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Assessment of quality of life in IPF Patients: A multicenter observational study

Fatih Uzer[1], Aykut Cilli[1], Ismail Hanta[2], Funda Coskun[3], Can Sevinc[4], Ahmet Ursavas[3], Asim Leblebici[5], Gozde Yilmaz[2], Gamze Celik Yazici[3], Ibrahim Kamel[1]

[1]Department of Respiratory Medicine, Akdeniz University School of Medicine, Antalya, Turkey; [2]Department of Respiratory Medicine, Cukurova University School of Medicine, Adana, Turkey; [3]Department of Respiratory Medicine, Uludağ University School of Medicine, Bursa, Turkey; [4]Department of Respiratory Medicine, Dokuz Eylül University School of Medicine, İzmir, Turkey; [5] Department of Translational Oncology, Dokuz Eylül University Institute of Health Sciences, İzmir, Turkey

Abstract. *Aim:* This study aimed to examine how dyspnea, cough, sleep disruption, anxiety, depression, and physiological factors affect the quality of life in newly diagnosed, untreated IPF patients. *Methods:* This study is a multicenter observational study. Patients not receiving antifibrotic treatment were included. To assess patients' quality of life, Leicester Cough Questionnaire (LCQ), St. George's Respiratory Questionnaire (SGRQ), Short Form-36 (SF-36), Hospital Anxiety and Depression Scale (HADS), Borg Dyspnea Index (BDI), Modified Medical Research Council Dyspnea Scale (MMRC) score, Composite Physiological Index (CPI), Gender Age and physiology (GAP) score, and Pittsburgh Sleep Quality Index (PSQI) were administered. *Results:* Among 88 patients (mean age: 67.6±8.5 years), 81.9% were diagnosed with IPF through HRCT, 14.8% through surgery, and 3.4% via cryobiopsy. The average disease duration was 2.2±2.9 years. Over 50% experienced moderate to severe depression, and 40% had moderate to severe anxiety. In the IPF group, 13.6% had possible usual interstitial pneumonia (UIP), and 81.8% had definite UIP pattern. No significant differences were found between UIP groups in various scores. Anxiety and depression correlated negatively with respiratory function and positively with MMRC score and BDI. Sleep quality scores had similar correlations. Patients with good sleep quality had better respiratory parameters (p=0.013), lower MMRC (p=0.004), BDI (p=0.026), and CPI (p=0.047). *Conclusion:* A notable number of IPF patients in follow-up show symptoms of anxiety and depression. Moreover, declining respiratory function not only diminishes sleep quality but also elevates dyspnea scores.

Key words: IPF, mood disorders, quality of life, sleep disturbance

Introduction

Idiopathic pulmonary fibrosis (IPF) is a chronic and progressive interstitial lung disease characterized by the formation of fibrosis in the lungs, severely impacting respiratory function (1). Symptoms of IPF include shortness of breath, cough, fatigue, and decreased exercise tolerance. Presently used medications, nintedanib and pirfenidone, come with notable adverse effects. Furthermore, as the illness advances, patients experience profound debilitation and enduring reliance on supplementary oxygen. Hence, it is evident that IPF profoundly affects a patient's functional vitality and overall welfare. As IPF advances, dyspnea becomes a cause of substantial activity restrictions, resulting in noteworthy adverse effects on the emotional well-being and social roles of individuals with IPF.

IPF imposes a significant burden on patients and can negatively affect their quality of life. Despite the pronounced influence of IPF on the health-related quality of life of patients, there exists a scarcity of

Correspondence: Aykut Cilli
Akdeniz University, Department of Respiratory Medicine, Antalya, Turkey
Phone:+902422496692
E-mail: acilli@akdeniz.edu.tr

research addressing the health-related quality of life encounters of those affected by IPF. Assessing the quality of life in IPF patients is important to understand the effectiveness of treatment and care approaches and monitor the progression of the disease.

There is a lack of sufficient studies measuring the quality of life in IPF in Turkey. Furthermore, there is currently no specific scale or questionnaire available to assess health-related quality of life in IPF in daily clinical practice. Researchers mostly utilize scales and questionnaires developed for other respiratory diseases. Especially in interstitial lung diseases (ILD), it is important for the King's Brief Interstitial Lung Disease (K-BILD) questionnaire to provide insight into patients' health status (2). Previous studies have reported that IPF patients are more depressive compared to a healthy control group, and depressive symptoms deepen as breathlessness increases (3,4). In more recent studies, IPF has been shown to have a similarly detrimental impact on the quality of life of patients, particularly in the domains of physical function, anxiety, pain, depression, and fatigue (5).

