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Case Report

Snoring Patterns During Hypoglossal Nerve Stimulation Therapy Up-Titration

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Key Words: Consumer sleep technology, snoring, hypoglossal nerve stimulation, upper airway stimulation, Inspire, obstructive sleep apnea, smartphone application, digital health.

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INTRODUCTION

Loud snoring is one hallmark symptom of obstructive sleep apnea (OSA) and one of the most commonly reported concerns from OSA patients. Snoring sounds are associated with social stigma, anxiety, and concern for bedpartner burden.[1] Reduction of snoring sounds is the primary treatment goal for 16% of OSA patients presenting for sleep surgery evaluation.[1] OSA therapies are associated with OSA-related symptom improvement, improved sleep quality of life, and decrease in subjective snoring scores based on patient or bedpartner report.[2] Snoring intensity is correlated with OSA severity as measured by apnea-hypopnea index (AHI).[3] Objective changes in snoring time and loudness are potential markers for OSA disease change and therapy effectiveness. Understanding the abilities of specific OSA therapies to alter snoring are focally important goals for patients, partners and providers.

Hypoglossal nerve stimulator (HNS) therapy is one surgical therapy option for patients who have failed or cannot tolerate first-line positive airway pressure (PAP) therapy. An HNS implant stimulates the hypoglossal nerve during sleep to curb upper airway collapse. Studies have demonstrated that HNS therapy reduces OSA disease severity based on the AHI and oxygen desaturation index (ODI) and reduces snoring based on bedpartner report.[4–6] One unique feature of HNS therapy involves patient self-titration of implant stimulation amplitude after device activation. Patients are instructed to increase the stimulation amplitude using their remote as tolerated. The therapeutic effectiveness depends on the balance between HNS stimulation comfort, consistent implant use, and stimulation settings required for adequate reduction of OSA severity. Therapeutic implant settings are determined based on sleep study testing. Outcomes are measured using either an in-lab titration polysomnogram (PSG) or a home sleep study (HST) preferably at one implant stimulation amplitude over a full night of sleep recording. Currently, there are no measurable objective criteria that indicate that patients have reached their target amplitude beyond the sleep study metrics. The ideal timeframe of post-activation sleep study testing for an individual patient is unknown and often based on symptom improvement, queries about snoring change, and clinician preferences.

Consumer sleep technology (CST) includes wearable devices, bed monitors, and smartphone applications that are marketed to consumers to monitor and track sleep. CST has the potential to provide daily longitudinal sleep metrics and snoring sound data. However, many devices lack validation, and few have United States Food and Drug Administration approval for clinical use.[7] Methods to use CST to understand sleep patterns and snoring in OSA remain poorly defined, yet patients are often tracking their own sleep and snoring data. SnoreLab (Reviva Softworks Ltd, United Kingdom) is one smartphone application that tracks user snoring intensity and duration. For this study, SnoreLab was chosen based on its availability and popularity as a snore tracking app available on both iOS and Android platforms. Compared to measurements obtained by polysomnography (PSG) in a sample of 19 patients, SnoreLab provided accurate snoring detection ranging from 63% to 95%.[8]

This pilot study aims to measure snoring changes during HNS therapy up-titration and demonstrate the use of a smartphone application, SnoreLab, to measure longitudinal snoring changes. This case series examines

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the feasibility of using snore sound tracking in association with HNS therapy uptitration and sleep apnea treatment.

METHODS

This study received approval from the University of California, San Francisco Institutional Review Board. Between November 2019 and May 2021, patients who underwent HNS implantation (Inspire Medical Systems, Inc., Minneapolis, MN) were recruited at one academic center. Patients were recruited at the activation visit with information about the study and the SnoreLab app. Inclusion criteria included willingness to use the SnoreLab app multiple nights per week. Patients were excluded if they denied baseline snoring, could not consistently use the app, were unable to sleep in a quiet room without background noise, or kept their phone in another room during sleep. All patients provided electronic informed consent for participation and access to relevant medical records, including sleep study results. Snorelab (Reviva Softworks Ltd, United Kingdom) application codes were donated by Reviva Softworks Ltd.; the company had no input into study design, data acquisition, analysis, or manuscript review.

