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Quality of life in multiple sclerosis patients with urinary disorders: Discriminative validation of the English version of Qualiveen

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Abstract

The Qualiveen questionnaire is a urinary disorder (UD)-specific health related quality of life (HRQL) instrument. Recent data suggests Qualiveen has excellent validity in French-speaking multiple sclerosis (MS) patients. *Aim*: To assess discriminative measurement properties of the English version of Qualiveen. *Methods*: Fifty-five Canadian MS out-patients completed a set of questionnaires, including Qualiveen, MSQOL-54, a MS-specific HRQL questionnaire, urinary function assessments and the Expanded Disability Status Scale (EDSS) twice at an interval of two to four weeks. *Results*: Qualiveen proved internally consistent (Cronbach's alpha coefficients 0.73 to 0.90 for the four Qualiveen domains) and test–retest reliable (intraclass correlation coefficients 0.88 to 0.94). Consistent with a priori predictions, we found a strong association between overall Qualiveen score and the degree of incontinence (0.63), a moderate correlation with the type of urinary symptoms (0.49), a weak association with manner of voiding (0.28) and weak or absent correlations with MSQOL-54 domains, EDSS bladder/bowel and global EDSS. Predictions proved generally accurate (weighted $\kappa = 0.65$). *Conclusion*: The internal consistency, test–retest reliability and cross-sectional construct validity of the English version of Qualiveen are excellent, and similar to the original French version. Further studies should explore Qualiveen's longitudinal validity and responsiveness.

Key words: Multiple sclerosis, Neurogenic bladder dysfunction, Quality of life

Abbreviations: EDSS – expanded disability status scale; HRQL – health related quality of life; MS – multiple scleosis; MSQOL-54 – MS quality of life-54 questionnaire; UD – urinary disorders

Introduction

While urinary problems have a major adverse impact on the health-related quality of life (HRQL) of patients with multiple sclerosis (MS) [1, 2] existing HRQL instruments designed to explore the full range of problems of MS patients fail to focus adequately on urinary problems [3]. Existing UD-specific HRQL questionnaires were developed and validated primarily either in men [4–8] or in women [9–13], restrict their focus to urinary incontinence [14–17] or are unsuitable for MS patients whose activity limitations may be due to mobility rather than bladder problems [16].

In response to the need for an instrument to assess the impact of urinary disorders on HRQL in MS patients, we tested Qualiveen, a questionnaire originally developed for French-speaking patients with spinal cord injury [18]. We found Qualiveen's measurement properties excellent in MS patients [3]. The current report explores the internal consistency, the test–retest reliability and the validity of the English version of Qualiveen in discriminating between patients' HRQL impairment at a single point in time.

Methods

HRQL Instruments

Qualiveen

Qualiveen [18] 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 (5 items). Response options are framed as 5-point Likert-type scales with 0 indicating no impact of urinary problems on HRQL and 4 indicating a high adverse impact of urinary difficulties on HRQL. 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.

Translation and cultural adaptation of Qualiveen into English. Well-established methods guided the translation and linguistic validation of Qualiveen [19]. Two professional translators produced forward translations from French to English and met with an HRQL specialist in the United Kingdom to produce a reconciled forward translation. A native French speaker fluent in English produced a backward translation. A review of the backward translation revealed six minor discrepancies that were corrected. Ten patients found the questionnaire clear, and easy to complete. They identified two wording problems that were corrected for the final English version of Qualiveen.

Patients

Between January and July 2003, we asked 78 consecutive eligible patients with MS referred to an MS clinic at McMaster University (Hamilton, Ontario), or seen in the prior year at a rehabilitation clinic at Chedoke Hospital (entire sample of eligible patients), to participate in this study. All patients had clinically definite MS (Poser criteria [20]), knowledge of their MS diagnosis, and stable urinary disorders. We excluded patients with concomitant neurological illness, urinary disorders unrelated to MS, and those with difficulty answering the questionnaire because of language or cognitive limitations. All participants signed an informed consent that the Hamilton Health Sciences Ethics Committee had approved.

