

Transcranial MRI-guided focused ultrasound thalamotomy for neuropathic pain

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg632

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

- 1.1 Current evidence on the safety of transcranial MRI-guided focused ultrasound thalamotomy for neuropathic pain shows there are serious safety concerns. There is very limited evidence of efficacy. Therefore, this procedure should not be used. Find out [why NICE recommends not to use some procedures on the NICE interventional procedures guidance page](#).

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 clinical guideline on neuropathic pain in adults: pharmacological management 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 3 sources, which was discussed by the committee. The evidence included 3 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.
- 3.4 Patient commentary was sought but none was received.

Committee comments

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

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Endorsing organisation

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