

Which type of allergic rhinitis is more associated with impaired quality of life and sleep and increased symptoms of anxiety and depression?

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Abstract

The present study aimed to assess the symptoms of anxiety and depression, quality of life (QoL), and sleep quality in patients with allergic rhinitis (AR). Additionally, the study sought to analyze the relationship between these parameters and the severity of the disease, duration of symptoms, seasonality, predominant symptoms, and the coexistence of asthma. A total of 88 patients with AR without any systemic comorbidity and 78 healthy controls were enrolled. Patients with AR were grouped as mild or moderate-severe, seasonal or perennial, intermittent or persistent, and sneezers-runners or blockers. The Hospital Anxiety Depression Scale (HADS), Short Form-36 (SF-36), and Single-item Sleep Quality Scale (SQS) were assessed. HADS depression and anxiety scores were elevated in patients with AR compared to healthy controls ($p=0.006$ and $p=0.025$, respectively), and SF-36 physical role functionality and general health perception domains and SQS scores were lower ($p<0.001$, $p<0.001$, and $p=0.004$, sequentially). HADS anxiety scores were more elevated in individuals with AR and concomitant asthma ($p=0.037$). Higher depression and anxiety scores and lower sleep quality were observed in the moderate-severe group relative to the mild group ($p=0.038$, $p=0.028$, and $p<0.001$, respectively), and in the persistent group relative to the intermittent group ($p=0.010$, $p=0.030$, and $p<0.001$ sequentially). Blockers had higher HADS scores ($p=0.010$ and $p=0.015$, respectively) and lower sleep quality and social role functioning than sneezers-runners ($p=0.040$ and $p=0.034$, in sequence). Our study showed that AR downgraded patients' well-being. The severity, persistence, perennialism, nasal obstruction, and asthma comorbidity of the disease in question had a deleterious effect on the QoL and sleep, as well as mood.

Keywords: Allergic rhinitis, seasonality, anxiety and depression, quality of life, sleep quality, asthma

Introduction

Allergic rhinitis (AR) is a prevalent disease all over the world with rates ranging from 5% to 50%, depending on geographic and genetic differences, as well as differences in age groups and methods of diagnosis in studies. According to epidemiologic studies, the prevalence of AR continues to increase worldwide [1,2]. AR causes a significant disease burden because it reduces the general and disease-specific quality of life (QoL) by affecting both physical and mental health. AR has been also shown to impair sleep quality in relation to its severity, therefore, affecting QoL even more negatively. Nevertheless, QoL and sleep behaviors have been shown to improve with appropriate treatment [1,3,4].

Numerous studies have demonstrated a strong connection between AR and symptoms of depression and anxiety [5,6].

While numerous studies have established a link between the severity of AR and diminished QoL, sleep quality, and mental health, the literature presents inconsistent findings concerning the differences between patients with perennial AR and those with seasonal AR, as well as between patients with persistent AR and those with intermittent AR [7-9].

In light of all these data, we can say that assessment of QoL, sleep quality and emotional status in the management of the AR process is essential. However, in the literature, the data reported about association between these well-being parameters and AR types are limited. We believe that uncovering the most relevant types of AR according to seasonality, predominant symptom, severity and persistence, as well as whether or not co-occurring asthma will help physicians develop standard management and follow-up strategies for AR patients.

CITATION

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Our study aimed to determine the differences in QoL, sleep quality, and mood outcomes between individuals with AR and healthy controls, as well as among AR patients based on seasonality, predominant symptom, severity, and persistence.

Material and Methods

Study Population and Design

This study was planned as a case-report study. The sample for this study was made up of patients with AR as well as healthy controls with no history of allergic disease. The patients included were aged 18 years and over who were diagnosed as having AR in the Adult Allergy-Immunology Outpatient Clinic of Bolu Abant İzzet Baysal University Training and Research Hospital between December 2022 and August 2023. The data of patients diagnosed with AR were obtained retrospectively after ethics committee approval. Those AR patients except the patients who had exclusion criteria made up our AR group. The inclusion of healthy controls in the study was carried out as soon as ethics committee approval was received. Healthy controls were selected from counselees without any disease who attended the Family Medicine Clinic between May 2024 and June 2024. Exclusion criteria for both patients and healthy controls were any systemic and psychiatric disorders.

