



Research Article

Quality of Life in Multiple Sclerosis Patients With Urinary Disorders: Reliability and Validity of the Turkish Version of Qualiveen

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Summary

Background: Multiple sclerosis (MS) results in a wide range of functional limitations that can lead to multiple disabilities. Symptoms arising from bladder dysfunction can profoundly affect various aspects of an individual's daily life. Therefore, in determining bladder problems and initiating the appropriate treatment, there is increasing interest in the use of well-constructed questionnaires studying quality of life. The aim of the study was to demonstrate the reliability and validity of the Qualiveen scale in Turkish language in patients with MS.

Methods: Thirty seven MS patients with urinary problems were included in the study. For analysis of test-retest reliability, Turkish version of Qualiveen scale developed by "translation-back translation" method was performed to patients on the day of admission and one week after admission. To assess validity, patients were also evaluated with the Multiple Sclerosis Quality of Life Scale (MQoL-54) and Expanded Disability Status Scale (EDSS)

Results: Internal consistency (Intraclass correlation coefficient: 0.81-0.92) and test-retest reliability (Cronbach alpha score: 0.82-0.92) of Qualiveen were found to be high. All the sub-scores of Qualiveen questionnaire, except for the limitations sub-score, showed a significant correlation with MQoL-54 Physical Health ($p<0.05$). In addition, all the sub-scores of Qualiveen questionnaire, except for inconvenience and limitations sub-scores, showed a significant correlation with MQoL-54 Mental Health ($p<0.05$). Moreover, a significant correlation was found between all sub-scores of Qualiveen questionnaire and EDSS ($p<0.05$).

Conclusion: The Turkish Qualiveen questionnaire is a comprehensive questionnaire for quality of life evaluations in patients with urinary dysfunction that has proved to be useful for MS patients.

Key words: Qualiveen questionnaire, multiple sclerosis, bladder problems, validity, reliability

İdrar Sorunu Olan Multipl Skleroz Hastalarında Yaşam Kalitesi:Qualiven Ölçeği'nin Türkçe Geçerlilik ve Güvenirliği

Özet

Amaç: Multipl Skleroz (MS), çok sayıda fonksiyonel kısıtlılığa yol açarak ciddi özürüllüğe yol açan bir hastalıktır. Mesane fonksiyon bozukluğuna bağlı olarak oluşan semptomlar hastaların günlük yaşam aktivitelerini değişken derecede etkilemektedir. Bu açıdan mesane problemlerinin belirlenmesinde ve buna yönelik tedavinin başlanmasında, buna uygun ölçeklerle sorgulanması önemlidir. Bu nedenle çalışmamızda, Qualiveen ölçeğinin Türkçe geçerliliğini ve güvenilirliğinin ortaya konulması amaçlanmıştır.

Method: 37 üriner problemi olan MS hastası çalışmaya alındı. Güvenirlik analizi için, türkçe Qualiveen ölçeği "çeviri-geri çeviri" metoduna göre başvuru anında ve başvurudan 1 hafta

sonra tekrarlandı. Geçerlilik analizi,Multipl Skleroz Yaşam Kalitesi Ölçeği (MQoL-54) ve Expanded Disability Status Scale (EDSS) ile yapıldı.

Sonuçlar: Qualiveen ölçeğinin içsel tutarlılığı (intraclass correlation coefficient 0.81-0.92) ve test-tekrar test güvenilirliği (cronbach alpha skoru: 0.82-0.92) yüksek olarak bulundu. Qualiveen anketinin kısıtlılık alt skoru dışındaki tüm alt grupları, MQoL-54-fiziksel sağlık ile anlamlı korelasyon gösterdi ($p<0.05$). Buna ek olarak, Qualiveen anketinin uygunluk ve kısıtlılık dışındaki tüm alt grupları ile MQoL-54- mental sağlık anlamlı korelasyon gösterdi ($p<0.05$). Ayrıca, Qualiveen anketinin tüm alt grupları ile EDSS arasında anlamlı korelasyon bulundu ($p<0.05$).