Very few studies in the literature primarily concern the validation of existing quality of life tests (6–8). In this study, our aim was to investigate the correlation between multiple quality of life tests in routine use and physiological parameters in patients with IPF. Scales and questionnaires are commonly used to assess quality of life. In this study, an appropriate scale and questionnaire were selected to measure the quality of life in IPF patients. The results of the study can contribute significantly to evaluating the factors influencing the quality of life in IPF patients and the effectiveness of current treatment options. Additionally, this study can contribute to the development of future interventions to improve the quality of life in IPF patients.

Patients and method

This study is a multicenter cross-sectional study. IPF patients diagnosed in four tertiary care centers in Turkey were included in the study. The patients who applied between May 1 and October 31, 2018, were included in the study. Only patients not receiving any antifibrotic treatment were included. To assess patients' quality of life, Leicester Cough Questionnaire, St. George's Respiratory Questionnaire (SGRQ), Short Form-36 (SF-36), Hospital Anxiety and Depression Scale (HADS), Modified Medical Research Council Dyspnea Scale (MMRC) score, Composite physiologic index (CPI) Borg dyspnea index (BDI) and Pittsburgh Sleep Quality Index (PSQI) were administered. The questionnaires were administered to patients under the supervision of the treating physician and the Turkish versions of these questionnaires, with reliability and validity, were utilized. The completion of all surveys took an average of 30 minutes during outpatient clinic visits and face-to-face interviews. Patients diagnosed with IPF according to the ERS/ALAT/ATS guidelines were included in the study (1). Patients receiving antifibrotic treatment, those with non-IPF interstitial lung diseases, IPF patients with malignancy, those with rheumatologic diseases, patients who refused to answer the questions, and patients with cognitive impairments such as Alzheimer's or dementia were excluded from the study.

Short Form-36 (SF-36)

The SF-36 was used to assess the quality of life. This questionnaire was developed by the Rand Corporation and has been translated into Turkish with a conducted validity and reliability study (9). It consists of 36 items that measure eight dimensions: physical function, social function, role limitations due to physical problems, role limitations due to emotional problems, mental health, energy/vitality, pain, and general perception of health. The subscales evaluate health on a scale of 0 to 100, where 0 indicates 'poor health' and 100 indicates 'good health'.

Leicester Cough Questionnaire (LCQ)

LCQ measures the impact of cough on quality of life. It consists of 19 questions and has psychological, social, and physical subdimensions. The cut off value for the scale has not been defined; lower scores indicate a greater impact from cough, representing a worse quality of life.

St. George's Respiratory Questionnaire (SGRQ)

SGRQ is a self-administered questionnaire designed to measure health impairment in patients with airway diseases such as asthma and chronic obstructive pulmonary disease (COPD). It contains 50 items divided into three components: Symptoms

(8 items), Activity (16 items) and Impacts (26 items). The SGRQ total score ranges from 0 to 100, where 100 indicates the worst quality of life, and its minimum clinically important difference (MCID) value is 4 units.

Pittsburgh Sleep Quality Index (PSQI)

PSQI is a self-report questionnaire that assesses sleep quality over a 1-month period. The Pittsburgh Sleep Quality Index (PSQI) was originally developed by Buysee et al.(10) in 1988 to assess sleep quality. Agargun et al. (11) conducted the Turkish validity and reliability study for the PSQI. The results of the study indicated a high level of internal consistency for the scale. The PSQI consists of a total of 24 questions, with 19 of them being self-report questions. The remaining five questions are answered by a spouse or roommate and are used for clinical information purposes only, not included in the scoring process. Question 19, which asks about the presence or absence of a roommate or partner, is not considered in the calculation of the component scores of the scale. The 19 self-report questions included in the scoring are grouped into seven component scores, some consisting of a single question's score while others are obtained by combining multiple questions. These components cover various aspects of sleep, including sleep quality, sleep onset latency, sleep duration, sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction. Each component is scored on a scale of zero to three. The sum of the scores from the seven components yields the PSQI score, which ranges from 0 to 21. Individuals with a total score below five are considered to have good sleep quality, while those with a score of five or higher are classified as having poor sleep quality.

