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Original Research Article

Understanding a standard approach to the treatment of interstitial cystitis

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ABSTRACT

Background: Interstitial cystitis/bladder pain syndrome (IC/BPS) is a chronic and painful bladder-related disorder which is characterized by pain and urinary symptoms. It is divided into 2 varieties based on morphological findings i.e. presence of Hunner's lesion (HL) or no Hunner's lesion (NHL). It can cause other problems like cognitive, behavioural, emotional and sexual symptoms. Grading is done based on Copenhagen classification and following which a treatment is devised which consists of medical or intravesical or surgical therapy.
Methods: A prospective, case-control study was done from the period of January 2019 to July 2022, where the patients were treated by a staged and standard approach, following the treatment protocol strictly. Patients were subjected to a cystoscopy and therapeutic hydro-dissection under spinal anaesthesia and oral therapy. If first line doesn't work, a cocktail was given via intravesical route following which surgery was done. Later for quality-of-life multiple scales are used on day 0 which is the day patient presented and 90 days after the treatment.
Results: Majority in earlier phase of disease required only first line of treatment. While with HL intravesical therapy showed promising results. Only a few required surgical interventions.
Conclusions: IC/BPS understanding suggest that multifactorial etiology of this disease require phenotypic classification to differentiate between bladder-centric and/or bladder-beyond patho-physiologies. The future research shall focus on exploring IC/BPS pathophysiology underscoring angiogenic and immunogenic abnormalities and evolution of novel therapeutic regimens for this multi-factorial disease.

Keywords: Interstitial cystitis, Bladder pain syndrome, Hunner's lesion, Intravesical therapy, Hydro-dissection, Cystoplasty

INTRODUCTION

Interstitial cystitis/bladder pain syndrome (IC/BPS), is often comorbid and potentially devastating pelvic pain disorder. It is characterized by a chronic painful bladder, urinary symptoms and pelvic pain, without any identifiable cause. IC/BPS, though uncommon, can be seen in both men and women. The AUA defines IC/BPS as "an unpleasant sensation (pain, pressure, discomfort) perceived to be related to the urinary bladder, associated with lower urinary tract symptoms of more than 6 weeks of duration, in the absence of infection or other identifiable causes." ESSIC's definition includes symptoms of "chronic pelvic pain (>6 months), pressure or discomfort perceived to be related to the urinary bladder accompanied by at least one other urinary symptom like persistent urge to void or frequency.

Classification of BPS might be performed according to findings at cystoscopy with hydro-distension and morphological findings in bladder biopsies. The presence of other organ symptoms as well as cognitive, behavioural, emotional, and sexual symptoms should be addressed".[1,3]

IC/BPS pathophysiology considers bladder centric symptoms, with possible peripheral aetiologies including urothelial and epithelial cell abnormalities. Based on the underlying pathophysiology, IC/BPS can be categorized as ulcerative or non-ulcerative. Research also suggests clinically important linkage between platelet-activating factor (PAF) - an inflammatory mediator, vascular changes, angiogenic factors and IC/BPS.[2,4]

The AUA recommends that treatment for IC/BPS shall start with conservative approaches like behaviour and diet changes, cold or heat packs, reduction of psychological stress, pelvic floor exercises and bladder training. Once the treatment exposure with oral medication is completed, some patients may experience remission, some permanently. Clinicians may consider simultaneous treatment and then advance toward more invasive options as necessary. Surgical interventions can have long-term benefit for some patients, but have more associated risks. Oral medications and bladder intravesical therapy are considered as vital treatment as per the AUA guidelines for the diagnosis and treatment of IC/BPS. Tricyclic antidepressants, cimetidine, hydroxyzine, and pentosan polysulfate sodium are some of the commonly used oral medications; whereas dimethyl sulfoxide, lidocaine, and heparin are common intravesical therapies. Cystoscopy with hydro-distention is indicated in complex cases; neuro-modulation and cyclosporine A, the neuromodulating drug, should be reserved for non-responding cases; surgical treatment like diversion with/without cystectomy and substitution cystoplasty are reserved for refractory cases.[5]

Aims and objectives

Aims and objectives of the study were to understand optimal drug modalities for each patient of interstitial cystitis diagnosed at Shree Krishna Hospital, and to document findings from cystoscopy with hydro-distention and different drug modalities in IC/BPS patients.

METHODS

Study design

Prospective, case-control study based on primary data collection and analysis, pertaining to IC/BPS patients enrolled during January 2019 to July 2022.

