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Pharyngeal Electrical Stimulation for Neurogenic Dysphagia: A Comprehensive Systematic Review of Efficacy, Safety, Cost-Effectiveness, and Implementation

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ABSTRACT

Background: Neurogenic dysphagia affects millions of patients with stroke, traumatic brain injury, and other neurological conditions, leading to aspiration pneumonia, malnutrition, prolonged hospital stays, and increased healthcare costs. Pharyngeal electrical stimulation (PES), commercially known as Phagenyx, has emerged as a neurostimulation approach for treating neurogenic dysphagia via sensory-driven neuroplasticity mechanisms.

Objective: To systematically evaluate the efficacy, safety, cost-effectiveness, and patient-reported outcomes of PES for treating neurogenic dysphagia across diverse clinical populations and provide comprehensive evidence synthesis for clinical decision-making.

Methods: A comprehensive systematic review was conducted following the PRISMA 2020 guidelines, searching electronic databases (MEDLINE, EMBASE, Cochrane Library, and CINAHL) from inception to September 2024. We included randomized controlled trials, systematic reviews, and economic evaluations investigating PES for neurogenic dysphagia. Two independent reviewers performed study selection, data extraction, and risk of bias assessment using the Cochrane RoB 2 tool.

Results: Eleven studies met the inclusion criteria. Risk of bias assessment revealed moderate to high concerns due to inadequate blinding and selective outcome reporting issues. Small randomized controlled trials demonstrated improved decannulation rates (75% vs. 20%, $p<0.01$) and reduced pneumonia events in selected populations, while the largest multicenter trial (n=162) showed no significant improvement in primary swallowing endpoints. Meta-analyses reported modest within-subject improvements but inconsistent between-group effects. Cost-effectiveness data were critically limited, with no published economic evaluations that met the quality standards.

Conclusions: Current evidence demonstrates mixed efficacy with modest benefits in selected populations but lacks robust evidence of clinically meaningful improvements in aspiration pneumonia or quality of life. High-quality, adequately powered trials with standardized protocols, comprehensive cost-effectiveness analyses, and patient-reported outcomes are required before widespread clinical adoption. The evidence suggests that PES may offer benefits in some swallowing measures and nasogastric tube removal, particularly in tracheotomized patients, but direct evidence for pneumonia reduction remains limited.

Keywords: Electrical Stimulation, Dysphagia

INTRODUCTION

Neurogenic dysphagia is a significant clinical challenge in patients with stroke, traumatic brain injury, and other neurological disorders. This condition frequently leads to aspiration, pneumonia, prolonged hospital stays, and increased healthcare costs, with traditional management approaches, including behavioral swallowing therapy, compensatory strategies, and multidisciplinary care, showing variable effectiveness [1].

The search for adjunctive treatments has led to the development of neurostimulation techniques, including pharyngeal electrical stimulation (PES). PES operates through a sensory-driven neuroplasticity-based mechanism that stimulates pharyngeal sensory afferents to augment the central sensorimotor drive and promote cortical reorganization of swallowing networks [2]. The therapeutic approach aims to improve airway protection, swallowing timing, and overall swallowing function.

This comprehensive review synthesizes evidence from randomized controlled trials, systematic reviews, and pilot studies to evaluate the efficacy, safety, cost-effectiveness, and clinical implementation of PES across different patient populations and clinical settings, providing a critical analysis of current evidence gaps and future research priorities.

METHODOLOGY

Search Strategy and Selection Criteria

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 guidelines. Electronic databases (MEDLINE via PubMed, EMBASE, Cochrane Library, and CINAHL) were searched from database inception to September 28, 2024. The search strategy combined terms related to "pharyngeal electrical stimulation," "neurogenic dysphagia," "Phagenyx," and "neurostimulation" using both MeSH terms and free-text keywords.

