NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Electrical stimulation of the pharynx for neurogenic dysphagia

Neurogenic dysphagia is difficulty swallowing (dysphagia) caused by conditions that affect the nervous system (neurogenic), for example stroke, multiple sclerosis, and Parkinson's disease. It can cause coughing and choking, and food or drink may go into the lungs, which can lead to chest infections. In this procedure, a catheter is passed through the nose and into the throat (pharynx). The catheter delivers small amounts of electricity to the pharynx, which travels to the areas of the brain involved in swallowing. The aim is to improve swallowing and reduce other symptoms.

NICE is looking at electrical stimulation of the pharynx for neurogenic dysphagia.

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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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

Issue date: September 2022

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: 21 October 2022

Target date for publication of guidance: March 2023

1 Draft recommendations

1.1 Evidence on the safety and efficacy of electrical stimulation of the pharynx for neurogenic dysphagia is inadequate in quality and quantity. 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 should be in the form of randomised controlled trials comparing the procedure with standard care. It should report details of patient selection (including the cause of dysphagia and the timing of the intervention) and the treatment protocol (including the method of stimulation, stimulation intensity, and duration of delivery).

2 The condition, current treatments and procedure

The condition

2.1 Difficulty in swallowing (dysphagia) can be caused by neurological impairment affecting the muscles of the oropharynx. It can happen because of several conditions including stroke, traumatic brain injury, disorders of cerebral development, neurodegenerative diseases, major head and neck surgery (for example, to remove cancer) and intensive care treatment (intubation and tracheostomy). Dysphagia may lead to malnutrition, dehydration, aspiration pneumonia and death.

Current treatments

2.2 Treatment options depend on the cause and severity of the dysphagia. Typical treatments include diet modification (inclusion of thicker fluids and foods) and swallowing therapy (to help relearn swallowing and strengthen muscles). In severe cases, nasogastric

tubes, or percutaneous endoscopic gastrostomy or jejunostomy tubes, may be used to provide nutritional support.

The procedure

2.3 A catheter with 2 electrodes on the outside is passed through the nose into the pharynx. Guide marks on the catheter are used to ensure it is correctly positioned to deliver low-level pharyngeal electrical stimulation. The catheter is connected to a portable base station, which stores patient information and adjusts the stimulation variables. The exact stimulation level is calculated on an individual basis at the start of each treatment session. Treatment is given by a healthcare professional with appropriate training and typically consists of 10 minutes of stimulation each day for 3 consecutive days. People may experience a fizzing or tingling sensation in the throat during the procedure. The focused stimulation aims to increase brain activity in the swallowing control centre and restore neurological control of the swallowing function. The dual function catheter enables administration of enteral nutrition and fluids, if needed, as well as delivering electrical stimulation.

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 systematic reviews and meta-analyses, 2 randomised controlled trials, 1 registry analysis, and 2 pilot studies. 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: improved dysphagia, less need for nasogastric and percutaneous endoscopic gastrostomy or jejunostomy feeding, and less time to tracheostomy decannulation.

3.3 The professional experts and the committee considered the key safety outcomes to be: device-related discomfort and aspiration.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 Most of the evidence reviewed by the committee was from people with stroke. One of the randomised controlled trials in this population showed no benefit of electrical stimulation of the pharynx.

3.6 The committee was informed that the optimal treatment protocol had not been defined.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
September 2022

ISBN: