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Original Article

The efficacy of three different mask styles on a PAP titration night

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ABSTRACT

Background: This study compared the efficacy of three different masks, nasal pillows, nasal masks and full face (oronasal) masks, during a single night of titration with continuous positive airway pressure (CPAP).

Methods: Fifty five subjects that included men ($n = 33$) and women ($n = 22$) were randomly assigned to one of three masks and underwent a routine titration with incremental CPAP applied through the different masks.

Results: CPAP applied through the nasal pillows and nasal mask was equally effective in treating mild, moderate, and severe sleep apnea. However, CPAP applied through the oronasal mask required a significantly higher pressure compared to nasal masks to treat moderately severe ($2.8 \text{ cm of H}_2\text{O} \pm 2.1 \text{ SD}$) and severe ($6.0 \text{ cm of H}_2\text{O} \pm 3.2 \text{ SD}$) obstructive sleep apnea.

Conclusion: CPAP applied with either nasal mask was effective in treating mild, moderate, and severe sleep apnea. The oronasal mask required significantly higher pressures in subjects with moderate to severe disease. Therefore, when changing from a nasal to an oronasal mask, a repeat titration is required to ensure effective treatment of sleep apnea, especially in patients with moderate to severe disease.

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1. Introduction

Positive airway pressure (PAP) continues to be the most effective treatment for obstructive sleep apnea (OSA) [1]. PAP treatment is essentially a pneumatic splint that maintains patency of the upper airway, thereby preventing obstructive respiratory events [2]. A number of studies have shown the benefits of PAP treatment on measures of daytime function for patients treated for OSA [3–6]. Conditions such as congestive heart failure [7–9], stroke [10,11], pulmonary [12–14] and systemic [15–18] hypertension, and mortality [19] have been associated with untreated OSA. Despite the dangers of OSA, patient compliance with PAP treatment continues to be surprisingly low [20,21]. Often, patients complain that their reason for discontinuing treatment is the discomfort of the PAP mask. Therefore, sleep laboratories often try different mask styles until one is found that makes the patient reasonably comfortable during a PAP titration study. Based on anecdotal reports, oronasal

masks are used frequently because of excessive mouth leak while using nasal masks.

A few studies have looked at compliance with different types of PAP masks [22]. However, little attention has been paid to the effect of different styles of masks on the effectiveness of PAP titration. One study showed significant improvement in the apnea/hypopnea index (AHI) with the application of CPAP through an oronasal mask compared to the baseline condition [23]. However, in a small sample of patients with severe sleep apnea, CPAP was not effective in treating sleep apnea when applied through a full face mask [24]. Another more recent study found no difference in final AHI between nasal masks and nasal pillows, but did not investigate oronasal interfaces [25]. Two studies comparing oronasal vs. nasal masks on auto-titrating PAP trials found no difference in final PAP between the two mask styles [26,27]. However, both studies found that the number of residual respiratory events was significantly greater in the oronasal compared to the nasal mask groups.

In contrast, in a pilot study that assessed the efficacy of the three types of masks, we found significant differences in the treatment levels of CPAP between the various masks [28]. Therefore, the goal of the current study was to compare the efficacy of oronasal masks, nasal masks, and nasal pillows during a PAP titration study on CPAP-naïve patients. Unlike the previous studies using auto-titrating PAP, an attempt was made in this study to reduce the

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number of respiratory events equally in all groups by manually titrating PAP.

2. Methods

Approval for this study was granted by the Institutional Review Board at Weill Cornell Medical College. Informed consent was obtained for each participant in this study.

2.1. Subject

Fifty-five subjects that included men ($n = 33$) and women ($n = 22$) with mild, moderate, and severe obstructive sleep apnea were recruited (see Table 1). Each subject demonstrated obstructive sleep apnea based on the American Academy of Sleep Medicine (AASM) definition of an Apnea Hypopnea Index (AHI) of $>5/h$ on an all-night sleep recording. All patients were evaluated and sleep recordings were performed at the Weill Cornell Center for Sleep Medicine.