Other instruments

We used a number of instruments to explore Qualiveen's discriminative validity.

EDSS

The Expanded Disability Status Scale (EDSS) [21] assesses impairment and disability through ratings of eight functional systems using neurological examinations and the assessment of the patient's walking ability. Evidence suggests the EDSS is valid, reliable and poorly responsive [22, 23].

MSQOL-54

The MS Quality Of Life-54 questionnaire (MSQOL-54) [24] combines the 36 items from the SF-36 and 18 additional items specific to MS into 14 domains. Evidence supports its cross-sectional construct validity and reliability [24].

Self-reported symptoms, manner of voiding, and degree of incontinence

We developed self-report questions regarding urinary symptoms, manner of voiding and reasons for wearing continence protections if patients needed them.

First, we asked patients whether they experienced symptoms regarding voiding. We then grouped the symptoms as irritative symptoms (urgency and frequency), obstructive symptoms (dysuria, retention), and urge incontinence.

We created categories of symptom complexes according to postulates about increasing impact on HRQL: (a) irritative symptoms or obstructive symptoms, (b) irritative and obstructive symptoms (without incontinence) or urge incontinence without other symptoms, (c) urge incontinence with either obstructive or irritative symptoms. We also

recorded the number of urinary symptoms, which could range from 0 to 5.

Secondly, we asked patients to choose one of seven options to describe their manner of voiding and grouped them according to postulates about increasing impact on HRQL as follows: (a) normal, (b) permanent drainage, (c) abdominal contraction, manual pressing or percussion, (d) self-catheterization, catheterization by another or (e) continuous leakage.

We asked patients whether they used any form of continence protection and, if they did, the reason: (1) as a precaution, (2) urine leakage regularly between urinations, (3) permanent incontinence.

Questionnaire Administration

Patients received questionnaires by mail and completed self-administered versions of Qualiveen and MSQL-54 and the urinary function assessment in their home at baseline and 2 to 10 weeks later.

The attending neurologist categorized patients' disability status using the EDSS at baseline.

Statistical analysis

Internal consistency
To assess the internal consistency, Cronbach's alpha coefficients were calculated for the four domains and the overall score.

Cross-sectional construct validity of Qualiveen
We evaluated cross-sectional construct validity by Qualiveen with age, duration of MS and urinary disorders, urinary status (symptoms, manner of voiding, degree of incontinence), disability status assessed by EDSS score and dimension scores of MSQOL-54 questionnaire.

We made a priori predictions regarding correlations we would anticipate if Qualiveen is measuring what is intended. We used four categories: strongly correlated, $r > 0.5$; moderately correlated, $r = 0.36$-0.5; poorly correlated, $r = 0.20$-0.35; and no correlation $r < 0.2$. Pearson correlations provide measures of strength of association for continuous variables, and Spearman rank correlation for ordinal outcomes.

A weighted kappa using quadratic weights provided a measure of the magnitude of agreement between the predicted and observed correlations [25].

Test–reset reliability
We calculated an intraclass correlation coefficient for each of the domains and the Overall Qualiveen score to determine test–reset reliability.

Results

Of the 78 eligible patients who initially received the questionnaires, 19 refused to participate and four questionnaires were returned undeliverable. Table 1 describes the demographic and MS features of the 55 patients who returned completed on two occasions, while Table 2 presents their urinary features.

Internal consistency

Cronbach's alpha was 0.90 for the entire 30 items, 0.83 for the bother with limitation domain, 0.83 for the frequency of limitation domain, 0.73 for the fear domain, and 0.84 for the feeling domain.

