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ORIGINAL ARTICLE

Insomnia symptoms influence CPAP compliance

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Abstract
Purpose The aim of this study is to determine parameters which influence 6-month compliance of continuous positive airway pressure therapy (CPAP) in patients with obstructive sleep apnea syndrome (OSAS).
Methods This prospective study investigated 73 patients (24 females) with OSAS and medical indication for CPAP therapy: age 55.1±11.5 years, body mass index (BMI) 30.8±5.0 kg/m2, Apnea–Hypopnea Index (AHI) 39.2±26.7/h, Oxygen Desaturation Index (ODI) 33.2±25.4/h, minimum O_2 saturation 78.9±7.6%. The influence of baseline parameters (demographic and polysomnographic data, sleeping medication intakes, BMI, psychometrics [Epworth Sleepiness Scale, Regensburg Insomnia Scale, Vigilance test and Beck Depression Inventory]) on 6-month compliance was evaluated with a correlation and a linear regression analysis.
Results The baseline value of the Regensburg Insomnia Scale (RIS) predicts 6-month CPAP compliance (r=−0.376, R^2=0.14, p<0.001), although no other baseline parameter correlates. Patients with a compliance of <4 h/night show higher RIS scores, i.e., more insomnia symptoms (17.6±8.8) compared to those with ≥4 h/night (12.6±6.9; p<0.05).
Conclusions Insomnia symptoms prior to the beginning of CPAP treatment show a negative influence on CPAP compliance. Further studies should clarify, if a treatment of insomnia symptoms leads to a benefit in compliance.

Keywords Continuous positive airway pressure · Obstructive sleep apnea syndrome · CPAP compliance · Insomnia · Regensburg insomnia scale

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Introduction

According to the International Classification of Sleep Disorders (ICSD-2), obstructive sleep apnea syndrome (OSAS) is characterized either by an Apnea–Hypopnea Index (AHI) of >15/h or an AHI of >5/h in combination with typical clinical symptoms [1]. OSAS is a common, chronic and complex disease that is economically and socially detrimental to both the patient and the public [2].

Untreated OSAS may cause daytime sleepiness or disturbed sleep and increases the risk for cardio- and cerebrovascular diseases [3]. Continuous positive airway pressure (CPAP) is the first line treatment for moderate to severe OSAS [4, 5]. By using CPAP, the detrimental effects of OSAS can be reversed or reduced [6], but in order to maintain this improvement, continued use of CPAP must be optimal [7]. Although effective treatment can also reduce morbidity and mortality, moderate to low CPAP adherence rates are reported without a clear consensus of causes [8].

Adherence to CPAP therapy (continued use of CPAP) and CPAP compliance (hours of CPAP use per night) have been investigated in previous studies over periods of several months and years [9]. Results vary widely and are dependent on the primary selection of patients and the duration of follow-up visits. A review, including ten studies, found a short time compliance (1–6 months)

between 3.2 and 4.7 h/night and a long-term compliance (12–39 months) between 4.9 and 6.2 h/night [9].

Several studies have focused on factors influencing compliance. A recent study investigated the influence of demographic and clinical variables on CPAP compliance and found no significant predictor [10]. Another study showed a high prevalence of insomnia in OSAS patients, but observed no impact of insomnia on CPAP acceptance or 6-month compliance [11]. A study determined that compliance is related to the severity of OSAS [12]. Additionally, a relationship between CPAP compliance, mask leakage and oxygen desaturation was established [13]. Psychological factors such as control belief seem to have an influence on adherence [14]. Additional studies focused on the possible methods for improving compliance. It was shown that intensive patient education [15] or video education [16] may increase CPAP compliance. The patients' sleep laboratory experience with CPAP and the support and education provided by sleep technologists were found to be important factors in facilitating CPAP compliance [17]. More than one third of previously non-adherent patients continuing follow up achieved adherence with secondary intervention [18]. Furthermore, a modest cognitive–behavioural intervention may substantially increase CPAP use and vigilance in older adults [19].

