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Validation of the Russian version of the pelvic pain and urgency/frequency patient symptom scale (C.L. Parsons, 2000) for patients with chronic recurrent uncomplicated cystitis

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ABSTRACT

BACKGROUND: Questionnaires allow to objectify and quantify the disease severity, especially at the patient's initial visit, its impact on the patients' quality of life, as well as the dynamics of symptoms during treatment.

AIM: To validate the Russian version of the Pelvic Pain and Urgency/Frequency Patient Symptom Scale (PUF scale; C.L. Parsons, 2000) for patients with chronic recurrent uncomplicated cystitis.

MATERIALS AND METHODS: The Russian version of the PUF Scale was suggested to two respondent groups aged 19 to 53 years: relatively healthy volunteers, 15 women who did not complains of urinary disorders or pain/discomfort in the bladder, and 14 patients with verified diagnosis of chronic recurrent uncomplicated cystitis.

RESULTS: The resulting data demonstrate the validity of the proposed Russian version of the PUF Scale. Statistically significant differences were noted in the answers to most of the questionnaire issues between two respondent groups: conditionally healthy volunteers and patients with chronic recurrent uncomplicated cystitis. A high level of internal consistency of the questionnaire was found. Cronbach's alpha coefficient in the main group was 0.888, in the control group — 0.819.

CONCLUSIONS: The study findings proved that the Russian version of the Pelvic Pain and Urgency/Frequency Patient Symptom Scale (C.L. Parsons, 2000) is a valid tool for subjective assessment of the severity of chronic recurrent uncomplicated cystitis symptoms.

Keywords: lower urinary tract infection; cystitis; Pelvic Pain and Urgency/Frequency Patient Symptom Scale; PUF Scale; dysuria.

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Валидация русскоязычной версии шкалы симптомов тазовой боли, императивного, учащенного мочеиспускания (C.L. Parsons, 2000) для пациенток с хроническим рецидивирующим неосложненным циститом

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АННОТАЦИЯ

Актуальность. Использование опросников позволяет объективизировать и количественно оценить степень тяжести заболевания, особенно при первичном приеме пациента, его влияние на качество жизни больных, а также динамику симптоматики в процессе лечения.

Цель — провести валидацию русскоязычной версии Шкалы симптомов тазовой боли, императивного, учащенного мочеиспускания (PUF Scale, C.L. Parsons, 2000) для больных хроническим рецидивирующим неосложненным циститом.

Материалы и методы. Русскоязычная версия Шкалы симптомов тазовой боли, императивного, учащенного мочеиспускания была предложена двух группам респондентов в возрасте от 19 до 53 лет: условно здоровым добровольцам — 15 женщин, не предъявлявших жалобы на расстройства мочеиспускания или боль/дискомфорт в мочевом пузыре, и 14 пациенткам с верифицированным диагнозом хронического рецидивирующего неосложненного цистита.

Результаты. Полученные данные свидетельствуют о валидности предложенной русскоязычной версии опросника Шкалы симптомов тазовой боли, императивного, учащенного мочеиспускания. Отмечены статистически значимые различия в ответах на большинство вопросов опросника между двумя группами респондентов — условно здоровыми добровольцами и пациентками с хроническим рецидивирующим неосложненным циститом. Выявлен высокий уровень внутренней согласованности опросника. Коэффициент альфа Кронбаха в основной группе составил 0,888, в контрольной группе — 0,819.

Выводы. Результаты исследования подтверждают, что русскоязычная версия Шкалы симптомов тазовой боли, императивного, учащенного мочеиспускания (C.L. Parsons, 2000) является валидным инструментом субъективной оценки выраженности симптоматики хронического рецидивирующего неосложненного цистита.

Ключевые слова: инфекция нижних мочевых путей; цистит; Шкала симптомов тазовой боли, императивного, учащенного мочеиспускания; PUF Scale; дизурия.

