NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

Off-pump minimal access mitral valve repair by artificial chordae insertion to treat mitral regurgitation

The mitral valve controls blood flow between the upper and lower left-sided chambers of the heart. If the mitral valve does not close properly, blood flows backwards through the valve (regurgitation) when the heart contracts. So, the heart must work harder to pump blood around the body. This can lead to heart failure. Mitral valve regurgitation can be caused by ruptured chordae (thin cord-like structures that connect the valve to small muscles on the inner wall of the heart).

In this procedure, which is done under general anaesthesia, a device is inserted into the mitral valve through a cut on the left side of the chest (minimal access). The device is used to insert artificial chordae, which help the valve to close properly. Stopping the heart and using a heart-lung machine is not needed for this procedure (off-pump). The aim is to reduce symptoms and improve quality of life.

Guidance development process

NICE interventional procedures guidance evaluates procedures used for treatment or diagnosis. It provides evidence-based recommendations about how safe and efficacious these procedures are. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible care. By reviewing clinical evidence and considering patient outcomes, NICE aims to improve patient safety and treatment choices in the NHS.

Find out more on the NICE webpage on interventional procedures guidance.

Issue date: September 2025

NICE is producing this guidance on off-pump minimal access mitral valve repair by artificial chordae insertion to treat mitral regurgitation in the NHS. The interventional procedures advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for consultation with the stakeholders. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of efficacy reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If committee meets again it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on off-pump minimal access mitral valve repair by artificial chordae insertion to treat mitral regurgitation. The recommendations in section 1 may change after consultation.

Issue date: September 2025

More details are available in NICE's interventional procedures programme manual.

Key dates:

Closing date for comments: 28 October 2025

Second committee meeting: 11 December 2025

1 Recommendations

When open-heart surgery and other mitral valve procedures are unsuitable

1.1 Off-pump minimal access mitral valve repair by artificial chordae insertion can be used in the NHS during the evidence generation period, as an option to treat mitral regurgitation caused by mitral valve leaflet prolapse in adults when open-heart surgery and other mitral valve repair procedures are unsuitable. There must be enhanced informed consent and auditing of outcomes.

When open-heart surgery or other mitral valve procedures are suitable

1.2 More research is needed on off-pump minimal access mitral valve repair by artificial chordae insertion to treat mitral regurgitation caused by mitral valve leaflet prolapse in adults when open-heart surgery or other mitral valve repair procedures are suitable, before it can be used in the NHS.

1.3 This procedure should only be done as part of formal research and a research ethics committee needs to have approved its use.

What this means in practice

When open-heart surgery and other mitral valve repair procedures are unsuitable

There are uncertainties around the safety and efficacy of this procedure. It can be used for this group, if needed, while more evidence is generated.

After this, this guidance will be reviewed and the recommendations may change.

Healthcare professionals do not have to offer this procedure and should always discuss the available options with the person with mitral regurgitation before a joint decision is made.

Hospital trusts will have their own policies on funding procedures and monitoring results. NHS England may also have policies on funding of procedures.

Enhanced informed consent

Because there are uncertainties about whether this procedure is safe and efficacious, there must be an emphasis on informed consent. Healthcare professionals must make sure that people (and their families and carers as appropriate) understand the uncertainty and lack of evidence around a procedure's safety and efficacy using NICE's advice on shared decision making and NICE's information for the public. Healthcare professionals must also inform the clinical governance leads in their organisation if they want to do the procedure.

When open-heart surgery or other mitral valve repair procedures are suitable

There is not enough evidence on the safety and efficacy of this procedure. Off-pump minimal access mitral valve repair by artificial chordae insertion should only be done as part of formal research in this group.

For everyone having the procedure

Auditing of outcomes

Healthcare professionals doing this procedure should collect data on safety and outcomes of the procedure. Enter details about everyone having this procedure into the National Institute for Cardiovascular Outcomes Research (NICOR) Transcatheter Mitral and Tricuspid Valve procedure registry. Regularly review the data on outcomes and safety.

Who should be involved with the procedure

Patient selection should be done by a multidisciplinary team including cardiac surgeons, cardiologists and cardiac anaesthetists with experience in this procedure.

This procedure should only be done by a cardiac surgeon with experience in mitral valve surgery and with expert 2D and 3D transoesophageal echocardiography support.

This procedure should only be done in cardiac surgery centres experienced in minimal access valve surgery with transoesophageal echocardiography. Centres should follow any proctoring requirements associated with the device used.

What evidence generation and research is needed

More research, ideally in the form of randomised controlled trials in people with mitral regurgitation caused by mitral valve leaflet prolapse, is needed. Healthcare professionals must collect data specifically around the safety and efficacy of this procedure.

This includes:

- patient selection, including:

  - mitral valve prolapse anatomy
  - criteria to assess procedure suitability
- adverse events
- patient-reported outcomes
- quality of life outcomes
- survival
- longer-term outcomes.

Why the committee made these recommendations

There is a lack of high-quality evidence on the efficacy and safety of this procedure. The available clinical evidence comes mainly from short-term, small observational studies or registries that are not based in the UK. This evidence shows that there are well-recognised safety concerns but suggests that the procedure can reduce mitral regurgitation and associated symptoms.

There are limited options for treating mitral regurgitation caused by mitral valve prolapse when open-heart surgery and other mitral valve repair procedures are unsuitable. This procedure may have potential benefits for people when there are no alternative treatments, so it can be used with evidence generation in this group.

For some people, open-heart surgery or other mitral valve repair procedures may be suitable. For these people, it is unclear whether the benefits of this procedure outweigh the risks. Therefore, this procedure should only be done within formal research in this group.

