Effectiveness of Continuous Positive Airway Pressure in Mild Sleep Apnea–Hypopnea Syndrome

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The aim of this trial was to evaluate the effectiveness of continuous positive airway pressure (CPAP) in patients with mild sleep apnea–hypopnea syndrome (SAHS). One hundred forty-two consecutive patients with mild SAHS (apnea–hypopnea index 10–30, without severe sleepiness) were randomly assigned to receive conservative treatment (CT)—sleep hygiene and weight loss—(65 patients) or CT plus CPAP (77 patients), and 125 patients (86% males, age: 54 ± 9 yr, BMI: 29 ± 4 kg/m^2, AHI: 20 ± 6, ESS: 12 ± 4) completed the follow-up. The following outcomes were assessed at inclusion and after 3 and 6 mo of treatment: sleepiness (Epworth scale, multiple sleep latency test [MSLT]), other symptoms related to SAHS, cognitive function, and perceived health status (Functional Outcomes of Sleep Questionnaire [FOSQ], Nottingham Health profile). The relief of SAHS-related clinical symptoms was significantly greater in the CPAP group than in the CT group; the Epworth scale and FOSQ also showed more improvement in the CPAP group but did not reach significance. There were no significant differences in the other tests performed probably because the baseline values were normal. CPAP compliance was 4.8 ± 2.2 h and treatment continuation was accepted by 62% of the patients at the end of the study. These results suggest that CPAP can be considered in treating patients with mild SAHS on the basis of an improvement in symptoms.

Keywords: mild SAHS; CPAP treatment; clinical questionnaires; health status

Sleep apnea–hypopnea syndrome (SAHS) is a common clinical disorder affecting 2–4% of the adult middle-aged population. Nasal continuous positive airway pressure (CPAP) is the treatment of choice for this disorder (1). CPAP acts as a pneumatic splint by stabilizing the upper airway, thereby preventing its periodic collapse during sleep. As a consequence, the respiratory events and sleep fragmentation occurring in these patients during the night disappear, and normal sleep architecture is restored with clinical improvement in symptoms attributed to SAHS.

The effectiveness of CPAP has been assessed in controlled nonrandomized as well as in controlled randomized studies (2–6). However, these studies included mainly patients with moderate–severe SAHS. The effectiveness of CPAP in mild cases remains controversial and the degree of severity at which patients benefit from this treatment is unclear.

Recent studies have indicated that even minor degrees of sleep-disordered breathing are associated with increased risk of complications, such us hypertension (7), cognitive deficits (8), low quality of life (9), excessive daytime sleepiness, and road traffic accidents (10). This evidence suggests that patients with mild illness could also benefit from this treatment. However, the best treatment in these cases remains to be demonstrated. Only a small number of controlled studies have evaluated the effectiveness of CPAP in mild SAHS (11–13). Their results indicate some beneficial effects of CPAP in the short term compared with placebo or conservative measures, but further information is needed to improve our understanding and justify therapeutic decisions for the subgroup of less severe patients.

Our purpose was to evaluate the effectiveness of CPAP in a large group of patients with mild SAHS in the long term. To this end, we conducted a multicentric, prospective, randomized, controlled trial to compare the effect of conservative measures with that of conservative measures plus CPAP in SAHS-related clinical symptoms, daytime function, cognitive performance, and self-perceived health status, at 3 and 6 mo.

METHODS

Subjects and Design

Patients referred on suspicion of SAHS were recruited from six sleep clinics in Spain. All of them had mild SAHS, defined as an apnea plus hypopnea index (AHI) between 10 and 30 recorded during a full, standard polysomnography, and absence of severe daytime sleepiness in accordance with the ASDA criteria (14). Exclusion criteria were as follows: apnea index greater than 20 (to make an allowance for treating patients with a known increased mortality [15]), hazardous jobs (drivers or those who handle dangerous machinery), notable cardiovascular disease, and conditions that may affect cognitive or quality of life evaluation: severe neurological or psychiatric disease, severe chronic disease, or illiteracy. The protocol was approved by the Human Ethics committee of each hospital and informed consent was obtained from all patients.

