

Evaluation of urgency in women, with a validated Urgency, Severity and Impact Questionnaire (USIQ)

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Abstract The objective of this study is to develop a validated, patient-oriented questionnaire to assess urgency and associated life impact. We interviewed six urogynecologists and urologists and five patients with overactive bladder (OAB) symptoms about urinary urgency. Based on this data, we composed the first draft of our Urgency Severity and Impact Questionnaire (USIQ). A focus group of OAB patients provided feedback on the USIQ draft. The revised questionnaire has two parts: symptom severity (USIQ-S) and related quality of life (USIQ-QOL). The questionnaire was given to patients with clinically diagnosed OAB to establish face, content and discriminatory validity. Cronbach's alpha for the USIQ-S and USIQ-QOL were 0.85 and 0.90, respectively. USIQ-QOL was moderately correlated with UDI-6 ($r=0.49$, $p<0.001$), IIQ-7 ($r=0.77$, $p<0.001$), and OAB-q ($r=0.73$, $p<0.001$). Mean

USIQ-QOL and USIQ-S scores differed by clinical diagnosis. The USIQ is an easily understood questionnaire with adequate validity for use in clinical practice and research.

Keywords Urgency · OAB · Lower urinary tract · Questionnaire · Health related quality of life

Introduction

The International Continence Society (ICS) defines urinary urgency as “the complaint of a sudden compelling desire to pass urine that is difficult to defer.” [1]. As currently defined, urgency describes an abnormal sensation that is distinguishable from the normal feeling of “urge” to void, which occurs during a normal bladder-filling cycle. Attempts to measure urgency are confounded by difficulties in understanding its definition and the context of the normal urge to void. Although urinary urgency is a key symptom of overactive bladder (OAB), most OAB research concentrates on urinary incontinence and urinary frequency. This may be partly due to the controversy surrounding the term ‘urgency’. The aim of our current study was to develop and validate a urinary urgency questionnaire to measure the severity and quality of life (QOL) impact from urinary urgency, in order to advance the clinical understanding of urinary urgency, and ultimately to guide the evaluation and treatment of patients with OAB.

Materials and methods

Ethical approval for all aspects of this research was granted by our Institutional Review Board. Developing the USIQ was a multi-step process (Fig. 1).

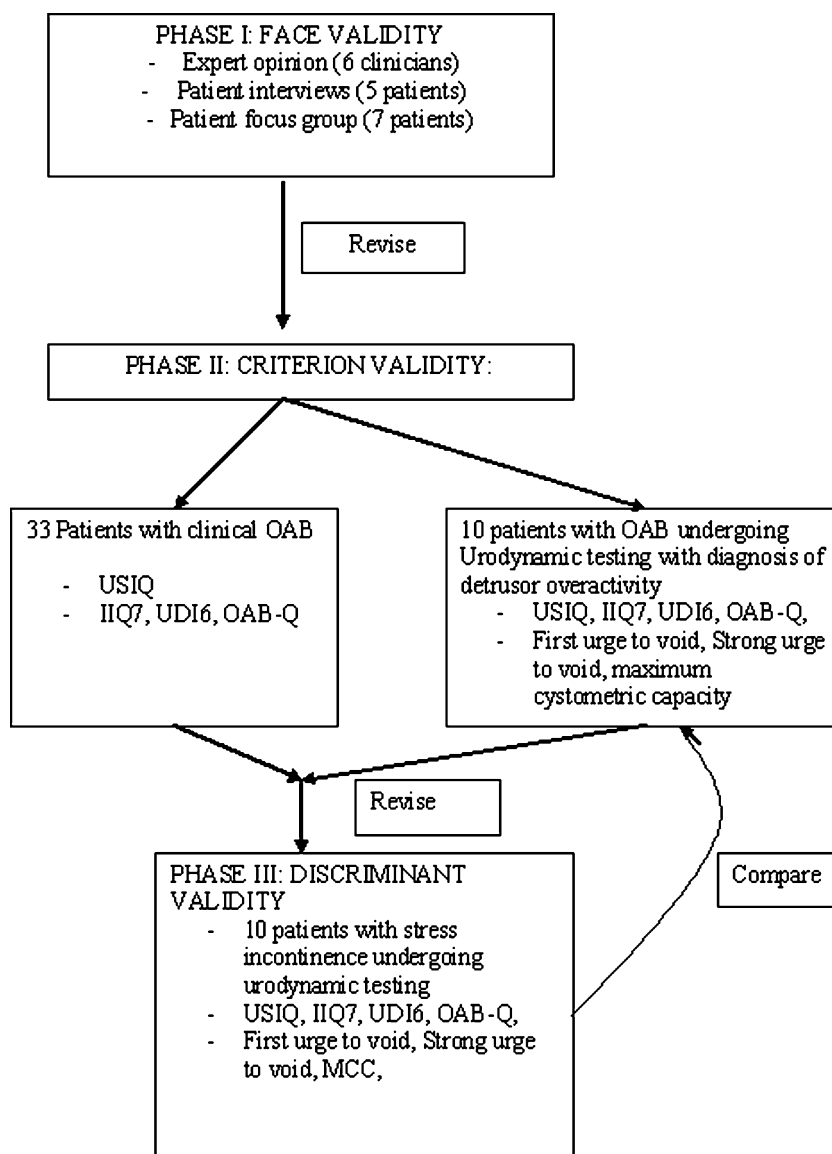
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Fig. 1 Overview of the validation of the USIQ



