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### **Review Article**

# **Electrical Stimulation of Cranial Nerves for Treating Dysphagia: A Critical Review**



Medipace Inc, Pasadena, CA, USA

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#### **Abstract**

Dysphagia, a severe comorbidity of many neurological diseases, often lacks targeted therapies. Electrical stimulation of cranial nerves represents a novel therapeutic class. This critical review assessed the clinical effectiveness and safety of various approaches for electrical stimulation of the cranial nerves for treating dysphagia, categorized as implantable (directly targeting the nerve), minimally invasive (pharyngeal electrical stimulation), and non-invasive (transcutaneous). A critical literature review was conducted following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The PubMed database was comprehensively searched, and studies were rigorously assessed for inclusion and exclusion criteria. The Newcastle-Ottawa Scale was used to assess the risk of bias. The analysis included 15 clinical studies: four assessing vagus nerve stimulation (including implantable and transcutaneous approaches) and eleven assessing pharyngeal electrical stimulation. Most evaluated studies, particularly for pharyngeal electrical stimulation and transcutaneous vagus nerve stimulation, demonstrated significant beneficial effects on validated dysphagia outcome measures. Importantly, no long-term severe adverse effects were reported across the evaluated stimulation approaches. Cumulative evidence indicates that vagus nerve stimulation and pharyngeal electrical stimulation approaches can effectively alleviate dysphagia symptoms. The different stimulation approaches appear to be complementary, with distinct profiles rendering them suitable for different therapeutic contexts (e.g., short-term hospital-based vs. long-term at-home treatment). Consequently, they represent distinct and valuable options for individualized dysphagia therapy.

#### Introduction

Dysphagia, or difficulty in swallowing, is a significant medical condition often stemming from various neurological, muscular, or structural issues. This condition is a major health burden, associated with complications including malnutrition, dehydration, and aspiration pneumonia. The scale of the problem is underscored by its high prevalence: estimates suggest dysphagia affects 31% of healthy elderly people, 87% of patients with Parkinson's disease, 31–68% of post-stroke patients, and 39–100% of individuals with other neurodegenerative diseases.<sup>2</sup>

Dysphagia is classified anatomically into two types. Oropharyngeal dysphagia involves difficulty initiating a swallow and moving a bolus from the mouth to the esophagus, while esopha-

Keywords: Vagus nerve stimulation; Pharyngeal electrical stimulation; Dysphagia; Cranial nerves; Transcutaneous auricular stimulation, Autonomic neuromodulation. \*Correspondence to: Victor Pikov, Medipace Inc., Pasadena, CA 91101, USA. OR-CID: https://orcid.org/0000-0003-0124-0877. Tel: +1-6264979441, E-mail: pikov@hotmail.com

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geal dysphagia involves difficulty in swallowing distal to the oropharynx (esophagus, lower esophageal sphincter, or cardia) due to a structural or functional abnormality.<sup>3,4</sup> The oropharynx and larynx are essential for swallowing and airway protection. Normal swallowing is not merely a muscular action but a complex, highspeed sensorimotor reflex involving precise and timely coordination of the central nervous system and peripheral nerves innervating different muscles of the oral cavity, pharynx, and airway.<sup>5</sup> This coordination relies on precise sensory input (afferent signals) and coordinated motor output (efferent signals). The primary sensory triggers, which detect the bolus and initiate the swallow, are carried by the glossopharyngeal nerve (cranial nerve (CN) IX) and the pharyngeal branch of the vagus nerve (CN X). In response, the vagus nerve (CN X) provides the principal motor innervation to the pharyngeal constrictors, longitudinal pharyngeal muscles, and all intrinsic laryngeal muscles. Other nerves, including the trigeminal (CN V), facial (CN VII), and hypoglossal (CN XII) nerves, are crucial for the preparatory phase and laryngeal elevation. Many forms of neurogenic dysphagia represent a failure of this sensorimotor coordination, with electrical stimulation potentially restoring or enhancing this critical sensorimotor coordination.

