

## Reliability, Sensitivity and Validity of the MSQoL-54 Instrument: Brazilian Version

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### Abstract

**Objective:** To evaluate the reliability, sensitivity and validity of MSQoL-54 that was previously translated into Brazilian Portuguese and to finalize the validation of the Brazilian Version for this instrument. **Methods:** The test-retest reproducibility (n=20) was evaluated by the Intraclass Correlation Coefficient. This instrument was applied in a sample of 100 patients in order to evaluate the reliability through the Internal Consistency test, so as to validate the construction through a correlation of MSQoL-54 with BDI and WHOQOL-bref and with criterion validities correlating to EDSS with the translated instrument. **Results:** The average age of the patients was 41 years old. There were a higher proportion of females (2.4:1). 78% of the participants had an Expanded Disability Status Scale (EDSS)  $\leq$  3.5. Relapsing-remitting was the most common disease form (98%) and 58% of the evaluated patients were under a treatment with Glatiramer Acetate. The Internal Consistency test for the Physical Health and the Mental Health components was 0.85 and 0.80, respectively. When considering the 12 subscales, they revealed values of between 0.63 and 0.93. In terms of the criterion validities, the EDSS scores presented moderate correlations in the domain function of health ( $r=-0.545$ ,  $p \leq 0.001$ ). In terms of the construction validities, the BDI had strong correlations ( $r=-0.78$ ) with the Mental Health components and moderate ones with the Physical Health components ( $r=-0.61$ ). The Physical Health components correlated moderately with almost all of the domains of WHOQOL-bref. The Mental Health components correlated strongly with general WHOQOL-bref and moderately with the 4 domains which showed good correlations to the other instruments with the same purpose. **Conclusion:** The adaptation of the Brazilian Version of MSQoL-54 into Portuguese was considered satisfactory in order to evaluate the qualities of life that were related to the health of those patients with multiple sclerosis.

**Keywords:** *Quality of life; Multiple sclerosis; Validation; MSQoL-54*

## 1. Introduction

Multiple Sclerosis (MS) is a chronic degenerative disease, and it is one of the main causes of disability in young adults [1]. The multiplicity of symptoms which may emerge means that the physical, cognitive and psychosocial consequences are very extensive, variable and complex [2]. The outbreaks are frequently associated with significant functional losses and a decrement in the Quality of Life (QL) related to health [3].

A Health-Related Quality of Life - HRQL is an expression that is often used in a similar way to a QL. It refers to a QL that depends on, or is related to, the disease and the treatments, in such a way that they are connected to the physical, psychological and social domains of health. Even though they are related, a QL has a wider sense, especially when they are frequently used as synonyms, mainly when related to the disease. In recent years, researchers have greatly dedicated their time to the study of a QL [4].

The specific instruments evaluate in an individual manner, those certain aspects related to the pathology by which a QL is being evaluated [5]. MSQoL-54 (Multiple Sclerosis Quality of Life) is a specific evaluation instrument for a QL evaluation in those patients with MS. Created in 1995 by Barbara Vickrey [6], it is often used in scientific environments, and it has been validated in several languages [7-14]. When a questionnaire is elaborated, its measured properties need to be tested and validated by a group, and then afterwards, it can be used in population studies [15].

This study has aimed at evaluating the psychometric measurements of MSQoL-54 that has been previously translated into Brazilian Portuguese, in a sample of patients with MS, in the Southern Region of Brazil. The MSQoL-54 procedure was well accepted and understood by this population, being highly approved in the transcultural adaptation processes of the Portuguese Translated Version (Brazil) [16].

## 2. Methods

After the translation and the transcultural adaptation of MSQoL-54 (published in another essay), the reproducibility, reliability and the validities of criterion and construction were analyzed [17]. The individuals were recruited from a convenient sample of patients that were observed in the neurology ambulatory of Hospital das Clínicas de Porto Alegre, Brazil (HCPA). The study was evaluated and was approved by the HCPA Research Ethic Committee. The eligible patients were informed about the study's objectives and about the non-disclosure of information. They then signed the Informed Consent Form.

MSQoL-54 is an instrument constituted of 36 general items (SF-36) that is further complemented with 18 more specific items that are divided into 5 domains, numbering 12 domains, with two additional measurements (sole items). These domains are divided into two scores: a Physical Health Component (PHC) and a Mental Health Component (MHC). The scores are then transformed into a scale of 0 up to 100. A higher score indicates a better health related QL.

