Generic Health-Related Quality of Life in Patients Seeking Care for Pelvic Organ Prolapse

Developed by the Pelvic Floor Disorders Registry

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Objective: Using the American Urogynecologic Society multicenter Pelvic Floor Disorder Registry for Research, we (1) compared generic quality of life (QOL) in women planning pelvic organ prolapse (POP) treatment (surgery vs pessary), (2) correlated generic and condition-specific QOL scores, and (3) identified associations between generic QOL and other factors.

Methods: This cross-sectional analysis assessed generic physical and mental QOL using the Patient-Reported Outcomes Measurement Information System Global Health Scale at baseline. Global Physical and Mental T-scores center on a representative US population sample (mean [SD], 50 [10]; higher scores, better health). Condition-specific QOL was assessed with Pelvic Floor Distress Inventory, Pelvic Floor Impact Questionnaire, and POP/Urinary Incontinence Sexual Function Questionnaire. Linear regression models identified associations between clinical factors and Global Physical/Mental scores.

Results: Five hundred sixty-eight women (419 surgery, 149 pessary) were included. Surgery patients were younger, heavier, and more often sexually active (all P's ≤ 0.01). Global Physical scores were lower in the surgery versus pessary group, but not likely clinically meaningful (mean [SD], 48.8 [8.1] vs 50.4 [8.5]; $P = 0.035$); Global Mental scores were similar (51.4 [8.4] vs 51.9 [9.5], $P = 0.56$). Global Health scores correlated with Pelvic Floor Distress Inventory, Pelvic Floor Impact Questionnaire, and POP/Urinary Incontinence Sexual Function Questionnaire scores (all P's < 0.0001). In multivariable models, menopause was associated with better physical QOL, and constipation, coronary artery disease, pelvic pain, and increased body mass index with worse physical QOL. Age was associated with better mental QOL, and constipation, fecal incontinence, pelvic pain, and coronary artery disease with worse mental QOL.

Conclusions: Women choosing POP surgery versus pessary had similar physical and mental generic QOL.

Key Words: pelvic organ prolapse, pessary, surgery, generic health-related quality of life, condition-specific quality of life, mental health status, physical health status, multicenter registry study

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Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.fpmrs.net).

DOI: 10.1097/SPV.0000000000001069

(*Female Pelvic Med Reconstr Surg* 2021;27: 337–343)

The American Urogynecologic Society's Pelvic Floor Disorder Registry for Research (PFDR-R) is a volunteer, multicentered, 3-year, prospective cohort of patients undergoing treatment for pelvic organ prolapse (POP).[1,2] The PFDR-R is designed to evaluate the effectiveness, quality of life (QOL) impact, and safety associated with surgical and nonsurgical (pessary) management of POP.

The concept of health-related QOL encompasses physical, mental, and social aspects of health and well-being. Assessing QOL outcomes is particularly important when studying POP treatments, as POP has a major negative impact on patients' lives but does not typically cause severe morbidity or mortality. Quality of life instruments include both generic and disease-specific or condition-specific measures.[3] Generic QOL measures assess broad levels of function and well-being in physical and social domains of life and can be obtained in populations that differ in disease and comorbidity. Disease-specific QOL instruments are designed to quantify the impact of specific diseases or conditions in affected populations.

Although most POP research assesses disease-specific or condition-specific QOL, we know less about generic QOL status in women with POP. Few studies have included generic QOL outcomes, and it is unclear whether generic QOL scores improve after POP treatment.[4–7] Information about generic QOL in women with POP will help us to better understand the overall health status of women seeking care for POP and allow comparisons of overall physical and mental health between women with POP and the general US female population or with subsets of women with specific diseases or conditions.

The PFDR-R provides an opportunity to study generic health-related QOL in a broad population of care-seeking POP patients. Thus, our objectives were to (1) compare generic health-related QOL in patients seeking surgical and pessary POP treatment in the PFDR-R, (2) assess correlations between generic and condition-specific QOL scores, and (3) identify associations between generic QOL and other patient health characteristics. Our primary hypothesis was that generic QOL would be worse in patients planning pessary compared with surgery for POP.

