Impact of different nasal masks on CPAP therapy for obstructive sleep apnea: a randomized comparative trial

Pierre-Charles Neuzeret and Laurent Morin
ResMed Science Center, Saint Priest cedex, France

Abstract

Introduction: Patient interface is important for the success of continuous positive airway pressure (CPAP), but few trials have examined the influence of mask choice on CPAP adherence.

Objectives: To compare the impact of different nasal masks on CPAP in patients with newly-diagnosed obstructive sleep apnea (OSA).

Methods: OSA patients were randomized in a 2:3 ratio to receive CPAP via different first-line nasal masks: ResMed Mirage FX® (MFX) or control mask (Fisher & Paykel Zest®, HC407® or Philips EasyLife®). Mask acceptance, CPAP compliance and Home Care Provider (HCP) interventions were compared between groups after 3 months of CPAP therapy using modified intent-to-treat (mITT; after exclusion of patients with mouth leaks during CPAP initiation) and on-treatment (OT; CPAP adherent) analyses.

Results: Of 285 randomized patients, 90 requiring a full-face mask were excluded, leaving 195 and 151 in the mITT and OT analyses, respectively. Mask acceptance rate was higher in the MFX versus control group (mITT: 79% vs 68%, \(P = 0.067\); OT: 90% vs 76%, \(P = 0.022\)). CPAP compliance was higher (5.9 ± 1.8 vs 5.1 ± 1.6 h/night, \(P = 0.011\)) and nasal mask issue-related HCP visits lower (3% vs 17%, \(P = 0.006\)) in the MFX group. Nasal mask failures due to mask discomfort (5% vs 1%) or unintentional leakage (5% vs 0%) were higher in control vs MFX group. Mask acceptance was significantly associated with fewer mask leaks (\(P = 0.002\)) and higher pressure therapy (\(P = 0.042\)).

Conclusions: This study highlights differences between nasal masks for CPAP delivery and shows that initial mask selection can influence adherence and healthcare utilization during CPAP.

Please cite this paper as: Neuzeret P-C and Morin L. Impact of different nasal masks on CPAP therapy for obstructive sleep apnea: a randomized comparative trial. Clin Respir J 2017; 11: 990–998. DOI:10.1111/crj.12452.

Introduction

There are a range of interface options available for delivering positive pressure therapy in obstructive sleep apnea (OSA). These include nasal pillows, nasal mask (NM), oronasal mask (ONM; full-face mask [FFM]) and custom-made interfaces. NMs are usually the first-choice interface during titration of continuous positive airway pressure (CPAP) therapy, largely because the majority of studies evaluating the effectiveness of CPAP in OSA patients have used a NM (1). Patients receiving nasal CPAP (nCPAP) often complain about side effects related to mask fit, such as eye irritation, silicone allergies, pain or abrasion to the bridge of the nose, pressure sores and air leaks, all of which reduce adherence to therapy. Therefore, selecting an appropriate nasal mask is essential for ensuring successful CPAP therapy.

Key words
acceptance – compliance – continuous positive airway pressure – health care utilization – nasal mask – randomized controlled trial

Correspondence
Pierre-Charles Neuzeret, PhD, ResMed Science Center, Saint Priest cedex, France. Tel: +49 89 9901 1040 Fax: +49 89 9901 1020 email: pierre-charles.neuzeret@resmed.com

Received: 02 July 2015
Revision requested: 11 December 2015
Accepted: 04 January 2016
DOI:10.1111/crj.12452

Authorship and contributorship
Pierre-Charles Neuzeret wrote the paper and Laurent Morin designed research.

Ethics
The trial design was approved by a French National Ethic Committee and authorized by the French data protection authority. Informed consent was obtained from all participants. The study was conducted in accordance with Good Clinical Practice and the principles of the Declaration of Helsinki. The study was registered at ISRCTN registry (NCT01186926).

Conflict of interest
This study was funded by ResMed, Saint Priest, France. P-C Neuzeret and L Morin are both employees of ResMed.
the tolerability of treatment (2, 3). Air leakage is a significant problem during CPAP therapy, is experienced by up to 50% of nCPAP users (3), can cause a drop in pressure leading to suboptimal treatment (4), and may result in poor compliance (5). Estimates in the literature suggest that although CPAP is effective at treating OSA, 29% to 83% of patients are nonadherent (usage for <4 h/night) (6). In addition, 8% to 15% of patients refuse to continue with CPAP after a single night of therapy (7). Furthermore, it has been shown that the pattern of adherence to CPAP at 3 days and 7 days after treatment initiation is strongly predictive of longer-term (1-month) adherence (8). These results underline the importance of ensuring good patient compliance in the first few days of CPAP therapy and reinforce the importance of selecting the right interface for treatment initiation. Making the right mask selection in the first instance is also critical to avoid repeated interface changes that both impact patient compliance and increase therapy-related costs for healthcare providers. The mask is a relatively expensive consumable for home care providers (HCPs), especially if the initial choice does not suit the patient. Replacement masks and repetitive home visits can have a negative impact on HCP profitability. To reduce costs and increase acceptance of the first-choice mask in patients starting CPAP therapy, HCPs have developed the concept of “first intention”, which involves selecting a single mask for treatment initiation in all patients that provides a good compromise between cost, ease of use, and performance.

