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Approbation and validation of Russian version of the interstitial cystitis symptoms and problem index

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ABSTRACT

BACKGROUND: Improving the effectiveness of diagnosing and treating patients with primary bladder pain syndrome is crucial in current urology owing to the high prevalence of the condition, its significant impact on the quality of life, and the similarity of its clinical manifestations to other diseases. The clinical manifestations of primary bladder pain syndrome is typically evaluated using specialized questionnaires, with one of the most commonly utilized being the Interstitial Cystitis Symptoms and Problem Index.

AIM: This study aimed to validate the Russian version of the Interstitial Cystitis Symptoms and Problem Index and thus assess its reliability and validity in accurately measuring the symptoms and problems associated with interstitial cystitis.

MATERIALS AND METHODS: The study included 62 participants and divided them into two groups. Group A included 32 patients diagnosed with primary bladder pain syndrome, comprising 26 women and 6 men, with an average age of 55 years. Group B consisted of 30 conditionally healthy volunteers, comprising 20 men and 10 women, with an average age of 46 years. All participants were required to complete the Russian version of the Interstitial Cystitis Symptoms and Problem Index, Pelvic Pain and Urgency/Frequency (PUF) scale, and International Prostate Symptom Score (IPSS) and maintain a voiding diary. Additionally, patients with PBPS underwent cystoscopy with bladder hydrodistention. Data collected from the participants were utilized to determine the internal consistency, external validity, and test-retest reliability of the questionnaires using the interclass correlation coefficient.

RESULTS: The mean of the Interstitial Cystitis Symptoms and Problem Index total in group A was 31.55 ± 7.07 , which significantly ($p < 0.001$) exceeded the score of group B (2.90 ± 1.47). The Cronbach's alpha of the total and "ICSI" and "ICPI" domains was 0.990, 0.834, and 0.854 respectively, confirming the high internal consistency of the Russian version of the Interstitial Cystitis Symptoms and Problem Index. External validity was verified by the relevant correlations with other questionnaires. Moreover, the total score of the questionnaire correlated with the clinical manifestations of primary bladder pain syndrome, the presence of Hunner's lesions, and bladder capacity.

CONCLUSIONS: The study findings indicate that the Russian version of the Interstitial Cystitis Symptoms and Problem Index exhibits good validity and reliability. Therefore, it can be recommended for use in clinical practice as an effective tool for assessing symptoms and problems associated with interstitial cystitis.

Keywords: primary bladder pain syndrome; Interstitial Cystitis Problem Index; Interstitial Cystitis Symptoms Index.

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Апробация и валидизация русскоязычной версии опросника «Индекс симптомов и качества жизни пациентов с первичным мочепузырным болевым синдромом»

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АННОТАЦИЯ

Актуальность. Повышение эффективности диагностики и лечения пациентов с первичным мочепузырным болевым синдромом является важной задачей современной урологии. Актуальность обусловлена высокой распространенностью, значительным влиянием на качество жизни, схожестью клинических проявлений с другими заболеваниями. Для объективации жалоб используют различные специальные опросники, в том числе «Interstitial Cystitis Symptoms and Problem Index» («Индекс симптомов и качества жизни пациентов с первичным мочепузырным болевым синдромом»).

Цель — апробация и оценка валидности русскоязычной версии опросника «Индекс симптомов и качества жизни пациентов с первичным мочепузырным болевым синдромом».

Материалы и методы. В исследовании участвовали 62 человека. Группу А составили 32 пациента с первичным мочепузырным болевым синдромом (26 женщин и 6 мужчин), средний возраст составил 55 лет. В группу В вошли 30 условно здоровых добровольцев (20 женщин и 10 мужчин), средний возраст — 46 лет. Всем участникам исследования было предложено заполнить опросник «Индекс симптомов и качества жизни пациентов с первичным мочепузырным болевым синдромом», переведенный на русский язык, анкеты PUF-Scale, IPSS и дневник мочеиспускания. Полученные данные были использованы для оценки внутренней согласованности, внешней валидности и достоверности опросника. Всем пациентам с первичным мочепузырным болевым синдромом под спинномозговой анестезией была выполнена цистоскопия и гидродистензия мочевого пузыря.

