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ARTICLE

The urinary disorder-specific quality of life in patients after spinal cord injury: Polish translation, adaptation and validation of the Qualiveen and SF-Qualiveen

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Abstract

Study Design Prospective cohort validation study.

Objectives In spinal cord injury (SCI), neurogenic lower urinary tract dysfunction is associated with a reduced quality of life. No specific questionnaire has been translated, culturally adapted, and validated into Polish language to assess urinary disorder-specific quality of life in people after SCI. In this study, we translated, adapted, and validated the Polish versions of the Qualiveen and SF-Qualiveen in individuals with SCI.

Setting University Hospital in Krakow, Poland.

Methods Translation and cross-cultural adaptation of the Qualiveen and SF-Qualiveen were done using international recommendations and well-established methods. Adult patients with SCI from the Department of Urology at the University Hospital in Krakow, Poland completed the Polish versions of the Qualiveen, SF-Qualiveen, and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) at baseline and 2 weeks later. The ICIQ-SF served as the reference instrument. Validity and reliability were determined.

Results Polish-speaking patients with SCI ($n = 178$) were included. Content validity/cross-cultural adaptation of the translated questionnaires was investigated during face-to-face interviews. Construct/criterion validity was assessed, and positive correlations were found between the Qualiveen and ICIQ-SF as well as the SF-Qualiveen and ICIQ-SF. A reliability study revealed good internal consistency (Cronbach's alpha > 0.8) and reproducibility (intraclass correlation coefficients > 0.8) for both adapted questionnaires. We did not identify floor or ceiling effect.

Conclusions The Polish versions of the Qualiveen and SF-Qualiveen showed good measurement properties. Polish healthcare providers can now reliably and directly assess the urinary disorder-specific quality of life in individuals after SCI.

Introduction

Neurogenic lower urinary tract dysfunction (NLUTD) results from nervous system disorders and remains one of the most challenging problems in neuro-urology. There are various diseases or injuries that affect the nervous system, which can lead to this chronic detrusor-sphincter dysfunction. The type of disorder depends on the dysfunction level, time span, and completeness of central or peripheral nervous system damage. Thus, spinal cord injuries (SCIs) need particular attention because their medical presentation differs and evolves in these individuals. Immediately after SCI, during a temporary spinal shock phase, the bladder is acontractile, usually with normal sphincter function, which results in urine retention. Then, the detrusor may become overactive (reflex incontinence) and discoordination between the detrusor and the sphincter may additionally appear (retention). In some patients, the detrusor may remain acontractile (retention) with sphincter failure (leading to constant incontinence) [1].

Most individuals with SCI will have some grade of urinary impairment within 1 year after injury [2]. Furthermore, <1% of them will be fully recovered [3]. NLUTD after SCI typically presents with urinary incontinence and/

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or inability to empty the bladder, which substantially decreases patients' quality of life and socialization. Therefore, it is currently recommended to assess the quality of life in these patients using validated questionnaires because physicians and patients have contrasting views about the effects of a long-lasting disease such as SCI. Increasing the life quality in individuals with SCI should be one of the main goals in their treatment related to the injury [4].

The Qualiveen [5] and its short form (SF-Qualiveen) [6] are well-known and recommended questionnaires that investigate urinary disorder-specific quality of life in people with NLUTD. The two questionnaires have proven to be valid for multiple sclerosis (MS) and SCI [5–7]. Although bladder-sphincter dysfunction types in MS and SCI patients may have common features, clinical presentations and their effect on the quality of life may significantly differ (e.g., progression of the primary disease in patients with MS and severe beginning in SCI; impaired sensation in MS and frequent complete loss of sensation in SCI). Therefore, it is currently recommended to independently validate urinary disorder-specific questionnaires that assess quality of life in specific patient populations [8, 9].

No questionnaire for evaluation any type of quality of life, specifically in individuals with SCI, is available in the Polish language. There are some extant questionnaires in the Polish language to assess lower urinary tract symptoms; however, these instruments were not designed or recommended for patients with NLUTD. There is also no instrument in the Polish language to assess urinary disorder-specific quality of life in individuals after SCI. Therefore, the aim of this study was to translate, culturally adapt, and validate the Polish versions of the Qualiveen and SF-Qualiveen in this specific population.

