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

Chancellor M[1], Burks J[2], Signori M[3], Globe D[3], Hudgens S[4], Perrin-Ross A[5], Gonzales G[6], MacDiarmid S[7], Nitti V[8], Mehnert U[9], Bates D[10], Panicker J[6]

1. University of Pittsburgh School of Medicine, **2.** Burks & Associates, **3.** Allergan, **4.** Mapi Values, **5.** Loyola University Medical Center, **6.** Department of Uro-Neurology, University College London, **7.** Alliance Urology Specialists, **8.** New York University Langone Medical Center, **9.** Balgrist University, **10.** University of Newcastle

Actionable
MS Urinary Function Screening Tool

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:

- Conducted face-to-face concept elicitation (CE) interviews with MS patients with NDO in order to identify relevant concepts
- 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
- 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 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."*

Following development, the Actionable MS Urinary Function Screening Tool was tested for psychometric validation to 1) assess the feasibility of administering a screening measure to identify the symptoms and impact of NDO on MS patients, 2) to assess the psychometric characteristics of the screener, 3) to assess the feasibility of reducing the number of items in the questionnaire, and 4) to develop a scoring algorithm which could be easily implemented in a clinical setting. This was a five-month observational study involving 151 patients who had MS with and without previously identified NDO. Sensitivity, specificity, and concurrent validity were assessed against the Overactive Bladder Questionnaire (OAB-q SF).

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. The cognitive interviews 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 impact of urinary incontinence in MS patients which provides useful screening information to clinicians in determining whether patients are appropriate for referral for urologic evaluation.

Steps in developing the Actionable MS Urinary Function Screening Tool

Concept Elicitation
- Clinician and patient
- 23 Items

→ **Cognitive Interviews**
- Patient
- 16 Items

→ **Quantitative Validation**
- Patient
- 16 Items

→ **Short-Form Development**
- Clinician and patient
- 8 Items

→ **Scoring**
- Patient
- 8 Items

Concepts covered in 23-item draft screener

Symptoms	Coping	Impacts
Urge	Bathroom mapping	Activities with friends and family
Incontinence	Daytime bladder protection	Work
Leakage	Nighttime bladder protection	Relationship with spouse or partner
Nocturia	Fluid intake	Travel
Daytime frequency		Sleep
		Emotional impact items: —Embarrassed —Frustrated —Worried —Depressed

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)
- Female: 77%
- Mean years since diagnosis of MS: 9 (SD=7.2)
- Employed: 50%
- Live alone: 23%
- Earn >$50,000 per year: 59% (US middle class)
- NOT previously diagnosed with bladder symptoms: 59%

Concurrent validity with OAB-q SF

Score	OAB-q SF Score		History of Urinary Incontinence (n=149)	Request for Help With Bladder Problem
	Symptom Severity (n=151)	Total HRQOL (n=151)		
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 (>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
≥27	.	20.41	100.00	100.0	72.3	74.2	0.602
..	...	..	..	..	..	..	..
≥13	86.22	81.63	95.10	**88.9**	91.5	90.7	0.884
..	..	..	..	..	..	..	..
≥1	.	100.00	13.73	35.8	100.00	41.7	0.569

Cut point: Score selected based on the Actionable MS Urinary Function Screening Tool.
Odds ratio: Likelihood (strength of association) that patient has bladder problems based on cut point score.
Sensitivity: Proportion of those correctly identified as having bladder problems.
Specificity: Proportion of those correctly classified as NOT having bladder problems.
Positive predictive value: Proportion of patients with bladder problems who are correctly diagnosed.
Negative predictive value: Proportion of patients WITHOUT bladder problems who are correctly diagnosed.
C statistic: Probability that the model used will place a patient in the right order, giving the higher probability to the one who develops bladder problems than to the one who does not.

Assessment of the psychometric properties of the 17-item screener demonstrated acceptable sensitivity and specificity; 88.9% of patients scoring 13 or higher were correctly classified as actually having a bladder problem (positive predictive value [%]).

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.