Randomization was performed with a computer-generated allocation schedule restricted by center. Consecutive individuals were assigned to two different groups: group I followed a program of conservative measures consisting of weight loss program following a home diet, if their body mass index (BMI) was > 27 kg/m^2; avoidance of sedatives and alcohol consumption; avoidance of supine position during sleep; and adequate hours of sleep every night. Group II received in addition treatment with CPAP. Full polysomnography for CPAP titration was performed following the baseline evaluation, after which the patients were instructed on the use of CPAP and alerted to the possible side effects. All the patients in both groups had a follow-up through appointments at 15 d and 1, 3, and 6 mo at the outpatient clinic to encourage patient compliance. Moreover, they were supplied with a telephone number to contact the medical team in case of questions.

(*Received in original form August 3, 2000 and in revised form May 2, 2001*)

Supported in part by grants 98/0055-01 from the Fondo de Investigaciones Sanitarias (FIS) de la Seguridad Social, and the Sociedad Española de Neumologia y Cirugia Toracica (FEPAR-Cooperación interterritorial 1996). Silvia Vidal is a 1999 Predoctoral Research Fellow at the Ciutat Sanitària i Universitària de Bellvitge. Anna Navarro is a 1997 Predoctoral Research Fellow at the Ciutat Sanitària i Universitària de Bellvitge.

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This article has an online data supplement, which is accessible frolm this article's table of contents online at www.atsjournals.org

Am J Respir Crit Care Med Vol 164. pp 939–943, 2001
Internet address: www.atsjournals.org

Assessments

All patients were evaluated at inclusion and after 3 and 6 mo of treatment through different self-administered questionnaires and a battery of cognitive tests for measuring the following domains.

SAHS related symptoms. We applied a shortened version of the SAHS-related symptoms questionnaire developed by Ballester and coworkers (4, 6) that has proved to be valid and sensitive to change after CPAP treatment. It contains eight items that evaluate the frequency of SAHS symptoms: snoring, breathing pauses, nocturia, choking, morning headache, nonrestorative sleep, morning drowsiness, and concentration difficulties. The possible answers are scored as follows: never = 1, rarely = 2, sometimes = 3, frequently = 4. The results range from 8 (absence of symptoms) to 32 (maximum symptomatic patient).

Sleepiness. Sleepiness was evaluated by means of the Epworth sleepiness scale (ESS) (16, 17) using the cross-culturally valid Spanish version (18). In a subgroup of patients who were all the patients from one of the centers (Hospital Txagorritxu) the multiple sleep latency test (MSLT) (19) was also performed (n = 40; 20 in group I and 20 in group II).

Perceived health status and quality of life. These were evaluated through a generic instrument, the Nottingham Health Profile questionnaire (NHP) (21, 22), and a specific questionnaire (20) to assess the impact of excessive sleepiness on everyday activities, the Functional Outcomes of Sleep Questionnaire (FOSQ), which was validated to Spanish (18).

Cognitive function. Cognitive function was assessed by an extensive neuropsychological battery administered at the same time of day in each evaluation (9:00 A.M.) by a trained psychologist who was blinded (23–27) (*see* Table 2).

Body weight, office daytime arterial blood pressure, CPAP pressure and compliance (monitored by the time clocks on the CPAP units), and side effects were also recorded. After 6 mo of treatment, polysomnography was repeated in all patients (with CPAP at pressure prescribed throughout the night in group II) and these were asked whether they wished to continue with the treatment or choose another option.

