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# Pressure adjustment is the most useful intervention for improving compliance in telemonitored patients treated with CPAP in the first 6 months of treatment

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## Abstract

**Purpose** Telemonitoring (TMg) for patients treated with continuous positive airway pressure (CPAP) is now routine care in some sleep labs. The purpose of the present study was to identify technical interventions associated with improved CPAP compliance in a real-life cohort of newly telemonitored patients with obstructive sleep apnea (OSA) during the first 6 months of treatment.

**Methods** All patients with moderate-to-severe OSA (apnea-hypopnea index (AHI) ≥ 15/h) who were newly treated with CPAP were included in the study and telemonitored. A group educational session was scheduled after 1 month. Technical interventions were performed at the patient's request and during scheduled visits and the impact of each intervention on CPAP therapy compliance was collected.

**Results** Between May 2018 and Dec 2019, 349 patients newly diagnosed with OSA were hospitalized in the sleep lab for CPAP titration and 212 patients were included (mean age 54.6 ± 13.1 years, mean BMI 31.7 ± 5.8 kg/m$^2$, mean AHI 42.8 ± 22.0). TMg acceptance rate was 87%. Mean 6-month compliance was 275 ± 154 min, 13% stopped CPAP, and 17% were non-compliant. Correlations were observed between BMI ($r = 0.15$, $p = 0.029$), median and 95th percentile leaks ($r = -0.23$ and $-0.18$, $p = 0.016$ and 0.002), and CPAP compliance.

During follow-up, 92 interventions were required, mainly for mask change ($n = 80$). Pressure modification ($n = 16$) was the only intervention that increased CPAP use ≥ 30 min/night, $p = 0.021$.

**Conclusion** Pressure modification was the only adaptation that significantly increased CPAP compliance during the first 6 months. Remote TMg allows providing daily, accurate, and immediate feedback that could help clinicians to confirm that the CPAP treatment is effective.

**Keywords** Compliance · Telemonitoring · CPAP · Obstructive sleep apnea · Pressure · Leaks

## Introduction

The prevalence of obstructive sleep apnea (OSA) is increasing and is closely related to the global obesity epidemic.

Continuous positive airway pressure (CPAP) and oral appliances are the most common specific medical therapies for OSA, but CPAP is the most frequently used and effective treatment for moderate and severe OSA. CPAP has been proven to offer a survival benefit in patients with severe disease, to improve sleep quality and health-related quality of life, and to decrease cardiovascular events, such as stroke and myocardial infarction [1, 2].

When treating OSA with CPAP, it is essential to overcome the challenge of obtaining adequate compliance. Compliance is defined as use during at least 4 h/night and for more than 70% of nights [3]. However, on an individual basis, greater compliance is required as the effects of CPAP grow with

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increased use. Longer CPAP use also achieves greater reductions in blood pressure and sleepiness [4].

Bouloukaki et al. [5], in a cohort of 3100 patients on CPAP randomized to intensive vs. standard interventions, confirmed the positive effects of greater CPAP use (6.9 vs. 5.2 h/night) on cardiovascular outcomes, indicating that a regular 5-6 h of use/night is required.

Predictive factors of low compliance have been identified in several studies. Low CPAP use at 1 month and side effects at 1 month are predictors of low 12-month CPAP compliance [6]. Oro-nasal masks, depression, and low effective pressure are also predictors of poor compliance [7]. Indeed, consistent and inconsistent users can be distinguished within the first week, as compliance at 1 month is associated with compliance at 24 months [8].

CPAP devices have evolved and now offer, on a daily basis, accurate data on compliance, mask leaks, residual apneas, and CPAP pressure. Currently, the majority of CPAP devices on the market have wireless built-in connectivity, such that they have the ability to transfer technical data on a daily basis, via a central secured data center (a cloud), to sleep labs or to home care providers. It is also possible to remotely change the settings of the device. The usefulness of telemonitoring (TMg) for caregivers/patients has been now widely reported, but conflicting data remain regarding its impact on CPAP compliance [9, 10].

TMg is now routine care in some sleep labs. The purpose of the present study was to identify interventions and treatment adaptations associated with improved CPAP compliance in a real-life cohort of telemonitored patients with OSA newly treated with CPAP based on a daily CPAP device report, allowing immediate identification of the effects of technical interventions on CPAP use and efficacy.

