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ORIGINAL ARTICLE

The Fibromyalgia Bladder Index in 100 consecutive women with fibromyalgia

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Abstract

Introduction and hypothesis The Fibromyalgia Bladder Index (FBI) is a validated instrument to quantify bothersome bladder symptoms specifically in women with fibromyalgia syndrome (FMS). The FBI includes two sub-scales: one addressing urinary urgency and bladder pain (UP), the other addressing urinary frequency and nocturia (FN). The objectives of this study are to evaluate the FBI in a cohort of patients with FMS, to correlate it with certain characteristics in this cohort, and to compare it with controls.

Methods We performed a case–control study of 100 women with FMS and 155 controls. Demographic data, comorbidities, and other characteristics were registered. Comparison between FBI scores of participants with and without FMS, as well as correlation of FBI scores with the characteristics of FMS patients, were undertaken using independent two-sample *t* test for continuous outcomes and Pearson's Chi-squared test for categorical outcomes.

Results The mean UP subscale score of the FBI was significantly higher in the FMS group (10.29 ± 5.61) compared with the controls (1.65 ± 2.65; (p = 0.001). The mean FN subscale score was significantly higher in the FMS group (9.93 ± 5.37) compared with the controls (2.95 ± 3.27; p = 0.001). FMS patients diagnosed >3 years ago had a higher UP subscale score and a higher FN subscale score compared with FMS patients diagnosed <3 years ago (p = 0.020 and p = 0.024 respectively). Menopause and parity significantly increased the FBI scores. Smoking and a history of depression did not significantly affect any of the FBI subscale scores in the FMS group.

Conclusion Women with FMS suffer from bothersome bladder symptoms that can be readily identified and quantified.

Keywords Fibromyalgia · Painful bladder syndrome · Interstitial cystitis · Fibromyalgia Bladder Index · O'Leary–Sant questionnaire

Abbreviations

BMI	Body mass index
FBI	Fibromyalgia Bladder Index
FMS	Fibromyalgia syndrome
OS	O'Leary–Sant
PBS/IC	Painful bladder syndrome/interstitial cystitis

Some of the data in this study were included in an abstract (Nouran Hamed, Mohammad Ali Rida, Mariam Assad, Tony Bazi. Prevalence of Interstitial Cystitis/Painful Bladder Syndrome in Patients with Fibromyalgia) at the International Continence Society (ICS) 49th Annual Meeting; 3–6 September 2019, Gothenburg, Sweden

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The study was conducted after securing the local IRB approval

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PBS Painful bladder syndrome
UP Urinary urgency and bladder pain
FN Frequency and nocturia

Introduction

Fibromyalgia syndrome (FMS) is a complex heterogenous chronic disease that can have a profound detrimental effect on the quality of life (QoL). Chronic widespread pain, the hallmark symptom in FMS, is thought to be due to the central amplification of pain perception, characterized by allodynia and hyperalgesia [1]. It can affect 2–3% of the population worldwide, with a 3:1 female-to-male ratio [2]. Commonly associated symptoms include sleep disturbances, generalized fatigue, anxiety, depression, and cognitive dysfunction [3]. Patients with FMS have a higher incidence of genitourinary symptoms such as frequency, urgency, nocturia, and pelvic pain, with no signs of genitourinary infection [4].

Painful bladder syndrome/interstitial cystitis (PBS/IC) is defined by The European Society for the Study of Interstitial Cystitis as "chronic pelvic pain, pressure, or discomfort perceived to be related to the urinary bladder, with at least one other urinary symptom, such as persistent urge to void or urinary frequency" [5]. Cystoscopy in painful bladder syndrome (PBS) revealed glomerulations, or "Hunner's ulcers," in less than one third of patients [6]. Owing to the lack of an identifiable objective test to diagnose this condition, there continues to be no consensus on the definition of PBS [5], thus leading to inconsistent prevalence estimates, the most quoted of which being 2% of the general population, with a 9:1 female to male ratio [7]. FMS and PBS share many demographic and associated features, including a devastating impact on quality of life (QoL) [5, 7].

