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COMPARISON OF BASELINE UROLOGIC SYMPTOMS IN MEN AND WOMEN IN THE MULTIDISCIPLINARY APPROACH TO THE STUDY OF CHRONIC PELVIC PAIN (MAPP) RESEARCH COHORT

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Abstract

INTRODUCTION—The clinical features of interstitial cystitis/ bladder pain syndrome (IC/BPS) are similar to those of chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS). However, no studies have directly compared the characteristics of these syndromes in men and women.

METHODS—The Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) research network recruited 191 men and 233 women with IC/BPS or CP/CPPS. Baseline data included demographics, the Interstitial Cystitis Symptom Index (ICSI) and Problem Index (ICPI), the Genitourinary Pain Index (GUPI), the American Urological Association Symptom Index (AUASI), Likert scales to assess urinary urgency, frequency, pain and overall symptom severity, and a single question about the most bothersome pelvic symptom.

RESULTS—After adjustment for age, income and symptom duration, measures of pain severity were similar across genders. Mean scores for the ICSI, ICPI and AUASI were significantly higher in women than men, reflecting more bladder-focused symptoms in women. The most bothersome single symptom in both men and women was pain in the pubic/bladder area (34% of men, 58% of women). The characteristics of the men and women in the MAPP cohort were similar to those reported in other research cohorts of IC/BPS and CP/CPPS.

CONCLUSIONS—Our findings indicate that pain severity is similar in both sexes, and that bladder-focused symptoms (urgency, suprapubic pain, frequency) are more common in women. However, a substantial proportion of men also report these types of bladder symptoms.

Keywords

interstitial cystitis; bladder pain syndrome; chronic prostatitis; chronic pelvic pain syndrome; characteristics; pain

Introduction

Interstitial cystitis/ bladder pain syndrome (IC/BPS) is defined by pain, pressure or discomfort associated with the bladder in the absence of an identifiable cause. Patients with IC/BPS often report marked urinary urgency, urinary frequency and pain throughout the pelvis[1]. In addition, these patients often describe pain in extragenital locations, such as the lower abdomen and back[2]. IC/BPS has traditionally been considered a syndrome primarily affecting women, with a female to male prevalence ratio of 10:1. However, more recent studies suggest that this syndrome is more common in men than previously observed[3,4].

Most men with chronic urological pelvic pain are considered to have chronic prostatitis/ chronic pelvic pain syndrome (CP/CPPS), characterized by pain in the perineum, suprapubic region, testicles or tip of the penis in the absence of another etiology[5]. Pain associated with CP/CPPS frequently worsens upon urination or ejaculation. Urinary symptoms such as sense of incomplete bladder emptying and urinary frequency are also commonly reported.

These observations suggest there may be substantial overlap between the defining clinical features of CP/CPPS and IC/BPS. Thus, it is not surprising that some men have symptoms which would meet the research definitions for both syndromes. Despite similar clinical presentations, previous studies have mostly been limited to patients of one sex (females in IC/BPS studies, males in CP/CPPS studies). No study to date has prospectively recruited and directly compared the characteristics of men and women with urologic pain symptoms using the same instruments. We compared baseline demographic characteristics and urologic symptoms in men and women with IC/BPS and CP/CPPS enrolled in a multi-center, prospective observational study, the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP).

Methods

Overview of the MAPP network

This NIH-sponsored multi-center research network includes six discovery sites that conduct the research studies and two core sites that coordinate data collection, analyze tissue samples, and provide technical support[6]. The MAPP protocol involves an in-depth baseline ‘phenotyping’ evaluation, with abridged follow-up assessments at 6 and 12 months[7]. During the 12-month study, subjects also complete biweekly internet-based questionnaires about their symptoms and treatments. This report includes data from the baseline pheontyping visit.

