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ORIGINAL ARTICLE

Turkish validation of the overactive bladder symptom score (OABSS) and evaluation of mirabegron treatment response

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Abstract

Introduction and hypothesis Overactive bladder (OAB) is a syndrome with symptoms such as urinary frequency, urinary urgency and urge incontinence. The aim of this study is to assess the validity and reliability of the Turkish overactive bladder symptom score (OABSS) and to evaluate the results of mirabegron treatment with OABSS.

Methods The study was carried out with 117 patients who applied to the urology outpatient clinic between June 2018–January 2019. OABSS Turkish validation was developed from the English version. Demographic data of the patients were recorded. The OABSS, overactive bladder questionnaire (OAB-v8) and International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) were filled out by the patients. The patients were asked to fill in these questionnaires after 2 weeks. Patients receiving mirabegon treatment were evaluated with the same questionnaires and bladder diaries after 8 weeks.

Results A total of 117 OAB patients, including 82 OAB-wet and 35-OAB dry, were included in the study. The mean age of the patients was 46.79 ± 14.26 (18–78) years, and the mean duration of OAB complaint was 32.28 ± 32.21 months. The mean score of the OABSS is 9.9 ± 3.14. The results of the reliability assessment showed that the intraclass correlation coefficient of the total OABSS score was 0.71 (weighted coefficients of individual item points, 0.635–0.831), and the Cronbach α was 0.736. In the validity analysis, the OABSS total score was highly correlated with that belonging to other questionnaire forms (OAB-v8, ICIQ-SF and bladder diary). After the treatment with mirabegron, mean OABSS scores of the patients improved significantly from baseline to the 8th week ($p < 0.001$).

Conclusion The Turkish version of the OABSS has been approved as a valid and reliable tool for evaluating OAB. Mirabegron used daily improved the symptoms of OAB in patients.

Keywords Mirabegron · OABSS · Overactive bladder · Urgency · Validation

Introduction

Overactive bladder (OAB) is defined as a group of symptoms with or without frequent urinary incontinence in the absence of an infection or other obvious pathologies, often with complaints of frequent urination and urinary urgency (day and night) along with or without urge incontinence [1]. OAB is initially diagnosed only on the basis of the symptoms without referring to urodynamic tests. OAB, especially with urinary incontinence, has a significant negative effect on patients' quality of life (QOL) [2, 3]. Based on the new definition of OAB, the overall prevalence was between 11.8–16.9% [4, 5]. The prevalence of symptoms of urinary urgency in Turkey was reported to be 29.3% [6].

OAB is a condition diagnosed with subjective symptoms rather than objective measurements. The patients' opinions and the effects of this condition on their quality of life are important in the evaluation of these patients. Numerous research surveys have been used to identify the epidemiology of OAB and to estimate the prevalence, incidence and remission of the disease [7–10]. However, these surveys assess the discomfort caused by symptoms or the effects on the daily life of the patient rather than evaluating the symptoms of OAB as they are. To be appropriate for the assessment of the patients'

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conditions, the patient-reported outcome (PRO) should be supported by evidence that it is easy to use and practical, along with having reliability, validity and sensitivity [11]. A questionnaire called the overactive bladder symptom score (OABSS), which was originally used in Japanese, was developed to express the symptoms associated with OAB in a single score [12]. The validation study of the questionnaire's English version was conducted in 2014 [13].

OABSS consists of four questions, including frequency of daytime urination (OABSS-1), frequency of nocturia (OABSS-2), frequency of urinary urgency (OABSS-3) and urgency incontinence (OABSS-4), and it scores the simple sum of four symptoms. The severity of these four symptoms was rated as 0–2, 0–3, 0–5 and 0–5, respectively, on the Likert scale. The total score of OABSS ranges from 0 to 15, and as the score increases, the symptoms become more severe. With this brief and clear questionnaire, patients can be evaluated more clearly. The Turkish validation of the OABSS questionnaire is not yet available.

The main aim of this study is to evaluate the validity and reliability of the Turkish version of OABSS (OABSS-Turkish). The secondary aim of the study is to evaluate the efficacy of mirabegron treatment in patients with OAB.

Materials and methods

This non-invasive, observational study was conducted between June 2018 and January 2019. The study was approved by the local ethics committee with number 970/2018. Written consent was obtained from all patients. The study was designed in accordance with the Helsinki Declaration.