Instrument development

We composed the first draft of the USIQ questionnaire after interviewing six urogynecologists and urologists across the United States with expertise in the evaluation and treatment of OAB. Experts offered their opinions and perceptions regarding important aspects (domains) of patients' experiences of urinary urgency and associated bother.

Next, we recruited five patients with OAB and symptoms of urge incontinence based on clinical diagnosis, from our referral urogynecology clinic. Consenting patients met one-on-one with a psychologist (LH), who explored and characterized their experience of urinary urgency, including descriptions of its severity and effects on activities of daily living. Patients again offered their opinions and perceptions about their experiences of urinary urgency and associated bother.

Important domains thus identified were used to construct the initial version of the USIQ, which consisted of two parts with an initial filter question, designated for self-administration. We utilized the ICS definition for urgency for this filter question. To ensure patients related their responses only to urgency symptoms, we added the following paragraph to our written instructions "The following questions are only about your experience of urinary urgency. *Not* about other urinary symptoms"

The first part, the Urgency Severity Questionnaire-USIQ-S), consisted of eight items which inquired about urgency symptoms and severity; the second part, the Urgency Impact Questionnaire-Quality of Life (USIQ-QOL), consisted of seven questions adopted and modified from the widely recognized and accepted Incontinence Impact Questionnaire (IIQ-7) [2]. The IIQ was found to capture all the domains which brought up by both the

patients and the experts. Each item of the bother from urgency was measured originally using two different scales: (1) a categorical scale similar to the existing IIQ-7 and (2) a ten-point Likert scale with '0' indicating no bother at all, and '10' indicating maximum bother.

Face validity

A psychologist (LH) then led a focus group of seven women recruited from our urogynecology clinic. All participants had a clinical diagnosis of OAB and reported urge incontinence on the Medical Epidemiological and Social Aspects of Aging questionnaire (MESA) [3]. Focus group participants reviewed the USIQ draft and each participant individually completed and added written comments on the specific USIQ items. Next, the group together discussed issues related to symptoms of urgency, the impact of urgency on patients' lives and feedback on the ability of the USIQ to capture urgency symptoms. Based on the response of our focus groups, a question about the impact of urgency on sexual function was added to the USIQ-QOL.

Criterion validity

Criterion validity was established by measuring the strength of the relationship between the USIQ-S and USIQ-QOL score(s) and existing, validated measures of OAB symptom severity. Since there is no gold standard measure of the severity of urinary urgency, we explored the magnitude of the associations between the USIQ scores and the validated Urogenital Distress Inventory (UDI-6) [2], Incontinence Impact Questionnaire (IIQ-7) [2], and Overactive Bladder symptom and health-related quality of life questionnaire (OAB-Q) [4]. Forty-three patients with a clinical diagnosis of OAB, ten of whom also had urodynamically confirmed DOI, were recruited from our outpatient clinic to take part in this phase of the study. Consenting participants provided demographic data and completed the IIQ7, UDI6, OAB-Q, and USIQ. Criterion validity was established by correlating urodynamic parameters and responses to the different questionnaires.

