INTERNATIONAL VALIDATION OF A BLADDER SCREENING TOOL FOR OVERACTIVE BLADDER

Hypothesis / aims of study
The objective was to quantitatively assess the performance of the Actionable Bladder Symptom Screening Tool (ABSST) in men and women with overactive bladder (OAB) and urgency urinary incontinence (UUI). The ABSST was previously validated in patients with multiple sclerosis (MS) and in non-diabetic women with OAB and UUI[1,2]. The present study was designed to further validate the ABSST using data from both men and women to establish the utility of the tool in screening a broader population who may benefit from further diagnosis and treatment of OAB and UUI.

Study design, materials and methods
A cross-sectional online survey was completed by OAB patients residing in North American, Europe, and Australia between December 2012 and March 2013. To be included in the study, patients were required to be 18 years or older with at least 1 incontinence episode in the past 12 months at the time of screening; those who reported predominantly stress incontinence were excluded. Patients reported the number of incontinence episodes in the past 3 days and whether they had ever been diagnosed with OAB. Several validated questionnaires were administered including the ABSST. The ABSST is an 8-item patient-completed measure comprised of 5 bladder symptom questions and 3 bladder impact questions. A 4-point response scale and 7 day recall period are utilized for each item. The total ABSST score ranges from 0 to 8 with a score of 3 or higher indicating a need for further urological evaluation/referral [1]. In addition to ABSST, patients also completed the Overactive Bladder Questionnaire (OAB-q) Symptom Bother scale, Urinary Incontinence-Specific Quality of Life Instrument (I-QOL), and the International Consultation on Incontinence Questionnaire (ICIQ) volume of urine leakage (ICIQ-UL) item. Descriptive statistics, reliability and validity of the ABSST score were examined. Concurrent validity of ABSST was evaluated by correlation with the OAB-q Symptom Bother score and I-QOL Total score. Known group validity was evaluated based on patient groups with different levels of severity as measured by the ICIQ-UL item and by the median of the I-QOL Total score. All analyses were conducted using SAS v9.2.

Results
Nine hundred forty-eight (70.7%) women and 393 (29.3%) men with or without self-reported past diagnosis of OAB/UUI and at least 1 episode of urinary incontinence within the past 12 months completed the online survey. The mean age was 54.5 ± 14.3 years. Compared to the female sample, the male sample was slightly older (55.9 vs. 53.9 years, p-value 0.018), and had higher rates of comorbid conditions, such as diabetes (22.4% vs. 11.5%), heart disease (9.9% vs. 3.5%), hypertension (42.2% vs. 30.8%), and high cholesterol (35.4% vs. 27.4%). Women were more obese than men (21.4% vs. 16.8%). The mean scores for the ABSST (adjusted), OAB-q Symptom Bother scale (unadjusted), and I-QOL Total (unadjusted) are shown in Table 1. Independent t-test analyses showed that male patients had a higher average score than female patients on OAB-q Symptom Bother (48.2 vs. 44.2) and a lower I-QOL Total score (64.1 vs. 66.8) suggesting that men had slightly more severe OAB/UUI.

Analysis of covariance (ANCOVA) however indicate there was no significant difference in ABSST mean scores between men and women after controlling for age, country, OAB-q Symptom Bother and previous OAB diagnosis. Overall, 40.3% (46.6% for men and 37.8% for women) of patients had ABSST score ≥ 3. The reliability of the ABSST score in both women and men was supported by a Cronbach alpha (0.79 and 0.77). Among both females and males, high correlations with the OAB-q Symptom Bother (r=0.67 and 0.62) and I-QOL Total (r=−0.67 and −0.60) supported that the ABSST was measuring the OAB/UUI symptom severity (concurrent validity). Known group validity was demonstrated by significant differences in adjusted (controlled for age) ABSST scores between patients who leaked none/small and moderate/large amount of urine (1.3 vs. 3.4 for women and 1.6 vs. 3.6 for men). Known group validity was also supported by the significant differences in adjusted (controlled for age) ABSST scores for subjects with I-QOL Total scores below the median versus those with scores at or above the median (1.8 vs. 3.8 for women and 2.4 vs. 4.1 for men).

