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CORRELATES OF 1-YEAR CHANGE IN QUALITY OF LIFE IN PATIENTS WITH UROLOGIC CHRONIC PELVIC PAIN SYNDROME: FINDINGS FROM THE MULTIDISCIPLINARY APPROACH TO THE STUDY OF CHRONIC PELVIC PAIN (MAPP) RESEARCH NETWORK

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Abstract

PURPOSE: To evaluate and identify baseline factors associated with change in health-related quality of life (HRQOL) among patients with interstitial cystitis/bladder pain syndrome (IC/BPS) and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS).

METHODS: A total of 191 men and 233 women with IC/BPS or CP/CPPS (collectively referred to as urologic chronic pelvic pain syndrome, or UCPPS) were followed for 12 months with bimonthly completion of the Short Form 12 (SF-12) to assess general mental and physical HRQOL, and with biweekly assessment of condition-specific HRQOL using the Genitourinary Pain Index. A functional clustering algorithm was used to classify participants as improved, stable, or worsened for each HRQOL measure. Ordinal logistic regression was used to determine baseline factors associated with change.

RESULTS: Physical HRQOL improved in 22% of the participants, mental HRQOL improved in 25%, and condition-specific HRQOL improved in 47%. Better baseline physical HRQOL, older age, and the presence of non-urologic symptoms were associated with lower likelihood of improvement in physical HRQOL. Better baseline mental HRQOL, female sex, and greater baseline depression and stress were associated with lower likelihood of improvement in mental HRQOL. Better baseline condition-specific HRQOL and more severe baseline UCPPS pain symptoms were associated with lower likelihood of improvement in condition-specific HRQOL.

CONCLUSION: While several non-UCPPS factors influenced the trajectory of general HRQOL over time, only condition-specific baseline HRQOL and UCPPS symptoms were associated with UCPPS-specific HRQOL change. Significant differences in how UCPPS impacts various aspects of HRQOL suggest a multidisciplinary approach to assessment and treatment of these patients.

Brief Descriptive Running head

Quality of life change in urologic chronic pelvic pain syndrome

MeSH

Interstitial cystitis; bladder pain syndrome; chronic prostatitis; bother

Introduction

Interstitial cystitis/bladder pain syndrome (IC/BPS) and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) are common and debilitating urologic pain conditions. IC/BPS is characterized by bladder pain, with symptoms that typically worsen with bladder filling and/or relieved by urination. CP/CPPS is characterized by male pelvic pain, which is localized to the perineum, genitalia, or suprapubic region. These two conditions share many similarities[1,2], and can be collectively referred to as 'urologic chronic pelvic pain syndrome (UCPPS)'[3]. Numerous cross-sectional studies have documented the dramatic impact of UCPPS symptoms on health-related quality of life (HRQOL)[4–7]. No studies, however, have evaluated changes in HRQOL prospectively among patients with UCPPS. Both generic and illness specific measures were used to examine illness impact on individuals' HQOL. Generic measures provide data related to a wide array of physical and mental functioning and can be used to compare across chronic conditions, while disease-specific measures focus on areas of common symptoms for a particular disorder and are used to measure the efficacy of interventions and treatments[8]. Utilizing data from UCPPS participants enrolled in the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network's Epidemiology and Phenotyping Study (EPS)[9], we assessed general HRQOL and UCPPS disease-specific HRQOL over a 12-month period. We examined potential

demographic, disease-related, and psychosocial characteristics that might be correlated with HRQOL change.

Methods

The MAPP Research Network consists of 6 Discovery Sites which recruit UCPPS participants into research studies, a Data Core, and a Tissue and Technology Core[3]. The study design, eligibility criteria and aims of the MAPP EPS protocol have been previously described[9]. A total of 191 male and 233 female participants with UCPPS were followed for one year and received usual care for their UCPPS symptoms. After an intensive baseline phenotyping evaluation, abridged in-person follow-up assessments were conducted at 6 and 12 months. Participants also completed a comprehensive battery of online questionnaires every 2 months, and a brief online questionnaire every 2 weeks.

