

Understanding NICE guidance

Information for people who use NHS services

Catheter insertion of a new aortic valve to treat aortic stenosis

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how catheter insertion of a new aortic valve can be used in the NHS to treat people with aortic stenosis. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe aortic stenosis or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

What has NICE said?

There is not much evidence about how well this procedure works or how safe it is, especially in the long term. There are serious safety concerns; however, patients who require this procedure are also at a high risk of death or serious complications if they are not treated or if they are treated with standard open heart surgery. If a doctor wants to use this procedure to insert a new aortic valve, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the uncertainty surrounding potential risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

Further information on the safety of this procedure and how well it works will be helpful. NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a central store of information at the NHS Information Centre for Health and Social Care (www.ccad.org.uk) so that the safety of the procedure and/or how well it works can be checked over time. NICE may look at this procedure again if more information becomes available.

A team of healthcare professionals, including specialist doctors who are experienced in the management of aortic stenosis, should decide which patients are suitable for this procedure. The team should include a heart surgeon, a heart anaesthetist and a specialist in heart procedures using catheters (known as an interventional cardiologist).

NICE has also said that this is a difficult procedure. It should only be carried out by doctors with special expertise/training in interventional cardiology. The procedure should be carried out in units with specialists in heart and blood vessel surgery available in case emergency treatment is needed.

Other comments from NICE

In the studies that NICE looked at, the patients selected for this procedure were at high risk of death if treated with conventional open heart surgery. Further studies may be helpful.

There are different types of devices and techniques used for this procedure, which continue to change as doctors become more experienced in the procedure.

Catheter insertion of a new aortic valve

The medical name for this procedure is 'transcatheter aortic valve implantation'.

The procedure is not described in detail here – please talk to your doctor for a full description.

Stenosis means narrowing, and in aortic stenosis, the aortic valve in the heart has become narrow. Normally, this valve lets blood flow forward and out of the heart, and stops it from flowing backwards. But when the valve becomes narrow, it doesn't open properly, so blood can't flow so easily out of the heart. This puts a strain on the heart, and over time the heart muscle may get thicker in an attempt to push the blood harder through the partly open valve. People with aortic stenosis may have chest pain, feel breathless and dizzy, and may faint. Eventually some people develop heart failure.

A new valve may be inserted to replace the narrow aortic valve. In transcatheter aortic valve implantation, the valve is inserted via a thin tube (called a catheter) into the heart. The catheter can be inserted into the body through a large blood vessel, usually in the groin, under a local anaesthetic. Alternatively, it can be inserted directly into the heart through a small cut to the chest, under a general anaesthetic.

The standard operation for aortic stenosis involves opening up the chest (this is called open heart surgery) and putting the patient onto a heart and lung machine (heart–lung bypass). The valve can then be replaced.

The new procedure has been used in older patients and/or patients with additional illnesses, who might not survive open heart surgery.

This procedure may not be the only possible treatment for aortic stenosis. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

What does this mean for me?

If your doctor has offered you catheter insertion of a new aortic valve, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. Your doctor should tell you that the long-term benefits are uncertain and that there may be some serious risks, including the possibility of death or the need for emergency heart surgery. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

You may want to ask the questions below

- 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 operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described here. NICE looked at eight studies on this procedure.

How well does the procedure work?

In three studies of patients who had the procedure through a large blood vessel, a total of 146 out of 172 replacement valves were inserted successfully. One of these studies reported that 35 out of 43 patients who had a successful procedure were still alive a year later, and another reported that 11 out of 27 patients were still alive 6 months after the procedure. A further study found that 5 out of 11 patients were still alive 10 months after the procedure. Tests to measure blood flow across the valve and the size of the valve were carried out on patients before and after the procedure, and symptoms of breathlessness were assessed. Overall, patients were found to have less severe aortic stenosis and reduced breathlessness.

In a study of seven patients who had the procedure through a small cut in the chest, the patients' symptoms improved or disappeared. All seven patients were found to have less severe aortic stenosis after 1 month and still showed improvement after 6 months.

In two other studies using this technique, 4 out of 59 and 3 out of 50 patients had to have open heart surgery because of problems during the procedure. Of the patients who had a successful procedure and who were still alive 6 months later, all were found to no longer have severe aortic stenosis using tests of blood flow.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that how well the procedure works can be assessed by the successful replacement of the valve, an improvement in blood flow across the valve and in the valve area, an improvement in the patient's symptoms and by the initial and longer term survival of the patient.

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Risks and possible problems

Of 172 patients (in three studies) who had valve replacement through a large blood vessel, 22 died within 30 days of the procedure. Two patients died in hospital after the procedure in a study of 13 patients. One study reported that a patient died after the mitral valve of the heart was damaged during the procedure. Twelve out of 157 patients in four studies had a stroke within 30 days of the procedure. Other serious problems were reported in 19 patients, including a slow heart rate (in four patients), serious bleeding (in two), a build up of fluid around the heart (in nine), injury to the blood vessels carrying blood to the legs needing repair (in two) and infection of the catheter insertion site needing antibiotic treatment (in two).

In three studies of patients who had valve replacement through a small cut in the chest, 8 out of 59, 4 out of 50 and 1 out of 7 patients died within 30 days of the procedure. In the study of seven patients, two had leaking around the new valve, which improved after a further procedure. In the study of 59 patients, 18 had a build up of fluid around the lungs, 18 had an abnormal heartbeat, 3 had a build up of fluid around the heart and 2 had a stroke. Additionally, 18 patients needed to have temporary support using a kidney machine, 8 needed an opening made through the neck into the windpipe to allow air to pass, 8 patients needed further surgery through another small cut in the chest, and 4 patients needed emergency resuscitation.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that possible problems include blockages in blood vessels caused by blood clots, problems at the place of entry of the tube, the need for open heart surgery or a permanent pacemaker, and movement, incorrect placement, and uncertain lifespan of the artificial valve.

More information about aortic stenosis

NHS Direct online (www.nhsdirect.nhs.uk) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about 'Transcatheter aortic valve implantation for aortic stenosis'. This leaflet and the full guidance aimed at healthcare professionals are also available at www.nice.org.uk/IPG266

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1603).

We encourage voluntary sector organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.