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Pharyngeal Electrical Stimulation for the Treatment of Dysphagia Associated With Neurologic Conditions

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Key Messages

- Horizon Scan reports provide brief summaries of information regarding new and emerging health technologies.
- These technologies are identified through the CADTH Horizon Scanning Service as topics of potential interest to health care decision-makers in Canada.
- This Horizon Scan summarizes the available information regarding an emerging technology, Phagenyx, a pharyngeal electrical stimulation device for the treatment of difficulty swallowing associated with neurologic conditions.

Pharyngeal Electrical Stimulation for the Treatment of Dysphagia Associated With Neurologic Conditions

Difficulty with swallowing or dysphagia can occur in several conditions, such as stroke or multiple sclerosis, and can lead to pneumonia, malnutrition, or dehydration. Several treatment modalities for dysphagia are available, including the Phagenyx electrical stimulation device which directly stimulates the sensory nerve fibres within the tissues of the throat.

How It Works

Phagenyx[1] (Phagenesis, Manchester, UK) is a pharyngeal electrical stimulation device developed for patients with difficulty swallowing. Phagenyx aims to address the neurological cause of dysphagia by stimulating the sensory nerve fibres within the pharynx, a tubular organ at the back of the throat that helps in swallowing and breathing. This nerve stimulation indirectly stimulates the part of the brain that controls swallowing and could help restore swallowing function.[2]

The Phagenyx device consists of a base station and a single-use nasogastric tube or catheter (Figures 1 and 2). The catheter is inserted into the patient's pharynx through the nose, similar to a feeding tube. There are small electrodes embedded in the catheter; markings are present to ensure the correct placement. The catheter is connected to the portable base station, which is used to send small electrical currents to the pharynx through the electrodes. The base station is intended to be operated by a health care professional, who can adjust and optimize the amount of electrical current delivered.[1]

The recommended treatment with the Phagenyx device is to apply electrical stimulation with a frequency of 5 Hz for 10 minutes a day for 3 consecutive days[1] (up to 6 consecutive days if necessary).[3] The level of electric current applied is determined based on the minimum level at which a sensation is felt and the maximum tolerable level for each patient. After each session, the catheter can be disconnected from the base station. The catheter can also be used as a feeding tube; therefore, it can be left in place for the duration of treatment without needing to insert separate catheters for feeding and treatment. The base station can also record and store patient treatment information.[1,4]

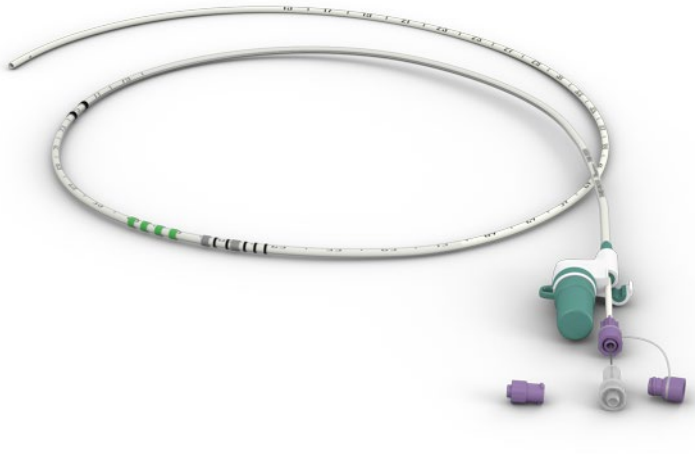
Who Might Benefit?

Dysphagia can occur in several conditions affecting the pharyngeal musculature, such as stroke, multiple sclerosis, cerebral palsy, and brain tumours.[5] Dysphagia can lead to malnutrition and increased risk for pneumonia, and may lead to poorer outcomes and higher

Figure 1: Phagenyx Base Station

Source: Image courtesy of Phagenesis Ltd.

Figure 2: Phagenyx Catheter



Source: Image courtesy of Phagenesis Ltd.

cost of treatment.[6] Patients with dysphagia due to neurologic causes such as stroke or multiple sclerosis could benefit from pharyngeal electrical stimulation using Phagenyx. In Canada, more than 62,000 people have a stroke every year, and approximately 405,000 people are living with the effects of a stroke.[7] It is estimated that approximately half of those who experience a stroke report symptoms related to dysphagia.[8] Multiple sclerosis, another cause of dysphagia, affects approximately 93,000 people in Canada.[9] Approximately 43% of patients with multiple sclerosis have difficulty swallowing.[10] These individuals may benefit from treatment with Phagenyx.

Availability in Canada

Phagenyx is not currently available in Canada, and it is unknown whether the manufacturer has plans to market the device in Canada. The device obtained a CE mark and has been available for use in Europe since 2012.[11] Phagenyx received FDA breakthrough device status in early 2020.[12]

What Does It Cost?

The cost of Phagenyx includes that of the base station as well as the single-use catheters. At present, the pricing information is unavailable. Because the device is intended for use by trained health care providers, the time associated with training may be an additional cost of implementation.