Measurement of HRQOL

General HRQOL was evaluated bimonthly using the Medical Outcomes Study 12-item Short Form Health Survey (SF-12)[10–13]. The SF-12 comprises eight domains of health status: physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, energy/vitality, social functioning, role limitations due to emotional problems, and mental health. The SF-12 yields composite scores for physical functioning (PCS) and mental functioning (MCS) each ranging from 0–100, with higher scores indicating better functioning.

UCPPS condition-specific HRQOL was assessed biweekly using the QOL subscale of the Genitourinary Pain Index (GUPI)[14]. The GUPI is used to assess pelvic pain symptoms, urinary symptoms, and HRQOL in both men and women. The GUPI QOL subscale includes 3 items which are combined into a single QOL subscale score, ranging from 0–12, with higher scores indicating worse condition-specific HRQOL. The GUPI QOL items ask: ‘How much have your symptoms kept you from doing the kinds of things that you would usually do, over the last week?’ (None - 0, Only a little - 1, Some - 2, A lot - 3), ‘How much did you think about your symptoms, over the last week?’ (None - 0, Only a little - 1, Some - 2, A lot - 3), and ‘If you were to spend the rest of your life with your symptoms just the way they have been during the last week, how would you feel about that?’ (Delighted - 0, Pleased - 1, Mostly satisfied - 2, Mixed (about equally satisfied and dissatisfied) - 3, Mostly dissatisfied - 4, Unhappy - 5, Terrible - 6).

Other demographic and symptom variables

Additional variables assessed at baseline included: the baseline value of the respective HRQOL score, sex, age, composite UCPPS pain severity score[15], composite UCPPS urinary symptom severity score[15], UCPPS symptom duration, pain catastrophizing score (using the Coping Strategies Questionnaire)[16], anxiety and depression (using the Hospital Anxiety and Depression Scale (HADS)[17]), perceived life stress (using the Perceived Stress Scale (PSS)[18,19]), sleep disturbance (using the NIH Patient Reported Outcomes Measurement Information System (PROMIS)[20] questionnaire), degree of non-urological symptoms (using

the Complex Multi-Symptom Inventory (CMSI)[21]), and spatial distribution of pain (using the sum of pain locations marked on a standardized body map)[22,23].

Longitudinal HRQOL

A functional clustering procedure was applied to the three longitudinal HRQOL scores (SF-12 PCS, SF-12 MCS, and GUPI QOL) to classify the overall HRQOL trajectory for each participant as worsening, stable, or improving over the 52-week study period[2]. To decrease the influence of study entry effects (regression to the mean) on outcome classification, the first month of HRQOL scores were not used in the clustering algorithm[24], and the HRQOL scores at study week 4 were used as the baseline values. Therefore, the maximum number of possible SF-12 scores (bimonthly) for analysis was 7, and the maximum number of GUPI QOL scores (biweekly) was 23. The analysis was limited to participants who completed the baseline assessment and at least one post-baseline assessment (n=376 for SF-12 and n=395 for GUPI QOL).

Statistical Analysis

Unadjusted and adjusted ordinal logistic regression models were used to determine baseline factors that were associated with change in each of the three HRQOL measures. For each analysis an odds ratio (OR) greater than 1 indicated a greater likelihood of HRQOL improvement (i.e., likelihood of being stable vs. worse, or improved vs. stable) with higher values of the given baseline characteristic; conversely, an OR <1 indicates a lower likelihood of improvement with higher values. Unadjusted models included baseline HRQOL and the indicated demographic or symptom measure. Adjusted models included all variables.

