Pelvic Floor Myofascial Pain Might Influence Treatment Outcome of Interstitial Cystitis/bladder Pain Syndrome

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Research Article

Keywords: interstitial cystitis/bladder pain syndrome; pelvic floor muscle, myofascial pain, trigger point, vaginal digital examination, treatment outcome

Posted Date: December 29th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-1176386/v1>

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Abstract

Introduction

In patients with interstitial cystitis or bladder pain syndrome (IC/BPS), 85% were found to have pelvic floor myofascial pain (PFMP) and hypertonicity (PFH). However, they are not typically trained to consider or assess PFMP as a contributing factor to patients' IC/BPS symptoms. This study aimed to explore the relationship between PFMP and treatment outcomes in women with IC/BPS.

Methods

Patients with IC/BPS who received any type of treatment were prospectively enrolled. They underwent vaginal digital examination at baseline. PFMP severity was quantified on the visual analog scale (VAS). Subject assessment items included O'Leary-Sant symptom score (OSS), Global Response Assessment (GRA), and Beck's anxiety inventory. Object assessment items included bladder computed tomography (CT), urodynamic parameters, maximum bladder capacity, and grade of glomerulation.

Results

A total of 65 women with IC/BPS (mean age, 57.1 ± 11.3 years) were enrolled in the study. Patients with more severe PFMP had significantly higher rate of dyspareunia ($p = .031$); more comorbidities ($p = .010$); higher number of PFMP sites ($p < .001$); and higher OSS ($p = .012$). PFMP severity was not significantly correlated with bladder conditions, whether subjective or objective. Moreover, PFMP severity (VAS) was significantly negatively associated with GRA score.

Conclusion

PFMP might affect the subjective results of IC/BPS treatment but not the bladder condition. Therefore, in the future treatment of patients with IC/BPS, digital vaginal examinations of pelvic floor muscles should be performed and focused more on the PFM-related conditions, and necessary PFM treatments, such as the vaginal pelvic floor muscle message, should be scheduled.

Introduction

Interstitial cystitis/bladder pain syndrome (IC/BPS) is a disease of unknown etiology. This multifactorial clinical condition is typically characterized by irritative voiding symptoms in the form of urinary frequency and urgency, with debilitating episodic chronic pain.¹ IC/BPS has been included in myofascial pain and neuropathic pain syndromes interrelated with the immune and inflammatory systems.² The prevalence rate of IC/BPS is between 3% and 10% and more frequent among women.³ To date, classic Hunner's lesion interstitial cystitis (HIC) is a bladder disease, and bladder treatment improves symptoms. Non-Hunner's lesion interstitial cystitis (NHIC) likely has multiple etiologies and, in many cases, is difficult to treat. The bladder might be an innocent bystander in a larger pelvic process,⁴ and systemic and immune

conditions are in need of further attention. Jiang et al. even pointed out that suburothelial inflammation and apoptosis are highly prevalent in the bladders of patients with urolithiasis, which even had a smaller maximal bladder capacity (MBC).⁵ Our previous study also demonstrated that stress is positively associated with pain in patients with IC/BPS, while stress reduction can lead to a simultaneous decrease in the severity of other symptoms.⁶

Pelvic floor muscle (PFM) is often associated with urological, gynecological, gastrointestinal, and sexual problems and chronic pelvic pain.⁸ Several researchers also noted that PFM hypertonicity (PFH), also called pelvic floor myofascial pain (PFMP), could affect treatment outcome and quality of life.^{2,7-9} The prevalence of PFMP in patients with IC/BPS ranges from 50% to 90%.⁴ When muscle fiber trauma occurs, inflammatory mediators, such as bradykinin, serotonin, prostaglandins, adenosine triphosphate, and histamine, are released locally, which sensitize muscle nociceptors and reduce their mechanical threshold and result in muscle hyperalgesia and mechanical allodynia.¹⁰ Myofascial pain can also develop secondary to the presence of bladder pain syndrome.¹¹ The location and severity of PFMP are significantly correlated with degree of symptoms, even after controlling for postmenopausal status.⁹