Although associations between FMS and PBS/IC have been described [8], little is known about whether one condition triggers the other or if they arise independently, according to a common pathophysiological scheme. Knowing the exact epidemiological relationship between these conditions could be of great help in understanding the pathophysiological link between the two. The difficulty achieving this goal notwithstanding, it is important to identify comorbidities and "extra-skeletal" symptoms in patients with FMS, and to address them in a timely fashion to improve QoL in patients living with this condition.

The Interstitial Cystitis Symptom Index and Problem Index, often referred to as the O'Leary–Sant (OS) questionnaire is a symptom questionnaire that has been widely used since its introduction in 1997 to identify patients with PBS and quantify their symptoms [9]. It consists of 8 questions, 4 of which are related to the frequency of occurrence of symptoms of (urgency, urinary frequency, nocturia, and bladder pain), whereas the other four questions are related to the degree of bother of each of these four symptoms (Appendix). All questions are graded according to a Likert scale. Although no cut-off value of the sum has been suggested as being diagnostic for PBS, the change in scale has been used to measure treatment outcome and evaluate new therapies for diagnosed patients [10].

The Fibromyalgia Bladder Index (FBI) was proposed and validated as an instrument to assess bladder symptoms specifically in patients with FMS [11]. The FBI consists of two subscales within the OS questionnaire: one addressing urgency and pain (questions 1 and 4 of the Symptom Index, and questions 3 and 4 of the Problem Index) and the other addressing frequency and nocturia (questions 2 and 3 of the Symptom Index, and questions 1 and 2 of the Problem Index). Although the FBI makes intuitive sense, no published data have used this instrument in patients with FMS since its validation in this specific group of patients. The objectives of this study are to determine the FBI in a cohort of women with FMS, to evaluate possible associations with patients' characteristics, and to compare the findings with those of controls.

Materials and methods

This is a case–control study comparing two groups: women with FMS and women without FMS.

The OS questionnaire was translated into the native language (Arabic), taking cue from the validated Arabic version of the global Pelvic Floor Bother Questionnaire [12]. The latter consists of questions related to nine domains of pelvic floor disorders that include all four symptoms addressed in the OS questionnaire: urinary frequency, urinary urgency, nocturia, and bladder pain. Following that, the Arabic version was given to a focus group of bilingual individuals, including students, nurses, and secretaries. Comments from the focus group were unanimous, confirming the clarity of terms describing the time interval and numerical frequency of events.

Inclusion criteria included women above 18 years of age, diagnosed with FMS, according to the 1990 ACR Criteria, presenting to the private clinics of one of the authors (I.U.) or to the Outpatient Department at the American University of Beirut Medical Center, managed by another author (M.R.). Controls were healthy females above 18 years of age working at, or visiting the American University of Beirut or its Medical Center (not as patients), and not having a history of any rheumatological or urinary tract conditions. They were recruited on a voluntary basis after advertising at the university and its Medical Center with flyers. Exclusion criteria included pregnancy, genitourinary neoplasm, vaginitis, cystitis, urethral diverticulum, and urinary tract calculi.

Following informed consent, participants were anonymously surveyed regarding demographics: age, height, weight, parity, mode of delivery, previous medical comorbidities and surgeries, history of depression, smoking, menopausal status, and treatments for FMS. Participants also anonymously filled in the translated OS questionnaire.

Descriptive baseline characteristics of recruited FMS patients and controls were compared using independent two sample *t* test for continuous outcomes, reported as mean and standard deviation, and Pearson's Chi-squared test for categorical outcomes, reported as frequencies/proportions. Analysis of score differences between FMS patients and controls in the OS and the subscales of the FBI: bladder urgency and pain (UP) subscale, and the bladder frequency and nocturia (FN) subscale was performed using an independent *t* test. Unconditional multivariate regression was performed to adjust for possible confounding. All statistical tests were two-sided with a significance level of 0.05. All analyses were performed using SPSS 25 statistical software package (IBM, Armonk, NY, USA).

Institutional Review Board approval was secured before conducting the study.

