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Predictors of Success and Satisfaction of Nonsurgical Therapy for Stress Urinary Incontinence

Joseph Schaffer, MD,

University of Texas Southwestern, Dallas, TX

Charles W. Nager, MD,

University of California San Diego, San Diego, CA

Fang Xiang, MS,

University of Michigan, Ann Arbor, MI

Diane Borello-France, PT, PhD,

Duquesne University, Pittsburgh, PA

Catherine S. Bradley, MD, MSCE,

University of Iowa, Iowa City, IA

Jennifer M. Wu, MD,

Duke University, Raleigh-Durham, NC

Elizabeth Mueller, MD,

Loyola University, Maywood, IL

Peggy Norton, MD,

University of Utah, Salt Lake City, UT

Marie Fidela R. Paraiso, MD,

Cleveland Clinic, Cleveland, OH

Halina Zyczynski, MD, and

Magee Womens, Pittsburgh, PA

Holly E. Richter, PhD, MD

University of Alabama at Birmingham, Birmingham, AL

Abstract

Objective—To identify factors that may predict success and satisfaction in women undergoing nonsurgical therapy for stress urinary incontinence (SUI).

Methods—Baseline demographic and clinical characteristics of women participating in a multicenter randomized trial of pessary, behavioral, or combined therapy for SUI were evaluated for potential predictors of success and satisfaction. Success and satisfaction outcomes were assessed at 3 months and included the Patient Global Impression of Improvement (PGI-I), stress

Corresponding Author: Holly E. Richter, PhD, MD, University of Alabama at Birmingham, 1700 6th Av South, Suite 10382, Birmingham, AL 35233, Phone: 205-934-1704, Fax: 205-975-8893, hrichter@uabmc.edu.

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incontinence subscale of the Pelvic Floor Distress Inventory (PFDI), and Patient Satisfaction Questionnaire (PSQ). Logistic regression was performed to identify predictors, adjusting for treatment and other important clinical covariates. Adjusted odds ratios (AOR), 95% confidence intervals (CI), and associated *P*-values are presented.

Results—Four hundred forty-six women were randomized. College education or higher and no previous UI surgery predicted success based on the stress subscale of the PFDI (AOR=1.61, 95% CI 1.01 to 2.55; *p*=0.04; AOR=3.15, 95% CI 1.04 to 9.53; *p*=0.04, respectively). Menopausal status predicted success using the PGI-I (AOR=2.52 postmenopausal vs premenopausal, 95% CI 1.29 to 4.95; AOR=1.32 unsure menopausal status vs pre-menopausal, 95% CI 0.65 to 2.66; *p*=0.03 across all three groups). Less than 14 incontinence episodes per week predicted satisfaction with the PSQ (AOR=1.97, 1.21 to 3.19; *p*=0.01). These predictors did not differ across the three treatment groups.

Conclusions—Menopause, higher education, no previous UI surgery and lower incontinence frequency were found to be predictors of success and satisfaction with nonsurgical therapy for SUI. This information may help better align provider and patient expectations with nonsurgical treatment outcomes.

Clinical Trial Registration—ClinicalTrials.gov, www.clinicaltrials.gov, NCT00270998.

INTRODUCTION

Stress urinary incontinence (SUI), the complaint of involuntary loss of urine with physical exertion, sneezing or coughing,(1) is a highly prevalent condition affecting up to 35% of women.(2,3) Non-surgical options such as behavioral therapy and pessaries are low-risk and low-cost interventions compared to surgical options for SUI, but there is less data about their effectiveness. Several clinical trials have shown that SUI symptoms improve when women are taught how to actively use their pelvic floor muscles to prevent urine loss.(4–8) Likewise, continence pessaries have been successfully used to manage SUI (9–11) although few randomized trials exist on this modality.(12,13) A recent multicenter, randomized trial comparing the effectiveness of continence pessary to behavioral therapy to combined therapy (behavioral + pessary), the Ambulatory Treatments for Leakage Associated With Stress incontinence study showed that behavioral therapy resulted in greater patient satisfaction and fewer bothersome SUI symptoms compared to pessary at three months, the primary outcome time-point, but these differences did not persist at one year. (8)

The ability to predict which patients with SUI will be successfully treated and satisfied with non-surgical therapies would enhance patient counseling, with respect to both patient expectations of treatment and medical decision-making regarding treatment. Obesity, pelvic organ prolapse, severe SUI along with high psychological distress and poor physical health were associated with a poor outcome after physical therapy for SUI in a study by Hendriks and colleagues.(14) In contrast, Theofrastus and coworkers studied SUI symptoms after pelvic floor muscle training and could find no significant correlations with demographic variables, incontinence severity or urodynamic measures.(15) While some conflicting data exist regarding predictors of success for behavioral therapy, information for continence pessaries is lacking.

