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Fibromyalgia among patients presenting to a rheumatology clinic: prevalence and diagnosis

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Abstract

Introduction: Fibromyalgia (FM) syndrome is a chronic musculoskeletal disorder with extensive symptoms. Its most characteristic manifestation is the presence of persistent and diffuse chronic pain. The prevalence of this disease is 1% to 6% in different studies. Its exact nature and manifestations are not fully known; hence the empirical diagnosis of doctors and the proposed diagnostic criteria may differ in diagnosis.

Objectives: This study aims to investigate the prevalence of FM symptoms among rheumatology patients, identify components of symptom and laboratory markers, and determine the interrater agreement between clinician judgment and diagnostic criteria.

Patients and Methods: During one year, all patients referred to the rheumatology clinic were selected by simple sampling and underwent medical history collecting and physical examination by a single experienced rheumatologist, and the clinician's judgment on the diagnosis of FM in the patients was recorded. Also, the American College of Rheumatology (ACR) standard questionnaire was used to evaluate the diagnosis of FM.

Results: Between May 2018 and May 2019, 1762 patients were recruited, of whom 1428 (81%) were female, and 334 (19%) were male, with a mean age of 48.4±13.4 years. According to the rheumatologist and ACR criteria, 620 (35.1%) and 491 (27.8%) were diagnosed with FM respectively. Analysis indicated a lower agreement between the two in patients with underlying rheumatologic conditions of a mechanical origin. Younger age in patients with FM ($P<0.001$). A higher prevalence of FM was found among women ($P<0.001$). There was a significant correlation between concomitant rheumatologic conditions and FM occurrence ($P=0.0004$). Symptoms were clustered into 10 components with the component including fatigue explaining 22.18% of the variance in the results. Laboratory markers were clustered into 5 components.

Conclusion: Fibromyalgia is a widespread disease among women that is frequently comorbid with other rheumatologic conditions. Agreement between ACR criteria and rheumatologist judgment is acceptable but can be improved by examining the symptoms in clusters rather than individually.

Keywords: Fibromyalgia, Socioeconomic factors, Education, Widespread pain index

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Introduction

Fibromyalgia (FM) syndrome is a musculoskeletal disorder of adults characterized as a diffuse chronic pain accompanied by specific symptoms with varying degrees of severity (1). The estimated prevalence rate of FM in the general population varies by study and geographical location, it has been reported to be prevalent in less than 1% of Denmark population to more than 2-3% in Spain and North America, and even up to 6% in other countries (2,3). FM is more prevalent in females with most patients ranging from 30 to 50 years of age (4-6).

Fibromyalgia however is not simply defined only by chronic diffuse pain; patients' complaints range from tenderness at various spots during the physical examination, to various seemingly unrelated symptoms such as sleep disorders, headaches, fatigue, affective-cognitive disorders (7,8). In 1990, the American College of Rheumatology (ACR) developed diagnostic criteria for FMS that was mainly driven by investigational intents during its first years without applicability in clinical care; in 2010, however, a new version of the diagnostic criteria was presented by ACR with due attention to epidemiological features of the syndrome criteria for FM syndrome (9). In the updated version, chronically persistent pain is conceptualized as the main symptom of FM and patients provide a subjective evaluation of their symptoms including the presence and severity of fatigue, sleep disorders, headaches, irritable bowel syndrome,

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Implication for health policy/practice/research/ medical education

- Fibromyalgia (FM) patients suffer from sleep issues, memory problems, and fatigue (which may be associated with their lower levels of TSH more frequently in comparison to other rheumatologic illnesses.
- The presence of concomitant rheumatologic conditions was in association with a higher prevalence of FM. Patients who had other rheumatic manifestations seemed to suffer from concomitant FM.
- There is still a difficulty in the diagnosis of patients with FM, which decreases the rate of agreement between the criteria and the physician's discretion.
- Clustering symptoms might increase diagnosis reliability and can help identify common etiologic factors.

memory disorders, and cognitive impairments (9,10).

Despite current advances in the diagnostic criteria of FM, the diagnosis of FM is still a matter of controversy with reports of overdiagnosis in many circumstances (11). The main underlying reasons for uncertainty emerge from the self-reported nature of the disease manifestations and the lack of an accurate definition for the syndrome (12). Since the components of FM symptoms are not yet fully understood, questionnaires and clinicians put them at equal weights despite the difference in their correlation to the confounding factors of the disease.

