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# Predictors of Outcomes in the Treatment of Urge Urinary Incontinence in Women

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## Abstract

**Introduction and Hypotheses—**Women with urge predominant urinary incontinence (UUI) received active intervention (drug therapy alone or combined with behavioral therapy) for 10 weeks, then stopped all therapy and were followed for 6 more months. In this planned secondary analysis, we aimed to identify predictors of therapeutic success at 10 weeks (≥70% reduction in incontinence) and of ability to discontinue treatment and sustain improvements 6 months later.

**Methods—**Using data from 307 women, we performed logistic regression to identify predictors for outcomes described above.

**Results—**After controlling for group, only younger age was associated with short-term success (OR:0.8, 95% CI:0.66,0.96). At 6 months, controlling for group and short-term outcome, only greater anterior vaginal wall prolapse was associated with successful discontinuation (**POP-Q** point Aa; OR:1.33, 95% CI:1.03,1.7).

**Conclusion—**These findings are not of sufficient strength to justify withholding conservative therapies, but might be used to promote realistic expectations when counseling patients.

### Keywords

urge urinary incontinence; randomized trial; predictors of outcome

## Introduction

Although many studies report the outcomes of drug and behavioral therapies for the treatment of urinary incontinence, only a few have identified predictors of outcome with

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For a list of UITN investigators see appendix A

either therapy alone or when combined. Furthermore, there are no reports describing variables associated with successful discontinuation of active therapy and maintenance of long-term benefit.

Studies of behavioral treatment for urge predominant urinary incontinence have yielded inconsistent results with regard to predictors of outcome. Some studies have reported better outcomes with younger patients, [1] while others show no relationship to age.[2,3] In some studies, successful outcomes were associated with not wearing any form of protection for incontinence and fewer baseline incontinence episodes, variables that reflect baseline incontinence severity, [4,5] while others showed no relationship to severity. [6,7] Most studies that have examined type of incontinence or urodynamic parameters reported no association of these factors with outcome. [2,4,6,7]

Research on drug therapy for UUI has also reported that younger age, lesser severity and lower final tolterodine dose were associated with treatment efficacy. [8] However, this effect for age was not replicated in a second study, in which patients <65 years of age had greater improvement in voiding frequency than older patients, but did not have greater reduction of incontinence episodes, increased voided volume, reduction of urgency or less medication discontinuation secondary to side effects. [9]

Two retrospective studies have described patient characteristics associated with success utilizing aggressive combined drug and behavioral therapy. [10,11] Subjective improvement in stress, urge and mixed incontinence symptoms was not associated with performing a urodynamic evaluation, menopausal status or a history of previous surgery. [10] One year follow-up of a multi-component program including pelvic floor muscle exercises, bladder retraining, estrogen replacement, biofeedback, functional electrical stimulation and pharmacologic therapy found that improvement in symptoms was related to younger age and greater incontinence severity, but not type of incontinence. [11]

This paper reports on a planned secondary analysis of outcome data from the Behavior Enhances Drug Reduction of Incontinence (BE-DRI) study, a multi-site, randomized, controlled trial comparing the effects of drug therapy alone to combined behavioral and drug therapy for urge-predominant urinary incontinence (UUI) in women. [12] The purposes of this analysis were to identify predictors of successful outcomes of drug therapy alone and combined drug and behavioral treatment and to identify predictors of successful discontinuation of drug and active behavioral intervention, while maintaining clinically meaningful reductions in incontinence.

## Materials and Methods

### Overview

The BE-DRI study was a two-stage randomized clinical trial conducted by 9 clinical centers and a biostatistical coordinating center in the U.S. Participants were women with urge urinary incontinence randomly assigned to receive drug therapy alone or drug therapy in combination with behavioral training. In Stage 1, participants in both groups received 10 weeks of active treatment. In Stage 2, drug therapy was discontinued in both groups, and behavioral training visits were discontinued, although participants receiving behavioral therapy were instructed to continue their program at home. Outcomes were measured at the end of active therapy (Week 10) and at 6 months after discontinuation of therapy (8 months post randomization). Details of the methodology have been described previously. [13] The study was approved by the Institutional Review Boards of the participating centers. All participants provided written informed consent.

