Accuracy of an Unattended Home CPAP Titration in the Treatment of Obstructive Sleep Apnea

F. SÉRIÈS
Unité de Recherche, Centre de Pneumologie, Hôpital et Université Laval, Québec, Canada

Treatmen of sleep apnea–hypopnea syndrome (SAHS) by fixed continuous positive airway pressure (CPAP) requires an in-laboratory titration procedure to determine the effective pressure level (Peff). We recently reported that one auto-CPAP machine can be used without titration study allowing Peff determination. The aim of this study was to evaluate the accuracy of an auto CPAP trial at home. A 1- or 2-wk automatic CPAP trial was done at home in 40 patients by estimating the reference pressure (Pref) to be set and a Pref + 3 cm H₂O/–4 cm H₂O pressure interval. Peff was then determined according to the percentage of CPAP time that was spent < Pref. This Peff value was set on a fixed CPAP machine for two additional weeks and a control sleep study was done. The pressure setting on fixed CPAP had to be increased by 1 ± 1 cm H₂O (mean ± SD) above estimated Pref. Sleep improved with fixed CPAP, with a normalization of the apnea–hypopnea index (AHI) in 38 of 40 and resumption of diurnal hypersomnolence. CPAP compliance remained excellent (CPAP use: 6.1 ± 1.7 h/night) after 6.5 ± 2.8 mo of CPAP treatment. These results indicate that auto-CPAP therapy represents a new useful and accurate way to identify conventional CPAP setting outside hospital and sleep laboratories.

Obstructive sleep apnea–hypopnea syndrome (SAHS) is highly prevalent in the middle-aged active population (1). It significantly interferes with quality of life (2) and is associated with an increase in morbidity and mortality (3). It is currently admitted that nasal continuous positive airway pressure (nCPAP) represents one of the most effective treatments for SAHS. The determination of the effective pressure level (Peff) is realized during a titration sleep study that is routinely achieved during in-laboratory sleep studies and consists of the continuous acquisition of electrophysiologic, ventilatory, and respiratory efforts and transcutaneous SaO₂ characteristics. Peff corresponds to the pressure level that abolishes obstructive apnea and hypopnea and sleep fragmentation related to flow-limited breaths in every sleep stage and body position. In expert hands, this procedure can also be realized automatically outside sleep laboratories during in-hospital recordings using auto-titrating continuous positive airway pressure (CPAP) machines that allow a continuous self-adjustment of the positive pressure level to the required needs (4).

Even if obstructive breathing disorders are theoretically abolished at the end of the CPA P titration night, this procedure only provides useful information on the Peff level during one single night in a dedicated environment. However, other factors such as body length or neck position, weight changes, and nasal obstruction may further contribute to modify Peff (5–7). One way to bypass these intra-night and night-to-night changes in Peff is to use automatic CPAP machines at home (8, 9). However, up to now the identification of patients who will benefit from these new devices compared with conventional CPAP remains unknown, making constant CPAP the standard treatment mode in the majority of patients with SAHS. However, considering that sleep conditions during the titration sleep study may significantly differ from those encountered at home and do not take into account the night-time variability in the Peff level, an ideal CPAP titration procedure should be based on a CPA P titration trial conducted at home during several nights.

We have recently reported that one of the first-generation auto-CPAP machines (M orphée Plus/Cloudnine, Pierre Médi-cal/Nelcor Puritan Bennett, Minneapolis, MN) can be used without titration sleep study by estimating the pressure around which the machine is constantly tuning to identify the minimal effective pressure level (reference pressure: [Pref]) (10). In these circumstances, the ability of the device to decrease the positive pressure level below Pref decreases with increasing Pref underestimation, with a negative relationship between the percentage of CPA P time = Pref and the difference between Peff and Pref. A according to this relationship, one could determine Peff by measuring the percentage of CPA P time spent below Pref for a given estimated Pref value. We reasoned that the aforementioned relationship could be used to determine the adequate setting for fixed CPA P therapy after an automatic CPA P trial at home for several days without need of an in-hospital titration sleep study. We therefore designed a study to evaluate the accuracy of such a procedure to determine the positive pressure level setting for fixed CPA P therapy using the M orphée Plus/Cloudnine machine at home during 1 or 2 wk in newly diagnosed, untreated patients with SAHS.

