SMART Topic

Auricular Percutaneous Electrical Nerve Field Stimulation in Pediatric Disorders of Gut–Brain Interaction: A Clinician's Approach

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1. Overview

Chronic abdominal pain, chronic nausea and autonomic symptoms are common, debilitating complaints in children and young adults with disorders of gut–brain interaction (DGBI).[1] Despite a broad range of pharmacologic and behavioral therapies, many patients experience incomplete relief or medication-related side effects, underscoring a major unmet need for safe, non-pharmacologic neuromodulatory treatments.[1,2]

Auricular percutaneous electrical nerve field stimulation (PENFS), delivered via a small wearable device placed behind the ear, represents an emerging, minimally invasive neuromodulation strategy aimed at modulating central autonomic and visceral pain pathways.[3] By stimulating afferent auricular branches of the cranial nerves supplying the gastrointestinal (GI) tract, predominantly the vagus nerve, this therapy seeks to rebalance dysregulated gut–brain signaling implicated in nausea, visceral hypersensitivity, and autonomic dysfunction.[4]

This article outlines the physiologic rationale for auricular PENFS, available devices, predicted effectiveness across relevant clinical conditions, and a practical approach to patient selection, treatment implementation, and monitoring in clinical practice.

2. Introduction

Functional dyspepsia, irritable bowel syndrome (IBS), chronic abdominal pain, chronic nausea, cyclic vomiting syndrome (CVS), and postural orthostatic tachycardia syndrome (POTS) frequently overlap and share common pathophysiologic features, including[1]:

- Visceral hypersensitivity
- Altered autonomic tone (sympathetic predominance, vagal withdrawal)
- Central sensitization
- Dysregulated gut–brain communication

Current therapies—antiemetics, neuromodulators, prokinetic medications that enhance gastrointestinal motility (e.g., erythromycin, metoclopramide), and behavioral interventions—are variably effective and often limited by side effects, adherence challenges, or delayed onset of benefit. Consequently, there is a growing interest in neuromodulation as a targeted, mechanism-based alternative that can complement existing treatments without systemic pharmacologic burden.[1]

3. Proposed Mechanisms

Although several neurophysiologic and autonomic pathways have been proposed, the precise mechanisms underlying symptom improvement with aVNS/PENFS remain incompletely understood. Current hypotheses are primarily derived from translational studies, autonomic testing, neuroimaging data, and early clinical observations. Additional mechanistic and disease-specific studies are needed to better define how vagal neuromodulation influences visceral sensitivity, central pain processing, autonomic regulation, and gut–brain communication across individual DGBIs

The vagus nerve is central to visceral pain processing, regulation of nausea and emesis, gastric accommodation and motility, and maintenance of autonomic balance.[5]

Abbreviations: DGBI, disorders of gut–brain interaction; PENFS, auricular percutaneous electrical nerve field stimulation; GI, gastrointestinal; IBS, irritable bowel syndrome; CVS, cyclic vomiting syndrome; POTS, postural orthostatic tachycardia syndrome; aVNS, auricular vagal nerve stimulation; NTS, nucleus tractus solitarius; FD, functional dyspepsia; ARFID, avoidant/restrictive food intake disorder; FAP-NOS, functional abdominal pain–not otherwise specified; FAPD, functional abdominal pain disorders.

