

0406

PHASE 1 STUDY OF A NOVEL INTRANASAL POSITIVE EXPIRATORY AIRWAY PRESSURE DEVICE TO TREAT MODERATE SEVERITY OBSTRUCTIVE SLEEP APNOEA

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Introduction: Obstructive sleep apnoea (OSA) is a condition characterised by repetitive occlusion of the upper airway during sleep. Continuous Positive Airway Pressure (CPAP) is the gold standard for treating OSA. Despite efficacy, variable patient compliance limits the effectiveness of this therapy. External nasal expiratory valves are a commercialised product, that increase resistance on expiration increasing upper airway pressure similarly to CPAP. These have shown efficacy in Randomised Control Trials but widespread usage is limited by poor comfort and tolerability. A novel prototype device has been developed, (RHI003 NBV001 Rhinomed) is an internally applied nasal dilator and expiratory pressure valve designed to stent the anterior nasal airway and provide positive expiratory airway pressure, pneumatically splinting the upper airway. This device is potentially superior to externally applied valves with placement of the device in the anterior airway potentially improve device stability and enhance inspiratory flow. This phase 1 pilot study assesses the efficacy and tolerability in a series of 20 patients with moderate severity OSA.

Methods: 12 subjects have been recruited to date from sleep disordered breathing clinics with moderate severity obstructive sleep apnoea (AHI 15-29). They were evaluated for a week with a diary to evaluate baseline sleep and snoring. Subjects then trialed the device on night eight using nocturnal polysomnography to evaluate their sleep apnoea whilst wearing the RHI003 NBV001. Fourteen days supply of RHI003NBV001 was then provided to the patients to trial at home a diary and actigraphy to assess tolerability. Baseline subject characteristics, demographics and comorbidities were collected. Data analysed using paired t-test.

Results: Twelve subjects underwent repeat polysomnography using the IPEAP device. Average age 51 (S.D. 15), BMI 31 (SD 5). There was a mean improvement of 5.6 (p 0.023) although two subjects failed to respond. Of the subjects who had a fall in AHI 5 had a fall in AHI of > 50% or to less than 5. The device was well tolerated with 80% usage.

Conclusion: Results demonstrate improvement in OSA severity and the device was well tolerated. More patients will be recruited to better identify factors that determine responders from non-responders.

Support (If Any): Financial support by Rhinomed.

0407

CPAP THERAPY, VITAMIN D AND BONE TURNOVER MARKERS - A RANDOMIZED CONTROLLED TRIAL

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Introduction: Vitamin D deficiency has been associated with diabetes, hypertension and incident stroke, all of which are also overrepresented in patients with obstructive sleep apnea (OSA). In addition, studies have shown vitamin D deficiency to be more common in OSA patients compared with controls. The aim of this study was to investigate

whether continuous positive airway pressure (CPAP) treatment could modulate serum vitamin D (25-hydroxyvitamin D (25OHD)) and bone turnover markers (collagen type 1 cross-linked C-telopeptide (CTX), osteocalcin and N-terminal propeptide of type 1 collagen (PINP)) in a randomized controlled trial.

Methods: Sixty-five otherwise healthy CPAP naïve male OSA patients (age = 49 ± 12 years, apnea-hypopnea-index (AHI) = 39.9 ± 17.7 events/h, body mass index = 31.3 ± 5.2 kg/m²) were randomized to receive either real (n = 34) or sham (n = 31) CPAP for 12 weeks. At 12 weeks, all participants received real CPAP for an additional 12 weeks.

Results: After 12 weeks of CPAP (real vs sham) there were no between group differences for any of the main outcomes (25OHD: -0.80 ± 5.28 ng/ml (mean ± SE) vs. 3.08 ± 3.66 ng/ml, p = 0.42; CTX: 0.011 ± 0.014 ng/ml vs. -0.004 ± 0.009 ng/ml, p = 0.48; osteocalcin: 1.13 ± 1.12 ng/ml vs. 0.46 ± 0.75 ng/ml, p = 0.80; PINP: 2.07 ± 3.05 µg/L vs. -1.05 ± 2.13 µg/L; p = 0.48). The results remained also in subgroup analyses (vitamin D deficient patients, CPAP compliant patients, patients with severe OSA or sleepy patients). However, the 24 week analysis, in the whole group, showed increased vitamin D in patients with severe OSA (9.56 ± 5.51 ng/ml, p = 0.045) and in sleepy patients (14.0 ± 4.69 ng/ml, p = 0.007). Also, there was a significant increase in osteocalcin at 24 weeks (3.27 ± 1.06 ng/ml, p = 0.01) in compliant patients.

