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ORIGINAL RESEARCH

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Hypoglossal nerve stimulator patient usage: Patterns and trends over time

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Abstract

Objective: Hypoglossal nerve stimulation (HNS) is an effective treatment for obstructive sleep apnea (OSA) patients intolerant of continuous positive airway pressure but is only effective if used regularly. Usage patterns have not been studied in detail. In this study, we aimed to characterize granular HNS usage patterns.

Methods: Patients implanted by a single surgeon at an academic medical center from August 2016 to January 2021 were identified from a prospective database, which was merged with the Inspire Cloud usage database. Patient, OSA, and usage characteristics were summarized, and patient- and OSA-related characteristics were associated with usage characteristics by Wilcoxon rank-sum analyses. Usage trends over time were summarized in the overall cohort and stratified by initial usage.

Results: Fifty patients were included. Median usage was 94% of nights (interquartile range [IQR]: 82%–98%) for 5.8 h per night (IQR: 4.9–6.4). Higher post-operative apnea–hypopnea index predicted fewer nights used (92% [IQR: 82%–97%] vs. 96% [IQR: 91%–99%]). No other characteristics examined were significantly associated with usage. Median hours used per night decreased from 6.80 h (IQR: 5.32–7.94) on Day 1 to 5.76 (IQR: 1.81–7.13) on Day 361. This decrease was most pronounced in the quartile with the lowest initial usage.

Conclusion: This study found that most patient and OSA characteristics were not associated with HNS usage, and that usage generally decreased over time. This decrease in usage over time was most pronounced in patients with the lowest initial usage. Further work should identify interventions to improve usage patterns to optimize clinical outcomes.

Level of Evidence: 4.

KEYWORDS

apnea–hypopnea index, CPAP intolerance, Epworth sleepiness scale, obstructive sleep apnea, sleep medicine, upper airway stimulation

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1 | INTRODUCTION

Obstructive sleep apnea (OSA) is a very common disorder, affecting 10%–17% of males and 3%–9% of females.[1] It is characterized by intermittent airway obstruction during sleep, causing arousal events and reducing sleep quality. Symptoms include daytime fatigue and somnolence, and OSA has been associated with many adverse health effects including diabetes, liver disease, hypertension, coronary artery disease, and an increased mortality risk.[1–5] Continuous positive airway pressure (CPAP) is typically considered first-line treatment for OSA as it stents the airway open and is effective at preventing airway collapse in most patients. However patient compliance with CPAP is poor, with CPAP adherence as low as 34% in some studies.[6] With this low adherence rate, many patients with OSA are untreated or insufficiently treated.

Various surgical interventions are used for OSA, including tongue base reduction, hyoid suspension, uvulopalatoplasty, septoplasty, and mandibular advancement surgeries. These surgeries, however, are typically only beneficial in specific populations and many patients will not benefit from these traditional surgical interventions.[7] Furthermore, they are invasive and require significant airway soft tissue work with its accompanying morbidity. Hypoglossal nerve stimulator (HNS) therapy is a novel treatment for OSA, approved by the FDA in 2014. An implantable device stimulates the branches of the hypoglossal nerve (cranial nerve XII) innervating tongue protrusors.[8] A breathing sensor lead is placed in the chest wall and is used to monitor breathing pattern to predict the start of inspiration. Just prior to the start of each inspiration, a generator lead produces a pulse which causes the stimulation lead to stimulate the hypoglossal nerve, causing contraction of tongue protrusor muscles and tongue stiffening, thereby opening the airway and preventing obstructive events.

HNS therapy has been shown to effectively reduce apnea–hypopnea index (AHI) and normalize sleep for many patients that are unable to tolerate CPAP, and is currently considered second-line therapy for OSA after CPAP failure.[9] Compliance with HNS is generally considered favorable compared to CPAP, however, there are no reports of granular usage data in the literature.[9–11] One component of the Inspire HNS device is the Inspire Cloud, which is a cloud-based database of patient usage parameters that can then be analyzed by the surgeon and sleep medicine physician. Cloud data collected includes number of nights used, hours per nights, and therapy pauses per night.

In this study, we sought to describe granular HNS device usage patterns in our patient population. We analyzed device usage patterns in our population, associated device usage patterns with patient- and OSA-related characteristics, and examined device usage over time. We hypothesized that patient- and OSA characteristics predicted HNS usage patterns, and that usage changed over time. Our findings will allow for targeted interventions to improve HNS device usage.

