NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor

Essential tremor has no known cause but may get worse with time and be resistant to treatment. This procedure uses a special head frame that allows ultrasound to be applied to a specific area on 1 side of the brain (thalamus) with MRI guidance. The aim is to reduce the tremors.

The National Institute for Health and Care Excellence (NICE) is looking at unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor. 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.

Issue date: February 2018

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, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 22 March 2018

Target date for publication of guidance: June 2018

1 Draft recommendations

1.1 The evidence on the safety of unilateral MRI-guided focused ultrasound unilateral thalamotomy for treatment-resistant essential tremor raises no major safety concerns. However, current evidence on its efficacy is limited in quantity. Therefore, this procedure should not be used unless there are special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to do unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients and their carers understand that this procedure can only treat tremor on 1 side of the body, and that the impact of this on the functional ability and quality of life of patients with bilateral disease is uncertain. Explain all alternative treatment options to patients, including those that can treat tremor on both sides of the body. Provide patients with clear written information to support shared decision-making. In addition, the use of NICE's information for the public *[[URL to be added at publication]]* is recommended.
- Audit and review clinical outcomes of all patients having unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.

1.3 Patient selection should be done by a multidisciplinary team experienced in managing essential tremor, including clinicians with specific training in the procedure.

1.4 Further research, which could include randomised controlled trials, should address patient selection, report on functional improvement and quality of life, and provide long-term follow-up data.

2 The condition, current treatments and procedure

The condition

2.1 Essential tremor is the most common cause of disabling tremor and is distinct from Parkinson's disease. It typically affects the arms and hands, although it may also involve the head, jaw, tongue and legs. The cause is not known but many patients have a family history of the condition. At first, the tremor may not be present all the time. However, it gradually worsens. Purposeful movement, stress, tiredness, hunger, heightened emotions or extremes in temperature make it worse.

Current treatments

2.2 Treatment for essential tremor includes medications such as beta blockers (for example, propranolol), anti-epileptics (for example, primidone) or sedatives (for example, clonazepam). Rarely, injections of botulinum toxin may be used.

2.3 Surgery may be considered in people whose condition has not responded adequately to best medical therapy. Surgical treatments include deep brain stimulation and radiofrequency thalamotomy.

The procedure

2.4 This procedure is carried out with the patient lying supine inside an MRI scanner. The patient’s head is shaved and a stereotactic head frame is attached. Patients are kept 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 (sub-lethal) ultrasound is delivered to confirm the chosen location. Then, high-power focused ultrasound pulses are administered to irreversibly ablate target tissue. Chilled water is circulated around 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 symptom relief should be immediate.

2.5 The potential benefits of unilateral MRI-guided focused ultrasound thalamotomy are that it: is less invasive than the other existing procedures; results in a faster recovery time; and allows for testing of the effects of sub-lethal doses before ablation. However, unlike deep brain stimulation, it can only be done on 1 side.

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 10 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial (2 publications providing 1 and 2 years follow-up), 2 non-randomised comparative studies and 6 case series, and is presented in table 2 of the interventional procedure overview. Other relevant literature is in appendix A of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: sustained reduction in tremor, improved quality of life and functional improvement.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: unintentional neurological consequences and intracerebral bleeding.

3.4 No patient commentary was sought because this procedure is currently only done in research in the UK.

Committee comments

3.5 The committee noted that essential tremor can have major consequences on the quality of life for many people.

3.6 This procedure is an alternative to more invasive methods of lesioning the thalamus and the lesion produced should be considered permanent.

3.7 While this procedure does not preclude subsequent treatments for essential tremor (such as deep brain stimulation), the effects on those subsequent treatments are unknown.

3.8 There is a comprehensive training programme offered by the company manufacturing the device used in this procedure.

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Chairman, interventional procedures advisory committee
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