Как цитировать

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BACKGROUND

Urinary tract infections are the second most common bacterial infections affecting organs and systems [1, 2]. Approximately 15% of all prescribed antibiotics are used to treat urinary tract infections [3]. Almost 60% of women report at least one episode of lower urinary tract infection (LUTI) in their lifetime, with 25% of them experiencing recurrence [4]. Uncomplicated LUTIs are defined as sporadic or recurrent cases affecting non-pregnant, pre-menopausal women without known anatomical or functional abnormalities of the lower urinary tract or comorbidities [5]. Acute uncomplicated cystitis, the most common LUTI, poses no significant diagnostic or treatment challenges [6]. A bladder inflammatory infection is considered to be complicated in males, pregnant females, patients with anatomical or functional abnormalities of the urinary system, urinary catheters, diabetes mellitus, immune system deficiencies, and chronic kidney disease [5].

Recurrent cystitis may be classified as either uncomplicated or complicated LUTI. Recurrent cystitis is usually defined as 3 episodes of LUTI within the previous 12 months, or 2 episodes within the previous 6 months. Although recurrent LUTIs are not usually life-threatening, they have a significant negative impact on the patient's quality of life. This may result in psychoemotional distress, impaired social and sexual functioning, low self-esteem, and reduced capacity to work [7]. Due to the nature of the disease, the number of patients with recurrent cystitis cannot be definitively established. Notably, the prevalence of cystitis in Russia has not been investigated through epidemiological studies for a considerable period of time. It is therefore evident that the incidence of cystitis is frequently misrepresented by outdated or averaged estimates, with figures often referenced as 15–20 thousand per 1 million people annually [8]. Postcoital cystitis can be defined as a specific form of chronic recurrent uncomplicated cystitis (CRUC), which presents with the initiation of sexual activity and develops after sexual intercourse [9]. This can result in patients refusing to have sexual intercourse, with subsequent implications for childbearing and family life, and a decline in their overall quality of life. Consequently, CRUC has been identified as a significant medical and social concern, with a higher prevalence observed in females and its incidence increased with patient age [10, 11].

The treatment of CRUC is primarily based on the administration of antibacterial agents. However, the increasing resistance of urinary tract infection pathogens to antimicrobial agents represents a significant challenge to the clinical efficacy of this approach. The lack of novel antibiotic agents has prompted the need for the development of alternative treatments and strategies to enhance the efficacy of existing pharmaceuticals. Currently, the scientific literature demonstrates a growing interest in systemic enzyme therapy (SET), which has emerged as a promising area for the treatment of urinary tract infections in both men and women [12–17]. The meta-analysis demonstrated the significant efficacy of SET in the combined treatment of bacterial infections in men [12]. Furthermore, studies have corroborated the efficacy of enzymes, particularly Wobenzym, in combination with other treatments for individuals diagnosed with CRUC and sexually transmitted infections [13], including chlamydia [14, 15], herpesvirus infection [16], and gynecological diseases [17]. Therefore, the use of SET as part of the combination treatment of female patients with CRUC and sexually transmitted infections resulted in the resolution of dysuric symptoms and leukocyturia two-fold the rate observed in the control group. Additionally, clinical recovery with the complete elimination of urinary pathogens was documented in 95.8% and 77.5% of patients, respectively [13]. The enzyme treatment of women with chlamydia demonstrated a 91% efficacy in eliminating the pathogen and facilitating recovery, as compared with a 76% success rate reported for antibacterial therapy alone [15]. In patients with genital herpes, SET has been demonstrated to reduce the duration and severity of symptoms, prolong the remission, and decrease the annual number of recurrences, from an initial average of 5.9 to 0.85 by the end of the treatment period [16]. The results of numerous urological, obstetric, and gynecological studies have consistently demonstrated the efficacy of enzymes in the treatment of infections and inflammatory conditions affecting the urinary and genital systems. The use of SET for the treatment and prevention of CRUC has been demonstrated to result in a more rapid reduction of symptoms, and a concomitant decrease in the total number of recurrences.