Discriminant validity

Discriminant validity was established by asking patients without a clinical diagnosis of OAB to complete the same measures at the time of urodynamic testing. Ten patients with urodynamic stress incontinence (USI) who did not have urge incontinence (they did not respond positively to any urge item on MESA-urge subscale) provided demographic data and completed the USIQ, IIQ7, UDI6, OAB-Q. Participants were asked to complete the USIQ questionnaire even if they did not have urgency symptoms and the answer for the first question was 'No'. We aimed to

establish that USIQ score(s) are higher among patients with OAB than patients with USI.

Statistical analysis

Decision rules for item reduction were (1) low-item to total correlations (<0.4); or (2) inadequate factor loading on any factor (<0.4). All items on each USIQ subscale were summed to score each USIQ scale. The mean value for USIQ-S and USIQ-QOL items (item range 0–4) was calculated, and multiplied by 25 to achieve a range of 0 to 100. Items which were responded as 'unknown' were recorded as missing values. Higher scores indicate more severe urgency symptoms and greater impact on quality of life respectively. Cronbach's alpha was used to assess the internal consistency of the USIQ-S and USIQ-QOL. An average Cronbach's alpha of 0.7–0.8 is generally considered acceptable for demonstration of internal consistency [5]. However, a very high alpha above 0.9 suggests highly-related items, and item redundancy. Pearson's correlation coefficient was used to compare responses to the USIQ-S and USIQ-QOL instruments to IIQ-7, UDI-6, OAB-Q, scores and urodynamic parameters; first desire to void, strong desire to void, and maximum cystometric capacity (MCC). Discriminatory validity was ascertained by comparing USIQ scores between clinical groups (controls without urgency versus patients with OAB) using a two-sample *t*-test and the area under the Receiver Operating Characteristic (ROC) curve. Exploratory factor analysis was applied to estimate factor loading and to determine the individual contribution of each item to the composite score. A 0.05 significance level was used for all statistical tests. No one-sided tests were done.

Results

Fifty three women with a mean age of 56 (29–87) years participated in this study. Most participants were Caucasian (87%).

Item reduction

We omitted the ten-point Likert scale questions leaving five symptom severity items and eight QOL items due to the high correlation between responses, on the five-point categorical HRQOL scale and the ten-point Likert scale to bother from urgency items, ($r=0.89$, $p<0.001$); the lower discriminatory power of the ten-point Likert scale questions, measured by the area under the ROC curve (0.82 versus 0.77, respectively); and the simplicity of the categorical scale. All items had good loading scores ranging from 0.48 to 0.85 (Table 1).

Table 1 Exploratory factor analysis and correlation between specific items with total USIQ subscale score

Item analysis	Factor loading	Correlation with total score (rho)	P value
USIQ-S			
During the last month what percentage of urinations had urgency?	0.71	0.79	0.0001
When you have urgency is it typically...	0.76	0.83	0.0001
How long can you wait once you have urgency?	0.47	0.65	0.0001
During the last month how much did urinary urgency bother you?	0.86	0.87	0.0001
In an average 24 hours how often was urinary urgency present?	0.86	0.87	0.0001
USIQ-QOL			
Ability to do household chores, work?	0.72	0.71	0.0001
Ability to do physical activity such as walking, swimming or other exercise?	0.67	0.82	0.0001
Ability to have an intimate relationship or sexual intercourse?	0.52	0.62	0.0001
Entertainment activities such and going to movie or concert?	0.92	0.85	0.0001
Ability to travel by car or bus for a distance greater than 30 minutes away from home?	0.82	0.85	0.0001
Participating in social activities outside your home?	0.80	0.85	0.0001
Emotional health (nervousness, depression, etc)?	0.57	0.64	0.0001
Feeling frustrated?	0.8	0.81	0.0001

Internal consistency for the USIQ-S and USIQ-QOL as measured by Cronbach's alpha was excellent, 0.85 and 0.90, respectively. USIQ-S and USIQ-QOL scores moderately correlated ($r=0.69$, $p<0.001$), thus supporting the association between the two parts of the questionnaire.