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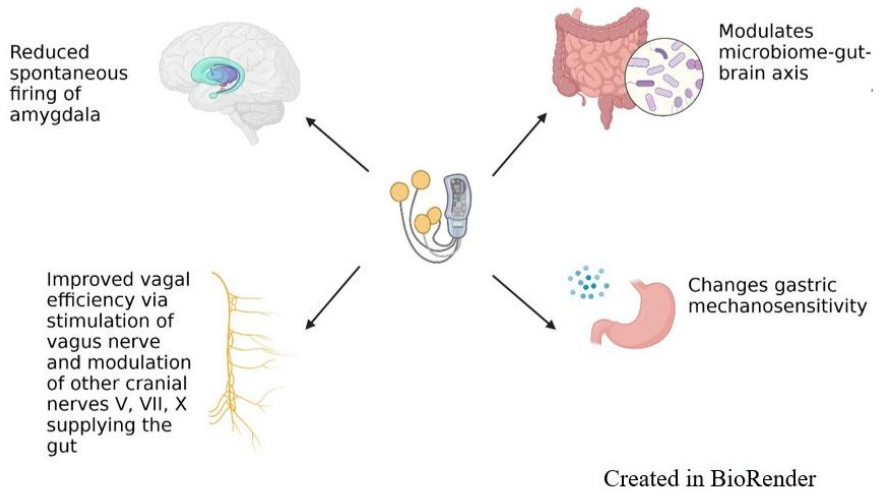
Auricular vagal nerve stimulation (aVNS) is thought to stimulate sensory auricular branches of cranial nerves, including vagal pathways in the external ear, with downstream effects on the nucleus tractus solitarius (NTS) and related brainstem centers involved in autonomic regulation and visceral sensation, including the area postrema, a key trigger zone for nausea and vomiting.[5,7] However, the precise neural pathways responsible for clinical benefit remain incompletely understood, and proposed effects may involve modulation of afferent sensory signaling, central autonomic and limbic networks, and potentially multiple neural signaling pathways.

Proposed mechanisms of benefit include[5,7]:

- Reduction in visceral hypersensitivity
- Modulation of brain–gut signaling
- Increased parasympathetic (vagal) activity
- Dampening of nausea-related neural circuit
- Reduced amygdala (limbic) firing (Figure 1)

Unlike implanted vagal nerve stimulators, auricular devices are non-invasive, removable, and well tolerated, making them particularly suitable for pediatric and adolescent patients. (Table 1)

Figure 1. Plausible mechanism of action of PENFS



Stimulation of the auricular branches of the cranial nerves, particularly the vagus nerve, likely improves GI outcomes via modulation of amygdala firing, vagal efficiency, gastro-mechanosensitivity, and gut-microbiome diversity

Table 1. Auricular nerve stimulation devices used for GI symptom relief.

Device Name	Manufacturer	Method	Approval
IB-Stim®	NeurAxis	Percutaneous ear placement targeting cranial nerve branches	FDA cleared for treatment of children 11-18 years with IBS
The Parasym™*	Parasym	Transcutaneous over-the-ear device targeting the vagus nerve[6]	CE certified
VIVO*	Aurimod	Auricular transcutaneous vagus nerve stimulation	CE certified

*Not available in USA, only available in Europe.

4. Device and How It Works

Auricular PENFS is delivered through IB-stim® (NeurAxis, Versailles, IN).[3] (Figures 2,3)

- Small, battery-powered, adhesive device placed behind the ear.
- Worn continuously for 5 days, followed by a 2-day break.
- Typically applied weekly for 4 consecutive weeks (4 total devices).
- Operates using a single, manufacturer-programmed stimulation setting that cannot be adjusted by clinicians or patients.
- Delivers a standardized stimulation pattern consisting of 1-ms biphasic pulses at alternating frequencies of 1 Hz and 10 Hz (3.2 V output), alternating every 2 seconds.
- Stimulation is delivered in repeated 2-hour-on/30-minute-off cycles throughout the 5-day treatment period.