Результаты. Средний балл по оцениваемому опроснику в группе А составил $31,55 \pm 7,07$, что достоверно ($p < 0,001$) превысило значения показателя в группе Б ($2,90 \pm 1,47$). Коэффициент альфа Кронбаха в целом для опросника и по доменам «Индекс симптомов интерстициального цистита» (Interstitial Cystitis Symptoms Index, ICSI) и «Индекс качества жизни при интерстициальном цистите» (Interstitial Cystitis Problem Index, ICPI) равнялся 0,990, 0,834 и 0,854 соответственно, что указывает на высокую внутреннюю согласованность анкеты. Внешняя валидность опросника подтверждена наличием высокой тесноты связи значений с результатами других опросников. Сумма баллов опросника также коррелирует с клиническими проявлениями первичного мочепузырного болевого синдрома, наличием гуннеровских поражений и емкостью мочевого пузыря.

Выводы. Русскоязычная версия опросника «Индекс симптомов и качества жизни пациентов с первичным мочепузырным болевым синдромом» является валидным и надежным инструментом оценки симптомов заболевания и может быть рекомендована к использованию в клинической практике и научных исследованиях.

Ключевые слова: первичный мочепузырный болевой синдром; Interstitial Cystitis Problem Index; Interstitial Cystitis Symptoms Index.

Как цитировать

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BACKGROUND

Primary bladder pain syndrome (BPS) is chronic or recurrent pain localized in the bladder area, which is accompanied by at least one more symptom, including pain when filling the bladder and frequent urination during the day and/or at night [1]. The frequency of occurrence in the general population ranges from 0.06% to 35%. The syndrome is 10 times more common in women than in men. Varying data may be associated to the use of different criteria for diagnosing the disease, heterogeneity of symptoms, and similarity of manifestations with several urologic, gynecologic, neurologic, and surgical diseases [1, 2].

The causes of the syndrome remain unclear. However, its polyetiological nature is known. BPS is characterized by persistent or recurrent pain; discomfort or heaviness in the projection of the bladder, which increases when it is filled; persistent urge to urinate; and increased daytime and/or night urination in the absence of infectious or organic damage to the bladder. It is more pronounced in patients with Hunner's lesions in the bladder [3, 4]. The importance of early diagnosis and adequate treatment of this disease is associated with its significant impact on the patient's quality of life [5]. The urological status of patients with BPS should be comprehensively assessed, including obtaining complaints, anamnesis assessment, physical examination, blood and urine tests, and cystoscopy with hydrodistention under general anesthesia, which is the primary option for diagnosing damage to the glycosaminoglycan layer of the urothelium in BPS based on the recommendations of the International Society for the Study of Interstitial Cystitis (European Society for the Study on IC/BPS) [3, 6, 7].

To demonstrate and detail the patient's complaints in urological practice, a urination diary and various questionnaires are used. Questionnaires should have properties such as validity and reproducibility. The translation and wording of the questions should be understandable to the patient, and the original text and the Russian version should be translatable and equivalent.

In most foreign neurology clinics, BPS diagnosis begins with filling out questionnaires, such as the Interstitial Cystitis Symptoms and Problem Index (ICSPI).

This study aimed to translate the ICSPI questionnaire into Russian and test and evaluate the validity of the Russian version.

MATERIALS AND METHODS

The original English version of the questionnaire ICSPI was translated into Russian by a professional translator, a native speaker of Russian, according to the algorithm of linguistic and cultural adaptation. Then, five English-speaking urologists studied the translation to determine

its accuracy, reliability of the content, and equivalence to the English version. Afterward, a native English speaker who speaks Russian translated the Russian version back into English. The translators who participated in this study revealed that the original text and the Russian version were translatable and equivalent. The final version of the translation was provided to the study participants.

