GYNECOLOGY

# Natural history of lower urinary tract symptoms in treatment-seeking women with pelvic organ prolapse; the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN)

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**BACKGROUND:** The association of pelvic organ prolapse with overactive bladder and other lower urinary tract symptoms, and the natural history of those symptoms are not well characterized. Previous cross-sectional studies demonstrated conflicting relationships between prolapse and lower urinary tract symptoms.

**OBJECTIVE:** This study primarily aimed to determine the baseline association between lower urinary tract symptoms and prolapse and to assess longitudinal differences in symptoms over 12 months in women with and without prolapse. Secondary aims were to explore associations between lower urinary tract symptoms and prolapse treatment. We hypothesized that: (1) prolapse is associated with the presence of lower urinary tract symptoms, (2) lower urinary tract symptoms are stable over time in patients with and without prolapse, and (3) prolapse treatment is associated with lower urinary tract symptom improvement.

**STUDY DESIGN:** Women enrolled in the Symptoms of Lower Urinary Tract Dysfunction Research Network Observational Cohort Study with adequate 12-month follow-up data were included. Prolapse and lower urinary tract symptom treatment during follow-up was guided by standard of care. Outcome measures included the Lower Urinary Tract Symptoms Tool total severity score (in addition to overactive bladder, obstructive, and stress urinary incontinence subscales) and Urogenital Distress Inventory-6 Short Form. Prolapse (yes or no) was defined primarily when Pelvic Organ Prolapse Quantification System points Ba, C or Bp were >0 (beyond the hymen). Mixed-effects models with random effects for patient slopes and intercepts were fitted for each lower urinary tract symptom outcome and prolapse predictor, adjusted for other covariates. The study had >90% power to detect differences as small as 0.4 standard deviation for less prevalent group comparisons (eg, prolapse vs not).

**RESULTS:** A total of 371 women were analyzed, including 313 (84%) with no prolapse and 58 (16%) with prolapse. Women with prolapse were older (64.6±8.8 vs 55.3±14.1 years; $P<.001$) and more likely to have prolapse surgery (28% vs 1%; $P<.001$) and pessary treatment (26% vs 4%; $P<.001$) during the study. Average baseline Lower Urinary Tract Symptoms Tool total severity scores were lower (fewer symptoms) for participants with prolapse compared with those without (38.9±14.0 vs 43.2±14.0; $P=.036$), but there were no differences in average scores between prolapse groups for other scales.

For all urinary outcomes, average scores were significantly lower (improved) at 3 and 12 months compared with baseline (all $P<.05$). In mixed-effects models, there were no statistically significant interactions between pelvic organ prolapse measurement and visit and time-dependent prolapse treatment groups ($P>.05$ for all regression interaction coefficients). The Lower Urinary Tract Symptoms Tool obstructive severity score had a statistically significant positive association with Pelvic Organ Prolapse Quantification System Ba, Bp, and point of maximum vaginal descent. The Lower Urinary Tract Symptoms Tool total severity scale had a statistically significant negative association with Pelvic Organ Prolapse Quantification System Ba and point of maximum vaginal descent. No other associations between prolapse and lower urinary tract symptoms were significant ($P>.05$ for all regression coefficients). Symptom differences between prolapse groups were small: all regression coefficients (interpretable as additive percentage change in each score) were between -5 and 5 (standard deviation of outcomes ranged from 14.0—32.4).

**CONCLUSION:** Among treatment-seeking women with urinary symptoms, obstructive symptoms were positively associated with prolapse, and overall lower urinary tract symptom severity was negatively associated with prolapse. Lower Urinary Tract Symptoms Tool scores improved over 12 months regardless of prolapse status, including in those with treated prolapse, untreated prolapse, and without prolapse.

**Key words:** cohort study, Lower Urinary Tract Dysfunction Research Network (LURN), lower urinary tract symptoms, natural history, overactive bladder, pelvic organ prolapse

**Cite this article as:** Kowalski JT, Wiseman JB, Smith AR, et al. Natural history of lower urinary tract symptoms in treatment-seeking women with pelvic organ prolapse; the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN). Am J Obstet Gynecol 2022;227:875.e1-12.

0002-9378/$36.00
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https://doi.org/10.1016/j.ajog.2022.07.038

## Introduction

The association of pelvic organ prolapse (POP) with overactive bladder (OAB) and other lower urinary tract symptoms (LUTS), and the natural history of those symptoms are not well characterized. Results from cross-sectional studies are variable. A review published in 2010 identified 4 studies that all concluded that women with POP had a higher prevalence of OAB symptoms than women without POP.[1] Another survey-based study from 2011 found POP to be an independent risk factor for symptomatic OAB.[2] Similarly, Yuan et al[3] found that increasing anterior vaginal wall descent may be related to increasing OAB severity. Conversely, Schimpf et al[4] reported that urgency

## AJOG at a Glance

### Why was this study conducted?

The association of pelvic organ prolapse with overactive bladder and other lower urinary tract symptoms (LUTS), and the natural history of those symptoms in treated patients are not well characterized.

### Key findings

In a multicenter cohort of women with bothersome LUTS, obstructive voiding symptom severity was positively associated with prolapse, whereas overall LUTS severity was negatively associated with prolapse (at all time points). LUTS improved at 3- and 12- month follow-up, regardless of prolapse or prolapse treatment (improvement did not differ in patients with treated prolapse, untreated prolapse, and no prolapse).

### What does this add to what is known?

Among treatment-seeking women, obstructive voiding symptoms were most clearly associated with prolapse. All LUTS (including overactive bladder and stress urinary incontinence) improved over 12 months regardless of the presence of prolapse or prolapse treatment. These results should be considered by clinicians counseling patients about likely outcomes of prolapse treatment.

incontinence and voiding dysfunction were not more common in women with stage ≥2 POP compared with women with POP, stage 0 to 1. A cross-sectional study of 270 women enrolled in the Women's Health Initiative (WHI) trial with and without POP found that obstructive urinary symptoms, but not stress urinary incontinence (SUI) or OAB, were associated with vaginal wall descensus.[5]

Whether LUTS are associated with POP change over time (particularly in untreated women) has been poorly studied to date. Bradley et al[6] followed up 270 women enrolled in the WHI trial annually with symptom questionnaires and POP Quantification System (POP-Q) exams, and found in multivariable longitudinal models that increasing vaginal descent over time was associated with increased painful and obstructive urinary symptoms. Increasing vaginal descent over time was not associated with changes in SUI, urgency incontinence, or other OAB symptoms.