## Materials and methods

### Design

This was a prospective longitudinal cohort study performed in the sleep unit of the Saint-Pierre University Hospital in Brussels, Belgium (tertiary referral hospital).

### Patients

All newly diagnosed adult patients with OSA treated with CPAP exhibiting an apnea-hypopnea index (AHI) $\geq$ 15/h on a diagnostic polysomnography were included in the study the morning following CPAP titration night. The patients were asked to agree to TMg follow-up in addition to routine clinical follow-up. Eligible patients were aged $\geq$ 18 years old. Exclusion criteria were previous exposure to CPAP, language barrier, and cognitive or psychiatric disorders.

All included patients provided written informed consent to participate in the study. The study protocol was approved by the Saint-Pierre University Hospital ethics committee (CE-18-04-10). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

### CPAP devices and telemonitoring system

Fixed CPAP-pressure devices (AirSense$^{TM}$ 10 Elite, ResMed) were given to the patients. TMg was implemented with the AirView, which is a ResMed's cloud-based patient management solution. Briefly, to summarize the workflow, the medical data collected by device are transmitted via GSM/GPRS network to the data center where it is stored securely. Authenticated users can then access data in the AirView application via the internet. The system allows collecting on a daily basis usage of CPAP, usage pattern, CPAP pressure, leaks (median, maximum, 95th percentile), apnea index (central, mixed, obstructive, unclassified), and Cheynes-Stokes respiration.

### Routine clinical follow-up

After the CPAP titration night, patients were instructed to use the device each night for the whole night. They received written instructions and could contact the sleep technicians (phone call, visit) as often as needed, during weekdays, in order to resolve any current problem interfering with CPAP use. Two routine visits were also scheduled: a group educational session 1 month after CPAP initiation and a visit to the pneumologist 2 months after CPAP initiation. During these visits, CPAP treatment adaptations were also performed when problems were identified.

### Communication with patients and telemonitoring usage

Communication with patients was based on patient request. No contact was proactively taken on the basis of the TMg as the sleep lab technicians did not connect routinely on the AirView application. The TMg was used in the event of a problem reported by the patient, in order to better identify the source of the technical problem, before arranging an appointment at the sleep laboratory for a face-to-face technical intervention.

## Data collection

On the basis of TMg data and the medical file of the patients, we collected data on the number of interventions for each patient, the effect of any technical/educational intervention on CPAP compliance by comparing the compliance during the 14 days before and after intervention, and the attendance to the educational session. Leaks (median and at 95th percentile) and residual AHI (provided by the CPAP device) were also documented.

For each patient contact, several interventions were possible: education, change of mask model, change of mask type (nasal, oro-nasal, nasal pillows), addition of humidification, and pressure modification.

Adequate compliance was defined as CPAP use $\geq$ 4 h/night.

## Statistics

Data treatment and statistical analyses were performed using the Python and SPSS software (version 23.0.0, SPSS, Inc., Chicago, IL).

The aims of the analysis were as follows:

1. Analysis of the baseline characteristics of the patients
2. Analysis of CPAP treatment characteristics at baseline and at 6 months
3. Analysis of the effect of interventions on CPAP compliance
4. Predictive factors of CPAP compliance
5. Identification of the best intervention to improve CPAP compliance

For demographic characteristics, statistical analysis includes descriptive statistics. For continuous variables (age, BMI, and AHI), median, minimal, and maximal values are reported. For qualitative variables (sex, ethnicity), we calculated proportions in percentages.

Descriptive statistics were applied to analyze the CPAP characteristics (pressure, first mask type, chinstrap, humidification) at baseline, interventions during treatment (mask or pressure changes and humidification), and CPAP compliance at 6 months.

To analyze the effect of the intervention on CPAP compliance, leaks, and residual AHI, a paired *t*-test was used to compare the compliance value before (day −15) and after (day +15) intervention.

The initial predictive factors of CPAP compliance at 6 months were tested with the Pearson correlation in case of continuous variables (age, BMI, AHI, CPAP pressure, leaks, residual AHI). For qualitative variables (sex, ethnicity, attendance of educational therapy, mask type), the unpaired *t*-test was applied.

To identify the best intervention, the CPAP compliance before and after intervention was extracted and delta values were calculated (CPAP compliance after–before). The intervention groups with less than 8 subjects were excluded for the statistical analysis. In case of mask change, delta values for leaks and residual AHI were also calculated.

