Comments on “Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes”

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We enjoyed the article by Woodson et al recently published in this journal.1 The authors presented an excellent case for upper airway stimulation (UAS) as an alternative treatment for select patients with obstructive sleep apnea (OSA) who are intolerant of positive airway pressure (PAP) therapy. The data demonstrated clinically and statistically significant improvements in apnea-hypopnea index (AHI), oxygen desaturation index, Epworth Sleepiness Scale scores, Functional Outcomes of Sleep Questionnaire scores, and snoring ratings. Perhaps the most impressive finding is the stability of these improvements over the 5-year follow-up with this cohort of patients.

While the authors present a well-designed study, the omission of data demonstrating the amount of device usage by the patients is a substantial limitation. A strength of the UAS system is the ability to provide these data objectively. Given the length of follow-up and absence of these data, one is left to speculate if these patients who were not adherent to PAP therapy are similarly not adherent to this therapy. Notably, other studies describing the effectiveness of UAS therapy, with shorter follow-up, presented the usage data.2,3 Possibly the greatest advantage that UAS therapy can have over PAP therapy is improved compliance with treatment, as intolerance to or unwillingness to accept PAP therapy is the primary indication for device implantation.

The published AHI reductions with UAS are encouraging. However, these reductions are not quite as effective as PAP therapy. Since PAP therapy is effective only for the time that it is used, with a return to the patient’s baseline AHI during periods of nonusage, the “effective AHI” may in fact be improved with UAS.4 The surgical sleep community has recognized the difference between efficacy and effectiveness in the context of poor PAP compliance and treatment limitations when patients do not use the prescribed therapy. Historically, one of the potential benefits of surgery is that compliance has not been a factor. As highlighted by the “therapy withdrawal” portion of the STAR trial, UAS should be viewed differently than other surgery, since compliance with therapy is required.5 However, UAS therapy with increased frequency and duration of usage can provide a more substantial disease-altering effect on OSA through more consistent use and thus a lower effective AHI.

We look forward to a response from the authors that can clarify this issue of device usage, as we believe that this will strengthen the case for this revolutionary OSA treatment.

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**Reply on “Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes”**

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I would like to thank Drs Scalzitti, Mysliwiec, and O’Connor for their comments on the omission of device usage data in “Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes.” Device usage is an important variable with cranial nerve implant technology, and not including this data point was inadvertent. The study methodology included patient self-reported device usage at all scheduled follow-up visits. For the STAR trial at 5-year follow-up, 92 patients completed the study, and 80% reported using the device every night. Patients volunteering for 5-year polysomnography (n = 71) reported 81% nightly use, and reports did not differ between responders and nonresponders according to Sher criteria for surgical success (apnea-hypopnea index [AHI] <20 events per hour and >50% reduction). Among all patients who were eligible for 5-year follow-up, 74 of 110 (67%) reported nightly use.

Disease burden in sleep apnea is the result of many variables. How best to measure disease burden in sleep apnea is not established. It is increasingly accepted that the commonly used AHI metric weakly correlates to clinical outcomes for many patients. For devices such as upper airway stimulation, “effective AHI,” which accounts for residual “therapy on” AHI and adherence, seems intuitively more appropriate. However, direct data supporting this measure are lacking. Ultimately, disease burden for patients with obstructive sleep apnea is likely the result of multiple factors. The nature and severity of residual respiratory events over time, oxygen desaturation measures, the impact of obstructive sleep apnea on sleep and sleepiness, phenotypic properties of the individual patient, and other measures may all contribute. Early attempts at including multiple variables to create a disease measure were suggested for surgical patients, but none are yet validated. Such measures are necessary to better assess and compare the benefits versus harms of medical and surgical therapies.

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