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Late-breaking Abstract

SESSION TITLE: Late-breaking Abstracts
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EFFECTS OF TRANSVENOUS PHRENIC NERVE STIMULATION ON CENTRAL SLEEP APNEA AND SLEEP ARCHITECTURE: THE 5 YEAR ANALYSIS

SHAHROKH JAVAHERI ALAN SCHWARTZ WILLIAM ABRAHAM SANJAYA GUPTA SCOTT MCKANE ROBIN GERMANY AND MARIA ROSA COSTANZO

PURPOSE: Central sleep apnea (CSA) is a disorder involving disruption in the neural drive to breathe occurring predominantly during non-REM sleep. Sleep architecture is characterized by repetitive arousals following central apneas, light sleep stages, and, rarely, deep sleep. Therapies to improve CSA and sleep quality are needed. The remedē System (Respicardia, Inc.) unilaterally stimulates a phrenic nerve to induce diaphragmatic contraction producing a negative intrathoracic pressure similar to normal breathing, resulting in stabilized breathing. Transvenous phrenic nerve stimulation (TPNS) safely and effectively treated CSA in a randomized pivotal trial. Since then, participants were enrolled and followed in a single arm study (all on active therapy) for 5 years post implant to monitor safety and efficacy of TPNS as a condition of FDA approval.

METHODS: This analysis of centrally scored polysomnograms (PSG) assesses the efficacy of TPNS on CSA and changes in sleep architecture 5 years post implant. All patients remaining in the Pivotal Trial at study closure were asked to consent to continued follow-up. Index results are presented as median [interquartile range] events/hour (/hr) and percentage of total sleep time (TST) in each sleep stage is presented as mean ± standard deviation. Analysis is limited to patients with paired data at baseline and 5-years.

RESULTS: At the time of abstract submission, 32 of 53 enrolled subjects completed study testing including a 5-year PSG; results for remaining subjects will be available for presentation at the annual meeting. No unexpected safety events have been observed through 5 years. With TPNS, the apnea hypopnea index (AHI) decreased by a median of 24/hr [-43, -9] of sleep at 5 years (median residual AHI of 16/hr [7, 33]). The median reduction in the central apnea index was 24/hr [-37, -13] (median residual of 1/hr [0, 3]).

The distribution of sleep stages as a percentage of TST at baseline was N1=33±18%, N2=49±16%, N3=4±8% and REM sleep=13±6%. In parallel with changes in AHI and CAI, sleep architecture improved. At 5 years, paired absolute changes from baseline revealed: N1 decreased by 20±13 percentage points, whereas N2 increased by 12±20, N3 by 2±17, and REM by 6±9. The arousal index decreased by 14/hr [-24, -2] and 4% oxygen desaturation index by 22/hr [-39, -9].

In addition to improved sleep architecture, the Epworth Sleepiness Scale decreased significantly from a median of 11 [5, 14] at baseline to 4 [3, 9] at 5 years (change from baseline $p<.001$).

CONCLUSIONS: In conclusion, this 5-year analysis from the subset of enrolled pivotal trial subjects shows that TPNS therapy has sustained safety and efficacy treating CSA, accompanied by significant improvement in sleep architecture and daytime sleepiness.

CLINICAL IMPLICATIONS: TPNS therapy has sustained 5-year safety and efficacy treating CSA, accompanied by improvement in sleep architecture and daytime sleepiness.

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