The use of various diagnostic scales and questionnaires is becoming increasingly popular among researchers and practitioners worldwide. These tools facilitate objective and quantitative assessments of disease severity, particularly at the initial admission of the patient and throughout the course of treatment [18, 19].

In urology, a variety of scales and questionnaires are used to assess the severity of pain syndrome, urination disorders, and impaired sexual function, particularly in patients with CRUC. Currently, the VZM-III08-2018 Phase III clinical trial is entering its final stages. This is a double-blind, randomized, placebo-controlled, multicenter study investigating the efficacy and safety of Wobenzym as a component of the combination therapy in patients experiencing an exacerbation of CRUC. The study is conducted in accordance with the Rules of Good Clinical Practice at 20 clinical sites, with 640 patients being randomly assigned to one of the study groups. This study marked the introduction of the Russian version of the Pelvic Pain and Urgency/Frequency (PUF) Patient

Symptom Scale (copyright by D. Pushkar, Atrium Innovations RUS, Nestle, Nestle Health Science).

The PUF Patient Symptom Scale was initially developed in 2000 by C. Lowell Parsons as a screening tool for the detection of interstitial cystitis and painful bladder syndrome (PBS) in women presenting with chronic pelvic pain and lower urinary tract symptoms [20]. The scale comprises two domain scores. The first score (score range: 0–23 points) is used to assess the severity of PBS, pelvic pain, and symptoms associated with sexual intercourse. The second score (score range: 0–12 points) evaluates the extent to which the patient is distressed by these symptoms. The total score for PUF symptoms, which is the sum of both scores, ranges from 0 to 35 points. The initial validation of the PUF Patient Symptom Scale was carried out using the Potassium Sensitivity Test (PST). A higher score on the PUF Patient Symptom Scale was associated with an increased probability of a positive PST result, reaching up to 90%. It has been reported that the scale is a useful tool for screening patients, assessing the severity of their symptoms, monitoring the efficacy of symptom management, and evaluating the recurrence or progression of symptoms. Furthermore, it has been widely adopted by clinicians worldwide. The scale has been translated into many languages, and its linguistic and cultural validity has been established in multiple countries. It is widely used by healthcare professionals across a range of therapeutic areas [21].

In 2017, Al-Shukri et al. first adapted the PUF Patient Symptom Scale for use among patients with PBS in Russia [22]. In their study, which included 90 individuals (50 healthy volunteers and 40 patients with PBS), the authors demonstrated the reliability of the Russian version of the questionnaire. The reliability coefficient was 0.961. The statistical analysis supported the high degree of discrimination of the questionnaire among individuals exhibiting varying degrees of symptom severity. The results demonstrated a correlation between the total scores and the severity of symptoms, as well as cystoscopy findings [22].

As the symptoms of inflammatory and non-inflammatory bladder diseases may appear similar, we have proposed a concept for validating the scale for patients with CRUC.

*The study aimed t*o validate the Russian version of the Pelvic Pain and Urgency/Frequency (PUF) Patient Symptom Scale (C. Lowell Parsons, 2000) for patients with CRUC.

MATERIALS AND METHODS

Characteristics of respondents

The scale was validated in individuals who met the following criteria: females aged 18 or older, with oral and written fluency in Russian, clear consciousness, and congruent behavior. The study included two groups of respondents: female healthy volunteers who did not report any urinary disorders or bladder discomfort, and female patients with a confirmed diagnosis of chronic recurrent uncomplicated cystitis.

Statistical analysis

The internal consistency of the PUF Patient Symptom Scale was evaluated throughout the data processing by calculating Cronbach's alpha (α). The α-value was calculated separately for the two groups of respondents. The α-values were interpreted using the following grading system: >0.9, very good; >0.8, good; >0.7, sufficient; >0.6, doubtful; >0.5, bad; and ≤0.5, insufficient. The statistical data analysis was performed using specialized software, specifically the R programming language and RStudio, the Integrated Development Environment for the R programming language.

