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ORIGINAL ARTICLE

Validation of the Russian Version of the Prolapse Quality-of-life Questionnaire and its Application to Assess the Impact of Pelvic Organ Prolapse on Quality of Life and the Effect of Treatment in Women Undergoing Reconstructive Surgery

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Abstract

Introduction and hypothesis The objective was to validate the translated Russian version of the prolapse quality-of-life (P-QoL) questionnaire and test its applicability to assess the impact of pelvic organ prolapse (POP) on QoL and the effect of treatment in women undergoing reconstructive surgery.

Methods Following a forward- and back-translation of the original English P-QOL questionnaire into Russian, the translated questionnaire was reviewed by a group of patients as well as an expert panel. Women with POP who were admitted to a university hospital for reconstructive surgery were recruited. All the women completed the P-QoL questionnaire, Pelvic Floor Distress Inventory (PFDI-20) and 36-Item Short Form Survey (SF-36) questionnaires before surgery. Clinical data and POP Quantification (POP-Q) Index according to the International Continence Society were obtained. Psychometric properties of the questionnaire were assessed.

Results A total of 303 women with POP were included in the study. Most patients presented with POP-Q >2. The P-QoL questionnaire demonstrated good psychometric properties. High internal consistency was shown in all domains (Cronbach's alpha coefficient from 0.65 to 0.92). The test–retest reliability confirmed a highly significant stability between the total scores for each domain. Significant correlations of the P-QoL domains with the PFDI-20 and SF-36 scales ($p < 0.05$) were obtained, demonstrating satisfactory convergent validity. Discriminative construct validity was proved by the differences in the mean scores for P-QoL domains across POP-Q stages ($p < 0.05$): general health perceptions, role limitations, physical limitations, social limitations and severity measures were significantly higher for POP-Q stages 3 and 4 than for POP-Q stage 2 ($p < 0.01$); general health perceptions and severity measures were higher for POP-Q stage 4 than for POP-Q stage 3 ($p < 0.05$); sleep/energy was higher for POP-Q stage 3 than for POP-Q stage 2 ($p < 0.05$). Significant improvement of QoL in the 2 months after surgery ($p < 0.05$) indicated that the P-QoL questionnaire is sensitive to change.

Conclusions The Russian version of the P-QoL questionnaire is characterized by appropriate psychometric properties. The P-QoL questionnaire is a useful tool for describing the QoL profile in women with POP before reconstructive surgery and evaluating treatment outcomes after the procedure.

Keywords Quality of life · Pelvic organ prolapse · Reconstructive surgery · Questionnaire · Validity · Reliability · Responsiveness

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Introduction

Pelvic organ prolapse (POP) is a common female disorder. It is mostly benign, but is distressing and disabling, and may be accompanied by significant quality-of-life (QoL) impairment [1–3]. Improvement in QoL is one of the main outcomes in the management of POP [4, 5]. Therefore, QoL is one of

the key outcomes of reconstructive surgery in women with POP and may be of value for decision making [6]. A valid way to evaluate the patient´s condition and treatment effect from the patient's perspective is the use of condition-specific QoL questionnaires [7]. The prolapse quality-of-life (P-QoL) questionnaire is one of only a few validated and reliable condition-specific questionnaires developed to assess the impact of pelvic organ prolapse on the QoL of patients [8]. The questionnaire covers various domains of life, including general health, prolapse impact, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep/energy disturbances and prolapse severity. The P-QoL questionnaire has been successfully translated into various languages, and has proved to be a simple, valid and reliable instrument of assessing symptom severity, QoL and treatment outcomes in women with POP [9]. The lack of a validated Russian version of the P-QoL questionnaire limits studies evaluating the symptom burden and QoL impairment in women with POP before treatment as well as measuring outcomes of reconstructive surgery in Russia.

The aim of the study was to develop a Russian version of the P-QoL questionnaire and to evaluate its psychometric properties; namely, validity, reliability and sensitivity to change. We also aimed to test its applicability as a reference instrument to assess the impact of POP on QoL and the effect of treatment in women undergoing reconstructive surgery.