### Participants

Participants were 307 community-dwelling women with urge-predominant incontinence recruited through the investigators' clinical practices, study announcements, advertisements, and referrals. Only women with pure or predominant urge UI, defined as urge symptom index > stress symptom index on the Medical, Epidemiological, and Social Aspects of Aging Questionnaire (MESA), were included. [14] Clinical evaluation included medical history, physical examination (height, weight, pelvic and rectal examination, and targeted neurological assessment) and bladder diary. Pelvic floor muscle strength was assessed using the Brinks scale, [15] and pelvic organ prolapse was quantified using the pelvic organ prolapse quantification system (POP-Q). [16] To be eligible for the study, women had to report ≥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 UI, and no evidence that incontinence was secondary to neurologic or other systemic diseases.

### Randomization and Intervention

Eligible participants were randomly assigned to drug therapy alone or combined drug + behavioral therapy. Treatment in both groups was conducted in 4 visits, at intervals of 2 to 3 weeks, over a 10-week period. Both groups completed a daily bladder diary throughout the 10 weeks of active therapy.

Drug therapy was tolterodine tartrate (extended-release capsules, 4 mg per day). The dose could be decreased to 2 mg to minimize side-effects, or if not tolerated, another antimuscarinic medication could be prescribed. Participants also received recommendations for fluid intake and managing common drug side-effects (dry mouth and constipation).

Combination therapy included drug and behavioral training. The behavioral intervention was provided by a nurse practitioner, nurse specialist, and/or physical therapist and included teaching pelvic floor muscle control and exercises (using vaginal palpation); behavioral strategies to diminish urgency, suppress bladder contractions, and prevent both stress and urge incontinence; [17] delayed voiding to increase voiding intervals for those who voided >8 times per day; and individualized fluid management for those with excessive urine output (> 2100 ml per day). After 10 weeks of active intervention, drug therapy was discontinued and women were provided with a maintenance exercise program and advised to continue their behavioral program to sustain their clinical improvements.

### Measurements

Participants were assessed at baseline, the end of Stage 1 (10 weeks), and at the end of Stage 2 (6 months post treatment discontinuation, 8 months post randomization). At the end of active treatment (Stage 1), outcome was defined as a success if the patient achieved a 70% or greater reduction in the frequency of incontinent episodes as recorded in bladder diaries. The criterion of 70% reduction in incontinence episodes was based on data indicating that this was a critical threshold for patient satisfaction.[18]

At the end of Stage 2, outcome was “successful discontinuation of drug,” defined as not taking drug or receiving any other therapy for urge incontinence *and* a 70% or greater reduction in frequency of incontinence episodes on bladder diary compared to baseline.

In addition to the bladder diary, severity of symptom distress and bother were measured using the Urogenital Distress Inventory (UDI) [19] and the Overactive Bladder Questionnaire (OAB-q). [20] Condition-specific impact of incontinence was assessed using the Incontinence Impact Questionnaire (IIQ), [19] and impact on quality-of-life was

measured using the Short-Form Health Survey (SF-12) and Health Utility Index (HUI-2). [21]

### Statistical Analysis

Several variables were selected for analysis as potential predictors of treatment outcome, including: demographic characteristics (age, race/ethnic group, education level, income); severity of incontinence (MESA score, number of incontinence episodes on bladder diary, IIQ score, OAB-q score, duration of incontinence); prior treatment/surgery for incontinence; self-assessment of overall health (excellent to poor); fluid intake; current estrogen use; diabetes; presence of fecal incontinence; body mass index (BMI); POP-Q measures; baseline pelvic floor muscle strength; SF-12 score; and HUI-2 score.

Analyses were conducted separately for each outcome: successful initial treatment (10 weeks) and successful drug withdrawal (6 months after treatment discontinuation). All potential predictors were each explored separately using logistic regression to determine their relationship to treatment outcome. Treatment group (drug alone or combined drug + behavior) was included in all of these individual models whether statistically significant or not. For the analysis of the 6-month outcomes, outcome at 10 weeks was also added, whether significant or not, in every logistic regression model that includes each predictor separately. All analyses were carried out using the personal computer version of SAS statistical software (SAS Institute, Inc, Cary, NC. Version 9.1). Statistical significance was defined by a p-value $< 0.05$.