Nevertheless, no single factor has been consistently identified as predictive for continued CPAP use [20]. Therefore, diagnostically conclusive parameters influencing CPAP compliance are still missing. As the adherent use of CPAP is necessary for effective treatment [7], predictors for CPAP compliance are important. Considering possible health consequences of CPAP non-compliance, a predictor could point out those OSAS patients who require more attention. Consequently, this study is focusing on parameters which allow foretelling of 6-month compliance.

Methods

Participants

This study included patients (>18 years) with OSAS according to ICDS-2 criteria and a medical indication for CPAP therapy. From April 2009 to June 2010, all consecutive patients at the Sleep Disorders Center Regensburg, Germany, were asked to participate.

Diagnostics and procedure

Diagnosis was verified by medical and sleep history, somatic and psychiatric examination, psychometrics (see Parameters) and 1-night diagnostic polysomnography (PSG). All patients were treated with CPAP according to the ICSD-2 guidelines [1]. In two consecutive PSG-nights with manual pressure titration, we optimized and controlled the effectiveness of CPAP. The titration procedure was performed similar to the clinical guidelines for manual titration of the American Academy of Sleep Medicine [21]. At an outpatient follow-up visit 1 month after treatment initiation, possible difficulties with CPAP use (e.g., handling or mask pressure marks) were addressed and adjusted. At the 6-month follow-up, we collected operating hours from the CPAP device memory recording. In addition, the Epworth Sleepiness Scale (ESS) [22] and the Regensburg Insomnia Scale (RIS) were administered again. As bedtime and sleep latency are confounding factors for compliance, we asked for the average bedtime and wake-up time.

Parameters

We analyzed the influence of following baseline parameters on 6-month adherence (continued use of CPAP) and 6-month CPAP compliance (hours of CPAP use per night):

- Age, sex, educational level, body mass index (BMI), intake of hypnotic medication
- PSG diagnostic data: AHI, Oxygen Desaturation Index (ODI), minimum O_2-Saturation (min. O_2), Arousals/hour (Arousal Index)
- Vigilance test: Mean reaction time (RT) and missed reactions (MR) of sustained attention task with monotonous conditions from the Vienna test system (25 min duration, Version Quatember and Maly)
- Psychometrics:

1. Epworth Sleepiness Scale [22]: An eight-item self-rating test (sum score 0 to 24) to verify subject's habitual "likelihood of dozing or falling asleep" [23].
2. Beck Depression Inventory (BDI) second version [24] in German language [25]: A 21-item self-report inventory for measuring the severity of depression.
3. Regensburg Insomnia Scale: A ten-item self-rating scale for psychological symptoms of insomnia and sleep quality parameters. It was validated in a sample of insomnia patients with the Pittsburgh Sleep Quality Index (PSQI) [26]. Items are rated between 0 and 4 points, with higher scores indicating more impairment.

Statistics

For the statistic analysis we used SPSS® 18.0 (SPSS Inc., Chicago, IL, USA). The two-tailed significance level was set at 0.05. To investigate differences between withdrawers and continuing CPAP users, a Mann–Whitney *U*-test for numeric variables was used. In case of ordinal variables, a

chi square test was used and controlled with a Fischer's exact test. With a correlation analysis (Pearson for numeric and Kendall tau for ordinal variables), we analyzed the relationship between 6-month compliance and the baseline parameters. In the case of a significant correlation between parameters and compliance, we calculated a linear regression analysis (using the backward method) to examine the expressiveness. To determine the impact of the individual RIS items on compliance, we computed a Kendall correlation.

Source of funding and ethical considerations

This prospective study was planned and conducted in accordance with the Declaration of Helsinki and ethical laws pertaining to the medical professions. The design was approved by the Ethics Committee of the University Medical Center in Regensburg, Germany. This study was conducted independent of any institutional influence and was not funded externally. All patients signed an informed consent form.

Results

Study sample (n=73)

Eighty-two patients (26 females) were initially included. Nine patients were excluded because of incomplete data, resulting in a study sample of 73 patients (24 females). Data from the study sample is presented in Table 1.

