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Translation, transcultural adaptation, and validation of the Serbian version of the PSS-QoL questionnaire – a pilot research

Prevod, transkulturalna adaptacija i validacija srpske verzije upitnika PSS-QoL – pilot istraživanje

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Abstract

Background/Aim. The assessment of health-related quality of life (HRQoL) is fundamental for a better understanding of the effect of a disease on different aspects of a patient's daily functioning and the efficacy of the treatment modalities. Primary Sjögren's Syndrome (SS) Quality of Life Questionnaire (PSS-QoL) is the first disease-specific instrument for evaluating HRQoL in patients with primary SS. The aim of this study was to formally translate the PSS-QoL questionnaire from English to Serbian, assess its psychometric properties, and validate it for use in the Serbian population. **Methods.** The research was designed as a pilot study and included 30 participants. Internal consistency was determined by calculating Cronbach's alpha coefficient. The construct validity of the questionnaire was estimated by the correlation of its overall result with the patients' EuroQoL-5D, European League Against Rheumatism (EULAR) SS Patient Reported Index, Oral Health Impact Profile-14, and Emotion Regulation Questionnaire scores. **Results.** There were 29 (96.7%) female participants and one (3.3%) male participant in the research. The average (± standard deviation) score of PSS-QoL was 44.63 ± 12.901 at baseline and 41.70 ± 12.075 at follow-up. Cronbach's alpha value of the Serbian version of PSS-QoL was 0.922. The test-retest intraclass correlation coefficient was 0.981 (95% confidence interval: 0.436–0.996). Analysis revealed a statistically significant moderate to strong correlation between PSS-QoL scores and EuroQol-5D (r_s = -0.696), EULAR SS Patient Reported Index (r_s = 0.883), and Oral Health Impact Profile-14 scores (r_s = 0.809). **Conclusion.** Serbian adaptation of the PSS-QoL instrument can be used to evaluate HRQoL of patients with primary SS both in academic research and clinical practice as a novel outcome measure.

Key words:
quality of life; serbia; sjogren's syndrome; surveys and questionnaires; translations.

Apstrakt

Uvod/Cilj. Procena kvaliteta života povezanog sa zdravljem – *health-related quality of life* (HRQoL), je esencijalna za bolje razumevanje uticaja bolesti na različite aspekte svakodnevnog funkcionisanja bolesnika i efikasnost modaliteta lečenja. Upitnik primarnog Sjegrenovog sindroma (SS) – *Primary Sjögren's Syndrome QoL* (PSS-QoL), je prvi instrument za procenu HRQoL koji je specifičan za primarni SS. Cilj rada bio je da se upitnik PSS-QoL prevede sa engleskog na srpski jezik, procene njegova psihometrijska svojstva i da se validira za upotrebu u srpskoj populaciji. **Metode.** Istraživanje je osmišljeno kao pilot studija i obuhvatilo je 30 učesnika. Interna konzistencija izračunata je određivanjem Kronbahovog alfa koeficijenta. Valjanost upitnika procenjena je korelacijom njegovog ukupnog rezultata sa rezultatima *EuroQoL-5D*, *European League Against Rheumatism (EULAR) SS Patient Reported Index*, *Oral Health Impact Profile-14* i *Emotion Regulation Questionnaire* upitnika. **Rezultati.** U istraživanju je učestvovalo 29 (96,7%) žena i jedan (3,3%) muškarac. Prosečna (± standardna devijacija) vrednost PSS-QoL bila je 44,63 ± 12,901 na početku i 41,70 ± 12,075 prilikom ponovnog merenja. Vrednost Kronbahove alfa vrednosti za srpsku verziju PSS-QoL bila je 0,922. Test-retest koeficijent korelacije iznosio je 0,981 (95% interval pouzdanosti: 0,436–0,996). Analiza je otkrila statistički značajnu, umerenu do jaku korelaciju, između PSS-QoL rezultata i *Euro-QoL-5D* (r_s = -0,696), *EULAR SS Patient Reported Index* (r_s = 0,883) i *Oral Health Impact Profile-14* rezultata (r_s = 0,809). **Zaključak.** Srpska verzija instrumenta PSS-QoL može se koristiti za procenu HRQoL kod bolesnika sa primarnim SS, kako u akademskim istraživanjima tako i u kliničkoj praksi.

