Development and validation of the urinary incontinence in multiple sclerosis screening tool

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Hypothesis/Aims of Study
Urinary incontinence from neurogenic detrusor overactivity (NDO) is a common problem in patients with multiple sclerosis (MS). Currently there is no screening tool specifically developed for bladder overactivity in the MS population. The aim of the study was to develop and psychometrically validate a patient-completed screening tool to identify MS patients who could benefit from neurogenic detrusor overactivity specific treatment.

Study design, materials, and methods
The Actionable MS Urinary Function Screening Tool is a questionnaire asking patients to rate their symptoms, coping strategies, and impacts of NDO. The Actionable MS Urinary Function Screening Tool contains an additional item asking the patient if they would like to receive help for their bladder problems. The Actionable MS Urinary Function Screening Tool was created through the following qualitative methods:

1. Conducted face-to-face concept elicitation (CE) interviews with MS patients with NDO in order to identify relevant concepts.
2. Held a one-day item generation meeting to review the results of the CE interviews, agreed on the list of items for the newly developed treatment satisfaction questionnaire, and reached a consensus on the preliminary structure and format of the questionnaire.
3. Tested the face and content validity of the new questionnaire through face-to-face cognitive interviews with MS patients with NDO.

Examples of qualitative quotes
Leakage: “I wear a minipad as protection. I mean I’ve never fully pee’d in my pants. That’s never happened. But I have gone to the point where I just made it and a little bit will get on the pad. So I protect myself.”
Leakage: “That usually happens when I haven’t been – well, if I’ve been drinking a lot of water or drinking a lot of coffee, then I’ll have some leakage and if I don’t get to the bathroom in time, I can have a lot of leakage.”
Embarrassed: “I’m 52 years old and have to wear diapers. Not all the time, but when you have to wear a diaper and you’re 52 years old, it’s horrifying and I don’t care what the commercials say, you can see them under your clothes.”

Steps in developing the Actionable MS Urinary Function Screening Tool

Concepts covered in 23-item draft screener

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Coping</th>
<th>Impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urge</td>
<td>Bathroom mapping</td>
<td>Activities with friends and family</td>
</tr>
<tr>
<td>Incontinence</td>
<td>Daytime bladder protection</td>
<td>Work</td>
</tr>
<tr>
<td>Leakage</td>
<td>Nighttime bladder protection</td>
<td>Relationship with spouse or partner</td>
</tr>
<tr>
<td>Nocturia</td>
<td>Void intake</td>
<td>Travel</td>
</tr>
<tr>
<td>Daytime frequency</td>
<td>Sleep</td>
<td></td>
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</tbody>
</table>

Emotional impact items:
- Embarrassed
- Depressed
- Worried

Results
The initial version of the screening tool consisted of 23 items. The concept of incontinence was represented by three sets of two questions (frequency and severity) in order to test which were preferred by patients. A similar strategy was employed by testing four items for nocturia. During the cognitive interviews, the patients identified their preferred wording for the incontinence and nocturia items, as well as wording pertaining to coping strategies, and impacts of urinary incontinence. Patient feedback about response option similarities resulted in the reduction of response options from five to four for all items. The items about incontinence severity (amount) and travel impacts were deleted because of varied interpretations by patients and minimal clinical usefulness in the screening tool as identified by the key opinion leaders. In addition, the patients supported the content validity of the draft screening tool. Following the cognitive interviews to support the content validity, the screener was reduced to a 16-item Actionable MS Urinary Function Screening Tool (with an additional ‘yes/ no’ item asking if patients would like to receive help for their bladder problems) covering symptoms, coping strategies, and impacts of a five-month occurrence in MS patients and provides useful screening information to clinicians in determining whether patients are appropriate for referral for urologic evaluation.

Summary of quantitative analysis patient sample
151 patients with diagnosed MS have completed the 17-item measure
- Mean age: 48 years old (SD=12.1)
- Employed: 50%
- Female: 77%
- Live alone: 23%
- Mean years since diagnosis of MS: 9 (SD=7.2)
- Earn ≥$50,000 per year: 59%
- MS Urinary Function Screening Tool (with an additional ‘yes/ no’ item asking if patients would like to receive help for their bladder problems)
- 59% of patients scoring 13 or higher were correctly classified as actually having a bladder problem (positive predictive value [PPV] = 59%)
- 88.9% of patients scoring 13 or higher were correctly classified as actually having a bladder problem (positive predictive value [PPV] = 88.9%

Concurrent validity with OAB-q SF
Score | OAB-q SF Score | Symptom Severity (n=151) | Total HRQOL (n=151) | History of Urinary Incontinence (n=149) | Request for Help With Bladder Problem |
---|---|---|---|---|---|
Bladder symptoms | 0.83 | 0.84 | 0.80 | 0.69 |
Coping strategies | 0.78 | 0.82 | 0.71 | 0.65 |
Impact of bladder symptoms | 0.83 | 0.85 | 0.75 | 0.71 |
16-item total score | 0.87 | 0.90 | 0.81 | 0.74 |

High correlation with OAB-q SF; history of incontinence, and request for help (r=0.7) demonstrated acceptable concurrent validity.

Sensitivity and specificity

Cut Point for Total Score | Odds Ratio | Sensitivity | Specificity | Positive Predictive Value (%) | Negative Predictive Value (%) | % Correctly Classified | C Statistic |
---|---|---|---|---|---|---|---|
≥13 | 20.41 | 100.00 | 100.00 | 72.3 | 74.2 | 0.602 |
≥7 | 100.00 | 100.00 | 100.00 | 100.00 | 41.7 | 0.569 |

Interpretation of results
MS patients involved in the development process were able to communicate symptoms, coping strategies, and the impact of urinary incontinence. The urinary symptoms most commonly reported by MS patients interviewed were urgency to urinate, nocturia, leakage, frequency of urination, and incontinence. The impact of urinary incontinence included emotional aspects (embarrassed, frustrated, worried, annoyed, depressed, angry); social impacts; impacts on relationships with partners, spouse and/or friends; and sexual intercourse. Additional impacts included changes in wearing clothing, effects on walking, and impact on sleep. The balance of patient-centric concepts and clinical insight into identification of important items to include for screening highlights the benefits and outcomes of the qualitative work directly with patients and refined with clinician input. This maintains a balance between patient focus and clinical relevance for this screening tool.

Concluding message
The Actionable MS Urinary Function Screening Tool is a psychometrically validated screening tool feasible for use in clinical practice. The development of this screening tool was patient-centric and this focus will continue through development of a short-form version of the tool and finalization of a simple scoring method.