Hospital Anxiety and Depression Scale (HADS)

HADS aims to measure symptoms of anxiety and depression and consists of 14 items, with seven items for the anxiety subscale (HADS Anxiety) and seven for the depression subscale (HADS Depression). Each item is scored on a scale ranging from 0 to 3. The two subscales are obtained by summing the responses after adjusting for six reversed-scored items. Recommended cut off scores are 8-10 for doubtful cases and ≥11 for definite cases.

Composite physiologic index (CPI)

It is developed as a tool to reflect the morphologic extent of pulmonary fibrosis in IPF on computed tomography. CPI was calculated according to Wells et al.(12): CPI parameters as follows: 91.0 − (0.65 × DLCO percentage of the predicted value [% pred]) − (0.53 × FVC % pred) + (0.34 × forced expiratory volume [FEV1] % pred). Mura et al.(13) showed that a CPI>41.0 was significantly associated with 3-year survival in a prospective cohort (hazard ratio [HR]=5.36, P=0.0071), as well as in a retrospective cohort (HR=4.20, P=0.042).

The modified Borg dyspnea score

It uses a scale from 0 to 10, where 0 represents no dyspnea and 10 represents maximal dyspnea. Scores are obtained at the end of the 6MWD test and reflect the maximum degree of dyspnea at any time during the walk test.

The ethical approval for the study was granted by the Uludağ University Faculty of Medicine Clinical Research Ethics Committee with decision number 2018-7/28 on April 10, 2018.

Statistical analysis

The suitability of variables for normal distribution was assessed using the Shapiro-Wilk test. Continuous variables were expressed as mean ± SD values. Categorical variables were presented as n (%). Categorical variables were compared using the Chi-Square test between groups. In comparisons between two groups where normal distribution was not met according to the normality test, the Mann-Whitney U test was applied. For comparisons between two groups with normal distribution, independent samples t-test was employed. Relationships between continuous variables were examined using correlation analysis, and Spearman's correlation coefficient was calculated. Statistical analyses were conducted using SPSS (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) software, and $p<0.05$ was considered statistically significant.

Results

A total of 88 patients with a mean age of 67.6±8.5 were included in the study. Seventy-five (81.9%) of the

patients received an IPF diagnosis based on HRCT, 13 (14.8%) through surgery, and 3 (3.4%) via cryobiopsy. The average duration of disease was 2.2±2.9 years, and 2.3% (2) of the patients had a family history of IPF. The most common symptoms were cough (89.8%), dyspnea (86.4%), and exercise intolerance (83%), while the most common physical examination finding was velcro rales (97.7%). The basic characteristics of the patients are presented in Table 1.

The mean Borg score was 3.6±2.1, MMRC score was 2.0±1.0, and PSQI score was 6.3±3.9 for the included patients. The St. George's Respiratory Questionnaire, SF-36 scores, and Leicester Cough Questionnaire scores are presented in Table 2. More than 50% of the patients showed symptoms of moderate to severe depression, and over 40% showed symptoms of moderate to severe anxiety. The HADS scores of the patients are presented in Figure 1.

Among IPF patients, 12 (13.6%) had possible usual interstitial pneumonia (UIP), and 81.8% (74) had definite UIP pattern. No statistically significant differences were found between patients with definite UIP and possible UIP patterns in terms of SF-36 components, SGRQ scores, cough questionnaire scores, depression scores, anxiety scores, and sleep quality (Table 3).

Anxiety and depression scores exhibited a negative correlation with FVC, FEV1, DLCO, and DLCO/VA, and a positive correlation with MMRC score and BDI. SGRQ and PSQI scores were found a negative correlation with DLCO and a positive correlation with MMRC score and BDI. Furthermore, the Leicester Cough Questionnaire demonstrated a positive correlation with DLCO and DLCO/VA, while showed a negative correlation with MMRC and BDI (Table 4).

Patients with good sleep quality were found to have higher DLCO (p=0.013), lower MMRC (p=0.004), BORG Dyspnea Index (p=0.026), and CPI (p=0.047) values (Table 5).

Prevalence of depression and anxiety according to GAP Stage were presented in Figure 2.