The primary aim of this planned secondary analysis was to identify baseline factors that might predict treatment success and patient satisfaction in women undergoing non-surgical therapy for SUI. Our secondary aim was to evaluate whether these factors differed among treatment approaches including the continence pessary, behavioral therapy, or combined therapy.

MATERIALS AND METHODS

The Ambulatory Treatments for Leakage Associated With Stress trial methods were previously reported. (16) Briefly, adult women with symptoms of SUI were randomized to receive one of three non-surgical interventions: continence pessary, behavioral therapy (pelvic floor muscle training and continence strategies), or combined therapy stratified by incontinence episode frequency (<14 versus ≥14 incontinence episodes per week) and whether stress UI only or stress predominant mixed UI. Institutional review board approval was obtained at each site and the data coordinating center, and written informed consent was obtained from all participants. As in the primary analysis, the primary outcomes used to define success and satisfaction with therapy at 3 months were: the Patient Global Impression of Improvement (PGI-I) and the stress incontinence subscale of the Pelvic Floor Distress Inventory (PFDI). Treatment satisfaction was assessed with the Patient Satisfaction Questionnaire (PSQ). For PGI-I, success was defined as a response of “much better” or “very much better” among responses on a 7-point Likert scale ranging from “very much worse” to “very much better”. For the stress incontinence subscale of the PFDI (Urogenital Distress Inventory [UDI]-stress), success was defined as the absence of bothersome stress incontinence symptoms, i.e., an answer of “no” to all six of the stress incontinence subscale items or a response of “yes,” but with a bother of “not at all” or “somewhat.” PSQ was used to assess patient satisfaction with treatment, defined as “completely satisfied” or “somewhat satisfied” on a 4-point Likert scale. An intention-to-treat analysis was performed, including all subjects who were eligible and randomized to treatment. Participants who received any other treatment for incontinence and withdrawals were also considered randomized treatment failures.

Potential predictors for the primary outcomes and satisfaction included demographic variables (age, race, ethnicity, education, employment status), clinical variables (body mass index (BMI), smoking status, alcohol usage, parity, medical co-morbidity (where high comorbidity is defined as ≥2 medical conditions and low comorbidity as <2), menopausal status, estrogen status, hysterectomy, prior pelvic surgery, and prior treatment of pelvic organ prolapse), anatomic measures (Pelvic Organ Prolapse–Quantification [POP-Q] measures Aa, Ap, Ba, Bp, GH with strain and TVL; and Brink score), and quality of life measures (SF-36 mental composite summary score, SF36 physical composite summary score), baseline Pelvic Organ Prolapse Distress Inventory (POPDI) and Pelvic Organ Prolapse Impact Questionnaire (POPIQ) scores, as well as incontinence type and incontinence frequency by 7-day bladder diary all measured at baseline.

Statistical Analysis

Logistic regression was used to assess the relationship between potential predictors and each outcome. The model-building strategy to identify factors that might predict success and satisfaction outcomes was: (1) fit simple (univariable) logistic regression models for each potential predictor; (2) test for interaction of significant predictors with treatment approach to assess whether predictors of success and satisfaction differed by treatment; and (3) fit multivariable logistic regression to evaluate the effects of the predictors significant from the univariable logistic regression analyses with $p < 0.05$, adjusting for treatment, two stratification factors (incontinence type and incontinence frequency) and other important clinical covariates based on the literature including age, Bp, GH with strain, TVL, BMI, POP-Q stage, and hysterectomy (regardless of their significance in the simple regression model). Due to the high correlation (Pearson correlation coefficient > 0.99 , $p\text{-value} < 0.0001$) between Ap and Bp, we only included Bp (the leading edge of the posterior wall) in the multivariable model. Analyses were performed using SAS 9.2 (Cary, NC) with statistical significance defined at 5%.