The study received approval from the institutional ethics committee (Approval no: 2024/92). The patients included in the study received sufficient information and gave their informed consent in writing to participate in that study.

The sociodemographic characteristics of the patients such as age, sex, education status, occupation, and clinical details such as disease duration, symptom frequency, symptom duration, predominant symptoms, allergic sensitization, skin prick test results, presence of accompanying asthma, and treatment were recorded. Asthma control status, disease severity, asthma phenotype, and the patients' who had comorbid asthma treatment step were also recorded. The scores of the Hospital Anxiety Depression Scale (HADS), Short Form 36 (SF-36) and Single-item Sleep Quality Scale (SQS) for both patients and healthy volunteers were noted.

The patients were divided into perennial and seasonal groups based on seasonal nature of their symptoms and their allergic sensitization. Skin prick tests with house dust mite (HDM) (*Dermatophagoides pteronyssinus*, *Dermatophagoides farinea*), molds (*Alternaria alternata*, *Aspergillus fumigatus*), animal epithelia (dog and cat), goose/chicken feather, latex and pollens (grass, tree, and cereal) were performed and/or sp IgE was measured for these common aeroallergens. Patients classified under the 'perennial' group exhibited symptoms year-round and showed sensitization to allergens such as house dust mites, molds, animal epithelia, goose/chicken feathers, or latex. Conversely, patients in the 'seasonal' group experienced symptoms restricted to the pollen season and demonstrated sensitization to pollen [10]. Patients with AR were further classified as 'intermittent' or 'persistent' based on the symptom frequency per week. Moreover, patients were grouped into 'mild' and 'moderate'

according to the level of impairment in daily activities (one or more of sleep, work, school, bothering symptoms) [11]. Further, they were defined as 'sneezers-runners' or 'blockers' according to their predominant symptoms.

Measurements

Patients with seasonal AR were asked to complete the questionnaires and forms between March and June, when their symptoms were active. For patients with perennial AR, the time of completing the form was not important.

Anxiety and Depression Symptoms

Anxiety and depression symptoms were evaluated using the HADS, for which the Turkish adaptation, as well as its validity and reliability, was established by Aydemir et al. [12]. The scale is not intended to make a diagnosis, it is used for measuring anxiety and symptoms. The HADS is a 14-item self-report scale, comprising seven items for anxiety and seven for depression, with scores ranging from 0 to 21 and a threshold of 8 [13].

Quality of Life

The quality of life was assessed by means of the Turkish version of the SF-36 questionnaire [14]. The SF-36 survey form consists of eight subheadings and 36 questions. Positive and negative aspects of health status can be evaluated by obtaining separate scores for each subscale. Subscale scores span from 0 to 100, where higher scores denote better health status.

Sleep Quality

The Single-item Sleep Quality Scale (SQS), self-administered questionnaire, which was shown to be valid and reliable in Turkish society by Dereli et al., was used to assess sleep quality [15]. Patients are asked to answer by giving a score between 0 and 10 to the following question: "How would you rate your general sleep quality in the last 7 days?" (0= Terrible, 10= Excellent). Patients were also advised to think about their sleep quality in general and indicate their score by considering the following questions: "How many hours did you sleep, how easily did you fall asleep, how often did you wake up during the night (except to go to the toilet), how often did you wake up earlier than you should in the morning, and how restful was your sleep?"

Statistical Analysis

Statistical analyses were performed utilizing SPSS version 26 software. The normality of variable distributions was assessed using the Kolmogorov-Smirnov and Shapiro-Wilk tests. For variables following a normal distribution, descriptive statistics were presented as mean and standard deviation, while the median and interquartile range were used for variables not normally distributed. Categorical data were analyzed using the Chi-square test for comparisons between two independent groups. The significance of mean differences in normally distributed groups was evaluated through student-t test, whereas the Mann-Whitney U was employed to assess the significance of median differences in non-normally distributed groups. Statistical significance was defined as $p < 0.05$.