The standard of care for dysphagia involves swallowing exer-

Table 1. Search keywords for PubMed for the evaluated cranial nerve stimulation therapies

Stimulation approach	Search keywords for PubMed
implantable and transcutaneous	("vagus"[Title] OR "vagal"[Title] OR "pharyngeal"[Title] OR "auricular"[Title] OR "laryngeal"[Title] OR "glossopharyngeal"[Title] OR "trigeminal"[Title] OR "mylohyoid"[Title] OR "facial"[Title] OR "hypoglossal"[Title]) AND ("nerve"[Title] OR "nerves"[Title] OR "branch"[Title]) AND "stimulation"[Title] AND ("dysphagia"[Title] OR "dysphagic"[Title])
PES	"pharyngeal electrical stimulation"[Title] AND ("dysphagia"[Title] OR "dysphagic"[Title] OR "swallowing disability" [Title])

PES, pharyngeal electrical stimulation.

cises intended to gradually improve neural control of oropharyngeal and laryngeal muscles.<sup>6</sup> This standard of care, however, relies on patient effort and cortical-driven neuroplasticity, which can be slow and ineffective, particularly in patients with severe sensory deficits or cognitive impairment. Electrical stimulation of the CNs is investigated not simply as a tool for muscle rehabilitation, but as a neuroplasticity driver that provides a direct, consistent, and potent afferent signal to the swallowing centers in the brainstem to accelerate the neuroplastic changes that swallowing exercises aim to achieve. Electrical stimulation can be applied to the CNs based on three wellestablished approaches for electrode placement: 1) implantable, with a cuff electrode placed directly around the target nerve; 2) transcutaneous, with self-adhesive electrodes placed on the skin above the target nerve; and 3) pharyngeal electrical stimulation (PES), with electrodes attached to a catheter inserted into the pharynx. Unlike the implantable and transcutaneous approaches that target specific nerves, the PES approach targets multiple sensory nerve endings in the oropharyngeal mucosa, primarily the pharyngeal branch of the vagus nerve and the glossopharyngeal nerve.<sup>7</sup>

In summary, despite the availability of symptomatic treatments for dysphagia, there remains a gap in therapies that specifically target the underlying disease pathophysiology. The aim of this critical review is to assess the effectiveness and safety of several CN stimulation approaches, including implantable, minimally invasive, and non-invasive (transcutaneous), in addressing dysphagia symptoms.

The critical review was performed per the 2020 version of the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement.<sup>8</sup>

#### Data sources and searches

On November 1, 2025, the PubMed database was searched for scientific papers. The search keywords are provided in Table 1.

#### Data collection and evaluation

All identified records were reviewed, with the abstracts initially screened, followed by a full-text review per the inclusion and exclusion criteria. Data from included studies were extracted and synthesized narratively. Key extracted data included study design, patient population, stimulation approach and parameters, primary dysphagia outcome measures, and reported adverse events.

#### **Study selection**

Both sham-controlled and open-label single-arm studies were included in this review. The following inclusion criteria were used:

- 1. Papers published in English, as a vast majority of high-impact clinical research is published in English;
- 2. Papers with full-text availability, as the critical review requires assessment of a study's quality and risk of bias; and
- 3. Presentation of statistical results, as the critical review requires the means and standard deviations.

A pragmatic exception was made for the studies involving implantable vagus nerve stimulation (VNS) therapy, which were included regardless of statistical presentation. This exception was deemed necessary because the high invasiveness and surgical risks associated with this approach inherently limit study sample sizes; excluding such studies based on a lack of statistical power would have omitted an entire therapeutic category from the review. Animal studies, reviews, abstracts, and case studies were excluded from consideration. Presence or absence of specific predefined efficacy and/or safety outcomes was not an inclusion or exclusion criterion of any clinical studies.

#### Risk of bias assessment

Methodological quality of the selected studies was assessed using the modified Newcastle–Ottawa Scale (NOS) for cohort studies. The NOS was selected due to its applicability to both nonrandomized and randomized studies, while the Risk of Bias 2.0 tool by Cochrane is designed only for randomized controlled trials . The modified NOS evaluates the selection, comparability with the general population, and outcome assessment, and generates a 9-point scale indicating overall methodological quality, which can be classified as low (scores of 0–3), moderate (scores of 4–6), or high (scores of 7–9).

#### **Search outcomes**

For the implantable and transcutaneous approaches, seven records were identified on the PubMed database and assessed for eligibility. The three excluded records comprised one animal study and two case reports. Subsequently, four records (four clinical studies) were included in the analysis.

For PES, 27 records were identified on the PubMed database and assessed for eligibility. The 17 excluded records comprised seven reviews, two animal studies, three case reports, one clinical study protocol, and two clinical studies not assessing dysphagia-related clinical outcomes. Subsequently, 11 clinical studies (from 12 records) were included in the analysis.

While the search keywords encompassed all types of dysphagia (see Table 1), all included studies were performed in patients with oropharyngeal dysphagia rather than esophageal dysphagia. The dysphagia outcomes are presented as the mean  $\pm$  standard deviation.