The study was performed throughout the whole of the year 2013. The participants were patients with MS who were taking medicines provided by the State Government through the Brazilian Health Ministry (HM). Some of the patients were under medical supervision in the HCPA. The HM provides a high-cost treatment for several diseases for free. The patients have to meet clinical protocol inclusion criteria in order to receive the treatments from the government. In the case of MS, Decree No.

1,353 at a date of November 25<sup>th</sup>, 2013, was approved by the Clinical Protocol and Therapy Guidelines for Multiple Sclerosis [18].

The test-retests occurred on two distinct occasions with a maximum interval of 20 days between them. The reproducibility analyzes of MSQoL-54-Portuguese were assessed by the Intraclass Correlation Coefficient (ICC) and by the Internal Consistency (IC) test, using Cronbach's Alpha Coefficient. Values of ICC above 0.75 indicated an excellent concordance; values of ICC between 0.60 - 0.74, a good concordance; values of ICC between 0.40 - 0.59, a fair to moderate concordance; the concordance was weak below 0.40 [19].

For reliability, the 12 domains were checked to see if they were congruent with the two components. These confirmations were analyzed by the *Internal Consistency* (IC) reliability test. The higher that the correlation was, among the domains themselves and among the domains with the correspondent components, the higher was the accuracy [20]. The values of Cronbach's Alpha Coefficient were between 0 and 1. Values of 0 to 0.6 represented an unsatisfactory reliability; values of 0.6 to 0.7 represented a satisfactory reliability; and values >0.7 represented a high reliability [21]. These values are regarded as being the standardized values for the evaluations in all of the domains and components in the MSQoL-54 Brazilian Version.

The concurrent criterion validities were evaluated by correlations of the domains in the MSQoL-54-Portuguese Version when using Kurtzke's Expanded Disability Status Scale (EDSS) [22,23] and the Time for the Diagnoses. The convergent construction validities were evaluated by correlating the PHC and the MHC with the domains of Beck's Depression Inventory (BDI) [24,25] and with the domains of the World Health Organization Quality of Life Evaluation Instrument (abbreviation - WHOQOL-bref) [26]. The EDSS was applied to all of the participants by a neurologist. The correlations were calculated by Pearson and Spearman's Coefficients.

Along with the already mentioned instruments, a formulary was applied regarding each patient's clinical and socio-demographical characteristics. A complementary form that defined the patient's socio-economical classification was also applied [27]. The economical class definitions were determined by a family's average income: (R\$): A1 (11,480.00), A2 (8,295.00), B1 (4,754.00), B2 (2,656.00), C1 (1,459.00), C2 (962.00), D (680.00) and E (415.00).

WHOQOL-bref is an abbreviated version of WHOQOL-100 that was developed by the QL Group of the World Health Organization in the year 2000. The questionnaire has 26 domains that are composed of 4 main domains: Physical, Psychological, Social Relations and Environment [28]. Beck's Depression Inventory (BDI) is a self-reporting inventory that is constituted by 21 multiple choice items that are related to depressive symptoms [24,25].

The descriptive analyzes were made according to the frequencies of the categorical variables and the position measurements, as well as the dispersion of the continuous variables. The distribution of the scores of the domains was evaluated by the Shapiro-Wilk test in order to analyze the normality. The statistical analyzes were performed by using the Statistic Package for Social Science (SPSS) Software Version 21.0.

### 3. Results

100 patients with MS were included in the study and all of them understood the questionnaire, with only 20 of them needing any assistance. They took an average of 19 minutes (7 - 39 min) to conclude the 54 questions. All of the participants answered all of the questions.

The characteristics of the studied patients are described in TABLE 1. The studied patients were aged 16 years old up to 69 years old and they were predominantly female - with a proportion of 2.4:1. Regarding their social class, the majority were from the B classification (51%), 19% were from the B1 classification, 38% were from the C classification, 28% were from the C1 classification and 10% were from the C2 classification. 47% of the patients had completed secondary grade or high school and 57% were actively working.

TABLE 1. Demographic and clinical data of the patients.