2 | MATERIALS AND METHODS

2.1 | Patient population

We included all patients with HNS implanted by a single surgeon at a single medical center from August 2016 to January 2021. These patients were identified from a prospective database kept by the implanting surgeon. Patients in this database who also had data uploaded into the Inspire Cloud were included. Patients without data in the Inspire Cloud, patients with less than 180 days of usage in Inspire Cloud, and patients implanted after analysis began were excluded. Patients with incomplete data for specific variables in the prospective database were excluded from individual analyses but included in the overall cohort. All patients underwent a routine post-implantation protocol, with an activation approximately 1 month after implantation followed by a period of adaptation and slow ramping of device usage and either a titration polysomnogram (PSG) or home sleep test. Those with inadequate improvement in AHI were brought back to clinic for additional troubleshooting including changing device voltage and settings. Those with discomfort during activation were also brought back to clinic to systematically adjust device settings. Follow-up frequency varied based on the specific patient concerns.

2.2 | Variables

Patient-related characteristics, including age at implantation, gender, and body mass index (BMI) at implantation were obtained from our prospective database. OSA-related characteristics, specifically pre-operative AHI, pre-operative Epworth Sleepiness Scale (ESS), most recent post-operative AHI, and post-operative ESS were also obtained from this prospective database. Full-night PSGs were used for post-operative AHI when available; final AHI on titration PSG was used when not. From the Inspire Cloud, we obtained usage data for each patient. Specifically, we obtained overall nights with device implanted, nights used, median hours per night used, and median therapy pauses per night. For examination of trends in usage over time, we also obtained the number of hours the device was used each night since activation for each patient.

2.3 | Statistical analysis

The prospective patient database and Inspire Cloud data were merged by HNS serial number data. Patient demographics, OSA-related variables, and usage data as detailed above were summarized as medians with interquartile ranges for continuous variables due to their non-normal distribution and as proportions for categorical variables. Usage data was summarized for the first 180 days of usage due to a smaller number of patients with usage data available after 180 days; cutoff at 180 days ensured sufficient sample size. Patients were classified as above or below the median for continuous variables for subsequent

analyses. Patients in the bottom 50% were compared to patients in the top 50% for each variable. Patient- and OSA-related characteristics were assessed for association with usage characteristics by univariable Wilcoxon rank-sum analyses. Specifically, Wilcoxon rank-sum analyses were performed to assess association with percentage of nights used, hours per night used, and pauses per night. For the analyses of post-operative AHI, change in AHI, preoperative ESS, postoperative ESS, and change in ESS, data were not available for all patients therefore patients with missing data for these parameters were excluded from these individual analyses.

For usage trends over time, hours used per night were summarized as medians for the 7 days following Day 1, Day 91, Day 181, Day 271, and Day 361 since device implantation for the entire cohort. All patients had data available up to Day 181; statistics beyond those timepoints were only for patients with data available. Subjects were then split into quartiles based on hours used per night in the first 30 days of usage, and this analysis was repeated for the different quartiles to assess differences in trends based on initial usage.

All analyses were conducted in Stata 16.0 (StataCorp, College Station, TX). Two-sided $p < .05$ was used for statistical significance. This study was approved by the Weill Cornell Institutional Review Board.

3 | RESULTS

3.1 | Clinical characteristics

Patient demographic and OSA-related characteristics are summarized in Table 1. Fifty patients met inclusion criteria out of a total of 121 patients who were implanted during this time period. Three of 50 were female (6%); the remainder were male. Median age at implantation was 56 years (interquartile range [IQR] = 50–63), and median BMI was 29.8 (IQR = 27.7–31.7). Median preoperative AHI was 39 (IQR = 26.5–50) and median preoperative ESS was 11.1 (7–17). Median postoperative AHI was 13 (IQR = 7–20), and median change in AHI was 22 (IQR = 12–37). Median postoperative ESS was 8 (IQR: 3–11) and median change in ESS was 3 (IQR: −1 – 8). For analyses regarding preoperative ESS scores, data were available for 46 patients. For analyses regarding postoperative ESS scores, data were available for 32 patients. Data regarding change in ESS were available for 31 patients. For analyses regarding postoperative AHI and change in AHI, data were available for 44 patients.

TABLE 1 Patient characteristics

Variable	Number (%)	Number missing
Gender		
Male	47 (94%)	0
Female	3 (6%)	0
	Median (IQR)	
Age	50–63	0
BMI	27.7–31.7	0
Pre-operative AHI	26.5–50	0
Post-operative AHI	7.2–20	6
Change in AHI	11.8–36.6	6
Pre-operative ESS	7–17	4
Post-operative ESS	3–11	18
Change in ESS	−1–8	19

Notes: Demographic and sleep characteristics of the included cohort. The number of included patients with missing data for each datapoint are shown.
Abbreviations: AHI, apnea–hypopnea index; BMI, body mass index; ESS, Epworth Sleepiness Scale; IQR, interquartile range.

