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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Air pressure therapy for difficult-to-treat Ménière's disease

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 air pressure therapy can be used in the NHS to treat people with difficult-to-treat Ménière's disease. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

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 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 Ménière's disease or the procedure in detail – a member of your healthcare team should also 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 6.

What has NICE said?

There is not much good evidence about how safe this procedure is and there is only a limited amount of evidence about how well it works. If a doctor wants to use air pressure therapy for difficult-to-treat Ménière's disease, 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 air pressure therapy for difficult-to-treat Ménière's disease.

Other comments from NICE

NICE noted that vertigo can significantly disable some people and there are not many reliable treatments for chronic (long-term) vertigo in Ménière's disease. NICE said that if air pressure therapy could be shown to work it could be a useful option to improve quality of life in some people with the condition.

Air pressure therapy for difficult-to-treat Ménière's disease

This procedure may not be the only possible treatment for Ménière's disease. 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 ‘micropressure therapy for refractory Ménière's disease’.

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

Ménière's disease is a disorder caused by raised pressure in the inner ear that can affect hearing and balance, which gets worse over time. It can affect one or both ears. Symptoms include vertigo, hearing loss and tinnitus. Medications and/or a low salt diet aim to treat symptoms (usually the loss of balance and dizziness) but if they fail, surgery can be used to reduce pressure in the inner ear and correct problems with balance.

Air pressure therapy aims to reduce pressure in the inner ear, relieving symptoms and avoiding the need for more invasive surgery.

Using either local or general anaesthetic, a grommet (small tube) is inserted into the eardrum of the affected ear. Several weeks later, after making sure the grommet isn’t blocked, the patient inserts a special plug attached to an air pressure generator into their ear. The generator then sends three 60-second air pressure pulses into the ear, with rest periods of less than 1 minute in between. This is done by the patient at home, usually three times a day. Treatment usually lasts 4–6 weeks but can go on for longer.

What does this mean for me?

If your doctor has offered you air pressure therapy for difficult-to-treat Ménière's disease, 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.

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your 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 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?

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 6 studies on this procedure.

How well does the procedure work?

In one study, 40 patients were treated for up to 8 weeks. Twenty patients treated with air pressure therapy had fewer vertigo attacks on average than 20 patients treated with a sham (dummy) procedure in the last 4 weeks of treatment (1.9 attacks compared with 4).

In a study of 36 patients, 25 went from having between 81 and 120 vertigo spells every 6 months to having no vertigo at all when they were checked at 2 years.

In a study of 22 patients, 20 had significantly fewer vertigo attacks on average after the grommet was inserted (from 9.22 to 1.28). When air pressure therapy was started after 20 days in 18 of these patients, the average number of vertigo attacks was reduced from 9.22 to 1.67. After 40 days there was no significant difference in the number of vertigo attacks between patients who only had the grommet inserted and patients who also had air pressure therapy.

In a study of 37 patients, 27 out of 34 patients who were checked after 2 years said the treatment had been helpful and they were better able to carry out daily tasks and work.

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 aims of the procedure are to reduce the frequency and severity of vertigo, improve hearing, reduce tinnitus and reduce the need for further treatment.

Risks and possible problems

In the study of 37 patients, 5 developed a middle ear infection. They were given antibiotics, the grommet was replaced and they were able to carry on with air pressure treatment.

In the study of 36 patients, 2 had a discharge from their ear immediately after the grommet was inserted.

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 discharge from the ear, the need for the grommet to be replaced if a 'short-stay' grommet is used and permanent ear drum perforation if a 'long-stay' grommet is used. They also said that in theory other problems are infection of the grommet, the grommet becoming lost in the middle ear, scarring of the ear drum and hearing loss.

More information about Ménière's disease

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.

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. HealthTech 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 'micropressure therapy for refractory Ménière's disease'. This document and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG285

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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