Validation of an Overactive Bladder Awareness Tool for Use in Primary Care Settings

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ABSTRACT

Overactive bladder (OAB)—a syndrome characterized by urinary urgency, with or without urge incontinence, urinary frequency and nocturia—is estimated to affect 10% to 20% of the US and European populations. This study was carried out to validate a patient-administered screening awareness tool to identify patients with bothersome OAB symptoms. Patients were recruited from 12 primary care and 1 gynecology practice during regularly scheduled appointments. Enrollees completed an 8-item questionnaire assessing the amount of "bother" they associated with OAB symptoms. Clinicians then asked the patients 4 questions regarding urinary frequency, urgency, nocturia, and incontinence. If the screening was positive for symptoms of OAB or if the patient provided positive responses to the urinary symptom questions, the clinician asked additional questions regarding lifestyle and coping behaviors. The clinician then diagnosed the patient, placing him or her in the "No OAB," "Possible OAB," or "Probable OAB" category. Multivariable logistic regressions controlling for age and sex were performed to assess the applicability of the tool for identifying patients with OAB. A total of 1299 patients were enrolled, and 1260 provided complete data. Patients were aged 51.6±17.0 years, 62% were female, most (89%) were Caucasian, 22% experienced urinary urgency, and 18% experienced urge incontinence. The prevalence of Probable

©2005 Health Communications Inc Transmission and reproduction of this material in whole or part without prior written approval are prohibited. OAB was 12%. The c-index of the model identifying patients with a diagnosis of Probable OAB was 0.96, with a sensitivity and specificity of 98.0 and 82.7. For OAB-V8 scores \geq 8, the odds ratio for Probable OAB was 95.7 (95% CI: 29.3; 312.4). The OAB-V8 performed well in helping clinicians identify patients with bothersome OAB symptoms in a primary care setting and will assist clinicians in identifying patients who may benefit from treatment.

Keywords: overactive bladder; primary care; awareness tool; questionnaire; urinary incontinence

INTRODUCTION

Overactive bladder (OAB) is a syndrome characterized by urinary urgency that may or may not be accompanied by urge incontinence, but is usually accompanied by increased urinary frequency and nocturia.¹ It has been estimated that OAB affects 10% to 20% of the US and European populations^{2,3} yet Milsom and colleagues found that only 27% of all patients with OAB receive medication to relieve its symptoms. The reasons for this low treatment rate for OAB appear to be varied. Certainly, the underreporting of symptoms,^{4,5}—whether because of the social stigma associated with bladder control problems,⁶ lack of knowledge about available treatments,⁷ or the belief that these symptoms are part of the normal aging process^{7,8}—results in undertreatment. However, it also appears that physicians do not routinely screen patients for urinary incontinence,⁹ much less bothersome urinary symptoms. Additionally, patients with OAB tend to employ coping behaviors that allow them to tolerate their symptoms.¹⁰ It is apparent that the symptoms of OAB are quite bothersome and have a tremendously negative impact on health-related quality of life (HRQL).¹¹⁻¹³ Consequently, identifying patients with OAB could facilitate patientphysician communication regarding bothersome OAB symptoms and perhaps result in patients obtaining symptom relief and improved HRQL.

From a primary care perspective, the reporting of symptoms is key to the differential diagnosis of OAB, because there are currently no "gold standard" diagnostic tests for OAB. The goal of this study was to validate a screening awareness tool to help physicians identify patients who have urinary symptoms consistent with OAB in primary care settings.

METHODS

Study Design

In this cross-sectional study, adult patients were recruited from 12 primary care practices and 1 general gynecology practice. Patients who were younger than 18 years, unable to read or speak English, pregnant, cognitively or otherwise too impaired to complete a self-administered questionnaire (eg, visual impairment), or had a severe psychiatric comorbidity were excluded from enrollment. All consecutive, non-urgent patients who went to a physician's office for a clinical appointment or entered an examination room were asked by site personnel if they would be willing to complete a short survey. If the patient agreed, he or she was then asked to complete the awareness tool. Institutional review board approval was obtained prior to the enrollment of any patients. Importantly, this study was designed to mimic primary care practice and how physicians would use an awareness tool in their office.

