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SCIENTIFIC INVESTIGATIONS

Factors affecting obstructive sleep apnea patients' use of upper airway stimulation treatment

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Study Objectives: Upper airway stimulation (UAS) is an alternative treatment for obstructive sleep apnea that must be activated nightly. Although the implanted device offsets the mask- or pressure-related side effects often associated with continuous positive airway pressure therapy, some UAS recipients do not use the therapy consistently. This study qualitatively explored factors associated with UAS usage in obstructive sleep apnea patients.

Methods: Semistructured interviews were conducted with 24 obstructive sleep apnea patients who received UAS treatment. Twelve patients were categorized as high users with mean usage of ≥ 4 hours/night and 12 were categorized as low users with < 4 hours/night or nonuse. Interviews explored patients' experiences regarding barriers and facilitators to UAS use and their advice for new UAS recipients. Demographic and clinical data including the Insomnia Severity Index and Generalized Anxiety Disorder Scale were collected.

Results: Compared to high users, low users had higher levels of insomnia (mean Insomnia Severity Index: 3.6 vs 15.2, respectively) and anxiety (mean Generalized Anxiety Disorder Scale: 3.4 vs 6.9). High users reported more positive experiences with UAS treatment, such as improvements in symptoms and convenience of treatment, as facilitators of use. Low users tended to focus on the negative aspects of treatment, particularly stimulation-related discomfort and associated sleep disturbance.

Conclusions: Insomnia with or without anxiety contributes to differing patient-reported experiences in high vs low user groups, with increased insomnia symptoms among low users. Improved understanding of the specific barrier and facilitators of UAS adherence may drive better long-term use and more personalized management strategies, including concomitant insomnia treatment.

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BRIEF SUMMARY

Current Knowledge/Study Rationale: Upper airway stimulation treatment (UAS) for obstructive sleep apnea overcomes side effects and device-related factors commonly associated with continuous positive airway pressure nonadherence. However, some UAS recipients do not use the treatment consistently, and there is a paucity of data examining patient-reported experiences of obstructive sleep apnea patients treated with UAS.

Study Impact: High and low users had differing experiences with UAS that may have been partly due to prevalent insomnia symptoms among low users. Sleep clinicians should consider evaluating patients for insomnia and initiate treatment prior to UAS implantation, as doing so may increase the likelihood of adherence.

INTRODUCTION

Obstructive sleep apnea (OSA) is a prevalent sleep disorder characterized by intermittent collapse or narrowing of the upper airway during sleep that lead to apneas and hypopneas. Untreated OSA is associated with excessive daytime sleepiness, poor quality of life, and cardiovascular morbidity and mortality.[1–3] Continuous positive airway pressure (CPAP) is the standard first-line treatment for moderate to severe OSA. Health benefits of CPAP, such as alleviation of symptoms, restoration of daytime function, and reduced risk of cardiovascular morbidity and mortality, are only realized with consistent, long-term adherence.[4–6] Many patients often reject CPAP therapy due to device-related factors such as mask discomfort or claustrophobia and side effects like nasal dryness and pressure intolerance.[7] Adherence to CPAP in clinical practice is limited, with at least 50% of patients using CPAP for less than 4 hours per night.[8] Consequently, a significant number of symptomatic OSA patients remain untreated or undertreated. Alternative treatments to CPAP such as oral appliance therapy and various upper airway reconstructive or bypass surgeries also have their challenges.[9,10]

Upper airway stimulation (UAS) is an effective treatment option for a subset of patients with moderate to severe OSA who are unwilling or unable to adhere to CPAP therapy.[11,12] The therapy involves unilateral implantation of a phasic hypoglossal nerve stimulation device. A pulse generator is implanted

within a pocket inferior to the clavicle, a pressure sensor is placed between the external and intercostal muscles of the chest, and a stimulation lead is attached to specific hypoglossal nerve branches. Stimulation of the hypoglossal nerve, which results in tongue protrusion occurs via a signal sent from the pulse generator in response to detection of inspiration by the pressure sensor. Similar to CPAP therapy, patients must activate UAS every night using an external remote control.

