

Objective measurement of compliance with nasal CPAP treatment for obstructive sleep apnoea syndrome

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ABSTRACT: Compliance with nasal continuous positive airway pressure (CPAP) has become a major concern, since this treatment is efficacious, but constraining. In 46 consecutive obstructive sleep apnoea (OSA) patients, we measured compliance with nasal CPAP by establishing a mean rate of use, with a built-in time counter read at three-month intervals, over a mean follow-up period of 232 ± 27 days. The mean rate of use in the whole group was 5.14 ± 0.31 hours per day. The acceptance rate was 90.9-93.2%, showing that patient acceptance is not a limitation in the use of nasal CPAP.

Eur Respir J. 1988, 1, 436-438.

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Keywords: CPAP; sleep; sleep apnoea syndrome.

Received: August 7, 1987; accepted December 22, 1987.

Obstructive sleep apnoea syndrome (OSA) is a life threatening condition characterised by the occurrence during sleep of repeated respiratory arrests due to upper airway occlusion. Traffic and work accidents due to daytime somnolence, cardiac arrhythmias, systemic hypertension leading to ischaemic brain and heart attacks, as well as pulmonary hypertension and possible cor pulmonale are the main complications which account for the seriousness of the disease and have justified various attempts at therapy.

Among these, nasal continuous positive airway pressure is invariably efficient [1, 2] in that it always eliminates obstructive apnoeas during sleep. However, because of the constraints due to the wearing of a nasal mask during sleep, it has been claimed that the main limitation of this treatment is its poor acceptance [3]. Recent studies have reported acceptances of 75 to 90% [4, 5]. However, the estimation of acceptance in these studies relies on the patients' reports of how and to what extent they used their CPAP device; these reports may be inaccurate because of an over-evaluation by the patients. Therefore, we seized the opportunity of the presence of an in-built time counter in the CPAP device used by our patients (Pression +, SEFAM, Nancy, France) to calculate a daily rate of use as an objective measure of treatment acceptance.

Subjects and methods

The reported data were obtained from 48 patients on home treatment for OSA diagnosed by an initial

polysomnographic recording. Their mean (\pm SEM) age was 55.6 (± 4.3) years. Their apnoea index before treatment was 55.2 (± 1.7) apnoeas per hour's sleep.

Every three months these patients were sent a questionnaire concerning possible difficulties encountered in the use of their device and asking them to give the reading of the built-in time counter, which measured the time during which the CPAP unit was running. Periodic visits by the technicians who serviced the device permitted a check of the indicated values and made a 100% response rate possible. Two patients living in a remote area, for whom these data were not available, were dropped from the study.

Since in five patients the treatment had been initiated with a device which did not include a time counter, the follow-up was somewhat shorter (232 ± 27 days; range 13-345) than the treatment duration (298 ± 43 days; range 13-1200).

In thirteen patients the follow-up period was less than three months, and thus, only one evaluation was available. The data for the remaining 33 patients were based on 120 evaluations.

Results

One patient interrupted her treatment before the first evaluation was performed. This patient suffered from severe rheumatoid arthritis which confined her to bed. Although her daytime sleepiness improved, she could not cope with long-term home treatment.

For the remaining 45 patients, the mean rate of use over the whole follow-up period was 5.14 ± 0.31 hours per day. Among the 32 patients for whom more than one evaluation was available, the mean rate of use was 4.98 ± 0.37 hours per day for the whole follow-up period and 5.37 ± 0.40 hours per day for the last

Part of these data (35 patients) was presented at the International Symposium 'Sleep in medical and neuropsychiatric disorders' (Milan, 1987) and will be published in abstracted form in the proceedings of the Symposium.

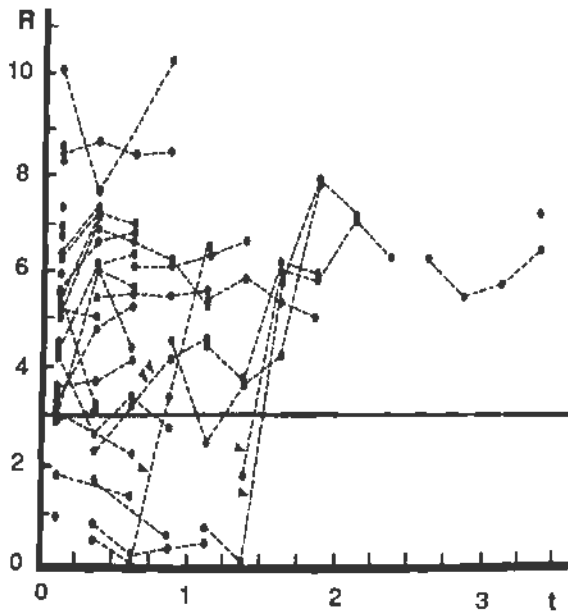


Fig. 1. Rate of use (R, hours per day) over time (t, treatment duration, years) in 46 OSA patients. Each patient is represented by the successive values of the rate of use of his CPAP device over the follow-up period. The rate of use was calculated as the difference between time-counter readings at three month intervals, divided by the corresponding number of days.

three-month period ($p < 0.05$), indicating that globally the rate of use increased with time.