The interval (quantitative) data were described using an arithmetic mean, standard deviation, median, lower (25%) and upper (75%) quartiles, minimum, and maximum. The categorical (qualitative) data were described using frequencies, percentages, or proportions.

The values were compared between healthy volunteers and patients using either the Mann–Whitney *U*-test (a non-parametric test for two independent samples with non-normal distributions) or the Student's *t*-test for independent samples (a parametric test for two independent samples with normal distributions). The normality was tested using the Shapiro–Wilk test. The Bartlett's test was used to determine whether the variances between the groups were equal or not. The level of statistical significance was set at 0.05 (5%).

RESULTS

A total of 29 respondents were included in the statistical analysis. The first group consisted of 15 healthy volunteers who did not report any urinary disorders or pain or discomfort in the bladder. The second group included 14 women with a confirmed diagnosis of CRUC. Table 1 presents the age characteristics of the study participants. All respondents from both groups spoke Russian fluently and demonstrated complete comprehension of the instructions for scale validation.

Table 2 shows the results of the comparative statistical analysis and descriptive statistics for each question of the Pelvic Pain and Urgency/Frequency (PUF) Patient Symptom Scale.

As evidenced in Table 2, the comparative analysis of several questions (1, 3a, 4, 6, and 7a) revealed no statistically significant differences between healthy volunteers and patients with CRUS ($p > 0.05$). Although the observed difference in mean scores between healthy volunteers and patients was not statistically significant, it is nevertheless noteworthy.

Question 1. How many times do you go to the bathroom during the day? 0.87 points for healthy volunteers; 1.14 points for patients with CRUC. The difference may be indicative of potential changes in the urination patterns observed in CRUC.

Question 3a. Do you have any pain during or after sexual activity? 1.00 points for healthy volunteers; 1.50 points for patients with CRUC. The difference may suggest the presence of pain symptoms, which are commonly observed in patients with cystitis.

Question 4. Do you have pain associated with your bladder, pelvis, vagina, perineum, or urethra? 0.87 points for healthy volunteers; 1.36 points for patients with CRUC. The difference may represent the impact of pain on overall well-being.

Question 6. Do you have urgency after you go to the bathroom? 0.60 points for healthy volunteers; 1.21 points for patients with CRUC. The difference may be attributed to the persistence of urgency, which may be associated with cystitis.

Table 1. Age characteristics of both group respondents

Таблица 1. Возрастная характеристика респондентов двух групп

Parameter	Group	*n*	Mean	*SD*	Median	$Q_{25\,\%}$	$Q_{75\,\%}$	Min	Max
Age, years	Healthy volunteers	13*	23.46	3.64	23.00	21.00	25.00	19	31
	Patients with CRUC	14	31.57	8.16	29.50	28.00	33.25	21	53

Note. Here and Table 2: *n* — number of patients; Mean — arithmetic mean; *SD* — standard deviation; Median — median; $Q_{25\%}$ — the lower quartile; $Q_{75\%}$ — the upper quartile; Min — minimum; Max — maximum; *p* — p-value; CRUC — chronic recurrent uncomplicated cystitis. *The age of two respondents is not recorded.

Примечание. Здесь и в табл. 2: *n* — число пациентов; Mean — среднее арифметическое; *SD* — стандартное отклонение; Median — медиана; $Q_{25\,\%}$ — нижний квартиль; $Q_{75\,\%}$ — верхний квартиль; Min — минимальное значение; Max — максимальное значение; *p* — уровень значимости; ХРНЦ — хронический рецидивирующий неосложненный цистит. *У двух респондентов не зафиксирован возраст.