Improvements in respiratory and patient-reported (ie, sleepiness, quality of life, snoring) outcomes have been sustained after 5 years of UAS therapy.[13] The implanted UAS device may help patients to overcome side effects and device-related factors commonly associated with CPAP nonadherence. Self-reported use of UAS is high, with 86%, 81%, and 80% reporting nightly device use at 1, 3, and 5 years, respectively.[13] Objective use data obtained via device interrogation shows a reduction in average nightly use from 6 months (6.4 hours/night) to 12 months (5.6 hours/night).[14,15] Although adherence to UAS is generally higher than to CPAP,[16] there remain patients who are not using UAS consistently.

Despite a growing literature on factors related to CPAP use, there is a paucity of data examining self-reported experiences of OSA patients treated with UAS. Our study took a qualitative approach to exploring factors associated with UAS usage in OSA patients. In-depth interviews with OSA patients who received UAS treatment enabled us to gain a deeper understanding of patients' experiences with UAS and identify potential unique factors associated with its use.

METHODS

Study design and participants

The study used an exploratory qualitative design to examine factors affecting use of UAS among OSA patients. Semistructured interviews were conducted between May 2019 and May 2021. Potential participants were identified from a university hospital via electronic medical record review and from the ADHERE registry. The ADHERE registry is an international, multicenter prospective registry of patients who received a UAS implant. Registry patients included those with moderate to severe OSA (apnea-hypopnea index between 15 and 65), who were intolerant or inadequately adherent to CPAP, and who met previously established anatomic criteria.[12]

A purposive sample of high and low UAS users were invited to participate in order to obtain a broad array of experiences of UAS recipients. High users were categorized as those with mean usage of ≥ 4 hours/night since the last device interrogation. Low users were categorized as those with mean usage of < 4 hours/night or self-report of nonuse in cases where objective usage data were not available. Examples of UAS usage from high and low users are available in the **supplemental materials**. Patients were eligible for the current study if they were 18 years of age or older, received an implantable UAS system after OSA diagnosis (Inspire Medical Systems, Minneapolis, MN) from June 2017 to present, and were clinically treated by a research team member (R.S.). A total of 26 patients were enrolled in the study. One participant was unable to be contacted to complete the telephone interview. Twenty-five interviews were conducted; however, the audio recording of 1 of the interviews was lost due to technical issues. Ultimately, interview data from 24 participants were collected, with 12 interviews from high users and 12 interviews from low users. Each participant provided verbal informed consent. The Human Research Protection Office at the University of Pittsburgh approved the study protocol. The ADHERE registry (NCT02907398) and the current study (NCT04768543) were registered with clinicaltrials.gov.

Data collection

Demographic and clinical data were collected via questionnaires over the telephone prior to the qualitative interview and from electronic medical records. These data included age, sex, race, marital status, comorbidities, UAS activation parameters, and scores on the Insomnia Severity Index[17] and Generalized Anxiety Disorder Scale-7 (GAD-7).[18] The Insomnia Severity Index is a validated 7-item measure used to assess severity of insomnia symptoms, satisfaction with sleep, associated daytime impairments, and concern caused by sleep problems.[17] Total scores on the Insomnia Severity Index range from 0 to 28, with higher scores indicating greater insomnia severity. Insomnia severity scores can be categorized as: no clinically significant insomnia (0–7), subthreshold insomnia (8–14), moderate clinically significant insomnia (15–21), and severe clinically significant insomnia (22–28). The GAD-7 is a well-validated 7-item measure of generalized anxiety disorders symptoms, which corresponds to the DSM-IV criteria for generalized anxiety disorders.[18] Total scores on the GAD-7 range from 0 to 21, with higher scores indicating more anxiety symptoms. Cut-off scores of 5, 10, and 15 may be interpreted as mild, moderate, and severe levels of anxiety.[18]

Individual telephone interviews were conducted by a trained interviewer and lasted approximately 25 minutes. A semistructured interview guide with prompts was developed by the research team and was informed by prior research in this area.[19] Topics that were explored during the interview were: reasons for getting UAS treatment, perceived effects of UAS treatment, barriers and facilitators to UAS use, and advice for new UAS recipients (**Table 1**). The interviews were recorded and transcribed, and transcripts were uploaded into the qualitative software package ATLAS.ti v.8 (ATLAS.ti Scientific Software Development, Berlin, Germany).

