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Correlates and Predictors of Patient Satisfaction with Drug Therapy and Combined Drug Therapy and Behavioral Training for Urgency Urinary Incontinence in Women

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Abstract

Introduction and Hypothesis—The goal was to identify correlates of patient satisfaction with drug and behavioral treatments for urge-predominant incontinence, which may help tailor treatments to improve satisfaction.

Methods—Planned secondary analysis of a multi-center, clinical trial randomizing 307 women to 10-weeks of tolterodine alone or combined with behavioral training. Satisfaction was measured using the Patient Satisfaction Question (PSQ). Potential correlates included baseline demographics, incontinence characteristics and prior treatments, history and physical parameters, expectations of treatment success, and outcome variables including the Global Perception of Improvement (GPI) and Urogenital Distress Inventory (UDI).

Results—After multivariable analysis, every ten-point increase in UDI change score increased odds of satisfaction by 11% (OR 1.11; 1.04-1.19). Odds of satisfaction increased among women reporting “much better” on the GPI (OR 13.8; 4.94-38.60).

Conclusions—Treatment satisfaction for women with urge-predominant incontinence was associated with patient-related outcomes reflecting impression of improvement and bother from incontinence-related symptoms.

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Keywords

patient satisfaction; outcome assessment; urge urinary incontinence; drug therapy; behavioral therapy

Introduction

Patient satisfaction is an important aspect of healthcare outcomes and a quality indicator. Some clinical trials of incontinence treatment now use the patient's satisfaction with outcomes or their perception of improvement as the primary outcome measure, [1,2]. The development of a validated instrument, the Patient Satisfaction Question (PSQ) has provided a measure of satisfaction with treatment in patients undergoing treatment for urinary incontinence, [3]. Although patient satisfaction is correlated with objective measures of improvement in incontinence, such as reduction in incontinence episodes on bladder diary, the correlation is not perfect, indicating that other factors enter into a patient's overall satisfaction with treatment. Few studies have examined factors that might influence or predict patient satisfaction with treatment.

The Behavior Enhances Drug Reduction of Incontinence (BE-DRI) trial investigated the effects of drug therapy alone versus drug therapy combined with behavioral training in women with urge predominate urinary incontinence with the aim of determining whether or not reductions in urge incontinent episodes could be sustained after drug therapy was discontinued, [4]. Success, which was defined a priori as achieving a 70% reduction in incontinence and remaining off drug therapy after 8-months, did not differ between groups. However, women who received combined therapy reported greater perceived improvement, satisfaction, and better scores on the Urogenital Distress Inventory and Overactive Bladder Questionnaire while on active therapy, [5]. This discrepancy among outcomes confirms that objective measures may not necessarily reflect treatment outcomes as experienced by the patient. While predictors of objective treatment response of urgency incontinence have been examined [6], predictors of patient satisfaction may complement these findings.

The goal of this paper is to identify correlates and predictors of patient satisfaction with treatment for urge-predominant urinary incontinence in women in the BE-DRI study.

Materials and Methods

The BE-DRI study was a two-stage randomized clinical trial conducted in 9 clinical centers in the U.S. from July 2004 to January 2006 (See Appendix for participating centers.) Details of the study design and methodology have been described previously, [4]. Women with urge-predominant urinary incontinence were randomized to receive drug therapy alone with open-label, extended-release tolterodine tartrate (Pfizer, Inc.) 4 mg daily or drug therapy combined with behavioral training (pelvic floor muscle exercises, bladder control strategies, and fluid management). In Stage 1, participants in both groups received 10 weeks of active treatment. In Stage 2, immediately following active treatment, drug and behavioral therapy were discontinued, although women who received behavioral training were encouraged to continue using behavioral measures. The primary outcome of the BE-DRI trial, measured at the end of Stage 2 (8 months post randomization), was successful discontinuation of drug, defined as not taking drug or receiving any other therapy for urgency incontinence *and* maintaining a 70% or greater reduction in frequency of incontinence episodes on bladder diary compared to baseline. The present paper reports on the secondary outcome of patient satisfaction at the end of active therapy (10 weeks).

The study was approved by the Institutional Review Boards of all clinical centers and the biostatistical coordinating center. All participants provided written informed consent.

Participants

Participants were 307 community-dwelling women with urge-predominant incontinence recruited through the investigators' clinical practices and advertisements. To be eligible, women had to report pure or predominant urgency incontinence, defined as urge symptom index greater than stress symptom index on the Medical, Epidemiological, and Social Aspects of Aging Questionnaire (MESA), [7]. Clinical evaluation included medical history, physical examination, and a 7-day bladder diary. Inclusion criteria included ≥ 7 episodes of incontinence on the 7-day baseline diary, persistent incontinence for at least 3 months, no current use of antimuscarinics or other medications that could impact incontinence, and no evidence that incontinence was due to neurologic or other systemic diseases.