The developer of OABSS was contacted, and the authors were allowed to translate the English version of OABSS (source) into the Turkish version. Turkish linguistic validation of OABSS was performed through a multi-stage procedure. Initially, the questionnaire was translated from English to Turkish by two independent, professional, native Turkish translators whose first foreign language is English. Translators and urologists (MGC and RBD) checked the translation. After that, the translated text was further developed to make it understandable to patients at different socio-cultural and educational levels. In the third step, the draft text, which is in Turkish, was translated back into English by two independent, professional translators who are native English speakers and whose first foreign language is Turkish. Back translations were reviewed and some minor changes made. This second draft was revised in terms of Turkish grammar and spelling. Finally, a pilot test was performed on five patients with OAB. The final changes were made, and the Turkish version of OABSS was accepted as ready for use. The English translation and original versions of the Turkish OABSS were also sent to the original author (Homma Y) for comparison.

Patients referred to the urology clinic with OAB symptoms were included in the study. For inclusion in the study, patients were required to read and write in Turkish, to understand what they read and to be > 18 years of age. Patients who were < 18 years of age, received active OAB treatment, could not read and write Turkish, could not understand what they read and did not agree to participate in the study were excluded.

The demographic characteristics of the patients were recorded, and physical examinations were performed. Paitents filled in the OABSS-Turkish form consisting of four questions, the overactive bladder questionnaire form (OAB-v8) and the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF). Three-day urinary diaries of the patients were recorded. The patients filled out the same forms again after 2 weeks. The group of these patients receiving mirabegron treatment filled out the OABSS-Turkish again after 8 weeks.

The OAB-V8 questionnaire consists of eight questions [2]. Evaluation is done with the score obtained from these eight questions. A total score of 0–40 is collected. Its Turkish form was validated in 2012 [14]. The ICIQ-SF questionnaire consists of six questions. The questionnaire is evaluated by the sum of the scores received from questions 3, 4 and 5. Its Turkish form was validated in 2004 [15].

The reliability of OABSS was assessed using test-retest reliability and internal consistency. Test-retest reliability was evaluated to measure the extent of the agreement between the two time points among the patients completing both the first and the second questionnaires. For test-retest reliability, the intraclass correlation coefficient (ICC) was calculated for the total score. The weighted kappa coefficient was calculated for each item.

Concurrent validity was used to assess the validity of OABSS. The concurrent validity was assessed by correlation with external criteria (OAB-v8, ICIQ-SF and bladder diaries). The correlation coefficient was interpreted according to the standard proposed by Cohen; correlation coefficient 0.1 was considered weak, 0.3 moderate and 0.5 strong [16].

Statistical analysis

Statistical analysis was performed with IBM Statistical Package for Social Sciences. IBM SPSS Statistics for Windows (version 22.0. Armonk, NY) was used to evaluate multiple steps. Significance level was set to $p < 0.05$. Internal consistency reliability was tested using Cronbach's α, and test-retest reliability was assessed with the Wilcoxon signed rank test. For concurrent external validity, Spearman rank correlation was used. For values > 0.70, it was assumed that there was sufficient consistency and reliability.

Results

In the first questionnaire, a total of 117 patients [OAB-wet = 82 (70.1%); OAB-dry = 35 (35.9%)] answered all the questions. Sixty-seven of these patients completed the second survey. Other patients did not attend follow-up visits 2 weeks later. In 56 patients, mirabegron treatment was started with 50 mg (Betmiga, Astellas Pharma, Japan) once a day. These patients were re-evaluated after 8 weeks.

Table 1 shows the demographic and clinical characteristics of the patients. The mean age was 46.79 ± 14.26 (18–78) years, and 89.7% of the patients were female. The mean duration of OAB complaints was 32.28 ± 32.21 months.

The mean OABSS score is 9.9 ± 3.14. When scores of OAB-wet and OAB-dry patients were compared, OABSS total, OABSS-2 and OABSS-4 were statistically higher in the OAB-wet group than in the OAB-dry group (Table 2).