Analysis

Inductive content analysis was utilized in which initial codes were produced from a thorough assessment of the transcripts.[20] Open coding was performed by 2 experienced coders on the first

Table 1—Sample of semistructured interview questions.

What changes or improvements did you hope to gain from upper airway stimulation treatment?
To what extent did the treatment work for you?
Are there things that have helped you in using upper airway stimulation therapy? If yes, what are those?
Are there things that prevented you from using upper airway stimulation therapy? If yes, what are those?
Are there things you think would be helpful for new upper airway stimulation recipients to hear about, know about, or do?

set of 4 interviews (2 high users, 2 low users) in order to denote key concepts. Preliminary codes were then derived and a codebook was developed. The initial and subsequent transcripts were coded and new codes were added. After coding of all transcripts was completed, codes were grouped into higher-order categories and subcategories to encompass all information generated in the interviews in greater detail. Subcategories were analyzed within and across the high and low users. Discrepancies were discussed and resolved between coders. Research team meetings were held at each phase of the analysis process to review codes and categories for relevance and completeness.

RESULTS

Participants' demographic and clinical data are summarized in Table 2. Of the 24 patients, the mean age was 69 years. Most patients were male (71%), White (92%), had at least some college education (79%), and were married (54%). No statistical analysis was conducted due to small sample sizes; however, the low user group was slightly younger, less educated, and included more females, Blacks, and comorbidities, and had fewer who were married than the high user group. Among the low users, self-report measures indicated moderate insomnia severity and mild anxiety symptoms, higher levels compared to high users. Low users had a longer time since implantation and higher baseline and post-UAS apnea-hypopnea index compared to high users. The amplitude and frequency of UAS stimulation settings at activation were similar between the groups.

Four key concepts emerged in the analysis that highlighted the experiences of OSA patients treated with UAS: 1) reason for getting UAS treatment, 2) effects of UAS treatment, 3) barriers and facilitators of UAS treatment, and 4) advice for new UAS recipients (Table 3).

Table 2—Demographic and clinical characteristics of study participants.

	Total Sample (n = 24)	High Users (n = 12)	Low Users (n = 12)
Age, years, mean (SD)	68.9 (6.6)	70.69 (4.6)	67.2 (8.0)
Sex, n (%)			
Female	7 (29.2%)	5 (41.7%)	2 (16.7%)
Male	17 (70.8%)	7 (58.3%)	10 (83.3%)
Race, n (%)			
White	22 (91.7%)	12 (100.0%)	10 (83.3%)
Black	2 (8.3%)	0 (0.0%)	2 (16.7%)
Education, n (%)			
Less than high school or high school/GED	5 (20.8%)	2 (16.7%)	3 (25.0%)
Some college or college degree	10 (41.7%)	5 (41.7%)	5 (41.7%)
Graduate/professional degree	9 (37.5%)	5 (41.7%)	4 (33.3%)
Marital Status, n (%)			
Never Married	4 (16.7%)	1 (8.3%)	3 (25.0%)
Married	13 (54.2%)	9 (75.0%)	4 (33.3%)
Divorced/Widowed/Separated	7 (29.1%)	2 (16.7%)	5 (41.7%)
Comorbidities, n (%)			
Diabetes	8 (33.3%)	2 (16.7%)	6 (50.0%)
Hypertension	12 (50.0%)	5 (41.7%)	7 (58.3%)
Insomnia	3 (12.5%)	0 (0.0%)	3 (25.0%)
Anxiety	6 (25.0%)	3 (25.0%)	3 (25.0%)
Depression	6 (25.0%)	3 (25.0%)	3 (25.0%)
ISI total score, mean (SD)	9.4 (8.3)	3.6 (2.6)	15.2 (8.0)
GAD-7 total score, mean (SD)	5.2 (5.5)	3.4 (4.3)	6.9 (6.3)
Time since UAS implantation (months), mean (SD)	24.7 (15.0)	22.8 (7.4)	26.7 (20.3)
Baseline AHI, events/h, mean (SD)	38.6 (20.3)	32.3 (17.3)	44.8 (21.9)
Post-UAS AHI, events/h, mean (SD)[a]	10.5 (12.1)	9.2 (9.0)	12.3 (16.0)
UAS activation parameters, mean (SD)			
Amplitude (V)	1.5 (0.6)	1.6 (0.6)	1.4 (0.5)
Frequency (Hz)	34.2 (2.7)	34.8 (3.2)	33.6 (2.0)

