Cross-cultural adaptation and validation of multiple sclerosis quality of life questionnaire (MSQOL-54) in a Turkish multiple sclerosis sample

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Abstract

Objective: Multiple sclerosis (MS) is a chronic progressive disease with multiple neurological impairments. The disease can also dramatically affect the health-related quality of life of patients. The objective of this study was to investigate the validation of the translated and cross-culturally adapted MSQOL-54 in 183 Turkish MS patients.
Methods: 183 adults classified as having definite MS patients were enrolled into the study. Patients were classified into four severity groups according to the expanded disability status scale (EDSS); group I (EDSS 0–4), group II (EDSS 4.5–5.5), group III (EDSS 6–6.5) and group IV (EDSS 7–8). MSQOL-54 questionnaire were translated and culturally adapted into Turkish. Associations between age, gender, disease duration, EDSS score, marital status, education and health insurance and the MSQOL-54 physical and mental health composite scores were determined.
Results: The mean age of the 183 patients (138 female and 45 male) was 39 ± 10 years. The questionnaire was well accepted but small cultural adaptations were required. EDSS scores showed significant associations with the MSQOL-54 physical and mental health composite scores. From the different EDSS groups only, the group I (EDSS 0–4) score was significantly associated with the physical health composite as well as the disease duration showed significant correlation with the physical and mental composite scores. None of the other EDSS groups and the other parameters showed correlation with physical health composite or mental health composite.
Conclusion: Assessment of quality of life of MS patients in addition to disease severity and disability level is important, because it provides unique information that is important to patients and to clinicians. A translation of an existing MS-targeted HRQOL measure from US English into Turkish was easily administered and well accepted in a Turkish MS sample.
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Keywords: Multiple sclerosis; Quality of life; Outcome measure; Expanded disability status scale; Validation

1. Introduction

Multiple sclerosis (MS) is a chronic disease of the central nervous system characterized by a broad spectrum of physical and psychosocial impairments [1]. Many patients with MS are affected in their productive ages and hence have to cope with various degrees of disability over a prolonged period [2,3]. In recent years, a number of measures have been developed to evaluate the impact of MS on health-related quality of life (HRQOL). In general, HRQOL instruments vary from disease-targeted measures tailored to HRQOL issues for a specific condition, to generic measures applicable across diseases or populations and addressing dimensions of HRQOL which may include

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emotional functioning, social role functioning, activities of daily living, physical health, and the ability to enjoy activities [4,5].

Although QOL assessment in MS gained more interest among researchers and clinicians, there are a limited number of available measures, with few direct comparisons. A recently developed HRQOL measure for MS combined an 18-item disease-targeted questionnaire for MS with a generic core measure, the SF-36 [6]. In this study, we have translated the MSQOL-54 questionnaire into Turkish and investigated its validity in a Turkish MS patient sample.

2. Patients and methods

Between April and September 2001, 183 patients diagnosed with multiple sclerosis were enrolled into the study. The samples were obtained from outpatient clinic settings. Informed consent was obtained from each patient.

2.1. Inclusion criteria were as follows

- be able to read and understand the questionnaire
- be over age 18 year
- have clinically definite MS diagnosis according to Poser's criteria [7].

2.2. Exclusion criteria were as follows

- exacerbation in the past month
- having other chronic illness (e.g. rheumatoid disease, diabetes, hypertension).

2.3. Instrument

The MSQOL-54 consists of 54 items [6]. Eighteen MS-targeted questions were added to a core generic HRQOL measure, the SF-36 [8–11], which has been validated for Turkish [12]. Vickrey et al. added 18 items on the original SF-36 which address health distress (4 items), sexual function (4 items), satisfaction with sexual function (1 item), overall quality of life (2 items), cognitive function (4 items), energy (1 item), pain (1 item) and social function (1 item). The MSQOL-54 instrument contains 52 items distributed into 12 multi-item scales, and two single items [6].

2.4. Translation and cross-cultural adaptation of questionnaire

A standard back-translation methodology was followed for the production of new Turkish version of the MSQOL-54 and cross-cultural adaptation. The objective of the translation was to consider the previous translations and decide whether they were acceptable or suggest alternative wording. The intention was that the final translations should

be expressed appropriately for the cultural environment of Turkey, while maintaining the concept expressed by the original US English questionnaire.

