

## The Role of Urgency, Frequency, and Nocturia in Defining Overactive Bladder Adaptive Behavior

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**Aim:** To determine the relation between urgency alone, or in combination with frequency and nocturia, and adaptive behavior in overactive bladder (OAB) syndrome. **Methods:** We used survey data from the General Longitudinal Overactive Bladder Evaluation (GLOBE) of primary care patients over 40. Participants (n=2,752: 1,557 females; 1,195 males) completed the same survey at two time points, 6 months apart. Questions assessed OAB symptoms and adaptive behavior. We estimated correlation coefficients ( $R^2$ ) between urgency, frequency, and nocturia symptom scores (alone and in combination) and adaptive behavior measures at baseline and change in symptom scores and behavioral measures from baseline to 6 months. **Results:** At baseline, urgency was the dominant predictor of all behavioral measures for females ( $R^2 = 0.19\text{--}0.48$ ) and males ( $R^2 = 0.15\text{--}0.39$ ). Lower  $R^2$  values were observed for the change in measures from baseline to 6 months, but again change in urgency was the strongest predictor of change in adaptive behavior ( $R^2 = 0.04\text{--}0.13$  in females, and  $0.02\text{--}0.08$  in males). The correlation between symptoms and measures of adaptive behavior was almost completely explained by the urgency score. Frequency and nocturia did not substantially improve the overall correlation. **Conclusion:** The relation between measures of OAB symptoms and adaptive behavior at baseline and over time are largely explained by urgency, not by frequency and nocturia. *NeuroUrol. Urodynam.* 30:406–411, 2011. © 2010 Wiley-Liss, Inc.

**Key words:** adaptive behavior; epidemiology; incontinence; overactive bladder

### INTRODUCTION

Overactive bladder syndrome (OAB), a highly prevalent condition,<sup>1–3</sup> is defined by consensus criteria<sup>4</sup> and characterized by urinary urgency associated usually with frequency and nocturia with or without urinary incontinence (UI).<sup>4</sup> Urgency is the complaint of a sudden compelling desire to pass urine, which is difficult to defer. Frequency and nocturia are complaints of increased urination by day and night, respectively.<sup>4</sup> Although urgency is the key OAB symptom, it is a subjective symptom and difficult to measure. Because of their objective nature, frequency, and nocturia are more readily quantifiable but themselves may not be entirely valid or reliable measures of OAB severity because they can result from other pathophysiologic processes unrelated to urgency and OAB. In addition urgency can also lead to changes in other behaviors (e.g., decreased fluid intake) that further affect the relationship between frequency or nocturia and urgency.<sup>5</sup>

The pathophysiology of OAB is not well understood.<sup>6</sup> Several studies investigating potential etiologies in the pathogenesis of OAB indicate that urgency is the first symptom that develops and thus may reflect the primary disorder.<sup>7–12</sup> Since urinary frequency and nocturia are objectively quantifiable and have been recognized by regulatory authorities (e.g., US Food and Drug Administration (FDA) and the European Medicines Agency (EMA)) as acceptable endpoints in drug registration trials, they are usually used as surrogate measures for OAB instead of (or in addition to) urgency in epidemiologic research addressing both, quality of life and adaptive behavior.<sup>1,2,6,7</sup> This is partly

because frequency and nocturia are objectively quantifiable, frequency and urgency are moderately correlated,<sup>13</sup> and because regulatory authorities such as the FDA and EMA have identified these measures as the acceptable endpoints in drug registration trials. Urgency is deemed less acceptable by regulatory authorities because it is based on subjective reports and because of concerns about the inability to distinguish pathologic urgency from the normal desire to void.<sup>6,14,15</sup> Since urgency is the hallmark of OAB diagnosis, it is important to develop highly reliable and valid measures of urgency and to assess its direct effect on quality of life.<sup>14,16</sup> There is no evidence to suggest that frequency and nocturia provide any additional information in the presence of urgency to define OAB-related adaptive behavior.