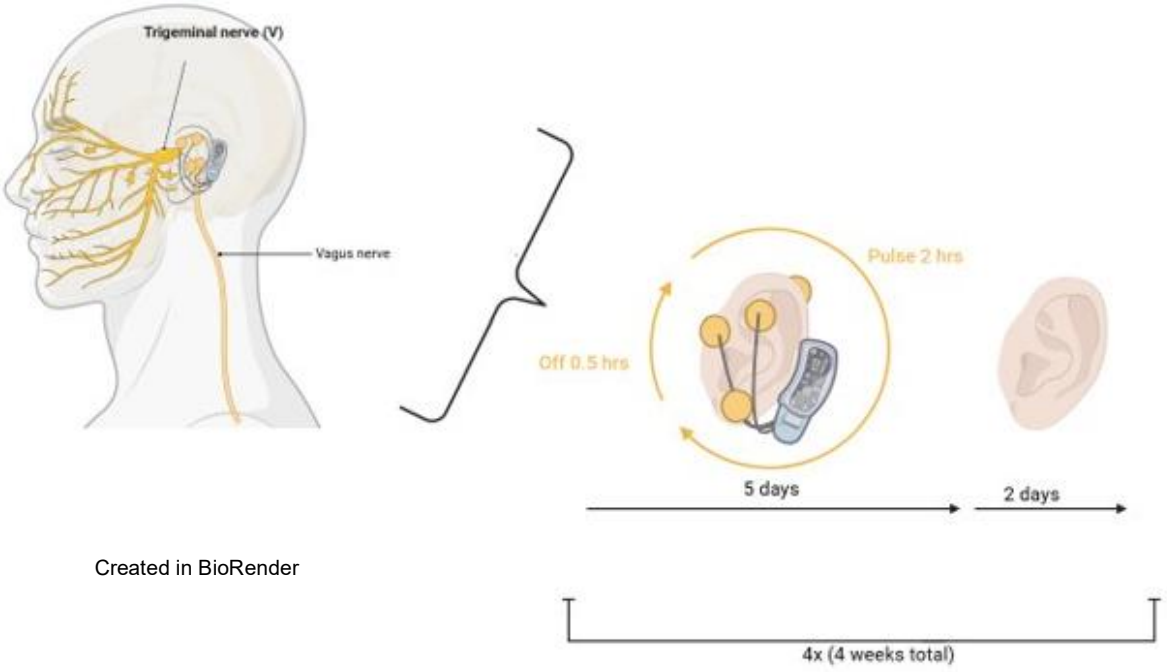
Treatment is not intended to be indefinite; however, selected patients may receive additional treatment cycles based on symptom recurrence, clinical response, and shared decision-making.

Other investigational or adult-focused aVNS devices exist, but IB-Stim has the most established pediatric safety and feasibility data.[7]

Patient Education and Device Training

A certified physician places the device each week in clinic. Patients and caregivers remove the device each week on day 5 at home. They are educated on device placement, skin care, activity precautions, and troubleshooting at the time of application by trained clinical staff. Families are instructed on maintaining device adhesion, avoiding excessive moisture exposure, and monitoring for local skin

Figure 2. Methodology of PENFS device



The device provides percutaneous electrical pulses to trigeminal and vagus nerves to alleviate GI symptoms.

irritation or discomfort during the treatment period. Written instructions and follow-up contact information are typically provided to reinforce adherence and address questions that may arise during therapy.

5. Efficacy

Irritable Bowel Syndrome (IBS)

Rationale: Targets visceral hypersensitivity and autonomic imbalance, key mechanisms in IBS.

Evidence: It is FDA-cleared for children and adolescents (ages 8–21y). A double-blind sham-RCT in adolescents with IBS showed improvements in worst and composite pain scores after 3 weeks of treatment with lasting effects up to 12 weeks. There were improvements in functional disability and related symptoms over 3–12 weeks of follow-up.[8]

Functional Dyspepsia (FD)

Rationale: Vagal modulation may improve gastric accommodation, visceral sensitivity, and nausea pathways — mechanisms implicated in FD. IB-Stim is now FDA-cleared for pediatric FD (ages 8–21y).[9,10]

Evidence: Retrospective clinical data in children with FD who completed four weeks of PENFS demonstrated significant improvements at 3 weeks and 3 months in abdominal pain, nausea, disability, sleep quality, somatization, and anxiety/depression scores.[10]

6. Other DGBIs with Potential PENFS Effects

Cyclic Vomiting Syndrome (CVS)

Rationale: CVS is a DGBI with strong autonomic involvement. Objective testing shows sympathetic dysfunction (e.g., abnormal sudomotor testing, orthostatic tachycardia) in pediatric and adults, indicating dysautonomia.[11] Neurophysiologic work also demonstrates altered parasympathetic outflow and central sensitization differences in CVS during noxious stimulation, consistent with central (brainstem–cortical) contributions.[12]

