Validation of the Croatian Version of the 8-Item Overactive Bladder Questionnaire (OAB-V8)

Mikuš, Mislav; Ostroški, Martina; Beljan, Petrana; Karadža, Magdalena; Dumančić, Stipe; Šprem Goldštajn, Marina; Ćorić, Mario; Kalafatić, Držislav; Orešković, Slavko

Source / Izvornik: **Female Pelvic Medicine & Reconstructive Surgery, 2021, 27, e687 - e690**

Journal article, Accepted version
Rad u časopisu, Završna verzija rukopisa prihvaćena za objavljivanje (postprint)

https://doi.org/10.1097/SPV.0000000000001098

Permanent link / Trajna poveznica: https://urn.nsk.hr/urn:nbn:hr:105:382368

Validation of the Croatian version of the 8-item overactive bladder questionnaire (OAB-V8)

Mislav Mikuš[1,2], MD, Martina Ostroški[1,2], MD, Petrana Beljan[1,2], MD, Magdalena Karadža[1,2], MD, Stipe Dumančić[2], MD., Prof. Marina Šprem Goldštajn[1,2], MD., PhD, Mario Ćorić[1,2], MD., PhD, Prof. Držislav Kalafatić[1,2], MD., PhD, Prof. Slavko Orešković[1,2], MD., PhD.

[1]Department of Obstetrics and Gynecology, University Hospital Center Zagreb, Croatia

[2]School of Medicine, University of Zagreb, Croatia

Corresponding author:

Mislav Mikuš, Department of Obstetrics and Gynecology, University Hospital Center Zagreb, Croatia, Petrova 13, Zagreb 10000

ORCID: 0000-0002-1365-8704

Contributions: All nine authors contribute equally according to the criteria for scientific authorship of the International Committee of Medical Journal Editors (ICMJE): 1. Substantial contributions to conception and design, data collection or analysis, and interpretation of data; 2. Writing of the article or critical review of the intellectual content; 3. Final approval of the version to be published; and 4. Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Work was carried out at University Hospital Center Zagreb on Department of Obstetrics and Gynecology, Petrova 13, 10 000 Zagreb.

Declarations of interest: none.

Funding: none.

Word count: 1780

Short running title: Croatian version of the OAB-V8.

Abstract

Objectives: The present study was conducted with the aim to translate, adapt and validate the 8-item overactive bladder questionnaire (OAB-V8) in Croatia.

Methods: This study included a total of 58 female patients with OAB and 66 healthy women. The translation to Croatian followed standardized procedure. All eligible participants completed OAB-V8 at inclusion and 2 weeks after to assess test-retest reliability. Cronbach α coefficient was calculated in order to assess internal consistency.

Results: Our study demonstrated high internal consistency for all items at both visits (Cronbach's α between 0.799-0.847), with stable internal consistency reliability across items during 2-week period. However, the exception is the item „waking up at night to urinate“, which significantly changed during 2-week period. Intra-class correlation (ICC) for OAB-V8 items ranged from 0.810 to 1.0, with Spearman's correlations above 0.9 for all items ($P < 0.01$). There were strong significant correlations between frequency urination during daytime, uncomfortable and sudden urge to urinate, and between nocturia and waking up at night. Discriminative validity showed statistically significant score differences between patient and control group.

Conclusions: The Croatian version of the OAB-V8 was successfully translated, adapted and validated so the questionnaire is now ready for use as a reliable tool for initial screening and assessing patients with OAB in everyday Croatian clinical practice.

Keywords: OAB-V8; overactive bladder; quality of life; questionnaire; validation

Introduction

According to International Continence Society (ICS), overactive bladder (OAB) presents a condition of “urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence (UUI), in the absence of urinary tract infection (UTI) or other obvious pathology”[1]. The most cited articles estimate a prevalence ranged between 12% and 17% of adults with similar reported prevalence in both men and women[2–4]. However, the potential for underreporting of OAB syndrome have also impact on establishing exact incidence and prevalence rate.