Very few trials have investigated the influence of mask choice on OSA treatment. In 2006, a Cochrane review of CPAP delivery interfaces in patients with OSA concluded that the optimal interface remained unclear, because of the limited amount of data available from randomized controlled clinical trials (1). This French study compared outcomes during CPAP therapy using different first-line nasal masks in patients with OSA-hypopnea syndrome (OSAHS).

Methods

This randomized, prospective, non-blinded, parallel study was conducted with the support of four healthcare provider centers based in France from January 2012 to June 2013. Randomization was performed using a secure web platform, which displayed the assigned treatment group after the HCP had entered the patient number. The trial design was approved by a French National Ethic Committee and authorized by the French data protection authority. Informed consent was obtained from all participants; the study was conducted in accordance with Good Clinical Practice and the principles of the Declaration of Helsinki. The study was registered at ISRCTN registry (NCT01186926).

Subjects

Newly diagnosed OSAHS patients were eligible for enrolment, if they had daytime sleepiness and ≥3 of listed symptoms (snoring, morning headaches, reduced alertness, libido disorders, hypertension, nocturia) associated with an apnea-hypopnea index (AHI) of >30/h or 5–30/h with ≥10 respiratory event-related arousals with an increase in respiratory effort documented by polysomnography (PSG), central apnea index of ≤20%, absence of nocturnal mouth leaks detected during diagnosis or screening CPAP treatment initiation, no known allergy to silicone, and were fitted with an automatic positive airway pressure (APAP) device (S9 AutoSetTM; ResMed). Determination of the effective pressure was done either automatically after one night of auto-titration or manually after one night of titration during PSG. Patients were excluded if they were prescribed a first-line mask other than those being assessed, had previously been treated with CPAP/APAP or noninvasive positive pressure ventilation, had undergone ENT surgery within the previous 6 weeks, had significant epistaxis in the previous 6 months, or were participating in another trial.

Study treatments

Eligible patients were randomized in a 2:3 ratio to receive CPAP (S9 AutoSet, ResMed) via different first-line nasal masks: ResMed Mirage® FX (MFX group), or one of the Fisher & Paykel Zest®, HC407® or Philips Respironics EasyLife® (control group) (Fig. 1). Control mask was selected by the patients’ HCP, and were the most consistently-used masks in study clinics over the trial period.

Data collection

Data were collected by HCPs during home visits and via telephone. At baseline, this included interface characteristics, CPAP settings, duration of procedures associated with choosing mask size, mask implementation and adjustment, and patient training. During the 3-month follow-up, HCPs recorded the number, duration and cause of mask-related contacts, number of visits dedicated to the mask, primary cause of a change in first-line mask or discontinuation of CPAP, compliance, and patient satisfaction (based on a patient questionnaire).
The primary endpoint was nasal mask acceptability, defined as continued use of the mask assigned at randomization. The modified intent-to-treat (mITT) population comprised all patients allocated to treatment without mouth leak during CPAP treatment initiation, and the on-treatment (OT) population included patients who were adherent with CPAP therapy at 3-month follow-up.

Sample size

The minimum difference in first-line mask acceptance between the MFX and control groups was determined to be ≥15%. It was assumed that 228 patients (91 MFX, 137 control) would be needed to reject the hypothesis that acceptance rate is the same in both groups based on a 5% one-sided alpha risk and 80% power.

Statistical analysis

Data management and statistical analysis were performed by Delta Consultants (CRO, Eybens, France). At the 3-month follow-up, nasal mask acceptability, CPAP compliance, causes of CPAP failure, and HCP interventions were compared in the mITT and OT populations. The Chi-square test or Fisher exact test (qualitative variables) and the Wilcoxon–Mann–Whitney non-parametric test (quantitative variables) were used to evaluate differences in baseline demographics between the MFX and control groups. A logistic procedure with backward stepwise regression analysis was used to determine independent predictive factors associated with nasal mask acceptance. Survival analysis of nasal mask failure was performed using Kaplan-Meier survival estimates and compared between groups using a Log-Rank test. Quantitative variables were described in terms of mean, standard deviation, median and range, and qualitative variables were described as absolute frequency and percentage. A P-value of <0.05 was considered statistically significant.