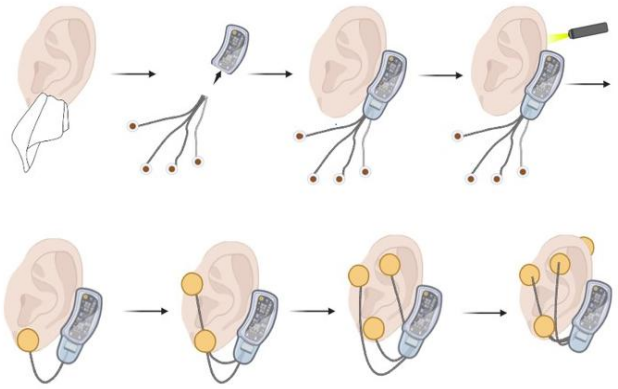
Predicted benefit: Moderate to high for reducing episode frequency/severity in selected patients, particularly where dysautonomia and nausea circuitry are prominent. (Direct trials of aVNS/PENFS specifically in CVS are limited, so it's a mechanism-based extrapolation from CVS dysautonomia + neuromodulation effects.)

Best candidates are patients with:

- Prominent nausea between episodes or severe prodromes
- Clear autonomic symptoms (orthostatic intolerance, tachycardia, sweating abnormalities)
- Episodes linked to stress and sleep disruption (common real-world triggers in CVS care)

Practical positioning: PENFS as an adjunct to standard CVS management (trigger control, sleep regularity, migraine-directed strategies, antiemetic/abortive plans), especially in patients with objective or clinical evidence of dysautonomia.[13]

Figure 3. Placement of the PENFS device.



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Placement includes cleaning the ear and placing the four electrodes on the vagus and trigeminal nerves.

Functional Nausea

Rationale: Effects on (NTS/area postrema), visceral hypersensitivity, and limbic modulation of emetic signaling.

Possible effect: Reduction in nausea severity and frequency (as reflected by lower Nausea Severity Scale [NSS] scores), improved oral intake, and better daily functioning, with secondary improvements in sleep and anxiety in nausea-predominant patients.[14]

Positioning: Adjunct to standard medical therapy (antiemetics, neuromodulators) and behavioral interventions

Functional Abdominal Pain–Not Otherwise Specified (FAP-NOS)

Rationale: Shares core mechanisms with IBS/FD (visceral hypersensitivity, central sensitization, autonomic imbalance).

Possible effect: Reduction in pain intensity and pain interference; improved functioning and sleep.

Positioning: Adjunct to behavioral therapy and neuromodulators.

7. Effects on other comorbidities

Postural Orthostatic Tachycardia Syndrome (POTS) and Autonomic Dysfunction

Rationale: Targets autonomic imbalance characterized by sympathetic predominance and relative vagal withdrawal.[15] Auricular vagal neuromodulation may enhance parasympathetic tone and stabilize brain–gut–autonomic signaling.[5]

Predicted benefit: Mild to moderate adjunctive benefit, particularly for nausea, abdominal pain, dizziness, and "autonomic flare" symptoms (e.g., tachycardia, lightheadedness, postprandial worsening), especially in patients with prominent GI manifestations.

Evidence: Although PENFS has not been studied as a primary therapy for POTS, experimental and clinical studies of transcutaneous auricular VNS (taVNS) demonstrate reductions in sympathetic activity and improvements in autonomic balance, supporting its physiologic plausibility in POTS.[16] In pediatric DGBI cohorts with overlapping autonomic symptoms, PENFS has shown improvements in nausea, sleep, anxiety, and disability—domains commonly affected in POTS—suggesting potential utility as an adjunct to standard autonomic and behavioral management rather than a stand-alone therapy.[17]