Results

For the SF-12, the mean number of bimonthly contacts per participant was 5.4, and 75% of participants completed at least 4 of the 7 contacts. For the GUPI, the mean number of biweekly contacts per participant was 15.8, and 73% completed at least 12 of the 23 contacts. Figure 1 shows the individual HRQOL trajectories by cluster, overlaid by the average HRQOL trajectory within the cluster. Physical HRQOL improved in 83 participants (22%), and worsened in 116 (30%). Mental HRQOL improved in 96 participants (25%), and worsened in 116 (30%). Condition-specific HRQOL improved in 187 participants (47%), and was stable/worsened in 208 (53%). Figure 2 is a Venn diagram which shows the overlap in participants who demonstrated improvement in any of the three HRQOL domains. There were 121 participants who did not improve in any of the categories, while only 14 improved in all three. A total of 32 participants improved only in the SF-12 PCS, while 36 participants improved only in the SF-12 MCS, and 100 participants improved only in the GUPI QOL assessment.

Results of the regression models are presented in Tables 1–3. Baseline HRQOL score was a strong predictor of HRQOL outcomes across all categories (C-statistic >0.7 SF-12 MCS and PCS; C-statistic=0.67 GUPI). Specifically, worse baseline physical HRQOL was associated with a greater likelihood of physical HRQOL improvement, worse baseline mental HRQOL was associated with a greater likelihood of mental HRQOL improvement, and worse

baseline UCPPS condition-specific HRQOL was associated with a greater likelihood of condition-specific HRQOL improvement.

For physical HRQOL (Table 1), the unadjusted analysis showed that the presence of increased non-urologic medical symptoms and widespread pain on the body map were associated with a lower HRQOL improvement over time. The multivariable adjusted analysis found that the presence of non-urologic symptoms remained associated, while increased age also emerged as associated with a lower likelihood of improvement.

For mental HRQOL (Table 2), almost all variables were associated with symptom trajectory in unadjusted analysis. Female sex, more severe baseline pain and urinary scores, catastrophizing, depression, anxiety, stress, non-urologic symptoms, and widespread pain were all associated with a lower likelihood of mental HRQOL improvement. After adjustment, only female sex, depression, and stress were independently associated with changes in mental HRQOL.

For condition-specific HRQOL (Table 3), more severe baseline UCPPS pain and urinary scores and female sex were associated with less favorable HRQOL trajectory in univariable analysis. After adjustment, only the UCPPS pain score was independently associated with condition-specific HRQOL change.

Discussion

Like most chronic pain conditions, UCPPS is a non-lethal but potentially debilitating disorder for which effective treatments are lacking. Optimal management involves an individualized approach that focuses on patient well-being as well as reducing the UCPPS symptoms. Maximizing quality of life (the ability to function despite the UCPPS symptoms) is perhaps equally important as pain control. This is the first study to prospectively assess HRQOL over time in a group of men and women with UCPPS. Over 12 months, general HRQOL status (mental and physical) was stable in about 45–50% of participants, improved in about 25%, and worsened in about 30%. UCPPS-specific HRQOL improved in 47% and was stable or worsened in 53%. The greater proportion with improvement in UCPPS-specific HRQOL (as opposed to general HRQOL) may reflect the fact that study participants were recruited from UCPPS referral sites and were receiving ongoing UCPPS treatments during the study time period, while other concomitant health conditions may have received less attention.

Poorer initial HRQOL predicted greater improvement across all three categories. This may in part be due to regression to the mean or the result of some patients volunteering for the study during a period of particularly high symptoms and problems which decreased over the course of the study. The analysis of HRQOL predictors also emphasizes important differences across the HRQOL domains. Overall, higher levels of baseline problems most connected to the domain seemed to be the best predictors of declining outcome on that domain after controlling for initial HRQOL levels.

Worsening physical HRQOL outcome was associated with the presence of more widespread pain and greater non-urologic symptoms. These findings highlight the importance of

recognizing and tracking generalized physical symptoms in UCPPS patients so that treatments for these symptoms may be offered or adjusted. Worsening HRQOL outcomes were also associated with increasing participant age. It is likely that this association is due to the presence of additional comorbidities in elderly patients, rather than specific UCPPS factors. This would explain why increased age was associated with less improvement in general HRQOL, while age was not associated with UCPPS-specific HRQOL trajectory.