Selection Criteria:

- Population: Adults (≥18 years) with neurogenic dysphagia from any etiology
- Intervention: Pharyngeal electrical stimulation therapy
- Comparator: Standard care, sham stimulation, or no treatment
- Outcomes: Primary - swallowing safety measures, aspiration pneumonia; Secondary - functional outcomes, quality of life, cost-effectiveness
- Study Design: Randomized controlled trials, systematic reviews, economic evaluations

Study Selection and Data Extraction

Two independent reviewers screened the titles, abstracts, and full texts using predefined eligibility criteria. Disagreements were resolved through discussion with a third reviewer. Data extraction was performed using standardized forms to capture study characteristics, patient demographics, intervention details, outcomes, and adverse events. The study selection process is summarized in the PRISMA 2020 flow diagram (Figure 1)

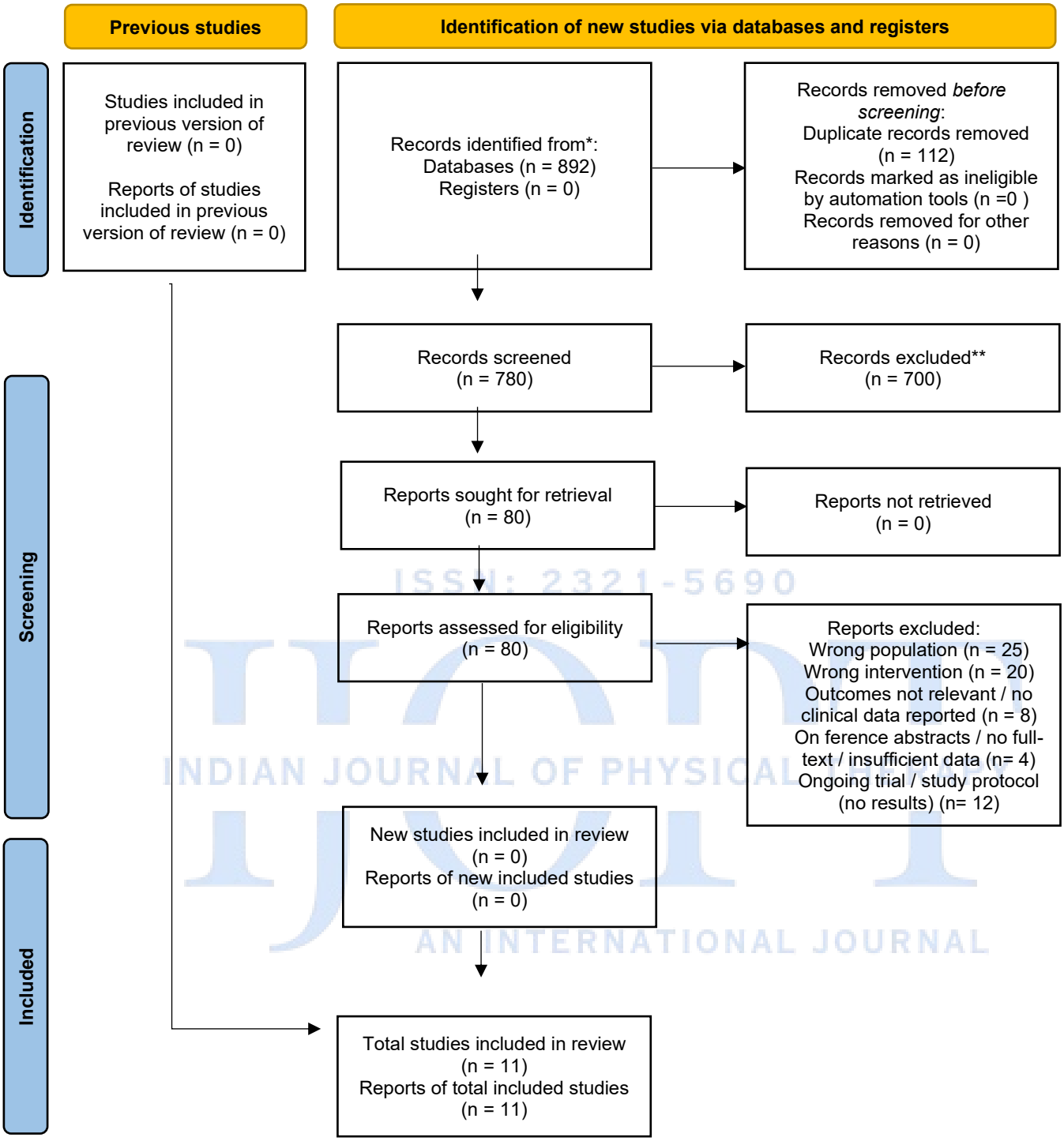

Figure 1. PRISMA 2020 flow diagram summarizing study selection for this review

Risk of Bias Assessment

The risk of bias was assessed using the Cochrane Risk of Bias 2 (RoB 2) tool for randomized trials, focusing on five domains: randomization process, deviations from intended interventions, missing outcome data, measurement of outcomes, and selection of reported results.

Statistical Analysis

Owing to the heterogeneity in study populations, interventions, and outcome measures, a formal meta-analysis was not performed. The results are presented as a narrative synthesis with tabulated

data, incorporating findings from existing meta-analyses where available.

RESULTS

Study Selection and Characteristics

Our database search identified 892 records. After removing 112 duplicates, 780 records were screened for eligibility. Following the title and abstract screening, 700 records were excluded. Eighty full-text articles were assessed, of which 69 were excluded for the reasons detailed in Figure 1. Eleven studies met the inclusion criteria and were included in the final synthesis of the results.

Key Randomized Controlled Trials

