NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

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

A paravalvular leak is when blood leaks around a replacement heart valve. It can cause symptoms of heart failure such as shortness of breath and swelling in the feet and legs. In this procedure, a small tube (catheter) is put into a large vein (for a mitral valve) or artery (for an aortic valve), typically at the top of the leg (percutaneous). A wire is guided through the catheter to the heart valve. Then a device is passed through the catheter and used to block the area that is leaking. The aim is to stop the leak.

NICE is looking at percutaneous insertion of a closure device to repair a paravalvular leak around a replaced mitral or aortic valve.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

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

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

Issue date: January 2021

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

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

Closing date for comments: 25 February 2021

Target date for publication of guidance: June 2021

1 Draft 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 interventional procedures 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.
- enter details about all patients having percutaneous insertion of a closure device to repair a paravalvular leak around a replaced mitral or aortic valve onto the British Cardiovascular Intervention Society database , review local clinical outcomes and publish results.
- 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 and anaesthetists.

1.4 This is a technically challenging procedure and it should only be done in highly specialised centres by a multidisciplinary team including clinicians with training and experience in this procedure. Clinicians should only do their initial procedure 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 adequate 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. One device is usually enough to close aortic paravalvular leaks.

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 interventional procedures 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 NYHA 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.

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.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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