

## COMPREHENSIVE BLADDER ASSESSMENT TOOL: INSTRUMENT DEVELOPMENT

### Hypothesis / aims of study

The traditional measurement of OAB symptoms has been based on the “gold standard” bladder diary supplemented with various psychometrically tested patient-reported outcome (PRO) measures. While useful in diagnosis, treatment assessment, and clinical research, there have been some challenges associated with bladder diaries. Notably, questions have been raised regarding the proper completion of a daily diary due to the complexity of the diary (particularly electronic) as well as the treatment effect of diary keeping. Recommendations have been made that a measure which includes PROs, such as Health-Related Quality of Life (HRQoL), satisfaction, and adverse events, in addition to symptoms would provide a more accurate measure. To that end, a comprehensive patient-completed Bladder Assessment Tool (BAT) is being developed to be used as a primary endpoint in OAB trials with the potential to also monitor patient benefit from treatment in clinical practice.

### Study design, materials and methods

Subjects were recruited for concept elicitation interviews if they met the following inclusion criteria: (1) symptoms of OAB (urinary frequency and urgency with or without urgency incontinence) for  $\geq 3$  months prior to the screening visit); (2) a grade of eight or above on the OAB Awareness Tool-V8 (OAB-V8); and (3) experience on average of at least 8 micturitions (excluding incontinence episodes) per 24-hour period. In addition, incontinent subjects were also required to report at least one incontinence episode per 24-hour period during the previous three days. The targeted demographics were subjects aged 18 and above with fifteen planned incontinent and continent subjects each.

Concept elicitation interviews were conducted in-person using a semi-structured concept elicitation interview guide. This included topics, questions, and probes designed to understand OAB signs/symptoms, impact (e.g., HRQoL), experiences related to the condition, and satisfaction with treatment from the patient's perspective, and the most bothersome and most important to treat signs/symptoms and their impact. Audio-recordings of the interviews were transcribed verbatim and anonymized by removing identifying information. Transcripts were coded using ATLAS.ti version 7.5.2.

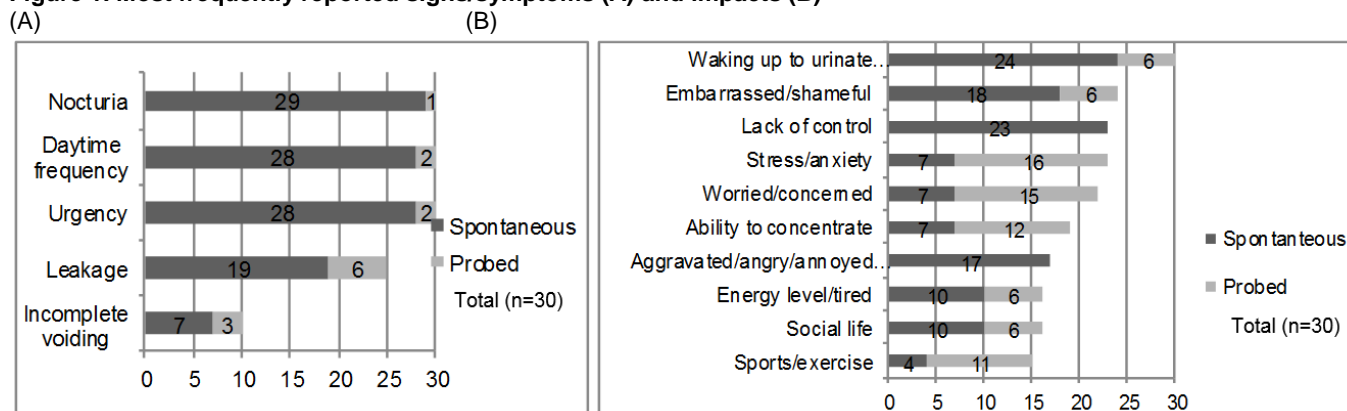
### Results

Thirty subjects (15 male and 15 female) were recruited. The majority of subjects considered their condition severity to be moderate ( $n=18$ , 60.0%). One incontinent subject considered his/her OAB to be very severe (7.7%), and more incontinent subjects considered their OAB to be severe than continent subjects [ $n=4$  (30.8%) versus  $n=1$  (5.9%)]. Overall, the average length of time that subjects had experienced OAB was 4.1 years, and the average OAB-V8 score was 20.8 (score scale 0-42).

