LETTER TO THE EDITOR

UDC: 159.938.37::616-06-036.86]:616-018.2
DOI: https://doi.org/10.2298/VSP230911068V

Re-evaluation of the psychometric properties of the Serbian version of the Primary Sjögren's Syndrome Quality of Life questionnaire

Reevaluacija psihometrijskih karakteristika srpske verzije Upitnika za procenu kvaliteta života osoba sa primarnim Sjegrenovim sindromom

To the Editor

Numerous research conducted worldwide have demonstrated that the health-related (HR) quality of life (QoL) – HRQoL – of patients with primary Sjögren's syndrome (PSS) is notably reduced compared to healthy controls due to the broad spectrum of daily problems they face [1, 2]. In the majority of these studies, HRQoL was assessed by the most frequently used instruments of a generic nature that cannot adequately capture all aspects of disease essential to patients [3–5]. Therefore, specific tools, such as the Primary Sjögren's Syndrome Quality of Life (PSS-QoL) questionnaire developed in 2018, are highly recommended [6]. The pilot study, published in 2022, revealed that the Serbian version of the PSS-QoL questionnaire showed satisfactory feasibility, reliability, and validity [7]. Hence, the aim of this article was to reassess the psychometric properties of the questionnaire in a larger and more diverse group of PSS patients regarding their socio-demographic characteristics, disease activity, and disease-related complications.

This prospective, non-interventional study was carried out at the Rheumatology Clinic of the University Clinical Center of Kragujevac, Serbia between July 2021 and September 2022. The research received approval from the Ethics Committee of the University Clinical Center of Kragujevac (No. 01/20-657). Eighty patients with the diagnosis of PSS established by two rheumatologists [according to the American College of Rheumatology (ACR) or the European League Against Rheumatism (EULAR) classification criteria], aged over 18, with sufficient mental, physical, and linguistic abilities, were enrolled in the study. Prior to the research onset, all participants provided their written informed consent. Patients under 18 with psychiatric disorders and those who refused to participate were excluded. Each participant completed five surveys, including the PSS-QoL, Euro Quality of Life-5D (EQ-5D), EULAR (E) Sjögren's Syndrome (SS) Patients Reported Index (ESSPRI), Oral Health Impact Profile-14 (OHIP-14), and Emotion Regulation Questionnaire (ERQ). Written permission was obtained from the authors of all scales applied in this study. Our pilot research conducted in 2022 provides a comprehensive explanation of the abovementioned questionnaires used [7]. Two methods of administration were tested. Formal translation, adaptation, and validation of the PSS-QoL were performed in the previously published study that included 30 participants, implementing the standard translation/back-translation protocol, adhering to the internationally accepted principles [7, 8]. Temporal stability was tested 14 days after the first completion of the questionnaire by researchers interviewing the participants.

Eighty subjects were enrolled in the study, with a mean age (± standard deviation) of 63.81 ± 10.8 years. The majority of the patients were women (96.2%). The average disease duration was 9.15 ± 7.1 years. The extraglandular manifestations of the PSS were detected in 87.5% of participants (musculoskeletal complications were the most prevalent). The patients were treated with antimalarial therapy, either alone (77.5%) or in combination with corticosteroids (22.5%).

The results that were obtained are given in the following text. The mean values of total and subscale scores of the PSS-QoL at baseline (both modes of administration) and follow-up are illustrated in Table 1. No statistically significant difference was observed between these results ($p > 0.05$). The feasibility of the PSS-QoL scale was excellent, as demonstrated by the high response rate (100%) and absence of missing data. The mean time for completing the questionnaire was 2.57 min (from 1.44 to 4.22 min) when the researchers were questioning the participants and 2.54 min (from 1.33 to 4.26 min) when the subjects did it themselves, indicating minimal patient burden.

Cronbach's alpha coefficient values were 0.931 (when the researcher completed the questionnaire) and 0.921 (when the participants did it on their own), so the reliability of the questionnaire was considered excellent. Seeing that the Spearman-Brown coefficient was 0.923 (when researchers were questioning the patients) and 0.890 (when subjects completed the questionnaire themselves), the reliability of the Serbian version of the PSS-QoL was confirmed. The intraclass correlation coefficient, a measure of temporal

Correspondence to: Jana Desnica, University of Kragujevac, Faculty of Medical Sciences, Svetozara Markovića 69, 34 000 Kragujevac, Serbia. E-mail: jana.desnica@gmail.com

Table 1

Baseline and follow-up PSS-QoL scores

PSS-QoL	Baseline		Follow-up
	rated by researchers	rated by patients	
Score	41.98 ± 16.50	42.24 ± 16.31	42.04 ± 15.51
Physical	14.01 ± 8.77	13.74 ± 8.49	14.90 ± 8.37
Discomfort	4.46 ± 3.55	4.19 ± 3.29	4.85 ± 3.28
Dryness	9.55 ± 5.53	9.55 ± 5.53	10.05 ± 5.42
Psychosocial	27.97 ± 8.83	28.50 ± 8.85	27.14 ± 8.19

PSS-QoL – Primary Sjögren's Syndrome Quality of Life.
Results are shown as mean ± standard deviation.

