ORIGINAL ARTICLE

Sleep Science

Patients' preferences and the efficacy of a hybrid model of a minimal contact nasal mask in patients with sleep apnea treated with CPAP

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ABSTRACT

Objectives: To evaluate patient`s satisfaction, efficacy and adherence to CPAP with a hybrid nasal mask (DW) we tested patients with OSA in unattended setting under real-life conditions. **Material and Methods:** Prospective, comparative study using DW mask 7 days against habitual mask in patients adapted to CPAP therapy. **Results:** We analyzed 52 patients: 35 men (67%) with IAH mean; 24.3±12.3 events/hour. At baseline mean compliance of 5.42±1.83 hours/night. After using DW mask, patients reported fewer marks, more comfort, greater partners acceptance, easier to use and was ranked higher to preventing leaks; $p<0.05$, and adherence (1 more hour per night, $p>0.0042$). Differences were not found in pressure 90th-95th percentile (9.6±9.2 cm of H2O, $p<0.5$), leaks (19.8±17 liters/min. $p<0.37$) or residual AHI (3.38±3.05 events/hour. $p<0.93$). **Conclusion:** In an uncontrolled non-randomized study, patients can use DW mask with similar leak level and better adherence as compared to conventional masks.

Keywords: Treatment Adherence and Compliance; Continuous Positive Airway Pressure; Monitoring; Sleep Apnea Syndromes.

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INTRODUCTION

Obstructive Sleep Apnea-Hypopnea Syndrome (OSA) is characterized by repeated obstructions of the upper airway with oxygen desaturation and fragmented sleep[1]. According to recent data, its prevalence in adult population of Latin America is > 32%[2].

If untreated, OSA may be associated with excessive daytime sleepiness, poor quality of life, medium-to-long term cardiovascular and cerebrovascular complications, and higher mortality rates[3].

Continuous positive airway pressure (CPAP) is the current gold standard to treat moderate-to-severe OSA[4,5]. When properly administered, CPAP therapy can relieve symptoms and improve quality of life[3-5]. CPAP therapy has been proposed to reduce cardiovascular risk, however recent studies have shown negative results in this regard and have shown the low adherence of patients to therapy in the medium term[6].

CPAP efficacy depends largely on proper use. When systematic programs of education and training are implemented in the use of CPAP, individual or group, it has been observed that compliance to treatment at the first year can exceed 80%[7,8].

The percentage of patients with medium-to-long term adherence varies considerably and is subject to complex factors, such as OSA severity, symptom perception, level of education and socioeconomic status[5-8]. Compliance also depends on a good first experience; therefore, the first week of CPAP therapy becomes crucial[9-12]. It is important to objectively estimate CPAP usage rate, since it has been shown that patients overestimate average CPAP use time in more than one hour per night[10]. Currently available CPAP devices have their own internal memory includes information on hours of effective use, pressure levels (per night), leaks, and residual respiratory events.

CPAP therapy success largely depends on selecting the right mask and training patients on proper use. The right size is very important to reduce leaks, red marks, and discomfort. At present, there is a large variety of masks, including oronasal masks, which cover patient's nose and mouth, nasal masks, which cover the area from the bridge of the nose to the upper lip; and nasal pillow masks, which have two nostril inserts. Nasal pillows have emerged as an alternative to nasal masks because they are smaller and have less contact with the face.

Oronasal masks are considered the best option for patients in need of CPAP therapy who suffer some degree of nasal obstruction or documented mouth leaks[13-15]. Since most patients prefer nasal masks, several models are available on the market. However, the level of scientific evidence necessary to validate the efficacy of these new models and their impact on patient's adherence to treatment is being questioned[14-16].

Borel et al.[17] conducted a descriptive study on 2,311 OSA patients and found statistically significant differences between the 3 types of masks. In terms of effective pressure during CPAP titration, the best results were obtained with oronasal masks, followed by nasal masks, and nasal pillows. Compliance, however, was higher with nasal masks.

