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RESEARCH ARTICLE

Clinical Features, Socio-cultural Characteristics, Sleep Patterns, and Depression in Fibromyalgia Patients from India: A Cross-Sectional Study

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Abstract:

Introduction:

Fibromyalgia (FM) is a complex and chronic disease with significant regional variation. There is a lack of studies on Fibromyalgia (FM) in Indian population.

Objective:

The aim of this study is to investigate the clinical features of FM patients in India, including the prevalence and distribution of comorbidities, sleep patterns, and depression.

Methods:

Cross-sectional analysis of patients attending outpatient rheumatology clinic from 2019-2020 fell in the ACR2016 criteria for FM.

Results:

Of the 121 patients enrolled in the study, the majority (93.4%) were female, with a female-to-male ratio of 14:1. The mean age of the patients was 45 ±11 years. The socio-cultural profile of the patients revealed that the majority were married (88%) and homemakers (68.8%), lived in nuclear families (56%) and were middle to upper middle class (68.6%). Contrary to the existing literature, a higher prevalence of FM has been observed in people with a higher educational status. Common clinical symptoms were extensive body aches (100%), fatigue (88%), difficulty concentrating (69.4%), irritability and gastrointestinal complaints (58.5%). We observed a high prevalence of primary headache (76%), mainly migraine (42%) and obsessive-compulsive (OCB) (71%). Sleep disturbances and depression were found in the significant number of patients with FM. The patients reported various sleep problems, such as snoring, waking up at night, daytime sleepiness, and taking daytime naps. Most of the patients had mild (50.8%) to moderate (29%) depression, while a smaller proportion experienced severe (6.6%) symptoms. Most of the patients had low serum vitamin D (91%). The presence of moderate to severe depression was associated with the severity of FM.

Conclusion:

The demographic profile of Indian patients was similar to that reported in the literature but had varied socio-cultural profiles needing further community-based studies. The high prevalence of psychological comorbidities and sleep disturbances highlights their importance in managing FM patients.

Keywords: Fibromyalgia, Primary headache, Chronic pain syndromes, Sleep abnormalities, Depression, Migraine.

1. INTRODUCTION

Fibromyalgia (FM) is a complex syndrome characterized by widespread chronic pain, which lacks observable abnormalities on laboratory and imaging tests. In addition to musculoskeletal pain, people with FM often experience somatosensory complaints that significantly impact their quality of life. This syndrome can also manifest in mood abnormalities and cognitive and personality traits, such as neocriticism and alexithymia. Although central pain sensitization plays a role in the development of FM, it does not

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fully explain patients' psychosocial and mood changes. In particular, previous social and physical experiences can also contribute to the genesis of FM. Furthermore, the gender prevalence of FM may suggest hormonal contributions, as well as hierarchical and social factors in society.

Given the widespread determinant factors associated with FM, the demographic profiles of patients can exhibit significant regional variation. Due to the traditional family and social structure of the Indian population, the clinical characteristics and patient profiles of Indian patients may differ from those of patients from other countries. Understanding these differences is crucial to better managing FM in the Indian setting. Factors such as social status, occupational profile, and family background can all affect the prevalence of FM and its clinical manifestations. Furthermore, the current diagnostic criteria for FM do not adequately account for the psychological, environmental, and socio-cultural factors that contribute to the onset, maintenance, diagnosis, and treatment of the syndrome. We conducted this study to better understand the socio-cultural factors, lifestyle, and psychological disorders associated with FM in an Indian setting.

1.1. Objectives

This study aims to investigate the clinical characteristics of patients with FM, including the prevalence and distribution of comorbidities, sleep patterns, and depression.

2. MATERIALS AND METHODS

2.1. Study Design and Participants

This study is a cross-sectional analysis carried out in a hospital-based tertiary healthcare research centre. Patients who visited the outpatient clinic of the rheumatology department between 2019 and 2020 with musculoskeletal complaints were screened, and those who met the ACR 2016 criteria for FM were included in the analysis. The study protocol was approved by the hospital's Ethics Committee (ECR/264/Inst/MH/2013/RR-20). Trained clinical researchers conducted interviews and collected data using a preapproved case record form.