Subject recruitment

Subjects were recruited from the MAPP Research Network discovery sites. Study entry criteria were broad to permit recruitment of participants with a range of symptoms and symptom severity and reflect those in several previous prospective cohort studies and clinical trials of these syndromes[8-12]. The inclusion criteria are described in detail elsewhere[7], and included a clinical diagnosis of IC/BPS or CP/CPPS, and a pain score of at least one on a Likert pain scale. To meet IC/BPS inclusion criteria, male or female subjects were required to have an unpleasant sensation of pain, pressure, or discomfort, perceived to be related to the bladder and/or pelvic region, associated with lower urinary tract symptoms. These symptoms had to be present for the majority of the time during any 3 months in the previous 6 months, and also had to be present for the majority of the time during the most recent 3 months. To meet CP/CPPS criteria, men were required to report pain or discomfort in any of the 8 items in the pain subscale of the Genitourinary Pain Index[13]. These symptoms had to be present for the majority of the time during any 3 months in the previous 6 months.

Persons were excluded from the study if they had a history of any non-dermatologic malignancy, systemic autoimmune disorder (such as inflammatory bowel disease, systemic lupus erythematosis, multiple sclerosis, or rheumatoid arthritis), neurologic disorder affecting bladder function, major psychiatric or medical disorder that would interfere with study participation, pregnancy, prior augmentation cystoplasty or cystectomy. Men were also excluded if they had isolated unilateral orchalgia with no additional pain symptoms, or had received selected previous prostate therapies (e.g., microwave, needle ablation, balloon dilation, laser procedure, or cryosurgery). If otherwise eligible, potential study participants could be deferred from study entry for three months if they had bacterial cystitis, other urogenital infections (epididymitis/orchitis, urethritis, vaginitis, etc.), recent prostate biopsy, or transurethral resection of the prostate. In addition, presence of hematuria required deferral until evaluation had been completed. All subjects provided a clinical history and underwent a physical examination to rule out other possible causes of their symptoms. Participants then completed an evaluation that included collection of extensive demographic data, measures of symptom severity and biological samples.

Questionnaire data

Age, sex, race/ethnicity, educational level, employment status, and household income were self-reported by the study participant. Symptoms characteristics were evaluated with the following self-completed questionnaires[7]:

Symptom severity—Likert scales inquired about urinary urgency, frequency, and pain in the preceding 2 weeks (Table 1). An additional question asked each subject to rate the overall severity of their urologic/ pelvic pain symptoms over the past 2 weeks.

Most bothersome symptom—Subjects were asked to indicate their most bothersome symptom over the preceding two weeks, “If you could get rid of your SINGLE most bothersome symptom over the past 2 weeks, which ONE would you choose?” Response options included:

- Pain, pressure or discomfort in your pubic or bladder area
- Pain/ discomfort during or after sexual activity
- Strong need to urinate with little or no warning
- Frequent urination during the day
- Frequent urination during at night
- Sense of not emptying your bladder completely
- Men only): Pain, pressure, discomfort in the area between your rectum and testicles (perineum)
- Women only): Pain, pressure or discomfort in the vaginal area
- Other:_____

Interstitial cystitis symptom index (ICSI) and interstitial cystitis problem index (ICPI)—These validated instruments consist of two 4-item questionnaires[14]. The ICSI was developed to quantify urinary and pain symptoms in patients with IC/PBS, and the ICPI assesses the degree of bother caused by these symptoms.

Genitourinary pain index (GUPI)—This instrument was developed to quantify and compare urologic pain symptoms across genders using three subscales that assess pain urinary symptoms, and quality of life[13]. The male version of the GUPI includes the entire chronic prostatitis symptom index[15] (CPSI) to facilitate comparisons with studies that used the CPSI to measure prostatitis symptoms.

American Urological Association symptom index (AUASI)—This instrument quantifies urinary storage and voiding symptoms in both men and women[16,17].