A recent literature review revealed 2 well-designed studies comparing the 3 types of masks in terms of CPAP efficacy[16,17]. Ebben el al.[18] evaluated 55 OSA patients and randomized them to CPAP titration with oronasal mask, nasal mask, or nasal pillow. The last 2 masks were similar in terms of CPAP levels, but consistently lower then oronasal ones. No differences were found in terms of residual AHI. One study[17] reported better adherence with nasal pillows than oronasal masks but another that assessed the combination of efficacy, patient's satisfaction, and adherence found adherence was lower with nasal pillows[19].

During this study, we evaluated patient's satisfaction, efficacy, and adherence to CPAP therapy with a hybrid model similar to a nasal pillow but without nostril inserts in-home unattended setting under real-life conditions.

OBJECTIVE

To evaluate patient satisfaction and preferences as well as the therapeutic efficacy an compliance of a hybrid nasal mask in OSA patients previously adapted to CPAP or automatic CPAP therapy.

METHODS

Design

Prospective, comparative, interventional, with unblinded follow-up.

Sample

This study enrolled patients diagnosed with OSA under CPAP therapy in 2 sleep units of university hospitals in Buenos Aires city during a 6-month period (from June to December 2017).

Inclusion criteria

Our study included > 18 year-old male and female patients who: 1) had been diagnosed with OSA by laboratory polysomnography or home-based respiratory polygraphy at least 6 months before enrollment and already under regular treatment with CPAP or automatic CPAP (> 5 nights per week, regardless of number of hours per night), 2) lived in the metropolitan area of Buenos Aires city and received routine care at the sleep units of participating sites and, 3) owned a CPAP or automatic CPAP machine with internal memory (i.e. SD card or similar) and capacity to record objective use, leaks, and residual events. All the patients included signed an informed consent form.

Exclusion Criteria

We excluded patients: 1) with OSA diagnosis and indication for CPAP therapy who do not use the machine, 2) with chronic respiratory failure who need treatment with O_2 or other type of home-based mechanical ventilation, 3) with a terminal condition or who receive intensive care at home for chronic illnesses, 4) with psychiatric and/or cognitive disorders and difficulties to understand and take part in study procedures, 5) with OSA who do not have their own CPAP machine and 6) who are already using the hybrid mask model under study.

Study Procedures

1st Visit: Patients were recruited during their visits to intervening sleep units. During the first visit, the following information was gathered through interviews and medical histories: anthropometric data, symptoms (daytime sleepiness and sleep apnea symptoms), comorbidities, sleep disorder severity and indicators, and treatment characteristics. The initial visit included the following procedures:

CPAP machine examination and data collection about usage, leaks, and treatment efficacy for the last week (Residual Apnea-Hypopnea Index, AHIr). Data were downloaded using specific software (Encore Pro II Philips-Respironics. USA) and ResScan (ResMed. Sidney, Australia). Patients also reported the type of mask they were using at enrollment.

Self-administered questionnaire about patient's level of satisfaction with their usual mask, perceived results, and treatment efficacy. This questionnaire was designed by study authors and is made up of 13 questions to be answered quantitively (1 to 10 visual numeric scale).

Epworth Sleepiness Scale (ESS).

Study nasal Mask

After patients signed the informed consent form, 2 physiotherapists specialized in sleep medicine made a 20-minute demonstration of how to use the new minimal-contact DreamWear™ nasal mask (Philips-Respironics. USA) without nostril inserts (*DW*). The best fitting model was delivered to each patient. No changes were made in pressure, mode, and settings of patients' CPAP machines.

***2nd Visit*:** The following procedures were conducted after 1 week of use:

CPAP machines were checked, and the following data were collected: use, leaks, and treatment efficacy (AHIr).

The self-administered questionnaire designed by study authors was distributed among patients.

Epworth Sleepiness Scale (ESS).

Indicators and metrics of CPAP machine memory as a study objective

Investigators calculated the average values for usage (hours/night and nights/week), leaks, and residual events for the last week of baseline treatment and the intervention week (study mask). Effective pressure values in the 90th (Philips devices) or 95th (ResMed devices) percentile (P90 and P95, respectively) were obtained using the corresponding software for each device.

Statistical Analysis

Categorical and numerical variables are presented as percentages or means ± standard deviation respectively. Differences were compared using Fisher's exact test, Mann-Whitney or $\chi 2$ test. Statistical analysis was conducted using GraphPad Prism-5™ software.

