NICE National Institute for Health and Care Excellence

NICE guidance

Percutaneous insertion of a closure device to repair a paravalvular leak around a replaced mitral or aortic valve

HealthTech guidance

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www.nice.org.uk/guidance/htg585

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 IPG700.

1 Recommendations

1.1 Evidence on the safety of percutaneous insertion of a closure device to repair a paravalvular leak around a replaced mitral or aortic valve shows that this procedure can cause potentially serious but well-recognised complications. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE guidance page.

1.2 Clinicians wishing to do percutaneous insertion of a closure device to repair a paravalvular leak around a replaced mitral or aortic valve should:

- Inform the clinical governance leads in their healthcare organisation.
- Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Review local clinical outcomes and enter details about all patients having percutaneous insertion of a closure device to repair a paravalvular leak around a replaced mitral or aortic valve into the British Cardiovascular Intervention Society database managed by the National Institute for Cardiovascular Outcomes Research. Contact bartshealth.nicor-generalenquiries@nhs.net for details.
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.

- Regularly review data on outcomes and safety for this procedure.

1.3 Patient selection should be done by a multidisciplinary team experienced in managing the condition including interventional cardiologists with specific training in the procedure, cardiac surgeons, specialists in cardiovascular imaging and cardiac anaesthetists.

1.4 This is a technically challenging procedure, and it should only be done in specialised centres by a multidisciplinary team including clinicians with training and experience in this procedure. Clinicians should only do their initial procedures with an experienced mentor.

1.5 Further research should report details of patient selection, device selection, procedural outcomes, long-term outcomes including quality of life, the need for repeat interventions or surgery, and complication rates.

2 The condition, current treatments and procedure

The condition

2.1 Paravalvular leak is a complication after surgical or transcatheter replacement of a mitral or aortic valve. Most leaks are not significant, but some leaks may lead to heart failure or haemolytic anaemia.

Current treatments

2.2 Current treatments include a second surgical procedure to replace the malfunctioning valve or a valve-in-valve transcatheter aortic valve insertion.

The procedure

2.3 The procedure is done using a combination of local anaesthetic and sedation, or general anaesthesia. The exact technique varies according to the type of leak being repaired.

2.4 For mitral valves, an antegrade transseptal approach is most commonly used. In this approach, transseptal left atrial catheterisation is done under imaging guidance using standard techniques. A guidewire may be used to cross the leak. A delivery sheath is then passed from the venous access and 1 or more closure devices are deployed to close the leak. Transoesophageal echocardiography is used to confirm adequate reduction of peri-mitral regurgitation and fluoroscopy is used to confirm normal mechanical prosthetic leaflet motion before closure device release.

2.5 For aortic valves, a retrograde approach is usually used. Transthoracic echocardiography may be enough to image the leak, but for posterior leaks,

transoesophageal echocardiography or intracardiac echocardiography may be needed. The leak is usually crossed using a guidewire over a catheter. After crossing, the guidewire is exchanged for a stiffer wire and a delivery sheath is advanced to deploy the closure device.

2.6 More than 1 device may be needed to adequately close the leak.

3 Committee considerations

The evidence

3.1 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 10 sources, which was discussed by the committee. The evidence included 1 systematic review and meta-analysis, 3 retrospective non-randomised studies, publications from 3 registries and 1 case series. It is presented in the summary of key evidence section in the overview. The committee also considered safety data from 1 conference abstract and 1 case report. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: improvement in quality of life, improvement in heart failure (including the New York Heart Association Functional Classification), reduction in the size of paravalvular leaks, reduction in haemolysis and the need for blood transfusion.

3.3 The professional experts and the committee considered the key safety outcomes to be: haemorrhage, cardiac perforation, device embolisation, infection, stroke and mortality.

3.4 Patient commentary was sought but none was received. One patient organisation representing patients who have had this procedure provided submissions and these were discussed by the committee.

Committee comments

3.5 The committee noted that the degree of invasiveness of this procedure was much less than the alternative of further open-heart surgery.

3.6 The committee noted that an important effect of this procedure is the

improvement of haemolytic anaemia and a reduction in the need for blood transfusions.

3.7 The committee noted that treatment of aortic and mitral paravalvular leaks were considered together in most of the studies and therefore not separated in this guidance recommendation.

3.8 The committee was informed that different devices are used for this procedure, that the device technology is evolving and that the current morbidity and mortality from this procedure may be lower than that in the published literature.

3.9 The committee was informed that having the procedure does not make subsequent open-heart valve surgery more difficult, if it is needed.

3.10 The committee was informed that there are substantial technical differences around closing the leak in mitral or aortic valves.

3.11 The procedures are usually elective but are sometimes done in an emergency. In these cases, the risk of adverse events is higher.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 700 has been migrated to HealthTech guidance 585. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.