Ključne reči:
kvalitet života; srbija; sjegrenov sindrom; ankete i upitnici; prevodilaštvo.

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Introduction

Primary Sjögren syndrome (SS) is an autoimmune rheumatic disease characterized by intense lymphocytic infiltration of exocrine glands, which results in their progressive and irreversible dysfunction [1]. It predominantly affects women in the 4th and 5th decade of life [2]. The main symptoms associated with primary SS are oral and ocular dryness, fatigue, and chronic pain [3]. In approximately 25–50% of patients, severe systemic features, including musculoskeletal, pulmonary, hematological, and neurological complications, might be present alongside glandular manifestations [4, 5]. Mental disorders, such as anxiety and depression, are also frequently reported [6]. It is suggested that both physical and psychological factors contribute to the decrease in the overall well-being of patients suffering from primary SS [7].

Health-related (HR) quality of life – QoL (HRQoL) is a multidimensional concept used as a patient-reported outcome measure in numerous clinical trials [8]. The assessment of HRQoL is fundamental for a better understanding of the effect of a disease on different aspects of a patient's daily functioning, the efficacy of the treatment modalities, and possible risk factors related to altered HRQoL [9, 10]. Over the years, various generic and disease-specific instruments have been developed and translated into different languages worldwide for HRQoL measurement.

Evaluation of HRQoL in SS has been, so far, mostly accomplished by implementing generic tools such as 36-Item Short Form Survey (SF-36) and EuroQol-5D (EQ-5D) [11]. On the other hand, primary SS QoL (PSS-QoL) questionnaire represents the first created disease-specific instrument for HRQoL assessment of patients with primary SS [9]. It consists of 25 questions divided into two dimensions – physical (dryness and discomfort) and psychosocial. The overall score of the questionnaire is obtained by simply adding the values of the items, and it may range from 0 to 92 for males and from 0 to 96 for females [9]. Higher results indicate a greater impairment of HRQoL.

The aim of this research was to formally translate the PSS-QoL questionnaire from English to Serbian, assess its psychometric properties, and validate it for use in the Serbian population.

Methods

The study was conducted on the premises of the Rheumatology Clinic of the University Clinical Center of Kragujevac between July 5 and December 15, 2021, and it was designed as a pilot study. The research was approved by the Ethics Committee of the University Clinical Center of Kragujevac (No. 01/20-657, from September 09, 2020). Before participating in the study, the aim and the protocol were explained to patients, and all of them signed the written informed consent. Thirty patients with primary SS that came to a regular checkup at the Rheumatology Clinic were recruited in the research. The study included patients with the diagnosis of primary SS according to the American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) classification recommendations and those aged 18 or above. The exclusion criteria were the following: age below 18, mental disorders, and patients unwilling to participate in the study. All of the patients filled in the following questionnaires: PSS-QoL, EuroQol-5D (EQ-5D), EULAR SS Patients Reported Index (ESSPRI), Oral Health Impact Profile-14 (OHIP-14), and Emotion Regulation Questionnaire (ERQ).

HRQoL of patients with primary SS was evaluated using the Serbian version of the PSS-QoL questionnaire, which was translated, adapted, and validated in this paper. Translation and cultural adaptation of the PSS-QoL questionnaire were made according to the standard protocol (translation/back-translation), following the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines [12]. The author of the original instrument (Dr. Angelika Lackner [9], Medizinische Universität Graz) provided written approval for translation and adaptation from English to the Serbian language. The original version of the questionnaire was first translated into Serbian independently by two authors of this article, whose native language is Serbian. After the translation was done, the authors compared the two versions and combined them, making minor wording adjustments to retain the linguistic properties of the Serbian language. The questionnaire was then back-translated into English by a proficient English speaker and a fluent Serbian speaker who had not been familiar with the original version. The back-translation was compared with the original, and the authors of the article agreed on the final Serbian version of the instrument. In order to test the psychometric properties of the PSS-QoL instrument, 30 patients completed the questionnaire twice in 14 days.