Characteristic		n (%) <sup>†</sup>	Média (± SD)
<b>Idade</b>			41 ± 10,99
<b>Diagnostic time (years)</b>			5,74 ± 6,19
<b>EDSS</b>			
	≤ 3,5	78 (78%)	1,84 ± 0,92
	≥ 4,0	22 (22%)	5,54 ± 1,14
<b>Marital status</b>			
	Single	36 (36)	
	Married/Cohabiting	48 (48)	
	Widowed	15 (1)	
	Separated/Divorced	1 (1)	
<b>Current employment status</b>			
	employed outside the home/student	55(55%)	
	Retired (service life/invalidity)	30 (30%)	
	Encostado	13 (13%)	
	Unemployed	2 (2%)	
<b>‡Economy Class</b>			
	A 2	9 (9%)	
	B 1 e 2	51 (51%)	
	C 1 e 2	38 (38%)	
	D	2 (2%)	
<b>Education</b>			
	Illiterate	6 (6%)	
	Primary	19 (19%)	

	Secondary	47 (47%)	
	University	18 (18%)	
	Postgraduate	10(10%)	
<b>Gender</b>			
	Female	71(71%)	
	Male	29 (29%)	
<b>MS type</b>			
	RR	94 (94%)	
	PP	2 (2%)	
	SP	4 (4%)	
<b>Treatment</b>			
	*INF-β1A (22, 30 e 44mcg)	29 (29%)	
	*INF -β1B 300mcg	12 (12%)	
	Glatiramer, Acetate	50 (50%)	
	Others	9 (9%)	

\*Beta interferona (INF-β),<sup>†</sup> n = 100, <sup>‡</sup> Source: Brazil Criterion - www.abep.org, EDSS= Expanded disability status scale, SD= Standard deviation, R = Relapsing-remitting, PP= Primary progressive, SP= Secondary progressive

All of the patients were under medical treatment within the period of the study. 50% of the studied patients were treated with Glatiramer Acetate and 9% of the studied patients were being treated with other substances (Azathioprine, Natalizumab, and Fingolimod). 94% of the studied patients presented a clinical form of Relapsing-Remitting (EM-RR). The diagnoses times varied from ≤ 1 year up to 31 years, but most of the patients took from 2 years up to 4 years to have their diagnosis assessed.

The EDSS values varied from 0.0 up to 7.0. 78% of the patients presented a low disability, with an average equal to 2.65 (standard deviation of ± 1.82). The most frequent EDSS values were: 1.0 (18%), 2.0 (16%), 2.5 (11%), 1.5 (10%) and 3.0 (9%). In Table 1, the EDSS values are stratified with values of ≤ 3.5 and ≥ 4.0.

The highest average value of the domain scores was the Social Function domain (68.3 ± 24.0). The lowest average value was the Physical Performance Limitations (PPL) (47.0 ± 41.1). According to TABLE 2, the PHC and the MHC were very similar, although the MHC presented much lower minimum scores.

TABLE 2. Description of MSQoL-54 composite scores.

Composite Score	*Mean ± SD	*Score minimum - maximum
Physical health composite score	58,07 ± 21,19	22,42 - 97,46
Mental health composite score	58,03 ± 21,33	8,27 - 96,78

\*Score (0-100), SD= Standard deviation

According to the medicine that was consumed, Tukey's test ( $p=0.05$ ) showed that AG and Beta Interferon ( $\beta$ -INF) ( $p=0.02$ ) presented differences between the averages, but in the Social Function domain,  $\beta$ -INF presented a higher average score than did AG.

### 3.1 Reproducibility

The 20 patients who participated in the test-retests took an average of 15 minutes to fill in MSQoL-54-Portuguese questionnaire. Using a scale of 0 (min.) up to 100 (max.), the average ( $\pm$  standard deviation) varied from  $47.0 \pm 42.1$  (PPL domain) up to  $68.3 \pm 24.0$  (Social Function domain).

According to TABLE 3, 8% of the domains presented minimum effects on the PPL scale, whereas 22% presented maximum effects on the PPL scale and on the Mental Performance Limitations (MPL) scale.

TABLE 3. Descriptive statistics and reabilities for MSQoL-54.