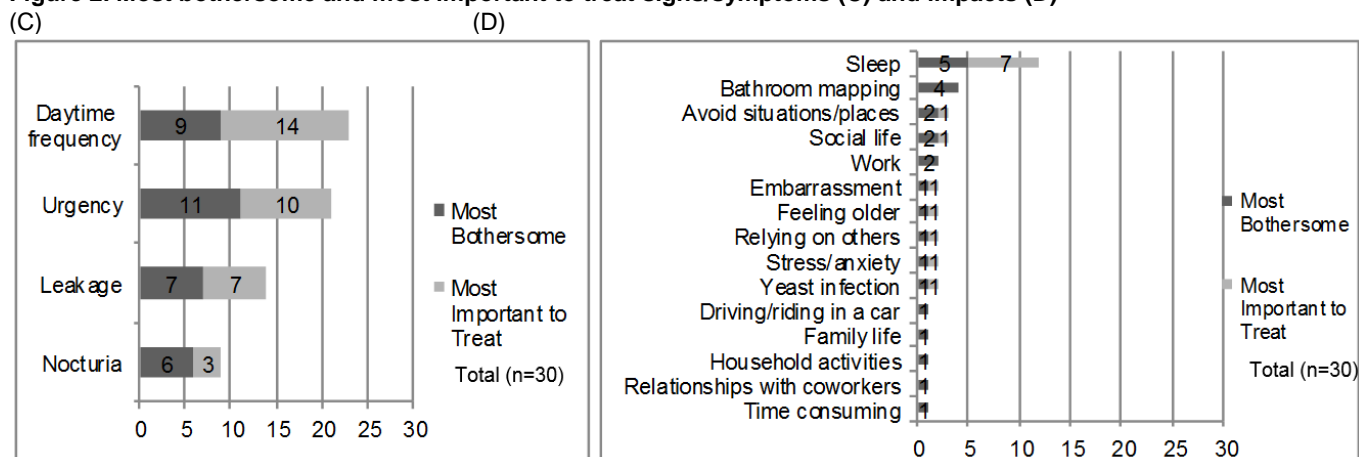
Night time urination, daytime frequency, and urgency were reported by all subjects, and leakage was reported by most of the subjects ( $n=25$ , 83.3%; Figure 1). Subjects reported urinating an average of three times per night, with responses ranging from one to eight times. Subjects reported urinating an average of eight times per day, with responses ranging from four to 16 times per day. The most commonly used words and phrases to describe urgency were “got to go” ( $n=8$ ), “pressure” ( $n=6$ ), and “urge” ( $n=4$ ). Twenty-nine subjects (96.7%) were familiar with the term urgency, and many used “urge”, “urgent”, and “urgency” interchangeably. Of the 25 subjects (83.3%) who reported incontinence, six subjects reported an average of 3.1 episodes per day with a range of 1 to 13.5, and six different subjects reported 2.3 episodes per week with a range of 1 to 4. Other subjects did not report a number and instead stated that incontinence episodes happened a “few times a week”, “quite often”, or “once every couple of weeks”. The symptom reported as most bothersome was urgency ( $n=11$ , 36.7%), with an average rating of 8.5 on a scale of 0-10 ( $n=11$ ) and 10 subjects (33.3%) reported urgency as most important to treat. Subjects also rated daytime frequency highly, with an average rating of 7.2 for bothersomeness and 14 subjects (46.7%) reported that it was the most important symptom to treat (Figure 2).

The most frequently reported impacts were waking up to urinate ( $n=30$ , 100.0%), embarrassment/shame ( $n=24$ , 80.0%), stress/anxiety ( $n=23$ , 76.7%), lack of control ( $n=23$ , 76.7%), and worry/concern ( $n=22$ , 73.3%) (Figure 1). Lack of control was spontaneously elicited by 23 subjects and was described either physically (“control your urine”) or emotionally (“I think I should have control of it. I feel like I'm a little child sometimes”). Subjects reported various coping mechanisms, including bathroom mapping ( $n=27$ , 90.0%), decreased fluid intake ( $n=24$ , 80.0%), and avoiding situations/places ( $n=16$ , 53.3%). The most bothersome impact was sleep deprivation ( $n=5$ , 16.7%) with an average rating of 8.9 ( $n=5$ ) and sleep was also reported as the most important impact to treat ( $n=7$ , 23.3%). The second impact most frequently reported as bothersome was bathroom mapping ( $n=4$ , 13.3%) (Figure 2).

**Figure 1. Most frequently reported signs/symptoms (A) and impacts (B)**



**Figure 2. Most bothersome and most important to treat signs/symptoms (C) and impacts (D)**



**Interpretation of results**

The results from the concept elicitation interviews provided evidence for the development of the BAT. Following analysis, a one-day item generation meeting was held with the steering committee to discuss concepts to be included as well as the overall preliminary structure and format of the instrument. Recommended items included the following: evaluations of daytime and night time frequency, urgency, and incontinence; an item that explores how bothered patients are by their OAB symptoms and an item asking about control of symptoms; and three to four broadly categorized impact items (i.e., collapsing the concepts of “travelling” and “driving/riding in a car” into a broad item of “interruption of daily activity”).

**Concluding message**

Further work on the BAT development will quantify OAB symptoms and incorporate evaluation of patient satisfaction and HRQoL. The BAT will be evaluated through cognitive debriefing interviews, and further refinement will be based on feedback from subjects.

**Disclosures**

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