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PATIENT EXPECTATIONS DID NOT PREDICT OUTCOME OF DRUG AND BEHAVIORAL TREATMENT OF URGENCY URINARY INCONTINENCE

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Abstract

Objectives—To determine whether expectations of treatment outcomes in women participating in a drug and behavioral treatment trial for urge urinary incontinence are related to patient factors, demographics, health-related locus of control and treatment outcomes.

Methods—Baseline assessments included expectations (improvement in bladder condition, time to improvement in bladder condition, and duration of improvement) and the multidimensional health locus of control (MHLC) scale. Outcomes were measured by patient global impression of improvement (PGI-I) at the end of active treatment (10 weeks) and 8 months after trial start.

Results—At baseline among 173 subjects, 114 (66%) believed their incontinence would get 'very much better,' 94 (55%) expected improvement by one month, and 111 (66%) expected improvement would last the rest of their lives.. There were no significant associations between baseline expectations or MHLC with PGI-I at 10 weeks or 8 months.

Conclusions—Expectations of treatment outcome and MHLC did not predict eventual patient-reported treatment outcome in this sample of women with urge-predominant urinary incontinence participating in a trial of drug and behavioral therapy.

Keywords

Urinary incontinence; urinary urgency incontinence; patient expectations

INTRODUCTION

Outcomes from treatment of urinary incontinence (UI) in women are assessed with a wide range of measures, including both bladder diary assessment of UI frequency and severity and patient-reported outcomes (PROs). Validated PROs are increasingly being used in UI treatment trials and include perception of UI severity, bother, and impact, as well as both UI-specific and general health-related quality of life. There has been little investigation of the impact of health beliefs, expectations, and psychological factors on diary and PRO UI treatment outcomes. A personality factor that reasonably could have a major impact on patient expectations and eventual treatment outcome is health locus of control (HLC). HLC is a patient's perception of whether their general or condition-specific health and their power to affect their health comes primarily from within themselves, is primarily subject to chance, or primarily under the control of others.¹

The objectives of this study were to determine whether, in a sample of women enrolled in a clinical trial for treatment of urgency-predominant UI, 1) expectations of treatment outcome were related to patient demographic factors, UI severity, comorbid conditions, and HLC; and 2) whether expectations of treatment outcome and HLC were significantly associated with eventual patient-reported treatment outcomes. Our study was prompted by the

hypothesis that patients' health beliefs, expectations of treatment, and other psychological factors may be important determinants of UI treatment outcomes as measured by PROs.

METHODS

The BE-DRI (Behavior Enhances Drug Reduction of Incontinence) study was conducted at nine university-based clinical centers of the NIH-sponsored Urinary Incontinence Treatment Network, supported by a data-coordinating center. The institutional review boards of the participating centers approved the study and all participants provided written informed consent.

The methods and primary results of this trial have been published elsewhere.² In brief, the BE-DRI study was a 2-stage randomized blinded clinical trial in which women with urgency or urgency-predominant UI were randomized to receive open-label drug therapy alone (tolterodine tartrate extended-release 4 mg daily) or drug therapy combined with behavioral training (instruction in performance of pelvic floor muscle exercises, individualized fluid management and strategies to decrease urgency, suppress bladder contractions, prevent UI, and decrease frequent voiding).

Women were eligible if they had urgency-predominant UI present for at least 3 months, recorded at least 7 UI episodes on a 7-day bladder diary, had no confounding comorbid conditions, and were not currently using medications that could affect UI. A total of 307 women were enrolled and randomized and 237 completed the study. Both groups completed daily bladder diaries during stage 1 (active therapy, 10 weeks). At the end of stage 1, both drug and behavioral training sessions were discontinued and subjects receiving behavioral therapy were asked to continue their behavioral program for the duration of the study. During the next 6 months (stage 2), subjects who requested to restart drug were allowed to resume the drug at no cost. Primary and secondary outcomes were assessed at the end of stage 2 (8 months after study start).