Last, several groups have also examined the effect of POP surgery on OAB symptoms. One 2007 study limited to women aged ≥65 years with stage 3 to 4 POP found a reduction in OAB symptoms following vaginal prolapse surgery.[7] Another 2013 study found that women with stage 3 to 4 POP were less likely than women with stage 1 to 2 POP to experience improvement in OAB symptoms following POP surgery,[8] but a similar study found significant improvement in OAB symptoms following POP surgery and no difference according to baseline severity of POP.[9] A systematic review published as part of the Fifth International Consultation on Incontinence in 2013 determined that bladder overactivity may resolve in 40% of patients undergoing POP surgery and that de novo overactivity occurs in 12%.[10]

The Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) was established in 2012 and completed a 1-year observational cohort study to increase our understanding of LUTS by identifying important subtypes of patients with LUTS.[11,12] Women with POP and LUTS represent a distinct subtype of patients with LUTS who have been well-characterized in this cohort study. To our knowledge, no studies have reported on the natural history of LUTS in women with POP compared with women without POP. This information would contribute additional insight for a better understanding of the associations between these common conditions in women.

The primary aims of this analysis, performed in treatment-seeking women with bothersome urinary symptoms, were to: (1) determine the baseline association between LUTS and POP, and (2) to assess longitudinal differences in LUTS over a 12-month period in women with and without POP. The secondary aim was to explore the association between LUTS and POP treatment. We hypothesized that: (1) POP is associated with the presence of LUTS, (2) LUTS are stable over time in patients with and without POP, and (3) POP treatment is associated with improvement in LUTS.

## Materials and Methods

The LURN Observational Cohort Study was a National Institutes of Health–funded multicenter study enrolling patients seeking treatment for LUTS at 6 clinical sites across the United States. Study methods have been previously described.[13] Men and women aged >18 years presenting to a LURN clinician with at least 1 LUTS as reported on the LUTS Tool[14] were enrolled. Patients were not required to be treatment-naive at enrollment. Medical history, self-reported LUTS, physical exam findings (including a POP-Q[15] and pelvic floor muscle strength assessment using the Oxford Scale[16]), and patient-reported outcomes (PROs) reporting on bowel functioning, psychological health, urologic pain, pelvic floor, and sexual function were collected at the baseline visit. PROs and treatment history (surgeries, medications, behavioral or physical therapies) were also assessed at 3- and 12-month clinic visits. Participants were treated by their physicians according to standard care practices. A negative urine culture was required before inclusion in the study.

The primary outcomes were self-reported LUTS using the LUTS Tool[14] and the Urogenital Distress Inventory-6 Short Form (UDI-6).[17] The LUTS Tool is a 44-item questionnaire assessing the severity and bother of 22 urinary symptoms (Appendix). An overall LUTS Tool severity score, used to show the total LUTS severity, was calculated as the Euclidean length of all LUTS Tool

severity questions and weighted by correlations between baseline LUTS Tool responses to account for redundancy between questions.[18] In addition to the LUTS Tool severity score, 3 urinary symptom subscales (OAB, obstructive, SUI) were defined for this analysis (definitions included in Appendix). The overall LUTS Tool severity score and the 3 subscales were normalized by their maximum value and scaled from 0 to 100 so that the scales can be interpreted on a percentage scale, with 0 being least severe (no symptoms) and 100 being most severe (most severe rating for all 22 symptoms). The UDI-6 assesses symptom bother for 6 urinary symptoms and ranges from 0 to 100, with higher scores indicating higher levels of urinary symptom bother.[17] All questionnaires were completed directly by the patient.

The primary exposure of interest was POP. Each outcome measure was evaluated using 6 different measures of the POP-Q exam, to assess the impact of overall, anterior-predominant, and posterior-predominant POP.[15] Both continuous and dichotomous POP measures were studied; dichotomous POP definitions identified POP as present if the POP-Q point of interest descended beyond the hymen (>0) because this "cut-point" for POP is most consistently associated with vaginal bulge symptoms.[19] The 6 measures were: (1) maximum vaginal descent (MVD; greatest value of Ba, C, or Bp) dichotomous (POP if MVD >0), (2) MVD continuous, (3) Ba dichotomous (POP if Ba >0), (4) Ba continuous, (5) Bp dichotomous (POP if Bp >0), and (6) Bp continuous. The first definition of POP (MVD >0) was used as the primary definition for prolapse (vs no prolapse) throughout the study.

The POP-Q exam was performed by the enrolling physician. POP-Q data for the cohort were independently examined by 2 investigators (J.T.K. and C.S.B.) using a priori established quality rules. Inconsistent or implausible POP-Q data points were flagged by each reviewer. The 2 reviewers met to review all flagged data and adjudicate whether the subject should be included. If the reviewers could not come to an agreement, the participant was reviewed by all clinicians participating in this study to arrive at a final decision.

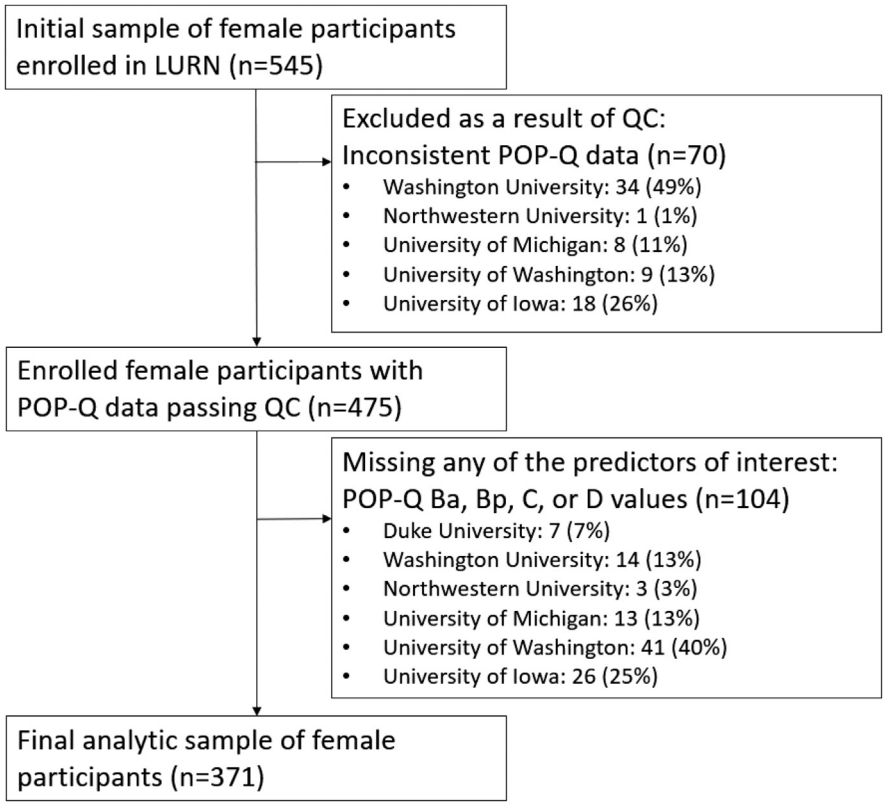
Unadjusted comparisons of demographics and clinical characteristics for dichotomous MVD groups were made using chi-square and Wilcoxon rank-sum tests. Mixed-effect models with random effects for patient slopes and intercepts were used to determine associations between each LUTS outcome and POP predictor of interest. The best-subsets method was used to determine which of the following covariates were associated with each outcome and included in each final model as fixed-effect predictors: age, race, ethnicity, body mass index, the functional comorbidity index, smoking status, diabetes mellitus, hysterectomy, postvoid residual, and LUTS treatment. Specific treatments assessed as potential covariates were prolapse surgery, placement of a sling, pessary, pelvic floor physical therapy, Kegel exercises, OAB medication, neuromodulation, and onabotulinumtoxinA injection. Time-dependent prolapse treatment groups were also created for the 3- and 12-month visits. Participants who received a pessary or had prolapse surgery between their baseline and 3-month visits were grouped as treated for prolapse at their 3- and 12-month visits, and otherwise grouped as untreated for the 3-month visit. Participants were grouped similarly at the 12-month visit. Interactions between visits and the exposure of interest were explored to assess temporal differences in associations between the outcomes and predictors. Interactions between the exposure of interest and time-dependent prolapse treatment groups were also tested to assess the moderating effect of prolapse treatment used throughout the study on the associations between outcomes and predictors. The study was designed to achieve >90% statistical power to detect differences as small as 0.4 standard deviations in the continuous outcomes (LUTS PRO scores) for less prevalent group comparisons such as those with vs without prolapse.[13] All analyses were performed using SAS software, version 9.4 (SAS Institute Inc, Cary, NC). Statistical significance was defined as $P<.05$.

