



Original Article

The sociodemographic and clinical predictors of symptom severity in patients with refractory interstitial cystitis/bladder pain syndrome

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ARTICLE INFO

Article history:

Received 9 December 2013

Received in revised form

31 December 2013

Accepted 27 January 2014

Keywords:

Bladder pain syndrome

Interstitial cystitis

Intravesical treatment

Lower urinary tract symptoms

ABSTRACT

Objectives: Interstitial cystitis/bladder pain syndrome (IC/BPS) has debilitating symptoms and results in a poor quality of life. This study investigated the associations between demographic and clinical factors and symptom severity in patients with IC/BPS in Taiwan.

Materials and Methods: Patients with documented IC/BPS refractory to conventional treatments from 2007 to 2009 were enrolled. Sociodemographic data and a medical history were obtained. Clinical assessments were performed using the O'Leary–Sant IC symptom index (ICSI) and problem index (ICPI), visual analog scale of bladder pain, and global response assessment to treatment. Patients kept a 3-day voiding diary of daytime and nighttime frequency, and functional bladder capacity (FBC) and uroflowmetry parameters (maximum flow rate, voided volume, and postvoid residual) were measured. Univariate and multivariate analyses were used to evaluate the associations between demographic/clinical factors and symptom severity.

Results: A total of 80 patients (75 women and 5 men) were enrolled. On univariate and multivariate analysis, the characteristics most associated with worse ICSI, ICPI, pain score, daytime frequency and nocturia episodes, and FBC were maximum bladder capacity (MBC) under anesthesia, duration of symptoms, body mass index (BMI), and employment status.

Conclusion: MBC and duration of symptoms were predictive factors of symptom severity in patients with refractory IC/BPS. BMI and employment status were also found to be associated with symptom severity in these patients.

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1. Introduction

Interstitial cystitis/bladder pain syndrome (IC/BPS) is a chronic bladder condition, which includes chronic pelvic pain, pressure, or discomfort, and is perceived to be related to the urinary bladder in the absence of urinary infection or other pathology [1,2]. IC/BPS is seen mainly in women (90%), at a median age of onset of 40 years [3,4]. The prevalence varies between populations [3,5–8]. Without a pathognomonic picture, the diagnosis can only be based on a combination of a thorough patient history, sterile and cytologically

negative urine, cystoscopic hydrodistention under anesthesia, and bladder biopsy [9].

IC/BPS is one of the most therapeutically frustrating problems of the urinary tract. Many different etiologies of IC/BPS have been proposed. However, none of these etiologies has been definitely proven. IC/BPS has been considered to result from long-standing inflammation of the bladder. Bladder histological analysis shows infiltrates of mast cells, eosinophilic leukocytes, and T-lymphocytes, which suggests the disease is mediated by the immune system [10–12]. Disruptions of the bladder mucosal barrier, the glycosaminoglycan layer, initiate a cascade of events in the bladder, leading to symptoms and IC/BPS [13,14]. A large range of treatments have been developed, but no single treatment has been reported to have long-term effects in eradicating symptoms [15–18].

Patients with IC/BPS have long-term bothersome symptoms characterized by suprapubic pain, urgency, frequency, and nocturia, and exacerbated by bladder filling. Their quality of life is markedly

Conflict of interest: none.

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<http://dx.doi.org/10.1016/j.tcmj.2014.02.003>

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compromised. Researchers have documented the comorbidities, risk factors, and impact on quality of life including physical, mental, sexual, and social function [19–25]. Few studies have focused on demographic and clinical characteristics that increase symptom severity. Obesity, depression, a low education level, postmenopausal status, being unemployed, being unmarried, and never having been pregnant were associated with worse symptom severity [26,27]. Volumes at first sensation and at maximal cystometric capacity in urodynamic studies were inversely associated with symptom severity in IC [19,28]. Cystoscopic findings such as glomerulations, ulceration, and bladder capacity were significantly correlated with symptoms such as pain and nocturia [22,29]. Histological analysis showed the detrusor mast cell count and intrafascicular fibrosis had statistically significant prognostic value for treatment intensity [30]. We found no study that demonstrated the factors associated with IC/BPS in the Taiwanese population.

Symptom severity is strongly related to quality of life. The treatment of IC/BPS is meant to alleviate symptoms. Identifying factors associated with increased symptom severity may provide an insight into the etiology and add potential benefits in the management of difficult cases. To investigate the association between demographic/clinical characteristics and symptom severity in patients with IC/BPS and to determine the predictors of symptom severity, we carried out a retrospective study in patients with refractory IC/BPS in Taiwan.