HNS Activation and Up-Titration

One month after surgery, the HNS implant was activated in the office. Sensory and functional thresholds were used for selecting the appropriate starting voltage and electrode setting. Based on comfort level, patients were started at the functional threshold voltage or one step below, and were instructed to uptitrate at home by increasing the voltage level (one step = 0.1 V) with the remote every 3–5 days. With discomfort, patients were instructed to reduce the voltage level and remain at that level for 5 days before increasing again. Patients were asked to uptitrate to the maximum comfortable level that allowed for consistent nightly implant use. Patients were instructed not to use SnoreLab scores as a direct assessment of therapy and were told that snoring changes are variable, take time, and they will not see immediate results. Self-up-titration occurred over 2–6 months after implant activation with monthly clinic visits for symptoms and HNS compliance (Inspire Cloud) evaluations.

SnoreLab Installation and Use

Upon HNS implant activation, participants installed and initiated use of the SnoreLab application premium version, which allows for data sharing. Patients were instructed to start the application before going to sleep each night and to place their mobile device face down next to their bed at approximately one arm's length away from their head with the phone microphone facing towards them. Participants were asked to avoid routine use of television, radio, music, fan, or white noise machine when going to sleep to reduce background noise. Every month, participants emailed their data from the SnoreLab app to the study team. App use was voluntary, and participants were asked to attempt to use the app at least 3 nights per week during the first 5 months after HNS activation.

HNS Use Data

Implant data, including nightly HNS therapy duration and voltage settings, were recorded through Inspire Cloud. Patient records were reviewed for pre-HNS sleep studies and post-HNS titration polysomnography (PSG) 2 to 9 months after implant activation. Full night home sleep apnea tests (HSATs) with HNS therapy at a single voltage were the standard for determining AHI. When a full night HSAT was unavailable, the AHI at the therapeutic amplitude from the titration PSG was used. Titration voltage was defined as the minimum HNS voltage level on titration PSG associated with an AHI of less than 10. The maximum sustained voltage was defined as the highest amplitude that a patient was able to tolerate for at least 2 weeks of consistent HNS use during self-up-titration.

Questionnaire Data

Participants were administered the Satisfaction, Alertness, Timing, Efficiency and Duration (SATED) sleep questionnaire, the Epworth Sleepiness Scale (ESS), the Functional Outcomes of Sleep Questionnaire (FOSQ-10), and the Insomnia Severity Index (ISI) at baseline prior to HNS activation, 2 months after activation, and 4 months after activation.

Statistical Analysis

Participants with both SnoreLab data and Inspire Cloud data for at least 5 months, when typical HNS uptitration is completed, were included in analysis. SnoreLab and Inspire data as well as patient survey responses were aggregated using Microsoft Excel 2016 (Microsoft Corp). SnoreLab data from nights with less than 4 h of HNS use were excluded. Snoring frequency (percentage of estimated total sleep time) and snore score (a SnoreLab metric incorporating snoring intensity with snoring percentage) were evaluated by monthly averages. The first 7 days of app use during the first 1–3 weeks of implant initiation were used for baseline snore values for each subject. Based on activation and stimulation levels, the initial month of therapy was subtherapeutic. Analysis included correlation within and between the patients longitudinally. Seven-day running averages of snore percentage were calculated. Welch's t-tests were used to compare individual changes in snoring metrics. Paired t-tests and ANOVA with repeated measures were used to compare cohort changes in snoring metrics and questionnaire data. Pearson correlation tests were performed between snoring percentage and two variables: therapy month and therapy voltage change from baseline. Pearson correlation tests were also performed between patient reported outcome measures (PROMs) and snoring percentage as well as snore score. Significance thresholds were established at $\alpha = 0.05$. Continuous variables and PROM are reported as means ± SDs (or ranges as appropriate). All statistical analysis was performed in Python (Python Software Foundation, www.python.org) using the SciPy package (v1.8.0).