Study site

Patient enrolment was done at a teaching hospital Shree Krishna Hospital affiliated to the Pramukh Swami Medical College, Bhaikaka University, Karamsad, District Anand in the state of Gujarat, India.

Study sample

About 60 patients presenting with IC/BPS clinically confirmed diagnosis were enrolled to pursue research objectives. Data pertaining to patient age, gender, diagnosis and therapeutic approach was collected for study purpose.

Inclusion criteria

Patients who are diagnosed with IC/BPS clinically confirmed.

Exclusion criteria

Patients who have not given consent for sharing their data. Patients who lost to follow up.

Patient enrolment and follow-up

From January 2019 to July 2022, about 60 patients were clinically diagnosed and treated for IC/BPS. A staged treatment policy was the standard approach and all the patients were treated following the same protocol. The patients suspected for IC/BPS were subjected to diagnostic cystoscopy and therapeutic hydro-distention under spinal anaesthesia for duration of 3 min; followed by oral therapy (combination of cystopen (pentosan) 100 mg od, amitriptyline 25 mg hs, hydroxyzine 25 mg hs, and gabapentine 100 mg hs for 3 months) as the first-line therapy.

If Hunner's lesion is found, it is fulgurated, bladder capacity and grade of mucosal changes are noted, and lesion were sent of biopsy. Patient with Hunner lesion were categorized as hl-IC/BPS (Hunner's lesion interstitial cystitis) and remaining were categorized as nhl-IC/BPS (non-Hunner's lesion interstitial cystitis). As Copenhagen cystoscopic classification of bladder mucosa under anaesthesia (grade 0: normal mucosa; grade 1: petechiae in at least two quadrants; grade 2: large sub-mucosal bleeding ecchymosis; grade 3: diffuse global mucosal bleeding; grade 4: mucosal disruption), with or without bleeding/oedema, it is to be categorized as Hunner's lesion, which are usually present on the first distention but petechiae and ecchymosis mostly develops either during the first distention or after first evacuation. Hence, it is very important to re-distend bladder to identify them.

If the first-line of therapy doesn't alleviate patient symptoms/pain, intravesical therapy is considered as second line treatment. Firstly, intravesical anaesthesia cocktail (2% 40 cc bupivacaine 5%, 2500-unit heparin and 2 cc dexamethasone) is given; and if this fail, tacrolimus (1 mg=1 kg) is instilled in bladder as second-line intravesical therapy. Distilled water was used to dissolve tacrolimus instead of dimethyl sulfoxide (DMSO), as it was more patient-friendly and increased compliance. Three sittings were done at the interval of 15 days. Surgical intervention such as substitution cystoplasty was considered only as a final line of therapy in patients with severe disease condition in both small capacity and normal capacity bladder.

All patients were contacted by phone on day-90th and asked to rate their IC/BPS symptoms experience as compared to when they started the treatment, based on various assessment scales such as interstitial cystitis symptoms index (ICSI), Indevus urgency severity scale (IUSS), visual analogue scale (VAS), patient overall rating of improvement of symptom (PORIS) and global response assessment (GRA).

Plan for analysis

A master chart was prepared to arrange the recorded parameters for each and every IC/BPS patient in Microsoft excel. Mean and standard deviation was used to represent continuous variables. Proportions were used for categorical variables. The t-test was used to evaluate relationship between continuous variables. Chi-square test was used to evaluate the relationship between categorical variables. P value less than 0.05 was considered as statistically significant. S.T.A.T.A. (version 14.2) was used to analyze study data.

Ethical consideration

All the suspected IC/BPS patients were explained about the study objectives and given participant information sheet (PIS) in local language. They were informed about the risks and benefits that might be incurred during the study. If participants accepted to participate in the research, they signed an informed consent form. The study proposal was presented to the august meeting of the ethics committee of HM Patel Centre for Medical Care and Education, Karamsad. The present study is approved via letter reference number IEC/BU/137/Faculty/08/199/2022 dated 22/08/2022.

RESULTS

Nearly half of the male (42%) and female (50%) participants were between the ages of 41 and 60 years. Between the ages of 21 and 40, there were 11 (42.3%) males and 8 (23.5%) females. There were only three females under the age of 20. In addition, the age of the four males and six females were more than 60 years.

More females were categorized under grade 0 (26.5% versus 19.2%) and grade 3 (29.4% versus 15.4%) compared to their male counterparts. In grade 1 (23.1% versus 1.8%), grade 2 (19.2% versus 14.7%) and grade 4 (23.1% versus 17.6%) there were more males categorized then the female counterparts.

