NICE National Institute for Health and Care Excellence

NICE guidance

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

HealthTech guidance
Published: 22 September 2021

www.nice.org.uk/guidance/htg592

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.

Contents

This guidance replaces IPG541 and IPG706.

1 Recommendations

1.1 Evidence on the safety of transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis is adequate and shows some serious but well-recognised complications. Evidence on its efficacy is limited in quality. So, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE guidance page.

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 healthcare organisation.
- Give patients (and their families and carers, as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients have been told and understand about all alternative treatment options and their advantages and disadvantages.
- Enter details about all patients having transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis onto a national registry when 1 is available.
- Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's 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 every patient having this procedure.

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

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 where 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 device most suitable for them.

1.5 The procedure is technically challenging and should only be done in specialised centres, and only by clinical teams with special training and experience in complex endovascular cardiac interventions, including regular experience in transcatheter valve implantation procedures. Centres doing these procedures should have cardiac surgical support for emergency treatment of complications and subsequent patient care.

1.6 Report any problems with a medical device using the Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme.

1.7 NICE encourages further research into transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis. Studies should include details on patient selection, type and size of valve used, functional outcomes (New York Heart Association functional class, mitral valve regurgitation), quality of life, patient-reported outcome measures, 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 The condition, current treatments and procedure

The condition

2.1 Mitral valve replacement is where an artificial prosthetic valve (bioprosthetic or mechanical) is inserted by open heart surgery. It is most commonly done for severe symptomatic mitral regurgitation but may also be done in patients with severe mitral valve stenosis or a combination of both. Symptoms of severe mitral valve disease typically include shortness of breath, fatigue and palpitations (because of atrial fibrillation).

2.2 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.

Current treatments

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 routine cardiopulmonary bypass and can be used to treat failed bioprosthetic mitral valves originally placed during open heart surgery.

The procedure

2.4 The procedure is done with the patient under general anaesthesia and using imaging guidance including fluoroscopy, angiography and transoesophageal echocardiography (TEE). Prophylactic antibiotics and anticoagulants are given

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

2.5 The mitral valve is accessed surgically through an apical puncture of the left ventricle using an anterior or left lateral mini thoracotomy (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 TEE to establish the size of the 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 TEE 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 left ventricular puncture and chest incisions are closed. Valve performance is then assessed using echocardiography and fluoroscopy.

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 13 sources, which was discussed by the committee. The evidence included 2 systematic reviews, 4 retrospective registry analyses, 3 retrospective comparative studies and 3 case series (one of which resulted in 2 publications). It is presented in the summary of key evidence section in the 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: technical success at 30 days, survival, haemodynamic improvement, reduction in mitral valve regurgitation symptom relief (improvement in New York Heart Association functional class) and improvement in quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be: device-related mortality and morbidity, left ventricular outflow tract obstruction, cardiac perforation and paravalvular prosthetic leak.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee was informed that 2 different access routes are used for this procedure, and the transseptal route is less invasive than the transapical route. This guidance refers to the transapical procedure.

3.6 The committee noted that several devices are used for the procedure. However, currently there is only 1 device CE marked for use through the transapical route and no devices with a CE mark are available for use through the transseptal route.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 706 has been migrated to HealthTech guidance 592. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8480-0

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.