OAB Screening Awareness Tool

The OAB-V8 was adapted from the Symptom Bother Scale of the OAB-q, a previously validated symptom bother and OAB-specific HRQL instrument.¹² The 8 items on the OAB-q Symptom Bother scale remained unchanged; however, the instructions for completing it and what to do after it was completed were modified into an awareness tool. A retrospective analysis of the Symptom Bother Scale/OAB-V8 was performed in an existing community sample dataset for the National Overactive Bladder Evaluation³ Program, which included normal controls and patients with OAB to evaluate its predictive validity. The OAB-V8 performed well in this retrospective analysis; however, men with OAB appeared to have a lower threshold for OAB symptoms, as indicated by the fact that they routinely had lower scores than women with OAB. For this reason, men were asked to add 4 points to their scores for the prospective validation study.

The OAB-V8 asks how bothered one is by the 4 hallmark symptoms of OAB: urinary frequency, urgency, nocturia, and urge incontinence (Appendix A). Patients respond on a 6-point Likert scale ranging from 0 (not at all) to 5 (a very great deal), with a maximum possible score of 40. After completing the awareness tool, patients were asked to calculate their scores by adding their responses.

Clinical Information

Once the awareness tool was completed and the scores calculated, the clinician or research personnel asked each patient 4 questions regarding urinary frequency, urgency, nocturia, and incontinence. The result of the screening was considered negative if the patient reported no urinary frequency, urgency, nocturia, or incontinence, and the interview was then considered complete. If the patient had a positive screen $(OAB-V8 \text{ score } \ge 8)$ or reported having at least 8 micturitions daily or nocturia, urinary urgency, or urge incontinence, the patient was asked an additional 9 questions by the clinician regarding his or her lifestyle and coping issues. The clinician had the option of ordering a urinalysis to rule out other causes of the urinary symptoms. Upon completion of the patient interview and urinalysis (if performed), the clinician would diagnose the patient as having either "No OAB," "Possible OAB," or "Probable OAB." Physicians were provided a guide for diagnosing OAB (Fig 1). Importantly, the diagnosis was not dictated by the awareness tool score, but by the patient interview. The awareness tool was used as a starting point to trigger a patient-physician communication regarding urinary symptoms. If the final clinician assessment was either Possible or Probable OAB, additional information was collected regarding comorbid conditions that could affect the treatment selected for the OAB symptoms. The reason for office visit, age, sex, and race were collected for all patients.

Fig 1. Considerations for diagnosing OAB.



Statistical Analyses

Data were analyzed utilizing SAS version 8.2. All statistical tests were two-tailed and conducted with a type I error probability of .05. No adjustments were made for multiple statistical comparisons. Descriptive statistics, χ^2 tests, *t* tests, and analyses of variance were used to evaluate the data. Scheffe's post hoc pairwise comparisons between groups were performed. A series of multivariable logistic regression models were performed to assess the ability of the awareness tool to identify patients with OAB. Age and sex were covariates in all models. The criteria for model fit were receiver operator curves (ROC),¹⁴ Hosmer and Lemeshow fit indices,¹⁵ and the Akaike Information Criterion (AIC).¹⁶ The ROC is a graph that is created by plotting the true positive rate (1 – specificity) over a series of cutoffs for defining a positive test. A diagonal line indicates no ability to distinguish persons with versus without a specific condition. The farther the curve extends toward the upper left corner of the graph, the better the test is at discriminating patients with the disease from those without it (ie, cases vs controls). Values near 0.50 indicate that the test cannot be used to discriminate cases from controls and that the results are no more predictive than a coin toss. Nonsignificant *P* values indicate an adequate model fit, according to Hosmer and Lemeshow. The AIC accounts for the number of parameters: the greater the number of items in the model, the more adverse the impact on the AIC. Values are considered on a relative scale within an analysis set, rather than on an absolute scale in terms of value. Lower values are preferable.

Odds ratios (OR), sensitivity, specificity, positive-predictive values, and negativepredictive values were calculated from the final fitted model. A prevalence rate of 12% was used in these calculations as this was the prevalence of Probable OAB in this patient sample.