## Results

Of the 545 female participants enrolled in the LURN Observational Cohort Study, 371 had complete POP-Q data following a quality control review (Figure 1). The excluded participants were similar to included participants in all characteristics except in body mass index, prevalence of diabetes mellitus, and function comorbidity index, which were all slightly higher in those who were excluded (data not shown). Among the 371 included females, 313 (84%) had no prolapse (ie, MVD ≤0) and 58 (16%) had prolapse (MVD >0). Participant characteristics (overall and for those with and without prolapse) are presented in Table. Participants with prolapse were older than those without prolapse (64.6±8.8 vs 55.3±14.1 years; $P<.001$), were more likely to be White than non-White (93% vs 79%; $P=.021$), and were more likely to be married or in a civil union (74% vs 55%; $P=.010$). Participants with prolapse had more prolapse surgery before the study (24% vs 2%; $P<.001$) and during the study (28% vs 1%; $P<.001$), more pessary use during the study (26% vs 4%; $P<.001$), and a higher postvoid residual (60.4±68.3 vs 38.3±45.0 mL; $P=.008$) at study initiation. Compared with those without prolapse, participants with prolapse had higher average POP-Q Ba (1.1 vs −2.0 cm; $P<.001$), POP-Q C (−2.8 vs −6.9 cm; $P<.001$), POP-Q GH (3.6 vs 2.7 cm; $P<.001$), POP-Q Bp (−0.3 vs −2.3 cm; $P<.001$), and POP-Q D (−5.2 vs −8.4 cm; $P<.001$) measurements. POP-Q metrics are presented in Supplemental Table 1 for all participants and in the Supplemental Figure by prolapse group.

Distributions of LUTS Tool and UDI-6 scores at each visit by MVD prolapse and prolapse treatment group are shown in Figure 2. For all scales, average scores were significantly lower (improved) at 3- and 12-month visits compared with the baseline visit (unadjusted for other covariates; all $P<.05$), but there was no statistically significant difference between average scores at 3- and 12-month

**FIGURE 1**
**STROBE diagram showing participant flow for this analysis**




Flow chart begins in topmost rectangle with total female participants consented, shows number of participants excluded because of quality control checks and missing data, and ends with the analyzable sample used in the bottommost rectangle.

*LURN*, Symptoms of Lower Urinary Tract Dysfunction Research Network; *POP-Q*, Pelvic Organ Prolapse Quantification System; *QC*, quality control; *STROBE*, Strengthening the Reporting of Observational Studies in Epidemiology.

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visits (*P* value range, 0.17−1.0). At baseline, average LUTS Tool total severity scores were lower (fewer symptoms) for participants with POP (MVD >0) compared with those without (38.9±14.0 vs 43.2±14.0; *P*=.036), but there were no differences in average scores between prolapse groups for other scales. There were no differences in average scores between prolapse groups for any of the scales at 3- and 12-month visits.

Mixed-effects model coefficients for each pair of outcomes and exposure of interest are presented in Figure 3 and Supplemental Table 2. In every model, there was no statistically significant interaction between the POP measure and visit (*P*>.05 for all regression coefficients for interactions between visit and POP measure in any of the performed regressions). There were also no statistically significant interactions between the POP measure and prolapse treatment groups. Therefore, only the average effect across all visits and treatments is presented in tables and figures. For the LUTS Tool obstructive severity score, there was a statistically significant positive association with POP-Q Ba (regression coefficient per cm increase=0.85; 95% confidence interval [CI], 0.00−1.70), POP-Q MVD (regression coefficient per cm increase=0.98; 95% CI, 0.15−1.81), and POP-Q Bp (regression coefficient per cm increase=1.13; 95% CI, 0.10−2.15) measurements. For the LUTS Tool total severity scale, there was a statistically significant negative association with POP-Q Ba prolapse group (regression coefficient=−3.70 for Ba prolapse vs not; 95% CI, −7.27 to −0.14) and POP-Q MVD prolapse group (regression coefficient=−3.75 for MVD prolapse vs not; 95% CI, −6.79 to −0.72). No other associations between POP and LUTS were statistically significant (ie, *P*>.05 for all regression coefficients for predictors of interest). Although trends were suggested (Figure 3) toward reduced OAB and SUI symptoms in participants with prolapse, particularly anterior-predominant prolapse, these associations did not meet statistical significance. All regression coefficients were between -6 and 5 (standard deviations of outcomes ranged from 14.0−32.4). These coefficients can be interpreted as changes on a percentage scale because scores were weighted on a scale of 0 to 100.

## Comment

### Principal findings

In this multicenter prospective cohort study of treatment-seeking women with at least 1 urinary symptom, prolapse was associated with more severe obstructive LUTS but less severe overall LUTS. Prolapse presence and severity were not clearly associated with OAB or SUI. LUTS Tool scores improved over 12 months regardless of prolapse status. Similar improvements in LUTS were observed in patients with treated prolapse, untreated prolapse, and without prolapse.