Intervention

In both drug therapy alone and drug therapy combined with behavioral therapy, treatment was implemented in 4 visits, at intervals of 2 to 3 weeks, over a period of 10-weeks. Drug therapy was extended release tolterodine tartrate at a dose of 4 mg per day. If not tolerated, the dose of extended release tolterodine could be decreased to 2 mg or another antimuscarinic medication could be substituted. At the initial visit, all participants received handouts with information about the drug, recommendations for managing the common drug side-effects of dry mouth and constipation, and fluid management.

Combination therapy included drug therapy and behavioral training, which was implemented by a nurse practitioner, nurse specialist, or physical therapist. Behavioral therapy included pelvic floor muscle training; behavioral strategies to diminish urgency as well as to prevent both stress and urgency incontinence [8, 9], delayed voiding to increase voiding intervals for those who voided more than 8 times per day; and individualized fluid management for those with excessive urine output (more than 70 oz. (2,070 mL) per day).

Measurements

Participants were assessed at baseline and the end of active therapy (10 weeks). At each time point, participants completed a 7-day bladder diary in which they recorded the time of each void and incontinence episode, and for two days, urgency scores using the Indevus Urgency Severity Scale (IUSS) [10] and measured intake and output. The patient's overall assessment of their treatment response was measured using the Global Perception of Improvement (GPI), [3]. This validated measure consists of a single item: "Overall do you feel that you are: Much Better, Better, the Same, Worse, or Much Worse?" Severity of distress and bother related to incontinence and related symptoms were measured using the Urogenital Distress Inventory (UDI) [11] and the Overactive Bladder Questionnaire (OAB-q), [12]. Condition-specific impact of incontinence was assessed using the Incontinence Impact Questionnaire (IIQ) [11] and impact on general quality-of-life was measured using the Short-Form Health Survey (SF-12) [13] and Health Utility Index (HUI-2), [14].

Patient satisfaction was measured using the single-item Patient Satisfaction Question (PSQ), a validated global rating of satisfaction with progress in the treatment program, [3]. Response options were "Completely," "Somewhat," or "Not at all." For the purposes of this analysis, patient satisfaction was defined as a PSQ response of "Completely Satisfied" (vs. "Somewhat" or "Not at all") at the 10 week visit.

Statistical Analysis

To identify potential correlates and predictors of patient satisfaction, the following categories of variables were examined: demographic characteristics, baseline characteristics of incontinence, prior treatment/surgery for incontinence, medical history and physical examination variables, menopause and estrogen status, diabetes, body mass index (BMI), Pelvic Organ Prolapse Quantification (POP-Q) scores; patient expectations of treatment success, and outcome variables (See Table 1 for variable distributions). These potential predictors were first explored in bivariate analyses.

Variables significantly related to outcome in bivariate analyses at the 0.05 level, as well as clinically relevant variables were entered into multivariable regression models to test their independent association with patient satisfaction. Treatment group (Drug versus Combined Drug and Behavior) and clinical site were entered into each model tested. Likelihood ratio tests were used to determine variables for inclusion in the final multivariable model. Only statistically significant variables ($p < 0.05$) remained in the final multivariable model.

Many women were missing patient expectation of treatment success information, because this form was not implemented until after enrollment to the study began. Assuming this information is missing at random, multiple imputation, a technique for analyzing data with missing values, was performed incorporating information from other covariates. Rather than exclude missing information, multiple imputation replaces each missing value with a set of plausible values that represent the uncertainty about the right value to impute, [15]. The final model excluding the missing values (complete case analysis) is compared to the multiple imputation model to be sure that the final model is robust.

Statistical analysis was performed using SAS Version 9.2 (SAS Institute, Inc, Cary, NC). A 5% two-sided significance level was used for all statistical testing.

Results

A total of 307 women were randomized to drug therapy alone ($n=153$) or combined drug and behavioral therapy ($n=154$). Baseline demographic and clinical characteristics are presented in Table 1. Participants had a mean age of 57 with a range of 21 to 87 years. There were no differences between groups on any baseline characteristics except occupational scores and household income. At the end of active treatment, 272 women completed the PSQ; 46.3% were completely satisfied with their progress, 48.5% were somewhat satisfied, and 5.1% were not at all satisfied. More women in the combined therapy group reported that they were completely satisfied with their progress compared to women in the drug alone group at the end of 10 weeks of treatment (56% vs. 43%, difference = 13%, 95% CI: 1% to 25%). Other outcomes of treatment are also shown in Table 1.