Methods

This was a prospective, cross-sectional (validation) study conducted at the Department of Urology of the University Hospital in Krakow, Poland after obtaining approval from the local research committee (1072.6120.222.2019) and written permissions from the MAPI Research Trust to translate, adapt, and validate the Qualiveen/SF-Qualiveen. The study was registered with ClinicalTrials.gov (NCT04185792). Written informed consent was obtained, and patient and disease characteristics were extracted from the medical records.

We invited all individuals after SCI with urinary symptomatology who were registered in our database at the outpatient department of our institution to participate in this study. Patients with Polish language difficulties, other concomitant neurological disorders, cognitive impairment, current urinary tract infection, or recent treatment changes (i.e., in last 3 months) were excluded. We also did not include patients with plans to modify their treatment, pharmacologically and surgically, during the study period. The proper translations of the Qualiveen and SF-Qualiveen to Polish language were evaluated by 40 individuals with SCI during direct interviews. Then, other individuals with SCI completed the Polish versions of Qualiveen, SF-Qualiveen, and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) at the outpatient department (test) and 2 weeks later at home (re-test). The validity and reliability were then assessed.

Measures

The Qualiveen is a validated questionnaire to assess urinary disorder-specific quality of life. It contains 30 questions related to four domains: bother with limitations (nine questions), frequency of limitations (eight questions), fears (eight questions), and feelings (five questions). The instrument uses a five-point Likert-like scale to rate responses; a score of 0 indicates "no impact" and 4 indicates "high impact". The total Qualiveen score is expressed as the mean of the four domains; the domain scores are given as the mean score of the responses per domain [10].

The SF-Qualiveen (validated short version of the Qualiveen) contains eight specific questions that assess the same four domains as the original Qualiveen. There are two questions for each domain. Consistent with the Qualiveen, responses are given on the same five-point Likert-like scale. The SF-Qualiveen total score is the mean of the eight individual scores from the eight included items and the domain scores are calculated as the mean score of the responses per domain [7].

The International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), a four-question instrument, is widely used in daily clinical practice in Poland, but it was not designed for individuals with NLUTD. Therefore, it is not validated and recommended to use in this specific patient group. It analyzes urinary incontinence with an implication on quality of life [11]. The ICIQ-SF was selected as a reference instrument due to the lack of an ideal gold standard questionnaire.

Validity process

International established recommendations for questionnaire validation were applied [12]. To culturally adapt the Qualiveen and SF-Qualiveen into Polish, two forward translations (English to Polish) were performed by professional, sworn, independent native Polish-speaking translators, followed by a meeting of these two and the primary investigator (MP) to reach an initial consensus. After the back-translation (Polish to English) by a

professional, sworn, independent native-English translator who was fluent in Polish, the Polish language versions of the questionnaires were finalized at a second consensus meeting attended by the Polish and English translators and the primary investigator (MP). Three staff urologists (PK, PD, PC) proofread the questionnaires and agreed on proposed versions of the Polish Qualiveen and SF-Qualiveen.

Content validity, confirming the use of clear and appropriate wording, was assessed by direct interviews with individuals after SCI and those with another neurourological conditions. First, we asked patients to answer the translated questions. Then, we discussed with the patients the content and phrasing of the questions. We were particularly interested to know whether the full scope of bladder problems that affected quality of life was included in the questions. Construct/criterion validity, which means verifying how well a test measured what it was supposed to measure, was demonstrated by analyzing the connection between the Qualiveen/SF-Qualiveen and the ICIQ-SF as a reference instrument. Ceiling effects, which prevent accurate interpretation of the data, were identified when more than 15% of participants acquired the highest or lowest possible result.