Statistical Analysis

The trial was estimated to require 150 patients, 75 in each group of treatment, based on the following assumptions: an expected improvement in ESS defined as 2 points with a standard deviation of 3.3 (16), 15% of patient loss at follow-up, and a statistical power of at least 90% at a significance level of 5%. The Mann-Whitney *U* test, *t* test, and the Chi-square test were applied (depending on type and distribution of variables; *see* footnotes to the tables) to compare baseline data between groups. To assess treatment effectiveness, the changes observed from baseline to 3 and 6 mo were compared by group using the nonparametric Mann-Whitney *U* test. The analysis was done on an intention-to-treat basis. All analyses were carried out with the Statistical Package for Social Sciences (SPSS, rel. 6.1.3 for Windows. SPSS Inc., Chicago IL). Staff who entered and analyzed data were blinded to treatment group.

RESULTS

A total of 184 patients with mild SAHS were initially evaluated but 42 of them were excluded (12 for hazardous jobs, 5 for coronary heart disease, 5 for illiteracy, 3 for neurological or psychiatric disease, 3 for other chronic diseases, 3 for apnea index > 20, 2 for severe sleepiness, and 9 patients who refused to participate). Therefore, 142 patients from the six centers were included and were randomly allocated into group I, 65 patients, for conservative treatment only (CT), and group II, 77 patients for conservative treatment and CPAP (CT+CPAP). A total of 17 patients (6 from group I and 11 from group II) withdrew early after the start of the study and were excluded from the analysis. As can be seen in Table 1, the final study population included 125 patients; 59 in group I and 66 in group II. The baseline characteristics for these patients were age: 54 ± 9 yr; BMI: 29 ± 4 kg/m^2; apnea–hypopnea index (AHI): 20 ± 6; ESS: 12.6 ± 4.6; 86% were male. At baseline there were no significant differences between the groups in terms of age, sex, BMI, AHI or in terms of the scores of any questionnaire or cognitive test (*see* column baseline in Tables 1 and 2). The mean CPAP pressure prescribed in group II was 7 ± 1.7 cm H_2O. The average nightly use of CPAP was 4.8 ± 2.2 h at 6 mo. At 6 mo, 64% of the patients used CPAP for more than 4 h/d.

Table 1 shows the main results, except cognitive function, at baseline and at 3 and 6 mon in both groups. The p value in the baseline group columns denotes the significance between groups I and II. The p values for the 3 and 6 mo columns indicate the significance of the differences in changes from baseline between groups I and II (Figure 1 displays the most representative data). Patients in group I (CT) lost significantly more weight than those in group II (CT+CPAP). The overall weight loss at 6 mo was 2.7 ± 4.3 kg in group I whereas no change (+0.1 ± 3.4 kg) was observed in group II. In Table 1 data are expressed as BMI. The daytime systolic and diastolic blood pressures recorded at 3 and 6 mo did not differ from those obtained at baseline, and no differences between the groups were detected (baseline: group I 132 ± 17/84 ± 11, group II 126 ± 17/81 ± 12; 3 mo: group I 131 ± 16/84 ± 10, group II 126 ± 15/81 ± 10; 6 mo: group I 130 ± 16/84 ± 11, group II 122 ± 22/80 ± 10). The mean basal scores in the SAHS-related symptoms questionnaire were 21 ± 3 in group I (CT) and 21 ± 4 in group II (CT+CPAP) (normal values in the general Spanish population: 14.3 ± 3; M. Solans, personal communication), and at 3 and 6 mo a greater and significant improvement in group CT+CPAP (to 14 ± 5 and 14 ± 5, respectively) compared with CT (to 19 ± 4 and 19 ± 4, respectively) was observed (Figure 1A). The basal ESS scores were 13.2 ± 4.3 in group I (CT) and 12.1 ± 4.9 in group II (CT+CPAP). At 3 and 6 mo ESS were 12.0 ± 5.4 and 11.8 ± 5.2, respectively, in group CT and 10.4 ± 4.9 and 9.6 ± 5.5, respectively, in group CT+CPAP (Figure 1B). Although the changes in group II (CT+CPAP) were greater, they did not reach significance. The baseline FOSQ and NHP scores were within the normal ranges. Despite this, they showed a slight improvement in both groups (Figures 1C and 1D). At 6 mo, the differences in the FOSQ score were almost significant ($p = 0.06$) in favor of group II (CT+CPAP). When the subscales in the FOSQ test were analyzed, no differences in the effect of treatment between the groups were found although there was a marginal trend toward difference in the domain of vigilance ($p = 0.06$), also in favor of group II (CT+CPAP). On the other hand, in the subgroup in which MSLT was also performed to evaluate somnolence (n = 40) no change from baseline (group I: 11 ± 5, group II: 10 ± 5) was observed in any of the groups at 6 mo (group I: 11 ± 5, group II: 10 ± 5). Finally at 6 mo a full polysomnography was repeated (in group II with CPAP) (Table 1). Group I demonstrated a small reduction in AHI (from AHI 21 ± 6 at baseline to AHI 17 ± 10 at 6 mo). The AHI reduction in group II (CT+CPAP) was significantly greater (from AHI 20 ± 6 at baseline to AHI 6 + 8 at 6 mo).

