NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Daytime intraoral neuromuscular electrical tongue stimulation using a removable device for obstructive sleep apnoea

Obstructive sleep apnoea happens when the airway in the throat narrows during sleep causing breathing to repeatedly stop for short periods. This narrowing may be caused by the tongue falling backwards.

In this procedure, a mouthpiece is placed around the tongue inside the mouth (intraoral). It delivers electrical stimulation to the muscles of the tongue (neuromuscular). The device is used at home during the daytime, typically for 20 minutes once a day for 6 weeks. The person using the device controls the level of stimulation. The aim is to reduce airway obstruction during sleep.

NICE is looking at daytime intraoral neuromuscular electrical tongue stimulation using a removable device for obstructive sleep apnoea.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts 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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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:

Issue date: November 2022

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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 January 2023

Target date for publication of guidance: April 2023

1 Draft recommendations

1.1 Evidence on the safety and efficacy of daytime intraoral neuromuscular electrical tongue stimulation using a removable device for obstructive sleep apnoea is inadequate in quality and quantity. So, this procedure should be used only in research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Further research should include suitably powered randomised controlled trials and analysis of observational data, to assess efficacy, safety and adherence. Research should report details of patient selection, duration of treatment and effect, effect on snoring, quality of life, and complications.

2 The condition, current treatments and procedure

The condition

2.1 Obstructive sleep apnoea (OSA) is a condition in which the upper airway narrows or closes during sleep when the throat muscles intermittently relax. This causes reduced breathing (hypopnoea) or breathing to temporarily stop (apnoea). OSA can lead to major neurocognitive and cardiovascular sequelae.

Current treatments

2.2 Management of OSA includes lifestyle changes (such as weight loss), continuous positive airway pressure, oral devices (mandibular advancement devices), neuromuscular electrical stimulation and upper airway surgery.

The procedure

2.3 In this procedure, an intraoral removable device is used to deliver electrical stimulation to the intrinsic and extrinsic (genioglossus) muscles of the tongue. The aim is to improve tongue endurance and reduce airway obstruction during sleep.

2.4 A mouthpiece with an electrode array that fits onto the tongue is placed in the mouth by the patient during the daytime while they are awake. Bipolar biphasic current is then delivered for about 20 minutes with predetermined low frequency stimulation and rest periods. The mouthpiece is removed once the session is complete. The intensity of the stimulation is controlled by the patient, for example by using a smartphone app. An entire therapy usually lasts about 6 weeks, with a 20-minute daytime session each day while awake.

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 2 sources, which was discussed by the committee. The evidence included 1 single-arm clinical trial (3 papers) and 1 pilot study. It is presented in the summary of key evidence section in 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: improvement in sleep apnoea, reduction in snoring and improvement in quality of life (of the person with obstructive sleep apnoea and their bed partner).

3.3 The professional experts and the committee considered the key safety outcomes to be: pain and tingling or unpleasant sensation in the mouth.

3.4 Two submissions from patient organisations about this procedure were discussed by the committee. Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that this procedure is currently only indicated for mild obstructive sleep apnoea.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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