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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Mitral valve repair using a supportive (annuloplasty) device inserted via a vein using a catheter

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

This leaflet is about when and how a supportive (annuloplasty) device can be used in the NHS to treat people with a heart problem called mitral regurgitation. 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.

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 mitral regurgitation 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 page 7.

What has NICE said?

The current evidence on this procedure is inadequate in quality and quantity for it to be used routinely. For this reason, NICE has said that this procedure should only be carried out as part of a research study (also called a clinical trial). The research should study the patients who have the procedure, any other treatments used, as well as how safe the procedure is. NICE may review the procedure if more evidence becomes available.

The procedure should only be done by heart specialists called interventional cardiologists who should have specific training in the procedure.

Mitral valve repair using a supportive (annuloplasty) device inserted via a vein using a catheter

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

The medical name for this procedure is 'Percutaneous mitral valve annuloplasty'. 'Percutaneous' means that this is a minimally invasive procedure done through small cuts in the skin rather than 'open' surgery.

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

The mitral valve is one of four valves in the heart that keep blood moving in the correct direction around the body. If the mitral valve does not close properly this is called mitral regurgitation. Blood flows less easily from the lungs and may cause breathlessness and heart failure. Severe mitral regurgitation may need to be treated with surgery.

Normally the annuloplasty procedure requires open heart surgery to place a supportive device around the opening of the mitral valve to reduce backwards leakage of blood and improve the functioning of the valve.

The minimally invasive version of the procedure is carried out with the patient under a general or local anaesthetic. Using X-ray images (fluoroscopy) and often special scans (transoesophageal echocardiography) to guide them, the doctor inserts a thin hollow tube (catheter) through a vein in the groin or the neck and into the heart. The supportive device is introduced through the catheter and manipulated to get it in the right position so that it supports the mitral valve.

What does this mean for me?

Your doctor should only offer you this procedure as part of a research study (also called a clinical trial)

NICE has recommended that some details should be collected about every patient who has this procedure in the UK. Your doctor may ask you if details of your procedure can be used in this way. 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

You might decide 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 7 studies on this procedure.

How well does the procedure work?

There was very little good evidence about this procedure.

In 1 small study of 48 patients, 18 were not suitable for the procedure, but 30 patients were successfully treated with a mitral annuloplasty device. Patients' progress was checked at 6 months after the procedure. One questionnaire assessed physical function, symptoms and quality of life, and gave a score of between 0 and 100 (higher scores are better). The average score before the procedure was 47 but this improved to 69 after 6 months. Another assessment (using the New York Heart Association classification) showed that the severity of heart failure symptoms had improved after the procedure. A test of how far patients could walk in 6 minutes also improved, from an average of 307 metres before the procedure to 403 metres after 6 months.

As well as looking at this study, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the aims of the procedure are to ensure the mitral valve works well in the short, medium and long term (10 years), reduce mitral regurgitation, improve heart function, increase 6-minute walk distance, improve quality of life, increase survival and reduce hospital admissions for patients with advanced heart failure.

Risks and possible problems

Again, there was very little good evidence available.

In the study of 48 patients, 1 patient died 22 days after the procedure (the patient had other health problems) and 3 had a heart attack within 24 hours of the procedure. Damage to the veins of the heart was reported in 3 patients in the same study, and in 2 of 5 patients in another study. In the study of 5 patients, 1 patient died from heart failure 148 days after the procedure (the patient was obese and had other health problems).

A heart condition known as atrioventricular block was reported in 1 patient after device implantation. This was successfully treated.

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 a possible complication is an emergency condition called cardiac tamponade, in which fluid accumulates in the sac around the heart. They also said that, in theory, problems could include compression of the coronary artery, perforation of the heart, hardening of the mitral valve and problems with the device (movement, breakage or inability to remove it).

More information about mitral regurgitation

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on mitral regurgitation, 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. This 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 'Percutaneous mitral valve annuloplasty'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG225

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2231). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

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

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