OAB is steadily becoming a significant public-health issue, impacting unfavourably on the quality of life (QoL), performance of daily activities, self-esteem, sleep, sexual function, social life and overall mental health[5–8]. A psychological impact on family members was also demonstrated[9,10]. On the other hand, with the increasing age of the population worldwide, large socioeconomic impact of OAB is expected[11]. Considering a cost-utility analysis provided across six European countries, the annual cost-of-illness estimated €7 billion per year with expected increasing tendency in years to come[7].

Despite the high impact on QoL in patients reporting OAB symptoms, treatment seeking remains very low[12]. Identifying patients and measuring OAB´s impact on symptom severity and patient´s health-related QoL is necessary to ensure proper treatment and facilitate communication between patients and doctors[13].

Given that numerous studies have confirmed an association between OAB and poor QoL, disease-specific instruments were needed to be developed to assess the aspects of QoL[13]. In order to overcome time impracticality, Coyne et al. developed and validated the 8-item overactive bladder questionnaire (OAB-V8)[14]. The OAB-V8 questionnaire is proved to be a reliable and valid questionnaire with its special feature

in clinical settings where an expeditious OAB burden and severity measure is required[15–19].

In the Croatian language, there is no validated questionnaire for evaluating the impact of OAB on QoL. The present study was conducted with the aim to translate, adapt and validate the OAB-V8 in Croatia.

Materials and methods

A prospective observational study was conducted between November 2019 and December 2020 at the Department of Obstetrics and Gynecology, University Hospital Center Zagreb, Croatia. The study was approved by the Institutional Review Board and all participants gave their written consent before inclusion. This validation study is a part of a prospective, observational study with aim of implementation of OAB-V8 as the first screening tool in OAB severity and burden measure in Croatian clinical practice (ClinicalTrials.gov Identifier: NCT04865328). The study was designed in accordance with the Helsinki Declaration.

To be eligible for participation, subjects are required to fulfill the following conditions: 1) females 18 years or older; 2) fluent and literate in Croatian language; 3) ability to independently understand the questions in the questionnaires; 4) not receiving active OAB treatment. The following are the exclusion criteria: 1) pregnancy; 2) any form of prior conservative treatment for OAB; 3) bladder malignancy or benign tumors; 4) anatomical abnormalities of the lower urinary tract; 5) diabetes mellitus; 6) active urinary tract infection and hematuria; 7) intellectual disability; 8) missing data in any of the responses of the questionnaire; 9) lack of informed consent. All respondents who agreed to participate had completed questionnaires at two predetermined time points: immediately after signed informed consent and two weeks after on a control visit.

The OAB-V8 is conceived as a modification from the Symptom Bother Scale of the OAB-q - a previously validated symptom bother and OAB-specific QoL tool[14]. The OAB-V8 particularly quantifies urinary frequency, urgency, nocturia and urge incontinence with 6-point Likert scale ranging from 0 (not at all) to 5 (a very great deal), with a maximum possible score of 40[14]. The threshold for consideration of OAB in initial screening is score of at least 8 points[14,16].

The translation to Croatian followed standardized procedure in which expert group, consisted of two gynecologists, a methodologist and an authorized translator, ensured cross-cultural equivalence of questionnaire. The initial translation was carried out independently by the two gynecologists, expert in field of urogynecology. They met and discussed discrepancies in translation and created a new, joint version of OAB-V8 questionnaire afterwards. A new version was then sent to an authorized translator who did not have access to the original version. Finally, an expert group have reviewed all versions of the translations and concluded that there were no major discrepancies and to ensure that the final version of a translated questionnaire is culturally congruent. Preliminary pilot-testing was conducted on a small sample (N=20) in order to check if participants understood questions and were asked for suggestions on how to improve the questionnaire. Preliminary results showed that all items from OAB-V8 were easily understandable and that the questionnaire was well received. The Croatian version of OAB-V8 were then established (Appendix).

Statistical analysis

Baseline demographic and clinical characteristics (age, education status, body mass index *BMI*, bladder symptoms' duration and smoking status), are presented

descriptively with mean and standard deviation (SD), number of cases and frequency (%), as applicable.

The reliability of the Croatian version of OAB-V8 questionnaire was assessed for internal consistency and test-retest reliability. Internal consistency reliability was evaluated using Cronbach's α for questionnaire items at Visit 1 and Visit 2. Feldt's statistic was computed for comparison of Cronbach's α between to visits, to determine if internal consistency reliability significantly changed during two-week period[20].