RESULTS

Six patients (5 men, 1 woman) participated in the study. The mean age was 60.2 (± 8.5) years and mean body mass index (BMI) was 27.5 (± 4.0) kg/m^2. The mean pre-implant AHI was 54.8 (± 20.5) whereas the mean post-HNS titration AHI was 4.9 (± 1.5) (Table I). Three patients had full night HSATs for their post-HNS AHI measurement. Participants activated both the SnoreLab app and HNS therapy for an average of 122 nights (range: 71–164 nights) over at least 5 months, as confirmed by app data and Inspire Cloud. The average baseline voltage level was 0.7 V (range: 0.4–1 V). At 5 months, the average voltage level change from baseline was 1.4 ± 0.5 V (range: 0.7–2 V). None of the participants

TABLE I.
Demographics

Patient	Sex	Age	BMI	Pre-HNS AHI (events/hour)	Baseline HNS Voltage	Self-titrated HNS Maximum Voltage	Titration Voltage (From Sleep Study)	Therapeutic/Titration AHI (events/hour)
1	M	59	27.0	56	0.9 V	2.9 V	2 V	2.4
2	M	51	31.6	61	0.4 V	1.4 V	1.4 V*	4*
3	F	57	21.0	65	0.8 V	2.1 V	1.9 V*	5.2*
4	M	54	30.8	76	0.7 V	1.4 V	1.3 V	4.7
5	M	66	29.3	16	1.0 V	2.7 V	2.9 V*	6.4*
6	M	74	25.1	55	0.6 V	2.2 V	1.7 V	6.5

*Indicates value derived from full night home-sleep study at one HNS setting.

reported significant changes in weight across the 5 months of the study. A comparison of patient BMI at the beginning of the therapy and 5 months afterwards demonstrated a clinically non-significant increase of 0.4 ($\pm$ 1.2) kg/m^2.

At baseline, average snore percentage was 42% ($\pm$ 11%); after 5 months, which declined to an average of 26% ($\pm$ 11%, $p = 0.002$) (Fig. 1). Average snore score at baseline was 40.8 ($\pm$ 16.0) which declined at 5 months to 20.9 ($\pm$ 11.0, $p = 0.04$). Repeated measures ANOVA showed a significant difference in both snore percentage ($p = 0.006$) and snore score ($p = 0.047$) over the 5 months of initial HNS therapy for the group. Overall, participants exhibited mean 38% decrease in average snoring percentage (net decrease 16%) and mean 49% decrease in snore score (net decrease 19.9).

Patterns of Snoring Change

Initial increases in average monthly snoring percentages were observed during the first 4 months in three patients (50%, Fig. 1). Individual analysis showed that the average snoring percentage was significantly lower at month 5 compared to baseline for 5 of 6 patients (83%, Table II). The average snore score was also significantly decreased at month 5 when compared to baseline in 4 of 6 patients (67%). One patient maintained a reduced snore percentage and snore score from month 5 to month 12.

Snore percentage was significantly negatively correlated with the voltage level in 83% of patients (5 of 6, Table II). Snore percentage and nightly hours of implant use were not significantly correlated. Notably the participant with the lowest baseline snoring percentage of 20% had the non-significant correlation between snore percentage and voltage (Table II, Patient 6). When comparing HNS stimulation amplitude and snoring percentage over time, some patients exhibited more acute changes in snoring with a stimulation increase (Fig. 2, Panel B) and other patients had more gradual reductions in snoring percentage (Fig. 2, Panels A and C). Continued snoring percentage decline with stable HNS amplitude settings was also notable (Fig. 2, Panels B and C). Night-to-night variability in snoring percentage was high, with an average 7-day SD ranging from 8% to 12%.