RESULTS

In the Ambulatory Treatments for Leakage Associated With Stress trial, 446 participants were randomly assigned to pessary (n=149), behavioral therapy (n=146), or combined therapy (n=151).⁽⁸⁾ One subject in the combined therapy group was found to be ineligible and was removed from subsequent analyses. Participants in the three treatment groups were similar in demographic and medical characteristics (Table 1). Overall, participants were on average 50 years of age, primarily Caucasian and parous. Approximately 20%, by self report, had attempted some non-surgical therapy for their urinary leakage, although not in a controlled setting. Nearly half of participants reported stress only symptoms and half reported stress predominant mixed urinary incontinence (UI) symptoms and 55% of subjects reported less than 14 incontinence episodes per week.

The results of the univariable regression analysis of potential predictors of success (PGI-I, UDI-stress) and satisfaction (PSQ) measures at 3 months are demonstrated in Table 2. Race and menopausal status were associated with success as defined by the PGI-I; education status, prior UI surgery, medical comorbidities, POPDI score and incontinence frequency were associated with success as defined by the UDI-stress subscale score. POP-Q posterior wall points Ap, Bp, and GH with strain and incontinence frequency were associated with success as defined by satisfaction. To identify whether predictors of success and satisfaction differed by treatment, we tested for interaction of treatment with the predictors that are significant in the bivariate analyses. None of the interactions were statistically significant ($p > 0.05$; results not shown).

In the final multivariable regression models (Table 3), menopausal status remained a significant independent predictor of success as defined by the PGI-I, after controlling for treatment and other factors. Specifically, the odds of being successful 3 months after treatment for post-menopausal women were nearly 2.5 times the odds for pre-menopausal women ($p=0.03$). Education and previous UI surgery were significant predictors of success as defined by the UDI-stress measure, after controlling for other predictors. The odds of success for college-educated women were about 1.5 times the odds for women with less than a college education ($p=0.04$). Women who had not had previous UI surgery had approximately 3 times the odds of success compared to women who did have previous surgery ($p=0.04$). Lastly, incontinence frequency predicted satisfaction after controlling for other predictors. The odds of being satisfied 3 months after treatment for women with fewer than 14 incontinence episodes per week at baseline was almost two times the odds for women with 14 or more episodes ($p=0.01$). POP-Q points Bp and GH with strain were no longer significant in the multivariable regression model ($p > 0.05$). These relationships were not affected by treatment.

Discussion

The results of this planned secondary analysis of data suggest that there are certain factors of women pursuing non-surgical therapy which increase the odds of treatment success and satisfaction. Women with <14 weekly UI episodes were more likely to be satisfied than women who experienced more frequent UI prior to intervention. This finding is similar to those of other investigators. Burgio and colleagues reported that women who experienced >10 SUI episodes/week prior to intervention were less likely to achieve success (a 75% reduction of incontinence episodes recorded on bladder diary) following behavioral treatment including pelvic muscle exercises and continence strategies.⁽¹⁷⁾ Similarly, Hendriks et al. identified severe SUI as one of 11 prognostic indicators of poor outcome (leakage severity and global perceived effectiveness) following physiotherapy for female SUI.⁽¹⁴⁾ Women that were college-educated were less likely to report symptom-related

distress compared to women with less education. Hendriks et al. also found women with lower education to have a poorer outcome related to leakage severity following a physiotherapy intervention for SUI.(14) Education level has also been reported to impact outcomes following interventions for other medical conditions such as chronic pain (18) and lumbar disc herniation.(19) Olson et al. also found education level impacted outcomes including bodily pain, physical function, and disability of persons who underwent nonsurgical interventions (physical therapy, education/counseling, home exercise, and non-steroidal anti-inflammatory drugs) for lumbar disc herniation. Individuals with higher education attained better outcomes up to 4 years following nonsurgical intervention. Interestingly, outcomes of persons who received surgical intervention did not differ by education level.(19) These investigators hypothesized that a difference in locus of control (the belief that one's health is contingent on one's own behavior) from external for surgical to internal for non-operative interventions may explain why education level impacted only those who underwent non operative interventions.(20) Future studies should investigate this relationship and its effect on UI intervention outcomes.