MATERIALS AND METHODS

This cross-sectional study used baseline data collected in the PFDR-R. The PFDR-R had central institutional review board approval, and all sites received approval from their local institutional review board. All participants completed informed consent before enrollment. These results are reported as recommended by the STROBE Guidelines for Reporting Observational Studies.[8]

Registry recruitment occurred between October 2015 and June 2018. The PFDR-R methods have been previously reported and are reviewed briefly.[2] Adult women seeking treatment of

prolapse with surgery or pessary at 1 of the 11 PFDR-R sites were enrolled. They were excluded if pregnant, unable to complete questionnaires in English, or anticipated that they would be unable to physically or mentally participate for 36 months after treatment. Participant baseline information included demographics, education level, parity (including delivery mode), menopausal status, systemic and topical estrogen use, comorbidities, current and former tobacco use, prior prolapse treatment, surgical history, clinical diagnosis of prolapse, and pelvic organ prolapse quantification (POP-Q) stage. Participants were dichotomized into 2 groups (pessary vs surgery) according to plan made at the baseline visit. Surgical patients were further categorized into 6 mutually exclusive groups based upon abdominal or vaginal approach (or combined approach) and mesh/graft use in the procedure to address POP.

Enrolled participants agreed to complete patient-reported assessments, using a Web-link sent by email, or if preferred, on paper. The 10-item National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health Scale (v. 1.1) was administered to assess generic health-related QOL.[9] Advantages of this measure is its brevity (10 items) and scoring metric, in which raw scores are converted to a T-score metric, allowing comparisons to "normal" populations and to populations with other conditions. Global Physical Health and Global Mental Health scores (primary outcomes for this study) were generated by summing responses to 8 of the 10 items. Raw scores were converted to T-score values using PROMIS score conversion tables such that a score of 50 represents the mean for the US general population with SD of 10. A higher score represents better health.[9] Participants who did not complete the Global Health Scale at baseline or had missing items from those required for score calculations were excluded. More details about the PROMIS Global Health Scale items, versions, and scoring can be found in Supplemental Table 1, http://links.lww.com/FPMRS/A248.

The Pelvic Floor Distress Inventory Short Form (PFDI-20) is a 20-item, condition-specific QOL questionnaire with 3 subscales that evaluates distress caused by pelvic floor symptoms including bowel, urinary, and POP complaints.[10] The PFDI items ask whether each symptom is experienced and the degree of bother. The Pelvic Floor Impact Questionnaire (PFIQ-7) is a condition-specific QOL questionnaire also with bladder, bowel, and POP subscales.[10] The PFIQ items assess the impact of symptoms on ability to do household chores, physical activities, entertainment activities, travel, social activities, emotional health, and frustration. Scores on the PFDI-20 and PFIQ-7 range from 0 to 300, with higher scores indicating worse symptoms and QOL. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire Short Form (PISQ-12) evaluates sexual function in women with prolapse and incontinence.[11] The PISQ-12 total score ranges from 0 to 48, and higher scores indicate better sexual function. The PISQ-12 was only administered if the participant reported that they were "sexually active with or without a partner." The International Consultation on Incontinence Questionnaire–Urinary Incontinence–Short Form (ICIQ-UI-SF) assesses urinary incontinence and its impact on QOL.[12] Total score ranges from 0 to 21, with higher scores indicating more severe and/or bothersome incontinence. A pain questionnaire was administered, modified from an instrument developed for the Trial of Midurethral Slings.[13] The questionnaire asks about pain occurring in the past 24 hours in 7 locations in the pelvic region and lower extremities, rated from 0 (no pain) to 10 (most intense pain). A summative score ranges from 0 to 70 (higher scores indicate more pain).

Participant characteristics were summarized using counts and percentages for categorical variables and means with SD or medians with interquartile range (IQR) for continuous variables. Comparisons between pessary and surgery groups were tested using Pearson χ^2, Fisher exact, unpaired *t*, and/or Wilcoxon rank sum tests as indicated by variable type and distributions. Global Physical Health and Global Mental Health scores were compared between surgery and pessary groups using unpaired *t* tests and between surgical categories using analysis of variance. Associations between PROMIS Global Health scores and other QOL scores were tested using Spearman correlations. Multivariable analyses were performed using linear regression models predicting Global Physical Health and Global Mental Health (separate models), adding treatment group as the primary predictor and other covariates. Covariates considered for inclusion were those collected in the entire cohort and associated with the primary outcomes at $P \leq 0.10$ in univariate analyses. Models were used to assess the most ideal collection of predictor variables (including treatment plan) to predict the continuous outcomes. The selection criterion used to compare model fits and select the optimal predictor set for reporting was the Akaike Information Criterion (AIC; a lower AIC suggests a better "fitting" model).[14] Statistical analysis was performed using SAS 9.4 (SAS Institute Inc, Cary, NC). Statistical significance was defined as $P < 0.05$.