Overall, the particular characteristics of FM diagnosis can result in misdiagnosis of patients, as well as a critical disagreement between physicians' and criteria-derived judgments (13-15). However, contrary to the concerns mentioned above, few studies have evaluated the concordance of the clinical decision making and standard diagnostic tools outcomes in patients, who are presumed of suffering from FM. On the other hand, not much data is available regarding the epidemiological characteristics of FM in the general population (13,16).

Objectives

The current study aimed to investigate the prevalence of FM in the patients referred to the rheumatology clinic according to the ACR questionnaires and to compare the results with the physician's judgment. This study also intends to identify components of symptom and laboratory markers to further increase our understanding of the significance of various symptoms in FM to facilitate the implementation of diagnostic criteria and possibly improve on them.

Patients and Methods

Study design

In this cross-sectional study, 1762 patients that referred to the Clinic, between May 2018 and May 2019 were enrolled by simple sampling. This study follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement (17).

Participants

Patients were recruited regardless of their chief complaints and underlying diseases: all patients of the clinic with rheumatologic conditions not in the active phase were included except for those who chose not to participate in the study and those unable to answer the subjective questions at hand. Subsequently, after enrollment, patients underwent medical history collection and physical examination by an experienced rheumatologist. Finally, the clinician's judgment on FM diagnosis was recorded for each patient.

Variables and measurements

We used the ACR standard questionnaire for evaluating FM syndrome. In addition to a survey of demographic data including age, gender, education, number of children, and marital status. The ACR questionnaire consists of three distinct parts, evaluating widespread pain index (WPI), symptom severity (SS), and specific signs and symptoms in the past three months. The WPI is defined as the total number of painful areas. Fatigue, unrefreshed waking up, and cognitive symptoms were categorized into four levels with regards to their severity and the presence of various somatic complaints were assessed.

After completion of the questionnaire, patients who got WPI>7 and SS>5 or patients with 3<WPI<6 and SS>9, received a diagnosis of FM. Additionally, laboratory tests results were obtained and compared between FM patients and other rheumatic diseases.

Statistical analysis

All data were analyzed using SPSS Statistics for Windows version 25.0 (IBM Corporation, Armonk, NY, USA). Descriptive data were reported either in mean ± standard deviation along with range for continuous variables or reported in number and frequency for categorical variables. Variable analysis was performed using student *t*-test or analysis of variance (ANOVA), and χ^2 test for paired data analysis, while the results with $p<0.05$ were considered as statistically significant. Linear regression was run to determine the effect of age, gender, education level, occupation, and marital status on FM's occurrence. Body mass index (BMI) was calculated and categorized according to WHO recommended classification (underweight <18.5 kg/m^2, normal 18.50-24.99 kg/m^2, overweight ≥ 25 kg/m^2, obese ≥ 30 kg/m^2). Cohen's kappa coefficient was used to determine the interrater agreement between the diagnosis made by the rheumatologist and 2010 ACR criteria in all the individuals. Different subgroups were then reported with 95% confidence intervals and demonstrated in a forest plot to illustrate the agreement in various subgroups of the data.

Individuals whose FM diagnosis was confirmed both by 2010 ACR criteria and the rheumatologist were enrolled in factor analysis to extract underlying components explaining the variance seen in the symptoms and

laboratory data. Factor analysis was carried out with the Equamax rotation method and Kaiser normalization to extract components from symptoms listed in the 2010 ACR criteria. During each iteration of factor analysis, factors not strongly associated with any component were eliminated until simple structure components were achieved. The same was done for laboratory data but due to the different nature of the data, the Promax method was used for rotation. Before doing factor analysis, Kaiser-Meyer-Olkin (KMO) and Bartlett's tests were used to ensure respectively sufficient sampling and sphericity of the data. Both initial and final component matrices of factor analysis after several iterations were used to report the factor loading in each component for both the symptoms and laboratory data.