Sleep disturbances

Rationale: Sleep disturbances are very common in DGBI and frequently co-occur with autonomic dysfunction, pain, and anxiety.[18] Sleep deprivation can exacerbate gut-brain dysregulation by exacerbating visceral perception, psychological distress, and functional impairment. By activating brainstem nuclei involved in autonomic control and sleep homeostasis, aVNS may have a positive impact on parasympathetic tone and sleep-wake regulation, thereby enhancing sleep quality and lowering sleep-related impairment in patients with DGBI.[10,18]

Predicted benefit: Improvements in subjective and objective sleep metrics (e.g. sleep quality, sleep onset latency, and sleep-related impairment) with secondary benefits on mood, pain, and general functioning, particularly when combined with multimodal therapy.

Evidence: According to emerging clinical data, over the course of a four-week treatment period, several sleep outcomes improved in adolescents with functional abdominal pain disorders (FAPD) receiving PENFS. Actigraphy revealed decreased sleep onset latency during treatment, and self-reported sleep disturbance and sleep impairment scores significantly improved following PENFS.[18] In a pediatric FD cohort treated with PENFS (with or without concurrent behavioral intervention), global sleep disturbance assessed significantly improved both during and at three-month follow-up after treatment.[10] Another open label study of auricular neurostimulation in children with CVS showed short-term improvements in sleep quality at six weeks of therapy, with median scores decreasing significantly from baseline.[19]

According to emerging clinical data, PENFS may help DGBI patients with FAP and comorbidities related to CVS by improving sleep quality and sleep related impairments.[18-19]

Avoidant/restrictive food intake disorder (ARFID) associated with postprandial symptoms

Rationale: FD is characterized by postprandial distress, early satiety, nausea, and epigastric pain. These symptoms often get worse when eating, which makes patients limit their oral intake. This symptom-avoidance pattern reflects maladaptive gut–brain signaling, visceral hypersensitivity, and autonomic dysregulation. By altering afferent vagal pathways implicated in nausea perception, visceral pain processing, stomach accommodation, and potential effects on the hypothalamic satiety centers, aVNS may enhance

nutritional intake and decrease symptom-based food avoidance.[20]

Predicted benefit: Adjunctive improvements in oral intake, weight, BMI along with improvements in pain, nausea, somatization and disability.

Evidence: New clinical findings from pediatric DGBI cohorts receiving PENFS show reductions in depression, functional impairment, nausea, and abdominal pain—symptoms that frequently induce restricted eating habits in people with ARFID. Oral intake improved in the cohort, specifically almost half of those on enteral tube feedings (n=12).[20]

Although the strongest evidence for PENFS currently exists in IBS and functional dyspepsia, interest in broader application across DGBIs is driven by the substantial overlap in underlying pathophysiologic mechanisms, including visceral hypersensitivity, autonomic dysfunction, altered gut–brain signaling, and central sensitization. In many of these conditions, existing therapeutic options remain limited, incompletely effective, or poorly tolerated. Consequently, clinicians may consider PENFS as an adjunctive, individualized, and relatively low-risk neuromodulatory intervention in carefully selected patients with refractory or functionally impairing symptoms, while recognizing that additional controlled disease-specific studies remain necessary.

8. How We Use Auricular Vagal Stimulation in Practice (Figure 4)

Patient Selection

We consider PENFS in patients who have:

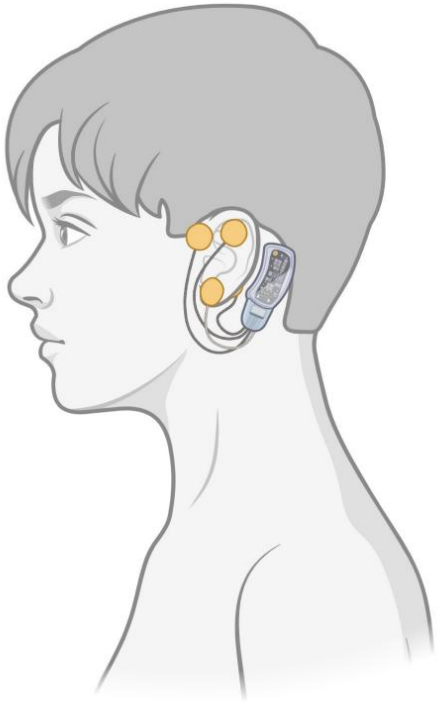
- Persistent nausea, abdominal pain, or dyspepsia interfering with daily activities
- Evidence of autonomic dysregulation (e.g., POTS, vagal withdrawal)
- Intolerance/poor response to medications
- Significant functional impairment (school absences, poor oral intake, weight loss, sleep disturbances)