Ethical Considerations

The protocol was approved by the Institutional Review Board and the Ethics Committee of participating sites (number protocol: #839). All patients signed a written informed consent. The identity of every patient was protected. At the end of the study, patients could decide whether to continue using their previous mask or not.

RESULTS

55 patients were enrolled. Data were collected and analyzed for the 52 patients who completed the protocol: 35 men (67%) and 17 women (69%). Their characteristics were; Age: 65.2±9.9 years, Body Mass Index (kg/m^2); 32.5±6.5, Epworth Sleepiness Scale basal value; 6.9±5.5, and AHI; 24.3±12.3 events/hour.

The most common comorbidities were arterial hypertension (57.6%), diabetes mellitus (15%), and the use of hypnotics or sedatives drugs (21%). 65% of subjects wore glasses, 15% had a beard, and 10% a mustache or long hair.

Baseline treatment with CPAP

At baseline, mean CPAP usage time was 8 months (range; 3-84 months) and mean baseline compliance was of 5.42 ± 1.83 hours/night across the entire population. 33% used fixed CPAP and 67% automatic CPAP. The mean prescribed CPAP pressure was 8.5±1.1 cm of H_2O for fixed CPAP machines and ranged from 4±2 (minimum) to 14.4±2.4 (maximum) for automatic CPAP machines. Baseline leaks were 18.3±14.2 liters/min and 5 patients (20%) had leaks above the maximum compensation limit recommended by manufacturer (42.3 ± 11.2 liters/min) during the observation period. The study mask was compared with 12 nasal models. Table 1 show types of commonly used masks.

Table 1. Types and models of masks routinely used at the beginning of the protocol.

Original Interface	n	%
Nasal	43	82.6
Oronasal	1	2
Pillow	8	15
Most frequently used models		
Pico	10	19.2
Easy Life	9	17
Mirage Fx	9	17
Comfort Classic	5	9
Wisp	4	7.6
Comfort Gel	5	9
Others	10	19.2

Subjective Questionnaires

The comparison between patients' previous masks and the *DW* mask revealed statistically significant differences in the visual numeric scale. After using the *DW* mask for one week, patients reported fewer red marks in their faces, more comfort, greater partner's acceptance, and stated the DW mask was more appealing (Figure 1) and easier to use (7.6 *vs.* 9.0; $p<0.001$). The DW model was ranked higher than other models in terms of preventing leaks (7.88 *vs.* 6.32;$p<0.05$ - Figure 2A).

The most frequents adverse events reported with the study mask were; leak towards the eyes (11.5%), face irritation 7.7% and rhinitis (13.4%). At the end of the study, 8 patients (15.4%) decided to go back to their previous mask.

At baseline, 25% of patients had ESS > 11. After using the study mask for seven days, this percentage fell by 11%.

Objective data from CPAP machine's memory

After one week of use, no statistically significant differences were found in pressure values between the 90th-95th percentile (9.6±9.2 cm of H_2O; $p=0.5$), leaks (19.8±17 Liters/min; $p=0.37$) or mean residual AHI (3.38±3.05 events/hour; $p=0.93$) in patients using automatic CPAP (Table 2).

Statistically significant differences were observed in terms of treatment adherence, after using the study mask for seven days ($p>0.004$) Figure 2B, and ESS > 11 (25% *vs.* 11%; $p<0.05$).

DISCUSSION

According to this pilot study conducted in a real-life setting the use of the new minimal-contact nasal mask is feasible and achieves better treatment adherence. In terms of efficacy, the new mask is comparable to other nasal masks available in the market and is well-accepted by patients. In our experience, patients already adapted to CPAP therapy were able to use the new mask properly after a basic demonstration performed at the sleep unit.

Data from other mask designs are not fully comparable and cannot be extrapolated to the new model, which has no nostril inserts. As mentioned before, two studies described the impact of mask types (nasal mask versus nasal pillow with nostril inserts) in CPAP therapy adherence and efficacy with inconsistent results[15-19].