Before completing PFDR-R enrollment, we conservatively estimated an available sample size of approximately 500 participants for this analysis. Assuming 500 participants with available data, $\alpha = 0.05$ and with score SD = 10, we would have power of 0.85 and 0.99 to detect a 3- and 5-point difference, respectively, between mean Global Health scores in surgery versus pessary groups. The minimal clinically important difference for the PROMIS Global Health Scale has not been empirically tested, but minimal clinically important difference in other PROMIS short-form scales, assessing fatigue, pain interference, physical function, gastrointestinal symptoms, and emotional well-being, has been estimated at 3 to 6 points.[15,16]

RESULTS

Among 1148 PFDR-R participants, 580 were excluded because of missing questionnaire data (557 did not complete baseline questionnaires and 23 had incomplete Global Health Scale data). Among the remaining 568 patients, 419 planned surgery and 149 planned pessary treatment (Fig. 1). Thirty-one patients planned but did not complete surgery. Surgeries performed (n = 388) included vaginal native tissue (n = 249, 64.2%), vaginal graft augmented (mesh/biologic) (n = 3, 0.8%), sacrocolpopexy (n = 104, 26.8%), combined approach graft augmented (mesh/biologic) (n = 1, 0.3%), abdominal native tissue (n = 8, 2.1%), and obliterative (n = 23, 5.9%).

Those PFDR-R participants who were included differed from those excluded, although differences were small. Included participants were older (62.5 vs 60.8 years, $P = 0.014$), had lower body mass index (BMI) (27.9 vs 28.5, $P = 0.03$), were more likely to report higher education (68.1% vs 57.6%, $P = 0.016$), and less likely to report smoking (3.5% vs 7.2%, $P = 0.005$) than those excluded. Women included were more likely to have had cancer (7.2% vs 4.5%, $P = 0.048$) and vaginal atrophy (19.2% vs 11%, $P < 0.001$), and less likely to take medication for pelvic pain (2.3% vs 9.1%, $P < 0.001$). They were more likely to have apical prolapse (74.8% vs 68.8%, $P = 0.023$) and less likely cystocele (65.5% vs 71.7%, $P = 0.023$), stress urinary incontinence (SUI; 34.3% vs 41.2%, $P = 0.016$), and urinary urgency (25.4% vs 31.6%, $P = 0.02$). Other patient characteristics were similar between included and excluded participants (data not shown).

Patients undergoing surgery were younger, less educated, and had higher BMI than patients treated with a pessary (Table 1). More patients undergoing surgery were sexually active and