2.2. Data Collection

The data collected included demographic information about the patient, clinical characteristics and comorbidities. To determine socioeconomic status, we used the modified Kuppuswamy criteria 2019 [1]. Furthermore, all patients were tested for ESR, CRP, and vitamin D levels.

2.3. Clinical Assessment

Clinical manifestations were evaluated, including the number of tender points), widespread body pain, fatigue, and fibromyalgia score were determined.

Other data collected included psychological comorbidities, sleep patterns and behaviour, and prevalence of depression based on the modified Hamilton score. [2] Patients with known rheumatologic disease were also included if they met the diagnostic criteria.

2.4. ACR 2016 Criteria

A patient satisfies the modified 2016 FM criteria if the following three conditions are met: (1) WPI $\geq$ 7 and SSS score $\geq$ 5 OR WPI of 4–6 and SSS score $\geq$ 9. (2) Generalized pain, defined as pain in at least 4 of the five regions, must be present. Jaw, chest, and abdominal pain are not included in the general definition of pain. (3) Symptoms have generally been present for at least three months. (4) A diagnosis of FM is valid regardless of other diagnoses. A diagnosis of FM does not exclude the presence of other clinically significant diseases [3].

2.5. Severity of Fibromyalgia

Although ACR criteria are used for the diagnosis of FM, it has been suggested that the total of WPI and SSSS should be used as a 'polysymptomatic distress scale', a 'fibromyalgianess scale,' or 'FMS survey score' for measuring the severity of fibromyalgia [4]. This composite FM score was used in our study to identify the factors associated with the severity of symptoms of fibromyalgia.

2.6. Statistics

Descriptive statistics are presented as mean and standard deviation (SD) for continuous variables and frequencies (%) for categorical variables. Kruskal-Wallis H tests were performed to determine associations between demographic and psychological factors with FM scores, considering p-values < 0.05 as statistically significant.

3. RESULTS

A total of 121 patients were included for analysis. The baseline characteristics of the patients are mentioned in Table **1**.

Table 1. Sociodemographic characteristics in patients with FM.

Characteristics	-	Observation
Mean Age ±STD (years)	-	45.5±11.0
Female	-	113 (93.4%)
Education level (%) **N=121**	Primary	40 (33.6)
	Secondary and higher secondary	36 (30.2)
	Graduate	43 (36.1)
Occupation (%) **N=115**	Homemaker	83 (68.8)
	Job/Service/ Student	32 (26.0)

(Table 1) contd.....

Characteristics	-	Observation
Marital status (%) **N=118**	Married	104 (88.1)
	Other (Unmarried/ Divorced/ Widow)	14 (11.9)
Family (%) **N= 117**	Nuclear	68 (56.2)
	Joint	46 (38.0)
	Other	3 (2.5)
Menstrual history (%) **N=109**	Premenopausal	48 (44.0)
	Perimenopausal	5 (4.6)
	Postmenopausal	56 (51.4)
Dietary habits (%) **N=119**	Vegetarian	71 (59.7)
	Nonvegetarian	48 (40.3)
Television activity **N=101**	Median TV time (IQR25-75) Hour	1.0 (0.0 – 2.0)
	TV in bedroom (%)	15 (14.9)
Active exercise (%) **N=107**	Yes	36 (33.6)
	No	71 (66.4)
Type of Exercise (%) **N=36**	Yoga	15 (41.7)
	Stretching	6 (16.6)
	Walk	15 (41.7)
Socioeconomic status (modified Kuppuswamy) (%) N=121	Upper	0
	Upper middle	33(27.3)
	Lower middle	50(41.3)
	Upper lower	38 (32.4)
	Lower	0
Serum Vitamin D (N=84)	Mean	19.0±10.9 ng/mL
	Normal (>30)	8(9.5)
	Insufficiency (21 to 30)	21 (25.5)
	Deficiency (≤20)	54 (65)

3.1. Demographics

The study included 121 patients with an age range of 10 to 73 years. The mean age of the patients was 45.5±11.0 years. Most of the patients were female (93.4%), with most in the age group 41 to 55 (52.5%).