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TABLE I. Questions in the Bladder Health Survey: Urgency, Frequency, Nocturia, Urine Loss, Adaptive Behavior (n = 162)

Question domain	Question	Test-retest reliability Spearman's r	
		Item	Composite score
Urgency	<i>How often in the past 4 weeks did you...<sup>a</sup></i>		
	1. Suddenly have a feeling that your bladder was full	0.80	0.86
	2. Have a sudden and uncomfortable feeling that you had to urinate soon?	0.76	
	3. Have such a strong urge to urinate that you had to stop what you were doing and rush to the bathroom?	0.83	
4. Have very little warning before you were about to lose urine beyond your control?	0.80		
Frequency	5. Urinate 8 or more times in 1 day (from waking up to when you go to sleep)?	0.77	0.86
	<i>In the past 4 weeks...</i>		
	6. How many times a day did you usually urinate (from waking up to when you go to sleep) <sup>b</sup> ?	0.75	
Nocturia	7. How often did you urinate during the day (from waking up to when you go to sleep) <sup>c</sup> ?	0.68	
	<i>How often in the past 4 weeks did you...<sup>a</sup></i>		
	8. Wake up at night because you had to urinate 1 or more times?	0.75	0.83
9. Wake up at night because you had to urinate 2 or more times?	0.80		
Urinary incontinence	<i>On how many days in the past 4 weeks did you...<sup>a</sup></i>		
	10. Lose any urine, even a small amount?	0.83	0.85
Stress incontinence	11. Lose more than a few drops or small amount of urine?	0.73	
	Urge incontinence	<i>In the past 4 weeks, when you lost urine, how often was it because you...<sup>a</sup></i>	
12. Were coughing hard, laughing, or sneezing?		0.74	0.77
Adaptive behavior	13. Were lifting, pushing, or pulling a heavy object?	0.71	
	14. Had trouble getting to the bathroom in time?	0.72	0.79
	15. Had a sudden urge to urinate?	0.73	
<i>On how many days in the past 4 weeks did you...<sup>a</sup></i>			
Adaptive behavior	16. Drink less fluid in the evening to keep from waking up to urinate?	0.78	0.88
	17. Look for a bathroom immediately when in a new place?	0.75	
	18. Drink less fluid because of problems with bladder control?	0.67	
	19. Avoid activities away from restrooms because of concerns about bladder control?	0.69	
	20. Choose to wear clothing that wouldn't show if you lost some urine?	0.68	
	21. Wear a pad or other material to absorb urine you may have lost?	0.89	

<sup>a</sup>0 = Never/rarely, 1 = A few times, 2 = About once a week, 3 = A few times a week, 4 = Every day.

<sup>b</sup>0 = less than 7 times/day, 1 = 7-8 times/day, 2 = 9-10 times/day, 3 = 11-12 times/day, 4 = 13+ times/day.

<sup>c</sup>0 = less than once every 4 hr, 1 = every 3-4 hr, 2 = every 1-2 hr, 3 = more than once an hour.

The objective of this study was to determine the relation of urgency, frequency, and nocturia alone, and in combination, as correlates of OAB-related adaptive behavior, and as predictors of change in behavior. In particular, we sought to determine the added benefit of frequency and nocturia in the presence of a robust urgency measure in explaining change in behavior such as fluid restriction, avoidance of activities, and wearing protective clothing.

## METHODS

We used data from the General Longitudinal Overactive Bladder Evaluation Study (GLOBE), a population-based study designed to understand the prevalence and natural history of bladder control problems. We have previously described the GLOBE study, the source population for the study sample, the methodology used for our sampling scheme, survey validation, and data collection.<sup>17</sup> The Geisinger Institutional Review Board approved the study. In brief, GLOBE involves a longitudinal survey of a random sample of Geisinger primary care patients age 40 and older, selected from a population of more than 400,000 patients. Data for this study were from the baseline and 6-month follow-up surveys. The Bladder Health Survey (BHS), a self-administered questionnaire, uses a 4-week recall period. It encompasses questions on frequency of occurrence

and degree of bother for urgency, frequency, nocturia, UI, and adaptive behaviors.

Most of the questions used in the BHS were from the NOBLE Study that was clinically validated in a population sample.<sup>2</sup> In the preparatory phase of the BHS, we decided to determine if the reliability of symptom measures could be improved while maintaining the validity of the original measures. In pilot testing the BHS questionnaire we included all NOBLE questions. We also included from other sources two urgency questions and one incontinence question, one frequency question, and two severity of incontinence questions (not used in this article) where either clinical or urodynamic validation studies have been previously done.<sup>18-21</sup> In the pilot study, we performed a content validity assessment where we met with an advisory board of three urogynecologists, two female urologists, one advanced nurse practitioner with expertise in UI, and two epidemiologists with expertise in both UI and questionnaire design. We had consensus from the panel on the questions to include in the pilot study.