This study included 62 participants. Group A consisted of 32 patients with primary BPS (26 women and 6 men). The average age of the patients was 55 years (24–78 years). Control group B included 30 conditionally healthy individuals (20 women and 10 men). The average age of the participants in the control group was 46 years (24–60 years). All study participants were asked to complete a specialized questionnaire translated into Russian, namely, "Index of symptoms and quality of life of patients with primary bladder pain syndrome"; the questionnaire "Pelvic Pain and Urgency/Frequency Scale" (PUF-Scale), translated and validated under the guidance of Prof. Al-Shukri in 2017; the International Prostate Symptom Score (IPSS) questionnaire; and the urination diary [8].

All patients with BPS under spinal anesthesia underwent cystoscopy with bladder hydrodistention, during which the mucosa was assessed for the presence of glomerulations, Hunner's lesions, anatomical capacity of the bladder, and bladder filling volume at which mucosal changes appeared [6].

The study results were statistically analyzed using the SPSS 22.0 software using parametric and non-parametric statistical methods. The internal consistency of the questionnaire was evaluated by calculating the Cronbach's alpha coefficient. A value >0.9 was considered as very good, >0.8 as good, >0.7 as sufficient, and >0.6 as doubtful. The external validity, that is, the consistency of the results with the data from other questionnaires, was investigated using Pearson correlation coefficients.

RESULTS

The Russian version of the "Index of symptoms and quality of life of patients with primary bladder pain syndrome" is presented in the appendix.

The average score according to the survey results in group A was 31.55 ± 7.07 , which significantly ($p < 0.001$) exceeded the values of the indicator in control group B (2.90 ± 1.47). Similar results were obtained separately for "Interstitial Cystitis Symptoms Index" (ICSI) and "Interstitial Cystitis Problem Index" (ICPI) (Table 1).

The Cronbach's alpha coefficients for the questionnaire as a whole and for the ICSI and ICPI domains were 0.990, 0.834, and 0.854, respectively, indicating a high internal consistency of the questionnaire.

Table 1. Interstitial Cystitis Symptoms and Problem Index for the main (A) and control (B) groups**Таблица 1.** Значения по опроснику Interstitial Cystitis Symptoms and Problem Index в основной (A) и контрольной (B) группах

Group	Average total score according to ICSPI, $M \pm m$	Minimum–maximum value	Average ICSI score, $M \pm m$	Average ICPI score, $M \pm m$
A ($n = 32$)	$31.55 \pm 7.07^*$	14–36	$16.51 \pm 4.97^*$	$15.03 \pm 2.21^*$
B ($n = 30$)	2.90 ± 1.47	1–5	2.74 ± 1.29	0.16 ± 0.37

*Differences with the values in group B are significant ($p < 0.001$).

*Различия со значениями в группе В достоверны ($p < 0,001$).

Table 2. Оценка валидности русскоязычной версии Interstitial Cystitis Symptoms and Problem Index (ICSPI)**Table 2.** Validity of the Russian version of the Interstitial Cystitis Symptoms and Problem Index (ICSPI)

Questionnaire	ICSPI	ICSI	ICPI	IPSS	PUF-Scale
ICSPI	1	0.988*	0.988*	0.812*	0.872*
ICSI	0.988*	1	0.988*	0.791*	0.851*
ICPI	0.988*	0.988*	1	0.810*	0.871*
IPSS	0.812*	0.791*	0.810*	1	0.760*
PUF-Scale	0.872*	0.851*	0.871*	0.760*	1

Note. The table shows the Pearson correlation coefficient (R) values between the ICSPI total score, the sum of ICSI and ICPI domain scores, and IPSS and PUF-Scale questionnaires. *Correlation is significant ($p < 0.01$).

Примечание. В таблице представлены значения коэффициента корреляции Пирсона (R) между суммарным баллом ICSPI, суммой баллов по доменам ICSI и ICPI, опросников IPSS и PUF-Scale. *Корреляция достоверна ($p < 0,01$).

The external validity was confirmed by the presence of a strong relationship with the results of other questionnaires (Table 2). The total score of the questionnaire was significantly correlated with the values of IPSS and PUF-Scale and with the number of urinations per day, the indicator of bladder capacity, and the presence of Hunner's lesions during cystoscopy. The Pearson correlation coefficient was 0.812, 0.872, 0.850, -0.842, and 0.950, respectively ($p < 0.001$).