3.2 | HNS usage data

HNS usage data is summarized in Table 2. Out of the 180 nights since activation, median usage was 94% (IQR: 82%–98%). Median hours per night was 5.8 (IQR: 4.9–6.4 h) and median therapy pauses per night was 0 (IQR: 0–1).

3.3 | Factors associated with HNS usage

The association of patient demographic characteristics with HNS usage parameters is summarized in Table 3, and the association of

TABLE 2 HNS usage data

Variable	Median (IQR)
Percentage of nights used	94 (82%–98%)
Mean hours per night used	5.8 (4.9–6.4)
Mean therapy pauses per night	0 (0–1)

Note: Summary of usage data for the overall cohort.
Abbreviations: IQR, interquartile range; HNS, hypoglossal nerve stimulation.

TABLE 3 Correlation between patient characteristics and usage data

	Median (IQR)		
Variable	Bottom 50%	Top 50%	*p*
Percentage of nights used			
Age	92% (87%–98%)	94% (81%–98%)	.75
BMI	94% (85%–98%)	93% (79%–98%)	.56
Median hours per night used			
Age	5.9 (5.2–6.4)	5.6 (4.7–6.4)	.51
BMI	5.7 (4.9–6.8)	5.8 (5.1–6.3)	.65
Median pauses per night			
Age	0 (0–0)	0 (0–1)	.52
BMI	0 (0–1)	0 (0–0)	.16

Note: Summary of correlations between usage data and demographic data for the overall cohort. "Bottom 50%" and "Top 50%" refers to the bottom 50% and top 50% for the row variable (age and BMI, respectively).
Abbreviations: BMI, body mass index; IQR, interquartile range.

TABLE 4 Correlation between HNS Efficacy and usage data

Variable	Median (IQR)		*p*-Value
	Bottom 50%	Top 50%	
Percentage of nights used			
Pre-operative ESS	95% (87%–99%)	92% (68%–98%)	.19
Post-operative ESS	94% (87%–99%)	93% (74%–95%)	.20
Change in ESS	94% (82%–99%)	92% (82–98%)	.76
Preoperative AHI	93% (84–96%)	96% (76%–99%)	.51
Postoperative AHI	96% (91%–99%)	92% (82%–97%)	.034*
Change in AHI	93% (84%–97%)	97% (89%–99%)	.23
Median hours per night used			
Preoperative ESS	5.9 (5.4–6.7)	5.4 (4.1–6.0)	.08
Postoperative ESS	5.9 (5.4–6.6)	5.4 (3.0–6.2)	.22
Change in ESS	5.8 (5.1–6.9)	5.6 (3.6–6.1)	.48
Preoperative AHI	6.0 (5.1–6.6)	5.7 (4.7–6.2)	.34
Posoperative AHI	5.7 (4.8–5.9)	6.0 (5.1–6.6)	.30
Change in AHI	5.9 (5.2–6.6)	5.5 (4.3–5.9)	.10
Median pauses per night			
Preoperative ESS	0 (0–1)	0 (0–1)	.89
Postoperative ESS	0 (0–0)	0 (0–1)	.70
Change in ESS	0 (0–0.5)	0 (0–1)	.97
Preoperative AHI	0 (0–1)	0 (0–0.5)	.57
Postoperative AHI	0 (0–1)	0 (0–7)	.17
Change in AHI	0 (0–0)	0 (0–2)	.07

Notes: Summary of correlations between usage data and sleep parameters for the overall cohort. "Bottom 50%" and "Top 50%" refers to the bottom 50% and top 50% for the row variable.
*statistically significant.
Abbreviations: AHI, apnea–hypopnea index; BMI, body mass index; ESS, Epworth Sleepiness Scale; IQR, interquartile range.

TABLE 5 Trends in usage over time

	Overall Median (IQR)	1st quartile Median (IQR)	2nd quartile Median (IQR)	3rd quartile Median (IQR)	4th quartile Median (IQR)
Day 1	6.8 (5.32–7.94)	5.39 (1.98–6.72)	6.2 (4.96–7.37)	7.11 (6.03–7.81)	7.72 (7.04–8.5)
Day 91	5.99 (3.34–7.39)	1.25 (0–5.22)	6.05 (4.91–7.37)	6.22 (4.94–7.21)	7.82 (6.9–8.46)
Day 181	5.54 (3.77–7.16)	3.58 (0–5.35)	5.27 (3.74–6.45)	6.37 (5.23–7.22)	7.29 (6.35–8.07)
Day 271	5.78 (2.95–7.48)	3.25 (0–5.42)	6.03 (4.38–6.94)	6.08 (4.07–7.3)	7.51 (6.35–8.2)
Day 361	5.76 (1.81–7.13)	N/A	N/A	5.99 (4.19–7.49)	N/A

Notes: Trends in usage over time in the overall cohort and in patients stratified by quartile of initial use, with quartiles defined by the hours used in the first 30 days. Times given are the means for a 1 week period following the day given. The first quartile had the lowest initial use, while the fourth quartile had the highest initial use.
Abbreviation: IQR, interquartile range.