Current Practice

Assessment of dysphagia is done using videofluoroscopy swallowing studies and endoscopic examination of the pharynx.[13] If dysphagia is diagnosed, tube feeding is sometimes required to ensure nutrition. The Canadian stroke treatment guidelines recommend treatments to restore swallowing, including lingual resistance, breath holds, and effortful swallows and compensatory techniques such as posture adjustment to aid swallowing.[13]

Other treatment modalities include neuromuscular electrical stimulation devices that externally stimulate the muscles of the pharynx with electrodes applied to the neck, transcranial direct stimulation devices that stimulate the brain cortex using an externally applied electrode on the skull, physical therapy, compensatory techniques, and medications.[5]

What Is the Evidence?

The evidence regarding the effectiveness of electrical stimulation of the pharynx (with the Phagenyx device or other devices) for the treatment of dysphagia is evolving. An international

trial (published in 2016) in which participants with post-stroke dysphagia were randomized to receive either electrical stimulation of the pharynx (using the Phagenyx device) or sham stimulation did not find any significant effect of electrical stimulation of the pharynx on clinical dysphagia or aspiration.[14] In a 2020 prospective, single-arm cohort study that included participants with neurogenic dysphagia from stroke, traumatic brain injury, or other causes, treatment with Phagenyx was found to be safe and lowered dysphagia severity scores when treatment was started early.[15] Similarly, in 2 trials in which patients who had a stroke and required a tracheotomy were randomized to receive Phagenyx treatment or sham treatment found that significantly more patients who received electrical stimulation of the pharynx using Phagenyx were clinically improved and ready for their tracheal tube to be removed within 3 days.[3,16] A preliminary study conducted in patients with multiple sclerosis suggested that treatment with Phagenyx has potential benefit in improving swallowing function.[17]

Three systematic reviews with meta-analysis were identified that examined the efficacy of several swallowing treatments, including electrical stimulation of the pharynx in patients who have dysphagia after a stroke.[18-20] It was unclear whether the Phagenyx device was used for the electrical stimulation in all the primary studies included in the systematic reviews. The results of 2 meta-analyses suggested that electrical stimulation of the pharynx did not have an effect on outcomes such as death, length of hospitalization, swallowing ability, nutrition, or complications such as pneumonia.[18,19] One meta-analysis suggested that swallowing therapy may have reduced length of hospital stay, dysphagia, and chest infections, and may have improved swallowing ability; the authors rated the evidence as low-to-moderate quality.[18] One meta-analysis found that electrical stimulation of the pharynx was effective in improving dysphagia compared with conventional treatment or sham stimulation in post-stroke patients, especially with early treatment.[20]

Safety

The evidence suggests that electrical stimulation of the pharynx treatment using Phagenyx is relatively safe with low risk of adverse events.[4] Across the trials, the occurrences of adverse events, such as pneumonia, vomiting, and other infections, were not different between patients who received Phagenyx treatment and those who received sham stimulation.[3,14,15] In 1 trial, 1 patient (out of 60 participants) reported a serious adverse event possibly related to catheter insertion which resulted in a chest infection.[15] No other serious device-related adverse events were reported in the trials.[3,14,15]

Issues to Consider

There are several clinical, operational, and implementation issues that need to be considered regarding the treatment of dysphagia using the Phagenyx device. The clinical evidence for the effectiveness of electrical stimulation of the pharynx with the Phagenyx device is limited. One treatment consideration is the correct placement of electrodes in the pharynx. Although the catheter has markings to guide its placement, ensuring that the electrode is positioned on the correct side of the pharynx to stimulate the nerves in need of treatment,[4] may require additional training. While a possible issue, this technique has demonstrated increasingly

promising evidence in improving swallowing performance.[4] The treatment is delivered in a hospital setting and special training is required for the health care staff to provide the treatment. The upfront cost of the device and the cost of treatment and of training staff are important factors to consider. No published literature exploring patients' perspectives was identified, and those perspectives are important to consider.

Related Developments

Neuromuscular electrical stimulation devices stimulate the pharynx externally to restore swallowing function. These devices have electrodes that can be applied to the surface of the neck. Devices such as VitalStim, Ampcare, and eSwallow provide a range of neuromuscular stimulation to patients with difficulty in swallowing. VitalStim is authorized by Health Canada and is available in Canada.[21]

Looking Ahead

Evidence regarding the long-term effectiveness and safety of the Phagenyx device is needed for people living with the effects of stroke and people with multiple sclerosis. Studies are also ongoing among patients with dysphagia who are on mechanical ventilation and are admitted to the intensive care unit.[22,23] Future well-designed trials are warranted to explore the efficacy of electrical stimulation of the pharynx in patients with stroke and other etiologies. A cost-effectiveness analysis of treatment with the Phagenyx device compared with current practice could help with purchasing and policy decisions. Treatment of dysphagia is critical to ensure patient well-being and for the rehabilitation of people living with the effects of stroke or for people with multiple sclerosis.

