

The urinary-specific quality of life of multiple sclerosis patients: Dutch translation and validation of the SF-Qualiveen

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Aims: The SF-Qualiveen is a short questionnaire that measures the impact of urinary symptoms on the quality of life of patients with urological dysfunction due to neurological disorders. The aim of this study is to translate, culturally adapt and validate a Dutch version of the SF-Qualiveen for use in Multiple Sclerosis (MS) patients.

Methods: Cross-cultural adaptation of the original English SF-Qualiveen into Dutch was performed according to standardized guidelines. Adult MS patients with symptomatic urinary disorders who visited the Urology or Rehabilitation outpatient clinic of the Erasmus Medical Center completed the SF-Qualiveen and the Urinary Distress Inventory-6 (UDI-6), that evaluates bother caused by lower urinary tract symptoms and was used as a gold standard, at baseline and 1-2 weeks later. A control group recruited from the Otolaryngology outpatient clinic completed the questionnaires once. Reliability and validity were determined.

Results: Fifty MS patients and 50 controls were included. SF-Qualiveen scores in patients were higher than in controls (on a scale of 0-4: 1.73 vs. 0.34; $P < 0.001$). Internal consistency (Cronbach's alpha > 0.8) and reproducibility (Intraclass correlation coefficients > 0.8) were good for the total SF-Qualiveen. Content validity was adequate and a significant relationship between SF-Qualiveen and UDI-6 ($r = 0.510-0.479$, $P < 0.001$) confirmed good criterion validity.

Conclusions: The Dutch SF-Qualiveen showed good measurement properties. We recommend its use to measure urinary-specific quality of life in MS patients in research and clinical practice in the Netherlands.

KEY WORDS

Netherlands, neurogenic, patient reported outcome measure, quality of life, surveys and questionnaires, urinary bladder, validation studies

1 | INTRODUCTION

Urological dysfunction is common in patients with multiple sclerosis (MS), with prevalence reported as high as 32-97%.¹ This variance is at least partly related to the stage of the progression of the disease. While urinary storage symptoms (urgency, frequency, and urinary incontinence) due to overactive contractions of the detrusor muscle often dominate

in earlier disease, voiding problems (straining, intermittence, residual urine, and retention) due to detrusor-sphincter dyssynergia often arise in addition to the storage symptoms in progressed disease.¹ This bladder dysfunction is associated with an important worsening of the quality of life in patients with MS.²

As differences have been noted between doctors' and patients' perceptions of the impact of a chronic disease like MS, there is a need for direct measurements of patients' experiences to be informed about their perception of the impact of the disease on the quality of life.³ The European

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Association of Urology (EAU) guidelines on Neuro-Urology highlight quality of life as an important aspect in the management of neuro-urological patients. The Qualiveen⁴ and its more practical short form (SF-Qualiveen)⁵ are validated questionnaires for patients with MS evaluating the urinary-specific quality of life by assessing the impact of a broad range of bladder problems. The Qualiveen or SF-Qualiveen is recommended by the EAU for the assessment of health related quality of life in this patient group.⁶

The Qualiveen contains 30 questions. It was developed and validated in French for both spinal cord injury and MS patients^{4,7} and underwent successful cross-cultural adaptation into English,⁸ German,⁹ Italian,¹⁰ Portuguese,¹¹ and Spanish.¹² The SF-Qualiveen with eight questions proved to have good measurement properties in MS patients and is currently available in French and English.⁵ The aim of our study is to translate, culturally adapt, and validate a Dutch version of the SF-Qualiveen in MS patients, so as to make the SF-Qualiveen suitable for MS patients in the Netherlands in both research and clinical practice.

2 | MATERIALS AND METHODS

2.1 | Study design and population

This is a single-center, prospective (cohort) validation study. The local medical research ethics committee reviewed the research proposal with the number MEC-2014-534 and concluded that the rules as stated in the Medical Research Involving Human Subjects Act do not apply.

Adult MS patients with urinary symptomatology, who visited the Urology outpatient clinic of the Erasmus University Medical Center (Erasmus MC) Rotterdam, the Netherlands, between October 2015 and April 2016 were invited for the study. MS patients with similar symptoms who visited the Rehabilitation outpatient clinic of the Erasmus MC between February 2016 and April 2016 were invited as well. Patients with Dutch language difficulties,

cognitive impairment, active malignant tumors, acute attacks of MS (defined as an acute episode of focal neurological disturbance), symptomatic urinary tract infections, and patients who changed treatment within the test-retest period were excluded. Patients were asked to complete two questionnaires (SF-Qualiveen and UDI-6); during a hospital visit (baseline) and 1-2 weeks later at home. All patients provided written informed consent. Patient and disease characteristics were retrieved from the medical files.

