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Percutaneous Approaches to Hypoglossal Nerve Stimulation: A Pilot Study During Drug-Induced Sleep Endoscopy

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Abstract

Hypoglossal nerve stimulation (HNS) is a surgical treatment option for select patients with obstructive sleep apnea that currently requires intraoperative dissection of the hypoglossal nerve (HGN) for implantation of an electrode array. Most HNS strategies target select HGN protrusor muscle branches and exclude undesirable retractor branches. We hypothesized that the target HGN branches could instead be selectively stimulated with a percutaneously delivered electrode array under ultrasound guidance via several anatomic approaches. Five different anatomic approaches were iteratively developed and evaluated during drug-induced sleep endoscopy across 14 patients: posterior, intraoral, anteromedial, anterolateral, and paracoronal. The paracoronal and anterolateral approaches were the most successful, with comparable changes in pharyngeal critical closing and opening pressures. Our data suggest that percutaneous delivery of an HGN electrode is feasible and may decrease the morbidity of HNS therapy implantation. Further work is necessary to ascertain what anatomic approach is optimal for percutaneous electrode delivery.

Keywords

hypoglossal nerve stimulation, obstructive sleep apnea, percutaneous neurostimulation, ultrasound

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Obstructive sleep apnea (OSA) is characterized by repetitive upper airway collapse during sleep and is associated with a variety of cardiovascular and neurologic comorbidities.[1-3] Continuous positive airway pressure is an efficacious first-line therapy, but it is poorly tolerated by a significant portion of patients.[4] Hypoglossal nerve stimulation (HNS) is an alternative surgical treatment for select patients with OSA.[5] The only currently Food and Drug Administration-approved HNS device requires 2 incisions for hardware implantation.[6] During surgery, a cuff electrode is selectively placed on the hypoglossal nerve (HGN) branches to the protrusor muscles of the tongue.[7] This procedure is associated with potential surgical morbidity, including pain, HGN injury, pneumothorax, and infection.[5]

The HGN can be identified with ultrasound. A prior report by our team documented successful HNS with a percutaneous, monopolar fine-wire cathode grounded to a cutaneous anode.[8] Nevertheless, successful implantation of a chronic, indwelling HNS system requires implantation of both circuit components, usually proximate to one another in an electrode array. This pilot study was designed to evaluate various percutaneous approaches to HNS electrode array placement and their subsequent effects on measures of airway collapsibility.

Methods

This clinical trial (clinicaltrials.gov identifier: NCT06283030) was approved by the Vanderbilt University Institutional Review Board (IRB#: 211150). Consenting patients with moderate-to-severe OSA were studied during drug-induced sleep endoscopy.[9] A pneumotachometer was connected to a nasal mask and a positive airway pressure machine to modulate airway collapsibility and document changes in airflow with HNS.[8] Unless otherwise noted, the HGN was identified under ultrasound (Mindray TE7 Max with L12-3RCs linear array transducer; Mindray DS USA Inc) and approached with a needle electrode followed by delivery of a 4 to 6 contact electrode array (SD04R-SP05X-000 or SD06R-AP58X-000; Ad-Tech Medical Instrument Corporation) by modified Seldinger technique. Positive airway pressure was decreased in 1 cm H_2O increments from non-flow-limited inspirations down to either atmospheric nasal pressure or apnea (**Figure 1**).[10] HNS was applied in a 3-breath off/on/off stimulation regime at each nasal pressure level.

Five different HGN anatomic approaches were iteratively developed and evaluated: posterior, intraoral, anteromedial,