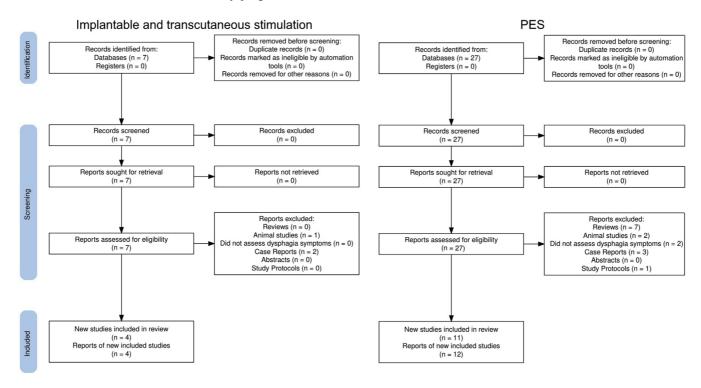


Fig. 1. PRISMA flow diagram of record selection. PES, pharyngeal electrical stimulation; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

tion of the difference between post-therapy data and pre-therapy data, where available.

A visual representation of the record selection process is depicted in Figure 1 using the PRISMA flow diagram.

Only VNS (rather than stimulation of any other CN) was used in all four identified implantable and transcutaneous stimulation studies, and the same PES method was used in all 11 identified PES studies. Risk of bias assessment of the 15 included studies was performed using the modified NOS, and the overall scores in all 15 studies ranged from 5 to 9, indicating moderate to high methodological quality (Table 2). 11-26

Among the four identified clinical studies using implantable and transcutaneous VNS, two applied transcutaneous cervical VNS (tcVNS) in stroke, one applied transcutaneous auricular VNS (taVNS) in stroke, and one applied implantable cervical VNS (icVNS) in multiple sclerosis patients (Table 3).<sup>11–14</sup>

A key finding was the extreme heterogeneity of these VNS interventions. Two tcVNS studies used direct current (DC) at 1 mA, <sup>11,12</sup> applied from the anode electrode on the left mastoid area behind and below the ear to the cathode on the opposite shoulder, to activate the cervical vagus at its exit from the skull through the jugular foramen. They used the DC electrical stimulator (IS200, Intelligent Electronic Industry Co., Ltd, Sichuan, China). In the active stimulation arm, DC was applied for 10–20 m, while in the sham stimulation arm, DC was applied for only 30 s. <sup>12</sup>

In contrast, the taVNS study used pulsed electrical stimulation at 25 Hz, <sup>13</sup> 0.5 ms pulse width, and average current amplitude of 1.5–2.0 mA (based on subject tolerance), applied to the cymba concha area of both ears. The taVNS was delivered via the bipolar taVNS electrodes attached to a taVNS stimulator (Xinzhile Medical Co., Ltd, Jiangxi, China). In the active stimulation arm, the actual current was applied, while in the sham stimulation arm, no

current was applied.

The icVNS study used yet another set of parameters delivered via a bipolar helical cuff electrode implanted on the left cervical

Table 2. Risk of bias assessment of included studies using the modified NOS

Stimulation method	Selec- tion	Compa- rability	Out- come	Overall score	Ref.
VNS	4	2	2	8	11
VNS	4	2	3	9	12
VNS	4	2	3	9	13
VNS	3	0	2	5	14
PES	4	0	2	6	15
PES	4	2	3	9	16
PES	4	2	3	9	17
PES	4	2	2	8	18
PES	4	2	2	8	19
PES	4	1	3	8	20
PES	4	1	3	8	21
PES	3	0	2	5	22
PES	4	2	2	8	23
PES	4	2	2	8	24
PES	4	2	2	8	25,26

NOS, Newcastle–Ottawa Scale; PES, pharyngeal electrical stimulation; VNS, vagus nerve stimulation.

Therapy type	Disease	Subjects per arm	Therapy duration	Daily dosage	ΔSSS	Δ FDS	Δ FCM	ΔSST	SAEs	Ref.
tcVNS (DC)	Stroke	56 (ES), 57 (NS)	3 days	10 m	-8.1 ± 4.2, p < 0.001	-23.6 ± 11.2, p < 0.001	ND	ND	ND	11
tcVNS (DC)	Stroke	29 (ES), 31 (SS)	4 weeks, 5 days/wk	20 m	ND	ND	3 (1–4), <i>p</i> < 0.05	ND	0	12
taVNS	Stroke	19 (ES), 20 (SS)	3 weeks, 5 days/wk	30 m × 2	ND	ND	3.05 ± 0.50, p < 0.001	ND	0	13
icVNS	Multiple sclerosis	3 (ES)	2 months	24 h at 51% duty	ND	ND	ND	-3.2	0	14

Table 3. Summary of clinical studies evaluating the effectiveness and safety of taVNS, tcVNS, and icVNS therapies on dysphagia