The PFMP may be quite severe and is usually accompanied by acute attacks that awake patients, and symptoms are usually vague and poorly localized.¹² However, pelvic pain is not perceived at the site of the trigger point origin but at a remote site (referred pain).^{11,13} Until very recently, these hypotheses were difficult to study because a standardized, reproducible examination for PFMP did not exist.⁶ In patients with IC/BPS, 85% were found to have PFMP and PFH.¹⁴ However, PFMP has remained largely understudied and poorly recognized by women's health providers who are not typically trained to consider or assess for PFMP as a contributing factor to patients' IC/BPS symptoms.⁶ This study aimed to explore the relationship between PFMP and treatment outcomes in women with IC/BPS.

Methods

This is a prospective study that enrolled 65 women who had been diagnosed with IC/BPS from September 2020 to June 2021. The Ethics Committee of Buddhist Tzu Chi General Hospital had approved the study. (IRB Number: IRB105-25-B). All methods were performed in accordance with the relevant guidelines and regulations. Patients were informed about the study rationale and procedures; written informed consent was obtained from all patients prior to enrolment and treatment. These women had been evaluated and treated by urologists, gynecologists, psychiatrist, and other medical specialists without resolution of their pain. The diagnosis of IC/PBS was established based on the characteristic symptoms and cystoscope findings of glomerulations, petechiae, or mucosal fissures after hydrodistention.¹⁵ They had received several treatments, including cystoscopic hydrodistention, intravesical botulinum toxin A injection, electrocoagulation of Hunner's lesions, and platelet-rich plasma (PRP) intravesical injection. All patients had received video urodynamic study (VUDS), bladder computed tomography (CT), and cystoscopic hydrodistention at baseline.¹⁵ Vaginal digital

examination was performed at the first visit to evaluate their PFM condition before treatment. The patients were investigated thoroughly upon enrolment and excluded if they did not meet the inclusion criteria of the National Institute of Diabetes and Digestive and Kidney Diseases.¹⁵

Our evaluation included a comprehensive history and pelvic examination performed by a certified nurse practitioner using the right hand with forefinger to examine all women in a comfortable dorsal lithotomy position.¹⁶ The pelvic examination included assessment of pubovaginalis, puborectalis, iliococcygeus, coccygeus, anal sphincter, obturator internus, piriformis, and tendinous arch. Pain was quantified on a 10-point visual analog scale (VAS) by the patient. A retrospective chart review was conducted to gather additional data. Descriptive statistics were used to describe the sample and distribution of variables, such as bladder condition and pain levels.

The evaluation items included patient's bladder characteristics, O'Leary-Sant score (OSS) with IC symptom index (ICSI) and IC problem index (ICPI), bladder CT, urodynamic parameters, MBC, and grade of glomerulation under cystoscopic hydrodistention. Global Response Assessment (GRA) was administered or determined at one month after treatment, and anxiety severity was assessed by the Beck's anxiety inventory (BAI). The BAI score was 0–18 points, indicating mild anxiety; 19–29 points indicating moderate anxiety; and 30–63 indicating severe anxiety.¹⁷

Statistical comparisons between the groups were tested using the Pearson's chi-square test or Fisher's exact test for categorical variables, and an independent t-test or analysis of variance for continuous variables, to use multiple linear regression analyses on factors associated with PFMP and pain severity. All statistical analyses were performed using SPSS (version 22.0, SPSS Inc., Chicago, IL), with a p-value <.05 being used as the criterion for statistical significance.

