

Transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg559

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

- 1.1 Current evidence on transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine raises no major safety concerns. The evidence on efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wishing to offer transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine should:
- Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
 - Audit and review clinical outcomes of all patients having transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine (see section 7.2).
- 1.3 Patient selection should normally be done by clinicians in specialist headache clinics.
- 1.4 NICE encourages further research on transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine. Data should be collected for all patients not entered into controlled trials. Studies should describe clearly whether the procedure is used for treatment or prevention. They should include details of patient selection and the dose and frequency of use. Outcome measures should include the number and severity of migraine episodes, quality of life in the short and long term and any changes in medication. The development of any complications after starting treatment should be documented. NICE may

update the guidance on publication of further evidence.

2 Indications and current treatments

- 2.1 Migraines are severe headaches that may last for hours, days or longer, often accompanied by nausea, photophobia, phonophobia and the perception of unpleasant odours. In some people migraines may be accompanied by an aura, characterised by the focal neurological symptoms that usually precede or sometimes accompany the headache. The [International Headache Society's international classification of headache disorders](#) classifies migraine types.
- 2.2 The usual treatment option for patients with migraine is medical therapy, either to stop or prevent attacks. Treatments for acute migraine attacks include medications such as analgesics, triptans and anti-emetics (as recommended in [NICE's guideline on headaches in over 12s](#)). Treatments to stop or reduce the frequency of migraine attacks include medications such as beta-blockers, tricyclic antidepressants and antiepileptics.
- 2.3 Invasive treatments are reserved for patients with distressing symptoms that are refractory to medical treatments. These include treatments such as nerve blocks, botulinum toxin (see [NICE's technology appraisal guidance on botulinum toxin type A for the prevention of headaches in adults with chronic migraine](#)), acupuncture or nerve stimulation.

3 The procedure

- 3.1 Transcutaneous supraorbital nerve stimulation uses small electrical currents to stimulate the supraorbital nerve. It aims to relieve headache and, when used regularly, to reduce the severity and the frequency of migraine attacks.
- 3.2 Therapy is administered by the patient, using a small battery-operated device (a headband with a central button) connected to a self-adhesive electrode patch applied to the forehead above the eyebrows. When the device is activated, small electrical impulses stimulate the supraorbital nerves (branches of the ophthalmic nerve, the first division of the

trigeminal nerve). The intensity of the electrical pulses increases periodically and this can be adjusted by the patient. Stimulation is applied for approximately 20 minutes daily.

- 3.3 The device can be used to treat acute migraine attacks and for prophylaxis between attacks.

4 Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 4.1 A multicentre double-blind randomised controlled trial (RCT) of 67 patients with migraine compared transcutaneous supraorbital neurostimulation (tSNS; n=34) against sham treatment (n=33). In the intention-to-treat analysis, there was a statistically significant decrease in the mean number of migraine days between baseline and 3 months after treatment in the tSNS group (6.94 ± 3.04 to 4.88 ± 3.46 ; $p=0.023$), but not in the sham group (6.54 ± 2.61 to 6.22 ± 2.99 ; $p=0.608$). The difference between the 2 groups was not statistically significant ($p=0.054$). A case series of 20 patients with migraine without aura reported a statistically significant decrease in the frequency of migraine days per month from 4.5 ± 0.24 at baseline to 2.06 ± 0.28 at 60-day follow-up ($p < 0.001$).
- 4.2 In the RCT of 67 patients the 50% responder rate (defined as the percentage of patients having a greater than 50% reduction in monthly migraine days) was statistically significantly higher in the tSNS group than in the sham group (38% [n=13] versus 12% [n=4]; $p=0.023$) in the intention-to-treat analysis. The percentage of patients with at least a 25% reduction (moderate improvement) in migraine days was also statistically significantly higher in the tSNS group than in the sham group (59% [n=20] versus 27% [n=9], $p=0.014$). The case series of 20 patients reported a 50% reduction in monthly migraine attacks and migraine days in 81% and 75% of patients respectively at 60-day follow-up.
- 4.3 In the RCT of 67 patients (intention-to-treat analysis) the monthly

migraine attack frequency was 4.37 ± 1.87 at baseline and 3.55 ± 2.94 at 3 months ($p=0.058$) in the tSNS group, and 4.04 ± 1.52 at baseline and 3.89 ± 1.89 at 3 months ($p=0.516$) in the sham group. The difference between the 2 groups was statistically significant ($p=0.044$).