Test-retest analysis was conducted using intraclass correlations (ICC) and Spearman's correlations to assess the degree of relationship between questionnaire scores at Visit 1 and 2. Coefficients greater than 0.5 indicated good correlation. Furthermore, dependent t-tests were performed to determine the significance of score differences between visits.

As part of construct validity, the discriminative validity was evaluated by comparing the scores of patients (case group) with those of healthy volunteers (control group) using the Mann-Whitney *U* test. For the analyses, P value <0.05 was considered to indicate statistical significance.

Domain structures were examined by inter-domain associations using Spearman's correlation coefficient (ρ), which was considered good with $\rho > 0.5$.

Statistical analysis was performed using SPSS IBM SPSS Statistics for Windows (version 26.0. Armonk, NY) and R software package (Version 1.1.463 © 2009-2018) for the conduction of Feldt's statistic[21].

Results

This study included 58 female patients with OAB, aged 42.7 years (SD=9.0) with 12.0 months of bladder symptoms, and 66 healthy women, aged 43.7 years (SD=8.4).

Summary of baseline demographic and clinical characteristics are presented in Table 1.

High internal consistency reliability for all items at both visits is shown in Table 2, presented by the Cronbach's α between 0.799-0.847, with stable internal consistency reliability across items during 2-week period. However, the exception is the item „waking up at night to urinate“, which significantly changed during 2-week period.

Correlation analyses showed strong relationship between OAB-V8 scores at Visit 1 and Visit 2 (Table 3). Intra-class correlation (ICC) for OAB-V8 items ranged from 0.810 to 1.0, with Spearman's correlations above 0.9 for all items ($P < 0.01$). Moreover, there were none of significant score changes between two visits.

The inter-domain correlations are shown in Table 4, with the value of 0.41 for the average inter-domain correlation. There were strong significant correlations between frequency urination during daytime, uncomfortable and sudden urge to urinate, and between nocturia and waking up at night. Contrary, items such as „nocturia“, „waking up at night to urinate“, „uncontrollable urge“ and „urine loss“ were moderate to weak degree in correlation with other items at both visits.

Discriminative validity showed statistically significant score differences between patient and control group, with P values ranging from $P < 0.001$ to $P = 0.027$, as shown in Table 5.

Discussion

The present study provides reliability and validity evidence to support the use of the Croatian version of the OAB-V8 in initial screening, everyday monitoring and measuring QoL of women with OAB. To our knolwledge, the findings of this study, although with negligible distinctions, are principally consistent with only three other

OAB-V8 cross-cultural adaptations and psychometric evaluations published to date[15,22,23]. The study from Reilly and associates demonstrated satisfactory linguistic validations of the OAB-V8 questionnaire in four languages: Afrikaans, Chinese (Taiwan), English (South Africa) and Slovak[22]. The authors underlined importance of revision of certain phrases in questionnaire when translated literally, such as “with little or no warning” or "urine loss"[22]. In our translation, we have accomplished linguistical and conceptual equivalence to the original US English questionnaire by using a multi-step process following the guidelines for cross-cultural adaptation of health-related QoL measures[24].

Culha et al. evaluated the validity and reliability of Turkish version of overactive bladder symptom score (OABSS) after the mirabegron treatment in 17 patients[19], but our study did not include pharmacologic intervention without the ability to compare results. Al-Shaiji and associates conducted analysis with similar methodology to our study[15]. However, the strength of our study was the ability to assess test-retest reliability, which was not the case in the latter.

The strength of this study was the ability to assess test-retest reliability. Our study demonstrated very good internal consistency and test-retest reliability which are nearly equivalent with the Spanish version of the questionnaire[23]. This similarity can be explained by comparable initial study setting, inclusion/exclusion criteria and final distribution of disease severity in analyzed sample. Furthermore, we can report stable internal consistency during 2-week period to be the strength of this study. Excellent internal consistency (Cronbach α=0.923) reported in validation of the Arabic linguistic version of OAB-V8[15] should be interpreted with caution, suggesting that some questionnaire items may be redundant[25]. Reliability was additionally confirmed by inter-domain correlations, with the average inter-domain correlation that indicates

acceptable level of consistency, as contrary to the latter. This is the first questionnaire tool in the OAB diagnosis to be introduced in Croatian clinical practice, predominantly within the Department for Obstetrics and Gynecology, University Hospital Centre Zagreb. With the validation analysis of this questionnaire, additional strength is the fact that these results can further confirm the OAB-V8 introduction.

