

Disease severity impairs sleep quality in allergic rhinitis (The SOMNIAAR study)

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Summary

Background Sleep is impaired in allergic rhinitis (AR) patients, with subsequent effects on daytime performance and health-related quality of life (QOL). Sleep quality in AR has rarely been considered through validated tools and consensus classifications.

Objective To evaluate sleep quality and daytime somnolence in AR patients, and to estimate its relationship to disease severity according to Allergic Rhinitis and Its Impact on Asthma (ARIA) conventional and modified classifications, as well as in terms of QOL and comorbidities.

Methods Allergic rhinitis adult patients were evaluated through a prospective, observational, multicentre survey in Spain. Symptoms were assessed using the Total Symptoms Score (TSS), specific QOL by the Rhinitis Quality of Life Questionnaire (RQLQ), sleep quality by Pittsburgh scale, and diurnal somnolence by a scale based on Epworth's, all recorded in a unique visit.

Results A total of 2275 patients were included. According to ARIA criteria, 50.2% had persistent and 49.8% intermittent rhinitis, whereas 87.6% were classified as moderate-severe and 12.4% as mild; 52.8% had poor sleep quality, with a global median score for Pittsburgh scale of 6 (normal < 5) and 21.1% suffered from excessive diurnal somnolence. Correlation between Pittsburgh scale and RQLQ was moderate ($r = 0.54$). Among symptoms, nasal obstruction and concomitant asthma mainly, contributed to bad sleep quality. In a logistic regression model, moderate-severe rhinitis and nasal obstruction were all associated with a worse sleep quality.

Conclusions and clinical relevance Sleep quality is altered in AR patients. Sleep quality was worse in moderate-severe, and particularly in severe AR. Nasal obstruction and RQLQ deterioration are associated with a poorer sleep quality. Sleep impairment is common in allergic rhinitis, particularly in more severe forms. Nasal obstruction and concomitant asthma should be considered as contributing factors.

Capsule summary This is a large epidemiological survey of patients with allergic rhinitis showing a strong relationship between disease severity, as assessed by a consensus classification, and sleep impairment, as measured by a validated sleep quality tool.

Keywords allergic rhinitis, ARIA, Pittsburgh Sleep Quality Index, quality of life, sleep disturbance, sleep initiation and maintenance disorders

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Introduction

Allergic rhinitis (AR) is a highly common and increasingly prevalent disease that generates high social and health care costs, and has a significant effect on

cognitive performance and quality of life (QOL) [1, 2]. Sleep is very important for physical and mental health, daytime performance, and personal welfare. Sleep disturbances make people more susceptible to cognitive impairment (memory, learning abilities, concentration)

[3, 4], functional problems (impaired psychomotor function and procedural skills, decreased productivity, increased accidents) [5–7], and psychological consequences (fatigue, irritability, malaise, anxiety, depression) [8]. Moreover, evidence indicates that sleep disturbances in patients with chronic disorders may exacerbate symptoms [9], complicate management [10], affect mood [11], and health-related QOL [12, 13]. Sleep-disordered breathing is also a troublesome factor in many chronic respiratory conditions, including allergic rhinitis, and can result in daytime somnolence and contribute to QOL impairment [14, 15].

Sleep disturbances are prevalent among the general population. Approximately 35% of adults experience transient or occasional difficulties while sleeping, whereas 10–20% adults suffer from chronic sleep disturbances [16]. Insomnia affects 20% to 30% of adults, and severe insomnia about 10% of adults [17]. This is probably an underestimate, as many patients do not report their sleep problems to healthcare professionals [18].

The relationships between AR, nasal obstruction, and abnormal breathing during sleep have been thoroughly reviewed [19–21]. Sleep has also been assessed among asthmatic patients by large epidemiological surveys; in these, associated allergic rhinitis [22], or perennial non-infectious rhinitis [23], were found to be independently related to difficulty in falling asleep and daytime somnolence. Also, sleep alterations in AR have been evaluated by complementary techniques such as polysomnography [24] and actigraphy [25].