Conclusion: Twelve weeks of CPAP did not increase vitamin D or modulate any of the bone turnover markers compared to sham. However, it is plausible that CPAP may have late beneficial effects on vitamin D levels and bone turnover markers in selected groups of OSA patients.

0408

DOES CPAP IMPROVE DRIVING BEHAVIOR IN INDIVIDUALS WITH SLEEP APNEA?

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Introduction: People diagnosed with sleep apnea are often characterized as inherently risky drivers and it is assumed that the gold standard treatment—continuous positive airway pressure (CPAP)—will reduce this risk. In a previous study, we showed that levels of risky driving behaviour did not differ between individuals with sleep apnea and age- and gender-matched controls. This study examines whether individuals with sleep apnea show improvement on self-reported and simulator driving behavior after 6 months of CPAP treatment, relative to individuals with sleep apnea who are non-adherent.

Methods: 23 participants: 14 CPAP adherent, age = 52.9 (11.8); 9 non-adherent, age = 44.6(10.1). Participants were recruited from sleep clinics immediately after receiving their polysomnography results from their doctor, before beginning treatment. All participants drove 1.5 hours in a driving simulator and completed the Driving Behavior Questionnaire, the Sleep Questionnaire, the Empirical Sleepiness and Fatigue Scale, and the Infractions Checklist. Participants were considered adherent if they used CPAP 4 hours/night at least 80% of the time. Both groups were tested at pre- and post-treatment.

Results: Results show no significant differences between adherent and non-adherent individuals to treatment for driving simulator variables, total sleep time, fatigue, sleepiness, reported driving infractions, aggressive driving, ordinary infraction, driving errors and lapses. All reported fewer driving infractions, aggressive driving, driving errors and fatigue 6 months after diagnosis. There was no such time effect for sleepiness.

Conclusion: Six months after diagnosis, there appeared to be a non-specific positive effect on driving behaviours for both adherent and non-adherent participants with sleep apnea. CPAP treatment has no

significant importance on driving variables. Future research should study larger samples.

Support (If Any): FQRSC, SAAQ, FRQS

0409

BEHAVIOUR OF AUTO-ADJUSTING POSITIVE AIRWAY PRESSURE DEVICES DURING WAKE. BENCH TEST STUDY

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Introduction: Auto-adjusting positive airway pressure (APAP) devices are designed to keep delivered PAP pressures low, and theoretically more comfortable, until obstructive events dictate pressure increases. False or unnecessary pressure increases could result in discomfort for the patient and disruption from sleep. Additionally, some devices now contain automatic algorithms to sense sleep onset and delay pressure increases until this time. However no studies have looked at the behaviour of APAP devices during wake.

Methods: We developed a bench model to accurately simulate the respiration of a typical patient during wake. The model consisted of normal breathing (16bpm @ 500ml VT) for 45 minutes with randomly inserted typical events to represent changes in breathing rate, tidal volume and swallowing, as typically found prior to sleep onset. We tested this patient model on several commercially available APAP devices.

Results: There was considerable variation during the simulated wake period. Additionally, some devices incorrectly increased delivered pressure based on non-obstructive events. The APAP pressures (in cm-H₂O) after 45 minutes of simulated wake for each device were: Apex XT Auto: 6.9; BMC Remsmart: 4.6; Fisher & Paykel Icon Auto (SensAwake setting on): 11.2cm; Fisher & Paykel Icon Auto (SensAwake setting off): 14.5; ResMed AutoSet for Her (Auto Ramp setting on): 4.8; ResMed AutoSet for Her (AutoRamp setting off): 5.2; ResMed AirSense 10 (Auto Ramp setting on): 5.4; ResMed AirSense 10 (Auto Ramp setting off): 5.8; Respirationics Remstar Auto: 6.5; Sefam Dreamstar: 4.0; Weinmann Prisma20A: 11.7; Weinmann Somnolance: 11.8.