In the second phase of the study, translated version of MSQOL-54 was filled in by four patients, the results of which were discussed at a second meeting that included patients and their proxies. The final version of the questionnaire was tested on 15 MS patients. The patients were interviewed in the researcher's office. They were given a brief explanation of the objective of the study and were asked to complete the measure after reading the instructions.

All patients were evaluated clinically by calculating expanded disability status scale (EDSS) scores [13].

2.5. Statistical analysis

Likert method: On a 0–100 scale, the higher the transformed score, the better the patients HRQOL.

In order to assess construct validity, mean MSQOL-54 physical health composite and mental health composite scores were compared by patient's age, gender difference, disease duration, EDSS score, marital status, education and health insurance.

Bivariate Pearson correlation analysis was used to investigate the relation between these clinical parameters and MSQOL-54 composite scores.

2.6. Results

All of the 183 patients were able to read and comprehend the questionnaire. Demographic and clinical characteristics of the study sample are shown in Table 1.

Most of the patients accepted the questionnaire well, and none of the items were found embarrassing. The time needed to complete the questionnaire was approximately 30 min (12–60 min); median time for questionnaire completion was 18 min. Since a large proportion of our patient population had low EDSS scores (EDSS 0–4, $n=133$), the need for physical help to read or mark the questionnaire was relatively low. Only 5 patients (2.7%) required assistance to sign the questionnaire. Patients who required help in general were approximately 19% ($n=36$). Thirty patients had difficulty understanding the items related to sexual function and satisfaction, 1 km walking distance and facial expressions on one of the overall quality of life items (25.1%, $n=46$).

Male patients had no difficulty by answering the items—on sexual function. In female patients, 11.47% ($n=21$) had problems understanding the item on sexual function. We determined almost 50% of the patients who answered positive on sexual function items, answered negatively on sexual satisfaction item, or vice versa.

The male patients showed an unexpected high rate of sexual satisfaction (100%). However, there is a high rate of sexual dysfunction problems in the MS practice at our department. Missed items were only seen in sexual function

Table 1
Characteristics of the patients (S.D.: standard deviation, EDSS: expanded disability status scale, RR: relapsing remitting, SP: secondary progressive, PP: primary progressive)

Characteristic	n (%)
Mean age ± S.D. (range)	39.23 ± 10.59 (18–68)
Male	45 (24.6)
Female	138 (75.4)
Mean disease duration (years)	
1–5 year	95 (51.9)
6–10 year	50 (27.3)
11–19 year	32 (17.5)
20+	6 (3.3)
Mean EDSS score	
0.0–4.0	133 (72.7)
4.5–5.5	23 (12.6)
6.0–6.5	17 (9.3)
7.0–8.0	10 (5.4)
Current disease course	
RR	145 (79.2)
SP	32 (17.5)
PP	6 (3.3)
Marital status	
Single	34 (18.6)
Married	128 (69.9)
Divorced	21 (11.5)
Education	
Primary	66 (36.1)
Secondary	61 (33.3)
University	56 (30.6)
Health insurance	
Yes	173 (94.5)
No	10 (5.5)

and satisfaction items: 6 (3.2%) of male and 29 (16%) of female patients did not answer some or all of these questions. Level of disability as measured by the EDSS was shown in Table 2. Moderate negative correlations were found between EDSS and both components of MSQoL-54. It is more prominent for the physical health composite scores than mental scores ($r = -0.54$ and $r = -0.48$, respectively). In the subgroup analysis in terms of EDSS scores, there was significant negative correlation between EDSS 0.0–4.0 and both components of MSQoL-54 ($r = -0.61$ for physical health composite and $r = -0.57$ for mental health composite.

Also, disease duration had a significant inverse relationship with MSQOL-54 composite scores ($p < 0.05$). Age, gender difference, marital status, education and health insurance status were not associated with MSQOL-54 composite scores ($p > 0.05$).

