The role of a novel oral appliance therapy device on pharyngeal pressure swings and CPAP requirements during sleep in obstructive sleep apnea:
A pilot study

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INTRODUCTION:

Oral appliance (OA) therapy is often an effective alternative to continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnea (OSA). However, OA treatment efficacy varies and is often poorly tolerated in people with high nasal resistance. A new OA therapy device that incorporates an opening to the oral cavity (Oventus, O_2Vent T) allows breathing through the device airway, which may reduce the high inspiratory pressures required to drive air through the pharynx in people with nasal obstruction. The goals of the current study were to: 1) assess pharyngeal pressure swings during sleep with and without the OA therapy device and 2) determine the effect of the device on the CPAP requirements to minimize pharyngeal pressure swings and abolish residual events.

METHODS:

Four individuals were studied overnight in the sleep physiology laboratory (3 male; age: 43-62 yrs, BMI: 28-33 kg/m²). In addition to standard polysomnography, subjects were fitted with a nasal CPAP mask and pneumotachograph to quantify airflow. Choanal pressure (Pcho) and epiglottic pressure (Pepi) were measured using pressure transducer-tipped catheters. Nasal resistance was quantified during quiet nasal breathing awake ([Pmask-Pcho]/flow@200ml/s). Nasal CPAP was carefully titrated during NREM sleep to determine "therapeutic CPAP" level. Participants were studied under the following conditions during supine NREM sleep: 1) no OA and no CPAP (baseline), 2) OA only, 3) CPAP only, and 4) OA and CPAP combination therapy. The degree of mandibular advancement with the OA therapy device was sub-optimal to allow expression of residual events that required combination OA and CPAP therapy. The apnea/hypopnea index (AHI) and nadir Pepi swings were determined during each condition. CPAP levels with OA therapy to achieve nadir Pepi values equivalent with therapeutic CPAP without the OA was also determined.

RESULTS:

Awake nasal resistance ranged between 2.8 and 20.6 cmH_2O/ml/s (12.3±8.2 cmH_2O/ml/s, mean±SD). 3/4 participants had high nasal resistance (>3 cmH_2O/ml/s). Baseline AHI was 37±35 events/hr, which decreased with OA therapy to 8±10 events/hr. Average nadir Pepi swings during baseline NREM sleep were -8.5±2.5 cmH_2O, falling to -4.1±1.6 cmH_2O with OA therapy. The therapeutic CPAP level required to abolish respiratory events during NREM sleep without OA therapy was 6.8±2.4 cmH_2O with corresponding nadir Pepi swings of -4.0±2.6 cmH_2O. With OA and CPAP combination therapy, a CPAP level of 2.3±0.9 cmH_2O abolished respiratory events and resulted in further reduction of the nadir Pepi swings to -2.7±1.1 cmH_2O.

CONCLUSIONS:

The oral appliance device with built in airway reduces pharyngeal pressure swings and the CPAP requirements necessary to achieve stable breathing during sleep. These options may be viable alternatives for the treatment of OSA in people with high nasal resistance.

SUPPORT:

Abstract ID Number 5

Poster presentation: AADSM, Boston. June 3, 2017 – 10am to 1030am

For Oventus queries email reception@oventus.com.au

See poster for final clinical data presented

OM156_Oct 2018

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Introduction

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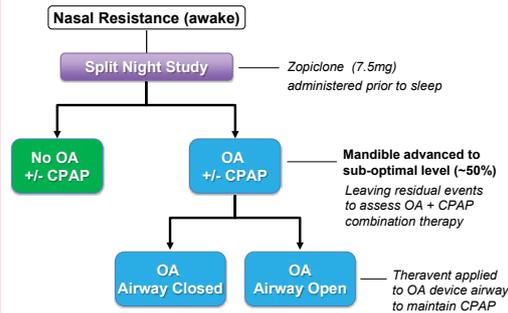
Aims

To determine: 1) pharyngeal pressure swings during sleep with and without the oral appliance therapy device and 2) the effect of the device on the CPAP requirements to minimize pharyngeal pressure swings and abolish residual respiratory events.

Methods

Participants and Study Design

- 4 individuals with suspected sleep-disordered breathing [3 male, 1 female; age: 43-62 yrs, BMI: 28-33 kg/m^2]

Nasal Resistance (awake)

Split Night Study — *Zopiclone (7.5mg) administered prior to sleep*

No OA +/- CPAP

OA +/- CPAP — **Mandible advanced to sub-optimal level (~50%)** *Leaving residual events to assess OA + CPAP combination therapy*

OA Airway Closed

OA Airway Open — *Theravent applied to OA device airway to maintain CPAP*

OA = oral appliance

Experimental Setup and Measurements

- Subjects were fitted with a nasal CPAP mask with a pneumotachograph (Hans-Rudolph 3700A) in series to measure flow. Mask pressure (Pmask) was also measured (Validyne DP-45)
- Choanal pressure (Pcho) & pharyngeal pressure (Pph; level of the epiglottis) were measured using pressure transducer-tipped catheters (Millar MPC-500)