According to the literature, oronasal masks may require higher effective titration pressure than smaller models[17,20-21]. This difference, however, was not observed when comparing nasal masks to this hybrid nasal pillow. In terms of P90 or P95, our study found no difference between the study mask and the home-based automatic CPAP models used for several nights by patients already adapted to CPAP therapy.

Residual AHI (AHIr) has been validated as a metric to infer the efficacy of CPAP therapy as < 5 events/hour correlate well with the results obtained by polysomnography and suggest proper treatment of the disorder[22]. We found that 7 nights using the *DW* mask did not increase AHIr.

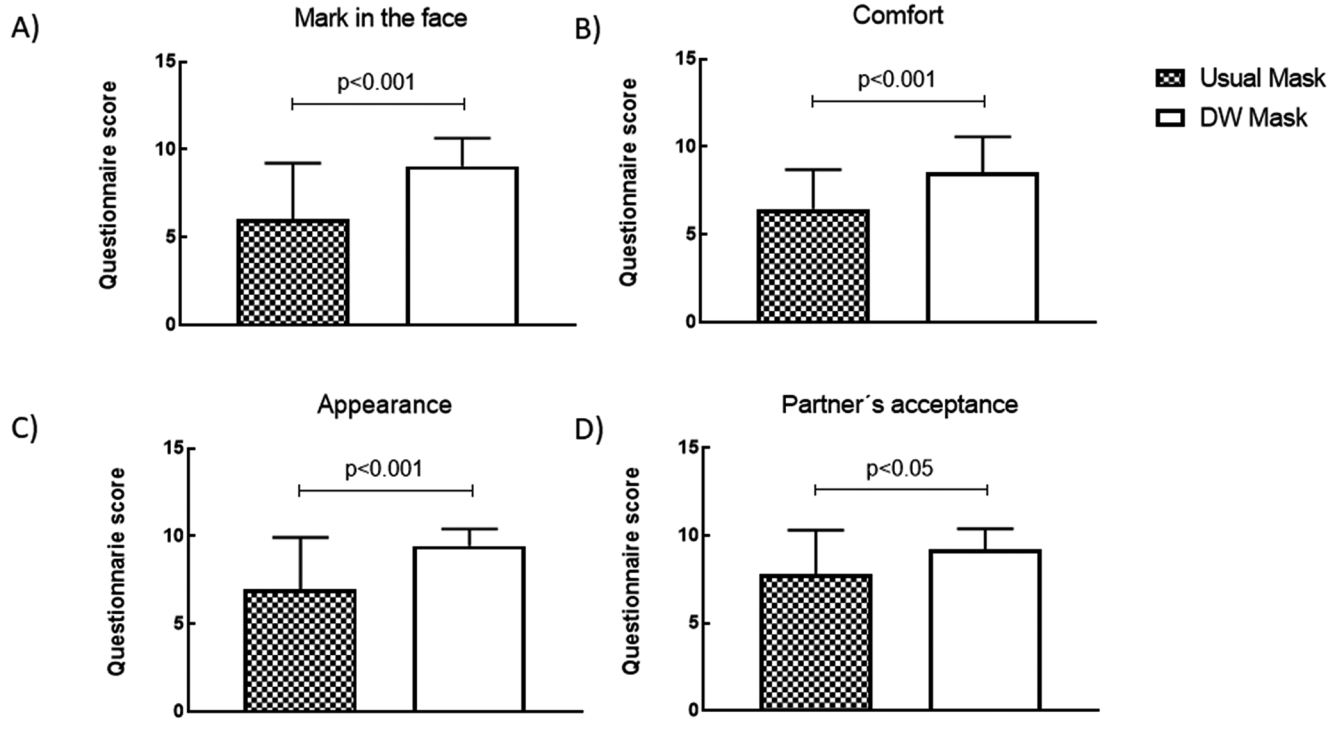

Figure 1. Marks in their faces, comfort and partner's acceptance reported by patients using DW test mask.