Figure 1 shows the increase in rate of use over time: apart from fluctuations related to interruptions due to vacations or hospitalizations unrelated to OSA, four patients exhibited progressive ($n=1$; \blacktriangledown \blacktriangledown) or sharp ($n=3$; \blacktriangledown) increases in rate of use. These were due either to a progressive adaptation to the constraints of CPAP therapy, or to a modification of the material used, in particular, an improvement of the nasal mask.

Comparison of the responses to the questionnaire indicated that the patients who used their device more than 3 hours per day did not mention any difficulties in its use.

Therefore, we chose to further examine the five patients whose mean rate of use over the whole follow-up period was less than three hours. One of these patients had low rates of use for the first three quarters, during which he did not reply to calls for further interviews; when finally reached, it appeared that he had domestic problems, the resolution of which, together with a change in nasal mask, led to an increase in rate of use to 3.4, then 6.6 hours per day. The four remaining patients had constantly low rates of use over the whole follow-up period. Two of them had severe chronic obstructive lung disease associated with OSA, which required repeated hospitalizations during the observation period. Since they used a device different from their own while hospitalized, the measured rate of use was spuriously low; these two patients were considered as drop-outs. Another

patient did not tolerate the nasal mask due to a cutaneous reaction, probably allergic in nature. Finally, in one patient, the low rate of use remained unexplained. The last two patients, and the one who interrupted treatment early on, constitute the three non-acceptance cases in the remaining 44 patients (6.82%).

When these five patients with a mean rate of use below three hours per day were left out of the analysis, the mean rate of use was 5.58 ± 0.28 hours per day over the whole period and 5.81 ± 0.23 hours per day for the last evaluated three-month period.

Among the thirteen patients for whom only one evaluation was available, all but one had a mean rate of use above three hours per day. According to the pessimistic hypothesis that this patient will not ultimately adapt to his device and increase his rate of use, the non-acceptance rate would be 9.09% (4 out of 44 patients).

Discussion

The present study is the first report of an objective measurement of compliance with nasal CPAP treatment for OSA.

Counter time may not actually reflect time of use, since patients may have removed their CPAP mask during the night and left their unit running; this is unlikely, since patients had been instructed not to do so, and because the CPAP device is very noisy when not connected to the patient; thus, the difference between counter time and time of use can be estimated to be minimal. Therefore, we consider the data from the present study more reliable than those obtained from questionnaires.

The acceptance rate of 90.9–93.2% demonstrated in this study, confirms previous results relying on the patients' statements [4, 5] and shows that the acceptance of CPAP home-treatment is not a limitation to its use.

Clearly, the factor limiting the acceptance of nasal CPAP is the discomfort due to the nasal mask, since for three out of four patients in whom the rate of use increased during the follow up this increase followed an improvement of the nasal mask.

A cut-off level of the rate of use of three hours per day for a good acceptance may appear to be low. However, this choice may be justified. The patients with a mean rate of use above three hours declared themselves to have had no trouble with the use of their device and to have been satisfied with the improvement they felt; actually, the mean rate of use among this group of patients was 5.58 hours per day, far above the cut-off level. This mean rate of use includes discontinuous use in some patients, due either to forced interruptions (travel, especially by train or plane, during which the size and weight (17 Kg) of the device precluded its being taken along) or to interruptions by choice for 'treatment holidays'.

Further evaluations will be necessary to determine whether, beyond the subjective improvement, the

improvement in objective symptoms of the disease (objective sleepiness, cognitive impairment, systemic hypertension, daytime blood gases, pulmonary hypertension) is related to the rate of use. Such a demonstration would prompt us to encourage our patients to maximise the use of their device. These studies are currently in progress, the data available from our patients being too scarce to draw any conclusions at the present time.

In addition to providing accurate information on the actual use of the device by patients, a built-in time counter permits early recognition of low rates of use. This leads to early examination of the causes of low use, and the solution of problems, whenever possible. This early intervention is probably a factor in improved acceptance.

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RÉSUMÉ: L'acceptation du traitement par la pression positive continue (PPC) est devenue une préoccupation majeure, puisque ce traitement est efficace, permettant toujours la suppression des apnées au cours du sommeil, mais représente une contrainte non négligeable. Des études antérieures de l'acceptation du traitement reposent sur les indications fournies par les patients, sujettes à caution. Dans ce travail, chez 46 patients traités à domicile pour un syndrome d'apnées du sommeil à apnées obstructives, l'acceptation est évaluée objectivement grâce à un compteur horaire, lu à intervalles de trois mois; la durée moyenne d'observation a été de 232 ± 27 jours. Le taux moyen de fonctionnement de l'appareil dans l'ensemble du groupe a été de $5,14 \pm 0,31$ heures par jour. Le taux d'acceptation du traitement était de $90,9 \pm 93,2\%$, indiquant que l'acceptation ne constitue pas un obstacle à l'utilisation du traitement par la PPC dans les syndromes d'apnées du sommeil.