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Original article

A prospective 8 week trial of nasal interfaces vs. a novel oral interface (Oracle™) for treatment of obstructive sleep apnea hypopnea syndrome

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Abstract

Objective: To compare efficacy, compliance rates, and side effects of a new strapless oral interface, the Oracle™, with available nasal masks over 8 weeks of use for the treatment of obstructive sleep apnea hypopnea syndrome (OSAHS). **Methods**: A total of 38 patients with OSAHS (respiratory disturbance index (RDI) $\geq$15/h) were enrolled after the diagnostic polysomnogram for subsequent continuous positive airway pressure (CPAP) therapy. After randomization, therapeutic pressures during a titration study were determined for 21 patients in the oral group and 17 patients in the nasal group. Comparisons for nasal and oral interfaces were made for baseline patient characteristics, average hours of CPAP use, side effects from therapy, and among questionnaires evaluating patients' subjective responses to therapy at months 1 and 2. **Results**: No significant difference was observed in the average hours of CPAP use between the oral (4.5 ± 2.1; 5.5 ± 2.6) and nasal groups (4.0 ± 2.6; 4.8 ± 2.5) for either month 1 or 2 ($P > 0.05$). The dropout rates were similar for both groups after 8 weeks of therapy. However, patients in the nasal group had higher occurrences of side effects such as nasal congestion, dryness, and air leaks, whereas patients in the oral group experienced more oral dryness and gum pain. **Conclusion**: Oral delivery of CPAP with the Oracle™ is an effective and suitable alternative for patients with OSAHS.

Keywords: Obstructive sleep apnea hypopnea syndrome; Continuous positive airway pressure; Compliance; Nasal masks; Oracle; Oral continuous positive airway pressure; Nasal continuous positive airway pressure

1. Introduction

Obstructive sleep apnea hypopnea syndrome (OSAHS) is a common disorder with an estimated prevalence of 4% among middle-aged men and 2% among middle-aged women [1]. It is believed to be a major public health hazard because of the associated health related effects. The disorder leads to excessive daytime somnolence and impaired psychomotor function that have been conclusively linked to the increased risk of motor vehicle accidents in various studies [2,3]. In recent studies, hypertension is recognized as a major complication of OSAHS independent of obesity, age, and sex [4,5]. Untreated OSAHS also results in elevated pulmonary artery pressure in 25% of patients, which may predispose these patients to development of corpulmonale, especially in patients with coexisting lung disease [6]. Other suspect outcomes including increased mortality, cardiac arrhythmias, ischemic heart disease, and stroke have not been as well established [7,8]. Failure to establish direct causal association is due to the inability of the studies to account for the confounding variables such as obesity, body mass index (BMI), diabetes, and smoking [9].

Since the first description in 1981 of the reversal of OSAHS by continuous positive airway pressure (CPAP) applied through nares, CPAP has remained the most effective medical treatment of OSAHS [10]. Many studies have confirmed the impact of CPAP on sleep apnea related symptoms including improved daytime function and quality of life, particularly, in moderate to severe cases of OSAHS [11,12]. Despite many developments in systems and masks used to deliver positive airway pressure, compliance has been less than ideal. Various interfaces including nasal and oro-nasal masks have been developed to reduce patients' intolerance due to mask-related side effects, thereby striving to improve compliance. The purpose of our study is to

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compare patients' compliance and reported side effects with a novel oral interface, the Oracle™, and standard nasal masks over period of 8 weeks.

2. Methods

2.1. Study participants

All participants were recruited prospectively from June 2000 to March 2001. The patients were referred to the sleep laboratory with a suspicion of OSAHS and underwent full polysomnography (PSG) utilizing standard methods to establish the diagnosis [13]. All eligible participants had a respiratory disturbance index (RDI) >15/h. Participants were excluded if they had severe cardiac disease, chronic pulmonary disease, or significant psychiatric illness. The Institutional Review Board approved the study protocol.

