



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	Pharyngeal electrical stimulation for neurogenic dysphagia
Topic exploration report number:	TER217

Introduction and aims

Dysphagia is a term used to describe any neurological or muscular condition that affects normal swallowing function. Neurogenic dysphagia occurs when there is damage to or disruption of any component of the nervous system involved in swallowing control. There can be many causes, but the most common include stroke, amyotrophic lateral sclerosis, or brain injury due to trauma or surgery.

Pharyngeal electrical stimulation (PES) is a rehabilitation treatment for neurogenic dysphagia, which uses electrodes inserted via an intranasal catheter to stimulate the pharynx directly. Other neurostimulation methods can also be used to treat neurogenic dysphagia, including repetitive transcranial magnetic stimulation and transcranial direct current stimulation. Surface neuromuscular electrical stimulation is another method of stimulation; this uses electrodes placed on the surface of the neck to stimulate the muscles involved in swallowing.

Health Technology Wales researchers searched for evidence on the effectiveness of pharyngeal electrical stimulation to treat neurogenic dysphagia, compared to any other treatment or to no treatment.

Summary of evidence

Secondary evidence

We did not identify any relevant health technology assessments or economic evaluations of PES for neurogenic dysphagia. In 2018, NICE published Interventional Procedures Guidance on transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia. As described above, this is an alternative type of stimulation and differs from PES in that it uses external electrodes to stimulate the swallowing muscles and is used in conjunction with swallowing exercises. The Guidance states that for adults with dysphagia after a stroke, the evidence on efficacy suggests a potential benefit, but is limited in quality and quantity. For adults with dysphagia not caused by a stroke, the Guidance states that there is insufficient

evidence on efficacy to support the use of transcutaneous neuromuscular electrical stimulation.

We identified two systematic reviews that studied PES, both of which only included people with post-stroke dysphagia and not other types of neurogenic dysphagia. One review (Scutt, 2015) conducted meta-analysis using individual patient level data to compare PES to no treatment/sham treatment, whilst the second (Chiang, 2019) studied a range of neurostimulation techniques, including PES, and compared them to each other or to no treatment/sham treatment using network meta-analysis. The two systematic reviews reached differing conclusions about the effectiveness of PES for post-stroke dysphagia. The review by Chiang et al reported that differences in swallowing function after PES treatment were not significantly different to placebo (but swallowing function did improve significantly with other neurostimulation techniques studied in the review). The review by Scutt et al reported improvements in clinical aspiration and dysphagia scores after two weeks in people treated with PES compared to no treatment, but not for other measured outcomes.

Primary studies

We found two randomised trials of PES in post-stroke patients that were not included in either systematic review (Suntrup, 2015; Dziewas, 2018, 69 and 30 patients studied respectively). Both studied PES compared to sham treatment in stroke patients who required a tracheostomy. Both trials reported that patients who received PES were more likely to be ready for decannulation at specified time intervals after treatment.

One small pilot randomised trial (Restivo, 2013) also studied PES in a non-stroke population (20 people with multiple sclerosis and dysphagia). Compared to sham treatment, 5 days of PES resulted in improvement in patients' penetration and aspiration score.

Ongoing research

We identified two ongoing systematic reviews of clinical effectiveness of interventions for dysphagia. These plan to cover a range of interventions including (but not specific to) PES. We also identified one ongoing systematic review of economic evaluations in this area.

Areas of uncertainty

Two existing systematic reviews of PES reach differing conclusions about its effectiveness on dysphagia. It is unclear whether this is due to the differing methods used or the different times at which the reviews were published (2015 and 2019). Although PES has been studied as part of several RCTs, all of these trials were relatively small: the total number of patients included ranged from 18 to 162.

The evidence available compares PES to sham/no treatment, or to other neurostimulation techniques (via an indirect comparison method). It is unclear whether this is representative of standard care in Wales. Although neurogenic dysphagia can have a range of causes, the majority of evidence from randomised trials describes its use to treat post-stroke patients.

Conclusions

Evidence on the use of PES to treat post-stroke dysphagia is available from systematic reviews of randomised trials, but these draw mixed conclusions about its effectiveness: one reported improvements in aspiration and dysphagia outcomes compared to sham treatment, but the second review found no statistically significant difference in swallowing function between