Results

A total of 285 OSAHS patients were initially enrolled; 90 (MFX: 27; control: 63) of these required a FFM (mouth leaks) and were therefore excluded. Therefore, 195 patients were included in the mITT analysis (MFX: 85; control: 110) and 151 patients in the OT analysis (MFX: 68, control: 83). The 44 subjects excluded from the OT population (MFX: 18; control: 35) stopped CPAP (mainly for pressure intolerance) before the 3-month follow-up visit.

Demographic data and treatment settings

Demographic data and treatment settings for the mITT population are shown in Table 1. Overall, 22.6%...
of patients had 1 home visit for any cause and 10.3% had 1 visit related only to a first-line nasal mask issue. Only 6.2% of subjects made a first-line nasal mask-related contact call. OT population data were similar, except duration of first-line mask use was significantly longer in the MFX group (84.7 ± 19.0 vs 76.9 ± 26.2 days, \( P < 0.0171 \)). Control mask size was standard for 74.2% of subjects and SlimLine 15-mm tubing was used in the majority (96.8%). There were no other differences between the two groups. CPAP device data are shown in Table 2.

### First-line mask acceptance

In the ITT analysis, first-line mask acceptance rate at 3 months was higher in the MFX versus control group (60% vs 45%; \( P = 0.0066 \)). After exclusion of patients requiring a FFM, first-line mask acceptance rate was higher in the MFX group, with differences versus control reaching statistical significance in the OT population (Fig. 2). The probability of rejecting the first-line nasal mask in the OT population increased over time in the control group but not in MFX group where

### Table 1. Demographic data and treatment settings in the modified intent-to-treat (mITT) population

| Variable                        | Overall (n = 195) | Control Mask (n = 110) | Mirage FX (n = 85) | P-value<sup>a</sup> |
|---------------------------------|-------------------|------------------------|-------------------|----------------------|
| **Sex, n (%)**                  |                   |                        |                   |                      |
| Male                            | 86 (44.1%)        | 50 (45.5%)             | 36 (42.4%)        | 0.67                 |
| Female                          | 109 (55.9%)       | 60 (54.5%)             | 49 (57.6%)        |                      |
| **Age, years**                  | n = 195           | n = 110                | n = 85            |                      |
| Mean ± SD                       | 54.7 ± 12.0       | 55.9 ± 11.9            | 53.2 ± 12.1       | 0.11                 |
| **Period of use, days**         | n = 194           | n = 110                | n = 84            | 0.32                 |
| Mean±SD                         | 76.4 ± 29.3       | 74.7 ± 30.5            | 78.6 ± 27.8       |                      |
| **EPR, n (%)**                  | n = 195           | n = 108                | n = 85            | 0.42                 |
| No                              | 39 (20.2%)        | 25 (23.1%)             | 14 (16.5%)        |                      |
| Ramp only                       | 23 (11.9%)        | 11 (10.2%)             | 12 (14.1%)        |                      |
| Full-time                       | 131 (67.9%)       | 72 (66.7%)             | 59 (69.4%)        |                      |
| **EPR level**                   | n = 131           | n = 72                 | n = 59            | 0.47                 |
| 1                               | 3 (2.3%)          | 2 (2.8%)               | 1 (1.7%)          |                      |
| 2                               | 107 (81.7%)       | 61 (84.7%)             | 46 (78.0%)        |                      |
| 3                               | 21 (16.0%)        | 9 (12.5%)              | 12 (20.3%)        |                      |
| **Ramp**                        | n = 192           | n = 107                | n = 85            | 1.00                 |
| Yes                             | 186 (96.9%)       | 104 (97.2%)            | 82 (96.5%)        |                      |
| No                              | 6 (3.1%)          | 3 (2.8%)               | 3 (3.5%)          |                      |
| **Duration, min**               | n = 183           | n = 102                | n = 81            | 0.73                 |
| Mean ± SD                       | 21.1 ± 9.0        | 20.9 ± 9.0             | 21.3 ± 9.0        |                      |
| **Humidifier, n (%)**           | n = 194           | n = 109                | n = 85            | 0.068                |
| Yes                             | 38 (19.6%)        | 16 (14.7%)             | 22 (25.9%)        |                      |
| No                              | 156 (80.4%)       | 93 (85.3%)             | 63 (74.1%)        |                      |

<sup>a</sup>Chi-square test (sex) or Fisher exact test (other qualitative variables), Wilcoxon-Mann-Whitney test (quantitative variables).

EPR, expiratory pressure relief; SD, standard deviation.
Quantitative variables are shown as mean ± standard deviation.

