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ORIGINAL ARTICLE

Comparison of physician and patient assessments of incontinence severity and improvement

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Abstract Compare the subjective and objective assessment of stress urinary incontinence (SUI) severity and improvement with treatment using patient- and clinician-rated global impression of severity (PGI-S, CGI-S) and improvement (PGI-I, CGI-I) scales. Five hundred fifty-three women with mild SUI were recruited via media advertising into a placebo-controlled duloxetine trial. PGI-S and CGI-S (normal, mild, moderate, severe) were administered at baseline and PGI-I and CGI-I (seven responses from "very much worse" to "very much better") during treatment. Incontinence episode frequency (IEF) was determined from diaries. Agreements between clinician and patient ratings were assessed using Kappa and degree of association with Spearman's correlation. There was only a slight agreement regarding severity, with 53% of ratings being different (Kappa=0.14; 95%CI=0.08, 0.20). When ratings differed, clinicians rated severity worse in 72% of cases than did patients. Agreement regarding improvement was moderate, with 42% of ratings being different (Kappa=0.45; 95%CI=0.39, 0.50). When ratings differed, clinicians rated improvement greater than did patients in 54% of cases. Patients' assessments of severity correlated better with IEF (0.33) than did the clinicians' (0.15). The correlations of PGI-I and CGI-I with IEF changes were similar (0.46 and 0.44). In this study, the subjective (patient) and objective (clinician) assessments of SUI improvement with treatment appear to be more closely aligned than are the assessments of initial SUI severity.

Keywords Stress urinary incontinence · Patient assessment · Clinician assessment · Incontinence severity · Global scales

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Introduction

Stress urinary incontinence (SUI) is the complaint of involuntary leakage of urine during effort, exertion, sneezing, or coughing. It is the most common type of urinary incontinence in women with 78% of women presenting with the symptoms of SUI in a pure (49%) or mixed (29%) form [1]. Although not life threatening, SUI can have a significant impact on quality of life, with the more severe the SUI, the larger the impact on quality of life. Despite the documented effects on quality of life, some women with SUI may seek medical care, and others may rely only on "coping" mechanisms such as pad use, lifestyle changes, and social isolation [2].

When women with SUI seek medical treatment, a determination of severity before treatment and improvement after treatment is mostly based on their subjective reporting of symptoms. Medically, the term "subjective" designates a symptom or condition as perceived by the patient, while the term "objective" indicates a symptom or condition perceived as a sign of disease by someone other than the patient. Little is known about how the patient's "subjective" and the physician's "objective" assessment of SUI severity or treatment effect are aligned in general, but different perceptions may lead to different expectation of intervention or subsequent success and ultimately disappoint the patient.

Table 1 Patient Global Impression of Severity (PGI-S) and Clinician Global Impression of Severity (CGI-S)

PGI-S: Check the one number that best describes how your urinary tract condition is now.	
CGI-S: Considering your clinical experience with this particular population, how severe is the patient's urinary tract condition at this time?	
1	Normal
2	Mild
3	Moderate
4	Severe

The aim of this study was to compare the subjective and objective assessment of SUI severity before treatment as well as the potential improvement after treatment using four global scales, two completed by the patient and two completed by her physician.

Materials and methods

This is a secondary analysis of data from a previously reported 12-week, double-blind, randomized, controlled trial comparing duloxetine with placebo for the treatment of women with SUI [3]. The study consisted of women aged 18 to 65 years who had a clinical diagnosis of SUI for at least 3 months in duration. Enrolled subjects reported

Table 2 Patient Global Impression of Improvement (PGI-I) and Clinician Global Impression of Improvement (CGI-I)

PGI-I: Check the one number that best describes how your urinary tract condition is now, compared with how it was before you began taking medication in this study.	
CGI-I: Rate the total improvement, whether or not in your judgment it is entirely due to drug treatment. Co pare to patient's condition at the study entry how much has she changed?	
1	Very much better
2	Much better
3	A little better
4	No change
5	A little worse
6	Much worse
7	Very much worse

