

USE OF IPSS-QOL IN ASSESSING SYMPTOMS AND QUALITY OF LIFE IN PATIENTS WITH STRICTURAL URETHRAL DISEASES IN MEN

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ABSTRACT

To assess symptoms and quality of life in men with urethral strictures, the IPSS-QoL questionnaire is used. Testing the psychometric properties of the questionnaire for this category patients were not carried out.

Purpose: to evaluate the psychometric properties of the IPSS-QoL questionnaire when used by patients with stricture of the anterior urethra.

Materials and methods: The IPSS-QoL questionnaire was completed by 35 men with urethral stricture. The reliability of the questionnaire was assessed by calculating Cronbach's α coefficient and coefficients item-scale correlations. Validity was determined by the method of "external criteria" – identifying correlations between survey results and objective indicators: maximum volumetric urination rate (Q_{max}) and residual urine volume (U_{res}), between the QoL scale score and the index and VAS (Visual analog scale) values of the EQ-5D questionnaire..

Results: IPSS-QoL content validity assessed by experts and patients: questions about storage symptoms are considered insignificant for patients with anterior urethral strictures, while the symptoms that were of primary importance (post-micturition dribbling) are not covered. Cronbach's α reliability was 0.65 (0.55–0.69 when one item was removed), those. was below the generally accepted threshold of 0.7. Item-scale correlation coefficients, equal to 0.146–0.585, for 2 out of 7 questions, turned out to be below the generally accepted limit of 0.2, which indicates about the internal inconsistency of the questionnaire. Construct validity assessment did not reveal relationship between survey results and objective indicators Q_{max} ($R=0.178$, $p=0.306$), U_{res} ($R=-0.074$, $p=0.673$). There were weak, statistically insignificant correlations relationship between the QoL scale score and the index values and VAS of the EQ-5D questionnaire: $R=-0.26$, $p=0.18$ and $R=-0.21$, $p=0.27$, respectively.

Conclusion: The IPSS-QoL questionnaire is not effective when used by men with anterior urethral stricture. Sufficient reliability and validity – the design does not allow adequate assessment all symptoms and reliability indicators are unsatisfactory; survey results are not have correlations with objective indicators. This questionnaire cannot be recommended for assessing the health status and quality of life of this category of patients.

Keywords: patient assessments; quality of life, strictures anterior urethra, IPSS-QoL questionnaire

INTRODUCTION

In modern clinical medicine, aimed at personalizing treatment, patient-reported assessments (PDRs) are becoming increasingly relevant [1]. Today, the description of health and quality of life (QoL) given by the patient himself has a value comparable in importance to the results of

objective examination methods, and plays a significant role in the choice of tactics and methods of treatment, and assessment of its effectiveness. Translation of subjective feelings into objective quantitative indicators allows assessment research tools given by patients - questionnaires, general and special, of which more than 900 have currently been developed [2]. Methodologically sound patient assessment studies involve the use of standardized questionnaires with proven psychometric properties [3].

Attempts to assess the patient's subjective sensations are also made in reconstructive urethral surgery. Wanting to objectify the PDRs, some urologists use questionnaires intended for other genitourinary diseases, without scientifically based evidence of their validity for patients with urethral strictures. The most commonly used questionnaire is the IPSS-QoL [4]. International Prostate Symptoms Score with Quality of life scale (IPSS-QoL) - an international specific questionnaire for assessing symptoms lower urinary tract (LUTS) and their impact on the quality of life of patients - developed in 1991 by the American Urological Association for patients with benign prostatic hyperplasia (BPH). Called AUA-7, it consisted of 7 questions, who assessed LUTS [5]. In 1992, this questionnaire, supplemented by an 8th question assessing the impact of LUTS on quality of life, has been recognized by WHO as an international tool for assessing symptoms and quality of life patients with BPH. To date, this questionnaire has been translated into many languages, including Russian [6–11]. Ethnolinguistic adaptation and reliability assessment of the Russian-language version of the questionnaire for patients with BPH were carried out in 1997. [12]. The questionnaire includes 7 questions, the answers to which determine how often the patient is bothered by LUTS (storage and emptying symptoms). Each question is rated on a scale from 0 to 5, where 0 means never and 5 means always. The sum of points indicates the severity of symptoms: 0–15 points – weak, 15–20 – moderate, 20–35 points – severe. The eighth question, separated into a separate QoL scale, assesses the impact of symptoms on patients' QoL from 0 to 6 points, where 0 is excellent, 6 is very bad. Despite the fact that this questionnaire was developed for men suffering from BPH, it is currently widely used for various diseases accompanied by LUTS, including urethral strictures [4]. This can probably be explained by the questionnaire's brevity and ease of use by both clinician and patient. According to the methodology for studying PDRs, assessment of the psychometric properties of a symptomatic questionnaire before using it in patients with other nosologies is a mandatory procedure. In such a case, it is enough to check the reliability - internal consistency, content and construct validity, sensitivity [13]. There have been no previous studies that can confirm the validity of the IPSS-QoL questionnaire in patients with urethral strictures.