Table 2. Descriptive statistics of responses to issues of the Pelvic Pain and Urgency/Frequency Patient Symptom Scale (PUF scale), scores

Таблица 2. Описательная статистика ответов на вопросов Шкалы симптомов тазовой боли, императивного, учащенного мочеиспускания (PUF Scale), баллы

Question No.	Group	*n*	Mean	*SD*	Median	$Q_{25\,\%}$	$Q_{75\,\%}$	Min	Max	*p*
1	Healthy volunteers	15	0.87	0.83	1.00	0.00	1.00	0	3	0.217
	Patients with CRUC	14	1.14	0.66	1.00	1.00	1.75	0	2	
2a	Healthy volunteers	15	0.67	0.90	0.00	0.00	1.00	0	3	0.007
	Patients with CRUC	14	1.64	1.01	1.50	1.00	2.00	0	4	
2б	Healthy volunteers	15	0.47	1.06	0.00	0.00	0.00	0	3	0.009
	Patients with CRUC	14	1.43	1.02	1.50	1.00	2.00	0	3	
3a	Healthy volunteers	15	1.00	0.85	1.00	0.00	2.00	0	2	0.217
	Patients with CRUC	14	1.50	1.02	1.00	1.00	2.00	0	3	
3б	Healthy volunteers	15	0.47	0.83	0.00	0.00	1.00	0	3	0.005
	Patients with CRUC	14	1.57	1.02	2.00	1.00	2.00	0	3	
4	Healthy volunteers	15	0.87	0.83	1.00	0.00	1.00	0	3	0.096
	Patients with CRUC	14	1.36	0.84	1.00	1.00	2.00	0	3	
5a	Healthy volunteers	15	0.73	0.70	1.00	0.00	1.00	0	2	0.010
	Patients with CRUC	14	1.57	0.85	2.00	1.00	2.00	0	3	
5б	Healthy volunteers	15	0.60	0.63	1.00	0.00	1.00	0	2	0.009
	Patients with CRUC	14	1.36	0.74	1.00	1.00	2.00	0	3	
6	Healthy volunteers	15	0.60	0.51	1.00	0.00	1.00	0	1	0.071
	Patients with CRUC	14	1.21	0.97	1.00	0.25	2.00	0	3	
7a	Healthy volunteers	15	0.80	0.94	1.00	0.00	1.00	0	3	0.138
	Patients with CRUC	14	1.43	1.16	1.50	0.25	2.00	0	3	
7б	Healthy volunteers	15	0.67	0.98	0.00	0.00	1.00	0	3	0.007
	Patients with CRUC	444	1.79	0.97	2.00	1.25	2.00	0	3	

Question 7a. If you still have urgency after you go to the bathroom, rate its intensity. 0.80 points for healthy volunteers; 1.43 points for patients with CRUC. The difference may suggest that individuals with CRUC experience more intense urgency.

The absence of statistically significant differences for the listed questions could also be attributed to factors affecting interpretation of the study results. Patients subjectively perceive and assess symptoms such as pain and discomfort. Furthermore, healthy individuals may exhibit a range of physiological features, including variations in urination frequency.

A comparative analysis of the remaining questions (2a, 2b, 3b, 5a, 5b, and 7b) revealed statistically significant differences in responses between healthy volunteers and patients with CRUC ($p < 0.05$). These findings support the validity of the Pelvic Pain and Urgency/Frequency Patient Symptom Scale.

The α-value was calculated using the R programming language (ltm library, version 4.2.2 or higher). The α-value was 0.819 for healthy volunteers and 0.888 for patients. The results demonstrate that the PUF Patient Symptom Scale has a good (>0.8) internal consistency.

DISCUSSION

The aim of the study was to validate the Russian version of the Pelvic Pain and Urgency/Frequency Patient Symptom Scale for patients with CRUC. The study population included Russian-speaking females aged 19 to 53 years. The study included two groups of respondents: healthy volunteers and patients diagnosed with chronic recurrent uncomplicated cystitis. The PUF Patient Symptom Scale, as used in the present study, has been translated and adapted for Russian-speaking patients. The ongoing clinical trial, VZM-III08-2018, involved a local modification of the original PUF Patient Symptom Scale (C. Lowell Parsons, 2000). The modified scale differed from the original version specifically in the following ways: 1. Clarification in Question 3: Patients are only required to answer questions 3a and 3b consecutively if they answered "yes" to Question 3, thereby indicating that they were sexually active. If the answer to the question was "no", Questions 3a and 3b should be disregarded. 2. In this modification the term "urgency" is interpreted as urge to urinate and frequent urination in Question 6 (Do you have urgency after you go to the bathroom?), Question 7a (If you still have urgency after you go to the bathroom, rate its intensity), and Question 7b (Does frequent urination bother you?).

