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Objective Evaluation of Overactive Bladder: Which Surveys Should I Use?

Michael Shy [Resident] and

Scott Department of Urology, Baylor College of Medicine, 6620 Main St, Suite 1375, BCM 380, Houston, TX 77030

Sophie G. Fletcher [Assistant Professor]

Department of Urology, Weill-Cornell Medical College, Director of Research, The Methodist Hospital, Center for Restorative Pelvic Medicine, 6560 Fannin, Suite 2100, Houston, TX 77030

Abstract

Overactive bladder (OAB) is a common condition that affects many adults, and prevalence increases with age in both men and women. It is characterized by symptoms of urinary frequency and urgency with or without urge incontinence in the absence of another proven etiology. As a diagnosis based solely on urinary symptoms, proper evaluation of OAB often depends on the use of psychometrically validated questionnaires to assess symptom severity and degree of bother. General urinary assessment forms can evaluate many urinary symptoms while modular questionnaires can focus on the most bothersome complaints. Many questionnaires have been formulated and validated to achieve these goals. Currently, the ideal questionnaire does not exist. This review attempts to outline the range of questionnaires available to the clinician to assist in evaluating symptoms as well as degree of impact on quality of life.

Keywords

Overactive bladder; Lower urinary tract symptoms (LUTS); Urinary incontinence; Questionnaire; Quality of life (QOL)

Introduction

Overactive bladder (OAB) is a common condition in the adult population, where large population studies in both the United States and Europe have demonstrated an overall prevalence of between 12% and 17% in the general population [1,2]. This prevalence increases to greater than 30% in adults over the age of 65 [2]. OAB can present a heavy burden on patients, often impairing quality of life and becoming a challenging stressor, while also taking an economic toll on the health care system. The definition of overactive bladder was revised in 2002 by the International Continence Society (ICS) in conjunction with providing new definitions for lower urinary tract dysfunction compatible with the WHO International Classification of Functioning, Disability and Health (ICIDH-2) and the International Classification of Diseases (ICD10) [3]. OAB is defined as “urgency, with or without urge incontinence, usually with frequency and nocturia, in the absence of infection or other proven etiology”. Increased daytime frequency of voiding is “the complaint by the

SGFletcher@tmhs.org.

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patient who considers that he/she voids too often by day”; nocturia is “the complaint that the individual has to wake at night one or more times to void” and urgency is “the complaint of a sudden compelling desire to pass urine which is difficult to defer”. Though OAB can also occur in conjunction with urinary incontinence, a large proportion of patients report urgency and frequency without incontinence [3, 4].

Prevalence

Until recently, there had been no large, coordinated studies of the general population looking at the symptoms of OAB without incontinence. The focus of previous studies has been on prevalence rates of urge incontinence [5]. The National Overactive Bladder Evaluation (NOBLE) study, conducted in adult population aged 18 years in the United States, reported that 16.9% of women and 16.0% of men had overactive bladder symptoms [2]. In Europe, the EPIC study (Sweden, Italy, Canada, Germany and United Kingdom) was the first large investigation assessing the prevalence of lower urinary tract symptoms based on the new ICS definitions. In this study of over 19,000 men and women over the age of 18 years, prevalence rates of OAB were 13% in women and 11% in men [1]. While these rates are similar in both sexes, there are gender differences in the age-specific estimates and regarding the predominant symptoms. The prevalence in women is higher before the age of 60 (10.6% to 8.1%), whereas the prevalence after this age is higher in men, up to 19.1% [1, 5]. In all age ranges, overactive bladder with incontinence is the most prevalent type in women while overactive bladder without incontinence predominates among men [2, 4].

Questionnaire Evaluation of OAB

It is generally recognized that a valid way of measuring the patient perspective of the condition is through use of psychometrically robust self-completion questionnaires [6, 7, 8]. The advantages of a questionnaire can be fairly obvious: cost, speed, quantitation, reproducibility, ease to administration, and noninvasiveness. On the other hand, it usually cannot definitively pinpoint a causal diagnosis or an anatomic abnormality and its subjectivity makes bias a distinct possibility. Overactive bladder is a diagnosis based solely on symptoms of the lower urinary tract. Patients with symptoms such as frequency, urgency and incontinence are a heterogeneous group, and simply categorizing these symptoms does not help with a mechanistic diagnosis. The contributing pathophysiologies include a wide differential: storage overactivity, voiding underactivity, outlet obstruction, fluid balance problems, “functional” incontinence of the elderly, and/or sphincter weakness. Conflicting data exists in the literature as to whether symptom questionnaire scores correlate to urodynamic findings such as detrusor overactivity, maximum detrusor pressures, cystometric capacity and stress incontinence [9-12].