The PSS-QoL questionnaire is the first disease-specific instrument designed to evaluate the HRQoL of patients with primary SS [9]. It is composed of 25 questions divided into physical and psychosocial dimensions. All questions refer to patients' complaints in the last four weeks. The physical domain consists of a numeric scale (from 0 to 10) for pain assessment and checkboxes for other disease-related physical symptoms that are known to alter HRQoL. The psychosocial dimension includes 14 items that can be scored on a 5-point Likert scale (from 0 – never to 4 – always). Statements 15 and 20 within the psychosocial domain have inverse scoring. The total score is calculated as a summary of individual items, and it may range from 0 to 96 (for females) and from 0 to 92 (for males, vaginal dryness is excluded). Higher scores indicate worse HRQoL [9].

EQ-5D is a reliable, self-completion HRQoL instrument used in many various diseases and health conditions [13]. It is the most widely implemented generic tool worldwide. EQ-5D consists of five domains – mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, and each of these dimensions has five levels of severity. EQ-5D also includes a visual analog scale (EQ-VAS) that provides individuals' perception of their general health, recorded on a vertical scale, numbered from 0 to 100 [13]. The final score of the questionnaire is calculated according to set values specific to different countries.

ESSPRI is a patient-reported outcome measure created to evaluate the main symptoms associated with primary SS, such as overall dryness, fatigue, and body pain. It contains three numeric scales (from 0 – no symptom to 10 – worst symptom imaginable) to assess symptoms' severity in the last two weeks. The overall result represents a mean value of the three domains' scores, ranging from 0 to 10 [14]. So far, ESSPRI has been widely used as an endpoint in clinical research because it is considered a useful predictor of the health status of primary SS patients and correlates well with HRQoL domains as well [15].

OHIP-14 is a self-filled questionnaire that consists of 14 questions divided into seven dimensions: functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap [16]. It is created to measure the impact of oral health on the overall QoL domains. Questions can be scored on a 5-point Likert scale, depending on how much a certain oral HR problem affects the patient's daily functioning. The final result is obtained by summing the 14 items' values, and the higher scores indicate a negative impact of oral conditions on HRQoL [16].

ERQ is a 10-item scale designed to assess individual differences in emotion regulation using two common strategies: cognitive reappraisal and emotion suppression [17]. Answers can be scored on a 7-point Likert scale (from 1 – strongly disagree to 7 – strongly agree). Questions numbered 1, 3, 5, 7, 8, and 10 belong to the cognitive reappraisal domain, while questions 2, 4, 6 and 9 contribute to emotion suppression. A score is calculated for each of the subscales, with the higher scores indicating greater utilization of that particular emotion regulation strategy [17, 18].