### Table 2. CPAP device data at 3-month follow-up in the modified intent-to-treat population

|                                | Control Mask (n = 110) | Mirage FX (n = 85) | P-value<sup>a</sup> |
|--------------------------------|------------------------|-------------------|----------------------|
| **Leakage rate, L/min**        |                        |                   |                      |
| Mean ± SD                      | 2.7 ± 4.4              | 1.4 ± 2.5         | 0.01                 |
| Median (Q1–Q3)                 | 1 (0–3.6)              | 0 (0–2.0)         |                      |
| **Leakage 95th percentile, L/min** |                        |                   |                      |
| Mean ± SD                      | 12.3 ± 10.0            | 10.9 ± 9.6        | NS                   |
| Median (Q1–Q3)                 | 10.0 (4.8–17.0)        | 8.0 (3.6–15.6)    |                      |
| **CPAP pressure, cmH2O**       |                        |                   |                      |
| Mean ± SD                      | 9.3 ± 2.1              | 7.9 ± 1.9         | NS                   |
| Median (Q1–Q3)                 | 8.2 (7.0–9.6)          | 8.0 (6.8–9.0)     |                      |
| **CPAP pressure 95th percentile, cm H2O** |            |                   |                      |
| Mean ± SD                      | 10.5 ± 2.0             | 10.3 ± 2.1        | NS                   |
| Median (Q1–Q3)                 | 11.0 (9.4–11.9)        | 10.6 (9.0–11.8)   |                      |
| **Residual AHI/h**             |                        |                   |                      |
| Mean ± SD                      | 1.5 ± 1.7              | 1.9 ± 3.7         | NS                   |
| Median (Q1–Q3)                 | 1.0 (0.4–2.0)          | 1.0 (0.3–2.0)     |                      |
| **Residual CSA,/h**            |                        |                   |                      |
| Mean ± SD                      | 0.4 ± 0.9              | 0.8 ± 3.0         | NS                   |
| Median (Q1–Q3)                 | 0 (0–0.4)              | 0 (0–0.5)         |                      |

AHI, apnea-hypopnea index; CPAP, continuous positive airway pressure; CSA, central sleep apnea; NS, not significant; Q, quartile; SD, standard deviation.
nasal mask failures occurred mostly during the first month of CPAP (Fig. 3).

Of the 18 subjects in the MFX mITT group who were no longer using their first-line mask at 3 months, the main reasons for non-acceptance were skin lesions ($n = 6$), mask discomfort ($n = 1$), wrong size ($n = 1$) or other ($n = 10$). Of the 35 control subjects who were no longer using their first-line mask at 3 months, the main reasons for non-acceptance were mask uncomfortable ($n = 6$), unintentional leakage ($n = 5$), skin lesions ($n = 7$), wrong size ($n = 1$) or other ($n = 14$). There were no statistically significant between-group differences in the reasons for first-line mask failure ($P = 0.4846$ [mITT], $P = 0.6836$ [OT]).

On multivariate analysis, median leakage rate and pressure were significantly associated with first-line mask acceptance. The odds ratio (OR) for first-line mask acceptance, adjusted for age, sex and baseline CPAP settings, was 0.847 (95% confidence interval [CI] 0.763–0.939; $P = 0.0017$) for a 1 L/min increase in median leakage, whereas a 1 cmH$_2$O increase in median pressure increased mask acceptance (OR 1.205, 95% CI 1.007–1.443; $P = 0.0422$).

Figure 2. First-line nasal mask acceptance rate at 90 days (mITT, modified intent-to-treat; OT, on-treatment; CPAP, continuous positive airway pressure; MFX, Mirage FX nasal mask).

Figure 3. Probability of rejecting first-line mask in the on-treatment population (Kaplan-Meier curves) (MFX, Mirage FX nasal mask).
CPAP use and compliance

Despite 10 more days with >4 h of CPAP usage per night (good adherence) in the MFX group, there were no significant differences versus control for all CPAP compliance data (mITT) (Table 3). In the OT population, mean CPAP usage and the proportion of days with good adherence were significantly higher in the MFX versus control group (Table 3).

Patient satisfaction

Satisfaction scores were similar in both groups (mITT). Lightness was cited more often as a positive point in the MFX group versus control (51.8% vs 18.5%, \( P < 0.0001 \)). This was never cited as a factor requiring improvement in the MFX group but was a problem for 29 control subjects (26.9%) \( (P < 0.0001) \). Conversely, air-tightness was more frequently cited as a positive point in the control versus MFX group (20.4% vs 4.8%, \( P = 0.0019 \)). Cleaning difficulties were noted more in the control than in the MFX group (34.3% vs 15.7%, \( P = 0.0038 \)). The ease of cleaning score was 7.9 ± 1.9 for MFX mask versus 6.7 ± 2.4 for control masks \( (P = 0.002) \) (scale: 1 = very poor, 10 = excellent).

