Percutaneous mitral valve leaflet repair for mitral regurgitation

Interventional procedures guidance
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nice.org.uk/guidance/ipg309

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 Guidance

1.1 Evidence on the safety and efficacy of percutaneous mitral valve leaflet repair for mitral regurgitation is currently inadequate in quality and quantity. Therefore, this procedure should only be used:
• with special arrangements for clinical governance, consent and research for patients who are well enough for surgical mitral valve leaflet repair to treat their mitral regurgitation, or

• in the context of research for patients who are not well enough for surgical mitral valve leaflet repair to treat their mitral regurgitation.

1.2 Clinicians wishing to undertake percutaneous mitral valve leaflet repair for mitral regurgitation in patients who are well enough for surgical mitral valve leaflet repair to treat their mitral regurgitation should take the following actions.

• Inform the clinical governance leads in their Trusts.

• Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.

1.3 The NHS Information Centre for Health and Social Care runs the UK Central Cardiac Audit Database. Clinicians should enter details about patients who are well enough to have surgical mitral valve leaflet repair to treat their mitral regurgitation and who are treated by percutaneous mitral valve leaflet repair onto this database.

1.4 Clinicians wishing to undertake percutaneous mitral valve leaflet repair for mitral regurgitation in patients who are not well enough for surgical mitral valve leaflet repair should do so in the context of research studies. Research outcomes should include the effect on symptoms, change in functional status, and effective measures of cardiac function, in addition to clear documentation of adverse events and survival.

1.5 Patient selection and treatment should be carried out in specialist units (with access to emergency cardiac surgery) by a multidisciplinary team, including an interventional cardiologist (with expertise in echocardiography or with support from an echocardiologist) and a cardiac surgeon.

1.6 This procedure should only be carried out by clinicians with specific training.
1.7 NICE is aware of current clinical trials involving this procedure, and may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Mitral regurgitation is characterised by backward flow of blood from the left ventricle to the left atrium during systole. Causes include rheumatic heart disease and annular dilation as a result of cardiomyopathy. Left untreated, moderate to severe mitral regurgitation can cause congestive heart failure. Its severity is usually graded by echocardiography on a scale from grade 1 (mild) to grade 4 (severe).

2.1.2 Patients with mild mitral may be managed conservatively. Severe regurgitation may require surgical valve repair or replacement using either an open or thoracoscopic approach.

2.2 Outline of the procedure

2.2.1 The aim of percutaneous mitral valve leaflet repair is to keep the two valve leaflets more closely apposed to each other during systole, thereby reducing regurgitation.

2.2.2 Percutaneous mitral valve leaflet repair is undertaken with the patient under general anaesthesia. Under fluoroscopy and transoesophageal echocardiography guidance, a catheter is advanced through the femoral vein to the right atrium and via a transseptal puncture into the left atrium. The mitral leaflets are partially clipped to each other (more than one clip may be used). Imaging is used to assess whether the reduction in mitral regurgitation is adequate. The clips may be repositioned if necessary.

2.2.3 Various devices have been used for this procedure.

Sections 2.3 and 2.4 describe efficacy and 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 overview.
2.3  **Efficacy**

2.3.1  In a multicentre case series of 107 patients with mitral regurgitation of grade 3 or 4 at baseline, there was successful clip placement (not otherwise defined) in 90% (96/107) of patients. Technical success (defined as a reduction in mitral regurgitation to grade '2+' or lower, based on the American Society of Echocardiography guidelines) was achieved in 74% (79/107) of patients. Of these patients, 77% (absolute figures not stated) and 66% (50/76) maintained the reduction in mitral regurgitation to grade 2+ or lower at hospital discharge and 12-month follow-up, respectively.

2.3.2  A further publication on this case series reported that mean mitral valve pressure gradient increased from 1.79 mmHg at baseline to 3.56 mmHg at 12-month follow-up (n = 13).

2.3.3  Specialist Advisers considered key efficacy outcomes to include successful clip deployment, reduction of mitral regurgitation, durability of outcome, left ventricular dimensions and function, need for subsequent mitral valve surgery and quality of life.

2.4  **Safety**

2.4.1  In the case series of 107 patients, 10 had a major adverse event within 30 days. Partial clip detachment (that is, from 1 of the 2 valve leaflets) occurred in 9% (10/107) of patients: 3 during the procedure, 1 before hospital discharge, 5 between discharge and 30-day follow-up, and 1 after 30 days. Partial clip detachment requiring further surgery before hospital discharge was reported in a patient in the case series of 47 patients (exact timing of event not stated).

2.4.2  In the case series of 107 patients, a patient had a non-embolic stroke with neurological deficit lasting 72 hours (resolved within 30 days).

2.4.3  Specialist Advisers considered theoretical adverse events to include leaflet tearing, clip embolism, partial clip detachment, complications from vascular access, cardiac tamponade from attempted transseptal puncture, atrial septal defect, and scar formation around clips, causing mitral stenosis.
2.5 Other comments

2.5.1 The Committee noted that ongoing development of the technology for this procedure may affect outcomes.

3 Further information

3.1 NICE has published interventional procedures guidance on thoracoscopically assisted mitral valve surgery.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). 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 procedure 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. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It has been incorporated into the NICE pathway on chronic heart failure, along with other related guidance and products.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

8 May 2012: minor maintenance.

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Contact NICE

National Institute for Health and Clinical Excellence
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk
nice@nice.org.uk
0845 033 7780

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.
Accreditation

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