Statistical data analysis was performed in the SPSS statistical program, version 22. The feasibility was determined by measuring participants' time for completing the PSS-QoL questionnaire and establishing the percentage of missing data for each question. The reliability of the Serbian version of the PSS-QoL was tested threefold. First, the internal consistency was estimated by calculating Cronbach's alpha (Cα) coefficient for the whole instrument. The internal consistency was considered satisfactory if the Cα coefficient was 0.7 or higher [12]. Second, the questionnaire was divided into two parts by the split-half method (even-numbered and odd-numbered questions), and Cα was determined for each of them, after which the Spearman-Brown coefficient was calculated. Third, the intraclass correlation coefficient (ICC) was evaluated for the questionnaire's test-retest reliability (temporal stability). Values of ICC above 0.7 indicated good reliability. To discover the principal factors of the Serbian version of the PSS-QoL instrument, the Principal Component Analysis (PCA) was performed, including only questions belonging to the psychosocial domain of the questionnaire (items in the physical dimension are not scored on a Likert scale). Prior to the PCA, the Kaiser-Meyer-Olkin (KMO) measure of Sampling Adequacy and Bartlett's test of sphericity were conducted to assess the sample suitability for this method. Then the factors were extracted based on Eigenvalues (> 1.0), scree-plot, and factor loading (> 0.3) [19]. The construct validity of the questionnaire was explored by the correlation of its overall result with the patients' EQ-5D, ESSPRI, OHIP-14, and ERQ scores, using Spearman's rank correlation. A *p*-value less than 0.05 was considered a measure of statistical significance for all statistical tests.

Results

A total of 30 primary SS patients with a mean [± standard deviation (SD)] age of 63.93 ± 10.48 years were included in the research. The average (± SD) disease duration was 111.200 ± 141.433 months. The sociodemographic characteristics of the study participants are given in Table 1.

Table 1

Sociodemographic characteristics of the study participants

Variable	n (%)
Gender	
male	1 (3.3)
female	29 (96.7)
Education	
elementary school	9 (30.0)
high school degree	11 (36.7)
university degree	7 (23.3)
doctorate	3 (10.0)
Employment status	
employed	3 (10.0)
unemployed	9 (30.0)
retired	18 (60.0)
Marital status	
single	1 (3.3)
married	20 (66.7)
divorced	7 (23.3)
widowed	2 (6.7)

The following scores of the PSS-QoL questionnaire were obtained: total PSS-QoL score (all questions), physical PSS-QoL (questions 1–11), discomfort PSS-QoL (questions 1–6), dryness PSS-QoL (questions 7–11), and psychosocial PSS-QoL (12–25) score. These results were calculated at baseline (total score: 44.630 ± 12.901) and two weeks after (total score: 41.700 ± 12.075) for the second evaluation of the questionnaire's psychometric properties.

Table 2 shows the scores of the EQ-5D, ESSPRI, OHIP-14, and ERQ questionnaires, including the results of their specific domains.

Feasibility

The feasibility of the questionnaire was satisfactory as there were no missing data, both at baseline and follow-up. The mean time for completing the questionnaire was 2.42 min (range from 1.41 to 3.23 min). The participants felt the questionnaire was easy to complete and the questions were relevant to their health status.

Reliability

The internal consistency of the questionnaire was assessed by calculating the Cα coefficient. The Serbian version of the PSS-QoL instrument recorded high reliability (Cα = 0.922).

After dividing the instrument into two parts by the split-half method, the Spearman-Brown coefficient was determined by the Spearman-Brown ‘prophecy’ formula and recorded a value of 0.972. Considering that the Spearman-Brown coefficient did not fall below 0.7 after the split-half method, the satisfactory reliability of the Serbian version of the PSS-QoL questionnaire was further verified.

All of the recruited patients filled out the questionnaire once again after two weeks for test-retest reliability evaluation (100% response rate). The value of ICC was 0.981 [95% confidence interval (CI): 0.436–0.996], which indicated excellent reliability of the PSS-QoL instrument.

The mean values of total and individual domain scores of PSS-QoL at baseline and follow-up are given in Table 3.

Principal Component Analysis

Considering that the KMO measure of Sampling Adequacy was 0.765 and Bartlett’s test of sphericity was significant ($p < 0.001$), PCA could be performed. Only one component was extracted (Eigenvalue = 8.343), explaining in total 59.592% of the variance. All of the items had high values of nonrotating factor weights (> 0.3; range from 0.667 to 0.932) for one component (Table 4). The scree-plot also suggested a one-factor solution. Therefore, the rotation was not conducted.