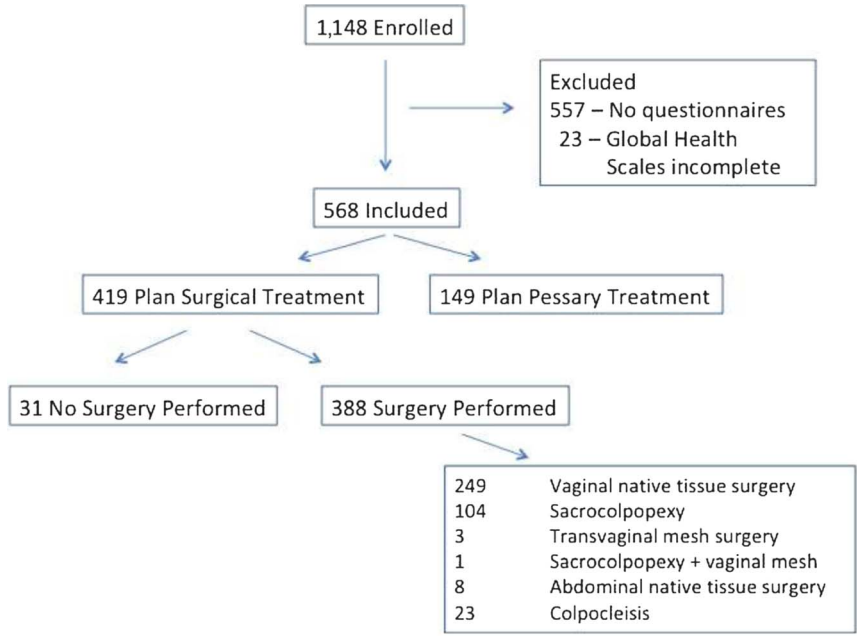

FIGURE 1. Participant flow diagram.

had SUI, rectocele, and inflammatory bowel disease compared with those electing pessary treatment. There were no differences between surgery and pessary groups in race, ethnicity, insurance, smoking status, menopausal status, medical comorbidities, POP-Q stage, or prior prolapse or incontinence surgery.

Surgery patients had slightly lower Global Physical Health scores (difference, 1.6), indicating worse generic physical health than pessary patients, but this difference is likely not clinically significant (Table 2). Global Mental Health scores were not different between the 2 groups. Apart from the ICIQ-UI-SF, condition-specific QOL scores reflected more bothersome symptoms and impact (worse condition-specific QOL) in patients planning surgery versus pessary treatment. Among surgery patients, there were no differences in generic and condition-specific QOL scores between surgery types (vaginal native tissue, sacrocolpopexy, and colpocleisis), except for the Pelvic Organ Prolapse Impact Questionnaire Short Form, which showed less impact in those who planned colpocleisis and more in those planning sacrocolpopexy (median [IQR], 9.5 [0, 38.1] vs 14.3 [4.8, 38.1] vs 0 [0, 19] for vaginal native tissue, sacrocolpopexy, and colpocleisis, respectively; $P = 0.046$; other data not shown).

Generic physical and mental QOL scores correlated in the direction expected with all condition-specific QOL and pain scores (Table 3). Correlations with condition-specific measures were weak to moderate (range, 0.3–0.6; all P's < 0.001) for generic physical QOL and weak (range, 0.2–0.4; all P's < 0.001) for generic mental QOL.

Bivariable and multivariable models suggested several patient characteristics were associated with global physical and mental health status (Table 4, Supplemental Table 2, http://links.lww.com/FPMRS/A249). In multivariable linear regression models, menopause was associated with higher Global Physical Health score (mean score difference [95% confidence interval (CI)], 2.3 [0.6, 4.0]). Constipation, pelvic pain, and coronary artery disease (mean score difference [95% CI], −2.6 [−4.4, −0.8], −6.6 [−9.6, −3.7], and −5.6 [−8.8, −2.4], respectively) and BMI (mean score difference [95% CI], −4.6 [−5.8, −3.4] per 10 kg/m^2) were associated with lower Global Physical Health score. Age was associated with higher Global Mental Health score (mean score difference [95% CI], 1.8 [1.2, 2.5] per decade) and constipation, fecal incontinence, pelvic pain, and coronary artery disease with lower Global Mental Health score (−3.1 [−5.1, −1.1], −3.6 [−6.1, −1.1], −5.5 [−8.8, −2.3], and −5.9 [−9.5, −2.3] per 10 kg/m^2, respectively). The decision to pursue surgery versus pessary treatment for prolapse in PFDR-R participants was not associated with generic physical or mental QOL scores in adjusted models.

Individual Global Health Scale item responses demonstrated small differences in surgery versus pessary groups (Supplemental Table 1, http://links.lww.com/FPMRS/A248). Patients undergoing surgery were less frequently able to carry out every day physical activities, had more fatigue, and had more pain than patients planning pessary (median [IQR], 4 [3, 5] vs 5 [4, 5], $P = 0.036$; 2 [2, 3] vs 2 [2, 3], $P = 0.02$; and 2 [0, 4] vs 2 [0, 3], $P = 0.01$, respectively). Surgical patients also were more often bothered by emotional problems than pessary patients (median [IQR], 2 [2, 3] versus 2 [1, 3], $P = 0.03$).

