Exploring the prevalence and clinical impact of fibromyalgia syndrome in patients with shoulder diseases: a cross-sectional study

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Abstract

Objective

Fibromyalgia (FM) is a musculoskeletal syndrome characterised by widespread chronic pain often associated with systemic manifestations such as mood disturbances, persistent fatigue, unrefreshed sleep, and cognitive impairment, substantially impacting patients' health-related quality of life. Based on this background, this study aimed to evaluate the prevalence of FM syndrome in patients referring to an outpatient clinic in a central orthopaedic institute for a painful shoulder. The demographic and clinical characteristics of patients fulfilling the criteria for FM syndrome were also correlated with the severity of symptoms.

Methods

Consecutive adult patients referring to the shoulder orthopaedic outpatient clinic of the ASST Gaetano Pini-CTO, Milan, Italy, to undergo a clinical evaluation were assessed for eligibility in an observational, cross-sectional, monocentric study.

Results

Two hundred-one patients were enrolled: 103 males (51.2%) and 98 females (48.8%). The mean age ± standard deviation (SD) of the patients was 55.3 ± 14.3 years in the whole population. Of all the patients, 12 (5.97%) fulfilled the 2016 FM syndrome criteria based on the FM severity scale (FSS). Of these, 11 were females (91.7%, p=0.002). The mean age (SD) was 61.3 (10.8) in the positive criteria sample. Patients with positive criteria had a mean FIQR of 57.3 ± 16.8 (range 21.6–81.5).

Conclusion

We found that FM syndrome is more frequent than expected in a cohort of patients referring to a shoulder orthopaedic outpatient clinic, with a prevalence rate (6%) more than double that of the general population (2%).

Key words

fibromyalgia, chronic pain, prevalence, shoulder diseases, clinical impact

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Introduction

Fibromyalgia (FM) is a musculoskeletal syndrome characterised by widespread chronic pain often associated with systemic manifestations such as mood disturbances, persistent fatigue, unrefreshed sleep, and cognitive impairment, substantially impacting patients' health-related quality of life (HRQoL) (1-4). Over the last years, it has become clear that patients with FM syndrome suffer more frequently than the general population from other pathological conditions, like rheumatoid arthritis and diabetes mellitus (5, 6).

The prevalence of FM syndrome in the Italian general population is 2.22% according to one study by Salaffi *et al.* (7), with a female:male ratio of 2:1 (1). This disease can develop at any age, including childhood, with reported differences among different countries, cultures, and ethnic groups (1, 8-10).

The aetiopathogenetic mechanisms of FM are not fully understood (2). The interaction among different mechanisms, including genetic factors, stressful life events, and peripheral (inflammatory) and central (cognitive-emotional) mechanisms, are thought to lead to an altered processing of pain and the development of nociplastic pain. The latter is defined as pain arising from an altered function of pain-related sensory pathways in the peripheral and central nervous system, causing increased sensitivity (11). Nociplastic pain is the result of the interplay of multiple different inputs causing or amplifying pain arising either as a bottom-up response to a peripheral nociceptive or a neuropathic trigger, a process named central sensitisation, or as a top-down response driven by the central nervous system (11). In the case of FM, it leads to hyperalgesia, a condition in which a painful stimulus is perceived as being even more painful, and allodynia, a condition in which a normally non-painful stimulus is perceived as being painful (2).

Frequently, patients who refer to the orthopaedic out-clinic for shoulder pain or discomfort with disorders such as cuff tears, capsulitis, or arthritis, also have FM, and symptoms of the different conditions overlap (12). In this case, a missed diagnosis of FM could affect the outcome of the patients undergoing conservative or surgical orthopaedic treatments (13). Indeed, several studies demonstrate that patients with FM have a significant heterogeneity of symptoms, needing multimodal treatments, including selected pharmacological and non-pharmacological therapies (1, 2, 14).

Based on this background, this study aimed to evaluate the prevalence of FM in patients with painful shoulders referring to an outpatient clinic in a central orthopaedic institute. The demographic and clinical features of the patients fulfilling the criteria for FM were correlated with the severity of symptoms.

Materials and methods

This is an observational, cross-sectional, single-centre study conducted following the ethical principles of the Declaration of Helsinki and following good clinical practice in compliance with regulatory and legal requirements. The study obtained approval from the Area 2 Ethics Committee of Milan on 05/11/2019 (no. 996_2019). The present study has been reported according to the STROBE guidelines (15).