Δ, difference of post-ES data minus pre-ES data. DC, direct current; ES, electrical stimulation; FCM, Functional Communication Measure; FDS, Functional Dysphagia Scale; icVNS, implantable cervical VNS; ND, no data; NS, no stimulation; SAEs, severe adverse events; SS, sham stimulation; SSS, Standard Swallowing Scale; SST, Swallowing Speed Test; taVNS, transcutaneous auricular VNS; tcVNS, transcutaneous cervical VNS.

vagus nerve<sup>14</sup>: frequency of 10 Hz, current amplitude of 1.25 mA, pulse width of  $250 \mu s$ , duty cycle of 51% (62 s on and 60 s off), delivered continuously for 24 h. The VNS electrode lead was tunneled to an implantable pulse generator (both from Cyberonics), placed in the subcutaneous pocket on the left chest wall.

This parametric variability suggests "VNS" is a broad category of distinct stimulation approaches with different biophysical mechanisms, rather than a single, unified therapy.

In the two tcVNS studies and the taVNS study, <sup>11–13</sup> effectiveness was assessed using various functional measures of dysphagia (Standard Swallowing Scale, Functional Dysphagia Scale, and Functional Communication Measure), with all measures indicating a significant improvement compared to pre-stimulation time. In the icVNS study, due to a small number of subjects with multiple sclerosis (n = 3), the statistical significance of the Swallowing Speed Test was not assessed. In three studies where VNS therapy was applied for several weeks, there was no occurrence of severe adverse events in any of the arms. <sup>12–14</sup>

The results of these four VNS studies are summarized in Table 3. Among the 11 identified clinical studies using PES, eight were performed outside the intensive care units (ICUs) in diverse patient populations (stroke, orally intubated and ventilated patients, traumatic brain injury, multiple sclerosis, and brain tumor patients), <sup>15–22</sup> and three were performed in the ICUs in stroke and orally intubated and ventilated patients (Table 4). <sup>23–26</sup>

In stark contrast to the VNS studies, the PES studies demonstrated high homogeneity. In all studies, PES was applied using a pair of ring electrodes inside a nasogastric catheter (11.5F outer diameter) connected to a benchtop stimulation device. The majority of studies used the Phagenyx system (Phagenesis Ltd, Manchester, UK), which has de novo clearance from the U.S. Food and Drug Administration (FDA) for short-term treatment in stroke patients.<sup>27</sup> This consistency extended to the stimulation parameters: duration of 10 m, frequency of 5 Hz, pulse width of 200 µs, and current amplitude of 20–30 mA (based on subject tolerance). In the sham stimulation arm, the PES catheter was inserted but no current was applied.

This high degree of homogeneity makes the cumulative evidence for PES more robust and interpretable. Effectiveness of PES therapy was assessed using several functional measures of dysphagia, including the Penetration-Aspiration Scale (PAS) and Fiberoptic Endoscopic Dysphagia Severity Scale, with all of these measures indicating a significant improvement compared to prestimulation time (with the exception of PAS in one study). Other functional measures of dysphagia, such as the incidence of re-intubation and the incidence of readiness for de-intubation in ICU

patients, also showed benefits when compared to post-stimulation time in the control arm.  $^{20,24}$  In three studies,  $^{16-18}$  the incidence of dysphagia (defined as PAS  $\geq$  3) was also compared to pre-stimulation time, but its statistical significance was not evaluated. PAS is a categorical 8-point scale used to characterize both the location of airway invasion events and a patient's response during videofluor-oscopic swallowing studies.  $^{28}$  In the evaluated PES studies, PAS was the most commonly used functional measure of dysphagia, allowing assessment of both statistical and clinical significance.  $^{29}$ 

In all studies where adverse events were monitored, there was no occurrence of severe adverse events in any of the arms, with the exception of one study, 15 reporting one case of chest sepsis possibly related to the PES catheter insertion, but not the stimulation itself.

The results of these 11 PES studies are summarized in Table 4.

#### **Discussion**

This critical review assessed the effectiveness and safety of several CN stimulation approaches (icVNS, taVNS, tcVNS, and PES) in patients with dysphagia. The principal finding is that converging evidence supports the effectiveness and safety of two distinct classes of CN stimulation: minimally invasive PES and non-invasive taVNS and tcVNS. The evidence for icVNS remains preliminary. Notably, the taVNS, tcVNS, and PES approaches have demonstrated significant beneficial effects on dysphagia symptoms. This is underscored by the PES approach obtaining FDA de novo clearance for short-term treatment of dysphagia in stroke patients.<sup>27</sup> None of the evaluated CN stimulation approaches was associated with long-term severe adverse effects.