OSA-related characteristics with HNS usage patterns is shown in Table 4. Overall, we found that a higher post-operative AHI was associated with decreased percentage of nights used (92% [IQR: 82%–97%] vs. 96% [IQR: 91%–99%]). None of the other demographic or OSA-related factors examined were significantly associated with percentage of nights used, mean hours per night, or mean pauses per night.

3.4 | Trends in usage over time

Trends in usage over time are shown in Table 5 and Figure 1. In the overall cohort, the hours used per night decreased from a median of 6.80 (IQR: 5.32–7.94) on Day 1 to a median of 5.76 (IQR: 1.81–7.13) on Day 361. In the quartile with the lowest initial use, this decreased from 5.39 h on Day 1 (IQR: 1.98–6.72) to 3.25 h on Day 271 (IQR: 0–5.42).

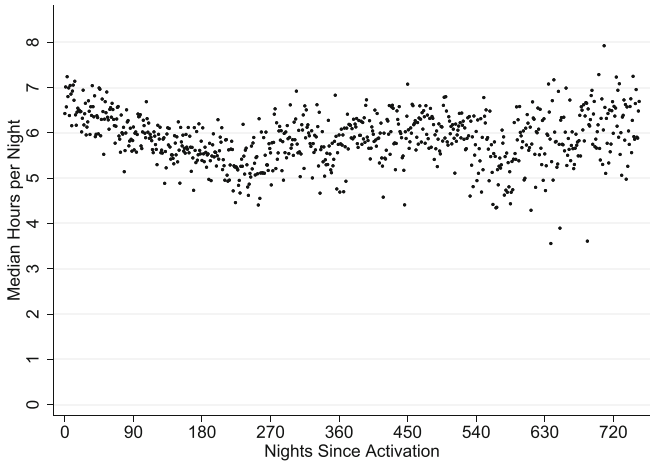

FIGURE 1 Trends in median hours per night used over time since implantation. This graph shows trends in median hours used per night since implantation in the overall cohort.

In the quartile with the highest initial use, no decrease was seen (7.72 h on Day 1 [IQR: 7.04–8.50] versus 7.51 h on Day 271 [IQR: 6.35–8.20]).

4 | DISCUSSION

In this study of 50 patients implanted with an HNS at a single center, we found high usage of HNS. We found that patients, on average, used their HNS 94% of nights and for 5.8 h per night. We also found low rates of therapy pauses at less than one pause per night on average. When we examined the association of various patient and clinical factors on these HNS usage patterns, we found that a higher therapy AHI was associated with use for fewer hours per night but did not find any association of the other patient or OSA-related factors examined with usage parameters. We also found that usage declines over time, and that this is seen more in those with lower initial usage rates.

In our cohort, we overall had very high usage patterns, with most patients using the device more than 90% of night and for more than 5 h per night used. This is significantly higher than CPAP usage statistics seen in other studies. For example, a recent meta-analysis by Rotenberg et al. found that the mean duration of CPAP use in a cohort of patient enrolled in clinical trials was just 4.7 h a night, and patients only used CPAP 10%–40% of nights.[6] It is worth noting, however, that our study only included patients with data uploaded into the Inspire Cloud, and therefore patients with HNS implanted but who had not completed activation and titration were not included. Despite this, these findings are in agreement with the well-established literature showing much higher compliance with HNS as compared to CPAP, which is one of the main advantages of the treatment.[8,9,12]

In addition, we found that there was an association of a lower post-operative (therapy) AHI with HNS use a higher percentage of nights using the device. We found that patients with a post-operative AHI above the median used their HNS 92% of nights (IQR: 82%–97%) versus 96% of nights (IQR: 91%–99%) in patients with a post-operative AHI below the median. This logically makes sense, as patients with a greater effect of HNS on sleep parameters are more likely to feel better with usage and therefore are incentivized to use the device more. To our knowledge, no prior work has examined the association of severity of OSA with HNS adherence. In the CPAP literature, there is some research suggesting that higher AHI predicts improved CPAP adherence, presumably because patients with more severe OSA may be more symptomatic and therefore more motivated to pursue treatment.[13–15]