Reliability process

The internal consistency, which refers to the general agreement between multiple items that make up a composite score of a questionnaire, was measured by computing Cronbach's alpha coefficients for the overall score for the Qualiveen and SF-Qualiveen and for each domain of both questionnaires. The test–retest reliability (i.e., reproducibility - the ability to produce repeated measurement that are consistent) was calculated using the intraclass correlation coefficients (ICCs) for the overall score of the Qualiveen and SF-Qualiveen as well as each domain of both questionnaires.

Special considerations for SCI

The validation process was also investigated for special aspects in patients with SCI. Based on the American Spinal Injury Association (ASIA) Impairment Scale [13] and the SCI level (cervical, thoracic, lumbar), different subgroups of patients were created. The post hoc tests assessing internal consistency and reproducibility as well as construct/criterion validity were performed in these patient subpopulations.

Statistical analyses

The mean ± standard deviation or the median (interquartile range) was used to represent values for continuous data; discrete data were represented by counts and percent. The correlation between the Qualiveen/SF-Qualiveen and the ICIQ-SF as the reference instrument to evaluate the construct/criterion validity were analyzed by Pearson's correlation coefficient in a case of a linear regression. Floor and ceiling effects were assessed by computing the proportions of respondents with the highest and lowest possible result. The internal consistency was considered to be good if the Cronbach's alpha coefficients was 0.7 or higher [14]. An ICC of 0.7 or higher reflected good reproducibility [14]. Statistical analyzes were performed using SPSS version 24.0 (IBM SPSS Statistics for Windows, Version 24.0; IBM Corp., Armonk, NY, USA). Statistical significance was considered at $p < 0.05$.

We aimed to include 100 patients with SCI to comply with the recommendations for validation of instruments [14]. However, based on the information that was provided by two independent Polish language specialists and one expert in health-related quality of life related to specific Polish language declensions, free word order, and pronunciation, the sample size was increased (i.e., all patients from our database were invited to this study and, if eligible, included with no limit of the sample size). This aspect had no negative affect on the validation process and it ensured more accurate values and a smaller margin of error as well as better identification of outliers [15]. For the same reasons, our goal was to include a minimum of 40 patients after SCI in direct interviews, even though a sample size of at least 10 individuals would allow the correct content validity.

Results

Cultural adaptation

We used in-person interviews with 40 patients after SCI and 20 patients who had other neurourological disorders, mostly MS, to gauge content validity. They identified one problem with wording in the Qualiveen and one problem in the SF-Qualiveen, which led to corrections in the final Polish versions of the questionnaires (Supplementary Material—Polish Qualiveen, Polish SF-Qualiveen). Implemented changes were connected with the fluidity of the Polish language and had no impact on understanding or substantive content. All patients reported that the complete range of urinary problems which affected quality of life had been encompassed by the translated questionnaires. All of them also highlighted the importance of, and need for, these questionnaires in daily clinical practice for urologists. The Polish Qualiveen and SF-Qualiveen were found to be easy to understand and complete and they were quick to fill in and non-offensive.

Validation

Because during cultural adaptation, the wording problems were identified and corrected (one problem each in the Qualiveen and in the SF-Qualiveen), we excluded from further validation the patients who had assessed content validity to minimize the risk of intra-observer bias. Other patients were invited to investigate construct/criterion validity, ceiling effects, and reliability. The demographics and clinical characteristics of the newly invited patients were not statistically different from the values of the individuals who assessed the content validity. Therefore, one hundred thirty-eight patients after SCI were invited to complete the Polish Qualiveen, Polish SF-Qualiveen and ICIQ-SF at baseline and 2 weeks later. Five patients did not answer the invitation and these patients had demographic and clinical characteristics that were not statistically different from the other invited patients. It was necessary to exclude four patients who, for unstated reasons, did not return the second set of questionnaires, one patient declined further participation, one patient changed medications during the study, and one patient had a stroke. Overall, 126 patients were included. These patients returned completed second set of questionnaires (retest) within 16.1 ± 9.9 days after the first set.

Patient characteristics are demonstrated in Table 1. Most of the participants were male and they required a wheelchair and catheterization of their bladder. Most of them also had thoracic SCI.