Sample Size and Power Analysis

For the sample size of our study, the sample size was 128 when d=0.5 (medium) for effect size, alpha value=0.05 (two-tailed) and the power of the study was 80%. In the post hoc analysis, we found the power of the sample to be 89.1% because a total of 168 patients were included during the recruitment period.

Results

One hundred sixty-six individuals were included in the study, comprising 88 patients with AR and 78 healthy controls (Figure 1). The mean age of the patients with AR was 34.08±12.99 and 80.7% (n=71) were women. No significant differences were observed between the patient and control groups in terms of age, sex, educational level, or employment status (Table 1).

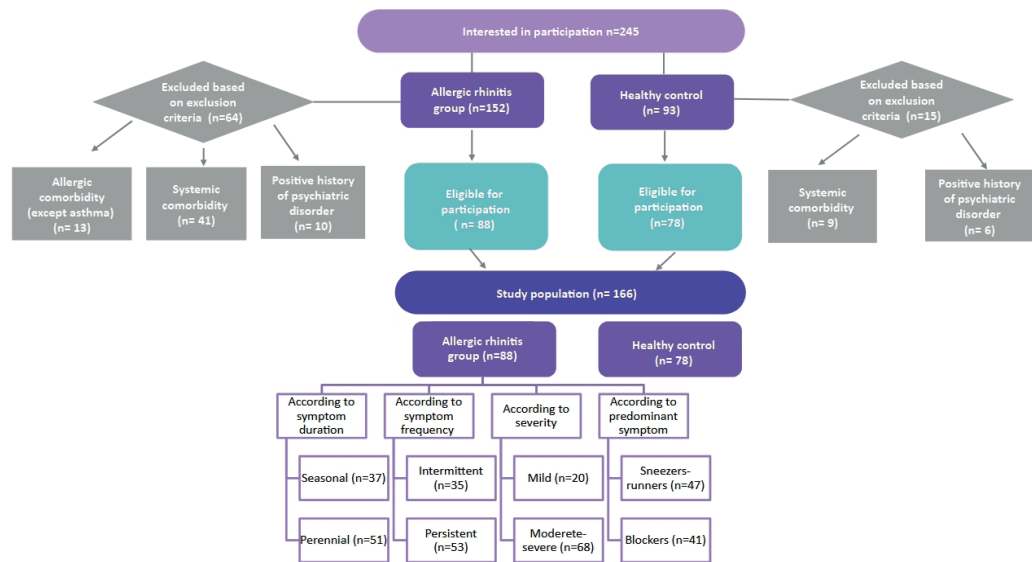


Figure 1. Study flowchart

Table 1. Demographic features of the study group

		Allergic rhinitis group (n=88)	Healthy control group (n=78)	p
Age mean±SD		34.08±12.99	35.15±9.26	0.537
Gender n (%)	Female	71 (80.7)	57 (73.1)	0.328
	Male	17 (19.3)	21 (26.9)	
Educational status n (%)	Elementary	16 (18.2)	7 (9)	0.145
	High school	43 (48.8)	37 (47.4)	
	College	29 (33)	34 (43.6)	
	Student	20 (22.7)	16 (20.5)	
Employment status n (%)	Housewife	18 (20.5)	18 (23.1)	0.507
	Civil servants	16 (18.2)	14 (17.9)	
	Self-employment	6 (6.8)	6 (7.7)	
	Retired	1 (1.1)	1 (1.3)	
	Worker	15 (17)	14 (17.9)	
Unemployed		12 (13.6)	9 (11.5)	

Data were presented as n (%) or mean±SD. P-values were calculated using a chi-squared test or Student-t test.

