

Backscattered Ultrasonographic Imaging of the Tongue and Outcome in Hypoglossal Nerve Stimulation

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Abstract

Objective. Hypoglossal nerve stimulation (HNS) is an increasingly used therapy. However, not all patients undergoing HNS implantation benefit from the treatment, making an improved patient selection a priority. This study investigates whether backscattered ultrasonographic imaging (BUI) can predict the response to HNS therapy.

Study Design. Cross-sectional study.

Setting. Secondary and tertiary hospital.

Methods. In this multicenter cross-sectional study, we recruited patients who had undergone HNS implantation during their scheduled follow-up consultation. HNS therapy parameters were collected. Standardized submental ultrasonographic examination and home sleep apnea testing were performed. The primary outcome was assessing the response to HNS therapy using ultrasonographic features and preoperative patient characteristics.

Results. In total, 62 participants, 49 male, with a median (interquartile range [IQR]) age of 62 (55–67) and a median (IQR) body mass index of 27.6 (25.2–29.7). The follow-up was a median (IQR) of 19.5 (4.8–41.4) months after implantation. The apnea-hypopnea index (AHI) was preoperatively 40.5 (29.8–58.0) and reduced at follow-up to 21.0 (11.0–35.3). In total, 42% were responders to HNS. Preoperative AHI (34.8/hour vs 49.3/hour, $r = 0.44$) was significantly higher in nonresponders than in responders. The average prediction accuracy of HNS therapy based on baseline AHI alone was 71%. A lower backscatter signal, indicating less fat deposition in the tissue, was observed in the responder group. When the baseline AHI and backscatter signal were combined, the prediction accuracy of response to the HNS reached 78%.

Conclusion. The combination of tissue composition analyzed using the backscattered signal and the preoperative AHI is highly predictive for determining the HNS treatment response.

Trial Registration. ClinicalTrials.gov identifier NCT06154577.

Keywords

hypoglossal nerve stimulation, obstructive sleep apnea, outcome, ultrasonography

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Hypoglossal nerve stimulation (HNS) is increasingly important in managing patients with obstructive sleep apnea (OSA) who do not tolerate continuous positive airway pressure therapy and are not eligible for other alternative treatment options, such as mandibular advancement devices or positional therapy.¹ The number of HNS implantations is increasing, with several thousand new implantations per year, and they have found their place in treatment guidelines.² Even with restrictive patient selection according to guidelines and optimal HNS titration, the responder rate remains around 50% to 60%.^{1,3–6}

Current anatomical and physiological selection criteria for respiration-triggered HNS include moderate to severe OSA, intolerance to continuous positive airway pressure therapy, body mass index (BMI), drug-induced sleep endoscopy (DISE), and exclusion of central sleep apnea,

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neurologic, and pulmonary comorbidities.^{1,7,8} Patients with complete concentric collapse at the palatal level in drug-induced sedation endoscopy must be excluded from the implantation of respiration-synchronized HNS.⁸ However, the visual assessment of collapse patterns during DISE is highly subjective and of high interrater variability.^{9,10} Further, it is invasive and associated with considerable health care costs. DISE has inherent limitations in that only one level can be observed at a given time, examination over a short period, and artificial sedation. However, the visual assessment of upper airway collapse is the gold standard.^{1,8,11,12}

Incomplete airway opening results in insufficient response to HNS, which can be at the retroglossal and retropalatal levels. The posterior upper airway space dimensions are crucial in managing patients with HNS.¹¹ Weiner et al found that a smaller transverse pharyngeal width, when measured in the supine position using a caliper, is associated with complete concentric palatal collapse and poor response to HNS.¹¹ A recent cohort study showed that standard B-mode ultrasonographic assessment of tongue morphology can predict pharyngeal patency in selective HNS.¹³ Preoperative ultrasonographic evaluation of tongue morphology could also yield predictors for response to improve patient selection.