Materials and Methods

Translation and Cultural Adaptation

After receiving the approval from the author of the P-QoL questionnaire, the cross-cultural adaptation was developed, according to the international guidelines [10]. At the first stage, the original version of the P-QoL questionnaire in English was translated independently into Russian by two English–Russian translators, native Russian-speaking, with experience in translating medical documents, to produce two Russian versions that were conceptually equivalent to the original questionnaires. These translations were reviewed by the Expert Committee and a reconciled version of the P-QoL questionnaire in Russian was created. Then the backward translation of the reconciled version of the P-QoL questionnaire into the English was conducted by another bilingual professional Russian–English translator, native English-speaking. At the next stage, the original version, the reconciled version in Russian and the backward translation were reviewed by the Expert Committee to ensure that the original content was retained and to reveal any misunderstandings in the Russian version. As a result of the harmonization stage the preliminary Russian version of the P-QoL questionnaire was produced. Afterwards, this version was tested in a pilot study for readability, convenience of use, clearness and equivalence through its administration to 10 native Russian-speaking women with POP. The women filled out the questionnaire on their own, and afterwards, they were interviewed face to face in order to identify and correct potential understanding difficulties of the items, as well as to judge the quality of the cultural adjustment. Minor discrepancies were identified and amended, and as a result of cognitive debriefing, the Russian version of the P-QoL questionnaire was obtained.

Study Design and Participants

This was an observational study carried out at the urogynecology unit of Saint-Petersburg State University Hospital (St. Petersburg) between May and October 2023. The women with POP who were admitted to the unit for reconstructive surgery were invited to participate in the study. The inclusion criteria were as follows: age ≥18 years old; confirmed diagnosis of POP; indication for reconstructive surgery; the ability of a woman to fill out the questionnaires. The exclusion criteria were: current pregnancy, neurological diseases or mental incapacity to properly fill out the questionnaires. All participants gave their written informed consent. There were the following types of reconstructive surgery: mesh-augmented repair (sacrospinous fixation with apical sling, laparoscopic sacrohysteropexy), native tissue repair (anterior and/or posterior colporrhaphy, Manchester procedure). Before surgery, women who agreed to participate in the study filled out the Russian versions of the following instruments: the P-QoL questionnaire, the Pelvic Floor Distress Inventory (PFDI-20), the 36-Item Short Form Survey (SF-36) and a sociodemographic checklist. Subsequently, women were examined in a supine position using the Pelvic Organ Prolapse Quantification System (POP-Q), approved by the International Continence Society (ICS) [11]. Clinical characteristics were obtained from medical records.

Instruments

The P-QoL questionnaire was developed in 2005 by Digesu et al. for an English-speaking population to assess the severity of POP symptoms and its impact on women's QoL [8]. It contains 20 simple questions representing nine important QoL domains for the concept of pelvic organ prolapse: general health perceptions, prolapse impact, role, physical and social limitations, personal relationships, emotions, sleep/energy and severity measures. The responses in the P-QoL questionnaire ranged from "none/not at all" through "slightly/a little" and "moderately" to "a lot". A four-point scoring system for each item and a total score for each domain ranging between 0 and 100. Higher scores indicate

a greater QoL impairment, and lower scores indicate a good QoL. Additionally, there are 18 questions regarding urinary, bowel and prolapse/vaginal symptoms that do not have an assigned score. The P-QoL questionnaire has been cross-culturally adapted and validated in several languages [9].

The PFDI-20 contains 20 questions divided into three domains: genital prolapse symptoms, colorectal–anal symptoms and urinary symptoms. The PFDI-20 total score and each subscale is interpreted as the higher the score, the worse the distress because of POP [12]. The RAND SF-36 is a widely known generic QoL questionnaire used in healthy subjects and in patients with chronic diseases [13]. The tool is intended for respondents from 14 years of age and consists of 36 questions that form eight scales: physical functioning (PF), role-physical functioning (RPF), bodily pain (BP), general health (GH), vitality (V), social functioning (SF), role-emotional functioning (REF), and mental health (MH). After the transformation of the raw data into scaling QoL scores, the results are ranged from 0 to 100 for each of the eight scales. The higher the score, the better the QoL.

Psychometric Properties and Statistical Analysis

The Russian version of the P-QoL questionnaire was assessed for validity, reliability, responsiveness and feasibility. Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) recommendations were used as a guide for evaluating the psychometric properties [14]. Reliability was assessed by the internal consistency and the test–retest reliability. Internal consistency was measured by means of Cronbach's alpha. The test–retest reliability was assessed by the intraclass correlation coefficient (ICC). For this purpose, 30 women in a stable condition without treatment were asked to complete the questionnaire at their initial visit to the unit and 2 weeks later.

Validity was assessed by the content and construct validity (convergent and discriminant). To prove the content validity of the Russian test-version 7 of the P-QoL questionnaire urologist clinicians participated in a pilot study to judge its ease, convenience, readability and usefulness in assessing POP symptoms and QoL. To test convergent validity the correlations between the P-QoL domains scores, PFDI-20 and SF-36 domains using Spearman's correlation (r) were evaluated. To test the discriminant validity the P-QoL scores of women with different POP-Q stages were compared using ANOVA.