Table 2

Multitrait-multimethod matrix

	PSS-QoL (R)	PSS-QoL (P)	EQ-5D (R)	EQ-5D (P)	ESSPRI (R)	ESSPRI (P)	OHIP-14 (R)	OHIP-14 (P)	ERQ (R)	ERQ (P)
PSS-QoL (R)	1	/	/	/	/	/	/	/	/	/
PSS-QoL (P)	0.999**	1	/	/	/	/	/	/	/	/
EQ-5D (R)	-0.766**	-0.771**	1	/	/	/	/	/	/	/
EQ-5D (P)	-0.763**	-0.766**	0.914**	1	/	/	/	/	/	/
ESSPRI (R)	0.848**	0.849**	-0.869**	-0.798**	1	/	/	/	/	/
ESSPRI (P)	0.846**	0.847**	0.917**	-0.821**	0.917**	1	/	/	/	/
OHIP-14 (R)	0.834**	0.836**	-0.767**	-0.746**	0.789**	0.808**	1	/	/	/
OHIP-14 (P)	0.809**	0.812**	-0.741**	-0.723**	0.750**	0.722**	0.967**	1	/	/
ERQ (R)	0.064	0.069	-0.028	-0.031	-0.068	-0.059	0.032	0.047	1	/
ERQ (P)	0.057	0.061	-0.019	-0.012	-0.044	-0.037	0.026	0.041	0.903**	1

R – rated by researchers; P – rated by patients; 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. * $p < 0.05$; ** $p < 0.001$.

stability, was 0.983 [95% confidence interval (CI): 0.973–0.989], suggesting high PSS-QoL reliability. Considering that all participants completed the questionnaire again after a 14-day interval, an attrition rate of 0% was observed.

The principal axis factoring method was employed for factor analysis. Using Promax rotation, we extracted two factors based on eigenvalue criteria, explaining 59.58% of the total variance. The first factor had an eigenvalue of 6.82 (accounting for 48.72% of variance), while the second factor had an eigenvalue of 1.52 (representing 10.86% of variance). Furthermore, a scree plot supported the decision to extract two factors, as demonstrated by a noticeable "elbow" on the graph. Most questionnaire items were loaded onto the first factor, except for items 12, 13, and 17.

The PSS-QoL outcomes were correlated with the results of EQ-5D, ESSPRI, and OHIP-14 questionnaires for estimating the scale's convergent validity. Spearman's rank correlation test illustrated a strong and significant correlation between observed scales (Table 2). Additionally, the divergent validity of the PSS-QoL instrument was assessed by comparing its total scores with those of the ERQ. The results suggested a weak and non-significant correlation, further indicating the PSS-QoL's ability to distinguish between different constructs (Table 2).

Overall, our findings indicated that the PSS-QoL is a valid scale that can be completed in under five minutes, as evidenced by results derived from both modes of administration. Additionally, PSS-QoL exhibited excellent reliability and significant convergent validity. These outcomes are similar to those attained by our pilot study and the original instrument's authors [6, 7].

In conclusion, the Serbian version of the PSS-QoL scale is a reliable and valid instrument for assessing HRQoL in PSS patients. This scale can be applied in both research and clinical settings as a valuable indicator of patients' QoL, now recognized as one of the crucial treatment outcomes.

Sanja Vujović, Jana Desnica, Momir Stevanović, Mirjana Veselinović, Aleksandra Lučić Tomić, Dragan Milovanović
University of Kragujevac, Faculty of Medical Sciences, Kragujevac, Serbia

REFERENCES

1. *Dias LH, Miyamoto ST, Giovelli RA, de Magalhães CIM, Valim V.* Pain and fatigue are predictors of quality of life in primary Sjögren's syndrome. Adv Rheumatol 2021; 61(1): 28.
2. *Miyamoto ST, Valim V, Fisher BA.* Health-related quality of life and costs in Sjögren's syndrome. Rheumatology (Oxford) 2021; 60(6): 2588–601.
3. *Azuma N, Katada Y, Yoshikawa T, Yokoyama Y, Nishioka A, Sekiguchi M,* et al. Evaluation of changes in oral health-related quality of life over time in patients with Sjögren's syndrome. Mod Rheumatol 2021; 31(3): 669–77.
4. *Rojas-Alcayaga G, Herrera A, Espinoza I, Rios-Erazo M, Aguilar J, Leiva L,* et al. Illness Experience and Quality of Life in Sjögren

Syndrome Patients. Int J Environ Res Public Health 2022; 19(17): 10969.

5. *Zhang Q, Wang X, Chen H, Shen B.* Sjögren's syndrome is associated with negatively variable impacts on domains of health-related quality of life: evidence from Short Form 36 questionnaire and a meta-analysis. Patient Prefer Adherence 2017; 11: 905–11.
6. *Lackner A, Stradner MH, Hermann J, Unger J, Stamm T, Graninger WB*, et al. Assessing health-related quality of life in primary Sjögren's syndrome-the PSS-QoL. Semin Arthritis Rheum 2018; 48(1): 105–10.
7. *Vujović S, Desnica J, Mijailović S, Milovanović D.* Translation, transcultural adaptation, and validation of the Serbian version of the PSS-QoL questionnaire – a pilot research. Vojnosanit Pregl 2023; 80(6): 493–9.
8. *Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A,* et al. Principles of good practice for the translation and cultural adaptation process for Patient-Reported Outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. Value Health 2005; 8(2): 94–104.

Received on September 11, 2023
Revised on June 20, 2024
Revised on July 22, 2024
Accepted July 30, 2024
Online First September 2024