Women without previous UI surgery were more likely to be successful based upon stress symptoms as measured by the stress subscale of the PFDI. This has also been noted in a previous study where women who had undergone incontinence surgery prior to pessary use had a discontinuation rate higher than those women without previous surgery (72% versus 27%; RR 1.62; 95% CI, 1.0–2.7). It was speculated that women with previous surgery may have had lower urethral closure pressures or lower urethral mobility resulting in an altered urethral continence mechanism suboptimally managed with a pessary. (9) Other investigators have noted that hysterectomy or other pelvic surgery predisposes to weakness of the pelvic floor affecting the ability to optimally retain a pessary. (21)

Finally, post-menopausal women were more likely to report a greater global impression of improvement of their continence status than pre-menopausal women. This finding was surprising given the reported decline in muscle strength that occurs in postmenopausal women.(22) However, in a recent literature review, Enns and Tiidus presented conflicting evidence regarding the impact of estrogen depletion on muscle structure (mass, size, or cross-sectional area) and function.(23) These authors attributed this inconsistency to a number of factors including the species examined, size and fiber type composition of muscles examined, prior state of fitness of subjects, and the type and intensity of exercise protocols examined. Therefore, the decline in strength that occurs in older women may not be strictly attributed to hormone status. Other factors such as overall physical activity, exercise levels, and body weight may have a greater impact on muscle structure and function. Given the evidence, clinicians should be cautious to assume that age or menopause will limit a woman's ability to benefit from a trial of pelvic floor muscle exercise.

We found predictors of success to be the same for continence pessary, behavioral therapy, and the combination of the two. Previous studies on the continence pessary for SUI did not identify menopausal status, education and incontinence severity as predictors of success, however these were retrospective reviews (9, 11). The randomized, prospective design of our trial allows for a much better understanding of the influence of these factors, and we believe this can be beneficial to practitioners in deciding which patients might be candidates for a continence pessary and/or behavioral therapy.

The strengths of this study include its prospective design and robust follow-up in a large, well characterized population of women interested in conservative treatment for stress predominant UI symptoms. Weaknesses include the relatively short-term follow-up of success and satisfaction outcomes and the potential lack of generalizability to community-based clinical populations as compared to academic practices. Despite these short-comings,

this information can be used to counsel women interested in conservative treatment for UI. Further, adverse events are rarely seen in these 2 conservative treatment approaches, therefore they should be considered for all women seeking care for urinary incontinence. Factors associated with longer-term non-surgical treatment outcomes are also needed.

In summary, our findings have real implications for clinical care and future research and may help align physician and patient expectations of treatment benefit with more realistic goals. These results can be used to inform patients of their prognosis if interested in pursuing these 2 non-surgical treatment modalities for stress predominant UI symptoms. It does not mean that patients that do not meet these criteria will not obtain benefit from non-surgical approaches for the management of SUI as there are other non-surgical treatment modalities including weight loss or the use of electrical stimulation. An individualized approach which balances available data and patient desires and needs continues to be a primary goal for optimized patient care.

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Table 1

Selected Participant Characteristics at Baseline

Characteristic	All (n=445)	Combined (n=150)	Behavioral (n=146)	Pessary (n=149)
Age (y)	49.8 ± 11.9 (19.0 – 89.2)	49.5 ± 11.8 (19.0 – 73.4)	49.6 ± 13.0 (21.2 – 89.2)	50.2 ± 11.0 (31.3 – 81.0)
Race				
White or Caucasian	379 (85.4)	122 (81.3)	332 (90.4)	125 (84.5)
Black or African American	45 (10.1)	20 (13.4)	10 (6.8)	15 (10.1)
Other	20 (4.5)	8 (5.3)	4 (2.7)	8 (5.4)
Vaginal deliveries	2 (1–3/0–11)	2 (1–3/0–6)	2 (1–3/0–11)	2 (1–3/0–11)
Menopausal status				
Premenopausal	214 (48.1)	68 (45.3)	71 (48.6)	75 (50.3)
Postmenopausal	188 (42.2)	66 (44.0)	62 (42.5)	60 (40.3)
Not sure	43 (9.7)	16 (10.7)	13 (8.9)	14 (9.4)
Prior nonsurgical UI	92 (20.7)	27 (18.0)	35 (24.0)	30 (20.1)
Prior UI surgery	27 (6.1)	10 (6.7)	7 (4.8)	10 (6.7)
Hysterectomy	110 (24.8)	32 (21.3)	39 (26.9)	39 (26.4s)
Incontinence type				
Stress only	204 (45.8)	70 (46.7)	65 (44.5)	69 (46.3)
Mixed	241 (54.2)	80 (53.3)	81 (55.5)	80 (53.7)
Incontinence frequency				
14 or more episodes per wk	202 (45.4)	67 (44.7)	67 (45.9)	68 (45.6)
Fewer than 14 episodes per wk	243 (54.6)	83 (55.3)	79 (54.1)	81 (54.4)

Data are mean ± standard deviation (range), n (%), or median (interquartile range or range).

UI, urinary incontinence.