Scale	n	Number of items	Mean	Standard deviation	Percentage scoring minimum	Percentage scoring maximum	Crombach's alpha	Test-retest reliability	Intraclass correlation coefficient
Physical function	20	10	55,9	31,1	4	7	0,84	0,72	0,72
Role-limitations – physical	20	4	47,0	42,1	8	22	0,96	0,93	0,93
Role-limitations – emotional	20	3	50,0	39,8	2	22	0,63	0,46	0,46
Pain	20	3	65,8	26,8	0	8	0,94	0,89	0,88
Emotional well-being	20	5	63,4	21,0	0	0	0,92	0,86	0,86
Energy	20	5	49,7	22,0	0	1	0,92	0,86	0,86
Health perceptions	20	5	58,4	23,3	0	1	0,84	0,72	0,72
Social function	20	3	68,3	24,0	0	11	0,91	0,84	0,84
Cognitive function	20	4	49,4	32,4	0	11	0,86	0,78	0,76
Health distress	20	4	58,4	26,6	0	5	0,80	0,67	0,66

<b>Overall quality of life</b>	20	2	67,9	16,9	0	1	0,88	0,78	0,78
<b>Satisfaction with sexual function</b>	20	1	57,2	39,1	2	15	0,91	0,84	0,84
<b>Sexual function</b>	20	4	64,6	37,1	1	9	0,85	0,75	0,73
<b>Change in health</b>	20	1	59,0	28,1	0	11	0,89	0,80	0,80
<b>Physical Health</b>	20	38	58,1	21,2	- <sup>a</sup>	- <sup>a</sup>	0,98	0,95	0,95
<b>Mental Health</b>	20	18	58,0	21,3	- <sup>a</sup>	- <sup>a</sup>	0,97	0,94	0,94

<sup>a</sup>Component Score

The IC test among the test-retest scales varied from 0.63 up to 0.98. The majority overcame the standard values for the comparisons among the groups - with the exception of the MPL domain, which stood a little below. The reliability of the test-retests which were measured by the ICC presented a variation among the domains and the components from 0.46 (MPL) up to 0.95 (PHC). Our study observed that there was little evidence of systematic average variations in the re-test evaluations, with the ICC equaling, or almost equaling, the reliability correlations of the test-retests for all of the scales. These evaluations, together with other information, are both presented in TABLE 3.

### 3.2 Reliability

In the sample of 100 patients, the average time for answering the MSQoL-54 questionnaire was 19 minutes (10 min up to 30 min). Cronbach's Alpha Coefficients of the PHC and MHC scores were 0.85 and 0.80, respectively. For the 12 scales, this varied from 0.63 up to 0.94. TABLE 3 shows the IC tests among the 12 scales and among themselves, together with the two components.

### 3.3 Convergent construction validity

Scores for the WHOQOL-bref and for the BDI did not present a normal distribution in the Shapiro-Wilk test, except for the WHOQOL-bref general results ( $p=0.2$ ). The scores of the two PHC and MHC components of the MSQoL-54-Portuguese Version with BDI had a moderate ( $r=-0.61$ ) and strong ( $r=-0.78$ ) correlation, respectively. Regarding these MSQoL-54-Portuguese scales, they were correlated with the 4 domains and the general results of the WHOQOL-bref. They presented positive and significant correlations ( $p=0.001$ ). The general QL of the WHOQOL-bref presented strong correlations ( $r=-0.76$ ) with the MHC, whilst for the other domains, the correlations were moderate. The PHC correlated moderately in all of the domains, except for the Social Relations domain ( $r=0.46$ ), although this domain was more directed to the Physical Issues.

### 3.4 Concurrent Criterion Validity

The correlations of the domains and the components of the MSQoL-54-Portuguese Version with EDSS were performed by the Pearson Correlation Test. The EDSS scores presented moderate correlations in the Physical Health domain ( $r=-0.545$ ,  $p\leq 0.001$ ). They were weak in the PHC ( $r=-0.252$ ,  $p=0.01$ ), in the cognitive functions ( $r=0.214$ ,  $p=0.04$ ) and in the PPL ( $r=-0.220$ ,  $p=0.03$ ). The diagnoses times presented weak correlations with the MPL ( $\rho=-0.240$ ,  $p=0.004$ ) and with the cognitive functions ( $\rho=-0.198$ ,  $p=0.05$ ).

