59

DuBeau C[1], Fitzgerald M P[2], Johnson H[3], Kraus S[4], Lemack G[5], Mallett V[6], Stoddard A[7], Tennstedt S[7], Zyczynski H[8]
1. *University of Chicago,* ***2.*** *Loyola University Medical Center,* ***3.*** *University of Maryland School of Medicine,* ***4.*** *Univ of Texas Health Science Center San Antonio,* ***5.*** *Univ of Texas Southwestern at Dallas,* ***6.*** *University of Tennessee,* ***7.*** *New England Research Institute,* ***8.*** *University of Pittsburgh*

EXPECTATIONS OF URGE INCONTINENCE TREATMENT AND THEIR RELATIONSHIP TO OUTCOMES

Hypothesis / aims of study

Previous work suggests that urinary incontinence (UI) treatment outcomes may be significantly related to patients' expectations of treatment success [1], but this has not been specifically tested prospectively for urge UI. The objectives of this study were to determine, in a sample of women enrolled in a clinical trial for treatment of urge-predominant UI, 1) the range of patients' expectations of the timing, degree, and duration of UI treatment outcomes; 2) whether baseline expectations of treatment outcomes are related to patient demographic factors, health-related locus of control, and UI severity; and 3) whether baseline expectations are associated with patient-based treatment outcomes.

Study design, materials and methods

We enrolled patients participating in a randomized therapeutic trial of drug and behavioral treatment for urge-predominant UI (methods and primary results published previously[2]). Active treatment was discontinuedat 10 weeks, and final assessment done at 8 months. In addition to routine study measures, patients completed an expectations questionnaire at baseline. The questionnaire included four domains of expectations: *improvement in bladder condition* ('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, get a lot worse'); *expected time until improvement in bladder condition* ('About a week, about 4 weeks, about 8 weeks, about 10 weeks, no opinion'); *expected duration of improvement* ('One month, 6 months, one year, for the rest of my life'); and the *expected reason for improvement* ('Mostly due to drug treatment, behavioral treatment, both treatments, uncertain.') Subjects whose expectation of improvement was "Get very much better" were considered to have *high expectations of improvement*, and those who reported "Get a little better/stay the same" were considered *moderate expectations of improvement*. We used the disease-specific form Multidimensional Health Locus of Control (MHLC) to assess patients' perception of UI-specific locus of control. MHLC is reported as mean score for each locus scale (Internal, Doctors, Chance, Others). Patient-based outcomes were assessed with the Patient Global Impression of Improvement scale (PGI-I) after 10 weeks of active treatment and again at trial end several months later. We used cross-classification and the Chi square test (categorical measures) or analysis of variance (continuous measures) to evaluate associations of participant characteristics with expectations.

Results

In the parent study, we screened 4043 women, consented 561, and randomly assigned 307 (mean age 55). The expectations questionnaire was added after enrollment in the parent study had begun, leading to 173 consecutive women (56%) enrolled for these analyses. Of these, 137 (79%) completed the questionnaire at baseline and 10 weeks. Overall, women had high expectations of UI-specific outcomes: 66% thought that their UI would get 'very much better' and 34% 'get a little better or stay the same,' 55% 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 expectation of improvement and expectations of onset and duration of improvement.
Expectations of improvement were significantly associated with several baseline clinical patient characteristics (Table). Women with high expectations of improvement ('get very much better') were more likely than those with moderate expectations ('get a little better or stay the same') to be nonblack (ie, Hispanic or other race); have greater urge UI and UI impact by both the MESA urge index and the Incontinence Impact Questionnaire (IIQ) but not by the Urinary Distress Inventory (UDI) or number of UI accidents per day; and have better UI-specific (OAB-q HRQL scale) and overall health related quality of life (SF-12) (Table). There were no significant associations between expectation of improvement and age, marital status, education, occupation, insurance, income, previous anti-UI surgery or non-surgical UI treatment, parity, BMI, or pelvic organ prolapse.

Characteristic	Baseline Expectation of Improvement		P value
	High (N=114)	Moderate (N=59)	
Race/ethnicity (%)			0.04
Hispanic	12	5	
Non-hispanic white	60	61	
Non-hispanic black	15	29	
Non-hispanic other	14	5	
MESA urge index (mean [SD])	64.1 (18.8)*	58.2 (16.5)	0.04
IIQ (mean [SD])	169 (103)*	122 (93)	0.004
UDI (mean [SD])	129 (49)*	116 (51)	0.11
Daily UI accidents (mean [SD])	3.8 (2.4)	3.7 (2.8)	0.72
OAB-q HRQL scale (mean [SD])	56 (25)	71 (22)**	0.0001
SF-12 (mean [SD])	91 (16)	99 (12)**	0.001

*higher scores indicate more severe symptoms/impact or worse quality of life
**higher scores indicate better quality of life

On the MHLC, women scored similarly for Doctors (mean 13 out of possible 18 points) and Internal (mean 19 out of possible 26), and lower for Others (mean 8.6 out of possible 18) and Chance (mean 12.7 out of possible 36). There were no significant associations between expectation of improvement and MHLC scores.

After active treatment, patient-based improvement (PGI-I) results were: 24% very much better, 12% a little better, 29% about the same, 24% a little worse, and 10% a lot worse; at trial end, PGI-I results were: 45% very much better, 34% a little better, 16% about the same, and 5% a little to a lot worse. There was no association between baseline expectations of improvement and PGI-I at 10 weeks or trial end. The percent of women with discordance between expectations and outcomes, however, did change from 10 weeks to trial end. Women with high expectations who reported that their bladder condition was the same or worse fell from 62% to 18%, while women with lower expectation who reported better to very much outcomes increased from 34% to 73%. There was no association between MHLC scale scores and PGI-I results at 10 weeks or trial end.

Interpretation of results: The majority of women participating in this OAB treatment trial expected not only that study treatment would greatly improve their bladder condition but that the improvement will be permanent. Higher expectations of improvement were associated with race, better baseline UI-specific and overall quality of life, and greater OAB impact as measured by some but not all measures, but not with locus of control. "Mismatch" between high expectations and poorer outcomes diminished over the course of the trial, possibly because drug use was open-label and/or re-alignment of expectations over the course of the trial.

Concluding message: OAB trial participants have very high expectations of outcome. In our sample, those expectations did not predict patient perception of OAB improvement. Further studies are needed to determine why high expectations are paradoxically related to more severe OAB yet better baseline quality of life, and to assess whether expectations predict other treatment outcomes and are similarly high in clinical practice.

References

1. Neurourol Urodynam 2005, 24:13-20
2. Ann Int Med 2008, 149:161-169

Specify source of funding or grant	**NIDDK UO1 DK 58231, UO1 DK 60379, UO1 DK 60397, UO1 DK 58225, UO1 DK 60395, UO1 DK 58234, and UO1 DK 58229; and Pfizer, Inc.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ClinicalTrials.gov registration number NCT00090584**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Institutional Review Boards of all Participating Centers (see author list)**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**