Patients with AR had the disease for a mean of 7.8±7.03 (min-max: 2-35) years. In these patients, HDM sensitization (n=46, 52.3%) was found to be the most common sensitization, followed by grass pollen (n=45, 51.1%), cereal pollen (n=27, 30.7%), tree pollen (n=25, 28.4%), mold (n=12, 13.6%), cockroach (n=8, 9.1%), cat epithelium (n=8, 9.1%), dog epithelium (n=4, 4.5%) goose/chicken feather (n=2, 2.3%), and latex (n=1, 1.1%) sensitizations. The treatments used by

patients with AR were as follows: intranasal corticosteroid (n=54, 61.4%), intranasal antihistamine (n=47, 53.4%), oral antihistamine (n=41, 46.6%), oral montelukast (n=41, 46.6%) and intranasal decongestant (n=7, 8%). Because there was no allergen immunotherapy product within the scope of reimbursement by the social security institution in our country during the study period, no patients were receiving allergen immunotherapy.

In the comparison of patients with AR and healthy controls, in patients with AR, both HADS depression and HADS anxiety scores were higher than in healthy controls ($p=0.006$ and $p=0.025$, respectively). Additionally, SF-36 physical role functioning, and general health perception domains were lower in patients with AR than in healthy controls ($p<0.001$ and $p<0.001$, respectively). Furthermore, the SQS score was lower in patients with AR compared with the healthy controls ($p=0.004$) (Table 2).

Table 2. Comparison of allergic rhinitis patients with healthy controls in terms of anxiety and depression symptoms and quality of life and sleep

	Allergic rhinitis group (n=88)	Healthy control group (n=78)	t	P
HADS depression score mean±SD	6.14±3.66	4.69±2.96	2.773	<u>0.006</u>
HADS anxiety score mean±SD	7.10±4.20	5.85±2.67	2.267	<u>0.025</u>
SF-36 physical functioning mean±SD	83.41±20.93	86.74±16.40	-1.085	0.265
SF-36 physical role functioning mean±SD	63.52±34.12	81.88±29.04	-3.640	<u><0.001</u>
SF-36 emotional role functioning mean±SD	64.45±35.07	69.57±41.12	-0.840	0.402
SF-36 vitality mean±SD	52.26±18.59	54.57±19.28	-0.757	0.450
SF-36 mental health mean±SD	60.03±14.94	62.20±18.88	-0.781	0.436
SF-36 social role functioning mean±SD	65.74±22.04	71.78±22.17	-1.699	0.091
SF-36 bodily pain mean±SD	66.34±23.91	71.88±22.43	-1.483	0.140
SF-36 general health perceptions mean±SD	54.44±16.35	65.65±17.61	-4.123	<u><0.001</u>
SQS mean±SD	5.01±2.04	5.99±2.08	-2.927	<u>0.004</u>

Data were expressed as mean±SD. The significance of mean differences across normally distributed groups was assessed via Student-t test. Statistical significance is at $p\leq0.05$; HADS: Hospital Anxiety and Depression Scale; SF: Short form; SQS: Single-item Sleep Quality Scale

Thirty-three patients with AR had accompanying asthma. The mean asthma control test scores at the last visit of the patients with asthma was 21.15±3.33 (min-max: 14-25). The distribution of asthma treatment steps was as follows: two (6.1%) patients in step 2, 15 (45.5%) patients in step 3, 10 (30.3%) in step 4, and six (18.2%) in step 5. Due to severe asthma, four (12.2%) patients were under biologic treatment. When patients with AR with accompanying asthma were compared with patients with AR alone, the analysis indicated that HADS anxiety scores were higher in patients with AR with accompanying asthma ($p=0.037$) and in these patients' mean HADS anxiety scores were above the cut-off value (8.30±4.47). The physical functioning and general health perception scores of the SF-36 were significantly lower in patients with AR who also had asthma, with p-values of 0.002 and 0.041, respectively (Table 3).