Six-month follow-up

Nine patients terminated CPAP use within the 6-month follow up period (adherence rate 87.7%) after a mean CPAP use of 142±82 days. Patients who quit CPAP therapy by choice, were subsequently labeled as withdrawers. Those who continued to use CPAP (n=64) did so for a mean of 4.8±2.0 h/night, which is 60% of the reported time in bed (8.0±2.0/night). Self reported CPAP use was 6.2±1.8 h/night on 6.6±1.1 days of the week. There were no significant differences in the baseline values between CPAP users and withdrawers for age, sex, BMI, CPAP pressure, min. O_2, AHI, ODI, AHI with CPAP, Arousal Index, ESS, RIS, BDI and vigilance test (mean reaction time or missed reactions).

Subsequently, we analyzed the relationship between the baseline parameters and the 6-month compliance for the continuous CPAP users. Of all investigated baseline parameters only the RIS showed a significant correlation with 6-month compliance (study sample including withdrawers: r=−0.347, p<0.001; continuous CPAP users excluding withdrawers: r=−0.376, p<0.001). According to patient reports, the average time in bed was 8.02±1.07 h/night.

Table 1 Psychometrics, demographic and polysomnographic data of the study sample (n=73)

	Mean (±SD/percentage)
Age	55.1 (±11.5)
BMI	30.8 (±5.0) kg/m^2
Sex	
Female	24 (32.9%)
Male	49 (67.1%)
Education	
<10 years	1 (1.4%)
10–12 years	56 (76,7%)
>12 years	14(19.2%)
Unknown	2 (2.7%)
PSG baseline	
AHI	39.2/h (±26.7)
ODI	33.2/h (±25.4)
Min. O_2	78.9% (±7.6)
Arousal Index	31.7/h (±19.7)
PSG with CPAP	
AHI	4.9 (±5.2)
ODI	4.9 (±5.2)
CPAP pressure (mbar)	6.3 (±1.7)
Psychometrics	
ESS baseline	9.4 (±4.9)
ESS 6-month follow-up	6.59 (±4.6)
RIS baseline	14.8 (±7.5)
RIS 6-month follow-up	10.52 (±7.3)
BDI	11.9 (±7.5)
Vigilance test	
reaction time (RT)	0.51 (±0.1)
missed reactions (MR)	5.5 (±10.8)
Hypnotic medication	20 (27.4%)

BMI body mass index, *RIS* Regensburg Insomnia Scale, *ESS*: Epworth Sleepiness Scale, *BDI* Beck Depression Inventory, *ODI* Oxygen Desaturation Index, *AHI* apnea–hypopnea index, *Arousal Index* arousals/hour sleep, *CPAP* continuous positive airway pressure, *PSG* polysomnography, *SD* standard deviation

Likewise, the adjusted compliance (operating hours per night/time in bed) was related to the baseline RIS (r=−0.314, p=0.015).

In a further subanalysis, we investigated the expressiveness of the RIS on the compliance, for the study sample as well as for the sample excluding the withdrawers. We calculated a regression analysis with compliance as the independent and the baseline RIS value as the dependent variable. The results of the study sample (β=−0.347, p=0.007, R^2=0.12, F=7.921) were comparable to the sample in which withdrawers were excluded (β=−0.376, p=0.007; R^2=0.14, F=8.05). The correlation of RIS and 6-month compliance is graphically presented in Fig. 1.