The normal distribution (Shapiro-Wilk test) and the equality of variance (Levene test) were tested. A one-way ANOVA was applied to compare the delta value for CPAP compliance between each intervention.

As each increase in level of CPAP use is considered to result in better outcomes [4, 5], we have considered that an increase of 30 min after intervention was clinically relevant.

Indeed, no minimal clinically important difference is established for increase of CPAP compliance. However, it has been shown that educational or behavioral interventions increase compliance for 35 min to 1h [11–14], leading to significant improvements in daytime sleepiness or subjective sleep quality. An increase of 42 min was shown to reduce Epworth sleepiness score (ESS) [11]. It has been demonstrated that 5.1 vs. 4.7 h of use allows obtaining normalization of ESS and that 5.3 vs. 4.6 h leads to Functional Outcome of Sleep Questionnaire normalization [15]. We can thus hypothesize that an increase of CPAP use of about 24-42 min could make a significant clinical difference for patients.

For each intervention, the subjects were classified with CPAP compliance value > 30 min (=1) or CPAP compliance value < 30 min (=0). To compare the binary CPAP compliance outcome (0/1) between interventions, a Chi-square test was applied together with the Yates correction for 2 × 2 pairwise calculation.

A threshold value of $p<0.05$ was adopted for ruling out the null hypothesis.

# Results

Between May 2018 and Dec 2019, 349 patients newly diagnosed with OSA were hospitalized in the sleep lab for CPAP titration and 212 patients were included. Reasons for non-inclusion were previous exposure to CPAP ($n$ = 20), language barrier ($n$ = 33), cognitive or psychiatric disorders ($n$ = 38), and refusal ($n$ = 46). Patient characteristics are reported in Table 1. At 6 months, 28 patients had stopped the therapy (13%), 24 for intolerance and 4 for improvement. A total of 37 patients were non-compliant but still using the CPAP (17%). Mean compliance was 275 ± 154 min of use/night. The technical aspects of CPAP therapy at baseline and at 6 months are summarized in Table 2.

A positive Pearson's correlation was observed between BMI and 6 months of CPAP compliance ($r$ = 0.15, $p$ = 0.029) and a negative correlation was observed between median and 95th percentile leaks ($r$ = −0.23 and −0.18, $p$ = 0.016

**Table 1** Demographic characteristics of the patients

| Baseline characteristics $n = 212$ | |
|---|---|
| Age (years) (Mean ± SD) | 54.6 ± 13.1 |
| BMI (kg/m$^2$) Mean ± SD | 31.7 ± 5.8 |
| AHI (events/h) Mean ±SD | 42.8 ± 22.0 |
| Sex | |
| Male | 141 (67%) |
| Female | 71 (34%) |
| Ethnicity, $n = 209$ | |
| Caucasian | 146 (80%) |
| Maghrebi | 42 (20%) |
| African | 20 (10%) |
| South-American | 1 (1%) |

*AHI* apnea-hypopnea index, *BMI* body mass index

and 0.002) but no significant correlations were observed for age, sex, ethnicity, attendance to educational session, initial mask choice, baseline AHI, residual AHI, and initial CPAP pressure.

During the 6 months of follow-up, 92 interventions were required at the request of the patient (21 during the first month of treatment) and 49 were performed during educational session. Mask change was the most common intervention and occurred 80 times.

Attendance to the educational session was poor, only 64%. Six-month CPAP compliance did not differ in patients attending or not the educational session ($p = 0.82$). The drop-out rate was also similar in the group that attended the session compared to those who did not attend, 15 vs. 13, $p = 0.2$.

According to the threshold of an increase of CPAP use of $\geq$ 30 min, the result of the Chi-square test showed a significant difference between the different interventions ($p = 0.028$). Pressure modification ($n = 16$, 12 decreases, 4 increases) was the only intervention able to reach this threshold, $p = 0.021$.

When comparing interventions to each other, the interventions were equivalent, except for pressure modification, which was better than change to nasal pillows ($p = 0.017$), to another nasal mask model ($p = 0.014$), to an oro-nasal mask ($p = 0.021$), and to the educational session ($p = 0.001$) (Fig. 1).

Mask change, regardless of the combination (from nasal to oro-nasal, nasal to pillows, nasal to nasal, etc.), did not result in any significant change in median leaks, 95th percentile leaks, or residual AHI.