Statistical analyses

Descriptive statistics were computed for continuous variables, and frequency distributions were summarized for categorical variables, both overall and stratified by sex. Unadjusted tests for symptom differences between males and females employed t-tests for continuous scales, the Wilcoxon rank-sum test for ordinal scales, and chi-square tests for nominal categorical variables. Tests adjusted for age, income, and duration of pelvic pain symptoms were completed by linear regression for ordinal and continuous scales and logistic regression for nominal categorical scales. We did not consider all known risk factors for UCPPS when selecting variables to include in adjustment. We adjusted for variables that were distributed differently between males and females, which is sufficient to account for confounding. To **account** for multiple comparisons, $p < 0.01$ was selected as the threshold for significant differences. This threshold was chosen as a compromise between the standard threshold of $p<0.05$ and thresholds suggested by standard multiple comparisons adjustments that were likely overly conservative considering the correlation in symptom measures[18]. Analyses were performed using SAS/STAT, version 9.3 (Cary, NC).

Results

Over a period of 36 months (December 2009 to December 2012), a total of 424 participants were recruited; 233 were female and 191 were male. On average, females were younger, had lower self-reported income and longer symptom duration than males (Table 2). After adjustment, scores of measures of pain severity (Likert pain severity scale, GUPI total score, GUPI pain subscale, and overall symptom severity) were generally similar across genders. In contrast, mean urgency scores, and mean scores for the ICSI, ICPI and AUASI were significantly higher in women than in men. Mean scores of individual items of these measures were higher (worse) in women across all items except those related to weak urinary stream and straining to void (which showed similar scores across genders) (Data not shown).

In both men and women, the most bothersome symptom was pain in the pubic/ bladder area (Table 3), but a significantly greater proportion of women (58%) reported this as their most bothersome symptom compared to men (34%) ($p<0.0001$). In women, 58% of subjects reported this as the most bothersome symptom, and the remaining symptom categories were chosen in a small minority of subjects (≤8% for each). Responses for the most bothersome symptom were more diverse in men, with perineal symptoms (23%) the second most bothersome symptom.

Discussion

We identified important gender differences in urologic pain symptoms. Storage (‘irritative’) symptoms, such as urgency, frequency and nocturia (as reflected in the ICSI, ICPI and AUASI responses), were reported more often by women than by men. Furthermore, most female participants indicated that pubic/bladder area pain was their most bothersome symptom, while the responses from male participants reported a more diverse set of most bothersome symptoms. These observed differences in symptom characteristics might be expected, as female participants were recruited based on the presence of IC/BPS (which by definition includes the presence of bladder-focused symptoms) while male participants could meet the study entry criteria if they had CP/CPPS symptoms only with few bladder symptoms. Clear criteria distinguishing between IC/BPS and CP/CPPS in male patients do not exist. Therefore, the MAPP did not focus on clinical diagnoses that had been assigned to participants. We focused on clearly characterizing participants’ symptoms. The numerous similarities between male and female UCPPS subjects could be interpreted as evidence that many men with UCPPS meet symptom criteria for IC/BPS. Whether a ‘bladder-focused’ male phenotype is associated with unique characteristics (e.g., associated conditions, natural history, etc.) needs to be explored, and a detailed analysis of these issues is in process.

Despite these observed gender differences in specific symptom characteristics, global measures of urologic pain severity (Likert pain scales, GUPI pain subscale) were similar across genders, with wide ranges in reported pain scores across all measures. This indicates that MAPP recruitment strategies proved successful in accruing participants with a broad range of symptoms, which is prerequisite for examining the impact of symptom characteristics on urologic pain. Future analyses will examine the impact of specific

symptom characteristics on quality of life, healthcare resource use, and symptom progression or regression.

Assessment of the 'most bothersome symptom' was a unique aspect of our analyses. We found that perineal pain represents a defining characteristic of male UCPPS, and that pubic/bladder pain is more common in women than in men with UCPPS. However, the data largely served to reinforce the similarities between the symptoms reported in both sexes. We are currently conducting more complex analyses to further examine the overlap and distribution of pain and urinary symptoms, using both baseline and longitudinal data in the MAPP population.