In our clinical practice, PENFS is generally considered in patients with persistent or functionally impairing symptoms. Often, standard of care treatment strategies such as dietary modifications, pharmacologic therapies, behavioral interventions, and/or treatment of associated autonomic dysfunction have not improved symptoms. PENFS can be considered first line therapy, especially for those on polypharmacy, sensitivity to medications or unable to comply with behavioral treatments. In fact, in a recent study by Kolacz et al., adolescents receiving antidepressant medications demonstrated less improvement in cardiac vagal efficiency following PENFS than those not receiving antidepressants, suggesting that concurrent pharmacologic therapy may influence treatment response and highlighting the need for further investigation into optimal patient selection and timing of PENFS therapy[21] Thus, the decision to initiate PENFS is individualized and based on symptom severity, functional impairment, patient preference, and tolerance of prior therapies.

We are cautious in patients with:

- Skin sensitivity/severe contact dermatitis
- Significant ear anatomy issues that preclude device placement

Figure 4. PENFS device



9. Side Effects and Tolerability

PENFS is generally very well tolerated. The most common side effect is mild skin irritation at the placement (usually transient).

Serious adverse events are rare, and the device is fully removable.

Contraindications:

Absolute contraindications

- Implanted electrical or metallic devices (e.g., pacemaker, implantable cardioverter-defibrillator, cochlear implant, other neurostimulators)
- Active infection at/near the ear placement site
- Known hypersensitivity to device materials/adhesives that cannot be mitigated

Relative contraindications / use with caution

- Bleeding disorders/therapeutic anticoagulation
- Severe dermatologic disease of the external ear (e.g., severe eczema, dermatitis)
- Anatomical ear abnormalities that preclude safe/stable placement
- Uncontrolled epilepsy/seizure disorder (limited safety data)
- Pregnancy (limited safety data)

- Inability to tolerate/comply with device wear (e.g., significant sensory aversion/ behavioral concerns)

10. Insurance Considerations

Insurance approval may require documentation of medical necessities, prior authorization/peer-to-peer review, occasionally, an appeal process

When insurance coverage is denied, some families elect to proceed with out-of-pocket payment or seek manufacturer/institutional assistance programs.

11. Conclusions

Auricular VNS represents a promising, non-invasive neuromodulation strategy for children and adolescents with refractory nausea, abdominal pain, and autonomic dysfunction. While further controlled trials are needed, early clinical experience supports its safety, feasibility, and potential to meaningfully improve quality of life in carefully selected patients.

As our understanding of gut–brain interactions evolve, aVNS may become an important component of precision, mechanism-based care for complex DGBI and autonomic disorders.