**Table 2** Descriptive statistics at baseline and 6 months

| | CPAP treatment initial settings ($n = 212$) | Changes during the 6 months FU | CPAP treatment at 6 months ($n = 184$) |
|---|---|---|---|
| CPAP fixed pressure (cm H20) | 10.4 ± 1.5 | | 10.3 ± 1.5 |
| Pressure changes | | $n = 16$ | |
| Mask | Nasal, $n = 191$ | | Nasal, $n = 134$ |
| | Oro-nasal, $n = 21$ | | Oro-nasal, $n = 42$ |
| | | | Pillows, $n = 8$ |
| Mask change, to: | | Nasal, $n = 41$ | |
| | | Oro-nasal, $n = 26$ | |
| | | Pillows, $n = 13$ | |
| Chin strap | 21 | | |
| Humidification | 19 | | 40 |
| Added | | 45 | |
| CPAP downloaded data | | | |
| Compliance (Mean ±SD) | | | 287 ± 137 |
| Residual AHI (events/h) (Mean ±SD) | | | 2.8 ± 3.8 |
| 95th percentile leaks, L/min (Mean ±SD) | | | 17.5 ± 14.5 |
| Median leaks, L/min (Mean ±SD) | | | 3.2 ± 4.6 |

*CPAP* continuous positive airway pressure, *FU* follow-up, *AHI* apnea-hypopnea index

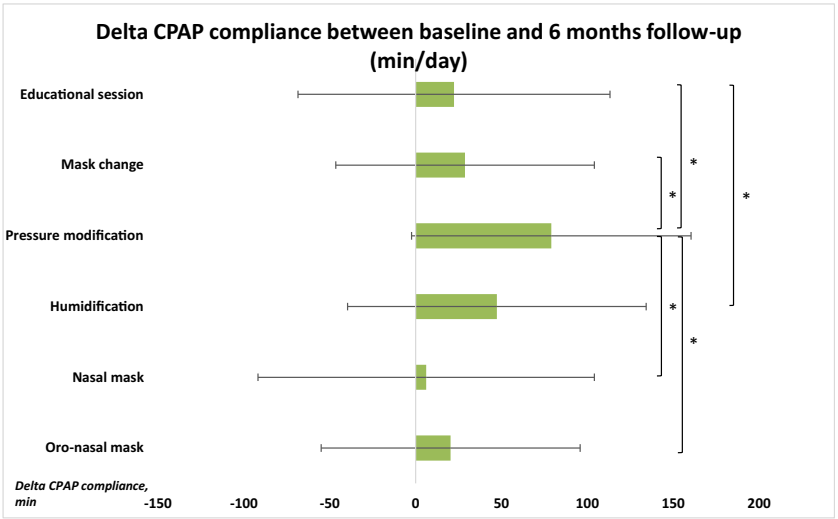


**Fig. 1** Comparison of the impact on CPAP compliance of different technical interventions in telemonitored CPAP-treated patients. *= $p < 0.05$, highlighting significant differences between interventions. CPAP: continuous positive airway pressure

## Discussion

The present study shows, for the first time, in a real-life cohort of telemonitored patients with moderate-to-severe OSA newly treated with CPAP, that the best intervention to improve compliance is pressure modification. Interestingly, education is less useful. Predictors of 6-month compliance were BMI and low leaks. TMg acceptance rate was very good since 87% of patients agreed.

Currently, CPAP titration can be performed at home, with auto-adjusting PAP (APAP), or in the sleep lab, with APAP or CPAP. It is recommended that healthcare providers carefully monitor the clinical response and PAP usage, especially if the titration takes place at home, to make necessary PAP adjustments [16]. As shown in the present study, this is also necessary when titration is performed in the sleep lab, as pressure requirements can evolve during the first days/weeks of use at home, according to treatment adaptation, alcohol consumption, body position, and also to the progressive decrease of upper airway inflammation [17]. It has also been shown that higher CPAP pressure is associated with greater compliance [8, 18, 19], such that it is important to start with correct effective pressure when patients are treated with CPAP. In our study, the mean fixed pressure was similar to other large studies [20], resulting in low residual AHI. However, this needed to be adapted, by both decreases and increases, in 7.5% of patients, with subsequent significant compliance improvements. Routine use of TMg in these patients could be reassuring as residual AHI can be remotely monitored to ensure that pressure adjustment resulted in effective treatment.