Table 2 shows the cognitive function data. The mean values at baseline were within the range of normality for all the tests performed, except for the trail-making test whose values were slightly low. Despite small differences in some tests at 3 mo (improvement in visual memory was greater in group II, whereas the improvement in other tests was greater in group I), these differences did not persist at 6 mo. The changes in percentage of hits in steer-clear, which measures vigilance, showed no difference between both groups; nor did the tests studying attention, memory, and executive function.

Of the 77 patients randomized in the CPAP group, 11 withdrew from the trial, 6 abandoned CPAP but continued in the

TABLE 1. MAIN RESULTS (EXCEPT COGNITIVE FUNCTION) AT BASELINE AND AT 3 AND 6 MONTHS*

	Baseline			3 mo			6 mo		
Variables	CT (*n* = 59)	CPAP (*n* = 66)	p Value†	CT	CPAP	p Value‡	CT	CPAP	p Value‡
Age, yr	54 (9)	53 (9)	0.72‡						
Sex, % males	91	81	0.13§						
BMI, kg/m^2	29.5 (3.3)	29.4 (3.7)	0.87‖	28.8 (3.5)	29.4 (4.0)	< 0.001	28.5 (3.5)	29.5 (2.8)	< 0.001
Syst. BP, mm Hg	132 (17)	126 (17)	0.05	131 (16)	126 (15)	0.80	130 (16)	122 (22)	0.87
Dias. BP, mm Hg	84 (11)	81 (12)	0.12	84 (10)	81 (10)	0.89	84 (11)	80 (10)	0.42
Symptoms	21 (3)	21 (4)	0.78	19 (4)	14 (5)	< 0.001	19 (4)	14 (5)	< 0.001
ESS	13.2 (4.3)	12.1 (4.9)	0.11	12.0 (5.4)	10.5 (5.0)	0.67	11.8 (5.2)	9.6 (5.5)	0.11
FOSQ	100 (15)	101 (18)	0.29	102 (17)	106 (18)	0.72	102 (21)	106 (20)	0.06
NHP	20 (16)	21 (20)	0.67	17 (17)	15 (16)	0.79	15 (15)	15 (18)	0.84
MSLT, min	11 (5)	10 (5)	0.70				11 (5)	10 (5)	0.87
AHI	21 (6)	20 (6)	0.21				17 (10)	6 (8)	< 0.001

Definition of abbreviations: AHI = apnea–hypopnea index; BMI = body mass index; BP = systolic blood pressure; CT = conservative treatment; Dias. BP = diastolic blood pressure; ESS = Epworth sleepiness scale; FOSQ = Functional Outcomes Sleep Questionnaire; MLST = multiple latency sleep test; NPH = Nottingham Health Profile.

* Data shown are expressed as mean (standard deviation).

† Mann-Whitney *U* test.

‡ Mann-Whitney *U* test comparing changes from baseline.

§ Chi-square test.

