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Palate shape is associated with Unilateral Hypoglossal Nerve Stimulation Outcomes

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Conflicts of Interest:

Kedarisetty, Sharma, Comness, Green, D'Agostino: None

Woodson: Inspire Medical Systems - research trial investigator; Nyxoah SA- research trial investigator, coordinating investigator; Medtronic - research trial investigator, consultant; CryOSA - advisory board member, stock options; Linguaflex - research trial investigator

Huyett: Inspire Medical Systems- research support, educational consultant; Nyxoah SA- research support

Kent: Laborie Medical Technologies Corp- Research Support; Inspire Medical Systems- Research Support; Invicta Medical, Inc- Consultant, Research Support; Nyxoah SA- Scientific Advisory Board Member, Intellectual Property Interests, Research Support

Kezirian: Inspire Medical Systems- research funding; CryOSA- consultant, medical advisory board; Nyxoah SA- consultant; Berendo Scientific- consultant, intellectual property; Magnap - intellectual property

Abstract

Objective: To determine the potential association between palate shape and unilateral hypoglossal nerve stimulation (HNS) outcomes.

Methods: Preoperative drug-induced sleep endoscopy (DISE) videos were reviewed and scored by 3 blinded reviewers to determine airway narrowing at the hard-soft palate junction (HP), soft palate genu, and inferior velum, as described by Woodson (2014). Scoring was 1–open airway, 2–narrow, 3–severe narrowing. Overall palate shape (oblique, intermediate, or vertical) was determined based on prior criteria. Successful surgical treatment was defined by the HNS titration polysomnogram as a reduction of 50% in the apnea-hypopnea index (AHI) to <15 events/hour.

Results: Of 332 adults, the majority was male (77%) with an average BMI of 29.2 +/- 3.6 kg/m². Overall success rate was 73%. Success rate was lower in patients with vertical palate shape compared to the other shapes (56% vs 75%, $P=0.029$). HP score 3 compared to scores 2 & 1 was associated with lower success rates (60% vs 76%, $P=0.028$), but genu and velum scores were not associated with outcomes. Patients with both HP score 3 and complete oropharyngeal lateral wall related obstruction had notably worse outcomes (22% vs 74%, $P=0.026$). HP score 3 (OR 0.45, 95% CI 0.22–0.92) and vertical palate shape (OR 0.33, 95% CI 0.15–0.78) were independently associated with lower odds of surgical response after adjustment for DISE findings, age, gender, and BMI.

Conclusion: Vertical palate shape and narrowing at the hard-soft palate junction are independently associated with lower HNS surgical success rates.

Short Lay Summary

This study reveals a new measurement involving the roof of the mouth that can help predict surgical success from hypoglossal nerve stimulation.

Keywords

Hypoglossal Nerve Stimulation; OSA; HNS; Inspire

Introduction

Unilateral hypoglossal nerve stimulation (HNS) is an important surgical treatment option for patients with obstructive sleep apnea (OSA) who do not tolerate positive airway pressure.

Key eligibility criteria for HNS include BMI, age, AHI, and the absence of complete concentric collapse related to the palate on drug induced sleep endoscopy (DISE)¹. However since HNS has gained popularity, a number of other factors have been associated with poorer (complete oropharyngeal lateral wall-related obstruction², greater preoperative AHI³, greater soft palate thickness⁴, and soft palate volume⁵) and better (tongue-related obstruction²) outcomes. Thus far, no in-office airway assessments have been associated with HNS outcomes. Assessments performed in the office during wakefulness could enhance surgical decision making and avoid the need for DISE, particularly for patients with office exam findings associated with poor HNS outcomes who would not consider other interventions.

Woodson has described soft palate phenotype or shapes (oblique, intermediate, and vertical, Figure 1) based on anatomical landmarks. The current approach to defining palate shape involves determining the degree of narrowing or airflow limitation at the hard-soft palate junction, soft palate genu, and distal soft palate (velum)⁶⁻⁸. Longer retropalatal airway has been associated with poorer surgical outcomes after soft palate surgery⁹, and vertical palate shape is theorized to be associated with poorer outcomes as well⁶. This concept has not been studied with HNS outcomes. The objective of this study was to determine if a more restricted airway determined by palate shape results in poorer unilateral hypoglossal nerve stimulation outcomes.

