

Transcranial magnetic stimulation for treating and preventing migraine

Interventional procedures guidance

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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, and specifically any special arrangements relating to the introduction of new interventional procedures. 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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

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. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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

Transcranial magnetic stimulation (TMS) has been evaluated for use during the aura before a migraine episode or at the start of a migraine episode, with the intention of stopping or reducing the severity of the episode ('treatment'); or at planned intervals, with the intention of reducing the frequency and/or severity of migraine episodes ('prevention').

- 1.1 Evidence on the efficacy of TMS for the treatment of migraine is limited in quantity and for the prevention of migraine is limited in both quality and quantity. Evidence on its safety in the short and medium term is adequate but there is uncertainty about the safety of long-term or frequent use of TMS. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Patient selection should normally be done in specialist headache clinics and the procedure should only be used under the direction of clinicians specialising in the management of headache.
- 1.3 Patients should be informed that TMS is not intended to provide a cure for migraine and that reduction in symptoms may be modest.
- 1.4 Clinicians wishing to undertake TMS for treating and preventing migraine should take the following actions.
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and 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 TMS for the treatment and prevention of migraine (see [section 7.1](#)).

- 1.5 NICE encourages further research on TMS for treating and preventing migraine. Data should be collected for all patients not entered into controlled trials. Studies should describe clearly whether its use is for treatment or prevention. They should report details of patient selection and the dose and frequency of use. Outcome measures should include the number and severity of migraine episodes, and quality of life in both the short and long term. The development of any neurological disorders (such as epilepsy) in the short or longer term after starting treatment should be documented.

2 Indications and current treatments

- 2.1 Migraine is a common condition characterised by recurrent, pulsatile, unilateral or bilateral headaches that may last from hours to days and are often accompanied by nausea and sensitivity to light and sound. Migraine headache may be preceded by an aura, which can include visual or olfactory disturbances, or difficulties with speech (dysphasia). The [International Classification of Headache Disorders](#) (International Headache Society) provides a classification of migraine types.
- 2.2 Current treatment for migraine aims to prevent or stop episodes and manage symptoms with drugs such as triptans, analgesics and anti-emetics (as recommended in [NICE's guideline on headaches in over 12s](#)). Other treatments include nerve blocks, botulinum toxin type A injections (as recommended in [NICE's technology appraisal guidance on botulinum toxin type A for the prevention of headaches in adults with chronic migraine](#)) or acupuncture.

3 The procedure

- 3.1 Transcranial magnetic stimulation (TMS) is a non-invasive procedure that aims to

treat or prevent migraine episodes in people with acute or chronic migraine (with or without aura). TMS is given using a tabletop or handheld device that delivers a predetermined level of magnetic pulse or pulses to the head.

- 3.2 The device is placed on the scalp and either single (sTMS) or repeated (rTMS) magnetic pulses are delivered. The frequency, intensity, duration and interval times of pulses can be varied. Treatments can be automatically recorded by the device in an integrated headache diary, which can be used to identify headache patterns and trigger factors. Patients may continue to use regular medications, including drugs to prevent migraines.

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 [overview](#).

- 4.1 A multicentre randomised controlled trial of 164 patients treated for at least 1 attack of migraine with aura with a handheld single transcranial magnetic stimulation (sTMS) device (n=82) or with sham stimulation (n=82) reported that pain-free rates 2 hours after stimulation were significantly better with sTMS (39% [32 out of 82]) than with sham stimulation (22% [18 out of 82]; p=0.018). Sustained pain-free response rates (with no recurrence and no rescue drug use) significantly favoured sTMS at 24 hours (29% [24 out of 82] versus 16% [13 out of 82]; p=0.0405) and 48 hours (27% [22 out of 82] versus 13% [11 out of 82]; p=0.0327) after treatment. There were no significant differences in secondary outcomes (headache response at 2 hours, use of rescue drugs, Migraine Disability Assessment [MIDAS] score and consistency of pain relief response) between groups.
- 4.2 A case series of 51 patients with 'medically resistant migraine' using repeated transcranial magnetic stimulation (rTMS) for prevention reported that 98% (50 out of 51) of patients had a greater than 50% reduction in headache frequency at the end of 1 week and the improvement persisted at follow-up of 4 weeks in 80.4% (41 out of 51) of patients. Headache frequency and severity, functional disability and use of rescue drugs were significantly reduced at all time points (1, 2, 3 and

