

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transapical transcatheter mitral valve-in-ring implantation after failed annuloplasty for mitral valve repair

If the mitral valve in the heart leaks, an annuloplasty ring can be surgically implanted to tighten the mitral valve ring (annulus) so the valve leaflets close properly.

In this procedure, a tube (catheter) is passed through a cut in the chest wall and then through the heart wall (transapical) and positioned across the leaking mitral valve. A bioprosthetic mitral valve is then passed through the tube (transcatheter) and placed within the existing mitral valve ring. The aim is to treat the leaking mitral valve without needing to repeat open heart surgery.

NICE is looking at transapical transcatheter mitral valve in ring implantation after failed annuloplasty for mitral valve repair.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants 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This document contains the [draft guidance for consultation](#).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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 25 March 2021

Target date for publication of guidance: July 2021

1 Draft recommendations

1.1 Evidence on the safety of transapical transcatheter mitral valve-in-ring implantation after failed mitral valve repair surgery is adequate and shows some serious but well recognised complications. Evidence on its efficacy is inadequate in quality. Therefore, 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 interventional procedures guidance page](#).

1.2 Clinicians wishing to do transapical transcatheter mitral valve-in-ring implantation after failed annuloplasty for mitral valve repair 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-ring implantation after failed annuloplasty for mitral valve repair onto the dataset managed by [National Institute for Cardiovascular Outcomes Research \(NICOR\)](#) and review local clinical outcomes. Contact bartshealth.nicor-generalenquiries@nhs.net for details.
- 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 clinician 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-ring implantation after failed annuloplasty for mitral valve repair. Studies should include details on patient selection, type and size of valve used, functional outcomes (NYHA 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 The mitral valve allows blood to flow from the left atrium to the left ventricle. Mitral valve regurgitation happens when the valve does not close properly and blood flows back into the atrium from the ventricle. The heart has to work harder to pump blood from the left ventricle to the aorta, resulting in an enlarged left ventricle. If not treated, this can lead to shortness of breath, fatigue and palpitations (from atrial fibrillation) and eventually heart failure.
- 2.2 If symptoms of mitral valve regurgitation are severe enough, mitral valve annulus surgical repair may be done by open heart surgery in patients who are well enough for this kind of operation. A surgical valve annulus repair may fail over time and can result in the need for further intervention.

Current treatments

- 2.3 The standard treatment after a failed mitral valve annuloplasty is repeat open heart surgery. Repeat open heart surgery is associated with a higher risk of morbidity and mortality than primary surgery. Transapical transcatheter mitral valve-in-ring implantation is a less invasive alternative. It avoids the need for cardiopulmonary bypass and can be used to treat failed annuloplasty rings originally placed during open heart surgery.

The procedure

- 2.4 The procedure is usually 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.
- 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 native mitral valve and into a pulmonary vein. A balloon catheter delivery system is then advanced over the guidewire into the left atrium. The inner diameter of the mitral valve annulus is measured using transoesophageal echocardiography to establish the size of bioprosthetic valve needed. Using the delivery system, the bioprosthetic valve is then introduced, manipulated into position (to align the valve with the mitral annulus) and slowly deployed within the surgically implanted mitral valve ring 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 from the left ventricle 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 5 sources, which was discussed by the committee. The evidence included 1 systematic review and meta-analysis, 3 retrospective registry analyses, and 1 case series. 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: technical success at 30 days, survival, haemodynamic improvement, symptom relief (improvement in NYHA 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.

Patient commentary was sought but none was received.

Committee comments

- 3.4 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.

- 3.5 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.

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Chair, interventional procedures advisory committee

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