## Results

A total of 307 women were randomized to either drug therapy alone (n=153) or combination therapy (n=154). Subjects had a mean age of 56.9±13.9 (range, 21 to 87). Other baseline demographic and clinical characteristics, overall and by group are presented in Table 1. There were no differences between groups on any of the patient characteristics except occupational scores and household income. Success/failure outcome data was available on 269 subjects at 10 weeks and 237 subjects at 6 months post treatment discontinuation. As previously reported, [12] there was no difference in treatment success between the cohorts at 10 weeks (69%, combined treatment versus 58%, drug only, p=0.06) post randomization and 6 months (41%, both groups, p=0.75) post discontinuation of therapy. Treatment group was controlled for in subsequent analyses.

Logistic regression analysis of success at 10 weeks, controlling for whether the patient had behavioral therapy or not is presented in Table 2. The only variable significantly associated with the 10-week outcome was age. Older women were less likely to have a successful outcome at 10 weeks as compared to younger women (OR for each increase in 10 years of age 0.8, 95% CI 0.66, 0.96; p=0.02). At 6 months, controlling for treatment group and success at 10 weeks, POP-Q point Aa was the only variable significantly associated with success, where increasing positiveness of point Aa is associated with treatment success (OR 1.33, 95% CI 1.03, 1.7, P=0.03) (Table 3).

## Discussion

Younger women in this study were more likely to have a successful short-term outcome of drug therapy alone or combined with behavioral treatment for UUI. Women with poorer anterior wall support (POP-Q point Aa) were more likely to successfully discontinue medication and sustain treatment benefit. No other variables were identified that were associated with outcomes of active treatment or successful treatment discontinuation.

As is the case with many medical conditions, the finding that younger women are more likely to experience good outcomes is probably based on better underlying physiology. For example, Kenton et al reported that urethral sensation increases with age. [22] It is biologically plausible that this finding, coupled with the increased urethral afferent activity as described by Shafik et al [23] could lead to increased urethrovesical reflex which could be manifested in increased detrusor overactivity incontinence and urge incontinence in the older woman. Other changes in the lower urinary tract may disadvantage the mechanism of action of the drug itself, such that antimuscarinics would be less effective in the aging detrusor. For example, Yoshida et al reported that as the human detrusor ages, it becomes less sensitive to acetylcholine, but more sensitive to purinergic signaling in a linear fashion. [24]

Our finding that poorer vaginal support may predict successful outcomes 6 months after treatment discontinuation was unexpected. Previously, the existence of prolapse has been associated with irritative bladder symptoms, including UUI. Also, several studies have documented that prolapse repair to restore anterior vaginal support results in improved UUI symptoms. [25-28] It is possible that, in our study, participants with more prolapse had less chance of urine in the proximal urethra during physical activity than those with better supported anterior vaginal walls, due to a “kinking effect.” Less urine in the urethra could translate into decreased UUI symptoms, based on the theory that fluid loss through the urethra may trigger a urethrovesical reflex or detrusor overactivity. [29] Theoretically, because prolapse has also been associated with less stress urinary incontinence [30], the finding that poorer anterior vaginal support was associated with successful outcomes could be due to greater reduction in stress urinary incontinence episodes, specifically leading to greater overall reduction in total number of incontinence episodes on bladder diary. However, when we examined the association between point Aa and the stress index of the MESA questionnaire, there was no direct association.

Given the safety and satisfaction associated with non-surgical therapies for UUI, and the lack of strong predictors for treatment success, we recommend that these forms of therapy be considered as first line treatments women with UUI. While age and anterior wall support have some predictive value, these findings are not of sufficient strength to justify withholding conservative therapies. However, they might be used to promote realistic expectations when counseling patients with UUI.

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This trial is registered at Clinicaltrials.gov NCT00064662.

## Appendix A: Urinary Incontinence Treatment Network Members

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## Table 1
## Baseline Characteristics by Treatment Group