Results

A total of 65 women with IC/BPS were included in this study. The mean age was 57.1 ± 11.3 years, and the mean duration of IC symptoms was 12.8 ± 10.5 years. They had received three types of treatment on average, seven (11%) patients underwent cystoscopic hydrodistention, three (5%) received intravesical botulinum toxin A injection treatment, 53 (82%) patients received PRP intravesical injection, and two (3%) patients received the electrocoagulation of Hunner's lesions treatment. Moreover, 55 (73.8%) patients have had a vaginal delivery. Regarding sexual behavior, 30 (46.1%) patients had sex within the recent one year, but 31 (47.7%) patients did not have sex for up to five years, and overall, up to 32 (49.2%) patients had pain during sexual intercourse. We also found that 29 (44.6%) patients had transvaginal surgery. The self-reported mean OSS was 25.9 ± 7.8 , self-reported lower abdominal pain score under the Numerical Rating Scale (NRS) was 6.1 ± 2.6 , and mean severity of anxiety using BAI was 21.4 ± 12.0 . All patients underwent cystoscopic hydrodistention, with a mean MBC of 801.6 ± 170.6 mL and mean glomerulation grade of 1.4 ± 1.1 .

When these patients underwent vaginal examination to assess their PFM trigger points, 56 (86.2%) patients had PFMP. Among the 14 assessment sites, the mean number of painful sites was 5.2 ± 4.4 , and the mean PFMP severity by VAS score was 6.9 ± 3.0 points. One month after treatment, 17 (26.1%) patients reported no change in GRA or even poor change ($\text{GRA} = -1 \sim -3$), nine (13.8%) patients had no change after treatment ($\Delta\text{GRA} = 0$), 20 (30%) patients reported slight improvement ($\Delta\text{GRA} = +1$), and 28 (43%) patients reported a significant improvement after treatment ($\Delta\text{GRA} = +2 \sim +3$). The most painful sites are the obturator internus (63.1%) and puborectalis (60%) (Figure 1). In the bladder CT of each patient with IC/BPS, we also noted that the bladder wall phenotype of 42 (66.7%) patients is smooth bladder wall. Furthermore, the bladder wall of 21 (33.3%) patients has a focal thickness or diffuse thickening.

When we divided the vaginal examination PFM trigger point pain score into three groups, 12 patients had mild PFMP (VAS of 0 to 3), 11 patients had moderate PFMP (VAS of 4 to 6), and 42 patients had severe PFMP (VAS of 7–10). Patients with more severe PFMP had significantly higher rate of dyspareunia in the sexual life (16.7% in the mild pain group, 45.5% in the moderate pain group, and 59.5% in the severe pain group, $p = .031$); more comorbidities (mild pain group, $.7 \pm .7$; moderate pain group, 2.6 ± 1.7 ; severe pain group, 2.2 ± 1.8 ; $p = .010$); higher number of myofascial pain sites (mild pain group, $.8 \pm 1.4$; moderate pain group, 3.6 ± 1.5 ; severe pain group, 6.8 ± 4.4 ; $p < .001$); and significant correlation with OSS (mild pain group, 19.9 ± 8.4 ; moderate pain group, 27.1 ± 9.2 ; severe pain group, 27.3 ± 6.6 ; $p = .012$) (**Table 1**).

Meanwhile, the self-reported treatment outcome (GRA) also had a significant correlation with different PFMP severity groups ($p = .015$). The GRA score was $2.2 \pm .9$ in patients with mild PFMP, which was higher than that in patients with moderate PFMP ($1.6 \pm .7$) and severe PFMP ($.9 \pm 1.5$) (**Table 1**). However, the PFMP severity was not significantly correlated with the bladder conditions, whether subjective or objective, such as the patient self-reported uncomfortable bladder condition severity (NRS), MBC, and glomerulation grade during cystoscopic hydrodistention, VUDS parameters, pelvic CT image, and even uroflowmetry parameters such as Q_{max} (Δp value = .176), voiding volume (Δp value = .31), and post-void residual urine (PVR) (Δp value = .770) (**Table 2**).

The final regression model revealed that the PFMP severity (VAS) as a dependent variable, including six independent variables, of which only GRA ($p < .001$) was statistically significant, and there was no significant difference with age, OSS, anxiety severity (BAI), glomerulation grade, and MBC. The results showed that an improvement of .10 on the PFMP severity (VAS) of relatives' GRA was associated with a decreased burden of 1.65 scale steps (**Table 3**).

