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CROSS-CULTURAL ADAPTATION OF THE SPECIALIZED QUESTIONNAIRE P-QOL IN RUSSIAN AND KAZAKH FOR WOMEN WITH GENITAL PROLAPSE IN KAZAKHSTAN

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Abstract

Introduction. The Prolapse Quality of Life (P-QoL) questionnaire is a simple and reliable tool for assessing the severity of genital prolapse symptoms and their impact on women's quality of life.

Objective. To adapt and assess the validity, reliability, reproducibility and feasibility of the P-QoL questionnaire for women in Kazakhstan to use it as a tool to assess the severity of symptoms and quality of life of women with genital prolapse, as well as a simple tool for "self-assessment" in women with prolapse.

Materials and methods. To assess the understanding of the questions, 20 patients with prolapse symptoms speaking Russian and 20 patients speaking Kazakh were invited. The next stage selected 175 patients with symptoms of prolapse and 81 patients with asymptomatic prolapse. Cross-cultural adaptation was carried out by the method of translation - reverse translation. Validity, reliability and feasibility of the questionnaire were assessed.

Results. The process of linguistic adaptation showed that women in Kazakhstan easily understand the content of the Kazakhstan version of the P-QoL questionnaire. There were statistically significant differences between the symptomatic and non-prolapse group. The Kazakh version of P-QoL showed high internal consistency and reliability by repeated testing in all respects. The average time to complete the questionnaire was 10.1 minutes. All women found the questionnaire simple.

Conclusion. In our study, the P-QoL questionnaire was adapted and validated to measure the severity of prolapse symptoms and the impact on quality of life.

Key words: genital prolapse, quality of life, P-QoL questionnaire, validity, reliability.

Резюме

КРОСС-КУЛЬТУРНАЯ АДАПТАЦИЯ СПЕЦИАЛИЗИРОВАННОГО ОПРОСНИКА P-QOL НА РУССКОМ И КАЗАХСКОМ ЯЗЫКАХ ДЛЯ ЖЕНЩИН С ГЕНИТАЛЬНЫМ ПРОЛАПСОМ В КАЗАХСТАНЕ

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Актуальность. Опросник качества жизни при пролапсе (P-QoL) - это простой и надежный инструмент для оценки тяжести симптомов генитального пролапса и их влияния на качество жизни женщин.

Цель. Адаптировать и оценить валидность, надежность, воспроизводимость и осуществимость опросника P-QoL для женщин Казахстана, чтобы использовать его в качестве инструмента для оценки тяжести симптомов и качества жизни у женщин с генитальным пролапсом, а также простого инструмента для «самооценки» у женщин с пролапсом.

Материалы и методы. Для оценки понимания вопросов были приглашены 20 пациентов с симптомами пролапса, говорящих на русском языке и 20 пациентов, говорящих на казахском языке. Следующим этапом отобрано 175 пациентов с симптомами пролапса и 81 пациент с бессимптомным пролапсом. Кросс-культурная адаптация проводилась методом перевода-обратного перевода. Оценена валидность, надежность и осуществимость опросника.

Результаты. Процесс лингвистической адаптации показал, что женщины Казахстана легко понимают содержание Казахстанской версии опросника P-QoL. Были статистически значимые различия между группой с симптомами пролапса и без симптомов. Казахстанская версия P-QoL показала высокую внутреннюю согласованность и надежность повторным тестированием по всем параметрам. В среднем время заполнения опросника составило 10, 1 минута. Все женщины сочли анкету простой.

Заключение. В нашем исследовании адаптирован и валидирован опросник P-QoL, позволяющий измерить выраженность симптомов пролапса и влияние на качество жизни.

Ключевые слова: генитальный пролапс, качество жизни, опросник P-QOL, валидность, надежность.

Түйіндеме

ҚАЗАҚСТАННЫҢ ЖЫНЫС ПРОЛАПСЫ БАР ӘЙЕЛДЕРГЕ АРНАЛҒАН ОРЫС ЖӘНЕ ҚАЗАҚ ТІЛДЕРІНДЕГІ P-QOL МАМАНДАНДЫРЫЛҒАН САУАЛНАМАСЫНЫҢ МӘДЕНИЕТАРАЛЫҚ БЕЙІМДЕЛУІ

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Кіріспе. Пролапсы бар әйелдердің өмір сапасының сауалнамасы (P-QoL) -жыныс пролапсы белгілерінің ауырлығын және олардың әйелдердің өмір сапасына әсерін бағалаудың қарапайым және сенімді құралы болып табылады.