DISCUSSION

When analyzing the validity and reliability of the Russian version, the Cronbach's alpha coefficient and inter-class correlation coefficient were obtained, which were comparable to the values described for the American version of the questionnaire [9, 10]. In a Turkish study, the results of 79 patients with BPS and 50 controls were analyzed. ICSI and ICPI indices showed high internal consistency. The Cronbach's coefficients were 0.879 and 0.923, respectively. Both index scores were significantly higher in the BPS group than in the control group ($p < 0.001$). Significant correlations were found between the 24-hour frequency of urination, nocturia, and scores on the visual analog scale of pain [11]. A study by scientists from Taiwan has shown that ICSPI may be used for screening for BPS and evaluating the results of treatment of interstitial cystitis [12]. However, in the Brazilian version of the questionnaire, the analyzed instruments did not reach

appropriate reliability values. Thus, future studies are required to analyze psychometric measures on a larger group of patients with BPS [13].

CONCLUSIONS

The Russian version of the "Index of symptoms and quality of life of patients with primary bladder pain syndrome" is a valid and reliable tool for assessing the symptoms of primary BPS and may be used in clinical practice and scientific research.

ADDITIONAL INFORMATION

Authors' contribution. All authors made a substantial contribution to the conception of the study, acquisition, analysis, interpretation of data for the work, drafting and revising the article, final approval of the version to be published and agree to be accountable for all aspects of the study. Personal contribution of each author: N.A. Bekker — collection of material, writing the text of the manuscript, analysis of the data obtained; E.S. Filippova — concept and design of the study, collection of material, analysis of the data obtained, writing the text of the manuscript; A.V. Zyryanov — concept and design of the study, analysis of the data obtained, editing the text of the manuscript; I.V. Bazhenov, A.A. Makaryan — analysis of the obtained data, editing the text of the manuscript.

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Competing interests. The authors declare that they have no competing interests.

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собор материала, анализ полученных данных, написание текста рукописи; А.В. Зырянов — концепция и дизайн исследования, анализ полученных данных, редактирование текста рукописи; И.В. Баженов, А.А. Макарян — анализ полученных данных, редактирование текста рукописи.

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Appendix

Questionnaire “Index of symptoms and quality of life of patients with primary bladder pain syndrome”

“Interstitial cystitis symptoms index” (ICSI) _____ points

1. During the past month, how often have you felt the strong need to urinate with little or no warning:

0 — Not at all

1 — Less than 1 time in 5

2 — Less than half the time

3 — About half the time

4 — More than half the time

5 — Almost always

2. During the past month, have you had to urinate less than 2 hours after you finished urinating?

0 — Not at all

1 — Less than 1 time in 5

2 — Less than half the time

3 — About half the time

4 — More than half the time

5 — Almost always

3. During the past month, how often did you most typically get up at night to urinate?

- 0 — Not at all
- 1 — Once per night
- 2 — 2 times per night
- 3 — 3 times per night
- 4 — 4 times per night
- 5 — 5 or more times per night

4. During the past month, have you experienced pain or burning in your bladder?

- 0 — Not at all
- 1 — Once
- 2 — A few times
- 3 — Fairly often
- 4 — Almost always
- 5 — Always

"Interstitial Cystitis Problem Index" (ICPI) _____ points

5. During the past month, how much has each of the following been a problem for you?

Frequent urination during the day

- 0 — No problem
- 1 — Very small problem
- 2 — Small problem
- 3 — Medium problem
- 4 — Big problem

Getting up at night to urinate

- 0 — No problem
- 1 — Very small problem
- 2 — Small problem
- 3 — Medium problem
- 4 — Big problem

Need to urinate with little warning

- 0 — No problem
- 1 — Very small problem
- 2 — Small problem
- 3 — Medium problem
- 4 — Big problem

Burning, pain, discomfort, or pressure in your bladder

- 0 — No problem
- 1 — Very small problem
- 2 — Small problem
- 3 — Medium problem
- 4 — Big problem

Total score _____

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