Discussion

To date, there is no gold standard treatment strategy for patients with IC/BPS, only a suitable treatment.¹⁸ Many efforts have been attempted to find a better treatment outcome for patients with IC/BPS, including antiviral treatment for Epstein–Barr virus infection,^{19,20} PRP injection for

increase in regenerative deficits in IC/BPS,^{19,20} and psychiatric consultation for psychosomatic dysfunction associated with IC/BPS.^{19,20} In this study, we also found that patients with IC/BPS have 2.0 ± 1.7 comorbid psychosomatic disorders, such as depression, insomnia, reflux esophagitis, asthma, irritable colon, and arrhythmia.²¹

Simultaneously, Gisela also reported the high frequency of comorbid disorders well beyond geographic contiguity with the bladder region affecting our pathophysiologic construct of IC/BPS, suggesting either some type of systemic disorder, a process under central nervous system (CNS) control, or both.²² An abnormal CNS drive seems likely to cause a secondary psycho-neuro-endocrine-immune dysfunction in patients with IC/BPS.²¹ Significantly more psychosomatic comorbidities are noted in the moderate PFMP severity group than that in the mild PFMP group ($p = .010$). Similarly, dyspareunia is also a significantly more common complaint in the severe PFMP group than in other groups ($p = .031$). These results are consistent with the results of a previous study.⁷

One previous study has revealed the high prevalence (78%–87%) of concomitant myofascial pain, frequently extending beyond the anatomical boundaries of the pelvis in women with IC/BPS. Almost a quarter of women with chronic pelvic pain (CPP) have musculoskeletal abnormalities.²²⁻²⁵ Interestingly, the mean PFM trigger point pain scores in healthy control women were lower than that in CPP and IC/BPS subjects.²⁴ It is likely that patients with CPP and IC/BPS might have more discomfort in the PFMs. Although the self-report IC/BPS symptom scores (ICSI, ICPI) are indeed relatively higher in the moderate to severe PFMP group ($p = .012$), there is no difference in the MBC ($p = .505$) and glomerulation grade ($p = .875$) and changes of uroflowmetry parameters (changes of p-value, Qmax: .176; voiding volume: .311; PVR: .770) among different PFMP groups. The self-report IC/BPS symptom and problem index (OSS) might be more related to the psychological condition rather than the bladder conditions, causing an increase in the patient's anxiety status score (BAI) with PFMP.⁶

Likewise, the GRA score also has a significant association with different PFMP severities. This result has repeatedly demonstrated that self-report treatment outcomes are closely related to PFM conditions, such as in the ICSI ($p = .029$), ICPI ($p = .007$), and even GRA ($p = .015$). Compared with another study reporting on CPP in women, PFMP was significantly higher than that in healthy women (58.3% vs. 4.2%, $P < .001$), and women with CPP had higher BAI score (22 vs. 13, $P = .02$), higher dyspareunia rate (63.5% vs. 28.9%, $P < .004$), and higher constipation rate (46.0% vs. 26.7%, $P = .05$) than those without PFMP.¹⁰

As mentioned above, the HIC subtype is a distinct inflammatory disease with proven bladder etiology and characterized by epithelial denudation and enhanced immune responses.²⁵ Meanwhile, the NHIC subtype is potentially associated with urothelial malfunction and neurophysiological dysfunction and frequently presents with somatic and/or psychological symptoms, which might result from psychosomatic disorders due to CNS sensitization. Furthermore, if CNS inflammation is the cause of bladder disorders in IC/BPS, the inflammatory responses in the CNS involve the participation of different cellular immune system and resident cells of the CNS, adhesion molecules, cytokines, and chemokines among other

protein components. If this process is not well controlled or is prolonged, the bladder will ultimately lose its regenerative and repair function and can be the cause of urothelial damage and bladder dysfunction.²⁶

In this study, 86.2% of patients with IC/BPS have PFMP, and patients with a higher pelvic pain severity also have more CNS sensitization comorbidities. However, the severity of pelvic pain is not significantly related to bladder conditions, such as MBC, glomerulation grade, and even urodynamic parameters, but is significantly related to self-reported bladder symptom index. Moreover, the multiple linear regression analyses also show that PFMP severity is significantly correlated with patient's self-reported treatment outcome. The results of this study reveal that the PFMP could influence the treatment outcome of women with IC/BPS.