Мақсат. Қазақстан әйелдеріне арналған P-QoL сауалнамасының жарамдылығын, сенімділігін, қайталануын және жүзеге асырылуын бейімдеу және бағалау, оны жыныс пролапсы бар әйелдерде симптомдардың ауырлығын және өмір сүру сапасын бағалау құралы, сондай-ақ пролапсы бар әйелдерде "өзін-өзі бағалау" үшін қарапайым құрал ретінде пайдалану.

Материалдар мен әдістер. Сұрақтарды түсінуді бағалау үшін орыс тілінде сөйлейтін пролапс белгілері бар 20 пациент және қазақ тілінде сөйлейтін 20 пациент шақырылды. Келесі қадам-пролапс белгілері бар 175 пациент және асимптоматикалық пролапсы бар 81 пациент. Мәдениетаралық бейімделу аударма-көрі аударма әдісімен жүзеге асырылды. Сауалнаманың жарамдылығы, сенімділігі және орындылығы бағаланды.

Нәтижелер. Лингвистикалық бейімделу процесі Қазақстанның әйелдері р-QOL сауалнамасының қазақстандық нұсқасының мазмұнын оңай түсінетінін көрсетті. Пролапс белгілері бар және белгілері жоқ топ арасында статистикалық маңызды айырмашылықтар болды. P-QoL қазақстандық нұсқасы барлық өлшемдер бойынша қайта тестілеудің жоғары ішкі келісімділігі мен сенімділігін көрсетті. Сауалнаманы толтыру уақыты орта есеппен 10, 1 минутты құрады. Барлық әйелдер сауалнаманы қарапайым деп тапты.

Қорытынды. Біздің зерттеуімізде пролапс белгілерінің ауырлығын және өмір сапасына әсерін өлшеуге мүмкіндік беретін р-QoL сауалнамасы бейімделген және тексерілген.

Түйінді сөздер: жыныстық пролапс, өмір сапасы, P-QoL сауалнамасы, жарамдылық, сенімділік.

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Introduction.

Pelvic organ prolapse is a displacement of the pelvic organs into the vaginal lumen or beyond (Krasnopol'sky V.I. et al., 2010) [10]. This pathology can be considered as a hernial protrusion of the pelvic organs, which is formed as a result of a defect in the pelvic fascia under the influence of an increase in intra-abdominal pressure [10]. Prevalence varies widely, with a global average of 25% according to the latest pooled data, with a peak over 50 years of age [7,10].

According to researchers, due to the increase in life expectancy and the growing problem of obesity in many countries of the world, which are proven factors in the development of genital prolapse, the prevalence of pelvic floor dysfunction will increase, and the proportion of women who will need surgical treatment will also increase [7, 10]. All these points will lead to an increase in financial costs for health care, especially considering that the recurrence after surgical treatment for prolapse is from 30-40% [10]. Genital prolapse is not life-threatening, but the symptoms of prolapse associated with discomfort and sensation of a foreign body in the perineum, dysfunction of the bladder and rectum lead to significant restrictions in daily life. Based on this, it can be objectively justified that the decision on surgical treatment should be based on the level of discomfort experienced by the patient herself. In clinical practice, we are faced with the fact that the initial stage of prolapse causes great discomfort to the patient, and she insists on surgical treatment, in other situations, having an advanced stage of prolapse, the patient categorically refuses surgical intervention. Two major international organizations in the field of urogynecology, the International Urinary Incontinence Society (ICS) and the International Urogynecological Association (IUGA), presented a joint report on key points for evaluating the results of prolapse surgery, which includes anatomical results as well as subjective patient assessments, their symptoms, quality of life and satisfaction [10], which in our opinion is absolutely correct for prolapse. With this pathology, an assessment of the quality of life is necessary for making decisions about treatment and monitoring the result of treatment. Thus, we need a prolapse-specific quality-of-life questionnaire. According to our estimates, there is no such questionnaire in Kazakhstan today.

The Prolapse Quality of Life (P-QoL) questionnaire is a simple and reliable tool for assessing the severity of genital prolapse symptoms and their impact on women's quality of life. In addition, using this questionnaire, you can easily assess the condition before and after treatment, which is

used in clinical practice in other countries [1,3,4,7,8,9,12]. Unlike the short questionnaires PFDI-20 and PFQ-7, which are designed to assess the severity of symptoms, and other questionnaires that assess the quality of life in general, the P-QoL questionnaire focuses on the impact of prolapse symptoms on different areas of life that are specific to pelvic floor dysfunction.