DISCUSSION

We present a comprehensive description of QOL outcomes in participants in a real-world, national registry of women seeking POP treatment. Approximately half of registry participants provided patient-reported data and were included. Our hypothesis was that women who chose pessary would have worse generic QOL. However, women who underwent surgery for POP had slightly worse physical generic QOL and similar mental generic QOL relative to those who selected a pessary. The small difference in physical health status between these groups was statistically significant but is likely too small to represent a meaningful clinical difference. The PROMIS Global Health Scale scores correlated with condition-specific QOL scores. In multivariable models, age and menopause were associated with better generic health-related QOL, whereas pelvic pain, defecatory disorders, and other medical comorbidities were associated with worse generic health-related QOL.

TABLE 1. Baseline Patient Characteristics in the PFDR-R by Surgery and Pessary Treatment Groups

Total, N = 568	Surgery (n = 419)	Pessary (n = 149)	*P*
Age, y	61.6 (10.5)	65.1 (12.2)	<0.001
Race (missing = 1)			0.536*
Black or African American	12 (2.9)	7 (4.7)	
White	386 (92.3)	136 (91.3)	
American Indian/ Alaska native	1 (0.2)	0	
Asian	4 (1.0)	1 (0.6)	
Native Hawaiian/ Pacific Islander	0	0	
Other/multirace	15 (3.6)	5 (3.4)	
Hispanic ethnicity (missing = 4)	11 (2.7)	3 (2.0)	>0.999
Education (missing = 198)			0.002
High school or less	101 (35.7)	17 (19.5)	
College	127 (44.9)	39 (44.8)	
Graduate school	55 (19.4)	31 (35.6)	
Insurance			
Blue Cross/Blue Shield	106 (25.3)	31 (20.8)	0.271
Medicare/Medicaid	120 (28.6)	45 (30.2)	0.718
Other	246 (58.7)	89 (59.7)	0.828
Current smoker (missing = 2)	17 (4.1)	2 (1.4)	0.181
Vaginal parity (median [IQR]) (missing = 31)	2 (2, 3); range, 0–9	2 (2, 3); range, 1–7	0.035
Postmenopausal (missing = 8)	347 (84.0)	124 (84.4)	0.924
Clinical diagnosis of prolapse			
Cystocele	280 (66.8)	92 (61.7)	0.263
Rectocele	243 (58.0)	44 (29.5)	<0.001
Uterine prolapse	237 (56.6)	82 (55.0)	0.747
Posthysterectomy vault prolapse	81 (19.3)	25 (16.8)	0.492
Enterocele	31 (7.4)	7 (4.7)	0.257
Urinary symptoms/conditions			
Stress incontinence	157 (37.5)	38 (25.5)	0.008
Urgency incontinence	129 (30.8)	43 (28.9)	0.660
Mixed incontinence	67 (16.0)	18 (12.1)	0.251
Frequency	58 (13.8)	21 (14.1)	0.939
Urgency	111 (26.5)	33 (22.2)	0.295
Hematuria	9 (2.19)	5 (3.42)	0.375
Interstitial cystitis	1 (0.2)	1 (0.7)	0.456
Recurrent urinary tract infection	15 (3.6)	9 (6.0)	0.200
Bowel symptoms/conditions			
Chronic constipation	68 (16.2)	16 (10.7)	0.105
Fecal incontinence	38 (9.1)	13 (8.7)	0.900
Irritable bowel syndrome	19 (4.62)	7 (4.79)	0.681
Sexually active (missing = 4)	232 (55.8)	65 (43.9)	0.013
Dyspareunia (if sexually active) (missing = 12)	71 (32.1)	15 (23.4)	0.182
Other pelvic symptoms/ conditions			
Vaginal atrophy	76 (18.1)	33 (22.2)	0.286
Pelvic pain	21 (5.0)	6 (4.0)	0.627
General medical history			
Diabetes	33 (7.9)	11 (7.4)	0.847
Coronary artery disease	16 (3.8)	7 (4.17	0.640
Cancer	29 (6.9)	12 (8.1)	0.646
Pulmonary disease (COPD, asthma)	36 (8.6)	14 (9.4)	0.766
Back/neck surgery	13 (3.1)	4 (2.7)	>0.999
Chronic pain/fibromyalgia	5 (1.2)	6 (4.0)	0.041
Other	170 (40.6)	57 (38.3)	0.620
Current medications			
Pain medication for pelvic pain	12 (2.9)	1 (0.7)	0.200
Steroids	10 (2.4)	4 (2.7)	0.767
Chemotherapeutic agents	5 (1.2)	3 (2.0)	0.438
Antirejection medication	5 (1.2)	0	0.333
Medication for overactive bladder	16 (3.8)	1 (0.7)	0.054
Estrogen treatment	141 (33.7)	52 (34.9)	0.841
Hysterectomy	130 (31.0)	38 (25.5)	0.212
Prior prolapse surgery	59 (14.1)	15 (10.1)	0.257
Prior incontinence surgery	26 (6.2)	8 (5.4)	0.712
Prior bowel/intestinal surgery	24 (5.7)	6 (4.0)	0.425
Prior pelvic surgery, other/ unknown	135 (32.2)	32 (21.5)	0.013
Body mass index (kg/m^2) (missing = 2)	28.3 (5.7)	26.7 (4.6)	0.003
POP-Q stage (missing = 19)			0.333
I	3 (0.7)	2 (2.1)	
II	171 (41.0)	59 (41.0)	
III	214 (51.3)	76 (52.8)	
IV	29 (7.0)	6 (4.2)	