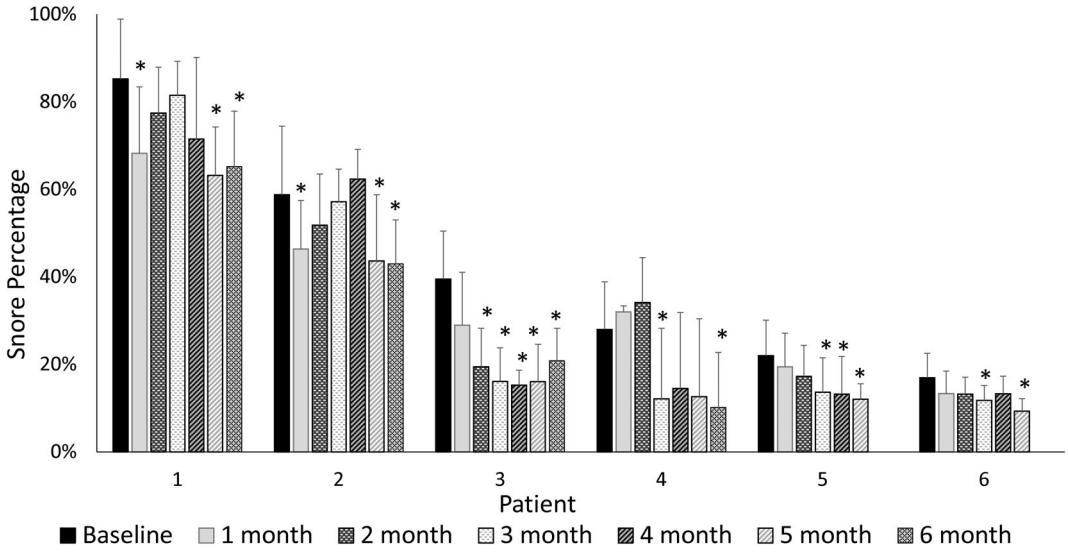

Fig. 1. Average monthly snore percentage declines during the first 5 months of HNS therapy. * Denotes p-value <0.05 for individual monthly comparison to baseline. ANOVA with repeated measures showed a significant decrease in snore percentage over time. Participants exhibited a mean 38% decrease in average snoring percentage and mean 49% decrease in snore score.

TABLE II.
Baseline and 5–month Snoring Metrics and Correlation of Snoring Percentage (%) and Hypoglossal Nerve Stimulator (HNS) Therapy Voltage (Stimulation Strength)

	Baseline		5-month			
Patient	Snore Score	Snore Percentage	Snore Score	Snore Percentage	Correlation Coefficient (Snoring % and HNS Voltage)	*p*-Value
1	49.5 ± 17.5	85% ± 14%	44.6 ± 13.1	63% ± 11%*	−0.21	0.02
2	72.8 ± 20.9	59% ± 15%	34.2 ± 15.9*	44% ± 15%*	−0.39	<0.001
3	19.4 ± 9.1	28% ± 11%	10.2 ± 14.6*	13% ± 18%*	−0.53	<0.001
4	64.0 ± 24.5	39% ± 11%	17.8 ± 7.8	16% ± 9%	−0.18	<0.001
5	22.1 ± 8.9	22% ± 8%	7.9 ± 3.2*	12% ± 4%*	−0.36	<0.001
6	16.9 ± 6.4	17% ± 6%	10.5 ± 4.2*	9% ± 3%*	−0.04	0.71

Snore score and snore percentage is presented as mean ± SD.
*Indicates significant difference compared to baseline ($p < 0.05$).

