Transcatheter valve-in-valve implantation for aortic bioprosthetic valve dysfunction

Information for the public
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What has NICE said?

Valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) is safe enough and works well enough for use in the NHS for patients with a failing aortic bioprosthetic valve for whom open heart surgery isn't an option.

There is not much good evidence about how well this procedure works or how safe it is for patients with a failing aortic bioprosthetic valve for whom open heart surgery is an option but poses a high risk. It should only be used in such patients if extra care is taken to explain the risks and extra steps are put in place to record and review what happens.

There is not enough evidence to be sure about how well this procedure works or how safe it is for patients with a failing aortic bioprosthetic valve for whom open heart surgery to replace the valve is an option and doesn't pose a high risk. For this reason, it should only be done in such patients as part of a research study.

NICE is asking health professionals to send information about everyone who has the procedure and what happens to them afterwards to the UK Central Cardiac Audit Database, so that the safety of the procedure and/or how well it works can be checked over time.

What does this mean for me?
If you have a failing aortic bioprosthetic valve and open heart surgery isn't an option, your health professional should fully explain what is involved in having this procedure and discuss the possible benefits and risks with you. You should also be told how to find more information about the procedure. All of this should happen before you decide whether you want to have this procedure or not. Your health professional should ask you if details of your procedure can be collected.

If you have a failing aortic bioprosthetic valve and open heart surgery is an option but poses a high risk, 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 possible side effects. You should also be told how to find more information about the procedure. You should only be asked if you want to agree to this procedure after having this discussion. Your health professional should ask you if details of your procedure can be collected.

If you have a failing aortic bioprosthetic valve and open heart surgery is an option and doesn't pose a high risk, your health professional can only offer you this procedure as part of a research study. Details of your procedure will be collected.

Other comments from NICE

NICE said that most of the evidence on the use of ViV-TAVI for patients with a failing aortic bioprosthetic valve comes from older patients at high risk from open heart surgery. It also noted that there is no published evidence on the use of ViV-TAVI in patients considered at low risk from open heart surgery to replace the valve.

NICE said that patients with small bioprosthetic valves and those in whom the main problem was narrowing (stenosis), rather than a leaking, of the existing valve were less likely to survive the procedure.

Your healthcare team

A healthcare team experienced in managing a failing aortic bioprosthetic valve 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 regular experience in the procedure. 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 aortic valve controls the flow of blood out of the heart’s left ventricle (left bottom chamber) to the body’s main artery (the aorta). It opens to allow blood to flow from the heart to the rest of the body when the left ventricle contracts. It then closes to prevent blood leaking back into the heart. The valve can start to fail, usually either because it becomes narrow or starts leaking. This affects the flow of blood from the heart into the body. It puts extra strain on the heart, which can lead to breathlessness and chest pain on exertion, and can eventually lead to heart failure.

Treatment for a failing aortic 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. Sometimes, transcatheter aortic valve implantation (TAVI) is used. This avoids open heart surgery by inserting a bioprosthetic valve within the failing valve rather than removing it. A catheter (tube) carrying the new valve is inserted through a small cut in the skin and then through the arteries or the heart, where the valve is placed within the failing valve to take over its function.

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

NICE has looked at using valve-in-valve transcatheter aortic 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 (inserted either through open heart surgery or by transcatheter aortic valve implantation [TAVI]) fails, another bioprosthetic valve can be placed within it using a catheter (tube). This is known as valve-in-valve (ViV) TAVI. The aim is to provide a less invasive alternative to open heart surgery to replace the failing bioprosthetic valve.

In this procedure, the new valve is inserted through a catheter into the heart using a general anaesthetic or a local anaesthetic with sedation. The catheter is normally inserted into the body through a cut in the skin into a large blood vessel, usually in the groin. Sometimes the valve is inserted directly into the heart through a small cut in the chest. The old valve is squashed and the new one is placed inside the squashed remains of the old one. Imaging is used to help the surgeon...
position the new valve correctly. 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 based its recommendations on the fact that most of the evidence on efficacy and safety came from older patients with a failing aortic bioprosthetic valve who were at high risk from open heart surgery. The 12 studies that NICE looked at involved a total of about 860 patients.

They showed the following benefits when a failing valve was replaced:

- 100% of valves implanted successfully, and 98% of implants were successful in the short term
- about 83% of patients still alive 1 year after the procedure
- improvement in symptoms in about 85% of patients, which was still evident 1 year after the procedure.

And showed the following benefit when a ViV-TAVI valve was poorly placed and needed redoing:

- about 96% of patients still alive 1 year after the procedure.

The studies showed that the risks of valve-in-valve transcatheter aortic valve implantation included:

- death within 30 days of the procedure in about 8% of patients treated for a degenerated valve
- blockage of the opening to the arteries of the heart in 2–4% of patients
- when a poorly placed valve needed retreatment, serious complications in 5% of patients 1 year after the procedure
- major stroke within 30 days of the procedure in about 2% of patients treated for a failing bioprosthetic valve
- heart attack in 8% of patients within 30 days of the procedure
- change to open heart surgery during the procedure because the valve moved in 2 patients, 1 of whom later died
- change to open heart surgery after the procedure in 2 patients because of bleeding where the catheter was inserted in one and heart failure in the other

- heart rhythm disorders in 6% of patients

- a pacemaker needed in 11% patients

- heart infection 3 months after the procedure in 1 patient, which was successfully treated by inserting a new valve by open heart surgery

- kidney failure needing dialysis after the procedure in 9% of patients and acute kidney injury in 7% of patients

- mild-to-moderate leaking in 10% of patients and a leaking valve in 4% of patients

- major bleeding in about 8% of patients

- complications where the catheter was inserted through the skin in 13% of patients (no further details given).

NICE was also told about some other possible risks reported by specialist advisers: cardiac tamponade (blood leaking around the heart, which impairs its function), a tear in the wall of the aorta and problems with the lower left chamber of the heart.

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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