The primary outcome of this analysis, assessed at trial end (8 months after study start), was a Patient Global Impression of Improvement (PGI-I) ("Overall, do you feel that you are much better, better, about the same, worse, or much worse?").³ In addition, at baseline patients completed two measures of symptom distress (Urogenital Distress Inventory [UDI] and the Overactive Bladder Questionnaire [OAB-q]; a measure of UI-specific impact (Incontinence Impact Questionnaire [IIQ]); and two measures of quality of life (the OAB-q health-related quality of life scale and the Short-Form Health Survey [SF-12]).⁴⁻⁶

In addition to routine study measures, patients completed an expectations questionnaire at baseline. Because little is known about patients' expectations of drug treatment, we designed the questionnaire to capture several domains of improvement (see Table 1) including degree of symptom change ("Get very much better / a little better / stay about the same as now / a little worse / a lot worse"); time of onset of symptom change ('About a week / about 4 weeks / about 8 weeks / about 10 weeks / no opinion'); and duration of symptom change ('One month / six months / one year / for the rest of my life').

Locus of control was assessed at baseline using the Medical Health Locus of Control (MHLC) for condition-specific health (Form C), using UI as the condition.¹ The MHLC Form C consists of 18 statements (items), each beginning with the stem, "Each item below is a belief statement about your health condition (here, urinary leakage) with which you may agree or disagree." Items are scored on a 6 point Likert scale (from 1, "strongly disagree" to 6, "strongly agree"), and are grouped into four control subscales: Internal locus of control, Chance, Doctors, and Other People (Table 2). Scores are reported as mean for each subscale;

there is no summary score. The MHLC questionnaire is included as an appendix to this paper.

Ten weeks after enrollment (after 8 weeks of active treatment), participants reported their treatment success using the Patient Global Impression of Improvement (PGI-I)³: “Overall, compared to before treatment, my bladder condition is now ... Very much better / A little better / About the same / A little worse / Very much worse.” The PGI-I was completed again at study end, after 8 further months without active treatment.

We used cross classification and Chi-square analysis to investigate factors associated with patient expectations and to determine whether baseline patient expectations predicted the patient reported PGI-I at 10 weeks and 8 months after the start of the study. Analyses were carried out using SAS statistical software, version 9.1 (SAS Institute, Inc. Cary, NC).

RESULTS

In the parent BE-DRI study, we screened 4,043 women, consented 561, and randomly assigned 307.² Development and face validation in a convenience clinical sample of urge incontinent women delayed introduction of the expectations questionnaire until after initial enrollment in the parent study had begun, so that only 173 of the total 307 women (56%) were consecutively enrolled for the current analyses. All 173 completed the expectations questionnaire at baseline. Of these, 137 (79%) had PGI-I outcome data at study end.

At baseline, women had high expectations of UI-specific outcomes (Table 3). All women expected that their UI would improve; 66% expected UI to get ‘very much better’ and 34% expected their UI would ‘get a little better or stay the same’. Fifty-five percent expected to experience improvement by one month, and 66% expected that improvement would last the rest of their lives. There were no significant associations between baseline degree of expected improvement, and either expected time to improvement or expected duration of improvement (data not shown).

At baseline, race/ethnicity and education were the only demographic or clinical patient characteristics associated with high expectation of improvement (‘get very much better’) (Table 4). Compared to other groups, non-Hispanic Black women had lower expectations of improvement. High expectations were also associated with greater baseline UI severity as measured by MESA urge index and IIQ, but not daily UI frequency on bladder diary. Similarly, subjects with high expectations reported greater UI impact on quality of life as measured by the OAB-q HRQL scale and the SF-12. However, there was no association between expectations and UI-related bother on the UDI.

For the MHLC at baseline, the inter-item reliability of the standardized scores for each subscale (Cronbach’s $\alpha = 0.58\text{--}0.86$) were similar to those previously reported for the condition-specific MHLC ($\alpha = 0.71\text{--}0.87$), suggesting that this adaptation of the MHLC Form C functioned well in this group of patients.⁷ The Doctors subscale had the lowest inter-item reliability, also consistent with previous literature.⁷ Women participating in this sub-study scored highest for ‘Doctors’ (mean 13.2 [SD 3.2]/median 13 out of possible 18 points) and ‘Internal’ control (mean 19.1 [6.5]/median 20 out of possible 36), and lower for ‘Others’ (mean 8.6 [3.9]/median 8 out of possible 18) and ‘Chance’ (mean 12.7 [6.7]/median 11 out of possible 36). UI-specific locus of control was not significantly related to expectations of treatment outcome.