2.2. Polysomnography

Previously described standard techniques were employed to diagnose obstructive sleep apnea on all-night sleep recordings using Medcare Rembrandt digital polysomnographs with an integrated Nonin clip oximetry. Standard polysomnogram montage and digital filter settings recommended by the AASM were employed [29]. Respiratory effort was measured by Pro-Tech Crystal Trace[®] piezo crystal belts placed around the rib cage and abdomen. Airflow was determined by a Pro-Tech PTAF lite[®] pressure transducer on the baseline study, and was taken from the Respiromics[®] Synchrony PAP machines during the titration study. Mask leak was also taken from the Respiromics[®] Synchrony PAP machines used to titrate patients. 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. Respiratory events were classified according to AASM criteria: an apnea 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 $\geq 4\%$ drop in the oxyhemoglobin saturation.

2.3. Masks

Three types of Phillips-Respiromics[®] masks were used: A Comfort Classic nasal mask, Optilife nasal pillows, and a Comfort Full, which is an oronasal mask that covers both the nose and mouth. The masks were randomly assigned to the subjects on the night of the titration.



2.4. Protocol

The sleep technicians were instructed to increase the mask pressure in 1 cm of H₂O increments until the AHI was $\leq 5/h$. They were required to wait at least 10 min between pressure changes.

2.5. Data analysis

Data analyses were performed using SPSS 19 (IBM, Corp., Armonk, New York). Final AHI was analyzed using a one-way analysis of covariance (ANCOVA). A preliminary analysis to evaluate homogeneity of slopes between the covariate and the dependent variable across groups, an assumption underlying ANCOVA, found a significant interaction for the analyses of final PAP and mask leakage. Therefore, simple main effects tests were conducted instead of ANCOVA to assess differences among these groups at low (1 SD below the mean), medium (mean), and high (1 SD above the mean) values of the covariates. A p -value of 0.017 (0.05/3) was required for significance for each of these tests (see Fig. 2). If any one simple main effect was significant, pair wise comparisons were evaluated at the same level (i.e., 0.017) as the simple main effects test, following the LSD procedure. Baseline AHI was the covariate used for the ANCOVA on final AHI and for the simple main effects test on final PAP. Final PAP was the covariate for the simple main effects test of mask leakage.

Table 1
Demographic information by mask style.

	Mask style		
	Nasal	Nasal pillows	Oronasal
Age	58.5 (±14.7)	57.5 (±14.9)	51.75 (±13.5)
Gender	5W, 16M	7W, 11M	10W, 6M
BMI	31.1 (±6.6)	35.6 (±7.9)	32.10 (±6.7)

Mean with standard deviation in brackets is listed for both age and BMI. No significant difference was found ($p < 0.05$) between the mask groups for the variables listed. BMI – Body mass index; W – women; M – men.

3. Results

3.1. Efficacy of PAP masks

Final AHI was not significant between groups, $F(2,46) = 0.143$, $p = 0.87$, $\eta^2 = 0.006$, indicating that the AHI for the oronasal, nasal, and nasal pillows did not differ. The mean final AHI for each group

was: oronasal $M = 3.62$ (3.18 SD), nasal $M = 2.71$ (2.26SD), and nasal pillows $M = 2.84$ (2.08SD). An AHI $<5/h$ was not achieved in three patients with oronasal masks, two with nasal pillows, and one with a standard nasal mask (see Fig. 1).

The low baseline AHI group on final PAP was not significant $F(2,46) = 0.058$, $p = 0.944$, $\eta^2 = 0.003$. In contrast, final PAP was significant for a medium value on the covariate, $F(2,46) = 8.89$,