2.2. Design

Prior to returning for a second night in the laboratory for CPAP titration, informed consent was obtained from the enrolled participants. Notably, patients were not made aware that compliance was a major outcome of the study. Subjects were randomized to receive CPAP therapy either via a nasal or oral (Fisher and Paykel, Oracle™) interface. Nasal masks were chosen from a large array for maximal patient comfort. As shown in Fig. 1A–C, the oral interface is a strapless butterfly-shaped device fashioned of medical silicone, and rests in the oral vestibule between the lips and teeth. Another 'snap-flap' (SnapFlap™) rests over the lips and cheeks to achieve a seal. A small plastic protrusion (tongue 'guide') is added to avoid tongue occlusion of the oral cavity and predominant nasal breathing.

A therapeutic pressure for each participant was established at the level sufficient to abolish apneas and arousals as assessed by PSG. Both treatment arms were given heated humidification (Fisher–Paykel HC100), adjusted just below the point of 'rainout' in the CPAP tubing, or to subjects' comfort level. Room temperature in the laboratory was maintained at 24°C. Subsequently, patients were discharged from the sleep laboratory and placed on the same interface at the achieved therapeutic pressure for home use. At home, all participants were treated with the Fisher–Paykel HC201 CPAP device with a built-in heated humidifier and hour counter meter. Patients were instructed to adjust the humidifier to the point just below 'rainout' at the room temperature most comfortable for their sleep quality.

2.3. Measurements

Clinical evaluation including general medical history and examination was performed. An Epworth sleepiness score (ESS) was recorded for each participant prior to enrollment in the study. Standard PSGs were performed that included central and occipital electroencephalograms (EEGs), left and right electroocculograms (EOGs), chin electromyogram (EMG), and monitoring of airflow at the nose and mouth with a thermistor. A pneumotachograph was used to monitor flow during CPAP titration. All PSGs were analyzed to derive the RDI, arousal/wake index, oxyhemoglobin saturation (SaO_2) nadir, and the therapeutic pressure, defined as the pressure required for the RDI to be ≤ 5 events/h and the SaO_2 $\geq 92\%$ [13]. All participants completed a morning questionnaire in the laboratory after

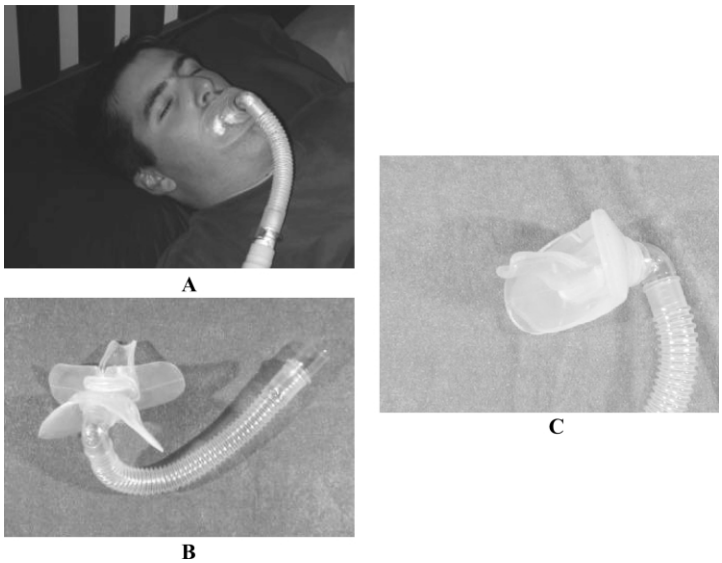

Fig. 1. Panel A shows a patient using the Oracle™, with the SnapFlap™ engaged. Panel B demonstrates the Oracle™ with the SnapFlap™ retracted. The inner mouthpiece and tongue guide are clearly viewed. Panel C shows the tongue guide in a closer view; this part of the interface prevents the tongue from occluding the oral cavity or allowing consequent nasal breathing during sleep. The SnapFlap™ has been engaged and mirrors the inner mouthpiece.