Results

Between April 2018 and July 2019, a total of 100 female patients with FMS and 155 female controls were recruited. Data were missing on the age of 2 participants in the control group, height or weight in 10 participants in the control group and 1 in the FMS group, history of depression in 1 participant in the control group, and on history of smoking in 1 participant in the FMS group.

Baseline characteristics are shown in Table 1. Patients in the FMS group had a higher mean BMI, a higher percentage of smokers, and a higher prevalence of depression. In the FMS group, 66% were on pharmacological treatment for FMS. The most commonly reported treatment was duloxetine (24% of the group), followed by pregabalin (18%).

The mean score of OS as well as both subscales of FBI were significantly higher in the FMS group compared with controls, all three with a p value <0.001 (Table 2). Multiple linear regression was applied to check if the significant difference in baseline characteristics between FMS patients and their controls could have affected the OS or the FBI scores. Only age was found to have a statistically significant effect, increasing the OS score by 0.122 per year (p value <0.001), the UP score by 0.053 per year (p value <0.001) and the FN score by 0.070 per year (p value <0.001).

Table 3 summarizes the FBI subscale average scores across different characteristics within the FMS group. Significantly higher scores were observed with the menopause, parity, and a diagnosis of FMS longer than 3 years. Depression and smoking did not affect the FBI scores. Patients receiving pharmacological treatment of FMS had a higher FN subscale score only. Comparison of the FBI scores between patients on pregabalin (n = 18) and those on duloxetine (n = 24) did not reveal any statistical differences (p = 0.182 for UP score and p = 0.296 for FN score). The numbers in the two groups, however, are too small to draw any significant conclusions.

Discussion

The demographic data and characteristics of FMS patients in this study were comparable with those reported by most other studies. In addition, and in agreement with the others, a higher BMI, current smoking, and a history of depression were more prevalent in FMS than in controls [1]. The results of this study strongly confirm the high prevalence of bothersome bladder symptoms among women with FMS.

The diagnosis of FMS was based on the 1990 ACR classification. Compared with the 2010 criteria and the modified 2010 criteria, the old classification is more restrictive, and results in a higher female-to-male ratio in the FMS population [13].

The OS questionnaire used in our study was proven to distinguish PBS from other pathological urinary tract conditions and can therefore be used to screen patients with urinary tract symptoms [14].

The higher prevalence of bothersome bladder symptoms among women with FMS was initially alluded to by Wallace in a study published in 1990, where 6 out of 50 female fibromyalgia patients complained of "urethral syndrome" symptoms compared with 0 out of 50 control patients diagnosed with other rheumatic diseases [15]. Comparable findings were

Table 1 Distribution of demographics and characteristics of patients with fibromyalgia syndrome (FMS) and controls

	Controls (n = 155)	N1	FMS (n = 100)	N2	p value
Age, mean (SD)	46.60 (19.40)	153	50.9 (13.16)	100	0.036*
BMI, mean (SD)	24.54 (4.66)	145	26.27 (5.81)	99	0.011*
Menopause, %	56.1	155	68	100	0.058
Current smoker, %	25.8	155	56	100	0.001*
History of depression, %	15.6	154	37	100	0.001*
Parous, %	45.2	155	70	100	0.001*

n denotes the total number of participants surveyed in each group. N1 and N2 denote the number of respondents in the control and FMS groups respectively. *Statistically significant

Table 2 Average scores (x) and standard deviations (SD) of the O'Leary–Sant voiding and pain indices (OS), the urgency and pain subscale (UP), and the frequency and nocturia subscale (FN) of the Fibromyalgia Bladder Index in patients with fibromyalgia syndrome (FMS) and controls

	Controls (n = 155)	FMS (n = 100)	95% CI	p value
OLS, x ± SD	4.66 ± 5.35	20.23 ± 10.36	(13.63, 17.52)	0.001
UP subscale, x ± SD	1.65 ± 2.65	10.29 ± 5.61	(7.62, 9.67)	0.001
FN subscale, x ± SD	2.95 ± 3.27	9.93 ± 5.37	(5.92, 8.05)	0.001

n denotes number of participants in each category. 95% CI denoted 95% confidence interval for the difference between fibromyalgia patients and controls. p 0.001: highly statistically significant

described by Paira in a prospective study involving 212 female patients with FMS [16].