The responsiveness or sensitivity to change was assessed in a subgroup of 57 women who filled out the P-QoL questionnaire twice: at baseline, and 8 weeks after surgery. In order to evaluate responsiveness, the effect size (ES) and the standardized response means (SRM) for the change in scores between pre- and post-surgery were used. The ES is the ratio between the mean change in score of an outcome instrument and the SD of the score of the outcome instrument at the baseline. The SRM is the ratio between the mean change in score of an outcome instrument and the SD of change in score of the outcome instrument. For SRM and ES, a value of 0.2–0.5 was considered small, 0.5–0.8 moderate, >0.8–1.0 good, and >1.0 excellent [15, 16]. An ES and SRM value of more than 0.80 is considered to be the optimal responsiveness of an outcome instrument. To compare scores before and after surgery the Wilcoxon signed-rank test was applied.

For feasibility, we examined the percentage of missing responses to the items across 20 questions of P-QoL domains and to the items across 18 additional symptom questions. If the percentage of missing responses was ≤5, the instrument was considered feasible. Also, the average administration time was calculated.

All statistical tests were two-tailed and a p value less than 0.05 was accepted as the level of statistical significance. All statistical analyses were performed using SPSS 23.0.

Results

Study Participants' Characteristics

A total of 303 women were enrolled into the study. Basic demographic and clinical characteristics of participants are summarized in Table 1. All the patients were symptomatic as they met the criteria for reconstructive surgery. The following types of reconstructive surgery were performed: mesh augmented repair—$n = 211$ (69.6%; sacrospinous fixation with apical sling, $n = 198$; laparoscopic sacrohysteropexy, $n = 13$); native tissue repair—$n = 92$ (30.4%; anterior and/or posterior colporrhaphy, $n = 82$; Manchester procedure, $n = 10$).

Cross-cultural Adaptation

The final version of the Russian P-QoL questionnaire maintains the structure of the original version. The cognitive interviews conducted as part of the translation process showed that most items were well understood by the women. One item and two response options appeared to be difficult to understand as intended. Literal translations did not work as they did not convey the same meaning and are not commonly used in everyday Russian language. After discussion with Expert Committee members and consultation with the author of the questionnaire during decentring the following amendments were made. Item "Please fill out this questionnaire even if you feel you do not have a prolapse" was modified to "Please fill out this questionnaire even if you do not feel a prolapse". The response option "Not applicable" for all items regarding symptoms of prolapse was modified to "No symptom/problem". In the response option "Once a week

Table 1 Sociodemographic and clinical characteristics

Characteristics	Value
Age	
Mean ± SD	58.6 ± 11.7
Median (Q1; Q3)	62 (50; 67)
Range	33–87
Place of living, *n* (%)	
Urban	254 (83.8)
Rural	48 (15.9)
ND	1 (0.3)
Education, *n* (%)	
Primary	3 (1.0)
College or University	127 (41.9)
High	151 (49.8)
ND	22 (7.3)
Family status, *n* (%)	
Married	187 (61.7)
Single	11 (3.6)
Divorced	46 (15.3)
Widow	41 (13.5)
ND	18 (5.9)
Employment, *n* (%)	
Employed	126 (41.6)
Housewife	47 (15.5)
Retired	119 (39.3)
ND	11 (3.6)
Nature of work (for those employed), *n* (%)	
Physical	20 (15.8)
Mental	68 (54.0)
Combined	35 (27.8)
ND	3 (2.4)
Comorbidity Index	
Mean ± SD	2.6 ± 1.9
Median (Q1; Q3)	3 (1; 4)
Range	0–9
Body mass index	
Mean ± SD	28 ± 5.3
Median (Q1; Q3)	27.6 (24.8; 30.4)
Range	16.1–59.5
POP-Q stage, *n* (%)	
2	84 (27.7)
3	204 (67.3)
4	15 (5.0)
Parity, *n* (%):	295 (97.4)
1	77 (26.1)
2	175 (59.3)
3	33 (11.2)
4	10 (3.4)
Duration of complaints related to POP, years	
Mean ± SD	6.6 ± 6.6
Median (Q1; Q3)	5 (3; 10)
Range	0–43

SD standard deviation, *ND* no data, *POP* pelvic organ prolapse, *POP-Q* pelvic organ prolapse quantification, *(Q1; Q3)* interquartile range

Table 2 Test–retest reliability scores for the prolapse quality of life (*P-QoL*) questionnaire

P-QoL domain scores	ICC	95% CI	
		Lower	Upper
General health perceptions	0.67	0.44	0.82
Prolapse impact	0.66	0.41	0.81
Role limitations	0.73	0.52	0.86
Physical limitations	0.76	0.56	0.87
Social limitations	0.62	0.31	0.80
Personal relationships	0.96	0.91	0.98
Emotions	0.79	0.60	0.89
Sleep/energy	0.77	0.58	0.88
Severity measures	0.85	0.72	0.92