The proposed modification was designed to address the primary symptoms observed in the study population and to provide a comprehensive representation of patient-reported symptoms and their impact on the individual's quality of life. A comparative analysis of certain questions (1, 3a, 4, 6, and 7a) revealed no statistically significant differences between the groups ($p > 0.05$). Although the observed difference in mean scores between healthy volunteers and patients was not statistically significant for these questions, it is still meaningful and may be indicative of potential differences. However, the statistical significance of differences for other questions (2a, 2b, 3b, 5a, 5b, and 7b) supports the validity of the Pelvic Pain and Urgency/Frequency Patient Symptom Scale.

The results of the validation study demonstrate the high internal consistency for the questionnaire administered to both groups of respondents, as evidenced by the Cronbach's alpha values.

CONCLUSIONS

The validation study results demonstrate that the Russian version of the Pelvic Pain and Urgency/Frequency Patient Symptom Scale (see Appendix) is a standardized, well-structured tool that facilitates an accurate, cost-effective, and prompt diagnosis of cystitis at the initial visit. Furthermore, this provides an objective evaluation of the efficacy of both treatment and prevention. The findings confirm that the Russian version of the Pelvic Pain and Urgency/Frequency Patient Symptom Scale (C. Lowell Parsons, 2000) has been successfully validated, demonstrating the high internal consistency in both healthy volunteers and patients with CRUC. The scale is therefore suitable for use in clinical practice and will facilitate the most accurate implementation of the scheduled diagnostic assessment in this group of patients.

ADDITIONAL INFORMATION

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Appendix / Приложение

PUF scale (C.L. Parsons, 2000) — Pelvic Pain and Urgency/Frequency Patient Symptom Scale

Шкала PUF (C.L. Parsons, 2000) — Шкала симптомов тазовой боли и императивного, учащенного мочеиспускания

		Points					Symptom score	Bother score
		0	1	2	3	4		
1	How many times do you go to the bathroom during the day?	3–6	7–10	11–14	15–19	20+	_____	
2	a) How many times do you go to the bathroom at night?	0	1	2	3	4+	_____	
	b) If you get up at night to go to the bathroom, does it bother you?	Never	Occasionally	Usually	Always			_____
3	Are you currently sexually active? Yes _____ No_____							
4	a) If you are sexually active, do you now have or have you ever had pain or symptoms during or after sexual activity?	Never	Occasionally	Usually	Always		_____	
	b) If you have pain, does it make you avoid sexual activity?	Never	Occasionally	Usually	Always			_____
5	Do you have pain associated with your bladder or in your pelvis (vagina, labia, lower abdomen, urethra, perineum, penis, testes, or scrotum)?	Never	Occasionally	Usually	Always		_____	
6	a) If you have pain, is it usually...		Mild	Moderate	Severe		_____	
	b) Does your pain bother you?	Never	Occasionally	Usually	Never			_____
7	Do you still have urgency after you go to the bathroom?	Never	Occasionally	Usually	Always		_____	
8	a) If you have urgency, is it usually...		Mild	Moderate	Severe		_____	
	b) Does your urgency bother you?	Never	Occasionally	Usually	Always			_____
					Symptom score (1, 2a, 4a, 5, 6a, 7, 8a)—Subtotal		_____	
					Bother score (2b, 4b, 6b, 8b)—Subtotal			_____
					Total score* (Symptom score + Bother score)		_____	

*In the published assessment of the PUF scale by Parsons et al,[9] a total PUF score of 15 or greater was associated with an 84% likelihood of having a positive potassium sensitivity