

Validation of Hebrew Versions of the Pelvic Floor Distress Inventory, Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire, and the Urgency, Severity and Impact Questionnaire

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Objective: Validated objective tools in the native languages of investigated populations are important for evaluating effects of medical disorders and treatments. The aim of our study was to validate a Hebrew version of the validated questionnaires commonly used in the field of urogynecology.

Methods: This is a 2-step, prospective, multicenter study. Using a back-translation method, Hebrew-language versions of the following questionnaires were developed: Pelvic Floor Distress Inventory, Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire, and the Urgency, Severity and Impact Questionnaire. The questionnaires were administered in both Hebrew and English to 56 bilingual patients with pelvic organ prolapse and/or urinary incontinence. To test reliability, the participants were asked to refill the questionnaires in Hebrew 2 weeks later. Scores from the Hebrew and English versions were compared, using the Wilcoxon signed rank test. Correlations between versions were assessed by the Spearman test. $P < 0.05$ or less was considered significant.

Results: Scores from the Hebrew and English versions were found to be highly correlated, $\rho = 0.61-0.96$; $P < 0.001$. No differences in total scores were detected between the 2 versions of the 3 questionnaires and their subcategories ($P > 0.05$). Cronbach alpha values were good (0.65–0.96) for all questionnaires. Scores were highly correlated when the patients refilled the questionnaires in Hebrew ($\rho = 0.81-0.98$; $P < 0.001$).

Conclusions: This study provides validated Hebrew versions of 3 well-accepted pelvic floor questionnaires. These questionnaires will enable standardization when assessing women with pelvic floor dysfunction.

Key Words: quality of life questionnaires, validation, Hebrew, pelvic organ prolapse, urgency, sexual function

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The World Health Organization Quality of Life project was initiated in 1991, with the aim of developing an international cross-culturally comparable quality-of-life (QOL) assessment instrument. From the convention emerged the constitution:

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Health is not only the absence of infirmity and disease but also a state of physical, mental, and social well-being.

Urogynecology deals mainly with improving patients' QOL. Pelvic floor dysfunction affects many aspects of women's lives: physical status, cognition, emotional and social functioning, pain, sexual functioning, and health perception. Until recently, there were only few and insufficient means of evaluating the relationship between symptoms and objective findings of pelvic floor dysfunction and the effect of surgical or conservative treatment on such symptoms. The development of QOL questionnaires has enabled more accessible assessment of the severity of symptoms and responses to treatment over time. These questionnaires need to be reliable, valid, responsive, and feasible and should quantify QOL issues. However, the validity of such tools is dependent on patients' ability to understand the questions. For appropriate analysis of findings and comparison among populations around the world, validation processes are required in the native languages of the target populations.

Currently, there are no validated Hebrew questionnaires that evaluate the severity of pelvic floor dysfunction and its effect on QOL. Although there are versions of Hebrew-translated QOL questionnaires, mere translation from English to Hebrew by bilingual individuals does not necessarily retain the meaning and validity of original questionnaires. For a translation to be comparable in different populations, a validation process of the translated version is required.

The aim of the current study was to translate and validate Hebrew versions of 3 commonly used validated questionnaires in the field of urogynecology. The questionnaires evaluate symptoms of pelvic organ prolapse, colorectal dysfunction, urinary incontinence, urgency symptoms, and sexual function.

MATERIALS AND METHODS

This is a multicenter prospective study. The study followed a 2-step protocol of translation followed by validation. English versions of 3 questionnaires were translated into Hebrew by the back-translation method.^{1–3} The process comprised translation from English to Hebrew, back translation of the Hebrew versions to English, and comparison of the English back-translated versions with the original English versions. Translation to Hebrew and back to English were performed by different translators who are fluent in English and Hebrew medical terminology. The back translations were compared with the original English versions by experts in urogynecology who speak both languages fluently to ensure that no meaning or concepts were lost during the translation process.

