Predictors of Response to a Novel Mandibular Advancement Device (Oventus O_2Vent T) in patients with OSA

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INTRODUCTION:

Obstructive sleep apnoea (OSA) treatment efficacy with traditional mandibular advancement devices (MAD) tends to be reduced in patients with high nasal resistance (NR). The Oventus O_2Vent T is designed with a built-in oral airway which permits breathing by this alternate route and may therefore be a more generally effective therapy for OSA, particularly in those with high NR.

METHODS:

OSA patients currently using a MAD were studied. Following baseline polysomnography (PSG) (PGS#1) without any MAD (wash-out >3 nights), participants underwent a titration PSG (PSG#2) with the O_2Vent T device airway OPEN to determine the optimal advancement. At optimal advancement, PSG#3 was performed to determine the effect of device airway CLOSED and OPEN (half of night in each condition, order randomised) on OSA severity (apnoea hypopnoea index, AHI). NR was determined from the slope of the relationship between nasal airflow and transpalatal (nasopharyngeal to nasal mask) pressure at a nasal flow rate of 0.1l/sec during supine nasal breathing prior to and following PSG#1. Comparisons of demographic, PSG and mean NR were made between treatment responders (AHI at PSG#3 <50%AHI at PSG#1) and non-responders.

RESULTS:

Data were available on 22 participants (6 female; mean age 55±10 years; BMI 28.2±3.2 kg/m^2; AHI 53.3±28.6 events/hr). Compared to PSG#1, mean AHI at PSG#3 decreased by 37.5±33.6 and 43.2±31.6% (p=0.27) with device airway CLOSED and OPEN, respectively. There was a greater reduction in supine AHI in those with lower supine NR with device airway CLOSED (r2=0.58; p<0.01) and OPEN (r2=0.32; p=0.03). Responders to device airway CLOSED (n=10) tended to have a higher hip circumference (106.2±7.5 vs 100.2±3.3; p=0.02). Responders to device airway OPEN (n=9) tended to be female (n=5; p=0.02) and have a smaller neck circumference (36.2±2.6 vs 40.1±2.8) and hip:waist ratio (0.9±0.1vs1.0±0.1). Seven participants responded to both device airway CLOSED and OPEN.

CONCLUSIONS:

On average, the Oventus O_2Vent T reduced AHI by approximately 40% in OSA patients; equally in the open and closed position, more so in those with lower NR. Access to an oral breathing route in a MAD may be most effective in sub-groups who are female, with smaller neck circumference and lower waist:hip ratio.

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Saturday October 20, 2018 – 11.18am – 11.24am

For Oventus queries email reception@oventus.com.au

See poster for final clinical data presented

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Background

- The efficacy of mandibular advancement device (MAD) therapy for obstructive sleep apnoea (OSA) tends to be reduced in patients with high nasal resistance
- The Oventus O_2Vent T is a novel MAD which permits oral breathing and may therefore be efficacious in people with high nasal resistance (NR)

Aims

- Examine the efficacy of the O_2Vent T with oral breathing route CLOSED and OPEN for the treatment of OSA
- Identify responders and non-responders to the O_2Vent T and investigate predictors of response
- Assess the relationship between NR and effect of the O_2Vent T (oral route CLOSED and OPEN) on OSA severity

Methods

Participants

- Participants were recruited from those already using a MAD for treatment of OSA

Protocol

- Participants underwent three polysomnography (PSG) studies:
  - PSG #1 established BASELINE OSA severity (total AHI, apnoea hypopnea index) without an OA
  - PSG #2 established the optimal level of advancement of the O_2Vent T with the oral route OPEN
  - PSG #3 established OSA severity with the oral route CLOSED vs OPEN (half night under each condition, order randomised) at the optimal level of advancement (or as close to it as tolerated)

Instrumentation/Analysis

- For all PSG studies participants wore a full face mask which was partitioned into nasal and oral sections and each connected to pneumotachographs to measure nasal and oral flow
- For PSG #1 and #3, a catheter was inserted via the nares to measure pressure at the retro-palatal (RP), retro-glossal (RG), hypo-pharyngeal (HP) and oesophageal regions
- Nasal resistance at a flow of 0.1l.sec^{-1} was determined (from the relationship between upper airway (UA) pressures & nasal flow) during wakeful supine nasal breathing in the evening prior to and morning following PSG #1 and #3
- Site of airway collapse was identified from divergence in UA and oesophageal pressures when airflow was reduced/absent during sleep
- PSGs were scored according to AASM 2012 criteria with oral flow used to differentiate apnoeas and hypopnoeas
- Responders to the O_2Vent T were those with AHI (CLOSED) and/or AHI (OPEN) <50% AHI (BASELINE)

Results

- Data from 22 participants (6 female); mean age 55±10 years; BMI 28.2±3.2kg.m^{-2} are available
- Compared to BASELINE, mean AHI at PSG #3 decreased by 38.2±34.0 and 43.3±31.2% with device airway CLOSED and OPEN respectively (Fig 1)
- Ten participants responded to device airway CLOSED and 9 responded to device airway OPEN

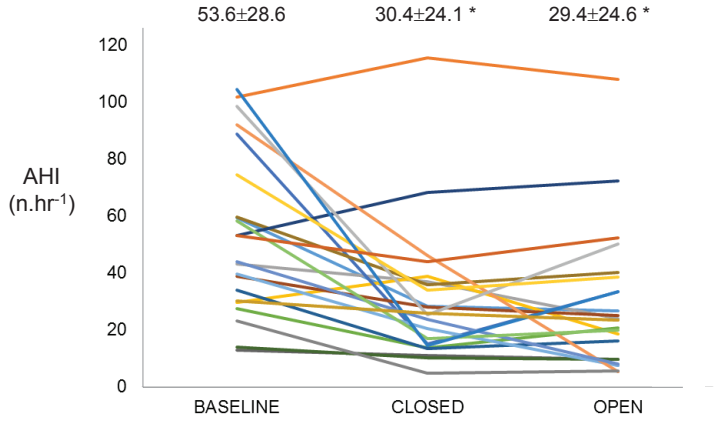

Figure 1. *AHI in BASELINE, CLOSED and OPEN conditions in all participants (n=22). Mean ± SD shown above each condition. * p<0.05 vs BASELINE*

- Supine AHI decreased more from BASELINE to PSG#3 in those with lower mean supine NR at BASELINE when device airway was CLOSED (r^2 = 0.54; p<0.01) and OPEN (r^2=0.21; p= 0.09)
- Responders to device airway CLOSED had a greater hip circumference (106±7 vs 100±3; p<0.02) and tended to have more severe OSA than non-responders (66±3 vs 43±23; p=0.06)
- Responders to device airway OPEN (n=9) tended to be female (n=5; p=0.02) and have a smaller neck circumference (36.2±2.6 vs 40.1±2.8cm) and hip:waist ratio (0.9±0.1vs1.0±0.1)
- UA collapse/narrowing at BASELINE was not different between responders (n=6 RP; n=1 nasal) and non-responders (n=9 RP; n=2 nasal) of device airway OPEN (p=0.89)
- Seven participants responded to both device airway CLOSED and OPEN

Conclusions

- On average, the Oventus O_2Vent T reduced AHI by approximately 40% in OSA patients; equally in the open and closed position, and more so in those with lower NR
- Access to an oral breathing route in a MAD may be most effective in sub-groups who are female, with smaller neck circumference and lower waist:hip ratio

Disclosure: This study was sponsored by Oventus Medical Ltd.