0752

PRELIMINARY EFFICACY OF A NOVEL ITERATIVE DEVICE AND MATERIAL

Mark Murphy[1], John Carollo[2], Kent Smith[3], Aditi Desai[4]
Funktional Sleep LLC [1] Dental Sleep Medicine NJ [2] Sleep Dallas [3] Dr Aditi Desai [4]

Introduction: Launching a new device design or use of a new material with optimistic expectations should always be undertaken with caution and an ounce of skepticism. When this novel device and material was first described in an IRB Abstract derivative report at the AASM, it was under the umbrella of a patient and provider preference survey. In April 2020, the broader availability post FDA clearance is providing strong early indications of excellent efficacy.
Methods: An analysis of data from four treatment centers using this novel device and material was undertaken. Patients were to be included if they had a diagnosis of mild, moderate, or severe OSA confirmed by a physician, and an AHI score >5 and a follow up study resulting in treatment success or failure. Results would be grouped as Complete Success = AHI <5, Clinical Success = 50% reduction and <10. All patients were to be treated with the Novel ProSomnus EVO Iterative advancement device.
Results: 55 total consecutive patients were treated at four centers for dental sleep medicine. 37 male and 18 female patients with an average age of 53.3 ranging from 30 to 78 with pre and post data were included and treated with a ProSomnus EVO. The initial AHIs ranged from 6.0 to 116.0 with an average of AHI pretreatment of 26.4 (15 mild, 23 moderate and 17 severe). Follow up testing for this group revealed an average overall reduction in AHI of 75%, from 26.4 to 6.6. Overall, 62% resolved to below an AHI of 5 (100% of mild, 65% of moderate and 24% of severe patients). Similarly, 85% resolved to below an AHI of 10 and a 50% reduction (100% of mild, 96% of moderate and 59% of severe patients)
Conclusion: This novel interactive device and material combination appear, after early analysis, appear to yield significantly better results that previous data has demonstrated. The literature suggests that legacy oral appliance efficacies range from 50%-62% and other AADSM poster/abstracts have reported similar precision milled, control cure PMMA appliances in the 74% - 76% range. These results suggest a need for further investigation of exceptional efficacy for this device design and material.
Support (If Any): No support was provided for this abstract

0753

PREDICTORS OF RESIDUAL SLEEP APNEA IN OSA PATIENTS ON PAP

Yuenan Ni[1], Robert Thomas[2]
Department of Respiratory and Critical Care Medicine, West China School of Medicine and West China Hospital, Sichuan University [1] Beth Israel Deaconess Medical Center [2]

Introduction: Positive airway pressure (PAP) is the first line therapy for patients with obstructive sleep apnea (OSA). However, clinical OSA may have multiple disease drivers beyond upper airway collapse, such as high loop gain and a low arousal threshold. The burden of residual sleep apnea in patients treated with PAP and it's predictors remained to be fully defined.
Methods: Adult patients who were diagnosed with OSA through a split-night polysomnography (PSG) in the AASM accredited sleep center at the Beth Israel Deaconess Medical Center, Harvard Medical School and followed using the EncoreAnywhereTM system were prospectively included. Monthly visual/manual scoring of residual events was done. The ratio of patients with residual sleep apnea (defined as a manually-scored respiratory event index (REI) ≥ 15 times/hour in the 3rd month and 12th month were calculated. A linear regression model was used to explore the predictors of residual sleep apnea on PAP.
Results: One hundred and ninety five patients were included. In the 3rd month, there were 166 patients still on PAP. There were 74 (44.58%) with a residual AHI ≥ 15 times/h. In the 12th month, there were 93 patients still on PAP and 41 (44.09%) had residual AHI ≥ 15. In the short term, treatment CAHI (β= 0.511, SE=0.123, p=0.001), age (β= 0.123, SE=0.054, p=0.025), and hypertension (β= 3.627, SE=1.536, p=0.019) were the predictors for residual sleep apnea. In the long term, treatment CAHI (β= 0.598, SE=0.163, p=0.001), male gender (β= -5.117, SE=2.005, p=0.013) and baseline mean arousal duration (β= -0.601, SE=0.184, p=0.002) were predictors for residual sleep apnea.
Conclusion: There was a high percentage of patients with OSA on PAP who have residual sleep apnea. Treatment CAHI is a strong predictor, and may reflect high loop gain effects.
Support (If Any): Category-I Strategic Research Award from the AASM Foundation to R. J. Thomas

0754

EFFECTS OF ATOMOXETINE PLUS A HYPNOTIC ON OBSTRUCTIVE SLEEP APNEA (OSA) SEVERITY IN PATIENTS WITH A MODERATELY COLLAPSIBLE PHARYNGEAL AIRWAY

Bruce Corser[1], Gregg Rucosky[1], Erica Eves[2]
Sleep Management Institute [1] Intrepid Research [2]

Introduction: The combination of atomoxetine and oxybutynin has demonstrated efficacy in the treatment of OSA. Oxybutynin may play a role as an upper airway dilator muscle activator and/or a hypnotic to improve sleep quality. We assessed the effectiveness of atomoxetine when combined with one of two hypnotics. Trazodone is a known hypnotic with possible effects on pharyngeal muscle activity. The other is lemborexant, an orexin antagonist. The effects of both combinations were assessed in patients with OSA and a moderately collapsible pharyngeal airway.
Methods: Recruited patients were 18 – 65 years of age, with an AHI 4 (4% desaturation criteria) of 10 – 55 and a BMI < 40 kg/m2. Each had to have a moderately collapsible pharyngeal airway using previously defined criteria based on the average percent desaturation during obstructive events (< 8%) and the ratio of hypopneas to total events (> 50%). After a qualifying PSG, each patient spent three nights in the sleep laboratory with approximately one week between studies. Nights were randomized to placebo, atomoxetine 80 mg plus trazodone 100 mg, and atomoxetine 80 mg plus lemborexant 10 mg. Primary outcomes were AHI 4 and the sleep apnea specific hypoxic burden (HB), the area under the SpO2 curve associated with disordered breathing events.
Results: Fifteen patients completed the trial (median [interquartile range] age was 52 [48-55] and BMI was 33.6 [30 – 35.1] kg/m2. Atomoxetine plus trazodone showed a strong trend for AHI 4 reduction from placebo (from 18.2 [11.8 – 31.3] to 7.4 [5.4 – 16.1] events/h, p=0.064), a significant reduction in HB from placebo (from 48.2 [31.2 – 79.6] to 18.7 [14.9 – 43.5] % min/h) and a trend for a reduction in HB with atomoxetine plus lemborexant (from 34.1 [12.1 – 128.8] to 18.7 [14.9 – 43.5] % min/h, p=0.055). There was no change in total sleep time or arousal index between treatment arms. Mild adverse events were reported on atomoxetine plus trazodone (2/15 sinusitis, 1/15 heartburn).