Table 5 details patient-reported outcomes as assessed by the PGI-I at 10 weeks and at trial end. The association between baseline degree of expected improvement and PGI-I was not statistically significant at either 10 weeks or trial end. Similarly, there was no association

between MHLC scale scores and PGI-I at 10 weeks or trial end (data not shown). We estimated the power to detect the results reported in Table 5 as statistically significant at the 5% significance level. The sample of 137 women provides 31% power to detect the observed association at 10 weeks and 16% power for the observed association at trial end. Sample sizes of 456 and 984 are needed to have 80% power for the observed associations at 10 weeks and trial end, respectively.

Discussion

In this sample of women with urgency-predominant UI participating in a drug and behavioral treatment trial, treatment outcome as assessed by the PGI-I was not predicted by either baseline degree of expected improvement, or by subjects' UI-specific health locus of control. In addition, we found that the MHLC appears to function adequately when used in women with urgency UI. It is not possible to directly compare our results to those of other researchers because there are no similar published studies among women with urgency UI. Our results contrast with other prior studies examining the relationship between expectations and treatment outcomes in other health conditions.⁷ The effect size of patient expectations on outcomes of laparoscopic surgery and of treatments for low back pain, myocardial infarction, obesity and psychiatric conditions has been demonstrated to be medium to large.⁷ However, our findings are similar to treatment trials in two patient reported, symptom-defined conditions, pain and chronic fatigue. There was no consistent relationship between expectations and health related locus of control in a trial of acupuncture,⁸ and no correlation between locus of control and PROs in a randomized treatment trial for fatigue in primary care patients.⁹

Flood et al.¹⁰ postulated 5 mechanisms by which expectations may affect outcomes: triggering a physiologic response; improving motivation to achieve better outcomes; changing understanding of the disease; psychological conditioning to observe or ignore certain symptoms; and acting together with anxiety to heighten or reduce symptoms. Thus, knowledge of the impact of expectations could be important for clinicians and researchers; for example, it has been suggested that patient support and education can be tailored to explicitly address and modify expectations with the aim of improving outcomes.

Outcomes from treatment of urinary incontinence (UI) in women have been assessed with a wide range of measures, ranging from quantification of UI severity to patient-reported outcomes (PROs) of UI severity, bother, and impact, and UI-specific and general health-related quality of life (QoL). With the increased use of validated PRO measures in UI treatment trials, it is extremely important to understand determinants of these PROs. Although UI frequency and patient report of the impact of UI generally parallel one another at baseline (i.e. patients with greater UI frequency have worse UI-specific QoL) and after treatment (decrease in UI frequency is associated with improved UI-specific QoL), there is significant inter-individual variation and overall correlations are accordingly moderate to small. The demographic factor age has variable effects on PRO and placebo response rates.^{11,12}

Our study was prompted by the hypothesis that patients' health beliefs, expectations of treatment, and other psychological factors may be important determinants of UI treatment outcomes as measured by PROs. Such factors are known to influence help-seeking for UI¹³⁻¹⁵ and to affect UI-specific QoL. For example, in women UI is associated with a lower sense of mastery and competence, and mastery is significantly associated with UI-specific QoL.¹⁶ Explanatory style, the habitual manner in which individuals employ specific types of causal explanations for bad events or illness, is related to urgency UI-specific QoL in older persons.¹⁷ There has been little investigation of the impact of health beliefs, expectations,

and psychological factors on UI treatment outcomes except regarding anti-UI surgery^{17, 18} and a small study of behavioral treatment.¹⁹ One relevant study regarding pharmacological treatment of urgency UI demonstrated that patients' belief that they had been randomized to active drug treatment in a randomized UI drug trial was significantly associated with favorable bladder diary and QoL outcomes,²¹ but did not measure patient expectations and could not be compared to our data.

