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**Information for the public**

National Institute for Health and Clinical Excellence

# Treating right ventricular outflow tract dysfunction with an artificial valve implanted using a catheter

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

This document is about when and how implanting an artificial valve using a catheter (a thin, hollow tube) can be used in the NHS to treat people with right ventricular outflow tract dysfunction. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech 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.

This document is written to help people who have been offered this procedure (or in the case of children, their parents or carers) to decide whether to agree (consent) to it or not. It does not describe right ventricular outflow tract dysfunction or the procedure in detail – a member of your healthcare team should give you full information and advice about these. The document 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 page 7.

## What has NICE said?

There is evidence that this procedure works well in the short term but not much evidence about how it works in the long term. People having this procedure are often very unwell and might otherwise need more risky open heart surgery. Therefore this procedure can be offered routinely as a treatment option for people with right ventricular outflow tract dysfunction provided that doctors are sure that:

- patients (or their parents or carers) understand what is involved and agree to the treatment, and
- the results of the procedure are monitored.

The procedure should only be carried out in specialist units with arrangements for heart surgery in case there are complications.

A team of healthcare professionals should decide who should have this procedure. The team should include a cardiologist with a special interest in congenital (present from birth) heart disease, an interventional cardiologist, and a cardiothoracic surgeon with a special interest in congenital heart disease.

NICE has also said that this is a difficult procedure to carry out. It should only be done by healthcare professionals with training and experience in interventional cardiology and congenital heart disease.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to the UK Central Cardiac Audit Database (http://www.ucl.ac.uk/nicor) so that its safety and how well it works can be checked over time.

### Other comments from NICE

NICE noted the risk that the stent (expandable mesh tube) inserted with the artificial valve may break in the longer term. This is why it said information still needs to be collected about what happens to patients who have the procedure. NICE said that devices are being developed that may work better in the future.

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*This procedure may not be the only possible treatment for right ventricular outflow tract dysfunction. Your healthcare team should talk to you about whether it is suitable for you (or your child) and about any other treatment options available.*

The medical name for this procedure is 'percutaneous pulmonary valve implantation for right ventricular outflow tract dysfunction'. 'Percutaneous' means in this case that it is done through a small cut in the skin and using a catheter rather than 'open' surgery.

The procedure is not described in detail here – please talk to your (or your child's) specialist for a full description.

Heart valves keep blood moving in the right direction through the heart. Faulty heart valves may leak or not let enough blood through. They are usually repaired or replaced using open heart surgery.

Implanting an artificial valve using a catheter is less invasive because the chest doesn't need to be opened or the heart stopped. The patient is given a general anaesthetic. The doctor inserts a narrow tube called a catheter into a vein, usually in the groin. The artificial valve (which is inside an expandable mesh tube called a stent) is moved through the catheter to the heart using imaging.

The new valve may need to be replaced over time, either because the valve has deteriorated, or in children and young people because they have grown.

## What does this mean for me or my child?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks it is suitable for you or your child, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

Your doctor may ask you if details of your (or your child's) 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 (or my child) might get?
- How good are my (or my child's) chances of getting those benefits? Could having the procedure make me (or my child) 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 (or my child) need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't (or my child doesn't) have the procedure?

## Summary of possible benefits and risks

*You might decide (or decide on behalf of your child) to have this procedure, to have a different procedure, or not to have a procedure at all.*

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 9 studies on this procedure.

### How well does the procedure work?

In 2 studies this procedure substantially reduced average pressure in the right side of the heart. In the first study it reduced from 57 to 42 mmHg in 52 patients who had the procedure only and from 65 to 41 mmHg in 54 patients who had a stent inserted first and then had the procedure. In the second it reduced from 63 to 45 mmHg in 155 patients. This was measured after a year in the first study and after the procedure in the second.

In a study of 102 patients valve leakage improved from 16% before the procedure to 1% afterwards.

In another study the number of patients who were not physically limited by their condition improved from 5 before the procedure to 27 of the 33 patients checked 6 months later. Six per cent of patients had been unable to do any physical activity without discomfort but after the procedure none of the patients were this limited.

Nearly 6 years (70 months) after treatment, almost three-quarters of the patients in a study of 155 had not needed surgery or another catheter procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that the main things that make the procedure a success were the valve working better, avoiding having to cut open the patient's breastbone and use a heart and lung machine, and shorter recovery time with less risk of infection or bleeding.

### Risks and possible problems

Two studies looked at how many patients died after the procedure. Out of a total of 244 patients, 5 died, 2 patients within 30 days of having the

procedure and 3 patients between 2 months and 2 years after the procedure.

In 2 studies of a total of 122 patients, 2 patients had inflammation in the heart (endocarditis). One had the valve taken out after 6 months and the other had the valve replaced after 6 months.

Two studies looked at how often the stent broke. In the first study, after a year it had broken in 29% of the 52 patients who were treated with the procedure only and in 17% of 52 patients who had a stent inserted first and then had the procedure. In the second study the stent broke in 21% of 155 patients. By just over 2 years after the procedure 9 of these patients had needed another procedure.

In a study of 36 patients the valve moved away from the correct position, once during the procedure (this was corrected) and in another 2 patients after the procedure – they had to have surgery to replace the valve.

In 2 patients in a study of 136 a tube in the heart had torn and needed treatment when they were checked after 6 months.

Two patients had to have the valve taken out 16 and 19 months after the procedure in the study of 108, 1 because of bleeding and 1 because of inflammation in the heart.

There was a problem with the heart rhythm during the procedure in 1 patient in the study of 102 patients. This returned to normal 21 days later.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that, in theory, things that could go wrong include tearing or cutting the pulmonary artery, a tear in the heart or a blood vessel, the valve becoming blocked, and bleeding where the catheter was inserted.

## More information about heart problems

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

For details of all NICE guidance on heart problems, visit our website at www.nice.org.uk

## 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 document is about 'Percutaneous pulmonary valve implantation for right ventricular outflow tract dysfunction'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/HTG297*

*The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on Accessibility at the bottom of the NICE homepage to use this service.*

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

**National Institute for Health and Clinical Excellence**
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT; www.nice.org.uk

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