A test-retest reliability study of the BHS was subsequently completed in a random sample of 161 Geisinger Clinic primary care patients, age 45-75, with a clinical encounter in the last 2 years (Table I). The age criterion was expanded to 40 years and older for the longitudinal study. Participants in the reliability study completed the same questionnaire twice with an ~2-week interval between mailings. We measured test-retest reliability (Spearman's r) of individual and composite responses

to urgency, frequency, nocturia, UI, stress UI, urgency UI, and adaptive behavior questions. We also performed construct validity by evaluating the extent to which questions within a given domain (e.g., urgency) were correlated. Some questions were dropped because of low reliability, others were omitted because cross-tabulations showed high correlations with other questions in the same symptom domain with little to no increase in the overall composite reliability score. The composite symptoms scores and adaptive behavior scores used in this study had very good to excellent test reliability, with Spearman's  $r$  between 0.77–0.88 (Table I).

The final BHS items includes questions on the occurrence (i.e., never or rarely, a few times, about once a week, a few times a week, every day) of urgency (four questions), frequency (three questions), nocturia (two questions), urine loss (two questions) (including stress and urgency UI), and adaptive behavior (six questions) in the previous 4 weeks (Table I). Of the six adaptive behavior questions, three symptom-specific behavior scores were derived for nocturia, urgency, and UI. Finally, an overall adaptive behavior score was developed using the sum of responses to the six questions with a score range from 0 to 18.

Separate analyses were completed for males and females because of inherent differences in the presumed pathophysiology of OAB in both genders (e.g., prostate conditions in men and pelvic organ prolapse in women). Analysis was also stratified using the following criteria: (1) any OAB symptoms (frequency, nocturia, and urgency) with or without UI; (2) OAB symptoms with urgency UI only (i.e., women with stress UI were excluded). We completed a cross-sectional analysis at baseline of the relationship between each composite score for urgency, frequency, and nocturia and all combinations of each score with the behavioral measures. Using linear regression, we tested the hypothesis of whether urgency alone explained as much variance in the behavioral measures as any other combination of one, two, or three symptom measures.

We used the linear regression model  $R^2$  as a measure of explained variance and compared the  $R^2$  across each model for each symptom alone and for all possible combinations. Using baseline and 6-month questionnaire data, we examined how change in symptom score predicted change in behavior scores. Again, we examined all possible combinations of one, two, or three symptom scores to test the hypothesis of whether urgency alone explained as much variance as any other combination of symptoms. Finally, we completed parallel analysis examining the relation of baseline symptom scores predicting change in behavior scores between the baseline and 6-month follow-up surveys. We also used linear regression for the latter two analyses, using a change score, where relevant, for the independent and dependent variables. As before, we used the  $R^2$  as a comparative measure of explained variance.

For all analyses, we derived the model  $R^2$  and the adjusted  $R^2$  statistic. The adjusted  $R^2$  differs from multiple  $R^2$  in that it takes into account the number of variables in the model. Since the multiple  $R^2$  increases as variables are added to the model, the adjusted  $R^2$  can be used to guard against this inflation when comparing models that differ in the number of explanatory variables. In all cases, the  $R^2$  and adjusted  $R^2$  were very close, and we report the adjusted  $R^2$  for all models. Using plots and frequency distributions and descriptive statistics, we examined the distributional properties of all variables used in the models. All variables were normally distributed with no outliers. Regression diagnostics were run for all models. For bivariate correlations, Pearson correlations were confirmed using Spearman correlations showing close agreement. SAS version 9.1 was used for all analysis (SAS Institute, Inc., Cary, NC).

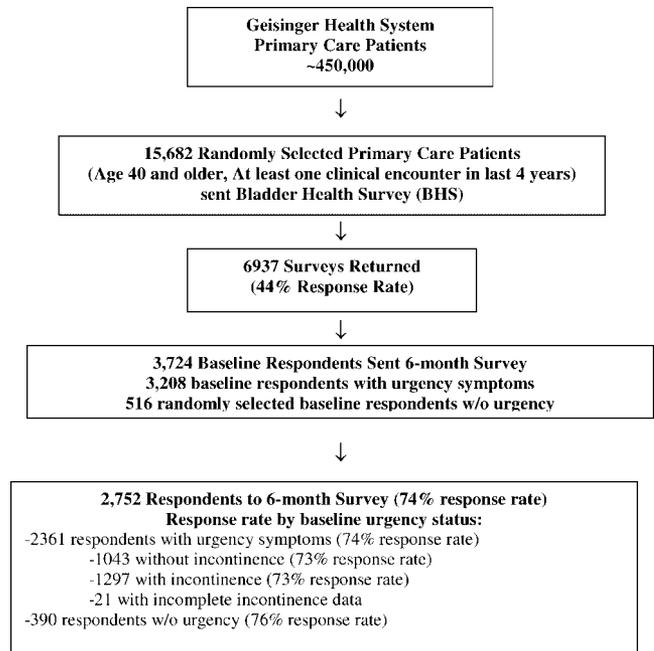


Fig. 1. Flow diagram of sample selection.

