

MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg671

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 Evidence on the safety of MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy shows there are serious but well-recognised safety concerns. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wishing to do MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy should:
 - Inform the clinical governance leads in their NHS trusts.
 - Give patients and their parents or carers clear written information to support shared decision making, including NICE's information for the public.
 - Ensure that patients and their parents or carers understand the procedure's safety and efficacy, as well as any uncertainties about these.
 - Audit and review clinical outcomes of all patients having the procedure. NICE has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).
- 1.3 Patient selection should be done by a multidisciplinary team experienced in managing drug-resistant epilepsy. This may include a neurologist, neurosurgeon, neurophysiologist, neuroradiologist and psychiatrist.
- 1.4 The procedure should only be done in specialist centres by clinicians

with experience and specific training.

- 1.5 Further research could be in the form of randomised controlled trials, large case series or collaborative registries. It should report details of patient selection, including the size and site of the lesions being created, patient-reported outcomes and long-term follow up, particularly neurodevelopmental outcomes in children.

2 The condition, current treatments and procedure

The condition

- 2.1 Epilepsy is a neurological condition characterised by episodes of abnormal electrical activity in the brain (recurrent seizures). The seizures can be focal or generalised.

Current treatments

- 2.2 The main treatment for epilepsy is antiepileptic drugs taken to prevent or reduce the occurrence of seizures. However, many people with epilepsy have drug-resistant epilepsy, which is refractory to drug treatment (estimates vary between 20% and 40% of people with epilepsy). They have frequent seizures and are at risk of status epilepticus and sudden unexpected death in epilepsy. If drug treatment fails to control the epilepsy adequately, surgery may be considered. Surgical options include open surgical resection (such as lesionectomy, anterior temporal lobectomy or hemispherectomy) or disconnection (such as multiple subpial transection or corpus callosotomy), neuroablation (for example, with stereotactic radiosurgery, radiofrequency thermocoagulation or MRI-guided focused ultrasound) or neuromodulation (such as cranial nerve stimulation, deep-brain stimulation or closed-loop stimulation).

The procedure

- 2.3 Preoperatively, an MRI scan is done to identify the part of the brain causing the seizures and to identify the entry location for the laser catheter. The procedure is usually done under general anaesthesia with the patient lying on an MRI couch. A small burr hole is made in the skull and a fine fibreoptic laser catheter is inserted into the target area under stereotactic guidance. Continuous real-time MRI scanning is done to allow visualisation of the exact target area to be ablated and the surrounding tissue, and to monitor the temperature in the brain during the procedure. Under computer guidance, laser energy is applied to the target area. The laser is switched off and removed when temperatures have reached levels sufficient to cause coagulation necrosis (usually 46°C to 60°C) and the target tissue has been ablated. After the procedure, an MRI is done to verify the location and volume of the tissue ablated. The aim is to precisely ablate the target tissue and to minimise damage to the surrounding area. MRI-guided laser interstitial thermal therapy has most commonly been used for patients with a well-defined epileptogenic focus, especially in the temporal lobe, but it can be used elsewhere in the brain.

3 Committee considerations

The evidence

- 3.1 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 7 sources, which was discussed by the committee. The evidence included 2 meta-analyses, 2 reviews, 1 retrospective case series and 2 case reports. It is presented in [table 2 of the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: frequency and severity of seizures, reduction in antiepileptic medication, reduction in the need for further surgery, and quality of life.

- 3.3 The professional experts and the committee considered the key safety outcomes to be: damage to adjacent structures, intracranial or cerebral haemorrhage, cranial nerve or neurological deficit, gait disturbance, visual field deficits, cognitive deficit or psychiatric disturbance, and amnesic disorder.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee noted that, in adults, the procedure has primarily been used to treat temporal lobe epilepsy. In children it has primarily been used for hypothalamic hamartomas.
- 3.6 The committee was informed that the procedure is much less invasive than open surgery.
- 3.7 The committee was advised that, in the future, this procedure may be offered as an alternative to drug treatment for epilepsy.
- 3.8 The committee was pleased to receive consultation comments from patients and their advocates.
- 3.9 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.