It is thought that AR can impair nocturnal sleep through both mechanical and inflammatory mechanisms. Congestion is a risk factor for respiratory sleep-disordered breathing, including snoring, hypopnoea, and apnoea [21, 26]. Fatigue, which is not considered a classic symptom of AR, is often regarded as a side effect of allergy medication, although it may be the result of nasal congestion and associated sleep disruption [27]. On the other hand, inflammatory cytokines released as part of the allergic reaction have been indirectly associated with suppression of both rapid eye movement (REM) and non-REM sleep [28]. REM sleep is associated with restorative function; therefore, its interruption leads to fatigue, reduced concentration, and diminished productivity. Adequate treatment for AR can improve sleep in these patients [29].

A correlation between sleep quality and AR severity has been assessed only occasionally using validated tools and consensus classifications [30], and rarely through surveys on large samples. Hence, we designed and conducted the SOMNIAAR* study (Effect of allergic rhinitis and its treatment on sleep) to evaluate sleep

quality and daytime somnolence in AR patients; to assess its association with symptoms, medication intake and QOL; and to estimate its correlation with disease severity, according to ARIA (Allergic Rhinitis and Its Impact on Asthma) conventional classification, and ARIA modified classification by Valero et al. [31], that discriminates between mild, moderate or severe disease.

Methods

The SOMNIAAR was a prospective, observational, cross-sectional, multicentre study performed on a sample of Spanish patients treated by an allergist or an otorhinolaryngologist (a total number of 127 investigators in 104 centres). Physicians were selected from all regions of Spain to rule out any geographical or seasonal constraint, and to take into account the distribution of population in the country (stratification according to geographical area). Every specialist had to include the first two patients presenting with AR and meeting the inclusion criteria on each day. A total of 20 patients were recruited by each investigator during 10 consecutive working days. This study was approved by the Ethical Committee of Hospital Clínico de Valencia (Valencia, Spain). Individual informed consent was required for all patients.

Patients and study design

Inclusion criteria were that patients (men or women) had to be aged 18 years or more, suffer from AR for at least 1 year duration, and have a score of 3 or higher in the T4SS (Total Four Symptoms Score, range 0–12 [32]). Exclusion criteria were the occurrence of nasal polyps and/or nasal septum deviation (or other major anatomical disorders as assessed by anterior rhinoscopy or nasal endoscopy), pregnancy and psychiatric diseases. Patients were evaluated in a single visit.

Allergic rhinitis symptoms were assessed by calculating the sum of scores for nasal blockade, rhinorrhea, nasal itching, and sneezing (Total Four Symptoms Score or T4SS). Each nasal symptom was scored on a scale from 0 to 3 (0, no symptoms; 1, mild; 2, moderate; 3, severe). Severity was assessed following ARIA recommendations [33]. In addition, a new criterion for severity according to Valero et al. [31] was also utilized; this is based on ARIA items (activities, work/school, sleep disturbances, and troublesome symptoms), but discriminates among three categories instead of two: mild (no item affected) moderate (one to three items affected), and severe (all four items affected). Health-related quality of life assessment included the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) [34] version adapted and validated for their use in the Spanish population [35].

*From the Latin root for sleep 'somnia' and the initials of allergic rhinitis.

Sleep quality was assessed by the existing Pittsburgh Sleep Quality Index (PSQI) [36] version adapted and validated for their use in Spanish population [37]. The PSQI is a short questionnaire, simple and well-accepted by the patients, designed to measure sleep disturbance over the previous month. It consists of 19 items over seven domains: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction; an additional (non-scored) question asks whether the patient has a bed partner or flatmate. Domains are scored on a 0–3 scale. Habitual sleep efficiency domain scores, which represent the percentage of time spent asleep in bed, were derived from answers to questions 1 (usual bed time), 3 (usual getting-up time), and 4 (actual hours of sleep). An overall PSQI score was calculated by adding the seven domain scores together (range from 0 = no difficulty to 21 = severe difficulties in all areas). A cut-off point of 5 (score ≥ 5 defining bad sleepers) has been proposed with a sensitivity of 89.6% and a specificity of 86.5% [36]. Pre-existing sleep disorders could not be excluded.