Construct validity

The correlation of the PSS-QoL scores with the scores of other similar HRQoL instruments (EQ-5D, ESSPRI,

Table 2

EQ-5D, ESSPRI, OHIP-14, ERQ scores

Instrument	Values, mean ± SD; median (IQR)
EQ-5D	
mobility	1.37 ± 0.808; 1.0 (1.0)
self-care	1.37 ± 0.808; 1.0 (1.0)
usual activity	1.53 ± 0.808; 1.0 (1.0)
pain/discomfort	2.53 ± 0.819; 3.0 (1.0)
anxiety/depression	2.77 ± 0.935; 3.0 (1.25)
score	0.74 ± 0.318; 0.83 (0.2)
ESSPRI	
dryness	5.33 ± 1.539; 5.0 (2.25)
fatigue	4.50 ± 2.224; 5.0 (3.0)
pain	3.83 ± 1.783; 4.0 (2.0)
score	4.67 ± 1.728; 5.0 (3.0)
OHIP-14	
functional limitation	2.53 ± 1.106; 2.5 (1.0)
physical pain	5.40 ± 1.113; 5.5 (1.0)
psychological discomfort	2.77 ± 1.135; 3.0 (2.0)
physical disability	6.27 ± 1.015; 6.0 (1.0)
psychological disability	2.70 ± 1.179; 2.5 (2.0)
social disability	2.07 ± 0.980; 2.0 (2.0)
handicap	3.23 ± 1.040; 3.0 (2.0)
score	24.97 ± 5.586; 26.5 (10.0)
ERQ	
cognitive reappraisal	24.15 ± 2.509; 24.0 (4.0)
expressive suppression	20.65 ± 4.345; 22.0 (4.0)
score	32.36 ± 20.847; 42.0 (47.0)

EQ-5D – Euro Quality of life-5D; ESSPRI – European League Against Rheumatism (EULAR) Sjögren’s Syndrome Patients Reported Index; OHIP-14 – Oral Health Impact Profile -14; ERQ – Emotion Regulation Questionnaire; SD – standard deviation; IQR – interquartile range.

Table 3

Mean values of PSS-QoL dimensions and total score at baseline and follow-up

PSS-QoL	Baseline (mean ± SD)	Follow-up (mean ± SD)
Score	44.63 ± 12.901	41.70 ± 12.075
Physical	14.73 ± 5.483	15.73 ± 5.644
Discomfort	5.00 ± 2.579	5.23 ± 2.541
Dryness	9.73 ± 3.542	10.50 ± 3.785
Psychosocial	27.40 ± 7.959	25.97 ± 7.434

PSS-QoL – Primary Sjögren’s Syndrome Quality of Life; SD – standard deviation.

Table 4

Component matrix

Items	Factor weights
I have a feeling that I am the only person with these complaints	0.773
I have a feeling that my complaints are not taken seriously	0.785
I have a feeling that my complaints are too much for me	0.704
I have a feeling that my family and friends are understanding	0.691
I am too tired to fulfill obligations to my family and friends	0.774
I am withdrawn	0.678
I am concerned about the side effects	0.853
I worry about the further course of my disease	0.853
I have a good feeling about my body	0.679
I cannot manage my everyday life as well as I did before I became ill	0.932
I tire easily	0.841
Everyday activities like driving, work, household, and sports are a challenge	0.731
Remedies like eye drops, creams, and physiotherapy impose a financial burden	0.667
The disease has reduced my quality of life	0.873

Extraction Method: Principal Component Analysis; One component extracted.