It is also useful to compare these MAPP data with previous IC/BPS and CP/CPPS patient cohorts (Table 4). The mean age in female MAPP subjects is somewhat less than the mean ages reported for other published IC/BPS cohorts, but this likely reflects the MAPP recruitment strategy of over-sampling subjects with symptom duration <2 years. Overall, the data in Table 4 suggest that the clinical characteristics of the MAPP subjects are similar to previously published IC/BPS and CP/CPPS cohorts. This is important, because it implies that the MAPP subjects are representative of 'typical' IC/BPS and CP/CPPS patients, and that MAPP research findings are likely to be generalizable to this broader patient population.

MAPP subjects reported a long duration of symptoms (mean values - 7.8 years in women and 9.1 years in men) despite our strategy to over-sample subjects with < 2 years of symptoms. Comparisons with published data suggest that female MAPP subjects have a similar reported symptom duration to other IC/BPS cohorts, while male MAPP subjects may have a somewhat shorter reported symptom duration than other CP/CPPS cohorts (Table 4). However, it is important to note that many published studies have not reported symptom duration values, and that these values may be subject to considerable recall bias.

Conclusions

Our findings suggest that there were significant differences in symptom characteristics in men and women participating in the MAPP study, with female subjects more likely to report bladder-focused symptoms. Despite these differences, overall pain severity proved similar across genders. More detailed analyses are needed to identify relevant patient subgroups (phenotypes), to assess their clinical significance, and to determine whether these phenotypes exist across genders. The ultimate goal is to determine if phenotypic differences in the clinical presentation of patients with urologic pain symptoms can determine the optimal evaluation and management of these common urological syndromes.

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Table 1

Pain, Urgency, Frequency, and Severity Scales

Symptom Severity Scales

Pain, Urgency, Frequency Severity Scales

1. Think about the pain, pressure, and discomfort associated with your bladder/prostate and/or pelvic region. On average, how would you rate these symptoms during the past 2 weeks?

No pain or pressure or discomfort										**Most severe discomfort I can imagine**
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

2. Urgency is defined as the urge or pressure to urinate. On average, how would you rate the urgency that you have felt during the past 2 weeks?

No urgency										**Most severe urgency I can imagine**
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

3. Think about your frequency of urination. On average, how would you rate your frequency of urination during the past 2 weeks?

Totally normal										**Most severe frequency I can imagine**
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Urologic or Pelvic Pain Symptom Severity Scales

5. Please rate the overall severity of your **UROLOGIC OR PELVIC PAIN SYMPTOMS** over the past 2 weeks:

No Symptoms										**Symptoms as bad as they can be**
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Table 2
Baseline Characteristics of MAPP Participants by Gender

		Sex		p values	
		Male	Female	Unadjusted	Adjusted†
Number of Participants	**N (%)**	191	233		
Age (years)	Mean (Range)	46.8 (19 - 82)	40.5 (19 - 78)	<0.001	
Race/Ethnicity	White	170 (89.0%)	204 (87.6%)	0.762	0.664
	Non-White	21 (11.0%)	29 (12.4%)		
Employment	Employed	134 (70.2%)	144 (61.8%)	<0.001	0.557
	Unemployed	19 (9.9%)	39 (16.7%)		
	Retired	30 (15.7%)	13 (5.6%)		
	Full-time homemaker	0 (0%)	12 (5.2%)		
	Disabled	8 (4.2%)	24 (10.3%)		
	Missing	0 (0%)	1 (0.4%)		
Income	$10,000 or less	9 (4.7%)	31 (13.3%)	<0.001	
	$10,001 to $25,000	12 (6.3%)	22 (9.4%)		
	$25,001 to $50,000	26 (13.6%)	43 (18.5%)		
	$50,001 to $100,000	61 (31.9%)	61 (26.2%)		
	More than $100,000	68 (35.6%)	52 (22.3%)		
	Prefer not to Answer	14 (7.3%)	23 (9.9%)		
	Missing	1 (0.5%)	1 (0.4%)		
Duration of Symptoms (years)	Mean (Range)	7.8 (0-54)	9.1 (0-47)	0.216	0.015‡
Pain (0-10)	Mean (Range)	4.9 (1-10)	5.2 (1-10)	0.059	0.838
Urgency (0-10)	Mean (Range)	4.7 (0-10)	5.4 (0-10)	0.009	0.040
Frequency (0-10)	Mean (Range)	4.6 (0-10)	5.1 (0-10)	0.059	0.195
Overall Symptoms (0-10)	Mean (Range)	5.0 (0-10)	5.4 (0-10)	0.077	0.713
GUPI Total Score (0-45)	Mean (Range)	24.6 (6-44)	26.4 (0-43)	0.026	0.593
GUPI Pain Subscale (0-23)	Mean (Range)	12.2 (2-23)	12.9 (0-21)	0.137	0.823
IC Symptom Index (0-20)	Mean (Range)	8.5 (0-20)	10.8 (0-20)	<0.001	<0.001
IC Problem Index (0-16)	Mean (Range)	7.3 (0-16)	9.5 (0-16)	<0.001	<0.001
AUA Symptom Score (0-35)	Mean (Range)	14.0 (0-33)	16.7 (1-35)	0.001	0.011