References

1. Drossman DA, Hasler WL. Rome IV-functional GI disorders: Disorders of gut-brain interaction. *Gastroenterology*. 2016;150(6):1257-61.
2. Singh R, Zogg H, Ghoshal UC, et al. Current treatment options and therapeutic insights for gastrointestinal dysmotility and functional gastrointestinal disorders. *Front Pharmacol*. 2022;13:808195.
3. Kovacic K, Hainsworth K, Sood M, et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: A randomised, double-blind, sham-controlled trial. *Lancet Gastroenterol Hepatol*. 2017;2(10):727–37.
4. Chogle A, El-Chammas K, Santucci N, et al. A multicenter registry study on percutaneous electrical nerve field stimulation for pediatric disorders of gut–brain interaction. *J Pediatr Gastroenterol Nutr*. 2024;78:817–26.
5. Wang Y, Duan C, Du X, et al. Vagus nerve and gut-brain communication. *Neuroscientist*. 2025;32(3):262-78.
6. Couceiro S, Sant'Anna L, Sant'Anna M, et al. Auricular vagal neuromodulation and its application in patients with heart failure and reduced ejection fraction. *Arq Bras Cardiol*. 2023;120(5):e20220581.
7. Kovacic K, Di Lorenzo C. Functional nausea in children. *J Pediatr Gastroenterol Nutr.* 2016;62(3):365-71.
8. Krasaelap A, Sood MR, Li BUK, et al. Efficacy of auricular neurostimulation in adolescents with irritable bowel syndrome in a randomized, double-blind trial. *Clin Gastroenterol Hepatol*. 2020;18(9):1987-94.e2.
9. Neuraxis awarded first-ever FDA clearance for treatment of pediatric functional dyspepsia and related symptoms. Retrieved February 5, 2026, from https://ir.neuraxis.com/news-releases/news-release-details/neuraxis-awarded-first-ever-fda-clearance-treatment-pediatric.
10. Santucci NR, Beigarten AJ, Khalid F, et al. Percutaneous electrical nerve field stimulation in children and adolescents with functional dyspepsia-integrating a behavioral intervention. *Neuromodulation*. 2024;27(2):372-81.
11. Venkatesan T, Prieto T, Barboi A, et al. Autonomic nerve function in adults with cyclic vomiting syndrome: A prospective study. *Neurogastroenterol Motil*. 2010;22(12):1303-7, e339.
12. Bolender A, Staley R, Garcia RG, et al. Altered parasympathetic outflow and central sensitization response to continuous pain in cyclic vomiting syndrome: A functional magnetic resonance imaging study. *Am J Physiol Gastrointest Liver Physiol*. 2025;328(2):G125-35.
13. Karrento K, Rosen JM, Tarbell SE, et al. North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition 2025 guidelines for management of cyclic vomiting syndrome in children. *J Pediatr Gastroenterol Nutr*. 2025;80(6):1028-61.
14. Nassif MA, El-Chammas K, Graham K, et al. A pilot study investigating improvement in functional nausea after percutaneous electrical nerve field stimulation (PENFS).
15. Castillo DF, Denson LA, Haslam DB, et al. The microbiome in adolescents with irritable bowel syndrome and changes with percutaneous electrical nerve field stimulation. *Neurogastroenterol Motil*. 2023;35(7):e14573.
16. Wang LB, Culbertson CJ, Deb A, et al. Gastrointestinal dysfunction in postural tachycardia syndrome. *J Neurol Sci*. 2015;359(1-2):193-6.

17. Stavrakis S, Chakraborty P, Farhat K, et al. Noninvasive vagus nerve stimulation in postural tachycardia syndrome: A randomized clinical trial. *JACC Clin Electrophysiol.* 2024;10(2):346-55.

18. Santucci NR, King C, El-Chammas KI, et al. Effect of percutaneous electrical nerve field stimulation on mechanosensitivity, sleep, and psychological comorbidities in adolescents with functional abdominal pain disorders. *Neurogastroenterol Motil*. 2022;34(8):e14358.

19. Karrento K, Zhang L, Conley W, et al. Percutaneous electrical nerve field stimulation improves comorbidities in children with cyclic vomiting syndrome. *Front Pain Res (Lausanne).* 2023;4:1203541.

20. Waheed U, VonAxelson A, El-Chammas K, et al. Percutaneous electrical nerve field stimulation improves weight and other anthropometric outcomes in children and adolescents with functional dyspepsia who restrict their oral intake. *Neurogastroenterol Motil*. In press.

21. Kolacz J, Roath OK, Lewis GF, et al. Cardiac vagal efficiency is enhanced by percutaneous auricular neurostimulation in adolescents with nausea: Moderation by antidepressant drug exposure. *Neurogastroenterol Motil*.2025;37(5):e15007.

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