

## Program Profile

# The Nonsurgical Sleep Medicine Physician Role in the Development of an Upper Airway Stimulation Program

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**Background:** Obstructive sleep apnea (OSA) is a common disorder in the US and other industrialized countries. Untreated OSA is associated with increased risk of coronary artery disease, cerebrovascular accidents, uncontrolled diabetes mellitus, poor workplace productivity, increased health care utilization, and higher risk of motor vehicle accidents. Continuous positive airway pressure (CPAP) is a commonly used treatment for OSA. CPAP nonadherence continues to be a major problem in clinical practice.

**Methods:** Upper airway stimulation (UAS) is an alternative op-

tion for management of OSA and has been shown to be safe and effective. This therapy involves electrical stimulation of the hypoglossal nerve to facilitate airway opening in the oropharynx.

**Results:** Although the UAS device is implanted by a surgeon in the operating room, the nonsurgical sleep medicine provider can play an important role in this type of therapy.

**Conclusions:** This article outlines opportunities for a nonsurgical physician to become a leader in development of an institutional UAS program.

Obstructive sleep apnea (OSA) is a common disorder in the US and other industrialized countries. The Wisconsin Sleep Cohort Study reported prevalence rates as high as 20% to 30% in men and 10% to 15% in women.<sup>1,2</sup> Several studies have shown high prevalence of OSA among veterans. Ancoli-Israel and colleagues reported a OSA rate of 36% in a cohort of elderly patients at a US Department of Veterans Affairs (VA) medical center.<sup>3</sup> A study by Kreis and colleagues showed that OSA was present in 27% of patients hospitalized on the medical ward at a VA hospital.<sup>4</sup> Incidence of sleep apnea among veterans in the US will likely increase over time as obesity is becoming more prevalent. Rates of obesity have increased from 14% in 2000 to 18% in 2010 among both male and female veterans.<sup>5</sup>

Untreated OSA is associated with increased risk of coronary artery disease, cerebrovascular accidents, uncontrolled diabetes mellitus, and other complications. Patients with OSA are less productive, have increased health care utilization, and have a higher risk of motor vehicle accidents.<sup>6</sup> Continuous positive airway pressure (CPAP) is the main form of treatment of OSA. However, despite the adverse outcomes of untreated sleep apnea, suboptimal CPAP adherence re-

mains a major problem in clinical practice. When adherence is defined as > 4 hours of nightly use, 29% to 83% of patients with OSA have been reported to be nonadherent to treatment.<sup>7</sup> Stepnowsky and colleagues estimated that 50% of patients with OSA for whom CPAP was recommended were no longer using it 1 year later.<sup>8</sup> CPAP adherence among veterans also has been poor. Wallace and colleagues reported that about one-third of patients with OSA at a VA Miami Healthcare System had mean daily use  $\geq$  4 hours.<sup>9</sup> Typical reasons for poor CPAP adherence include pressure intolerance, mask discomfort, nasal and oropharyngeal dryness and irritation.<sup>10</sup> Development and implementation of alternate treatment strategies for OSA is important to reduce disease burden of this widespread and debilitating condition.

Upper airway stimulation (UAS) is a novel therapy for management of OSA that has been gaining popularity and acceptance within the sleep medicine community in the past few years. This treatment option involves implantation of a neurostimulator with a sensing lead and a stimulation lead. The device is similar to a pacemaker and is surgically implanted in chest wall. The sensing lead is placed close to the diaphragm for monitoring of pleural pressure to help assess ventilation. The stimulation lead is placed

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under the tongue in proximity to the hypoglossal nerve (cranial nerve XII). The neurostimulator delivers electrical pulses to the hypoglossal nerve through the stimulation lead. These stimulating pulses are synchronized with the ventilation detected by the sensing lead. This electrical stimulation results in anterior displacement of the tongue via action of the genioglossus and geniohyoid muscles. Mechanical coupling with the palate also is common and leads to additional airway opening within the oropharynx to prevent apneic episodes. The patient turns on the stimulation through the use of a portable remote control and is turned off in the morning. The patient is able to operate the UAS device by placing the remote control on the skin in proximity of the device. The patient also is able to adjust device voltage within a range set by their physician. The effective voltage range is determined via an overnight sleep study titration performed 1 month after device activation. UAS therapy is not considered first-line treatment for OSA as it requires surgical implantation under general anesthesia; however, it provides an alternative to patients with OSA who are unable to tolerate traditional therapy with CPAP.

The landmark Stimulation Therapy for Apnea Reduction (STAR) trial showed effectiveness of UAS therapy at 12 months postimplantation.<sup>11</sup> Follow-up of these participants has proven the sustainability of this effect at 18, 24, 36, and 48 months of therapy.<sup>12-15</sup> Inclusion criteria of the study was moderate-to-severe sleep apnea with predominantly obstructive events. Subjects were excluded if there were anatomical abnormalities of the upper airway or if the pattern of airway collapse was not conducive to UAS on sedated endoscopy evaluation. Participants in the trial were predominantly white males, the average age was 54.5 years, and the average body mass index (BMI) was 28.4. The outcomes measured included Functional Outcomes of Sleep Questionnaire, Epworth Sleepiness Scale (ESS), percentage of sleep time with oxygen saturation < 90%, and subjective snoring. All of these objective and subjective markers of sleep improved significantly with UAS therapy at 12 months and were maintained at improved levels at 48 months of therapy.