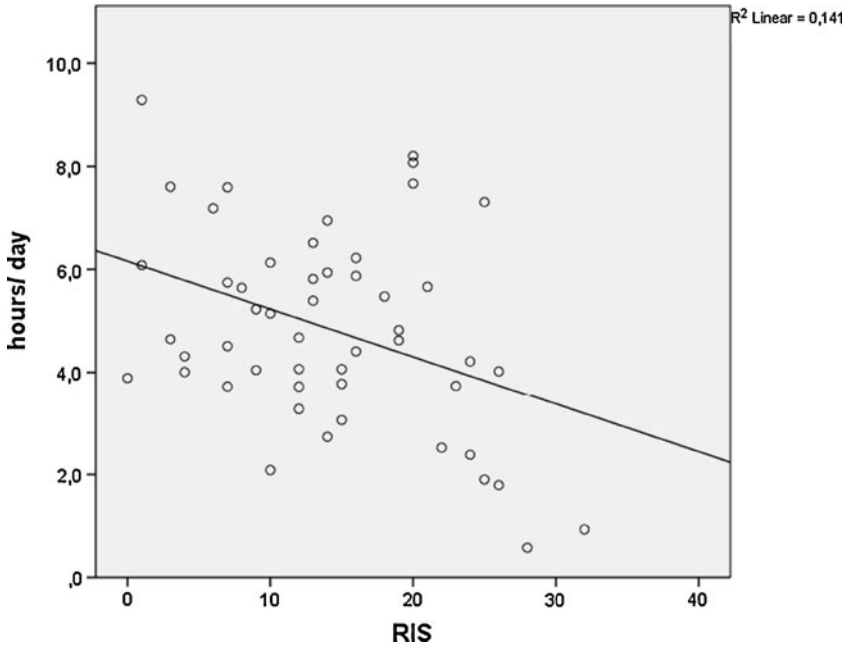

Fig. 1 Correlation of the Regensburg Insomnia Scale (RIS) and the 6-month compliance

The initial RIS score in patients with a compliance of <4 h (17.6±8.8) was higher compared to those with ≥4 h of CPAP use per night (12.6±6.9) (T=2.47, p=0.017). The RIS score improved significantly in the group with a compliance <4 h (RIS=13.6±6.9, T=3.86, p=0.001) and in the group with a compliance ≥4 h (RIS 7.9±6.4, T=5.19, p<0.001). The improvement in insomnia symptoms (measured with the RIS) did not differ between patients with lower and higher compliance (χ^2=17.3, df=21, p=0.691) (Fig. 2).

To analyze the relation between single items of the RIS and the compliance, we calculated a correlation analysis. Only item 6 ("I feel that I have not slept all night") and item 8 ("I am afraid to go to bed because of my disturbed sleep") from the RIS were shown to be in correlation with compliance (Table 2).

Discussion

The baseline RIS value is negatively correlated to the 6-month compliance and explains 12–14% of the variance in CPAP compliance. Independent from the compliance, both patients with high and low compliance benefit in insomnia symptoms approximately to the same extent (Fig. 2). Therefore, the baseline value of the RIS, not the improvement of the insomnia symptoms seems to determine compliance. However, in all other baseline parameters such as severity of OSAS, CPAP pressure, education, intake of sleeping medication or daytime impairment, we did not find evidence for any association.

In current literature, the impact of insomnia symptoms on adherence and compliance is still on debate. A recent review indicates that insomnia can be a risk for poorer adherence [24], whereas a study by Nguyên et al. [11] showed no impact of insomnia symptoms on compliance when measured with the Insomnia Severity Index (ISI).

In a comparison of the seven items of the ISI and the ten items of the RIS, similarities such as sleep parameters and

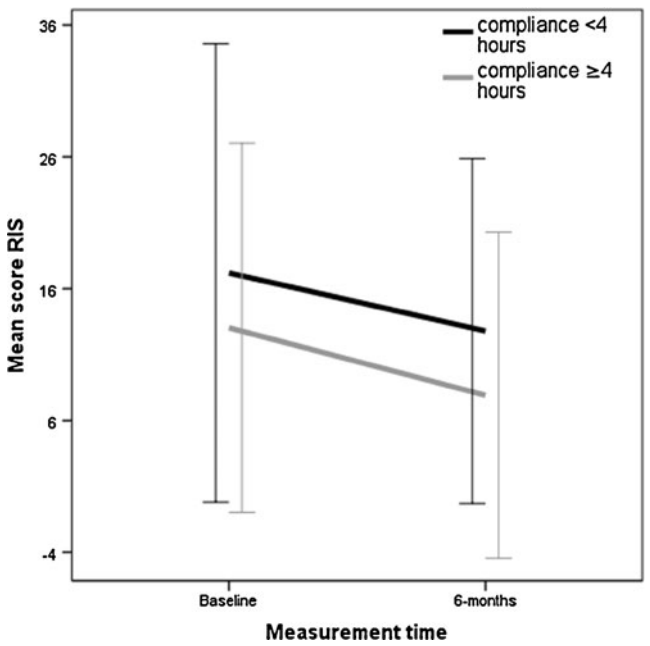

Fig. 2 Improvement of Insomnia symptoms measured with the Regensburg Insomnia Scale (RIS) in dependence of compliance (n=64)

