Validation of the Disease-specific Questionnaire MSQoL-54 in Bosnia and Herzegovina Multiple Sclerosis Patients Sample

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ABSTRACT

Introduction: The purpose of this study was to validate Bosnian translation of disease specific quality of life measure MSQoL-54 which is widely used in practice. **Material and Methods:** Previously translated and culturally adopted MSQoL-54 questionnaire used in this study has been provided and licensed by Optum Inc. The questionnaire was validated in 62 MS patients seen at Neurology clinic at University Clinical Center Sarajevo, during April 2016 until May 2016. Internal reliabilities of Bosnian version MSQoL-54 were assessed for multiple item scales by using Cronbach's alpha coefficient. Clinical validity was assessed comparing means of the two summary MSQoL-54 scores by the EDSS score. Pearson's (r) correlation coefficient was used to investigate the relationship between the composite scores and the main clinical and demographic variables. **Results:** Patients' participation was satisfactory and all scales fulfilled the usual psychometric standards. Highly significant inverse relationship was found between both composite scores and clinical characteristics of the disease and the EDSS. The lowest internal consistency reliability is found on social function scale (0.743), overall quality of life (0.782) and pain (0.833). The highest internal consistency reliability is found on role limitations due to physical problems (0.959), physical health (0.962) and role limitations due to emotional problems (0.966). The mean value of MSQoL-54 PHC (Physical Health Composite) and MHC (Mental Health Composite) were 49.82±18.90 (36.05-61.38) 51.84±22.22 (34.93-70.20) respectively. Our study has shown that the Bosnian version of MSQoL-54 is easy to administer and well accepted by patients and may be useful as clinical outcome measures in patients with MS.

Keywords: Multiple sclerosis, Quality of life, MSQoL-54, Validation, Bosnian.

1. INTRODUCTION

Multiple sclerosis (MS) is progressive, autoimmune neurodegenerative disorder, causing damage of the central nervous system (CNS) as a result of myelin sheath damage. Impact of nervous system results on impact on many other body systems and body as whole gradually as disease progress.

The disease mainly affects young adults; more often women (1). According to some studies, 70% of patients with multiple sclerosis are between 15 and 45 years of age (2). The prevalence of multiple sclerosis varies regionally, and is the largest in the countries of Northern Europe, Australia and the United States of America (3). It is estimated, based on data from clinics health insurance funds than MS affects more than 3.000 patients in Bosnia and Herzegovina (4). Kingwell et al published a study in 2013 stating that the inci-

dence of MS in Bosnia and Herzegovina is 1.6/100.000 (5). MS significantly impact patients' quality of life. Health related quality of life is often used as an outcome measurement in pharmacoeconomic evaluation of medicines which is used as tool for health care policy decision making tool. One of the most wide used disease specific instrument for measuring health related quality of life (HRQOL) in MS is the Multiple Sclerosis Quality of Life 54 (MSQoL-54). This instrument was developed in USA (6) and now it is available in different languages, with translation and cultural adaptation (7-11). Bosnian translation of MSQoL 54 is available and it was used in some studies and research projects in Bosnia and Herzegovina (12).

The 54 items of this questionnaire is distributed into 12 multi-item scales and 2 single items. Two summary scores physical health compos-

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ite (PHC) and mental health composite (MHC) can be derived from a weighted combination of scale scores.

The aim of this study was to assess validity of Bosnian translation of MSQoL-54 in population of 62 MS patients diagnosed MS according to well established diagnostic criteria (13).

2. METHODS AND MATERIALS

Sixty patients diagnosed with MS participated in this study, all admitted at Neurology clinic at University Clinical Center Sarajevo, during April 2016 until May 2016. Inclusion criteria were that they are older than 18 years, have diagnosed relapsing remitting MS according to McDonald's criteria and written informed consent. Exclusion criteria were an exacerbation in the last month, pre-existing other chronic illness and/or psychiatric disorders. Out of 95 patients seen in this period 65 met inclusion criteria, and 62 submit properly filled questionnaires, which has been taken into analysis. In this study we used MSQoL-54 already translated and culturally adopted into Bosnian language. Translated questionnaire has been provided and licensed by Optum Inc.

The MSQoL-54 questionnaire was filled in by the patients with presence of physician who could assist in of eventual problems in understanding questions and technical way of filling the questionnaire. Patient disability has been assessed by the neurologist using the Expanded Disability Status Scale (EDSS) score (14).

MSQoL-54 scale scores were created using the Likert method by averaging items within the scales and, then row scores were linearly transformed into 0–100 scales. Higher values indicate better quality of life. Assessment of patients' acceptability of MSQoL-54 was performed by noting the mean time required for completing the questionnaire and assistance in reading and/or writing. Missing data has been avoided because presenting physician supervised the process.

Internal reliabilities of Bosnian version MSQoL-54 were assessed for multiple item scales by using Cronbach's alpha coefficient (15), ranges from 0–1, where 1 means perfect reliability.