Table 5

Correlation of PSS-QoL scores with EQ-5D, ESSPRI, and OHIP-14 scores

	PSS-QoL				
	score	physical	discomfort	dryness	psychosocial
EQ-5D					
mobility	n.s.	n.s.	n.s.	n.s.	n.s.
self-care	n.s.	n.s.	n.s.	n.s.	n.s.
usual activity	n.s.	n.s.	n.s.	n.s.	n.s.
pain/discomfort	0.812**	0.873**	0.926**	0.635**	0.649**
anxiety/depression	0.666**	0.678**	0.656**	0.569**	0.646**
score	-0.696**	-0.720**	-0.701**	-0.613**	-0.636**
ESSPRI					
dryness	0.829**	0.818**	0.742**	0.713**	0.696**
fatigue	0.814**	0.735**	0.711**	0.611**	0.761**
pain	0.832**	0.876**	0.965**	0.634**	0.653**
score	0.883**	0.863**	0.866**	0.702**	0.739**
OHIP-14					
functional limitation	0.488**	0.435*	0.535**	n.s.	0.465**
physical pain	0.728**	0.721**	0.679**	0.638**	0.644**
psychological discomfort	0.659**	0.654**	0.660**	0.511**	0.581**
physical disability	0.599**	0.502**	0.415*	0.475**	0.558**
psychological disability	0.697**	0.683**	0.725**	0.461*	0.705**
social disability	0.507**	0.515**	0.656**	n.s.	0.422*
handicap	0.692**	0.692**	0.711**	0.550**	0.618**
score	0.809**	0.790**	0.821**	0.618**	0.718**

PSS-QoL – Primary Sjögren's Syndrome Quality of Life; EQ-5D – Euro Quality of life-5D; ESSPRI – European League Against Rheumatism (EULAR) Sjögren's Syndrome Patients Reported Index; OHIP-14 - Oral Health Impact Profile – 14.
n.s. – not significant; * *p* < 0.05; ** *p* < 0.001.

OHIP-14) was evaluated to assess the questionnaire's convergent validity (Table 5). PSS-QoL discomfort correlated very strongly with the same EQ-5D dimension. Furthermore, the psychosocial component of PSS-QoL had a moderate correlation with the EQ-5D anxiety/depression domain. Results revealed a moderate negative correlation between the total PSS-QoL and EQ-5D scores.

The PSS-QoL questionnaire correlated strongly with all of the ESSPRI dimensions. There was a very strong correlation between ESSPRI pain and PSS-QoL discomfort, and also a strong correlation between ESSPRI dryness and PSS-QoL dryness.

Regarding PSS-QoL and OHIP-14, the results showed a very strong correlation between their total scores. OHIP-14 psychological disability and PSS-QoL psychosocial domain recorded a strong correlation.

The divergent validity of the PSS-QoL questionnaire was established by correlating its overall score with the values of the ERQ. The obtained results indicated a weak and non-significant correlation (r_s = -0.137) between these two instruments.

Spearman's correlation coefficients are shown in the Multitrait-Multimethod matrix (Table 6).

Table 6

Multitrait-multimethod correlation matrix

	PSS-QoL					EQ-5D	ESSPRI	OHIP-14	ERQ
	score	physical	discomfort	dryness	psychosocial				
PSS-QoL									
score	‘1								
physical	0.941**	1							
discomfort	0.818**	0.855**	1						
dryness	0.853**	0.902**	0.587**	1					
psychosocial	0.869**	0.725**	0.624**	0.640**	1				
EQ-5D	-0.696**	-0.720**	-0.701**	-0.613**	-0.636**	1			
ESSPRI	0.883**	0.863**	0.866**	0.702**	0.739**	-0.854**	1		
OHIP-14	0.809**	0.790**	0.821**	0.618**	0.718**	-0.741**	0.848**	1	
ERQ	-0.137	-0.195	-0.187	-0.187	-0.217	0.383*	-0.210	-0.121	1

PSS-QoL – Primary Sjögren’s Syndrome Quality of Life; EQ-5D – Euro Quality of life-5D; ESSPRI – European League Against Rheumatism (EULAR) Sjögren’s Syndrome Patients Reported Index; OHIP-14 – Oral Health Impact Profile – 14; ERQ – Emotion Regulation Questionnaire.
*** $p < 0.05$; ** $p < 0.001$.**

Discussion

Assessment of patients’ HRQoL is fundamental for thoroughly comprehending the level of the burden that the disease puts on their daily activities and well-being. The most significant areas of QoL related to health are physical, emotional, and social functioning. The PSS-QoL is the first disease-specific questionnaire for primary SS. It covers all aspects relevant to patients’ HRQoL, unlike general tools, and much more precisely than commonly used instruments, such as EQ-5D and ESSPRI.