ICC interrater correlation coefficient, *95% CI* 95% confident interval

or more" for "How often do you open your bowels?" we changed the wording to "Once a week or rarer". In addition, the position of the response option "Not applicable" for the items of "Personal relationships" domain was placed after other response options as it sounded more natural in Russian. These amendments were approved during the additional cognitive interviews with 3 women and the final version of the Russian P-QoL questionnaire was approved. The Russian P-QoL questionnaire is designed in a three-page format.

Reliability

The P-QoL questionnaire demonstrated excellent internal consistency – Cronbach $\alpha = 0.92$. High internal consistency showed in all domains with a Cronbach's alpha coefficient range between 0.80 and 0.92, except for the "sleep/energy" (0.68) and "severity measures" dimensions (0.65), which were shown to be acceptable. The score of the internal consistency in "general health perceptions" and "prolapse impact" domains could not be calculated, because both domains only have one item. For the test–retest reliability, ICC coefficients ranged from 0.7 to 0.96 for all the domains, excluding social limitations (ICC = 0.62; Table 2). All the values were statistically significant ($p < 0.001$).

Validity

To guarantee adequate content validity, the Russian version of the P-QoL questionnaire was reviewed by seven urologists (mean age 34.6 ± 5.9 years; male/female – 6/1) who agreed that the questionnaire was convenient and useful for assessing the impact of POP of women's QoL and included all the relevant dimensions. The content validity ratio was excellent and its mean value was equal to 1.0. They also agreed on the clarity and simplicity of the tool.

Regarding the convergent construct validity, all P-QoL dimensions showed statistically significant positive mild or moderate correlations with the total PFDI-20 (Table 3). As for correlations with PFDI-20 domains, as expected, for the POP domain, namely Pelvic Organ Prolapse Distress Inventory, they were the highest, and for the bowel domain, namely Colorectal Anal Distress Inventory, the lowest. Also, all P-QoL dimensions, except for "sleep/energy", had significant negative mild or moderate correlations with the majority of SF-36 scales; namely, such dimensions as general health, prolapse impact, role, physical and social limitations, and severity measures correlated more highly with SF-36 scales related to physical functioning, whereas personal relationships and emotions had higher correlations with SF-36 scales related to mental well-being (Table 3).

Discriminative construct validity showed that the mean scores for P-QoL domains differed across POP-Q stages (Fig. 1). The domain scores for general health perceptions ($p < 0.001$), role limitations ($p = 0.001$), physical limitations ($p = 0.004$), social limitations ($p < 0.001$) and severity measures ($p < 0.001$) in women with POP-Q stage 3 and POP-Q stage 4 stage were significantly higher than in women with POP-Q stage 2 (Kruskal–Wallis ANOVA). Also, domain scores for general health perceptions were higher in women with POP-Q stage 4 than in women with POP-Q stage 3 ($p = 0.002$). As for sleep/energy domain scores, statistically significant differences were revealed only between women with POP-Q stage 2 and POP-Q stage 3 ($p = 0.033$).

Feasibility

The number of missing responses to the items across 20 questions of P-QoL domains was 3.7%, pointing to the feasibility of P-QoL domains. The number of missing responses to the items across all additional symptom questions was 5%, which is considered feasible. The average time for questionnaire administration was 7 (5–10) min for the Russian version of the P-QoL questionnaire.

Responsiveness

To assess responsiveness, of the total, 57 women filled out P-QoL before and 2 months after surgery. The values of ES and SRM are presented in Table 4. The values of ES were excellent (ES > 1.0) for the majority of domains except for "social limitations" and "sleep/energy", which were moderate and for "personal relationships", which were small (Table 4). The values of SRM were excellent (SRM > 1.0) for five domains, good or moderate for three domains ("sleep/energy" and "severity measures", and "personal relationships") and small for "social limitations".

Applicability to Assess the Impact of POP on QoL and the Effect of Treatment in Women Undergoing Reconstructive Surgery

The application of the Russian version of the P-QoL questionnaire in a sample of 303 women with POP who were admitted to the hospital for reconstructive surgery allowed this population of women to be described in terms of QoL deterioration and symptom severity. Mean scores were above 50 in the following domains: "prolapse impact" (79.8 ± 25.2), "physical limitations" (58.6 ± 33.4), "role limitations" (52.5 ± 34.1) and "general health perceptions" (50.8 ± 15.8), Fig. 1. Remarkably, the worst scores were for "prolapse impact"; they were high regardless of POP-Q stage. In addition, POP negatively impacted "personal relationships" and "emotions" regardless of POP-Q stage ($p > 0.05$). For the whole group mean scores were close to 50: 48.1 ± 40.0 and 49.0 ± 31.4 respectively. As for "severity measures", the mean scores were 39.4 ± 25.6, and quite expectedly, was higher in women with POP-Q stage 4 and lower in women with POP-Q stage 2 ($p = 0.001$).