Standardized submental ultrasonography offers a quantitative, reproducible way of assessing upper airway dimensions and the microstructure of the tongue in a rapid and noninvasive manner.¹⁴ In backscattered ultrasonographic imaging (BUI), the main factor derived is the Nakagami parameter, also referred to as the BUI value hereafter. The value reflects the echo amplitude distribution form, strongly correlated with the tight tissue microstructure, especially the fat content.¹⁵ A higher BUI value is associated with a higher grade of liver steatosis.^{15,16} In a recent study, patients with more severe OSA also have higher BUI values from the tongue tissue.¹⁴ Although no direct histopathological comparison in the tongue musculature has been made, these findings align well with previous magnetic resonance imaging studies.¹⁷ Currently, the value of preoperative ultrasonography for HNS candidacy is unknown. Patients with higher fat content in the tongue musculature, which can be assessed by BUI, might respond poorly to HNS therapy. The authors hypothesize that tongue tissue characterization can help predict patients' response to HNS therapy. This study assesses the predictive value of standardized submental ultrasonography for response to HNS.

Methods

Study Design and Participants

This multicenter study was conducted in patients with selective respiration-triggered HNS (Inspire Medical Systems, Inc.) consecutively recruited during routine follow-up appointments. The two participating centers

were a tertiary hospital (Inselspital, University Hospital, and University of Bern) and a secondary hospital (Kantonsspital Baselland, Liestal). All adult patients with HNS implantation were eligible. Excluded were those patients with previous neck surgery other than HNS and tonsillectomy due to postoperative alteration of the anatomy and patients with congestive heart failure, chronic obstructive pulmonary disease, comorbid sleep disorders, and pregnancy. All participants in this study have signed the informed consent form. The study was approved by the Swiss Association of Research Ethics Committees (Ethikkommission Nordwest- und Zentralschweiz EKNZ and Ethikkommission Bern, project ID 2023-00117) and conducted according to the Declaration of Helsinki.¹⁸ The study was registered on ClinicalTrials.gov (identifier NCT06154577). The study protocol is given in Supporting Material S1, available online. After informed consent was obtained, standardized ultrasonography was performed in addition to the routine follow-up and sleep testing. Historical data were collected from patient charts.

Clinical Examination and Sleep Testing

Implantation and preoperative sleep data were collected from patient charts. If no recent sleep testing was available or changes to HNS parameters had been made, a sleep testing was repeated using respiratory polygraphy (Nox T3, Nox Medical) or peripheral arterial tonometry (WatchPAT®, Itamar Medical). Data on the device function, usage history, and stimulation parameters were collected during the follow-up. Tongue protrusion during therapeutic stimulation was visually assessed with the mouth half opened.

Standardized Submental Ultrasonography

A standardized submental ultrasonography was performed in awake patients implanted with HNS during regular follow-up visits. An ultrasound system (Terason uSmart3200T, Teratech Corporation, FDA approval K193510) with a 2 to 5 MHz convex transducer (5C2A). To ensure standardized ultrasound scan and radio-frequency data collection, the transducer was mounted on a robotic arm and positioned along with the head using a laser alignment tool (FDA Establishment Registration & Device Listing No. 3015218501; AmCad BioMed Corporation), which marked the sagittal center plane, the Frankfurt horizontal plane, and the cross-sectional plane through the hyoid bone and ear opening (hyoid-external-meatus plane, H-M plane, **Figure 1**). Once aligned, the scan was automatically performed via robotic control, capturing transverse images of the upper airway 15 degrees above and below the H-M plane (**Figure 2**). Each scan was repeated three times during tidal breathing and stimulation of the hypoglossal nerve at the therapeutic level. The scans were divided into equal-angle sectors of the posterior tongue, approximately corresponding to the velum, oropharynx, and tongue base segments of the upper airway. The



Figure 1. Ultrasonography system with a robotic probe positioning and laser alignment tool to ensure standardized scanning of the upper airway (AmCad BioMed Corporation).