Inclusion criteria for participation in the study were women older than 18 years who stated that they were able to read both Hebrew and English and who were referred to a urogynecology with a primary complaint of pelvic floor disorder. Patients were

TABLE 1. Sociodemographic Data and Medical History

	Value
Age, mean ± SD	52 ± 9.98
Parity	3 (0–6)
BMI, mean ± SD	26 ± 5.62
Menopause, n (%)	38 (62.5)
Education level, n (%)	
Academic	42 (74.5)
High school	14 (25.5)
BMI, Body mass index.	

recruited from February 2010 to June 2011 from the urogynecology division of one of the 4 participating medical centers. After signing informed consent, each participant was asked to fill the questionnaires in English and in Hebrew. To avoid an order effect bias, the order of delivery of the 2 versions was determined randomly for each patient.

Instruments for Validation

1. The PFDI-20 is a validated short form of the Pelvic Floor Distress Inventory, which was designed to assess the impact of pelvic floor disorders on QOL.³ It consists of 20 questions with 3 subscales: the Pelvic Organ Prolapse Distress Inventory 6, the Urinary Distress Inventory 6, and the colorectal and anal distress inventory (CRADI 8).³ Responses are graded from 1 (not at all) to 4 (quite a bit). Scoring is from 0 (least distress) to 100 (greatest distress). Each scale can be used separately for specific assessment. The sum of the 3 subscales ranges from 0 to 300, with higher numbers indicating greater distress.³
2. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12) is a short form of a condition-specific, reliable, validated, self-administered instrument evaluating sexual function in women with pelvic organ prolapse and/or urinary incontinence.¹ The PISQ-12 has been correlated with the longer version and has demonstrated validity and reliability as an instrument for assessing treatment and intervention effects. Questions 1 to 4 are scored from 0 (never) to 4 (always), and questions 5 to 12 are scored in reverse. A higher total score indicates better sexual function.¹
3. The Urgency, Severity and Impact Questionnaire (USIQ) is a validated patient-oriented questionnaire assessing the

severity of urgency symptoms and their impact on QOL.² The questionnaire was designed for self-administration. It consists of 2 parts with an initial filter question. The first part, the Urgency Severity Questionnaire, consists of 5 items, which inquire about urgency symptoms and severity. The second part, the Urgency Impact Questionnaire-Quality of Life, consists of 8 questions, which inquire about bother and health-related QOL.^{2,4}

To evaluate the reliability of the questionnaires, the participants were asked to refill the Hebrew versions 2 weeks later. Since not all patients arrived for follow-up visits, some questionnaires were posted by mail with prepaid stamped envelopes.

Clinical data and medical history were retrieved from patients' electronic charts. Institutional review board approval was obtained in each participating medical center.

Statistical Analysis

Data were analyzed using SPSS version 18 (Chicago, IL). The Wilcoxon signed rank test was used to compare the mean total scores of the original English versions of the questionnaires and their translated forms. The Spearman correlation test was used to evaluate the agreement between participants' scores on the translated and the English versions. Reliability of the translated questionnaires was evaluated using Cronbach α . All tests were 2 tailed and considered significant at the 0.05 level.

Sample Size Estimate

Based on previous research that validated the Spanish translation of the Pelvic Organ Prolapse Incontinence and Sexual Questionnaire,⁵ we anticipated that 30 bilingual subjects would be needed to complete validation of the Hebrew questionnaires.

RESULTS

Overall, 56 women participated in the study. Of the 56 women, 54 were available to validate the PFDI questionnaire, 56 the PISQ, and 54 the USIQ. Most of the patients presented to our clinics with primary complaints of urinary incontinence (58%) or pelvic organ prolapse (32%), and the rest with chronic pelvic pain and fecal incontinence (10%). Sociodemographic and medical history characteristics are presented in Table 1.

The Hebrew versions of the Pelvic Organ Prolapse Distress Inventory 6, CRADI-8 and Urinary Distress Inventory 6, PISQ-12, Urgency Severity Questionnaire, and Urgency Impact Questionnaire-Quality of Life were found to be highly correlated

TABLE 2. Measures of the Validity and Reliability of Hebrew Versions of QOL Questionnaires