Sonuç: Türkçe Qualiveen Ölçeğinin idrar problemi olan MS hastalarının yaşam kalitesini belirlemeye uygun bir ölçek olduğu sonucuna varıldı.

Anahtar Kelimeler: Qualiveen ölçeği, multipl skleroz, idrar problemleri, geçerlilik, güvenilirlik

INTRODUCTION

Multiple Sclerosis (MS) is a progressive, demyelinating and autoimmune disease of the central nervous system. MS results in a wide range of functional limitations that can lead to multiple disabilities⁽³⁾. Symptoms arising from bladder dysfunction are a cause of discomfort, shame, and loss of self-confidence and can profoundly affect various aspects of an individual's daily life including social, psychological, occupational, domestic, physical, and sexual aspects. Daily activities such as hobbies, household chores, and physical recreation are often limited to areas around the location of toilets to avoid potentially embarrassing situations. These symptoms and coping strategies together have a negative effect on patients' health related quality of life^(6,8). Therefore, in determining bladder problems and initiating the appropriate treatment, there is increasing interest in the development and use of well-constructed questionnaires studying quality of life⁽⁴⁾. Existing health related quality of life instruments are unsuitable for MS patients whose activity limitations may be due to mobility rather than bladder problems, and they are designed to explore the full range of problems of MS patients failing to focus adequately on urinary problems⁽¹⁾. The Qualiveen scale is a questionnaire that assesses urinary problems in neurological diseases including MS, and its validity and reliability were assured in different

languages^(2,7,11). Since the validity and reliability of such scales in the languages to be used is important, this study aimed to demonstrate the validity and reliability of the Qualiveen scale in the Turkish language.

MATERIAL AND METHODS

Patients: The study included 37 MS patients with urinary problems, who were monitored in the Neurology polyclinic between September 2008 and May 2009 and assigned to physical medicine and rehabilitation for rehabilitation purposes. Inclusion criteria were age >18 years, clinically definite MS (Poser criteria)⁽¹²⁾, knowledge of their MS diagnosis, and stable urinary disorders. Exclusion criteria were congenital urological disorders, bladder cancer, concomitant neurological illness, exacerbation in the past month, urinary disorders unrelated to MS, and those with difficulty answering the questionnaire because of language or cognitive limitations.

Translation Process: The Qualiveen scale was translated into Turkish by three Turkish physical medicine and rehabilitation doctors who were proficient in English. They met to determine the translation that best reflected the meaning of English items. English back-translations from Turkish was done separately by two official linguists (1 native English speaker

who can speak Turkish and 1 teacher of English literature who has lived in England for 15 years) that were blind to the original version. Finally, they gathered to discuss and decide on the translations. This final version was compared with the original English version, which appeared to be identical. This Turkish version was delivered to 20 patients with spinal cord injury. They were asked whether they could understand all items of the Turkish Qualiveen scale. None of the patients in this initial group reported any difficulties in understanding any item of the Qualiveen scale.

Measures: Thirty-seven patients completed the Qualiveen scale during their first examination. Demographic (age, gender, education, and occupation) and clinical data (onset age of MS, MS duration, and course of MS) of patients were recorded from the patient files or by face-to-face interview. In addition, patients were evaluated with the Expanded Disability Status Scale (EDSS) score, EDSS bladder and bowel score and MS quality of life scale (MQoL-54). One week after the first assessment, the Qualiveen was completed by 37 patients for the second time to check for test-retest reliability. A time interval of one-week was chosen to minimize the effect of time on memory and due to the possibility of substantial changes in the neurological condition, which could interfere with the results of the study.

Methods used for patient evaluation are described below:

Qualiveen: The Qualiveen questionnaire⁽⁵⁾ has 30 items focusing on four aspects of patients' lives: bother with limitations (9 items), frequency of limitations (8 items), fears (8 items), and feelings (8 items). Response options are framed as 5 point Likert-type scales with 0 indicating no impact of urinary problems on health related quality of life (HRQL) and 4 indicating a high adverse impact of urinary difficulties on HRQoL. Qualiveen domain

scores are computed as an average of the scores for the items in that domain, with an overall score representing the mean of the four domains.

