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The Serbian version of the *King's Brief Interstitial Lung Disease* questionnaire and its validation in patients with idiopathic pulmonary fibrosis / progressive pulmonary fibrosis

Српска верзија упитника *King's Brief Interstitial Lung Disease* и његова валидација међу пацијентика са прогресивном плућном фиброзом / идиопатском плућном фиброзом

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SUMMARY

Introduction The KBILD (King's Brief Interstitial Lung Disease) is the first health status questionnaire developed for use in patients with interstitial lung diseases (ILD). There is no valid and reliable questionnaire in Serbian to assess the health status of ILD patients. Progressive pulmonary fibrosis (PPF) and idiopathic pulmonary fibrosis (IPF) are ILD diseases with a progressive course and poor prognoses, which have the greatest impact on patients' quality of life among all ILDs. The aim of the study is to validate the Serbian version of the KBILD questionnaire for use in patients with PPF, including IPF.

Methods The KBILD was translated into Serbian language. 35 patients with IPF or PPF completed a translated version of the KBILD questionnaire at the baseline, and 29 of them after one month. Pulmonary lung function tests as well as St. George's Respiratory Questionnaire (SGRQ) were completed at the baseline.

Results Internal consistency was high in the Total, Psychological, and Breathlessness and activities domains, and satisfactory for the Chest symptoms domain. The test-retest reliability was good for Psychological and Breathlessness and activities domains and excellent for Chest symptoms and Total score. All domains correlated strongly and very strongly with SGRQ, however, we found a weak correlation between the KBILD and lung function, and with Charlson comorbidity index.

Conclusions The Serbian version of the KBILD is valid and reliable for use in patients diagnosed with IPF/PPF.

Keywords: interstitial lung disease; idiopathic pulmonary fibrosis; questionnaire; quality of life

САЖЕТАК

Увод Упитник *King's Brief Interstitial Lung Disease* (КБИЛД) је први упитник о квалитету живота развијање за пацијенте са интерстицијумским болестима плућа (ИБП). Не постоји валидиран и поуздан упитник о квалитету здравља на српском језику намењен ИБП пацијентима. Прогресивна плућа фиброза (ППФ) и идиопатска плућна фиброза (ИПФ) су ИБП болести са прогресивним током и лошом прогнозом, које имају највећи утицај на квалитет здравља међу свим ИБП болестима. Циљ је да се уради валидација српске верзије упитника КБИЛД међу пацијентима са ППФ, укључујући ИПФ.

Методе КБИЛД упитник је преведен на српски језик. 35 пацијената са ППФ или ИПФ су попунили српску верзију упитника на почетку, и 29 од њих поново на крају истраживања. На почетку истраживања су урађени и тестови плућне функције, као и попуњавање упитника болнице „Свети Ђорђе" о респираторним тегобама.

Резултати Интерна конзистенција је била висока за Укупни скор, Психолошки, Недостатак ваздуха и активности домене, а задовољавајућа за Домен о респираторним симптомима. Тест-ретест поузданост је била добра за Психилошки и Недостатак ваздуха и активности домене, и одлична за домене Респираторни симптоми и Укупни скор. Сви домени снажно корелирају са резултатима упитника болнице „Свети Ђорђе", међутим корелација је слаба између резултата КБИЛД упитника и тестова плућне функције, као и Чарлсоновог индекса коморбидитета.

Закључак Српска верзија КБИЛД упитника је валидна и поуздана за примену код пацијената са идиопатском плућном фирбозом и прогресивном плућном фиброзом.

Кључне речи: интерстицијумске болести плућа; идиопатска плућна фиброза; упитник; квалитет живота

INTRODUCTION

More than 200 interstitial lung diseases (ILDs), ranging from extremely rare to relatively common, have been identified. The majority of ILDs are characterized by inflammation or fibrosis within the interstitial space, leading to impaired gas exchange, which manifests clinically as dyspnea, reduced exercise capacity, and impaired quality of life [1]. Progressive pulmonary fibrosis (PPF) is a subgroup of interstitial lung disease (ILD) that is characterized by more frequent exacerbations, a faster decrease in lung function, and earlier death compared to other interstitial illnesses that do not show a progressive-fibrous phenotype [2]. Besides idiopathic pulmonary fibrosis (IPF) being an ideal example of progressive fibrous interstitial lung disease, other conditions can also manifest similarly. These include connective tissue diseases with pulmonary involvement (such as rheumatoid arthritis, systemic sclerosis, polymyositis/dermatomyositis), hypersensitivity pneumonitis, pneumoconioses, sarcoidosis, nonspecific interstitial pneumonia, interstitial pneumonia with autoimmune features, unclassified interstitial lung diseases, and [2]. Progressive pulmonary fibrosis is occasionally a consequence of viral pneumonia, as reported in cases during the COVID-19 pandemic [3]. The chronic course of IPF/PPF affects the patient's quality of life (exertional dyspnea, need for oxygen therapy, frequent hospitalizations due to exacerbations, pulmonary controls, etc.).

In daily practice, questionnaires are used to quantify patient complaints. Questionnaires give patients the ability to take an active role in their healthcare by allowing them to describe symptoms and the impact those symptoms have on their day-to-day lives. They provide us with information regarding disease characteristics that are important to a patient but cannot be quantified using physiological tests like lung function [4]. The questionnaires should be administered regularly so that medical professionals can track the evolution of the condition

and change their treatment techniques accordingly [5]. However, there is no valid and reliable questionnaire in the Serbian language to assess the health status of ILD patients.

The KBILD (King's Brief Interstitial Lung Disease) questionnaire is the first health status questionnaire designed for use in patients with all ILDs. developed by Patel et al. [6] from King's College London in 2012. Since then, it has been translated into various languages (German, French, Italian, Swedish, Dutch, Portuguese, Chinese, etc.) and used in 24 countries [7–10]. The questionnaire consists of fifteen items that are categorized into three categories: breathlessness and activities, chest symptoms, and psychological aspects. A seven-point Likert scale is used to conduct the patient's evaluation of the response to each inquiry. The responses are summed up by the scoring algorithm, which then converts them into a range of 0 to 100 for each of the three domains and the total score. Higher scores indicate a better overall health status [6]. The minimal clinically important difference in the KBILD total score is a change of five units [11].

In this paper, we aimed:

• to develop the Serbian adaptation of the KBILD questionnaire

• to verify the reliability and validity of the Serbian adaptation of the KBILD questionnaire for its application in patients with PPF, including IPF. We also assessed the correlation between the KBILD score and patients' quality of life, comorbidities and lung function.

METHODS

The study was conducted at the Institute for Pulmonary Diseases of Vojvodina, Sremska Kamenica, Serbia from October 2023 until March 2024. Every patient was administered

antifibrotic medication, either pirfenidone or nintedanib. All patients completed a translated version of the KBILD questionnaire at the beginning of the study, and 29 of them also completed the questionnaire after one month (the other six patients did not complete the second KBILD questionnaire due to exacerbation of the IPF/PPF). At the baseline pulmonary lung function tests (PFT) were done using the Jaeger Master Screen Body (Germany) spirometer. Measurements included forced vital capacity (FVC), forced expiratory volume in 1 second (FEV1), total lung capacity (TLC), and diffuse lung capacity (DLCO), expressed as % of the predictive values according to the ATS/ERS criteria [12, 13]. Additionally, patients completed the St. George's Respiratory Questionnaire (SGRQ), a disease-specific instrument originally developed for chronic obstructive pulmonary disease and asthma, but also utilized for interstitial lung diseases due to the absence of a specific tool for these conditions [14, 15]. Furthermore, the study documented basic sociodemographic factors such as the patient's gender, age, and any existing comorbidities. The patient's medical histories and records were used to determine the presence of comorbid conditions.

The Charlson comorbidity index (CCI) is utilized as a metric to quantify the burden of comorbidities, as it has been demonstrated to impact outcomes in patients with interstitial lung disease (ILD) across multiple studies [16, 17]. The scoring system is based on 19 comorbid conditions, such as cardiac diseases, peripheral vascular diseases, cerebrovascular accident, dementia, chronic obstructive lung disease, connective tissue disease, peptic ulcer disease, liver disease, diabetes mellitus, chronic kidney disease, hematological and solid organ malignancy, and acquired immunodeficiency syndrome. Each condition is assigned a weight based on its potential impact on mortality.

Subjects

The study included 35 adult patients. The inclusion criteria were: a patient who had previously been diagnosed with either IPF or PPF based on the current clinical practice guidelines [2]; a patient not hospitalized at the time of the study due to IPF/PPF exacerbations

The exclusion criteria: the unwillingness to take part in the study; inability to complete the questionnaire due to cognitive or linguistic limitations; absence of signed informed consent; a patient unable to perform or have contraindications for performing spirometry.

Translation of KBILD into the Serbian language

Permission to translate and use KBILD in the Serbian language was obtained from the developer. A multi-stage forward-backward process was used to perform the translation of the KBILD questionnaire. First, it was independently translated into the Serbian language by two different clinicians respectively. There was a discussion with a third doctor about the disagreements that occurred between the two interpreters. The initial translation was then back-translated by a competent multilingual translator who was unaware of the questionnaire's aim. The back-translated version was then compared to the original KBILD version by members of the research team. If there were any misconceptions, the clinicians-translators discussed them. The preliminary version of the translated questionnaire was put through a pilot test on a group of patients consisting of ten patients with IPF who volunteered to answer the Serbian version of the questionnaire during their regular appointments. After completing the translated questionnaire, patients were interviewed by clinicians-translators to clear up any questions or concerns they had regarding the interpretation of the questions and the answers. The complete translation process is shown schematically in Figure 1.

The reliability and validity

Questionnaire reliability refers to the capacity of a questionnaire to accurately represent the actual value of the assessed qualities. Validity refers to the level to which the examined questionnaire properly evaluates its intended purpose. [17].

In our study, for reliability and validation, we tested the following:

1) internal consistency that measures the interrelatedness of items

2) test-retest reliability that measures repeatability of KBILD scores at baseline and after one month

3) concurrent validity showing correlations between KBILD scores and SGRQ scores, PFT

Furthermore, we evaluated whether there are statistical differences between different groups of patients according to gender and smoking status.

Statistical analysis

Nominal level measurement data are described using frequencies. Continuous data are described using the mean and standard deviation or the median and interquartile range as appropriate.

The reliability of internal consistency was examined using Cronbach's α coefficient and Gutman's λ 6. The criteria are as follows: ≤ 0.70 unacceptable, 0.70–0.83 satisfactory, 0.83–0.90 good, and ≥ 0.90 excellent. Test-retest reliability was examined using the intraclass correlation coefficient (ICC3) and Bland-Altman's plots. The interpretation of ICC3 is as follows: ≤ 0.50 is poor, 0.50–0.75 is moderate, 0.75–0.90 is good, and ≥ 0.90 is excellent.

Concurrent validity was evaluated by measuring correlations of KBILD to the SGRQ, PFTs, and CCI. The normality of the univariate distribution of items was tested using the Shapiro–Wilk test. Correlations between variables were examined using Pearson's correlation coefficient or Spearman's rank correlation coefficient.

Differences in the means of two groups for variables with a normal distribution were examined using the independent samples t-test. The assumption of equal variances was checked using Levene's test for equality of variances. If the variances were unequal, the Welch's t-test was used. Differences between groups for variables that do not meet the assumption of normal distribution were examined using the non-parametric alternative to the independent samples t-test, the Mann-Whitney test. The level of statistical significance was set at $p < 0.05$.

Ethics: Before the start of the study, approval was granted by the Ethics Committee of the Institute for Pulmonary Diseases of Vojvodina, Sremska Kamenica, Serbia (No.: 18-I/1).

RESULTS

Characteristics of patients

The study included 35 IPF/PPF patients, with their gender distribution, average age, smoking status, diagnosis, KBILD and SGRQ results, average values of FVC% and DLCO%, and CCI presented in Table 1.

The majority of patients within our cohort were elderly women with moderately impaired lung function and two or more comorbidities, mainly cardiovascular disease (46%, 16/35). The mean (SD) KBILD Total score in all patients was 50.87 (13.05).

Validation and reliability of the Serbian KBILD

Cronbach's α was high in the Total, Psychological, and Breathlessness and activities domains, and satisfactory for the Chest symptoms domain. Gutman's λ-6 was close to Cronbach's alpha values in all domains. The intraclass correlation coefficients (ICC3) were good for Psychological and Breathlessness and activities domains, and excellent for Chest symptoms and Total score (Table 2).

All domains of KBILD correlated strongly and very strongly with SGRQ, however, we found a weak correlation between the KBILD and lung function (FVC%, DLCO%, FEV1%, and TLC%), as well with CCI (Table 3).

We examined whether there is a difference in KBILD questionnaire results based on gender (males/females) and smoking status (non-smokers/smokers), and found no statistically significant correlation.

DISCUSSION

The Serbian version of the KBILD questionnaire is the first disease-specific tool in Serbian that measures health status in IPF and other ILDs. Recently, the King's Sarcoidosis Questionnaire was validated in the Serbian-speaking population. This represents a major advance in analyzing the health status of patients with sarcoidosis, but cannot be used for other ILDs [18].

Most of our patients were elderly with two or more comorbidities, a characteristic commonly observed in individuals with IPF/PPF. In our study, the majority of patients were female, which differs from the literature [19, 20, 21], with the assumption that the small sample size may

account for this. There were no significant issues experienced throughout the translation process. The questionnaire was well received by the patients, easily understandable, and required little time for completion. In our study, we demonstrated that the Serbian version of the KBILD has good internal consistency for each domain and total score, as well as good test-retest reliability. The mean (SD) KBILD total score in our cohort was 50.87 (13.05), which is similar to the original KBILD questionnaire [6], as well as in the study of Wapenaar et al. [4] and Szentes et al. [22]. Our patient group showed a reduced health-related quality of life in all domains of KBILD, with Breathlessness and activity domain being most impaired, followed by Psychological impact and Chest symptoms, which is in agreement with previous studies [4, 10, 22]. This gives significant support to the fact that KBILD is applicable and transferable on an international scale [22].

The correlation between KBILD and lung function (DLCO%, FVC%, FEV1%, and TLC%) was weak. Previous studies have indicated that the impact of FVC on quality of life is only partial, whereas the DLCO is more closely associated with the quality of life in patients with ILD [10, 14]. In the original KBILD questionnaire, the greatest correlation was observed between Breathlessness and activity score with lung function tests [6]. In other studies, correlations to FVC% and DLCO% were moderate to weak [9, 10]. However, in a study by Wapenaar et al. [4], KBILD showed a weak correlation with the results of pulmonary function tests. Further studies and the inclusion of a larger patient cohort will yield a more definitive understanding of the association between KBILD and pulmonary function tests, as well as the divergence between different ILD diseases.

Questionnaires are used in various diseases to measure patients' quality of life [23]. Only a few of them are validated and can be used in patients with IPF (ATAQ-IPF- „A Tool to Assess Quality of Life in IPF“, SF36- Short-Form 36-Item Questionnaire and SGRQ-I- St. George

Respiratory Questionnaire specific for IPF) while other ILD diseases are generally not considered in the available studies [24, 25, 26]. So far in our everyday clinical practice with ILD patients, we used only SGRQ as well as two measurements for dyspnea- the modified Medical Research scale and Borg's dyspnea scale. The KBILD questionnaire is the first valid, self-completed measurement of the health status of ILD patients and an additional tool to pulmonary function tests in assessing a patient's condition [6]. Concurrent validity of the KBILD domain and total scores were strong compared with the SGRQ domain and total scores ($r=-0,742$, $p < 0.01$), which is comparable to the original version of the questionnaire [6], and to the study by Wapenaar et al. [4]. It is shorter (15 questions) compared to ATAQ-IPF (72 questions), SF-36 (36 questions), and SGRQ-I (50 questions), making it easier for physicians to use during regular visits.

The presence of comorbidities influences the patient's perception of their health status and can influence responses [16, 27]. In our research, most patients (97%) had some of the most important comorbidities that could influence their perception of quality of life. However, our research did not find any association between the CCI and the KBILD outcomes, which is similar to the results of the Asian interstitial disease cohort [9], as well as the results of Szentes, et al. [22], in which only depression was negatively associated with the 'chest symptoms' domain. These could be explained by the fact that in the process of creating the original KBILD version, certain elements that could impact one's health condition, such as medications, cough, sleep, and sexual health, were excluded, and the KBILD items are specifically designed to evaluate the influence of lung disease on health status [6]. Additionally, the CCI is missing comorbidities that are commonly found in individuals with IPF/PPF, including gastric reflux, pulmonary hypertension, obstructive sleep apnea, and psychiatric disorders. The small size and homogeneity of our study cohort with respect to the CCI score may have contributed to the

observed results. Hence, the influence of various comorbidities on the overall health condition of individuals with ILD remains to be determined.

This study has several limitations. This is a single-center observational study in a relatively small group of patients, which is understandable since IPF/PPF are rare diseases. The methodological integration of these and future studies will justify the application of the KBILD in everyday clinical practice. Our study is cross-sectional, and we believe that a more extensive follow-up period is necessary to establish the true link between the KBILD and lung function tests. Our main goal was to validate the Serbian version of KBILD so it could be implemented in everyday medical practice.

CONCLUSIONS

The Serbian version of the KBILD is valid and reliable for use in patients diagnosed with IPF or PPF. There is no correlation between the lung function tests or CCI Score and KBILD, which supports the statement that questionnaires provide us with information that is important to a patient but cannot be measured using physiological tests. The KBILD is easy to use, and its implementation in clinical practice has the potential to provide new information about the quality of life, as well as contribute to a better understanding of the course and prognosis of IPF/PPF. We hope that the validation of the Serbian version of the KBILD will encourage physicians in Serbia to adopt it into their regular medical practice, and that it will become a valuable tool for the longitudinal monitoring and management of patients with IPF/PPF.

Conflict of interest: None declared.

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Table 1. Characteristics of patients at baseline

Characteristics	Value
Women n (%)	19 (54.29)
Men n (%)	16 (45.71)
Age, years ± SD	62.94 ± 10.9
Smoker (ex or current) n (%)	21 (60)
Non-smoker n (%)	14 (40)
IPF n (%)	24 (68.5)
SSc n (%)	5 (14)
HP n (%)	4 (11.5)
SLE n (%)	1 (3)
NSIP n (%)	1 (3)
FVC, % predicted ± SD	74.74 ± 20.57
DLCO, % predicted ± SD	44.55 ± 14.46
KBILD Total ± SD	50.87 ± 13.05
KBILD Psychological ± SD	52.06 ± 16.54
KBILD Breathlessness and activities ± SD	35.89 ± 22.72
KBILD Chest symptoms ± SD	53.61 ± 29.29
SGRQ Total ± SD	49.33 ± 20.40
SGRQ symptoms ± SD	47.04 ± 20.21
SGRQ activity ± SD	65.11 ± 22.48
SGRQ impacts ± SD	40.86 ± 22.71
CCI ± SD	2.46 ± 1.38

IPF – idiopathic pulmonary fibrosis; SSc – systemic sclerosis; HP – hypersensitive pneumonitis; SLE – systemic lupus erythematosus; NSIP – nonspecific interstitial pneumonia; FVC – forced vital capacity; DLCO – diffusing capacity of the lungs for carbon monoxide; KBILD – King's brief interstitial lung disease; SD – standard deviation; SGRQ – St. George's respiratory questionnaire

Table 2. Internal consistency and test-retest reliability of the KBILD questionnaire

KBILD	Cronbach's α	Gutman's λ-6	ICC3
Total	0.956	0.974	0.919
Psychological	0.939	0.942	0.884
Breathlessness and activities	0.913	0.897	0.879
Chest symptoms	0.794	0.782	0.910

KBILD – King's brief interstitial lung disease questionnaire; ICC3 – internal consistency coefficient

Table 3. Correlations between the KBILD and patients' quality of life, lung function, and comorbidities

KBILD	FVC%	DLCO%	FEV1%	TLC%	SGRQ Total	SGRQ symptoms	SQRQ activity	SGRQ impacts	CCI
Psychological	-0.086	0.193	0.111	0.062	-0.648**	-0.633**	-0.512*	-0.613*	0.120
Breathlessness and activity	0.110	0.212	0.083	0.220	-0.667**	-0.544*	-0.599*	-0.637**	0.023
Chest symptoms	-0.051	0.125	-0.032	0.015	-0.662**	-0.653**	-0.599*	-0.602*	-0.031
Total	-0.088	0.225	0.073	0.102	-0.742**	-0.686**	-0.651**	-0.695**	0.053