The results of the bivariate logistic regression models to identify potential correlates of patient satisfaction are shown in Table 2. None of the baseline factors were significantly associated with patient satisfaction, with the exception of menopause status. However, most of the outcome measures were associated with satisfaction. For example, for every 10% reduction in incontinence episodes on bladder diary, the odds of being completely satisfied with treatment increased by nearly 20% ($p < 0.001$). For every one unit improvement in Indevus Urgency Severity Scale Score, the odds of being “completely” satisfied with treatment nearly doubled ($p = 0.027$). Similarly, for every 10 unit increase in the difference between UDI scores from baseline to 10 weeks (baseline – 10 week), the odds of being completely satisfied with treatment increased by 16% ($p < 0.0001$). For every 10 unit increase in the difference between OAB-q scores from baseline to 10 weeks, the odds of being completely satisfied with treatment increased by nearly 20% ($p=0.002$). Women who

reported “much better” on the patient global perception of improvement (GPI) at 10 weeks were over 25 times more likely to report being “completely” satisfied with treatment; women who reported “better” were about twice as likely to report being “completely” satisfied with treatment at 10 weeks.

Because many of the covariates significant in bivariate modeling were highly correlated, a final multivariable model was constructed on the 260 women with complete information on all covariates (Table 3). The Hosmer-Lemeshow Goodness of Fit test p-value was 0.70, indicating no evidence of lack of model fit. Treatment group was no longer significant in the final multivariable model. Similarly, the postulated clinically relevant covariates (age, education level and MESA urge score) did not reach statistical significance. However, for every eleven-point increase in the difference in UDI score from baseline to 10 weeks, the odds of patient satisfaction increased by 12%. An 11-point increase in UDI has been shown to be the minimally important difference, i.e., the smallest change in score associated with a clinically meaningful change, [16]. The other correlate of patient satisfaction was their Global Perception of Improvement. Women who perceived their improvement was “much better” also had markedly higher odds of patient satisfaction compared with those who perceived they were the same or worse.

The previous analyses that included patient expectations of treatment success were repeated after performing the multiple imputation technique and the relationships between treatment group, change in UDI and patient perception of improvement were found to be similar (data not presented). This lends further support to the robustness of our final multivariable model.

Discussion

Patient satisfaction after medical and surgical treatment is increasingly important as shown by the recent trend toward patient-centered medical care, [17, 18]. Physician-centered outcomes differ considerably from patients' perceptions of satisfaction [19], and these differences become more apparent when treating disorders with high impact on quality of life, such as urinary incontinence, [20]. Identifying modifiable and non-modifiable factors associated with patient satisfaction after treatment for urinary incontinence may help tailor treatments for individual patients.

We did not identify any baseline factors associated with short-term patient satisfaction after antimuscarinic or antimuscarinic plus behavioral therapy in this cohort of women with urge-predominant urinary incontinence, including age, ethnicity, education, socioeconomic status, prior treatment for incontinence, smoking, menopause/hormone therapy use, body mass index, diabetes, or overall health status. Satisfaction was not associated with any objective or subjective baseline severity measures. Our data are consistent with other literature in pelvic floor disorders, which suggest that baseline severity does not predict satisfaction with treatment success, [20-22].

Interestingly, satisfaction was also not related to patients' expectations for treatment success in our study. Prior research has consistently demonstrated that patient satisfaction is primarily determined by their expectations for treatment, [18]. Investigators reported similar findings between patient satisfaction and pre-operative expectations in women undergoing surgery for urinary incontinence and/or pelvic organ prolapse, [22]. However, the expectations of women undergoing drug treatment may differ from women undergoing surgical treatment. Also, 30% of our participants had had antimuscarinic drugs in the past, which could have impacted their expectations. Another factor impacting expectations could be the design of the BE-DRI study, which included planned discontinuation of drug at 10 weeks, [4]. A limitation of our study is that the patient expectation measure was added after

the study was in progress, so only 56% of our study population provided data on expectations for treatment success.

We found that patient satisfaction after treatment was more strongly associated with a subjective patient-centered outcome measure, the Global Perception of Improvement than the more objective measure of success, reduction in incontinence episode frequency on bladder diary. Similarly, Barber et al recently reported that the most clinically relevant outcome of prolapse surgery was patient report of vaginal bulge while the more objectively measured clinical prolapse staging, was less relevant, [23]. Our findings are consistent with patient satisfaction after surgical treatment for pelvic floor disorders, which demonstrated that patient satisfaction after incontinence and prolapse surgery was associated with subjective measures of success, [20-22].