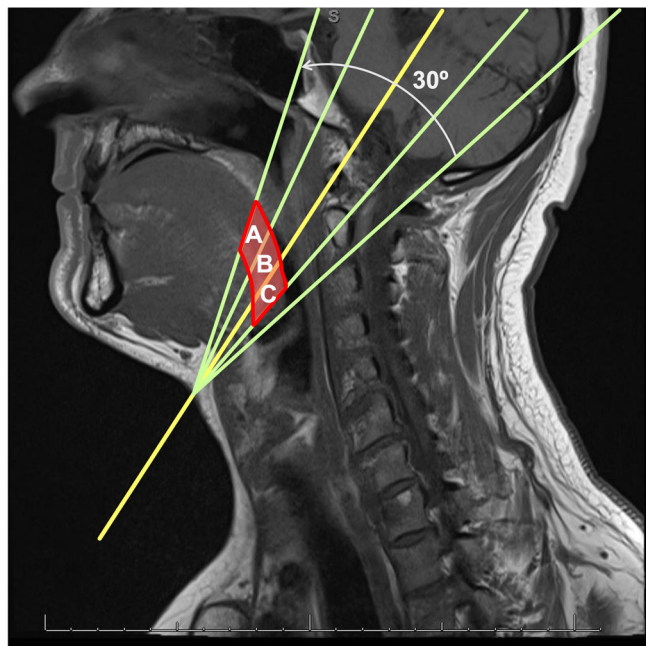


Figure 2. Sagittal magnetic resonance image with a 30-degree sector scan (red) covering the regions (A-C) where backscattered statistics were measured. The yellow line marks the hyoid-external meatus plane. Markings represent a 1-cm ruler.

posterior tongue tissue was selected for analysis due to its larger tissue area, which allowed for a BUI assessment. Image data were analyzed using AmCAD-UO and AmCAD-US (AmCad BioMed Corporation, FDA approval K180867 and K162574) to identify the tongue and tongue-airway interface and quantitatively characterize the posterior section of the tongue tissue.

Statistical Analysis

The primary endpoint was predicting therapeutic success with HNS based on tongue tissue characterization.

Responders were defined according to the Sher criteria, with a postoperative AHI below 20/hour and a greater than 50% reduction compared to the baseline.¹⁹

Sample Size Calculation

A sample size calculation was performed to estimate the required number of patients for this study. We assumed a significance level of .05 (alpha) and a power of 80%, that is, a type II error (beta) of .2 and at least one standard deviation difference of the means with 2/3 of the nonresponder to responder ratio.^{1,20} The sample size required for the nonresponder group was 14, and the sample size necessary for the responder group was 21. The total sample size required was 35. Assuming a drop-out rate of 10% (technical failures, incomplete data), the total number of patients needed was at least 39.

BUI from the posterior section of the tongue tissue was computed from collected radio-frequency ultrasonic data.¹⁴ The medians of BUI in regions A to C were calculated for the groups of responders and nonresponders to HNS. The Wilcoxon rank sum test's median difference and effect size (r) with corresponding confidence intervals were used to compare the demographics and quantified features between the two groups. The coefficient of variation (CV) was used to evaluate the reliability of the measurements. Statistical analyses were performed using MedCalc statistical software version 19.0.4 (MedCalc Software Ltd) and R version 4.4.1 (R Project for Statistical Computing).

Results

Basic Patient Characteristics

We consecutively enrolled 65 patients with HNS during follow-up visits: 56 at Kantonsspital Baselland, Liestal, and nine at Inselspital, University Hospital Bern. The image quality was insufficient in three patients, leaving 62 patients for further evaluation. Twenty-six patients were responders, and 36 were nonresponders. Responders and nonresponders were comparable in sex, age, BMI, and neck circumference. However, the baseline AHI was significantly higher, with a Wilcoxon effect size $r=0.44$ (95% CI, 0.23-0.64), in nonresponders versus responders (median difference, 15.4; 95% CI, 7.1-24.0). The follow-up was a median (interquartile range [IQR]) of 19.5 (4.8-41.4) months after implantation. The demographic characteristics of the patients are detailed in **Table 1**, and additional information is provided in Supporting Material S2, available online. BMI did not differ significantly between before implantation (27.4 ± 2.9 kg/m²) and the time of the follow-up examination (27.7 ± 2.9 kg/m², $P=.25$) or depending on responder status (responder -0.8 ± 0.8 kg/m², nonresponder -0.3 ± 1.7 kg/m², $P=.48$).