Daytime sleepiness was evaluated by questions based on Epworth scale [38] that assesses the likelihood of falling asleep in certain situations such as reading, watching television, or speaking. Questions were scored as no sleepiness, mild (no impact on daily activities), moderate (some repercussion on daily activities), and severe sleepiness (important repercussion on daily activities), in accordance with the scheme recommended by the American Thoracic Society (ATS) [39].

Statistical analysis

We performed data management and statistical analysis by using the SPSS software package (version 14; SPSS Inc. Chicago, IL, USA). Descriptive analyses for qualitative variables included number and percentage, whereas quantitative variables were analysed in terms of mean value, standard deviation, and median and extreme values.

Collected data were analysed for the total population and by subgroups of patients with good sleep quality (Pittsburg score < 5) and with bad sleep quality (Pittsburg score ≥ 5). Sleep quality was matched with i) type and severity of AR according to ARIA, and ii) severity of AR according to ARIA modification. For association of quantitative variables, the Kruskal–Wallis test and Mann–Whitney test were used; for association of qualitative variables Chi square test was used.

We determined predictive factors for sleep impairment by using logistic regression analysis. The predictors chosen were the variables with statistic association demonstrated in bivariate analyses. The associations of the regression model were then expressed using odds

ratios and the 95% confidence interval. Nagelkerke R^2 value was used to determine the prediction percentage of good sleep quality and Hosmer–Lemeshow test to determine the wellness of the model. P level of 0.05 was used to determine statistic association in all tests.

Results

Descriptive study

A total of 2310 patients from all around Spain were evaluated from March to October 2006. Following verification of criteria, 2275 of these patients, recruited by 101 clinicians, were retained for the analysis, thus constituting the SOMNIAAR population.

Demographic characteristics are summarized in Table 1. A percentage of 47.5 of patients were men, with a mean age of 36.2 years (SD: 12.9, range: 18–81). A total of 619 patients reported not carrying out any physical activity, whereas 826 (36.3%) performed low activity. A total of 1407 patients (62.2%) had never smoked, 397 declared to be former smokers (17.6%), and 457 active smokers (20.1%). A total of 752 patients (33.7%) reported drinking alcohol regularly. A total of 1451 patients (68.3%) were drivers, but only 185 patients (12.2%) affirmed to have suffered traffic accidents. A total of 558 patients (24.5%) received non-sedating antihistamines, 77 (3.4%) intranasal steroids, and 447 (19.6%) both medicaments together, whereas 1163 patients (51.1%) remained untreated.

Total Four Symptoms Score mean score was 5.59 (median 6, SD 1.59, range 3–12). According to ARIA 'conventional' classification, most patients had persistent, moderate/severe AR (46.2%) followed by intermittent, moderate/severe AR (41.4%), mild intermittent (8.8%), and mild persistent (3.6%). That is to say, the majority of the patients (87.6%) presented with moderate/severe AR. According to the modified ARIA classification [31], 1362 patients (59.9%) suffered from moderate AR, 630 (27.7%) severe and 283 (12.4%) mild (Table 2). A total of 599 patients (26.3%) from the total sample had concomitant asthma, most of them mild, according to GINA guidelines[40].

Quality of life

Figure 1 shows the relative percentages of patients included in each ARIA domain (Sleep, leisure activities, work/school performance, bothersome symptoms). Sleep domain was impaired in more than half (50.7%) the total sample.