*For *P* value calculation, American Indian/Alaska native, Asian, Native Hawaiian/Pacific Islander, and other/multirace categories were grouped and compared with Black/African American and White categories.

Data presented as mean (SD) or n (column %) unless otherwise indicated; % may not add to 100% because of rounding.

COPD, chronic obstructive pulmonary disease; IQR, interquartile range; PFDR-R, Pelvic Floor Disorder Registry for Research; POP-Q, pelvic organ prolapse quantification.

To our knowledge, this is the first study to use the PROMIS Global Health Scale to assess generic QOL in POP patients. One prior study of women undergoing surgery for POP tested a longer PROMIS generic QOL instrument, the PROMIS-57.[17] Similar to our findings, the PROMIS-57 domains correlated with preoperative PFDI-20 and PFIQ-7 scores. The PROMIS-57 does not provide summary scores, thus inhibiting comparison of our Global Health summary scores with that population.

The women seeking POP treatment in the PFDR-R had baseline Global Physical Health and Global Mental Health scores just above or below 50, suggesting generic QOL (mental/physical health status) similar to the overall US population. The US norms specific to women include means of 49.1 and 49.4 for Global Physical Health and Global Mental Health scores, respectively. Age-specific mean values range from 48.2 to 51.0 for Global Physical Health and 48.2 to 53.1 for Global Mental Health in adults 45 to 75 years.[18] Considering these subpopulation norms, the PFDR-R Global Physical Health scores are similar to the women-specific US mean. The PFDR-R Global Mental Health

TABLE 2. Baseline Health-Related QOL and Other Patient-Reported Measures in the PFDR-R: Surgery and Pessary Treatment Groups

	Surgery (n = 419)	Pessary (n = 149)	*P*
Global Health			
Physical T-score	48.8 (8.1)	50.4 (8.5)	0.035*
Mental T-score	51.4 (8.4)	51.9 (9.5)	0.556*
PFDI-20	93.9 (58.9, 137.5)	63.5 (38.5, 102.6)	<0.001
POPDI-6	33.3 (16.7, 54.2)	25 (8.3, 41.7)	<0.001
UDI-6	40.8 (22.9, 58.3)	25 (11.3, 41.7)	<0.001
CRADI-8	18.8 (7.7, 34.4)	12.5 (0, 25)	<0.001
PFIQ-7	42.9 (14.3, 85.7)	19 (7.5, 57.1)	<0.001
POPIQ-7	9.5 (0, 33.3)	0 (0, 19)	<0.001
IIQ-7	19 (4.8, 38.1)	9.5 (0, 23.8)	<0.001
CRAIQ-7	4.8 (0, 23)	0 (0, 9.5)	0.002
PISQ-12	32 (28, 37)	35 (31, 38)	0.033
ICIQ-UI-SF	5 (3, 9)	3 (0, 8)	0.353
Pain	5 (0, 11)	3 (0, 8)	0.014

**P* value calculated using Student *t* test; other *P* values from Wilcoxon rank sum test.

Data presented as mean (SD) or median (interquartile range).