3.2. Social Factors

Most patients were graduates (35.5%) and homemakers (68.8%). Most of the patients were married (88.1%) and lived in nuclear families (56.2%).

3.3. Socioeconomic Status

According to the modified Kuppuswamy scale, most of the individuals (41.3%) were classified as having a lower middle social status, followed by 27.3% of the people classified as upper middle and 32.4% as upper lower. None of the individuals were classified as having an upper or lower social status.

3.4. Habits and Lifestyle

About 60% of the patients followed a vegetarian diet, while 40% were non-vegetarians. The median time spent watching television (TV) was 1 hour (IQ 0.0-2.0). Only 14.9% of the patients reported having a TV in their bedroom. Approximately a third of the patients (33.6%) were reported participating in some form of active exercise, while the majority (66.4%) did not.

3.5. Clinical Manifestation

Among the 121 patients evaluated, all reported widespread body pain, while the number of tender points varied, with most patients (50.4%) reporting more than 15 tender points. Other commonly reported symptoms were fatigue (88%), waking up unrefreshed (80.1%), arthralgia (79.3%), difficulty concentrating (69.4%), feeling low energy during the day (69.4%) and irritability (69.4%) (Table **2**).

3.6. Comorbidities and Associated Conditions in Patients with FM

Hypothyroidism was the most common physical comorbidity, affecting 20 patients (16.5%). The most prevalent physical comorbidity was hypothyroidism (16.5%). Psychological comorbidities were fairly prevalent and were observed in a significant number of patients. Obsessive-compulsive disorder (OCD) affected 71% of patients, while increased self-reported anxiety affected 26.4%.

Furthermore, some patients with FM had rheumatological disorders such as knee osteoarthritis (16.5%), rheumatoid arthritis (9.9%), and spondyloarthropathy (7.4%). These conditions can cause joint pain and other symptoms that can worsen the overall impact of FM in patients. FM frequently co-occurs with chronic pain syndromes, with chronic low back pain affecting 86.7% of patients. Primary headaches were common, with migraines being the most common (45.6%) (Table **3**).

Table 2. Clinical manifestation in FM patients included in the study.

-	-	Frequency (%)
Tender points	≤12	16 (13.2)
	13-15	44 (36.4)
	>15	61 (50.4)
Widespread body pain	-	121 (100.0)
Fatigue	-	107(88)
Waking unrefreshed	-	97(80.1)
Arthralgia	-	96 (79.3)
Difficulty concentrating	-	84 (69.4)
Feeling low energy during the day	-	84 (69.4)
Irritability	-	84 (69.4)
Feeling depressed	-	77 (63.6)
Acid peptic symptoms	-	72 (58.5)
Abdominal cramps	-	21(17.3)

Table 3. Comorbid conditions associated with FM patients.

-	-	-	Frequency (%)
Associated physical comorbidities	Hypothyroidism	-	20 (16.5)
	Diabetes mellitus	-	5 (4.1)
	Hypertension	-	13 (10.7)
Associated psychological comorbidities	Self-reported increased Anxiety	-	38 (26.4)
	Obsessive-compulsive behaviour 86(71%)	cleanliness	70(82.5)
		perfection	11(13.4)
		work	5(6.1)
Associated rheumatological disorders	Osteoarthritis of knee	-	20 (16.5)
	Rheumatoid Arthritis	-	12 (9.9)
	Spondyloarthropathy	-	9 (7.4)
Other chronic pain comorbidities in FM patients	Primary Headache 92 (76.0%)	Simple headache	32 (34.7)
		Migraine headache	42 (45.6)
		Tension headache	18 (19.7)
	Chronic low backache	-	105 (86.7)

Table 4. Sleep and fibromyalgia.