## RESULTS

The BHS was mailed to a random sample of 15,682 individuals, 40+ years of age. The response rate to the baseline survey was 44% ( $n = 6,937$ ). Of those, we had complete data on 6,780 individuals (3,548 females and 3,232 males). At baseline, 1,550 women and 681 men were defined as having UI (baseline UI composite score of 2+, indicating that they had UI at least a few times a month). From the initial baseline of respondents, a sub-sample of 3,724 individuals received the same survey 6 months later. This included all baseline respondents with urgency and a random sample of respondents without urgency. At 6 months, response rates were 74% ( $n = 2,752$ ), comprising 1,557 women and 1,195 men. The breakdown of response rate by urgency and UI status is shown in (Fig. 1). A comparison of responders to non-responders to the baseline survey revealed that responders were more likely to be older and female than non-responders.

In all models, the composite measures of urgency, frequency, and nocturia were positively correlated with behavioral outcomes. In other words, a higher score on the symptom measure was associated with a higher score on the behavior measures. Moreover, these correlations were stronger in females than in males (Tables IIa and IIb). For example, the  $R^2$  for urgency alone as a predictor of general OAB behavior at cross-section was 0.48 for females compared to 0.39 for males. Similar (but lower) gender-specific trends in correlations were seen between change in symptom scores and change in behavior scores from baseline to 6 months. For example, the  $R^2$  for change (from baseline to 6 months) in urgency symptom as a predictor of change in urgency behavior was 0.13 in women compared with 0.08 in men. In the sub-group of participants where men and women with stress UI were excluded, baseline symptoms of urgency, frequency, and nocturia were more strongly correlated with baseline behavioral scores in males than in females (Tables IIIa and IIIb). Finally, correlations between baseline OAB symptoms and change in behavioral scores from baseline to 6 months were close to zero in both genders, irrespective of continence status (data not shown).

**TABLE IIA. Adjusted Correlations for the Association between Symptoms of OAB and Adaptive Behavior—All Females**

Symptoms	Adjusted correlation coefficients R <sup>2a</sup>							
	Baseline symptoms versus baseline behavior (n = 3,548)				Change in symptoms versus change in behavior (baseline to 6 months) (n = 2,732 <sup>b</sup> )			
	G	N	U	I	G	N	U	I
Urgency	0.48	0.19	0.39	0.31	0.13	0.05	0.10	0.04
Frequency	0.22	0.11	0.22	0.10	0.06	0.03	0.02	0.008
Nocturia	0.26	0.17	0.21	0.13	0.07	0.04	0.05	0.02
Urgency/frequency	0.49	0.20	0.41	0.31	0.15	0.06	0.10	0.04
Urgency/nocturia	0.51	0.24	0.42	0.32	0.16	0.07	0.12	0.04
Frequency/nocturia	0.33	0.19	0.29	0.16	0.10	0.05	0.06	0.02
Urgency/frequency/nocturia	0.52	0.24	0.43	0.32	0.17	0.08	0.12	0.04

G, general behavior; N, nocturia behavior; U, urgency behavior; I, incontinence behavior.

<sup>a</sup>All P values of the adjusted R<sup>2</sup> are <0.0001.

<sup>b</sup>Sample size reflects the weighted sample that adjusts for the sampling scheme used at 6 months.