3. Discussion

In general assessment of MS patients, HRQOL may be underutilized. Currently, outcome assessments are focused on neurological examination (e.g. neurological signs, neuroimaging, evoked potentials and cerebrospinal fluid) or only on disability.

Several MS-targeted HRQOL measures, e.g. Functional Assessment of Multiple Sclerosis (FAMS) [14], the Multiple Sclerosis Quality of Life Instrument (MSQOLI) [15] and Leeds Multiple Sclerosis Quality of Life (MSQOL) [16] scale have several similarities with the MSQOL-54. First, each combined generic and disease-specific assessment. Second, input from MS experts as well as patient input and caregiver input (only in structuring of MSQLI) was obtained in their development. Third, each of the three instruments has undergone reliability and construct validity testing. In general, all four questionnaires include some items on fatigue, pain, sexual function, bowel and bladder function, cognitive function, emotional functioning and social functioning.

MSQOL-54 was well accepted and easily administered questionnaire in Turkish MS population. Most of the patients accepted the questionnaire apparently and well, and none of the items were found embarrassing by patients except the sexual function items for the women in our sample group. This result is not different from those obtained from American (United States) and Italian MS patients [6,17]. Since a high proportion of our patient population ($n = 133$, 72.6%) scored low on EDSS (EDSS 0–4), the need for physical help was relatively low. Only 5 patients (2.7%) needed help in completing the questionnaire. In Italian validation study of MSQOL-54 questionnaire, 90% of patients considered that the questionnaire was easy to understand. The number of missing answers and contradiction in answers regarding sexual life can be attributed to cultural traditions. High levels of missing data from the sexual scales of the MSQOL-54 have been a consistent finding across studies. Probably, people with MS find questions on sex difficult to understand, distressing or too private or sensitive to answer. In Freeman's study, analysis of the non-responders indicated that missing data were strongly related to disability level [18]. Although it seems rational, there was no correlation between these two entities in our study. Freeman also emphasized that questions on sex were either too personal or irrelevant. Solari et al. identified the problem in Italian MS population as being embarrassed to record intimate aspects of their life [17]. This phenomenon was also reported in French people with MS. The authors of French version of the questionnaire modified the item on sexual function, and eliminated the sexual satisfaction item. Solari

Table 2
MSQOL-54 physical and mental health composite scores by ranges of EDSS

	Physical health composite score	Mental health composite score
	Mean ± S.D. (range)	Mean ± S.D. (range)
EDSS 0–4	61.9 ± 19.3 (5–98.3)	63.7 ± 20.3 (15.9–100)
EDSS 4.5–5.5	57.5 ± 24.9 (8–95.8)	61.3 ± (21.8 (20.4–93.1)
EDSS 6–6.5	58.9 ± 21.7 (25.7–94.4)	57.9 ± 18.5 (27.3–94.2)
EDSS 7–8	51 ± 24.6 (5–87.3)	58.1 ± 21.5 (26.8–85.7)

suggests an additional answer "no sex in the preceding four weeks". Interestingly in our study the male patients showed an unexpected high rate of sexual satisfaction (100%). However, this result when compared with the high rate of sexual dysfunction problems in the MS practice at our department emphasizes the difficulty of talking about sexual subjects in the daily life, and this is attributable to cultural and social characteristics.

Age, gender difference, marital status, education and health insurance revealed no significant correlation with both composite scores. As expected, disease duration showed significant inverse relationship to HRQOL, with those having longer disease reporting worse HRQOL.

It is not unexpected that the effect of neurological impairment was captured by the physical health composite. EDSS scores showed significant correlation with the physical health composite scores. In addition, there was also significant correlation between EDSS scores and mental health composite. Not surprisingly, we found inverse relation with EDSS 0–4 and quality of life scores ($p < 0.05$). These results are similar with the previous studies [15,19].

In conclusion, a Turkish version of MSQOL-54 questionnaire was well accepted by the participants, however the sexual function and sexual satisfaction domains were much less acceptable, with a high percentage of missing answers among women. On the basis of associations with EDSS scores, not only physical health but also mental health was related to disability, although associations with physical health were stronger.

Acknowledgements

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