| | Overall (n=307) | Drug Alone (n=153) | Drug Plus Behavior (n=154) |
|---|---|---|---|
| **Demographic Characteristics** | | | |
| Age - Mean (SD) | 56.9 (13.9) | 58 (13.5) | 55.8 (14.2) |
| Race/ethnic group - N (%) | | | |
| Hispanic | 30 (10) | 17 (11) | 13 (8) |
| Non-Hispanic White | 190 (62) | 85 (56) | 105 (69) |
| Non-Hispanic Black | 57 (19) | 35 (23) | 22 (14) |
| Non-Hispanic other | 28 (9) | 15 (10) | 13 (8) |
| Education level - N (%) | | | |
| <= High school | 71 (23) | 31 (20) | 40 (26) |
| >High school | 236 (77) | 122 (80) | 114 (74) |
| Income - N (%) | | | |
| <$20,000 | 70 (25) | 38 (27) | 32 (23) |
| $20,000-49,999 | 104 (37) | 38 (27) | 66 (46) |
| $50,000-79,999 | 59 (21) | 38 (27) | 21 (15) |
| $80,000+ | 51 (18) | 28 (20) | 23 (16) |
| Occupational Score - Mean (SD) | 60.7 (24) | 64 (24.3) | 57.5 (23.3) |
| **Baseline Incontinence Characteristics** | | | |
| MESA stress score - Mean (SD) | 10.6 (6.2) | 10.3 (6) | 11 (6.3) |
| MESA urge score - Mean (SD) | 11.1 (3.4) | 10.8 (3.2) | 11.3 (3.5) |
| Number of Incontinence Episodes per week on Bladder Diary at Baseline -Mean (SD) | 3.7 (2.4) | 3.7 (2.4) | 3.7 (2.5) |
| IIQ scores - Mean (SD) | 153.6 (99.5) | 153 (99.9) | 154.2 (99.4) |
| OAB-q score - Mean (SD) | 61.7 (24.1) | 61.5 (24.3) | 62 (24) |
| Duration of Incontinence - Mean (SD) | 9.5 (9.9) | 9.1 (10.3) | 9.8 (9.5) |
| Prior treatment/surgery for incontinence - N (%) | | | |
| Yes | 123 (40) | 57 (37) | 66 (43) |
| No | 184 (60) | 96 (63) | 88 (57) |
| **Medical History and Physical** | | | |
| Self assessment of overall health (question B1) - N (%) | | | |
| Excellent | 37 (12) | 17 (11) | 20 (13) |
| Very good | 104 (34) | 52 (34) | 52 (34) |
| Good | 108 (35) | 53 (35) | 55 (36) |
| Fair[a] | 50 (16) | 27 (18) | 23 (15) |
| Poor[a] | 7 (2) | 3 (2) | 4 (3) |
| Fluid Intake (oz) - Mean (SD) | 65.6 (28.2) | 67.3 (27.9) | 64 (28.5) |
| Current estrogen use - N (%) | | | |

| | **Overall (n=307)** | **Drug Alone (n=153)** | **Drug Plus Behavior (n=154)** |
|---|---|---|---|
| Post-menopausal on HRT | 54 (18) | 27 (19) | 27 (17) |
| Post-menopausal not on HRT | 151 (49) | 79 (51) | 72 (47) |
| Pre-menopausal | 102 (33) | 47 (31) | 55 (36) |
| Diabetes - N (%) | | | |
| Yes | 39 (13) | 20 (13) | 19 (12) |
| No | 268 (87) | 133 (87) | 135 (83) |
| Body mass index - Mean (SD) | 32.7 (8.6) | 32.3 (7.6) | 33.2 (9.5) |
| POP-Q - N (%) | | | |
| 0/I | 193 (63) | 93 (61) | 100 (65) |
| II | 103 (34) | 52 (34) | 51 (33) |
| III/IV | 10 (3) | 8 (5) | 2 (1) |
| POPQ_AA - Mean (SD) | -1.9 (1.1) | -1.8 (1.1) | -2.0 (1.0) |
| POPQ_BA - Mean (SD) | -1.9 (1.1) | -1.8 (1.2) | -2.0 (1.0) |
| POPQ_Bp - Mean (SD) | -2.2 (1.0) | -2.2 (1.1) | -2.2(1.0) |
| POPQ_C – Mean (SD) | -7.0 (3.0) | -6.7 (3.4) | -7.2 (2.5) |
| Pelvic floor muscle strength (Brink's score) - Mean (SD) | 8.9 (1.7) | 8.9 (1.7) | 8.9 (1.7) |
| Fecal Incontinence | | | |
| Yes | 56 (18) | 30 (20) | 26 (17) |
| No | 251 (82) | 123 (80) | 128 (83) |
| **SF-12** | | | |
| PCS12 - Mean (SD) | 45 (11.3) | 44.5 (11.6) | 45.5 (11.1) |
| MCS12 – Mean (SD) | 48.3 (10.6) | 48.9 (10.4) | 47.7 (10.8) |
| **HUI2 - Overall** - Mean (SD) | 0.8 (0.2) | 0.8 (0.1) | 0.8 (0.2) |

[a]The “fair” and “poor” groups were combined for analysis due to the small sample size in the “poor” group.

