NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Deep brain stimulation for refractory epilepsy

Epilepsy is when abnormal electrical activity in the brain causes fits (seizures). If it cannot be controlled by drugs it is called refractory epilepsy. In this procedure, electrodes are placed deep into the brain. They are connected by wires to a small electrical stimulator implanted under the skin on the chest. The wires pass under the skin behind the ear and down the neck. The aim is that electrical stimulation will stop abnormal electrical activity in the brain and reduce seizures.

This is a review of NICE's interventional procedures guidance on deep brain stimulation for refractory epilepsy.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

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

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation 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: 4 February 2020

Target date for publication of guidance: May 2020

1 Draft recommendations

1.1 Evidence on the safety and efficacy of deep brain stimulation for refractory epilepsy differs according to the site of stimulation:

- For anterior thalamic targets the evidence is limited in quantity and quality, therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.
- For targets other than the anterior thalamus the evidence is inadequate in quantity and quality, therefore this procedure should only be used in the context of research.

1.2 Clinicians wishing to do deep brain stimulation of anterior thalamic targets for refractory epilepsy should:

- Inform the clinical governance leads in their NHS trusts.
- Give patients clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients 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 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 epilepsy including a neurologist, neurophysiologist and neurosurgeon.

1.4 The procedure should only be done in neurosurgery centres that specialise in managing epilepsy.

1.5 Further research should describe patient selection and clearly define the target area of the brain. Outcomes should include reduction in seizure frequency and improvement in the epilepsy seizure outcome scale, quality of life, reduction in concomitant medication and hospital admissions.

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 which cause recurrent seizures. The seizures can be focal or generalised.

Current treatments

2.2 The main treatment for epilepsy is anti-epileptic drugs taken to prevent or reduce the occurrence of seizures. However, many people have drug-resistant (refractory) epilepsy. They experience frequent seizures and are at risk of status epilepticus and sudden unexpected death in epilepsy.

2.3 Surgery may be considered for refractory epilepsy. 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 (using 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

2.4 Deep brain stimulation involves implanting electrodes into specific target areas of the brain. Although the mechanisms of action are not fully understood, the aim of the procedure is to reduce or suppress seizure frequency. A potential advantage of the procedure is its reversibility. It is an option for some patients with medically refractory epilepsy when resective surgery is not indicated.

2.5 The procedure is done using general or local anaesthesia. A stereotactic frame may be used. Imaging (MRI or CT) is used to identify the target area of the brain (most commonly the anterior nucleus of the thalamus but may include the centromedian thalamic nucleus, hippocampus and nucleus accumbens). One or more small holes are drilled in the skull and electrodes are implanted into the target area.

2.6 A neurostimulator is surgically placed into a subcutaneous pocket below the clavicle. The electrodes are connected to the neurostimulator by leads that are tunnelled under the skin of the neck and scalp. Postoperative imaging is usually used to confirm the location of the electrodes. A handheld remote-control programming unit is used to turn the neurostimulator on or off, adjust stimulation parameters, and monitor activity.

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

13 sources, which was discussed by the committee. The evidence included 3 randomised controlled trials (one of which resulted in 3 publications), 3 systematic reviews, 1 non-randomised comparative study, 1 case series and 3 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 reduction in seizure frequency and improvement in the epilepsy seizure outcome scale, quality of life, reduction in hospital admissions and reduction in concomitant medication.

3.3 The professional experts and the committee considered the key safety outcomes to be device failure and off-target stimulation.

Committee comments

3.4 The committee noted that most of the evidence is from patients aged 18 to 70 years.

3.5 The committee was informed that the devices used for this procedure only have regulatory approval for use in adults.

3.6 The committee was informed that the efficacy of this procedure may vary by type of epilepsy.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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