managed by a GP only (n=662), proportions (95% CI) with EDS were: PAP nonuse (49% [42.8–54.9]), nonadherent (47% [31.5–63.2]), intermediate (47% [33.4–60.8]), and highly-adherent (35% [29.3–39.9]). Linear modeling (PAP users; n=398) showed an additional h/night of PAP use was associated with lower ESS scores (estimate [SE], –0.26 [0.13]; P<0.05); logistic regression showed association between PAP adherence and higher satisfaction with HCPs (adjOR=2.26; 95% CI=1.09–4.70; P<0.05) and OSA care (adjOR=1.58; 95% CI=0.75–3.36; P>0.05). There was an association between presence of EDS and lower satisfaction with their HCPs (adjOR=0.62; 95% CI=0.39–0.99; P<0.05) and OSA care (adjOR=0.49; 95% CI=0.31–0.79; P<0.05).

Conclusion: In a real-world population of participants with OSA receiving OSA care from GPs, EDS was common, even among highly-adherent PAP users. ESS scores were generally lower with increasing PAP adherence. PAP adherence was associated with increased satisfaction with their HCPs; EDS was associated with lower satisfaction with HCPs and overall OSA care.

Support (If Any): Jazz Pharmaceuticals

0760

EXCESSIVE DAYTIME SLEEPINESS, POSITIVE AIRWAY PRESSURE, AND PATIENT SATISFACTION WITH MULTIPLE ASPECTS OF CARE IN A REAL-WORLD POPULATION WITH OBSTRUCTIVE SLEEP APNEA

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Introduction: Excessive daytime sleepiness (EDS) is common in patients with obstructive sleep apnea (OSA) and can persist despite use of positive airway pressure (PAP) therapy. These analyses assessed relationships between EDS, PAP use, and patient satisfaction across several aspects of OSA care in a real-world population with OSA.

Methods: US residents (aged ≥18 years, self-reported physician OSA diagnosis [1/1/2015–3/31/2020]) completed a survey in Evidation Health's Achievement app assessing Epworth Sleepiness Scale (ESS), PAP usage, and satisfaction with care. Self-reported PAP use was categorized as nonuse, nonadherent (<4 h/night; <5 d/wk), intermediate (4–6 h/night, ≥5 d/wk), or highly adherent (≥6 h/night, ≥5 d/wk) (PAP-adherent=intermediate and highly adherent groups). Logistic regression models assessed impacts of PAP adherence and EDS on satisfaction with care across 7 domains. P-values are uncontrolled for multiplicity (nominal).

Results: Among all participants (N=2289; 50.3% female, 82.5% White, 44.8±11.1 years old [mean±SD], 35.4±8.7 kg/m2 body mass index [mean±SD]), 42.5% had EDS (ESS>10). PAP use was: nonuse (n=700), nonadherent (n=153), or adherent (n=1436; intermediate n=225, high n=1211). Within these subgroups, the proportions (95% CI) with EDS were: nonuse (47% [43.7–51.1]), nonadherent (52% [44.4–60.2]), intermediate (53% [46.4–59.4]), and highly adherent (36% [33.7–39.1]). Logistic regression (using data from PAP users) showed a positive association of PAP adherence with satisfaction with PAP (OR [95% CI]: 5.43 [3.73–7.90]); OSA treatment effectiveness (3.56 [2.48–5.12]); OSA symptom management (3.15 [2.17–4.57]); coordination of OSA care (2.60 [1.82–3.72]); and education from their healthcare provider on the impact of OSA on cardiovascular health (1.62 [1.13–2.35]), importance of using PAP (1.7 [1.15–2.52]), or availability of prescription drugs to treat OSA symptoms (1.55 [1.06–2.26]). The presence of EDS was associated with lower patient satisfaction in nearly all domains examined (ORs ranged from 0.44–0.62 across 6 of 7 domains).

Conclusion: EDS was common in this real-world population with OSA, even among participants who were highly adherent PAP users. PAP adherence was associated with higher patient satisfaction across all care domains; the presence of EDS was associated with lower patient satisfaction across 6 of 7 domains.

Support (If Any): Jazz Pharmaceuticals

0761

ADAPTABILITY OF THE TREATING OBSTRUCTIVE SLEEP APNEA USING TARGETED HYPOGLOSSAL NERVE STIMULATION (OSPREY) TRIAL

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Introduction: With few exceptions, clinical trials of hypoglossal nerve stimulation (HGNS) for obstructive sleep apnea (OSA) are single-arm, open-label studies sometimes followed by short-term, unblinded, randomized withdrawal. By contrast, the THN3 study was a parallel-arm, randomized, controlled trial (RCT) of targeted HGNS (THN) in moderate to severe OSA, and provided higher-level evidence of HGNS safety and efficacy.Despite generating strong evidence, conventional RCTs are risky due to their inherent inflexible designs. We therefore launched a confirmatory THN RCT (OSPREY) with an adaptive, Bayesian "Goldilocks" design that optimize its sample size dynamically, yet achieve high-confidence results.

Methods: Four scenarios were simulated within the OSPREY design framework (randomized 2:1 Treatment:Control) for the primary endpoint of apnea-hypopnea index (AHI) response rate (RR): nominal with results equal to those of THN3 (Treatment AHI RR 52%/Control AHI RR 20%), improved Treatment RR (63%/20%), worsened Treatment RR (41%/20%) and null [Treatment RR=Control RR] (20%/20%). Each scenario was simulated 10 times with 10,000 simulations of each interim analysis. Subject outcomes were determined by randomly drawing from a binomial distribution with the relevant AHI RR.Interim analyses in OSPREY begin at 50 randomized subjects and repeat every 20 additional subjects to the maximum sample size of 150, with opportunities for early success and futility at each milestone to generate high-confidence results from an optimal sample size. OSPREY assesses secondary endpoints including quality of life inventories (Epworth Sleepiness Scale; Functional Outcomes of Sleep Questionnaire; EQ-5D, SF-6D and PROMIS sleep questionnaires) and oximetry metrics (Oxygen Desaturation Index, %sleep time below 90% oxygen saturation). Previous results suggest secondary endpoints will be adequately powered at the final sample size determined by AHI RR.

Results: Simulations produced the following outcomes formatted as [scenario: randomized sample size, overall success rate, probability of early success, mean success probability]: null: 150, 0%, 0%, 2.47%; nominal: 130-150, 100%, 80%, 95.3%; improved: 90-130, 100%, 100%, 98.9%; worsened: 150, 100%, 0%, 68.6%.

Conclusion: OSPREY is uniquely able to adapt to various Treatment/Control response scenarios and should provide high-confidence confirmation of the safety and efficacy of THN therapy in moderate to severe OSA.

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