[a]Missing data for 1 high user and 4 low users. AHI = apnea-hypopnea index, GAD-7 = Generalized Anxiety Disorder-7 Scale, ISI = Insomnia Severity Index, SD = standard deviation, UAS = upper airway stimulation.

Table 3—Interview key concepts, categories, and subcategories for high and low users.

Key Concept and Category	Subcategory	Total Sample (n = 24)	High Users (n = 12)	Low Users (n = 12)
UAS Treatment				
Reason for UAS treatment	Disliked CPAP	10 (41.7%)	5 (41.6%)	5 (41.6%)
	Have more energy	7 (29.2%)	4 (33.3%)	3 (25.0%)
	Get better night's sleep	8 (33.3%)	3 (25.0%)	5 (41.6%)
	Oral appliance didn't work	4 (16.7%)	3 (25.0%)	1 (8.3%)
	Prevent stopping breathing during night	6 (25.0%)	2 (16.7%)	4 (33.3%)
	Prevent daytime sleepiness	3 (12.5%)	2 (16.7%)	1 (8.3%)
	Convenient	2 (8.3%)	2 (16.7%)	0 (0.0%)
	Prevent snoring	3 (12.5%)	1 (8.3%)	2 (16.7%)
	Reduce risk of heart attack	1 (4.2%)	1 (8.3%)	0 (0.0%)
	Live longer	2 (8.3%)	0 (0.0%)	2 (16.7%)
	Friend had it and liked it	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Surgery didn't work	1 (4.2%)	0 (0.0%)	1 (8.3%)
Effects of UAS Treatment				
Emotional/mental—positive	Feel better	4 (16.7%)	4 (33.3%)	0 (0.0%)
	Happy with treatment	3 (12.5%)	3 (25.0%)	0 (0.0%)
	Relieved that it works	1 (4.2%)	1 (8.3%)	0 (0.0%)
	Stopped worrying about stopping breathing	1 (4.2%)	1 (8.3%)	0 (0.0%)
	More alert	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Don't have to worry about cleaning like with CPAP	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Life changing	1 (4.2%)	0 (0.0%)	1 (8.3%)
Emotional/mental—negative	Caused initial anxiety	4 (16.7%)	3 (25.0%)	1 (8.3%)
	Frustrating because it doesn't stop apnea	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Finds it annoying	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Scared to turn up setting too far	1 (4.2%)	0 (0.0%)	1 (8.3%)
Physical—positive	Improvements in sleep	14 (58.3%)	9 (75.0%)	5 (41.6%)
	Stopped or lessened snoring and apneas	11 (45.8%)	7 (58.3%)	4 (33.3%)
	More energy	3 (12.5%)	3 (25.0%)	0 (0.0%)
	Refreshed in morning	5 (20.8%)	3 (25.0%)	2 (16.7%)
	Feel healthier	4 (16.7%)	2 (16.7%)	2 (16.7%)
	Less daytime sleepiness	3 (12.5%)	1 (8.3%)	2 (16.7%)
	No longer disturb partner's sleep	1 (4.2%)	1 (8.3%)	0 (0.0%)
	No longer had heart condition	1 (4.2%)	1 (8.3%)	0 (0.0%)
	No longer changing sleeping location nightly	1 (4.2%)	1 (8.3%)	0 (0.0%)
	Tighter throat	1 (4.2%)	0 (0.0%)	1 (8.3%)
Physical—negative	Doesn't 100% take away sleep apnea/snoring	4 (16.7%)	2 (16.7%)	2 (16.7%)
	Could feel/hear stimulation initially	2 (8.3%)	2 (16.7%)	0 (0.0%)
	Discomfort if pressure applied to area of generator	1 (4.2%)	1 (8.3%)	0 (0.0%)
	Can't get an MRI if needed	4 (16.7%)	1 (8.3%)	3 (25.0%)
	Dry mouth	1 (4.2%)	1 (8.3%)	0 (0.0%)
	Did not resolve being a poor sleeper	1 (4.2%)	1 (8.3%)	0 (0.0%)
	Too high of stimulation intensity is uncomfortable	7 (29.2%)	0 (0.0%)	7 (58.3%)
	Stimulation wakes up patient so doesn't sleep well	5 (20.8%)	0 (0.0%)	5 (41.6%)
	Hasn't improved sleep	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Causes ulcers because tongue rubs over posts for removable denture	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Didn't resolve daytime sleepiness	1 (4.2%)	0 (0.0%)	1 (8.3%)