people who had PES or sham treatment. Two randomised trials published after this review suggest PES may reduce the time to decannulation compared to sham treatment. Outside of non-stroke populations, PES has also been studied for use in people with MS in a small pilot randomised trial. We did not identify any evidence on the use of PES to treat dysphagia in other populations, such as after brain injury.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland	We did not identify any relevant guidance from this source
Health Technology Assessment Group	We did not identify any relevant guidance from this source
Health Information and Quality Authority	We did not identify any relevant guidance from this source
EUnetHTA	We did not identify any relevant guidance from this source
International HTA Database	Horizon Scanning Centre. Phagenyx for stroke-induced dysphagia. http://www.io.nihr.ac.uk/wp-content/uploads/migrated/2352.68b9021d.PhagenesisPhagenyxforstrokeinduceddysphagiaFINAL2.pdf
UK guidelines and guidance	
SIGN	Management of patients with stroke: Identification and management of dysphagia. SIGN guideline 119. June 2010. https://www.sign.ac.uk/our-guidelines/management-of-patients-with-stroke-identification-and-management-of-dysphagia/
NICE	<p>Transcutaneous neuromuscular electrical stimulation for oropharyngeal dysphagia in adults. Interventional procedures guidance [IPG634]. Published date: 19 December 2018. https://www.nice.org.uk/guidance/ipg634 <i>This guidance covers a potential comparator procedure and does not include any evidence on the effectiveness of PES.</i></p> <p>Stroke rehabilitation in adults. Clinical guideline [CG162]. Published date: 12 June 2013. https://www.nice.org.uk/guidance/cg162 <i>This guideline includes recommendations on swallowing therapy but does not recommend any specific type of treatment or method of rehabilitation.</i></p>
Secondary literature and economic evaluations	
https://www.epistemonikos.org/en/	Chiang CF, Lin MT, Hsiao MY, Yeh YC, Liang YC, Wang TG. Comparative Efficacy of Noninvasive Neurostimulation Therapies for Acute and Subacute Poststroke Dysphagia: A Systematic Review and Network Meta-analysis. Arch Phys Med Rehabil. 2019;100(4):739-750.e4. https://doi.org/10.1016/j.apmr.2018.09.117
https://www.tripdatabase.com/	Scutt P, Lee HS, Hamdy S, Bath PM. Pharyngeal Electrical Stimulation for Treatment of Poststroke Dysphagia: Individual Patient Data Meta-Analysis of Randomised Controlled Trials. Stroke Res Treat. 2015;2015:429053. https://doi.org/10.1155/2015/429053
Primary studies	
https://www.epistemonikos.org/en/	No additional resources found.

<p>https://www.tripdatabase.com/</p>	<p>Vasant DH, Michou E, O'Leary N, et al. Pharyngeal Electrical Stimulation in Dysphagia Poststroke: A Prospective, Randomized Single-Blinded Interventional Study. <i>Neurorehabil Neural Repair</i>. 2016;30(9):866-875. https://doi.org/10.1177/1545968316639129</p> <p>Bath PM, Scutt P, Love J, et al. Pharyngeal Electrical Stimulation for Treatment of Dysphagia in Subacute Stroke: A Randomized Controlled Trial. <i>Stroke</i>. 2016;47(6):1562-1570. https://doi.org/10.1161/strokeaha.115.012455</p> <p>Suntrup S, Marian T, Schröder JB, et al. Electrical pharyngeal stimulation for dysphagia treatment in tracheotomized stroke patients: a randomized controlled trial. <i>Intensive Care Med</i>. 2015;41(9):1629-1637. https://doi.org/10.1007/s00134-015-3897-8</p> <p>Dziewas R, Stellato R, van der Tweel I, et al. Pharyngeal electrical stimulation for early decannulation in tracheotomised patients with neurogenic dysphagia after stroke (PHAST-TRAC): a prospective, single-blinded, randomised trial. <i>Lancet Neurol</i>. 2018;17(10):849-859. https://doi.org/10.1016/s1474-4422(18)30255-2</p>
<p>Ongoing primary or secondary research</p>	
<p>PROSPERO database</p>	<p>Sallyanne Duncan, Jennifer McGaughey, Margaret Walshe, Danny McAuley, Bronagh Blackwood, Richard Fallis. Interventions for oropharyngeal dysphagia in acute and critical care. PROSPERO 2018 CRD42018116849 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42018116849</p> <p>Sergio Marin Rubio, Mateu Serra-Prat, Omar Ortega Fernandez, Pere Clavé Civit. Pharmacoeconomics and economic evaluations of interventions in oropharyngeal dysphagia after stroke: a systematic review. PROSPERO 2020 CRD42020136245 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42020136245</p> <p>Jennifer Schneider, Sonja Reckziegel, Reto Rhinisperger, Martin Weber. The strengthening of muscles involved in the act of swallowing for neurogenic dysphagia in acute and subacute stroke: a systematic review. PROSPERO 2020 CRD42020133205 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42020133205</p>
<p>Other</p>	
<p>Relevant evidence provided by the topic proposer and not listed above</p>	<p>Restivo DA, Casabona A, Centonze D, Marchese-Ragona R, Maimone D, Pavone A. Pharyngeal electrical stimulation for dysphagia associated with multiple sclerosis: a pilot study. <i>Brain Stimul</i>. 2013 May;6(3):418-23. https://doi.org/10.1016/j.brs.2012.09.001 <i>Pilot randomised trial (n =20) comparing PES to sham treatment.</i></p> <p>National Tracheostomy Safety Project/Faculty of Intensive Care Medicine/Intensive Care Society. Guidance for Tracheostomy Care. August 2020. https://www.ficm.ac.uk/sites/default/files/2020-08-tracheostomy_care_guidance_final.pdf</p>

	<i>Refers to PES as an option for managing oral secretions in people with tracheostomy.</i>
Studies included within the systematic reviews and not already listed above	Jayasekeran V, Singh S, Tyrrell P, Michou E, Jefferson S, Mistry S, Gamble E, Rothwell J, Thompson D, Hamdy S. Adjunctive functional pharyngeal electrical stimulation reverses swallowing disability after brain lesions. <i>Gastroenterology</i> . 2010 May;138(5):1737-46. https://doi.org/10.1053/j.gastro.2010.01.052

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Concepts used:	Electrical stimulation, dysphagia