To analyse QoL changes in affected women after reconstructive surgery mean scores of the P-QoL questionnaire before and 2 months after treatment were compared (Fig. 2). Mean scores of the P-QoL questionnaire for all domains decreased to a large extent after surgery compared with the scores before treatment. The scores decreased several times for "prolapse impact", "physical limitations", "role limitations" and "emotions" domains. All the changes were statistically significant and may be considered as indication of dramatic improvement of QoL after surgery. In addition, we examined QoL changes in women depending on the type of surgery. QoL improved in women who underwent both mesh-augmented repair ($n = 46$) and native tissue repair ($n = 11$). Changes were statistically significant for all the domains in the group who underwent mesh-augmented repair ($p = 0.001$ for "social limitations", $p = 0.035$ for "personal relationships", $p < 0.001$ for all other domains). In the group who underwent native tissue repair statistically significant improvement was shown for all the domains except "social limitations" and "personal relationships" ($p = 0.010$ for "general health perceptions", $p = 0.016$ for "prolapse impact", $p = 0.017$ for "role limitations", $p = 0.03$ for "physical limitations", $p = 0.008$ for "emotions", $p = 0.025$ for "sleep/energy" and $p = 0.014$ for "severity measures").

Discussion

It is obvious that determination of the degree of prolapse before and after reconstructive surgery alone is insufficient for the assessment of the treatment outcome. Decisions about the management of a woman with POP should also be

Table 3 Results from the analysis of convergent construct validity for prolapse quality of life (*P-QoL*) questionnaire with Pelvic Floor Distress Inventory (*PFDI-20*) and 36-Item Short Form Survey (*SF-36*; Spearman´s coefficient r)

P-QoL domain scores	POPDI-6	CRADI-8	UDI-6	Total PFDI-20	PF	RPF	BP	GH	V	SF	REF	MH
General health perceptions	**0.361**	**0.149**	**0.192**	**0.288**	**−0.368**	**−0.268**	**−0.290**	**−0.340**	**−0.247**	**−0.224**	**−0.192**	**−0.220**
	<0.001	0.014	0.002	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.002	<0.001
Prolapse impact	**0.289**	**0.243**	**0.231**	**0.305**	**−0.219**	**−0.158**	**−0.271**	**−0.138**	**−0.175**	**−0.212**	**−0.166**	**−0.148**
	<0.001	<0.001	<0.001	<0.001	<0.001	0.012	<0.001	0.031	0.005	<0.001	0.01	0.018
Role limitations	**0.511**	**0.227**	**0.314**	**0.450**	**−0.481**	**−0.507**	**−0.412**	**−0.273**	**−0.294**	**−0.391**	**−0.417**	**−0.303**
	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Physical limitations	**0.523**	**0.359**	**0.461**	**0.570**	**−0.463**	**−0.387**	**−0.340**	**−0.240**	**−0.271**	**−0.368**	**−0.329**	**−0.297**
	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Social limitations	**0.492**	**0.393**	**0.452**	**0.553**	**−0.367**	**−0.372**	**−0.358**	**−0.219**	**−0.294**	**−0.423**	**−0.333**	< 0.001
	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Personal relationships	**0.270**	**0.135**	**0.146**	**0.226**	**−0.070**	**−0.168**	**−0.190**	**−0.052**	**−0.197**	**−0.274**	**−0.107**	**−0.222**
	<0.001	0.053	0.036	0.001	0.324	0.017	0.005	0.467	0.004	<0.001	0.137	0.001
Emotions	**0.357**	**0.329**	**0.324**	**0.403**	**−0.202**	**−0.246**	**−0.304**	**−0.221**	**−0.447**	**−0.394**	**−0.296**	**−0.504**
	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.001	<0.001	<0.001	<0.001	<0.001
Sleep/energy	**0.546**	**0.368**	**0.483**	**0.577**	**−0.364**	**−0.408**	**−0.386**	**−0.231**	**−0.380**	**−0.394**	**−0.272**	**−0.340**
	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Severity measures	**0.703**	**0.314**	**0.463**	**0.624**	**−0.400**	**−0.323**	**−0.339**	**−0.209**	**−0.225**	**−0.253**	**−0.266**	**−0.165**
	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.01