The limitation of the study is that we recruited patients from a tertiary refferal urogynecological centre. In such setting, we assume to have more patients with worse OAB symptomatology, and therefore result generalization is limited. Another limitation is female-only sample (controls included) because purpose of this validation is to encourage Croatian urogynecological centres to provide more research in the field of OAB.

The Croatian version of the OAB-V8 was successfully translated, adapted and validated so the questionnaire is now ready for use as a reliable tool for initial screening and assessing patients with OAB in everyday Croatian clinical practice. We believe that this validation study will encourage physicians in multiple specialties and at different healthcare levels to conduct individual studies in order to expand overall knowledge of this syndrome.

Acknowledgments

None.

Disclosure

The authors have no conflicts of interests to declare in relation to this article.

References

1. Abrams P, Cardozo L, Fall M, et al. The standardisation of terminology in lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. *Urology*. 2003;61(1):37-49. doi:10.1016/S0090-4295(02)02243-4

2. Milsom I, Abrams P, Cardozo L, Roberts RG, Thüroff J, Wein AJ. How widespread are the symptoms of an overactive bladder and how are they managed? A population-based prevalence study. *BJU Int*. 2001;87(9):760-766. doi:10.1046/j.1464-410x.2001.02228.x

3. Irwin DE, Milsom I, Hunskaar S, et al. Population-based survey of urinary incontinence, overactive bladder, and other lower urinary tract symptoms in five countries: results of the EPIC study. *Eur Urol*. 2006;50(6):1306-1314; discussion 1314-1315. doi:10.1016/j.eururo.2006.09.019

4. Coyne KS, Sexton CC, Kopp ZS, Ebel-Bitoun C, Milsom I, Chapple C. The impact of overactive bladder on mental health, work productivity and health-related quality of life in the UK and Sweden: results from EpiLUTS. *BJU Int*. 2011;108(9):1459-1471. doi:10.1111/j.1464-410X.2010.10013.x

5. Bradley CS, Nygaard IE, Torner JC, Hillis SL, Johnson S, Sadler AG. Overactive bladder and mental health symptoms in recently deployed female veterans. *J Urol*. 2014;191(5):1327-1332. doi:10.1016/j.juro.2013.11.100

6. Melotti IGR, Juliato CRT, Tanaka M, Riccetto CLZ. Severe depression and anxiety in women with overactive bladder. *Neurourology and Urodynamics*. 2018;37(1):223-228. doi:10.1002/nau.23277

7. Milsom I, Coyne KS, Nicholson S, Kvasz M, Chen C-I, Wein AJ. Global Prevalence and Economic Burden of Urgency Urinary Incontinence: A Systematic Review. *European Urology*. 2014;65(1):79-95. doi:10.1016/j.eururo.2013.08.031

8. Vrijens D, Drossaerts J, van Koeveringe G, Van Kerrebroeck P, van Os J, Leue C. Affective symptoms and the overactive bladder — A systematic review. *Journal of Psychosomatic Research*. 2015;78(2):95-108. doi:10.1016/j.jpsychores.2014.11.019

9. Bartoli S, Aguzzi G, Tarricone R. Impact on Quality of Life of Urinary Incontinence and Overactive Bladder: A Systematic Literature Review. *Urology*. 2010;75(3):491-500. doi:10.1016/j.urology.2009.07.1325

10. Kinsey D, Pretorius S, Glover L, Alexander T. The psychological impact of overactive bladder: A systematic review. *J Health Psychol*. 2016;21(1):69-81. doi:10.1177/1359105314522084

11. Onukwugha E, Zuckerman IH, McNally D, Coyne KS, Vats V, Mullins CD. The total economic burden of overactive bladder in the United States: a disease-specific approach. *Am J Manag Care*. 2009;15(4 Suppl):S90-97.

