

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transcranial MRI-guided focused ultrasound thalamotomy for neuropathic pain

Neuropathic pain (nerve pain) can happen when damage to nerves affects pain signals to the brain. In this procedure, the patient lies inside an MRI scanner with a frame attached to their shaved head, and chilled water is circulated around the outside of the head to keep it cool. Focused ultrasound is then delivered to a small part of the brain responsible for transmitting pain signals (the thalamus) to destroy it. The procedure takes about 3 hours. The aim of the procedure is to relieve the pain.

The National Institute for Health and Care Excellence (NICE) is looking at transcranial MRI-guided focused ultrasound thalamotomy for neuropathic pain. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.

- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 23 August 2018

Target date for publication of guidance: November 2018

1 Draft recommendations

- 1.1 Current evidence on the safety of transcranial MRI-guided focused ultrasound thalamotomy for neuropathic pain shows there are potentially serious safety concerns. Also, there is very limited evidence of efficacy. Therefore, this procedure should not be used.

2 The condition, current treatments and procedure

The condition

- 2.1 Neuropathic pain results from dysfunction of sensory nerves and pathways in the nervous system. It can occur in a heterogeneous group of disorders, including painful diabetic neuropathy, post-herpetic neuralgia and trigeminal neuralgia. People with neuropathic pain may have altered pain sensation, areas of numbness or burning, and continuous or intermittent evoked or spontaneous pain. Neuropathic pain is an unpleasant sensory and emotional experience that can have a significant effect on a person's quality of life.

Current treatments

- 2.2 A range of different drugs are used to manage neuropathic pain, including antidepressants, anti-epileptic drugs, opioids, and topical treatments such as capsaicin and lidocaine (see NICE's guideline on [neuropathic pain: the pharmacological management of neuropathic pain in adults in non-specialist settings](#)). Neuropathic pain is often difficult to treat, because it can be refractory to many medications and because of the adverse effects associated with some drug treatments.
- 2.3 For neuropathic pain that is refractory to drug treatment, other options include percutaneous electrical nerve stimulation, spinal cord stimulation and deep brain stimulation.

The procedure

- 2.4 Transcranial MRI-guided focused ultrasound thalamotomy for neuropathic pain is done with the patient lying supine inside an MRI scanner. The patient's head is shaved and a stereotactic head frame is attached. Patients are awake so they can report any improvement or adverse events to the operator during the procedure. However, they may be offered light sedation. Continuous MRI and thermal mapping are used to identify the target area of the brain and monitor treatment. Low power ultrasound is delivered to confirm the chosen location. Then, high-power focused ultrasound pulses are administered to irreversibly ablate the target tissue. Chilled water is circulated around the outside of the head during the treatment to prevent thermal damage to the scalp caused by the increase in bone temperature. The procedure takes about 3 hours and pain relief should occur within a day of the procedure.

3 Committee considerations

The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 2 sources, which was discussed by the committee. The evidence included 2 case series, and is presented in table 2 of the [interventional procedures overview](#). Other relevant literature is in the appendix of the overview.

- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: reduced neuropathic pain, improved patient-reported outcomes including quality of life, and long-term efficacy.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: bleeding and inadvertent neurological damage, including stroke and cognitive dysfunction.

Committee comments

- 3.4 The committee was informed that surgical thalamotomy for neuropathic pain is not currently done in the UK.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

July 2018

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