- 4 weeks, $p < 0.0001$) but the maximum benefit was observed in the first 2 weeks.
- 4.3 A case series of 27 patients with migraine comparing low-frequency rTMS ($n=14$) against sham stimulation ($n=13$) for prevention reported no significant difference between groups for any reported outcome (including number and duration of migraine attacks, mean pain intensity and use of analgesics). The 'within-group' findings showed a significant decrease in the number of migraine attacks during 8 weeks within the rTMS group from 9.36 ± 2.82 attacks to 6.79 ± 4.28 attacks ($p=0.007$), and a non-significant decrease within the sham group (numbers not reported; $p=0.216$). There was a significant reduction in migraine days during 8 weeks in both rTMS and sham groups (from 17.69 ± 11.63 days to 13.15 ± 9.27 days [$p=0.012$] and from 14.36 ± 5.07 days to 9.50 ± 6.80 days [$p=0.006$] respectively). The rTMS group showed a significant reduction in migraine hours during 8 weeks from 125.93 ± 80.31 hours to 85.36 ± 72.27 hours ($p=0.035$); the difference was not significant in the sham group (numbers not reported; $p=0.080$).
- 4.4 The specialist advisers listed additional efficacy outcomes as complete resolution of a migraine attack, reduction in headache severity, and improvement in associated symptoms, disability and quality of life.

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 [overview](#).

- 5.1 No device-related serious adverse events were reported in the randomised controlled trial of 164 patients.
- 5.2 Slight 'unsustained' dizziness ($n=1$), drowsiness ($n=1$) and tiredness ($n=2$) were reported in a case series of 42 patients after treatment with low- or high-intensity transcranial magnetic stimulation (TMS). None of these events recurred or needed medical attention.
- 5.3 Amyostasia (muscle tremor causing difficulty in standing, $n=1$), irritability ($n=1$),

'vigorous dreams' (n=1) and phonophobia (n=1) were reported after repeated TMS (rTMS) treatment in the case series of 27 patients.

- 5.4 The specialist advisers listed transient muscle contraction, pain at the stimulation site and hearing impairment during rTMS as additional anecdotal adverse events. The specialist advisers considered theoretical adverse events to include local scalp irritation, mood disorders, cognitive impairment, triggering of epilepsy during treatment and 'kindling' leading to seizures. One adviser raised the theoretical possibility of 'permanent neural changes' with prolonged use of rTMS.

6 Committee comments

- 6.1 The Committee noted that there is uncertainty about the optimal dose of transcranial magnetic stimulation (TMS) for both treatment and prevention of migraine, and the optimal frequency of use for prevention.
- 6.2 The Committee noted variation among the published studies in the indications for TMS and the treatment parameters used. This variation made evaluation complex and underpinned the [recommendation in 1.5](#) for future studies to include clear descriptions of indications and treatment regimens.
- 6.3 The Committee noted the absence of evidence on the safety of long-term use of TMS, although there are currently no reports of the procedure causing harm in the long term. The [recommendation in 1.5](#) about documenting neurological disorders in the longer term is based on the lack of information about possible long-term effects of the procedure.
- 6.4 The Committee was advised that TMS treatment may have a particular role in the reduction or avoidance of drug therapy, either where preferred, or where contraindicated or best avoided (for example, in pregnancy).

7 Further information

- 7.1 This guidance requires that clinicians undertaking the procedure make special

arrangements for audit. NICE has identified relevant [audit criteria](#) and is developing an [audit tool](#) (which is for use at local discretion).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). 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](#).