Issue date March 2011

Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating difficult-to-control cluster headaches and other trigeminal autonomic cephalalgias using deep brain stimulation

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 deep brain stimulation can be used in the NHS to treat people with difficult-to-control cluster headaches and other trigeminal autonomic cephalalgias. 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 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 trigeminal autonomic cephalalgias 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.

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What has NICE said?

There is not much evidence about how well this procedure works and the evidence available is inconsistent. The evidence about how safe it is shows that there are serious but well-known side effects. If a doctor wants to use deep brain stimulation for difficult-to-control cluster headaches or other trigeminal autonomic cephalalgias, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the potential risks of the procedure. In particular, patients and their carers should be informed that the procedure may not control their headache symptoms and they should be told in full about the possible risks, including the small risk of death. 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.

Patients should be selected by a team specialising in pain management.

Other comments from NICE

It was difficult for NICE to interpret the evidence, some of which was about only a particular group of patients.

NICE noted that some patient feedback reported improvements in quality of life, even if pain was relieved only partially, and some patients said they no longer felt suicidal after this treatment.

Deep brain stimulation for difficult-to-control cluster headaches and other trigeminal autonomic cephalalgias

This procedure may not be the only possible treatment for trigeminal autonomic cephalalgias. 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 'deep brain stimulation for intractable trigeminal autonomic cephalalgias'.

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

Trigeminal autonomic cephalalgias (or TACs for short) are a type of headache that include cluster headaches and other severe headaches with some similar characteristics. Pain attacks are short-lasting but severe, and are accompanied by other symptoms such as sweating, flushing and a runny nose on the same side as the pain. Patients are usually treated with drug therapy initially. Surgery is sometimes used, but there is a risk of severe side effects.

This procedure involves stimulating precise areas of the brain using electrodes. Small holes are drilled into the skull and permanent electrodes are inserted into carefully selected targets deep in the brain using computer guidance. This is usually done with the patient under a local anaesthetic and/or sedation. A test stimulation is used to check for any problems. Wires from the electrodes are threaded under the skin and connected to a device called a 'pulse generator', placed into the chest, which controls the electrical stimulation.

What does this mean for me?

If your doctor has offered you deep brain stimulation for difficult-to-control cluster headaches or other trigeminal autonomic cephalalgias, 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. In particular, you should be informed that the procedure may not control your headache symptoms and you should be told in full about the possible risks, including the small risk of death. 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 leaflet, 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 5 studies on this procedure.

How well does the procedure work?

A study of 12 patients found no difference in the frequency of attacks, pain intensity and patient satisfaction reported by patients during periods of deep brain stimulation treatment compared with periods of treatment with the stimulator turned off. However, during a 10-month period of deep brain stimulation treatment, the average weekly attack frequency decreased by 48% (from 14 to 8 per week), and levels of anxiety and depression (measured using a questionnaire) were reduced.

A study of 20 patients reported that 16 patients treated for chronic cluster headache had relief from pain. On average, a response to treatment occurred after 42 days and 71% of days were pain free.
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 success factors include improvement in the number, severity and duration of attacks, and in quality of life.

Risks and possible problems

In a study of 6 patients with chronic cluster headache, 1 patient died 3 days after the procedure from a bleed in the brain which developed a few hours after the procedure.

The study of 12 patients reported infection just below the skin 3 weeks after surgery in 1 patient, and the study of 21 patients reported deep infection in 1 patient. Both recovered with antibiotic treatment and removal of the deep brain stimulation system.

In the study of 12 patients, a patient temporarily lost consciousness and became weak on one side shortly after test stimulation, followed by fainting due to low blood pressure when urinating.

Double vision and dizziness occurred in all patients when high levels of electrical stimulation were used in the study of 6 patients. One patient had increased breathing and heart rates during stimulation but recovered with electrode removal.

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 stroke, fits and movement of the wires.

More information about trigeminal autonomic cephalalgias

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 headaches, 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 'Deep brain stimulation for intractable trigeminal autonomic cephalalgias'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG252

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2472). 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 978-1-4731-8363-6
N2472 1P Mar 11