Table 1. Basic characteristics

	mean±sd
Age/years	67.6±8.5
BMI	27.6±3.6
Duration of disease	2.2±2.9
Smoking pack/year	24.3±24.8
GAP score	3.5±1.4
CPI	45.4±14.7
PFT	
FVC	73.4±16.6
FEV1	79.5±16.5
FEV1/FVC	
DLCO	53.1±17.4
DLCO/VA	69.8±20.8
6MWT	358.4±84.9
SpO_2 (min)	90.5±5.9
n(%)	
SpO_2 (rest)	94±3.1
Sex /male	68 (77.3)
Symptom	
Cough	79 (89.8)
Dyspnea	76 (86.4)
Exercise intolerance	73 (83)
Familial	2 (2.3)
Physical examination	
Velcro crackles	86 (97.7)
Clubbing	19 (21.6)
Smoking	
Current/former	64 (72.7)
Never	24 (27.3)
Comorbidity +	47 (53.4)
LTOT +	8 (9.1)
Diagnosis	
HRCT	75 (81.9)
Surgery	13 (14.8)
Criobiopsy	3 (3.4)

Abbreviations: BMI: body mass index, GAP: gender-age-physiology, PFT: pulmonary function test, LTOT: Long term oxygen treatment, CPI: Composite physiologic index, FVC: forced vital capacity, FEV1: Forced expiratory volume in the first second, DLCO: diffusion capacity for carbon monoxide, 6MWT: six minute walk test, SpO2: Finger tip oxygen saturation, HRCT: High-resolution computed tomography.

Discussion

IPF is a chronic and progressive lung disease that poses significant challenges in both diagnosis

Table 2. Dyspnea and/or quality of life questionnaire results.

Questionnaire	**mean±sd**
Borg dyspnea score	3.6±2.1
MMRC	2.0±1.0
SGRQ	
Symptoms	54.3±20.5
Activity	54.5±24.9
Impacts	39.6±25.4
Total	**46.7±22.4**
SF-36	
Physical functioning	52.6±26.4
Role-physical	41.8±43.9
Role-emotional	45.8±41.8
Vitality	49.3±22.4
Mental health	59.2±21.9
Social functioning	62.1±26.5
Bodily pain	71.6±25.9
General health	41.5±19.9
Leicester cough questionnaire	
Physical	4.5±1.3
Psychological	4.5±1.4
Social	4.8±1.7
Total	**13.8±4.2**
PSQI	6.3±3.9

Abbreviations: SGRQ: St. George's Respiratory Questionnaire, PSQI: Pittsburgh Sleep Quality Index, SF-36: Short form 36.

and management. In this study, we investigated various aspects of IPF, including patient demographics, clinical characteristics, psychological well-being, and their impact on pulmonary function. Our findings shed light on several key aspects of this complex disease. In our study, no statistically significant difference was found in terms of quality of life between patients with radiologically possible UIP and definite UIP. However, it was observed that a decrease in PFT tests was associated with an increase in anxiety and depression, an increase in DLCO was associated with an increase in SGRQ and LCQ scores, and BDI was found to be correlated with both sleep quality, anxiety, depression, and SGRQ

Our study included a cohort of 88 patients with a mean age of 67.6 years, which is consistent with the typical age range of individuals affected by IPF. The majority of patients received an IPF diagnosis through HRCT, highlighting the importance of this non-invasive imaging modality in the diagnostic process. Additionally, the presence of cough, dyspnea, and exercise intolerance as the most common symptoms underscores the clinical manifestations that are often associated with IPF. The primary concerns expressed by IPF patients typically include dyspnea and cough. Consequently, our assessment incorporated three dyspnea rating scales: the MRC scale and the BDI. In the absence of a dedicated Health-Related Quality of Life (HRQoL) questionnaire tailored