OBJECTIVE

To evaluate the psychometric properties of the IPSS-QoL questionnaire when used by patients stricture of the anterior urethra.

MATERIALS AND METHODS

Thirty-five men with an established diagnosis of anterior urethral stricture completed the IPSS-QoL questionnaire and the EQ-5D-3L general questionnaire, and also answered questions

regarding the structure of the questionnaire during an oral interview. The characteristics of the patients are presented in Table. 1.

Table-1.

Clinical characteristics of patients	
Age, years (M±m)	49,8±2,7
Length of stricture, cm (M±m)	4,9±0,7
Localization of stricture, n(%)	
Penile section	18(51)
Bulbous department	15(43)
Both departments	2(6)
Qmax, ml\s (M±m)	3,4±0,2
Ures,ml (M±mt)	64,5±5,4
Note: Qmax - maximum urination rate, Ures - volume of residual urine	

Reliability was assessed using Cronbach's α and item–item correlation coefficients. scale”, values >0.7 and 0.2 , respectively, were defined as threshold values [16, 17]. Content validity was assessed during interviews with urological experts and patients. Construct validity was determined by the “external criteria” method - identifying correlations between the results of the questionnaire and objective indicators: maximum volumetric urination rate (Qmax) and residual urine volume (Ures), and also between the QoL scale score and the index and VAS values of the EQ-5D-3L questionnaire. Statistical processing of the material was carried out using the SPSS Statistics 21.0 program (IBM, USA). Correlation analysis was carried out using the Spearman rank correlation method. The critical significance level (p) is taken equal to 0.05 .

RESULTS

The average score assessing LUTS obtained during a survey of men was 21.4 ± 1.2 (10–35 points). Average score QoL – 5.65 ± 0.77 (3–6 points). Assessing acceptability and content validity IPSS-QoL questionnaire. During the interview on the content of the questionnaire, all patients noted the clarity, clarity and correctness of the questions. Most men noted that a number of symptoms that were of primary importance to them (additional efforts to continue urinating, involuntary release of drops of urine after urination) were not covered in this questionnaire, while questions assessing storage symptoms were not of primary importance for patients. The design of the questionnaire was also analyzed by a group of urological experts - questions assessing storage symptoms (No. 2, No. 4, No. 7) for patients with anterior urethral stricture were considered irrelevant. Therefore, the content of the questionnaire is not covers the whole range of problems that concern patients with anterior urethral stricture. When assessing the reliability, Cronbach's α coefficient was 0.65 for the questionnaire as a whole and 0.55 – 0.69 for deleting one of the questions (Table 2).

Table-2.

Reliability indicators of the IPSS-Qol questionnaire		
Question	Item-scale correlation	Cronbach's α when deleting an item
B1	0,59	0,55
B2	0,4	0,61
B3	0,15	0,69
B4	0,53	0,56
B5	0,16	0,66
B6	0,46	0,59
B7	0,31	0,63