To assess construct/criterion validity, the Pearson correlation between the Qualiveen/SF-Qualiveen and ICIQ-SF was analyzed. A significant positive association was found between the total scores of the Qualiveen/SF-Qualiveen and the total score of the ICIQ-SF (Qualiveen: $r = 0.693$ and $P < 0.001$; SF-Qualiveen: $r = 0.611$ and $P < 0.001$). Therefore, the Qualiveen/SF-Qualiveen scores were associated positively with the acuteness of urinary symptoms that were evaluated by the ICIQ-SF, and we considered the construct/criterion validity to be good.

We did not identify ceiling effects. During testing, one patient each had the lowest and highest possible score. With retesting, no patient had the lowest possible score, whereas two patients had the highest possible score.

The internal consistency for the total Qualiveen and SF-Qualiveen can be considered to be good because Cronbach's alpha coefficients were 0.87 and 0.84, respectively. Some disparities were found between domains. Whereas the domains "bother with limitations", "feeling" and "fears" demonstrated good internal consistency, the internal consistency of the domain "frequency of limitations" needs to be considered as moderate. Table 2 presents more detailed data of this analysis.

Table 1 Demographic and clinical characteristics of patients.

Demographics	Number of participants ($n = 126$)
Age *median (interquartile range)*	46 (32–59)
Male	87 (69%)
Female	39 (31%)
SCI characteristics	
Years after SCI - *median (interquartile range)*	10 (5–14)
ASIA Impairment Scale	
A	55 (44%)
B	6 (4%)
C	16 (13%)
D	49 (39%)
Level of SCI	
Cervical	26 (21%)
Thoracic	78 (62%)
Lumbar	22 (17%)
Mobility	
Full ambulatory	12 (10%)
Limited	39 (31%)
Wheelchair	75 (59%)
Bladder emptying	
No catheter use	10 (8%)
Intermittent catheterization	61 (48%)
Indwelling catheter	55 (44%)

ASIA Impairment Scale American Spinal Injury Association Impairment Scale, *SCI* spinal cord injury.

Table 2 Internal consistency – Cronbach's alpha ($n = 126$ patients after spinal cord injury).

	Qualiveen	SF-Qualiveen
Total score	0.86	0.85
Bother with limitations	0.82	0.81
Frequency of limitations	0.65	0.66
Fears	0.73	0.82
Feeling	0.84	0.79

The reproducibility for the total Qualiveen and SF-Qualiveen as well as that for each domain in both questionnaires was good because the ICCs were high (Table 3).

Post hoc tests for different patient groups based on the ASIA Impairment Scale and the SCI level were performed (Table 4). We showed satisfying construct/criterion validity with statistically significant correlations between the total scores of the Qualiveen/SF-Qualiveen and the ICIQ-SF. We indicated optimal internal consistency, with a Cronbach's alpha coefficient of > 0.7, and positive reproducibility, with an ICC > 0.8.

Discussion

With this study, we provided the first Polish questionnaires to evaluate quality of life specifically in individuals after SCI. The Polish Qualiveen and SF-Qualiveen were characterized by good content and construct/criterion validity as well as good internal consistency and reproducibility. The measurement properties confirmed the proper use of the questionnaires for clinical practice and future research in Poland. Now, following SCI, Polish-speaking patients can use the Qualiveen and SF-Qualiveen to directly measure the effect of bladder symptoms on their quality of life.

The Polish Qualiveen and SF-Qualiveen correlated well with the ICIQ-SF, which showed that they successfully tested what they claimed to analyze. The validation study showed that the Polish versions of the questionnaires had a high discriminative power and measured the same general construct, with Cronbach's coefficient that was higher than 0.8. Reproducibility of the validated questionnaires has been shown with ICCs greater than 0.8. This corresponds with the results of other validation studies using the Qualiveen and SF-Qualiveen in patients with SCI [9]. Special statistical consideration for patients after SCI to analyze the impact of ASIA Impairment status, SCI level, and bladder emptying method on construct/criterion validity, internal consistency, and reproducibility showed that the Polish Qualiveen and SF-Qualiveen have good measurement properties, regardless of these features. We did not detect a statistically significant correlation between SF-Qualiveen and ICIQ-SF in patients with ASIA C impairment, and this may be related to the small size of this subgroup, which was insufficient to conduct a powerful statistical analysis.