METHODS

Subjects
Forty-two untreated consecutive patients with SAHS (age range, 37 to 66 yr) who were willing to undergo CPA P therapy as a treatment for their sleep disorder were included in the study. The only inclusion criterion was that they were living within 100 km from the hospital. Each patient had a baseline polysomnographic study to confirm clinical diagnosis (see Data and Statistical Analysis for details). The review board of our institution accepted the protocol and an informed consent form was obtained from each participating subject.

Protocol
A subjective assessment of diurnal hypersomnolence was done using the E pworth sleepiness score (11). Figure 1 illustrates our study design. After the baseline polysomnographic study, Pref was estimated according to the formula: Pref = 0.193 + body mass index (BMI) + 0.077 + neck circumference + 0.020 * apnea + hypopnea index (AHI) – 0.611. This formula differs slightly from that we previously used (9) but was prospectively validated in 50 consecutive patients previously investigated in our laboratory using our standard recording and interpretation methods. To evaluate the effect of the home titration duration on the accuracy of this titration procedure, patients were randomly allocated to a 1- or 2-wk home automatic CPA P trial, the two groups being paired (± 1 cm H₂O) for the estimated value of Pref. The automatic CPA P setting was then fixed to +3 cm H₂O above and –4 cm H₂O below the estimated Pref. All patients were non-smokers and treated for their sleep disorder were included in the study. The only inclusion criterion was that they were living within 100 km from the hospital. Each patient had a baseline polysomnographic study to confirm clinical diagnosis (see Data and Statistical Analysis for details). The review board of our institution accepted the protocol and an informed consent form was obtained from each participating subject.

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Séries: Home Auto-titration in SAHS

Auto-CPAP setting: reference pressure (Pref)

\[
\text{Pref} = 0.193 \times \text{body mass index} + 0.077 \times \text{neck circumference} + 0.02 \times \text{apnea} + \text{hypopnea index} - 0.611 \text{ and Pref} - 4 \text{ to Pref} + 3 \text{ cm H}_2\text{O pressure limits}
\]

1 week  Home Auto-CPAP therapy  2 weeks

Download Auto-CPAP pressure level information
Determination of the effective pressure level (Peff):

Peff = Pref - 0.056 \times \% \text{CPAP time} \leq \text{Pref} + 4.479

Fixed CPAP set at Peff for 2 weeks

Control PSG with fixed CPAP at Peff setting

Clinical follow-up at 3 to 13 months

H\textsubscript{2}O below the estimated Pref. CPAP installation, determination of the adequate size of nasal mask, and demonstration of the procedures to operate the machine and install the mask were made by a home care company (Vital Aire, Québec, Canada). In 17 patients, a heated humidifier was prescribed within the first days of treatment owing to nasal congestion and stuffiness secondary to CPAP use. In these patients, the pressure setting was adjusted so that the mask pressure corresponded to the prescribed pressure value when using the humidifier circuit.

At the end of the automatic CPAP trial, patients brought their machine back to the home care company, and a print-out of the night-by-night characteristics of positive pressure delivery was obtained. This chart provides the time during which a positive pressure was applied and the percentage of this time spent at the different pressure levels. According to these data, the investigator (F.S.) determined the percentage of CPAP time that was spent at or below Pref. Using the previously validated relationship that exists between the time spent at or below Pref and estimated Peff, it is possible to determine Peff according to the formula:

\[
\text{Peff} = \text{Pref} - 0.056 \times \% \text{CPAP time} \leq \text{Pref} + 4.479
\]

This formula was validated in 21 subjects, nine being added to our previously published results (9). This new pressure level was set on a conventional fixed CPAP machine for two additional weeks and a control sleep study was done while using their CPAP machine at the end of the study period. A new assessment of diurnal sleepiness with the Epworth sleepiness score was obtained.