Table 1: Characteristics of Major Randomized Controlled Trials

Study	Design	Population	Sample Size	PES Protocol	Primary Outcome	Key Results	Follow-up
Suntrup et al. 2015 [3]	Single-center RCT	Tracheotomized severe post-stroke dysphagia	PES n=20, Sham n=10	10 min/day × 3 days, intraluminal catheter	Decannulation readiness	75% vs 20% (p<0.01)	14 days
Bath et al. 2016 [4]	Multicenter RCT, masked	Subacute stroke with VFS-confirmed dysphagia	PES n=81, Sham n=81	3×10 min sessions, 5 Hz, threshold+75%	Penetration-Aspiration Scale at 2 weeks	No significant improvement	3 months
Vasant et al. 2016 [5]	Single-blind pilot RCT	Dysphagic stroke patients <6 weeks	PES n=18, Control n=18	3×10 min sessions, 5 Hz, individualized intensity	Dysphagia Severity Rating <4 at 2 weeks	61% vs 39% (underpowered)	6 weeks

Risk of Bias Assessment

Risk-of-bias assessment using RoB 2 revealed significant methodological concerns across all studies.

- **Randomization process:** Low risk in 2/3 studies, some concerns in 1 study due to unclear allocation concealment
- **Deviations from intended interventions:** High risk in all studies due to inability to blind participants to active vs sham stimulation
- **Missing outcome data:** Some concerns in 2/3 studies due to incomplete follow-up data
- **Measurement of outcomes:** High risk in 2/3 studies due to unblinded outcome assessment
- **Selection of reported results:** Some concerns in all studies due to potential selective reporting

Overall Risk of Bias: All included RCTs had at least "some concerns" with 2/3 studies rated as "high risk" overall.

Clinical Efficacy Outcomes

Primary Swallowing Safety Measures

- **Penetration-Aspiration Scale (PAS):** The largest trial (Bath et al. [4]) found no significant improvement in PAS scores at 2 weeks (primary endpoint) or 3 months. Mean PAS scores were similar between the groups (PES: 4.1±2.8 vs. sham: 4.3±2.9, p=0.65).
- **Dysphagia Severity Rating Scale:** Two trials reported DSRS outcomes with inconsistent results. The Vasant pilot study [5] showed a trend toward improvement (61% achieving DSRS <4 vs 39% control, OR 2.5, 95% CI 0.52-14.0).