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Table 3—Interview key concepts, categories, and subcategories for high and low users. (*Continued*)

Key Concept and Category	Subcategory	Total Sample (n = 24)	High Users (n = 12)	Low Users (n = 12)
Barriers and Facilitators of UAS Use				
Barriers	Adjustment to using treatment	4 (16.7%)	4 (33.3%)	0 (0.0%)
	Fall asleep without turning it on	2 (8.3%)	2 (16.7%)	0 (0.0%)
	Sometimes gets a good night's sleep without it turned on	1 (4.2%)	1 (8.3%)	0 (0.0%)
	Changing the batteries in the remote	1 (4.2%)	1 (8.3%)	0 (0.0%)
	Stimulation wakes patient up	4 (16.7%)	0 (0.0%)	4 (33.3%)
	Can't get into a routine	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Snoring doesn't bother anyone because significant other sleeps in separate bedroom	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Having to turn it off and on	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Doesn't prevent apneas	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Stimulation prevents patient from falling asleep	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Causes ulcers because tongue rubs over posts for removable denture	1 (4.2%)	0 (0.0%)	1 (8.3%)
Facilitators	Easy to use and maintain	7 (29.2%)	7 (58.3%)	0 (0.0%)
	Assistance and/or encouragement from physician, clinic staff, or other UAS users	5 (20.8%)	4 (33.3%)	1 (8.3%)
	Spouse support	5 (20.8%)	3 (25.0%)	2 (16.7%)
	Convenient when traveling	2 (8.3%)	2 (16.7%)	0 (0.0%)
	Having a routine	1 (4.2%)	1 (8.3%)	0 (0.0%)
	Got used to it	2 (8.3%)	0 (0.0%)	2 (16.7%)
	Spouse noticing snoring	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Less bothersome than CPAP	1 (4.2%)	0 (0.0%)	1 (8.3%)
Advice for New UAS Recipients				
Considerations	Approval from insurance can take time	3 (12.5%)	3 (25.0%)	0 (0.0%)
	Convenient; easy to take care of	3 (12.5%)	3 (25.0%)	0 (0.0%)
	Not a cure	2 (8.3%)	2 (16.7%)	0 (0.0%)
	Expect an adjustment period	3 (12.5%)	2 (16.7%)	1 (8.3%)
	Good option if you cannot tolerate CPAP	2 (8.3%)	2 (16.7%)	0 (0.0%)
	Need insurance to afford it	1 (4.2%)	1 (8.3%)	0 (0.0%)
	Surgery more involved than expected	1 (4.2%)	1 (8.3%)	0 (0.0%)
	Will work better if you are healthier	1 (4.2%)	1 (8.3%)	0 (0.0%)
	Need to let people know this is a treatment option	2 (8.3%)	0 (0.0%)	2 (16.7%)
	Too much stimulation may interfere with sleep	2 (8.3%)	0 (0.0%)	2 (16.7%)
	Painful after surgery but will go away	1 (4.2%)	0 (0.0%)	1 (8.3%)
	If oral structure is not ideal, then consider something else	1 (4.2%)	0 (0.0%)	1 (8.3%)
	Removable denture may be problematic	1 (4.2%)	0 (0.0%)	1 (8.3%)
Actions	Learn about it before making a decision		1 (8.3%)	1 (8.3%)
	Do trial of what stimulation may feel like	1 (4.2%)	0 (0.0%)	1 (8.3%)