After revision of the USIQ based on focus group feedback and analysis described above, an optimized version of the questionnaire with a reduced number of items and scoring methods for both urgency severity and for its impact on quality of life was obtained (Appendix A).

Criterion validity

USIQ-QOL, which measures the effect of urgency on HRQOL, correlated moderately with existing, validated HRQOL questionnaires; UDI-6 ($r=0.49$, $p<0.001$), IIQ-7 ($r=0.77$, $p<0.001$) and OAB-q ($r=0.73$, $p<0.001$). Similar correlations were found between the USIQ-S and UDI-6 ($r=0.34$, $p<0.02$), IIQ-7 ($r=0.42$, $p<0.002$), and OAB-q ($r=0.73$, $p<0.001$). Except for a strong inverse correlation between USSBQ-QOL and the volume at which patients had strong desire to void ($r=-0.81$, $p<0.015$), neither USIQ-S nor USIQ-QOL scores correlated with other urodynamic parameters.

Discriminant validity

Mean USIQ-QOL and USIQ-S scores differed by clinical diagnosis. OAB patients had higher mean USIQ-S and USIQ-QOL scores than patients with USI (66 ± 18 vs. 34 ± 24 , $p<0.001$ and 48 ± 22 vs. 19 ± 25 , $p<0.005$, respectively). The area under the ROC curve, which was used to assess "urgency" discrimination, was 0.87 and 0.82 for USIQ-S and USIQ-QOL, respectively.

Discussion

We present a new questionnaire which has excellent internal consistency, good construct, face and discriminatory validity, and effectively captures the severity of urgency and its impact on quality of life. The USIQ addresses items which are important to patients with symptoms of urgency regardless of their continence status.

As expected, we found a moderate correlation between severity of urgency symptoms and their effect on patients' quality of life. This is particularly important when evaluating whether an individual will benefit from a treatment for symptoms of urgency and for evaluating the efficacy of such treatment.

Previous published questionnaires evaluate urgency symptoms as part of the evaluation of OAB, including day time frequency, nocturia, urgency, and urgency incontinence. The Overactive Bladder Symptom Score (OABSS) [6], has been validated in a cohort of Japanese patients. It measures overall symptom severity due to day time frequency, nocturia, urgency, and urge incontinence. Urgency is evaluated in this questionnaire, by the following question "How often do you have a sudden desire to urinate, which is difficult to defer?". The OABSS total score (0–15) is obtained by simple summation of the four individual symptoms [6]. Validity and reliability was demonstrated to be good as it was tested for the total score. The severity of urgency is evaluated only by one question which inquires about the frequency that patient has urgency symptoms. Warning time and the severity of the urgency symptoms are not captured by this questionnaire.

The Overactive Bladder Questionnaire (OAB-Q) [4] and the primary OAB symptom Questionnaire (POSQ) [7] are validated questionnaires which evaluate OAB symptoms and

related bother. The OAB-Q [4] has a second part which assesses HRQOL in both continent and incontinent women. Both questionnaires have specific items which inquire about urge symptoms. A possible limitation of these questionnaires is using the term “urge” rather “urgency” as this may confuse patients who use the term urge for describing strong desire to void. In our new questionnaire, we used the ICS definition of urgency, and the results of our study suggest that the questionnaire was comprehended by all participants.

The Indevus Urgency Severity Scale (IUSS) is a validated questionnaire which evaluates the severity of urgency using a single question [8]. The questionnaire was validated on large population-based sample. Its main limitation is the use of a non-ICS definition of urgency [1], “Degree of urgency is meant to describe your urge to urinate”, a mixing of the terms “urge” and “urgency” that may lead to confusion. Using only one question may also limit the ability of the questionnaire to capture other dimensions of urgency.