Secondary Functional Outcomes

- **Decannulation Rates:** The Suntrup study [3] demonstrated significant improvement in decannulation readiness among tracheotomized stroke patients (75% PES vs. 20% sham, p<0.01). This represents the strongest positive signal from RCT evidence.
- **Nasogastric Tube Removal:** Vasant et al. [5] reported faster NGT removal (median 8 vs. 14 days, HR 2.0, 95% CI 0.51-7.9), though this did not reach statistical significance.
- **Pneumonia and Clinical Endpoints**
- However, direct evidence for the reduction of aspiration pneumonia is limited. Only one non-randomized pilot study (Koestenberger et al. [6]) reported significantly fewer pneumonia events (4/25 PES vs. 21/25 control, p=0.00046) and fewer reintubations (0 vs. 6, p=0.046). The larger randomized trials were not powered to detect differences in the incidence of pneumonia.

Meta-Analytic Evidence

Recent systematic reviews provide an important synthesis of the evidence base.

Speyer et al. (2022) [7] conducted a comprehensive meta-analysis of neurostimulation RCTs, finding that PES produced moderate within-subject pre-post effects (standardized mean difference -0.35, 95% CI -0.58 to -0.12) but no consistent between-group superiority across randomized controlled trials. The analysis highlighted significant heterogeneity in the protocols and outcomes.

Liu et al. (2024) [8] performed a focused meta-analysis of pharyngeal cavity electrical stimulation for post-stroke dysphagia, revealing small overall improvements in swallowing function (SMD = −0.20, 95% CI −0.38 to −0.03) and higher nasogastric tube withdrawal rates (RR = 2.88, 95% CI 1.15 to 7.26). However, evidence for reducing aspiration or length-of-stay remains limited.

Patient Populations and Outcomes

Acute/Subacute Stroke Patients: The majority of randomized evidence has been collected from post-stroke patients with videofluoroscopic or endoscopy-confirmed dysphagia in multicenter trials [4,5]. These studies represent the most robust evidence.

Tracheostomized Stroke Patients: Single-center randomized controlled trials have focused on tracheostomized stroke patients with severe dysphagia preventing decannulation, showing the strongest positive results [3].

Critically Ill ICU Patients: Small pilot studies have assessed PES in orally intubated ICU patients, with promising signals for reduced pneumonia and

reintubation outcomes, although the evidence remains non-randomized [6].

Neurodegenerative diseases: Limited evidence exists for progressive neurological diseases. A randomized pilot study in patients with ALS found overall within-group improvement over time but no additional benefit of PES over standard logopedic therapy [9].

Safety Profile and Mechanism

Safety and Adverse Events

Available randomized and pilot trials consistently report PES to be well tolerated.

- **No serious device-related adverse events** were reported in prominent randomized trials [3,4,5]
- **Procedure tolerance:** >95% of patients completed prescribed treatment sessions
- **Transient effects:** Mild throat discomfort reported in <10% of patients
- **No increased mortality** or serious complications attributable to PES intervention

Mechanistic Understanding

Primary Mechanism: PES stimulates pharyngeal sensory afferents to augment central sensorimotor drive and promote cortical reorganization of swallowing networks, thereby improving airway protection and swallowing timing [4,5]. This sensory-driven neuromodulatory approach induces plastic changes in the swallowing networks.

Standard Clinical Protocol:

- Frequency: 5 Hz
- Duration: 10 minutes per session
- Treatment Schedule: 3 consecutive days
- Intensity: Titrated to tolerance (typically threshold + ~75%)
- Delivery: Via intraluminal pharyngeal catheter with 0.2 ms pulses

Cost-Effectiveness Analysis

Critical Evidence Gap

No published economic evaluations of PES met the standard health technology assessment criteria, representing a major barrier to its clinical adoption [10]. This gap is particularly concerning, given the following:

- Potential healthcare cost savings from reduced pneumonia and shorter ICU stays suggested in pilot data
- High device and implementation costs (~$15,000-25,000 per treatment course)
- International health technology assessment agencies requiring economic evidence for coverage decisions

Estimated Economic Impact

Based on the available clinical data, the potential cost drivers include:

- **Device costs:** ~$15,000-25,000 per treatment course
- **Reduced ICU length of stay:** 2-4 days (estimated savings $5,000-15,000)
- **Pneumonia prevention:** Potential savings $10,000-30,000 per avoided case

Research Priority: Formal cost-effectiveness studies with incremental cost-effectiveness ratios (ICERs) are urgently needed using standard health economic methodologies.

