

Issue date **August 2013**

Information for the public

Implanting pressure monitors in the pulmonary artery to monitor chronic heart failure

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

This document is about when and how implanting pressure monitors in the pulmonary artery (the artery that takes blood from the heart to the lungs) can be used in the NHS to monitor patients with chronic heart failure. It explains guidance (advice) from NICE (the National Institute for Health and Care 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 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 document 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 chronic heart failure 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 8.

What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. If a doctor wants to implant a pressure monitor in the pulmonary artery to monitor chronic heart failure, 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 document 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.

NICE has encouraged further research into implanting pressure monitors in the pulmonary artery to monitor chronic heart failure. This research should look at the long-term effects of the procedure on hospital admissions and patients' quality of life and should record adverse events. NICE said this because most of the evidence about how well the procedure works comes from 1 study whose main aim was to follow patients' progress for only 6 months after the procedure.

There may be other ways to monitor heart failure. Your healthcare team should talk to you about whether this procedure is suitable for you and about any other options available.

Implanting pressure monitors in the pulmonary artery to monitor chronic heart failure

The medical name for this procedure is 'Insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure'.

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

Heart failure means the heart does not pump enough blood to meet all the needs of the body, usually because the heart muscle has been damaged. It is often associated with changes in the pressure inside the pulmonary artery, which takes blood from the heart to the lungs.

Chronic heart failure is usually treated with drugs, which aim to ease the workload of the heart, lower pulmonary artery blood pressure and remove excess fluid in the body.

Regular monitoring of their clinical condition may improve the quality of life for people with chronic heart failure and avoid hospital admission because treatment can be changed as soon as needed. Standard monitoring may involve regular visits to a heart failure clinic, home visits, usually from a nurse, or regular phone contact with a heart failure team. It may include checks to see if the person can carry out their usual activities, and whether there are any problems with the balance of fluids in the body, heart rhythm, memory, understanding or diet.

The procedure NICE has looked at allows some monitoring to be done without going to a clinic or having a home visit.

The procedure is usually carried out with the patient under a local anaesthetic. A small monitor without any batteries or leads is inserted into a vein in the groin through a puncture in the skin and passed

through the heart and into the pulmonary artery, where it settles in place. Information on pulmonary artery pressure is transmitted to an antenna, which may be inside a special pillow the patient can lie down on. The antenna transmits the information daily to a computer that the patient's medical team can access. The results can allow the team to detect changes in the patient's condition and suggest changes to treatment often before the patient has worsening symptoms, which may prevent the condition becoming worse.

What does this mean for me?

If your doctor has offered to implant a pressure monitor in your pulmonary artery to monitor your chronic heart failure, 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. 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 document, and have the opportunity to discuss it with your doctor before making your decision.

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

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

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 8 studies on this procedure.

How well does the procedure work?

A study of 550 patients with chronic heart failure compared pulmonary artery pressure monitoring with standard monitoring. At 6 months and an average of 15 months after the procedure, patients who had implanted pressure monitors had been hospitalised because of their heart failure fewer times (84 and 158 times) than patients who had standard monitoring (120 and 254 times). At 6 months patients in both groups had spent about the same number of days out of hospital (on average 174 days for patients who had implanted pressure monitors and 172 days for patients who had standard monitoring).

The same study used a questionnaire to measure how severe patients' heart failure was (lower scores mean a better quality of life). Six months after the procedure, the patients who had implanted pressure monitors had an average score of 45, and the patients who had standard monitoring had an average score of 51.

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 key outcomes for the procedure were fewer hospitalisations because of heart failure, improved quality of life, and longer life.

Risks and possible problems

In the study of 550 patients, 1 patient went into cardiogenic shock (when the heart can no longer pump enough blood to meet the body's needs). In 2 patients who already had an irregular heartbeat, this worsened during the procedure.

Part of the monitor had stopped working after 6 months in 1 patient in a study of 40 patients.

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 problems reported included a large drop in blood pressure and kidney problems caused by the aggressive treatments for raised pressure in the pulmonary artery. Other possible problems include the monitor coming loose and blocking the blood vessels in the lung, infection, a blood clot in or tearing of the pulmonary artery, the monitor moving inside the body, incorrect information being transmitted from the monitor, and incorrect decisions being made by healthcare professionals based on the information (even if the information is correct).

More information about chronic heart failure

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

For details of all NICE guidance on chronic heart failure, 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 'Insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/IPG463

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 document in their own information about this procedure.

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ISBN 978-1-4731-0255-2

Aug 13

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