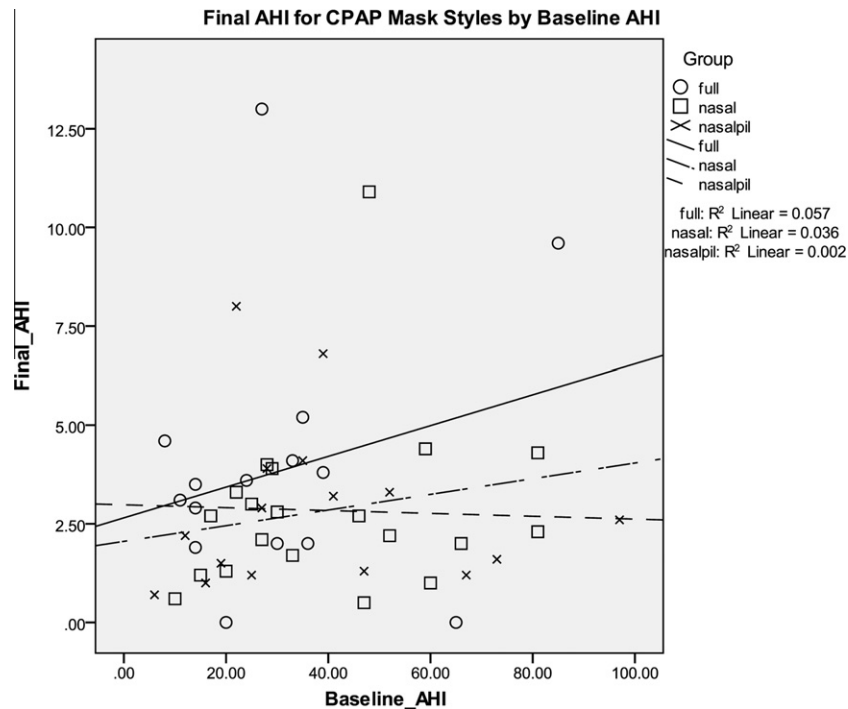


Fig. 1. The final AHI for each mask type is summarized. An AHI $<5/h$ was not achieved in three patients with oronasal masks, two with nasal pillow masks, and one with a standard nasal mask. However, no significant differences were found between mask styles on final AHI at a $p < 0.05$.

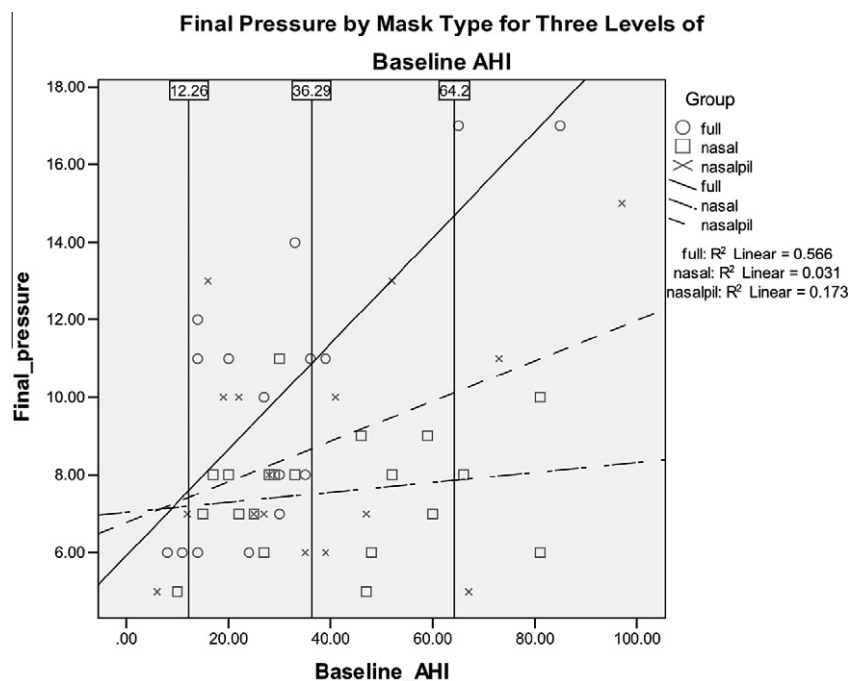


Fig. 2. Final PAP required by the three PAP mask styles to reduce AHI to $<5/h$, grouped by three levels of the covariate (low = 12.26, medium = 36.29, high = 64.2). Covariate groupings are denoted in the graph by vertical lines. As can be seen, final PAP was significantly higher for oronasal masks than for both nasal mask styles on medium to high levels of the covariate. The medium level of baseline AHI is the mean value of the covariate, and high and low values were calculated by adding (high) and subtracting (low) one standard deviation from the mean (or medium level).

$p = 0.001$, $\eta^2 = 0.28$, and for a high level on the covariate, $F(2,24) = 11.75$, $p = 0.000$, $\eta^2 = 0.34$. Pairwise comparisons indicated that patients titrated with oronasal masks had significantly higher ($p < 0.001$ for both medium and high levels of the co-variate) final PAP pressures compared to patients titrated with standard nasal masks or nasal pillows ($p = 0.012$ for medium levels and $p = 0.003$ for high levels of the co-variate). There was not a significant difference between final PAP pressures between nasal or nasal pillows on either medium or high levels of the covariate.