Patients

Consecutive adult patients referring to the shoulder orthopaedic outpatient clinic of the ASST Centro Specialistico Ortopedico Traumatologico Gaetano Pini-CTO to undergo a clinical evaluation were assessed for eligibility and enrolled according to the following inclusion criteria: adult patients with a painful shoulder, age >18 at the time of the examination, able to understand the study protocol and participate throughout the study; exclusion criteria were addiction to recreational drugs or alcoholics, psychiatric or oncologic disorders. The patients received, understood, and signed the informed consent to participate in the study.

Procedures

During the clinical evaluation, a researcher administered to all patients the revised 2016 version of the FM survey score (FSS) to assess the presence and severity of FM physical and

psychological manifestations (16). The FSS includes widespread pain index (WPI) and the symptom severity score (SSS). The WPI assesses the presence of pain in the left shoulder girdle, right shoulder girdle, left hip (buttock or trochanter), right hip (buttock or trochanter), left jaw, right jaw, upper back, lower back, left upper arm, right upper arm, left upper leg, right upper leg, chest, neck, abdomen, left lower arm, right lower arm, left lower leg and right lower leg. The symptom severity scale (SSS) score includes the sum of the severity (no problems, mild, moderate, and severe problems) of 3 symptoms, *i.e.* fatigue, waking unrefreshed and cognitive symptoms (0-9) over the past week plus the sum of the number of 3 symptoms, *i.e.* headache, pain or cramps in the lower abdomen and symptoms of depression occurring over the previous 6 months (0-3). The WPI and SSS scores range 0–19 and 0–12, respectively, with higher scores indicating greater symptom severity. To diagnose a patient as affected with FM, all the following criteria must be met: (a) WPI ≥7 and SSS ≥5; or WPI 4–6 and SSS ≥9; (b) presence of generalised pain defined as pain in 4 out of 5 regions including left upper region, right upper region, left lower region, right lower region, and axial region; (c) symptoms lasting for at least 3 months. A diagnosis of FM is valid irrespective of the presence of other diagnoses and does not exclude the presence of other diseases. Patients fulfilling the FM syndrome criteria were also given the Fibromyalgia Impact Questionnaire (FIQR) (17-19). To respect the patient's privacy, the researchers collected all the pseudonymised data in an electronic database protected with an alphanumeric password. An alphanumeric code uniquely identified each patient in the study. An investigator recorded all the demographic and clinical characteristics and comorbidities.

Statistical analysis

We tested the Gaussian distribution with the Shapiro-Wilk test for each continuous variable. Normally distributed quantitative variables were reported as mean and standard deviation (SD); median and interquartile range were used for non-normally distributed data. Data for categorical variables were reported as absolute frequency (percentage). For the comparison between categorical variables, the Chi-Square test was applied. The Mann-Whitney U-test was used to compare non-normal continuous variables.

The sample size was calculated based on a previous literature analysis on this topic. When the SD is equal to the average difference, the size of the group samples of 20 patients with FSS≥13 and 180 patients with FSS<13 reaches more than 80% of the power to detect a significant difference in each 2x2 *post-hoc* comparison corrected with Bonferroni (alpha error equal to 0.012) after a multilevel analysis when each subject is evaluated in 4 times.

Table I. Patient characteristics.