Methods

This was a retrospective multicenter cohort study of adults undergoing HNS (Upper Airway Stimulation; Inspire Medical Systems, Inc., Golden Valley, MN) for the treatment of OSA. This cohort was previously used to evaluate the association between DISE findings and HNS outcomes². Identical inclusion criteria were used: adults over the age of 21, availability of preoperative sleep study and post operative titration study, video recorded preoperative DISE, and absence of prior pharyngeal surgery except for tonsillectomy.

Demographics data such as age at time of implantation, sex, body mass index (BMI), preoperative sleep study data, and apnea-hypopnea index (AHI) on postoperative titration data (tPSG), were obtained. De-identified DISE data obtained in the supine position, and study subject data were available in a HIPAA-compliant, cloud-based database (Box.com; Box, Inc., Redwood City, CA). Consensus-based scores for the VOTE Classification and primary structure contributing to airway obstruction had been determined in the previous study. The study was approved by each center's institutional review board or similar committee.

For palate level and shape variables, DISE videos were reviewed and scored by three blinded reviewers (S.K., A.S., and E.C.) as follows. All database videos were recorded during DISE sedation, with the level of sedation varying by patient and surgeon/institutional standard practices. Scoring was performed based on a modification of Woodson's previous criteria⁶. Because the scoring was performed in the supine position during DISE sedation instead of wakefulness, we attempted to identify a standardized evaluation where the airway was in the most open state (not during apneic events) during restful, rhythmic breathing determined by lack of swallowing and periodic soft palate motion with or without snoring.

An initial testing sample of 10 subjects was used for training, with discussion of any disagreements among scorers. Degree of airway narrowing or airflow limitation in the anterior-posterior direction was determined at 3 different levels: (1) hard-soft palate junction (HP), (2) soft palate genu (Genu AP), and (3) inferior aspect of the velum (V). In addition, the degree of airflow limitation in the lateral direction at the level of the genu was separately scored (Genu LW). The HP location was approximated by the posterior end of the nasal septum, as this landmark was more-easily visualized during endoscopy. The soft palate genu location was approximated by a change in angulation of the nasal surface of the soft palate, by differences in reflection of endoscope light from different portions of the soft palate, and

the location of the levator veli palatini folds extending medially from the torus tubarius. The inferior aspect of the velum was approximated by the location of the uvula.

All levels were scored on a scale of 1–3 (1- open, 2- partial narrowing/flow limitation, 3- severe narrowing/most flow limitation). A priori criteria for consensus scoring and reconciliation was determined for each level as follows: a) the mode was chosen if there was agreement of at least 2 reviewers; b) in cases with no agreement (3 reviewers score 1, 2, and 3), the middle category (2) was chosen; c) if 2 reviewers cannot score for any reason such as insufficient data, that level is excluded; d) if 1 reviewer cannot score, that level is rescored by all reviewers independently. If consensus score is not obtained after rescoring, that level is excluded. Supplemental figures 1 and 2 and supplemental video demonstrate scoring methodology.

Next, overall palate shape was determined based on criteria modified from Woodson's prior description⁶. Vertical palate shape was scored as the greatest narrowing and airflow restriction at all levels, with scores of 3/3/3 at the HP, Genu AP, and Velum. Oblique palate shape is the most open with a HP score 1, Genu AP score 1–2, and any Velum score. All others were considered Intermediate shape.

Post-treatment AHI was based on results from titration polysomnogram (tPSG), a type 1 sleep study with remote adjustment of device settings by the sleep technologist to identify optimal settings. As therapeutic AHI and full night studies were not available due to differences in practice patterns across institutions, AHI from the optimal voltage tested was used for this study. Surgical response was defined as at least 50% decrease in the AHI to a level below 15 events/hour. Data analysis was performed using Stata/IC 10.1 (StataCorp, College Station, TX, USA). A priori sample size calculations indicated that 125 total subjects would provide power of 80% at $p < 0.05$ to detect a 20% difference in surgical success in vertical palate group compared to the rest of the subjects.