The RQLQ showed a global mean score of 1.9 (SD: 1.1, range: 0–6). Higher values corresponded to those items related to domains of activity limitation (mean 2.8 ± 1.4), nasal symptoms (mean 2.7 ± 1.4), and

Table 1. Demographic characteristics and its relation to sleep quality

Feature	All patients	Good sleep quality (PSQI < 5)	Bad sleep quality (PSQI ≥ 5)	Comments
n	2275	1069 (47%)	1206 (53%)	–
Age (years), mean (±SD)	36.2 (±12.9)	34.7 (±12.7)	37.6 (±13)	$P < 0.001$
Age: ≥50 years vs. < 50 years	338 vs. 1937	38.5% vs. 48.5%	61.5% vs. 51.5%	$P = 0.001$
Men/women (%)	47.5/52.5	50.2/44.4	49.8/55.6	$P = 0.005$
Body Mass Index, mean (±SD)	24.37 (±3.54)	24.2 (±3.6)	24.5 (±3.5)	$P = 0.021$
Urban setting	1605 patients (72.1%)	71%	70.1%	$P > 0.05$
Active smokers	20.1%	15.6%	24.1%	$P < 0.001$ vs. never- or former smokers
None or low physical activity (%)	63.6%	43.8%	56.2	$P < 0.001$ vs. moderate-intense physical activity
Habitual alcohol intake (Y/N,%)	33.7/62.3	41.2/49.9	58.8/50.1	$P < 0.001$
Motor vehicles' drivers (%)	68.3	67.2	69.1	$P = 0.351$
Suffered any traffic accident before (Y/N,%)	12.2/87.8	35.1/47.2	64.9/52.8	$P = 0.002$
Pharmacological therapy (Y/N,%)	56.1/43.9	50.8/44.9	49.2/45.1	$P = 0.052$
Non-sedating antihistamines only (%)	24.5	51.8	48.2	$P = 0.010$ vs. no antihistamine treatment
Intranasal steroids only (%)	3.4	55.8	44.2	$P = 0.115$ vs. no steroid therapy
Non-sedating antihistamines plus intranasal steroids (%)	19.6	47.6	52.4	$P = 0.115$ vs. no treatment, ns

Table 2. Allergic rhinitis classification by severity

ARIA Severity Classification		Modified ARIA severity classification [31]	
Grade	Frequency, n (%)	Grade	Frequency (%)
Mild Persistent	82 (3.6)	Mild	283 (12.4)
Mild Intermittent	201 (8.8)	Moderate	1362 (59.9)
Moderate/Severe Persistent	1050 (46.2)	Severe	630 (27.7)
Moderate/Severe Intermittent	942 (41.4)		
Total	2.275 (100.0)		

practical problems (mean 2.7 ± 1.6), with mean values greater than items related to sleep disturbance (mean 1.7 ± 1.5).

Sleep assessment

Pittsburgh Sleep Quality Index mean score in the total sample was 6.4 (median 6, SD: 3.7, range: 0–19). Subjective sleep quality was perceived as good enough by more than half (50.5%) the patients; the majority (72.6%) declared habitual efficient sleep, although mild sleep disturbances were recognized by 1539 patients (67.7%). 81.6% had used no sleep medications over the last month. Daytime dysfunction was not reported in 39.3% and mild in 38.6%, and was referred to as moderate or severe by 22.1% of patients only.

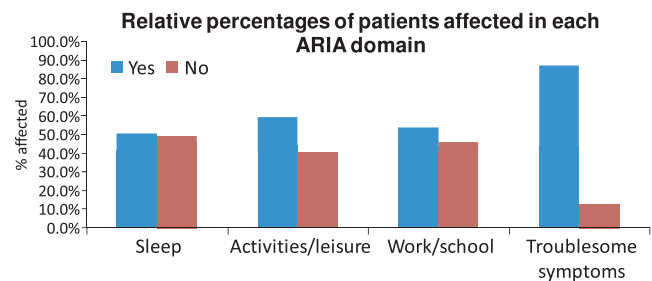


Fig. 1. Relative percentages of patients affected in each ARIA domain.