Despite the shortcoming, OAB surveys can provide the patient with a manner of tracking their expectations and/or satisfaction with treatment. Importantly, an adequate survey can assess the bother of symptoms for the individual. The extent of this perceived impact, which varies among individuals, is important and must be measured. Many clinical trials groups have acknowledged the importance of assessing quality of life in health outcomes research and thus have outlined policies stipulating that quality of life should be considered as an end point in all new trials [6, 8, 13]. Subsequent questionnaires, having undergone appropriate psychometric testing, adhered to this requirement and were recommended for use in research and clinical practice.

Psychometric Validation

After a questionnaire is developed, it needs to undergo psychometric testing for its validation. Patients must be able to understand each component of the survey and be able to

complete it within a reasonable amount of time. In order to determine its clinic utility, questionnaires are validated under the two fundamental properties of reliability and validity. The reliability of a questionnaire refers to its ability to be consistent and reproducible. Different types of reliability exist, all of which aim to measure a survey's stability: alternate-form, internal consistency, interobserver, intraobserver, and test-retest [14].

Validity refers to how well an instrument measures the characteristic it is intended to measure. There are five different kinds of validity: content, construct, criterion-concurrent, criterion-predictive, and face [14]. Other properties of a questionnaire can also be tested: responsiveness, or the ability of the survey to demonstrate a change when a clinical event has occurred; sensitivity, or the capacity of a responsive survey to demonstrate adequate change; and coverage, or the ability of the questions to cover the areas that are susceptible to change [15, 16].

Types of Surveys

This review does not attempt to argue for one survey over the other; rather it outlines several of the types of surveys out there available to the urologist. There is a spectrum of questionnaires at the clinician's disposal from the general to the specific and each complements an evaluation of the OAB patient in a different way. The role of generalized urologic surveys remains important, even within the setting of female urology. For an initial encounter, the patient will often present with several urologic complaints along with the frequency and urgency seen in OAB. Several of these questionnaires can be used not just to assess OAB symptoms, but also other urologic complaints. These questionnaires have also undergone robust psychometric testing and can be used by the urologist not just in the initial evaluation but in subsequent visits to assess treatment progress and quality of life impact.

For practical use, copies of questionnaires can be found in the appendix of each instrument's published validation article. References are provided for the questionnaires discussed below. The only exception is that of the ICIQ series, which can be accessed on line (www.iciq.net). In the case of research use, copywrite regulations apply, and questionnaire authors should be contacted directly.

General Surveys of Lower Urinary Tract Symptoms

AUASI

The American Urological Association Symptom Index (AUASI) is a series of seven questions that assess symptoms of storage and voiding. Though its original use was in benign prostatic hypertrophy in men, its use in female patients has been investigated [17, 18] but not well established. Scarpero et al. looked at the use of the AUASI and whether it correlates in women with the level of bother caused by lower urinary tract symptoms. They also determined whether the association varies with a woman's age and continent status and whether the AUASI and degree of bother correlate with the patient's quality of life assessment. The charts of over 1200 women were reviewed who filled out the AUASI as well as quality of life measurement. There was a strong correlation (defined as correlation coefficient value greater than 0.8, with maximum of 1.0) between symptoms and problems caused by symptoms (0.858, $P < 0.0001$). The correlation existed throughout various age groups and was independent of coexisting incontinence. The symptoms correlated with quality of life in a similar pattern [19].

UDI-6 and IIQ-7

Taken together, these two questionnaires assess urinary symptoms, the symptom bother, and the impact the bother has on patients' quality of life. The parent Urogenital Distress

Inventory (UDI) consists of 19 items, each with a four-point bother scale; they are divided into three subscales, relating to the bother associated with: (1) irritative (e.g., frequency, urgency, nocturia), (2) obstructive (e.g., difficulty emptying), and (3) stress symptoms (e.g., leakage with activity) [20, 21]. A mean (possible range 1-4) is calculated over all questions in a subscale, and a calculation is performed to change to a value ranging from 0 to 100. The three subscores are summed, giving a total score of between 0 and 300. The higher the total score, the more bother. The original Incontinence Impact Questionnaire (IIQ) consists of 30 questions gauging the impact of the above symptoms. The IIQ is scored in a way similar to that of the UDI [20, 21]. There are four subscales; physical activity, travel, social relationships, and emotional health. The mean of responses from the relevant IIQ questions is transformed to a subscore ranging from 0 to 100 and they are summed. Psychometric analysis demonstrated that these questionnaires exhibited strong reliability, validity and sensitivity [20].