### Results in the context of what is known

Overall, our results demonstrated a potential association between increasing prolapse in all compartments and obstructive LUTS. Patients with more anterior vaginal prolapse and overall prolapse also had lower total LUTS Tool severity scores, indicating fewer nonobstructive LUTS in patients with prolapse. Although symptom differences associated with increasing or decreasing prolapse measures in this study were small, the results were statistically significant after adjusting for other clinical factors, and were consistent across several definitions and measures of POP.

TABLE
**Participant baseline demographics and clinical characteristics**

| Participant characteristic | Total (n=371) | No prolapse (MVD ≤0, n=313) | Prolapse (POP MVD >0, n=58) | *P* value |
|---|---|---|---|---|
| Age | 56.8 (13.8) | 55.3 (14.1) | 64.6 (8.8) | <.001 |
| Race | | | | .021 |
| African-American | 46 (12) | 45 (14) | 1 (2) | |
| White | 301 (81) | 247 (79) | 54 (93) | |
| Multiracial/other | 24 (6) | 21 (7) | 3 (5) | |
| Hispanic/Latino | 13 (4) | 9 (3) | 4 (7) | .183 |
| Marital status | | | | .010 |
| Married/civil union | 216 (58) | 173 (55) | 43 (74) | |
| Living with a partner | 9 (2) | 7 (2) | 2 (3) | |
| Separated or divorced | 60 (16) | 50 (16) | 10 (17) | |
| Widowed | 26 (7) | 24 (8) | 2 (3) | |
| Single, never married | 59 (16) | 58 (19) | 1 (2) | |
| Education | | | | .469 |
| Less than HS diploma/GED | 6 (2) | 6 (2) | 0 (0) | |
| HS diploma/GED | 32 (9) | 28 (9) | 4 (7) | |
| Some college or tech school, no degree | 89 (24) | 71 (23) | 18 (31) | |
| Associate's degree | 43 (12) | 35 (11) | 8 (14) | |
| Bachelor's degree | 109 (29) | 97 (31) | 12 (21) | |
| Graduate degree | 88 (24) | 72 (23) | 16 (28) | |
| Employment status | | | | .177 |
| Employed part-time | 53 (14) | 43 (14) | 10 (17) | |
| Employed full-time | 152 (41) | 136 (43) | 16 (28) | |
| Unemployed (looking for work) | 10 (3) | 9 (3) | 1 (2) | |
| Not employed (not looking for work, includes stay-at-home, retired) | 153 (41) | 122 (39) | 31 (53) | |
| Body mass index | 29.9 (7.5) | 30.2 (7.7) | 28.5 (6.3) | .126 |
| Body mass index categories | | | | .137 |
| <25 | 109 (29) | 90 (29) | 19 (33) | |
| 25 to <30 | 103 (28) | 82 (26) | 21 (36) | |
| 30 to <35 | 82 (22) | 70 (22) | 12 (21) | |
| ≥35 | 76 (20) | 70 (22) | 6 (10) | |
| Current or former smoker (% yes) | 121 (33) | 101 (33) | 20 (34) | .702 |
| Diabetes mellitus (% yes) | 44 (12) | 39 (12) | 5 (9) | .406 |
| Number of pregnancies | 2.7 (4.4) | 2.7 (4.8) | 2.9 (1.5) | .033 |
| Number of vaginal deliveries | 1.8 (1.4) | 1.6 (1.4) | 2.5 (1.0) | <.001 |
| Hysterectomy (% yes) | 109 (29) | 94 (30) | 15 (26) | .522 |
| Previous prolapse surgery (% yes) | 20 (5) | 6 (2) | 14 (24) | <.001 |
| Previous pessary (% yes) | 51 (14) | 40 (13) | 11 (19) | .209 |
| Prolapse surgery during study (% yes) | 21 (6) | 4 (1) | 17 (29) | <.001 |

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(continued)

**TABLE**
**Participant baseline demographics and clinical characteristics** *(continued)*

| Participant characteristic | Total (n=371) | No prolapse (MVD ≤0, n=313) | Prolapse (POP MVD >0, n=58) | *P* value |
|---|---|---|---|---|
| Pessary during study (% yes) | 30 (8) | 15 (5) | 15 (26) | <.001 |
| Sling placement during study (% yes) | 45 (12) | 35 (11) | 10 (17) | .194 |
| Pelvic floor physical therapy during study (% yes) | 125 (34) | 107 (34) | 18 (31) | .641 |
| Kegel exercises during study (% yes) | 149 (40) | 123 (39) | 26 (45) | .430 |
| Pelvic floor physical therapy or Kegel exercises during study (% yes) | 198 (53) | 168 (54) | 30 (52) | .785 |
| OAB medication during study (% yes) | 87 (23) | 80 (26) | 7 (12) | .026 |
| Neuromodulation during study (% yes) | 8 (2) | 8 (3) | 0 (0) | .218 |
| OnabotulinumtoxinA during study (% yes) | 10 (3) | 10 (3) | 0 (0) | .168 |
| None of the above treatments during study (% yes) | 90 (24) | 82 (26) | 8 (14) | .043 |
| Functional comorbidity index | 2.3 (2.0) | 2.3 (2.1) | 2.1 (1.4) | .988 |
| PVR (mL) | 41.8 (50.0) | 38.3 (45.0) | 60.4 (68.3) | .008 |
| Pelvic floor muscle strength (Oxford Scale) | | | | .227 |
| Grade 0 | 34 (9) | 28 (9) | 6 (10) | |
| Grade 1 | 69 (19) | 58 (19) | 11 (19) | |
| Grade 2 | 75 (20) | 59 (19) | 16 (28) | |
| Grade 3 | 56 (15) | 48 (15) | 8 (14) | |
| Grade 4 | 44 (12) | 40 (13) | 4 (7) | |
| Grade 5 | 18 (5) | 18 (6) | 0 (0) | |
| POP-Q overall stage | | | | <.001 |
| Stage 0 | 76 (20) | 76 (24) | 0 (0) | |
| Stage 1 | 125 (34) | 125 (40) | 0 (0) | |
| Stage 2 | 138 (37) | 112 (36) | 26 (45) | |
| Stage 3 | 31 (8) | 0 (0) | 31 (53) | |
| Stage 4 | 1 (0) | 0 (0) | 1 (2) | |

Total and by prolapse group; all participants with nonmissing POP-Q overall stage and Ba, Bp, C, and D measurements, n=371. The MVD was used to group participants as having no prolapse (MVD≤0, not beyond the hymen) or prolapse (MVD>0, beyond the hymen). Missingness was ≤1% for all variables except pelvic floor muscle strength (Oxford Scale, 20% missingness).

*GED*, General Educational Development Test; *HS*, high school; *MVD*, maximal vaginal descent; *OAB*, overactive bladder; *POP-Q*, Pelvic Organ Prolapse Quantification System; *PVR*, postvoid residual.

