NICE National Institute for Health and Care Excellence

NICE guidance

Percutaneous mitral valve annuloplasty

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

This guidance replaces IPG352.

1 Recommendations

1.1 Current evidence on the safety and efficacy of percutaneous mitral valve annuloplasty is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research, which should clearly describe patient selection, concomitant medical therapies and safety outcomes. Both objective measurements and clinical outcomes should be reported.

1.2 Percutaneous mitral valve annuloplasty should only be carried out by interventional cardiologists with specific training in the procedure.

1.3 NICE 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 progressive congestive heart failure and eventually lead to death. Its severity is usually graded by echocardiography on a scale from grade 1 (mild) to grade 4 (severe).

2.1.2 Mitral regurgitation results from failure of apposition of the mitral valve leaflets, which may be due to abnormalities of the mitral leaflets or their subvalvar apparatus, or from dilation of the mitral annulus. Dilation of the mitral annulus is usually a consequence of left ventricular enlargement, and is often termed 'functional' mitral regurgitation.

2.1.3 Treatment of severe mitral regurgitation may include partial leaflet resection or chordal repair.

2.2 Outline of the procedure

2.2.1 The aim of percutaneous mitral valve annuloplasty is to place an intravascular device percutaneously into the coronary sinus (the large vein that forms at the level of the posterior mitral annulus and drains into the right atrium at its other end) to reduce its diameter when contracted and allow approximation of the mitral valve leaflets.

2.2.2 The procedure is carried out with the patient under general or local anaesthesia. Under fluoroscopic and often under transoesophageal echocardiographic guidance, the device is advanced on a catheter, normally via the femoral or jugular vein, towards the coronary sinus. It is deployed and usually anchored in the coronary sinus. Residual mitral regurgitation is assessed and further

percutaneous manipulation of the device may be used to reduce mitral regurgitation by changing the shape and size of the mitral valve annulus.

2.2.3 A range of different devices can be used for this procedure.

2.3 Efficacy

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.

2.3.1 A case series of 48 patients, of whom 18 were not suitable for the procedure and 30 were successfully treated with a mitral annuloplasty device, reported a significant increase in Kansas City Cardiomyopathy Questionnaire score (assesses physical function, symptoms, social function and knowledge, and quality of life on a scale from 0 to 100; higher scores better) from 47 at baseline to 69 at 6-month follow up ($p<0.001$). The 30 treated patients also had significantly improved physical function as measured using the New York Heart Association (NYHA) classification, from an average of 2.9 at baseline to 1.8 at 6-month follow up ($p<0.001$). Six-minute walk test results also improved, from an average of 307 m at baseline to 403 m at 6-month follow up ($p<0.001$).

2.3.2 The Specialist Advisers considered key efficacy outcomes to include mitral valve competence in the short (1 year), medium (5 years) and long term (10 years) for patients with degenerative disease, reduction in mitral regurgitation and mitral annular area, improved left ventricular function, improved NYHA classification, increase in 6-minute walk distance, increased quality-of-life scores and survival, and reduced hospital admissions for patients with advanced heart failure.

2.4 Safety

2.4.1 22 days after the procedure, in the case series of 48 patients. Progressive heart failure resulting in death 148 days after the procedure was reported in 1 patient

who was not eligible for surgical treatment because of morbid obesity and other comorbidities, in a case series of 5 patients (the device was shown to be well-positioned on postmortem examination).

2.4.2 Myocardial infarction not requiring hospital admission was reported in 7% (3/46) of patients within 24 hours after the procedure in the case series of 48 patients.

2.4.3 Coronary sinus dissection in 1 patient (resolved without treatment) and coronary sinus perforation in 2 patients (1 treated conservatively and the other required pericardial drainage) were reported in the case series of 48 patients. A case series of 5 patients reported anterior interventricular vein perforation and pericardial effusion in 1 patient, and transient atrial fibrillation during cannulation of the coronary sinus in another.

2.4.4 Atrioventricular block was reported in 1 patient after device implantation in a case report. This was successfully treated with a cardiac resynchronisation device.

2.4.5 The Specialist Advisers highlighted an anecdotal adverse event of cardiac tamponade. They considered theoretical adverse events to include compression of the coronary artery, rupture, erosion or thrombosis of the coronary sinus or its tributaries, cardiac perforation, progressive stenosis and deformation of the mitral valve orifice or its chordal apparatus, inability to remove the device, and device migration, embolisation or fracture.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 352 has been migrated to HealthTech guidance 225. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.