Contact calls and visits for mask issue

There was no difference between the MFX and control groups in the proportion of subjects with a first-line mask-related contact call, and call duration was similar (12.5 ± 6.6 min for MFX vs 8.1 ± 5.6 min for control, \( P = 0.3056 \)). However, the duration of a visit relating to a first-line mask only was significantly shorter in the MFX group (Table 4), and subjects using the MFX were significantly less likely than those using control masks to have a visit related only to the first-line mask (Table 4). Second-line mask requirement was lower in the MFX group versus control, significantly so in the OT population (Table 4).

Table 3. CPAP use and compliance

|                      | Control Mask (n = 110) | Mirage FX (n = 85) | \( P \)-value |
|----------------------|------------------------|--------------------|--------------|
| mITT population      |                        |                    |              |
| Duration of CPAP use, h/night |                      |                    |              |
| Mean ± SD            | 4.7 ± 2.0              | 5.1 ± 2.4          | 0.13         |
| Median (Q1–Q3)       | 5.0 (3.0–6.0)          | 5.0 (3.9–6.8)      | 0.12         |
| Nights with usage >4 h/night, n |          |                    |              |
| Mean ± SD            | 70 ± 30                | 74 ± 31            | 0.11         |
| Median               | 78                     | 88                 |              |
| OT population        |                        |                    |              |
| Duration of CPAP use, h/night |                      |                    |              |
| Mean ± SD            | 5.1 ± 1.6              | 5.9 ± 1.8          | 0.01         |
| Median (Q1–Q3)       | 5.0 (4.0–6.0)          | 6.0 (4.7–7.0)      |              |
| Nights with usage >4 h/night, n |            |                    |              |
| Mean ± SD            | 78 ± 22                | 84 ± 21            | 0.02         |
| Median               | 84                     | 94                 |              |

CPAP, continuous positive airway pressure; mITT, modified intention-to-treat; OT, on treatment; Q, quartile; SD, standard deviation.

Table 4. Second-line mask requirement and visits

|                      | mITT population (n = 195) | OT population (n = 151) | \( P \)-value |
|----------------------|---------------------------|-------------------------|--------------|
| Control Mask (n = 110) |                           |                         |              |
| Mirage FX (n = 85)    |                           |                         |              |
| Second-line mask required, n (%) | 21 (19.1) | 12 (14.1) | 0.36         |
| ≥1 visit for a nasal mask issue, n (%) | 16 (14.5) | 4 (4.7) | 0.02         |
| Duration of visit related to first-line mask only, min | 20.0 (9.0–35.0) | 15.5 (10.0–63.0) | 0.04         |
| Control Mask (n = 83) |                           |                         |              |
| Mirage FX (n = 68)    |                           |                         |              |
| Second-line mask required, n (%) | 20 (24.1) | 7 (10.3) | 0.03         |
| ≥1 visit for a nasal mask issue, n (%) | 14 (16.9) | 2 (2.9) | 0.01         |
| Duration of visit related to first-line mask only, min | 15.0 (8.0–30.0) | 10.0 (5.0–15.0) | 0.47         |

Values are number of patients (%) or median (interquartile range).
Discussion

The results of this study showed that patients receiving CPAP therapy via a first-line MFX nasal mask are more likely to accept the interface and adhere better to CPAP than patients treated via other nasal masks.

Adherence to CPAP is a crucial aspect of therapy, and the benefits of treatment are most evident in patients who comply with treatment and have longer durations of CPAP use (9–19). Nevertheless, an estimated 46–83% of patients are nonadherent with CPAP when compliance is defined as usage for ≥4 h/night (6). Therefore, many studies have investigated factors that might influence compliance with nocturnal CPAP to identify the best ways to maximize compliance. Along with patient education (20–22), clinical support (23–26), and behavioral interventions (21, 22, 27), CPAP equipment, including the interface, has been shown to be an important factor in determining compliance with therapy (28–33). The current results add to the body of evidence in this area.

Unintentional leakages in this study were lower in the group using an MFX nasal mask, and overall mask acceptance was significantly associated with fewer mask leaks. These findings are consistent with existing data showing that fewer leaks are associated with better CPAP compliance (34) and that leak is an independent predictor of CPAP compliance (35). Unintentional leaks may be caused by mouth opening or a poorly fitting mask (36). In the presence of mouth leak an early switch from a nasal mask to a FFM is indicated (36). Such early switching in mouth breathers was shown in our study. In clinical practice it is likely that during CPAP initiation a significant proportion of patients will not be eligible to use a nasal mask because of nocturnal mouth leaks and will therefore require a FFM as the primary interface. The main objective of our study was to compare acceptance of first-line nasal mask for CPAP delivery at 3-month follow-up and to minimize the effects of bias on the primary endpoint assessment resulting from a high early switch rate from a nasal mask to a FFM. As a result, patients with mouth leak were excluded from the study.

