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

Information for the public
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What has NICE said?

NICE only looked at this procedure for people for whom repeat open heart surgery isn't an option. There is not much good evidence about how well transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis works in the longer term, or how safe it is in these people. It should only be used if extra care is taken to explain the risks and extra steps are put in place to record and review what happens.

NICE is asking health professionals to send information about everyone who has the procedure and what happens to them afterwards to the National Institute for Cardiovascular Outcomes Research database (NICOR), so that the safety of the procedure and how well it works can be checked over time.

What does this mean for me?

Your health professional should fully explain what is involved in having this procedure and discuss the possible benefits and risks with you. In particular, they should explain the uncertainty about the evidence on how likely it is to improve your symptoms and the possibility of severe complications. You should also be told how to find more information about the procedure. You should only be asked if you want this procedure after having this discussion. Your health professional should ask you if details of your procedure can be collected.

Your healthcare team

An experienced healthcare team should decide which patients should be offered this procedure and should carry out the treatment. The team should include a heart surgeon, a specialist doctor in heart procedures using catheters (known as an interventional cardiologist), a heart anaesthetist and an expert in cardiac imaging who are experienced in managing the condition and who have specific training and experience in transcatheter valve implantation procedures. The procedure should be carried out in units with specialists in heart and blood vessel surgery available in case emergency treatment is needed.

The condition

The mitral valve lies between the left chambers of the heart. It prevents blood flowing back from the bottom chamber to the top chamber when the heart contracts to pump oxygenated blood from the lungs to the body. The valve can start to fail, usually either because it becomes narrow or leaky. This affects the flow of blood through the heart into the body. It puts extra strain on the heart, which can lead to breathlessness, tiredness and palpitations.

Treatment for a failing mitral valve usually involves removing the valve and replacing it with an artificial mechanical or bioprosthetic valve (a valve made of animal tissue or a combination of animal tissue and other materials). In people who are well enough, this is usually done by open heart surgery.

Bioprosthetic valves have some advantages over mechanical ones but are more likely to wear out and fail over time. A failed bioprosthetic valve is usually replaced through open heart surgery but the risks are higher with repeat surgery than during the first surgery.

NICE has looked at using transapical transcatheter mitral valve-in-valve implantation as another treatment option.

NHS Choices (www.nhs.uk) may be a good place to find out more.

The procedure

If a bioprosthetic valve fails, another bioprosthetic valve can be placed within it using a catheter (tube). This is called transapical transcatheter mitral valve-in-valve implantation. The aim is to insert a new valve without the need for open heart surgery in people for whom this would carry a high risk.

In this procedure, the new valve is inserted through a catheter into the heart using a general anaesthetic. The catheter is inserted into the body through a cut in the skin of the chest and through a small hole in the bottom of the heart wall. The old valve opening is widened and the new one is placed inside the old one via the catheter. Imaging is used to help the surgeon position the new valve correctly. The catheter system is then removed and the cut in the chest is closed. Antibiotics to prevent infection and drugs to prevent blood clots are given before and during the procedure. Sometimes, a heart–lung machine is used during the procedure to temporarily take over from the heart.

Benefits and risks

When NICE looked at the evidence, it decided that there's not much good evidence about how well transapical transcatheter mitral valve-in-valve implantation works in the longer term and that there is a possibility of serious complications. But, it did decide the evidence shows generally good symptom relief in the short term. The 8 studies (including a registry) that NICE looked at involved a total of 406 patients.

A study of 23 patients showed the following benefits:

- successfully implanted valve in 100% of patients
- 100% of patients alive 30 days after surgery, and 90% still alive after an average of 753 days
- improvement in symptoms of heart failure and in heart function.

The 8 studies showed that the risks included:

- 1 in 10 chance of death within an average of 753 days of surgery
- fatal pneumonia in 1 patient and the need for prolonged assisted ventilation in 3 patients
- major stroke in 3–4% of patients and a mini stroke in 1 patient
- major bleeding in 26% (6 of 23) of patients and late bleeding in 33% (2 of 6) of patients
- acute kidney injury in 11% (39 of 349) of patients
- wound infection in 25% (3 of 13) of patients
- 1 patient needed a permanent pacemaker
- a blood clot in the valve in 1 patient

- 1 patient needed a second valve implanted.

NICE was also told about another possible risk: blockage in the lower left chamber of the heart preventing blood flowing from the heart to the body.

If you want to know more about the studies, see the guidance. Ask your health professional to explain anything you don't understand.

Questions to ask your health professional

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

About this information

NICE interventional procedures guidance advises the NHS on the safety of a procedure and how well it works.

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