

CPAP treatment. Screening and management of OSA should be recommended to menopause patients who are not under HRT.

Support (If Any): OU-HCOM.

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A NOVEL MOUTHPIECE DEVICE DESIGN FOR THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA SYNDROME

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Introduction: Continuous positive airway pressure (CPAP) devices are considered as the first line therapy for obstructive sleep apnea syndrome (OSAS). However, there is an increasing tendency to use oral appliance as an alternative treatment due to poor patient compliance of CPAP devices. The most commonly used techniques to evaluate the efficacy of the novel oral appliances in the treatment of obstructive sleep apnea syndrome (OSAS) are magnetic resonance image segmentation of upper airway structures and polysomnographic variables. This study aims to evaluate the efficacy of a novel mouthpiece device on patients with OSAS by the comparison of oropharyngeal volume and polysomnographic variables with and without the device. The proposed mouthpiece device design increases intraluminal pressure by using patients' own breath while reshaping the lower jaw and tongue position.

Methods: Each patient (targeted n=8) underwent magnetic resonance imaging (MRI) of the upper airway during wakefulness at baseline and with the novel mouthpiece device. Since the proposed novel mouthpiece device design allows patient to breathe orally, the oropharyngeal volume change has been evaluated instead of the velopharyngeal volume. The oropharyngeal volumes of the participants have been reconstructed as 3D models from the acquired MRI images. Afterwards, each patient attended the sleep laboratory (Kozyatagi Acibadem Hospital, Istanbul, Turkey) on two nights with and without the novel mouthpiece device for full diagnostic polysomnography.

Results: The results (current n=5) show that the use of proposed device enlarged the oropharynx volume 75% on average while reducing the apnea hypopnea index by 60% on average. On the other hand, the polysomnographic variables have been significantly improved by the use of novel mouthpiece device. The oxygen desaturation index reduced 54% on average. Lowest oxygen saturation values improved 6.5% on average.

Conclusion: The clinical results show that the proposed mouthpiece design offers a promising alternative oral appliance for OSAS patients.

Support (If Any): -

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THE ROLE OF NIGHTLY ZOPICLONE ON OBSTRUCTIVE SLEEP APNEA SEVERITY AND SYMPTOMS IN PEOPLE WITH LOW TO MODERATE RESPIRATORY AROUSAL THRESHOLDS: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL

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Introduction: Single-night studies indicate that hypnotics can worsen obstructive sleep apnea (OSA) in some people and reduce

OSA severity in others. However, clinical trial data beyond night 1 is lacking. Accordingly, this study aimed to determine the effects of 1 month of nightly zopiclone on OSA severity and next day sleepiness and alertness in people predicted to yield a reduction in OSA severity with zopiclone (ACTRN12613001106729).

Methods: Screening polysomnography (PSG) quantified the respiratory arousal threshold (nadir epiglottic pressure prior to arousal) and nadir SaO₂ in 69 individuals. 30 eligible OSA patients (AHI=22.4±11.3 events/h sleep) with a low to moderate respiratory arousal threshold (0 to -25cmH₂O) and nadir SaO₂≥75% then underwent PSG on three occasions at baseline, night 1 and night 30. Participants received either nightly zopiclone (7.5 mg) or placebo during the 30 day trial according to a double-blind, randomized, parallel design. Subjective sleepiness (ESS and KSS) and next day alertness during a 30 minute driving simulator task (AusEd) were performed at each visit.

Results: The mean reduction in AHI from baseline on night 30 was 5.9±10.2 during zopiclone vs. 2.4±5.5 events/h sleep during placebo (p=0.2). The change in nadir SaO₂ was also not different between zopiclone and placebo (-0.9±3.2 vs. -0.1±5.6 %, p=0.6). Similarly, neither the change in ESS (-1.3±2.7 vs. -0.2±2.4), KSS (0±1.8 vs. 0±1.7) or steering deviation (0.3±4.4 vs. 3.9±10.3 cm) during the AusEd driving task from baseline to night 30 significantly differed between zopiclone vs. placebo (p>0.05).

Conclusion: One month of nightly zopiclone does not worsen OSA severity, daytime sleepiness or simulated driving performance in OSA patients with low to moderate respiratory arousal thresholds who do not have major hypoxemia at baseline. These findings challenge previous assumptions about the role of hypnotics in these patients.

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DRONABINOL REDUCES AHI AND DAYTIME SLEEPINESS IN PATIENTS WITH MODERATE TO SEVERE OBSTRUCTIVE SLEEP APNEA SYNDROME

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Introduction: There remains an important unmet need for fully effective and acceptable treatments in OSA, and at present there are no approved drug treatments. We previously published findings from a small-scale clinical pilot study showing promise for the nonselective cannabinoid agonist dronabinol as a potential OSA pharmacotherapy. Here, we present initial findings of the PACE (Pharmacotherapy of Apnea by Cannabimimetic Enhancement) trial, a fully-blinded two-center Phase II randomized placebo-controlled trial of dronabinol in patients with OSA.

Methods: By random assignment, 56 adult subjects with BMI<45, Epworth Sleepiness Scale (ESS)>7 and PSG-documented AHI between 15 and 50 received either placebo (N=17), 2.5mg (N=19) or 10.0mg (N=20) of dronabinol daily, one hour before bedtime for 6 weeks. Repeat in-laboratory PSG followed by maintenance of wakefulness (MWT) testing was completed every 2-weeks during the treatment period. At each visit, the ESS and Treatment Satisfaction Questionnaire for Medications also were completed.