Original article

Validation of the patient global impression of improvement questionnaire to the Hebrew language

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Abstract: *Objectives:* Validated objective tools play an important role in the evaluation of patients suffering from pelvic organ prolapse and in assessing surgical outcome. The aim of this study was to validate the Hebrew version of the Patient Global Impression of Improvement (PGI-I) questionnaire. *Methods*: A retrospective cohort study including all patients who underwent transvaginal hysterectomy and two-stitch utero-sacral ligament suspension (USLS) between October 2010 and September 2013. For the validation process a back translation method was used. A Hebrew version of the PGI-I questionnaire was created. Both Hebrew and English versions were used in a group of bilingual patients for validity. The test-retest method was then used for internal validity. *Results*: Sixty-six patients had undergone transvaginal hysterectomy and utero-sacral ligament suspension in the study period. Fifty nine of them completed the PGI-I questionnaire. A total of 22 bilingual patients participated in the validation process. The Hebrew version of the PGI-I questionnaire was found to be highly correlated with the English version with 100% correlation between the Hebrew and the English PGI-I answers. The test-retest measure in the validation process yielded a spearman correlation coefficient of 0.84 ($P<0.0001$) between the first Hebrew PGI-I, and the second Hebrew PGI-I, as answered two weeks later or more. *Conclusions:* Transvaginal hysterectomy and two-stitch uterosacral ligament suspension has high short term cure and patient satisfaction rates. The PGI-I questionnaire, now validated to Hebrew is a powerful tool to evaluate patient satisfaction.

Keywords: Pelvic organ prolapse (POP); Urogynecology; Pelvic medicine and reconstructive surgery; Patient global impression of improvement questionnaire; Vaginal hysterectomy.

INTRODUCTION

Assessment of surgical outcomes comprises of both objective and subjective measures. While the objective measures are usually clear postoperative outcomes, assessment of subjective improvement and patient satisfaction may sometimes be difficult to define.

Pelvic organ prolapse (POP) affects up to 50% of women in the United States and varies widely among different ethnic populations around the world, with ranges from 30% to 93%[1-3]. These numbers are expected to rise as population ages[4]. The assessment of patients presenting with POP includes a thorough medical history, physical exam as well as additional tests as indicated. Objective as well as subjective measures are imperative in order to give an accurate evaluation of patients' clinical status. Over the years, symptoms and quality of life (QOL) questionnaires have been developed and have become an essential part of symptom assessment as well as a measure of patients' response to treatment. For these questionnaires to be valid, patients answering them must understand the questions asked and need be able to comprehend the concepts presented. Comparison of populations around the world is only possible with proper translation and validation of such questionnaires into the native language of the population being treated.

The Patient Global Impression of Improvement (PGI-I) questionnaire is an important tool used to evaluate patients who undergo treatment for stress urinary incontinence[5]. It is a transition scale that is a single question asking the patient to rate their urinary tract condition now, as compared with how it was prior to beginning treatment on a scale from 1= Very much better, to 7= Very much worse. It is a simple, direct, easy to use scale that is intuitively understandable to patients and clinicians[5]. Although originally designed for women with stress urinary incontinence, it has widely been used in the evaluation of patients' satisfaction following POP repair and was recently validated in this population[6-8].

The aim of this study was to validate the PGI-I questionnaire in the Hebrew language in a population of patients who underwent trans-vaginal hysterectomy (TVH) with utero-sacral ligament suspension (USLS) for POP.

MATERIALS AND METHODS

This is a prospective study following a 2 step protocol of translation. Included were patients over the age of 21, fluent in both English and Hebrew who underwent TVH and USLS between October 2010 and September 2013 at the division of Female Pelvic Medicine and Reconstructive Surgery at Hadassah Medical Center, Ein Kerem, Jerusalem, Israel. The study was approved by the Institutional Review Board.

Patients were presented with the PGI-I questionnaire, at least three months after surgery, either in the clinic or by a telephone interview. Women, who were both Hebrew and English speakers, were questioned a second time, two weeks at least after the first PGI-I, by mail, for validation purposes alone.

An English version of the PGI-I questionnaire was translated into Hebrew by the back-translation method. This process comprised translation from English to Hebrew, back translation of the Hebrew version to English, and comparison of the English back-translated version with the original English version. The translation process was performed by different translators who were fluent in both English and Hebrew medical terminology. The back translation was compared with the original English version by experts in Urogynecology who are fluent in both English and Hebrew to ensure that no meaning or concepts were lost during the translation process.

After signing an informed consent, each participant was asked to answer the questionnaire 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. To evaluate the reliability of the questionnaire, the test-retest technique was used.

A pre-stamped envelope with another questionnaire was given to each participant of the validation process. Participants were asked to fill out the PGI-I questionnaire again, in an interval of at least two weeks.

For statistical analysis SPSS version 18 (Chicago, IL) was used. P value of 0.05 or less was considered statistically significant. All tests were two-tailed, establishing a relationship between the variables, but without reference to directionality. The Spearman correlation test was used to assess agreement between the English and translated Hebrew version.

TABLE 1. Patient demographics and baseline characteristics.