Adult patients who visited the Otolaryngology outpatient clinic between March and May 2016 were invited for the study as well. We considered these patients a proper control group, since Otolaryngology pathology is often limited to the organ and has no relationship with bladder problems. This group completed the questionnaires only once. Exclusion criteria for this group were: neuro-urological dysfunction (patients reporting both bladder symptoms and MS or spinal cord injury), cognitive impairment and Dutch language difficulties.

2.2 | Questionnaires

The SF-Qualiveen⁵ is a validated short version of the Qualiveen-30⁴ questionnaire and evaluates urinary-specific quality of life. The SF-Qualiveen consists of eight questions and reports on four domains of two questions each: bother with limitations, fears, feelings, and frequency of limitations. Table 1 displays the items of the SF-Qualiveen. Responses are given on a 5-point Likert like scale, where a score of 0 indicates “no impact” and 4 “high impact.” The SF-Qualiveen total score is calculated as the mean of the eight responses and the domain scores are calculated as the mean score of the responses per domain.

The Dutch Urinary Distress Inventory (UDI-6) evaluates bother caused by lower urinary tract symptoms.¹³ It consists of six questions and reports on three domains: irritative, stress, and obstructive/discomfort symptoms. Answers can be given on a 4-point Likert like scale. The questionnaire is validated, but not specifically for neuro-urological patients.

TABLE 1 Items of the SF-Qualiveen

Domains:	Questions:
Bother with limitations	1. In general, do your bladder problems complicate your life? 2. Are you bothered by the time spent passing urine or realizing catheterization?
Fears	3. Do you worry about your bladder problems worsening? 4. Do you worry about smelling of urine?
Feeling	5. Do you feel worried because of your bladder problems? 6. Do you feel embarrassed because of your bladder problems?
Frequency of limitations	7. Is your life regulated by your bladder problems? 8. Can you go out without planning anything in advance?

2.3 | Cross-cultural adaptation

The cross-cultural adaptation of the original English SF-Qualiveen into the Dutch language was performed according to standardized guidelines for linguistic validation.¹⁴ The forward-translation was performed by two professional native Dutch-speaking translators separately, followed by a consensus meeting of these two and the primary investigator (SR). The consensus version was backward translated by a native English speaking translator. During a consensus meeting with the Dutch translators, the English translator and the primary investigator (SR) a few minor adjustments were made. Two urologists (BB and JS) proof-read and agreed on this version of the Dutch SF-Qualiveen. It was then evaluated on content validity,¹⁵ i.e., pre-tested, in face-to-face interviews with patients during August and September 2015. We aimed to include at least 10 MS patients for the face-to-face interviews. These patients were first asked to complete the questionnaire. Thereafter, content and wording of the questions were discussed with the patients and suggestions for improvement were solicited.

2.4 | Validation – reliability

2.4.1 | Internal consistency

This is the intercorrelation of the questions of a questionnaire and demonstrates if the questions measure the same underlying concept. The correlation between the questions of the SF-Qualiveen for the total score and for the separate domains were measured by determination of the Cronbach's alpha. If Cronbach's alpha was between 0.7 and 0.95, internal consistency was considered good.¹⁵

2.4.2 | Reproducibility

The intraclass correlation coefficients (ICC) for agreement were calculated for the overall SF-Qualiveen score and for the four domains to test the test-retest reliability. A score of 0.7 or higher was considered good.¹⁵

2.4.3 | Limits of agreement

The limits of agreement (LOA) were calculated as the mean change in scores of repeated measurements $\pm 1.96 \times SD$ of the changes. Provided differences within the LOA could be interpreted as measurement error and would not be clinically important.¹⁶

2.5 | Validation – validity

2.5.1 | Content validity

During the cross-cultural adaptation process, content validity was assessed by patient interviews.

2.5.2 | Construct validity

Predefined hypotheses about the relation of the SF-Qualiveen to other measures were tested:

- “Patients with higher SF-Qualiveen scores (indicating higher impact on urinary-related quality of life) will have higher scores on the UDI-6 (indicating more bother of urinary symptoms).” The association between the SF-Qualiveen and UDI-6 scores will be assessed using the Pearson's correlation coefficient in case of a linear association.
- “The SF-Qualiveen scores in the patient group will be higher than the reference group.” The Student's *t*-test will be used to assess the differences between groups.