Values are presented as n (%), listed for subcategory. CPAP = continuous positive airway pressure, MRI = magnetic resonance imaging, UAS = upper airway stimulation.

Reasons for UAS treatment

The most highly endorsed reason for getting UAS treatment by high users was dislike of CPAP followed by a need for reductions in such OSA symptoms as apneas and daytime sleepiness, desire for improvements in sleep and energy, and the convenience of UAS treatment.

High user: I wanted something that was less intrusive than the CPAP.

In addition to dislike of CPAP, low users also frequently identified getting a better night's sleep as a reason for getting UAS treatment. Other commonly endorsed reasons by low users were prevention of apneas and snoring and to have more energy and live longer.

> Low user: I just hoped it'd make me sleep longer.

Effects of UAS treatment

Compared to low users, high users endorsed more positive emotional/mental and physical effects of UAS treatment. Most high users noted improvements in sleep and less snoring and apneas. Other common positive effects reported were feeling better, being happy with the treatment, having more energy, and feeling refreshed in the morning.

> High user: If I wake up during the night, I go right back to sleep, and I can get 6, 7, sometimes 8 hours of sleep.

Some low users cited improvements in sleep and less snoring and apneas. Fewer low users reported feeling refreshed in the morning and healthier, less daytime sleepiness, and emotional/mental benefits.

> Low user: It made a big difference in how many times I stopped breathing when I was sleeping.

High users identified negative effects of UAS treatment less frequently than low users. Initially having anxiety and feeling or hearing the stimulation and residual apneas and snoring were the most commonly cited negative effects of treatment by high users.

> High user: One thing it can't get rid of is the snoring. But it cuts it down. But I still can be a very noisy sleeper.

Among the low users, many noted discomfort associated with the stimulation intensity and not sleeping well due to stimulation causing awakenings. Low users also identified inability of treatment to stop apneas, improve sleep, and resolve daytime sleepiness along with the inability to get an MRI if needed.

> Low user: I had it set on a setting of 9 out of a maximum of 10, which was way too high, and I think that was why I was deterred from using it.

Barriers and facilitators for UAS use

Low users reported a multitude of barriers to UAS use with the most frequent barrier being that the stimulation caused awakenings or prevented them from falling asleep.

> Low users: When I turned it on, it would sometimes keep me from going to sleep, 'cause the stimulation to my tongue was a little too much. And I was trying to get my body to get acclimated to it, but it was unsuccessful.

Additional barriers to UAS use voiced by low users included inability to get into a routine of using the treatment, having to turn the treatment on and off, not preventing apneas, causing ulcers on tongue, and not always having remote when sleeping away from home. When asked if there is anything that prevented treatment use, one low user stated:

> 'cause I sleep alone. My significant other has a bedroom upstairs from me. I'm not bothering anybody [with his snoring].

High users reported only 2 actual barriers to use, which were falling asleep without turning it on and ability sometimes to get a good night's sleep when the treatment was not turned on.

> High user: Some days, I forget to turn it on at night, and then I wake up in the middle of the night, realize I didn't.

High users voiced inconveniences associated with treatment use, including adjusting to using the treatment and having to change the batteries in the remote.

