

Questionnaire Survey on Overactive Bladder

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INTRODUCTION

Overactive bladder (OAB) syndrome is defined by the International Continence Society (ICS) as urgency with or without urge incontinence, usually with frequency and nocturia, in the absence of local pathological or endocrine factors [1]. The diagnosis of OAB is independent of the urodynamic diagnosis of detrusor overactivity [1, 2]. The new definition provides a foundation for patient-physician communication, and also allows the non-specialist to diagnose and manage OAB based on an assessment of specific symptoms. Recent research has focused on this common disorder, not only in terms of the physical limitations for patients, but also the association of this disorder with social, psychological, and sexual problems as well [2]. All symptoms of OAB are associated with a reduction in the quality of life (QoL) and also with the possibility of developing other disabling conditions, especially urge incontinence which appears to have the greatest negative consequences [3].

In 2003, Steward conducted a National Overactive Bladder Evaluation Program (NOBLE) in a broad spectrum of the United States population and found that the overall prevalence of OAB was similar between men (16.0%) and women (16.9%) [4]. In the United States, up to 33 million people (16.45%) are affected, by OAB, but sex-specific prevalence differs substantially by the severity of symptoms. Across all age groups, OAB without urge incontinence is more common in men than in women. Urge incontinence presents in 33% of the OAB population (OAB wet), while 66% of the OAB population does not have urge incontinence (OAB dry).

People with OAB, with or without urge incontinence, are associated clinically and significantly with lower QoL scores, higher depression scores, and poorer quality of sleep than matched controls [4]. Our previous survey revealed that approximately two thirds of the women with OAB had restricted their social activities (due to worrying about wetting or leakage and having no toilet facilities available), and approximately 19% of the incontinent women's sexual lives were affected. However, only 27.1% of the women with urinary incontinence and related symptoms in this study had reported seeking medical services to solve these problems [5].

Necessity of a Questionnaire for Surveying OAB

In 1999, Wein and Rovner estimated that 30% of the populations with OAB were not assessed for their symptoms, and approximately 80% of their OAB symptoms were not treated [6]. Because people consider OAB syndrome to be an inevitable part of aging, they think no treatment is available, and they are too embarrassed to discuss

their problem with their healthcare providers. In order to gather relevant information about a patient's problem, and to determine the nature of the problem, the frequency and extent of symptoms, questionnaires are useful in assessing the conditions that have an impact on the patients' activities and well-being [7]. Questionnaires provide information that can also facilitate communication among patients, clinicians, and caregivers as well as ensure proper treatment. A series of questionnaires have been developed to survey the prevalence of OAB by patient self-identification screening, patients' health-related QoL (HRQL) in order to measure the negative impact of OAB on daily life, and treatment outcomes.

Recently, the progress of treatment outcomes for OAB has been addressed. Many questionnaires that validate patients' reported outcomes have been developed and focus on the effects of the symptoms on the patient's daily routine and well-being. The efficacy of treatment is also acknowledged via objective evaluation and subjective evaluations of symptom improvement. Furthermore, questionnaires are also used to demonstrate a link between improved outcomes and adherence to medication as well as a link between patient satisfactions with adherence [8].

Concept of developing OAB Questionnaires

OAB is not life-threatening but is a chronic condition. The communication gap that exists between health care providers and patients with OAB symptoms may be a barrier to patient's self-reports and appropriate medical treatment. Currently, questionnaires for OAB vary from measuring severities of symptoms, assessing health-related QoL caused by OAB, and evaluating treatment outcomes through patient-reports [8]. In the 1990s, two validated symptom-specific questionnaires such as the King's Health Questionnaire (KHQ) and the Bristol Female Lower Urinary Tract Symptom (BFLUTS) questionnaire were commonly used for evaluating the prevalence and severity of lower urinary tract symptoms as well as the impact of specific lower urinary tract symptoms on the QoL.