Table 3. Comparison of patients with allergic rhinitis alone and those with allergic rhinitis with accompanying asthma

	Patients with allergic rhinitis alone (n=55)	Patients with allergic rhinitis with accompanying asthma (n=33)	t	p
HADS depression score mean±SD	5.71±3.69	6.85±3.55	-1.421	0.159
HADS anxiety score mean±SD	6.38±3.89	8.30±4.47	-2.119	0.037
SF-36 physical functioning mean±SD	89.27±15.11	73.64±25.47	3.204	0.002
SF-36 physical role functioning mean±SD	67.82±32.49	56.36±36.04	1.537	0.128
SF-36 emotional role functioning mean±SD	65.08±34.88	63.42±35.90	0.217	0.331
SF-36 vitality mean±SD	52.28±19.35	52.24±17.53	0.008	0.993
SF-36 mental health mean±SD	60.75±16.46	58.85±12.14	0.574	0.567
SF-36 social role functioning mean±SD	66.96±21.99	63.71±22.31	0.666	0.507
SF-36 bodily pain mean±SD	69.55±21.48	60.98±26.99	1.642	0.104
SF-36 general health perceptions mean±SD	57.18±16.12	49.86±15.93	2.071	0.041
SQS mean±SD	5.18±2.25	4.73±1.64	1.091	0.278

Data were expressed as mean±SD. The significance of mean differences across normally distributed groups was assessed via Student-t test. Statistical significance is at $p\leq0.05$; HADS: Hospital Anxiety and Depression Scale; SF: Short form; SQS: Single-item Sleep Quality Scale

Among patients with AR, when perennial perineal (n=51) and seasonal (n=37) groups were compared in terms of HADS, SF-36, and sleep quality, there was only significance in HADS depression, which was higher in the perennial group ($p=0.032$). Comparing the patients with AR according to disease severity as mild (n=20) and moderate-severe (n=68), HADS depression and anxiety scores were statistically significantly higher ($p=0.038$ and $p=0.028$, respectively), and SF-36 social functionality and

sleep quality scores were significantly lower in the moderate-severe group ($p=0.002$ and $p<0.001$, respectively).

When comparing patients based on symptom frequency, categorized as intermittent ($n=35$) and persistent ($n=53$), HADS depression and anxiety scores were significantly greater in the

persistent group, with p -values of 0.010 and 0.030, respectively. Among the SF-36 domains, physical role functioning, vitality, and social role functioning scores were lower in the persistent group ($p=0.015$, $p=0.027$ and $p=0.002$, respectively). The SQS score was significantly diminished in the persistent group ($p<0.001$) (Figure 2).



Figure 2. Comparison of intermittent and persistent groups

Grouping according to predominant symptoms, there were 47 (53.4%) blockers and 41 (46.6%) sneezers/runners. Forty-three (91.5%) of the 'blockers' had perennial allergen sensitivity and symptoms, and 33 (80.5%) of the 'sneezers-runners' had seasonal AR ($p<0.001$). Persistent symptoms were present in 34 (72.3%) of the 'blockers', compared with 19 (46.3%) of the 'sneezers-runners' ($p=0.013$). The rate of being in the moderate-severe group was 87.2% ($n=41$) in 'blockers' and 65.9% ($n=27$) in 'sneezers-runners' ($p=0.33$). Asthma accompanied AR in

23 (48.9%) of the 'blockers', whereas it was present in just 10 (24.4%) of the 'sneezers-runners' ($p=0.018$). In terms of HADS depression and anxiety, QoL, and sleep quality, 'blockers' had significantly higher HADS depression and anxiety scores than 'sneezers-runners' ($p=0.010$ and $p=0.015$, respectively). Sleep quality and SF-36 social role functioning were significantly lower in 'blockers' than in 'sneezers-runners' ($p=0.040$ and $p=0.034$, respectively) (Table 4).

