Comparison of an Interstitial Cystitis/Bladder Pain Syndrome Clinical Cohort With Symptomatic Community Women From the RAND Interstitial Cystitis Epidemiology Study

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Abbreviations and Acronyms

CC = clinical cohort

IC/BPS = interstitial cystitis/bladder pain syndrome

ICPI = Interstitial Cystitis Problem Index

ICSI = Interstitial Cystitis Symptom Index

RICE = RAND Interstitial Cystitis Epidemiology

RICE I = RICE high sensitivity

RICE II = RICE high specificity

SF-36® = short form health survey

Submitted for publication June 3, 2011.

Study received institutional review board approval (RAND IRB # b4822-04-01).

Supported by National Institute of Diabetes and Digestive and Kidney Diseases Grant UO1 DK070234.

* Financial interest and/or other relationship with RAND Corporation (Health Unit).

† Financial interest and/or other relationship with Cypress Biosciences Inc., Eli Lilly and Company, Forest Laboratories Inc., Jazz Pharmaceuticals Inc., Merck & Co. Inc, Pierre Fabre Pharmaceuticals USA, Pfizer Inc. and UCB Inc.

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§ Financial interest and/or other relationship with Merck, Pfizer, Lilly, Afferent Pharmaceuticals Inc. and United Biosource Inc.

See Editorial on page 381.

For other articles on a related topic see pages 715 and 725.

Purpose: The RAND Interstitial Cystitis Epidemiology survey estimated that 2.7% to 6.5% of United States women have urinary symptoms consistent with a diagnosis of interstitial cystitis/bladder pain syndrome. We describe the demographic and clinical characteristics of the symptomatic community based RAND Interstitial Cystitis Epidemiology cohort, and compare them with those of a clinically based interstitial cystitis/bladder pain syndrome cohort.

Materials and Methods: Subjects included 3,397 community women who met the criteria for the RAND Interstitial Cystitis Epidemiology high sensitivity case definition, and 277 women with an interstitial cystitis/bladder pain syndrome diagnosis recruited from specialist practices across the United States (clinical cohort). Questions focused on demographic information, symptom severity, quality of life indicators, concomitant diagnoses and treatment.

Results: Average symptom duration for both groups was approximately 14 years. Women in the clinical cohort reported worse baseline pain and maximum pain, although the absolute differences were small. Mean Interstitial Cystitis Symptom Index scores were approximately 11 for both groups, but mean Interstitial Cystitis Problem Index scores were 9.9 and 13.2 for the clinical cohort and the RAND Interstitial Cystitis Epidemiology cohort, respectively ($p < 0.001$). The RAND Interstitial Cystitis Epidemiology subjects were more likely to be uninsured.

Conclusions: The RAND Interstitial Cystitis Epidemiology community cohort was remarkably similar to an interstitial cystitis/bladder pain syndrome clinical cohort with respect to demographics, symptoms and quality of life measures. In contrast to other chronic pain conditions for which clinical cohorts typically report worse symptoms and functional status than population based samples, our data suggest that many measures of symptom severity and functional impact are similar, and sometimes worse, in the RAND Interstitial Cystitis Epidemiology cohort. These findings suggest that interstitial cystitis/bladder pain syndrome is significantly burdensome, and likely to be underdiagnosed and undertreated in the United States.

Key Words: cystitis, interstitial; epidemiology; prevalence; questionnaires

Interstitial cystitis/bladder pain syndrome is an elusive disease that is difficult to define, diagnose and treat. Previous studies have suggested that the condition is more common than current rates of diagnosis would imply.[1–5] We

0022-5347/12/1872-0508/0
THE JOURNAL OF UROLOGY®
© 2012 by American Urological Association Education and Research, Inc.
Vol. 187, 508-512, February 2012
Printed in U.S.A.
DOI:10.1016/j.juro.2011.10.040

recently published national IC/BPS prevalence estimates as part of the RICE survey.[6] Using standard case definitions with known sensitivity and specificity values, we estimated that between 2.7% and 6.5% of American women have bladder symptoms consistent with a diagnosis of IC/BPS. This suggests that IC/BPS is a pervasive condition affecting millions of American women.