P-QoL was developed in 2005 by Digesu et al. for the English speaking population [7]. Later it was adapted and used in many countries (for example, Spain, Italy, Turkey, Slovakia, Brazil, Germany, Taiwan, Iran, Chile, China, Japan) [2,3,6,7,8,9,11,12], in Russia, a PD-QoL questionnaire was created on its basis [1]. It consists of 38 questions, 9 domains, each of which represents all the important areas of life that change under the influence of prolapse.

The objective of our work is to adapt and assess the validity, reliability, reproducibility and feasibility of the P-QoL questionnaire for women in Kazakhstan in order to use it as a tool for assessing the severity of symptoms and quality of life in women with genital prolapse, as well as a simple tool for "self-assessment" in women with prolapse.

Materials and methods.

At the first stage, the P-QOL questionnaire, developed for English-speaking patients, was translated by translation-back translation methods into Russian and Kazakh languages by two obstetrician-gynecologists who are fluent in Russian, Kazakh and English, then the questionnaires were translated from Russian and Kazakh by two professional translators' language into English. The results were evaluated by two other obstetrician-gynecologists who are fluent in three languages.

All subsequent stages were performed according to the methodology described in previous studies [1,2,3,9,12].

To assess the understanding of the questions, 20 patients with prolapse symptoms speaking Russian and 20 patients speaking Kazakh were invited. After examining the patients, a questionnaire was conducted, then a conversation with patients about informed voluntary consent and the following changes were adjusted: in the domain "Symptoms and their perception", the question "how often do you empty your bowels" was excluded, since the respondents did not see a difference between this question and "Constipation" question. Three questions were added from the Russian version of the PD-QoL questionnaire: "Are you concerned about the symptoms of "stool or gas incontinence?", "Feeling of incomplete emptying of the bladder", "Need to hold the vaginal walls with your hand or

reset the prolapsed vaginal walls in order to urinate" [1]. The question: "Give finger assistance during the act of defecation" is supplemented with the phrase: "Hold with your hand or set the prolapsed parts of the vagina to empty the intestines." In the "Severity of symptoms" domain, the questions "Pain and discomfort due to prolapse" and "Does prolapse prevent you from standing" were excluded, since, according to the respondents, they were already reflected in the "Symptoms and their perception" domain. The first question: "Do you use tampons, pads, specialized underwear" was changed and supplemented with the phrase: "change wet underwear / to keep underwear clean / dry" [1]. We also included specialized underwear in the question "Do you use vaginal rings, pessaries" [1], since all these devices are used to support organs. In Kazakhstan, vaginal rings and pessaries are more often prescribed. The question "Do you control the amount of fluid you drink" [1] was added; many of the respondents controlled the amount of fluid they drank, both with urinary incontinence and with difficulty urinating, being afraid to overfill the bladder.

As a result, the P-OQL questionnaire, adapted for women in Kazakhstan, consists of 9 domains, 40 questions:

1. General health status - 1 question;
2. Impact of symptoms - 1 question;
3. Symptoms and their perception - 20 questions;
4. Role restrictions - 2 questions;
5. Physical and social restrictions - 4 questions;
6. Interpersonal interactions - 3 questions;
7. Emotional problems - 3 questions;
8. Violation of sleep and wakefulness - 2 questions;
9. The severity of symptoms - 4 questions.

At the next stage, 175 patients with symptoms of prolapse and 81 patients with asymptomatic prolapse were selected, the sample size was justified by the experience of previous studies and our own calculation.

After taking voluntary informed consent, patients were examined on a gynecological chair. The degree of prolapse was assessed according to the international POP-Q classification recommended in the clinical protocol for the diagnosis and treatment of female genital prolapse dated November 20, 2015 Protocol No. 16.

To identify and assess the degree of functional disorders of the pelvic organs, such as urinary incontinence, difficulty urinating, fecal and gas incontinence were evaluated using functional tests during examination on the gynecological chair (stop test, cough test, digital elevation test, test with residual urine). The degree of frequent urination, as assessed by completed urination diaries, "less than 8 times a day" was not considered frequent urination, "from 8-15 times a day" and "more than 15 times a day" were considered frequent. The severity of constipation was assessed by indicators: "daily" - the norm, "once every two days" and "less than once every two days" were considered constipation. [1].

The reliability of the questionnaire was assessed through internal consistency testing using Cronbach's alpha. As acceptable we determined Cronbach's alpha not lower than 0.6 [5, 9]. To measure the reproducibility of the questionnaire, the reliability factor was calculated by repeated testing. Patients were interviewed after two weeks again, the interval was so chosen. The reason for this is that the symptoms of prolapse did not change during this

time, and at the same time, the respondents could not accurately remember their previous answers [1]. The retesting reliability factor is taken as 0.7 as acceptable.

