A More Specific Meaning for Global Severity Anchors in a Population with Urinary Incontinence

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ABSTRACT

Background: Subjective expressions of patient status are being increasingly relied upon to inform researchers and clinicians about important changes in the overall severity of their condition. **Objective**: To better describe the specific meaning behind patient-reported severity, we asked a group of 19 women with urinary incontinence (UI) to define the specific attributes of "mild, moderate and severe." **Methods**: For each severity anchor, participants provided qualitative descriptions of UI in terms of frequency, volume, limitation/restriction and bothersomeness. Content analysis and a process of adjudication was used to synthesize quantifiable descriptors and allocate them appropriately across the severity anchors of mild, moderate and severe UI. **Results**: 71% of responders defined "mild" to mean leakage as 3 times per week to once daily; and 94% of responders defined severity as several times per day to hourly. The common terms most identified for mild/moderate/severe volume of leakage were "dampen, wet and soak". The most common descriptions of bothersomeness was none/not very (for mild), somewhat/very (for moderate), and very much/extremely (for severe). Limitations were expressed as none/few (mild) to nearly total (severe) restriction of activities, choices and mobility. **Conclusions**: Patient-based descriptive language can be used to further quantify UI-severity anchors as well as help develop meaningful response categories for other severity-linked analyses supporting clinical research.

OBJECTIVE

The objective of this work was to develop more specific descriptors for self-reported UI severity. Ideally, these descriptors would be anchored on patients' perceptions of their condition and would, therefore, be useful in developing an expanded set of response options for inclusion in outcomes measures designed for research purposes.

METHODS

Patient Population

19 adult women (over 20 years of age) were recruited to participate in the qualitative exploration. Six of these women (32%) were between 20 and 45 years of age, 9 (47%) were between 46 and 55 years of age, and four (21%) were 56 years or older. Seven of these women (37%) self-reported symptoms consistent with Stress Urinary Incontinence (SUI), while 5 (26%) reported Mixed UI; 2 (11%) reported symptoms of frequency/urgency; and 5 (26%) reported combine symptoms of both stress and urge UI.

Procedures

Patients were oriented to the purpose of their visit, and signed consent forms prior to participation. They were shown a severity-indicator-thermometer (see Figure 1) and asked to focus on the most severe case of urinary incontinence they could imagine. Each participant was then asked to identify a FREQUENCY of leakage they would attribute to a person with that severity of UI (see Figure 2a). They were then asked to imagine a very mild case of UI and asked again about the frequency of urinate they would associate with that level of severity. To obtain a value for "moderate", the midpoint between the two extremes was identified. Then the exercise was repeated for VOLUME (see Figure 2b), and again for how RESTRICTED a patient might be with the different degrees of severity of UI (see Figure 2c). Finally, the exercise was repeated one more time to elicit the level of associated BOTHER each participant would ascribe to various severity levels of UI (see Figure 2d).

RESULTS

Figure 1. Qualitative Interview for Severity Anchors

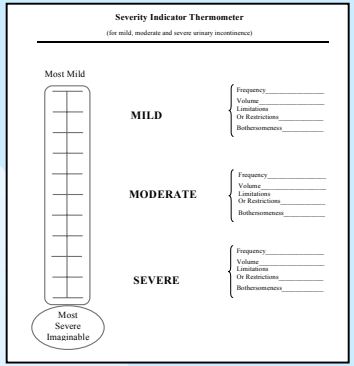

Figure 3. Suggested Frequency and Volume Items That map to patient reported severity for UI

On average, *during the last month*, on those times when you leaked urine (*when you didn't want to*) were you:

0 *(no leakage)*
1 ALMOST DRY — MILD
2 DAMP (Your Underwear) — MILD
3 WET (Your Underwear) — MODERATE
4 SOAKED (Your Clothes) — SEVERE

On average, *during the last month*, how many times did you leak urine (*even a small amount*) when you didn't want to?

0 NOT AT ALL in the last month
1 AMOUNT ONCE A MONTH — MILD
2 SEVERAL TIMES A MONTH — MILD
3 ABOUT ONCE A WEEK — MODERATE
4 SEVERAL TIMES A WEEK — MODERATE
5 ABOUT ONCE A DAY — SEVERE
6 SEVERAL TIMES A DAY — SEVERE

Figure 2a. Synthesis of Qualitative Definitions - Frequency

Severity in Terms of Frequency

		Hourly	Daily	Weekly	Monthly	
MILD	Mild			1 2	2 3	Weekly – or less (once per week to 3 x per month)
	Moderate	2	1 1	1 2 2 2	2	
	Severe	1		1		
MODERATE	Mild		1 1-2	3 3		Daily – or less (once a day to 3 x per week)
	Moderate	1	1 1 1-2 2 2	1 3 3	2-3	
	Severe	2		2-3		
SEVERE	Mild		1 2 3 8			Hourly or less (hourly to several times per day)
	Moderate	C 1 2 2	1 1 1 2 3	3		
	Severe	C 3				

Note: #'s denote frequency of episode within each time column; "C" denotes someone who answered constantly".

Figure 2b. Synthesis of Qualitative Definitions - Volume

Severity in Terms of Volume

		Dampens	Wets	Soaks
MILD	Mild	1 1 1 1		
	Moderate	1 1 1 1 1 1 1	1 1	
	Severe	1		
MODERATE	Mild		1 1 1 1	
	Moderate	1 1	1 1 1 1 1 1	1
	Severe	1		
SEVERE	Mild		1 1	1 1
	Moderate	1	1	1 1 1 1 1 1 1 1
	Severe			1

Figure 2c. Synthesis of Qualitative Definitions - Restrictions

Severity in Terms of Limitations / Restrictions

MILD	Mild	No limitations and few restrictions
	Moderate	No limitations to limit some activities
	Severe	No limitations to limit some activities
MODERATE	Mild	Limit some activities and have restrictions
	Moderate	Limit some activities to limits choice
	Severe	Limit some activities to limits choice
SEVERE	Mild	Limits all activities to restricts mobility
	Moderate	Limits all activities to restricts mobility
	Severe	Restricts mobility

Responses could be put into four categories: Planning, Limitations, Choice, and Fear

Figure 2d. Synthesis of Qualitative Definitions - Bother

Severity in Terms of Bother

MILD Severity	None (2) Hardly noticeable (2) Mildly (2) Only in morning (1) Momentary (1) Somewhat (4) Not very (3) Very much (1)	NONE to NOT VERY
MODERATE Severity	Somewhat (5) Sometimes (1) Slightly (1) Fairly (1) Manageable (1) Concerned (1) Very (4) Always in back of mind (1) Constant (1)	SOMEWHAT to VERY
SEVERE Severity	Somewhat (1) Always on mind (1) Very (2) Very, very much (1) "Freaked out" (1) Embarrassing (1) Needs treatment (1) Severe (1) Painful (2) Depressing (1) Extremely (4)	VERY, VERY MUCH to EXTREMELY

Note: # in parentheses represents number of people giving this response.

CONCLUSION

Results from this qualitative exploration demonstrate the possibility to use more specific patient-based descriptors to evaluate the patient's perception of their UI severity. Traditional use of the "mild/moderate/severe" response options has supported a wide variety of analytic investigations in both epidemiological studies and clinical trials. A more broad distribution of severity-linked response options in key outcome variables (particularly frequency and volume of leakage) would be expected to provide a greater sensitivity in the resulting data. The above results would suggest that this approach would be useful in research that relies upon symptom-based outcomes to reflect changes in the patients' UI status.