The adverse effects (AEs) associated with

device implantation and subsequent UAS therapy have been infrequent and mostly transient. Out of 126 device implantations, there were 2 participants who had serious AEs due to implantation and required repositioning and fixation of the neurostimulator to resolve discomfort. Other AEs related to the procedure, including sore throat and muscle soreness, were considered nonserious and resolved with supportive care. AEs related to subsequent UAS therapy included temporary tongue weakness and tongue soreness/abrasion. These complications also have either resolved spontaneously or with use of supportive strategies such as a mouth guard. Due to the sustained clinical benefit and acceptable AE profile as demonstrated by the STAR trial, UAS has emerged as a realistic alternative for management of OSA.

Development of a successful program that provides and supports all aspects of UAS, including device implantation and follow-up, necessitates a multispecialty team approach. Ideally surgical and nonsurgical sleep physicians as well as clinical and administrative support staff should be part of this group.

This study is based on the experience of the development of the UAS program at the Clement J. Zablocki VA Medical Center (CJZVAMC) in Milwaukee. Currently, there are 25 patients who are part of this UAS program. The inclusion and exclusion criteria were adopted from the STAR trial. The patient population is similar to the population in that trial. They are all white males with average age of 57.2 years and BMI of 31.3. The CJZVAMC UAS Program consists of multidisciplinary group of health care professionals. This article describes the role of a nonsurgical sleep medicine physician that was crucial in the development of this UAS program.

## PROCESS

Introduction of this novel alternative therapy has sparked much interest among health care providers (HCPs) at CJZVAMC. However, there has been much misunderstanding among patients and HCPs about what this treatment involves and how it is implemented. For example, many patients that called the sleep clinic to set up an evaluation for UAS did not realize that this is a surgical procedure that requires

general anesthesia. One of the most important tasks for a nonsurgical sleep physician is to educate patients and HCPs about this therapy. Most of patient education at CJZVAMC has been done during individual clinic appointments; however, setting up group educational classes for patients is a more efficient strategy to deliver this information. Similarly, giving a lecture on UAS at medicine (or another specialty) grand rounds has been effective in the education of HCPs who refer patients to the sleep clinic. If possible, a combined lecture with a surgical colleague could provide a more balanced and complete depiction of UAS and help to answer a broader range of questions for the audience.

### Screening

Screening and identification of appropriate candidates is an important first step in the patient pathway in the UAS therapy. Failure of CPAP therapy is a key starting point in this screening process. When patients present to the sleep clinic with difficulty tolerating CPAP therapy, an extensive and thorough troubleshooting process needs to take place to make sure that all CPAP options have been exhausted. This process would typically include trial of various masks, including different mask interfaces. A dedicated appointment with a registered polysomnographic technologist (RPSGT) or another clinic staff member with vast experience in PAP mask fitting is typically part of this effort.

Adjustment of CPAP pressure settings also may be helpful as high PAP pressure may be another obstacle. Patients frequently have trouble tolerating higher pressure settings especially when they are new to this therapy. Pressure restriction to 4-cm to 7-cm water pressure on auto CPAP has been a helpful technique to allow patients to become more comfortable with this therapy. Once patients are able to use PAP at lower pressures, these settings can be titrated up gradually for optimal effectiveness. Other desensitization techniques, such as use during daytime while distracted by other activities (such as watching TV) can be helpful in adjustment to PAP therapy. Addressing problems with nasal congestion can help improve PAP adherence. Finally, patients should be offered opportunities

for education about their PAP machine on an ongoing basis. Lack of proficiency with humidifier use is a very common obstacle and frequently leads to PAP nonadherence. Teaching PAP operation should correspond to the patient's level of education to be effective. PAP therapy remains the first-line treatment strategy for OSA as it is not invasive and highly effective. Nonsurgical sleep medicine physicians are uniquely positioned to implement and troubleshoot this therapy for sleep apnea patients before considering UAS.

As part of the screening process, it can be helpful to conduct routine multidisciplinary meetings to discuss patients who are being evaluated for UAS implantation. These meetings should include the otolaryngologist, nonsurgical sleep medicine physician, as well as additional staff (nurses, respiratory therapists, etc) who are involved in the UAS process. Having a mental health care provider as part of the multidisciplinary team during the screening process also could be a valuable addition as this specialist could evaluate and provide insight into a patient's emotional status prior to implantation. This is common practice during evaluation for organ transplantation and would help to predict patient's psychological well-being after this life-changing procedure.<sup>16</sup> Having multidisciplinary agreement on patient's candidacy for UAS therapy could improve long-term success of this treatment. Additionally, these multidisciplinary meetings as part of the UAS program can improve team camaraderie and prevent miscommunications during this therapy.