Prediction of AHI Response

BUI values were moderately higher in nonresponders, with $r=0.35$ (95% CI, 0.12-0.58) at tongue region A

Table 1. Demographic and BUI Values Measured for Subjects Recruited for the Study

	Overall	Responder	Nonresponder	Median difference (95% CI) ^a	r (95% CI) ^b
Sample size, no.	62	26	36		
Age, y, median (IQR)	62 (55-67)	65.5 (56-69)	61 (53-65)	-4.0 (-9.0 to 1.0)	0.19 (0.02-0.44)
BMI, kg/m ² , median (IQR)	27.6 (25.2-29.7)	26.7 (25.1-28.8)	28.6 (26.0-29.9)	1.66 (0.0-2.96)	0.25 (0.03-0.47)
Neck, cm, median (IQR)	42.0 (40.0-44.0)	41.0 (39.0-42.0)	42.0 (40.5-44.0)	1.0 (0.0-3.0)	0.24 (0.02-0.46)
Male female, no.	49 13	20 6	29 7		
Baseline AHI, events/h, median (IQR)	40.5 (29.8-58.0)	34.8 (25.6-42.0)	49.3 (38.6-67.4)	15.4 (7.1-24.0)	0.44 (0.23-0.64)
Postoperative AHI, event/h, median (IQR)	21.0 (11.0-35.3)	10.1 (6.2-12.2)	33.5 (24.8-40.5)	23.2 (18.5-28.2)	0.83 (0.76-0.86)
BUI value, A region, median (IQR)	0.86 (0.80-0.89)	0.81 (0.79-0.86)	0.88 (0.82-0.90)	0.05 (0.02-0.08)	0.35 (0.12-0.58)
BUI value, B region, median (IQR)	0.84 (0.80-0.87)	0.82 (0.79-0.84)	0.86 (0.81-0.88)	0.03 (0.01-0.06)	0.30 (0.05-0.52)
BUI value, C region, median (IQR)	0.83 (0.78-0.86)	0.82 (0.78-0.84)	0.83 (0.78-0.87)	0.01 (-0.02-0.04)	0.12 (0.01-0.36)

Abbreviations: AHI, apnea-hypopnea index; BMI, body mass index; BUI, backscattered ultrasonographic imaging; IQR, interquartile range.

^aHodges-Lehmann median difference.^bWilcoxon effect size.

(median difference, 0.046; 95% CI, 0.015-0.079) and $r = 0.30$ (95% CI, 0.05-0.52) at tongue region B (median difference, 0.034; 95% CI, 0.005-0.064) (**Figure 3** and **Table 1**).

The area under the receiver operating characteristic curve (AUROC) for predicting responders using baseline AHI alone was 0.76 (95% CI, 0.63-0.86). A baseline AHI ≤ 39 events/hour threshold provided the maximum balanced accuracy (average of sensitivity and specificity) of 71% with a sensitivity of 73% and specificity of 69%. The AUC of BUI value at tongue region A alone was 0.71 (95% CI, 0.58-0.82). When the BUI value at tongue region A was combined with baseline AHI, the maximum balanced accuracy reached 77%, with the specificity improved markedly from 69% to 89%. For a baseline AHI threshold of ≤ 65 events/hour, as suggested by the Inspire HNS system's indication for use, the addition of BUI significantly improved the balanced accuracy from 63.9% to 78%, with a sensitivity of 88% and specificity of 67%. The highest AUROC of 0.77 was achieved when the baseline AHI ≤ 65 was combined with the BUI values at tongue region A (**Figure 4**).