CPAP titration, examining various aspects and characteristics of their initial experience with treatment and interfaces. Patients were contacted by telephone within the first 3 days to assure that there were no major difficulties. When necessary, subsequent pressure or mask adjustments were done as requested by the treating physician. At the end of the first and second months, a respiratory therapist visited each patient to check the equipment and to record the hour counter meter data to calculate average hours use per day. At the same visit, a questionnaire was completed to gauge opinion and perceptions of the nasal and oral interfaces. While the questionnaires were not blinded to the therapists, the patient filled out the entire form independently. Causes of potential side effects, including claustrophobia, leaks, gum and lip irritation, oral drying, bleeding of the gums, bloating, gag, chest discomfort, and nasal congestion amongst others, were examined in detail. Patients scored each question on a scale of either 1–5 or 1–6, the highest number being best and the lowest number being worst. The side effects experienced were considered severe if scored ≤ 3 by the patient.

2.4. Statistical analysis

Non-parametric inferential techniques were used (i.e. Friedman's test and Kruskal–Wallis) to analyze the differences among the groups, the timepoints, and for the interaction between the groups and timepoints. All values are shown as the mean and standard deviation (SD). A P-value of <0.05 was considered significant. Patients who abandoned therapy or used their CPAP less than 20 min per night were considered 'dropouts' and removed from analyses in the month that therapy was not used.

3. Results

3.1. Patient characteristics

During the study, a total of 42 participants who fulfilled the inclusion criteria were enrolled and randomized to either the oral or nasal groups. Data could be retrieved for 38 subjects, comprising 21 patients in the oral and 17 patients in the standard nasal interface groups, respectively. Table 1 shows the patients' characteristics in each group. The oral and nasal groups did not differ significantly for the variables including RDI, BMI, age, and sex ($P > 0.05$). Additionally, the therapeutic pressure requirement for each interface did not differ significantly for the two groups.

3.2. Compliance data

Fig. 2 shows comparisons of the compliance rates. Overall, the compliance rates were similar in both groups and did not achieve statistical significance for either month

Table 1
Patient characteristics

	Nasal ($n = 17$)	Oral ($n = 21$)
Variable	AVG ± SD	AVG ± SD
Age (years)	50.9 ± 11.0	52.5 ± 12.6
Sex M/F	11/6	13/8
ESS	12.6 ± 3.6	13.8 ± 5.1
RDI (events/h)	63.0 ± 39.3	58.5 ± 34.8
Sleep efficiency (%)	70.7 ± 17.9	74.5 ± 14.6
AWI (events/h)	40.3 ± 34.4	49.8 ± 29.4
SaO_2 nadir (%)	82.1 ± 5.6	78.0 ± 9.6
BMI (kg/m^2)	34.2 ± 6.0	34.9 ± 5.4
Pressure (cm H_2O)	9.6 ± 2.0	9.8 ± 1.2

Data shown as mean ± SD. ESS, Epworth sleepiness scale; RDI, respiratory disturbance index measured as apnea/hypopnea index; AWI, arousal wake index; BMI, body mass index; SaO_2, oxyhemoglobin saturation.

1(oral 4.6 ± 2.1 h; nasal 4.3 ± 2.6 h) or 2 (oral 5.5 ± 2.6 h; nasal 4.6 ± 2.5 h) ($P > 0.05$). There was also no significant difference in average hours of use of CPAP therapy within each group for months 1 and 2. The subjective reporting of average nightly use of CPAP at months 1 and 2, respectively, was 5.8 ± 1.7 and 5.7 ± 2.6 in the nasal group and 5.8 ± 1.4 and 5.8 ± 1.7 in the oral group. In the study, 11/21 (52%) and 11/15 (73%) of the study patients in the oral group were using therapy at least 4 h per night of CPAP at months 1 and 2, respectively, whereas 8/17 (47%) and 8/12 (67%) of patients were consistently using nasal CPAP at least 4 h per night at months 1 and 2, respectively. However the difference was not statistically significant ($P \geq 0.14$; $P \geq 0.28$, at months 1 and 2, respectively).