An equally strong association between FMS and PBS is uncovered upon evaluation of FMS in women with PBS. In a study examining concomitant morbidities in 205 women with PBS using biopsychosocial phenotyping, irritable bowel syndrome and FMS were found to be significantly more prevalent than in controls [8]. Using the national health database in Taiwan, a study including 9,269 subjects diagnosed with PBS within the last year concluded that this population had a higher prevalence of 32 medical conditions, including rheumatoid arthritis, systemic lupus erythematosus, and ankylosing spondylitis [17]. It is not clear why FMS was not alluded to, and whether this reflects coding issues.

In a unique study comparing two cohorts (60 FMS patients and 30 PBS patients with a mutually exclusive diagnosis), the two groups were found to share a wide array of symptomatology related to different organ systems [18]. It was suggested that the two entities could have common pathogenic mechanisms resulting in disruption in autonomic function and visceral nociception.

In our study, we compared FMS patients with "healthy controls", rather than with non-FMS patients with rheumatological disorders. We believe that this in fact accentuates the difference in OS and FBI scores, because PBS has been associated with a range of rheumatological and autoimmune disorders, most notably with Sjögren syndrome [19].

The finding that parity and menopause increased the FBI scores was not surprising. In fact, all pelvic floor disorders, including the ones evaluated by the FBI subscales, are known to have a higher prevalence with parity and menopause [20]. The exact magnitude of the synergistic effect of FMS on the PBS symptomatology in parous and post-menopausal women remains difficult to quantify.

An interesting finding in our study was that FMS patients on pharmacological treatment have higher FBI scores compared

Table 3 Averages of scores of urgency and pain (UP) and frequency and nocturia (FN) subscales of the Fibromyalgia Bladder Index across characteristics in 100 women with FMS

	Characteristics		95% confidence interval	p value
	Pre-menopause (n = 32)	Menopause (n = 68)		
UP subscale	7.41 (5.43)	11.65 (5.20)	(2.00, 6.49)	0.001*
FN subscale	6.62 (6.11)	11.48 (4.20)	(2.45, 7.27)	0.001*
	Non-smoker (n = 44)	Smoker (n = 56)		
UP subscale	9.36 (6.07)	11.02 (5.16)	(−0.58, 3.88)	0.153
FN subscale	9.14 (5.60)	10.55 (5.14)	(−0.72, 3.55)	0.192
	Nulliparous (n = 30)	Parous (n = 70)		
UP subscale	8.33 (5.74)	11.129 (5.38)	(0.42, 5.17)	0.022*
FN subscale	7.43 (6.16)	11.00 (4.65)	(1.04, 6.09)	0.007*
	No depression (n = 63)	Depression (n = 63)		
UP subscale	9.635 (5.48)	11.40 (5.73)	(−0.52, 4.06)	0.128
FN subscale	9.889 (4.90)	10.00 (6.17)	(−2.26, 2.48)	0.926
	Diagnosis <3 years (n = 65)	Diagnosis> 3 years (n = 35)		
UP subscale	9.34 (5.37)	12.06 (5.70)	(0.44, 5.00)	0.020*
FN subscale	9.05 (5.48)	11.57 (4.82)	(0.34, 4.71)	0.024*
	On no medication (n = 34)	On medication (n = 66)		
UP subscale	8.76 (5.64)	11.08 (5.47)	(−−0.01, 4.63)	0.051
FN subscale	8.03 (5.56)	10.91 (5.04)	(0.69, 5.07)	0.010*