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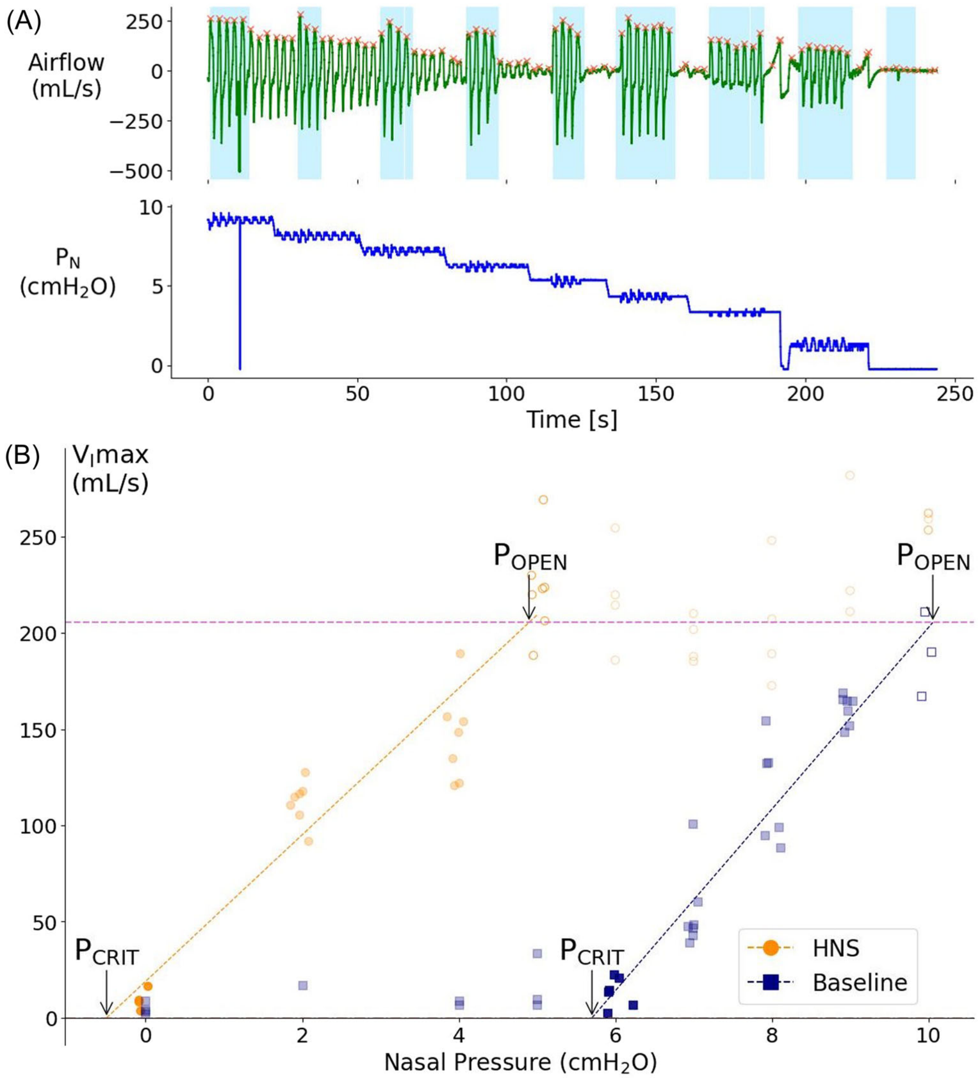

Figure 1. An illustrative example of a single experimental run with a percutaneously placed hypoglossal nerve stimulation (HNS) electrode array. (A) Changes in peak inspiratory airflow ($V_I$max; green tracing) with HNS were measured as nasal pressure (P_N) was decreased in 1 cm H_2O increments from nonflow-limited inspirations down to apnea. (B) Pharyngeal critical closing (P_{CRIT}) and opening (P_{OPEN}) pressures were derived from pressure-flow curves derived from the plotted $V_I$max measurements.

anterolateral, and paracoronal (**Figure 2**). The posterior approach was in a parasagittal plane on a line roughly between the genial tubercle of the mandible and the lesser cornu of the hyoid bone as previously described,[8] in-plane with both the ultrasound probe and the HGN. In the intraoral approach, the electrode array was delivered without the use of ultrasound into the genioglossus muscle through the mouth in a paramedian approach, posterior to the sublingual caruncle. The anteromedial and anterolateral approaches both used the same parasagittal plane of ultrasound as the posterior approach, but the HGN was instead approached from either anteromedially or anterolaterally and outside the plane of ultrasound. In the paracoronal approach, the HGN was approached in-plane with the ultrasound probe, which was angled posteriorly from the coronal plane in the submental triangle, anterior to the anterior border of the hyoglossus muscle.

Pressure-flow curves were constructed to calculate changes in measures of airway collapsibility, including the pharyngeal critical closing (ΔP_{CRIT}) and opening (ΔP_{OPEN}) pressures.[10] Kruskal-Wallis H test was used to evaluate changes in ΔP_{CRIT} and ΔP_{OPEN} with statistical significance set at $\alpha < .05$. Qualitative observations of tongue movement with HNS were collected from oral cavity examination and pharyngoscopy.

Results

Fourteen participants were studied (**Table 1** and Supplemental Table S1, available online). Only 1 to 2