This study showed that higher pressure therapy was associated with better mask acceptance and therefore also potentially better CPAP adherence. A similar association has been reported previously between pressure and compliance showing that patients who required higher CPAP pressures were those with more severe OSA, making them more likely to comply with therapy (37–39). However, we couldn’t link higher CPAP pressures with greater OSA severity in this study because data on indicators of OSA severity (e.g. AHI, oximetry) were not available. Of note, the effect shown in this study was relatively small, at the lower end of the confidence interval.

Across a range of diseases, greater treatment satisfaction is associated with better compliance, and higher levels of dissatisfaction are predictive of poor compliance (40). In this study we have explored potential differences between the two groups with respect to several components of interface satisfaction. We found that patients reported that the MFX mask was more lightweight and easier to clean than control masks. Conversely, control masks were rated as more air tight than the MFX. Despite these differences, none of the mask characteristics mentioned allowed us to identify any specific reasons for patient satisfaction or dissatisfaction that could have compromised CPAP use and therefore reduce first-line mask acceptance in the control group. There are relatively few studies comparing the effect of different CPAP interface types on CPAP adherence and even fewer studies have investigated their impact on patient satisfaction. In addition, available data have focused mainly on the comparison between FFM and nasal masks (1). In a randomized crossover trial comparing a nasal mask with FFM, CPAP was used for one additional hour per night with the nasal mask (41). During that trial this nasal mask was rated more comfortable and less claustrophobic by most of the participants. In non-invasive ventilation, patient interface preference has been also shown to be a key factor in treatment compliance (42). Device satisfaction may enhance CPAP use (41) and patients who experience difficulties with CPAP treatment in the early days of treatment may be at risk for CPAP discontinuation (43). In addition, there is an important link between experience during the first week of CPAP therapy and long-term adherence to therapy (8). Both of these findings mean that the choice of first mask is one of the most important shared decisions made with the patient during the CPAP initiation process. Considering the scarcity of data available regarding the different types of mask further research is need to assess the weight of patients satisfaction and preference in improving long term compliance.

The requirement to switch and replace the mask during CPAP therapy may represent a hidden cost for healthcare providers. A US study reported a high rate of mask replacement over 2 years’ CPAP therapy in OSA patients (24% in year 1, 29% in year 2) (44). In our study, a second-line mask was required less in the MFX group, which could result in a lower cost and logistical burden in terms of interface replacement. Importantly, although the number and duration of calls was similar in the two mask groups, the MFX
group had significantly fewer and shorter first-line mask-related visits, reducing HCP workload. A randomized, controlled trial showed that home visits made by a specialist were time-consuming and expensive and that much of this reflected travel costs (45). Therefore, delivering the appropriate mask first time might reduce provider costs.

This study had a number of limitations which need to be taken into account when interpreting the findings. First, we did not reach the 228 patients required for the mITT analysis due to the high number excluded with mouth leaks. That may explain why the primary endpoint comparison only reached statistical significance in the OT analysis. Furthermore, it was not possible to assess each control mask individually because of the large number of subjects this would require. Nearly a quarter of patients discontinued CPAP therapy (mainly for pressure intolerance). It is difficult to define the role that first-line mask choice played in these discontinuations, but the problem was similar in both groups. Additionally, the follow-up was only 3 months, meaning that no definitive predictions can be made about the contribution of first-line mask choice to longer term CPAP adherence. However, given the strong link between early compliance and persistence with CPAP, it is likely that the results can be generalized over a longer period. In addition, mask use survival curves indicated that if primary mask failure occurred in the MFX group, this happened primarily during the first month of CPAP, with patients who did well on MFX over the first 30 days continuing to successfully use it for the study period. This randomized trial has been conducted under real-life practice conditions with the same CPAP device, the control mask provided was dependent on individual experiences and preferences of the healthcare provider. On the other hand, the control group may have benefited from greater provider expertise relating to the mask that they use on a daily basis.

In conclusion, the results of this randomized, prospective study suggest that there may be differences between outcomes, including adherence and healthcare utilization, based on the choice of initial interface for delivery of CPAP in patients with OSA.

Acknowledgements

Medical writing support was provided by Nicola Ryan, independent medical writer, funded by ResMed.