n denotes the number of patients in each category, and () denotes the standard deviation. *Statistically significant with patients on no treatment. Although paradoxical at first glance, this could be interpreted on the basis that “more symptomatic” patients, who necessitated pharmacological intervention, are more likely to have at the same time more prevalent and more severe bothersome bladder symptoms. The adaptation of the FMS patients to urinary and pelvic symptomatology may be jeopardized because of the known up-regulation of pain sensory mechanisms [1], as well as a higher incidence of anxiety and depression in this population [3]. In fact, it was shown that FMS patients with pelvic organ prolapse experience 50% greater symptom bother than their counterparts with the same degree of prolapse [21]. Furthermore, in a cross-sectional study including South Korean men and women, subjects with FMS had worse symptomatology of overactive bladder (OAB) after adjusting for confounding variables [22]. It is noteworthy that OAB, a fairly common condition, is defined as urgency with or without frequency and nocturia and does not include painful urination, as in BPS [23]. In yet another cross-sectional study evaluating urinary symptoms in women, FMS patients displayed a poorer perception of QoL related to incontinence, compared with controls [24].

An important finding in our study is the significantly higher FBI scores when patients' diagnosis with FMS is more than 3 years old. This suggests that FMS could precede the onset of bladder-related symptoms, especially that FMS often takes more than 2 years to diagnose, following several consultations with different physicians [25]. In fact, it was shown that patients with PBS have a higher prevalence of "cluster syndromes" prior to the onset date of diagnosis of their condition [26]. A most significant cluster syndrome before the diagnosis of PBS was that of fibromyalgia-chronic widespread pain, chronic fatigue syndrome, sicca syndrome, and irritable bowel syndrome [26].

It is not clear, however, whether FMS is a "risk factor" for PBS or that the two conditions share common environmental risk factors. The "risk factor" hypothesis was addressed in an animal study, where an FMS model was induced in rats via gluteal intramuscular injection of HCL and validated by demonstrating increased plantar sensitivity. The index rats developed urinary frequency (a hallmark of PBS in animals) that was successfully "treated" following gluteal lidocaine injection [27]. In addition to the implication in the “sequencing” of events between FMS and BPS, the findings in this animal study further support the theory of "cross-sensitization" between somatic and visceral pathways. At the time of writing this manuscript, we had not identified a longitudinal study of FMS patients that evaluates the prevalence of PBS at different points throughout the history of the condition. An interesting alternative theory is that both conditions have a common genetic etiology that manifests sequentially at consecutive time intervals. This theory is alluded to in a population-based genealogical database study in the state of Utah (USA), where FMS and constipation were more commonly found in first-degree and second-degree relatives of 248 patients with PBS [28]. Furthermore, the prevalence of PBS was higher in first-degree and second-degree relatives of FMS patients and patients with constipation [28]. Although genetic variants have been strongly suggested in the populations of both FMS and PBS [28, 29], there has not been yet any established common variant found in patients exclusively diagnosed with FMS and PBS.

Irrespective of the interpretation, the finding that bothersome bladder symptoms are more prevalent later in time during the course of FMS has a considerable impact on the management of FMS patients. As this population is affected by an almost lifelong disabling condition, caregivers need to be aware of the possibility of a new onset of symptoms unrelated to the musculoskeletal organ system during the course of the condition. Consequently, patients should be queried during their regular visits about changes in urinary habits and symptoms, even when these are not brought up as complaints. This is especially important in view of available treatment strategies for PBS that could improve QoL in suffering patients. Although both FMS and PBS may respond to common pharmacological and non-pharmacological treatment [10, 30], there is a wide choice of PBS-specific treatments, including intravesical instillations, albeit with partial efficacy [10].

Although having two separate scales within the OLS questionnaire makes intuitive sense regarding treatment options, the results of our study are not enough to confirm a benefit from adopting the FBI instead of the OLS. Nevertheless, applying the FBI could allow for a quick discriminatory screening of patients and possibly targeting specific symptomatology prior to referral to a urologist or a gynecologist. For instance, it is possible that nocturia (in the FN subscale of the FBI index) could be a manifestation of a sleep disorder rather than a manifestation of a bladder sensory pathology [31]. This is most relevant, as sleep disorder is a well-established symptom that could coexist with FMS [3].