A follow-up visit was obtained after 3 to 12 mo of CPAP therapy to determine the number of patients who were still using the machine and to estimate CPAP observance by measuring the difference in time counter hours from the beginning of treatment.

Data and Statistical Analysis

Sleep (electroencephalogram [EEG], electro-oculogram [EOG], submental electromyogram [EMG], anterior tibialis EMG) and respiratory variables (nasal flow, thoracoabdominal movements, transcutaneous Sa\textsubscript{O\textsubscript{2}}, breathing noise) obtained during the baseline and control CPAP polysomnographic studies were analyzed manually according to standard criteria (12–14). For the CPAP sleep study, breathing disorders were scored on the instantaneous flow tracing provided by a pneumotachograph (Hamilton Medical flow sensor, ViaNova, Switzerland) connected to the nasal mask. Comparison of the two groups' characteristics at baseline values were compared by an unpaired t test. To compare the changes obtained in the 1- and 2-wk auto-CPAP groups, a repeated analysis of covariance with baseline data as covariate was performed. The α level was set at 0.05. Data were analyzed by using the SA S statistical package (SA S Institute, Inc., Cary, NC).

RESULTS

The CPAP trial was interrupted during the home auto-CPAP trial in two subjects owing to incapacity to wear the mask (claustrophobia) in one, and to the wife's complaints concerning CPAP treatment requirements in the other. We will therefore present the data obtained in 40 subjects. Characteristics of the patients are reported in Table 1. No difference was found in any of these variables between the two groups. No subject experienced any difficulty in initiating CPAP treat-

Figure 1. Schematic representation of our study design.

Figure 2. Correlation between the percentage of positive pressure time that is spent at or below the Pref and the difference between the measured Peff and Pref. There is a significant negative relationship between these variables.
ment. Treatment compliance was high during the home titration phase as assessed by the number of hours the machine was used (6.6 ± 1.5 h/night) and the number of hours a positive pressure was applied (5.9 ± 1.4 h/night) during this study period. No significant difference in these parameters was found between the 1- and 2-wk auto-CPAP titration groups. The percentage of CPAP time that was spent below estimated Pref measured at the end of this home titration phase was 63.8 ± 13.0%. The number of patients corresponding to each amount of pressure change calculated according to the previously described relationship between the percentage of CPAP time and the difference between estimated Pref and the constant pressure level to be set is represented in Figure 3. For the whole group, the mean calculated pressure setting was 1 ± 1 cm H$_2$O higher than estimated Pref. This new pressure level was set on a fixed CPAP machine for two additional weeks. There was no dropout during this second part of the study.

The changes in sleep and respiratory variables and in subjective daytime sleepiness are described in Table 2. A significant improvement was observed in each of these parameters (sleep architecture, sleep fragmentation, AHI, nocturnal desaturation). The AHI normalized (< 10/h) in all but two subjects. In the first one, the calculated pressure setting was 10 cm H$_2$O. His AHI was 15.2h, apneic and hypopneic events being essentially central in nature. We asked this patient to interrupt CPAP therapy for 1 wk to realize a conventional sleep study. Peff level measured during this titration night was 9 cm H$_2$O but central events were even observed at this pressure level, which was the optimal one to abolish induced obstructive breathing disorders. In the other subject, the AHI was 35/h (obstructive events). It was retrospectively found that his auto-CPAP machine was unfortunately damaged during the first home CPAP trial, and that this interfered with the ability of the compressor to adequately adapt the positive pressure level. The arousal index with CPAP was 15.9 ± 6.7/h and the frequency of respiratory-related arousals was normal (< 15/h) in all patients but the two subjects whose AHI remained abnormal (9.4 ± 9.4 n/h). The Epworth sleepiness score significantly improved (Table 2), the score going down to normal values (< 10) in 33 subjects. In the seven others, three had sleep fragmentation because of periodic leg movements, two because of persisting sleep apneas, the sleep study being normal in the other two.

