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What has NICE said?

There is not much good evidence about how well <u>transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine</u> works, but there are no major safety concerns. It should only be used if extra care is taken to explain the risks and extra steps are put in place to record and review what happens.

More research on this procedure is needed and NICE may look at it again if more evidence is published.

What does this mean for me?

Your health professional should fully explain what is involved in having this procedure and

discuss the possible benefits and risks with you. In particular, they should explain the uncertainty about the evidence on how likely it is to improve your symptoms. You should also be told how to find more information about the procedure. You should only be asked if you want this procedure after having this discussion. Your health professional should ask you if details of your procedure can be collected.

Other comments from NICE

NICE said that patients who have had the procedure had favourable comments about it. Further studies are being done.

The condition

Cluster headaches are attacks of severe pain on one side of the head, usually around the eye. Other symptoms include a red and watery eye and a runny nose. Cluster headaches can happen many times a day and last from a few minutes to several hours, over a period of days, months or years.

Migraines are severe headaches, often associated with feeling sick and sensitivity to light and sound. Some patients have some form of warning (an 'aura'), which can include visual disturbances, confusion or difficulty speaking, usually before the headache starts. Migraines can last for several hours or days, or longer.

The usual treatment for cluster headache attacks is oxygen or drugs such as triptans.

Drugs such as corticosteroids or verapamil may stop or reduce the frequency of attacks.

For migraine attacks the usual treatment is drugs including triptans, painkillers and antisickness drugs. Types of drug that can help stop or reduce the frequency of attacks are beta-blockers, tricyclic antidepressants and some drugs used for treating epilepsy.

Other procedures, including different types of nerve stimulation, are sometimes tried if the person's cluster headaches or migraine do not respond to drug treatment.

NICE has looked at using <u>transcutaneous stimulation of the cervical branch of the vagus</u> <u>nerve</u> as another treatment option.

NHS Choices and NICE's information for the public about headaches in over 12s may be a

good place to find out more.

The procedure

Transcutaneous vagus nerve stimulation uses electrical current from a small handheld device to stimulate a nerve in the neck. The aim is to relieve pain and reduce the number of cluster headache or migraine attacks.

The person places the device, which is the size of a mobile phone, on the side of their neck. The level of stimulation is increased slowly until small muscle contractions are felt under the skin. The device is then held in position for about 90 seconds. It can be used to treat attacks, and between attacks to try to reduce the number of attacks.

Benefits and risks

When NICE looked at the evidence, it decided that there was not enough evidence about how well the procedure works. The 5 studies that NICE looked at involved a total of 214 patients.

Generally, they showed the following benefits of using the device over 1–2 months compared with the standard treatment for cluster headache:

- · fewer headache attacks
- complete pain relief in some patients, within minutes of using the device
- other headache treatments were needed on fewer occasions
- improved quality of life.

Generally, they showed the following benefits of using the device for migraine:

- pain relief in about half of patients, and complete pain relief in about 20% of patients, within 2 hours of using the device
- relief of sickness, sensitivity to light and noise in about 30–50% of patients
- recovery from disability caused by migraine in about 30% of patients within 2 hours of using the device

 other migraine treatment was needed in just over half of patients 2 hours after using the device.

There were no serious risks associated with using the device. The studies included reports of the device causing headaches, dizziness, neck stiffness, pain in the mouth and throat, shoulder pain, palpitations, muscle spasm, mild lip or facial drooping, temporary mild confusion and reddening of the skin around the treatment site in a small number of patients.

NICE was also told about some other possible risks: shortness of breath and changes in blood pressure.

If you want to know more about the studies, see the <u>guidance</u>. Ask your health professional to explain anything you don't understand.

Questions to ask your health professional

- 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?

About this information

NICE <u>interventional procedures guidance</u> advises the NHS on the safety of a procedure and how well it works.

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Accreditation