## 4. Discussion

Twenty per cent (20%) of the patients needed help in order to read and/or answer the questionnaires. This was due to disabilities that were presented by the disease and not for a lack of comprehension. The average time to answer the questionnaires was close to the Serbian, the Italian and the Turkish studies [7,9,10]. As with the results that were found by Barbara Vickrey et al., [6], most parts of the scales presented a wide dissemination in the scores. The same was observed in the American study. However, all of their scales presented minimum (0) and maximum (100) values. Within this study, the domains of emotional well-being, energy, health concerns and the QL in general, had no minimum effects (0) as they presented very low scores. This showed that these scores did not interfere so much in the QL when in comparison to the others. The energy domain did not present any maximum effects (100).

The highest average score was observed in satisfaction within the Social Function domain and the lowest was in the PPL. This meant that these were the ones that caused the highest positive and negative effects in the studied sample. This was strengthened even more with the highest subsequent scales of energy/fatigue and the cognitive functions. Tadic et al. [29] found similar results in their study.

In this study, the reliability results showed that the questionnaire that had been translated into the Portuguese language presented adequate reliabilities within the Brazilian population. This fact showed that the measured scales for the MSQoL-54-Brazilian Version were adequately measured. The sample of patients ( $n=100$ ) with MS presented an IC that varied from 0.63 up to 0.94, with values below 0.7 in the Social Function domain. The same results can also be observed in the Serbian [9] and in the Israeli studies [30], since they both obtained similar results in their studies for IC and for the Social Function domain, which were 0.66 and 0.69, respectively. In the Japanese study [14] with a sample of 65 patients, the variation was from 0.65 up to 0.93. A study that was performed in the United States (USA) showed good IC (Cronbach's Alpha Coefficient was from 0.75 up to 0.96). In our study, except for the mentioned domain, the others presented an IC above 0.71.

Questions 17, 18 and 19 only presented two scores, 0 (minimum) for the *positive* answer and 100 (maximum) for the *negative* one. Regarding the 20 patients, two of them had a variation in these answers between the test and the re-test (they answered *yes* in the test and answered *no* in the re-test, or vice versa). One patient changed the answers for questions 7 and 18; the other changed the answers for questions 17 and 19. The MPL domain (composed by the items 17-19) presented an ICC = 0.46. The domains presented a variation in the ICC from 0.46 up to 0.95.

The MSQoL-54-Portuguese Version had good construction validities with both of the instruments that were applied simultaneously, as was presented in most of the correlations. A great number presented moderate correlations, with weak

correlations occurring in the Social Relations domain (WHOQOL-bref) regarding the PHC and the MHC (MSQoL-54-Portuguese). Between the BDI and the MHC, there were strong correlations, which reaffirmed the expected results. This was strengthened even more by the fact that the psychological domain (WHOQOL-bref) had greater correlations with the MHC when in comparison with the PHC. These results cannot be compared with the ones of other studies, due to the non-application of WHOQOL-bref, but regarding the BDI, the Italian study presented similar results [7].

The diagnoses times presented weak correlations with the MPL ( $\rho=-0.240$ ,  $p=0.004$ ) and the cognitive functions ( $\rho=-0.198$ ,  $p=0.05$ ), which meant that over the course of time, the psychological issues affected the patient more than did the physical issues. The EDSS scores presented moderate correlations in the Physical Health domain ( $r=-0.545$ ,  $p \leq 0.001$ ), but they were weak in the PHC components ( $r=-0.252$ ,  $p=0.01$ ), in the cognitive functions domain ( $r=0.214$ ,  $p=0.04$ ) and in the PPL ( $r=-0.220$ ,  $p=0.03$ ). The higher the scores that were presented by the EDSS, the lower were the quality of life scores and these were related mainly to the Physical Health issues.

The MSQoL-54 scales were reliable in the Serbian population, as they were in other places. Coherent with recently published data from an Israeli validation study, they also discovered that great parts of the scales showed adequate reliabilities and that they were also related to the instruments that were used for the comparisons.

## 5. Final Considerations

The results have allowed for us to consider that the MSQoL-54-Portuguese Version adaptation was satisfactory. It was effective for the Quality of Life that was related to the health evaluations of those patients with MS. When in comparison to the original essay that is in the English language, the MSQoL-54 validation of the Brazilian Version may be accepted.

## 6. Ethical Approval

All of the procedures that were performed in the studies that involved human participants were in accordance with the Ethical Standards of the Institutional and/or National Research Committee and with the 1964 Helsinki declaration and its later amendments, or of comparable Ethical Standards.

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