2.5.3 | Criterion validity

For the SF-Qualiveen no perfect gold standard exists. In the absence of a perfect gold standard the UDI-6 is used as a gold standard to determine criterion validity. The correlation of the SF-Qualiveen to the UDI-6 is determined by using the Pearson correlation coefficient in case of a linear association.

2.5.4 | Floor and ceiling effects

If more than 15% of respondents achieved the highest or lowest possible score, floor or ceiling effects are presumed to be present. We calculated the percentages of patients with the highest or lowest possible score.

2.6 | Further statistical methods

We aimed at a sample size of 50 MS patients and 50 control persons based on guidelines for validation of questionnaires.¹⁵ SPSS version 21 was used to perform the statistical analyses in this study. Mean \pm standard deviations were used to present descriptive results for continuous data and counts and percentages for discrete data. Differences between groups were tested with χ^2 tests for categorical variables and with Student's *t*-tests for continuous variables. *P*-values of less than 0.05 were considered to reflect statistical significance.

3 | RESULTS

Fifty-six MS patients with symptomatic urinary disorders were initially included in the study. Patients signed informed consent and filled in the baseline questionnaire. Six patients were excluded afterwards for the following reasons: four patients did not return the second questionnaire for unknown reasons, one refused to fill in the second questionnaire and one changed treatment within the test-retest period.

TABLE 2 Patient and clinical characteristics

	Patients	Controls	P-value
Characteristics			
n	50	50	
Age at examination (years)	50.3 ± 11.7	42.3 ± 14.2	0.013
Gender			
Male	11 (22.0%)	26 (52.0%)	0.002
Female	39 (78.0%)	24 (48.0%)	
MS characteristics			
Duration of MS since diagnosis (years)	13.3 ± 9.0		
MS course			
Relapsing-remitting	30 (60.0%)		
Primary progressive	5 (10.0%)		
Secondary progressive	11 (22.0%)		
Missing	4 (8.0%)		
Mobility			
Fully ambulatory	16 (32.0%)		
Limited walking	23 (46.0%)		
Wheelchair bound	10 (20.0%)		
Missing	1 (2.0%)		
Urinary symptoms			
Duration of urinary symptoms (years)	7.6 ± 5.5		
Urinary symptoms			
Storage	7 (14.0%)		
Voiding	8 (16.0%)		
Storage + voiding	35 (70.0%)		
Manner of bladder emptying			
(normal) voiding	36 (72.0%)		
Intermittent catheterization	10 (20.0%)		
Indwelling catheter	4 (8.0%)		

Eventually the data of 50 MS patients could be used for analyses. The mean time between completing the first and second questionnaire was 15.7 ± 10.6 days.

Fifty persons who visited the Otolaryngology outpatient clinic of the Erasmus MC between March and May 2016 completed the questionnaires once as a control group. Table 2 displays the characteristics of the included MS patients and controls. The MS patient group was significantly older ($P = 0.013$) and had more females ($P = 0.002$) than the control group. Most patients had relapsing-remitting MS (60%), were limited in walking (46%), voided without catheterization (72%), and experienced both storage and voiding urinary symptoms (70%).

3.1 | Validation – reliability

3.1.1 | Internal consistency

With Cronbach's alpha's of >0.8 , the internal consistency for the total SF-Qualiveen can be considered good. (Table 3) With a Cronbach's alpha of >0.7 the domains “bother with limitations” and “feeling” showed a good internal consistency as well. The domain “frequency of limitations” showed moderate internal consistency and the domain “fears” showed weak internal consistency.

3.1.2 | Reproducibility

The ICCs for agreement for the total SF-Qualiveen and the four domains were all higher than 0.7, indicating good reproducibility. (Table 4)

3.1.3 | Limits of agreement

The LOA ranges of the total SF-Qualiveen and the domains are presented in Table 4. A change of less than 0.76 in the total SF-Qualiveen score could be interpreted as measurement error.

3.2 | Validation – validity

3.2.1 | Content validity

This was evaluated in face-to-face interviews with 11 MS patients and 12 other neuro-urological patients. The importance of all questions, to assess the broad range of bladder problems patients experience, was confirmed by the majority of patients. The Dutch-version questionnaire was found generally accessible, clear, easy to understand, and fast to complete and it was not necessary to make adjustments.