Construct validity was assessed as follows:

1. The stage of genital prolapse was compared with the total score of each domain according to the Spearman correlation coefficient (SCC), correlation from 0.3-0.6 was accepted as acceptable, from 0.7 and above - strong.

2. A comparison was made of the relationship between the objective presence of stress urinary incontinence and the analysis of completed urination diaries. The objective method included functional tests, according to the established degrees of incontinence, frequent urination. Diaries of urination and the severity of constipation were filled in by the respondents and compared with the answers of the "Symptoms and their perception" domain according to the Spearman correlation coefficient (SCC), from 0.3-0.6 the correlation was accepted as acceptable, from 0.7 and above - strong.

3. Correlation of the final value of the "Symptoms and their perception" domain, which directly reflects the symptoms of genital prolapse, with the final values of other domains.

4. Comparison of quality of life indicators according to the calculated index of quality of life in symptomatic and asymptomatic prolapse using a non-parametric criterion U criterion - Mann - Whitney.

Statistical analysis was carried out using the SPSS Statistics 26 software.

Results:

In 71 (87.7%) women with asymptomatic prolapse, I degree according to POP-Q was observed, in 10 women (12.3%) II degree of prolapse. In the group with symptoms of prolapse, one patient (0.6%) had grade I prolapse, 60 patients (34.3%) had grade III prolapse, and 114 patients (65.1%) had grade IV. The absence of symptoms was observed only at the initial stage of prolapse ($p < 0.001$).

The analysis of internal consistency in all domains was acceptable, the Cronbach's Alpha score was at least 0.6, the lowest was noted in the domains: "Interpersonal interactions" (0.69) and "Severity of symptoms" (0.633). In other domains, this indicator was higher than 0.9 (Table 1). The retest reliability index was also high in all domains, with all values above 0.8, with a $p < 0.001$ significance level indicating good reproducibility.

Table 1. Reliability of P-QOL Domain Estimates.

Domain	Reliability by repeated testing	p	Internal consistency Cronbach's Alpha
General health	0,999	$p < 0,001$	-
Impact of symptoms	0,998	$p < 0,001$	-
Symptoms and their perception	0,960	$p < 0,001$	0,917
Role Restrictions	0,988	$p < 0,001$	0,965
Physical and social limitation	0,983	$p < 0,001$	0,813
Interpersonal interactions	0,964	$p < 0,001$	0,69
Emotional problems	0,988	$p < 0,001$	0,97
Sleep and wake disturbance	0,978	$p < 0,001$	0,933
Severity of symptoms	0,843	$p < 0,001$	0,633

We can see that the relationship was high between patients' subjective assessment of symptoms of stress urinary incontinence, urinary frequency and constipation and objective assessment at the time of examination ($p < 0.001$) (Table 2).

Table 2. Correlation of the presence of objective symptoms with the values of the "Symptoms and their perception" domain.

Stress urinary incontinence		p	
	objectively	subjectively	
objectively	1,0	0,982	<0,001
subjectively	0,982	1,0	<0,001
Frequent urination			
objectively	1,0	0,977	<0,001
subjectively	0,977	1,0	<0,001
Constipation			
objectively	1,0	0,876	<0,001
subjectively	0,876	1,0	<0,001

We were also concerned about the relationship of the total subjective indicator of the third domain "Symptoms and their perception" - the pelvic floor dysfunction index (PFD) with the values of the other domains.

The relationship was strong when compared with 1,2,7 domains and the total index of quality-of-life assessment, in the remaining domains 3,4,5,6,8,9 the relationship was acceptable at a significance level of 0.01 (point 4). Note that

Table 5. Differences between groups with and without symptoms of prolapse.

domain	symptomatic		asymptomatic		Significance level p
	Me(Q1-Q3)	M	Me(Q1-Q3)	M	
1. General health	3,0 (1)	2,66	0 (0)	0	<0,001
2. Impact of symptoms	3,0 (1)	2,67	0(0)	0	<0,001
3. Symptoms and their perception	26 (8)	27,01	0(0)	0,19	<0,001
4. Role Restrictions	5 (2)	5,17	0(0)	0	<0,001
5. Physical and social limitation	10(4)	9,61	0(0)	0	<0,001
6. Interpersonal interactions	4(5)	3,91	0(0)	0,11	<0,001
7. Emotional problems	9(2)	8,11	0(0)	0	<0,001
8. Sleep and wake disturbance	2(6)	2,75	0 (0)	0,11	<0,001
9. Severity of symptoms	4(4)	4,46	0 (0)	0,26	<0,001
Quality of life index	66(14)	66,35	0(1)	0,67	<0,001

M - mean, Me - median, Q1-Q-3 - interquartile range

The average time to complete the questionnaire was 10.1 minutes. The number of missed questions was 0 in all nine domains. All difficult to understand paragraphs and words were eliminated during a survey of 20 women in Russian and Kazakh, in the future there were no more problems with understanding the questions. All women found the questionnaire simple and easy to fill out.