Multiple Sclerosis Quality of Life Scale (MQoL-54): MQoL-54 combines the 36 items from the SF-36 and 18 additional items specific to MS into 14 domains. Two summary scores of physical health composite (PHC) and mental health composite (MHC) can be derived from a weighted combination of scale scores^(9,13).

Expanded Disability Status Scale (EDSS): The EDSS assesses impairment and disability through ratings of eight functional systems using neurological examinations of patients' walking ability. In this scale, which consists of 0.5 interval and 20 steps, 0 represents normal neurological pressure and 10 represents death due to MS⁽¹⁰⁾.

The study was approved by the local ethics committee of our institution and informed consent was obtained from all the patients that participated.

Statistical Analysis: Data were entered into the SPSS package, version 16.0. Descriptive statistics were used to characterize the sample. Intraclass correlation coefficient (ICC) was used to assess the item-specific test-retest reliability of Qualiveen. For the consistency of the whole scale, a reliability analysis was performed, Cronbach alpha coefficients were calculated and item total correlation was assessed. Correlation between subdivisions of scales and other parameters determined were assessed by Pearson's correlation analysis. A p-value below 0.05 was considered as statistically significant.

RESULTS

The study included 37 MS patients. Demographic and clinical summaries of patients and the average scores of the Qualiveen scale are shown in Table 1. Internal consistency (Intraclass correlation coefficient: 0.81-0.92) and test-retest

reliability (Cronbach alpha score: 0.82-0.92) of Qualiveen were found to be high (Table 2). All the sub-scores of Qualiveen questionnaire, except for limitations, showed a significant correlation with MQoL-54 Physical Health ($p<0.05$, Table 3). In addition, all the sub-scores of

Qualiveen questionnaire, except for inconvenience and limitations sub-scores, showed a significant correlation with MQoL-54 Mental Health ($p<0.05$, Table 3). Moreover, a significant correlation was found between all sub-scores of Qualiveen questionnaire and EDSS ($p<0.05$, Table 3).

Table 1: Demographic, Clinical Data and the Mean Scores of Qualiveen Scale in Patients with Multiple Sclerosis

Multiple Sclerosis	n: 37
Age (mean± SD, year)	38.19±11.65
Gender (female, %)	81.1
Education (university, %)	43.2
Occupation (retired + house wife, %)	56.7
MS start age (mean ± SD, year)	29.16±9.34
MS period (month, mean ± SD)	119.49±9.34
MS process (relapse/remission; %)	73
EDSS score (mean ± SD)	3.43±1.92
EDSS (bowel/bladder) score (mean ± SD)	1.57±1.39
Qualiveen scale (mean ± SD)	
Inconvenience	8.92±8.22
Limitations	9.97±7.87
Fears	4.57±5.44
Impact on daily life	4.59±5.49
SIUP Index	28.05±24.29
General Quality of Life	2.49±7.58

MS: Multiple Sclerosis, EDSS: Expanded Disability Status Scale, SIUP: Specific Impact of Urinary Problems on Quality of Life,

Table 2: Internal Consistency and Test-Retest Reliability of the Turkish Qualiveen Questionnaire

Qualiveen Questionnaire	ICC	Crohnbach alpha
Inconvenience	0.81	0.82
Limitations	0.92	0.92
Fears	0.86	0.88
Impact on daily life	0.88	0.88
SIUP Index	0.86	0.86
General QoL	0.83	0.83

ICC: Intraclass correlation coefficient, SIUP: Specific Impact of Urinary Problems on Quality of Life, QoL: Quality of Life

Table 3: Structural Validity: Correlation between Qualiveen Scale and MS Quality of Life Scale (MQoL-54)

Qualiveen questionnaire	Inconvenience	Limitations	Fears	Impact on daily life	SIUP Index	General Quality of Life
MQoL-54- Physical health	-0.52**	-0.37	-0.51**	-0.50**	-0.58*	0.61**
MQoL-54-Mental health	-0.27	-0.27	-0.34*	-0.40*	-0.36*	0.55**
EDSS	0.55**	0.51**	0.42**	0.39*	0.52**	-0.45**
EDSS bowel/bladder	0.62**	0.56**	0.44**	0.55**	0.62**	-0.41*

MQoL-54: Multiple Sclerosis Quality of Life Scale, EDSS: Expanded Disability Status Scale, SIUP: Specific Impact of Urinary Problems on Quality of Life,** p<0.01, * p<0.05

DISCUSSION

The results of this study suggest that the Turkish version of Qualiveen is internally consistent, test-retest reliable and as valid as the original version and thus results in an equally satisfactory measure of perceived health in MS patients with urinary disorders.