- 4.4 In the RCT of 67 patients (intention-to-treat analysis) there was a statistically significant decrease in monthly days with any headache between baseline and 3 months after treatment in the tSNS group (7.78 ± 4.00 to 5.27 ± 3.55 ; $p=0.011$), but not in the sham group (6.72 ± 2.63 to 6.49 ± 3.20 ; $p=0.674$). The difference between the 2 groups was statistically significant ($p=0.041$).
- 4.5 In the RCT of 67 patients (intention-to-treat analysis) the mean headache severity per migraine day (on a 4-point scale, 0 indicating no pain and 3 indicating severe pain prohibiting daily activities) was 1.96 ± 0.46 at baseline and 1.8 ± 0.60 at 3 months ($p=0.131$) in the tSNS group, and 1.78 ± 0.41 at baseline and 1.73 ± 0.53 at 3 months ($p=0.443$) in the sham group. The difference between the 2 groups was not statistically significant ($p=0.301$). In the case series of 20 patients there was a statistically significant reduction in average pain intensity (measured on a visual analogue scale from 0 to 10, 0 indicating no pain and 10 indicating severe pain) during migraine attacks, from 8.0 ± 0.1 at baseline to 6.7 ± 0.2 at 60-day follow-up ($p=0.002$).
- 4.6 In the RCT of 67 patients (intention-to-treat analysis) there was a statistically significant decrease in the monthly intake of migraine drugs for acute attacks in the tSNS group (11.45 ± 8.35 to 7.25 ± 7.31 ; $p=0.0057$), but not in the sham group (9.24 ± 4.75 to 9.28 ± 5.69 ; $p=0.822$). The difference between the 2 groups was statistically significant ($p=0.0072$). In the case series of 20 patients, there was a statistically significant reduction in the use of rescue drugs from 5.6 ± 0.4 medications at baseline to 2.2 ± 0.3 at 60-day follow-up ($p < 0.001$). Statistically significant reductions were also seen in the intake of non-steroidal anti-inflammatory drugs, from 3.2 ± 0.6 medications at baseline to 1.3 ± 0.4 at 60-day follow-up ($p=0.02$), and in triptans, from 2.4 ± 0.7 medications at baseline to 0.9 ± 0.3 at 60-day follow-up ($p=0.04$).
- 4.7 In the RCT of 67 patients the percentage of very or moderately satisfied

patients was higher in the tSNS group (70%) than in the sham group (39%). The case series of 20 patients reported 100% satisfaction with tSNS treatment at 60-day follow-up.

- 4.8 The specialist advisers listed key efficacy outcomes as changes in monthly migraine days, migraine attacks, total headache days, headache load (severity multiplied by duration), headache-free days and analgesic-free days.
- 4.9 Twenty commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

5 Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 One or more adverse events (minor and reversible) were reported in 4% (99/2,313) of patients in a case series of 2,313 patients. Some patients reported more than 1 event.
- 5.2 Local pain or intolerance to paraesthesia induced by the electrical stimulation was reported in 2% (47/2,313) of patients in the case series of 2,313 patients. All patients stopped the treatment.
- 5.3 Skin problems were reported in less than 1% (9/2,313) of patients in the case series of 2,313 patients. These included transient local skin allergy in 2 patients, reversible forehead skin irritation in 5 patients, and a feeling of bruising on the forehead in 2 patients.
- 5.4 Arousal and sleep changes were reported in less than 1% (19/2,313) of patients in the case series of 2,313 patients. These included insomnia in 4 patients, fatigue in 3 patients and sleepiness in 12 patients.
- 5.5 Tension-type headache was reported in less than 1% (12/2,313) of patients in the case series of 2,313 patients.

- 5.6 Weakness in jaw muscles and in upper and lower extremity muscles was reported in 1 patient 17 minutes after starting the device on the lowest setting. The patient also developed significant dizziness. These symptoms increased until the use of the device was stopped. After stopping the device, the muscle weakness and dizziness took approximately 2 hours to resolve completely. This adverse event was reported in the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database by a physician.
- 5.7 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: hyperalgesia, somnolence and local discomfort. They considered that the following were theoretical adverse events: hyperstimulation of the supraorbital nerve, headache exacerbation or aggravation.

6 Committee comments

- 6.1 The committee noted the large amount of supportive patient commentary received on this procedure. The committee also noted that this procedure may be particularly useful for patients who do not want to take medication or who cannot tolerate it.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).
- 7.2 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed [NICE's interventional procedure outcomes audit tool](#) (which is for use at local discretion).

Information for patients

NICE has produced information on this procedure for patients and carers ([information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).

Accreditation