Table 4. Comparison of groups according to predominant symptoms

	Allergic rhinitis sneezers/runners (n=41)	Allergic rhinitis blockers (n=47)	t	p
HADS depression score mean±SD	5.07±2.93	7.06±4.00	-2.629	<u>0.010</u>
HADS anxiety score mean±SD	5.95±3.49	8.11±4.53	-2.471	<u>0.015</u>
SF-36 physical functioning mean±SD	87.80±15.17	79.57±24.42	1.924	0.058
SF-36 physical role functioning mean±SD	64.88±33.29	62.34±35.18	0.346	0.730
SF-36 emotional role functioning mean±SD	64.46±35.47	64.45±35.10	0.001	1.000
SF-36 vitality mean±SD	54.66±19.66	50.17±17.55	1.133	0.260
SF-36 mental health mean±SD	61.02±17.80	59.17±12.04	0.564	0.575
SF-36 social role functioning mean±SD	71.03±22.21	61.12±21.04	2.150	<u>0.034</u>
SF-36 bodily pain mean±SD	70.49±22.95	62.71±24.39	1.533	0.129
SF-36 general health perceptions mean±SD	57.02±17.15	52.18±15.45	1.394	0.167
SQS mean±SD	5.49±2.06	4.60±1.95	2.082	<u>0.040</u>

Data were expressed as mean±SD. The significance of mean differences across normally distributed groups was assessed via Student-t test. Statistical significance is at $p\leq0.05$.; HADS: Hospital Anxiety and Depression Scale; SF: Short form; SQS: Single-item Sleep Quality Scale

Discussion

The present study demonstrated that patients with AR exhibited diminished QoL, heightened anxiety and depression symptoms, and suboptimal sleep quality relative to healthy individuals. The coexistence of AR and asthma increased the anxiety symptoms and decreased the physical functioning and general health perceptions even further. The severity and persistence of the disease were found to be associated with a range of adverse outcomes, including depression and anxiety, QoL, and sleep quality. Quality of life and sleep quality were independent of seasonality, but perennial AR was associated with more depression symptoms. Patients with predominant nasal blockage experienced more depression and anxiety symptoms, had more limited social functioning, and worse sleep quality.

In our study, in patients with AR compared with healthy controls, depression and anxiety symptoms were more common, QoL was worse, and sleep quality was poorer. This primary finding is consistent with previous studies. An association between AR and depression and anxiety, poor sleep quality, and decreased QoL has been shown in multiple studies [6,16-20]. At the macro level, this triangular relationship could be explained by withdrawal from the social environment, impairment of work and productivity, affected communication, deterioration of sleep quality due to AR symptoms, and subsequent worsening of mood and decreased QoL, and eventually further worsening of AR symptoms. The inflammatory response in AR may be considered a micro-mechanism, as it is known to cause neuroinflammation, oxidative stress and central neurotransmitter disorders, as well as genetic susceptibility [5]. We also think that the increased depressive and anxiety symptoms, poor QoL, and sleep quality in our patients with AR may be due to our patients not receiving allergen immunotherapy because most of our patients had moderate-to-severe AR and had indications for allergen immunotherapy. However, at the time the study was conducted, there were no immunotherapy products available in our country that were within the scope of reimbursement by the social security institution and patients could not afford to pay the immunotherapy fee.

According to our results, adverse outcomes including increased depression and anxiety symptoms, and decreased QoL and sleep were even worse in the severe and persistent groups. Parallel to our results, it has been shown in many studies that these adverse outcomes associated with AR increase, especially as the disease severity increases. Regarding symptom persistence, many studies have shown that disease persistence has a similar impact on QoL, anxiety, depression, and sleep quality as disease severity [21-23]. Conversely, some studies have indicated that the severity of the disease is a more significant factor than whether it is intermittent or persistent. In a study with a large patient population, the effect of disease severity on QoL was found to be much more important than its persistence [24]. In a separate study, symptom severity was found to be the most significant factor associated with increased anxiety and depression, as well as poor sleep,

regardless of persistence. However, symptom severity and persistence were also found to be independently associated with decreased QoL [9]. Another study investigating the effect of AR on sleep quality found that severe symptoms significantly reduced sleep quality, but being intermittent or persistent had no effect on sleep quality [25].