Clinical validity was assessed comparing means of the two summary MSQoL-54 scores by the EDSS score.

Pearson's (r) correlation coefficient was used to investigate the relationship between the composite scores and the main clinical and demographic variables. Statistical analysis is done using SPSS v 16.0 software.

3. RESULTS

Demographic and clinical characteristics of patients enrolled in the study are presented in Table 1, including type of treatment receiving at the moment of filing the questionnaire. All patients were diagnosed as relapsing remitting multiple sclerosis and 33 are treated with immunomodulatory therapy (53.2%), steroid pulse therapy is applied at 20 (32.3%) patients while 9 (14.5%) patients are not treated at the moment of study conduction.

All patients clearly comprehend questionnaire. Average time to complete the questionnaire was 14 minutes, ranging from 4 to 20 minutes. Six (10%) patients need-

Characteristic		Number	%
Gender	Male	24	38.7
	Female	38	61.3
Therapy	IM	33	53.2
	SPT	20	32.3
	WoT	9	14.5
Age (years) ^a		39.8±10.9	(31.0-46.5)
	Male	40.9±12.4	(31.0-50.5)
	Female	39.1±9.9	(33.5-46.0)
EDSS ^a		2.9±1.9	(1.0-4.5)

IM –immunomodulatory therapy; SPT- steroid pulse therapy ;WoT-without therapy ^aMean ± SD (range) EDSS—Expanded Disability Status Scale

Table 1. Demographic and clinical characteristics of patients with multiple sclerosis

	N	Mean	SD	Range		Cronbach's Alpha	Number of items
				(25 th)	75 th)		
Physical Health	62	55.97	34.56	(25.00)	85.00)	0.962	10
Role limitations due to physical problems	62	14.92	32.79	(0.00)	45.22)	0.959	4
Role limitations due to emotional problems	62	23.66	41.55	(0.00)	41.67)	0.966	3
Pain	62	59.52	27.71	(38.33)	79.58)	0.833	3
Emotional well-being	62	65.35	19.20	(52.00)	81.00)	0.894	5
Energy	62	49.68	18.92	(35.00)	60.00)	0.837	5
Health Perceptions	62	47.02	25.11	(25.00)	70.00)	0.857	5
Social function	62	64.52	26.39	(47.92)	91.67)	0.743	3
Cognitive function	62	36.21	13.78	(30.00)	46.25)	0.921	4
Health distress	62	60.08	26.53	(43.75)	80.00)	0.934	4
Sexual function	62	70.99	33.68	(42.80)	100.00)	0.926	4
Change in health	62	42.34	25.04	(25.00)	50.00)	a	1
Satisfaction in sexual function	62	68.44	35.62	(50.00)	100.00)	a	1
Overall quality of life	62	63.06	19.69	(45.00)	79.18)	0.782	2

^aAlpha reliability could not be computed because the scale is based on a single item

Table 2. Descriptive statistics and reliability for the Bosnian version MSQoL-54

	N	Mean	SD	Range	
				(25 th)	75 th)
MSQOL-54 Mental Health *	62	49.82	18.90	(36.05)	61.38)
MSQOL-54 Physical Health *	62	51.84	22.22	(34.93)	70.20)

Table 3. Descriptive statistics MSQOL-54 Composite Score

	Pearson Correlation	p
Mental Health	-0.584(**)	0.0001
Physical Health	-0.765(**)	0.0001

Table 4. Clinical validity: Correlation of MSQOL-54 Composite Score with EDSS

ed help; four (6%) needed help in reading and 3 (5%) required writing help.

The mean scale scores and internal consistency (Cronbach's alpha) are presented in Table 2.

The lowest means are recorded for disabilities due to physical problems (14.92 ± 32.79), disabilities due to emotional problems (23.66 ± 41.55) and cognitive function (36.21 ± 13.78). The highest mean values are recorded at emotional well-being (65.35 ± 19.20), sat-

	Pearson Correlation	p
Physical Health	-0.841**	0.0001
Role limitations due to physical problems	-0.294*	0.020
Role limitations due to emotional problems	-0.327**	0.010
Pain	-0.689**	0.001
Emotional well-being	-0.508**	0.0001
Energy	-0.611**	0.0001
Health Perceptions	-0.512**	0.0001
Social function	-0.695**	0.0001
Cognitive function	-0.511**	0.0001
Health distress	-0.470**	0.0001
Sexual function	-0.616**	0.0001
Change in health	-0.492**	0.0001
Satisfaction in sexual function	-0.648**	0.0001
Overall quality of life	-0.606**	0.0001