### Drug-Induced Sedated Endoscopy

Patient pathway to neurostimulator implantation involves evaluation of the upper airway using drug-induced sedated endoscopy (DISE). This procedure helps determine whether the patient's anatomy is appropriate for UAS. DISE also can evaluate the pattern of airway closure during an apneic episode. Anterior-posterior pattern of closure is associated with greater UAS effectiveness compared with concentric pattern of airway closure. DISE is typically performed by the otolaryngologist scheduled to implant the UAS. However, nonsurgical physicians who are part of the patient's care team

can be trained to perform this procedure especially if they have experience in performing endoscopy of the upper airway (such as a pulmonary specialist). This can make the evaluation process more efficient and dramatically improve access to care.

#### COORDINATION OF CARE

In order for the UAS program to be successful, the patient's care team has to work closely with the device manufacturer throughout the implantation pathway and for ongoing patient care. The device manufacturer can assist with education of HCPs, surgical physicians, clinical support staff, and the patient. However, an even more essential role for industry support is during UAS device activation and subsequent titration of UAS via an overnight in-laboratory sleep study.

After surgical implantation, the UAS device activation can be performed in the nonsurgical sleep clinic and is done about 1 month later. This period allows for tissue healing after the surgery and for the patient to get accustomed to having this new device in their body. This activation can be done with assistance from an industry technician until the HCP is comfortable with this process. The multidisciplinary UAS team could choose to delegate device activation to a technician with specialized relevant training, such as RPSGT or respiratory therapist (RT).

This procedure involves determination of sensory and functional threshold for UAS. Sensory threshold is minimum voltage required for the patient to feel the stimulation. The functional threshold is the minimum voltage required to move the tongue past the lower front teeth during stimulation. After these thresholds are established, a voltage range is set on the device. The voltage at functional threshold is typically set at the lower level of this range, and the maximum level is set at 1 volt higher. Patients are able to adjust voltage within this range and are instructed to increase the voltage gradually (0.1-volt increments) while maintaining levels that are comfortable during sleep.

About a month after device activation, patients undergo another overnight polysomnogram for titration of UAS device. In order to educate and train the institutional RPSGT on how to perform this type of ti-

tration, an industry technician is required for the first few overnight titrations. The goal of this study is to establish appropriate voltage to resolve sleep-disordered breathing and insure patient comfort at this setting. Patients typically leave the study with a new voltage range. They are asked to keep effective voltage in mind and make appropriate adjustments to maintain comfortable therapy.

Successful UAS therapy includes multiple steps, such as implantation, activation, and titration. This protocol requires effective coordination of care that includes communication with surgical staff, patients, support staff, and industry liaison. Nonsurgical sleep medicine physicians can play a vital role by helping to coordinate care at the early stages of UAS therapy and facilitate effective communication among various providers involved in this process.

#### FOLLOW-UP

After completion of the initial therapeutic pathway, patients continue to follow up regularly, monitoring for AEs from UAS therapy and sleep apnea symptoms. Patients can be followed in the nonsurgical sleep clinic after the initial postoperative appointment with the surgeon. Frequency of follow-up depends on the presence and severity of any AEs and residual symptoms of sleep apnea. Even though most AEs related to UAS therapy reported in the STAR trial were nonserious and transient, 2% of participants required surgical revision.<sup>3</sup> Therefore, maintaining open channels of communication among the entire UAS patient care team even months and years after surgical implantation is important. The nonsurgical sleep medicine physician who will continue to monitor the patient's progress may need to consult with the surgical colleague or industry liaison at any point during treatment.

#### Limitations

This review outlines the UAS therapy pathway and emphasizes the role of the nonsurgical sleep medicine provider. However, the experience describes a UAS program development at a single VA medical center. Since this UAS device and therapy have already been approved by the VA on a national level, we did not face any challenges with

authorization and insurance compensation. Therefore, this review does not provide any guidance with these matters. These are certainly common concerns for sleep medicine providers who offer UAS therapy in medical practices outside the VA, and these would hopefully be addressed in the future.

Furthermore, this review is based on the pulmonary sleep medicine provider's experience and perspective. Therefore, certain aspects of UAS therapy could be better addressed by nonsurgical sleep medicine providers in different fields of expertise. For example, a study by a psychiatrist or psychologist could provide insight into the emotional concerns of patients who are undergoing this novel and life-altering treatment that includes surgical implantation of hardware into the body. A neurologist could explore the long-term effects of recurrent electrical stimulation on the autonomic and somatic nervous system as well as the musculature of the upper airway.

## CONCLUSION

Multidisciplinary perspectives are needed to provide guidance for practitioners and institutions looking to set up and improve established UAS programs. As the long-term outcomes of the STAR trial continue to be published and provide more validation for UAS, this novel therapy will likely continue to gain acceptance as a safe and effective treatment for OSA.<sup>11</sup>

## Author disclosures

The author reports no actual or potential conflicts of interest with regard to this article.

## Disclaimer

The opinions expressed herein are those of the author and do not necessarily reflect those of *Federal Practitioner*, Frontline Medical Communications Inc., the US Government, or any of its agencies.

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