In clinical application, the length of these questionnaires may present a significant burden to the patient. Thus the UDI-6 and IIQ-7 were subsequently developed from the parent surveys as shorter versions that reduced the UDI from 19 items to six and the IIQ from 30 items to seven. Subset regression analysis was performed to obtain the subset questions that best approximated the parent survey scores [22]. These short form versions have been more widely adopted for clinical use.

BFLUTS

The Bristol Female Lower Urinary Tract Symptoms (BFLUTS) Questionnaire was developed with an emphasis on symptom quantification as well as on quality of life. There are 12 items regarding storage symptoms and voiding, eight items relating to incontinence, nine items regarding quality of life and four items relating to sexual function. Four of the eight items in the questionnaire that relate to incontinence quantify the leakage in terms of incontinence episodes and pad use. In the post-survey psychometric assessment, the questionnaire demonstrated reliability and validity. Construct validity and criterion validity were demonstrated. Reliability was good; a Cronbach's alpha of 0.78 indicated that the symptom questions had high internal consistency, while stability was excellent, with 78% of symptoms and problems answered identically on two occasions, and strong (greater than 0.8) Spearman rank correlation coefficients of 0.86 and 0.90, respectively [23].

Surveys Focusing on OAB

OAB-q

The OAB-q questionnaire was designed to assess symptom bother and quality of life in patients with both continent and incontinent OAB [24]. This questionnaire was psychometrically validated, demonstrating internal consistency reliability, validity, responsiveness [24], and test-retest reliability [25]. Moreover, these reliable differences in symptom bother and quality of life measures can be demonstrated distinctly among normal, continent, and incontinent patients of OAB [24]. The OAB-q consists of an eight-item symptom bother scale and 25 quality of life items that form four subscales (coping, concern, sleep, social interaction), and a total quality of life score [24, 26]. Patients rate each item on a six-point Likert scale ranging from "none of the time" to "all of the time" for the quality of life items and "not at all" to "a very great deal" for the symptom bother items. Items for each scale are summed and transformed into scores ranging from 0 to 100.

UQ

The Urgency Questionnaire (UQ) consists of 15 Likert-scale items and four visual analog scales rating the severity and impact of urinary urgency symptoms. The five-point Likert

items range from “none of the time” to “all of the time” and form four subscales (nocturia, fear of incontinence, time to control urge, and impact on daily activities). The four visual analog scales assess urinary urgency’s severity, intensity, impact, and discomfort. The UQ has been shown to have internal consistency reliability, construct validity, responsiveness [27], and test-retest reliability [25].

POSQ

The Primary OAB Symptom Questionnaire (POSQ) is a five-item questionnaire that assesses which symptom of OAB is the most bothersome to patients. On the first four items, patients rate how bothered they have been by each OAB symptom (urinary urgency, urinary frequency, nocturia, and urge incontinence) over the past 2 weeks. The fifth item asks patients to indicate which of the four OAB symptoms bothers them the most. Content validity of the POSQ has been evaluated through cognitive debriefing interviews with patients [25].

OAB-S

Another facet of patient assessment is the measurement of satisfaction with treatment. Patient satisfaction is important to a treatment paradigm as this often influences compliance as well as the doctor-patient relationship. It has also been shown to be associated with good health status, fewer medical encounters and shorter hospital stays [28]. The Overactive Bladder Satisfaction Questionnaire (OAB-S) was developed to assess patients’ satisfaction with OAB treatment including medications or other treatments, i.e., physical therapy or biofeedback. The OAB-S has five scales: OAB Control Expectations (ten items); Impact on Daily Living with OAB (ten items); OAB Control (ten items); OAB Medication Tolerability (six items); and Satisfaction with Control (ten items). Then there are five single-item overall assessments: patient’s fulfillment of OAB medication expectations, interruption of day-to-day life due to OAB, overall satisfaction with OAB medication; willingness to continue OAB medication and improvement in day-to-day life due to OAB medication. Internal consistency reliability and test-retest reliability were demonstrated for all dimensions [29].