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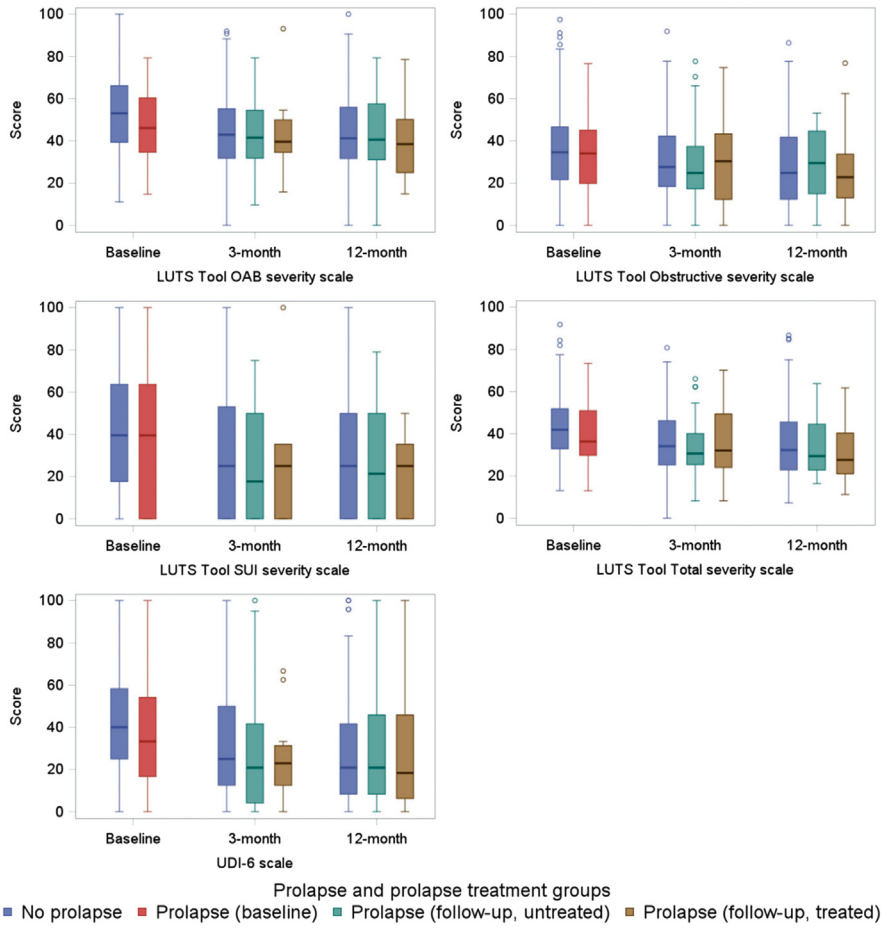
We observed no significant relationship between OAB or SUI and POP. However, results suggested a trend toward fewer OAB and SUI symptoms in patients presenting with LUTS who had prolapse, especially when only considering anterior vaginal wall prolapse. These results demonstrate some similarity to a cross-sectional study by Schimpf et al[4] evaluating the association between anterior vaginal wall prolapse and LUTS. They found that stage ≥2 anterior vaginal wall prolapse was not associated with urgency incontinence or voiding dysfunction but that women without POP were more likely to report SUI. Similarly, in a cross-sectional study of women enrolled in the WHI, Bradley et al[5] found prolapse to be associated with obstructive voiding symptoms but not OAB symptoms.

In contrast, other studies have demonstrated an association between POP and OAB symptoms.[1,20,21] For example, Digesu et al[21] found that urinary urgency and frequency were significantly associated with the presence of prolapse symptoms. However, the population in this study comprised women presenting for care in outpatient general gynecology clinics, very different from the population of women seeking care for LUTS in this study. Furthermore, although that study determined that women with symptomatic prolapse had more OAB symptoms than community-dwelling women with prolapse symptoms, increasing severity of prolapse was not correlated with those symptoms. The need to strain and the feeling of incomplete emptying were the only

FIGURE 2
**Boxplot distributions of LUTS Tool and UDI-6 scales**




Distributions by prolapse group over time and paneled by scale. Within each box, the horizontal line represents the median and the circle represents the mean. *Lines* at the bottom and top of each box represent the 25th and 75th percentiles, respectively. The *whiskers* at the bottom and top of each plot extend to observations closest to 1.5 times the IQR, and *dots* represent observations outside of this range. *Blue* boxplots indicate distributions for participants with no prolapse, *red boxes* indicate participants with prolapse at baseline, *green boxes* indicate participants with untreated prolapse at follow-up, and *brown boxes* indicate participants with treated prolapse at follow-up. Prolapse was defined as present if the point of MVD was beyond the hymen based on Pelvic Organ Prolapse Quantification exam. Prolapse treatment included pessary use and/or surgery.

*IQR*, interquartile range; *LUTS*, lower urinary tract symptom; *MVD*, maximum vaginal descent; *OAB*, overactive bladder; *POP*, pelvic organ prolapse; *SUI*, stress urinary incontinence; *UDI-6*, Urogenital Distress Inventory-6 Short Form.

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urinary symptoms significantly correlated with increasing POP.[21]

Finding increased obstructive LUTS with increasing POP may make physiological sense. Postvoid residual was significantly higher in the POP group in this cohort, and this is consistent with previous research.[21,22] Obstructive LUTS logically may be associated with decreased ability to completely empty the bladder as the bladder descends inferior to the pubic symphysis. In addition, this same phenomenon may lead to a concomitant decrease in other LUTS, such as SUI, resulting in lower overall severity scores.[23]

## Clinical implications

Our findings are most applicable to patients presenting for treatment to tertiary-care urology or urogynecology clinics. In this population, patients with POP may be no more likely to have bothersome LUTS than patients without POP. Patients presenting with LUTS, regardless of the presence of POP, can also be reassured that their symptoms are likely to improve over the course of 3 to 12 months of follow-up and treatment. The underlying cause for this decrease in symptoms cannot be determined by this study. However, this was a treatment-seeking cohort. Thus, this improvement may be evidence that LUTS treatment is effective. In addition, at a minimum, this cohort had 3 visits with a healthcare provider regarding their LUTS over the study period and completed numerous questionnaires about their LUTS. Completing frequent questionnaires may have had a therapeutic benefit. Alternatively, this may represent observational bias.