	Overall	Negative FM criteria	Positive FM criteria	*p*-value*
No. of patients (%)	201	189 (94.03%)	12 (5.97%)	-
Age at baseline				
Mean ± SD	55 ± 14	55 ± 14	61 ± 11	0.144
Sex (%)				
Females	98 (48.8%)	87 (46%)	11 (91.7%)	**0.002**
Males	103 (51.2%)	102 (54%)	1 (8.3%)	
BMI (kg/m²)				
Mean ± SD	24.8 ± 4	24 ± 3.9	25.7 ± 4.8	0.514
Smoking (%)				
Former/current smoker	37 (18.4%)	36 (19%)	1 (8.3%)	0.353
Non-smoker	164 (81.6%)	153 (81%)	11 (91.7%)	
Allergies (%)				
Yes	63 (31.3%)	59 (31.2%)	4 (33.3%)	0.878
No	138 (68.7%)	130 (68.8%)	8 (66.7%)	
Rheumatological comorbidities (%)				
Yes	20 (10%)	15 (7.9%)	5 (41.7%)	**<0.001**
No	181 (90%)	174 (92.1%)	7 (58.3%)	
Dominant side (%)				
Left	7 (3.5%)	6 (3.2%)	1 (8.3%)	
Right	193 (96%)	182 (96.3%)	11 (91.7%)	0.621
Both	1 (0.5%)	1 (0.5%)	0	
Painful side (%)				
Left	78 (38.8%)	73 (38.6%)	5 (41.7%)	
Right	120 (59.7%)	114 (60.3%)	6 (50%)	0.120
Both	3 (1.5%)	2 (1.1%)	1 (8.3%)	
Lifestyle (%)				
Active	88 (43.8%)	82 (43.4%)	6 (50%)	0.654
Sedentary	113 (56.2%)	107 (56.6%)	6 (50%)	
Sport level (%)				
No sport	86 (42.8%)	80 (42.3%)	6 (50%)	
Amateur	97 (48.3%)	91 (48.1%)	6 (50%)	0.520
Professional	18 (9%)	18 (9.5%)	0	

BMI: body mass index; FM: fibromyalgia syndrome; IQR: interquartile range; SD: standard deviation. *Significance of the between-group difference (chi-square or Mann-Whitney U-test), bold indicates *p*<00.05.

Results

Two hundred-one patients were enrolled, 103 of whom were male (51%) and 98 female (49%). The characteristics of the patients enrolled are reported in Table I. The mean age (SD) of the patients was 55 ±14 years in the total population. Of the whole cohort, 12 patients (6%) fulfilled the 2016 FM criteria (16). Of these, 11 were females (92%, p=0.002) with a mean age (SD) of 61±11. In the group of patients with criteria, there was a higher percentage of patients with rheumatological diseases at the time of enrolment compared with patients without criteria (42% *vs*. 8%, p<0.001). No statistically relevant association emerged from the analysis of the painful and dominant side, smoking habits, allergic history, lifestyle, BMI, and level of sport ac-

Table II. Medications for painful shoulder.

	Overall	Negative FM criteria	Positive FM criteria	*p*-value*
Medications (%)				
Yes	129 (64.2%)	118 (62.4%)	11 (91.7%)	**0.041**
No	72 (35.8%)	71 (37.6%)	1 (8.3%)	
NSAIDs (%)				
Yes	96 (47.8%)	87 (46%)	9 (75%)	0.051
No	105 (52.2%)	102 (54%)	3 (25%)	
Corticosteroids (%)				
Yes	13 (6.5%)	12 (6.3%)	1 (8.3%)	0.786
No	188 (93.5%)	177 (93.7%)	11 (91.7%)	
Opioids (%)				
Yes	4 (2%)	4 (2.1%)	0	0.610
No	197 (98%)	185 (97.9%)	12 (100%)	
Other (%)				
Yes	49 (24.4%)	44 (23.3%)	5 (41.7%)	0.150
No	152 (75.6%)	145 (76.7%)	7 (58.3%)	

FM: fibromyalgia syndrome; NSAIDs: non-steroidal anti-inflammatory drugs.
*Significance of the between-group difference (chi-square or Mann-Whitney U-test), bold indicates $p<0.05$.

Table III. Characteristics of the underlying shoulder disease in the study population.