Parameter	-	Observation
Sleep duration (range) (hours) **N=121**	-	6.1±1.4 (3 to 10)
Snoring **N=105**	-	49 (46.7)
Get up at night. **N=121**	-	16 (13.2)
Day time somnolence **N=99**	-	56 (56.6)
Day time sleep **N=34**	1/2 hr	1 (2.9)
	1 hr	26 (76.5)
	2 hr	7 (20.6)

3.7. Sleep Patterns and FM

The mean daily duration of sleep was 6.1±1.4 hours. The study found that 49.7% of patients reported snoring, while 12.2% experienced nighttime awakenings. Daytime somnolence was quite common (56.6%), with the majority (76.5%) reporting a daytime nap of 1 hour (Table **4**).

Table 5. Shows the severity of depression in the study population of patients with FM based on their scores on the hamilton depression rating scale.

Score	Depression Category	Observation (n=120)
0-7	No	21 (17.5)
8-13	Mild	61 (50.8)
14-18	Moderate	29 (24.2)
19-22	Severe	8 (6.6)
≥23	Very severe	1 (0.8)

Table 6. Comparative analysis of the association of demographic and psychological factors with FM scores.

-	-	-	FM Scores		-
-	-	n	Mean ± SD	Median (IQR)	P-value (Kruskal Wallis H test)
Age Group (years)	10-30	7	20.14±1.07	21(19-21)	0.108969
	30-50	73	19.60±1.66	19(19-21)	
	>50	41	20.25±1.26	21(19-21)	
Gender	Male	8	20±1.41	20.5(19.5-21)	0.78694
	Female	113	19.84±1.54	21(19-21)	
Occupation Score	3	55	19.89±1.5	21(19-21)	0.911437
	5	34	19.65±1.61	20(19-21)	
	6	15	20.07±1.44	20(19-21)	
	7	17	19.94±1.64	21(19-21)	-
Socioeconomic class	Upper middle	33	19.79±1.76	20(19-21)	0.953222
	Lower middle	50	19.88±1.55	21(19-21)	
	Upper Lower	38	19.87±1.32	21(19-21)	
Educational level	Primary	31	20.06±1.26	21(19-21)	0.873078
	Secondary and higher secondary	25	20.04±1.77	21(19-21)	
	Graduate	23	19.87±1.60	21(19-21)	
Family Type	Nuclear	68	19.89±1.66	21(19-21)	0.884998
	Joint family	46	20.15±1.35	21(19-21)	
Depression	No to mid	82	19.43±1.61	19(19-21)	**0.0321**
	Moderate to severe	38	20.09±1.44	21(19-21)	

3.8. Depression and FM

Most of the patients with FM in this study had mild (50.8%) mild to moderate 24.2% depression. Only a small proportion of the patients had severe depression (6.6%) (Table **5**).

3.9. Serum Vitamin D levels

The patient's mean serum vitamin D level of the patient in the study was 19.0±10.9 ng/mL. Most patients (65%) had deficient vitamin D levels, 25% had insufficient levels, and only 9.5% had normal vitamin D levels.

3.10. Association with FM Scores

Analysing the relationship between demographic and psychological characteristics and FM severity scores revealed that there were no statistically significant differences between FM severity and other parameters, including age, gender, occupation, socioeconomic class, educational level, and type of family. However, the severity of depression was significantly associated with the severity of FM (Table **6**).

4. DISCUSSION

The present study aimed to investigate the characteristics of patients with FM in the Indian population. We recruited 121 patients over a fixed period in an outpatient rheumatology-based setting. Our results indicate that FM affects females (93%), with an average age of approximately 45 years, consistent with the FM national epidemiology of the condition as established by previous research [5, 6]. Female preponderance in FM is believed to be due to hormonal, genetic, or socio-cultural factors. However, recent unbiased, community-based studies have challenged the notion of a marked female predominance [7].

Interestingly, we observed that individuals with a better educational status (66.6%) had a higher prevalence of FM than those with a lower educational level, in contrast to the results reported in the literature [8 - 10]. We suggest two potential explanations for this discrepancy. First, according to the literature, lower educational status may be related to lower income, leading to increased social stress and poorer access to healthcare. However, in the Indian social support model, lower education status may be associated with a more traditional joint

family living arrangement, resulting in better social support and pain-coping mechanisms. Second, our study was hospital-based, which may be biased toward patients with lower educational status who have poorer access to healthcare facilities. Additionally, lower levels of education in Indian patients may be associated with poorer healthcare literacy, leading to less awareness of symptoms and reduced utilization of healthcare.

