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EDITORIALS

Standardized Reporting for Hypoglossal Nerve Stimulation Outcomes

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Hypoglossal nerve stimulation (HGNS) therapy is an increasingly popular tool for the treatment of obstructive sleep apnea (OSA) in patients unable to tolerate positive airway (PAP) pressure. Since the publication of the pivotal Stimulation Therapy for Apnea Reduction (STAR) trial leading to FDA approval in 2014,[1] the majority of publications are composed of single institution experiences with inconsistent, perhaps misleading, reporting of outcomes. In this editorial, we will argue for the following measurements to be reported in all future HGNS publications:

1. Full-night efficacy (ie, single device setting) studies from either a home sleep apnea test (HSAT) or in-laboratory polysomnography (PSG)
2. 4% oxygen desaturation index as the primary outcome of therapy effectiveness

While PAP device pressures are often set according to the treatment apnea-hypopnea index (AHI) from a titration PSG, ongoing device assessments for both usage (hours per night) and efficacy (residual AHI) are available to ensure effectiveness. This combination of features is not yet available in PAP alternative devices; in this way, the supporting literature for PAP alternatives historically reports efficacy data from full-night HSAT or PSG. A large number of HGNS publications, however, use treatment AHI.[2,3] Treatment AHI is fraught with issues related to the lack of standardization for minimum duration, position, or sleep stage. In addition, Inspire utilizes a standard 30-minute start delay without active therapy as well as patient-activated 15-minute therapy cessation pauses during the night. The first author (RCD) examined data from the Emory HGNS cohort (n = 43), comparing treatment AHI to full-night efficacy AHI. The mean treatment AHI was 7.7 events/h, compared to 19.2 events/h from full-night efficacy studies. Accordingly, using Sher success criteria of 50% reduction in AHI and AHI < 20 events/h, HGNS appeared 91% successful using treatment AHI while 52% successful using full-night efficacy AHI.

In order to move this promising therapy forward, standardization of a primary outcome is imperative. Such standardization allows for accurate pre-intervention and post-intervention comparisons, and—equally importantly—data compilation across institutions. While self-reported symptoms remain important secondary outcomes, the 4% oxygen desaturation index represents the single most important outcome measure for two reasons. First, there exists immense heterogeneity in scoring of sleep-disordered breathing events, particularly hypopnea definitions. At present, hypopneas range from 3% desaturation or arousal to 4% desaturation only to peripheral arterial tonometry-based scoring. The use of oximetry represents the common denominator with relatively uniform data acquisition algorithms. Secondly, the target HGNS population is an at-risk cardiovascular population based on FDA candidacy criteria using a minimum AHI of 15 events/h. Punjabi et al. demonstrated that the 4% oxygen desaturation index, not 3% oxygen desaturation index, was independently associated with cardiovascular disease in the Sleep Heart Health Study.[4]

In conclusion, PAP is a highly efficacious, first-line therapy for OSA with relatively poor acceptance[5]; thus, the need for PAP alternatives is abundantly clear. Hypoglossal nerve stimulation represents a novel, physiologic therapy with unquestionable potential. As patient selection remains its Achilles' heel, uniform data collection and reporting are necessary to improve our understanding of relevant patient factors. A full-night 4% oxygen desaturation index at a single device setting yields a clinically meaningful and representative data point for therapy effectiveness, serving to advance our collective knowledge of this new paradigm in OSA therapy.

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