Increased anxiety symptoms and decreased physical functioning and general health perception were found in our patients with AR with accompanying asthma. In a study that included 524 patients and used the symptom check list-90 (SCL-90) to evaluate psychological status, it was found that patients with coexistent asthma and AR were more affected than patients with AR alone [26]. In another study, QoL was worse in patients with coexistence of asthma and AR than in patients with AR alone [8]. A meta-analysis of 19 studies involving 106,813 patients with asthma indicated 32% 0.32 (95% CI: 0.22–0.43) and 24% 0.24 (95% CI: 0.13–0.41) prevalence of anxiety symptoms and anxiety disorders, respectively. These figures represent an extremely high rate. [27]. When all these literature data and our results are evaluated together, the importance of questioning and monitoring patients with AR in terms of asthma emerges.

In our study, patients with perennial AR had more depression symptoms than those with seasonal AR. In different studies, results regarding the effect of seasonality on mood in patients with AR are contradictory. A study found no difference in anxiety or depression scores between patients with seasonal AR and those with perennial AR [6]. In a study conducted in Spain, similar to the results of our study, HAD depression scores were higher in the perennial group than in the seasonal group, and the risk of depression was 3.3 times higher compared to the seasonal group [9]. In another study, seasonal AR was found to be linked to anxiety, while perennial AR was associated with depression [28]. A study investigating depressive and anxiety symptoms and their relationship with inflammatory parameters in patients with seasonal AR indicated that depressive symptoms increased during the pollen season and that this increase was linked to an elevation in the IL-6, IL-6/IL-10 and IFN- γ /IL-10 ratio [29]. Although the results of that study seem to contradict ours, the relationship revealed in the study between depression and inflammation parameters suggests that the long allergen exposure period in patients with perennial AR in our study may cause chronic inflammation and ultimately trigger depression.

The effects of dominant symptoms on patients' QoL, sleep quality, and depression and anxiety symptoms were evaluated in the current study and 'blockers' had more depression and anxiety symptoms and lower sleep quality and social functioning. It has been shown in different studies that nasal congestion and obstruction, among the symptoms of AR, significantly affect sleep quality and consequently QoL [30,31]. However, limited research has explored the impact of AR symptoms on psychological well-being. In one of these studies, depression was associated with sneezing and runny nasal discharge, and anxiety showed a positive association with nasal itching and nasal

obstruction [32]. Our finding in ‘blockers’ of more depressive and anxiety symptoms might be because they had more severe, persistent, and perennial symptoms and a higher rate of asthma.

It is important to acknowledge the limitations of this study. The primary limitation lies in the difficulty of establishing a cause-and-effect relationship due to the cross-sectional study design. Additionally, the assessment of depression, anxiety symptoms, QoL, and sleep quality was performed using subjective measurement methods, which constitutes another significant limitation.

Conclusion

In conclusion, the present findings suggest that AR affects QoL, causes symptoms of depression and anxiety, and disrupts sleep quality. In addition, disease severity, persistence, and having nasal blockage as the predominant symptom impacts on these worse outcomes. Comorbid asthma increased anxiety symptoms, and perennial AR was associated with more depression symptoms than seasonal AR. The findings of our study indicate the significance of meticulous identification of patients with AR, assessment of the presence of asthma, and, most importantly, consideration of the psychological state and QoL in each patient.

Conflict of Interests

The authors declare that there is no conflict of interest in the study.

Financial Disclosure

The authors declare that they have received no financial support for the study.

Ethical Approval

The local ethics committee of Bolu Abant İzzet Baysal University, School of Medicine, approved the study (Approval no: 2024/92). The study was conducted pursuant to the Declaration of Helsinki.

Patient Informed Consent

The authors declare that they have followed the protocols of their work centre on the publication of patient data and that the patients included in the study received sufficient information and gave their informed consent in writing to participate in that study.

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