Conclusion

PFMP might affect the subjective results of IC/BPS treatment but not bladder conditions. Therefore, in the future treatment of patients with IC/BPS, digital vaginal examinations of PFMs should be performed in every patient with IC/BPS and focused more on PFM-related conditions, and necessary PFM treatments, such as the vaginal PFM message, should be scheduled.

Declarations

Conflict of interest

The authors declare no conflicts of interest.

Data Availability

To protect patient privacy and comply with relevant regulations, identified data are unavailable. Requests from qualified researchers with appropriate ethics board approvals and relevant data use agreements for de-identified data will be available.

Acknowledgements

This study was supported by TCGH IRB: 105-25-B from the Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation.

Author contributions

HCK and WRY conceived the study, made critical comments, and provided supervision. HACK was the principal investigator of this study and designed the study. WRY designed the study workflow and acquired, analyzed, and interoperated the data, in addition to drafting the article and making critical revisions. All authors reviewed the manuscript.

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Tables

Table 1. Correlation between subjective measured parameters of IC/BPS among different PFM pain severities from vaginal digital examination (n = 65)

PFM pain severity (VAS)		Mild pain VAS 0–3 (n = 12)	Moderate pain VAS 4–6 (n = 11)	Severe pain VAS 7–10 (n = 42)	P-value
Age		55.2 ± 13.9	52.4 ± 8.7	58.8 ± 10.9	.199
Sexual activity	Continue to have sex	7(58.4%)	5(45.5%)	15(35.7%)	.734
	No sexual intercourse within a year	1(8.3%)	0(.0%)	2(4.8%)	
	No sexual intercourse within 3 years	1(8.3%)	1(9.0%)	2(4.8%)	
	No sexual intercourse more than 5 years	3(25.0%)	5(45.5%)	23(54.7%)	
Dyspareunia		2(16.7%)	5(45.5%)	25(59.5%)	.031*
Duration of IC/BPS		10.4 ± 10.1	9.9 ± 6.5	14.2 ± 11.3	.340
Transvaginal surgery experience		5(41.7%)	3(27.3%)	21(50.0%)	.392
Comorbidities		.7 ± .7	2.6 ± 1.7	2.2 ± 1.8	.010*
Type of treatment		3.7 ± 1.3	3.2 ± .9	3.2 ± 1.4	.513
Number of PFMP sites		.8 ± 1.4	3.6 ± 1.5	6.8 ± 4.4	<.001*
BAI		15.3 ± 8.3	19.5 ± 11.5	23.7 ± 12.6	.082
ICSI		10.1 ± 4.9	14.1 ± 5.0	13.8 ± 4.0	.029*
ICPI		9.8 ± 3.8	13.0 ± 4.4	13.5 ± 3.0	.007*
OSS		19.9 ± 8.4	27.1 ± 9.2	27.3 ± 6.6	.012*
NRS (self-reported lower abdomen pain severity)		4.7 ± 3.2	6.7 ± 2.6	6.4 ± 2.3	.093
GRA		2.2 ± .9	1.6 ± .7	.9 ± 1.5	.015*

IC/BPS, interstitial cystitis/bladder pain syndrome; PFM, pelvic floor muscle; VAS, visual analog scale; BAI, Beck's anxiety inventory; ICSI, interstitial cystitis symptom index; ICPI, interstitial cystitis problem

index; OSS, O’Leary-Sant score; NRS, numerical rating scale; GRA, global response assessment; *p < .05

Table 2. Correlation between objective measured parameters of IC/BPS among different PFM pain severity from vaginal digital examination (n = 65)