RESULTS

A total of 1299 patients were enrolled from 13 clinical sites; 1260 provided data that were suitable for analysis. The mean age was 51.6 ± 17.0 years; additionally, 62% were female and the majority (89%) were Caucasian (Table 1). Patients urinated an average of 5.7 ± 3.2 times during the day and 1.3 ± 1.2 times during the night; 22% reported urinary urgency and 18% reported urge incontinence. In terms of outcome, 12.1% of patients were diagnosed with Probable OAB, 19.7% with Possible OAB, and 68.3% with No OAB. The diagnosis of Probable OAB and Possible OAB was at the discretion of the physician and based on his or her clinical experience, given the awareness tool score and clinical information they had gathered from the patient. When diagnosis groups were compared by micturition variables, significant differences were found, with the Probable OAB patients reporting significantly more urinary frequency, nocturia, urgency, and urge incontinence (Table 1). Additionally, patients diagnosed with Probable OAB were significantly older than patients with no OAB (61.0 vs 48.6, respectively; *P*=.03).

Patients with either a positive awareness tool score (≥ 8) or positive answers to the micturition questions (n=696) questions were asked about their lifestyles and coping strategies (Table 2). Patients diagnosed with Probable OAB were slightly more likely to use a diuretic (*P*=.03) and significantly more likely to report a higher frequency of using all coping behaviors than other patients (*P*<.0001), reporting that they used coping behaviors 33.6% to 69.1% of the time compared with 5.1% to 23.6% of the time for No OAB patients.

To assist in the differential diagnosis, urine dipsticks were obtained in 26.2% of the sample to rule out a urinary tract infection. The rate of positive urine dipsticks ranged from 14.4% (Possible OAB) to 19.6% (Probable OAB) (Table 3). When examining OAB diagnosis by clinical site, the prevalence of Probable OAB ranged from 2.8% to 17.4% at each site, with the majority of the sites reporting a prevalence rate of 7% to 15%.

Patients with Probable OAB were significantly older than patients with Possible OAB and No OAB (61.0, 56.4, and 48.6 years, respectively; P<.03). The most prevalent clinical status among patients with Probable OAB was postmenopausal for women (60.6%) and having an enlarged prostate for men (69.0%) (Table 4). A greater proportion of patients with Probable OAB than Possible OAB had stress incontinence (35% vs 18.1%, respectively; P=.0003). A greater portion of patients with Probable OAB that probable OAB had stress incontinence (35% vs 18.1%, respectively; P=.0003). A greater portion of patients with Possible OAB had shift probable OAB had stress incontinence (35% vs 18.1%, respectively; P=.0003). A greater portion of patients with Possible OAB had shift probable OAB had shift probable OAB had stress incontinence (35% vs 18.1%, respectively; P=.0003). A greater portion of patients with Possible OAB had shift probable OAB had shift probable OAB had stress incontinence (35% vs 18.1%).

| | | | Possible | Probable | |
|---|---|--|---|---|----------------------------|
| Variable | Overall n=1260 | No OAB n=860 | OAB n=248 | OAB n=152 | P Value* |
| Age, mean (SD) | 51.6 (17.0) | 48.6 (16.7) | 56.4 (15.9) | 61.0 (15.1) | .03 |
| Sex, n (% female) | 778 (61.7) | 533 (62.0) | 151 (60.9) | 94 (61.8) | .95 |
| Race, n (%) African American Asian Caucasian Hispanic Other Missing | 43 (3.4) 43 (3.4) 1122 (89.0) 41 (3.3) 8 (0.6) 3 (0.2) | 29 (3.4) 34 (4.0) 761 (88.5) 26 (3.0) 7 (0.8) 3 (0.3) | 9 (3.6) 4 (1.6) 225 (90.7) 10 (4.0) 0 | 5 (3.3) 5 (3.3) 136 (89.5) 5 (3.3) 1 (0.7) 0 | .66 |
| Urinary frequency per day, mean (SD) | 5.70 (3.2) | 4.94 (2.0) | 6.78 (4.0) | 8.23 (4.8) | <.0001 |
| Urinary frequency per night, mean (SD) | 1.25 (1.2) | 0.85 (0.9) | 1.94 (1.4) | 2.3 (1.4) | <.01 |
| Urinary urgency, n (% yes) If yes, mean no. | 274 (21.8) 6.61 (9.7) | 50 (5.8) 3.1 (2.8) | 116 (46.8) 7.4 (12.1) | 108 (71.1) 7.4 (8.5) | <.0001 .03 ⁺ |
| of episodes (SD) Urge urinary incontinence, n (% yes) If yes, mean no. of episodes (SD) | 225 (17.9) 4.82 (6.7) | 47 (5.5) 3.02 (3.8) | 91 (36.7) 4.8 (7.4) | 87 (57.2) 5.8 (7.0) | <.0001 NS |
| Clinical diagnosis No OAB, n (%) Possible OAB, n (%) Probable OAB, n (%) | 860 (68.3) 248 (19.7) 152 (12.1) | | | | |

Table 1. Patient Demographics and Clinical Characteristics

*Based on *t* tests for continuous data and χ^2 analyses.