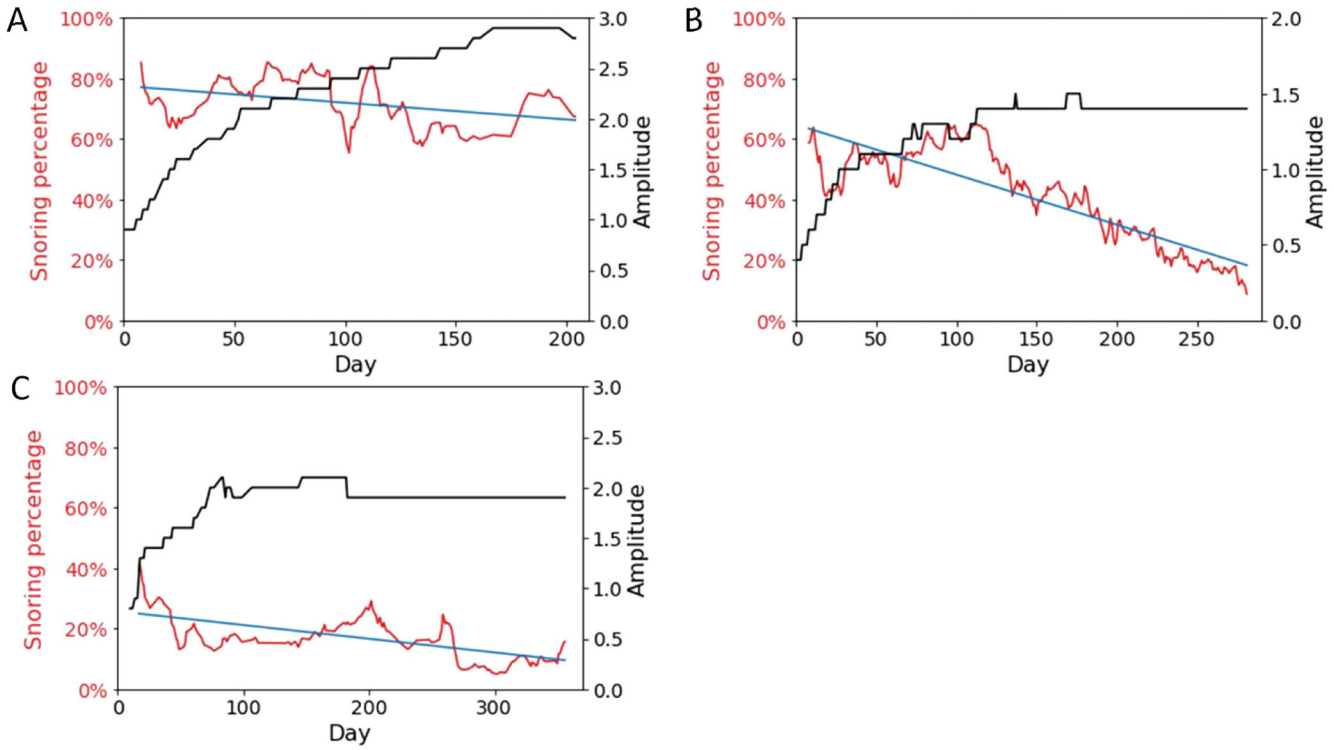

Fig. 2. Individual stimulation amplitude level (right axis, black) and snoring percentage (left axis, red) changes over time for 3 patients (A, B, C). Snoring percentage displayed as 7–day running averages over time. Patient B exhibited acute changes in snoring with an increase in stimulation to 1.4 V after day 100. Patient A and C experienced more gradual reductions in snoring percentage. Both patients B and C exhibited continued snoring percentage decline at stable HNS settings. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

Questionnaires

Snoring level was queried at visits and changes in snoring were reported by the patient. Two subjects reported improvement in snoring described by their bed-partner, one reported no change, and three had no bed-partner report.

Four patients completed the SATED, ESS, ISI, and FOSQ-10 questionnaires. Baseline averages of the questionnaires were SATED 4.8 (± 1.3), ESS 11.5 (± 5.7), ISI 14.0 (± 5.0), and FOSQ-10 15.9 (± 2.4). SATED scores significantly increased at 4 months compared to baseline ($p = 0.01$) with a mean increase of 2.8 (95% confidence interval: 1.2–4.3). ESS, ISI, and FOSQ-10 changes were not significant. There is a significant negative correlation for SATED with snoring percentage in 3 of 4 patients ($r = –0.33, –0.23, –0.26$; $p < 0.03$) and a significant positive correlation for ESS with snore score in 3 of 4 patients ($r = 0.31, 0.25, 0.25$; $p < 0,03$) and ESS with snoring percentage in 2 of 4 patients ($r = 0.31, 0.25$; $p < 0.01$).

DISCUSSION

This pilot study examines snoring changes during HNS therapy up-titration and demonstrates the feasibility of a smartphone application to track snoring changes. Overall snoring percentage and snore score declined by 30–50% within the first 5 months of HNS therapy. However, snoring was not fully resolved or absent with therapy. Snoring changes were associated with HNS amplitude increases; and in some subjects, snoring percentages did continue to decline with stable HNS settings. High variability in night-to-night snoring measures was noted, and multiple nights of snoring data were required to understand longitudinal snoring changes.

Snoring is a common symptom of OSA and may be a marker for disease presence and severity.[9,10] Snoring sounds, associated bedpartner disturbance, and associated social anxieties are common patient-defined concerns and snoring reduction is a common treatment goal reported by OSA patients.[1] Understanding objective snoring changes after OSA treatment is important for adequate patient counseling and shared decision making about PAP alternative therapies and surgery. Most surgical studies have reported decreases in subjective snoring using self- or bedpartner-reported snoring with OSA treatments.[6] An industry sponsored study of 97 patients who underwent HNS implantation noted that improvements in bedpartner-reported snoring intensity was maintained at 5 years post-implantation. At baseline, 83% of patients reported loud snoring compared to 14% after 1-year and 10% after 5-years of implant therapy.[6] Another study has demonstrated the limitations of patient and bedpartner reported snoring after an in-office palate surgical procedure.[11] Bed-partner reported snoring on the visual analog scale (VAS) was compared to home sleep study tests (HSAT) 30, 90, and 180 days after the procedure, showing a significant reduction in VAS rating but not in objective metrics of snoring percentage or intensity (decibels).[11] As prior studies have shown that bedpartner and self-report of snoring correlate poorly to objective measures of snoring,[12,13] we attempted to capture longitudinal snoring measures in this study.