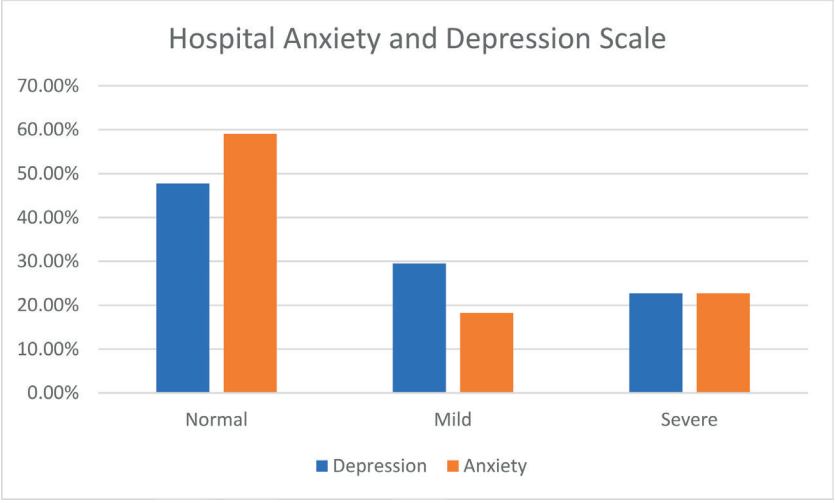

Figure 1. Distribution of the HADS questionnaire results.

Table 3. Comparison of quality of life, cough, sleep, anxiety, and depression status according to possible-definite uip (radiologically)

		Possible-UIP (n=12)	Definite-UIP (n=74)	p
SGRQ	Symptoms	52.7±23.3	54.5±20.5	0.771
	Activity	56.3±22.6	54.2±25.3	0.788
	Impacts	40.3±20.6	39.4±26.1	0.907
	Total	47.4±19.7	46.5±22.9	0.908
Leicester cough questionnaire	Physical	4.4±1.4	4.5±1.3	0.918
	Psychological	4.5±1.5	4.5±1.4	0.941
	Social	4.6±1.5	4.8±1.7	0.716
	Total	13.6±4.3	13.8±4.3	0.839
SF-36	Physical functioning	64.5±24.9	50.6±26.2	0.089
	Role-physical	39.5±43.2	42.1±44.2	0.854
	Role-emotional	38.8±42.2	46.9±41.9	0.539
	Vitality	49.1±22.3	49.3±22.6	0.980
	Mental health	62.0±25.1	58.7±21.5	0.640
	Social functioning	62.5±27.7	62.0±26.5	0.953
	Bodily pain	79.7±22.9	70.2±26.2	0.238
	General health	49.5±21.6	40.2±26.2	0.132
HADS	Anxiety	6.4±3.9	7.5±4.4	0.406
	Depression	5.5±3.9	7.2±4.7	0.252
PSQI		5.5±2.4	6.4±4.1	0.485

Abbreviations: SGRQ: St. George's Respiratory Questionnaire, PSQ: Pittsburgh Sleep Quality Index, SF-36: Short form 36, HADS: Hospital Anxiety and Depression Scale.

specifically for IPF, we employed a general questionnaire, namely the SF-36, alongside a disease-specific HRQoL questionnaire for pulmonary conditions, the SGRQ. Additionally, the HAD Questionnaire was utilized to appraise the psychosocial dimensions of the illness.

Dyspnea stands out as one of the most prevalent symptoms experienced by individuals with IPF. It is evident that the degree of dyspnea is closely linked to the severity of the disease in IPF patients. Numerous studies have delved into the impact of dyspnea on the Health-Related Quality of Life (HRQoL) of IPF patients (14–17). Our examination of dyspnea scale scores revealed a noteworthy association with anxiety, depression, LCQ, and SGRQ. In a study involving 23 patients with ILD, Mahler and Wells explored clinical methods for assessing dyspnea and observed a significant correlation between dyspnea ratings and PFTs. Additionally, Tzanakis et al.(4) demonstrated a substantial correlation between dyspnea scales and KCO. According to Chang et al.'s study on 50 IPF patients, the SGRQ symptom score was found to be an average of 50.5, while the activity score was 54.4, the impact score was 28.4, and the total score was 38.9 (18). In our study, the included patients had an average SGRQ symptom score of 54.3, an activity score of 54.5, an impact score of 39.6, and a total score of 46,7. The values obtained in our study were high, indicating a low quality of life. On the other hand, we observed that SGRQ scores were negatively correlated with DLCO, suggesting that greater symptom burden is associated with worse pulmonary function. Additionally, the Leicester Cough Questionnaire exhibited a positive correlation with DLCO and DLCO/VA, indicating that improved cough-related quality of life may be associated with better gas exchange.