In other chronic pain states such as fibromyalgia and irritable bowel syndrome it has been shown that clinical cohorts experience substantially greater symptom severity and quality of life impact than corresponding community samples.[7–12] This referral and selection bias suggests that one cannot assess the comprehensive symptom burden of these conditions simply by extrapolating the symptom burden in the clinic by the known prevalence from population based studies. To ascertain if this pattern also persists in IC/BPS study populations, we examined the demographic and clinical characteristics of the large community based RICE cohort, and compared them with those of a smaller, clinically managed IC/BPS cohort typical of study populations traditionally used in IC/BPS research.

METHODS

Clinical Cohort

Details about recruitment of the clinical cohort have been previously published.[13] This cohort consisted of 277 adult women previously diagnosed with IC/BPS with or without additional diagnoses such as endometriosis and vulvodynia. They were referred for RICE study participation by 8 urologists and 16 gynecologists across the United States with recognized expertise in managing IC/BPS. These women completed a questionnaire which included demographic information and information about IC/BPS symptoms.

RICE High Sensitivity and High Specificity IC/BPS Case Definitions

Using methods previously described 2 epidemiological case definitions for IC/BPS were developed.[13] The high sensitivity definition yielded 81% sensitivity and 54% specificity, while the high specificity definition yielded 48% sensitivity and 83% specificity. These 2 IC/BPS case definitions were then used in a national survey designed to estimate the prevalence of IC/BPS in American women.

A 2-stage national screening process was then conducted using an ongoing survey mechanism.[6] A total of 146,231 United States households were screened by telephone to identify adult women with IC/BPS symptoms. Previous diagnoses of similar disorders such as endometriosis or vulvodynia were not exclusionary. The survey identified 3,397 women who met the RICE high sensitivity definition, of whom 1,469 also met the RICE high specificity definition. For the purposes of this study those women who only met the criteria for the high sensitivity definition (but not the high specificity definition) were designated the RICE I cohort (1,928), while the women who met the criteria for the RICE high sensitivity and high specificity definitions were designated the RICE II cohort (1,469). All RICE women were used for comparative analysis against the clinical cohort.

Strategy for Comparative Analysis

The questionnaires used in the original clinical cohort and RICE surveys contained many identical items measuring demographic and socioeconomic information, as well as symptom characteristics and medical management (diagnoses and treatment). In particular, both surveys included standardized, validated tools such as the ICSI,[14] ICPI[14] and the SF-36.[15] These common items allowed us to compare responses from the RICE I and RICE II cohorts to those of the clinical cohort.

Statistical Analysis

For each of the 3 cohorts (RICE I, RICE II and clinical) descriptive statistics were calculated for the clinical characteristic variables of age, race/ethnicity, work loss, insurance status, employment status, social characteristics, symptom duration and severity, diagnostic tests, medication use, concomitant diagnoses, ICSI, ICPI and SF-36 scales. CC data were unweighted, and RICE data were weighted for sample design and nonresponse in all analyses. Analyses were conducted in SAS® 9.2 using survey procedures to adjust for the effects of weighting RICE data. Differences between groups were tested using weighted linear and logistic regression for continuous and categorical variables, respectively. All reported sample sizes represent unweighted sample sizes whereas all reported percentages and means represent weighted results (where applicable). All SF-36 T-score means and ranges were adjusted for age and gender (mean 50, SD 10).

RESULTS

Clinical Cohort vs Entire RICE Sample

Demographics. Results for the comparison of the CC with the entire RICE cohort are presented in the table. In the 2 groups mean age (approximately 45 years) and employment rates were similar (36% to 39% employed full-time, 13% to 17% employed part-time and approximately 47% not employed, no significance). The RICE cohort included fewer white subjects ($p < 0.01$) and more Hispanic women (10.8% vs 3.6%, $p < 0.001$). RICE women were considerably more likely to be uninsured (13.4% vs 2.2%, $p < 0.001$). On average, RICE women were less likely to be married ($p < 0.001$) and had more children ($p < 0.001$).

Symptom severity. CC and RICE women reported similar bladder symptom duration (13.6 vs 14.6 years, respectively, no significance). CC women reported somewhat worse levels of baseline pain (5.9 vs 5.4, $p < 0.001$) and maximum pain (8.0 vs 6.6, $p < 0.001$). CC women scored slightly higher on the ICSI (11.3 vs 10.7, $p < 0.05$) and lower on the pain component of the SF-36 (38.3 vs 40.7, $p < 0.01$, data not shown), indicating mildly worse symptom severity than the combined RICE cohort.

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