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Title: PREVALENCE AND IMPACT OF OVERACTIVE BLADDER IN THE US: RESULTS FROM THE NOBLE PROGRAM

Aim of Study:

Overactive bladder (OAB) is a common problem affecting millions of people in the US. There are no reliable data as to the prevalence and burden of illness of this condition. Although OAB is an inclusive term describing the population of patients suffering from urinary urgency and frequency with or without urge incontinence, there are no data at all as to the clinical significance and impact of OAB without incontinence (OAB Dry) as compared with individuals with incontinence (OAB Wet). In addition, although OAB is easily understood clinically, there is no agreed objective definition for research use. The National Overactive BLadder Evaluation (NOBLE) Program was conducted to provide a clinically valid research definition of OAB, then to establish estimates of its overall prevalence, the individual burden of illness, and to explore differences between the OAB Wet and OAB Dry populations.

Methods:

A computer assisted telephone interview (CATI) was developed to estimate variation in prevalence of OAB by demographic and other factors. The CATI was assessed for reliability and clinical validity. Clinical validity of the CATI was assessed in a Baltimore-based community sample, where the CATI diagnosis was compared to a clinician's diagnosis. The sensitivity and specificity of the CATI for OAB were 61% and 91%, respectively. As previously reported, the CATI was proven reliable [1]. The validated US national telephone survey used a quota sampling method to select 5,204 English-speaking adults (≥18 years of age) representative of the US non-institutionalized population with regard to gender, age, and geographic region. OAB Dry was defined ≥4 episodes of urgency in the preceding 4 weeks, and either frequency more than 8 voids/day or the use of one or more coping behaviors to control bladder function. OAB Wet included the same criteria as OAB Dry plus ≥3 episodes of urinary incontinence in the past 4 weeks that could not be explained by stress symptoms. During the CATI, participants were asked questions about bladder symptoms and coping behaviors. To assess illness impact, OAB cases and matched controls from the national survey completed self-administered questionnaires on quality of life (SF-36), quality of sleep (MOS Sleep), and depression status (CES-D questionnaire).

Results:

The overall prevalence of OAB was 16.9% in women and 16.0% in men, increasing with age. The overall prevalence of OAB Dry and OAB Wet was 7.6% and 9.3% in women, respectively, and 13.6% and 2.6%, respectively, in men. Quality of life and symptom data were collected on 215 OAB Dry and 164 OAB Wet cases and 512 matched controls. After adjusting for differences in comorbid illnesses (ie, congestive heart failure, diabetes, selected neurological diseases, and cancer) and other demographic factors, OAB Wet and Dry cases in women and men had clinically and significantly lower quality of life (SF-36 subscores), lower depression status (higher CES-D depression scores), and poorer quality of sleep (higher MOS sleep scores). For many of the measures, OAB Dry was similar to OAB Wet (Table).

Mean scores (SE) in measures of QoL (SF-36, depression, and sleep) between OAB cases and age-matched controls				
Outcome	**Gender**	**Controls**	**OAB Dry**	**OAB Wet**
SF-36				
--Physical Health Summary Score	W	49.4 (0.6)	45.3 (1.4)**	39.3 (1.2)***
	M	49.8 (0.7)	46.3 (1.0)**	41.3 (1.9)***
SF-36				
--Mental Health Summary Score	W	49.7 (0.6)	45.1 (1.4)**	46.8 (1.0)*
	M	53.6 (0.6)	49.3 (0.9)***	47.7 (1.9)***
CES-D (overall score)	W	11.7 (0.6)	17.3 (1.6)***	17.1 (1.1)***
	M	7.4 (0.6)	13.0 (0.9)***	16.7 (1.8)***
MOS Sleep (mean)	W	26.4 (0.9)	35.4 (2.4)***	38.6 (1.8)***
	M	20.1 (1.1)	27.5 (1.5)***	32.9 (2.8)***

W = women; M = men *p < 0.05; ** p < 0.01; ***p < 0.005

Conclusions:

We present the first validated and reliable data on the prevalence of OAB in the US, demonstrating that 16% of both men and women suffer with the condition. For the first time we have shown that OAB has a substantial individual impact, even among those without incontinence. Clinically and statistically significant differences in quality of life, mental health, and quality of sleep are revealed. Differences remain significant after adjusting for other comorbid illnesses and stress incontinence symptoms. We have established a statistically rigorous objective definition of OAB that can be used in future research and clinical trials.

Reference:

1. Stewart W, Payne C, Herzog R, Norton P. Reliability of reporting on symptoms and features of overactive bladder in a community sample. Presented at International Continence Society 30th Annual meeting, Tampere Finland, 2000, abstract 307.

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