

Unilateral MRI-guided focused ultrasound thalamotomy for moderate to severe tremor in Parkinson's disease

Interventional procedures guidance
Published: 28 February 2018

www.nice.org.uk/guidance/ipg606

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 and efficacy of unilateral MRI-guided focused ultrasound thalamotomy for moderate to severe tremor in Parkinson's disease is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- 1.2 Further research, which could include randomised controlled trials, should address patient selection and report on long-term follow-up.

2 The condition, current treatments and procedure

The condition

- 2.1 Parkinson's disease is a progressive neurodegenerative disease characterised by gradually worsening tremor, muscle rigidity, and difficulties with starting and stopping movements. The tremor in Parkinson's disease occurs at rest and becomes less prominent with voluntary movement. It typically occurs first in the distal upper extremities then moves proximally and spreads to affect other parts of the body over time.

Current treatments

- 2.2 Treatment for Parkinson's disease includes supportive therapies and medications such as levodopa, dopamine agonists and monoamine oxidase B inhibitors.
- 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 5 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial and 4 case series and is presented in [table 2 of the interventional procedure 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 device used for unilateral MRI-guided focused ultrasound thalamotomy is CE marked for use in unilateral procedures, so the procedure can only treat tremor on 1 side of the body.
- 3.6 There is a comprehensive training programme offered by the company manufacturing the device used in this procedure.

ISBN: 978-1-4731-2836-1

Endorsing organisation

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