The OABSS-Turkish translation had moderate to good test-retest reliability. For each symptom score, kappa coefficients ranged from 0.635 to 0.831, and the coefficient for the total symptom score was 0.710 (95% confidence interval, 0.488–0.731). In addition, the Cronbach's alpha value was 0.736 (Table 3).

When correlation analyses with OABSS, OAB-v8 and ICIQ-SF questionnaires were examined for concurrent validity, the OABSS was found to be highly correlated with OAB-v8 (Spearman correlation: 0.715, $p = 0.001$) and ICIQ-SF (Spearman correlation: 0.714, $p = 0.001$) (Table 4).

The mean total OABSS scores of the 56 patients receiving mirabegron treatment decreased from 11.47 ± 2.85 to 6.53 ± 4.58 ($p < 0.001$). The same decrease was observed in the OAB-v8 and ICIQ-SF scores ($p < 0.001$ for OAB-v8 and $p = 0.001$ for ICIQ-SF). This improvement in symptom scores was also observed in bladder diary values (Table 5). The treatment was stopped for two patients using mirabegron when they had hypertensive attacks (TA > 190/130).

Discussion

In this study, the validity and reliability of the Turkish version of OABSS were evaluated using the data collected from OAB patients residing in Turkey. For assessing the reliability, the test-retest reliability and internal consistency (ICC) of OABSS were evaluated. The ICC for this study was > 0.7 (0.71), which provided a sufficient condition for clinical trials. For each item in OABSS, weighted kappa coefficients ranging from 0.64 to 0.83 were found. The highest weighted kappa coefficient was for the fourth question (frequency of incontinence), while the lowest weight was for the frequency for urinary urgency. For internal consistency, a Cronbach α value of 0.736 was calculated, and it was determined that the survey was valid. The Cronbach α value depends on the correlations between the items and the number of items in the questionnaire.

Concurrent and known group validities were evaluated for the validity of OABSS. The Turkish version of OABSS was strongly correlated with the OAB-v8 and ICIQ-SF questionnaires. There was also a high correlation with the 3-day bladder diary. The results of the known group validity assessment showed that the group of patients with severe OAB symptoms reported a high total score.

OAB diagnosis is based on symptoms that are not indicative of physiological disease activity. However, there is no consensus on what symptoms or assessments should be used to identify the OAB. [17]. There are many questionnaires in which patients' complaints are evaluated. However, most of the existing questionnaires evaluate OAB symptoms rather than their impact on daily life.

Although the bladder diary plays an important role in the evaluation of OAB, patients should prepare a container to measure the amount of urine and record the amount of urine produced each time to complete the diary, which is not applied in daily life and can interrupt one's night sleep. Compared with the 3-day bladder diary, filling in OABSS in a few minutes is faster and easier. If OABSS can reflect the symptoms of OAB, it can replace the 3-day bladder diary and can be very helpful for patients.

Table 1 Characteristics of the patients

	OAB ($n = 117$)	OAB-wet ($n = 82$)	OAB-dry ($n = 35$)	p
Patients (male/female)	12/105	2/80	10/25	< 0.001
Age (years)	46.79 ± 14.26 (18–78)	48.67 ± 13.32	45.88 ± 14.25	0.07
BMI (kg/m^2)	27.52 ± 5.50 (16.26–41.15)	28.60 ± 5.27	26.96 ± 5.24	0.11
Duration of symptoms (months)	32.28 ± 32.21 (3–120)	35.49 ± 28.67	25.11 ± 28.69	0.012
Smoking status (no/yes)	86/31	60/22	26/9	0.901
Number of pads (daily)	2.17 ± 2.04 (0–10)	3.01 ± 1.82	0.20 ± 0.76	< 0.001
Incontinence frequency (daily)	2.38 ± 2.20 (0–10)	3.30 ± 1.94	0.20 ± 0.78	< 0.001