A comparative analysis suggests these stimulation approaches are not interchangeable, as their clinical profiles stem from likely different therapeutic mechanisms. PES directly targets the afferent pathways (CN IX and pharyngeal CN X) in the oropharyngeal mucosa. Its mechanism is therefore hypothesized to be the restoration and upregulation of the brainstem swallowing reflex. This sensory-driven, reflex-based mechanism may explain its rapid action, with benefits seen during 10-m sessions. In contrast, cervical VNS (both icVNS and tcVNS) targets the main vagal trunk, containing both sensory and motor fibers. Its mechanism may be less about the immediate reflex and more about driving central cortical and brainstem plasticity over a longer term. Finally, taVNS targets the auricular branch of the vagus nerve, a purely sensory pathway that projects to the nucleus tractus solitarius in the brainstem, a key swallowing coordination

Table 4. Summary of clinical studies evaluating the effectiveness and safety of PES therapy on dysphagia

Therapy location	Disease	Subjects per arm	Therapy duration	Daily dosage	Δ PAS	Δ DPAS	ΔΔ RI or DI	Δ FEDSS	SAEs	Ref.
Non-ICU	Stroke, OIV, TBI	89 (ES)	3 days	10 min	-1.5 ± 1.5, p < 0.05	ND	ND	ND	1*	15
Non-ICU	Stroke	18 (ES), 18 (SS)	3 days	10 min	ND	-33% at 2 weeks	ND	ND	0	16
Non-ICU	Stroke	16 (ES), 12 (SS)	3 days	10 min	ND	–37% at 2 weeks	ND	ND	0	17
Non-ICU	Stroke	70 (ES), 56 (SS)	3 days	10 min	-1.2 ± 1.8, p < 0.05	-5% at 2 weeks	ND	ND	0	18
Non-ICU	Stroke	38 (ES), 34 (SS)	3 days	10 min	-1.5 ± 3.1, p > 0.05	ND	ND	ND	ND	19
Non-ICU	Stroke	30 (ES), 66 (SS)	3 days	10 min	ND	ND	40% DI, p < 0.001	ND	0	20
Non-ICU	Multiple sclerosis	10 (ES), 10 (SS)	3 days	10 min	$-3.3 \pm 0.8$ , p < 0.01	ND	ND	ND	0	21
Non-ICU	Stroke, Brain tumors	24 (ES)	3 days	10 min	$-2.8 \pm 0.4$ , p < 0.001	ND	ND	ND	0	22
ICU	OIV	18 (ES), 112 (NS)	3 days	10 min	-2.0 ± 1.3, p < 0.01	ND	ND	ND	0	23
ICU	OIV	15 (ES), 25 (NS)	3 days	10 min	ND	ND	–24% RI	ND	0	24
ICU	Stroke	23 (ES), 30 (SS)	3 days	10 min	ND	ND	ND	-3.0 ± 0.7, p < 0.001	ND	25,26

 $\Delta$ , difference of post-ES data minus pre-ES data;  $\Delta\Delta$ , difference of post-ES data minus post-NS data; \*SAE (chest sepsis) is possibly related to PES catheter insertion. DI, readiness for de-intubation; DPAS, dysphagia defined as PAS  $\geq$  3; ES, electrical stimulation; FEDSS, Fiberoptic Endoscopic Dysphagia Severity Scale; ICU, intensive care unit; ND, no data; NS, no stimulation; OIV, orally intubated and ventilated; PAS, Penetration-Aspiration Scale; RI, re-intubation; SAEs, severe adverse events; SS, sham stimulation; TBI, traumatic brain injury.

center.<sup>30</sup> This makes the mechanism of taVNS more analogous to PES (afferent-driven modulation) than to cervical VNS.

These distinct profiles define their different clinical niches. PES is defined by its confirmed effectiveness and FDA clearance for hospital-based short-term treatment of dysphagia in stroke patients. Its key advantages are this robust evidence base and its proven utility in acute settings, including for orally intubated and ventilated patients in the ICU. These benefits are balanced by its disadvantages: it is minimally invasive, requiring nasogastric catheter placement, and involves moderate device cost and extensive clinical resources for repeated daily therapy procedures. Consequently, PES is not suitable for long-term use and cannot be used at home by a patient. Its clear clinical niche is the acute and subacute hospital setting for patients, often with severe dysphagia.