PFM pain severity (VAS)			Mild pain VAS 0–3 (n = 12)	Moderate pain VAS 4–6 (n = 11)	Severe pain VAS 7–10 (n = 42)	P-value
MBC			750.0 ± 179.6	804.6 ± 179.5	816.3 ± 166.9	.505
Glomerulation grade			1.5 ± 1.2	1.3 ± .9	1.3 ± 1.2	.875
Bladder CT finding	Smooth		10(83.4%)	5(50.0%)	27(65.9%)	.474
	Focal		1(8.3%)	4(40.0%)	9(22.0%)	
	diffuse		1(8.3%)	1(10.0%)	5(12.1%)	
VUDS parameter	FSF		125.9 ± 38.0	122.5 ± 46.2	116.8 ± 46.4	.800
	FS		217.1 ± 81.7	194.6 ± 62.9	197.3 ± 74.5	.688
	CBC		254.8 ± 91.5	243.6 ± 66.2	259.8 ± 126.9	.914
	Pdet		15.5 ± 7.3	19.3 ± 6.4	19.3 ± 12.6	.569
KCL test	Negative		2(16.7%)	0(.0%)	2(4.8%)	.065
	Positive with pain		7(58.3%)	7(63.6%)	36(85.6%)	
	Positive with urge		3(25.0%)	2(18.2%)	2(4.8%)	
	Positive with pain and urgency		0(.0%)	2(18.2%)	2(4.8%)	
Uroflowmetry	Qmax	Baseline	12.3 ± 5.5	10.9 ± 5.9	11.1 ± 5.5	.771
		After treatment 1M	13.8 ± 8.3	16.7 ± 6.4	19.0 ± 11.8	.318
		Δ	1.5 ± 8.7	5.6 ± 6.4	7.9 ± 11.5	.176
	Voiding-volume	Baseline	233.4 ± 111.0	214.2 ± 85.0	221.4 ± 118.2	.915
		After treatment 1M	172.8 ± 72.9	237.4 ± 171.7	197.3 ± 104.6	.392

		Δ	-60.7 ± 110.4	23.2 ± 161.6	-24.1 ± 126.9	.311
	PVR	Baseline	42.1 ± 86.6	45.5 ± 71.0	54.5 ± 108.3	.913
		After treatment 1M	17.3 ± 18.4	37.4 ± 48.5	23.4 ± 28.7	.290
		Δ	-24.8 ± 77.3	-8.1 ± 88.5	-31.1 ± 99.3	.770
Voiding condition	PRES		2(16.7%)	0(.0%)	8(19.0%)	.640
	DV		1(8.3%)	1(9.1%)	4(9.6%)	
Storage condition	HSB		9(75.0%)	8(72.7%)	32(76.2%)	.267
	DO		1(8.3%)	3(27.3%)	3(7.1%)	

IC/BPS, interstitial cystitis/bladder pain syndrome; PFM, pelvic floor muscle; VAS, visual analog score; MBC, maximal bladder capacity; CT, computed tomography; VUDS, video urodynamic study; FSF, first sensation of filling; FS, full sensation; CBC, cytometric bladder capacity; Pdet, detrusor pressure; Qmax, maximum flow rate; PVR, post-void residual urine; PRES, poor relaxation of external urethral sphincter; DV, dysfunctional voiding; HSB, hypersensitivity bladder; DO, detrusor overactivity; *p < .05

Table 3. Multiple linear regression analyses on factors associated with PFM pain severity (VAS) (n = 65)

Constant	Coefficient (β)	95% CI		P-value
Age	-.059	-.015	.133	.116
OSS	.096	-.018	.210	.098
BAI	-.001	-.082	.080	.975
Glomerulation grade	-.099	-1.054	.856	.836
GRA	-1.645	-2.293	-.996	<.001*
MBC	-.001	-.007	.004	.597

OSS, O'Leary-Sant score; BAI, Beck's anxiety inventory; GRA, global response assessment; MBC, maximal bladder capacity; *p < .05

Figures

Figure 1

Pelvic floor muscle pain statistical chart (n = 65)