‖ *t* test for independent samples.

trial, and at the end of the study 12 patients preferred other treatments (11 conservative measures, 1 uvulopalatopharyngoplasty), whereas 48 (62%) decided to continue on CPAP. Of the 66 patients in the group of conservative measures, 5 abandoned the trial, 10 chose other treatments at the end of the study (9 CPAP and 1 uvulopalatopharyngoplasty), and 49 (77%) decided to continue this treatment.

DISCUSSION

Our study was designed to obtain evidence of the effectiveness of CPAP therapy in patients with mild SAHS (IAH between 10 and 30 and absence of severe sleepiness). We observed that CPAP improved physiology, and that the relief of SAHS-related clinical symptoms after 3 and 6 mo was greater in the group receiving conservative treatment plus CPAP than in the group treated with conservative measures alone. The difference persisted despite excluding the questions about "snoring" and "breathing pauses," which are more easily corrected with CPAP ($p < 0.001$). The improvement in somnolence measured by the Epworth scale was also greater, although it did not reach the level of significance. When somnolence was measured by MSLT, no effect of treatment was found, but this was done only in a subgroup of 40 patients, and the finding of nonsignificant changes in the MSLT is not inconsistent with earlier studies with a series of more affected patients (2, 28). Greater changes in sleepiness would be expected in more severely affected patients.

TABLE 2. RESULTS ON COGNITIVE FUNCTION AT BASELINE AND AT 3 AND 6 MONTHS*

	Baseline			3 mo			6 mo		
Variables	CT (*n* = 59)	CPAP (*n* = 66)	p Value†	CT	CPAP	p Value‡	CT	CPAP	p Value‡
Attention									
Digit symbol (WAIS) (23), SS	9 (3)	9 (3)	0.98	9 (3)	9 (3)	0.80	9 (2)	9 (3)	0.97
Digits forward and backward (WAIS) (23), SS	10 (3)	10 (2)	0.62	10 (3)	10 (2)	0.04	11 (2)	11 (3)	0.56
Mental control (WMS) (23), p	45 (28)	48 (27)	0.58	52 (29)	46 (27)	0.02	53 (27)	51 (27)	0.08
Memory									
Verbal paired associated (WMS) (24), p	31 (27)	30 (26)	0.89	40 (30)	35 (30)	0.67	43 (32)	41 (30)	0.63
Visual memory (WMS) (24), SS	58 (23)	50 (27)	0.12	60 (26)	61 (24)	0.03	63 (25)	61 (24)	0.06
Executive function									
Verbal fluency (25), p	66 (28)	69 (29)	0.32	72 (23)	72 (25)	0.61	70 (29)	69 (27)	0.53
Block design (WAIS), (23), SS	10 (3)	10 (3)	0.83	12 (3)	11 (3)	0.02	11 (3)	11 (3)	0.82
TMT A(26), s	54 (18)	56 (26)	0.70	51 (21)	51 (21)	0.33	49 (20)	49 (19)	0.76
TMT B(26), s	125 (47)	121 (44)	0.65	109 (40)	115 (43)	0.14	100 (39)	106 (42)	0.15
PASAT 4-s (26), correct	13 (4)	13 (5)	0.57	15 (3)	14 (4)	0.41	16 (4)	14 (4)	0.20
PASAT 3-s (26), correct	13 (5)	14 (5)	0.47	15 (4)	14 (4)	0.01	15 (4)	15 (4)	0.20
PASAT 2-s (26), correct	10 (5)	10 (4)	0.55	12 (4)	11 (4)	0.23	12 (4)	12 (4)	0.12
PASAT 1-s (26), correct	4 (3)	4 (3)	0.70	6 (3)	5 (3)	0.05	5 (3)	5 (4)	0.32
Vigilance									
Steer-clear (27), % hits	10 (3)	10 (8)	0.91	10 (14)	10 (12)	0.65	8 (10)	8 (9)	0.88

Definition of abbreviations: CT = conservative treatment; p = percentile; PASAT = paced auditory serial addition test (reduced version with 20 items for each condition); ss = scaled scores (mean 10, SD 3); TMT = trail-making test; WAIS = Wechsler Adults Intelligence Scale; WMS = Wechsler Memory Scale.