CRADI-8, Colorectal Anal Distress Inventory short form, missing = 10; CRAIQ-7, Colorectal Anal Distress Impact Questionnaires short form, missing = 24; ICIQ-UI-SF, International Consultation on Incontinence Questionnaire-Urinary Incontinence–short form, missing = 26; IIQ-7, Incontinence Impact Questionnaire short form, missing = 12; PFDI-20, Pelvic Floor Distress Inventory short form, missing = 16; PFDR-R, Pelvic Floor Disorder Registry for Research; PFIQ-7, Pelvic Floor Impact Questionnaire short form, missing = 24; PISQ-12, Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire short form, reported for those participants who reported sexual activity, missing = 11; POPDI-6, Pelvic Organ Prolapse Distress Inventory short form, missing = 4; POPIQ-7, Pelvic Organ Prolapse Impact Questionnaire short form, missing = 21; UDI-6, Urinary Distress Inventory short form, missing =4.

scores of 51.4 and 51.9 for surgery and pessary groups, respectively, appear slightly higher (better mental health) than the women-specific US population mean. Our study population (women presenting for POP treatment) was older on average than the overall US population. Interestingly, in the PFDR-R, we found increasing age was associated with better general physical and mental health status. Age-specific scores for Global Mental Health from the general US population are also highest in the oldest age group (75 years and older), suggesting this phenomenon (better mental status scores in older people) is not unique to women with POP.[18] This finding may also result from healthy subject bias, if older patients with better physical and/or mental health were more likely to participate in the PFDR-R than those with poorer health.

In the PFDR-R, coronary artery disease and other medical comorbidities were associated with poorer generic QOL. Pelvic pain and constipation were also associated with worse physical and mental QOL scores; fecal incontinence was associated with worse mental QOL. Previous research has demonstrated the negative impact of fecal incontinence on generic QOL,[19] but studies on the generic QOL impact of co-occurring pelvic floor disorders are sparse. Richter et al[20] studied women with POP planning sacrocolpopexy with and without SUI, and reported women with co-occurring pelvic floor disorders (SUI and POP) had poorer physical and mental component scores on the SF-36 than women with only POP. In the PFDR-R, urinary incontinence (stress, mixed, and urgency urinary incontinence) was not associated with reduced generic QOL.

We rejected our hypothesis that patients selecting pessary treatment would have poorer generic QOL scores. Pessary treatment was historically recommended for elderly women and those with high surgical risk, but today pessaries are considered a viable, long-term, nonsurgical option for all women. Although the difference was small, PFDR-R participants who elected surgery had lower physical generic QOL scores. Surgical patients were more likely to report difficulty in carrying out every day physical activities, fatigue, and pain, and they had greater functional impact from their prolapse symptoms than women who elected pessary. This suggests they may have elected surgery to achieve greater (or more definitive) resolution of symptom bother.

Our results demonstrate the utility of including a generic QOL assessment in POP research both to better describe a study population and to more broadly assess treatment impact. Use of condition-specific QOL assessments limits comparisons with outcomes in other surgical fields or across other health conditions. A recent study combining data from 4 large multicenter POP surgical trials concluded that assessments of generic QOL are valid and responsive to POP treatment and recommended inclusion of generic health-related QOL measures in future trials.[21]

The PFDR-R is the first multicenter national registry of patients seeking POP treatment. It was built to supplement real-world patient care with additional patient-reported and clinical data to support rigorous characterization of the impact of POP treatment on objective outcomes, subjective symptoms, and QOL. Because strict inclusion criteria in many controlled randomized studies often exclude a true heterogeneous population, registry data can inform decision-making across a broader patient population. Our study is also strengthened by the robust sample size, including women from 11 different US sites, as well as the use of validated, self-administered instruments, including the new PROMIS Global Health Scale, a generic QOL instrument that allows comparison with results from other populations. We also acknowledge study limitations. Although only 57% of PFDR-R patients provided baseline questionnaire data, differences between those who did and did not provide these data were small. We performed many analyses in this study and did not adjust statistically for multiple comparisons. Thus, our secondary results should be considered exploratory. Lastly and importantly,

TABLE 3. Correlations Between PROMIS Global Health Scale Scores (Generic Health-Related Quality of life) and Condition-Specific Quality of Life Measures

	Global Physical Health Score	Global Mental Health Score
PFDI-20	−0.485	−0.297
PFIQ-7	−0.521	−0.380
PISQ-12	0.315	0.226
Pain	−0.594	−0.317
ICIQ-UI-SF	−0.252	−0.154

Spearman correlations presented. *P* values all <0.001.