One study of women with stress incontinence treated pharmacologically found a strong relationship between reduction in incontinence episodes on bladder diary and clinically meaningful improvement in condition-specific quality of life, [24]. However, unlike stress incontinence, urgency incontinence usually occurs as one component of overactive bladder syndrome, a composite of lower urinary tract symptoms, including urgency, frequency, nocturia, and urgency incontinence. Each of these symptoms taken in isolation such as incontinence episodes on a bladder diary or the Indevus urgency score may not adequately reflect the patient's overall bother from overactive bladder symptoms which may explain why individual measures did not sufficiently capture patients' true satisfaction with treatment. The UDI captures bother associated with multiple urinary and pelvic floor symptoms and was associated with patient satisfaction. It may also be that the GPI was so strongly associated with satisfaction because it allowed the patient to consider improvement related to multiple symptoms. These findings are consistent with the EPIC survey, which showed that patients with OAB and voiding and post-micturition symptoms had lower levels of health-related quality of life and overall health, as well as clinically elevated depression scores, compared with patients with OAB with incontinence, but no voiding or post-micturition symptoms, [25]. Further studies to better understand patient expectations for urge-predominant incontinence treatment, including delineation of the most bothersome symptoms, may help direct individualized therapies and improve satisfaction.

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Appendix: Urinary Incontinence Treatment Network

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Table 1
Distributions of Characteristics Considered as Correlates of Satisfaction with Treatment

	N	Mean(SD) or Percent
Study Treatment		
Drug only	153	50%
Drug plus behavioral therapy	154	50%
Demographic Characteristics		
Age	307	56.9 (13.9)
Race/ethnic group		
Hispanic	30	10%
Non-Hispanic White	190	62%
Non-Hispanic Black	57	19%
Non-Hispanic other	28	9%
Missing	2	<1%
Education level		
Less than high school ^a	13	4%
High school/GED ^a	58	19%
Some college	118	38%
Completed college	72	24%
Graduate/professional school	46	15%
Income		
<\$20,000	70	23%
\$20,000-49,999	104	34%
\$50,000-79,999	59	19%
\$80,000+	51	17%
Missing	23	7%
Baseline incontinence characteristics		
MESA stress score	307	10.6 (6.2)
MESA urge score	307	11.1 (3.4)
Pad use		
No pads	83	27%
Mini pads	73	24%
Full size pads	120	39%
Diapers	22	7%
Missing	9	3%
Prior treatment (behavioral, medical or surgery) for incontinence	123	40%
Prior antimuscarinic medication(s) for incontinence	85	30%
Medical history and physical health		
Self assessment of overall health		

	N	Mean(SD) or Percent
Excellent	37	12%
Very good	104	34%
Good	108	35%
Fair ^b	50	16%
Poor ^b	7	2%
Missing	1	<1%
Menopausal status/HRT status		
Post-menopausal on HRT	54	18%
Post-menopausal not on HRT	151	49%
Pre-menopausal	102	33%
Diabetes	39	13%
Body mass index	300	32.7 (8.6)
POP-Q Stage		
0/I	193	63%
II	103	34%
III/IV	10	3%
Missing	1	<1%
Patient expectations of treatment success		
Very much better	114	37%
Little better/same	59	19%
Missing	134	44%
HUI - Pain	304	0.88 (0.18)
OUTCOMES (change is baseline – 10 week visit)		
Percent reduction in incontinence episodes (diary)	269	72% (32%)
Change in frequency of voids (diary), voids/24 hours	269	-0.14 (2.58)
Change in nocturia (diary)/night	269	-0.01 (0.83)
Change in Indevus Urgency Severity Scale Score	154	0.48 (0.62)
Change in IIQ	271	85.82 (82.90)
Change in UDI	272	67.76 (56.18)
Change in UDI-I	272	32.98 (25.74)
Change in UDI-O	272	9.79 (14.07)
Change in UDI-S	272	25.00 (29.72)
Change in OAB-q	270	-23.89 (21.85)
Patient Global Perception of Improvement		
Much better ^c	109	36%
Better ^c	117	38%
About the same ^c	41	13%
Worse ^c	5	2%

	N	Mean(SD) or Percent
Missing	35	11%

^aThe “less than high school” and “high school/GED” groups were combined for analysis due to the small sample size in the “less than high school” group.

^bThe “fair” and “poor” groups were combined for analysis due to the small sample size in the “poor” group.

^cThe “much better” and “better” groups each were combined compared to the combined “about the same” and “worse” groups for analysis.