A few authors studied psychologic distress in IPF patients and reported a prevalence of the affective disorder varying from 25% to 58%.(3,19). Depression was found in patients with more severe illness, and poorer physical status. In 41 patients with IPF, De Vries et al. reported that approximately 25% experienced depressive symptoms (3). Moreover, Lindell et al.(19) reported anxiety in IPF patients. Our study revealed a concerning aspect of IPF, with

Table 4. Correlation of sleep quality, depression, and anxiety with physiological parameters

		PSQI	Anxiety	Depression	SGRQ	LCQ
FVC	r	-0,051	-0,239	-0,255	-0,112	-0,078
	p	0,637	**0,025**	**0,017**	0,303	0,475
FEV1	r	-0,106	-0,274	-0,231	-0,247	-0,016
	p	0,324	**0,010**	**0,030**	**0,022**	0,886
DLCO	r	-0,314	-0,286	-0,249	-0,295	0,204
	p	**0,004**	**0,008**	**0,022**	**0,007**	**0,038**
DLCO/VA	r	-0,196	-0,240	-0,243	-0,338	0,230
	p	0,076	**0,029**	**0,027**	**0,002**	**0,038**
6MWT	r	-0,160	-0,069	-0,118	-0,174	0,003
	p	0,157	0,545	0,295	0,127	0,981
SpO_2 (rest)	r	-0,156	-0,234	-0,213	-0,120	0,097
	p	0,167	**0,036**	0,057	0,294	0,392
SpO_2 (min)	r	-0,161	-0,233	-0,217	-0,104	0,126
	p	0,155	**0,037**	0,054	365	266
MMRC	r	0,432	0,419	0,318	0,680	-0,367
	p	**<0,001**	**<0,001**	**0,003**	**<0,001**	**<0,001**
Borg dyspnea	r	0,340	0,385	0,342	0,584	-0,233
	p	**0,001**	**<0,001**	**0,001**	**<0,001**	**0,030**
Duration of Symptom	r	0,181	-0,010	-0,078	0,082	0,056
	p	0,092	0,924	0,472	0,454	0,604

Abbreviations: FVC: forced vital capacity, FEV1: Forced expiratory volume in the first second, DLCO: diffusion capacity for carbon monoxide, 6MWT: six minute walk test, SpO2: Finger tip oxygen saturation, BDI: The Baseline Dyspnea Index, PSQI : Pittsburgh Sleep Quality Index.

Table 5. Comparison of physiological parameters and dyspnea scores according to sleep quality

	PSQI (Good sleep quality)	PSQI (Poor sleep quality)	p
FVC	74.4±15.2	72.7±17.7	0.651
FEV1	80.8 ±15.2	78.6±17.3	0.548
DLCO	58.8±15.1	49.2±17.9	0.013
DLCO/VA	72.1±20.6	68.3±20.9	0.407
6MWT	367.3±62.5	352.2±97.9	0.439
SpO_2 (rest)	94.6±2.2	93.5±3.5	0.138
Spo2(min)	91.7±3.9	89.6±6.9	0.125
MMRC	1.6±0.6	2.2±1.0	0.004
BORG	2.7±1.4	3.7±2.4	0.026
GAP	3.3±1.5	3.6±1.4	0.386
CPI	41.7±12.7	47.8±15.5	0.047

Abbreviations: GAP: gender-age-physiology, CPI: Composite physiologic index, FVC: forced vital capacity, FEV1: Forced expiratory volume in the first second, DLCO: diffusion capacity for carbon monoxide, 6MWT: six minute walk test, SpO2: Finger tip oxygen saturation.

more than 50% of patients exhibiting symptoms of moderate to severe depression, and over 40% displaying symptoms of moderate to severe anxiety. Additionally, we found that anxiety and depression were not related to the patient's GAP stage but with respiratory function tests. In our study, we can attribute the high incidence of anxiety and depression in IPF patients to inadequate social support and insufficient

