NICE guidance

Pharyngeal electrical stimulation for neurogenic dysphagia

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg781

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

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 can be used in the NHS while more evidence is generated. It can only be used with special arrangements for clinical governance, consent, and audit or research.

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 and with specific training in the procedure. An endoscopic or videofluoroscopic 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, more research is needed on pharyngeal electrical stimulation.

1.7 This procedure should only be done as part of a formal research study and a research ethics committee needs to have approved its use.

1.8 More research is needed on:

- details of patient selection (including the cause of dysphagia and the timing of the intervention)
- effects on length of hospital stay compared with usual care.

Why the committee made these recommendations

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

Tracheostomy tube removal is an important outcome for people with neurogenic dysphagia after a stroke. Early removal 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 and improve quality of life. 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. But, evidence on other clinical efficacy outcomes including the degree of aspiration and the severity of dysphagia is unclear, so more evidence 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. Research studies in this group do not show clear evidence that the procedure leads to better clinical outcomes compared with placebo treatments. 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) is caused by neurological impairment. 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), trauma 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. Compensatory strategies include modifying diet (including thicker fluids and foods) and in moderate or severe dysphagia, nasogastric tubes, percutaneous endoscopic gastrostomy tubes or jejunostomy tubes may be used to provide nutritional support. Rehabilitation strategies include swallowing therapy (to help relearn swallowing and strengthen muscles) and for some people, transcutaneous neuromuscular stimulation.

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 the person's information and adjusts the stimulation variables. The exact stimulation level is calculated for each person at the start of each treatment session. Treatment is given by a healthcare professional with appropriate training and typically a treatment cycle consists of 10 minutes of stimulation each day for 3 consecutive days, for up to 2 cycles. 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 can also be used to administer 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 severity of 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 and a letter to NICE 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 (the Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial [PhEAST]) being done in people with neurogenic dysphagia after stroke who do not have a tracheostomy. This is due to complete in 2025. There is also an ongoing RCT in people with post-extubation dysphagia that is due to complete in 2025 (Pharyngeal ICU Novel Electrical Stimulation Therapy [PhINEST] study).

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation