Psychometric Characteristics of the Serbian Version of the Leicester Cough Questionnaire in Sarcoidosis Patients

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SUMMARY

Introduction: Cough is frequent symptom in sarcoidosis and there are no specific tools for measurement of its severity in Serbia.

Aim: The goal of this study was to translate and validate the Serbian version of the Leicester Cough Questionnaire (LCQ) in a population of sarcoidosis patients.

Methods: After the LCQ forward-backward translation process, in the cross-sectional study in 275 (180 female) sarcoidosis patients Serbian version of the LCQ was administered together with other standardized instruments for measurement of Patient Reported Outcomes (PROs) – symptoms of dyspnea (assessed by MRC and Borg scales) and fatigue (measured by Fatigue Assessment Scale and List of Daily Activities), and patients' health status (assessed by generic tool – 15D). Pulmonary function tests (spirometry and diffusing capacity for carbon monoxide) were also measured.

Results: Serbian LCQ version showed excellent internal consistency (Cronbach's alpha of its different scores ranged between 0.901 for physical domain and 0.951 for the total score). Concurrent validity assessed by correlations of all LCQ scores with other PROs and pulmonary function tests was very good, since all these correlations were statistically significant.

Conclusions: Our results confirmed that the Serbian version of LCQ is a valid instrument to monitor the influence of chronic cough on quality of life in sarcoidosis patients.

Keywords: sarcoidosis, cough, dyspnea, fatigue, pulmonary function tests

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INTRODUCTION

Sarcoidosis is a chronic multisystem granulomatous disease of unknown origin that is most commonly present in the lungs but may also involve any other organ [1].

Patients with pulmonary sarcoidosis may have symptoms related directly to the chest such as dyspnea on exertion, chest pain, chest discomfort, cough, and wheeze. Patients may also develop symptoms related to extra-pulmonary organ involvement. In addition, sarcoidosis may cause constitutional symptoms such as fatigue, fever, anorexia, weight loss, generalized weakness, and pain that are not attributable to involvement of any specific organ [2,3].

Nowadays design of most of the international clinical drug trials includes Patient-Reported Outcomes (PROs) as study endpoints, and their changes during treatment period represent either secondary and exploratory (in phases II or IIIa) or even primary (in phases IIIb and IV) study objectives. Food and Drug Administration (FDA) defines PROs as measurement of any aspect of a patient's health status that comes directly from the patient, without interpretation of the patient's responses by a physician or anyone else [4]. PROs encompass symptoms and signs of disease, treatment satisfaction and quality of life (QoL) of patients. This is increasingly observed as the regulatory authorities' requirement due to several limitations of the objective disease outcomes, like pulmonary function tests or radiographic findings. Moreover, numerous studies showed that correlations between PROs as subjective outcomes and objective outcomes are rather mild or moderate or even do not exist at all [5].

The assessment of all endpoints should be possible in all subjects in a consistent and reproducible manner, using the same techniques applicable to all subjects in the study. Thus, questionnaires have been developed and validated in order to assess PROs in a standardized way.

Recently, more attention has been paid to the cough in patients with sarcoidosis and we now have a validated tool – Leicester Cough Questionnaire (LCQ) for measuring this important symptom [6]. Currently only a few studies used LCQ for assessing cough in sarcoidosis patients [7-9].

LCQ is a 19-item validated specific QoL measure of cough over the period of privious two weeks [6]. Its scores can be calculated in 3 domains covering physical (8 items), psychological (7 items), and social (4 items) aspect of chronic cough, in addition to the total score. It evaluates the impact of cough on patients' quality of life. It takes 5 to 10 minutes to complete. Scores are calculated by domain (range from 1 to 7) and then added to obtain the total score (range from 3 to 21), with higher scores indicating a better QoL.

The LCQ has been translated into several languages including Dutch, Korean, Lithuanian, Mandarin, Polish, Portuguese, German and Spanish, and validated in corresponding cohorts [10-19]. It has been also validated for different diseases, like chronic cough itself, cystic fibrosis including affected children, bronchiectasis, COPD [17,20-22], and recently for sarcoidosis [8]. A validated Serbian version does not exist, so our aim was to translate and validate Serbian version of the LCQ in sarcoidosis patients in order to provide an instrument for future multinational studies on chronic cough in sarcoidosis patients in particular.

METHODS

The original English version of the LCQ was translated into Serbian language in a forward-backward approach. Three authors (BSG, VMV, MHV) independently translated the LCQ nad mutually agreed about the final working Serbian version. After that the professional translator experienced and familiar with medical terminology performed back-translation of the agreed Serbian version. After comparing back-translated LCQ version with the original one, the authors agreed that there was no need for further corrections of the Serbian version. So, this Serbian version of the LCQ was initially administered among ten sarcoidosis patients at the Clinic for Pulmonology, Clinical Center of Serbia in Belgrade, Serbia, in order to assess their understanding of each particular question. All of them understood questions from the questionnaire very well and had no additional questions. Therefore, the implemented version of the LCQ did not need any modifications and we accepted it as the final Serbian version.

Most patients recruited in this cross-

sectional study in the period from April to November 2018 are members of the Serbian Association of Sarcoidosis, which now includes more than 2,000 patients with different clinical forms of sarcoidosis. We enrolled 275 biopsy positive sarcoidosis patients diagnosed at the Clinic for Pulmonary Diseases of the Clinical Centre of Serbia in Belgrade, Serbia. All subjects were ≥ 18 years old and they did not have any associated ilnesses that could influence their health status (those with significant comorbidity, like cardiac or respiratory disorders other than sarcoidosis, were excluded from analysis). These patients were examined during regularly scheduled clinical visits and the patients voluntarily completed the self-administered PROs and performed pulmonary function testing.

This study was approved by the institution's ethics committee and all patients consented to participation.

Validity of the Serbian version of the LCQ was examined by the assessment of internal consistency (calculating the Cronbach's Alpha coefficient) and concurrent validity (correlating the LCQ scores with other standardized instruments for measurement of symptoms of dyspnea and fatigue, health status and pulmonary function parameters in sarcoidosis patients).

Following PROs were administered:
1) Dyspnea instruments: Modified Medical Research Council (MRC) Dyspnea Scale [23] and Borg dyspnea category-ratio-10 scale (CR-10) [24],
2) Fatigue questionnaires: Fatigue Assessment Scale (FAS) [25] and Daily Activity List (DAL) [26], and
3) QoL scales: LCQ [6] and General health status questionnaire 15D [27].

Modified Medical Research Council (MRC) Dyspnea Scale classifies subjects into one of five categories according to their degree of dyspnea when performing certain activities [23]. Scores range from the 0 to 4, with the higher scores indicating more severe dyspnea. We previously used it in patients with sarcoidosis [28,29].

Borg dyspnea category-ratio-10 scale (CR-10) [24] is an 11-point scale on which dyspnea is graded from 0 (nothing at all) to 10 (maximum). It is widely used in clinical trials in different respiratory and cardiovascular diseases.

Fatigue was assessed by the standardized *Fatigue Assessment Scale* (FAS) [25]. The FAS is a 10-item self-report fatigue questionnaire. The response scale is a 5-point Likert scale (1 never to 5 always). Total scores on the FAS can range from 10 to 50, with high scores

Table 1. Descriptive statistics for PRO scores and pulmonary function tests

X = mean;
SD = standard deviation;
MRC = Modified Medical Research Council Dyspnea Scale;
Borg = Borg dyspnea category-ratio-10 scale;
FAS-TS = Fatigue Assessment Scale – Total score;
DAL = List of Daily Activities;
LCQ = Leicester Cough Questionnaire;
15D = Fifteen-dimensional measure of health-related quality of life;
FEV_1 = Forced expiratory volume in one second;
FVC = Forced expiratory vital capacity;
PEF = Peak Expiratory Flow;
DLCO = transfer factor of the lung for carbon monoxide.

	X ± SD	Range
Sex, m/f	95/180	
Age, years	50.13 ± 11.07	28 – 76
Disease duration, years	15.62 ± 8.56	1 – 40
Dyspnea scores		
MRC	0.89 ± 0.69	0 – 3
Borg	1.43 ± 1.54	0 – 9
FAS-TS	24.55 ± 6.23	15 – 42
DAL	3.00 ± 2.50	0 – 10
LCQ Scores		
Total score	16.94 ± 3.68	5.48 – 21
Physical domain score	5.48 ± 1.18	1.88 – 7.00
Psychological domain score	5.64 ± 1.29	1.86 – 7.00
Social domain score	5.82 ± 1.33	1.75 – 7.00
15D	0.85 ± 0.11	0.49 – 1.00
FEV_1 (% predicted)	99.60 ± 20.02	34 – 150
FVC (% predicted)	108.52 ± 17.40	41 – 156
FEV_1/FVC	76.57 ± 8.51	31.63 – 91.36
PEF (% predicted)	105.61 ± 21.79	30 – 169
DLCO (% predicted)	81.55 ± 17.46	37 – 111

Table 2. Internal consistency of the LCQ scores

Criteria of drug imputability	Criteria of drug imputability	Criteria of drug imputability
Total Score All items (1 - 15)	19	0.951
Physical Items: 1, 2, 3, 9, 10, 11, 14, 15	8	0.901
Psychological Items: 4, 5, 6, 12, 13, 16, 17	7	0.922
Social Items: 7, 8, 18, 19	4	0.918

indicating more fatigue. FAS total score < 22 indicates no fatigue. The psychometric properties (reliability and validity) of the FAS are good, and it was also shown in sarcoidosis patients [30,31]. The Serbian version proved to be valid in rheumatoid arthritis [32] and sarcoidosis [33].

The degree of limitation in daily life activities was evaluated with the Daily Activity List (DAL), a scale that was originally designed by Stewart and coworkers [26]. It has 11 items that are related to the usual activities that persons with good health can perform without particular effort. The number of positive responses comprises the DAL score and indicates the degree of impairment. The scale has been used in several studies in patients with chronic pulmonary diseases [34,35,28].

We used the standardized questionnaire for the measuring of health status: a generic measure – The fifteen-dimensional measure scale of health-related quality of life (15D) [27]. 15D is a multiatributive instrument for measurement of health-related quality of life that was initially developed and validated in a large Finnish population. It consists of 15 different and mutually exclusive health dimensions, each represented by one item. The total questionnaire score ranges between 0 and 1, where 1 signifies the highest level of health status. 15D was used in different diseases in many different countries. The Serbian version of 15D was previously used in patients with sarcoidosis where it demonstrated good psychometric measurement properties [28,36].

On the same day subjects completed the questionnaires and performed pulmonary function tests – spirometry and the transfer factor of the lung for carbon monoxide (DLCO). Spirometry parameters included pre-bronchodilator forced expiratory vital capacity (FVC), forced expiratory volume in one second (FEV_1), FEV_1/FVC, peak expiratory flow (PEF) and it was measured with a pneumotachograph (Masterlab, Jaeger, Wurzburg, Germany). DLCO was measured using the single-breath method (Masterlab, Jaeger,

Wurzburg, Germany). The European Respiratory Society criteria for lung function impairments was used [37].

A probability value of $p < 0.05$ was considered to be statistically significant, and $p < 0.01$ highly statistically significant. Statistical analysis was performed using the standard computer statistical package ("SPSS Version 18.0 for Windows", 2011).

RESULTS

The descriptive statistics for PRO scores and pulmonary function tests for all 275 subjects are presented in Table 1. The total time required to complete the LCQ, dyspnea and fatigue scales and 15D questionnaire ranged from 30 to 40 min.

Indicators for internal consistency are presented in Table 2. Cronbach's alpha of different LCQ scores ranged between 0.901 for physical domain and 0.951 for the total score.

Regarding the concurrent validity, we observed strong correlations (all in the expected directions) of all LCQ scores with all examined dyspnea and fatigue scores (Table 3). It was also the case with 15D scores. All correlations, as assessed by the Pearson's coefficient of linear correlaton, were highly statistically significant (p<0.001 for all correlations). The highest correlation coefficients with all PROs' scores were noticed for the LCQ Physical domain score. They were particularly high with DAL scale and 15D (Pearson coefficient 0.636 and 0.632, respectively).

As pulmonary sarcoidosis is thought to be an interstitial lung disease, the traditional primary endpoint that has been selected for clinical trials is the forced vital capacity (FVC) [38]. Its mean value in our study population was pretty high (108.52 ± 17.40) and only 5% of them had values <80%. However, when considering the restrictive pattern treshold of FEV_1/FVC >80 then we noticed that 38% of our patients had lung restriction. In addition, the disease may predominantly affect the airways in some of the patient population and

Table 3. Concurrent validity of the Serbian version of the LCQ – Correlations of the LCQ scores with PROs scores and pulmonary function tests

k = Pearson coeffitient;
p = Probability;
FAS-TS = Fatigue Assessment Scale – Total score;
MRC = Modified Medical Research Council Dyspnea Scale;
Borg = Borg dyspnea category-ratio-10 scale;
DAL = List of Daily Activities;
LCQ = Leicester Cough Questionnaire;
15D = Fifteen-dimensional measure of health-related quality of life;
FEV1 = Forced expiratory volume in one second;
FVC = Forced expiratory vital capacity;
PEF = Peak expiratory Flow;
DLCO = transfer factor of the lung for carbon monoxide.

		LCQ - Physical Domain Score	LCQ - Psychological Domain Score	LCQ - Social Domain Score	LCQ - Total Score
MRC Score	k	-.572	-.482	-.500	-.543
	p	.000	.000	.000	.000
Borg Scale Score	k	-.589	-.507	-.555	-.579
	p	.000	.000	.000	.000
FAS Total Score	k	-.476	-.358	-.429	-.440
	p	.000	.000	.000	.000
DAL Score	k	-.636	-.506	-.570	-.596
	p	.000	.000	.000	.000
15D Score	k	.632	.508	.562	.594
	p	.000	.000	.000	.000
FVC (L)	k	.321	.297	.294	.324
	p	.000	.000	.000	.000
FVC (%)	k	.134	.128	.142	.141
	p	.027	.040	.020	.021
FEV1 (L)	k	.340	.303	.317	.334
	p	.000	.000	.000	.000
FEV1 (%)	k	.187	.174	.199	.186
	p	.002	.004	.001	.002
FEV1/FVC	k	.186	.172	.211	.180
	p	.002	.004	.000	.003
PEF (L)	k	.310	.276	.289	.300
	p	.000	.000	.000	.000
PEF (%)	k	.219	.211	.218	.212
	p	.000	.000	.000	.000
DLCO	k	.403	.465	.409	.439
	p	.025	.008	.022	.013
DLCO (%)	k	.389	.418	.440	.430
	p	.031	.019	.013	.016

cause significant airflow obstruction as measured with the criterion $FEV_1/FVC < 70$ [38]. In our study group there were 17% of patients with obstructive pattern. Correlations of the LCQ scores with all spirometry parameters were statistically significant, but weaker than with the PROs scores. The strongest correlations were noticed for the parameter FEV_1.

Transfer factor of the lung for carbon monoxide was performed in only 31 subjects, since in comparison with spirometry this test is not routinely assessed in all sarcoidosis patients. Correlations of the LCQ scores with DLCO values were stronger than with spirometric parameters.

DISCUSSION

Incorporation of PROs is very important in designing of the clinical trials protocols, especially in chronic diseases like sarcoidosis where objective outcomes cannot fully direct treating physicians in therapeutic decision making and follow up of their patients. Potential endpoints in sarcoidosis research should include: QoL measures, symptoms of cough, dyspnea, and wheeze, the frequency of disease exacerbations (requiring corticosteroid bursts or additional anti-sarcoidosis therapy), and corticosteroid-sparing effects of interventions [38].

In this study, we translated the LCQ

Cronbach's alpha coefficient							
LCQ Scores	English LCQ - Chronic cough [6]	Dutch LCQ - Chronic cough [10]	Dutch LCQ - COPD [121]	Polish LCQ - Chronic cough [12]	Korean LCQ - Chronic cough [14]	German LCQ - Sarcoidosis [8]	Serbian LCQ - Sarcoidosis
Total	0.92	0.93	0.86	0.89	0.91	/	0.95
Physical	0.79	0.77	0.67	0.82	0.84	0.87	0.90
Psychological	0.89	0.84	0.75	0.86	0.86	0.94	0.92
Social	0.85	0.83	0.74	0.78	0.87	0.92	0.92

Table 4. Comparison of internal reliability of different versions of LCQ

into Serbian language, and examined its psychometric properties in a sarcoidosis cohort.

Internal consistency, as assessed by the Cronbach's alpha coefficient, of different LCQ scores were between 0.901 (for Physical domain) and 0.951 (for Total score). Cronbach's alpha values between 0.7 and 0.8 can be considered as good, values between 0.90 and 0.95 as excellent. Values higher than 0.95 indicate item redundancy [39, 40]. So, reliability of the Serbian verssion of the LCQ proved to be excellent. The subscale „physical" was the one with the weakest performance regarding internal consistency and it is in accordance with the results of Schupp and coauthors who validated the German version of the LCQ among 200 sarcoidosis patients [8]. Cronbach's alpha coefficients were similar with those in our study. Moreover, in other studies that validated the LCQ [6, 10, 12, 14], Cronbach's alpha values were also the lowest for Physical domain (Table 4). On the other hand, Cronbach's alpha values were highest for Psychological domain of the LCQ.

Concurrent validity proved to be strong when LCQ scores were compared to the severity of the most frequent symptoms of sarcoidosis patients – dyspnea and fatigue, as well as to their general healt as assessd by the 15D questionnaire. In other publish studies [12,13,16,19,41] correlations between LCQ scores and different PROs (mainly genetic QoL instruments) were mostly moderate as it was also the case with the original LCQ validation [6].

Concurrent validity of the Polish LCQ [12] was tested in chronic cough patients population by comparing it with frequently used PROs – the respiratory-specific St. George's Respiratory Questionnaire (SGRQ) [42, 43], generic QoL instrueement Euro-Quality of Life Questionnaire (EQ-5D) [44] together with its related Visual Analogue Scale (EQ5D-VAS), and Hospital Anxiety and Depression Scale

(HADS) [45]. All correlations were significant, except for those with the HADS. The strongest correlations of total LCQ scores were noticed with the generic EQ-5D questionnaire (Spearman's coefficient was -0.49, p = 0.002), that is in accordance with the result of our study when the total LCQ scores were compared with scores of generic 15D insturment (Pearson's coefficient 0.59, p<0.001).

Similar degree of correlation was seen during the validation of Korean LCQ [14] among patients wiht chronic cough, where it was compared with the most commonly used generic health status questionnarioe SF-36 (Spearman's correlation coefficient for total scores was 0.55, P<0.0001) [46].

Berkhof et al [21] validated the Dutch version of the LCQ in COPD patients and assessed concurrent validity comparing it with the SGRQ and SF-36 scores. Their results were in accordance with other autohors, with expected stronger correlations noticed with SGRQ than with SF-36.

In the other study of validation of the Durch LCQ in chronic cough patients Huisman and coauthors [10] compared its scores with SF-36 and HADS. Correlations with SF-36 scores were statistically significant, and it was also the case for HADS that was different from results in the study of Dąbrowska and coworkers [12].

LCQ scores in our study significantly correlated with all pulmonary function parameters. However, correlations of LCQ scores and pulmonary function tests in different patients' populations were not frequently performed. Judson et al found that cough was not statistically significantly different in terms of spirometric measures (FEV$_1$%, FVC% and FEV$_1$/FVC) [7].

Spanish study of LCQ validation in children with cystic fibrosis [22] correlated its scores with disease-specific QoL questionnaire „Cystic Fibrosis Questionnaire-Revised"

(CFQ-R) [47] and spirometry parameters FEV_1 and FVC. All these correlations were statistically significant. The degree of correlation with spirometry parameters was higher than in our study for patients with sarcoidosis.

CONCLUSION

We conclude that the Serbian version of LCQ is a valid instrument for monitoring the influence of chronic cough on QoL in sarcoidosis patients. In comparison to other versions translated to other languages, its psychometric charactersistics are similar and we can recommend its use in clinical practice and research in sarcoidosis patients.

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CONFLICTS OF INTEREST

None of the authors disclosed any potential conflicts of interest.

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Psihometrijske karakteristike srpske verzije lesterskog upitnika o kašlju kod bolesnika sa sarkoidozome

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KRATAK SADRŽAJ

Uvod: Kašalj je čest simptom u sarkoidozi i trenutno u Srbiji ne postoji specifičan instrument za merenje njegove težine.

Cilj: Cilj ove studije je bio da se prevede i validira srpska verzija Lesterskog upitnika o kašlju (engl. Leicester Cough Questionnaire, LCQ) u populaciji pacijenata sa sarkoidozom.

Metodologija: Nakon postupka prevođenja LCQ, u studiji preseka 275 pacijenata sa sarkoidozom (od toga 180 osoba ženskog pola) je popunilo srpsku verziju LCQ zajedno sa ostalim standardizovanim upitnicima za merenje ishoda saopštenih od strane pacijenta (eng. Patient Reported Outcomes, PROs) – simptoma dispneje (korišćenjem MRC i Borgove skale), zamora (merenim "Skalom za procenu zamora" i "Listom dnevnih aktivnosti") i zdravstvenog statusa pacijenata (procenjenim generičkim upitnikom 15D). Takođe je sprovedeno merenje testova plućne funkcije (spirometrija i difuzijski kapacitet pluća za ugljen-monoksid).

Rezultati: Srpska verzija LCQ ima odličnu internu konzistentnost (koeficijent Krombah alfa se kretao između 0,901 za oblast fizičkih aktivnosti upitnika i 0,951 za njegov totalni skor). Konkurentna validnost LCQ procenjena je stepenom povezanosti njegovih skorova sa skorovima drugih ispitivanih PROs i vrednostima testova plućne funkcije i pokazala se kao veoma dobra s obzirom na to da su sve pomenute korelacije bile statistički značajne.

Zaključak: Naši rezultati su potvrdili da srpska verzija LCQ predstavlja validan instrument za merenje uticaja hroničnog kašlja na kvalitet života bolesnika sa sarkoidozom.

Ključne reči: sarkoidoza, kašalj, dispneja, zamor, testovi plućne funkcije