Three participants were in the age-group <20-year, and each one was categorized under grade 0, grade 1 and grade 2, respectively. Most participants in grade 0 were in the age-group 41-60-year (N=7), followed by 21-40-year (N=4). In grade 1 and grade 2, most participants were in 41-60-year age-group. In grade 3, majority of the participants were from 21-40-year (N=8) age-group followed by 41-60-year age-group (N=5). In grade 4, out of 12 participants, 7 were in the age-group 41-60-year, 3 were >60-year and 2 were 21-40-year age-groups.

Out of the 60 participants, Hunner's lesion was confirmed in 16 (27%) participants. Hunner's lesion (HL) was found in almost equal proportion among sexes, 7 (26.9%) of the males and 9 (26.5%) of the females. There were no HL confirmed participants under the age of 20. In the age group of 21-40-year, three (15.8%) had HL. Ten people in the age-group 41-60-year had HL and about 30% or 3 participants in >60-year age-group were confirmed to have HL.

Distribution of HL by IC/BPS grading found statistically significant association ($p<0.001$). All the patients with HL were either in grade 3 (25%) or grade 4 (75%) as compared to as compared to only 23% IC/BPS patients without HL under these grading. IC/BPS patients without HL were almost equally distributed under grade 0 (31%), grade 1 (23%), grade 2 (23%) and grade 3 (23%).

As per Table 1, total of 39 patients were treated by oral therapy alone as the first-line therapy. In addition, 8 patients received oral therapy in conjunction with intravesical cocktail (N=2), tacrolimus (N=4) and surgery (N=2). If the first-line of therapy doesn't alleviate patient symptoms/pain and intravesical therapy is considered as second line treatment. Two patients received intravesical cocktail as monotherapy and two patients received it in conjunction with oral therapy.

About 9 patients received tacrolimus as monotherapy whereas 4 patients received it together with oral therapy. Tacrolimus (1 mg=1 kg) was instilled in the bladder for treatment.

Surgical intervention such as substitution cystoplasty was considered only as a final line of therapy in patients with severe disease condition in both small capacity and normal capacity bladder. Two patients each received surgical intervention following their treatment with oral therapy and tacrolimus, respectively.

At day zero, mean ICSI scores for oral therapy, Intravesical cocktail, Tacrolimus and surgery were 15.4±3.19, 15.7±3.86 ,18.2±1.83, and 17.0±3.46, respectively. One can observe gradual increase in ICSI mean score with first, second and third line of treatment for IC/BPS. However, there was no statistically significant association between mode of treatment and ICSI score ($p>0.05$).

There wasn't any clear pattern of increase or decrease in ICSI mean score with mode of treatment at 90-day follow-up. The mean score of 10.5±5.91 was the lowest for Intravesical cocktail and 13.75±5.96 was the highest for surgical intervention.

As per Tables 2 and 3, only one patient reported mild IUSS at day-0, and about two-third (N=34; 61.8%) reported

severe IUSS. Among those who reported severe, 20 received oral therapy and 7 received tacrolimus. All four patients who received surgical interventions were categorized as severe on the IUSS. Among those who reported moderate, 15 received oral therapy and 5 received tacrolimus.

Chi^2 test revealed IUSS score had statistically significant association with treatment modality ($p<0.05$).

As per Table 4, about 6 patients reported "none" and 2 reported "severe" on the IUSS at day-90. Of the four patients who received surgical intervention, 3 reported "mild" and 1 reported "moderate" on the IUSS at day-90. About three quarters (76%) of the patients reported, "mild" on the IUSS, of whom 28 (66.6%) received oral therapy and 7 (16.6%) received tacrolimus, followed by 4 and 3 patients receiving Intravesical cocktail and surgical intervention. Chi^2 test revealed IUSS score had no statistically significant association with treatment modality ($p>0.3$).

About half of the patients (N=28) reported severe pain on visual analogue scale (VAS) at day-0 and this remain almost similar with 56.4% (N=31) reporting "severe pain" at day 90. Only one patient reported "no pain" at day-0, which compares to 6 patients reporting "no pain" at day-90. Three patients reported "mild pain" at day-0 which increased with 6 patients reporting "mild pain" at day-90.

Four surgery patients who reported "mild", "moderate", "severe" and "very severe" pain on VAS at day-0; only 1 reported "mild pain" and 3 reported "severe pain" on VAS at day-90.

Ten patients reported "very severe pain" at day-0 which decreased to 2 patients reporting "very severe pain" at day-90. Among those who reported "very severe pain" at day-0, 4 received oral therapy, 5 received tacrolimus and 1 received surgical intervention.