Categorical variables were reported as frequency and percentage, and continuous variables were reported as mean and standard deviation. Univariate associations between HNS outcomes and palate shape variables were tested, both for the entire study population and for subgroups defined by DISE findings. Comparisons for continuous variables were made using paired *t*-tests and for categorical variables using Pearson chi-square tests. Interrater reliability was defined by the Scott/Fleiss Kappa statistic. Multivariate logistic regression models were created using significant palate shape measures that were added to the models using in the previous study². *P*-values < 0.05 were considered significant.

Results

There was a total of 343 adults who underwent HNS treatment. After DISE video reviewed, 11 were excluded due to inadequate view of the palate, leaving a study sample of 332 subjects. Relative distribution from 10 centers is shown in Table I. Study subjects were primarily older (mean age 60.6 \pm 10.7 years), majority were male (77%), and the mean BMI was 29.2 \pm 3.6.

Subjects primarily had moderate to severe OSA (mean preoperative AHI 35.8 \pm 15.2). AHI improved in the overall cohort, with the majority dropping into the mild or no OSA category (mean postoperative AHI 11.1 \pm 14.2). Overall surgical response rate was 73%. Table II presents AHI data at baseline and during ideal settings from the tPSG.

Consensus scores for palate levels and overall shape are presented in Tables III and IV, respectively. Forty subjects were excluded for the hard palate scoring due to at least 2 reviewers agreeing to exclude (inability to visualize posterior septum on recorded DISE video), 11 videos were completely excluded from this study as mentioned previously (agreed upon by at least 2 reviewers) for insufficient soft palate visualization, and 28 videos were rescored independently due to only 1 reviewer suggesting to exclude on initial review. Among the 4 variables assessed across all videos, no agreement among the three reviewers (respective scores of 1, 2, and 3) was encountered 49 times and a score of 2 was chosen. Overall, there was poor inter-rater reliability for scoring at the velum (0.138), and fair reliability for scoring at the other levels (Hard Palate 0.219, Genu AP 0.203, Genu LW 0.276).

Univariate analyses for association between surgical response and individual palate level scores or overall palate shape are presented in Table V. HP score 3 (HP3) and vertical palate shape were associated with surgical response, but other findings were generally not associated with surgical outcome.

Additional analyses did not demonstrate any association in subgroups defined by DISE findings: complete tongue-related obstruction, complete velum-related obstruction, and primary site of obstruction (data not shown). However, among those with complete oropharyngeal lateral wall-related obstruction, HP3 was associated with poorer outcomes compared to HP scores of 1 and 2 (success rates $n=2/9$, 22%, vs $n=14/19$, 74%, $P=0.026$). There were no subjects in this subgroup with vertical palate shape.

Vertical palate shape was associated with somewhat greater preoperative AHI (41.2 \pm 15.7 vs 34.9 \pm 15.1 events/hour, $P=0.04$). However, postoperative AHI was not significantly different (13.4 \pm 14.0 vs. 10.9 \pm 14.3 events/hour, $P=0.39$). BMI and age also were not different in the two groups (data not shown).

Multivariate logistic regression was performed to evaluate the independent association between palate level or shape and surgical response, with and without adjustment for potential confounders, such as age, gender and BMI. Vertical palate was associated with poorer outcomes in both the unadjusted and adjusted models (Table VI). Similar findings were seen for HP3 (Table VII). Other factors such as oropharyngeal lateral wall obstruction were not significantly associated with outcomes in this multivariate model, although the point estimates were almost identical to those in the previous study, suggesting that the lack of statistical significance may be related to sample size.

Discussion

To our knowledge, this is the largest study examining the association between palate shape and surgical outcomes and the first study to examine these in the context of HNS outcomes.

Vertical palate shape and narrowing at HP were associated with poorer outcomes. There was a consistent negative association with HNS outcomes on univariate and multivariate analyses, including after adjustment for age, gender, and BMI.