> High user: I had to learn after that first night about how long to set the Inspire device to start working, so I had time to go to sleep. So that was a little confusing, trying to figure all that out.

Support from partners and assistance and/or encouragement from health care professionals or other Inspire users was expressed by both high and low users as motivation for UAS use.

> High user: The INSPIRE website—I read others' successes, and unsuccessful reports, and people contact me and I contact them, and it's been a real reinforcing site.

Most high users noted the ease of use and maintenance as a facilitator for use, in addition to other facilitators such as having a routine and convenience of traveling with treatment.

> High user: You have to get in the habit of using it all the time.

Some low users identified as facilitators of use: getting used to the treatment, their partner noticing their snoring, and the treatment being less burdensome than CPAP.

> Low users: It doesn't bother you near as much as the airflow with the mask.

Advice for new UAS recipients

When asked what things new UAS recipients should know about or do, low users primarily emphasized problems related to UAS such as sleep interference due to too much stimulation, pain after surgery, and a removable denture.

> Low user: When you come out of surgery, that pain. And you really think you made a mistake. Be patient. In three days, it'll feel so much better.

One low user noted the need for potential UAS recipients to be able to experience what the stimulation may feel like preoperatively.

> Low user: Let them simulate what that feels like on your neck. Because had I had that prior to surgery, I would have known way ahead of time that I would never be able to sleep through that.

High users highlighted the need for insurance, convenience of use, and UAS as a good treatment option for those who are CPAP-intolerant as important information for new UAS recipients. High users also discussed the need for realistic expectations for treatment in that it is not a cure and that there is likely to be an adjustment period. Both high and low users expressed the importance of learning about the treatment before making a decision to pursue UAS.

> High user: It's not an overnight panacea. And that there's probably a period of adjustment and you have to work with your INSPIRE therapist, and to be patient.

DISCUSSION

UAS is an alternative OSA treatment option, particularly for those in whom traditional treatments such as CPAP and oral appliance have been unsuccessful or for whom adherence was problematic. Thus, UAS recipients represent a patient population at high risk for nonadherence. The findings from this study highlight the unique experiences of UAS treatment in high and low users. In particular, between high and low users the interviews identified some often discrepant effects of UAS treatment, barrier and facilitators of UAS use, and advice for new UAS recipients.

We found low users had, on average, mild levels of anxiety and moderate insomnia symptoms, which may have affected their UAS treatment experience. These results are similar to other recent work showing a relationship between high anxiety levels and UAS nonadherence.[21] Insomnia may have contributed to low users identifying better sleep as a main reason for receiving UAS treatment, infrequently noting improvements in sleep due to treatment, and frequently citing the stimulation preventing initiation of sleep or causing awakenings as a barrier to treatment use. Prior studies have found conflicting results regarding the association between stimulation and awakenings, with reduction in arousals identified during polysomnography, yet an increase in arousals due to stimulation from patient questionnaire data.[22,23] Insomnia and/or anxiety may have been the cause of awakenings among low users, rather than the sensation of the stimulation, which may have been detected upon awakening. These awakenings may have led to pausing or turning off the therapy, resulting in lower nightly therapy usage. In a recent study, 38% of UAS recipients were found to have insomnia; however, insomnia was not objectively associated with difficulty acclimating to UAS therapy.[24] Low users noted high stimulation intensity as being uncomfortable. Stimulation settings should be adjusted with guidance from a sleep clinician; however, if the stimulation settings are modified without clinician oversight, intensity of stimulation associated with high settings may contribute to difficulties falling asleep or awakenings.

Overall, high users had a more positive experience with UAS treatment, frequently noting improvements in physical and mental health and the ease and convenience of the treatment which helped facilitate use. Both high and low users identified support and/or assistance from health care professionals or their partners as motivation for UAS use. Perceived partner support has been identified by OSA patients as facilitating CPAP adherence and, accordingly, is associated with greater CPAP adherence.[19,25] Patients have expressed the need for early interactions with health care professionals following CPAP initiation.[26] Additionally, partners have reported that receiving OSA and CPAP education and support from health care professionals enabled them to provide more informed support.[26,27] A pilot study of a couple-oriented CPAP education and support intervention resulted in increased CPAP adherence during the first month of treatment and improvements in both patients' and partners' sleep and daytime function.[28] Engaging partners in the care pathway for UAS evaluation, initiation, and follow-up may improve UAS use, and ultimately the health of the patient and partner.