Table 3 Global Impression of Severity

Clinician	Patient			
	Normal	Mild	Moderate	Severe
Normal	3	5	10	3
Mild	24	112	51	4
Moderate	33	124	140	8
Severe	3	10	18	4

predominant symptoms of SUI with four or more stress incontinent episodes weekly, where an episode was defined as an easily noticeable leakage of urine that wets a pad or clothing and occurred with physical stress such as coughing, sneezing, or exercising. Additional requirement included urinary diurnal frequency ≤7 per day, nocturnal frequency ≤2 per day, the absence of predominant symptoms of enuresis or urge incontinence, and no previous continence or prolapse surgical procedures. All women underwent a supine, 400-ml saline solution bladder infusion with a funnel at a rate of 100 ml per min without pressure measurements. Subjects who were unable to tolerate the filling, who had a first sensation of bladder filling at <100 ml, or who had no sensation at anytime during the filling were excluded. After bladder filling, both a positive cough stress test and stress pad test were required for inclusion. A subgroup of 86 women had multichannel urodynamics, of which 92% had confirmed urodynamic stress incontinence. The study was conducted at 48 centers in the USA. The institutional review board for each site approved the study. Written and informed consent was obtained from every participant.

The primary severity measure at baseline and during treatment was incontinence episode frequency (IEF), recorded real-time on daily diaries for 1 week before baseline and each treatment visit. Another efficacy measure at baseline and during treatment was the Incontinence Quality of Life (I-QOL), a 22-item validated condition-specific questionnaire [4, 5]. Patient- and clinician-completed global impression of severity scales (PGI-S and CGI-S) described in Table 1 were administered at baseline, and similar global impression of improvement scales (PGI-I and CGI-I) described in Table 2 were administered after randomization at each treatment visit. The last post-randomization visit scores for the improvement scales were used as endpoint. The PGI-S is a single-item global rating of severity that asks the patient to describe her current urinary tract condition. There are four possible responses: normal, mild, moderate, and severe. The CGI-S is a clinician rated single-item scale that uses the same four-point response criteria as the PGI-S. The PGI-I is a single-item global rating of change scale that asks the patient to describe how her urinary tract condition is now compared to how it was before treatment [6]. There are seven possible responses: very much better, much better, a little better, no change, a little worse, much worse, and very much worse. The CGI-I is a clinician rated single-item scale that uses the same seven-point response criteria as the PGI-I. Both PGI-I and PGI-S were validated [6]. No formal validation work has been published for CGI-I and CGI-S.

The agreements between clinician and patient ratings were assessed using Kappa statistic and its 95% confidence interval. Degree of associations between (1) the severity ratings and baseline IEF and (2) improvement ratings and change in IEF with treatment were assessed with Spearman's correlation coefficient (Rho).

Table 5 CGI-S and PGI-S associations with IEF and I-QOL

Scale	Mean IEF		Mean I-QOL	
	CGI-S	PGI-S	CGI-S	PGI-S
Normal	13	9	58	74
Mild	12	11	71	75
Moderate	14	18	66	58
Severe	19	24	62	44
Rho	0.15	0.33	−0.10	−0.50

CGI-S Clinician Global Impression of Severity; *PGI-S* Patient Global Impression of Severity; *IEF* incontinence episode frequency; *I-QOL* Incontinence Quality-of-Life

Table 4 Global Impression of Improvement

Clinician	Patient					
	Very much better	Much better	A little better	No change	A little worse	Much worse
Very much better	27	22	4	0	0	0
Much better	36	67	40	8	1	0
A little better	4	20	84	24	2	0
No change	0	6	27	113	11	3
A little worse	0	0	2	1	11	2
Much worse	0	0	1	1	2	0

Table 6 CGI-I and PGI-I associations with median percent change in IEF and mean change in I-QOL

Scale	Mean IEF		Mean I-QOL	
	CGI-I	PGI-I	CGI-I	PGI-I
Very much better	−93	−93	19	16
Much better	−70	−60	9	11
A little better	−51	−55	6	6
No change	−15	−20	3	3
A little worse	30	−17	.1	−1
Much worse	88	+60	−3	−5
Rho	0.46	0.44	0.40	−0.40

