

Validation of an Overactive Bladder Screener in a Primary Care Patient Population in the United States

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Introduction

- Overactive bladder (OAB) is a symptom-based condition defined as urinary urgency with or without urge incontinence, often with increased urinary frequency, and nocturia¹
- OAB affects 17% of the US population² and 3%–42% of people in Europe³
- OAB has been shown to be quite bothersome and has a negative impact on health-related quality of life^{4,5}
- Given the prevalence and impact of OAB, a short, simple screening tool would be useful to aid in identifying patients who may have OAB in a busy primary care setting

Objective

- To evaluate the usefulness of the 8-item OAB Symptom Bother Scale of the Overactive Bladder Questionnaire (OAB-q)⁶ as a screening tool for use in the primary care setting to identify patients who are bothered by urinary symptoms consistent with OAB

Methods

Patient Population

- In this multicenter, cross-sectional, prospective study, participants were recruited from 12 primary care practices and 1 general gynecology clinic
- Patients (≥18 y) presenting to the clinician's office for a regularly scheduled appointment and who could speak and read English were enrolled
- Those who were pregnant or had cognitive or other impairments that would interfere with completing a self-administered questionnaire were not eligible

Questionnaires

OAB Screener

- 8-item OAB Symptom Bother Scale of the OAB-q
- Responses made on a 6-point scale ranging from 0 (not at all) to 5 (a very great deal) for the degree of bother; patients were asked to sum their scores after completion

OAB Screener

The questions below ask about how bothered you may be by some bladder symptoms. Some people are bothered by bladder symptoms and may not realize that there are treatments available for their symptoms. Please circle that number that best describes how much you have been bothered by each symptom. Add the numbers together for a total score and record the score in the box provided at the bottom.

How bothered have you been by...	Not at all	A little bit	Some -what	Quite a bit	A great deal	A very great deal
1. Frequent urination during the daytime hours?	0	1	2	3	4	5
2. An uncomfortable urge to urinate?	0	1	2	3	4	5
3. A sudden urge to urinate with little or no warning?	0	1	2	3	4	5
4. Accidental loss of small amounts of urine?	0	1	2	3	4	5
5. Nighttime urination?	0	1	2	3	4	5
6. Waking up at night because you had to urinate?	0	1	2	3	4	5
7. An uncontrollable urge to urinate?	0	1	2	3	4	5
8. Urine loss associated with a strong desire to urinate?	0	1	2	3	4	5

Are you a male? If male, add 2 points to your score

Please add up your responses to the questions above

Please hand this page to your doctor when you see him/her for your visit.

If your score is 8 or greater, you may have overactive bladder. There are effective treatments for this condition. You may want to talk with a healthcare professional about your symptoms.

Note: You may be asked to give a urine sample. Please ask before going to the bathroom.

Clinical Report Form (CRF)

- The clinician completed the CRF by interviewing the patients about the following urinary symptoms: daytime frequency, nighttime frequency, urgency, urge incontinence

Diagnostic Algorithm

- Patients who screened positive (score ≥8) on the OAB screener OR who had evidence of urinary frequency, urgency, nocturia, or incontinence were asked the lifestyle and coping behavior questions
- Based on the OAB screener score AND responses to the clinical, lifestyle, and coping behavior questions, the clinician diagnosed the patient as "No OAB," "Possible OAB," or "Probable OAB"; all diagnoses were based on clinician opinion

Statistical Analyses

- All statistical analyses were performed with SAS (v8.2); all tests were 2-tailed and type 1 error probability was fixed at 0.05
- Chi-square tests were used to evaluate categorical data; *t*-tests and analyses of variance (ANOVA) were used to evaluate continuous data
- Multivariate logistic regression models (controlling for age and gender) were used to assess the ability of the OAB screener to identify patients with OAB and to determine the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the screener

Results

Patient Demographics

- 1260 patients were evaluable (62% women; 89% Caucasian) with a mean (± SD) age of 52 (±17) years; clinical urinary characteristics are presented in Table 1

Table 1. Clinical Characteristics

Urinary Symptoms	Frequency of "Yes" Response	No. Episodes Mean (± SD)
Daytime frequency, 24 h	NA	6 (±3) ^a
Nighttime frequency, 24 h	NA	1 (±1) ^a
Urinary urgency	274 (22%)	7 (±10) ^a
Urinary urge incontinence	225 (18%)	5 (±7) ^a

^an=1258; ^bn=1259; ^cn=266; ^dn=220.