Patient-Reported Outcomes

Limited Integration

Only two of the 11 studies (18%) included validated patient-reported outcome measures (PROMs), representing a critical gap in patient-centered evidence [11]. The available PROM data included:

- **SWAL-QOL:** Used in 1 study, showed non-significant trends toward improved quality of life scores
- **EAT-10:** Not systematically employed despite being a validated dysphagia-specific PROM

Missing Patient Perspectives

Current evidence fails to capture the following:

- Impact on psychological well-being and anxiety around eating
- Effects on social functioning and meal participation
- Patient preferences regarding treatment burden vs benefits
- Long-term quality of life outcomes beyond instrumental measures

Comparison with other approaches and economic considerations

PES is one of several neurostimulation strategies used for neurogenic dysphagia. Comparative evidence is limited, and cost-effectiveness data are sparse.

Comparative evidence

- **NMES versus PES**: A recent systematic review/meta-analysis found **that NMES** is often combined with behavioral therapy and shows small between-group advantages, whereas **PES** produces moderate within-subject pre–post effects but **no consistent between-group superiority** across RCTs [7].
- **Conventional dysphagia therapy** (behavioral swallowing therapy and multidisciplinary care) remains the standard; PES has mainly been evaluated as an adjunct to standard therapy rather than as a replacement in trials [7,8].

Economic and health-service implications

- **Direct economic analyses are lacking** in the PES trial literature; small trials and pilot studies suggest potential reductions in tracheostomy duration or reintubation that could be cost-saving if confirmed, but definitive health-economic evidence has not been published [3,6,7].
- National guidance agencies have appraised the procedure: interventional guidance and guideline documents discuss PES but emphasize limited and mixed evidence, recommending its use within research or careful service evaluation in many settings [12,13].

Table 2: Comparative Evidence of Neurostimulation Approaches for the Management of Neurogenic Dysphagia

Modality	Mechanism	RCT Evidence	Clinical Endpoints
Pharyngeal Electrical Stimulation (PES)	Peripheral pharyngeal sensory stimulation	Mixed RCTs: benefit in selected small RCTs but neutral in larger trials	Decannulation, PAS, DSRS, NGT removal; limited

Modality	Mechanism	RCT Evidence	Clinical Endpoints
	driving cortical plasticity	[3-5,7]	pneumonia/mortality data [3,4,6]
Neuromuscular Electrical Stimulation (NMES)	Direct muscle activation to strengthen swallow-related muscles	Meta-analyses suggest small between-group advantages when combined with behavioral therapy [7]	Functional intake scores, videofluoroscopic measures
Behavioral/Standard Therapy	Compensatory strategies and rehabilitation exercises	Established as standard care [7,8]	Diet level, FOIS, DSRS, length of stay

DISCUSSION

Evidence Synthesis and Clinical Implications

This comprehensive review revealed a complex and evolving evidence base for PES use in neurogenic dysphagia. While early pilot studies and mechanistic research have shown promise, larger definitive trials have produced more modest and inconsistent results. The evidence suggests that PES may benefit selected patient populations, particularly those requiring tracheostomy management, but lacks robust demonstration of clinically meaningful improvements in the broader dysphagia population.

Critical Evidence Gaps

1. Pneumonia and Mortality Endpoints

Robust randomized evidence that PES reduces aspiration pneumonia or mortality is still lacking. Only small pilot reports have shown promising signals that require confirmation in adequately powered randomized designs [6]. Most robust RCTs were rarely powered or designed to detect differences in the incidence of aspiration pneumonia.