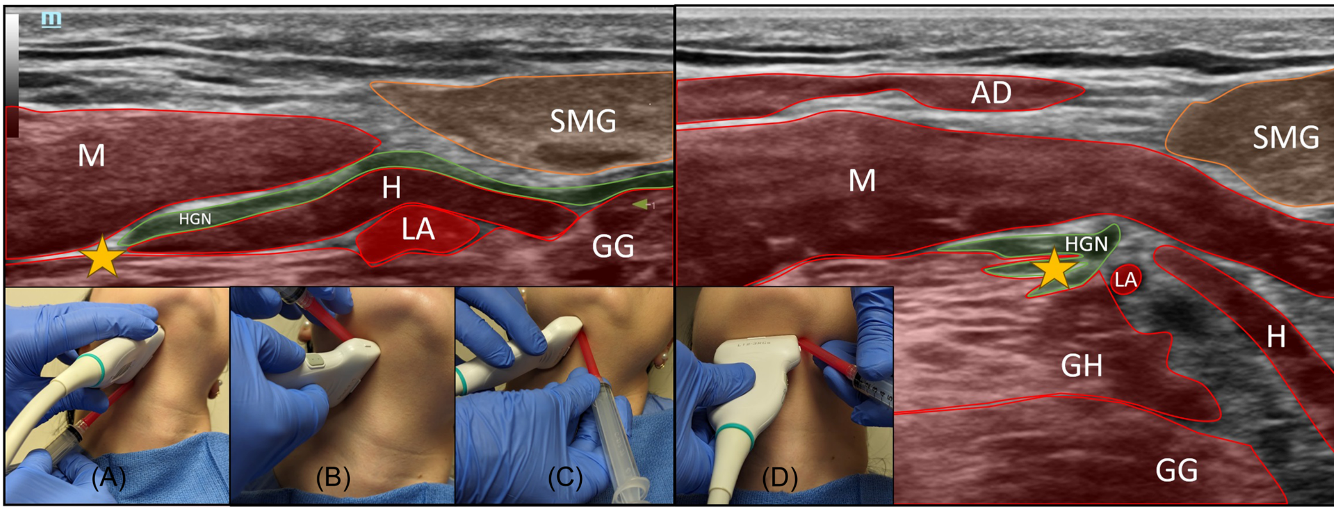

Figure 2. Ultrasound-guided approaches to the HGN. The posterior (A), anterolateral (B), and anteromedial (C) approaches all used a parasagittal ultrasound plane to target the medial branch of the HGN (yellow star). The paracoronal approach (D) crossed the submental triangle from contralaterally in-plane with the ultrasound probe. AD, anterior digastric muscles; GG, genioglossus muscle; GH, geniohyoid muscle; H, hyoglossus muscle; HGN, hypoglossal nerve; M, mylohyoid muscle; SMG, submandibular gland.

Table 1. Summary of Tested Anatomic Approaches for Percutaneous Hypoglossal Nerve Stimulation

Anatomic approach	Participants (n)	Guide needle activation (n)	Tongue protrusion with electrode (n)	ΔP_{CRIT} (cm H2O)	ΔP_{OPEN} (cm H2O)
Intraoral	3	3	0	-	-
Anteromedial	2	2	0	-	-
Anterolateral	5	5	5	−4.0 ± 2.0	−3.6 ± 2.4
Paracoronal	4	4	3	−3.3 ± 2.1	−5.9 ± 3.0
Posterior	8	8	2	−4.3	−7.7

ΔP_{CRIT} and ΔP_{OPEN} are presented as mean ± standard deviation except for the posterior approach, where it could not calculated for a sample size of 2.
Abbreviations: ΔP_{CRIT}, critical collapsing pressure of the pharynx; ΔP_{OPEN}, critical opening pressure of the pharynx.

anatomic approaches were evaluated in each participant to reduce potential trauma risk and time under anesthesia. The HGN was positively identified with ultrasound and stimulated via needle electrode in all 14 participants. Oral tongue protrusion with contralateral deviation was observed after needle placement in all but 1 participant, where an attempted posterior approach only yielded mixed protrusor and retrusor activation of the HGN. After electrode array insertion, tongue protrusion was observed orally and endoscopically in 0/3 intraoral, 2/8 posterior, 0/2 anteromedial, 5/5 anterolateral, and 3/4 paracoronal approaches. Large decreases in airway collapsibility resulted in nonflow-limited breathing even at atmospheric nasal pressure in 1 posterior and 2 anteromedial approach participants, preventing derivation of ΔP_{CRIT} and ΔP_{OPEN}. Mean ΔP_{CRIT} and ΔP_{OPEN} were -3.19 ± 2.2 and -4.5 ± 2.2 cm H_2O, respectively, across the 3 approaches with tongue protrusion after electrode array insertion. No significant differences were detected in ΔP_{CRIT} and ΔP_{OPEN} between the different approaches ($P = .56$ and .76, respectively). No adverse events were observed.

Discussion

This pilot study demonstrated that HNS electrode array delivery via a percutaneous approach is feasible and can be accomplished via several different anatomic approaches. The paracoronal and anterolateral approaches had the highest success rates, with comparable changes observed in measures of airway collapsibility. Interestingly, the previously described posterior approach yielded mixed activation of the HGN in 75% of attempts after electrode array placement.[8] We postulate that diffuse current spread from the larger electrode surface area caused retrusor branch recruitment, while more anterior advancement of the electrode array in this approach caused loss of HGN capture as the distal nerve coursed superomedially. The anterolateral and paracoronal approaches were more orthogonal to the course of the distal HGN, likely reducing the probability of undesirable proximal retrusor branch capture.

This study was limited by the small sample size and diversity of anatomic approaches, prohibiting definitive assessment of an optimal percutaneous HGN approach. The iterative development of the various approaches and limited testing in each participant may have introduced additional bias. Percutaneous electrode array delivery may significantly decrease the morbidity of HNS implantation, but further work is necessary to ascertain what anatomic approach is most optimal.

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Author Contributions

David T. Kent, substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work, drafting the work or reviewing it critically for important intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; **Yike Li**, substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work, drafting the work or reviewing it critically for important intellectual content, final approval of the version to be published, agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Disclosures

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Supplemental Material

Additional supporting information is available in the online version of the article.

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