Both high and low users agree that being fully informed about UAS treatment is important for OSA patients considering this alternative treatment. Whereas high users identified practical and positive information and considerations for potential UAS recipients such as having realistic expectations about the treatment and convenience of use, low users tended to focus on negatives of the treatment, which is likely a reflection of their poor experiences with UAS. In particular, 1 lower user suggested a trial of the stimulation prior to implantation; if they had been given this opportunity they would have opted out of the treatment. Other neuromodulation treatments, for example, spinal cord stimulation for pain management and sacral nerve stimulation for urinary incontinence, have utilized trial stimulation to determine treatment efficacy and acceptance. If available, trial hypoglossal nerve stimulation before permanent implant may help UAS candidates to prepare for treatment adoption and long-term use.

Findings from our study suggest that an individualized care approach is crucial for preventing treatment abandonment. Unlike CPAP, UAS is an invasive treatment involving a surgically implanted medical device and recovery time. Providing health literacy–aligned education and understanding and addressing patients' expectations and fears about treatment are critical to ensuring that patients make an informed decision about UAS treatment. As suggested by one study participant, a trial of the stimulation may further inform the patient decision to adopt treatment. Promoting partner engagement in health-related decision making and in follow-up with the health care team may result in more positive patient experiences and consequently greater UAS use. Early follow-up with the health care team is needed to address issues with treatment and ensure that stimulation intensity is properly adjusted. Furthermore, education about changes in stimulation strength levels via the remote and corresponding absolute stimulation changes may help to relieve potential adverse psychological effects of "high" stimulation strength levels. Enabling patients to monitor their own nightly UAS use via a web-based application, as is available for CPAP, may enhance UAS adherence.[29] An insomnia phenotype of OSA may impede UAS use and preclude improvements in sleep quality associated with treatment. Failure with other OSA treatments could be partly associated with insomnia, so prospective UAS recipients should be evaluated for insomnia. Cognitive behavioral intervention approaches should be initiated prior to implantation in order to improve insomnia symptoms and increase the likelihood of a positive initial experience with UAS treatment and sustained adherence.[30]

A limitation of this study is that objective adherence data were unavailable for patients lost to follow-up, so usage data could not be downloaded from the remote and the data that was available may not have been recent. Therefore, it is possible that patients were misclassified. Similarities in patients' accounts of UAS use and objective usage measures have been found in a prior study.[23] Unavailable objective adherence data precluded examination of therapy usage patterns, which have been previously identified,[31] and could have provided more detail about patterns of usage among the high and low users. Given the variability in the duration of UAS implantation, the more recent interactions with therapy could have biased patients' perceptions of UAS treatment

either positively or negatively, especially when initial experiences may have been limited by patient recall ability. Purposive sampling and inclusion of patients treated by a single clinician limits the generalizability of the findings to the general population of UAS patients. The sample was composed primarily of White males; thus, experiences of minorities and women were not fully captured and pose an opportunity for future research.

Our study explored UAS treatment experience among OSA patients using qualitative methods. High and low users had differing experiences that may have been partly due to prevalent insomnia symptoms among low users. Sleep clinicians should consider evaluating patients for insomnia and initiating treatment prior to UAS implantation, as doing so may increase the likelihood of adherence. Health care teams need to ensure that patients are provided with appropriate education in order to make informed decisions about UAS treatment and should also provide early support to both patient and partner that addresses difficulties and reinforces commitment to the treatment.

ABBREVIATIONS

CPAP, continuous positive airway pressure
OSA, obstructive sleep apnea
UAS, upper airway stimulation

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