

Understanding NICE guidance

Information for people who use NHS services

Relieving chronic sinusitis using an inflatable balloon

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 an inflatable balloon can be used in the NHS to treat people with chronic sinusitis. 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 chronic sinusitis 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?

This procedure can be offered routinely as a treatment option for people with chronic sinusitis provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

The procedure should only be done by doctors who are experienced in complex sinus surgery and who have specific training in the procedure.

NICE has also said that further information on the safety of this procedure and how well it works, particularly in the long term, will be helpful.

Other comments from NICE

NICE noted that it can be difficult to decide which patients should be offered this procedure and also which sinuses should be treated. The available evidence was about patients whose chronic sinusitis had not resolved with medicine. NICE also noted that the procedure is often carried out at the same time as other procedures.

Relieving chronic sinusitis using an inflatable balloon

The medical name for this procedure is 'Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis'. It may also be called 'balloon sinuplasty'.

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

Sinusitis is an inflammation or infection of the sinuses (small air-filled cavities inside the cheekbones and forehead). Symptoms may include fever, pain and tenderness over the affected area together with a blocked or runny nose. There are two types of sinusitis. Acute sinusitis often develops quickly (over a few days) following a cold or influenza (flu). Chronic sinusitis produces symptoms lasting for weeks or even months.

For many patients with sinusitis, no treatment is needed. Sometimes painkillers, decongestants, nasal sprays or steroids may be needed and antibiotics may be offered to clear up the infection. For some patients, the sinusitis becomes chronic and does not clear up (either on its own or with antibiotics) or keeps coming back, so surgery may be recommended.

The procedure is carried out with the patient under a general anaesthetic. A small balloon is introduced, through a flexible tube in the nostril, into the blocked sinus. The surgeon guides the balloon into the correct place using X-ray video images. The balloon is gently inflated to open the blocked area. The balloon is then deflated and removed, allowing the unblocked sinus to drain properly and work normally.

What does this mean for me?

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

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 four studies on this procedure.

How well does the procedure work?

In a study of 115 patients, the balloon was successfully inserted in 347 out of 358 sinuses (97%). After 1 week, 232 out of 341 sinuses were clear (68%) and after 24 weeks, this had increased to 246 out of 304 sinuses being clear (81%).

Two studies looked at symptom relief. A study of 1036 patients reported that 95% of patients had improved symptoms and 73% of patients were completely free of symptoms after an average of 40 weeks following the procedure. The study of 115 patients measured symptoms using a scale which ranged from 0 (least severe) to 5 (most severe). Before the procedure, the average score was 2.14. After the procedure, the average score had improved to 1.27.

Another study of 70 patients, in which 35 patients had this procedure and 35 patients had a different procedure (called functional endoscopic sinus surgery), showed that the patients in the balloon group had greater improvements.

Two studies looked at whether any further procedures were needed. Out of a total of 1145 patients, 28 needed a further 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 aims of the procedure are to have clear sinuses, improved symptoms scores and improved quality of life.

Risks and possible problems

In the study of 115 patients, 9 patients (8%) developed a sinus infection that was successfully treated with antibiotics. In the same study (which looked at a total of 358 sinuses), there was a small number of problems with the equipment used (the balloon tore in 7 cases and there was a problem with the end of the flexible tube in 4 cases).

In the study of 70 patients, slightly more patients in the balloon group (8 out of 35 patients, or 23%) had scarring on the wall of the sinuses.

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 complications are damage to the bones of the skull or around the eyes, leakage of the fluid around the brain, scarring inside the sinuses and bleeding. Other potential complications are placing the balloon in the wrong place and damage to the outer layer of the brain.

More information about chronic sinusitis

NHS Direct online (www.nhsdirect.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 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 'Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IIPG273

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1693).

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

National Institute for Health and Clinical Excellence

MidCity Place, 71 High Holborn, London, WC1V 6NA; www.nice.org.uk

ISBN 1-84629-810-5
N1693 1P Sep 08