N=22	Value
Mean Age (±SD)	71.31 (±8.68)
Parity (Mean (range))	3.41 (1-9)
Menopausal (%)	86.4
Sexually active (%)	59.1
Smoker (%)	9.1

RESULTS

Sixty six patients underwent TVH with USLS out of which 59 patients answered the PGI-I questionnaire. Of those, 22 were bilingual for both English and Hebrew, and 19 answered the Hebrew PGI-I a second time. Patients' demographic data are presented in table 1. Mean age was 71.3 years and median parity was 3.4 (range 0-9). Eighty six percent were menopausal and 59.1% were sexually active. All patients had undergone vaginal hysterectomy and two-stitch USLS.

At a median follow-up of 23.6 (2-155) weeks, nearly all POP-Q measures were significantly improved compared to preoperatively. Specifically, significant improvement was noted in the three most important points (Ba, C and Bp) with all differences being statistically significant. Anatomical cure, defined as no POP-Q point above stage 0-1, was 83.6%. Clinical cure rate was 96.4%. Most patients had concomitant procedures.

Ninety-six percent of patients stated that they felt much better or very much better postoperatively. The average time between surgery and the PGI-I questionnaire was approximately 517 days. Patients' satisfaction according to the PGI-I questionnaire are presented in table 2.

The Hebrew version of the PGI-I questionnaire was found to be highly correlated with the English version with 100% correlation between the Hebrew and the English PGI-I answers (n=22). The test-retest measure in the validation process yielded a spearman correlation coefficient of 0.84 ($P<0.0001$) between the first Hebrew PGI-I, and the second Hebrew PGI-I, as answered two weeks later or more (n=19).

DISCUSSION

In this study we present validation of the PGI-I questionnaire to the Hebrew language. Symptoms and quality of life questionnaires as well as evaluation of patient satisfaction are becoming an inseparable part of surgical outcome assessment. POP by nature is clinically important due to its detrimental effect on women's quality of life. Therefore, subjective assessment of treatment outcome is crucial in this case. Validation of assessment tools to the native language is imperative in order to guarantee the highest standard of medical care. The PGI-I questionnaire is highly accessible with its main advantage being its simplicity compared to other more cumbersome questionnaires. It gives a good indication to the patients' overall clinical status with one easy to answer question.

TABLE 2. Patient satisfaction according to PGI-I.

PGI-I frequencies n (%)	
Very much better	48 (81.4)
Much better	9 (15.2)
A little better	0 (0)
No change	1 (1.7)
A little worse	0 (0)
Much worse	0 (0)
Very much worse	1 (1.7)
PGI-I success defined as answers 1 or 2 n (%)	57 (96.6)

Our results showed very high correlation between the English and Hebrew versions of the questionnaire as well as test-retest reliability. The main strengths of the study include the standard validation method used as well as the long term follow up achieved. The latter is an important point since the PGI-I questionnaire was shown to be valid in the Hebrew language for long term follow up as well.

The main limitation of this study is recall bias. Moreover the patients in this study were assigned as their own control a fact which may increase the rate of similar answers given between the English and Hebrew versions. Our solution to this was randomization of the order in which the English and Hebrew versions were presented to the patients in the study. Another limitation is the fact that since most women expressed high satisfaction, variability of patients' answers was low. This may have had an effect on the validation process, though we believe this point does not undermine the results of the study.

In conclusion the PGI-I questionnaire is now validated to the Hebrew language. Using this tool, we have shown that two-stitch vaginal uterosacral ligament suspension is a POP repair procedure associated with high satisfaction rate. We believe this questionnaire may prove helpful to clinicians in evaluating this important aspect of patient-centered outcome.

DISCLOSURE STATEMENTS

There was no conflict of interest, informed patient consent was obtained, and the study was approved by the local ethical committee.

REFERENCES

1. Shull BL, Bachofen C, Coates KW, Kuehl TJ. A transvaginal approach to repair of apical and other associated sites of pelvic organ prolapse with uterosacral ligaments. Am J Obstet Gynecol 2000; 183 (6): 1365-1374.
2. Nygaard I, Barber MD, Burgio KL et al. Pelvic Floor Disorders Network (2008) Prevalence of symptomatic pelvic floor disorders in US women. JAMA; 300(11):1311-6.
3. Hendrix SL, Clark A, Nygaard I, Aragaki A, Barnabei V, McTiernan A. Pelvic organ prolapse in the Women's Health Initiative: gravity and gravidity. Am J Obstet Gynecol 2002; 186: 1160-6.
4. Eilber KS, Alperin M, Khan A et al. Outcomes of vaginal prolapse surgery among female medicare beneficiaries: the role of apical support. American college of obstetricians and gynecologists 2013; 122 (5): 981-987.
5. Yalcin I, Bump R. Validation of two global impression questionnaires for incontinence. Am J Obstet Gynecol 2003; 189: 98-101.
6. Lawndy SS, Kluivers KB, Milani AL, Withagen MI, Hendriks JC, Vierhout ME. Which factors determine subjective improvement following pelvic organ prolapse 1 year after surgery? Int Urogynecol J. 201; 22 (5): 543-9.
7. Srikrishna S, Robinson D, Cardozo L. A longitudinal study of patient and surgeon goal achievement 2 years after surgery following pelvic floor dysfunction surgery. BJOG. 2010; 117 (12): 1504-11.
8. Srikrishna S, Robinson D, Cardozo L. Validation of the Patient Global Impression of Improvement (PGI-I) for urogenital prolapse. Int Urogynecol J. 2010; 21 (5): 523-8.

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