* Data shown are expressed as mean (standard deviation).

† Mann-Whitney U test.

‡ Mann-Whitney U test comparing changes from baseline.

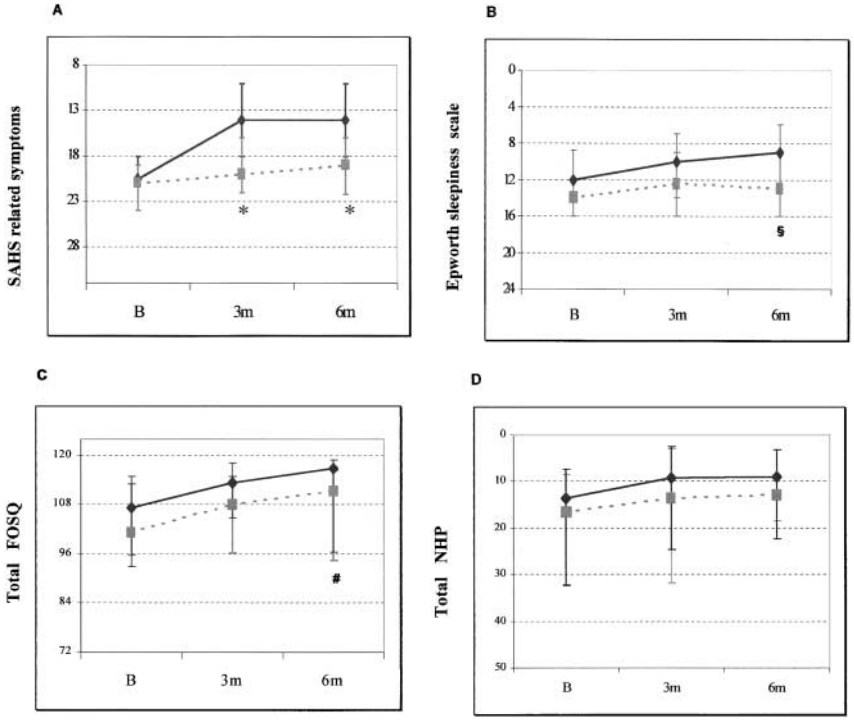

Figure 1. Evolution from baseline to 3 and 6 mo, for each group of treatment on SAHS-related symptoms questionnaire (*A*), Epworth sleepiness scale (*B*), Functional Outcomes of Sleep Questionnaire (*C*), and Nottingham Health profile (*D*). The results are shown as median and interquartile ranges. *Solid line*: CPAP group; *dotted line*: conservative treatment group. *$p < 0.001$, §$p < 0.11$, #$p < 0.06$.

We also evaluated the impact of SAHS on everyday activities using the FOSQ questionnaire and the greater improvement in the CPAP group was almost significant. Similar behavior occurred in the subscale of vigilance. The normal initial values obtained for both groups probably render the observation of any further improvement more difficult. A ceiling effect was also found for the Nottingham Health Profile: initial values were within normal ranges and although they improved in both groups, no treatment effect was detected. On the other hand, all the initial mean values of the cognitive tests performed were not impaired (except TMT A and B slightly) and no consistent differences between both groups were detected in any domain.

Good compliers (more than 4 h/d of CPAP use) from group II (CT+CPAP) were compared with group I in an attempt to detect significant differences, but these were not found. However, it is worth stressing that mean compliance in the whole group was fairly high, 4.8 h, even better than that observed in other series of SAHS patients including moderate–severe cases (29, 30). On the assumption that all the patients lost at follow-up had a compliance equal to zero, and assuming a 10% reduction in compliance obtained by measuring effective pressure instead of switched-on time (29), then the compliance would be around 3.7 h. Treatment acceptance was also good, because 62% of individuals chose to continue with CPAP at the end of the trial (analyzing by intention to treat). Given that both compliance and acceptance of CPAP were not as bad as expected in patients with mild SAHS, they cannot be regarded as drawbacks in the decision to treat these patients.