In addition to examining the symptoms of patients with FM, we also investigated other lifestyle factors such as diet, exercise, and television habits. In particular, most of the participants in the study were vegetarians. Our findings suggest that participants generally had low levels of physical activity, with only a minority reporting regular exercise.

Previous studies have shown that social support plays a crucial role in the genesis and treatment of FM by facilitating coping mechanisms. Low socioeconomic status and divorce have been associated with a higher prevalence of FM [11]. However, we found that most of the patients in our study were married and homemakers who remained in nuclear families, highlighting the importance of conducting culturally specific research to better understand the socio-cultural determinants of FM. However, there is limited research exploring the impact of socio-cultural factors on FM, particularly in India, where social structures and marriage patterns differ from other regions.

The literature indicates that people with a lower socioeconomic status can experience a higher prevalence and severity of symptoms related to FM due to limited access to medical care, poor health literacy, low adherence to management recommendations and financial restrictions [12, 13]. However, we had a relatively even distribution across the three middle social status categories, with few individuals at the extremes of the upper or lower status. This may be due to the variable socioeconomic status structures of Indian society.

All our patients have reported widespread body pain, specific tender points, and other accompanying symptoms such as cognitive dysfunction, mood disturbances (such as depression and anxiety), and gastrointestinal issues. These symptoms varied in frequency, intensity, and distribution, meaning that each patient with FM may have a similar profile but with different intensity and functional outcomes. Although there is no universal agreement on a quantitative measurement for the severity of fibromyalgia, we utilized the Fibromyalgia Score as a measure of severity and investigated the association between the severity of FM and associated factors. Our findings revealed that depression was the only factor significantly associated with severity. This finding is consistent with findings from other authors and may warrant a psychiatric consultation for every patient with FM to improve their management [14].

One of the key strengths of our study was the use of the ACR 2016 criteria, which enabled us to include patients with other primary rheumatological and pain disorders in the classification of FM. Our study identified the coexistence of other autoimmune diseases, such as rheumatoid arthritis in 10% of patients and ankylosing spondylitis in 7.5%. The relationship between FM and autoimmune diseases remains complex and is not fully elucidated. While some evidence suggests an autoimmune pathogenesis for FM, further investigation is required to confirm this hypothesis [15]. The literature also suggests a higher incidence of FM in patients with other autoimmune diseases, along with a higher severity of FM in these individuals [16, 17]. These findings highlight the need for more research to understand FM's underlying mechanisms and potential therapeutic targets of FM and its relationship with autoimmune disorders.

We also found that a significant number of patients had comorbid conditions, which can be grouped into three main categories: physical comorbidities, psychological comorbidities, and other chronic pain syndromes. These comorbidities included conditions such as FM-associated headaches and chronic low back pain. Especially, headache was a common symptom among our patients, with a higher incidence of migrainous-type headaches than chronic tension headaches. These findings align with other studies exploring the association between FM and headache [18 - 20]. The precise mechanisms underlying this relationship are not yet fully understood. However, it is postulated that central sensitization, a process in which the central nervous system becomes hyperresponsive to stimuli, may play a role in the development of both conditions [21]. This finding is significant because it highlights the complexity of FM and its association with other chronic conditions. By recognizing and understanding these comorbidities, healthcare professionals can provide more comprehensive and targeted care to patients with FM.

Our findings suggest that sleep disturbances are common in individuals with FM; many experience snoring, awakening at night, daytime sleepiness, and taking daytime naps.

The findings are consistent with the existing literature on the subject. For example, a systematic review and meta-analysis of sleep in FM found that individuals with FM had reduced sleep duration and efficiency, increased sleep latency, and more awakenings compared to healthy controls [22 - 25]. Other studies found that individuals with FM reported more snoring and sleep apnoea compared to healthy controls [26, 27]. This highlights the importance of addressing sleep disturbances in the treatment of FM.