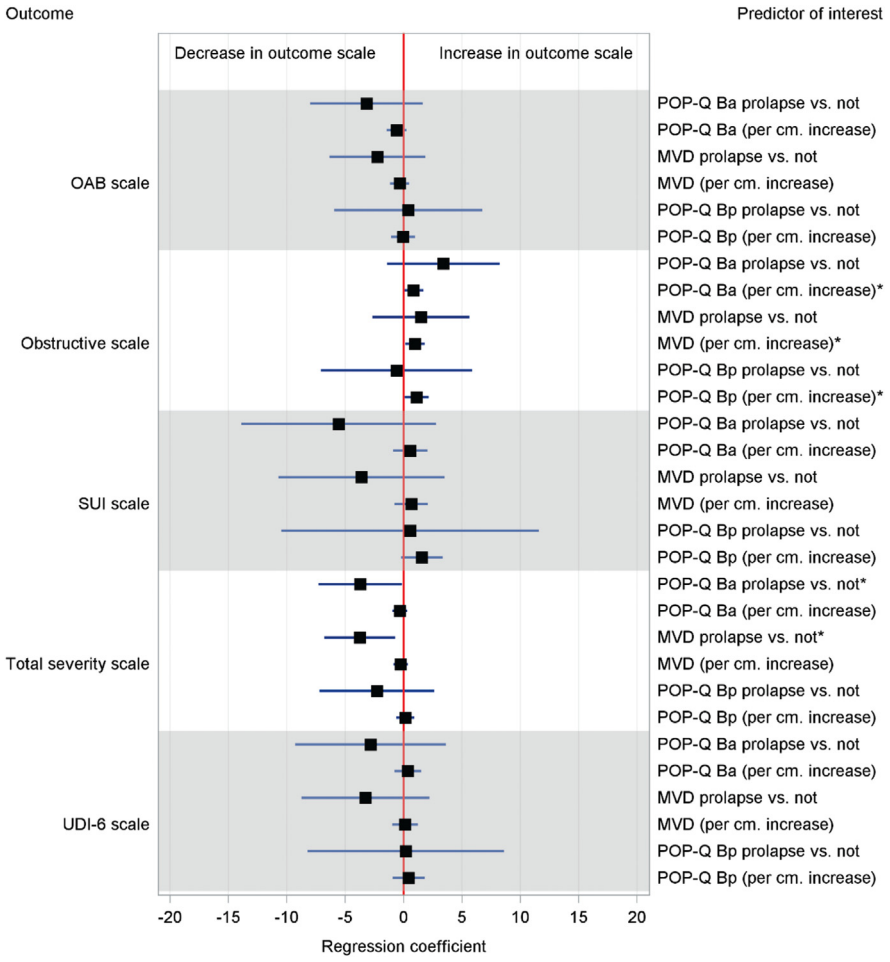
## Research implications

Given that we observed improvement in LUTS in subjects with and without prolapse, LUTS-specific treatment may be as effective in women with POP as in those without POP. Although some of the improvement in LUTS in the POP group may be attributable to POP surgery or pessary use, this is not certain. Even women meeting our definitions of POP who did not have POP treatment showed improvement in LUTS during follow-up. Thus, women seeking treatment specifically for LUTS and not bothersome POP may be as likely to have improvement in their LUTS even if their POP goes untreated. Future research needs to better define: (1) which women with POP will have improvement in OAB symptoms and other LUTS with POP treatment, (2) which women with POP will require additional OAB or LUTS treatment even after POP treatment, and (3) which women with POP could have improvement in OAB or LUTS symptoms without POP treatment.

## Strengths and limitations

The primary strength of this study is that subjects were well characterized with a detailed demographic and medical history, validated questionnaires, and physical exams with POP-Q exams. The

**FIGURE 3**
**Forest plot of associations between LUTS scores and prolapse predictors**




Presented as mixed-effects model regression coefficients. For each prolapse predictor shown on the right y-axis, the mixed-effects model coefficient is shown (ie, the estimated average change in the LUTS scale score shown on the left y-axis, per unit change or between prolapse groups). LUTS Tool scales were normalized by the maximum value and scaled from 0 (least severe) to 100 (most severe) so that regression coefficients represent additive changes on a percentage scale. In every model, there was no statistically significant interaction between prolapse measure and visit, thus the average effect across all visits is presented. The *blue horizontal lines* represent 95% confidence intervals for each estimate, with any *blue horizontal line* not crossing the vertical reference line at 0 representing statistical significance at the 0.05 level. Prolapse was identified as present for dichotomous definitions if the POP-Q exam vaginal point specified was beyond the hymen. Models included clinical covariates identified using the best-subsets method for each outcome from the following: age, body mass index, comorbidity index, smoking status, diabetes mellitus, hysterectomy, baseline LUTS scale score, and LUTS treatment. The *asterisk* denotes statistically significant at 0.05 level.

*LUTS*, lower urinary tract symptom; *MVD*, maximum vaginal descent; *OAB*, overactive bladder; *POP-Q*, Pelvic Organ Prolapse Quantification System; *SUI*, stress urinary incontinence; *UDI-6*, Urogenital Distress Inventory-6 Short Form.

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POP-Q data underwent careful quality control review before analysis. Subjects also came from geographically diverse tertiary-care urology and urogynecology clinics.

Many subjects had to be excluded from this analysis because of inconsistent or missing POP-Q data, and the total number of subjects with clinically significant POP was lower than we had expected. This may have limited our power to find differences between the groups, especially when comparing POP subjects who did and those who did not have POP treatment. Furthermore, POP-Q measurements were only available at baseline. Prolapse may change over time regardless of whether specific POP treatment occurs, and this may affect LUTS. The study population was predominantly White, which may limit generalizability to other racial or ethnic groups. Finally, there may have been selection bias. Subjects with POP may have been primarily seeking care for their POP rather than their urinary symptoms, whereas subjects without POP were probably more likely to be seeking care for and be bothered by OAB symptoms or other LUTS.

## Conclusions

Obstructive voiding symptoms and overall LUTS severity were associated with prolapse in a cohort of treatment-seeking women. LUTS scores improved over 12 months in patients regardless of prolapse or prolapse treatment. These results should be considered by clinicians counseling patients about likely outcomes of prolapse treatment. ■


## Acknowledgments

The following individuals were instrumental in the planning and conduct of this study at each of the participating institutions:

Duke University, Durham, North Carolina (DK097780): PIs: Cindy Amundsen, MD; Eric Jelovsek, MD; Co-Is: Kathryn Flynn, PhD; Jim Hokanson, PhD; Aaron Lentz, MD; David Page, PhD; Nazema Siddiqui, MD; Kevin Weinfurt, PhD; Lisa Wruck, PhD; Study Coordinators: Paige Green; Magaly Guerrero, BSc.

University of Iowa, Iowa City, Iowa (DK097772): PIs: Catherine S. Bradley, MD, MSCE; Karl Kreder, MD, MBA; Co-Is: Bradley A. Erickson, MD, MS; Daniel Fick, MD; Vince Magnotta, PhD; Philip Polgreen, MD, MPH; Study Coordinators: Sarah Heady, BA; Chelsea Poesch, BA; Shelly Melton, BA; Jean Walshire, AAS.