Modified from Richter HE, Burgio KL, Brubaker L, et al. Continence pessary compared with behavioral therapy or combined therapy for stress incontinence: a randomized controlled trial. *Obstet Gynecol* 2010;115:609–17.

Univariable Logistic Regression Analyses of Potential Variables Associated With Success and Satisfaction as Measured Using the Patient Global Impression of Improvement, Urogenital Distress Inventory-Stress and PSQ^{*}

Table 2

Predictor	Statistic/Category	PGI-I			UDI-Stress			PSQ (Satisfaction)		
		Success (n=211)	Failure (n=234)	OR (95% CI)	Success (n=186)	Failure (n=259)	OR (95% CI)	Success (n=322)	Failure (n=123)	OR (95% CI)
<i>Age (yrs)</i>	mean (SD)	50.66 (12.26)	48.96 (11.56)	1.01 (1.00, 1.03)	49.09 (11.76)	50.25 (12.02)	0.99 (0.98, 1.01)	50.33 (12.05)	48.28 (11.46)	1.01 (1.00, 1.03)
	White or Caucasian	175 (46.2)	204 (53.8)	1.00	155 (40.9)	224 (59.1)	1.00	273 (72.0)	106 (28.0)	1.00
	Black or African American	29 (64.4)	16 (35.6)	2.11 (1.11, 4.02)	23 (51.1)	22 (48.9)	1.51 (0.81, 2.81)	36 (80.0)	9 (20.0)	1.55 (0.72, 3.33)
<i>Race, n (%)</i>	Other	7 (35.0)	13 (65.0)	0.63 (0.25, 1.61)	8 (40)	12 (60)	0.96 (0.38, 2.41)	13 (65.0)	7 (35.0)	0.72 (0.28, 1.86)
	Fewer than 4 years of college	117 (47.2)	131 (52.8)	1.00	92 (37.1)	156 (62.9)	1.00	176 (71.0)	72 (29.0)	1.00
	4 years or more of college or graduate or professional degree	94 (47.7)	103 (52.3)	1.02 (0.70, 1.49)	94 (47.7)	103 (52.3)	1.55 (1.06, 2.26)	146 (74.1)	51 (25.9)	1.17 (0.77, 1.78)
<i>BMI (kg/m²), n (%)</i>	Lower than 25	56 (44.4)	70 (55.6)	1.00	56 (44.4)	70 (55.6)	1.00	94 (74.6)	32 (25.4)	1.00
	25–30	67 (48.2)	72 (51.8)	1.16 (0.72, 1.89)	66 (47.5)	73 (52.5)	1.13 (0.70, 1.83)	105 (75.5)	34 (24.5)	1.05 (0.60, 1.84)
	Greater than 30	87 (49.7)	88 (50.3)	1.24 (0.78, 1.96)	64 (36.6)	111 (63.4)	0.72 (0.45, 1.15)	123 (70.3)	52 (29.7)	0.81 (0.48, 1.35)
<i>POP-Q Stage, n (%)</i>	0	25 (50.0)	25 (50.0)	1.00	23 (46.0)	27 (54.0)	1.00	41 (82.0)	9 (18.0)	1.00
	1	99 (48.5)	105 (51.5)	0.94 (0.51, 1.75)	92 (45.1)	112 (54.9)	0.96 (0.52, 1.79)	150 (73.5)	54 (26.5)	0.61 (0.28, 1.34)
	2	85 (45.7)	101 (54.3)	0.84 (0.45, 1.57)	68 (36.6)	118 (63.4)	0.68 (0.36, 1.27)	127 (68.3)	59 (31.7)	0.47 (0.22, 1.04)
<i>POP-Q Point Ap, cm</i>	Mean (SD)	−2.27 (0.80)	−2.14 (0.92)	0.84 (0.67, 1.04)	−2.25 (0.82)	−2.16 (0.90)	0.88 (0.71, 1.1)	−2.26 (0.85)	−2.04 (0.90)	0.76 (0.60, 0.96)
<i>POP-Q Point Bp, cm</i>	mean (SD)	−2.26 (0.80)	−2.13 (0.93)	0.83 (0.67, 1.04)	−2.25 (0.82)	−2.15 (0.91)	0.87 (0.70, 1.08)	−2.26 (0.85)	−2.03 (0.92)	0.75 (0.60, 0.95)
<i>POP-Q Point GH with strain, cm</i>	mean (SD)	3.11 (1.00)	3.17 (1.02)	0.94 (0.78, 1.13)	3.17 (1.02)	3.13 (1.00)	1.04 (0.86, 1.26)	3.08 (1.01)	3.30 (1.00)	0.81 (0.66, 0.99)
<i>POP-Q Point TVL, cm</i>	mean (SD)	9.44 (1.28)	9.57 (1.19)	0.92 (0.79, 1.07)	9.46 (1.34)	9.55 (1.15)	0.94 (0.81, 1.09)	9.50 (1.27)	9.54 (1.12)	0.97 (0.82, 1.15)
<i>Menopausal status, n (%)</i>	Premenopausal	85 (39.7)	129 (60.3)	1.00	86 (40.2)	128 (59.8)	1.00	147 (68.7)	67 (31.3)	1.00
	Postmenopausal	106 (56.4)	82 (43.6)	1.96 (1.32, 2.92)	80 (42.6)	108 (57.4)	1.10 (0.74, 1.64)	144 (76.6)	44 (23.4)	1.49 (0.96, 2.33)
	Not sure	20 (46.5)	23 (53.5)	1.32 (0.68, 2.55)	20 (46.5)	23 (53.5)	1.29 (0.67, 2.50)	31 (72.1)	12 (27.9)	1.18 (0.57, 2.43)
<i>Hysterectomy, n (%)</i>	Yes	57 (51.8)	53 (48.2)	1.00	46 (41.8)	64 (58.2)	1.00	84 (76.4)	26 (23.6)	1.00
	No	153 (45.9)	180 (54.1)	0.79 (0.51, 1.22)	139 (41.7)	194 (58.3)	1.00 (0.64, 1.54)	236 (70.9)	97 (29.1)	0.75 (0.46, 1.24)
<i>Previous UI surgery, n (%)</i>	Yes	11 (40.7)	16 (59.3)	1.00	5 (18.5)	22 (81.5)	1.00	17 (63.0)	10 (37.0)	1.00
	No	200 (48.0)	217 (52.0)	1.34 (0.61, 2.96)	181 (43.4)	236 (56.6)	3.37 (1.25, 9.08)	304 (72.9)	113 (27.1)	1.58 (0.70, 3.56)
<i>Co-Morbidity, n (%)</i>	Low	99 (43.8)	127 (56.2)	1.00	105 (46.5)	121 (53.5)	1.00	160 (70.8)	66 (29.2)	1.00