⁺*P* value for patients with diagnosis of No OAB vs Probable or Possible OAB.

| | Νο ΟΔΒ | Possible | Probable OAB | | |
|--|------------|------------|-----------------|----------|--|
| | n=296 | n=248 | n=152 | P Value* | |
| Lifestyle behaviors | | | | | |
| Drink more than 8 glasses of fluid a day | 170 (57.4) | 125 (50.4) | 70 (46.1) | .07 | |
| 2. Drink more than 4 cups of caffeinated beverages a day | 97 (33.2) | 84 (33.9) | 57 (37.5) | .64 | |
| Drink a lot of carbonated or high-acid beverages or eat spicy or high-acid foods | 88 (29.7) | 76 (30.6) | 43 (28.3) | .83 | |
| 4. Use a diuretic | 57 (19.3) | 52 (21.0) | 46 (30.3) | .03 | |
| 5. Use an over-the-counter diet pill or any other weight loss product | 10 (3.4) | 7 (2.8) | 4 (2.6) | .88 | |
| Coping behaviors | | | | | |
| Frequently limit fluid intake when away from home so that you won't have to worry about finding a restroom | 40 (13.5) | 78 (31.5) | 74 (48.7) | <.0001 | |
| 2. Adjust travel plans so that you are always near a restroom | 23 (7.8) | 43 (17.3) | 63 (41.4) | <.0001 | |
| 3. When in a new place, you make sure you know where the restroom is | 70 (23.6) | 104 (41.9) | 105 (69.1) | <.0001 | |
| 4. Avoid places if you think there won't be a restroom nearby | 29 (9.8) | 51 (20.6) | 58 (38.2) | <.0001 | |
| 5. Go to the restroom so often that it interferes with things that you want to do | 15 (5.1) | 34 (13.7) | 51 (33.6) | <.0001 | |
| 6. Bladder symptoms make you feel like there is something wrong with you | 26 (8.8) | 65 (26.2) | 79 (52.0) | <.0001 | |

Table 2. Lifestyle and Coping Behaviors by Diagnosis Group

All values expressed as n (% yes).

*P value based on χ^2 analyses comparing frequency of "yes" vs "no" responses from patients

in the 3 diagnosis groups.

The reason for office visit differed slightly in a few sites (Table 5). The majority of patients (42.9%) went to their primary care clinician for follow-up of another medical issue. Approximately half (56%) of the women recruited through the gynecology office were there for a routine yearly exam; most of the rest (41.8%) were there because of a specific medical problem. In one primary care office, most (71.9%) were present for a routine physical exam.

Of the patients who were diagnosed with Possible or Probable OAB, many (40.8%) requested no follow-up for their symptoms (Table 5). Approximately 31% planned to schedule a follow-up visit to discuss their bladder symptoms further. Therapy was provided for only 11.3%; 28 patients (7.2%) received pharmacologic therapy and 26 (6.7%) received nonpharmacologic therapy.

| Clinical Variable | Dipsticks Obtained n | Positive Dipstick Reading n (%) |
|------------------------|-------------------------|------------------------------------|
| Urine dipstick results | | |
| No OAB | 84 | 16 (19.1)* |
| Possible OAB | 139 | 20 (14.4)* |
| Probable OAB | 107 | 21 (19.6)* |

Table 3. Clinical Diagnosis and Urine Dipstick Results

*Urinalysis was positive for: leukocytes (n=11), blood (n=2), protein (n=1), or nitrates (n=1),

no specific results were specified (n=1).