† Adjusted for age, income and symptom duration.

‡ Adjusted for age and income.

Table 3

Most Bothersome Symptom

Symptom	Sex		p-value
	Male	Female	
Symptoms in pubic/bladder area	65 34%	134 58%	< .0001
Symptoms in perineum	45 24%		NA
Symptoms in vaginal area		11 5%	NA
Symptoms during/after sexual activity	9 5%	12 5%	0.836
Strong need to urinate	9 5%	13 6%	0.689
Frequent urination during the day	17 9%	15 6%	0.341
Frequent urination at night	15 8%	19 8%	0.910
Sense of not emptying bladder completely	5 3%	16 7%	0.053
Other	22 12%	11 5%	0.012
Missing data	4 2%	2 0.9%	
Total	**191**	**233**	

Table 4

Characteristics of published IC/BPS and CP/CPPS cohorts

Reference	Patient Source	No. Male Subjects	Mean Age (Range)	Mean Symptom Duration, Years (Range)	Mean CPSI Score (Range)
MAPP	Seven clinical sites in the U.S.	191	46.8 (19-82)	7.8 (0-54)	22.5 (0-43)
Samplaski 2012[19]	U.S. single institution	220	44.6 (11-79)	2* (0.1 – 36)	25.0 (3-39)
Magri 2010[20]	Two clinical sites in Italy and Germany	1227	45.8 (NR)	NR	21.3
Clemens 2006[21]	U.S. single institution	174	52 (24-90)	NR	15.3 (0-43)
Nickel 2005[22]	65 urologists in Canada	166	50 (22-83)	3.1 (0.1-33)	19.7 (0-40)
Schaeffer 2002[8]	Seven clinical sites in the U.S. and Canada	488	42.8 (20-83)	NR	22.6 (0-43)

Reference	Characteristics of Study Sample	No. Female Subjects	Mean Age (Range)	Mean Symptom Duration, years	Mean ICSI Score (Range)	Mean ICPI Score (Range)
MAPP	Seven clinical sites in the U.S.	233	40.5 (19-78)	9.1 (sd 10.5)	10.8 (0-20)	9.5 (0-16)
Konkle 2012[23]	8 urologists and 16 gynecologists in the U.S.	277	45.1 (NR)	13.6 (se 0.77)	11.3 (NR)	NR
Nickel 2010[24]	Nine clinical sites in the U.S., Canada, India, Denmark	207	49.6 (NR)	NR	12.2 (0-20)	10.6 (0-16)
Tripp 2009[25]	Three clinical sites in the U.S. and Canada	115	50.5 (NR)	6.2 (sd 5.7)	12.4 (NR)	10.8 (NR)
Clemens 2006[21]	Single institution	111	50 (23-89)	NR	10.3 (0-20)	8.9 (0-16)

Sd = standard deviation

Se = standard error

NR = not reported

* median