NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Percutaneous mitral valve leaflet repair for mitral regurgitation

Mitral regurgitation happens when the mitral valve in the heart does not close properly. This allows blood to flow back the wrong way. The heart has to work harder to pump blood around the body, which can lead to heart failure. In this procedure, a small clip is guided into the heart through a catheter (thin tube) inserted into a vein in the groin. The clip is attached to the leaflets (flaps) of the mitral valve to help it close more completely. The aim is to improve symptoms and quality of life.

The National Institute for Health and Care Excellence (NICE) is looking at percutaneous mitral valve leaflet repair for mitral regurgitation. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide.

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of

discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 07 January 2019

Target date for publication of guidance: TBC

1 Draft 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.

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 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 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, making this population at high or prohibitive risk of 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. It involves the use of a clip that mimics a surgical technique known as the 'Alfieri stitch'. The procedure is done under general anaesthesia using transoesophageal echocardiography guidance and the optional use of fluoroscopy. Access is provided through the femoral vein and an atrial trans-septal puncture is done to reach the delivery site.

2.5 The device is lowered through the mitral valve into the left ventricle. The arms of the clip grip the leaflets, bringing them closer together, and the clip is released from the delivery system. Adequate reduction of MR is assessed using echocardiography. If the reduction in MR is inadequate with 1 device it may be removed, or a second device placed alongside the first. 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 11 sources, which was discussed by the committee. The evidence included 3 randomised controlled trials, 4 single-arm observational studies, 1 systematic review and meta-analysis, and 2 comparative observational studies, and is presented in table 2 of the interventional procedures overview. The committee also considered data from the NHS England Commissioning through Evaluation (CtE) 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 20 commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

3.5 This guidance is a review of NICE's interventional procedures guidance on percutaneous mitral valve leaflet repair for mitral regurgitation.

Committee comments

3.6 The committee was advised that mentoring should be done for a minimum of 20 procedures.

3.7 The committee was informed that a trained company representative is present for each procedure.

3.8 The committee was informed that the device used in this procedure has evolved over time.

3.9 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.

3.10 The committee was informed that the outcome of the procedure is better in patients with well-preserved left ventricular function.

3.11 The committee received a number of patient commentaries, most of which were positive about this procedure.

Tom Clutton-Brock
Chairman, interventional procedures advisory committee
November 2018

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