We believe that one explanation for the poorer HNS success rates with the vertical palate shape is a failure of HNS to open the retropalatal airway space adequately. Nonresponders to HNS have lesser opening of the retropalatal airway space, compared to responders¹⁰. Difference in palatal anatomy, such as vertical shape, may partially explain this. The vertical palate shape represents the greatest degree of airway narrowing along the length of the soft palate, and a key component of the vertical palate shape is HP narrowing. While HNS directly produces anterior tongue movement, the effect on the retropalatal airway may be indirect due to palatoglossal coupling¹¹ or by preventing tongue prolapse into the palate¹². In cases of a vertical palate shape or HP narrowing, palatoglossal coupling may be inadequate to open a retropalatal airway that is especially narrow.

Among the components of the vertical palate shape, HP narrowing was the most important level-specific finding. Findings for other levels were not associated with HNS outcomes. A posterior position of the hard-soft palate junction has been examined using lateral X-rays as the distance between the posterior nasal spine and C1; this study showed no association between this measurement and HNS outcomes⁴. Differences in our findings could be explained by the fact that our greater sample size, use of a subjective (vs. objective) assessment, or that these are somewhat different measures of hard palate narrowing (distance to the posterior pharyngeal wall vs. C1).

Prior research using this database found that complete oropharyngeal lateral wall-related obstruction was negatively associated with HNS outcomes², but with statistical adjustment for a vertical palate shape or HP3, the association was no longer statistically significant. The difference in significance could be explained by different and/or smaller study populations (a total of 51 subjects from the previous study were excluded from these analyses in the current study - 11 videos completely excluded for insufficient soft palate visualization, 40 videos for insufficient hard palate visualization). This is supported by multiple previous studies that have demonstrated complete oropharyngeal lateral wall-related obstruction to be negatively associated with HNS outcomes^{2,3}. It is unclear whether the synergistic negative effect of these two findings occurs through a similar (e.g., both findings are associated with a lower likelihood of opening the retropalatal airway with HNS) or different mechanism. We believe that these represent distinct anatomic factors, the combination of complete oropharyngeal lateral wall-related obstruction and vertical palate shape/HP3 is associated with especially poor outcomes.

This study has important limitations. First, our assessment of outcomes was limited to the AHI on the titration PSG rather than a full-night sleep study assessment, other objective (e.g., oxygen desaturation index), or subjective (e.g., Epworth Sleepiness Scale or the Functional Outcomes of Sleep Questionnaire) measures of OSA severity. Unfortunately, these other data were not available in this database. Second, the inter-rater reliability for palate level scores among the 3 blinded reviewers demonstrated poor to fair agreement, which reflects the subjective nature of the scoring from pre-recorded DISE videos. Our

use of 3 blinded reviewers and an a priori process for developing consensus scores was an attempt to enhance the analyses. We also rescored 28 subjects for whom the reviewers did not originally agree and excluded a total of 40 subjects for whom a majority of the reviewers determined that the videos did not permit adequate evaluation of hard palate narrowing. In addition, the classification scheme used in this study based on palate shape grading is not a validated measurement tool. Initial description of palate shape was during awake upright laryngoscopy in the office, whereas this study utilized the supine sedated state. We believe that the differences may be smaller for hard palate narrowing than other aspects of palate shape, such that the positive findings for hard palate shape are still meaningful. However, further studies would need to be performed to determine the differences in the two positions.

A strength of this study is the use of a database spanning multiple institutions, enhancing the study generalizability, though only generalizable to a population of patients eligible for HNS. Overall HNS response rates were similar to those from previous studies^{13–16}.

Future work may include development of objective measures of palate level measurements and palate shape. Various endoscopic measuring systems exist, especially in the gastroenterology literature^{17,18}. Alternatively, cephalometric X-rays or CT imaging may be able to measure distances from HP to the posterior pharyngeal wall or C1, as in previous research⁴. Future studies can also examine associations between palate shape, DISE findings, and HNS outcomes defined by dedicated, full-night effectiveness sleep studies. Finally, these assessments are performed during DISE, but future research can evaluate the determination during awake examination in the office. This could enhance counseling and surgical decision making.