CGI-I Clinician Global Impression of Improvement; *PGI-I* Patient Global Impression of Improvement; *IEF* incontinence episode frequency; *I-QOL* Incontinence Quality-of-Life

Results

A total of 553 women with mean weekly IEF of 9.57 were randomized to either duloxetine 20 mg/day (n=138), duloxetine 40 mg/day (n=137), duloxetine 80 mg/day (n=140), or placebo (n=138). None of the demographic or baseline data differed significantly amongst the four treatment groups [3].

Table 3 shows self-reported ratings and clinician-reported ratings at baseline of urinary tract function using the PGI-S and the CGI-S. At baseline, there was only a slight agreement regarding severity (PGI-S compared to CGI-S), with 53% of ratings being different (Kappa=0.14; 95%CI=0.08, 0.20). When severity ratings differed, clinicians rated severity worse than did patients in 72% of cases.

Table 4 shows self-reported ratings and clinician-reported ratings of improvement after treatment of urinary tract function using the PGI-I and the CGI-I. Agreement regarding improvement was moderate, with 42% of ratings being different (Kappa=0.45; 95%CI=0.39, 0.50). When improvement ratings differed, clinicians rated improvement greater than did patients in 54% of cases.

Table 5 shows the PGI-S and CGI-S with IEF and I-QOL. Table 6 shows the PGI-I and CGI-I with IEF and I-QOL. Patients' assessments of severity correlated better with IEF (Rho=0.33) than did the clinicians' assessments (Rho=0.15). The correlations of the improvement ratings with the change in IEF were similar for the PGI-I and CGI-I (Rho=0.46 and 0.44, respectively; both P<0.0001).

Discussion

In this sample of women enrolled in a clinical trial for treatment of SUI, the patient and clinician assessment of SUI improvement with treatment appears to be more closely aligned than the assessments of initial SUI severity. On average, agreement on severity was low. When severity ratings differed, physicians rated severity of SUI more severe than the women suffering from SUI. Agreement between clinicians and women regarding improvement in SUI symptoms was better. When improvement ratings differed, clinician tended to rate improvement above what the patient rated. Although agreement for severity was not as good as for improvement, it is reassuring to note that very few patients who rated their SUI as mild were considered to have severe SUI by the physician and that very few patients who rated their SUI as severe were considered to have mild SUI by their physician. In addition, the patient's assessments of severity correlated better with IEF and I-QOL than did the clinician's assessments.

Conflicting results have been reported in a study involving a sample of women that attended a specialty clinic with the complaint of incontinence [7]. In that population of women, there was a high correlation between patient report and physician assessment of UI severity [7]. On average, patients rated their incontinence slightly more severe than their physicians rated, with agreement between ratings highest for mild incontinence and lowest for more severe incontinence [7]. When women with urinary symptoms had their first consultation at other specialty clinics, the clinicians significantly underestimated the patients' degree of bother [8].

Differences between the results for these studies may have come from inherent differences in study populations (women seeking treatment for incontinence at a clinic vs women enrolling in clinical trial to treat SUI) and in type of incontinence (any incontinence vs women with SUI). Women were required to report at least four IEF per week to be included in the study. This inclusion criterion caused the study population to be less severe (mostly mild to moderate SUI) than a typical SUI clinical trial population. In a clinical practice, clinician may be seeing more severe patients because most women do not see their health care professional unless the condition is severe enough. The clinical trials try to find patients by advertising in the media (therefore encouraging the women who are not severe enough to see their physicians). Therefore, it is very likely that clinicians in this clinical trial compared the trial participants to those they see in their daily practice biasing them to rate more severe than what a patient thinks.

The agreement in the improvement in the patients' condition in this study may have resulted from enhanced awareness and observation for changes in symptoms of both patients and physicians in the setting of the clinical trial and may not apply to the daily clinical practice.

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