**TABLE IIB. Adjusted Correlations for the Association between Symptoms of OAB and Adaptive Behavior—All Males**

Symptoms	Adjusted correlation coefficients R <sup>2a</sup>							
	Baseline symptoms versus baseline behavior (n = 3,232)				Change in symptoms versus change in behavior (baseline to 6 months) (n = 2,104 <sup>b</sup> )			
	G	N	U	I	G	N	U	I
Urgency	0.39	0.15	0.38	0.16	0.08	0.02	0.08	0.02
Frequency	0.21	0.11	0.21	0.06	0.03	0.006*	0.02	0.02
Nocturia	0.21	0.14	0.18	0.06	0.02	0.01	0.02	0.003*
Urgency/frequency	0.41	0.17	0.40	0.16	0.09	0.01	0.08	0.03
Urgency/nocturia	0.42	0.19	0.40	0.16	0.09	0.02	0.09	0.02
Frequency/nocturia	0.29	0.17	0.27	0.08	0.04	0.01	0.04	0.02
Urgency/frequency/nocturia	0.43	0.20	0.41	0.16	0.09	0.02	0.09	0.03

G, general behavior; N, nocturia behavior; U, urgency behavior; I, incontinence behavior.

<sup>a</sup>P < 0.01.

<sup>b</sup>All P values of the adjusted R<sup>2</sup> are <0.0001, except where otherwise indicated.

<sup>c</sup>Sample size reflects the weighted sample that adjusts for the sampling scheme used at 6 months.

**TABLE IIIA. Adjusted Correlations for the Association Between Symptoms of OAB and Adaptive Behavior—Urgency Incontinent\* Females**

Symptoms	Adjusted correlation coefficients R <sup>2a</sup>			
	Baseline symptoms versus baseline behavior (n = 484)			
	G	N	U	I
Urgency	0.32	0.10	0.30	0.13
Frequency	0.15	0.07	0.16	0.05
Nocturia	0.14	0.11	0.09	0.07
Urgency/frequency	0.33	0.10	0.31	0.13
Urgency/nocturia	0.36	0.15	0.32	0.15
Frequency/nocturia	0.21	0.13	0.18	0.08
Urgency/frequency/nocturia	0.36	0.15	0.32	0.15

G, general behavior; N, nocturia behavior; U, urgency behavior; I, incontinence behavior.

<sup>a</sup>Baseline UI composite score = 2+; urgency UI score = 1+; stress UI score = 0.

<sup>b</sup>All P values of the adjusted R<sup>2</sup> are <0.0001.

**TABLE IIIB. Adjusted Correlations for the Association Between Symptoms of OAB and Adaptive Behavior—Urgency Incontinent\* Males**

Symptoms	Adjusted correlation coefficients R <sup>2a</sup>			
	Baseline symptoms versus baseline behavior (n = 528)			
	G	N	U	I
Urgency	0.40	0.18	0.35	0.15
Frequency	0.19	0.08	0.18	0.06
Nocturia	0.20	0.11	0.18	0.05
Urgency/frequency	0.41	0.19	0.37	0.16
Urgency/nocturia	0.42	0.20	0.38	0.16
Frequency/nocturia	0.27	0.13	0.26	0.08
Urgency/frequency/nocturia	0.43	0.20	0.39	0.16

G, general behavior; N, nocturia behavior; U, urgency behavior; I, incontinence behavior.

<sup>a</sup>Baseline UI composite score = 2+; urgency UI score = 1+; stress UI score = 0.

<sup>b</sup>All P values of the adjusted R<sup>2</sup> are <0.0001.

At baseline, urgency was the dominant predictor of all behavioral outcomes for both males and females. This was true even for the nocturia behavioral score. The contribution of nocturia and frequency to the overall model R<sup>2</sup> was relatively small when urgency was included in the model. With a few exceptions, adding frequency and nocturia to the model did not produce a meaningful increase in the overall correlation of symptoms with behavioral scores above and beyond the

correlation observed for urgency alone. For example, in women with UI, correlation between urgency symptom and urgency behavior at baseline had an adjusted R<sup>2</sup> = 0.30. Adding nocturia to the model increased the adjusted R<sup>2</sup> to 0.34, and adding nocturia and frequency increased the adjusted R<sup>2</sup> to 0.35 (Table IIIa). Similar trends were seen in men (Table IIIB). Combining symptoms of frequency and nocturia with urgency added only a relative increase of 15% or less to the adjusted R<sup>2</sup> in

explaining behavior related to urgency, UI, and overall behavior. Only for nocturia behavior, when the symptom of nocturia is combined with urgency, did nocturia add a meaningful relative increase (25–30%) in the adjusted  $R^2$  value. Although correlation coefficients between change in OAB symptoms and behavioral change were weaker longitudinally (from baseline to 6 months), urgency remained as the dominant predictor of all behavioral outcomes in both males and females, irrespective of UI status. For example, correlation between change in urgency symptom and change in urgency behavior in males was 0.08 compared with 0.02 for frequency symptom change and 0.02 for nocturia symptom change. Furthermore, combining frequency and nocturia with urgency added very little value to the adjusted  $R^2 = 0.09$  (Table IIb).