3.3. Subjective data

Subjective scores were analyzed for patients' overall satisfaction, level of functioning, complaints of sleepiness, feelings of being refreshed, and quality of sleep, memory, and concentrating abilities while using CPAP therapy with each interface. Patients' perception of feeling refreshed in the morning trended higher for the oral group for both months 1 (4.4 ± 0.8) and 2 (4.7 ± 0.5) compared to the nasal group during months 1 (4.0 ± 1.0) and 2 (4.2 ± 0.8) (scale 1–5); however, the difference reached statistical significance only at month 2 ($P \leq 0.04$). Also, the level of wakefulness was reportedly higher in the oral group at month 2 (oral 5.9 ± 1.0; nasal 5.4 ± 1.2; scale 1–6) ($P \leq 0.04$). While comparison of other variables trended toward better symptomatic improvement in the oral group, the difference between the two groups did not reach statistical significance for either month.

3.4. Reported side effects

Table 2 shows the side effects observed with each

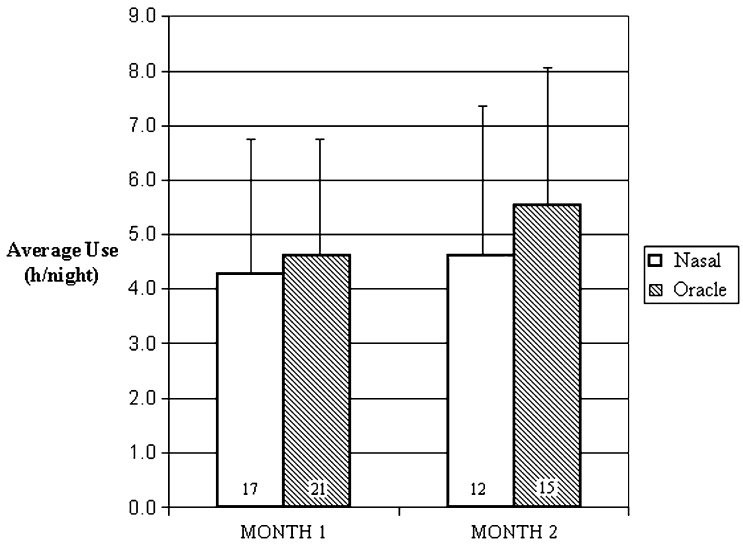

Fig. 2. The graph shows average compliance (h/night) for both nasal and oral users over 2 months. The numbers inside the bars indicate the number of patients in each group. There were no significant differences across groups for either month, nor were there significant within group differences for months 1 and 2.

interface. The nasal group experienced more nasal dryness ($P \leq 0.04$) during month 1. Nasal congestion was significantly higher with nasal interfaces for months 1 and 2, respectively (month 1, $P \leq 0.001$; month 2, $P \leq 0.05$). Excessive nasal dryness (scale of ≤ 3) was reported by two, congestion by six, and epistaxis by two patients at month 1 in the nasal group. In comparison, the oral group had more complaints of oral dryness ($P \leq 0.007$, month 1; $P \leq 0.02$, month 2) and gum pain ($P \leq 0.02$, month 1; $P \leq 0.01$, month 2). In the patients using the oral interface, 11 reported excessive oral dryness and three reported severe gum pain at month 1. For both groups, the change in each variable over a period of 2 months showed no significant improvement with the continued use of therapy. There were significantly more air leaks in the nasal group (month 1, 3.9 ± 1.1; month 2, 4.1 ± 1.2) in comparison to the oral group (month 1, 4.6 ± 0.8; month 2, 4.9 ± 0.5) for both months ($P \leq 0.05$ month 1; $P \leq 0.01$ month 2). The results of analyses of other variables including gag reflex, bloating, mask dislodgement, and headache in each group failed to reveal any significant difference (data not shown). The number of patients reporting a sensation of excessive pressure experienced with CPAP therapy was 7/17 (41%) and 4/21 (19%) at month 1 in the nasal and oral group, respectively. At month 2, however, only 2/15 (13%) patients in the nasal group had this complaint. Also, in the nasal group, 2/15 (13%) patients during the first month and 3/13 (23%) patients during the second month reported severe claustrophobia (score ≤ 3 on scale of 1–5); only 1/18 (5.5%) patients had claustrophobia in the oral group during month 1, and none had this symptom in month 2. The difference, however, was not statistically significant.