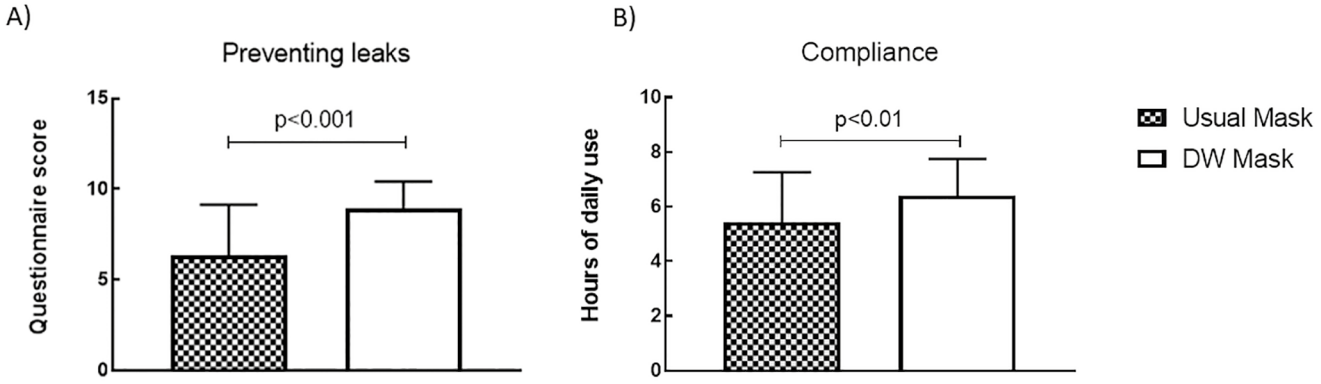

Figure 2. A. Differences in the prevention of leak related to the mask (subjective appreciation of the patient). B. Objective Compliance (data obtained from the internal memory of CPAP devices).

Table 2. Comparison of CPAP objective variables between routine mask and test mask.

		Routine Mask	DW Mask	
	n	Mean / SD (±)	Mean / SD (±)	Fisher Test (*p*)
Effective pressure Pth 90-95%	35	9.6±2.9	9.2±2.6	0.5
Compliance (hours)	52	5.4±1.8	6.4±1.3	0.0042
Mean leak (liters /min)	52	19.8±15.6	17±14.8	0.37
Residual AHI (events/hour)	52	3.38 ± 3.59	3.05±2.7	0.93
Epworth Sleepiness Scale (ESS)	52	6.9±5.5	4.7±4.8	0.01

Effective pressure Pth 90-95%: therapeutic pressure in the 90th or 95th percentile according to the CPAP device.

A recent study with a similar design with nasal pillows and found no short/long-term differences[23]. After 7 days, we observed greater usage time with the *DW* mask (1 hour more on average). This finding, however, calls for a cautious interpretation since it may derive from the effect of the visit to the sleep unit, the training demonstration, and memory card surveillance.

Despite these problems, ESS scores were lower, and most patients seemed willing to continue using the minimal-contact mask after the 7-day trial period. This suggests that it is feasible to use the new mask model in real-life settings.

Minimal-contact masks offer an alternative to conventional nasal masks and seem effective for OSA treatment. In addition, these masks are lighter and could be better accepted by claustrophobic patients, patients with a beard or mustache, and patients who want to wear glasses while using the mask[24].

Limitations

Our study has some limitations. Firstly, we have a heterogeneous control group because patients used different types of masks and CPAP machines. Results refer only to the first week of use and, therefore, it would be necessary to conduct mid-term studies to verify our results. In addition, all the patients knew that they would use a new test mask and this could introduce biases. Patients reporting fewer marks and more comfort may be due to better instructions by the research team, regarding principally the subjective assessments, but also the objective outcomes. Our results cannot be extrapolated to patients not adapted to CPAP treatment and devices. Finally, AHIr and leak metrics are not consistent across manufacturers making result interpretation more difficult.

CONCLUSION

In an uncontrolled non-randomized study, patients already adapted to CPAP therapy can use the new DW mask properly and effectively treat their disorder with a similar leak level and better adherence (1 hour more after 7 days) as compared to conventional masks.

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NO funds or other benefits were received by investigators or Sleep Unit personnel for developing the protocol or recruiting / following up patients.

Masks were donated by Philips-Respironics. Investigators delivered the masks to participants at no cost. Philips-Respironics did not take part in study design, clinical procedures, data management, result analysis, or report writing.

The authors declare no conflicts of interest in the subject linked to the manuscript.

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