References

1. Chai CL, Pathinathan A, Smith B. Continuous positive airway pressure delivery interfaces for obstructive sleep apnoea. Cochrane Database Syst Rev 2006:CD005308.
2. Pepin JL, Leger P, Veale D, Langevin B, Robert D, Levy P. Side effects of nasal continuous positive airway pressure in sleep apnea syndrome. Study of 193 patients in two French sleep centers. Chest 1995;107: 375–81.
3. Richards GN, Cistulli PA, Ungar RG, Berthon-Jones M, Sullivan CE. Mouth leak with nasal continuous positive airway pressure increases nasal airway resistance. Am J Respir Crit Care Med 1996;154: 182–6.
4. Coller D, Stanley D, Parthasarathy S. Effect of air leak on the performance of auto-PAP devices: a bench study. Sleep Breath 2005;9: 167–75.
5. Valentin A, Subramanian S, Quan SF, Berry RB, Parthasarathy S. Air leak is associated with poor adherence to autoPAP therapy. Sleep 2011;34: 801–6.
6. Weaver TE, Grunstein RR. Adherence to continuous positive airway pressure therapy: the challenge to effective treatment. Proc Am Thorac Soc 2008;5: 173–8.
7. Smith I, Lasserson TJ. Pressure modification for improving usage of continuous positive airway pressure machines in adults with obstructive sleep apnoea. Cochrane Database Syst Rev 2009;CD003531.
8. Budhiraja R, Parthasarathy S, Drake CL et al. Early CPAP use identifies subsequent adherence to CPAP therapy. Sleep 2007;30: 320–4.
9. Barbe F, Duran-Cantolla J, Capote F et al. Long-term effect of continuous positive airway pressure in hypertensive patients with sleep apnea. Am J Respir Crit Care Med 2010; 181: 718–26.
10. Barnes M, Houston D, Worsnop CJ et al. A randomized controlled trial of continuous positive airway pressure in mild obstructive sleep apnea. Am J Respir Crit Care Med 2002;165: 773–80.
11. Campos-Rodriguez F, Pena-Grinan N, Reyes-Nunez N et al. Mortality in obstructive sleep apnea-hypopnea patients treated with positive airway pressure. Chest 2005;128: 624–33.
12. Duran-Cantolla J, Aizpuru F, Montserrat JM et al. Continuous positive airway pressure as treatment for systemic hypertension in people with obstructive sleep apnoea: randomised controlled trial. BMJ 2010;341: c3991.
13. Engleman HM, Kingshott RN, Wraith PK, Mackay TW, Deary IJ, Douglas NJ. Randomized placebo-controlled crossover trial of continuous positive airway pressure for mild sleep Apnea/Hypopnea syndrome. Am J Respir Crit Care Med 1999;159: 461–7.
14. Lozano I, Tovar JL, Sampol G et al. Continuous positive airway pressure treatment in sleep apnea patients with resistant hypertension: a randomized, controlled trial. J Hypertens 2010;28: 2161–8.
15. Montesi SB, Edwards BA, Malhotra A, Bakker JP. The effect of continuous positive airway pressure treatment on blood pressure: a systematic review and meta-analysis of randomized controlled trials. J Clin Sleep Med 2012;8: 587–96.
Different nasal masks for CPAP