As per Table 5, of 35 patients who received oral therapy, 18 reported "moderately improved" symptoms on PORIS at day-90. Among patients who received surgical intervention, one each reported "slight improvement" and "not much improvement", whereas 2 patients reported "moderate improvement".

Findings from PORIS at day-90 revealed that about 45% (N=25) patients reported "moderately improved" symptoms, followed by nearly 22% patients reporting "not much improvement" and "slight improvement". Only 4 (7%) and 2 (4%) patients reported "severe" and "no problem", respectively. There wasn't any statistically significant association between PORIS at day-90 and treatment modalities ($p>0.9$). Of 35 patients who received oral therapy, 19 reported "moderately improved" symptoms on GRA at day-90. Among patients who received surgical intervention, two each reported "slight improvement" and "moderate improvement" on GRA at day-90.

Findings from global response assessment (GRA) at day-90 revealed that about 50% (N=27) patients reported "moderately improved", followed by nearly 33% patients reporting "slightly improved". Only 6 (11%) 3 (5%) and 1 (2%) patient reported "markedly improved", "no change" and "moderately worse", respectively. There wasn't any statistically significant association between GRA at day-90 and treatment modalities ($p>0.7$).

Table 1: Treatment by sex, age, grade and HL.

Characteristics	Treatment (%)				P value
	Oral therapy	Intravesical cocktail	Tacrolimus	Surgery	
Sex					
Male					0.59
N	19	1	4	2	
%	73.1	3.8	15.4	7.7	
Female					
N	20	3	9	2	
%	58.8	8.8	26.5	5.9	
Age (in years)					
<20					0.31
N	2	-	1	-	
%	66.7	-	33.3	-	
21-40					
N	10	3	3	3	
%	52.6	15.8	15.8	15.8	
41-60					
N	18	1	8	1	
%	64.3	3.6	28.6	3.6	
>60					

Continued.

Characteristics	Treatment (%)				P value
	Oral therapy	Intravesical cocktail	Tacrolimus	Surgery	
N	9	-	1	-	
%	90.0	-	10.0	-	
Grade					
0.00					
N	11	-	2	1	
%	78.6	-	14.3	7.1	
1.00					
N	7	1	1	1	
%	70.0	10.0	10.0	10.0	
2.00					
N	7	-	2	1	0.40
%	70.0	-	20.0	10.0	
3.00					
N	10	2	2	-	
%	71.4	14.3	14.3	-	
4.00					
N	4	1	6	1	
%	33.3	8.3	50.0	8.3	
HL					
No					
N	33	2	6	3	
%	75.0	4.5	13.6	6.8	0.03
Yes					
N	6	2	7	1	
%	37.5	12.5	43.8	6.3	

Table 2: Difference in ICSI distribution across treatment from day zero to day 90.

Parameters	N	Mean (ICSI diff score)	Standard deviation	P value
Oral therapy	35	2.6286	6.37129	
Intravesical cocktail	4	5.2500	5.61991	0.54
Tacrolimus	12	5.5833	7.22946	
Surgery	4	3.2500	5.43906	
Total	55	3.5091	6.42585	

Table 3: IUSS at day zero across the groups.

Group	IUSS at day-0			Total	P value
	Mild	Moderate	Severe		
Oral therapy	-	15	20	35	
Intravesical cocktail	1	-	3	4	0.008
Tacrolimus	-	5	7	12	
Surgery	-	-	4	4	
Total	1	20	34	55	

Table 4: IUSS at day 90 across the treatment groups.

Group	IUSS at day-90				Total	P value
	None	Mild	Moderate	Severe		
Oral therapy	5	28	1	1	35	
Intravesical cocktail	-	4	-	-	4	0.38
Tacrolimus	1	7	3	1	12	
Surgery	-	3	1	-	4	
Total	6	42	5	2	55	

Table 5: Patient overall rating of improvement of symptom (PORIS).

Group	PORIS at day-90					P value
	No problem	Slightly improved	Moderately improved	Not much improved	Severe	
Oral therapy	1	5	18	8	3	0.94
Intravesical cocktail	-	2	1	1	-	
Tacrolimus	1	3	4	3	1	
Surgery	-	1	2	1	-	
Total	2	11	25	13	4	

DISCUSSION

About 60 patients presenting with clinically confirmed diagnosis for IC/BPS were enrolled to pursue study objectives. In certain populations, females are more likely to get affected by IC/BPS compared to their male counterparts.[5] The sex-wise prevalence is reported to be around 2.7% and 1.9% among females and males, respectively.[3,4] One more study from the U.S. Veterans Health Administration data reported female and male prevalence of 1.08% and 0.66%, respectively.[6]

Copenhagen cystoscopic classification of bladder mucosa under anaesthesia revealed that 23% (14), 17% (10), 17% (10), 23% (14) and 20% (12) were classified under grade 0 (normal mucosa), grade 1 (petechiae in at least two quadrants), grade 2 (large sub-mucosal bleeding ecchymosis), grade 3 (diffuse global mucosal bleeding) and grade 4 (mucosal disruption), respectively. Patients in >60-year age-group were suffering from more severe form of the disease symptoms (grade 4) compared to their younger counterparts in <60-year age-group or the overall study group (30% versus 20%).