Table 2
Side effects

	Nasal	Oral	Nasal	Oral
Oral dryness**	4.1 ± 0.9	3.3 ± 0.9	4.3 ± 0.9	3.4 ± 0.9
Nasal dryness**	4.4 ± 0.9	4.9 ± 0.39	4.3 ± 1.2	4.8 ± 0.8
Nasal congestion*	3.6 ± 1.2	4.8 ± 0.5	4.4 ± 1.1	4.8 ± 0.6
Gum pain*	4.7 ± 1.0	4.3 ± 0.8	4.6 ± 1.2	4.1 ± 0.8
Air leaks*	3.9 ± 1.1	4.6 ± 0.8	4.1 ± 1.2	4.9 ± 0.5

Data are shown as mean $\pm$ SD. Scoring was done on a Scale of 1–5; 1, worst; 5, best. *$P < 0.05$ both at months 1 and 2. **$P < 0.05$ at month 1.

3.5. Patients who stopped therapy

Five patients in the nasal group (29%) abandoned therapy before completion of 8 weeks. Intolerable nasal congestion, throat inflammation (pharyngitis), severe claustrophobia, and excessive pressure from the tight fitting mask were the most frequent complaints reported by these patients. Six patients in the oral group (28.5%) dropped out. One patient stopped CPAP therapy due to a major cerebrovascular accident (CVA). Excessive oral dryness and gum pain were the leading side effects experienced by three patients and requiring a change from the oral interface to a nasal mask. One patient stopped using CPAP completely and another declined to participate further in the study.

4. Discussion

Our study introduces for the first time the Oracle™, a strapless oral interface, as an effective alternative for the delivery of CPAP in moderate to severe OSAHS. CPAP delivery has always been done through the nose, but we

describe a new approach that works as well. Historically, the use of effective mouth intermittent positive pressure ventilation has been described for management of post-polio and neuromuscular diseases. This oral interface required a gooseneck holder to prevent dislodgement. A Bennett lip seal was used to avoid excessive loss of insufflated air [14]. Another study described a custom fabricated oral–nasal (SONI) strapless interface for positive pressure ventilation [15]. However, these devices and oral interfaces, in general, were never adapted to CPAP therapy for sleep apnea.

Traditionally, CPAP has been applied via the nasal route, although patient compliance with the use of nasal CPAP has been less than ideal. Studies with nasal interfaces have revealed compliance rates ranging from 46 to 90% [16–21]. Variable results are likely as some of these studies used subjective reporting of CPAP use, and authors used different definitions of compliance. Interestingly, European studies have generally reported higher compliance rates [20]. Our study shows compliance rates of 52% at month 1 and 73% at month 2 based on the criteria of >4 h/night use in the oral group and this level was maintained at 8 weeks of use [19]. Not surprisingly, the subjective compliance reported by the patients was slightly higher than the corresponding objective compliance for both months in each group. In addition, the proportion of patients abandoning CPAP prior to the completion of 8 weeks was 29 and 28% for the nasal and oral groups, respectively. This result is similar to other studies reporting 19–37% dropout rates [16,19,22–25].