TABLE 3 Internal consistency – Cronbach's alpha ($n = 50$ MS patients)

	Test	Re-test
SF-Qualiveen total	0.84	0.85
SF-Qualiveen subscales:		
Bother with limitations	0.72	0.78
Fears	0.26	0.40
Feeling	0.77	0.75
Frequency of limitations	0.43	0.66

3.2.2 | Construct validity

Both predefined hypotheses about the relation of the SF-Qualiveen score to other measures were confirmed:

- We found a significant linear correlation between the total score of SF-Qualiveen and total score of UDI-6 in the patient group (T0: $r = 0.510$ and $P < 0.001$; T1: $r = 0.479$ and $P < 0.001$). This confirmed the hypothesis “patients with higher SF-Qualiveen scores have higher UDI-6 scores.”
- The mean of the total score of the SF-Qualiveen differed between patient and the control group (1.73 vs. 0.34; $P < 0.001$). The hypothesis “SF-Qualiveen scores in the patient group are higher than in the control group” is hereby confirmed.

3.2.3 | Criterion validity

A significant relationship was found between the UDI-6 total score, and the SF-Qualiveen total score in both MS patient group (T0: $r = 0.510$ and $P < 0.001$; T1: $r = 0.479$ and $P < 0.001$) and the control group ($r = 0.632$ and $P < 0.001$).

3.2.4 | Floor and ceiling effects

In the patient group no floor or ceiling effects were found in total or domain scores. Two percent of patients had the lowest possible total score and no patients had the highest possible score. Four to ten percent of the patients reported the lowest possible scores for the separate domains. Zero to four percent of the patients reported the highest possible scores for the separate domains.

In the control group, floor effects were found in all domains and in the total score. (domains: 58-86% and total score: 50%). No ceiling effects were found in the control group.

4 | DISCUSSION

We translated the SF-Qualiveen into Dutch, and culturally adapted and validated it for use in MS patients. The measurement properties demonstrated the Dutch version of the SF-Qualiveen to be valid, reliable, and consistent. This enables the use of the SF-Qualiveen for future research and clinical practice in the Netherlands.

For chronic diseases like MS, quality of life is an important aspect of healthcare. The urinary symptoms that are often described in patients with MS can diminish the quality of life.² This study makes it possible for Dutch-speaking MS patients to directly measure the impact of urinary symptoms on the quality of life with the SF-Qualiveen. We chose to translate and validate the short form because this is more practical, easier to implement into research, and clinical practice, and causes less patient burden to complete. In validation studies of the Qualiveen the length of the questionnaire has been mentioned as a limitation.^{11,12} The Dutch SF-Qualiveen can be a valuable addition to diagnostics, so as the EAU guidelines recommends its use.⁶

The Cronbach's alpha of >0.8 indicates good internal consistency for the entire SF-Qualiveen questionnaire. For the development of the SF-Qualiveen Bonniaud et al.⁵ selected two questions per domain of the Qualiveen-30, based on the most responsive items to represent that domain. The authors did not address the internal consistency of the SF-Qualiveen, neither for the total score, nor for the domain scores. The internal consistency of a questionnaire is dependent upon the number of items in a scale.¹⁵ In a short questionnaire like the 8-item SF-Qualiveen categorization into four domains might therefore be questioned. In our study, the domains “bother with limitations” and “feeling” showed good internal consistency and the domain “frequency of limitations” showed moderate internal consistency. The domain “fears” showed weak internal consistency. Although its two questions (see

TABLE 4 Reproducibility of SF-Qualiveen

	Test (mean \pm SD)	Re-test (mean \pm SD)	Mean change (mean \pm SD)	ICC	LOA
SF-Qualiveen total score	1.73 \pm 0.84	1.73 \pm 0.84	0.00 \pm 0.39	0.90	-0.76 to 0.76
Bother with limitations	1.67 \pm 1.10	1.70 \pm 1.06	0.03 \pm 0.61	0.84	-1.17 to 1.23
Fears	1.59 \pm 0.98	1.58 \pm 0.96	-0.01 \pm 0.53	0.85	-1.05 to 1.03
Feeling	1.56 \pm 1.09	1.50 \pm 1.09	-0.06 \pm 0.73	0.78	-1.50 to 1.38
Frequency of limitations	2.09 \pm 0.95	2.13 \pm 1.02	0.00 \pm 0.39	0.72	-0.76 to 0.76

SD, standard deviation; ICC, intraclass correlation coefficient; LOA, limits of agreement.