The proportion of patients having IC/BPS with HL is found to be much higher in our study population compared to other studies that have reported about 41% of patients with either newly diagnosed or suspected IC/BPS cases with HL.[7,8] However, this is comparable to a study done in the Mexican private uro-gynecology setting, which reported HL in 28% IC/BPS patients.[9] This could be attributed to under diagnosis, access to health services especially consultation with a urologist, and even death of the least healthy individuals in the population.

The mode of treatment and patients with HL or no-HL showed statistically significant association ($p<0.05$). About 50% IC/BPS patients with HL required third or final line of treatment with tacrolimus or surgery compared to 20% IC/BPS patients without HL requiring such treatments. Our study also captured patient experience with regards to their IC/BPS related symptoms before treatment and followed-up 3-month after treatment. Such pre-post assessment was done ICSI, IUSS, and VAS.

Analysis of ICSI scores at baseline revealed gradual increase in ICSI mean score with first, second and third line of treatment for IC/BPS. However, there wasn't any clear pattern of increase or decrease in ICSI mean score with mode of treatment at 3-month follow-up. One of the studies has reported that in their evaluation ICSI was considerably decreased in the amitriptyline (MD: -4.9), cyclosporine A (MD: -7.9), and certolizumab pegol (MD: -3.6) groups compared to the placebo group.[10,11] Analysis of IUSS scores at baseline found that about two-third (61.8%; N=34) patients with IC/BPS experienced severe disease condition. At 3-month follow-up, about three quarters (76%; N=42) patients with IC/BPS experienced mild disease condition. Chi^2 test revealed statistically significant association between IUSS scores and treatment modality at baseline ($p<0.05$), but no such association was observed at 3-month follow-up ($p>0.3$).

Analysis of VAS at baseline and 3-month follow-up revealed that almost similar proportion of patients with IC/BPS reported severe pain experience (51% versus 56%). Ten patients (18%) reported "very severe pain" at day-0 which decreased to two patients (4%) reporting "very severe pain" at day-90. VAS scores are also likely to differ for different treatment modalities, as inferred from a systematic review study which reported that VAS score improved in cyclosporine A group compared to pentosan polysulfate sodium group.[10,11] In our study, 11% and 42% patients who received oral therapy and tacrolimus, respectively, had "very severe pain" in VAS assessment at baseline, which reduced to 3% and 8%, respectively, at 3-month follow-up.

In addition, this study also captured patient experience at 3-month follow-up using patient overall rating of improvement of symptom (PORIS) and global response assessment (GRA). Findings from PORIS at 3-month follow-up revealed that about 45% (N=25) patients reported "moderately improved" symptoms. There wasn't any statistically significant association between PORIS at day-90 and treatment modalities ($p>0.9$). Findings from GRA at day-90 revealed no statistically significant association between GRA at day-90 and treatment modalities ($p>0.7$).

CONCLUSION

Given the complexity involved around the IC/BPS and limited understanding of immediate and long-term patient outcomes, it is critical to study the patient experience using available assessment tools. The current evidences related

to IC/BPS understanding suggest that the multifactorial etiology of this disease require phenotypic classification to differentiate between bladder-centric and/or bladder-beyond patho-physiologies. The future research shall focus on exploring IC/BPS pathophysiology underscoring angiogenic and immunogenic abnormalities, which could help pathology-based phenotyping and evolution of novel therapeutic regimens for this multi-factorial disease. It is also imperative that future research shall design IC/BPS-specific QoL assessment tool to determine the treatment success. Comprehensive management of IC/BPS patients with underlying comorbid conditions can greatly benefited by a unified multi-modal assessment and corresponding recommendations for therapeutic management.

Limitations of this study include less resources for using multiple novel therapies in treatment of IC/BPS. Given the complexity involved around the IC/BPS and limited understanding of immediate and long-term patient outcomes, it is critical to study the patient experience using available assessment tools which needs to be developed more. Pathophysiology of IC/BPS requires revision due to further complexity seen while treating the patient.

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