Results

Participants and demographics

The current study was performed on 1762 patients referred to the Rheumatology Clinic with different underlying diseases and complaints. Of the 1762 participants, one was excluded because of not meeting the minimum age requirement of the study. In total, 1762 patients were enrolled in the analysis of whom 1428 (81 %) were women. There was no significant difference in the average age of men and women (P = 0.240) with an average age (± standard deviation) of 48.46 ± 13.45 years among all the participants. About half of the individuals (49.8%) were literate but had a high school education or less. Overweight patients, constituted the major BMI groups with 35.0 % of the study population. Among participants with a diagnosis of FM either using 2010 ACR criteria or rheumatologist's clinical judgment, overweight and class I obese patients had almost the same frequency and constituted the majority of the cases. The detailed demographic and clinical characteristics of the studied population are presented in Table 1. Patients with the underlying disease were classified into 9 subgroups with patients with osteoarthritis and cartilage, bone, and heritable connective tissue disorders comprising the two

Table 1. Baseline demographic and clinical characteristics of the patients included in the analysis in total and in subgroups based on the diagnosis made by clinical judgment or 2010 ACR criteria

	Total patients (n=1762)	Patients diagnosed with FM by clinical judgement (n= 620)	Patients diagnosed with FM by 2010 ACR criteria (n= 491)
Female sex, n (%)	1428 (81.0)	559 (90.2)	443 (90.2)
Age (year), mean ± SD (min–max)	48.46 ± 13.45 (17–86)	46.59 ± 11.69 (19 - 78)	46.84 ± 11.72 (22–78)
Men	47.61 ± 14.75 (18–86)	42.82 ± 12.45 (23–76)	44.65 ± 14.06 (23–78)
Women	48.66 ± 13.12 (18–80)	47.00 ± 11.54 (19 - 78)	47.07 ± 11.43 (22–78)
Level of education, n (%)			
Illiterate	542 (30.8)	192 (31.0)	154 (31.4)
High school or less	877 (49.8)	313 (50.5)	254 (51.7)
Higher education	343 (19.5)	115 (18.5)	83 (16.9)
Marital status, n (%)			
Married	1522 (86.4)	535 (86.3)	419 (85.3)
Single	124 (7.0)	32 (5.2)	26 (5.3)
Divorced	22 (1.2)	19 (3.1)	17 (3.5)
Widowed	94 (5.3)	34 (5.5)	29 (5.9)
BMI, mean ± SD	28.71 ± 5.93	30.63 ± 6.16	30.86 ± 6.35
BMI categories, n (%)			
Underweight (<18.5)	25 (1.4)	3 (0.5)	4 (0.8)
Normal (18.5-24.9)	461 (26.2)	106 (17.1)	82 (16.7)
Overweight (25-29.9)	617 (35.0)	195 (31.5)	143 (29.1)
Obesity class 1(30-34.9)	433 (24.6)	190 (30.6)	156 (31.8)
Obesity class 2(35-39.9)	172 (9.8)	93 (15.0)	76 (15.5)
Obesity class 3(>40)	54 (3.1)	33 (5.3)	30 (6.1)
Underlying rheumatologic disease classification, n (%)			
Rheumatoid Arthritis	382 (21.7)	100 (16.1)	84 (17.1)
Spondyloarthritis	97 (5.5)	31 (5.0)	28 (5.7)
Systemic lupus erythematosus and related syndromes	135 (7.7)	35 (5.6)	32 (6.5)
Systemic sclerosis, inflammatory myopathies, and overlap syndromes	31 (1.8)	4 (0.6)	5 (1.0)
Vasculitis	53 (3.0)	8 (1.3)	7 (1.4)
Crystal-induced and inflammasome-mediated inflammation	48 (2.7)	7 (1.1)	5 (1.0)
Cartilage, bone, and heritable connective tissue disorders	527 (29.9)	134 (21.6)	98 (20.0)
Periarthritis	138 (7.8)	29 (4.7)	17 (3.5)
Other	108 (6.1)	29 (4.7)	18 (3.7)

SD, Standard deviation; BMI, Body mass index; ACR, American College of Rheumatology.

most common subgroups.

Interrater agreement

The participating rheumatologist's clinical judgment followed the result of the 2010 ACR criteria in 1595 cases, the former diagnosing 620 individuals with FM and the latter 491. Cohen's Kappa interrater agreement coefficient showed a 0.782 rate of agreement between the clinical judgment and 2010 ACR criteria with 95% CI [0.751, 0.813] in all of the cases. The interrater agreement showed no significant variation among the BMI subgroups. The same was true about the nine subgroups of the underlying diseases but the two raters had significantly lower agreements among patients with underlying diseases of mechanical pathology versus patients with inflammatory ones (0.714, 95% CI [0.652, 0.775] for mechanical underlying disorders versus 0.818, 95% CI [0.771, 0.866] for inflammatory). The detailed figures of this analysis can be found in Table S1 (See Supplementary file 1).