The low final pressure group on mask leakage was not significant $F(2,47) = 1.132$, $p = 0.331$, $\eta^2 = 0.046$. However, significant differences were found on both medium ($F[2,47] = 8.328$, $p = 0.001$, $\eta^2 = 0.26$) and high ($F[2,47] = 11.736$, $p = 0.000$, $\eta^2 = 0.333$) values of the covariate. Pairwise comparisons showed that patients titrated with oronasal masks had a significantly higher mask leakage compared to nasal pillows ($p < 0.000$), but not to standard nasal masks at both moderate and high final PAP pressures.

4. Discussion

The major finding of this study is that CPAP applied through either a nasal mask or nasal pillow is equally effective in treating patients with mild, moderate, and severe sleep apnea. This finding is consistent with Ryan et al. [25], who showed comparable efficacy between standard nasal masks vs. nasal pillows. However, with oronasal masks considerably higher final pressures were needed to treat patients with moderate and severe sleep apnea. In fact, CPAP applied through the oronasal mask required an average of 2.8 cm of H₂O (± 2.1 SD) more pressure in patients with a moderately severe baseline AHI and 6.0 cm of H₂O (± 3.2 SD) more pressure for severe obstructive sleep apnea (see Fig. 3) compared to using a nasal mask (no significant difference in pressure requirement between the two styles of nasal mask were found, as described in Section 3). These findings demonstrate that one cannot assume that the effective final nasal CPAP pressure will result in effective treatment with an oronasal mask, especially in patients with moderate or severe sleep apnea.

Our findings are not necessarily inconsistent with recent studies [26,27] that have found no difference between the final PAP of nasal vs. oronasal masks during an auto-titrating PAP trial. In

both of these studies residual respiratory events on PAP were significantly higher in the oronasal group compared to the nasal group. Presumably, if the PAP had been increased in the oronasal group the respiratory disturbance index could have been reduced to a level not significantly different from the nasal mask group, thereby showing a similar finding to our study. Moreover, in the Bakker et al. study [27] there was not a washout period between treatment trials. Given Kribbs et al.'s [30] finding that chronic PAP use can have a carryover effect, the lack of a washout period may have blunted the differences between the masks tested.

The effect of applying PAP simultaneously through the nasal and oral pharynx can have markedly different mechanical effects on the collapsible portion of the upper airway compared to exclusively oral or nasal pressure delivery. Kuna and Remmers originally speculated that oronasal masks would not effectively treat OSA because the airway dynamics of pressure applied orally and nasally simultaneously causes a posterior force against the soft tissues in the upper airway, which would prevent the opening of the airway [31]. Subsequently, in a study of six patients with severe sleep apnea, nasal CPAP eliminated sleep apnea by raising the intraluminal (transmural) pressure above a critical opening or collapsing pressure of the upper airway (Pcrit) [24]. In fact, all apneas, hypopneas, and inspiratory flow limitations were abolished as pressures elevated to roughly 7.5 cm of H₂O above the Pcrit. In contrast, when CPAP was applied through an oronasal mask, the airway was not opened at pressures elevated to 10 cm of H₂O above the nasal Pcrit. It was hypothesized that the simultaneous application of nasal and oral CPAP prevented the necessary increase in transmural pressure needed to open the airway.

CPAP applied primarily through the oral route was effective in two subsequent studies. In the first study the mouth of two patients was opened with an oral device and the disordered breathing was adequately treated [23]. In the subsequent study seven patients were titrated with either a nasal or an oral CPAP device [32]. Regardless of the primary route of pressure, each patient demonstrated an identical Pcrit and final effective pressure. These studies imply that if CPAP is applied solely to either the nose or mouth, the intraluminal pressure is appropriately raised above the Pcrit and sleep apnea is eliminated. The fact that the current study demonstrated a variable response in subjects with mild

