Sleep Medicine 15 (2014) 619–624

Contents lists available at ScienceDirect

Sleep Medicine

journal homepage: www.elsevier.com/locate/sleep

Original Article

A randomised controlled trial on the effect of mask choice on residual respiratory events with continuous positive airway pressure treatment ☆

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ARTICLE INFO

Article history:
Received 1 November 2013
Received in revised form 17 January 2014
Accepted 20 January 2014
Available online 8 February 2014

Keywords:
CPAP
Full face mask
Oronasal mask
Nasal mask
Obstructive sleep apnoea
Hypopnoea
Treatment

ABSTRACT

Introduction: It has been found that mask style can affect the amount of continuous positive airway pressure (CPAP) required to reduce an apnoea/hyponoea index (AHI) to <5/h on a titration study. However, it was not previously known whether switching from one CPAP mask style to another post titration could affect the residual AHI with CPAP. The purpose of this study was to investigate the differences in residual AHI with CPAP treatment between oronasal and nasal masks.

Methods: Twenty-one subjects (age mean (M) = 62.9, body mass index (BMI) M = 29.6 kg/m^2) were randomised (14 subjects completed the protocol) to undergo an in-laboratory CPAP titration with either a nasal mask or an oronasal mask. Subjects were then assigned this mask for 3 weeks of at-home CPAP use with the optimal treatment pressure determined on the laboratory study (CPAP M = 8.4 cm of H_2O). At the end of this 3-week period, data were collected from the CPAP machine and the subject was given the other mask to use with the same CPAP settings for the next 3 weeks at home (if the nasal mask was given initially, the oronasal one was given later and vice versa). On completion of the second 3-week period, data on residual AHI were again collected and compared with the first 3-week period on CPAP.

Results: A Wilcoxon Signed-Rank Test (two-tailed) revealed that residual AHI with CPAP treatment was significantly higher with the oronasal compared with the nasal mask ($z = -3.296$, $p < 0.001$). All 14 subjects had a higher residual AHI with the oronasal versus nasal mask, and 50% of the subjects had a residual AHI >10/h in the oronasal mask condition, even though all of these subjects were titrated to an AHI of <5/h in the laboratory.

Conclusion: A higher residual AHI was seen in all patients with the use of an oronasal mask compared with a nasal mask. Switching to an oronasal mask post titration results in an increase in residual AHI with CPAP treatment, and pressure adjustment may be warranted.

1. Introduction

Positive airway pressure (PAP) continues to be the most effective treatment for obstructive sleep apnoea (OSA) [1]. A number of studies have shown the benefits of PAP treatment on measures of daytime function for patients treated for OSA [2–5]. Untreated OSA has been associated with adverse medical conditions including congestive heart failure [6–8], stroke [9,10], pulmonary [11–13] and systemic hypertension [14–16], cancer [17] and increased mortality [18]. PAP therapy consists of a blower unit (a medical quality air compressor) connected by a hose to a mask sealed to the patient's face in order to pressurise the upper airway. The four primary categories of masks are: oral (covers only the mouth), nasal (covers only the nose), nasal pillows (seals at the nares), and oronasal (covers both the nose and mouth).

The fact that continuous positive airway pressure (CPAP), when used, is highly effective in the majority of patients with OSA may be the reason why few studies have investigated the differences in efficacy between different types of equipment. However, since the initial conception of CPAP, some researchers have questioned whether oronasal masks could be used to successfully pressurise the upper airway [19]. The first small-scale studies investigating this issue showed conflicting results, likely due to the differences in study design [20–22]. The previous studies that found oronasal interfaces to be effective in treating sleep-disordered breathing utilised subjects with nasal obstruction [20,22]. Moreover, one

☆ Registered on Clinicaltrials.gov: protocol #1108011845.

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http://dx.doi.org/10.1016/j.sleep.2014.01.011
1389-9457/

study investigating an oral-only mask also found that this mask style effectively treated sleep apnoea [23]. In contrast, a study that did not focus on an oral-only method of pressure delivery found the oronasal mask to be ineffective in eliminating airway obstruction [21].

More recently, Teo et al. [24] conducted a study showing that when oronasal versus nasal masks are compared with the use of auto-titrating CPAP, the use of the oronasal mask resulted in a significantly higher apnoea/hyponoea index (AHI) compared with that of the nasal mask, which suggests that mask style may result in an inadequate auto-titration. A similar result was also found by Bakker et al. [25]; however, in this study, although a significant difference was found in residual AHI between mask styles, residual events continued to be within the proper treatment range with all tested masks. Alternatively, our group [26] found that when patients are manually titrated on CPAP, the oronasal mask resulted in significantly higher pressures for patients with moderate to severe OSA compared with standard nasal and nasal pillow masks. This finding was confirmed by a large-scale correlational study that was recently published [27].

Regardless of these findings, it is common clinical practice to switch between mask styles without making adjustments to the level of PAP. We hypothesised that switching between mask styles, post CPAP titration, would result in a change in residual respiratory events, and we designed a randomised prospective crossover study to test this hypothesis. The goal of the current study was to investigate if switching from an oronasal to a nasal mask or vice versa post titration will result in a change in residual respiratory events with CPAP treatment.