For the possible confounding effect of BMI, we have analyzed its relationship with backscattered statistics and HNS treatment response. The correlation between BMI and backscattered statistics at region A is weak (rank correlation coefficient = 0.10, $P = .43$), indicating that the fat composition of the tongue may not entirely depend on weight. When BMI was included alongside baseline AHI in predicting the treatment response, the maximum balanced accuracy was only 71% for a baseline AHI threshold of ≤ 39 and dropped to 68% for a threshold of ≤ 65 events/hour.

Reliability of BUI

Out of 62 patients, 56 had at least two ultrasound scans of sufficient quality to assess the reliability of BUI. The estimated CV for BUI value was 5.2% (95% CI, 3.8-6.3) at tongue region A, 4.4% (95% CI, 3.0-5.5) at region B, and 4.3% (95% CI, 3.2-5.2) at region C. These CV values indicate excellent reliability of the measurements, with low variability across the regions analyzed.

Discussion

In several controlled studies, HNS proved to be a safe and effective treatment.^{1,6} Higher baseline AHI, higher BMI, and male sex have been demonstrated as negative predictors of success.⁴ Female sex and greater age are favorable factors for therapeutic outcomes. However, despite the unquestionable effectiveness and stringent patient selection, 30% to 40% of the patients are nonresponders.^{5,6} Given the invasiveness and costs of HNS, a better understanding of favorable anatomical and physiological traits is crucial to improve patient selection.

We examined consecutive patients during routine follow-up checks. Therefore, the present study's responder

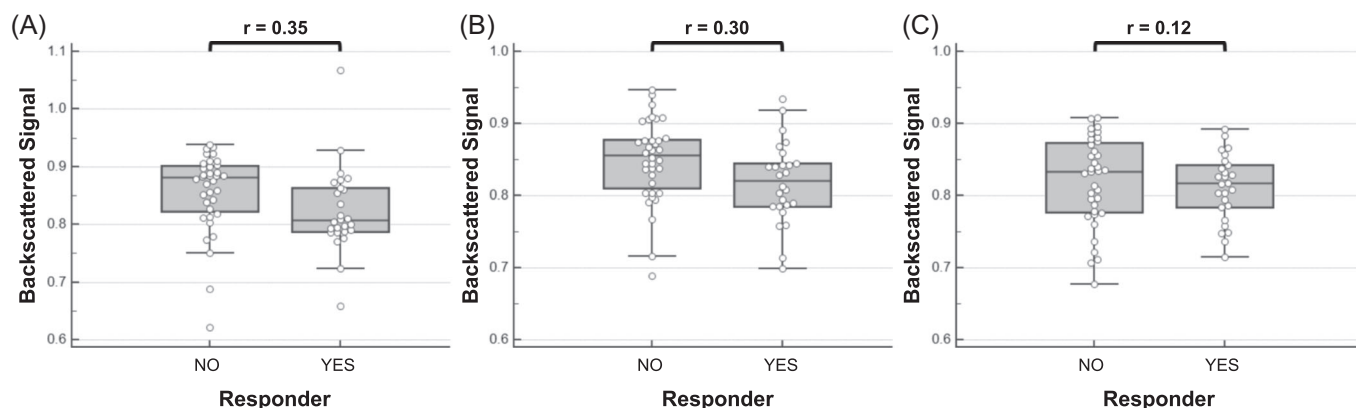


Figure 3. Backscattered statistics for regions A-C (A–C) in responders and nonresponders.