The non-invasive VNS approaches (taVNS, tcVNS) have a profile defined by their non-invasive nature, inexpensive cost, and suitability for at-home use by a patient. Also, the effectiveness and safety of the taVNS approach are supported by FDA clearances for its use in non-dysphagia indications, including a recent FDA clearance for treating another gastrointestinal motility disease, irritable bowel syndrome. These are significant advantages, making taVNS and tcVNS appropriate for both short-term and long-term use. The primary disadvantages are that they are not yet FDA cleared for treating dysphagia and require patient education to learn the correct location for electrode placement (e.g., cymba concha or mastoid area). The clinical niche for these non-invasive approaches appears to be mild-to-moderate dysphagia in an out-

patient or home setting, where long-term rehabilitation is the goal.

Finally, the implantable VNS (icVNS) approach is defined by its invasiveness. Its primary theoretical advantage is the "implant it and forget it" nature, which could achieve very high patient adherence for long-term therapy, particularly in patients with reduced cognitive or physical abilities. Its long-term safety profile is confirmed by its FDA approval for non-dysphagia indications (e.g., epilepsy). However, these potential benefits are offset by major disadvantages: high device cost, the need for extensive surgical resources, and the significant risks associated with surgery and longterm implantation. Most critically, its effectiveness for dysphagia is not confirmed in large clinical studies, as evidenced by the study included in this review (n = 3), and it is not FDA-approved for treating dysphagia. This makes icVNS a non-viable clinical option at present. For severe dysphagia, the use of minimally invasive PES (or perhaps icVNS in a future investigational context) may become a choice based on the risk-benefit ratio.

The summary comparing these CN stimulation approaches for dysphagia treatment is outlined in Table 5.

This review has limitations, including the exclusion of studies published in other languages and the restriction to a single database (PubMed), which may have resulted in missed studies. Furthermore, the primary literature itself has significant limitations. The VNS studies, in particular, suffer from major methodological and parametric heterogeneity, making it impossible to draw firm conclusions about an optimal VNS protocol. Due to the heteroge-

Table 5. Summary of advantages and disadvantages of icVNS, taVNS, tcVNS, and PES approaches for dysphagia treatment

CN stimula- tion approach	Advantages	Disadvantages
icVNS	"Implant it and forget it" approach of achieving very high patient adherence for long-term therapy use, which is particularly important for patients with reduced physical or cognitive abilities; Confirmed safety for long-term use based on FDA approval for non-dysphagia indications	Effectiveness is not confirmed in large clinical studies; High device cost and extensive clinical resources for performing the implantation procedure; Risks associated with the surgery and long-term implantation; Not FDA approved for treating dysphagia
taVNS, tcVNS	Confirmed effectiveness; Non-invasive; Inexpensive; Suitable for short-term and long-term use; Can be used at home by a patient; Confirmed safety for short-term and long-term use based on FDA clearances for non-dysphagia indications	Requires the patient to learn the location of cymba concha area inside the ear (taVNS) or mastoid area behind and below the ear (tcVNS); Not FDA cleared for treating dysphagia
PES	Confirmed effectiveness; FDA cleared for hospital- based short-term treatment of dysphagia in stroke patients; Can be used in orally intubated and ventilated patients at the ICU	Minimally-invasive; Moderate device cost and extensive clinical resources for performing repeated daily therapy procedures; Not suitable for long-term use due to its invasiveness and use of clinical resources; Cannot be used at home by a patient

CN, cranial nerve; FDA, U.S. Food and Drug Administration; ICU, intensive care unit; icVNS, implantable cervical VNS; PES, pharyngeal electrical stimulation; taVNS, transcutaneous auricular VNS; tcVNS, transcutaneous cervical VNS.

neity of functional outcome measures (e.g., PAS, Functional Dysphagia Scale, Standard Swallowing Scale) in the included studies and the small number of included studies, a meta-analysis was not performed. Another limitation is that all included studies were performed in patients with oropharyngeal dysphagia, so the observed effectiveness of various CN stimulation approaches may not be applicable to patients with esophageal dysphagia. Yet another limitation is that the literature search and analysis of data were performed by a single author, therefore introducing serious risks of selection bias, extraction bias, error accumulation, and inability to identify disagreements among the authors.

Additional clinical studies must be conducted to further evaluate the effectiveness of the icVNS, taVNS, and tcVNS approaches toward obtaining FDA approval (for icVNS) or FDA clearance (for taVNS and tcVNS) for their use in treating dysphagia in specific patient populations. Availability of these CN stimulation approaches provides clinicians with valuable options for optimizing the treatment of dysphagia based on severity and etiology.