2. Methods

The Institutional Review Board at Weill Cornell Medical College granted approval for this study (approval #1108011845). Informed consent was obtained for each participant in this study.

2.1. Subjects

A total of 21 subjects that included men ($n = 14$) and women ($n = 7$) with moderate and severe OSA, who presented for office follow-up prior to CPAP titration, consented to mask randomisation (see Table 1 and Fig. 1) from 26 September 2011 to 16 July 2013. Out of the 21 subjects randomised, 14 completed the study. Each subject demonstrated OSA based on the American Academy of Sleep Medicine (AASM) definition of an AHI of $\geqslant 16$/h on an all-night sleep recording. All subjects were evaluated and sleep recordings were performed at the Weill Cornell Center for Sleep Medicine. All subjects were CPAP naïve and had no previous history of airway surgeries.

2.2. Polysomnogram

Previously described standard techniques were employed to diagnose OSA on all-night sleep recordings using Grass Technologies Twin® digital polysomnographs (Natus Neurology Incorporated-Warwick, RI) with an integrated Nonin clip oximetry (see Tables 2 and 3 for polysomnogram (PSG) measures from baseline and CPAP titration studies). Standard polysomnograph montage and digital filter settings recommended by the AASM were employed [28]. Respiratory effort was measured by Sleepsense® inductive plethysmography belts (S.L.P. Inc.- Elgin, IL) placed around the rib cage and abdomen. Airflow was determined by the Pro-Tech PTAF lite® pressure transducer (Phillips-Respironics-Andover, MA) on the baseline study. The nasal cannula for the pressure transducer was placed at the level of the upper lip in midline position. A continuous electrocardiogram recorded heart rate and rhythm. During the titration study, participants were randomly assigned to either ResMed VPAP™ Tx ($n = 7$) or Respironics® OmniLab Advanced ($n = 7$) PAP machines (Andover, MA) using a CPAP setting. Airflow and mask leak were recorded from these PAP machines. Respiratory events were classified according to AASM criteria: an apnoea was defined as a decrease in peak nasal pressure of >90% of baseline, lasting at least 10 s. Hypopnea was defined by a decrease of >30% of the baseline nasal pressure, lasting at least 10 s and associated with a $\geqslant 4\%$ drop in the oxyhaemoglobin saturation.

2.3. Masks

Two models of ResMed masks, Mirage™ FX and Quattro™ FX (San Diego, CA), were randomly assigned to the subjects on the night of titration. Mirage™ FX is a nasal mask and Quattro™ FX is an oronasal mask that covers both the nose and mouth. We chose these two masks because at the time of the study they were the most commonly used standard nasal and oronasal masks used in our laboratory.

2.4. Protocol

Subjects were randomised to either the nasal or oronasal mask on the night of the CPAP titration study. A randomised envelope, which contained the name of the mask to be used on the study night, was placed by the recruiting physician in the subjects' chart for the night-time titration study. Before starting the study, the night-time technician would open the sealed envelope that specified the mask style to use on the titration night. The entire set of randomised envelopes was created by author MRE at the beginning of the study (once the envelopes were created, they were shuffled to mix up the mask styles), and a set of envelopes was given to each subject recruiter before starting the study.

During the titration study, the sleep technicians were instructed to increase the PAP in 1 cm of H_2O increments until the AHI was $\leqslant 5$/h, and they were required to wait for at least 10 min between pressure changes. Once completed, the study was scored by a registered sleep technician and was reviewed by a board-certified sleep specialist. The subjects were scored in the same manner as the rest of our clinical patients, and the scoring technicians were not made aware of the fact that these data were being used for a research study. Based on a review of the study, subjects were prescribed CPAP at the lowest pressure that reduced their AHI to $\leqslant 5$/h with the mask used on the study night. Only one subject had a residual AHI of >5/h with treatment. This subject was in the nasal mask titration group and had a residual AHI with treatment of 5.5/h. All subjects in the oronasal titration group had a residual AHI with treatment of $\leqslant 5$/h on the CPAP titration night. After 3 weeks of CPAP with the first randomised mask, data were collected from the CPAP machine and the subject was given the other mask to use with CPAP for the next 3 weeks (if the nasal mask was given initially, the oronasal one was given later and vice versa). At the conclusion of the second 3-week study period, the subject was informed as to which mask reduced AHI the most based on the data collected from the CPAP machine. All machines used at-home collected AHI and leakage values daily. The machines used at home were the ResMed S9 Elite™ ($n = 6$) (San Diego, CA) and Phillips-Respironics REMstar® Pro ($n = 8$) (Andover, MA). Variability in insurance coverage and durable medical equipment contracts accounted for these differences in machine allocation. Furthermore, the machines used for in-laboratory titration differed from the at-home units, as the laboratory models were specifically designed for manual titration by a night-time sleep technician.