NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Pharyngeal electrical stimulation 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. People with severe dysphagia may need a tracheostomy.

NICE is looking at pharyngeal electrical stimulation for neurogenic dysphagia. In this procedure, a catheter is passed through the nose and into the throat (pharynx). The catheter delivers small amounts of electrical current to the pharynx. The electrical current travels to the brain and stimulates the areas involved in swallowing. The aim is to improve swallowing and reduce other symptoms.

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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

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- 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: 21st September 2023

Target date for publication of guidance: January 2024

1 Draft recommendations

People with neurogenic dysphagia who have a tracheostomy after stroke

1.1 For people with neurogenic dysphagia who have a tracheostomy after stroke, pharyngeal electrical stimulation 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 wanting to do pharyngeal electrical stimulation for people with neurogenic dysphagia who have a tracheostomy after stroke should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.

- Regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should be done by healthcare professionals experienced in managing neurogenic dysphagia with specific training in the procedure. An endoscopic assessment may be used.

1.5 The procedure should only be done by healthcare professionals with specific training in the procedure.

People with neurogenic dysphagia after stroke who do not have a tracheostomy, and people with other causes of neurogenic dysphagia

1.6 For people with neurogenic dysphagia after stroke who do not have a tracheostomy and people with other causes of neurogenic dysphagia, pharyngeal electrical stimulation should be used only in research. Find out what only in research means on the NICE interventional procedures guidance page.

1.7 Further research should report:

- details of patient selection (including the cause of dysphagia and the timing of the intervention)
- the treatment protocol (including the method of stimulation, stimulation intensity and duration of delivery)
- effects on length of hospital stay compared with usual care.

Why the committee made these recommendations

People with neurogenic dysphagia have an increased risk of getting food or drink in the lungs, which can cause infection (aspiration pneumonia). In severe cases, they may need ventilation in an intensive care unit, and a tracheostomy and feeding tubes. There are limited treatment options for people with neurogenic dysphagia. There are no safety concerns about pharyngeal electrical stimulation, but there is more evidence on clinical efficacy for 1 group of people than for the others.

Clinical trial and registry evidence shows that pharyngeal electrical stimulation allows the tracheostomy tube to be removed earlier for people with neurogenic dysphagia after stroke. This helps with recovery, because having a tracheostomy makes it difficult to take part in other rehabilitation treatments. Tracheostomy removal also allows earlier transfer out of intensive care and may reduce overall length of hospital stay. This is an important benefit for these people, but more data on other clinical efficacy outcomes is needed. So, for people with neurogenic dysphagia who have a tracheostomy after stroke, this procedure should only be used with special arrangements.

The evidence on clinical efficacy of pharyngeal electrical stimulation for people with neurogenic dysphagia after stroke who do not have a tracheostomy is not clear. There is also not enough evidence to show clinical efficacy for people with other causes of neurogenic dysphagia. So, for people with neurogenic dysphagia after stroke who do not have a tracheostomy, and people with other causes of neurogenic dysphagia, this procedure should be used only in research.

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 pharynx. 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 management includes diet modification (including thicker fluids and foods) and swallowing therapy (to help relearn swallowing, and strengthen muscles). Transcutaneous neuromuscular electrical stimulation has also been used for pharyngeal dysphagia. In moderate or 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 6 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

8 sources, which was discussed by the committee. The evidence included 2 systematic reviews and meta-analyses, 3 randomised controlled trials (RCTs), 1 registry analysis and 2 pilot RCTs. 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:

- time to tracheostomy removal (decannulation)
- degree of aspiration
- change in dysphagia
- the need for nasogastric and percutaneous endoscopic gastrostomy or jejunostomy feeding.

3.3 The professional experts and the committee considered the key safety outcomes to be:

- device-related discomfort or injury
- degree of aspiration.

3.4 Three telephone and 6 survey commentaries from people who have had this procedure were discussed by the committee.

Committee comments

3.5 The intensity of electrical stimulation applied is higher in more recent clinical practice and trials compared with earlier studies.

3.6 There is a large ongoing RCT being done in people with stroke without a tracheostomy. This is due to complete in February 2025. There is an ongoing registry study in people with acute neurogenic dysphagia that is due to complete in December 2024.

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Chair, interventional procedures advisory committee

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