NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis

When the mitral valve in the heart does not work properly it may be replaced with a bioprosthetic artificial valve (made of biological tissue) through open heart surgery. If a bioprosthetic valve subsequently fails, another valve can be placed inside the first valve using a tube (catheter) inserted through a cut in the chest wall and then through the wall of the heart (transapical). The aim is to replace the faulty valve without needing repeat open heart surgery.

NICE is looking at transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis.

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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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: February 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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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 March 2021

Target date for publication of guidance: July 2021

1 Draft recommendations

1.1 Evidence on the safety of transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis is adequate and shows some serious but well recognised complications. Evidence on its efficacy is inadequate 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 transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis 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 have been told and understand about all alternative treatment options and their advantages and disadvantages.
- Enter details about all patients having transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis onto the database managed by National Institute for Cardiovascular Outcomes Research. (NICOR) and review local clinical outcomes. Contact bartshealth.nicor-generalenquiries@nhs.net for details.
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 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.

1.4 Patient selection should be done by a multidisciplinary team which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging, and where appropriate, a cardiac anaesthetist and a specialist in medicine for older people. The multidisciplinary team should determine the risk level for each patient and the device most suitable for them.

1.5 The procedure is technically challenging and should only be done in specialised centres, and only by clinical teams with special training and experience in complex endovascular cardiac interventions, including regular experience in transcatheter valve implantation procedures. Centres doing these procedures should

have cardiac surgical support for emergency treatment of complications and subsequent patient care.

1.6 Report any problems with a medical device using the Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme.

1.7 NICE encourages further research into transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis. Studies should include details on patient selection, type and size of valve used, functional outcomes (NYHA functional class, mitral valve regurgitation), quality of life, patient reported outcome measures, survival and complications. Studies should report long-term follow up of clinical outcomes and valve durability. NICE may update this guidance on publication of further evidence.

2 The condition, current treatments and procedure

The condition

2.1 Mitral valve replacement is where an artificial prosthetic valve (bioprosthetic or mechanical) is inserted by open heart surgery. It is most commonly done for severe symptomatic mitral regurgitation but may also be done in patients with severe mitral valve stenosis or a combination of both. Symptoms of severe mitral valve disease typically include shortness of breath, fatigue and palpitations (because of atrial fibrillation).

2.2 Bioprosthetic valves have some advantages over mechanical valves, but they are more likely to degenerate and fail over time. This can result in severe stenosis or regurgitation, needing replacement of the bioprosthetic valve.

Current treatments

2.3 The standard treatment for a failed bioprosthetic valve is repeat open heart surgery to replace the valve. Repeat open heart surgery is associated with a higher risk of morbidity and mortality than primary surgery. Transapical transcatheter mitral valve-in-valve implantation is a less invasive alternative when repeat open heart surgery is considered to have a high risk. It avoids the need for routine cardiopulmonary bypass and can be used to treat failed bioprosthetic mitral valves originally placed during open heart surgery.

The procedure

2.4 The procedure is done with the patient under general anaesthesia and using imaging guidance including fluoroscopy, angiography and transoesophageal echocardiography (TEE). Prophylactic antibiotics and anticoagulants are given before and during the procedure. Temporary peripheral extracorporeal circulatory support (usually through the femoral vessels) is sometimes used.

2.5 The mitral valve is accessed surgically through an apical puncture of the left ventricle using an anterior or left lateral mini thoracotomy (transapical approach). A guidewire is placed across the existing mitral prosthetic valve and into a pulmonary vein. A balloon catheter delivery system is then advanced over the guidewire. When there is severe prosthetic mitral valve stenosis a balloon valvuloplasty may be done first. The inner diameter of the degenerated valve is measured using TEE to establish the size of the new bioprosthetic valve needed. Using the delivery system, the new bioprosthetic valve is then introduced, manipulated into position and slowly deployed within the degenerated mitral valve under fluoroscopic and TEE guidance. Often rapid ventricular pacing is used to reduce movement of the heart. After valve deployment, the catheter delivery system, guidewires and pacing

wires are removed and the left ventricular puncture and chest incisions are closed. Valve performance is then assessed using echocardiography and fluoroscopy.

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 11 sources, which was discussed by the committee. The evidence included 2 systematic reviews, 3 retrospective registry analyses, 3 retrospective comparative studies and 2 case series (one of which resulted in 2 publications). It is presented in the summary of key evidence section in the interventional procedures overview. 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: technical success at 30 days, survival, haemodynamic improvement, reduction in mitral valve regurgitation symptom relief (improvement in NYHA functional class) and improvement in quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be: device related mortality and morbidity, left ventricular outflow tract obstruction, cardiac perforation and paravalvular prosthetic leak.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee was informed that 2 different access routes are used, and the transseptal route is less invasive than the transapical route. This guidance refers to the transapical procedure.

3.6 The committee noted that several devices are used for the procedure. However, currently there is only one device CE marked for use through the transapical route and no devices with a CE mark are available for use through the transseptal route.

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Chair, interventional procedures advisory committee
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