Mental HRQOL outcomes were impacted by almost all measured variables including female sex, baseline UCPPS symptoms, widespread pain, non-urologic medical symptoms, and all measured psychosocial variables. Stress, depression, and female sex remained independently associated with poorer HRQOL outcomes after multivariable analysis. These findings primarily highlight the impact of psychosocial factors on the HRQOL of UCPPS patients. Clinicians who treat UCPPS should involve mental health care in the management of patients who exhibit symptoms of depression, stress, or poor coping.

As noted above, condition-specific HRQOL improved in almost 50% of participants. Very few of the examined variables, however, correlated with UCPPS HRQOL trajectory. Worse baseline UCPPS symptoms were associated with less favorable outcomes, while psychosocial variables and degree of widespread pain/symptoms were not associated. These findings reinforce the need for more effective UCPPS treatment approaches, as improved HRQOL is clearly tied to UCPPS symptom reduction.

These results can be compared with a previous MAPP study that used similar statistical methods to assess predictors of UCPPS symptom change over 12 months[2]. In that study, the primary predictors of declining UCPPS symptoms were the presence of widespread pain, greater non-urologic symptoms, and poorer overall health, while psychosocial variables had a minimal impact. Taken together, the findings provide empiric evidence that optimal outcomes require a reduction in UCPPS symptoms, widespread/nonurologic pain, and psychosocial symptoms.

The MAPP cohort study provides an enormous amount of prospective data with a very high retention rate, but the follow-up period was limited to 12 months. Therefore, any changes/trends were relatively short-term in nature, especially for a chronic disorder like UCPPS. Study participants, however, reported a broad range of symptom duration (range 1–54 years, mean 8 years)[25], and the association between symptom duration and our HRQOL outcomes was not significant, suggesting that these findings may be applicable with longer-term follow-up. We also acknowledge that this was a ‘treated natural history’ study, in which UCPPS participants received usual care for their symptoms. These treatments may have varied considerably across providers and treatment sites. Individual treatment regimens were not closely tracked in this study, and therefore we are not able to correlate specific treatments with HRQOL data. A second MAPP cohort study is underway which will address some of these limitations. In this second study, participants will be followed for a longer time period (up to 3 years), and UCPPS treatment details will be collected longitudinally so that specific treatments effects can be correlated with individual participant phenotypes.

Conclusions

Over 1 year, nearly half of the participants demonstrated improved UCPPS-specific HRQOL while only a quarter showed improved general HRQOL. Poorer initial HRQOL predicted greater improvement across all three categories. Greater UCPPS pain predicted worse improvement in UCPPS-specific HRQOL while higher non-urological pain and stress predicted general physical and mental HRQOL, respectively. Additional research with longer follow-up is necessary to better understand the complexity of factors associated with improvement in UCPPS-specific HRQOL.

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Abbreviations

CP/CPPS	Chronic Prostatitis/Chronic Pelvic Pain Syndrome
EPS	Epidemiology and Phenotyping Study
GUPI	Genitourinary Pain Index
HRQOL	Health Related Quality Of Life
IC/BPS	Interstitial Cystitis/Bladder Pain Syndrome
MAPP	Multidisciplinary Approach to the Study of Chronic Pelvic Pain
MCS	Mental Functioning
PCS	Physical Functioning
QOL	Quality of Life
SP-12	Short Form Health Survey
UCPPS	Urologic Chronic Pelvic Pain Syndrome