Despite our close follow-up, our results in weight loss in each arm of treatment were marginal (2.7 kg in group I and no change in group II). It is possible that this minor difference could be attributed to the lower motivation for losing weight in patients who achieved improvement with CPAP. Nevertheless, our results are comparable to those found in recent studies (31). On the other hand, the effect of weight loss (IMC reduction > 0.5 kg/m^2) on improvement of several outcome variables was tested by using an analysis of variance with repeated measures, but this was not significant. The influence of other covariates included in the multivariate models (IAH, ESS) was not significant (data not shown).

A recently published meta-analysis (32) has challenged the effectiveness of CPAP treatment, and as a consequence public health authorities have questioned funding for SAHS management without carrying out an analysis of the clinical benefits, especially in milder cases. Three previously published studies analyzed the effectiveness of CPAP in mild cases (11–13). In two randomized placebo-controlled, crossover studies including 16 and 34 patients at 4 wk. Douglas and coworkers (11, 12) provided evidence of the effectiveness of CPAP in mild SAHS. In the first study, the symptom-questionnaire score and one of the several cognitive tests improved. In the second study, the authors found moderate improvement in the symptom-questionnaire score, the Epworth Sleepiness Scale (the decrease was 5 points with CPAP versus 2 points with placebo), other cognitive tests, and in subscales of SF-36. Our study seeks to compare the effectiveness of CPAP with the usual approach, that is, conservative measures such as sleep hygiene and weight loss programs, which appear to be less expensive and more appealing alternatives to those responsible for funding. We provide evidence of the effectiveness of CPAP treatment in the relief of SAHS-related clinical symptoms even though significant changes were not demonstrated in domains that at baseline were almost unaffected or within normal values. It could be questioned whether it is necessary or clinically relevant to improve domains that are within the range of normality. However, it is possible that these patients without alterations in somnolence or cognitive functions have more subtle impairments in other areas that are usually not measured. This hypothesis is consistent with the results of Redline and coworkers (13), who analyzed the effects of CPAP with respect to general measures in mood, well-being, and functional status in mild SAHS, and found that CPAP had a greater effect than general measures. Thus, daytime impairment exists in these patients possibly before the appearance of

overt daytime somnolence, and should therefore be measured with instruments different from those usually employed with moderate–severe SAHS. These instruments should address consequences other than somnolence and cognitive function (such as loss of energy, tiredness, irritability, etc.) and/or specific quality of life related not only to somnolence but also to other symptoms associated with SAHS.

On the other hand, the decision to treat patients with mild SAHS should be made taking into account two considerations: the relief of clinical symptoms and the minimization of cardiovascular risks. Although the latter consideration is presumably less important in patients with mild SAHS, recent studies demonstrate increased risk of hypertension with low degrees of IAH (7). The only parameter of cardiovascular repercussion that we assessed was office blood pressure and no change throughout the study was observed. Our results do not support the use of CPAP in preventing an increased cardiovascular risk, but because our study was not designed to address the long-term impact on morbidity and mortality related to SAHS, we cannot draw a definitive conclusion. Further studies are therefore warranted to shed more light on this matter.

To sum up, the present study assessed the effect of CPAP on patients with mild SAHS with respect to conservative treatment. To our knowledge, our multicentric study includes the largest population of patients with mild SAHS followed up for the longest period (6 mo). The effect of CPAP in neurocognitive tests, quality of life, or in MSTL was not better than that of the conservative therapy alone, probably because most tests were within normal values at baseline. The Epworth Sleepiness Scale improved but did not reach significance. However, we were able to demonstrate a significant improvement in SAHS directly related symptoms. This finding suggests a potential role of CPAP in treating mild SAHS patients on the basis of a beneficial effect on symptoms.

Acknowledgment: The authors thank Dr. D. Rodenstein and Dr. F. Manresa for their critical and helpful comments.

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