Conclusion: These results suggest that APAP device behaviour during wake may influence patient's comfort by increasing pressure, and stress the importance of monitoring the behaviour of the APAP devices during patient treatment.

Support (If Any): This work was carried out within the framework of a ResMed-University of Barcelona contract aimed at bench testing automatic CPAP devices

0410

CPAP MACHINE INACCURACY IN DETECTING RESIDUAL OBSTRUCTIVE SLEEP APNEA

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Introduction: There is mounting evidence that treatment of OSA may reduce the risk of medical complications. Despite the growing number of novel treatments for OSA, continuous positive airway pressure (CPAP) remains the gold standard. Newer generation CPAP machines monitor both compliance and the degree of residual, untreated respiratory disturbances. However, prior studies have shown that residual OSA may be common despite the use of CPAP. We sought to determine the accuracy of the apnea-hypopnea index (AHI) as measured

by CPAP machines when studied simultaneously with a home sleep testing device in patients suspected of having residual OSA.

Methods: Over a 12 month period, 92 patients with suspected residual OSA underwent a single night of home sleep testing using the WatchPAT 200 (Itamar Medical, Israel) while simultaneously using CPAP. All patients were tested because of clinical suspicion of incompletely treated OSA despite CPAP use. Clinical criteria for this suspicion included significant weight gain, residual daytime sleepiness or new or worsening medical comorbidities. CPAP and WatchPAT data were then analyzed and compared.

Results: The CPAP machines registered an AHI in the normal range (mean AHI 2.1, range 0-5.5) for all 92 patients. Simultaneous WatchPAT testing revealed that 31 patients had an elevated AHI (mean 10.8, range 0-27) and RDI (mean 16.5, range 7-33). In 20 patients, the mean REM AHI was 17.6, range 9-34. There was no correlation between these discrepancies and the CPAP settings, machine brand, compliance, treatment duration or OSA severity.

Conclusion: WatchPAT AHI was significantly higher than CPAP AHI in some patients with suspected residual OSA. CPAP machines may be unreliable in detecting residual OSA. WatchPAT may be useful to evaluate clinically suspected, residual OSA in the setting of a normal CPAP AHI.

0411

INTERMITTENT POSITIVE PRESSURE STIMULATION WITH TRILOGY VS BIPAP IN THE MANAGEMENT OF OSA PATIENTS THAT FAIL CPAP THERAPY

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Introduction: Sleep apnea patients that fail to respond to CPAP therapy have very few options. Some of these patients respond to BiPAP therapy. The aim was to document the response to intermittent positive pressure stimulation (IPPS) in these patients

Methods: Patients diagnosed with obstructive sleep apnea syndrome (OSA) were titrated with CPAP. Twelve patients failed to reduce their apnea hypopnea index (AHI) below 10/hour and were evaluated for BiPAP or IPPS using a portable ventilator (Trilogy). One other patient with an AHI of 7/hr was included in this study for choking and gasping episodes at night with loud snoring and excessive daytime sleepiness. An overnight PSG with BiPAP titration was performed the first half of the night and IPPS via Trilogy the rest of the night.

Results: Six patients responded well to BiPAP and 2 patients had partial response only (AHI between 7-10). The lowest AHI was over 40/hr on CPAP titration in 5 patients and over 50/hr in 2 patients on BiPAP. Nine patients responded well to Trilogy. One patient had partial response to trilogy and one patient that failed was unable to sleep secondary to ventilator alarm. The 4 patients that failed BiPAP did respond to Trilogy

Conclusion: We conclude that patients that fail both CPAP and BiPAP titration should be evaluated with IPPS. This therapy has shown to be effective even in patients with very severe obstructive sleep apnea syndrome alleviating respiratory and cardiac issues and preventing recurrent hospital admissions