ICIQ

In regards to urinary incontinence and the effort to assess the symptoms and the impact of those symptoms on quality of life in an accurate and efficient manner, the Symptom and Quality of Life Assessment Committee of the First ICI met in 1998 to perform a detailed review of the literature and questionnaires related to urinary incontinence [30]; this review was updated in 2001 [31]. The committee identified a number of published questionnaires that had been developed to assess urinary incontinence and subsequently applied grades of recommendation to each based on their degree of validation of each questionnaire [30, 31]. In addition to utilizing these surveys in clinical practice and research, there was a push to develop a unified survey, broadly applicable to the population. In this time, there was development of a questionnaire that would facilitate such assessment: the International Consultation on Incontinence Questionnaire (ICIQ) [8, 32]. A detailed review of the literature and expert opinions yielded a preliminary questionnaire; several studies were undertaken to evaluate the psychometric properties of the questionnaire, including content, construct and convergent validity, reliability and sensitivity to change [8]. The final ICIQ comprises three scored items (prevalence, frequency, and impact on quality of life) and an unscored self-diagnostic item (perceived cause of leak) [32]. In the analysis, the ICIQ was easily completed, with little missing data (mean 1.6%). It demonstrated construct validity, convergent validity, and test-retest reliability [32].

ICIQ Modular Questionnaire

The work with the ICIQ continued with the formulation of the ICIQ Modular Questionnaire. The ICIQ Advisory Board which was formed to direct development of the ICIQ in 1999 and it was decided that from the ICIQ, separate modular surveys could be created to target more specific patient populations [33]. The first module to be developed was the ICIQ-UI Short Form for urinary incontinence. The ICIQ-UI Short Form has now been fully validated and published [32]. Furthermore, given the desire for universal applicability, translations of the ICIQ were created with and subjected to the same psychometric testing.

In the development of the ICIQ modules, it was understood that a unified set of modules emanating from the original ICIQ did not require reinventing the wheel; the Advisory Board recommended adoption of previously psychometrically tested and robust questionnaires ICIQ modules [33]. The BFLUTS was renamed the ICIQ-FLUTS Long form, assessing female urinary tract symptoms (the short form was also renamed accordingly). For OAB, the ICIQ-OAB was derived from the male ICSmale [34] and female BFLUTS [23] questionnaires. The OAB-q quality of life assessment was used to derive the ICIQ-OABqol [24]. Per ICS, all modules were awarded a grade A recommendation meaning they have undergone psychometric testing and have published data sets demonstrating validity, reliability and responsiveness.

The ICIQ Advisory Board recently proposed the development of the ICIQ website, www.iciq.net, which was registered in 2004. The website maintains a database of the ICIQ modules, and informs users on the phase of development of each of these modules [33]. They can be accessed for both clinical and research purposes. The objective is to draw both clinicians and researchers throughout the world to collaborate to further the goal of a universally accepted questionnaire.

Conclusion

Overactive bladder is a prevalent condition and undoubtedly presents a challenge to current and future urologists. In order to better manage the condition, accurate patient assessment based on patient-centered goals is vital. Quality of life impact is an essential component of the patient-centered paradigm and validated assessment tools are available to guide the clinician in this endeavor. This can be achieved using general urinary assessment forms which casts a wide net and can identify other issues outside of OAB. Single-item questionnaires such as the ICIQ Modular questionnaires can be used to focus on the most bothersome symptoms. The modular format can have great utility as clinicians can select only those sections that apply to their condition of interest. However, he or she must strike a balance as it may be conceivably burdensome if subjects are asked to complete multiple modules [32]. To date, one questionnaire does not fit all. It is therefore up to the clinician to create an individualized evaluation of the tools that exist, to modify or combine if necessary, to better assess, treat and manage patients.

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Table 1

<u>Selected general questionnaires for lower urinary tract symptoms in women</u>
American Urological Association Symptom Index (AUASI) [15]
Urogenital Distress Inventory (UDI) [16]
Incontinence Impact Questionnaire (IIQ) [16]
Bristol Female Lower Urinary Tract Symptoms (BFLUTS) [18]

Table 2

Validated questionnaires for evaluation of overactive bladder
Overactive Bladder Questionnaire (OAB-q) [19]
Urgency Questionnaire (UQ) [20]
Primary OAB Symptom Questionnaire (POSQ) [20]
International Consultation on Incontinence Questionnaire (ICIQ) [27]
ICIQ Modular Questionnaires:
ICIQ-OAB (derived from ICSmale and BFLUTS) [18, 29]
ICIQ-OABqol (quality of life) (derived from OAB-q) [19]