2 Information about the procedure

2.1 This transcatheter (minimal access) procedure for mitral regurgitation is done under general anaesthesia on a beating heart with no need for cardiopulmonary bypass (off-pump). Using transoesophageal echocardiography imaging, a left-sided anterior thoracotomy is used to access the left ventricle. The device delivery system is passed through the wall of the left ventricle with

purse-string sutures, into the left side of the heart to the target mitral valve leaflet. Once it is correctly positioned, artificial chordae are passed through the target mitral valve using a needle and anchored to the leaflet. Typically, 3 to 4 chordae are placed along the free edge of the mitral valve leaflet to re-suspend the prolapsed segment. The delivery system is removed, and the purse-string suture is tightened. The tension on the chordae is adjusted until there is improvement or elimination of the mitral regurgitation, as confirmed on transoesophageal echocardiography imaging. The endings of the chordae sutures are then secured to the outside of the heart.

2.2 This procedure has a lower risk of compromising subsequent surgical mitral valve repair than some other transcatheter techniques for mitral regurgitation. It may also be suitable for people for whom open-heart surgery is not considered safe because of other health conditions.

3 Committee discussion

The condition

3.1 The mitral valve allows blood to flow from the left atrium to the left ventricle. Mitral regurgitation happens when the valve does not close properly, allowing blood to flow back into the atrium from the ventricle during systole (when the heart contracts). The heart must work harder, resulting in an enlarged left ventricle. If untreated, this can lead to problems including heart failure. Mitral regurgitation can be degenerative (primary or structural) or functional (secondary). Degenerative mitral regurgitation is caused by 'wear and tear' to the chordae and leaflets in the valve. In functional mitral regurgitation the chordae and leaflets are structurally normal but there is geometrical distortion of the subvalvular apparatus. This is caused by idiopathic cardiomyopathy or weakening of the cardiac

walls because of coronary artery disease (ischaemic mitral regurgitation).

Current practice

3.2 Degenerative mitral regurgitation is typically managed with open-heart surgery to repair or replace the mitral valve. This requires a sternotomy to access the heart and the use of cardiopulmonary bypass. Functional mitral regurgitation can be managed conservatively with medical treatments for heart failure, but this approach is not curative. Surgical procedures such as undersized annuloplasty may also be an option. People with mitral regurgitation of either cause are usually older (typically over 70 years) and frailer, with multiple comorbidities.

Unmet need

3.3 Open-heart surgery may pose excessive risks for some people, particularly those who are older, frailer, or who have multiple or complex comorbidities. For people for whom open-heart surgery is prohibitively high risk, minimal access surgical approaches have been developed, such as transcatheter artificial chordae insertion. These approaches can often be done through smaller incisions and without the need to stop the heart or use cardiopulmonary bypass. These options aim to reduce perioperative risk and improve recovery, although they may not be suitable for all anatomical presentations of mitral valve prolapse that cause mitral regurgitation.

The evidence

3.4 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 12 sources, which was discussed by the committee. The evidence included 7 prospective case series, 2 retrospective registry studies,

2 retrospective cohort studies, and 1 retrospective 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. The evidence informing this guidance was only in one device. This is the only device currently used for this procedure in the UK.

3.5 The professional experts and the committee considered the key efficacy outcomes to be:

- quality of life
- patient-reported outcomes
- survival
- mitral regurgitation grade reduction
- echocardiographic outcomes.

3.6 The professional experts and the committee considered the key safety outcomes to be:

- conversion to open-heart surgery
- mortality
- cardiovascular and cerebrovascular adverse events
- septicaemia
- bleeding
- pericardial and pleural effusion
- kidney injury
- heart rhythm conduction disturbances.

3.7 Patient commentary was sought but none was received.

Committee comments

3.8 The committee noted that if this procedure fails, it does not preclude the use of further interventions. This procedure can also be used in people who have already had open-heart surgery.

3.9 Published evidence focused on process outcomes and technical success, with signals of efficacy not as strong.

3.10 A clinical expert highlighted the need to focus on outcomes that are most important to people having the procedure.

3.11 A clinical expert emphasised the importance of mitral regurgitation reduction, and echocardiographic outcomes associated with this procedure.

3.12 The committee noted the importance of an experienced multidisciplinary team including a cardiac surgeon and a 2D and 3D transoesophageal echocardiography operator with experience of this procedure. It also noted the need for proctoring to assist surgeons who are new to the procedure.

3.13 A clinical expert noted that an isolated P2 prolapse is associated with the best outcomes for this procedure. For more complex anatomy, the experience of the surgeon must be taken into consideration.

3.14 The committee noted that centres should follow any proctoring and training requirements associated with the device used.

3.15 The committee noted that there is currently only one device used for this procedure in the UK, and that the company reviews transoesophageal echocardiograms for every person who will have the procedure and provides advice about the procedure's technical feasibility.

3.16 This procedure should only be done by cardiac surgeons because of the need for thoracotomy or sternotomy, the risk of bleeding and the potential for urgent conversion to open-heart surgery.

Equality considerations

3.17 The prevalence of mitral regurgitation increases with age.

3.18 The prevalence of valvular disease is similar in men and women.

3.19 People with degenerative mitral valve disease may be considered disabled under the Equality Act 2010 if their condition has a substantial adverse impact on normal day to day activities for longer than 12 months.

4 Committee members and NICE project team

This topic was considered by specialist committee members appointed for this topic and NICE's interventional procedures advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Tom Clutton-Brock

Chair, interventional procedures advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Jakob Falloon

Technical lead

Amy Crossley

Technical adviser

Alan Ashworth

Consultant clinical advisor

Corrina Purdue

Project manager

Emily Eaton Turner

Associate director

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