Interestingly, we did not find that there was any association of ESS with HNS compliance. We had hypothesized that those with a higher pre-operative ESS and lower post-operative ESS would be more compliant with usage, as many people seek treatment for OSA due to their daytime sleepiness symptoms and therefore may have been more likely to use a therapy that alleviates those symptoms. In the CPAP literature, there is limited evidence that this may be the case, however, again this has been inconsistent.[16] Furthermore, we did not find that age was associated with usage, in contrast to the findings in a recent retrospective analysis by Hofauer et al., in which the authors found that older age was associated with higher usage.[17]

One parameter that our study uniquely examined and reported was the frequency of therapy pauses during the night. We found a very low rate of therapy pauses, with less than one pause each night on average. To our knowledge, objective rates of therapy pauses have not previously been reported. This low rate of pauses is a positive sign, as it suggests that patients are not frequently experiencing adverse effects from their device during the night that necessitate pausing. Hofauer et al. found that 59% of patients self-reported using the pause function, but did not obtain objective data, nor data on the frequency of pausing.[17] Our findings, however, are limited by the fact that our study looked at patients who may have had multiple adjustments in order to optimize comfort, and it is important to emphasize the need for this to patients.

When we examined trends in usage over time, we found that hours used per night declined over time since device activation. Specifically, we found that usage decreased from a median of 6.80 h per night on night one to 5.76 h per night on Day 361. However, this trend was more pronounced in patients with decreased initial usage. In patients in the bottom quartile of usage, usage decreased from a median of 5.39 h at Day 1 to 3.25 h at Day 271. In contrast, patients in the top quartile for usage in the first 90 days had very little change in usage, with usage of a median of 7.72 h at Day 1 and 7.51 h at Day 361. Our finding of decreased usage with time and more pronounced decreases in those with lower initial use has not previously been reported in the literature for HNS therapy. However decreased usage with time, even with behavioral interventions, is well-established in the CPAP literature.[16,18–20] In addition, multiple prior studies assessing CPAP compliance have shown that poorer initial use is predictive of poorer subsequent use as well.[16,21,22] As a result of this, some have suggested that interventions to improve compliance should be targeted to the first several days of CPAP use. This will allow patients to establish good initial compliance, which may set them on a better

compliance trajectory.[10] Similar interventions could be considered for HNS therapy to improve initial compliance.

HNS therapy has been a significant advance in the management of OSA, and is recommended as second-line treatment for appropriately-selected patients intolerant of CPAP. In contrast to some other surgical interventions, it produces reliable improvements in OSA in the vast majority of patients. However, unlike traditional soft tissue surgery for OSA, because HNS therapy involves a device that patients must use, compliance with therapy remains a challenge that must be overcome. Most studies of HNS efficacy examine ideal or near-ideal usage, however, this is not what is seen in the real world.[8,9] Imperfect usage is frequent, particularly because these patients have already failed CPAP and therefore have proven difficulty complying with device use. Furthermore, most studies examine use over a relatively short time period. We show here that usage is variable among patients, and that usage declines with time. Many studies examining HNS likely do not capture these patients and therefore may overestimate the usage and efficacy of HNS. Despite the fact that our findings and findings in other studies have shown that HNS compliance is significantly superior to CPAP compliance, more work is indicated to identify factors that may predict better usage, and interventions to improve usage in patients.

There are many important limitations to this study. First, our sample size of just 50 patients limited the power of some analyses. Some data points were incomplete for individual patients, further limiting sample sizes. Furthermore, Inspire Cloud data is only collected for patients who are regular users of their HNS, and therefore this sample was more compliant with therapy than the average patient. There is no remote monitoring capabilities for HNS therapy and therefore we are unable to access usage data for patients that followed up with sleep medicine physicians rather than in our office. Future availability of remote monitoring will allow for a better understanding of therapy usage and ability to intervene. In addition, this data and analysis are subject to the limitations inherent to its retrospective design. Nonetheless, we feel that our findings are an important contribution to the literature examining HNS usage patterns.

5 | CONCLUSION

In conclusion, in this study, we characterized granular data regarding HNS usage in a cohort of 50 patients. We found that most patient and OSA-related factors were not related to usage patterns. We found that HNS usage declines over time, and this decline is particularly evident in patients with lower initial usage. Future work should further characterize and identify factors associated with usage parameters, and identify interventions to improve usage patterns.

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CONFLICT OF INTEREST

Maria Suurna serves as a consultant for Inspire Medical Systems and receives research funding from Inspire Medical Systems.

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