Underlying components

Following the factor analysis, 10 components were extracted for symptoms presented in the 2010 ACR criteria and 5 for laboratory data. The extracted components for symptoms explained 64.16% of the variance seen in the data, all having Eigenvalues higher than 1. During the iterations of factor analysis, 12 of the 40 symptoms were excluded due to not having a strong impact on any component. These symptoms are muscle pain, irritable bowel syndrome, headache, dizziness, pain in the upper abdomen, wheezing, Raynaud's phenomenon, seizures, loss of appetite, easy bruising, hair loss, and frequent urination.

The most prominent underlying component found in the symptoms included nervousness, fatigue/tiredness, insomnia, thinking or memory problem, depression, numbness/tingling, and chest pain, explaining 22.18% of the variance. Almost all symptoms had positive factor loading showing a positive correlation with FM occurrence except for vomiting and muscle weakness which had a negative factor loading in two different components, showing an inverse correlation with oral ulcers and bladders spasm respectively. Detailed component matrix of the initial iteration and the last iteration of factor analysis for both symptoms and laboratory data can be found in Tables S2-S4.

For each participant in the study, 14 laboratory analytes were measured that included rheumatologic markers, thyroid hormones, electrolytes, and vitamin D. Factor analysis showed 5 underlying components in the data explaining 62.12% of the variance, with phosphor and albumin levels not being associated with any of them and all components having Eigenvalues higher than 1. The most important component included anti-cyclic citrullinated peptides (anti-CCP), anti-thyroid peroxidase (anti-TPO), antinuclear antibodies (ANA), and rheumatoid factor (RF), explaining 26.21% of the variances in the data. Levels of three laboratory markers showed an inverse correlation in three different components accompanying calcium, free T3, and thyroid stimulating hormone (TSH) levels. Tables 2 and 3 list the factor loadings found in each component underlying the data.

Discussion

Since its definition as a disease, several etiologies have been proposed for FM, including autoimmunity, infection, and psychosomatic manifestations, making the syndrome a conflicting and challenging condition for physicians to diagnose (18,19). Although the primary etiology of FM syndrome is still unknown, and predisposing factors are a topic of debate, the disease has been generally diagnosed, treated, and cared for by rheumatologists (20,21).

In our study, the overall prevalence rate of FM in the participants was approximately 35% by clinicians'

Table 2. Factor Loadings of the underlying components seen in factor analysis of the symptoms checked in 2010 ACR criteria carried out using Promax rotation method with kaiser normalization method on n = 1595 patients with FM diagnosis confirmed both by a rheumatologist and 2010 ACR criteria

Component #	Positive factor loadings	Negative factor loadings
1	Nervousness, fatigue/tiredness, insomnia, thinking or memory problem, depression, numbness/tingling, chest pain	-
2	Blurred vision, loss/change in taste, hearing difficulties	-
3	Dry mouth, dy eyes	-
4	Ringing in ears, hives/welts, heartburn, itching	-
5	Rash, sun sensitivity	-
6	Pain/cramps in abdomen, Itching, Shortness of breath	-
7	Fever, nausea	-
8	Diarrhea, constipation	-
9	Oral ulcers	Muscle weakness
10	Bladder spasms	Vomiting
Symptoms excluded in factor loading	Muscle pain, irritable bowel syndrome, headache, dizziness, pain in the upper abdomen, wheezing, Raynaud's seizures, loss of appetite, easy bruising, hair loss, frequent urination	

Table 3. Factor Loadings of the underlying components seen in factor analysis of the laboratory data carried out using Equamax rotation method with kaiser normalization method on 1595 patients with FM diagnosis confirmed both by a rheumatologist and 2010 ACR criteria

Component number	Positive factor loadings	Negative factor loadings
1	Anti-CCP, Anti-TPO, ANA, RF	-
2	Free T4,CRP	-
3	Calcium	IPTH
4	Free T3	25OH-VitD3
5	TSH	ESR
Laboratory analytes not included in the factor loading	Phosphor Albumin	