The aim of the study was to translate the PSS-QoL questionnaire from English to Serbian, evaluate its psychometric properties, and validate it for use in the Serbian population. Preliminary results of this pilot research showed that the Serbian translation exhibits satisfactory feasibility, reliability, and validity.

The assessment of PSS-QoL’s reliability (Cα = 0.922) revealed similar results to the original questionnaire (Cα = 0.892) and HRQoL instruments for other rheumatic diseases, such as Rheumatoid QoL (RAQoL, Cα = 0.92) and Ankylosing Spondylitis QoL Questionnaire (ASQoL, Cα = 0.91) [9, 20, 21]. Likewise, the Serbian version of the PSS-QoL instrument demonstrated satisfactory temporal stability.

PCA identified only one factor that accounted for nearly 60% of the variance. Seeing that all the items had high values of factor weights, it could be concluded that they all measure the construct they are designed to, which is the psychosocial dimension of the HRQoL. Since the authors of the original study did not present their data regarding factor analysis, we could not compare our findings.

So far, the HRQoL of primary SS patients has been evaluated using generic measures, like EQ-5D. Our study demonstrated a moderate correlation between these two instruments. EQ-5D does not include some of the most important aspects of primary SS, especially dryness-related symptoms that might pose a great burden to patients’ daily lives [9, 22]. Therefore, the implementation of disease-specific questionnaires, like PSS-QoL, into routine clinical practice could lead to significant improvement in patient’s well-being as all of their needs would be addressed.

The results of our research indicated a strong correlation between PSS-QoL and ESSPRI domains. Both instruments emphasize that the sicca complex is an important predictor of altered HRQoL in pSS patients [22]. In the ESSPRI, dryness is evaluated as an overall item, while PSS-QoL provides a more precise description of all patient’s symptoms, not only regarding severity levels, and it also includes the psychosocial component of HRQoL.

OHIP-14 is an instrument designed to assess the impact of oral conditions, including xerostomia, on HRQoL domains [16]. Our study found that total scores of PSS-QoL and OHIP-14 correlate strongly. OHIP-14 psychological disability and PSS-QoL psychological dimension have a strong correlation as the social component is a very significant part of HRQoL, and it may be affected due to oral health problems. Xerostomia, a hallmark of primary SS, might lead to various intraoral manifestations and severe oral dysfunction [23]. The PSS-QoL questionnaire covers different oral-related symptoms, such as taste alteration, burning sensation, and dental problems. Therefore, it can be used for determining the extent of the oral disorders present during primary SS and their impact on HRQoL.

The main limitation of our study is the small sample size. Furthermore, we did not test and compare the results of different modes of questionnaire administration. In addition, one of the properties we could not evaluate is the questionnaire’s sensitivity to change, mostly related to the administration of effective medication, which is not yet widely available for patients with primary SS. Our next aim is to conduct prospective research involving more participants to re-assess the questionnaire’s psychometric properties in a more diverse group of primary SS patients regarding their sociodemographic characteristics, disease activity, and disease-related complications.

Conclusion

Our pilot study demonstrated that the Serbian version of the PSS-QoL questionnaire is as reliable as the original instrument in English. Therefore, the Serbian adaptation of the PSS-QoL instrument may be used to evaluate the HRQoL of patients with primary SS, both in academic research and everyday clinical practice, as a novel outcome measure. Still, future clinical trials that will include a more significant number of patients are needed to confirm further its validity in the Serbian population.

Conflict of interest

The authors declare no conflict of interest.

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