** Correlation is significant at the 0.01 level, * Correlation is significant at the 0.05 level

Table 5. Clinical validity: Correlation of Bosnian version MSQoL-54 with EDSS

Figure 1. Comparison of median scale scores of the American, Hungarian, Italian and Bosnian multiple sclerosis patient sample. PH=Physical Health; RP=Role limitations–physical; RE=Role limitations–emotional; PN=Pain; EB=Emotional well-being; EN=Energy; HP=Health Perceptions; SF=Social function; CF=Cognitive function; HD=Health distress; SX=Sexual function; CH=Change in health; SS=Satisfaction in sexual function; OQ=Overall quality of life

isfaction in sexual function (68.44 ± 35.62) and sexual function (70.99 ± 33.68). Internal consistency reliability for these scales ranged from 0.743 on social function to 0.966 on role limitations due to emotional problems. The lowest internal consistency reliability is found on social function scale (0.743), overall quality of life (0.782) and pain (0.833). The highest internal consistency reliability is found on role limitations due to physical problems (0.959), physical health (0.962) and role limitations due to emotional problems (0.966).

The mean value of MSQoL-54 PHC (Physical Health Composite) and MHC (Mental Health Composite) were 49.82 ± 18.90 (36.05–61.38) 51.84 ± 22.22 (34.93–70.20) respectively as presented in Table 3.

Both MSQoL-54 composite scores showed strong correlation with the EDSS ($r = -0.765$; $P = 0.0001$) for PHC, and $r = -0.584$; $P = 0.0001$ for MHC) as shown in Table 4.

Statistically significant inverse (negative) correlations were found between EDSS score and all scales of MSQoL-54 (Table 5).

The most significant correlations are found between EDSS score and pain ($r = -0.689$, $p < 0.0001$), social function ($r = -0.695$, $p < 0.0001$) and physical health ($r = -0.841$, $p < 0.0001$). The lowest negative correlation is found on role limitations due to physical problems ($r = -0.294$, $p < 0.020$), role limitations due to emotional problems ($r = -0.327$, $p < 0.010$) and health distress ($r = -0.470$, $p < 0.0001$).

Comparison of our results with the data from the original American study and validation studies from Hungary and Italy between the mean scale scores of the patients groups is presented in Figure 1.

4. DISCUSSION

The Bosnian MSQoL-54 questionnaire was easy to administer and well accepted by our MS patients, with 95% of them stating that no embarrassing or difficult to interpret questions were present. This result is not different from those obtained from American (US), Italian, Turkish and Serbian MS patients (6, 7, 9, 11). Small percentage of patients needed help and assistance from physician to complete questionnaire. For small number of patients (5%) questions related to sexual function and satisfaction with sexual function caused inconvenience. In previously published similar studies these questions were main source of missing data (11, 16). Missing data in our study are avoided due to additional explanations and support by presenting physician. It is also noted that these questions are more embarrassing to females than males which could be result of cultural reasons. Solari et al proposed adding an additional response 'not applicable' to one sexual function item and to the sexual satisfaction item in order to reduce rate on missing data (17).

Average time to complete questionnaire was 14 minutes, ranging from 4 to 20 minutes which means that it was not a difficult task for the patients and that questionnaire was easy to understand. Similar results are found in other studies where average time to complete the MSQoL-54 ranged between 11.8–30 minutes (7, 18, 19).

In our MS patients, we found that internal consistency reliability for these scales ranged from 0.743 on social function to 0.966 on role limitations due to emotional problems. MSQoL-54 scales were reliable in the Bosnia and Herzegovina population as elsewhere (11, 20).

EDSS scores in our study correlated significantly negatively with all MSQoL-54 health dimensions. These correlations are similar to previously conducted validation studies. PHC and MHC also showed significant correlation with EDSS. Serbian validation study found that these domains significantly correlated with patients' age, education and employment status. Hungarian validation study reported that the patient group having lower EDSS score had better HRQoL scores on each scale. Solari et al also found high correlation between both composite scores and age. Other factors can also influence quality of life of MS patients. In Hungary validation study showed that. Younger patients with a higher level of education, shorter duration of the disease and a first attack or benign clinical form of the disease had a better quality of life. Previous studies showed that unemployed

patients reported low scores in some HRQoL domains, such as physical role limitation, physical function, and emotional limitation (21). Also, education seems to have some impact on HRQoL where high school or college graduates had higher physical health composite scores than patients with a low educational level (22). Study conducted in Bosnia and Herzegovina showed that sustained employment and development of vocational rehabilitation programs for MS patients living in the country with high unemployment level is an important factor in improving both physical and mental health outcomes in MS patients (23).

5. CONCLUSIONS

Our study has shown that the Bosnian version of MSQoL-54 is easy to administer and well accepted by patients. Its internal consistency reliability measured by Cronbach alpha coefficient is well above the minimum requirement in case of all scales. Use of this instrument in routine practice could provide additional information about treatment outcomes related to patients' quality of life to the physicians.

- **Conflict of interest:** The authors declare that they have no conflict of interest.
- **Informed consent:** "Informed consent was obtained from all individual participants included in the study."

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