Methods to track longitudinal snoring changes with OSA therapy have not been defined. Few studies examine snoring recordings or quantification schemes of snoring duration, frequency or loudness with OSA therapy. Equipment availability, cost, and lack of accepted standard snoring metrics have limited access and utility of snoring sound analyses in the past. The potential use of CST in a phone application to track changes in snoring patterns with OSA treatment is a novel approach that utilizes accessible technology to help patients understand snoring changes. Fluctuations in snoring metrics are influenced by potential changes in position, nasal congestion, sleep environment, and concurrent medication or alcohol intake. Our study found that night-to-night variability in snoring measures was high, suggesting that multiple nights of consistent app use and snoring data are required to evaluate for an effective response to treatment and snoring changes. One or two days of isolated snoring data from PSG or an app may not be adequate given this high nightly variability. Rather, longitudinal tracking with daily to weekly evaluation of snoring changes may be required to assess snoring improvements with OSA therapy.

Our findings indicate snoring frequency and relative intensity (snore score) changes with HNS therapy amplitude of stimulation during the initial up-titration period of therapy. Snoring percentage was negatively correlated with voltage level but not correlated with nightly therapy use time. Continued decreases in snoring percentages were observed despite stable HNS amplitude settings suggesting a potential time-period of physiologic acclimation to therapy.

Because of HNS amplitude targets are unknown for individual patients, changes in snoring frequency and intensity may predict individual responses to HNS therapy. Response to HNS therapy depends on multiple factors including symptomatic response (improved daytime sleepiness), reduced snoring, patient comfort and adherence to therapy, sleep patterns, and reduction in OSA severity measured with a sleep study. The relationships between timing of snoring change and OSA severity change require further study with more granular sleep study testing than the current clinical paradigm.[14] Further evaluations of how to integrate CST into treatment paradigms for OSA therapy are required and have potential implications. Longitudinal tracking of snoring metrics may have a role in chronic disease monitoring in OSA. Significant changes in snoring may assist in determining the need and timing for updated sleep study evaluations. Clinicians often rely on bedpartner reports of snoring as a proxy for continued OSA disease. Use of a phone app or other CST can be useful to patients without bedpartners or to clinicians for more objective metrics. However, the utilization of CST data for clinical decision-making and use for therapy optimization requires further study. Mandibular advancement devices and other titratable therapies can also benefit from low-cost CST-based longitudinal tracking of sleep and snoring to determine optimal timing for sleep study evaluations for therapeutic responses.

Limitations

This study has a few limitations. SnoreLab accuracy is dependent on recorded audio to determine snoring percentage and metrics are affected by significant background noise. Studies have shown varying accuracies of SnoreLab compared to gold standard polygraphy at different percentages of total snoring.[8] Snoring data accrual was also dependent on the participant to activate the app prior to sleep and participants were able to visualize their nightly snoring metrics. Because of inconsistent app use prior to HNS activation, we used the initial 7 days of app data after implant initiation as the baseline. This may underestimate the effect of HNS therapy on true baseline snoring without therapy, even though most patients are subtherapeutic within the first month of HNS uptitration. There are nightly variations in snoring due to several factors such as sleep position and environment, nasal congestion, and use of alcohol. We were not able to adjust for

these factors on a nightly basis but utilized the overall weekly average in analysis of snoring metric changes over time in attempts to minimize the impact of these sources of nightly variability in snoring and sleep. This case series had a limited number of participants, each with data accrued over multiple days per week across 5 months. A larger participant sample would be required to generalize the results and understand the factors that lead to significant snoring changes, including whether predominance of apneas versus hypopneas at baseline is a predictor of snoring change after HNS therapy.

CONCLUSION

This case series demonstrates changes in snoring frequency during HNS therapy up-titration using a smartphone application. Snoring percentages declined over the initial 5 months of HNS use and were associated with increases in HNS stimulation amplitudes. We observed notable variability of snoring levels on a nightly basis, which illustrates the need for multiple nights of measurement for snoring assessments. A phone application for snore tracking may be a useful supplement to traditional sleep testing measures for examining longitudinal snoring changes with therapy.

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CONFLICT OF INTEREST STATEMENT

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