The Urgency Perception Score (UPS) was also found to be a validated and reliable tool for evaluating urgency symptoms [9]. The strength of this new tool is its ability to score urgency sensation on a continuous scale with different grades of severity. As was recognized by the authors, a limitation of this questionnaire is that validation in males and females was not done separately. The authors acknowledged that the two sexes may have different etiologies for urgency and urgency may be perceived in a different way. In addition, the UPS

questionnaire does not evaluate the effect of urgency symptoms on patients’ quality of life.

Finally, a new validated urgency questionnaire was published by Al-Buheissi et al. [10]. This questionnaire contains ten items which evaluates urgency severity and urge incontinence symptoms. The main limitation of this questionnaire is that its scoring system does not differentiate between symptoms of urgency and urge incontinence. Moreover, the terms urgency and urge are used interchangeably [10]. The USIQ evaluates urgency symptoms independent of urge incontinence. In order to ensure that patients related their responses only to urgency symptoms, we emphasized in our written instruction of the questionnaire that the questions inquire about urgency symptoms and not about other lower urinary tract symptom.

In conclusion, the USIQ is an easily understood questionnaire with adequate validity for use in research and in clinical practice to describe the severity and life impact of urinary urgency. Future testing will be needed to evaluate the stability (test–retest reliability) and sensitivity to change following treatment for urgency symptoms.

Conflicts of interest None.

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Appendix A

The following questions are only about your experience of urinary urgency, NOT about other urinary symptoms.

1. During the last month, what proportion of your urinations had urgency associated with them?

<input type="checkbox"/>	None or almost none of the urinations	<input type="checkbox"/>	About half of the urinations	<input type="checkbox"/>	All or almost all of the urinations
<input type="checkbox"/>	Some of the urinations	<input type="checkbox"/>	Most of the urinations	<input type="checkbox"/>	Don't know

2. When you have urgency, is it typically

<input type="checkbox"/>	Extremely Mild	<input type="checkbox"/>	Moderate	<input type="checkbox"/>	Extremely Severe
<input type="checkbox"/>	Mild	<input type="checkbox"/>	Severe	<input type="checkbox"/>	Don't know

3. Check the best answer for how long can you wait to urinate once you have urgency.

<input type="checkbox"/>	Half an hour or more	<input type="checkbox"/>	Less than 5 minutes but more than 1 minute	<input type="checkbox"/>	I cannot wait at all
<input type="checkbox"/>	Less than half an hour but more than 5 minutes	<input type="checkbox"/>	Less than 30 seconds	<input type="checkbox"/>	Don't know

4. During the last month, how much has urinary urgency bothered you?

<input type="checkbox"/>	None	<input type="checkbox"/>	Moderate	<input type="checkbox"/>	Extensive
<input type="checkbox"/>	Slight	<input type="checkbox"/>	Considerable	<input type="checkbox"/>	Don't know

5. In an average 24 hour period how much of the time is urinary urgency present?

<input type="checkbox"/>	Never	<input type="checkbox"/>	Sometimes	<input type="checkbox"/>	Always
<input type="checkbox"/>	Rarely	<input type="checkbox"/>	Usually	<input type="checkbox"/>	Don't know

 II. The following statements are about the impact of urinary urgency on your life.

	This question does not apply to me	Not At All	Somewhat	Moderately	Quite A Bit	Always
1	How much does urinary urgency affect your: Ability to do household chores, do your work or schoolwork?					
2	How much does urinary urgency affect your: Ability to do physical activities such as walking, swimming or other exercise?					
3	How much does urinary urgency affect your: Ability to have an intimate relationship or sexual intercourse?					
4	How much does urinary urgency affect your: Entertainment activities such as going to a movie or concert?					
5	How much does urinary urgency affect your: Ability to travel by car or bus for a distance greater than 30 minutes away from home?					
6	How much does urinary urgency affect your: Participating in social activities outside your home?					
7	How much does urinary urgency affect your: Emotional health (nervousness, depression, etc)?					
8	How much does urinary urgency affect your: Feeling frustrated?					

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