SCI significantly decreases patients' quality of life. In urology, monitoring patients' perspectives about bothersome symptoms and their impact on quality of life is recommended using patient self-completed questionnaires [1, 4]. The use of validated questionnaires also helps to plan the optimal treatment, which is strongly connected with the quality of life. Thus, medical professionals must keep abreast of their patients' urinary-affected quality of life. The discriminating power and the test–retest reliability showed that the Polish Qualiveen and SF-Qualiveen can be reliably used for routine clinical practice and that they are also excellent tools for research trials. We suggest that our validated questionnaires should be implemented into the urological management of patients after SCI in all urology and rehabilitation departments in Poland. The Polish versions of Qualiveen and SF-Qualiveen should now be considered to be an alternative to the ICIQ-SF in the clinical assessment of individuals with SCI.

The Qualiveen and SF-Qualiveen are questionnaires that are designed with special attention to neurourological patients, especially those after SCI. The Qualiveen is a comprehensive instrument that enables an extensive evaluation of the patient. The SF-Qualiveen is a more practical short form that supports large-scale population surveys by

Table 3 Test–retest reliability (reproducibility) - intraclass correlation coefficients (ICCs) ($n = 126$ patients after spinal cord injury).

	Qualiveen	SF-Qualiveen
Total score	0.92	0.93
Bother with limitations	0.89	0.85
Frequency of limitations	0.77	0.75
Fears	0.91	0.89
Feeling	0.85	0.88

Table 4 Post hoc tests for different subgroups of patients after spinal cord injury.

	Number of participants	Cronbach's Alpha coefficients	ICCs	Correlation between scores of Qualiveen and ICIQ-SF	Correlation between scores of SF-Qualiveen and ICIQ-SF
ASIA Impairment Scale					
A	55 (44%)	0.89–0.95	0.96	$r = 0.625$, $p < 0.001$	$r = 0.599$, $p < 0.001$
B	6 (4%)	0.81–0.86	0.89	$r = 0.703$, $p = 0.023$	$r = 0.728$, $p = 0.035$
C	16 (13%)	0.79–0.83	0.84	$r = 0.684$, $p = 0.049$	$r = 0.657$, $p = 0.061$
D	49 (39%)	0.84–0.89	0.94	$r = 0.712$, $p < 0.001$	$r = 0.656$, $p < 0.001$
SCI level					
Cervical	26 (21%)	0.92–0.98	0.97	$r = 0.797$, $p < 0.001$	$r = 0.738$, $p < 0.001$
Thoracic	78 (62%)	0.85–0.89	0.93	$r = 0.617$, $p < 0.001$	$r = 0.611$, $p = 0.01$
Lumbar	22 (17%)	0.81–0.86	0.92	$r = 0.721$, $p = 0.005$	$r = 0.681$, $p = 0.03$
Bladder emptying					
No catheter use	10 (8%)	0.89–0.93	0.93	$r = 0.792$, $p = 0.01$	$r = 0.713$, $p = 0.014$
Intermittent catheterization	61 (48%)	0.89–0.91	0.91	$r = 0.604$, $p = 0.001$	$r = 0.582$, $p = 0.001$
Indwelling catheter	55 (44%)	0.84–0.91	0.92	$r = 0.792$, $p < 0.001$	$r = 0.762$, $p < 0.001$

ASIA Impairment Scale American Spinal Injury Association Impairment Scale, *ICC* Intraclass Correlation Coefficient, *SCI* Spinal Cord Injury.

decreasing the time and financial costs of data collection [7]. We decided to translate, culturally adapt, and validate both forms because of the paucity of such measures in Poland and their use in clinical and research settings.

