

# Percutaneous mitral valve leaflet repair for mitral regurgitation

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg649](http://www.nice.org.uk/guidance/ipg649)

## 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.

This guidance replaces IPG309.

# 1 Recommendations

- 1.1 Current evidence on the safety and efficacy of percutaneous mitral valve leaflet repair for mitral regurgitation is adequate to support the use of this procedure, in patients for whom open surgery is contraindicated following risk assessment, provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Patient selection should be done by a multidisciplinary structural heart team, typically including an interventional cardiologist, an expert in transoesophageal echocardiography, an expert in heart failure, a cardiac anaesthetist, a cardiac surgeon and a specialist nurse.
- 1.3 Percutaneous mitral valve leaflet repair for mitral regurgitation should only be done in specialised centres with access to both cardiac surgical and vascular surgical support in case emergency treatment of complications is needed.
- 1.4 This procedure should only be done by clinicians with specialist training and supervision by an experienced mentor for at least the first 20 procedures.
- 1.5 Clinicians should enter details about all patients having percutaneous mitral valve leaflet repair for mitral regurgitation onto the National Institute for Cardiovascular Outcomes Research database.

## 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 (MR) happens when the valve doesn't close properly, allowing blood to flow back into the atrium from the ventricle during systole. The heart has to work harder, resulting in an enlarged left ventricle. If not treated, this can lead to problems including heart failure.
- 2.2 MR can be degenerative (primary or structural) or functional (secondary). Degenerative MR is caused by 'wear and tear' to the chords and leaflets in the valve. In functional MR the chords and leaflets are structurally normal but there is geometrical distortion of the subvalvular apparatus caused by idiopathic cardiomyopathy, or weakening of the cardiac walls caused by coronary artery disease (ischaemic MR).

### Current treatments

- 2.3 Degenerative MR is treated by surgery to repair or replace the mitral valve. Functional MR can be conservatively managed using drugs for treating heart failure but this is not curative, and surgical options such as undersized annuloplasty may be an option. However, people with MR of either cause are usually older (typically over 70 years) and frail, with multiple comorbidities. This increases the perioperative risks of morbidity and mortality for open heart surgery. For these patients, percutaneous mitral valve leaflet repair (PMVR) may be an appropriate management option.

### The procedure

- 2.4 PMVR is a treatment option for MR if the mitral valve meets the anatomical eligibility criteria for coaption length, coaption depth, flail gap

and flail width. The procedure is done using general anaesthesia and transoesophageal echocardiography guidance, with the optional use of fluoroscopy. Access is provided through the femoral vein and an atrial trans-septal puncture is done to reach the mitral valve.

- 2.5 The device is lowered through the mitral valve into the left ventricle. The arms of the device grip the leaflets, bringing them closer together, and the device is released from the delivery system. Adequate reduction of MR is assessed using echocardiography. Sometimes, more than 1 device is needed. After the procedure, patients usually have anti-platelet therapy for 6 months.

## 3 Committee considerations

### The evidence

- 3.1 To inform the committee, 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 17 sources, which was discussed by the committee. The evidence included 3 randomised controlled trials, 4 single-arm observational studies (1 of which was a register), 3 systematic reviews, 3 comparative observational studies and 3 case reports, and is presented in [table 2 of the interventional procedures overview](#). The committee also considered data from the NHS England Commissioning through Evaluation MitraClip registry. Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: reduction in mitral regurgitation, improved quality of life, improved symptoms according to the New York Heart Association classification, reduced hospital admissions, and survival.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: cardiac tamponade, bleeding and embolisation.
- 3.4 [Twenty commentaries from patients](#) who had experience of this procedure were received, which were discussed by the committee.

## Committee comments

- 3.5 The committee was informed that a trained company representative is present for each procedure.
- 3.6 The committee was informed that the device used in this procedure has evolved over time.
- 3.7 The committee was informed that the outcomes of the procedure differ between patients with degenerative mitral valve regurgitation and those with functional mitral valve regurgitation.
- 3.8 The committee was informed that the outcome of the procedure is better in patients with well-preserved left ventricular function.
- 3.9 The committee received a number of patient commentaries, most of which were positive about this procedure.
- 3.10 The committee noted that most of the evidence comes from 1 device (MitraClip).

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## Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).