In correlations for domains psychological, total, and Charlson comorbidity index (CCI), due to deviations from normal distribution, we used the Spearman correlation coefficient, while for other parameters, we used the Pearson correlation coefficient;

KBILD – King's brief interstitial lung disease; FVC – forced vital capacity; DLCO – diffusing capacity of the lungs for carbon monoxide; FEV1 – forced expiratory volume i n 1 second, TLC – total lung capacity; SGRQ – St. George's respiratory questionnaire;

*$p < 0.05$

**$p < 0.01$

Figure 1. Stages of translating the questionnaire

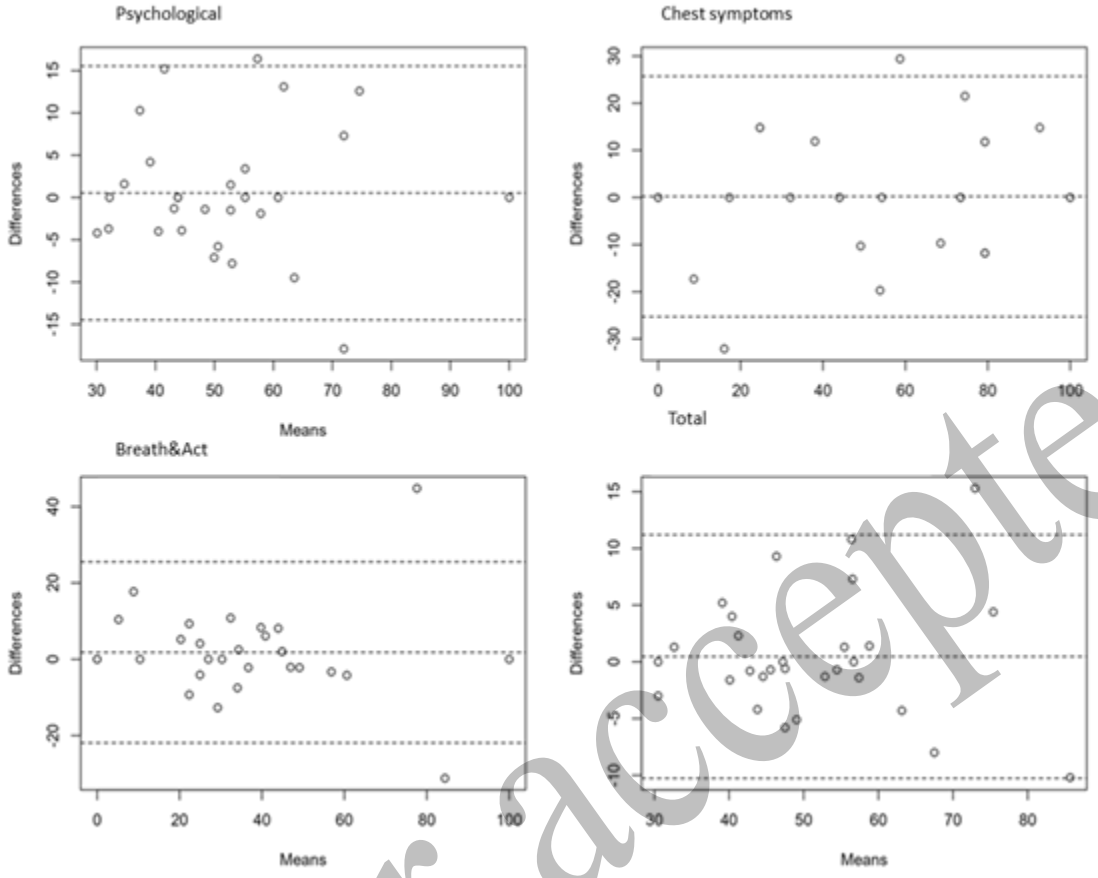

Figure 2. Bland–Altman plots for all domains; "Means" represents the average of measures, while "Differences" shows the difference between the two paired measurements