References

1. Phagenesis. 2021; http://www.phagenesis.com/. Accessed 2021 Sep 1.
2. Jayasekeran V, Singh S, Tyrrell P, et al. Adjunctive functional pharyngeal electrical stimulation reverses swallowing disability after brain lesions. *Gastroenterology.* 2010;138(5):1737-1746. PubMed
3. 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. *Lancet Neurol.* 2018;17(10):849-859. PubMed
4. Restivo DA, Hamdy S. Pharyngeal electrical stimulation device for the treatment of neurogenic dysphagia: technology update. *Med Devices (Auckl).* 2018;11:21-26. PubMed
5. Paik N, Moberg-Wolff E, Ed. Dysphagia treatment & management. *Medscape Drugs & Diseases.* 2020 Mar 20; https://emedicine.medscape.com/article/2212409-treatment. Accessed 2021 Sep 9.
6. Cohen DL, Roffe C, Beavan J, et al. Post-stroke dysphagia: a review and design considerations for future trials. *Int J Stroke.* 2016;11(4):399-411. PubMed
7. (Dis)connected: how unseen links are putting us at risk. 2019 report on heart, stroke and vascular cognitive impairment Ottawa (ON): Heart and Stroke Foundation of Canada; 2019: https://www.heartandstroke.ca/-/media/pdf-files/canada/2019-report/heartandstrokereport2019.ashx. Accessed 2021 Aug 24.
8. Martino R, Foley N, Bhogal S, Diamant N, Speechley M, Teasell R. Dysphagia after stroke. *Stroke.* 2005;36(12):2756-2763. PubMed
9. Multiple Sclerosis International Federation. Atlas of MS, 3rd edition, Part 1: Mapping multiple sclerosis around the world – key epidemiology findings. Toronto: Multiple Sclerosis International Federation (MSIF); 2020: https://mssociety.ca/research-news/article/prevalence-and-incidence-of-ms-in-canada-and-around-the-world. Accessed 2021 Aug 24.
10. Aghaz A, Alidad A, Hemmati E, Jadidi H, Ghelichi L. Prevalence of dysphagia in multiple sclerosis and its related factors: Systematic review and meta-analysis. *Iran J Neurol.* 2018;17(4):180-188. PubMed
11. Phagenyx for stroke-induced dysphagia. *Horizon Scanning Review*. University of Birmingham: NIHR Horizon Scanning Centre (NIHR HSC); 2013: https://www.io.nihr.ac.uk/wp-content/uploads/migrated/2352.68b9021d.PhagenesisPhagenyxforstrokeinduceddysphagiaFINAL2.pdf. Accessed 2021 Sep 9.
12. WCG FDAnews. Phagenesis' dysphagia treatment grabs FDA Breakthrough Device status. 2020 Jan 14; https://www.fdanews.com/articles/195492-phagenesis-dysphagia-treatment-grabs-fda-breakthrough-device-status. Accessed 2021 Aug 24.
13. Teasell R, Salbach NM, Foley N, et al. Canadian stroke best practice recommendations: Rehabilitation, recovery, and community participation following stroke. Part one: Rehabilitation and recovery following stroke; 6th Edition Update 2019. *Int J Stroke.* 2020;15(7):763-788.
14. Bath PM, Scutt P, Love J, et al. Pharyngeal electrical stimulation for treatment of dysphagia in subacute stroke: a randomized controlled trial. *Stroke.* 2016;47(6):1562-1570. PubMed
15. Bath PM, Woodhouse LJ, Suntrup-Krueger S, et al. Pharyngeal electrical stimulation for neurogenic dysphagia following stroke, traumatic brain injury or other causes: Main results from the PHADER cohort study. *EClinicalMedicine.* 2020;28. PubMed
16. Suntrup S, Marian T, Schröder JB, et al. Electrical pharyngeal stimulation for dysphagia treatment in tracheotomized stroke patients: a randomized controlled trial. *Intensive Care Med.* 2015;41(9):1629-1637. PubMed
17. 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. *Brain Stimul.* 2013;6(3):418-423. PubMed
18. Bath PM, Lee HS, Everton LF. Swallowing therapy for dysphagia in acute and subacute stroke. *Cochrane Database Syst Rev.* 2018;10:CD000323. PubMed
19. 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.e734. PubMed
20. Cheng I, Sasegbon A, Hamdy S. Effects of neurostimulation on poststroke dysphagia: a synthesis of current evidence from randomized controlled trials. *Neuromodulation.* 2020;10:10. PubMed
21. Chattanooga. Vitalstim Therapy. 2021; https://www.chattanoogarehab.com/vitalstim-therapy. Accessed 2021 Sep 9.
22. Schefold JC, Backlund M, Ala-Kokko T, et al. The PhINEST study - Pharyngeal ICU Novel Electrical Stimulation Therapy: Study protocol of a prospective, multi-site, randomized, sham-controlled, single-blind (outcome assessor-blinded) study. *Medicine.* 2020;99(11):e19503. PubMed
23. University Hospital Muenster. NCT04010617: PES to avoid extubation failure in intubated stroke patients at high risk of severe dysphagia. *ClinicalTrials.gov*. Bethesda (MD): U.S. National Library of Medicine; 2019: https://clinicaltrials.gov/ct2/show/NCT04010617. Accessed 2021 Sep 9.