NICE National Institute for Health and Care Excellence

NICE guidance

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

HealthTech 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, 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

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 considered unsuitable by the multidisciplinary team. 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 considered suitable by the multidisciplinary team, 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, NICE will review this guidance 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 the procedure's safety and efficacy, 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.

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) National Adult Cardiac Surgery Audit. 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.

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

There is not enough evidence to know if this procedure is safe and effective. Off-pump minimal access mitral valve repair by artificial chordae insertion should only be done as part of formal research in this group.

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What evidence generation and research is needed

Evidence generation and research is needed on:

- mitral regurgitation grade reduction
- 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, including:
  - freedom from recurrent mitral regurgitation
  - freedom from reintervention
  - durability
  - echocardiographic outcomes
- outcomes for people who need re-repair.

Why the committee made these recommendations

There is a lack of high-quality evidence on the safety and efficacy of this procedure. The available clinical evidence comes mainly from short-term, small observational studies or registries that are not based in the UK, and that include a highly selected group of participants. 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 considered

unsuitable by the multidisciplinary team. 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 considered suitable by the multidisciplinary team. For these people, it is unclear whether the benefits of this procedure outweigh the risks. So, this procedure should only be done as part of formal research in this group.

2 Information about the procedure

2.1 This 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 a purse-string suture and 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 or 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 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 interventional procedures advisory committee considered evidence on off-pump minimal access mitral valve repair by artificial chordae insertion from several sources. This included evidence submitted by NeoChord, a review of efficacy and safety evidence, and responses from stakeholders. Full details are available in the project documents for this guidance.

NICE did a rapid review of the literature on the efficacy and safety of this procedure. The evidence included 7 prospective case series, 3 retrospective registry studies, 3 retrospective cohort studies, 2 retrospective case series and 2 case reports. It is presented in the summary of key evidence section in the interventional procedures assessment report. Other relevant literature is in the appendix of the assessment report. The evidence informing this guidance was from only 1 device. This is the only device currently used for this procedure in the UK.

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 such as 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 artificial chordae insertion. These procedures 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 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.

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

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

3.6 Patient commentary was sought but none was received.

Committee comments

3.7 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.

3.8 Published evidence focused on process outcomes (such as procedural and technical success), with signals of efficacy not as strong.

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

3.10 The committee noted the importance of an experienced multidisciplinary team being involved in decisions about suitability of this procedure or other procedures, including open-heart surgery. The team should include 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. Centres should follow any proctoring and training requirements associated with the device used.

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

3.12 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 account when considering this procedure.

3.13 The committee noted that there is currently only 1 device used for this procedure in the UK. It also noted that the company reviews transoesophageal echocardiograms for every person who will have the procedure during the proctoring period and is available to provide advice about the procedure's technical feasibility.

3.14 The committee heard that this procedure may be a useful option for people who need re-repair because it avoids open-heart surgery. The committee noted that the evidence for the use of this procedure for re-repair is very limited and uncertain, and based on a carefully selected population. It acknowledged the need for targeted evidence collection to better identify the re-repair population, and to understand the size and balance of potential benefits and harms of the procedure in this group.

Equality considerations

3.15 The prevalence of mitral regurgitation increases with age.

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

3.17 The committee acknowledged that open-heart surgery and other mitral valve procedures may not be suitable for people who are older, frailer, or who have multiple or complex comorbidities. This procedure provides a treatment option for this group.

3.18 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.

Chairs

Rick Body
Chair, interventional procedures advisory committee

Tom Clutton-Brock
Former 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 consultant clinical adviser, a project manager and an associate director.

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