Several studies analyzing the factors affecting long-term CPAP use have led to variable results, with only weak correlations to compliance rates. Reeves-Hooch et al. reported no correlation between compliance and initial apnea hypopnea index (AHI), age, gender, BMI, weight loss, or years of schooling completed. Moreover, they found no difference between degrees of prescribed mask pressure and compliance [24]. However, McArdle et al. reported disease severity and subjective sleepiness as predictors of long-term use of CPAP therapy [21]. The studies evaluating correlations among the side effects related to nasal interfaces and compliance rates have revealed controversial results [26]. Clinicians frequently face complaints of side effects with the use of currently available masks [16,27], but the impact on initial acceptance or ultimate adherence to therapy remains unclear.

In comparison to reported side effects with nasal masks, our study showed similar levels of severe nasal dryness (12%), congestion (35%), and epistaxis (12%) as reported in other studies [16,22,27]. Other major complaints with nasal masks included intolerable nasal congestion, significant mask leaks, frequent mask dislodgement, and claustrophobia. Notably, air leaks occurred significantly more in the nasal group. Ill-fitting masks can potentially lead to dry eyes and conjunctivitis. Moreover, tightening of the headgear to avoid leaks and dislodgement can cause such mechanical side effects as contact dermatitis, skin breakdown, and even serious infectious complications. While these issues were not a factor with the oral interface, patients did develop annoying oral dryness (52%) and gum pain (14%). These were the two main side effects reported with the oral interface, necessitating three patients to change over to a nasal mask. With further refinements of the oral interface, however, we believe that these particular complaints can be reduced.

Overall satisfaction with the oral interface was similar to nasal masks. Moreover, in the oral group, there were improved levels of subjective daytime wakefulness and feeling refreshed. However, as outlined in the consent at enrollment, patients in the oral group were aware that the Oracle™ was a new device; this could have theoretically affected their responses. A cross-over design, not provided by our study, could have addressed this issue and yielded further insights into patients' preferences. Interestingly, mask dislodgements were similar for both interfaces even though the oral interface is a strapless device. Nevertheless, the lack of headgear is a distinct advantage for the oral interface. Another notable feature was the higher number of patients who experienced a sensation of excessive pressure with nasal masks during first month of use (41%) as compared to the oral group (19%), even though the therapeutic pressures were similar for both groups. During the second month of CPAP use, the excessive pressure felt by the patients improved in the nasal group (13%) as patients became acclimatized to CPAP. We conjecture that this sensation is related to the smaller area of the nasal cavity compared to the oral cavity as positive pressure is applied.

There were, however, some drawbacks in the study. Patients' initial reactions to the oral interface and nasal masks were not measured at the time they were first presented with either interface in the laboratory. Thus, we were unable to document accurately the number of patients who refused the oral interface or nasal masks after an initial trial in the sleep laboratory. It would of interest to know patients' initial acceptance rate or preference of one interface over another when masks are first offered to them. Also, a cross-over study is required for patients who abandoned therapy or had poor compliance with a given interface to assess whether there would be an improvement by changing to a nasal or oral route of delivery of CPAP.

Development of improved mask designs provides a wide array of selection to optimize therapy for a given patient. The oral interface has the advantage of being strapless and without significant dislodgement issues. Also, oral delivery of pressure can potentially circumvent anatomical nasal obstruction or ineffective pressurization occasionally seen in patients using nasal interfaces with mouth leaks. We also believe that the availability of this strapless device might encourage the daily nocturnal use of CPAP, especially in the female subset of OSAS patients who dislike the effects of headgear on their hairdos. However, there may be a possible limitation with the oral interface in patients with

macroglossia, where the tongue guide could potentially fail to prevent oral cavity occlusion.

In conclusion, our findings show that oral delivery of CPAP is as effective as a nasal interface with the advantage of fewer side effects. Moreover, the compliance rates and therapeutic pressure needs were similar in both groups. There are likely so many interfaces because no one is ideal. The Oracle™ adds to the current armamentarium of the available masks to suit each patient's requirements. With further revisions, this oral interface holds great promise, providing both patients and physicians an excellent alternative for the CPAP therapy.

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