Table 1. Clinical and demographic characteristics of MS population

Characteristics	
Sex, n(%)	
Male	17 (31)
Female	38 (69)
Age at examination	
Year, mean ± sd (range)	49.9 ± 11.8 (26–79)
Age at onset	
Year, mean ± sd (range)	34.8 ± 11.1 (16–71)
Duration of MS since onset of disease	
Year, mean ± sd (range)	15.2 ± 9.1 (1–41)
Duration of urinary disorders	
Year, mean ± sd (range)	7.0 ± 5.7 (1–23)
MS course, n (%)	
Relapsing-remitting	15 (27)
Relapsing-progressive	1 (2)
Primary-progressive	12 (22)
Secondary-progressive	27 (49)
EDSS score on examination	
Mean ± sd (range)	6.5 ± 1.6 (2–9)
EDSS bowel/bladder score on examination	
Mean ± sd (range)	2.5 ± 1.2 (1–5)

Table 2. Distribution of bladder problems in 55 MS patients

Characteristics	Males n	Females n n (%)
Urinary symptoms		
None	2	6 8(14)
Irritative	0	2 2(4)
Obstructive	0	2 2(4)
Irritative + urge incontinence	5	8 13(24)
Obstructive + urge incontinence	0	2 2(4)
Irritative + obstructive	4	5 9(16)
Irritative + obstructive + incontinence	6	13 19(34)
Manner of voiding		
Normal	11	14 25(46)
Abd. contraction, pressure, percussion	2	10 12(22)
Catheterization	2	3 8(14)
Permanent drainage	1	6 7(13)
Continuous leakage	1	2 3(5)
Degree of incontinence		
None	6	15 21(39)
Mild	6	9 15(27)
Moderate	4	11 15(27)
Severe	1	3 4(7)

Test–reset reliability

Overall test–reset reliability and within each domain was high with intraclass correlation coefficients consistently greater than 0.8 (Table 3).

Table 3. Test–retest reliability of QoL scores in all 55 patients

Domains	Intraclass correlation coefficients
Overall Qualiveen	0.84
Bother with limitations	0.89
Frequency-limitations	0.92
Fears	0.80
Feelings	0.86

Validity

Tables 4 and 5 present the extent of agreement between observed and predicted cross-sectional correlations. The data demonstrate strong correlations between the degree of incontinence and bother with limitation, frequency of limitation domains, and overall Qualiveen score. Correlations were moderate between overall Qualiveen score and the type of urinary symptoms and weak with manner of voiding.

The data also showed weak but significant correlations between at least one Qualiveen domain and each of the MSQOL-54 dimensions. The exceptions were health perception and sexual satisfaction which were uncorrelated with all Qualiveen domains, and health distress, which had moderate correlations with three of Qualiveen domains and Overall Qualiveen (Table 5).

Table 4. Cross-sectional construct validity: Pearson's or Spearman's rank correlations between urinary status, duration of MS and UD, EDSS scores, EDSS bladder/bowel scores, age and Qualiveen scores

	Bother with limitations	Frequency-limitations	Fears	Feelings	Overall Qualiveen
Type of symptoms	0.59*	0.54*	0.22↓	0.29↓	0.49↓
Number of symptoms	0.55↑	0.39*	0.17↓	0.31*	0.42*
Degree of incontinence	0.70*	0.61*	0.42*	0.40*	0.63*
Manner of voiding	0.23*	0.33*	0.18↓	0.20*	0.28*
MS duration	0.02*	0.13↓	0.05*	0.02*	0.05↓
UD duration	0.30↑	0.11*	0.19*	0.28↑	0.26↑
EDSS	0.06*	0.33↑	0.07*	0.01*	0.06*
Age	0.10*	0.07*	0.03*	0.14*	0.11*

Predictions fell in the following categories: strongly correlated, $r > 0.5$; moderately correlated, $r = 0.36$–0.5; poorly correlated, $r = 0.20$–0.35; not correlated, $r < 0.20$.

Correlation significant at the 0.001 level are shaded in deep grey, correlations significant at the 0.01 level in moderate grey, and correlations significant at the 0.05 level in light grey. Correlations greater than 0.05 are unshaded.

* Denotes full agreement between predicted and observed correlations (70 % of correct predictions).

↓ One arrow down denotes observed correlations one category lower than predicted correlations.

↑ One arrow up denotes observed correlations one category higher than predicted correlations (30 % of observed correlations were one category lower or higher than predicted correlation).