The PSQI > 5 was more common in women (55.6% vs. 49.8%, $P = 0.005$), and older (>50 years old) patients ($P = 0.001$). Regarding marriage status, PSQI > 5 was more widespread in widows/widowers (64.1%), and especially in divorcees/separated (72.4%) ($P < 0.001$). Concerning physical activity, PSQI > 5 was more common in sedentary, or poorly active patients ($P = 0.001$). A bad sleep quality was also more prevalent among smokers (63.5% of smokers had bad sleep quality, $P < 0.001$) and alcohol consumers (58.8%, $P < 0.001$). A mean body mass index (BMI) of 24.2 was associated with PSQI < 5, whereas a mean BMI of 24.5 or higher was associated to bad sleep quality ($P = 0.008$). The use of non-sedating antihistamines was associated with PSQI < 5 ($P = 0.01$). No significant relationship was found between sleep quality and urban or rural habitat, kind of work, regular or professional driving, or the use of intranasal steroids. Patients with

Table 3. Clinical symptoms, quality of life and its relation to sleep quality

Feature	All patients	Good sleep quality (PSQI < 5)	Bad sleep quality (PSQI ≥ 5)	Comments
n	2275	47%	53%	—
T4SS score, mean ± SD (range: 3–12)	5.59 ± 1.59	5.5 ± 1.5	6.0 ± 1.6	$P < 0.001$
RQLQ global score, mean ± sd	1.9 ± 1.1	1.48 ± 0.9	2.36 ± 1.1	$P < 0.001$
RQLQ sleep domain score, mean ± SD	1.7 ± 1.5	0.8 ± 1	2.4 ± 1.5	$P < 0.001$
Concomitant asthma (Y/N)	26.3%/73.7%	39.1%/49.6%	60.1%/50.4%	$P < 0.001$

Table 4. Daytime sleepiness according to Epworth scale categories and 'daytime dysfunction' domain from PSQI

Epworth scale categories	Frequency (%)	Frequency (%)	Daytime dysfunction from PSQI (Score range)
No diurnal somnolence	1799 (79.1)	887 (39.3)	No dysfunction
Mild diurnal somnolence	355 (15.6)	870 (38.6)	Mild dysfunction (1–9)
Moderate diurnal somnolence	116 (5.1)	391 (17.3)	Moderate dysfunction (10–18)
Severe diurnal somnolence	5 (0.2)	108 (4.8)	Intense dysfunction (19–27)
Total	2275	2256	Total

Pearson's $r = 0.37$; $P < 0.0001$

concomitant asthma had a worse sleep quality (PSQI > 5 in 60.1% vs. 50.4% in non-asthmatics, $P < 0.001$) (Table 3).

According to Epworth scale categories, the majority of patients (79.1%) accredited no daytime sleepiness, whereas 20.9% had excessive diurnal somnolence (15.6% mild). This was correlated with the PSQI domain 'daytime dysfunction' (Pearson's $r = 0.37$, $P < 0.0001$) (Table 4).

Relationships between rhinitis and sleep

Correlation between Pittsburgh index and RQLQ was significant, although moderate ($r = 0.54$). Taking each domain separately, higher RQLQ values were associated with worse sleep quality in all ($P < 0.001$).

Correlation between sleep quality (PSQI), daytime somnolence and ARIA categories for AR are summarized in Figs 2 and 3. As expected, the poorest sleep quality and greatest sleepiness were associated to persistent, moderate/severe AR (PSQI > 5 in 58.8%, excessive diurnal sleepiness in 25.3%) followed by intermittent, moderate/severe AR (PSQI > 5 in 53.9%, excessive diurnal sleepiness in 20.2%) ($P < 0.001$).