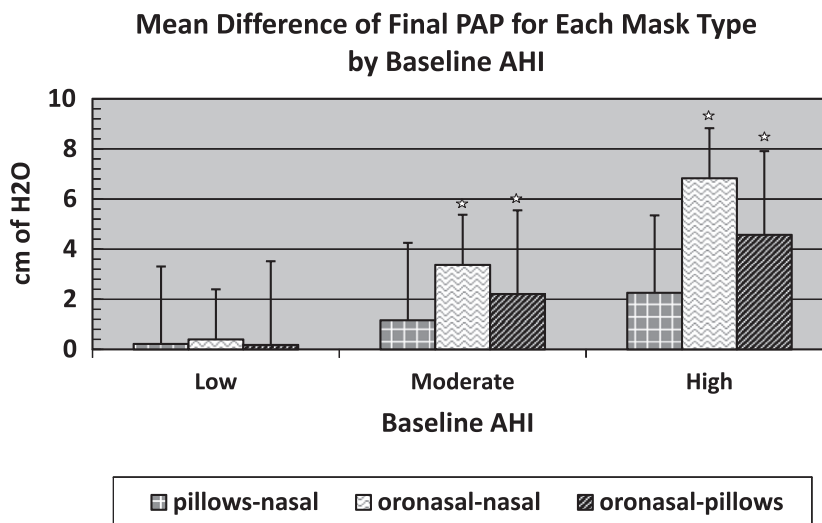


Fig. 3. The end-titration AHI for the oronasal interface, nasal mask, and nasal pillows masks did not differ (see Fig. 1). However, a higher final PAP was required when using the oronasal interface compared with the nasal mask and nasal pillows in those patients with a moderate and high baseline AHI. Mean difference in final PAP is shown for nasal pillows minus nasal masks (pillows–nasal), oronasal minus nasal masks (ornasal–nasal), and oronasal minus nasal pillows (ornasal–pillows). Each difference score is grouped by three levels of the baseline AHI (low = 12.26, moderate = 36.29, high = 64.2). The moderate level of baseline AHI is the mean value, and high and low values were calculated by adding (high) and subtracting (low) one standard deviation from the mean (or moderate level). Error bars show standard deviation. *Significant difference at a $p < 0.017$ for pairwise comparisons between the variables shown in each bar.

Table 2

Baseline sleep architecture and respiratory data by mask style.

	Mask style		
	Nasal	Nasal pillows	Oronasal
TST (min)	302.38 (83.98)	333.56 (±65.17)	340.56 (±54.75)
SL (min)	17.12 (±15.28)	23.91 (±25.45)	17.11 (±15.74)
SE%	69.51 (±19.92)	76.53 (±11.11)	78.94 (±10.87)
N1%	15.24 (±11.84)	12.87 (±6.4)	12.01 (±7.93)
N2%	45.54 (±15.63)	54.45 (±11.12)	51.26 (±14.85)
N3%	3.35 (±5.97)	3.87 (±5.42)	4.53 (±7.2)
REM%	7.93 (±6.92)	8.19 (±5.37)	11.73 (±5.25)
AHI	39.80 (±21.37)	37.88 (±24.54)	30.31 (±20.26)
Mean SaO ₂ %	93.03 (±2.12)	93.71 (±1.41)	93.39 (±1.84)
SaO ₂ < 90% (min)	50.94 (±88.05)	30.74 (±8.22)	51.54 (±12.88)

All data are listed as mean with standard deviation in brackets. TST – Total sleep time; SL – Sleep latency; SE – Sleep efficiency; AHI – Apnea hypopnea index; Mean SaO₂ – Mean blood oxyhemoglobin saturation during the study night; SaO₂ < 90% – The total amount of time on the study night during which the patient's oxyhemoglobin saturation was below 90%. No significant difference was found ($p < 0.05$) between the mask groups for the variables listed.

compared to moderate and severe disease can be best explained as follows: (1) In the subjects with mild disease, the mouth most likely remained closed and the pressure in the nose and upper airway was raised analogous to nasal CPAP. (2) In moderate to severe OSA higher CPAP caused an opening of the patient's mouth by forcing the jaw down, which compromised the efficacy of treatment due to the change in airway dynamics described above.

Of note, because a between-subject design was used in the study, there remains the possibility that the differences found between masks may be due instead to differences in the patient pool for each mask type. However, this risk was moderated by random assignment of patients into each mask group. Moreover, no significant differences were found between mask groups on demographic variables or for baseline polysomnogram findings (see Tables 1 and 2).

In summary, we have shown that CPAP applied through a nasal mask or nasal pillow treats all patients with mild, moderate, and severe sleep apnea. In contrast, CPAP applied through an oronasal mask is not as effective and requires significantly higher pressures than nasal CPAP in patients with moderate to severe disease. These findings imply that when changing from a nasal to an oronasal mask, a repeat titration is required to ensure effective treatment of sleep apnea in patients with moderate to severe disease.

Conflict of interest

The ICMJE Uniform Disclosure Form for Potential Conflicts of Interest associated with this article can be viewed by clicking on the following link: [doi:10.1016/j.sleep.2012.02.004](https://doi.org/10.1016/j.sleep.2012.02.004).

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