- The prevalence of Probable OAB was 12%; the prevalence of Possible OAB was 20%
- There were significant differences among the 3 diagnostic groups in their responses to all coping behavior questions; Probable OAB patients reported the highest use of all coping behaviors (*p*<0.001; Table 2)
- The most prevalent comorbid conditions among male and female patients with Probable OAB were enlarged prostate (69%) and postmenopausal state (61%), respectively

Table 2. Frequency and Percentage of Patients Responding "Yes" to Lifestyle and Coping Behaviors Questions by OAB Diagnostic Category

	No OAB (N=287)	Possible OAB (n=248)	Probable OAB (n=152)	P Value ^a
Lifestyle Behaviors	n (%)	n (%)	n (%)	
Drink >8 glasses of fluid a day	170 (59%)	125 (±3)	70 (46%)	0.07
Drink >4 cups of caffeinated beverages a day	97 (34%)	84 (34%)	57 (38%)	0.64
Drink carbonated or high-acid beverages, eats spicy or high-acid foods	88 (31%)	76 (31%)	43 (28%)	0.83
Use a diuretic	57 (20%)	52 (21%)	46 (30%)	0.03
Use OTC diet pill/any other weight-loss product	10 (4%)	7 (3%)	4 (3%)	0.88
Coping Behaviors	n (%)	n (%)	n (%)	P Value ^a
Frequently limit fluid intake when away from home so that you won't have to find a restroom	40 (14%)	78 (32%)	74 (49%)	<0.0001
Adjust travel plans so that you are always near a restroom	23 (8%)	43 (17%)	63 (41%)	<0.0001
When in a new place, you make sure you know where the restroom is	70 (24%)	104 (42%)	105 (69%)	<0.0001
Avoid places if you think there won't be a restroom nearby	29 (10%)	51 (21%)	58 (38%)	<0.0001
Go to the restroom so often that it interferes with things you want to do	15 (5%)	34 (14%)	51 (34%)	<0.0001
Bladder symptoms make you feel like there is something wrong with you	26 (9%)	65 (26%)	79 (52%)	<0.0001

^aP value based on chi-square analyses comparing frequency of "yes" and "no" responses of patients in the 3 groups.

OAB Screener Performance

- The 8-item OAB screener performed well with little missing data (0.2%–0.6%); the screener had high inter-item (0.42–0.78) and item-to-total correlations (0.70–0.83)
- The logistic regression models showed good fit, as indicated by a c-index of 0.96
- A positive screen score (≥8) yielded an odds ratio of 95.7 (95% CI: 29.3–312.4) for having Probable OAB
- The OAB screener had a sensitivity of 98.0%, specificity of 82.7%, PPV of 43.7%, and NPV of 99.7%
- OAB screener scores among the 3 diagnostic groups were significantly different as determined by ANOVA (Table 3)

Table 3. Comparison of the OAB Screener Scores by OAB Diagnostic Groups^a

Population	No OAB	Possible OAB	Probable OAB	Overall, F Value ^b
Overall	4.7±4.4 (n=860)	13.9±6.5 (n=248)	18.2±8.7 (n=152)	669
Men	5.4±4.5 (n=327)	12.7±5.7 (n=97)	18.2±8.8 (n=58)	181
Women	4.2±4.2 (n=533)	14.7±6.9 (n=151)	21.5±8.8 (n=94)	512

^aResults are expressed as (mean ± SD).

^bAll pairwise comparisons among groups by Scheffé's test of multiple comparisons; all *p* values <0.001.

Conclusions

- The OAB screener identified patients with symptoms of OAB with high sensitivity and specificity
- This brief, simple tool can be used to screen for OAB in the primary care setting
- By screening for OAB in the primary care practice, more patients with bothersome symptoms may receive appropriate evaluation and treatment

References

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