Table 2 Symptom scores of the patient groups

	Symptom/frequency	OAB ($n = 117$)	OAB-wet ($n = 82$)	OAB-dry ($n = 35$)	p
OABSS-1	Frequency				
0	≤ 7	28*	25	3	
1		67	43	23	
2		22	14	9	
Mean ± SD		0.96 ± 0.66	0.87 ± 0.68	1.17 ± 0.57	0.022
OABSS-2	Nocturia				
0		7	6	1	
1		22	9	13	
2		38	29	9	
3		50	38	12	
Mean ± SD		2.13 ± 0.92	2.21 ± 0.91	1.91 ± 0.92	0.115
OABSS-3	Urgency				
0		2	0	2	
1		2	1	1	
2		10	6	4	
3		6	5	1	
4		53	37	16	
5		44	33	11	
Mean ± SD		4.04 ± 1.10	4.16 ± 0.92	3.74 ± 1.40	0.061
OABSS-4	Urgency incontinence				
0		32	2	30	
1		7	5	2	
2		10	9	0	
3		14	12	2	
4		30	30	0	
5		24	24	1	
Mean ± SD		2.66 ± 1.94	3.65 ± 1.31	0.37 ± 1.09	< 0.001
OABSS (total)		9.79 ± 3.14	10.89 ± 2.70	7.20 ± 2.53	< 0.001

*Number of patients

OAB: overactive bladder; OABSS: overactive bladder symptom score

Mirabegron (Betmiga 50 mg, Astellas Pharma, Japan) is a new generation beta-3 adrenergic receptor agonist drug used in the treatment of OAB. Previous studies have shown that mirabegron is highly effective in reducing the symptoms of OAB [18, 19]. It is a powerful drug that can be preferred because it has fewer side effects than anticholinergic drugs. Mirabegron, which has less side effect potential, was used in patients who were diagnosed with OAB in the control visits.

Table 3 Descriptive statistics and reliability for the OABSS item and total scores ($n = 117$)

	Mean	SD	Range	Reliability
OABSS-1	0.96	0.66	0–2	0.803*
OABSS-2	2.12	0.92	0–3	0.692*
OABSS-3	4.03	1.10	0–5	0.635*
OABSS-4	2.67	1.95	0–5	0.831*
OABSS-total	9.79	3.14	2–15	0.736 [y]

OABSS: overactive bladder symptom score; SD: standard deviation

*Weighted kappa coefficient ($n = 67$)

[y] Intraclass correlation coefficient ($n = 67$)

Table 4 Correlations between the OABSS total score and external criteria (OABv8, ICIQ-SF; $n = 117$)

	OABSS total score
OABv8	0.715*
ICIQ-SF	0.714*
Incontinence	0.708*
Micturition	0.716*
Nocturia	0.678*

*$p < 0.001$

OABv8: overactive bladder questionnaire; ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form

Spearman correlation

Table 5 Change in voiding diary and OABSS variables after mirabegron treatment ($n = 56$)

	Before mirabegron treatment	After mirabegron treatment	p
Incontinence	2.65 ± 2.42	1.41 ± 0.78	0.001
Micturition (day)	12.56 ± 5.63	10.84 ± 2.85	0.001
Nocturia	2.13 ± 0.84	0.87 ± 0.65	0.001
OABSS	11.47 ± 2.85	6.53 ± 4.58	< 0.001
OABv8	27.93 ± 5.36	12.69 ± 8.10	< 0.001
ICIQ-SF	15.23 ± 6.39	7.69 ± 5.78	0.001

Mirabegron is only used at 50-mg doses in Turkey. This study was also a first in Turkey to show the effects of mirabegron on the symptoms of OAB by using the Turkish version of OABSS. Our results showed that OAB symptoms of patients receiving mirabegron 50-mg treatment decreased significantly.

The study has some limitations. The first is that the patient group was included in the study, whereas a healthy control group was not included. The fact that the majority of the patients included in the study were female and the number of male patients was not evenly distributed was another limitation. Since male patients may have more obstructive symptoms due to benign prostatic hyperplasia, many patients were excluded from the study. No 3-month follow-up period has been given for mirabegron treatment. A longer follow-up period was not chosen because mirabegron showed its effect up to the 8th week.

Conclusion

The OABSS-Turkish version has been developed and approved as a reliable tool for evaluating patients with OAB. This study showed that mirabegron is an effective agent in the treatment of OAB, urinary frequency and urge incontinence and for improving OABSS, OAB-v8 and ICIF-SF scores. This simple questionnaire is expected to be useful in clinical studies and medical applications among Turkish-speaking OAB patients.

Compliance with ethical standards

Conflict of interest None.

The study was approved by the Institutional Review Board of Okmeydani Training and Research Hospital, and written informed consent was obtained from all participants.

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