Patients were seen at follow-up after 6.5 ± 2.8 mo of CPAP treatment using the pressure setting determined during the auto-CPAP trial. Thirty-six of them were still on CPAP (two stopped CPAP therapy because the machine was too cumbersome, one because of pressure discomfort, and one owing to financial considerations). Symptom relief was still present in each of them. The number of hours the machine was turned on from the beginning of fixed CPAP therapy was 6.1 ± 1.7 h/night.
with mask leaks or mouth breathing), and to analyze the positive pressure trend to determine the effective pressure level. Such expertise is not required in the algorithm of effective pressure determination that is described in the present study. In fact, determining Peff only requires (1) estimating the reference pressure to be set on the M orphée Plus/Cloudnine machine (using the formula with BMI, neck circumference, and AHI values); (2) measuring the percentage of CPA P time that was spent below Pref during the home CPA P titration period; and (3) correcting for Pref estimate according to the percent CPA P time \( \approx \) Pref/Peff–Pref relationship. These different steps could be done automatically by the auto-CPA P machine with a dedicated program.

Besides the efficacy of this titration procedure after 2 wk of fixed CPA P therapy, the present results provide very important information on the feasibility of CPA P treatment without in-hospital recording in patients whose first experience with this treatment was done at home without any on-line recording or attending by specialized personnel. Furthermore, our results demonstrate that this strategy does not alter treatment compliance during the initial titration period, neither during conventional CPA P therapy for both short- and long-term treatment periods, because CPA P therapy was accepted by 86% of patients at the control visit. The proposed home titration procedure is simple, requiring only good training of patients by the home care company; according to this strategy, a simple computer analysis of positive pressure changes during the trial allows a determination of the fixed pressure level to be set at home. From our data, a 1-wk trial is as efficient as a 2-wk period to determine Peff.

As previously mentioned, Peff corresponds to the pressure level that abolishes obstructive respiratory events and sleep fragmentation related to flow-limited breaths. It could be argued that the home titration procedure that we propose could be imperfect because the apparatus that we used only detects and corrects apneic and hypopneic events but does not identify flow-limited breaths. This potential drawback is compensated by the relationship that is used to calculate Peff according to the percentage of positive pressure time spent \( \approx \) Pref because in the patients in whom the formula was validated, Peff was determined during a conventional titration sleep study and therefore met the ideal Peff measurements criteria.

It can be asked if our procedure to determine Peff could be improved by further tuning of our formula to estimate Pref (i.e., increase Pref by 1 cm H\(_2\)O, which is the average difference between Peff and Pref in our study population). We believe that this will not bypass the need for an auto-CPA P trial because improving Pref accuracy (i.e., mean pressure change \( \approx \) zero in a given patient population) would mean that an equal number of subjects need an increase or a decrease in their pressure setting. Therefore, Peff determination will still have to be checked by the home auto-CPA P trial.

The results of this study should have important practical repercussions on the way CPA P treatment is initiated in obstructive sleep apnea patients. A short auto-CPA P trial at home for 1 or 2 wk could be proposed by home care services before setting fixed CPA P therapy. However, it is particularly important to be aware that the algorithm of Peff determination that we have validated cannot be applied to other auto-CPA P devices that have different pressure limits and pressure responses criteria that should obviously modify the relationship that is used to determine Peff. A nother important clinical issue arising from our results is that auto-CPA P titration at home must be accompanied by a strict follow-up of these patients. In those whose clinical response is not optimal, a control polysomnographic study with the determined pressure setting should be done to distinguish between inadequate pressure setting and other causes of persisting hypersomnolence (periodic leg movements, idiopathic).

We conclude that auto-CPA P therapy represents a new useful and accurate way to identify conventional CPA P setting outside hospital and sleep laboratories, and that CPA P titration procedures should be realized in patients in whom this strategy had failed.

References