Conclusion

Vertical palate shape and HP narrowing found on DISE are independently associated with poorer HNS outcomes. This association is even greater among those with complete oropharyngeal lateral wall-related obstruction. These findings identify novel associations with HNS outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Palate Shape Representations

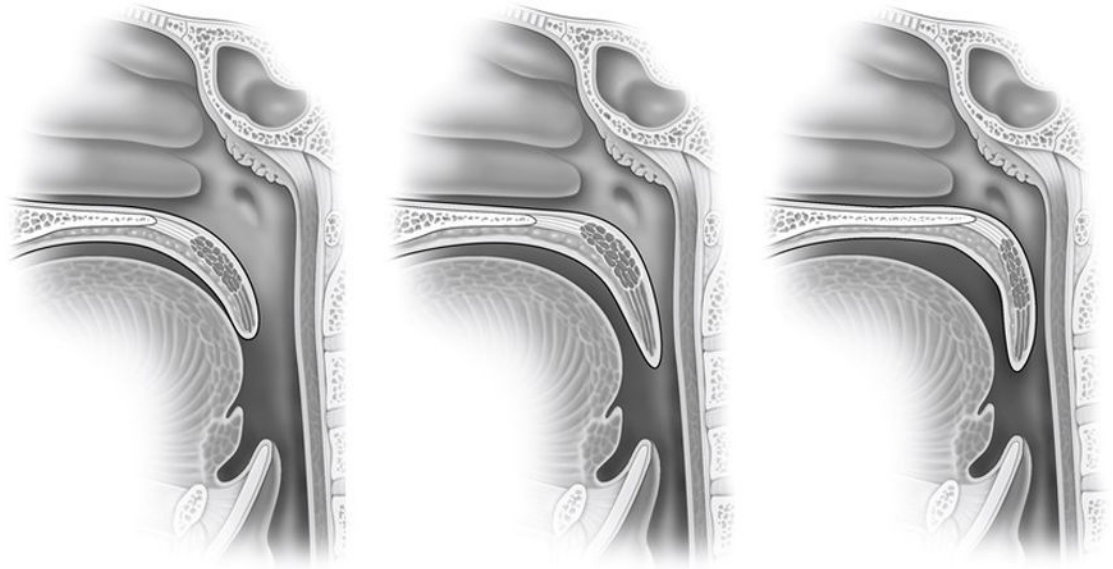


Figure 1. These are pictorial demonstrations of the 3 palate shapes, oblique, intermediate, and vertical from left to right.

Table 1 -

Distribution of Subjects Across Centers

Center	N (%)
Medical College of Wisconsin	43 (13)
Middlesex Hospital	14 (4)
Technische Universität München	34 (10)
Thomas Jefferson University Hospital	42 (13)
University of Colorado	30 (9)
University of Pittsburgh Medical Center	90 (27)
University of Southern California	16 (5)
Vanderbilt University Medical Center	25 (8)
Weill Cornell Medicine	28 (8)
Wayne State University	10 (3)
Total	332

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Table 2 –

Obstructive Sleep Apnea Severity

	Pre-operative	Post-operative
None (0-5), n (%)	0 (0)	144 (43)
Mild (5 - <15), n (%)	12 (4)	109 (33)
Moderate (15 - <30), n (%)	124 (37)	55 (17)
Severe (>30), n (%)	196 (59)	24 (7)

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Table 3 –

Palate level distribution

Score	Hard Palate n (%)	Genu AP n (%)	Velum n (%)	Genu LW n (%)
1	103 (31)	31 (9)	2 (1)	259 (78)
2	144 (43)	188 (57)	74 (22)	57 (17)
3	45 (14)	113 (34)	256 (77)	16 (5)
Not Scorable	40 (12)	0 (0)	0 (0)	0 (0)