12. Gomes CM, Averbeck MA, Koyama M, Soler R. Impact of OAB symptoms on work, quality of life and treatment-seeking behavior in Brazil. *Current Medical Research and Opinion*. 2020;36(8):1403-1415. doi:10.1080/03007995.2020.1760806

13. Malde S, Kelly S, Saad S, Sahai A. Case-finding tools for the diagnosis of OAB in women: A narrative review. *Neurourology and Urodynamics*. 2020;39(1):13-24. doi:10.1002/nau.24171

14. Coyne KS, Zyczynski T, Margolis MK, Elinoff V, Roberts RG. Validation of an overactive bladder awareness tool for use in primary care settings. *Adv Therapy*. 2005;22(4):381-394. doi:10.1007/BF02850085

15. Al-Shaiji TF, Alkabbani M, EL-Nahas AR, Thahir A, Almutairi MF, Al-Terki A. Validation of the Arabic linguistic version of the 8-item overactive bladder questionnaire (OAB-V8). *Int Urogynecol J*. 2019;30(12):2153-2156. doi:10.1007/s00192-019-03905-0

16. Peterson AC, Sehgal A, Crump RT, Baverstock R, Sutherland JM, Carlson K. Evaluating the 8-item overactive bladder questionnaire (OAB-v8) using item response theory. *Neurourology and Urodynamics*. 2018;37(3):1095-1100. doi:10.1002/nau.23420

17. Araujo TG, Schmidt AP, Sanches PRS, Silva Junior DP, Rieder CRM, Ramos JGL. Transcutaneous tibial nerve home stimulation for overactive bladder in women with Parkinson's disease: A randomized clinical trial. *Neurourol Urodyn*. 2021;40(1):538-548. doi:10.1002/nau.24595

18. Kızılay F, İrer B, Özalp Kızılay D, et al. Evaluation of lower urinary tract symptoms in children with Down syndrome: A prospective, case-controlled cohort study. *Neurourology and Urodynamics*. 2020;39(2):833-840. doi:10.1002/nau.24293

19. Culha MG, Degirmentepe RB, Ozbir S, Cakir SS, Homma Y. Turkish validation of the overactive bladder symptom score (OABSS) and evaluation of mirabegron treatment response. *Int Urogynecol J*. 2019;30(12):2121-2126. doi:10.1007/s00192-019-04054-0

20. Bujang MA, Omar ED, Baharum NA. A Review on Sample Size Determination for Cronbach's Alpha Test: A Simple Guide for Researchers. *Malays J Med Sci*. 2018;25(6):85-99. doi:10.21315/mjms2018.25.6.9

21. Charter RA, Feldt LS. A Comprehensive Approach to the Interpretation of Difference Scores. *Applied Neuropsychology*. 2009;16(1):23-30. doi:10.1080/09084280802644110

22. Reilly K, McKown S, Gawlicki M, Coyne K. PUK24 LINGUISTIC VALIDATION OF THE OVERACTIVE BLADDER QUESTIONNAIRE (OAB-Q), OVERACTIVE BLADDER SHORT FORM QUESTIONNAIRE (OAB-Q SF), AND OAB ASSESSMENT TOOL (OAB-V8) IN 4 LANGUAGES. *Value in Health*. 2006;9(6):A391-A392. doi:10.1016/S1098-3015(10)63791-6

23. Brenes FJ, Angulo JC, Ochayta D, et al. Validación psicométrica de las escalas OAB-V8 y OAB-V3 para la detección de pacientes con probable vejiga hiperactiva en la población española. *Medicina Clínica*. 2014;143(12):521-529. doi:10.1016/j.medcli.2013.10.032

24. Gjersing L, Caplehorn JRM, Clausen T. Cross-cultural adaptation of research instruments: language, setting, time and statistical considerations. *BMC Med Res Methodol*. 2010;10:13. doi:10.1186/1471-2288-10-13

25. Tsang S, Royse CF, Terkawi AS. Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine. *Saudi Journal of Anaesthesia*. 2017;11(Suppl 1):S80-S89. doi:10.4103/sja.SJA_203_17