⁺Urinalysis was positive for: leukocytes (n=7), blood (n=10), glucose (n=1), protein (n=1), or nitrates (n=1). ⁺Urinalysis was positive for: leukocytes (n=13), blood (n=6), glucose (n=1), or nitrates (n=1).

| Table 4. | Complicating | Conditions | for | Possible | and | Probable | OAB |
|----------|--------------|------------|-----|----------|-----|----------|-----|
|----------|--------------|------------|-----|----------|-----|----------|-----|

| Condition | Possible OAB n (%) n=248 | Probable OAB n (%) n=152 | <i>P</i> Value* |
|---|--------------------------------|--------------------------------|-----------------|
| Presence of neurological problems | 7 (2.8) | 1 (0.7) | .13 |
| Interstitial cystitis | 3 (1.2) | 1 (0.7) | .58 |
| Diabetes | 56 (22.6) | 34 (22.4) | .88 |
| Congestive heart failure | 12 (4.8) | 9 (5.9) | .67 |
| Stress urinary incontinence | 45 (18.1) | 53 (34.9) | .0003 |
| History of bladder stones | 8 (3.2) | 5 (3.3) | 1.0 |
| Enlarged prostate, hesitancy, weak stream, or incomplete emptying of the bladder, n=155 (% yes) | 36 (37.1) (n=97) | 40 (69.0) (n=58) | .0002 |
| History of urinary retention (% yes) | 19 (7.7) | 18 (11.8) | .17 |
| Currently pregnant, n=245 (% yes) | 0 | 0 | |
| Postmenopausal, n=245 (% yes) | 88 (58.3) (n=151) | 57 (60.6) (n=94) | .86 |
| History of pelvic organ prolapse, n=245 (% yes) | 25 (16.6) (n=151) | 11 (11.7) (n=94) | .27 |
| History of constipation, n (% yes) | 43 (17.3) | 13 (8.6) | .01 |

*Based on χ^2 analyses comparing patients with a diagnosis of Probable OAB vs Possible OAB.

| Reason | Total Responses Provided | Patients n (%) | Possible OAB n=248 | Probable OAB n=152 | <i>P</i> Value |
|-----------------------------------|--------------------------------|-------------------|--------------------------|--------------------------|----------------|
| Reason for office visit | 1260 | | | | |
| Acute illness | | 295 (23.4) | 54 (21.8) | 33 (21.7) | .08 |
| Follow-up | | 541 (42.9) | 117 (47.2) | 79 (52.0) | |
| Routine physical | | 288 (22.9) | 56 (22.6) | 26 (17.1) | |
| Other* | | 136 (10.8) | 21 (8.5) | 14 (9.2) | |
| Patient disposition | 400+ | | | | |
| No follow-up requested | | 159 (40.8) | 107 (44.4) | 52 (34.9) | .06 |
| Educational material | | | | | |
| provided to patient | | 80 (20.5) | 49 (20.3) | 31 (20.7) | .94 |
| Will discuss further at | | | | | |
| next appointment | | 122 (31.1) | 79 (32.6) | 43 (28.7) | .41 |
| Treatment prescribed | | 44 (11.3) | 12 (5.0) | 32 (21.3) | <.0001 |
| Pharmacologic treatment | | | | | |
| prescribed [‡] | | 28 (7.2) | 8 (3.4) | 20 (13.3) | <.001 |
| Non-pharmacologic | | | | | |
| treatment prescribed [§] | | 26 (6.7) | 7 (2.9) | 19 (12.8) | <.001 |
| Other | | 31 (8.0) | 18 (7.5) | 13 (8.7) | .67 |

Table 5. Reason for Office Visit and Patient Disposition

*Reasons include accompanying patient to physician office, acupuncture, allergies, flu shot, lab work, obtaining a second opinion, preoperative physical, research study visit, and various medical complaints.

[†]Disposition only recorded for patients with Possible/Probable OAB diagnosis.

⁺Pharmacologic treatment included Detrol (n=10), Ditropan (n=4), Oxytrol (n=3), and BPH meds (n=6), UTI treatment (n=1), Levsin (n=1), follow-up with urologists (n=1), or treatment for other conditions (n=1), patient refused meds (n=1).

[§]Nonpharmacologic treatment included advice to alter fluid intake (n=20), referral to urologist/surgeon (n=3), Kegel exercises (n=1), or pessary (n=1), contraindication to pharmacologic treatment (n=1).

^{II}Currently treated for OAB or under urology care, discussed cause with patient (patient drinks lots of fluid), referred to urologist (possible urethral stricture), patient already taking Bactrim and Pyridium (discharged with UTI), patient dealing with other health issues (OAB symptoms will be addressed at a later date).

Screening Awareness Tool Performance

Few data were missing for patients who completed OAB-V8 (0.2%-0.6% missing data per question). Patients were able to calculate their responses correctly according to instructions 97.3% of the time. The OAB-V8 inter-item correlations ranged from 0.42 to 0.78, and item-to-total correlations ranged from 0.70 to 0.83; all were statistically significant (P<.0001).