Regarding other interventions, humidification was used in 30% of patients, started immediately after CPAP titration or during the first 6 months of treatment. However, humidification addition did not result in greater CPAP compliance in all patients, as shown by the large range of responses. Although some studies have shown improved compliance with humidification [21], others did not [22]. However, humidification is certainly useful in a small subset of patients in order to decrease nasal inflammation and associated symptoms [23].

We have also shown that there was no significant influence of mask change, mask type, or mask choice on CPAP compliance. Mask change was obviously necessary in an important proportion of our patients in order to increase comfort and to reduce side effects, but it was, overall, not associated with improved/decreased compliance or in any significant modifications in leaks or residual AHI. Similar findings have been reported by Rowland et al. in severe patients with OSA [24]. In contrast to previous studies [7], the use of oro-nasal mask was not associated with poor compliance in our patients. In randomized controlled studies, nasal mask has not been proven to be associated with better compliance compared to oro-nasal mask [16, 25].

Nasal mask use is also associated with fewer residual apneas, fewer leaks, and lower effective pressure [26]. However, in the current study, mask change did not result in significant changes in residual apneas and leaks, but more leaks were associated with poorer 6-month compliance, as previously demonstrated [27]. In clinical practice, this means that regardless of the initial type of mask (nasal or oro-nasal), technicians and clinicians should focus on controlling leaks from the start of treatment. However, they should not be afraid of the influence of changing the mask in case of discomfort: There is no negative impact on the effectiveness compliance to treatment.

In the present study, OSA severity was not shown as a predictor of 6-month compliance. Inconsistent data have been reported regarding the influence of the severity of OSA on compliance, with negative [8, 28, 29] and positive associations [30–32].

Disappointingly, the educational session was not well attended and did not improve compliance, contrary to findings in recent reviews [10, 13]. However, this may be explained by a couple of different factors, including the fact that the education was already performed during in-lab titration polysomnography in all the patients, and during each patient's contact for technical intervention. We must therefore question the patient's care path in our center. It

would appear useful to optimize the therapeutic education before the CPAP titration and to eliminate the group therapy education session scheduled 1 month after the initiation of treatment.

TMg acceptance rate was very good since 87% of patients agreed. However, previous studies reported an important rate of acceptance of TMg, 77% [33] with 78% still telemonitored 10 months later despite the fact that 40% considered the TMg as intrusive. The difference with the present study was a regular check of the TMG data with a proactive contact taken with the patient in case of problem that can be considered "intrusive". Other researchers have assessed patient's satisfaction in TMg CPAP patients compared to standard care. Although satisfaction was high in both group, it was even better in the standard care group [34]. This aspect should be further studied, mainly with regard to long-term follow-up.

Finally, despite the interest of TMg in  of patients with OSA, its implementation remains limited. There are still unresolved issues regarding the security and privacy of TMg, reimbursement, cost-effectiveness, responsability, safety, and patient's acceptance. Indeed, 13% of patients refused TMg in the present study. The key and complex question is also what is the best way to use TMg. Do we have to use it proactively with regular checks of CPAP parameters? What should be the ideal frequency? Do we have, as in the current study, to use it solely to support patient's requests? and to confirm, during the days following intervention, that changes are appropriate?

## Limitations of the study

This is a longitudinal cohort study lacking a control group to assess accurately the specific impact of TMg in patients newly treated with CPAP. Also, patient's satisfaction of TMg and quality of life were not addressed in the present study. Further controlled study needs to be conducted, including patient-reported outcome measures.

In conclusion, remote TMg of patients newly treated with does not affect the type of interventions needed to improve CPAP compliance but TMg allows providing daily, accurate, and immediate feedback that could help clinicians to confirm that the CPAP treatment is effective. This seems interesting, especially when CPAP pressure modifications are made, as this intervention was the most useful adaptation to increase CPAP compliance during the first 6 months of therapy in the present study.

However, usefulness of TMg is still controversial and adequately powered well-designed controlled trials are needed to further explore the validity, generalizability, and cost-effectiveness of this CPAP follow-up care path.

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**Author contribution** SC and MB collected the data; SC, AVB, and MB performed data analyses and prepared the manuscript and approved the final version of the manuscript.

**Data availability** **The data are available on request addressed to the corresponding author.**

## Declarations

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

**Conflict of interest** The authors declare no competing interests.

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