

## **Understanding NICE guidance**

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**Information for people who use NHS services**

# **Image-guided mitral leaflet repair for mitral regurgitation**

*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 image-guided mitral leaflet repair can be used in the NHS to treat people with mitral regurgitation. 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 faulty mitral valves 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.

## What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is.

For patients well enough to undergo conventional heart surgery, NICE has said this procedure can be used, providing doctors explain the uncertainty about how well it works and potential risks. 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.

For patients not well enough to undergo conventional heart surgery, NICE has said that the procedure can only be used as part of a research study. The research should look at how the procedure affects symptoms, the change in how patients function and how their hearts work, and should record patients' survival and if anything goes wrong.

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 ([www.ccad.org.uk](http://www.ccad.org.uk)) so that the safety of the procedure and/or how well it works can be checked over time.

A team of specialist doctors should decide who can have this procedure, including a cardiologist expert in echocardiography and a cardiac surgeon. The procedure should be carried out in specialist units with access to emergency cardiac surgery, by cardiologists with specific training.

NICE is aware of ongoing research and may review the procedure if more evidence becomes available.

## Other comments from NICE

NICE noted that the technology for this procedure is still developing, which may affect the success of the procedure.

*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.*

## Image-guided mitral leaflet repair for mitral regurgitation

The medical name for this procedure is 'percutaneous mitral valve leaflet repair for mitral regurgitation'. 'Percutaneous' means through the skin and 'regurgitation' is when blood leaks the wrong way through a heart valve. The procedure is not described in detail here – please talk to your surgeon 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 work properly, blood flows backwards towards the lungs. This is called mitral regurgitation. Severe mitral regurgitation may need either open or minimally invasive surgery.

This procedure is carried out with the patient under a general anaesthetic. A thin hollow tube (catheter) is inserted through a vein in the groin and guided to the heart. The surgeon clips the leaflets of the mitral valve together using X-ray imaging.

## What does this mean for me?

If you are well enough for conventional heart surgery and your doctor has offered you this procedure, 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 and discuss possible benefits and risks. You should only be asked if you want to agree to this procedure after this. You should be given written information, including this leaflet, and be able to discuss it with your doctor before you decide.

If you are not well enough for conventional heart surgery, your doctor can only offer you this procedure as part of a research study because there is not yet enough evidence to show whether it is suitable for you.

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

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 5 studies on this procedure.

## How well does the procedure work?

In a study of 107 patients with moderate to severe mitral regurgitation, the clips were successfully implanted in 96 patients. After the procedure symptoms improved in 79 patients, and 50 patients still showed the same improvements when their progress was checked 12 months after the procedure.

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

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 the main success factors are successful clip placement, reduced mitral regurgitation, for the repair to be maintained, the size and functioning of the left main chamber of the heart, the need for further surgery, and quality of life.

## Risks and possible problems

In the study of 107 patients, 10 patients had a major complication within 30 days of the procedure (the study did not state what happened). In the same study the clips became partially detached in 10 patients, and in another study of 47 patients, this happened to 1 patient. In the study of 107 patients, 1 patient had a stroke and some neurological (nerve) problems after the procedure, but the study reported that the symptoms got better within 30 days.

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 leaflet tearing; the clip partially detaching; complications with the vein used for access; fluid accumulating in the sac around the heart; abnormal blood flow in the heart; and scarring around the clips, which could narrow the mitral valve.

## More information about mitral regurgitation

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 valves, visit our website at [www.nice.org.uk](http://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](http://www.nice.org.uk/aboutguidance)*

*This leaflet is about 'percutaneous mitral valve leaflet repair for mitral regurgitation'. This leaflet and the full guidance aimed at healthcare professionals are available at [www.nice.org.uk/IPG309](http://www.nice.org.uk/IPG309)*

*You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email [publications@nice.org.uk](mailto:publications@nice.org.uk) and quote reference N1968). 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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ISBN 978-1-84936-055-5  
N1968 1P Aug 09