## Table 2

**Association of potential predictors with initial success at 10 weeks controlling for treatment group**

| | Failure (N=94) | Success (N=175) | P-value * |
|---|---|---|---|
| **Demographic Characteristics** | | | |
| Age - Mean (SD) | 60.2 (13.3) | 55.9 (13.8) | **0.02** |
| Ethnicity - % | | | 0.67 |
| Hispanic | 8.5 | 8.6 | |
| Non-Hispanic Whites | 67.0 | 61.5 | |
| Non-Hispanic Blacks | 16.0 | 20.1 | |
| Other | 8.5 | 9.8 | |
| Education - % | | | 0.40 |
| 0:<=HS/GED | 20.2 | 25.7 | |
| 1:>HS | 79.8 | 74.3 | |
| Household Income - % | | | 0.86 |
| 1: <$20,000 | 24.7 | 23.9 | |
| 2: $20,000-$49,999 | 36.5 | 35.0 | |
| 3: $50,000-$79,999 | 23.5 | 22.1 | |
| 4: >=$80,000 | 15.3 | 19.0 | |
| Occupational Score - Mean (SD) | 61 (24.4) | 61.8 (23.5) | 0.61 |
| **Baseline Incontinence Characteristics** | | | |
| Mesa Urge Score - Mean (SD) | 10.9 (3.3) | 11.3 (3.5) | 0.38 |
| Mesa Stress Score - Mean (SD) | 11.2 (6) | 10.7 (6.1) | 0.46 |
| Number of Incontinence Episodes per week on Bladder Diary - Mean (SD) | 3.5 (2.1) | 3.8 (2.5) | 0.27 |
| IIQ scores - Mean (SD) | 152.1 (90.4) | 150.4 (102.3) | 0.89 |
| OAB-q score - Mean (SD) | 62.3 (22.2) | 62.2 (24.4) | 0.97 |
| Duration of Incontinence - Mean (SD) | 9.6 (8.9) | 9.9 (11) | 0.83 |
| Prior Treatment/Surgery for Incontinence - % | | | 0.32 |
| Yes | 36.2 | 43.4 | |
| No | 63.8 | 56.6 | |
| **Medical History and Physical Exam** | | | |
| Self assessment of Overall Health -% | | | 0.36 |
| 1: Excellent | 9.6 | 12.6 | |
| 2: Very Good | 36.1 | 34.8 | |
| 3: Good | 29.8 | 36.6 | |
| 4: Fair | 21.3 | 14.3 | |
| 5: Poor | 3.2 | 1.7 | |
| Fluid Intake - Mean (SD) | 62.9 (24.5) | 66.5 (29) | 0.24 |
| Current Estrogen Use - % | | | 0.18 |

| | **Failure (N=94)** | **Success (N=175)** | **P-value *** |
|---|---|---|---|
| Post-menopausal on HRT | 17.0 | 17.1 | |
| Post-menopausal not on HRT | 56.4 | 45.1 | |
| Pre-menopausal | 26.6 | 37.7 | |
| Diabetes - % | | | 0.43 |
| Yes | 14.9 | 11.4 | |
| No | 85.1 | 88.6 | |
| Body Mass Index - Mean (SD) | 32.9 (7.1) | 32.9 (9.1) | 0.96 |
| POP-Q scores (Stage) - % | | | 0.99 |
| Stage 0/I | 61.7 | 60.9 | |
| Stage II | 35.1 | 36.2 | |
| Stage III/IV | 3.2 | 2.9 | |
| POPQ_AA - - Mean (SD) | -1.9 (1.1) | -1.9 (1.1) | 0.79 |
| POPQ_BA - - Mean (SD) | -1.8 (1.2) | -1.9 (1.1) | 0.59 |
| POPQ_Bp - - Mean (SD) | -2.2 (1) | -2.1 (1.1) | 0.27 |
| POPQ_C - - Mean (SD) | -6.7 (3) | -7.1 (2.8) | 0.32 |
| Pelvic floor muscle strength (Brinks) | 8.7 (1.8) | 8.9 (1.7) | 0.31 |
| Fecal Incontinence - % | | | 0.53 |
| Yes | 18.1 | 21.1 | |
| No | 81.9 | 78.9 | |
| **SF-12** | | | |
| PCS12 - Mean (SD) | 44.4 (12.5) | 45.1 (10.7) | 0.72 |
| MCS12 - Mean (SD) | 49.2 (9.7) | 48.3 (10.8) | 0.55 |
| **HUI2 Overall** - Mean (SD) | 0.8 (0.1) | 0.8 (0.2) | 0.62 |