## DISCUSSION

We found that a composite measure of urgency was the single most powerful symptom correlate of OAB-related adaptive behavior in our sample, superior to nocturia or frequency. This relationship between urgency and adaptive behaviors was true at baseline and was strengthened by the finding that change in urgency was significantly correlated with change in behavior scores over 6 months. Nocturia was a distant second correlate of behavior scores, and when combined with the urgency score, added little to the overall correlation of urgency with behavior scores. Even for nocturia behavior, urgency was as strong or stronger correlate than the measure of nocturia. Those findings support the notion that a robust urgency measure alone is sufficient to define OAB-related adaptive behavior in epidemiologic studies. We believe that the minimal gains achieved in explained variance by combining nocturia, frequency, or both, to urgency in defining OAB adaptive behavior do not justify the additional question burden on survey participants, even if this involves one additional question each for frequency and nocturia.

Interestingly, OAB symptom scores of women in general are more strongly correlated with behavior scores than those observed for women with urgency UI, but a similar trend was not seen in men. We performed a similar analysis in both sexes using any UI (instead of only urgency UI) to define our OAB wet population (data not shown) and we obtained similar results. One explanation for the sex differences is that the symptom of UI in general (or urgency UI in particular), when present, is the stronger mediator of OAB adaptive behaviors in women. Hence, in the presence of UI, the explanatory power of urgency, frequency, and nocturia is somewhat reduced in women. The differences by gender may be explained by the fact that OAB-wet is more common and bothersome among women, whereas it is OAB-dry that primarily affects men.<sup>1,2</sup> Consequently, UI confounds the relationship between symptoms of OAB (urgency, frequency, and nocturia) and adaptive behavior, with the effect being more striking in women.

The dominance of urgency as a predictor of bladder control behavior could be explained by the possibility that urgency is a more reliable measure than nocturia or frequency. In general, assuming all other factors are equal, the explanatory power of a covariate will decrease as the test–retest reliability of the measure decreases. This is unlikely to explain the results in the current study. Test–retest reliability of the composite symptom scores of urgency, frequency, and nocturia were essentially the same. Another observation in our study is that the  $R^2$  for the correlations at baseline were much higher than those from baseline to 6 months. While there was a change in symptoms

over time, the majority of scores remained relatively the same between baseline and 6 months. Therefore, it is not surprising that correlations between baseline scores and change over time are low compared to cross-sectional correlations.<sup>22</sup>

We believe these results support the external validity of urgency as the primary driver of OAB adaptive behavior and it does not appear that routinely adding questions on urinary frequency and nocturia in conducting population-based studies of quality of life and adaptive behavior in patients with OAB adds value. One exception may be the symptom of nocturia in the context of evaluating nocturia behavior. These findings are only relevant to individuals in the population who are 40 years of age and older. A potential weakness of this study is that responders were older than non-responders and we did not control for age in our analysis. It is possible that adaptive behavior in response to symptoms of OAB may be different in older than younger individuals. However, this lower response rate in younger people is typical of most population-based studies.<sup>23</sup> Moreover, prevalence of OAB increases with age and it affects older people at a much higher rate than younger people.<sup>1,2</sup> Another weakness is that our response rate was relatively low at 44%. However, the response rate is similar to other population-based studies.<sup>22</sup> Furthermore, there is no evidence of a non-responder bias in people over the age of 40 in surveys assessing urinary symptoms.<sup>24</sup> Finally, we do not have information on whether study participants were receiving OAB treatment during the study period. Therefore, the  $R^2$  may underestimate the true correlations between symptoms and behavior. However, it would be expected that this potential estimation error proportionally affects the individual correlations of urgency, frequency, and nocturia vis-à-vis the adaptive behaviors, and hence resulting in little to no impact on our findings that urgency is the key correlate of adaptive behavior in OAB.

In conclusion, under most circumstances, urgency alone, as opposed to the other OAB measures of frequency, nocturia or a combination of all three measures, appears to be a necessary and sufficient criterion explaining OAB-related adaptive behavior in the general population. These results reflect general population data and should be translated cautiously into clinical practice. More research is needed to determine if these findings also hold true for OAB symptom severity, bother and impact on quality of life.

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