Interpretation of results
ANCOVA results show that male and female patients had similar ABSST scores. Cronbach alpha coefficient showed that ABSST is a reliable measure. High correlations between ABSST and OAB-q Symptom Bother and I-QOL Total scores support its concurrent validity. Finally, significant differences between the ABSST mean scores between patient groups with different severity levels of OAB/UUI demonstrated that it has known group validity. These results show that the ABSST is reliable and valid and performs similarly in men and women, as in MS patients and non-diabetic female patients.

Concluding message
There are no significance differences in the validity of the ABSST in men and women with OAB/UUI in this multinational population of OAB patients. The ABSST is valid and useful for identifying female and male OAB/UUI patients with bothersome or severe symptoms who might benefit from further diagnosis and treatment.
Table 1: Mean Total Scores of ABSST, OAB-q Bother Scale, and I-QOL

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Mean Score (SD)</th>
<th>Total Sample (n=1341)</th>
<th>Male Sample (n=393)</th>
<th>Female Sample (n=948)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSST</td>
<td>2.4(1.9)</td>
<td>2.6(2.0)</td>
<td>2.3(1.9)</td>
<td>0.078</td>
<td></td>
</tr>
<tr>
<td>OAB-q Symptom Bother</td>
<td>45.3(21.7)</td>
<td>48.2(20.1)</td>
<td>44.2(22.2)</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>I-QOL Total</td>
<td>66.0(22.8)</td>
<td>64.1(21.5)</td>
<td>66.8(23.3)</td>
<td>0.045</td>
<td></td>
</tr>
</tbody>
</table>

aStandard error of the adjusted mean are shown for the ABSST score.
bANCOVA adjusted for age, country, past OAB diagnosis, and OAB-q Symptom Bother.
cIndependent groups t-test comparing male and female without controlling for covariates.

Actionable Bladder Symptom Screening Tool (ABSST):

For the following questions, please put a check below the response which best describes your bladder symptoms over the past 7 DAYS.

1. During the day, how often did you feel that you had to urinate right away?
   - None of the time
   - Some of the time
   - Most of the time
   - All of the time

2. How often have you had urinary accidents/leakage?
   - Not at all
   - A little
   - Moderately strong
   - Extremely strong

3. During the day, how strong was the feeling that you needed to urinate right away?
   - None of the time
   - One time
   - Two times
   - Three or more times

4. On a typical night, how often did you wake up in the night to urinate?
   - 0-3 times
   - 4-6 times
   - 7-11 times
   - 12+ times

5. On a typical day, how many times did you urinate?
   - 0-3 times
   - 4-6 times
   - 7-11 times
   - 12+ times

For the following questions, please put a check below the response which best describes impacts from bladder symptoms you may have experienced over the past 7 DAYS.

6. How much have your activities with friends and family been limited by your bladder problems?
   - Not at all
   - A little
   - Moderately
   - Extremely

7. How embarrassed have you been because of your bladder symptoms?
   - Not at all
   - A little
   - Moderately
   - Extremely

8. How much have you ability to work (paid or volunteer) outside the home been limited by your bladder problems?
   - Not at all/Does not apply
   - A little
   - Moderately
   - Extremely

Add the total number of boxes checked from the two right-hand columns in the shaded blue area

WOULD YOU LIKE TO RECEIVE HELP FOR YOUR BLADDER PROBLEMS?

Yes ☐ No ☐

References
2. Nitti VW, Dmochowski R, Chen WH, Signori M, Globe D, Wiklund I, et al. Content Validity of the Actionable Bladder Symptom Screening Tool (ABSST) In Non-Diabetic Females With Overactive Bladder (OAB) and Urgency Urinary Incontinence (UUI). Poster accepted for presentation at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 18th Annual International Meeting to be held May 18-22, 2013 in New Orleans, LA USA

Disclosures
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