Neuzeret and Morin

16. Stradling JR, Davies RJ. Is more NCPAP better? Sleep 2000; 23 Suppl4: S150–3.
17. Weaver TE, Maislin G, Dinges DF et al. Relationship between hours of CPAP use and achieving normal levels of sleepiness and daily functioning. Sleep 2007;30: 711–9.
18. Zimmerman ME, Arnedt JT, Stanchina M, Millman RP, Aloia MS. Normalization of memory performance and positive airway pressure adherence in memory-impaired patients with obstructive sleep apnea. Chest 2006;130: 1772–8.
19. Arzt M, Floras JS, Logan AG et al. Suppression of central sleep apnea by continuous positive airway pressure and transplant-free survival in heart failure: a post hoc analysis of the Canadian Continuous Positive Airway Pressure for Patients with Central Sleep Apnea and Heart Failure Trial (CANPAP). Circulation 2007;115: 3173–80.
20. Amfilochiou A, Tsara V, Kolilekas I et al. Determinants of continuous positive airway pressure compliance in a group of Greek patients with obstructive sleep apnea. Eur J Intern Med 2009;20: 645–50.
21. Damjanovic D, Fluck A, Bremer H, Muller-Quernheim J, Idzko M, Sorichter S. Compliance in sleep apnoea therapy: influence of home care support and pressure mode. Eur Respir J 2009;33: 804–11.
22. Smith I, Nadig V, Lasserson TJ. Educational, supportive and behavioural interventions to improve usage of continuous positive airway pressure machines for adults with obstructive sleep apnoea. Cochrane Database Syst Rev 2009: CD007736.
23. Chervin RD, Theut S, Bassetti C, Aldrich MS. Compliance with nasal CPAP can be improved by simple interventions. Sleep 1997;20: 284–9.
24. Golay A, Girard A, Grandin S et al. A new educational program for patients suffering from sleep apnea syndrome. Patient Educ Couns 2006;60: 220–7.
25. Hoy CJ, Vennelle M, Kingshott RN, Engleman HM, Douglas NJ. Can intensive support improve continuous positive airway pressure use in patients with the sleep apnea/hypopnea syndrome? Am J Respir Crit Care Med 1999;159: 1096–100.
26. Lewis KE, Bartle IE, Watkins AJ, Seale L, Ebden P. Simple interventions improve re-attendance when treating the sleep apnoea syndrome. Sleep Med 2006;7: 241–7.
27. Aloia MS, Di Dio L, Ilinczyk N, Perlis ML, Greenblatt DW, Giles DE. Improving compliance with nasal CPAP and vigilance in older adults with OAHs. Sleep Breath 2001;5: 13–21.
28. Massie CA, Hart RW. Clinical outcomes related to interface type in patients with obstructive sleep apnea/hypopnea syndrome who are using continuous positive airway pressure. Chest 2003;123: 1112–8.
29. Ryan S, Garvey JJ, Swan V, Behan R, McNicholas WT. Nasal pillows as an alternative interface in patients with obstructive sleep apnoea syndrome initiating continuous positive airway pressure therapy. J Sleep Res 2011;20: 367–73.
30. Weaver TE. Adherence to positive airway pressure therapy. Curr Opin Pulm Med 2006;12: 409–13.
31. Wimms AJ, Richards GN, Benjafeld AV. Assessment of the impact on compliance of a new CPAP system in obstructive sleep apnea. Sleep Breath 2013;17: 69–76.
32. Borel JC, Tamisier R, Dias-Domingos S et al. Type of mask may impact on continuous positive airway pressure adherence in apneic patients. PLoS One 2013;8: e64382.
33. Andrade RG, Piccin VS, Nascimento JA, Viana FM, Genta PR, Lorenzi-Filho G. Impact of the type of mask on the effectiveness of and adherence to continuous positive airway pressure treatment for obstructive sleep apnea. J Bras Pneumol 2014;40: 658–68.
34. Baltzan MA, Elkholi O, Wolkove N. Evidence of interrelated side effects with reduced compliance in patients treated with nasal continuous positive airway pressure. Sleep Med 2009;10: 198–205.
35. Sopkova Z, Dorkova Z, Tkacova R. Predictors of compliance with continuous positive airway pressure treatment in patients with obstructive sleep apnea and metabolic syndrome. Wien Klin Wochenschr 2009;121: 398–404.
36. Kushida CA, Chediak A, Berry RB et al. Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. J Clin Sleep Med 2008;4: 157–71.
37. Campos-Rodriguez F, Martinez-Garcia MA, Reyes-Nunez N et al. Long-term continuous positive airway pressure compliance in females with obstructive sleep apnoea. Eur Respir J 2013;42: 1255–62.
38. Kohler M, Smith D, Tippett V, Stradling JR. Predictors of long-term compliance with continuous positive airway pressure. Thorax 2010;65: 829–32.
39. Oksenberg A, Arons E, Froom P. Does the severity of obstructive sleep apnea predict patients requiring high continuous positive airway pressure? Laryngoscope 2006;116: 951–5.
40. Barbosa CD, Balp MM, Kulich K, Germain N, Rofail D. A literature review to explore the link between treatment satisfaction and adherence, compliance, and persistence. Patient Prefer Adherence 2012;6: 39–48.
41. Mortimore IL, Whittle AT, Douglas NJ. Comparison of nose and face mask CPAP therapy for sleep apnoea. Thorax 1998;53: 290–2.
42. Fernandez R, Cabrera C, Rubinos G et al. Nasal versus oronasal mask in home mechanical ventilation: the preference of patients as a strategy for choosing the interface. Respir Care 2012;57: 1413–7.
43. Sawyer AM, Gooneratne NS, Marcus CL, Ofer D, Richards KC, Weaver TE. A systematic review of CPAP adherence across age groups: clinical and empirical insights for developing CPAP adherence interventions. Sleep Med Rev 2011;15: 343–56.
44. Rosenbalm TE, Redline S, Rosenberg C, Disch A, McFadden G, Stohl KP. Health care delivery in a sleep center. Sleep Breath 1997;2: 23–32.
45. Palmer S, Selvaraj S, Dunn C et al. Annual review of patients with sleep apnea/hypopnea syndrome—a pragmatic randomised trial of nurse home visit versus consultant clinic review. Sleep Med 2004;5: 61–5.