POPDI-6 Pelvic Organ Prolapse Distress Inventory, *CRADI-8* Colorectal Anal Distress Inventory, *UDI-6* Urinary Distress Inventory, *PF* physical function, *RPF* role-physical functioning, *BP* bodily pain, *GH* general health, *V* vitality, *SF* social functioning, *REF* role-emotional functioning, *MH* mental health

Spearman´s coefficient r is in bold, *p* level is in regular font

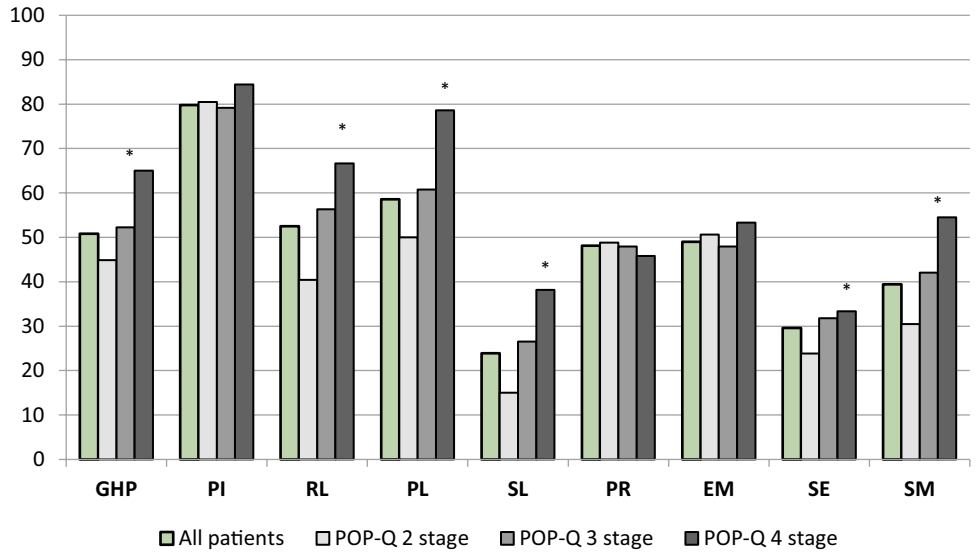

Fig. 1 Distribution of P-QOL score according to the POP-Q stage. *Asterisks* indicate a statistically significant difference. Post-hoc comparisons: for general health perception (*GHP*)—$p<0.001$ between POP-Q stage 2 and POP-Q stage 3, $p<0.001$ between POP-Q stage 2 and POP-Q stage 4, $p=0.002$ between POP-Q stage 3 and POP-Q stage 4; for role limitation (*RL*)—$p=0.001$ between POP-Q stage 2 and POP-Q stage 3, $p=0.009$ between POP-Q stage 2 and POP-Q stage 4; for physical limitations (*PL*)—$p=0.017$ between POP-Q stage 2 and POP-Q stage 3, $p=0.003$ between POP-Q stage 2 and POP-Q stage 4; for social limitations (*SL*)—$p=0.003$ between POP-Q stage 2 and POP-Q stage 3, $p=0.004$ between POP-Q stage 2 and POP-Q stage 4; for sleep/energy (*SE*)—$p=0.033$ between POP-Q stage 2 and POP-Q stage 3; for severity measures (*SM*)——$p=0.001$ between POP-Q stage 2 and POP-Q stage 3, $p=0.001$ between POP-Q stage 2 and POP-Q stage 4. *PI* prolapse impact, *PR* personal relationships, *EM* emotions

Table 4 Results from the analysis of responsiveness for the prolapse quality of life (*P-QoL*) questionnaire

P-QoL domain scores	ES	SRM
General health perceptions	2.147	1.432
Prolapse impact	1.821	1.158
Role limitations	1.214	1.314
Physical limitations	1.189	1.212
Social limitations	0.533	0.461
Personal relationships	0.384	0.531
Emotions	1.091	1.163
Sleep/energy	0.761	0.876
Severity measures	1.008	0.935