Data Analysis

Nasal Resistance (Rnasal)
- Measured awake during quiet breathing supine
- Quantified at Flow = 0.2 l/s by:

$$Rnasal = \frac{Pmask - Pcho}{Flow}$$
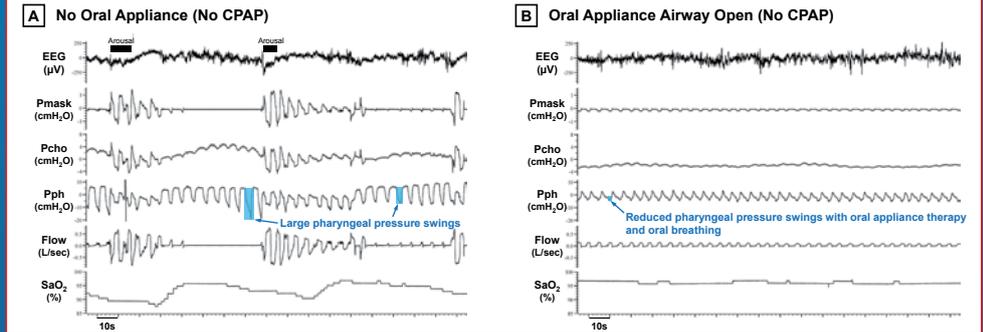
Pharyngeal Pressure Swings
- Negative pharyngeal pressure swings (see Figure 2A) were averaged over 10-15 mins of stable NREM sleep for each condition

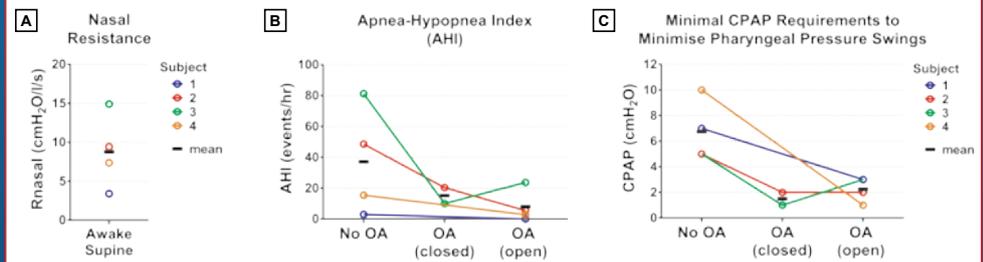**Figure 1: Oral Appliance Device**

Image (left) and schematic (right) of the novel oral appliance device (Oventus O_2Vent T) used in this study. The device advances the mandible and provides the option for oral breathing via the device airway.

Airway to permit oral breathing — *Airflow* — *Screw to advance mandible*

Results

A — No Oral Appliance (No CPAP)
B — Oral Appliance Airway Open (No CPAP)

Large pharyngeal pressure swings
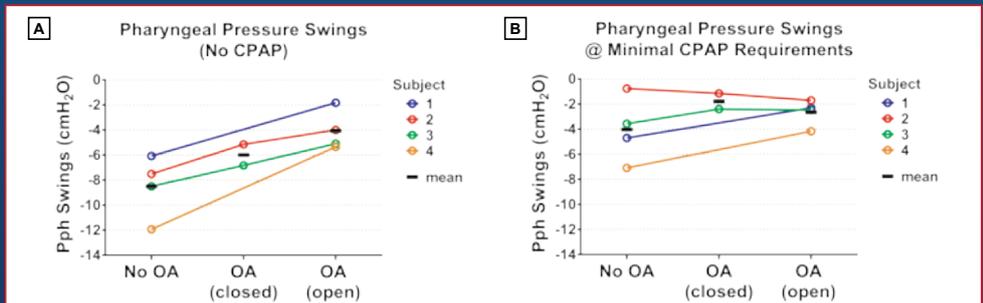*Reduced pharyngeal pressure swings with oral appliance therapy and oral breathing*

Figure 2: Raw Data with and without Oral Appliance Device

Raw data recordings from a single subject during NREM sleep under conditions of A) no oral appliance and no CPAP and B) oral appliance airway open and no CPAP. Note the large decrease in pharyngeal pressure (Pph) swings and normalization of respiratory events with the oral appliance airway open (B) compared with no oral appliance (A). Pmask = mask pressure. Pcho = choanal pressure. SaO$_2$ = oxygen saturation.

A — Nasal Resistance
B — Apnea-Hypopnea Index (AHI)
C — Minimal CPAP Requirements to Minimise Pharyngeal Pressure Swings

Figure 3: Nasal Resistance, AHI and Minimum CPAP Requirements

Individual subject (different color circles and lines) and mean (black bar) data for A) awake nasal resistance and B) OSA severity (apnoea-hypopnoea index [AHI]) and C) minimum CPAP requirements to minimise pharyngeal pressure swings during NREM sleep under each oral appliance (OA) condition. Note that 3/4 subjects had elevated nasal resistance (>3 cmH$_2$O/l/s) (A). AHI decreased with OA therapy airway closed (n=2) and was even lower with OA airway open (except subject 3). Similarly, CPAP requirements were reduced by ~66% when combined with OA therapy airway open.

A — Pharyngeal Pressure Swings (No CPAP)
B — Pharyngeal Pressure Swings @ Minimal CPAP Requirements

Figure 4: Pharyngeal Pressure Swings

Pharyngeal pressure swings for each oral appliance (OA) condition with A) No CPAP and B) CPAP at minimum required levels (from Figure 3C). Pharyngeal pressure swings were reduced with OA therapy, and were lowest during OA airway open, i.e. ~52% decrease OA (open) vs. No OA (A). The reduction in pharyngeal pressure swings during OA airway open was similar to CPAP alone (B, No OA condition). When combined with CPAP, OA therapy decreased pharyngeal pressure swings further, i.e. ~68% decrease for OA (open)+CPAP (B) vs. No OA (No CPAP) (A).

Summary and Conclusion

During sleep, the oral appliance with built-in airway:
1. ↓ Pharyngeal pressure swings
2. ↓CPAP level required to abolish respiratory events & achieve stable breathing

The oral appliance device alone or combined with CPAP may be viable alternatives for the treatment of OSA in people with high nasal resistance.

Acknowledgements