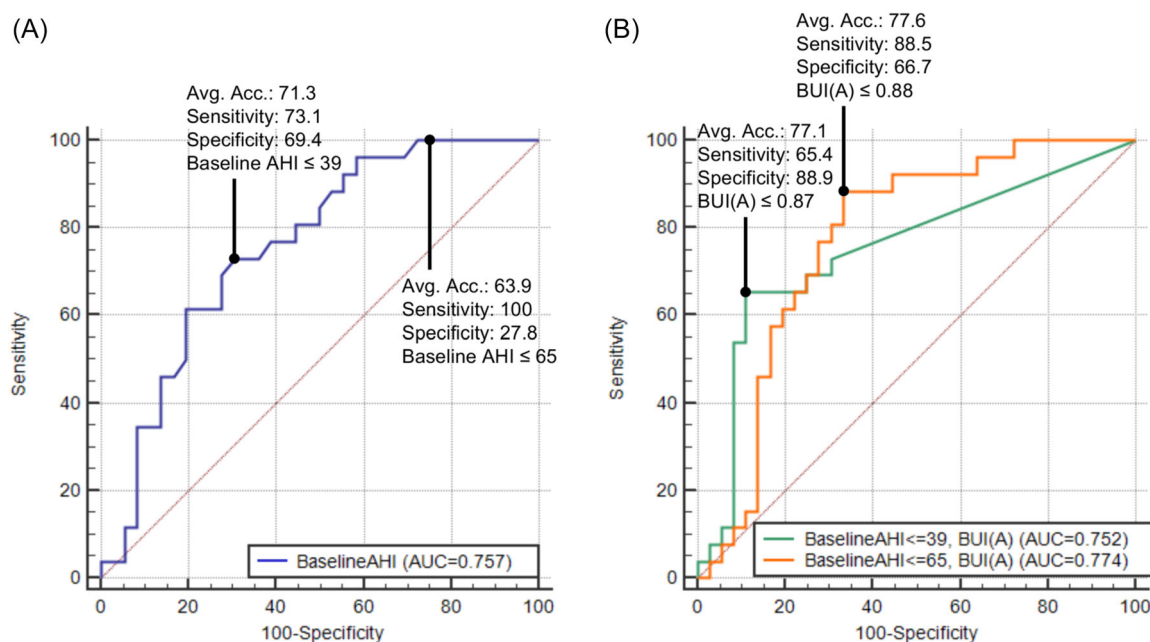


Figure 4. Receiver operating characteristic (ROC) curves predicting responsiveness to hypoglossal nerve stimulation using (A) baseline AHI and (B) backscattered statistics with baseline AHI ≤ 39 events/hour (green) and backscattered statistics with baseline AHI ≤ 65 events/hour (orange).

rate does not necessarily represent the success rate of our whole patient cohort. Nevertheless, we saw a high rate of nonresponders even though all patients underwent a meticulous selection process and fulfilled the FDA criteria for HNS before implantation. These findings, combined with 30% to 40% nonresponders in the literature, suggest that the current selection criteria may be incomplete and could be further improved.^{5,6}

Our study shows that the baseline AHI and BUI of the tongue at region A, the portion of tongue muscle near the soft palate, allow for a better average accuracy of at least 77% in predicting responder status after HNS. Two options for clinical decision-making emerge based on AHI thresholds. For a better clinical decision to ensure the success of HNS, a lower AHI threshold of ≤39, combined with a lower BUI value of ≤0.87, leads to a specificity of 88.9%, effectively reducing the percentage of

nonresponders to 11%. Alternatively, if the suggested AHI (≤65) is followed to include a broader patient population, a BUI value of ≤0.88 is recommended for better patient selection to improve the specificity from 27.8% to 66.7%, reducing nonresponders by approximately 40%. The BUI value offers a valuable addition to the existing selection process, further optimizing treatment outcomes. It is noteworthy that BUI measurements were more predictive than BMI, suggesting that the location of fat accumulation is a crucial factor in OSA. In particular, fat accumulation in the tongue muscle, as indicated by a higher BUI value, appears to more significantly impact HNS outcomes than fat in other body areas, such as the hips or abdomen.¹⁷

DISE is currently an essential tool for selecting patients for HNS therapy. The value of DISE, however, may be questioned. Though DISE has a good correlation between

natural and drug-induced sleep and test-retest reliability, the examination also has a moderate to high interrater variability, possibly contributing to suboptimal patient selection.^{10,21,22} Based on one night's measurement, AHI also entails a high degree of uncertainty due to the well-known and relevant night-to-night variability.^{23,24} Compared to these examinations, standardized ultrasonographic imaging with BUI showed a high reliability based on our estimate of CV values. These scans are obtained rapidly, with an acquisition time of approximately 10 minutes. BUI functionality can be integrated into ultrasound probes, subject to the specific hardware and manufacturer.