ES effect size, *SRM* standardised response means

based on her QoL. Clinical management of POP should consider the severity of symptoms and the impact on a woman's QoL in choosing the most appropriate treatment as well as evaluate its effectiveness [17, 18]. In other words, improvement in QoL should be the main aim of any prolapse treatment. As the prolapse may affect different aspects of a woman's life, by limiting emotional, physical, social and sexual domains of her life, the severity of these limitations and their impact on the quality of a patient's life becomes an important source of information for a surgeon while decision making. The P-QoL questionnaire is a useful tool for assessing QoL in women with POP in a routine clinical practice and treatment follow-up [8]. Like other diagnostic procedures, patient-reported outcome (PRO) measures should be valid, reliable and sensitive over time [19]. The P-QoL questionnaire has been proven to be a valid and reliable instrument for the assessment and management of women with POP symptoms in clinical and research practice [20–26]. Until now, the Russian version of the P-QoL questionnaire has never been developed and tested in a population of Russian women with POP. In the present study the results of the development and validation of the Russian version of the P-QoL questionnaire are examined. Cross-cultural adaptation of the P-QoL questionnaire was performed in accordance with international guidelines [10] and content validity of the Russian version was determined in a similar way, as described in previous validation studies [20–28]. Emphasis was given to maintain the original context and meaning of the words rather than a direct word-by-word translation. Several amendments were implemented in the final version as a result of decentering to make the phrases sound more natural in Russian. Also, the Russian P-QoL questionnaire is designed in a three-page format (compared with five-page format of the original), which was convenient to patients. We found the Russian P-QoL questionnaire to be content valid after excellent expert panel agreement on the relevance of items (a content validity index mean of 1.0) and pilot testing among women affected by POP. The tool appears

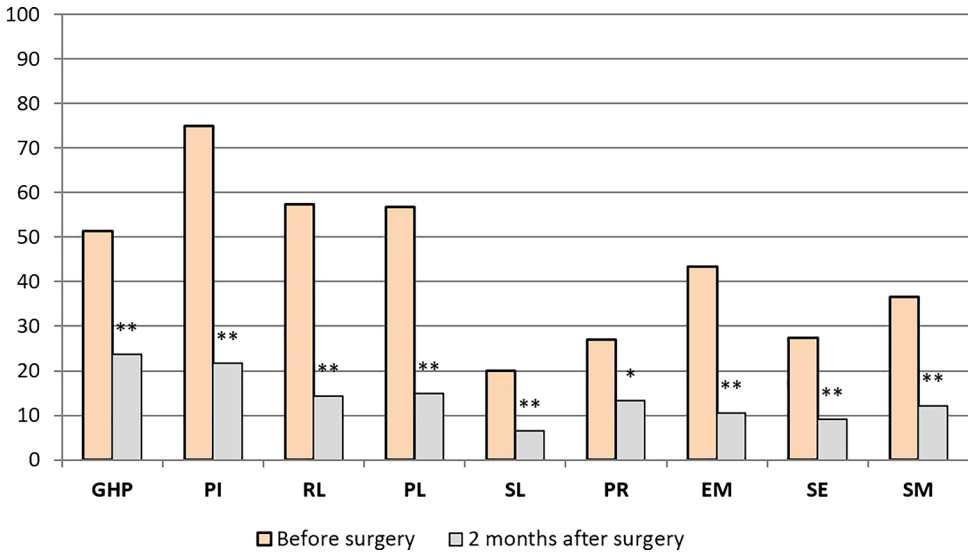

Fig. 2 Prolapse quality of life (*P-QoL*) questionnaire mean scores before and 2 months after reconstructive surgery. *$p = 0.008$, **$p < 0.001$

to be acceptable to patients and does not constitute an extra burden to the professionals using it. We concur with other investigators that the P-QoL questionnaire is easy to use in a busy clinical setting [29].

In order to prove the quality of all the steps of development of the Russian version of the tool testing of psychometric properties is worthwhile. Validation is needed to ensure that the Russian version of the P-QoL questionnaire preserves the characteristics of the original tool, and has similar validity and reliability. In our study, the Russian version demonstrated excellent reliability and construct validity. Internal consistency was very high in all dimensions except in the "sleep/energy" and "severity measures" dimensions, which were shown to be acceptable. These data are similar to those that have been reported in other validation studies [20–23]. Excellent agreement was observed between the paired test–retest scores – ICC coefficients ranged from 0.7 to 0.96 for all the domains excluding social limitations (ICC = 0.62). The 2-week recall period was chosen for test–retest reliability because this time is long enough to avoid recall bias and short enough for the condition to remain unchanged. These data are comparable with the results for the original version and other translations [8, 24, 25].

In our study we proved convergent and discriminant validity of the Russian P-QoL questionnaire. To measure convergent validity we analysed correlations between the P-QoL domain scores with the PFDI-20 and SF-36 domains. In women's health, the PFDI-20 is a PRO measure that is often used in clinical practice and clinical trials to assess the distress caused by the presence of pelvic floor dysfunction [12]. This PRO measure is advised as a grade A recommendation by the International Consultation on Incontinence for clinical practice [30] and has been translated and validated into several languages, including Russian. As far as in women affected by POP QoL is impaired before surgery and may dramatically improve after treatment, generic questionnaires, such as SF-36, are often used in this patient population. According to the results obtained, P-QoL dimensions showed statistically significant correlations with the total PFDI-20 and SF-36 scales. Regarding discriminant validity we observed significant differences for P-QoL scores in women according to POP-Q stage ($p < 0.001$), indicating a higher stage associated significantly with worse P-QoL scores. The association of P-QoL scores with POP-G stage was observed in other studies [20, 21, 29]. To note, existing correlation with the stage of POP does not mean that P-QoL assessment substitutes or replaces physical examination.