One strength of our study is that participants (cases and controls) anonymously and privately filled in the translated OS questionnaire. This “written disclosure” is arguably superior to information gathered during interviews, when queries could be considered by some women to be embarrassing. All OS surveys were completely filled in. Furthermore, we believe that the reasonably low number of missing items in the demographics did not affect our data analysis. Our study has some limitations. First, although we grouped the FMS patients into two categories depending on the time since diagnosis (<3 years vs >3 years), we did not correlate the OS or the FBI scores with the bother score of FMS, such as the one derived from the Fibromyalgia Impact Questionnaire [32].The latter has not been routinely used by our rheumatologists. Such a correlation could be interesting to explore in future research, especially as it may affect the treatment strategies for FMS. Second, we did not enquire whether FMS patients were already under treatment for bladder-related symptoms, or if they had already consulted a specialist or even discussed their bladder symptoms with their rheumatologist. It is important to understand patients' views and attitudes toward their bladder symptomatology, which could be interpreted by some patients as a manifestation of their already diagnosed condition. Although we registered the pharmacological treatment that FMS patients were receiving, we did not capture whether this was actually prescribed to target bladder symptoms as well. Third, information on estrogen hormone replacement, whether systemic or vaginal, was not captured among menopausal patients; we cannot predict whether such a variable could have affected our results. Finally, a possible limitation of our study is that it evaluated FMS patients in only one medical center and geographic area. However, it is safe to assume that our sample is quite representative of patients from different regions and socioeconomic brackets in Lebanon, as the recruitment venues included both private and "non- private" outpatient departments in a University Medical Center.

Only female patients were evaluated in our study. Our findings cannot therefore be extrapolated to both sexes. Although there seems to be an inconsistent gender difference in the component symptoms of FMS [33], the differential in gender comorbidities, including bladder symptoms, has not been satisfactorily evaluated in the literature. On the flip side of the equation, women with PBS were found to have a higher incidence of "non-bladder" systemic disorders compared with their male counterparts, particularly FMS, which was reported to be ten times more prevalent in women than in men with PBS [34].

Conclusions

Women with FMS display bothersome bladder symptoms that affect their QoL. Menopause, parity, and a duration of 3 years since the diagnosis of FMS represent identifiable risk factors that could alert clinicians to screen for these symptoms.

Authors contributions NH: protocol development, literature search, data collection, and manuscript review; MAR: protocol development, literature search, data collection, and manuscript review; IU: protocol development, literature search, data collection, and manuscript review; LET: statistical analysis and manuscript review; MA: data collection, statistical analysis, and manuscript review; EM: protocol development, literature search, and manuscript review; TB: study design, literature search, and manuscript writing, editing, and submission.

Compliance with ethical standards

Conflicts of interest None.

Appendix

Interstitial Cystitis Symptom Index	Interstitial Cystitis Problem Index
Q 1. During the past month, how often have you felt the strong need to urinate with little or no warning?	During the past month, how much has each of the following been a problem for you?
0 : not at all	Ql. Frequent urination during the day?
l: less than 1 time in 5	0: no problem
2: less than half the time	1: very small problem
3: about half the time	2: small problem
4: more than half the time	3: medium problem
5: almost always	4: big problem
Q2. During the past month, have you had to urinate less than 2 h after you finished urinating?	Q2. Getting up at night to urinate?
0: not at all	: no problem
l: less than 1 time in 5	1: very small problem
2: less than half the time	2: small problem
3: about half the time	3: medium problem
4: more than half the time	4: big problem
5: almost always	Q3. Need to urinate with little warning?
Q3. During the past month, how often did you most typically get up at night to urinate?	0: no problem
0: none	1: very small problem
1: once	2: small problem
2: 2 times	3: medium problem
3: 3 times	4: big problem
4: 4 times	Q4. Burning, pain, discomfort, or pressure in your bladder?
5: 5 or more times	0: no problem
Q4. During the past month, have you experienced pain or burning in your bladder?	l: very small problem
0: not at all	2: small problem
2: a few times	3: medium problem
3: almost always	4: big problem
4: fairly often	Add the numerical values of the checked entries for the total score
5: usually	
Add the numerical values of the checked entries for the total score	

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