A strength of this study is that these patients are a homogenous group with the same general condition (i.e. SCI). The study results, therefore, clearly show the validity and reliability of the Qualiveen and SF-Qualiveen in this specific population of patients. In other validation studies of the Qualiveen and SF-Qualiveen, authors included different neurourological individuals, and the results from the different subgroups were not individually described [16]. This may lead to a significant bias because perception of the quality of life may vary across different patient populations. For example, those with congenital neurological diseases such as meningomyelocele should not be analyzed together with those with acquired diseases such as SCI or even MS [16]. Thus, current validation studies should be conducted in specific patient groups.

Polish is the second most-spoken Slavic language after Russian. The present study is the first rigorous adaptation and validation of the Qualiveen and SF-Qualiveen in the family of Slavic languages. Use of the questionnaires, which were obtained in this study, outside of Poland needs to be considered because there are approximately 20 million people of Polish ancestry living outside of Poland, many of whom still consider Polish to be their first language; this makes the Polish diaspora one of the largest and most widely dispersed in the world [17]. Although the language may be the same, the phrasing, idioms, and culture can vary. Thus, for Polish-speaking patients with SCI who reside outside Poland, we propose a new validation process before introducing the Polish Qualiveen and SF-Qualiveen. However, the Polish language is characterized by its consistency, which may support use of the Polish versions outside of the country if no other tool is available.

There are several limitations that need to be considered. First, we were not able to investigate the responsiveness of the Qualiveen and SF-Qualiveen. In the clinic and research laboratory, the Polish Qualiveen and SF-Qualiveen instruments may not be flawless in appraisal of the effects of treatments on urinary quality of life. However, responsiveness of the Qualiveen and SF-Qualiveen has been already shown in other studies [18]. The presented Polish versions of the questionnaires should be especially considered in cross-sectional and observational studies. Second, there is no other validated questionnaire to measure the urinary disorder-specific quality of life in neurogenic individuals in Poland. For lack of an ideal measure, we selected the ICIQ-SF questionnaire, which is a commonly used questionnaire and suboptimal medium that has already been used and tested as a reference instrument in other validation studies involving the Qualiveen and SF-Qualiveen [16, 19, 20]. Third, included patients represent a highly selected cohort that was treated at a single, high-volume academic center and reference institute of neurourology for southern Poland. Thus, the obtained results may not be fully transferable to all clinical settings. However, the group of patients with SCI at our institution was relatively large. Furthermore, the Qualiveen and SF-Qualiveen demonstrated optimal measurement properties in the multicenter original and in the adapted validation studies [5, 7, 16]. Although we did not include a control group (non-neurogenic patients) in this study, a control group is not required for successful translation, adaptation, and validation [14]. A control group was not included during original development of both questionnaires [5, 7]. Our implementation process for both questionnaires followed all the required criteria for the validation of an instrument, detailed by Terwee et al [14], because our study introduces the Qualiveen and SF-Qualiveen into the family of Slavic languages. Furthermore, ceiling effects were not observed. Fourth, we did not complete the retest phase in seven patients because they did not complete the second set of questionnaires. However, the Qualiveen and SF-Qualiveen scores of these patients from the test phase were similar to the scores of the included patients (test and retest). Demographics and clinical characteristics of these seven patients were also not different from the other patients who were included in the study. Therefore, we did not expect selection bias to be an important consideration.

Concluding, the present study provides reliable, valid, and consistent Polish instruments to measure urinary disorder-specific quality of life in patients after SCI. The measurement properties of the Polish versions are similar to the original versions of the Qualiveen and SF-Qualiveen. These instruments will support both clinical practice and research in Poland.

Data archiving

All data generated or analysed during this study are included in this published article and its supplementary information files.

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Author contributions MP and PCH conceived the concept of the study. MP contributed to the design of the research. All authors were

involved in data collection. MP analyzed the data. MP and PCH coordinated funding for the project. All authors edited and approved the final version of the manuscript.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Statement of ethics We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research. The study was approved by the research committee of Jagiellonian University Medical College (1072.6120.222.2019) and registered with ClinicalTrials.gov (NCT04185792).

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