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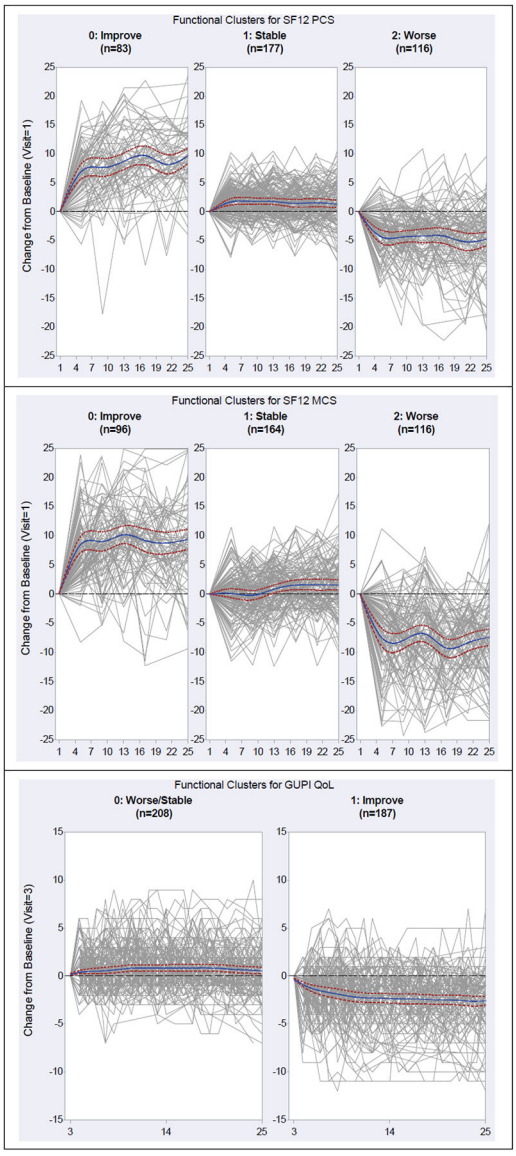

Figure 1.

Functional clustering of participants based on longitudinal HRQOL ratings (in grey), classified into one of three clusters (Improved, Stable, Worse). Clustering was done separately for SF-12 PCS score (top), SF-12 MCS score (middle) and GUPI QOL subscale score (bottom). For the GUPI QOL scale, the analysis resulted in only two clusters (Stable vs Improved). Blue lines show the mean HRQOL scores for each cluster, and red lines show the 95% confidence interval for these mean values.