Table 3

Final Multivariable Logistic Regression Analyses of Baseline Factors Associated With Success and Satisfaction

Outcome	Predictor		Adjusted Odds Ratio (95% CI)	P
PGI-I	Race	White or Caucasian	1.00	0.06
		Black or African American	2.26 (1.13, 4.50)	
		Other	0.81 (0.30, 2.20)	
	Menopausal status	Premenopausal	1.00	0.03
		Postmenopausal	2.52 (1.29, 4.95)	
		Not sure	1.32 (0.65, 2.66)	
UDI-Stress	POPDI		1.00 (0.99, 1.00)	0.08
	Education	Fewer than 4 years of college	1.00	0.04
		4 or more years of college or graduate or professional degree	1.61 (1.01, 2.55)	
	Previous UI surgery	Yes	1.00	0.04
		No	3.15 (1.04, 9.53)	
	Co-Morbidity	Low	1.00	0.18
		High	0.72 (0.45, 1.16)	
	Incontinence frequency	14 or more episodes per week	1.00	0.11
		Fewer than 14 episodes per week	1.45 (0.92, 2.30)	
	POP-Q Point Bp		0.80 (0.58, 1.10)	0.17
PSQ (Satisfaction)	POP-Q Point GH with strain		0.90 (0.70, 1.16)	0.42
	Incontinence Frequency	14 or more episodes per week	1.00	0.01
		Fewer than 14 episodes/week	1.97 (1.21, 3.19)	

CI, confidence interval; PGI-I, Patient Global Impression of Improvement; POPDI, Pelvic Organ Prolapse Distress Inventory; UDI, Urogenital Distress Inventory; UI, urinary incontinence; PSQ, Patient Satisfaction Questionnaire.

Age, Bp, GH with strain, total vaginal length, body mass index, POP-Q stage, hysterectomy, treatment, incontinence type and incontinence frequency were included in all models regardless of statistical significance from the simple logistic regression models. Additionally, the following variables were included in the multivariable models because they were statistically significant in the simple logistic regression models: PGI-I model -race and menopausal status; UDI-stress model -POPDI score, education status, previous UI surgery and comorbidity; PSQ model-none.