2. Materials and methods

Patients who were diagnosed as IC/BPS refractory to conventional treatment at Hualien and Taipei Buddhist Tzu Chi General Hospitals from 2007 to 2009 were enrolled in this retrospective study. All patients were over 18 years old and had symptoms characteristic of IC/BPS. They had been previously treated conservatively with pentosan polysulfate and/or intravesical heparin instillation for at least 6 months without clinical improvement [31]. Urodynamic study with a 0.4 M potassium chloride (KCl) test was performed routinely at baseline. All descriptions and terminology in this report were in accordance with recommendations of the International Continence Society [1]. The patients received cystoscopic hydrodistention under general anesthesia at an intravesical pressure of 80 cm water and were proven to have characteristic glomerulations. The grade of glomerulations was classified as 0 to 4, indicating none, mild, moderate, or severe glomerulations and patients were also evaluated for the presence of Hunner's lesion [32,33]. The maximal bladder capacity (MBC) was recorded. Patients with a cystometric bladder capacity of more than 350 mL, without a positive KCl test, or with a glomerulation grade of less than 2 were not included in this study. Patients with a urinary tract infection, stress urinary incontinence, chronic urinary retention, pelvic organ prolapse, or neurogenic voiding dysfunction were also excluded.

Sociodemographic data including age, sex, body mass index (BMI), employment status, lifestyle factors such as smoking or consumption of alcohol, and a medical/reproductive history were obtained. The history considered comorbidities such as hypertension, myocardial infarction, irritable bowel syndrome, urinary incontinence, erectile dysfunction, arthritis, fibromyalgia, migraine headaches, diabetes, sinusitis, allergies, asthma, endometriosis, hysterectomy, and nonurogenital cancer.

Our patients were treated with intravesical hyaluronic acid (HA) instillations 40 mg in 50 mL solution (Cystistat) weekly for 4 weeks followed by monthly instillation for 5 months [34–37], or intravesical botulinum toxin A (Botox) 100 U injections as previously described [38–42]. Patients were informed of the possible complications associated with intravesical HA instillation, such as

urinary tract infection. Written informed consent was obtained from every patient prior to participating in the present study.

Clinical assessments performed at baseline, 1 month, and 6 months after treatment start included IC/BPS symptoms, a 3-day voiding diary, and uroflowmetry. The IC/BPS symptoms were assessed using the O'Leary–Sant IC index, which is composed of two subscales that measure the frequency of IC/BPS symptoms (IC symptom index, ICSI; range 0–20) and the degree of bother associated with symptoms (IC problem index, ICPI; range 0–16) [43,44]. Bladder pain was assessed by a visual analog scale (VAS), ranging from 0 (no pain) to 10 (severe pain). The patients kept a 3-day voiding diary to record the functional bladder capacity (FBC), number of urinary daytime voidings, and nocturia episodes. Uroflowmetry and the postvoid residual volume measurement were also carried out at each time point. A self-assessed global response assessment (GRA) was used to rate bladder symptoms compared with baseline on a seven-point centered scale.

Continuous variables were expressed as mean \pm standard deviation (SD), and categorical data were expressed as number and percentages. Statistical comparisons between the subgroups were tested using the Chi-square test for categorical variables, and the independent *t* test for continuous variables. The paired *t* test was used to evaluate significant differences in the variables at baseline and after treatment. All statistical assessments were two-sided and considered significant at $p < 0.05$.

Because the outcomes of interest indicative of symptom severity of IC/BPS were in a repeated measurement manner, we used the generalized estimating equations (GEE) model to assess the association between them and demographics and clinical factors. The dependent variables including the ICSI, ICPI, pain score, frequency and nocturia episodes, and FBC measured at three time points were considered the repeated effect. The independent variables were demographics and clinical factors and were considered the fixed effect. The correlation structure was unstructured after fitness testing. Univariate and multivariate analyses were performed. Based on distribution of case volume, we stratified age, BMI, MBC, symptom duration, and number of children into tertiles. The estimate was exponentiated in the form of β . Covariates that retained $p < 0.15$ on univariate analysis or had a trend toward a worse outcome were entered into the multivariate regression models. There were similarities between our dependent variables (ICSI, ICPI, pain score, frequency, nocturia episodes, and FBC). There might have been collinearity between these variables. Therefore, an individual regression model was applied for each dependent variable. All statistical tests were two-sided and used a significance level of 5%. All statistical tests were performed using SAS for Windows, version 9.1 (SAS Institute Inc., Cary, NC, USA).

3. Results

A total of 80 patients including 75 women and 5 men were enrolled in this study. Their demographic characteristics and baseline data, such as symptom duration, daytime frequency and nocturia episodes, FBC, MBC, ICSI, ICPI, and VAS pain scores, are shown in Table 1. Fifty six patients received intravesical HA instillation and 24 patients received intravesical Botox injections. There were no significant differences in the demographic characteristics between the two treatment groups. All patients had moderate to severe glomerulations in cystoscopic hydrodistention, but none had a Hunner's ulcer.

3.1. Univariate analysis

On univariate analysis fitted by a GEE model, we found that the independent variables associated with outcome parameters indicative of symptom severity were MBC, duration of symptoms, BMI,

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