Our study is limited by its sample size with associated low power and by its generalizability, but strengthened by the inclusion of well-characterized patients from several centers. It is also possible that our expectations questionnaire was not sensitive enough to adequately discern expectations of degree, onset, or duration of improvement after treatment. Further, dichotomization of improvement into high vs low expectation may have made it more difficult to demonstrate a significant correlation between patient expectation and treatment results. Our study is also limited by the fact that all women were enrolled in a treatment trial and specifically seeking pharmacologic treatment for UI, leading to the very high expectations at baseline. Participants were unlikely to be naive to prior behavioral and/or drug treatment, which could have mitigated expectations. It is possible that if our sample had been more broadly representative of women with UI and with more variable baseline expectations, an association between expectation and outcome would have been evident. Furthermore, attrition bias could be masking an association if women who had lower (or higher) expectation and higher (or lower) perceived improvement were less likely to complete the follow-up assessment.

Another personality factor that could reasonably have an important impact on eventual treatment 'success' as measured by PROs is a patient's baseline degree of optimism/pessimism. Along with further assessment of patient expectation and HLC, this could be a focus of future research.

In conclusion, this analysis suggests that women seeking treatment for urge-predominant urinary incontinence in a randomized trial have very high expectations for treatment that were not associated with outcomes. Further studies are needed to assess whether expectations of treatment in clinical settings may relate to PROs and diary outcomes.

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Appendix

D1. If my urine leakage worsens, it is my own behavior that determines how soon I will feel better again.

D2. As to my urine leakage, what will be will be.

- D3. If I see my doctor regularly, I am less likely to have problems with my urine leakage.
-
- D4. Most things that affect my urine leakage happen to me by chance.
-
- D5. Whenever my urine leakage worsens, I should consult a medically trained professional.
-
- D6. I am directly responsible for my urine leakage getting better or worse.
-
- D7. Other people play a big role in whether my urine leakage improves, stays the same, or gets worse.
-
- D8. Whatever goes wrong with my urine leakage is my own fault.
-
- D9. Luck plays a big part in determining how my urine leakage improves.
-
- D10. In order for my urine leakage to improve, it is up to other people to see that the right things happen.
-
- D11. Whatever improvement occurs with my urine leakage is largely a matter of good fortune.
-
- D12. The main thing which affects my urine leakage is what I myself do.
-
- D13. I deserve the credit when my urine leakage improves and the blame when it gets worse.
-
- D14. Following doctor's orders to the letter is the best way to keep my urine leakage from getting any worse.
-
- D15. If my urine leakage worsens, it's a matter of fate.
-
- D16. If I am lucky, my urine leakage will get better.
-
- D17. If my urine leakage takes a turn for the worse, it is because I have not been taking proper care of myself.
-
- D18. The type of help I receive from other people determines how soon my urine leakage improves.
-

Figure 1. Study flow diagram

Note: Reasons for declined participation, ineligibility, and exclusion are described previously.²

Table 1

Expectation Domains

Degree of improvement	"Based on what you have heard about the study, after completing the study treatments, do you expect your bladder condition will get very much better, a little better, stay about the same as now, get a little worse, a lot worse?"
Reason for improvement	"If you are assigned to have both drug and behavioral therapy, do you expect that the improvement in your bladder condition will be mostly due to the effect of the drug, of the behavioral therapy, due to equal effects of drug and behavioral therapy, or no opinion about whether due to drug or behavioral therapy?"
Time until improvement	"How long do you think it will take the treatment you receive to begin to improve your bladder condition, about one week, 4 weeks, 8 weeks, 10 weeks, no opinion?"
Duration of improvement	"How long do you believe that the improvement in your bladder condition will last after you finish this study, one month, 6 months, one year, for the rest of life?"

Table 2

Examples of Condition-Specific MHLC items by Domain

Domain	Number of Items	Item Example
Internal	6	If my urine leakage worsens, it is my own behavior that determines how soon I will feel better again
Chance	6	Most things that affect my urine leakage happen to me by chance
Doctors	3	If I see my doctor regularly, I am less likely to have problems with my urine leakage
Other People	3	Other people play a big role in whether my urine leakage improves, stays about the same, or gets worse

Table 3

Patient expectations at baseline (n=173).