In general, observed correlations corresponded closely with a priori predictions (Tables 4 and 5). The weighted kappa between the predicted and observed correlations was 0.65.

Discussion

One adapts a HRQL questionnaire into another language and culture hoping to produce an instrument with similar or superior measurement properties. The results of this study suggest that the English version of Qualiveen is as internally consistent, test–reset 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.

A rigorous translation is necessary to produce a HRQL questionnaire that functions well in a culture and language that differs from that for which the instrument was originally designed [26–29]. We used a process of forward-translation/back-translation to revise Qualiveen, originally developed in French, for an English-speaking population. A possible concern was our use of a translation designed for the UK with a Canadian population. English as used in UK can be slightly different from that used in other English-speaking countries as happens in other languages [30, 31].

As it turned out, Canadians had no problems with the UK version of Qualiveen, which showed satisfactory measurement properties not only for the instrument as a whole but also for the individual domains. Internal consistency proved greater than 0.8 for 3 of the 4 domains and greater than 0.7 for the fourth. Intraclass correlation coefficients, reflecting test–reset reliability, were 0.8 or greater than for all 4 domains [18].

We found strong evidence of Qualiveen's discriminative construct validity including a strong association between Qualiveen scores and the degree of incontinence, a strong to moderate cor-

Table 5. Spearman's rank correlations between MSQOL-54 dimension scores and Qualiveen scores

	Bother with limitations	Frequency-limitations	Fears	Feelings	Overall Qualiveen
Physical function	0.12↓	0.21↓	0.23↑	0.19↓	0.22*
Role limitation-physical	0.15↓	0.38↑	0.14↓	0.11*	0.23*
Emotional well-being	0.09↓	0.14↓	0.23*	0.24↓	0.21↓
Role limitation-emotional	0.20↑	0.13*	0.32*	0.34*	0.29*
Health distress	0.18↓↓	0.36↑↑	0.35↑	0.41*	0.39*
Health perception	0.18*	0.17*	0.08↓	0.11*	0.16*
Cognitive function	0.08↓	0.10↓	0.07↓↓	0.22*	0.15↓
Energy	0.08↓	0.15*	0.21*	0.25↓	0.21*
Pain	0.01*	0.20↑	0.18*	0.23↑	0.19*
Social function	0.09*	0.20↑	0.19*	0.24*	0.22*
Sexual function	0.17↓	0.02↓	0.26↑	0.30*	0.23*
Sexual satisfaction	0.08*	0.09*	0.04*	0.01*	0.002*
Overall QoL	0.08*	0.17*	0.29↑	0.31↑	0.26↑

Predictions fell in the following categories: strongly correlated, $r > 0.5$; moderately correlated, $r = 0.36$–0.5; poorly correlated, $r = 0.20$–0.35; not correlated, $r < 0.20$.

Correlation significant at the 0.001 level are shaded in deep grey, correlations significant at the 0.01 level in moderate grey , and correlations significant at the 0.05 level in light grey. Correlations greater than 0.05 are unshaded.

* Denotes full agreement between predicted and observed correlations (52 % of correct predictions).

↓ One arrow down denotes observed correlations one category lower than predicted correlations.

↓↓ Two arrows down denotes observed correlations two categories lower than predicted correlations

↑ One arrow up denotes observed correlations one category higher than predicted correlations.

↑↑ Two arrows up denotes observed correlations two categories higher than predicted correlations (43 % of observed correlations were one category lower or higher than predicted correlation); (5 % of observed correlations were two categories lower or higher than predicted correlation).

relation with the type of urinary symptoms, a weak association with the way of voiding and weak or absent correlations with MSQOL-54 domains. Our results showed, in general, good agreement with a priori predictions (weighted $\kappa = 0.65$). These findings are very similar to those obtained in our French Qualiveen validity study in MS patients [3].

In conclusion, the translation and testing process has produced an English version of Qualiveen that functions similarly to the original French language version. Investigators can use the instrument to measure the extent to which MS patients' HRQL is impaired by urinary-related problems. Future research should evaluate the evaluative properties of both the French and English versions of Qualiveen.

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