#### **Conclusions**

The application of CN stimulation approaches, particularly icVNS, taVNS, tcVNS, and PES, holds significant promise for the treatment of dysphagia, especially in patients who have experienced stroke or other neurological impairments. These stimulation approaches are believed to act by modulating neural pathways involved in swallowing, leading to improved functional outcomes. Cumulative evidence from the evaluated studies is preliminary but promising in indicating that these approaches effectively alleviate dysphagia symptoms. They represent valuable, complementary options rather than competitors, with some approaches being more suited for short-term vs. long-term therapy and for at-home vs. hospital-based treatment. Despite their potential, attention must be given to the safety profile and adverse events associated with these procedures. Future research should focus on refining these approaches, conducting larger-scale randomized trials with standardized outcomes, and exploring their roles across different patient populations to establish standardized treatment protocols for dysphagia management.

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#### **Conflict of interest**

Victor Pikov is the founder and CEO of Medipace Inc. The author declares no other conflicts of interest.

#### **Author contributions**

VP is the sole author of the manuscript. The author has approved the final version and publication of the manuscript.

### References

- [1] Roden DF, Altman KW. Causes of dysphagia among different age groups: a systematic review of the literature. Otolaryngol Clin North Am 2013;46(6):965–987. doi:10.1016/j.otc.2013.08.008, PMID:242
- [2] Ribeiro M, Miquilussi PA, Gonçalves FM, Taveira KVM, Stechman-Neto J, Nascimento WV, et al. The Prevalence of Oropharyngeal Dysphagia in Adults: A Systematic Review and Meta-analysis. Dysphagia 2024;39(2):163–176. doi:10.1007/s00455-023-10608-8, PMID:376 10669.
- [3] Thiyagalingam S, Kulinski AE, Thorsteinsdottir B, Shindelar KL, Takahashi PY. Dysphagia in Older Adults. Mayo Clin Proc 2021;96(2):488–497. doi:10.1016/j.mayocp.2020.08.001, PMID:33549267.
- [4] Clavé P, Shaker R. Dysphagia: current reality and scope of the problem. Nat Rev Gastroenterol Hepatol 2015;12(5):259–270. doi:10.1038/nrgastro.2015.49, PMID:25850008.
- [5] Wei KC, Wang TG, Hsiao MY. The Cortical and Subcortical Neural Control of Swallowing: A Narrative Review. Dysphagia 2024;39(2):177–197. doi:10.1007/s00455-023-10613-x, PMID:37603047.
- [6] Crossman C, Piol S, Price D, Veit K, Molfenter SM. The State of Exercise-Based Dysphagia Intervention in the Literature: A Scoping Review. Laryngoscope Investig Otolaryngol 2025;10(4):e70180.

- doi:10.1002/lio2.70180, PMID:40630224.
- [7] Wang Q, Hu J, Tian Y, Li C, Xu N, Wen H, et al. An experimental study on the optimal timing of modified pharyngeal electrical stimulation for the treatment of dysphagia after stroke in rats. Brain Res Bull 2025;227:111390. doi:10.1016/j.brainresbull.2025.111390, PMID: 40393633.
- [8] Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. Int J Surg 2021;88:105906. doi:10.1016/j.ijsu.2021.105906, PMID:33789826.
- [9] Wells GA, Shea B, O'Connell D, Peterson J, Welch V, Losos M, et al. The Newcastle- Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. Available from: https://www. ohri.ca/programs/clinical\_epidemiology/oxford.asp.
- [10] Sterne JAC, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ 2019;366:14898. doi:10.1136/bmj.14898, PMID:31462531.
- [11] Yan X, Zhang X, Huang C, Jiang Y, Wan C. Applications of transcranial direct current stimulation over vagus nerve on dysphagia after stroke. J Neurophysiol 2025;133(2):464–471. doi:10.1152/jn.00588.2024, PMID:39835801.
- [12] Chen S, Xu S, Liang C, Huang Z, Dai X, Su X, et al. Transcranial direct current stimulation over the vagus nerve promotes post-stroke dysphagia recovery: a randomized, double-blind, sham-controlled clinical trial. Am J Phys Med Rehabil 2025. doi:10.1097/PHM.0000000000002823, PMID:40857053.
- [13] Wang Y, He Y, Jiang L, Chen X, Zou F, Yin Y, et al. Effect of transcutaneous auricular vagus nerve stimulation on post-stroke dysphagia. J Neurol 2023;270(2):995–1003. doi:10.1007/s00415-022-11465-5, PMID:36329182.
- [14] Marrosu F, Maleci A, Cocco E, Puligheddu M, Barberini L, Marrosu MG. Vagal nerve stimulation improves cerebellar tremor and dysphagia in multiple sclerosis. Mult Scler 2007;13(9):1200–1202. doi:10.1177/1352458507078399, PMID:17623740.
- [15] Bath PM, Woodhouse LJ, Suntrup-Krueger S, Likar R, Koestenberger M, Warusevitane A, 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;28:100608. doi:10.1016/j.eclinm.2020.100608, PMID:33294818.
- [16] Vasant DH, Michou E, O'Leary N, Vail A, Mistry S, Hamdy S, Greater Manchester Stroke Research Network. Pharyngeal Electrical Stimulation in Dysphagia Poststroke: A Prospective, Randomized Single-Blinded Interventional Study. Neurorehabil Neural Repair 2016;30(9):866– 875. doi:10.1177/1545968316639129, PMID:27053641.
- [17] Jayasekeran V, Singh S, Tyrrell P, Michou E, Jefferson S, Mistry S, et al. Adjunctive functional pharyngeal electrical stimulation reverses swallowing disability after brain lesions. Gastroenterology 2010;138(5):1737–1746. doi:10.1053/j.gastro.2010.01.052, PMID: 20138037.
- [18] Bath PM, Scutt P, Love J, Clavé P, Cohen D, Dziewas R, et al. Pharyngeal Electrical Stimulation for Treatment of Dysphagia in Subacute Stroke: A Randomized Controlled Trial. Stroke 2016;47(6):1562–1570. doi:10.1161/STROKEAHA.115.012455, PMID:27165955.
- [19] Everton LF, Benfield JK, Michou E, Hamdy S, Bath PM. Effects of