Note: P-values are from logistic regression models including each covariate separately controlling for treatment group

## Table 3

**Odds ratios (ORs) with 95% confidence intervals and p-values predicting the probability of "success" at 6 months after discontinuation of active treatment**

| | OR (95% CI) | p-value |
|---|---|---|
| **Demographic characteristics** | | |
| Age (per 10 years) | 0.85 (0.7, 1.04) | 0.12 |
| Ethnicity | | 0.95 |
| Non-Hispanic Whites | Reference | |
| Non-Hispanic Blacks | 1.06 (0.5, 2.25) | |
| Hispanic | 0.74 (0.26, 2.1) | |
| Other | 0.95 (0.32, 2.8) | |
| Education | | 0.83 |
| 0:<=HS/GED | Reference | |
| 1:>HS | 1.07 (0.56, 2.06) | |
| Household Income | | 0.74 |
| 1: <$20,000 | Reference | |
| 2: $20,000-$49,999 | 1.1 (0.52, 2.33) | |
| 3: $50,000-$79,999 | 0.71 (0.29, 1.77) | |
| 4: >=$80,000 | 1.17 (0.48, 2.87) | |
| Occupational Score (per 10 units) | 1.01 (0.9, 1.14) | 0.84 |
| **Baseline Incontinence Characteristics** | | |
| Mesa Urge Score | 1.02 (0.94, 1.11) | 0.56 |
| Mesa Stress Score | 1.01 (0.97, 1.06) | 0.61 |
| Number of Incontinence Episodes on Bladder Diary | 0.98 (0.87, 1.1) | 0.72 |
| IIQ scores (per 10 units) | 0.997 (0.97, 1.03) | 0.85 |
| OAB-q score | 1.002 (0.99, 1.01) | 0.77 |
| Duration of Incontinence | 0.999 (0.97, 1.03) | 0.92 |
| Prior Treatment/Surgery for Incontinence (%) | | 0.16 |
| Yes | 0.66 (0.37, 1.17) | |
| No | Reference | |
| **Medical History and Physical** | | |
| Self assessment of Overall Health | | 0.08 |
| 1: Excellent | 0.49 (0.14, 1.63) | |
| 2: Very Good | 1.74 (0.78, 3.92) | |
| 3: Good | 0.96 (0.42, 2.23) | |
| 4: Fair/poor | Reference | |
| Fluid Intake | 0.99 (0.98, 1) | 0.17 |
| Current Estrogen Use | | 0.13 |
| 1: Post-menopausal on HRT | 1.53 (0.68, 3.46) | |
| 2: Post-menopausal not on HRT | 0.7 (0.37, 1.32) | |

| | **OR (95% CI)** | **p-value** |
|---|---|---|
| 3: Pre-menopausal | Reference | |
| Diabetes (%) | | 0.33 |
| Yes | 0.63 (0.25, 1.59) | |
| No | Reference | |
| Body Mass Index | 0.99 (0.96, 1.02) | 0.51 |
| POP-Q scores (Stage) | | 0.57 |
| Stage 0/I | 3.24 (0.36, 28.87) | |
| Stage II | 3.23 (0.36, 29.36) | |
| Stage III/IV | Reference | |
| POPQ _AA | 1.33 (1.03, 1.7) | **0.03** |
| POPQ BA | 1.25 (0.99, 1.59) | 0.06 |
| POPQ_Bp | 0.95 (0.73, 1.24) | 0.73 |
| POPQ C | 0.98 (0.88, 1.08) | 0.64 |
| Pelvic floor muscle strength (Brinks) | 0.97 (0.82, 1.15) | 0.73 |
| Fecal Incontinence | | |
| Yes | 0.79 (0.39, 1.59) | 0.50 |
| No | Reference | |
| **SF-12** | | |
| PCS12 | 1.02 (0.99, 1.04) | 0.18 |
| MCS12 | 0.99 (0.96, 1.02) | 0.48 |
| **HUI2 Overall** | 2.9 (0.4, 21.24) | 0.30 |

Note: * P-values, OR's and 95% CI's are from logistic regression models including each covariate separately controlling for treatment group and treatment outcome at 10 week