To determine the prevalence of depression among patients with FM, we used the Hamilton scoring criteria. Our findings revealed that most (82.5%) of FM patients had symptoms of depression, with a significant proportion (31.6%) exhibiting moderate to severe depression. This is consistent with previous research in the literature that consistently reports depression as a common comorbidity among people with FM. In a systematic review of 32 studies, the current and lifetime prevalence rates of depression were reported to be 63% and 43%, respectively [28]. Furthermore, our study highlights the high prevalence of comorbidities such as obsessive-compulsive behaviour in patients with FM.

Although our study aimed primarily to investigate the prevalence and associations of these factors, it is imperative to recognise that the relationships among them are often multifaceted and can exert mutual influences. For example, the

high prevalence of psychological comorbidities such as depression and anxiety may contribute to sleep disturbances and exacerbate the perception of pain among FM patients. On the contrary, the chronic pain and sleep disturbances inherent in FM could potentially contribute to the development or intensification of psychological conditions. This bidirectional relationship between FM and other psychological and chronic pain syndromes may be due to shared predisposing and trigger factors, such as central sensitisation and initiation, involvement of brain areas that regulate pain and mood, and changes in the hypothalamic-pituitary-adrenal axis (HPA axis) [14].

Most of the patients in our study had a vitamin D deficiency, which aligns with previous research. Although there is no consensus on the relationship between vitamin D and FM, a recent meta-analysis has shown that serum levels of vitamin D in patients with FM are significantly lower than in control groups [29]. Additionally, some studies have found that vitamin D supplementation may alleviate pain and other symptoms in people with FM, which could have therapeutic implications.

Our study is limited by its modest sample size and the fact that it was conducted in a tertiary hospital, which can introduce some degree of bias in estimating the actual distribution of our findings. Future research may benefit from larger community-based observations to confirm our results. A notable strength of our study is the use of the ACR 2016 criteria, which considers other primary disorders that can cause pain. This comprehensive approach enables a more accurate assessment of FM, particularly in cases where other comorbidities can contribute to pain symptoms. By incorporating these criteria, our study provides a more pragmatic approach to evaluating FM in a clinical setting [30].

CONCLUSION

Our study suggests that the typical profile of a patient with FM in India is that of a middle-aged married homemaker living in a nuclear family within a middle to upper-middle-class society and with a satisfactory educational status. Although this demographic profile is similar to that reported in the literature, we observed varied socio-cultural profiles, which may require further community-based prevalence studies to delineate the profile of FM patients in the Indian population. Our study highlights the high prevalence of sleep disorders and other chronic psychological comorbidities, including depression and obsessive compulsive behaviour, among Indian patients with FM. Presence of moderate to severe depression was associated with the severity of FM.Future research exploring these associations may provide valuable insights into the pathogenetic mechanisms of FM. Overall, our study contributes to the growing body of knowledge on the epidemiology and management of FM worldwide, providing valuable information on the clinical features of FM in India.

LIST OF ABBREVIATIONS

ACR	=	American College of Rheumatology
CRP	=	C-reactive Protein
ESR	=	Erythrocyte Sedimentation Rate
FM	=	Fibromyalgia
HPA	=	Hypothalamic-pituitary-adrenal axis
SSS	=	Symptom Severity Score
TV	=	Television
WPI	=	Widespread Pain Index

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study protocol was approved by the hospital's Ethics Committee (ECR/264/Inst/MH/2013/RR-20).

HUMAN AND ANIMAL RIGHTS

No animals were used in this research. All procedures performed in studies involving human participants were in accordance with the ethical standards of institutional and/or research committee and with the 1975 Declaration of Helsinki, as revised in 2013.

CONSENT FOR PUBLICATION

Informed consent was obtained from all participants.

STANDARDS OF REPORTING

STROBE guidelines were followed.

AVAILABILITY OF DATA AND MATERIALS

The data supporting the findings of the article is available in the Zenodo repository at https://zenodo.org/record/8421568, reference number https://doi.org/10.2174/0118743129267713231006113813.

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