Table 2 RIS item analysis in correlation with 6-month compliance

	Compliance (continuous CPAP users)		Compliance (study sample)	
	tau b	*p*	tau b	*p*
1. How many minutes do you need to fall asleep?	−0.052	0.664	−0.129	0.237
2. How many hours do you sleep during the night?	−0.133	0.244	−0.141	0.178
3. My sleep is disturbed.	−0.022	0.845	−0.066	0.519
4. I wake up from the slightest sound.	−0.046	0.684	−0.149	0.151
5. I wake up too early.	−0.198	0.074	−0.184	0.071
6. I feel that I have not slept all night.	−0.248	0.028	−0.255	0.013
7. I think a lot about my sleep.	−0.092	0.427	−0.105	0.322
8. I am afraid to go to bed because of my disturbed sleep.	−0.278	0.017	−0.331	0.002
9. I feel fit during the day.	−0.015	0.891	−0.005	0.963
10. I take sleeping pills in order to get to sleep.	0.083	0.485	0.009	0.937

tau b Kendall tau correlation, *p p* value

scaling were noted. However, unique to the RIS are two questions, which are specifically correlated with compliance ("I feel I have not slept all night" and "I am afraid to go to bed because of my disturbed sleep"). The questions on sleep parameters as well as daytime impairment, which are similar in RIS and ISI, showed no association with compliance (Table 3). In consideration of the fact that comorbidity of insomnia in OSAS patients may lead to increased OSAS severity [27], the results underline the necessity of focusing on insomnia symptoms in OSAS patients.

The questions within the RIS, which showed a correlation with 6-month compliance, focus primarily on feelings. This indicates the questions emphasizing psychological factors could be more predictive of compliance than other questions, which are more fact-oriented. This supports the notion that psychological factors are key determinants of non-adherence [28]. Psychological constructs such as self-efficacy, coping, social support, treatment satisfaction and self-reported daytime sleepiness are established as predictors of CPAP adherence [29]. Edinger et al. explained 63% of the variance for CPAP adherence by including inter alia psychological factors in the predictive model [30]. Common facilitators for adherence were the fear of negative social consequences, and the negative psychological effects of the equipment that were found to be barriers [8]. Further social–cognitive factors might be associated with CPAP adherence [31] and therefore, assessing psychological well-being may enable one to identify patients in risk of abandoning the treatment [32]. Engleman and Wild [33] summarized the psychological aspects of CPAP adherence and concluded that the inclusion of and attendance to cognitive constructs may offer a potential explanation for adherence. Nevertheless, all mentioned variables in this study refer to CPAP adherence, and the influence of psychological variables on compliance is still unclear. However, the current results underline that psychological factors could influence not only adherence (continuous CPAP use) but also CPAP compliance (extended duration of CPAP use per night).

The following limitations must be recognized when interpreting these results. We used a naturalistic design. As a consequence, the baseline means show a wide standard deviation. Furthermore, the effectiveness of CPAP treatment was controlled in two PSG nights, but there was no PSG following the 6-month follow-up to control the continued efficiency of the therapy. In addition, we measured daily compliance with the automatically calculated operating hours of the CPAP machine. As sleeping time has a wide individual range, the operating hours are only a rough estimation of real compliance. The adjustment of compliance to time in bed is completely dependent on the patients' reports.

Insomnia symptoms as measured by the RIS explain only 12–14% of the variance in CPAP compliance. This may seem a powerless effect, but we should consider that compliance is the grand total of the therapeutic process, determined by a multitude of factors with a minute individual influence. Most of these factors cannot be controlled or influenced by the therapist. Therefore, it is worthwhile to optimize those factors, which we can work on. Further studies should clarify if concurrent treatment of insomnia symptoms in OSA patients leads to a better CPAP compliance.

Conflict of interest The authors declare that they have no conflict of interest.

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