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Table 4 –

Palate shape distribution

Palate shape	N (%)	Pre-operative AHI	Post-operative AHI	Success Rate (%)
Oblique	81 (24)	34.6 +/- 15.8	11.3 +/- 14.9	71.6
Intermediate	184 (55)	35.0 +/- 14.8	10.7 +/- 14.0	76.6
Vertical	27 (8)	41.2 +/- 15.7	13.4 +/- 14.0	55.6

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Table 5 -

Associations between surgical response and palate level or overall palate shape

Palate level		N (%)	P Value
Hard Palate	1 vs 2 vs 3	74 (72%) vs. 113 (78%) vs. 27 (60%)	0.046
	1 vs 2&3	74 (72%) vs. 140 (74%)	0.681
	3 vs 1&2	27 (60%) vs. 187 (76%)	0.028
	3 vs 1	27 (60%) vs. 74 (72%)	0.15
Genu AP	1 vs 2 vs 3	21 (68%) vs. 136 (72%) vs. 84 (74%)	0.76
	1 vs 2&3	21 (68%) vs. 220 (73%)	0.53
	3 vs 1&2	84 (74%) vs. 157 (72%)	0.61
	3 vs 1	84 (74%) vs. 21 (68%)	0.46
Velum	1 vs 2 vs 3	2 (100%) vs. 55 (74%) vs 184 (72%)	0.63
	1 vs 2&3	2 (100%) vs. 239 (72%)	0.38
	3 vs 1&2	184 (72%) vs. 57 (75%)	0.59
	3 vs 1	184 (72%) vs. 2 (100%)	0.38
Genu LW	1 vs 2 vs 3	191 (74%) vs. 41 (72%) vs. 9 (56%)	0.31
	1 vs 2&3	191 (74%) vs. 50 (68%)	0.37
	3 vs 1&2	9 (56%) vs. 232 (73%)	0.13
	3 vs 1	9 (56%) vs. 191 (74%)	0.127
Overall Shape			
	Oblique vs. Intermediate vs. Vertical	58 (72%) vs. 141 (77%) vs. 15 (56%)	0.064
	Oblique vs. Intermediate and Vertical	58 (72%) vs. 156 (74%)	0.69
	Vertical vs Oblique and Intermediate	15 (56%) vs. 199 (75%)	0.029
	Vertical vs Oblique	15 (56%) vs. 58 (72%)	0.12

* Total N for Hard palate and overall shape is 292 and for rest is 323. Bold signifies P value < 0.05

Table 6 -

Logistic regression model for surgical response association with specific DISE findings and vertical palate shape

	Unadjusted		Adjusted	
	Odds Ratio	95% CI	Odds Ratio	95% CI
Velum *	1.37	0.79–2.36	1.38	0.79–2.42
Oropharynx *	0.48	0.21–1.12	0.53	0.23–1.24
Tongue *	1.57	0.88–2.80	1.33	0.73–2.42
Epiglottis ^	0.63	0.31–1.29	0.67	0.32–1.38
Vertical shape	0.34 **	0.15–0.78	0.33 **	0.14–0.79
Age (y)	-	-	1.01	0.99–1.04
BMI	-	-	0.96	0.88–1.04
Male sex	-	-	0.49	0.23–1.06

* complete obstruction at this level

^ any epiglottis related obstruction

** P value < 0.05

Table 7 -

Logistic regression model for surgical response association with specific DISE findings and Hard Palate Score 3

	Unadjusted		Adjusted	
	Odds Ratio	95% CI	Odds Ratio	95% CI
Velum *	1.32	0.77–2.27	1.32	0.76–2.29
Oropharynx *	0.55	0.24–1.30	0.62	0.26–1.46
Tongue *	1.56	0.88–2.77	1.34	0.74–2.43
Epiglottis ^	0.69	0.34–1.40	0.74	0.36–1.53
Hard Palate 3	0.47 **	0.24–0.94	0.45 **	0.22–0.92
Age (y)	-	-	1.00	0.99–1.04
BMI	-	-	0.96	0.89–1.04
Male sex	-	-	0.48	0.23–1.04

* complete obstruction at this level

^ any epiglottis related obstruction

** P value < 0.05