OAB was defined as a symptom syndrome in 2002. Afterwards, the OAB questionnaire (OAB-q), the OAB-q Short Form (OAB-SF), and the OAB-V8 (a screening and awareness tool) were developed in American English for identifying OAB patients and measuring the impact of OAB on symptom severity and patients' QoL [9,10]. These tasks were sponsored and collaborated on by Pfizer Inc. The validated instruments for an OAB survey have been posted at <http://www.oabq.com/> and welcome investigators to access for free, as well as use these instruments in clinical trials in other countries.

In 2006, Acquadro et al [10] published an article in *Urology* and described the processes of successfully translating and validating the OAB-q and its subset instruments into 14 different languages. They highlighted the following six steps for translating these questionnaires in each language: two forward translations, comparison and reconcilia-

Received: January 17, 2008 Accepted: February 1, 2008

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tion of the translations, back-translation, comparison of the source and back-translation, review by one urologist or gynecologist, and a comprehension test using patients. Currently, these questionnaires have been linguistically translated and validated in more than 40 different languages to facilitate data collection cross-culturally and the international comparison of troubling symptoms and the HRQL in patients with OAB [11].

Several investigators have addressed that urgency is the cornerstone (or core) symptom of OAB syndromes [1,12,13]. It has been defined as the compelling feeling of impending incontinence that is difficult to defer and is also different from the normal feeling of "urge to void", which occurs during a normal bladder-filling cycle [1,13]. The cause of urgency is not fully understood and may vary from patient to patient according to the patient's perception. It is also difficult to measure urgency because of difficulty in understanding its definition and the context of normal urge to void. However, in this new era, some investigators have developed an urgency questionnaire, urgency perception scale, and primary OAB symptom questionnaire to quantify changes of response of urgency [11,14-16]. These questionnaires have been used to quantify the treatment outcomes and calculate combined changes in urgency, frequency, urge and urinary incontinence episodes.

From the end of the last century, the trend of measuring treatment outcomes has been based on patient centric end points. Incorporating patient-reported outcomes (PROs) into clinical trials has become an increasingly common means of assessing treatment efficacy for symptom-based conditions. This concept is reflected in the recommendation by the European Medicines Agency to use subjective outcome measures in clinical trials assessing treatment for urinary incontinence [17]. In order to expand multinational trials, a PRO instrument, generic PRO or a disease-specific instrument, have been linguistically and culturally validated in different languages for measuring more comprehensive information of efficacy in treating OAB [8].

Furthermore, single-item global questions, i.e. patient perception of bladder condition, have been developed for measuring the patient's response to treatment. This questionnaire is patient-based so as to consider all symptoms, not just one, in addition to possible treatment side effects, cost versus benefit, and other factors related to the disease or treatment [18]. In addition, another questionnaire has been developed for evaluating treatment efficacy of medication and patient adherence to treatment [19]. Patients are asked to administer global assessments of treatment as a perceived benefit, satisfaction with treatment, and willingness to continue treatment (the BSW). This questionnaire a useful tool to capture patients' global impressions of the above three key elements of treatment outcome and it can facilitate patient-physician communication as well as be informative to researchers.

Eligible Validated OAB Questionnaires

For determining the diagnosis of OAB and evaluating treatment outcomes, objective instruments such as bladder diaries including micturition frequency, number of urgency and incontinence episodes, voiding volume per micturition, and urodynamic parameters were used for making a diagnosis and assessing changes of response. Recently, the European Medicines Agency recommended using subjective outcome measures in clinical trials to assess the treatment for urinary incontinence [17]. Several eligible questionnaires of subjective assess-

ment of symptom-specific, severity rated, and patient-reported outcomes are as follows: King's Health Questionnaire, Bristol Female Lower Urinary Tract Symptom Questionnaire, OAB Questionnaire, OAB questionnaire short form, OAB-V8, Urgency Questionnaire, Urgency Perception Scale, Primary OAB Symptom Questionnaire, Patient Perception of Bladder Condition and the BSW.

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