The responsiveness or sensitivity to change was assessed in a subgroup of women who filled out the P-QoL before and 2 months after surgery. We used the values of ES and SRM, which are both often used together to explore the responsiveness of the tool. The values of ES and SRM were excellent for the majority of domains indicating that the instrument is sensitive to changes after treatment. These data are even more encouraging than in the previous studies [22, 24, 29].

In addition, we examined the feasibility of the Russian version of the P-QoL questionnaire. Our findings are similar to those for other language versions [20–25]. It suggests the easy completion and good acceptability of the Russian P-QoL questionnaire and indicates that this PRO measure is applicable for clinical practice.

Finally, we demonstrated the applicability of the Russian version of the P-QoL questionnaire as a reference instrument to assess the impact of POP on QoL and the effect of treatment in women undergoing reconstructive surgery. Remarkable improvement of QoL after surgery was demonstrated for all P-QoL domains, indicating that this instrument is able to detect changes in the well-being of this population of women. The P-QoL questionnaire is an informative

instrument to be used in clinical practice and research in order to assess and document the severity and impact of POP in the affected women undergoing surgery.

We consider our results to be robust for several reasons. First, we used COSMIN recommendations for the reporting of measurement properties [14], which is the current reference standard for reporting measurement properties. Second, we analysed sufficiently sensitivity to change in women with POP who underwent reconstructive surgery. Responsiveness is of particular importance in urogynecology, where the primary aim of an intervention is mostly to improve the individual's QoL [16]. Therefore, we consider responsiveness to be a fundamental psychometric characteristic that should be assessed in a validation study. In terms of responsiveness of the Russian version of the P-QoL questionnaire we identified pronounced positive changes of QoL after surgery using this PRO measure. Noteworthy, in the 2 months after reconstructive surgery the scores for the "prolapse impact", "physical limitations", "role limitations" and "emotions" domains improved several times compared with baseline scores. Furthermore, all the changes in domain scores before and after surgery were statistically significant.

There are some limitations worthy of discussion. First, all women in our sample were symptomatic for POP, which differs from other validations [20–29] that included asymptomatic women as a control group. We do not have an asymptomatic group because all women were referred to reconstructive surgery and validation of the P-QoL questionnaire was conducted in this population of women. Second, all the women were attending the urogynecology unit of a single center in St. Petersburg, and this may have introduced some degree of selection bias. As with all questionnaire studies, women may have had personal reasons for participating in the study (or not) and so there will be a degree of response bias in our results. However, this will be present in any research in this area and is not possible to account for. Finally, the group that was assessed twice, before and after surgery, was not large. This is explained by the fact that the majority of women were not citizens of St. Petersburg; they came for treatment from different Russian regions and therefore it limited their follow-up visits. The way out for future studies is the use of a on-line P-QoL questionnaire. However, the psychometric properties of the on-line version should be tested before its use. Further research into online formats of the P-QoL questionnaire is warranted.

Conclusions

The Russian version of the P-QoL questionnaire is valid, reliable, sensitive to change and feasible for use among Russian women with POP. The applicability of the Russian version of the P-QoL questionnaire as a reference instrument for assessing the impact of POP on QoL and the effect of treatment in women undergoing reconstructive surgery was proved. Further implementation of this PRO measure in routine practice will be beneficial for assessing the outcomes of reconstructive surgery from affected women's perspective. Its incorporation along with other PRO measures into studies evaluating the effect of reconstructive surgery in women with POP will provide an in-depth comprehensive understanding of changes in the well-being of women with POP after surgery.

Authors' contributions Rustam Shakhaliev, Tatiana Ionova, Tatiana Nikitina: protocol and project development; Rustam Shakhaliev: data collection, Rustam Shakhaliev, Nikita Kubin: project development, manuscript review and writing; Tatiana Ionova, Tatiana Nikitina: manuscript writing; Dmitry Shkarupa, Alessandro Digesu: manuscript review.

Declarations

Ethical approval The local ethics committee of Saint-Peterburg State University Hospital approved the study and all the participants gave their written informed consent (ref: EC № 05/23 dated 18.05.2023).

Conflicts of interest None.

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