Discussion.

Pelvic organ prolapse is not a life-threatening disease, but the symptoms of prolapse limit social life, lead to psychological and emotional disorders, affect family and intimate life, that is, in general, have a negative impact on quality of life. International associations recommend taking into account the assessment of the quality of life for the choice of treatment, as well as assessing its effectiveness. It is fair to conclude that for genital prolapse the main indication for surgical treatment is the patient's subjective assessment of her condition, the effectiveness of treatment should also be evaluated taking into account the assessment of quality of life.

The correlation between the degree of pelvic organ prolapses and the value of each domain was found to be strong in 1,2,3,4,7 domains. In 5,6,8,9 domains and the total index of quality of life (QOL) correlation was acceptable at a significance level of 0.01 (Table 3).

Table 3. Correlation between domains and genital prolapse by objective assessment.

domain	degree	p	PFD	p
1. General health	1,0	0,01	0,715	0,01
2. Impact of symptoms	0,759	0,01	0,734	0,01
3. Symptoms and their perception	0,724	0,01	0,658	0,01
4. Role Restrictions	0,707	0,01	0,618	0,01
5. Physical and social limitation	0,690	0,01	0,581	0,01
6. Interpersonal interactions	0,550	0,01	0,726	0,01
7. Emotional problems	0,751	0,01	0,339	0,01
8. Sleep and wake disturbance	0,357	0,01	0,536	0,01
9. Severity of symptoms	0,568	0,01	0,826	0,01
Quality of life index (QLI)	0,671	0,01	0,715	0,01

the correlation between PFD, i.e., the subjective assessment of the patient and QOL was higher than the objective staging of prolapse and QOL (Table 3).

The total scores in all domains, assessed using the U test - Mann - Whitney, significantly differed significantly in women with and without symptoms of prolapse ($p < 0.001$) (Table 4.)

The P-QOL is a specialized questionnaire for assessing the symptoms of pelvic floor dysfunction and its impact on quality of life. This is a special tool not only for assessing symptoms and their impact on life, but also an indicator of the effectiveness of treatment, which is confirmed in many studies, in addition, being easy to understand, allows for "self-assessment", which is important for raising patients' awareness of prolapse and its state [6-15].

The P-QoL was developed and validated for English-speaking women and has been adapted and validated in many languages [6-15]. Our goal was to adapt and validate this questionnaire for the population of Kazakhstan, due to the fact that its use is convenient in clinical practice.

The process of linguistic adaptation showed that women in Kazakhstan easily understand the content of the Kazakh version of the P-QoL questionnaire. We adapted the questions for our population, taking into account the fact that all the aspects covered are relevant for the population of Kazakhstan, taking into account the changes made to the

Russian version of the QOL, in connection with the cultural and historical commonality of our countries.

To the best of our knowledge, the P-QoL questionnaire is the only specialized tool that has been adapted and validated to assess the impact of pelvic organ prolapse on quality of life in Kazakhstan.

The results of our study confirm that the majority of asymptomatic women do not have stage II prolapse.

The Kazakh version of P-QoL showed high internal consistency and reliability by repeated testing in all respects. The assessment of the relationship between the objective assessment of the degree of urinary incontinence, frequent urination and constipation and the degree of subjective assessment of patients was high. The implementation of the questionnaire was 10.1 minutes. After making changes at the first stage of adaptation of the questionnaire, there were no further problems with understanding.

The correlation between the degree of subjective assessment of patients and the total index of quality of life assessment was higher than with an objective assessment during a gynecological examination. This confirms our assumption that the patient's assessment of his condition is to a greater extent an indication for making a decision on the choice of a treatment method for this pathology. The questionnaire cannot replace an examination to detect an early stage of prolapse in order to prevent the development of a more advanced one, however, when deciding on a method of treatment and monitoring the condition after treatment, it can be a reliable tool for clinical evaluation.

Conclusions.

In our study, the P-QoL questionnaire was adapted and validated to measure the severity of prolapse symptoms and the impact on quality of life. This questionnaire can be recommended for use in clinical practice, including for identifying patients who need treatment. As well as assessments after treatment.

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The Kazakh version of the P-QOL in Russian and Kazakh is available from the author upon request.

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