Since for symptomatic questionnaires a value of $\alpha > 0.7$ is considered satisfactory, the level of reliability of the questionnaire according to this criterion is unsatisfactory. The correlation coefficients between any of the elements and the total score on the LUTS scale lie in range from 0.146 to 0.585, while for 2 out of 7 questions this value is below the generally accepted limit of 0.2, which indicates the inconsistency of the questions within the design of the questionnaire (see Table 2). When determining construct validity by assessing the relationship between questionnaire scores and “external criteria” did not reveal a correlation between the survey results and objective indicators. The correlation coefficient of the sum of points with the Qmax indicator was 0.178 ($p=0.306$), with the Ures indicator - -0.074 ($p=0.673$). Consequently, the design of the IPSS questionnaire does not allow adequate assessment of the symptoms of patients with anterior urethral stricture. The validity of the QoL scale, which assessed the impact of LUTS on the quality of life of patients, was separately analyzed. This scale is represented by one question. The analysis was carried out by identifying correlations between the score on the QoL scale and the value of the index and the VAS “thermometer” of the general questionnaire EQ-5D-3L. The average QoL score was 5.65 ± 0.77 , EQ-5D index - 0.64 ± 0.05 , EQ-5D VAS score - 56.7 ± 3.75 .

Table-3.

Correlation of the Qol scale score with the EQ-5D-3L questionnaire scores		
Indicators	R	P
Qol and VAS EQ-5D	-0,21	0,27
Qol and index EQ-5D	-0,26	0,18

As can be seen from table. 3, there are weak correlations between the QoL scale score and the EQ-5D VAS score and the EQ-5D index value, while these connections not statistically significant. Thus, the QoL scale assesses the impact of LUTS on the quality of life of patients with urethral stricture, but at the same time it is obvious that one question does not cover all the parameters of quality of life and the likelihood of obtaining unreliable data is quite high. Since the IPSS-QoL questionnaire cannot be considered valid and reliable for assessing the symptoms and quality of life of patients with anterior urethral stricture, we considered it inappropriate to assess its sensitivity.

DISCUSSION

Anterior urethral strictures have a significant negative impact on the quality of life of affected men. Assessing the results of treatment for anterior urethral strictures, taking into account quality of life and patient satisfaction with treatment as one of the effectiveness criteria, seems relevant. To objectify the PDRs, special tools with proven psychometric properties are needed - valid questionnaires. A review of publications in MedLine in 2013 found 15 studies that included the study of PDRs after surgical treatment of anterior urethral strictures [4]. Most of them used the American Urological Association AUA-7 questionnaire [5], better known as The IPSS questionnaire was developed for patients with BPH, but has not been validated for men with urethral strictures. Obviously, LUTS caused by BPH and resulting from urethral stricture are very similar, but G. R. Nuss et al. [14] found that in 21% of men with existing urethral stricture, when surveyed using the IPSS questionnaire, symptoms of urinary disorders were not identified. Another study using the IPSS questionnaire showed differences in the opinions of patients and doctors about the success of treatment [15]. During the survey 78% of 203 patients who underwent urethroplasty with a good effect, and 80% of 30 patients for whom the outcome of urethroplasty was considered unsuccessful, were satisfied or very satisfied with the result of the operation [15]. Results of the above studies indicate the imperfection of the IPSS-QoL questionnaire when used by patients with anterior urethral stricture, as well as the divergence of opinions in determining the success of treatment between doctors and patients. This dictates the need to use a specialized valid tool to assess the subjective state of this category of patients, as well as a more detailed study of the results of treatment of anterior urethral strictures from the perspective of the PDRs. Our findings suggest that the IPSS-QoL questionnaire does not fully cover all health problems in men with anterior urethral stricture. Reliability indicators. This questionnaire turned out to be below generally accepted threshold values, which indicates the inconsistency of questions within the design of the questionnaire. The survey results do not have correlations with objective parameters of urination (Q_{max} , U_{res}), therefore, this tool does not allow adequate assessment of the symptoms and quality of life of men with anterior urethral strictures. It is important to note that the IPSS questionnaire, widely introduced into the daily practice of a urologist, is a short and simple diagnostic test for identifying LUTS and determining the degree of their severity. At the stage of initial treatment of patients suffering from LUTS and diagnostic search, this tool allows you to obtain important information about the patient and determine further tactics for his examination. At the same time, for patients with an established diagnosis of anterior urethral stricture, it is more advisable to use the specialized PROM-USS questionnaire, which allows you to reliably assess the symptoms and quality of life of this category of patients, as well as satisfaction with their treatment [16, 17].

CONCLUSION

The psychometric properties of the IPSS-QoL questionnaire do not justify its recommendation as a tool for assessing symptoms and their impact on QoL in patients with anterior urethral stricture.