A general linear model controlling for age and sex was used to compare OAB-V8 scores for the 3 diagnosis groups. As expected, the differences among the scores were highly significant (5.4 vs 12.7 vs 21.0, respectively; all *P*<.001).

Two primary multivariable logistic regression models were performed. The first model used the OAB diagnosis as the dependent variable to compare patients with No OAB versus Probable OAB, and the second model compared patients with No OAB versus Possible or Probable OAB. The models controlled for age and sex. Initially, when the OAB-V8 score was entered as a continuous number, the c-index was 0.96; however, an adequate model fit was not achieved. As a result, categorical variables were created from the calculated OAB-V8 score as follows: 0 to <8=low score (and reference for other scores); ≥ 8 to 16=medium score; and ≥ 16 =high score. This categorization of OAB-V8 scores dramatically improved the model fit (Table 6) and maintained a c-index of 0.96 when predicting Probable OAB (Fig 2) and a c-index of 0.92 when predicting Possible or Probable OAB. The OR for having a medium OAB-V8 score (≥ 8 to 16) and having Probable OAB was 95.7 (95% CI: 29.3; 312.4), while the OR for having a high OAB-V8 score (>16) and having Probable OAB was 806.6 (95% CI: 235.9; >999). Differences in age were significant between the Probable OAB alone and Possible/Probable OAB groups, with older participants being more likely to have a diagnosis of Possible or Probable OAB than younger participants.

| Table 6. Summary of Logistic Regression Models | | | | | | |
|--|------------|----------|----------------|-------|--|--|
| | d Lemeshow | , | | | | |
| Models | C-index | χ^2 | <i>P</i> Value | AIC | | |
| No OAB vs Probable OAB | 0.96 | 3.82 | .87 | 374.1 | | |
| No OAB vs Probable/Possible OAB | 0.92 | 9.57 | .30 | 840.3 | | |

As noted above, men had been asked to add 4 points to their scores. Upon further examination of the scoring, however, it appears that the additional points for men were overestimated, as sex was significant in all models. When only 2 points were added to the raw score for men, sex was no longer a significant covariate. Therefore, the final OAB-V8 requests that men add only 2 points to their final score.

With a prevalence of 12%, the sensitivity and specificity of the OAB-V8 were 98.0 and 82.7, respectively; additionally, the positive-predictive value was 43.7 and the negative-predictive value was 99.7. When evaluating the utility of the OAB-V8 in predicting Possible or Probable OAB, the sensitivity and specificity decreased.





DISCUSSION

This was the first validation of a screening awareness tool for OAB in an adult primary care setting. The OAB-V8 demonstrated excellent screening properties, with a high c-index, strong model fit, and high sensitivity and specificity to patients with Probable OAB. Importantly, 12% of this population was diagnosed with Probable OAB and nearly 20% with Possible OAB, thus calling attention to the need to increase awareness of OAB among both patients and physicians. The prevalence of OAB in the sample was much higher than the 1% and 3% prevalence rates found by Parazzini and colleagues¹⁷ in their study of general practitioners and much closer to the 16% rate found in the National Overactive Bladder Evaluation study.³ The differences in prevalence rates between our population and that in the Parazzini study may be due to a multitude of factors, such as a reporting bias attributed to the physician-conducted interview used by Parazzini and the self-administered questionnaire used in this study, a sampling bias, or the use of different diagnostic criteria. The Parazzini team did not assess patient symptom bothersomeness, only just the presence of urge incontinence, urgency, and frequency.

Because OAB is a symptom-based syndrome, it is logical and conceptually consistent to assess the bothersomeness of its symptoms. An argument could be made for determining the presence of symptoms; however, the need for a short, simple awareness screening tool coupled with the desire to treat only symptoms that are bothersome provides justification for assessing only those symptoms. Additionally, in the initial validation of the OAB-q Symptom Bother Scale (also known as the OAB-V8), the frequency and bothersomeness of symptoms were both assessed and resulted in a correlation of 0.88,¹² indicating a strong similarity between the factors being measured.