Anti-CCP; Anti-cyclic citrullinated peptides, Anti-TPO; Anti-thyroid peroxidase, ANA; Antinuclear antibodies, RF; Rheumatoid factor, CRP; C-reactive protein, TSH; Thyroid stimulating hormone, IPTH; Intact parathyroid hormone, ESR; Erythrocyte sedimentation rate

diagnosis which lies in the upper range of previous studies (22); however, a higher prevalence rate among rheumatologic patients in comparison to the general population was not unexpected. A significant difference in the presence of symptoms between those with and without FM was observed since only rheumatic patients with 'inactive' disease were enrolled in this study. Additionally, patients with underlying rheumatologic conditions had a higher rate of FM compared to those without any other rheumatologic conditions, indicating the presence of some common etiologies as suggested by previous studies. Despite the absence of specific diagnostic guidelines, newly designed criteria have changed the disease definition through the years, resulting in an increased rate of diagnostic agreement between clinical experts (4,23,24). However, as demonstrated by our study and the existing literature, there are still obscurities in the diagnosis of patients with FM, decreasing the rate of agreement between criteria and physician's judgment (25,26). Wolfe et al demonstrated various biases that can affect a clinician's diagnosis of FM (27). In our study, there was a significant discrepancy in FM diagnosis of patients with underlying rheumatologic conditions of a mechanical etiology, possibly since they have a bias towards previous mechanical pressure and its association with higher FM incidence and more severe disease (28-30). Considering the results of a previous study combined with our findings, it can be suggested that clinicians' understanding of a patient's prior history of rheumatologic disorders might result in clinician bias (31).

Consistent with the existing literature on the diseases, common rheumatic- and inflammatory-associated laboratory tests including erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), ANA, RF, anti-CCP, and anti-TPO all had significantly fewer positive rates in FM patients than other rheumatic diseases (32). TSH levels were significantly lower in FM patients than other rheumatologic conditions, which might be associated with their complaints of fatigue and lethargy (33).

In the current study, diagnosis of FM in patients referring to rheumatology clinic was investigated, not only to determine its prevalence but also to identify hidden confounding factors which could aid us in defining the disease and understanding it. We identified 10 components among symptoms and 5 components among laboratory markers. The symptom component best explaining the variance observed in the result included nervousness, fatigue/tiredness, insomnia, cognitive problems, depression, numbness/tingling, and chest pain, all of which have been investigated as core symptoms of FM and can be considered as correlating symptoms. Furthermore, oral ulcers and muscle weakness were found to have a negative association in the same component, same as bladder spasms and vomiting. Research can be carried out to identify the confounding factors and provide a clearer etiology for the condition.

Conclusion

Fibromyalgia is a common condition that mostly affects women, which accompanies other rheumatologic diseases in most cases. Patients report many symptoms, especially fatigue, which may be associated with their lower levels of TSH. The authors suggest considering symptoms as clusters for diagnosis instead of looking at individual symptoms separately. Such an approach can not only help reduce false negatives of FM diagnosis but can also increase the agreement between clinician judgment and ACR criteria by identifying symptoms with common underlying etiology.

Limitations of the study

Our study had some limitation. Firstly, the collected data for evaluating the presence of FM were based on subjective reports provided by the patients, resulting in an unneglectable bias. Secondly, some patients refused to respond to all items of the intended questionnaire and provided partial and incomplete data, obligating us to eliminate them from the study. Thirdly, while examination and inspection of the patients by a single rheumatologist might have eliminated inter-observer bias, we were not able to evaluate the rate of diagnostic agreement between various clinicians and the American College of Rheumatology criteria for FM diagnosis.

Authors' contribution

Conceptualization; MM and KS.
Methodology; AP.
Validation: AP, KS and SM.

Formal analysis: AP, KS and SMHM.
Investigation: all authors.
Resources: FR.
Data Curation: FR.
Writing—Original Draft Preparation: KS, AP, FR, SMHM and SM.
Writing—Review and Editing: MM and SMHM.
Visualization: SM.
Supervision: MM.
Project Administration: MM.

Availability of data and materials

During the current study, the datasets generated and analyzed are not publicly available due to respect for participants' rights to privacy and protect their identity but are available from the corresponding author on reasonable request.

Conflicts of interest

The authors declare that they have no competing interests.

Ethical issues

The research followed the tenets of the Declaration of Helsinki. The Ethics Committee of Qom University of Medical Sciences approved this study. The institutional ethical committee at Qom University of Medical Sciences approved all study protocols (Ethical code# IR.MUQ.REC.1398.081). Accordingly, written informed consent taken from all participants before any intervention. Besides, ethical issues (including plagiarism, data fabrication and double publication) have been complete observed by the authors.

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Supplementary files

Supplementary file 1 contains Tables S1-S4.

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