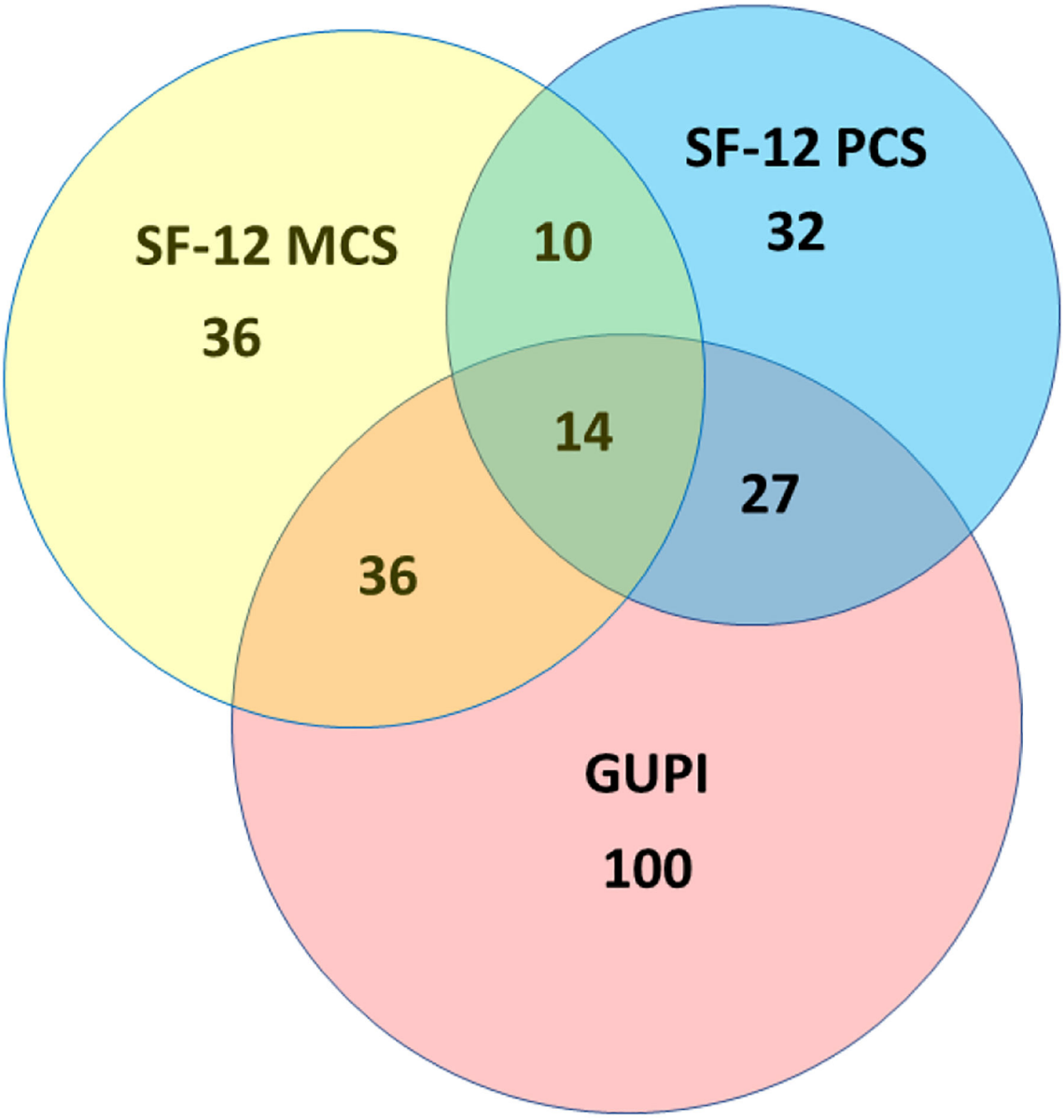

Figure 2.
Overlap of HRQOL Improvement.

Table 1.

Association of baseline characteristics with change in physical health-related quality of life

SF-12 PCS	n	Unadjusted[1]		Adjusted[2]	
		OR (95%CI)	p	OR (95%CI)	p
Baseline SF-12 PCS	376	0.914 (0.895–0.933)	**<0.0001**	0.892 (0.869–0.915)	**<0.0001**
Sex (Female)	376	0.724 (0.483–1.087)	0.12	0.730 (0.476–1.119)	0.15
UCPPS Pain Score	376	0.995 (0.957–1.034)	0.80	0.997 (0.957–1.038)	0.87
UCPPS Urinary Symptom Score	375	0.984 (0.951–1.018)	0.34	0.991 (0.957–1.026)	0.61
Increased Age (per decade)	376	0.894 (0.787–1.015)	0.08	0.866 (0.760–0.987)	**0.0306**
Symptom Duration (per 5 years)	368	0.950 (0.865–1.044)	0.29	1.003 (0.906–1.111)	0.95
Catastrophizing Score	374	1.011 (0.986–1.036)	0.39	1.005 (0.979–1.031)	0.73
Depression Score	374	0.971 (0.921–1.023)	0.27	0.976 (0.923–1.031)	0.38
Anxiety Score	374	0.988 (0.945–1.032)	0.58	0.994 (0.948–1.043)	0.81
Perceived Stress	373	0.987 (0.961–1.014)	0.34	0.989 (0.960–1.019)	0.49
Sleep Disturbance Score	375	0.977 (0.950–1.004)	0.09	0.982 (0.954–1.011)	0.22
Non-Urologic Medical Symptoms	374	0.947 (0.915–0.980)	**0.0018**	0.958 (0.922–0.996)	**0.0300**
Body Map Sites	376	0.846 (0.757–0.946)	**0.0033**	0.899 (0.793–1.020)	0.10

[1]Includes baseline SF-12 PCS

[2]Includes: baseline SF-12 PCS, Age, Non-Urologic Medical Symptoms, and Body Map Sites

Note: An Odds Ratio (OR) <1.0 indicates that this variable predicts a lower likelihood of HRQOL improvement

Table 2.