Northwestern University, Chicago, Illinois (DK097779): PIs: James W. Griffith, PhD; Kimberly Kenton, MD, MS; Brian Helfand, MD, PhD; Co-Is: Carol Bretschneider, MD; David Cella, PhD; Sarah Collins, MD; Julia Geynisman-Tan, MD; Alex Glaser, MD; Christina Lewicky-Gaupp, MD; Margaret Mueller, MD; Study Coordinators: Sylwia Clarke; Melissa Marquez, MBA; Pooja Sharma; Malgorzata Antoniak, PhD;

Pooja Talaty, MS; Francesca Moroni; Sophia Kallas. B.H. and P.T. are at NorthShore University HealthSystem.

University of Michigan Health System, Ann Arbor, Michigan (DK099932): PI: J. Quentin Clemens, MD, FACS, MSCI; Co-Is: John DeLancey, MD; Dee Fenner, MD; Rick Harris, MD; Steve Harte, PhD; Anne P. Cameron, MD; Aruna Sarma, PhD; Giulia Lane, MD; Study Coordinators: Linda Drnek, CCRP; Marissa Moore; Greg Mowatt, BA; Sarah Richardson, BS; Julia Chilimigras, MPH.

University of Washington, Seattle, Washington (DK100011): PI: Claire Yang, MD; Co-I: Anna Kirby, MD; Study Coordinators: Brenda Vicars, RN; Lauren Daniels, MA.

Washington University in St. Louis, St. Louis, Missouri (DK100017): PI: H. Henry Lai, MD; Co-Is: Gerald L. Andriole, MD; Joshua Shimony, MD, PhD; Fuhai Li, PhD; Study Coordinators: Linda Black; Vivien Gardner; Patricia Hayden; Diana Wolff; Aleksandra Klim, RN, MHS, CCRC.

Arbor Research Collaborative for Health, Data Coordinating Center (DK099879): PI: Robert Merion, MD, FACS; Co-Is: Victor Andreev, PhD, DSc; Brenda Gillespie, PhD; Abigail Smith, PhD; Project Manager: Melissa Fava, MPA, PMP; Clinical Monitor: Melissa Sexton, BA, CCRP; Research Analysts: Margaret Helmuth, MA; Jon Wiseman, MS; Jane Liu, MPH; Sarah Mansfield, MS.

Division of Kidney, Urology, and Hematology, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, Maryland: Project Scientist: Ziya Kirkali, MD; Project Officer: Christopher Mullins, PhD; Project Advisor: Julie Barthold, MD.

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Received April 4, 2022; revised July 7, 2022; accepted July 19, 2022.

The authors report no conflict of interest.

This is publication number 33 of the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN).

This study was supported by the National Institute of Diabetes and Digestive and Kidney Diseases through cooperative agreements DK097780, DK097772, DK097779, DK099932, DK100011, DK100017, DK099879. Research reported in this publication was supported at Northwestern University, in part, by the National Institutes of Health's National Center for Advancing Translational Sciences (grant number UL1TR001422). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

The individuals listed in the acknowledgments were instrumental in the planning and conduct of this study at each of the participating institutions as outlined.

This study was presented at the Pelvic Floor Disorders Week 2021 of the American Urogynecologic Society, Phoenix, AZ, October 12—15, 2021 and the International Continence Society Conference 2021, held virtually, October 14—17, 2021.



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# Appendix

## Lower urinary tract symptom tool questions & groupings

1. How often during the past week did you urinate too frequently?
2. During a typical day in the past week, how many times did you urinate during waking hours?
3. During a typical night in the past week, how many times did you wake up because you needed to urinate?
4. During the past week, how often have you had the feeling your bladder was not empty after urinating?
5. During the past week, how often have you had a trickle or dribble at the end of your urine flow?
6. During the past week, how often have you had a sudden need to rush to urinate?
7. During the past week, how often have you had a delay before you start to urinate?
8. During the past week, how often did your urine flow start and stop while you were urinating?
9. During the past week, how often did you strain to urinate or strain while you were urinating?
10. During the past week, how often have you had a weak urine stream?
11. During the past week, how often have you had splitting or spraying of your urine stream?
12. During the past week, how often have you had a sudden need to rush to urinate for fear of leaking urine?
13. During the past week, how often have you had pain or discomfort in your bladder area?
14. During the past week, how often have you had a burning feeling when you urinate?
15. During the past week, how often did you leak urine?
16. Below are several situations in which people can leak urine. How often in the past week have you…
    a. Leaked urine just after you have finished urinating?
    b. Leaked urine in connection with a sudden need to rush to urinate?
    c. Leaked urine in connection with laughing, sneezing, or coughing?
    d. Leaked urine in connection with physical activities, such as exercising or lifting a heavy object?
    e. Leaked urine when you are sleeping?
    f. Leaked urine during sexual activity?
    g. Leaked urine for no reason?

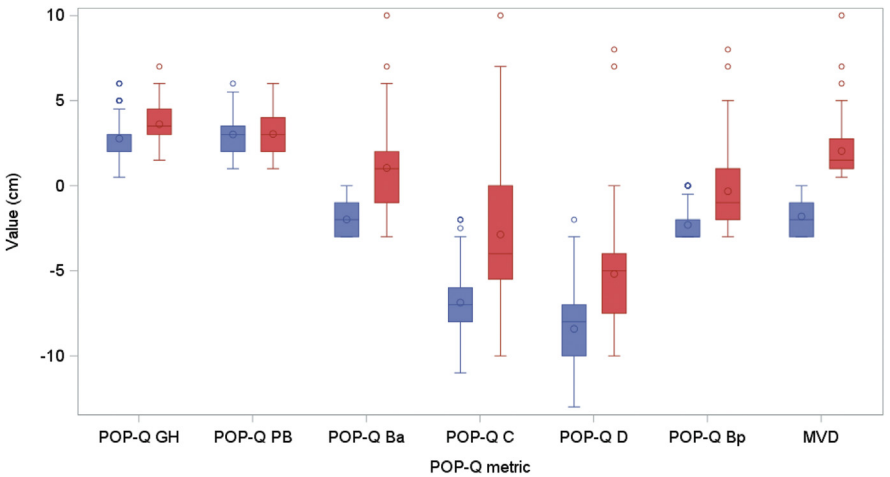
Overactive bladder (OAB) subscale=1−3, 6, 12, 16b

Obstructive subscale=4−5, 7−11, 16a

Stress subscale=16c−d

Overall severity score=1−15, 16a−g (all 22 severity items)

**SUPPLEMENTAL FIGURE**
**Box plot distributions of POP-Q metrics (by prolapse group)**




Box plot distributions of POP-Q metrics (by prolapse group). Within each box, the *horizontal line* represents the median and the circle represents the mean. *Lines* at the bottom and top of each box represent the 25th and 75th percentiles, respectively. The *whiskers* at the bottom and top of each plot extend to observations closest to 1.5 times the IQR, and dots represent observations outside of this range. *Blue boxplots* indicate distributions for participants with no prolapse and *red boxplots* indicate distributions for participants with prolapse at baseline. Prolapse was defined as present if the point of MVD was beyond the hymen based on POP-Q exam. Prolapse treatment included pessary use and/or surgery.