Obstruction, rhinorrhea, and pruritus all contributed to bad sleep quality ($P < 0.001$), whereas sneezing intensity did not appear to be associated with PSQI > 5. The percentages of involved patients increased with T4SS values, and a Mann–Whitney non-parametric test showed significant differences in symptom scores between patients with good or bad sleep quality ($P < 0.001$). As already stated, patients with concomitant asthma had a worse sleep quality, too (PSQI > 5 in 60.1% vs. 50.4% in non-asthmatics, $P < 0.001$). But taken the different AR severity categories, the coexistence of asthma was a factor worsening sleep quality

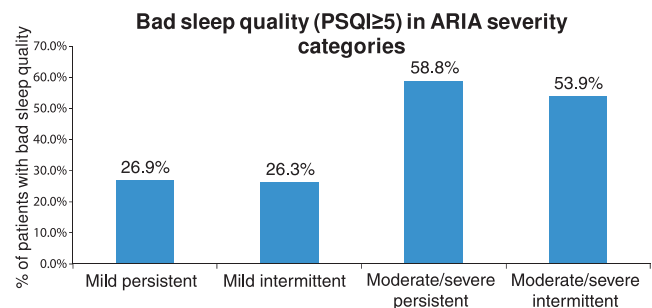


Fig. 2. Bad sleep quality (PSQI ≥ 5) in ARIA severity categories.

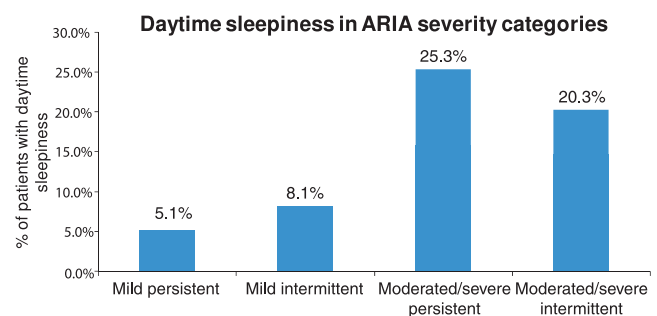


Fig. 3. Daytime sleepiness in ARIA severity categories.

only in moderate AR ($P < 0.002$) but not in mild, neither severe AR (Fig. 4).

In a logistic regression model, nasal obstruction (OR 1.6 CI 95% 1.2–2.14) and moderate-severe rhinitis (OR 1.8 CI 95% 1.07–3.06) were associated with a worse sleep quality.

Discussion

The term respiratory sleep-disordered breathing is commonly used to describe the full range of breathing

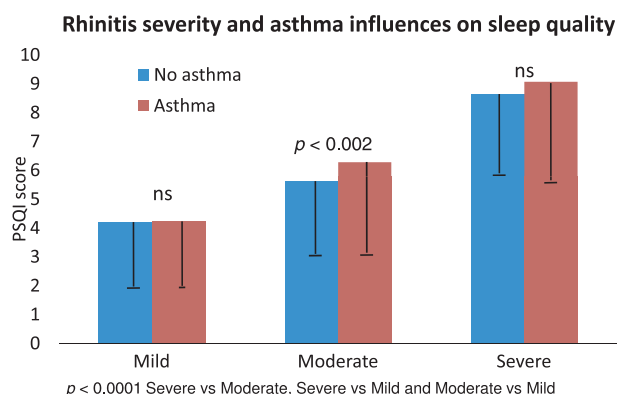


Fig. 4. Rhinitis severity and asthma influences on sleep quality. $P < 0.0001$ Severe vs. Moderate, Severe vs. Mild and Moderate vs. Mild.

problems during sleep (snoring, hypopnoea and apnoea). Sleep-disordered breathing is associated with a variety of health hazards, especially with an increased risk of driving accidents and other sleep deprivation-related events. It constitutes a troublesome factor not only in obstructive sleep-apnoea syndrome but also in AR, leading to daytime fatigue, somnolence, and QOL impairment. On one hand, AR impairs sleep; on the other hand, it seems demonstrated that poor sleep can also worsen allergic rhinitis [41]. Thus, a correlation between sleep quality and AR has been widely considered. However, this correlation has only occasionally been assessed before by surveys on large populations. In a recent French study carried out on 591 patients suffering from AR [30], sleep disorders and sleep quality were assessed through a number of different validated tools. This study demonstrated that all dimensions of sleep were impaired for AR, and showed a positive correlation between AR severity (either intermittent or persistent), and deterioration of sleep quality.