Table 2
Bivariate Analyses of Correlates of Patient Satisfaction with Treatment

	OR (95% CI)*	p-value
Study Treatment Group		0.02
Drug only	0.56 (0.34, 0.92)	
Drug plus Behavioral Therapy	Reference	
Demographic Characteristics		
Age (per 10 years)	0.87 (0.71, 1.06)	0.16
Race/ethnic group		0.31
Hispanic	3.01 (0.86, 10.51)	
Non-Hispanic White	2.13 (0.84, 5.42)	
Non-Hispanic Black	2.26 (0.81, 6.31)	
Non-Hispanic Other	Reference	
Education level		0.14
High school/GED or less	2.45 (1.07, 5.59)	
Some college	1.33 (0.62, 2.86)	
Completed college	1.70 (0.73, 3.96)	
Graduate/professional school	Reference	
Income		0.86
<\$20,000	1.40 (0.60, 3.25)	
\$20,000-49,999	1.08 (0.50, 2.37)	
\$50,000-79,999	1.16 (0.49, 2.73)	
\$80,000	Reference	
Baseline Incontinence Characteristics		
MESA stress score	1.02 (0.98, 1.06)	0.36
MESA urge score	1.06 (0.98, 1.14)	0.16
Pad use		0.36
No pads	0.96 (0.35, 2.65)	
Mini pads	1.61 (0.58, 4.49)	
Full size pads	0.93 (0.35, 2.49)	
Diapers	Reference	
Pad use (2 categories)		0.56
No pads	0.85 (0.48, 1.48)	
Any pads	Reference	
Prior treatment/surgery for incontinence		0.61
Yes	0.88 (0.52, 1.47)	
No	Reference	
Prior antimuscarinic medication(s) for incontinence		0.33
Yes	0.76 (0.43, 1.33)	
No	Reference	

	OR (95% CI)*	p-value
Medical History and Physical Health		
Self assessment of overall health		0.42
Excellent	1.58 (0.63, 3.97)	
Very good	1.82 (0.88, 3.75)	
Good	1.70 (0.81, 3.57)	
Fair/Poor	Reference	
Menopausal status/HRT use		0.031
Post-menopausal on HRT	1.60 (0.75, 3.39)	
Post-menopausal not on HRT	0.63 (0.36, 1.13)	
Pre-menopausal	Reference	
Diabetes		0.30
Yes	1.48 (0.71, 3.08)	
No	Reference	
Body mass index	0.98 (0.95, 1.01)	0.30
POP-Q		0.55
O/I	0.43 (0.09, 2.09)	
II	0.41 (0.08, 2.01)	
III/IV	Reference	
Patient Expectations of Treatment Success		0.73
Very much better	1.14 (0.55, 2.35)	
Little better/same	Reference	
HUI – Pain	1.17 (0.30, 4.56)	0.82
OUTCOMES		
Percent reduction in incontinence episodes (diary) for every 10% decrease	1.19 (1.07, 1.31)	<0.001
Reduction in frequency of voids (diary)	1.09 (0.99, 1.21)	0.088
Reduction in nocturia (diary)	1.00 (0.73, 1.36)	0.98
Change in Indevus Urgency Severity Scale Score	1.90 (1.07, 3.38)	0.027
Change in IIQ (per 10 unit increase)	1.02 (0.99, 1.05)	0.31
Change in UDI (per 11 unit increase)	1.17 (1.10, 1.25)	<0.001
Change in UDI-I (per 10 unit increase)	1.34 (1.20, 1.50)	<0.001
Change in UDI-O (per 10 unit increase)	1.45 (1.19, 1.76)	<0.001
Change in UDI-S (per 10 unit increase)	1.20 (1.09, 1.32)	<0.001
Change in OAB-q (per 10 unit increase)	0.82 (0.72, 0.93)	0.002
Patient Global Perception of Improvement		<0.001
Much better	25.07 (9.30, 67.61)	
Better	2.16 (0.84, 5.54)	
About the same/worse	Reference	

* Odds ratios (ORs) with 95% confidence intervals controlling for site and treatment group and predicting the probability of being “completely” satisfied with treatment outcome.

Table 3
Final Multivariable Model for Correlates of Patient Satisfaction

	OR (95% CI)	P Value
Change in UDI (per 11 unit increase)	1.12 (1.04,1.21)	0.002
Patient Global Perception of Improvement		<0.001
Much Better	13.80 (4.94,38.60)	
Better	1.45 (0.54,3.91)	
About the Same/Worse/Much Worse	1 (Reference)	
Study Treatment Group		0.30
Drug only	0.72 (0.39, 1.34)	
Drug plus Behavioral Therapy	Reference	