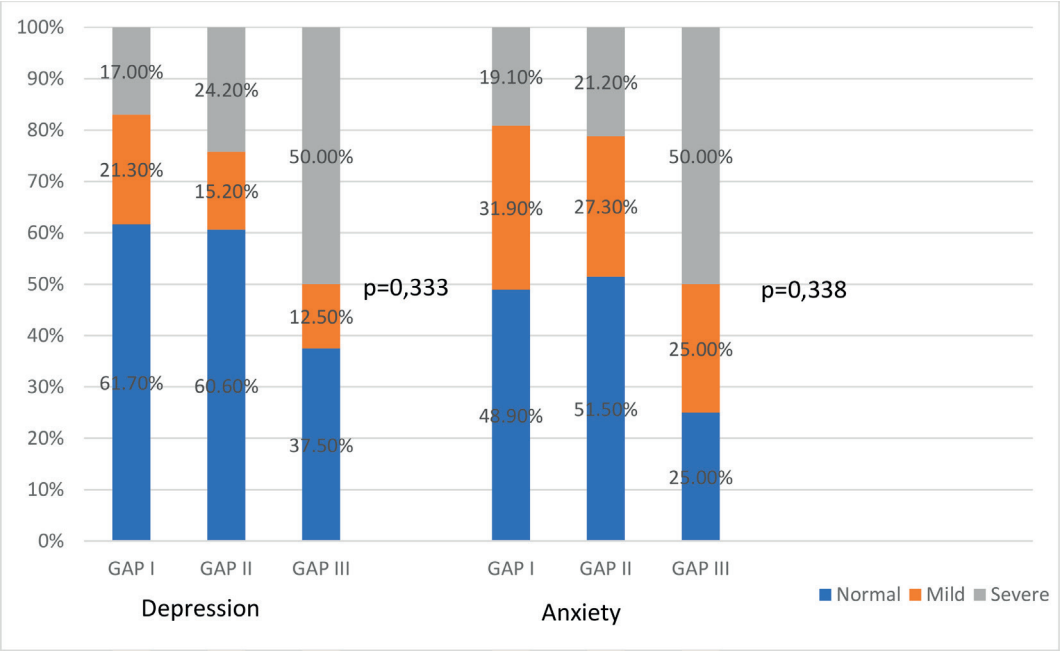

Figure 2. Prevalence of depression and anxiety According to GAP Stage.

patient care. In Turkey, there is no routine support program for this patient group. The negative correlation observed between anxiety and depression scores and pulmonary function parameters (FVC, FEV1, DLCO, and DLCO/VA) suggests a potential bidirectional relationship between psychological distress and disease severity in IPF. This highlights the importance of addressing mental health in the holistic care of IPF patients and considering psychological interventions as part of their management.

In our study, a significant proportion of IPF patients exhibited a definite UIP pattern on imaging, consistent with the expected radiological pattern seen in IPF. However, a notable minority presented with a possible UIP pattern. Importantly, we found no statistically significant differences between patients with definite UIP and possible UIP patterns in terms of various outcome measures, suggesting that radiological classification alone may not fully capture the clinical heterogeneity of IPF.

Finally, our study revealed that patients with good sleep quality had higher DLCO values and lower MMRC, BORG Dyspnea Index, and CPI values. This highlights the potential impact of sleep quality on both pulmonary function and symptom burden in IPF patients and suggests that interventions targeting sleep disturbances may have a role in improving patient outcomes.

Our study had several limitations. Firstly, the absence of a control group and the relatively small number of patients can be considered among these limitations. However, given the frequency of the disease, it is believed that the number of patients was sufficient for conducting the evaluation. Secondly, we are aware that the tests we used in our study are not specific to IPF, however, we believe that utilizing these tests will assist in understanding the challenges experienced by patients living with IPF.

Conclusion

In conclusion, our study provides valuable insights into the multifaceted nature of IPF. It underscores the importance of comprehensive patient assessment, including psychological well-being and sleep quality, in the management of IPF. Addressing the psychological and symptomatic aspects of the disease may improve the overall quality of life for IPF patients. Further research is warranted to explore the underlying mechanisms driving the observed relationships between psychological distress, sleep quality, and pulmonary function in IPF.

Declarations of Interest: none

Authors' Contribution: Fatih Uzer, Aykut Cilli, Ismail Hanta contributed to analysis, writing, and critical review, while Can Sevinc, Ahmet Ursavas, were involved in data collection and critical review. Other authors participated in data collection.

Ethics committee: The ethical approval for the study was granted by the Uludağ University Faculty of Medicine Clinical Research Ethics Committee with decision number 2018-7/28 on April 10, 2018.

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