The OAB-V8 is intended for use as an awareness-raising tool and to be a complement—not a replacement—for the clinical diagnosis of OAB. This study was designed to mimic a primary care setting where patients would provide their healthcare providers with a completed screening awareness tool. While it may be argued that the clinician's knowledge of the OAB-V8 score prior to making a diagnosis contributed to the high sensitivity of the OAB-V8, it was essential in the diagnosis. In primary care, the gold standard for diagnosing OAB is the physician's diagnosis based on the patient interview, history, and urinalysis results. In this study, the standard for determining the accuracy of OAB-V8 was, in turn, the physician's diagnosis of OAB. To provide consistency in diagnosing OAB, a structured interview was included (ie, questions regarding urinary frequency, as well as lifestyle and coping behaviors). Additionally, all of the physicians participating in this study received standardized training on the diagnosis of OAB. The study design was still limited by the lack of inter- and intra-rater reliability for the physician-derived diagnosis of OAB.

In a post-study survey of the primary care physicians, many physicians noted that they were surprised by the number of patients living with bothersome urinary symptoms and that the OAB-V8 was useful in bringing these symptoms to light. The fact that patients were bothered by their symptoms was an important part of the diagnostic process, in addition to the information concerning urinary frequency, nocturia, urgency, and urge incontinence.

Interestingly, only 21.3% of patients diagnosed with Probable OAB received pharmacologic or nonpharmacologic treatment during the clinic visit. These findings are consistent with those found by Milsom and colleagues.² However, it should be noted that the reason for this physician visit was not for OAB symptoms but for other health reasons. Other issues that may reflect the low treatment rate are the cost of medications and reluctance to take a medication for symptoms that are currently being managed with coping strategies. Importantly, many patients diagnosed with Probable OAB did request educational materials and follow-up visits, which would allow them time to consider potential treatment options and have opportunities to discuss their OAB symptoms with their clinicians again in the future. The use of a screening awareness tool opens the door to communication regarding bothersome urinary symptoms and assists in reducing previously identified barriers to treatment.⁴⁻⁷ More importantly, the use of an awareness tool, such as the OAB-V8, allows clinicians to inform patients that their symptoms are not "normal" and that further investigation of the symptoms with their healthcare provider is warranted.

CONCLUSION

The OAB-V8 was used in these primary care settings to identify patients with symptoms of OAB and demonstrated high sensitivity and specificity. Thus, it demonstrated that a brief and simple screening tool can work well as an awareness tool for OAB. While not a diagnostic tool, the OAB-V8 is a conversation facilitator for the patient and clinician to discuss bothersome urinary symptoms, the possible causes of such symptoms, and potential treatments. Although the patient may not receive treatment on that specific visit, the door has been opened to provide the patient with additional information to make an informed decision regarding treatment. Importantly, OAB is highly prevalent among adults in primary care settings. Although there is no evidence that early detection of OAB leads to better long-term outcomes, raising awareness of OAB may allow more patients with bothersome OAB symptoms to receive an appropriate evaluation and treatment.

ACKNOWLEDGMENTS

The authors would like to thank the following investigators and site coordinators for their efforts in patient recruitment: Colorado Springs, Colorado: Jay Adler, MD; Betteanne Barash. San Antonio, Texas: Pamela Ann Camosy, MD; Debra delaRosa. Binghamton, New York: Frank Steven Eder, MD; Marie Mullins; Victor A. Elinoff, MD; Michelle Klick. Spokane, Washington: Timothy Gardner, MD; Kami Halsey; Sue Healey. St. Louis, Missouri: Edward Heidbrier, MD; Jackie Terrell; Janice Boehme. Ridgewood, New Jersey: Martin N. Hochberg, MD; Jessica Brewster. Huntsville, Alabama: Timothy Howard, MD; Sherry Brooks; Andrea King. Wichita, Kansas: Tracy Klein, MD; Candace Ratcliff; Kathy Stoddard; Praful Mehta, MD; Shannon Thomas. Oregon, Wisconsin: PI: Zorba Paster, MD; Brenda Gehin. Foothill Ranch, California: Bakul Patel, MD. Charleston, West Virginia: Sue Westfall, MD; Natalie Tappe.

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APPENDIX: THE OAB-V8

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 the 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 |
| An uncomfortable urge to urinate? A sudden urge to urinate with little | 0 | 1 | 2 | 3 | 4 | 5 |
| or no warning? 4. Accidental loss of small amounts | 0 | 1 | 2 | 3 | 4 | 5 |
| 5. Nighttime urination? 6. Walking up at pight because you | 0 | 1 | 2 | 3 | 4 | 5 |
| had to urinate?An uncontrollable urge to urinate? | 0 | 1 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 an 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.