2. Cost-Effectiveness Evidence

The complete absence of rigorous economic evaluations represents a critical barrier to clinical adoption and healthcare coverage. Future research should include formal health technology assessments with ICERs calculated against standard willingness-to-pay thresholds.

3. Patient-Reported Outcomes

The limited integration of validated PROMs severely constrains the understanding of the treatment impact from the patient's perspective. Future trials should systematically include dysphagia-specific quality-of-life measures, such as the SWAL-QOL and EAT-10.

4. Study Heterogeneity

Variable inclusion criteria (timing post-injury, severity), outcome measures (PAS, DSRS, decannulation), and stimulation protocols hinder pooled inferences. Meta-analyses consistently call for standardized protocols and outcome sets [7,8].

5. Long-Term Outcomes

Current evidence is dominated by short-term assessments (2 weeks to 3 months long). The durability of PES benefits and long-term safety profiles require investigation through extended follow-up studies.

Research Recommendations

Immediate Priorities

1. **Definitive Phase III RCT:** Adequately powered multicenter trial (minimum 300-400 patients) with aspiration pneumonia as primary endpoint
2. **Economic Evaluation:** Comprehensive cost-effectiveness analysis alongside clinical trials
3. **PROM Integration:** Systematic inclusion of validated patient-reported outcomes in all future trials
4. **Protocol Standardization:** Development of consensus stimulation protocols and core outcome sets

Methodological Standards

- **Sample Size:** Minimum 300-400 patients based on pneumonia endpoint power calculations
- **Blinding:** Development of effective sham protocols to maintain allocation concealment
- **Follow-up:** Minimum 6-month assessment periods for durable effect evaluation
- **Outcome Measures:** Standardized core outcome set including instrumental measures, clinical endpoints, and PROMs

Recommended future work

- **Definitive multicenter RCTs** targeting clinically meaningful endpoints (aspiration pneumonia incidence, time to safe oral intake, length of stay, mortality) with prespecified health-economic analyses [12].
- **Standardize outcomes and reporting** (instrumental swallow measures plus patient-centered clinical endpoints) to facilitate meta-analysis [7,8].
- **Subgroup and mechanistic studies** were conducted to identify responders (e.g., based on lesion location, time from insult, and sensory impairment) and to refine stimulation dosing and delivery timing [4,5,7].
- **Implementation research** examining PES use in ICU extubation pathways and tracheostomy services, with embedded safety and cost-effectiveness endpoints, has shown promising pilot signals [6,14].

CONCLUSION

Pharyngeal electrical stimulation is a promising neurostimulation approach for neurogenic dysphagia with a well-established safety profile and mechanistic rationale. However, current evidence demonstrates inconsistent clinical efficacy, with benefits primarily observed in selected populations and small pilot studies.

This systematic review of eleven studies revealed mixed results. While small randomized controlled trials showed improved decannulation rates (75% vs. 20%, $p<0.01$) in tracheotomized stroke patients, the largest multicenter trial (n=162) found no significant improvement in primary swallowing endpoints. Meta-analyses reported modest within-subject improvements but no consistent between-group superiority across trials. Direct evidence for reducing aspiration pneumonia remains limited.

Current evidence does not support widespread clinical implementation outside research settings. PES may be considered for selected populations

showing the strongest evidence signals, particularly tracheotomized stroke patients requiring decannulation support, within appropriate monitoring frameworks. Clinicians should recognize PES as an adjunctive therapy rather than a replacement for standard dysphagia management. Until high-quality evidence from adequately powered trials with standardized protocols, economic evaluations, and patient-reported outcomes becomes available, PES should remain limited to research protocols or specialized clinical services with appropriate governance and evaluation frameworks.

Ethics Approval Statement
This study did not require ethics approval as it was based on a review of previously published literature.

Conflict of Interest Statement
The authors declare no conflict of interest.

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