OSA is a multifactorial disease, and several anatomical and physiological traits may contribute to a lack of therapeutic success with HNS. The most frequent causes for failure are persistent obstruction of the upper airway at the level of the palate due to insufficient palatal coupling and the inability of some patients to tolerate therapy at sufficient stimulation levels.²⁵ Our prediction model based on baseline AHI and BUI of the tongue does not consider these factors.

BUI of the tongue, combined with baseline AHI, has a high potential to improve patient selection for HNS therapy. The predictive accuracy may be enhanced by measuring multiple nights rather than relying on only one night for the assessment of baseline AHI. The authors hypothesize that our model, combined with anatomical traits such as tonsil status, may potentially replace DISE for a subset of patients in the selection process.

Limitations

Patients were consecutively recruited during routine follow-up consultations. As patients with unfavorable outcomes require more consultation, they may be overrepresented in our sample, potentially resulting in selection bias. Furthermore, we utilized home sleep testing instead of titration polysomnography, which Kaffenberger et al found to exhibit lower responder rates.²⁶ The robotic ultrasound scan and imaging analysis were blinded to responder status, but investigators were unblinded during follow-up consultation. Implantation and the use of HNS may alter the tongue's anatomy and influence results, which cannot be assessed as all measurements were performed postoperatively. Weight change might alter tongue anatomy; however, in our study, no changes in BMI were found. Further, the purely anatomical screening omits physiological attributes such as arousal threshold, loop gain, and compliance with therapy, which are also essential for treatment success. BUI of the tongue gives no information on the airway opening at the palatal level, so it cannot account for nonresponders with persistent palatal obstruction. Moreover, BUI alone cannot exclude the preoperative complete concentric collapse pattern observed during DISE.

Strengths

Our study is the first to investigate the value of backscattered ultrasound in patients with HNS therapy. BUI gives valuable information about the tongue's microstructure, which could otherwise only be obtained using MRI.

Future Research

Future studies should prospectively validate the results through preoperative ultrasound and BUI assessment. Additionally, the value of ultrasonic imaging in other OSA treatments should be evaluated. A more detailed investigation into ultrasonographic anatomy is warranted to enhance our understanding of its applications and limitations. The airway opening behind the tongue base observed via ultrasound may provide more clinically relevant information than the visual inspection of anterior tongue movement. Integrating other physiological parameters, such as the arousal threshold and loop gain, could further improve prediction. Implementing anatomical traits, such as tonsil status, in a refined statistical prediction model based on baseline AHI and BUI of the tongue deserves further investigation to improve patient selection for HNS implantation.

Conclusions

Standardized submental ultrasonography is a practical tool for assessing tongue morphology, especially lingual fat content. BUI is a new predictive parameter for the outcome of HNS. Including BUI in the preoperative patient selection may improve the success rate of the therapy.

Author Contributions

Concept and design: Kurt Tschopp, Samuel Tschopp, Vlado Janjic, Urs Borner, Marco Caversaccio, Argon Chen, Pei-Yu Chao, and Yili Lee. *Administrative, technical, or material support:* Kurt Tschopp, Urs Borner, and Marco Caversaccio. *Data collection:* Samuel Tschopp, Vlado Janjic, Urs Borner, and Kurt Tschopp. *Formal analysis and visualization:* Argon Chen, Pei-Yu Chao, Yili Lee, and Samuel Tschopp. *Drafting of the manuscript:* Samuel Tschopp, Kurt Tschopp, Pei-Yu Chao, and Argon Chen. *Critical revision of the manuscript:* all coauthors. *Final approval:* all coauthors.

Disclosures

Competing interests: Kurt Tschopp received grants from AmCad Biomed Corporation during this study.

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Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author, Samuel Tschopp.

Supplemental Material

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

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