The SOMNIAAR study (Effect of allergic rhinitis and its treatment on sleep), carried out on a sample of more than 2000 patients, yielded results that emphasize those findings. To the best of our knowledge, this is the largest epidemiological survey, in terms of number of patients, which demonstrates a measurable relationship between AR severity and sleep quality.

Our patients showed an inverse correlation between sleep quality (assessed by PSQI) and AR severity (measured by ARIA severity classifications, either conventional or modified). In addition, a significant, although modest correlation was perceived between sleep quality and health-related quality of life; in every RQLQ domain taken separately, there were higher values associated with worse sleep quality. Consistent with prior studies, a worse sleep quality and greater daytime sleepiness were associated with severe forms of AR rather than to milder ones, either intermittent or

persistent. For the first time in medical literature, the relationship of sleep quality and sleepiness was assessed using the subcategories of rhinitis severity suggested by Valero et al. [31]: mild (no ARIA items affected), moderate (one to three ARIA items affected), and severe (all four items affected), thus underlining the association between poor sleep quality and severe AR. Patients with associated asthma had a worse sleep quality, too. However, taken the different AR severity categories, concomitant asthma was a factor worsening sleep quality only in moderate, but not in mild or severe AR. This finding might suggest that severe AR is able to determine sleep-disordered breathing by itself, without the necessary concurrence of asthma.

Several studies show a correlation between the reduction in nasal congestion by intranasal corticosteroids and the improvement in sleep and daytime somnolence [21]. However, in our study the use of intranasal corticosteroids was not associated with better sleep quality. These results were unexpected, and we think they are due to the fact that intranasal corticosteroids are used only in severe disease, naturally associated with a worse sleep quality.

On the other hand, our patients on non-sedating H1 antihistamines showed better sleep quality than untreated patients. This might be due again to the exclusive use of antihistamines in milder disease with naturally better sleep-related outcomes; anyhow, it is consistent with previous studies in which oral H1 antihistamines have been shown to improve sleep and QOL –using generic or disease-specific QOL instruments [20].

In our study, more than 85% of patients reported to have moderate-severe symptoms (46.2% persistent, 41.4% intermittent), according to ARIA classification. However, 51% declared to be untreated, even with over-the-counter medications, an odd fact since patients must have a T4SS ≥ 3 for inclusion. In our opinion, these findings might be explained by the patients suffering from seasonal (either persistent or intermittent) AR who were recruited or interviewed out of the peak season, reporting on scales symptoms under their threshold for medicines intake.

Interestingly, in spite of this established association between AR severity and sleep quality, only one in five patients reported to feel diurnal somnolence when assessed, either by sleepiness scales or the 'daytime dysfunction' item of the PSQI. However, daytime somnolence is the suspected cause for AR to concern school performance and work productivity [24, 42]. Thus, properly identifying these patients at risk could have significant consequences in their overall quality of life. Discrimination between patients with moderate and severe AR should result in a more accurate diagnostic and therapeutic approach to their expected sleep

disturbances and their subsequent costs in daytime life.

Conclusion

Our data from a large epidemiological study based on validated questionnaires show that sleep quality is altered in AR patients, and that a greater severity of AR is clearly correlated with a poorer sleep quality. Sleep quality is worse in moderate-severe AR, according to ARIA classification; and is worse in severe AR with respect to mild or even moderate AR, according to the recent modification of this categorization. The poorest sleep quality is associated with nasal obstruction and with RQLQ deterioration.

Clinical implications

Sleep impairment is common in allergic rhinitis, particularly in more severe forms. Nasal obstruction and con-

comitant asthma should be considered as contributing factors.

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