Expectation Domain		<u>Baseline N (%)</u>
Degree of improvement	Get very much better	114 (65.9)
	Get a little better	56 (32.4)
	Stay about the same as now	3 (1.7)
	Get a little worse	0 (0)
	Get a lot worse	0 (0)
Onset of improvement	About one week	36 (20.9)
	About 4 weeks	58 (33.7)
	About 8 weeks	22 (12.8)
	About 10 weeks	13 (7.6)
	No opinion	43 (25.0)
Duration of improvement	One month	19 (11.2)
	6 months	21 (12.4)
	12 months	18 (10.7)
	For the rest of my life	111 (65.7)

Table 4

Association of Degree of Baseline Expectation of Improvement with Participant Characteristics

Characteristic	Baseline Expectation		p value
	Get very much better (n = 114)	Get a little better or stay the same (n =59)	
Age, Mean (SD)	55.6 (13.1)	54.4 (13.6)	0.57
Ethnicity, n (%)			0.04
Hispanic	13 (12)	3 (5)	
Non-Hispanic White	67 (60)	36 (61)	
Non-Hispanic Black	17 (15)	17 (29)	
Other non-Hispanic	16 (14)	3 (5)	
Marital status, n (%)			0.35
Married or living with partner	53 (46)	23 (39)	
Not married	61 (54)	36 (61)	
Level of education, n (%)			0.50
High school/GED or less	31 (27)	11 (19)	
Some college or associate's degree	37 (32)	25 (42)	
Completed 4 years of college	28 (25)	13 (22)	
Graduate or professional degree	18 (16)	10 (17)	
Mean Nam-Powers occupational status score (SD)	57.8 (25.0)	63.7 (24.3)	0.15
Has insurance, n (%)	90 (80)	49 (83)	0.67
Income, n (%)			0.29
< \$20,000	31 (29)	10 (19)	
\$20,000 – 49,000	32 (30)	21 (40)	
\$50,000 – 79,000	25 (24)	9 (17)	
\$80,000	18 (17)	12 (23)	
Incontinence			
Duration of UI (years), n (SD)	8.2 (7.4)	10.6 (9.3)	0.07
Previous nonsurgical UI treatment, n (%)	42 (37)	20 (34)	0.70
Previous anti-UI surgery, n (%)	17 (17)	7 (12)	0.58
Incontinence Severity			
Accidents per day, mean (SD)	3.8 (2.4)	3.7 (2.8)	0.72
MESA-urge index, mean (SD) *	64.1 (18.8)	58.2 (16.5)	0.04
MESA- stress index, mean (SD) *	41.4 (24.2)	39.8 (20.2)	0.65
Incontinence Impact			
IIQ, mean (SD) *	169 (103)	122 (93)	0.004
UDI, mean (SD) *	129 (49)	116 (51)	0.11

Characteristic	Baseline Expectation		p value
	Get very much better (n = 114)	Get a little better or stay the same (n =59)	
OAB-q HRQL scale, mean (SD) **	56 (25)	71 (22)	0.0001
SF-12, mean (SD) **	91 (16)	99 (13)	0.001
Parity, mean (SD)	3.5 (1.8)	3.1 (2.0)	0.26
Comorbidity			
Diabetes, n (%)	18 (16)	5 (8)	0.18
Body mass index (kg/m ²), mean (SD)	33.4 (9.1)	32.4 (8.2)	0.45

SD = standard deviation, IIQ = Incontinence Impact Questionnaire, UDI = Urinary Distress Inventory, OAB-q HRQL = Overactive Bladder Quality of Life Health Related Quality of Life scale, SF-12 = Medical Outcomes Study Short Form-12

* Higher score indicates more severe symptoms / greater impact, or worse quality of life

** Higher score indicates better quality of life

Table 5

Global impression of improvement (PGI-I) at 10 weeks and trial end, by baseline expectation of improvement (n=137)

PGI-I	Baseline Expectation of Improvement		Total	P Value
	Get very much better N = 93 (68%)	Get a little better or stay about the same N = 44 (32%)		
10 weeks	n (%)	n (%)		
Very much better	26 (28)	7 (15.9)	33	0.23
A little better or about the same	35 (37.6)	22 (50)	57	
A little worse or a lot worse	32 (34.4)	15 (34.1)	47	
Trial end				
Very much better	45 (48.4)	17 (38.6)	62	0.51
A little better or about the same	43 (46.2)	25 (56.8)	68	
A little worse or a lot worse	5 (5.4)	2 (4.5)	7	