for degenerated mitral bioprosthetic valves, the procedure was successful in 100% of patients. Procedural success was defined according to the Valve Academic Research Consortium-2 definition (device success and no occurrence of in-hospital or 30-day death). In 1 procedure, implantation through the left atrium via a right thoracotomy was unsuccessful (because the delivery system failed to align properly) but was successfully done via a left thoracotomy and transapical approach.
- 4.2 In the case series of 23 patients, survival at 30 day follow-up was 100%. At a median follow-up of 753 days (range 376 days to 1119 days), survival rate calculated using Kaplan–Meier analysis was 90%. In a case series of 6 patients, 5 patients were alive and had not had any valve-related events at a median follow-up of 70 days (range 25 days to 358 days).

- 4.3 In the case series of 23 patients, there was improvement in New York Heart Association (NYHA) functional class after the procedure. Before treatment, 96% (22/23) of the patients were in NYHA class III/IV and 1 patient was in class II. At last follow-up (range 376 days to 1119 days), 96% (22/23) of the patients had clinically improved to NYHA class I/II. One patient with hypertrophic obstructive cardiomyopathy continued to be in NYHA class III despite satisfactory valve function and septal ablation.
- 4.4 In the case series of 23 patients, there was a significant decrease in the mean mitral transvalvular pressure gradient after implantation (from 11.1 ± 4.6 mmHg to 6.9 ± 2.2 mmHg; $p=0.014$).
- 4.5 In the case series of 23 patients, mitral regurgitation reduced from severe or moderate regurgitation (in 61% [14/23] and 17% [4/23] of patients respectively) at baseline to mild or no regurgitation (in 52% [12/23] and 48% [10/23] of patients respectively) at discharge.
- 4.6 The specialist advisers listed key efficacy outcomes as: correct and stable positioning of a new valve; valve function (that is, no valvular or paravalvular regurgitation, no significant pressure gradient across the valve, and no left ventricular outflow tract obstruction); symptom improvement; survival; and long-term durability of the valve.

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 In a case series of 349 patients treated by transcatheter mitral valve-in-valve implantation for degenerated mitral bioprosthetic valves, 30-day all-cause mortality was reported as 9% (32/349) and 30-day cardiovascular death was reported as 6% (21/349). One patient died in a case series of 7 patients (mortality rate 14%); this patient had an unsuccessful transseptal approach for transcatheter mitral valve-in-valve implantation, which resulted in embolisation and the need for conversion to a prolonged open operation. The patient developed multisystem failure and died on the second postoperative day.

- 5.2 An all-cause mortality rate of 10% (2/23) at a median follow-up of 753 days was reported in a case series of 23 patients. Death was from respiratory failure in 1 patient (at 45 days) in whom the transatrial approach was converted to transapical implantation, and was from an unknown cause (defined as cardiovascular according to Valve Academic Research Consortium-2) in 1 patient (on day 135).
- 5.3 In-hospital fatal pneumonia (on day 34, due to respiratory failure) was reported in 1 patient with chronic obstructive pulmonary disease in the case series of 7 patients. The patient needed reintubation, but later died. Prolonged assisted ventilation (not defined) was reported in 25% (3/13) of patients who had transapical mitral valve-in-valve implantation in a retrospective case series of 20 patients (13 with degenerated valve in the mitral position and 7 with degenerated ring in mitral position).
- 5.4 Major stroke was reported in 3% (11/349) of patients in the case series of 349 patients at a median follow-up of 408 days. Major periprocedural stroke (complicated by nosocomial pneumonia and acute renal injury needing temporary renal replacement therapy) was reported in 1 patient in the case series of 23 patients. This patient had a prolonged intensive care stay and died on day 45 with respiratory failure, despite renal and neurological recovery.
- 5.5 Transient ischaemic attack was reported in 1 patient (who had transapical mitral valve-in-valve implantation) in the retrospective case series of 20 patients.
- 5.6 Major bleeding was reported in 26% (6/23) of patients in the case series of 23 patients (further details were not reported).
- 5.7 Late bleeding at the apical site was reported in 33% (2/6) of patients in a case series of 6 patients. One patient needed a further thoracotomy on day 4 because of haemothorax and had an uneventful recovery. One patient became haemodynamically compromised on day 6 and needed cardiopulmonary resuscitation, but died of haemorrhagic shock because of acute bleeding from the apical wound.
- 5.8 Gastrointestinal bleeding (caused by anticoagulation and sepsis 2 months after the procedure) was reported in 1 patient in the case series of 6 patients. The patient was admitted to hospital but no signs of endocarditis were found.

- 5.9 Bioprosthesis thrombosis (3 months after transcatheter mitral valve-in-valve implantation) was reported in a case report of 1 patient. The patient had increasing shortness of breath and transoesophageal echocardiography revealed symptomatic and severe mitral valve stenosis with unusual leaflet thickening. After antithrombotic treatment, there was a significant decrease in transvalvular gradient and significant regression of the leaflet thickening.
- 5.10 Acute kidney injury (Acute Kidney Injury Network staging 2 and 3) was reported in 11% (39/349) of patients in the case series of 349 patients with a median follow-up of 408 days. Further details were not reported. Continuous venovenous haemodialysis was needed in 18% (2/13) of patients who had transapical mitral valve-in-valve implantation in the retrospective case series of 20 patients.
- 5.11 Permanent pacemaker implantation (on day 3 for pre-existing atrioventricular conduction disturbance) was needed in 1 patient in the case series of 23 patients.
- 5.12 An incisional haematoma was reported in 1 patient in the case series of 23 patients (further details were not reported).
- 5.13 Wound infection was reported in 25% (3/13) of patients who had transapical mitral valve-in-valve implantation in the retrospective case series of 20 patients.
- 5.14 Atrial clot (detected at 6-month follow-up echocardiogram) was reported in 1 patient in the case series of 23 patients. The patient was asymptomatic with no embolic events but treated with systemic anticoagulation.
- 5.15 Haemothorax (drained with a thoracostomy tube) was reported in 1 patient in the case series of 23 patients.
- 5.16 Implantation of a second transapical transcatheter mitral valve-in-valve was needed (at 2 months; because of acute heart failure) in 1 patient in the case series of 23 patients. Echocardiography showed 4–5 mm atrial migration of the valve, which caused severe valvular regurgitation. A second transapical transcatheter mitral valve-in-valve implantation was done with no complications or valvular regurgitation.

5.17 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers described left ventricular outflow tract obstruction as an anecdotal adverse event. They considered that the following were theoretical adverse events: incorrect positioning of the transcatheter valve, paravalvular regurgitation, mitral stenosis and surgical wound infection.

6 Further information

6.1 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 [information for the public](#) explaining this guidance. Information about the [evidence](#) the guidance is based on is also available.

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Accreditation