ICIQ-UI-SF = International Consultation on Incontinence Questionnaire-Urinary Incontinence–short form, missing = 26; PFDI-20, Pelvic Floor Distress Inventory short form, missing = 16; PFIQ-7, Pelvic Floor Impact Questionnaire short form, missing = 24; PISQ-1, Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire short form, reported for those participants who reported sexual activity, missing = 11; PROMIS, Patient-Reported Outcomes Measurement Information System.

TABLE 4. Linear Regression Models Predicting PROMIS Global Physical Health and Mental Health QOL Scores

Dependent Outcome	Predictor	Mean Difference (95% CI)	*P*	AIC
Global Physical Health	Surgery vs pessary	−1.11 (−2.58, 0.36)	0.140	3643.2
	Menopause*	2.30 (0.56, 4.04)	0.010	
	Constipation	−2.63 (−4.43, −0.83)	0.004	
	Pelvic pain	−6.63 (−9.58, −3.68)	<0.001	
	Coronary artery disease	−5.60 (−8.79, −2.41)	<0.001	
	Body mass index (per 10 kg/m^2)	−4.60 (−5.82, −3.39)	<0.001	
Dependent Outcome	**Predictor**	**Mean Difference (95% CI)**	***P***	**AIC**
Global Mental Health	Surgery vs pessary	0.163 (−1.47, 1.80)	0.845	3751.65
	Age (per decade)	1.82 (1.15, 2.49)	<0.001	
	Constipation	−3.06 (−5.05, −1.07)	0.003	
	Fecal incontinence	−3.62 (−6.14, −1.10)	0.005	
	Pelvic pain	−5.52 (−8.79, −2.25)	<0.001	
	Coronary artery disease	−5.91 (−9.50, −2.32)	0.001	

*A similar model also performed well that included age rather than menopause; in this model, increasing age (per decade) was associated with mean difference (95% CI) of 0.70 (0.10, 1.13; $P = 0.023$), with minimal changes in the other predictor results (AIC, 3644.7).

AIC, Akaike Information Criterion; CI, confidence interval; PROMIS, Patient-Reported Outcomes Measurement Information System; QOL, quality of life.

our study population lacked racial and ethnic diversity, potentially limiting generalizability of our results.

Generic health-related QOL provides important information about a population's overall mental and physical health status. Our results improve understanding of generic QOL in women seeking POP care by providing data from a generalizable cohort. We did not identify major differences in generic physical and mental health QOL in patients seeking surgery versus pessary treatment, but we did find that associated pelvic pain and constipation were associated with poorer physical and mental health status. Future investigations in this rich patient registry will examine generic and condition-specific QOL changes after POP treatment.

ACKNOWLEDGMENTS

Publications Committee Reviewers: Vivian Aguilar, MD; Lauren Cadish, MD; Peter Jeppson, MD.

This research was supported by the American Urogynecologic Society. This study was also supported in part by the University of Iowa Institute for Clinical and Translational Science, which is granted with Clinical and Translational Science Award funds from the National Institutes of Health (UL1TR002537). C.S.B., S.S.S., U.U.A., L.A.Y.-K., A.M., A.O., R.T.F., J.T.A., G.C., and P.T.E. have declared they have no conflicts of interest. H.W.B. received a career development award support (K12 DK100022, PI Bjorling), is a consultant for Grand Rounds, Inc, and receives royalties from Wolters-Kluwer (UpToDate, Inc). R.E.G. is a consultant and researcher (unrestricted grant plus site PI Uphold LITE FDA trial) for Boston Scientific and an expert witness for sling class action cases at Johnson & Johnson. B.K. is a consultant for Intuitive Surgical Company. P.A.M. has received unrestricted research grant from Boston Scientific 2017–2019.

The views expressed in this manuscript are those of the authors and do not reflect the official policy or position of the Department of the Army, the Department of Defense, or the US Government.

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