- Pharyngeal Electrical Stimulation on Swallow Timings, Clearance and Safety in Post-Stroke Dysphagia: Analysis from the Swallowing Treatment Using Electrical Pharyngeal Stimulation (STEPS) Trial. Stroke Res Treat 2021;2021:5520657. doi:10.1155/2021/5520657, PMID:34211688.
- [20] Dziewas R, Stellato R, van der Tweel I, Walther E, Werner CJ, Braun T, 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. doi:10.1016/S1474-4422(18)30255-2, PMID:30170898.
- [21] 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. doi:10.1016/j.brs.2012.09.001, PMID:23040375.
- [22] Zhang X, Liang Y, Wang X, Shan Y, Xie M, Li C, et al. Effect of Modified Pharyngeal Electrical Stimulation on Patients with Severe Chronic Neurogenic Dysphagia: A Single-Arm Prospective Study. Dysphagia 2023;38(4):1128–1137. doi:10.1007/s00455-022-10536-z, PMID:364 04369.
- [23] Williams T, Walkden E, Patel K, Cochrane NE, McGrath BA, Wallace S. Research report: Management of dysphagia using pharyngeal electrical stimulation in the general intensive care population A service development. J Intensive Care Soc 2024;25(4):374–382. doi:10.1177/17511437241270244, PMID:39524066.
- [24] Koestenberger M, Neuwersch S, Hoefner E, Breschan C, Weissmann H, Stettner H, et al. A Pilot Study of Pharyngeal Electrical Stimulation for Orally Intubated ICU Patients with Dysphagia. Neurocrit Care 2020;32(2):532–538. doi:10.1007/s12028-019-00780-x, PMID:31313142.
- [25] Suntrup-Krueger S, Labeit B, Marian T, Schröder J, Claus I, Ahring S, et al. Pharyngeal electrical stimulation for postextubation dysphagia in acute stroke: a randomized controlled pilot trial. Crit Care 2023;27(1):383. doi:10.1186/s13054-023-04665-6, PMID:37789340.
- [26] Suntrup-Krueger S, Labeit B, von Itter J, Jung A, Claus I, Ahring S, et al. Treating postextubation dysphagia after stroke with pharyngeal electrical stimulation -insights from a randomized controlled pilot trial. Neurotherapeutics 2025;22(4):e00613. doi:10.1016/j.neurot.2025.e00613, PMID:40383663.
- [27] FDA. De Novo Clearance DEN220025 for Phagenyx System from phagenesis limited. 2022. Available from: https://www.accessdata. fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K243613.
- [28] Rosenbek JC, Robbins JA, Roecker EB, Coyle JL, Wood JL. A penetration-aspiration scale. Dysphagia 1996;11(2):93–98. doi:10.1007/ BF00417897, PMID:8721066.
- [29] Borders JC, Brates D. Use of the Penetration-Aspiration Scale in Dysphagia Research: A Systematic Review. Dysphagia 2020;35(4):583–597. doi:10.1007/s00455-019-10064-3, PMID:31538220.
- [30] Lang IM, Dean C, Medda BK, Aslam M, Shaker R. Differential activation of medullary vagal nuclei during different phases of swallowing in the cat. Brain Res 2004;1014(1-2):145–163. doi:10.1016/j.brainres.2004.03.061, PMID:15213000.
- [31] FDA. 510(k) Clearance K230526 for TEA Device from Transtimulation Research Inc. 2023; Available from: https://www.accessdata.fda. gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K230526.