Instrument	Correlations Between Hebrew and English Versions (Spearman ρ)	Differences Between Mean Total Scores of Hebrew and English Versions (Wilcoxon Signed Rank Test)	Test-Retest Reliability (Spearman ρ)	Differences Between Mean Total Scores of Repeated Hebrew Testing (Wilcoxon Signed Rank Test)	Cronbach α
POPDI-6	0.61 ($P < 0.001$)	21 ± 22 vs 24 ± 19 ($P > 0.05$)	0.81 ($P < 0.001$)	21 ± 22 vs 26 ± 25 ($P > 0.05$)	0.85
CRADI-8	0.76 ($P < 0.001$)	13 ± 17 vs 14 ± 17 ($P > 0.05$)	0.72 ($P < 0.001$)	13 ± 17 vs 16 ± 15 ($P > 0.05$)	0.65
UDI-6	0.71 ($P < 0.0001$)	26 ± 22 vs 26 ± 24 ($P > 0.05$)	0.73 ($P < 0.0001$)	26 ± 22 vs 33 ± 17 ($P > 0.05$)	0.71
PISQ	0.78 ($P < 0.0001$)	35 ± 12 vs 37 ± 15 ($P > 0.05$)	0.92 ($P < 0.0001$)	35 ± 12 vs 36 ± 6 ($P > 0.05$)	0.95
USIQ-S	0.90 ($P < 0.0001$)	39 ± 26 vs 43 ± 29 ($P > 0.05$)	0.90 ($P < 0.0001$)	39 ± 2 vs 46 ± 19 ($P > 0.05$)	0.96
USIQ-QOL	0.98 ($P < 0.0001$)	42 ± 27 vs 44 ± 26 ($P > 0.05$)	0.77 ($P < 0.0001$)	42 ± 27 vs 56 ± 45 ($P > 0.05$)	0.97

POPDI 6, Pelvic Organ Prolapse Distress Inventory 6; UDI, Urinary Distress Inventory; USIQ-QOL, Urgency Impact Questionnaire-Quality of Life; USIQ-S, Urgency Severity Questionnaire.

to their original English versions: Spearman ρ range, 0.61–0.98; $P < 0.0001$ (Table 2). Mean total scores did not differ significantly between the English and Hebrew versions for all the investigated questionnaires (Table 2). There were no statistically significant differences in the mean scores of the investigated questionnaires among the patients from the 4 different hospitals.

Test-retest reliability was found to be highly correlated for the investigated questionnaires: Spearman ρ range, 0.72–0.92; $P < 0.0001$ (Table 2). There was no statistical difference between the total scores of repeated measures of all the aforementioned questionnaires. The internal consistency of all the questionnaires was good: Cronbach α range, 0.65–0.97 (Table 2).

DISCUSSION

Our study is the first to validate Hebrew versions of QOL questionnaires in the field of pelvic floor disorder. Our validation process included a 2-step protocol of translation followed by validation. We selected questionnaires that involve different aspects of urogynecology.

The PFDI, PISQ-12, and USIQ were initially developed in English and were validated for English-speaking women. Recently, the PFDI and PISQ-12 were successfully translated and validated in several other languages, including Chinese, French, Portuguese, Spanish, Swedish, and Turkish.^{6–12} For the USIQ, the current Hebrew version is its first validated translation. We selected these particular questionnaires because they evaluate different aspects of pelvic floor disorders, are relevant to QOL issues, and have demonstrated capability of detecting changes over time and between pretreatment and posttreatment. Furthermore, the PFDI and PISQ-12 have already demonstrated validity in translated forms for women of different nationalities and cultural backgrounds.

Translating QOL tools to Hebrew enables comparison among different cultural groups within the country and promotes understanding of patient priorities and of the capability of improving QOL. Validating translations of QOL questionnaires enables the evaluation of Israeli patients according to internationally accepted criteria.

We combined data from 4 medical institutions from different parts of the country, serving a variety of communities with different backgrounds, to strengthen the validation process. A limitation of this study is possible recall bias. The fact that each participant served as her own control may have increased agreement between the English and Hebrew versions. We attempted to minimize this bias by randomizing women to fill in English or Hebrew versions first. Our investigation of the test-retest reliability of the Hebrew versions of the questionnaires showed good reliability. However, reliability of CRADI-8 was relatively low, Cronbach $\alpha < 0.7$. Comparison between the English version and the Hebrew version demonstrated a good correlation level: $\rho = 0.76$. This article describes the validation process of the PFDI, PISQ12, and USIQ questionnaires using a known and established back-translation

technique. Reliable and valid Hebrew versions of these QOL tools were produced (the questionnaires are available on www.gynecology.co.il). We expect that these tools will be of benefit in research projects that explore the characteristics of Israeli women and their response to different treatment modalities.

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