*IQR*, interquartile range; *LUTS*, lower urinary tract symptom; *MVD*, maximum vaginal descent; *OAB*, overactive bladder; *POP*, pelvic organ prolapse; *POP-Q*, Pelvic Organ Prolapse Quantification; *SUI*, stress urinary incontinence; *UDI-6*, Urogenital Distress Inventory Short Form.

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SUPPLEMENTAL TABLE 1

**Numeric summary of Pelvic Organ Prolapse Quantification results for all participants**

| Metric | N | Min. | Q1 | Median | Q3 | Max. | Mean | SD |
|---|---|---|---|---|---|---|---|---|
| Aa | 371 | −3.0 | −3.0 | −2.0 | −1.0 | 3.0 | −1.7 | 1.3 |
| Ba | 371 | −3.0 | −3.0 | −2.0 | −1.0 | 10.0 | −1.5 | 1.8 |
| C | 371 | −11.0 | −8.0 | −7.0 | −5.0 | 10.0 | −6.3 | 2.7 |
| GH | 368 | 0.5 | 2.0 | 3.0 | 4.0 | 7.0 | 2.9 | 1.1 |
| PB | 368 | 1.0 | 2.0 | 3.0 | 3.5 | 6.0 | 3.0 | 0.9 |
| TVL | 370 | 5.0 | 8.0 | 9.0 | 10.0 | 13.0 | 9.0 | 1.4 |
| Ap | 371 | −3.0 | −3.0 | −2.0 | −2.0 | 3.0 | −2.1 | 1.2 |
| Bp | 371 | −3.0 | −3.0 | −2.0 | −1.5 | 8.0 | −2.0 | 1.4 |
| D | 262 | −13.0 | −9.5 | −8.0 | −7.0 | 8.0 | −7.9 | 2.4 |
| MVD | 371 | −3.0 | −3.0 | −1.5 | 0.0 | 10.0 | −1.2 | 1.8 |

*Aa and Ba*, anterior vaginal wall points; *Ap and Bp*, posterior vaginal wall points; *C*, cervix or cuff; *D*, posterior fornix; *GH*, genital hiatus; *MVD*, maximal vaginal descent; *PB*, perineal body; *SD*, standard deviation; *TVL*, total vaginal length.

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SUPPLEMENTAL TABLE 2

**Associations between lower urinary tract symptom outcomes and prolapse based on repeated-measure linear regression models, adjusted for other clinical variables**

| LUTS outcome | Prolapse predictor of interest[a] | Linear regression coefficient (95% CI)[b] |
|---|---|---|
| LUTS Tool OAB scale | POP-Q Ba prolapse vs not | −3.17 (−7.99 to 1.64) |
| | POP-Q Ba (per cm increase) | −0.60 (−1.45 to 0.25) |
| | MVD prolapse vs not | −2.23 (−6.34 to 1.87) |
| | MVD (per cm increase) | −0.34 (−1.16 to 0.48) |
| | POP-Q Bp prolapse vs not | 0.41 (−5.94 to 6.75) |
| | POP-Q Bp (per cm increase) | −0.04 (−1.07 to 0.98) |
| LUTS Tool obstructive scale | POP-Q Ba prolapse vs not | 3.41 (−1.41 to 8.22) |
| | POP-Q Ba (per cm increase) | 0.85 (0.00—1.7)[c] |
| | MVD prolapse vs not | 1.49 (−2.66 to 5.64) |
| | MVD (per cm increase) | 0.98 (0.15—1.81)[c] |
| | POP-Q Bp prolapse vs not | −0.61 (−7.08 to 5.87) |
| | POP-Q Bp (per cm increase) | 1.13 (0.10—2.15)[c] |
| LUTS Tool SUI scale | POP-Q Ba prolapse vs not | −5.56 (−13.89 to 2.78) |
| | POP-Q Ba (per cm increase) | 0.57 (−0.90 to 2.05) |
| | MVD prolapse vs not | −3.60 (−10.71 to 3.51) |
| | MVD (per cm increase) | 0.65 (−0.77 to 2.07) |
| | POP-Q Bp prolapse vs not | 0.55 (−10.47 to 11.58) |
| | POP-Q Bp (per cm increase) | 1.57 (−0.21 to 3.35) |
| LUTS Tool total severity scale | POP-Q Ba prolapse vs not | −3.70 (−7.27 to −0.14)[c] |
| | POP-Q Ba (per cm increase) | −0.32 (−0.95 to 0.32) |
| | MVD prolapse vs not | −3.75 (−6.79 to −0.72)[c] |
| | MVD (per cm increase) | −0.25 (−0.86 to 0.36) |
| | POP-Q Bp prolapse vs not | −2.29 (−7.20 to 2.62) |
| | POP-Q Bp (per cm increase) | 0.14 (−0.63 to 0.91) |
| UDI-6 | POP-Q Ba prolapse vs not | −2.83 (−9.28 to 3.62) |
| | POP-Q Ba (per cm increase) | 0.37 (−0.77 to 1.51) |
| | MVD prolapse vs not | −3.26 (−8.74 to 2.22) |
| | MVD (per cm increase) | 0.13 (−0.97 to 1.23) |
| | POP-Q Bp prolapse vs not | 0.19 (−8.23 to 8.60) |
| | POP-Q Bp (per cm increase) | 0.44 (−0.93 to 1.81) |

Regression coefficients for each outcome represent the mean score difference between dichotomous predictor groups or the score difference for each cm increase for continuous predictors. LUTS Tool scales were normalized by the maximum value and scaled from 0 (least severe) to 100 (most severe). This allows regression coefficients to represent additive changes on a percentage scale.

*CI*, confidence interval; *LUTS*, lower urinary tract symptom; *MVD*, maximum vaginal descent; *OAB*, overactive bladder; *POP-Q*, Pelvic Organ Prolapse Quantification System; *SUI*, stress urinary incontinence; *UDI-6*, Urogenital Distress Inventory-6 Short Form.

[a] Prolapse identified as present for dichotomous definitions if the vaginal point specified was beyond the hymen based on POP-Q exam; [b] For each LUTS outcome and each POP predictor of interest, repeated-measures (within-subject) linear regression models were fitted. The best-subsets method was used to identify covariates associated with each outcome (varying by model) from the following: age, body mass index, comorbidity index, smoking status, diabetes mellitus, hysterectomy, baseline LUTS scale score, and LUTS treatment; [c] Statistically significant at 0.05 level.

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