Association of baseline characteristics with change in mental health-related quality of life

SF-12 MCS	n	Unadjusted[1]		Adjusted[2]	
		OR (95%CI)	p	OR (95%CI)	p
Baseline SF-12 MCS	376	0.905 (0.885–0.925)	**<0.0001**	0.831 (0.800–0.863)	**<0.0001**
Sex (Female)	376	0.556 (0.372–0.830)	**0.0041**	0.580 (0.380–0.885)	**0.0115**
UCPPS Pain score	376	0.960 (0.924–0.997)	**0.0361**	0.981 (0.941–1.023)	0.38
UCPPS Urinary Symptom score	375	0.961 (0.930–0.993)	**0.0175**	0.987 (0.952–1.024)	0.49
Age (per decade)	376	1.138 (0.993–1.304)	0.06	1.115 (0.963–1.290)	0.14
Symptom duration (per 5 years)	368	0.943 (0.859–1.036)	0.23	0.962 (0.872–1.060)	0.43
Catastrophizing Score	374	0.958 (0.932–0.985)	**0.0022**	0.996 (0.966–1.028)	0.81
Depression Score	374	0.863 (0.806–0.924)	**<0.0001**	0.907 (0.840–0.980)	**0.0130**
Anxiety Score	374	0.910 (0.860–0.963)	**0.0010**	0.985 (0.918–1.057)	0.67
Perceived Stress	373	0.907 (0.873–0.942)	**<0.0001**	0.932 (0.894–0.972)	**0.0010**
Sleep Disturbance Score	375	0.948 (0.921–0.975)	**0.0002**	0.974 (0.945–1.004)	0.09
Non-Urologic Medical Symptoms	374	0.955 (0.927–0.985)	**0.0033**	0.999 (0.965–1.035)	0.97
Body Map Sites	376	0.871 (0.784–0.968)	**0.0105**	0.949 (0.848–1.062)	0.37

[1] Includes baseline SF12 MCS

[2] Includes: baseline SF12 MCS, Sex, Depression Score, Perceived Stress, and Sleep Disturbance Score

Note: An Odds Ratio (OR) <1.0 indicates that this variable predicts a lower likelihood of HRQOL improvement

Table 3.

Association of baseline characteristics with change in UCPPS condition-specific health-related quality of life

GUPI QOL Subscale	n	Unadjusted[1]		Adjusted[2]	
		OR (95%CI)	p	OR (95%CI)	p
Baseline GUPI QOL Subscale	395	1.242 (1.154–1.336)	**<0.0001**	1.382 (1.257–1.518)	**<0.0001**
Sex (Female)	395	0.618 (0.405–0.946)	**0.0265**	0.682 (0.442–1.053)	0.08
UCPPS Pain Score	395	0.908 (0.867–0.952)	**<0.0001**	0.913 (0.870–0.957)	**0.0002**
UCPPS Urinary Symptom Score	394	0.942 (0.906–0.979)	**0.0025**	0.972 (0.931–1.015)	0.19
Age (per decade)	395	1.026 (0.895–1.177)	0.71	0.964 (0.834–1.115)	0.62
Symptom Duration (per 5 years)	387	0.965 (0.874–1.065)	0.48	0.975 (0.881–1.080)	0.63
Catastrophizing Score	393	0.975 (0.948–1.002)	0.07	0.988 (0.959–1.017)	0.40
Depression Score	393	0.993 (0.937–1.053)	0.82	1.007 (0.948–1.069)	0.83
Anxiety Score	393	1.027 (0.978–1.079)	0.29	1.038 (0.987–1.092)	0.15
Perceived Stress	392	1.003 (0.975–1.033)	0.81	1.011 (0.981–1.041)	0.49
Sleep Disturbance Score	394	0.979 (0.950–1.008)	0.15	0.995 (0.964–1.026)	0.73
Non-Urologic Medical Symptoms	393	0.971 (0.940–1.002)	0.07	0.989 (0.956–1.023)	0.52
Body Map Sites	395	0.954 (0.885–1.066)	0.41	0.986 (0.879–1.106)	0.81

[1] Includes baseline GUPI QOL

[2] Includes: baseline GUPI QOL, Sex, and UCPPS Pain Score

Note: An Odds Ratio (OR) <1.0 indicates that this variable predicts a lower likelihood of HRQOL improvement