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THE IMPACT OF URINARY DISORDERS ON HR-QOL IN MULTIPLE SCLEROSIS: ASSESSMENT WITH THE ITALIAN VERSION OF QUALIVEEN®

Hypothesis / aims of study

Qualiveen is an urinary disorders specific health related quality of life (HRQL) questionnaire. This instrument was first developed and validated in French and English version for patients with spinal cord injury (SCI). Recently, was used also in patients affected by Multiple Sclerosis (MS), and was demonstrated its good discriminative measurement properties. The primary aim of this study is to assess the impact of urinary disorders on HRQL of a large population of MS patients using an Italian translation of Qualiveen. The second aim is to examine the validity of Italian translation of Qualiveen to explore urinary disorders in MS patients correlating Qualiveen with urinary symptoms and other validated instruments (EDSS, OAB-q, SF-36).

Study design, materials and methods

Between January 2009 to January 2011 we asked 212 consecutive patients referred to a Neurorehabilitation clinic to participate in the study. All patients had clinically definite MS in accord with Poser criteria. We excluded patients with other concomitant neurological disorders, or urinary disorders unrelated with MS, and those with difficulty answering questionnaires because of language or cognitive limitations. All patients answered Qualiveen, a 30 items questionnaire focusing on 4 aspects of patients' lives (bother with limitations, frequency of limitations, fears and feelings). We also used, for all patients, EDSS (Expanded Disability Status Scale) to assess impairment and disability due to MS. All patients answered also OAB-q and SF-36 to assess general and urinary specific HRQL. Moreover, we developed self-report questions regarding urinary symptoms, degree of incontinence (we defined none incontinence the use of 0 pad, mild incontinence the use of at least 1 pad per day, moderate the use of 2 pads and severe incontinence the use of > 3 pads per day) and manner of voiding to characterize patients' urinary disorders.

We evaluated cross-sectional construct validity correlating Qualiveen with duration of MS, type of MS, urinary disorders (symptoms, manner of voiding, degree of incontinence), disability status and HRQL measured with validated instruments (OAB-q and SF-36) using Pearson's and Spearman's correlation coefficent when appropriate.

Results

Of 212 eligible patients, 147 were females and 65 were males. The mean age was 42.9 years (range 20-81). Mean duration of MS was 12.9 years (range 1-42). Sixty-seven patients presented a relapsing-remitting course of MS, 100 a primary-progressive and 47 a secondary-progressive course. Urinary symptoms, manner of voiding and degree of incontinence were summarized in table 1. Mean EDSS score on examination was 4.7 (range 2-8). Mean OAB-q score was 97.21 (range 71-159). Mean scores for the eight health domains of SF-36 were summarized in table 2. Mean Qualiveen scores were showed in table 3.

At Statistical analysis the data showed significant correlation between Qualiveen score and urinary symptoms and severity of incontinence ($p<0.001$), but none correlations with manner of voiding. Moreover we found correlation between MS duration and limitation domain and overall Qualiveen score ($p<0.01$), between EDSS score and Qualiveen total score ($p<0.001$). Finally we found a significant correlation between SF-36, OAB-Q scores and Qualiveen scores ($p<0.05$).

Table 1: Urinary symptoms

Characteristics	**N° of patients**	**Percentage**
Storage symptoms		
Urge-incontinence	44	20.7%
Urgency/frequency	96	45.2%
Mix incontinence	13	6.1%
Stress incontinence	10	4.7%
Voiding symptoms		
CIC	25	11.7%
Indwelling catheter	10	4.7%
Abdominal contraction, pressure, percussion	20	9.4%
Degree of incontinence		
None	41	19.3%
Mild	85	40.1%
Moderate	65	30.6%
Severe	26	12.2%

Table 2: SF-36

physical functioning	physical role limitation	bodily pain	general health perceptions	vitality	social functioning	role emotional limitation	mental health

40.32 (range 0-90)	54.53 (range 0-90)	61.62 (range 15-100)	46.20 (range 10-90)	47.50 (range 0-90)	53.44 (range 0-90)	46.20 (range 20-87)	56.53 (range 10-90)

Table 3: Qualiveen

Bother with limitations	Frequency-limitations	Fears	Feelings	Overall qualiveen
19.03 (2-31)	19.91 (6-29)	20.01 (4-31)	9.39 (2-16)	68.31 (14-102)

Interpretation of results

In this study an Italian translation of Qualiveen, initially developed to discriminate the impact of urinary difficulty of SCI patients, proven valid in discriminating between MS patients for urinary-specific HRQL. Our study had limitations because we addressed validity but not reliability and responsiveness of Qualiveen. Recent studies demonstrated good reliability and responsiveness of English version of Qualiveen in MS patients. Future studies are needed to validate Qualiveen in Italian language, to prove reliability and responsiveness of Italian version of Qualiveen in MS patients.

Concluding message

This study demonstrated the validity of italian translation of qualiveen to discriminate Urinary symptoms in MS patients and correlate these symptoms with patients HRQL.

References

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**observational study from data obtained without any additional therapy or monitoring procedure**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**