Table 1) are both important (as was confirmed during cross-cultural adaptation), the answers to these questions do not necessarily have to be associated. It is doubtful if the two questions measure the same underlying construct of “fears.” A potential explanation for the moderate internal consistency of the questions within the domain “frequency of limitations” (Table 1) is that patients’ answers to the last question might not be exclusively related to their bladder problems. The question arising from our study results on the internal consistency of the separate domains and that each consists of only a small number of questions, is whether the domains of the SF-Qualiveen can still be considered as actual domains. Therefore, we investigated this issue by performing a factor analysis of the eight questions of the SF-Qualiveen. This resulted in the identification of two components within the questionnaire. The first component is represented by the first seven questions and the second component by question 8. This indicates that the four Qualiveen domains can no longer be identified in the SF-Qualiveen and that question 8 might assess a different construct than the other questions. This reasoning is confirmed by the Cronbach's alpha rising from 0.835 to 0.855 at baseline and from 0.851 to 0.871 at re-test when excluding question 8 from the analysis. Therefore, exclusion of question 8 from the questionnaire can be considered. In view of the good internal consistency of the total SF-Qualiveen, the lack of identification of four domains in the SF-Qualiveen, the patients agreement on the importance of all 8 questions of the questionnaire (content validity), and to support consistent (international) usage of the SF-Qualiveen we recommend to use the entire SF-Qualiveen questionnaire and not the separate domains.

The ICCs showed a good reproducibility of the Dutch SF-Qualiveen. These ICCs are lower than reported in the original Qualiveen-30 questionnaire,⁴ but are comparable to those found in the French and English validation study of the SF-Qualiveen.⁵ The lower ICCs for the SF-Qualiveen are probably to the result of the shortening. We believe that the advantages of the short SF-Qualiveen (more practical, less patient burden, and easier to implement into practice) outweigh this minor disadvantage.

The Dutch SF-Qualiveen showed good validity. Predefined hypotheses to test construct validity could be confirmed. Patients’ scores on the SF-Qualiveen were significantly higher than those of controls, which demonstrates good discriminative ability of the SF-Qualiveen. Furthermore, a correlation was found between the UDI-6 as a gold standard and the SF-Qualiveen. This confirmed good criterion validity. In the patient group no floor or ceiling effects were found. As expected, a floor-effect was found in the control group (no urological patients).

One of the strengths of our study is that we followed all proposed quality criteria for the validation of a questionnaire of Terwee et al.¹⁵ Furthermore, we included a very homogeneous study population of only MS patients. Therefore, we conclude

that the SF-Qualiveen can be used to measure the urinary-specific quality of life for MS patients with symptomatic functional urologic disorders. Further research is needed to validate the questionnaire for other neurological diseases such as spinal cord injury.

A limitation of this study is that we were not yet able to measure the responsiveness of the SF-Qualiveen. Another limitation is that the exact response rate cannot be established. We aimed at including all consecutive eligible patients. Study inclusions were performed by selected urologists and a rehabilitation specialist specialized in the treatment of MS patients. We were not able to establish whether indeed all eligible patients were approached by these physicians and how many patients declined to participate. We could also have missed a small number of eligible patients who visited other (non-specifically MS specialized) urologists or rehabilitation specialists at our hospital during the inclusion period. Furthermore, there was no perfect gold standard questionnaire available. A perfect gold standard would be a questionnaire that is available in Dutch, commonly used, measures the urinary-specific quality of life and is validated in neuro-urological patients. In the absence of a perfect gold standard we chose the UDI-6, a commonly used questionnaire, which evaluates bother by lower urinary tract symptoms to function as the gold standard. Finally, due to the single-center design of the study in a referral center, the generalizability of the questionnaire is questionable. On the other hand, the SF-Qualiveen showed good measurement properties in the original validation multicenter study.⁵

5 | CONCLUSIONS

In conclusion, the Dutch version of the SF-Qualiveen showed good measurement properties. We recommend using the entire Dutch version of the short and practical SF-Qualiveen to measure urinary-specific quality of life experienced by MS patients in both research and clinical practice in the Netherlands. SF-Qualiveen outcomes can support healthcare professionals in treatment decision making to optimize patients’ quality of life.

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6 | POTENTIAL CONFLICTS OF INTEREST

Nothing to disclose.

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