REFERENCES

1. Cella D., Yount S., Rothrock N., Gershon R., Cook K., Reeve B., Ader D., Fries JF., Bruce B., Rose M. The Patient-Reported Outcomes Measurement Information System (PROMIS). *Med. Care.* 2007;45(5, suppl. 1):3–11. Doi: 10.1097/01. mlr.0000258615.42478.55.
2. Mapi Research Trust. ProQolid. Patient-Reported Outcome and Quality of Life Instruments Database. www.proqolid.org.
3. Novik A.A., Ionova T.I. Guide to the study of the Quality of Life in medicine. SPb: Olma-Press. 2002; 320 p. Russian.
4. Voelzke B.B. Critical review of existing patient reported outcome measures after male anterior urethroplasty. *J Urol.* 2013;189:182–188. Doi:10.1016/j.juro.2012.08.096.
5. Barry M.J., Fowler F.J. Jr, O'Leary M.P., Bruskewitz R.C., Holtgrewe H.L., Mebust W.K., Cockett A.T. The American Urological Association symptom index for benign prostatic hyperplasia. The Measurement Committee of the American Urological Association. *J. Urol.* 1992;148(5):1549–1557.
6. Badia X., Garcia-Losa M., Dal-Re R. Ten-language translation and harmonization of the International Prostate Symptom Score: developing a methodology for multinational clinical trials. *Eur Urol.* 1997;31(2):129–140.
7. Badia X., Garcia-Losa M., Dal-Re R., Carballido J., Serra M. Validation of harmonized Spanish version of the IPSS: evidence of equivalence with the original American scale International Prostate Symptom Score. *Urology.* 1998;52(4):614–620.
8. Choi E.P., Lam C.L., Chin W.Y. Validation of the International Prostate Symptom Score in Chinese males and females with lower urinary tract symptoms. *Health Qual Life Outcomes.* 2014;12:1. Doi: 10.1186 / 1477-7525-12-1.
9. Hammad F.T., Kaya M.A. Development and validation of an Arabic version of the International Prostate Symptom Score. *BJU Int.* 2010; 105(10): 1434–1438. Doi: 10.1111 / j.1464-410X.2009.08984.x.
10. Homma Y., Tsukamoto T., Yasuda K., Yoshida M., Shinji M. Linguistic validation of Japanese version of International Prostate Symptom Score and BPH impact index. *Nihon Hinyokika Gakkai Zasshi.* 2002; 93(6): 669–680.
11. Quek K.F., Chua C.B., Razack A.H., Low W.Y., Loh C.S. Construction of the Mandarin version of the International Prostate Symptom Score inventory in assessing lower urinary tract symptoms in a Malaysian population. *Int J Urol.* 2005;12(1):39–45. Doi: 10.1111 / j.1442-2042.2004.00988.x.
12. Savchenko N.E., Skobejus I.A., Oliferko S.A., Ol'man V. E., Tatarickij O.L. Approval of IPSS in the CIS countries, taking into account the cultural and linguistic characteristics. *Urol i nefrol.* 1997;5:26–27. Russian.
13. Novik A.A. Matveev S.A., Ionova T.I. Et al. Assessment of the Quality of Life in medicine. *Klin. medicina.* 2000;2:10–13. Russian.
14. Nuss, G.R., Granieri M.A., Zhao L.C., Thum D.J., Gonzalez C.M. Presenting symptoms of anterior urethral stricture disease: a disease specific, patient reported questionnaire to measure outcomes. *J Urol.* 2012;187:559–562. Doi: 10.1016/j.juro.2011.10.043.
15. Kessler T.M., Fisch M., Heitz M., Oleanas R., Schreiter F. Patient satisfaction with the outcome of surgery for urethral stricture. *J Urol.* 2002;167:2507–2511.

16. Jackson M.J., Chaudhury I., Mangera A. A Prospective Patientcentred Evaluation of Urethroplasty for Anterior Urethral Stricture Using a Validated Patient-reported Outcome Measure. *Eur Urol.* 2013;64:777–782.
17. Bazaev V.V., Shibaev F.N., Pavlova Y.V. Validation of the Russian version of the questionnaire to assess the effectiveness of surgical treatment of patients with anterior urethral stricture (PatientReported Outcame Measure for Urethral Stricture Surgery – PROMUSS): a pilot study. *Urologiia.* 2015;5:15–21. Russian.