The internal consistency of the Qualiveen scale in our study was found to be 0.82 - 0.92. In the study carried out with MS patients to investigate the validity of the English Qualiveen scale, it was observed that internal consistency (Cronbach alpha score) ranged from 0.73 to 0.90⁽²⁾; while internal consistency was found to be between 0.80 and 0.91 in the reliability studies of Qualiveen in Germany in spinal cord patients⁽¹¹⁾. In the reliability study of the Qualiveen scale including all neurological patients (spinal cord injury, multiple sclerosis, and myelomeningocele), internal consistency was found to range from 0.75 and 0.90⁽⁷⁾. Similarly, our study also revealed an internal consistency between 0.82 and 0.92. Considering these results, we can conclude that the Turkish Qualiveen has a high internal consistency.

Test-retest reliability was observed to range from 0.88 to 0.94 in the validity study of the English Qualiveen scale carried out on MS patients⁽⁶⁾. Test-retest reliability in Qualiveen's reliability study ranged from 0.62 and 0.86 in neurological patients (spinal cord injury, multiple sclerosis, and myelomeningocele)⁽⁷⁾. Consistent with these studies, the individual item test -retest coefficient in our study was found to range from 0.81 to 0.92, which proved its test-retest reliability.

In the French validity study of Qualiveen in MS patients, the correlation of Qualiveen with the Multiple Sclerosis Quality of life Questionnaire (SEP-59) bowel and bladder function domain showed a moderate to a strong relationship (r : 0.39-0.59). Relationships with other

SEP-59 domains were generally weak (r : 0.22-0.35), while the relationships with EDSS were very weak⁽¹⁾. Weak or absent correlations were found between Qualiveen and MSQoL-54 domains and EDSS in other studies carried out for the validation of the English version of Qualiveen in MS patients⁽²⁾. Besides, in its Portuguese translation, Qualiveen's structural validity in neurological patients (spinal cord injury, multiple sclerosis, and myelomeningocele) was performed by international consultation on an incontinence questionnaire-short form (ICIQ-SF)⁽⁷⁾ and a significant relationship was observed between Qualiveen scores and most ICIQ-Sf final scores (r : -0.396-0.643). In our study, a significant correlation was found between most of the subscores of Qualiveen and MSQoL-54 (physical health, mental health) and EDSS (total and bowel/bladder score). According to these results, it was concluded that Qualiveen alone may be sufficient to evaluate these patients.

Inclusion of a homogenous group (MS patients) may be considered a strength of our study. Although the number of patients in our study is lower than other studies, this number should not be considered low, since the study was carried out in a single centre. Therefore, the generalizability of these results may be limited and may not be reflecting a naturalistic setting. The sample consisted predominantly of female patients, which might have limited generalizability to men. However, women tend to report their symptoms more frequently than men making this result unremarkable. We were unable to assess the responsiveness of the questionnaire due to not considering the aim of the treatment as an intervention for urinary incontinence in MS patients. Considering this, we are conducting a separate study to demonstrate the sensitivity to change in MS patients. Nevertheless, a control group could provide an additional benefit for assessing correlation and sensitivity to change.

Addressing these limitations in future studies would be beneficial.

In our study, we have concluded that the Qualiveen scale is validated and reliable in MS patients with urinary disorders. The Turkish Qualiveen questionnaire is a comprehensive questionnaire for quality of life evaluations in patients with urinary dysfunction that has proven to be useful for MS patients. It enables in-depth evaluation of patient perception/well being, making Qualiveen an excellent instrument for research trials. It can be used for evaluation of general and urinary quality in MS patients in clinical research studies in Turkey.

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