	Overall	Negative FM criteria	Positive FM criteria	*p*-value*
Traumatic aetiology (%)				
Yes	63 (31.5%)	61 (32.3%)	2 (18.2%)	0.327
No	137 (68.5%)	128 (67.7%)	9 (81.8%)	
Main diagnosis (%)				
Instability	13 (6.5%)	13 (6.9%)	0	
Arthrosis	16 (8.0%)	15 (7.9%)	1 (9.1%)	
Rotator cuff tear	78 (39.0%)	74 (39.2%)	4 (36.4%)	0.832
Adhesive capsulitis	35 (17.5%)	32 (16.9%)	3 (27.3%)	
Calcific tendinopathy	25 (12.5%)	23 (12.2%)	2 (18.2%)	
Other	33 (16.5%)	32 (16.9%)	1 (9.1%)	
Conservative treatment (%)				
Yes	117 (59.7%)	110 (59.5%)	7 (63.6%)	0.783
No	79 (40.3%)	75 (40.5%)	4 (36.4%)	
Type of conservative treatment (%)				
No conservative treatment	81 (41.3%)	77 (41.6%)	4 (36.4%)	
Physiotherapy	30 (15.3%)	28 (5.1%)	2 (18.2%)	
Injection of collagen	5 (2.6%)	5 (2.7%)	0	
Injection of corticosteroids	42 (21.4%)	39 (21.1%)	3 (27.3%)	
Injection of hyaluronic acid	7 (3.6)	7 (3.8%)	0	0.929
Oral corticosteroids	5 (2.6%)	5 (2.7%)	0	
US-PICT	17 (8.7%)	15 (8.1%)	2 (18.2%)	
Anti-inflammatory	3 (1.5%)	3 (1.6%)	0	
Other	6 (3.1%)	6 (3.2%)	0	
Indication for surgery (%)				
Yes	73 (37.2%)	69 (37.3%)	4 (36.4%)	0.950
No	123 (62.8%)	116 (62.7%)	7 (63.6%)	
Type of surgery (%)				
No surgery	123 (62.8%)	116 (62.7%)	7 (63.6%)	
Arthroscopy	56 (28.6%)	53 (28.6%)	3 (27.3%)	0.994
Open	17 (8.7%)	16 (8.6%)	1 (9.1%)	

FM: fibromyalgia syndrome; US-PICT: ultrasound-guided percutaneous irrigation of calcific tendinopathy.
*Significance of the between-group difference (chi-square or Mann-Whitney U-test), bold indicates $p<0.05$

tivity (Table I). In Table II we report the medication taken by patients for shoulder pain. There was a statistically significant difference between drug use and FM criteria positivity (91.7% in patients with criteria *vs*. 62.4% in patients without criteria, $p=0.041$). In particular, patients with fulfilling criteria had a higher percentage of non-steroidal anti-inflammatory drugs (NSAIDs) use (75%) than patients not fulfilling diagnostic criteria (46%, $p=0.051$). There were no differences in the type of primary diagnosis, the indication for conservative treatment, and the surgical indication between the two groups. The traumatic origin of the painful symptoms did not appear to be associated with belonging to either group (Table III).

The mean (SD) WPI score was 3.3±2.7 (min-max 0–19) in the whole study population, while the mean (SD) SSS score was 2.6±2.4 (min-max 0-10), and the mean (SD) FSS score was 5.9±4.2 (min-max 0–25). Patients with positive criteria had a mean (SD) WPI score of 10.3±3.9, a mean (SD) SSS score of 6.5±1.9 and a mean (SD) FSS of 16.8±3.8. Patients fulfilling criteria for FM had a mean FIQR of 57.3±16.9 (range 21.7–81.5) (Table IV).

Discussion

We found that FM is more frequent than expected in a cohort of patients referring to an orthopaedic shoulder surgeon, with a prevalence rate (6%) more than double that of the general population. Salaffi *et al*. reported a FM prevalence of around 2% in the general population in the MAPPING study published in 2005 (7). Although this study employed the 1990 classification criteria of the American College of Rheumatology (ACR), Häuser *et al*. reported a 3.4% prevalence of FM syndrome in the German general population by using the 2016 classification criteria (20). Indeed, although the prevalence of FM in the general population may vary in the different nations and based on the different classification criteria employed, a systematic review of 26 epidemiological studies carried out in different nations reported an overall prevalence of 2.7% (21). Therefore, the present study shows that the painful shoulder population has around double the prevalence of FM than the general population. On the other hand, these observations are confirmed by Blonna *et al*., who reported that the shoulder is one of the most frequently affected sites in patients with FM and pain

Table IV. Fibromyalgia syndrome scores.

	Overall	Negative FMS criteria	Positive FMS criteria	*p*-value*
FSS score				
Mean ± SD	5.9 ± 4.2	5.2 ± 3.1	16.8 ± 3.7	**<0.001**
WPI score				
Mean ± SD	3.3 ± 2.6	2.8 ± 1.7	10.3 ± 3.9	**<0.001**
SSS score				
Mean ± SD	2.6 ± 2.3	2.3 ± 2.1	6.5 ± 1.8	**<0.001**
FIQ-R				
Mean ± SD	-	-	57.3 ± 16.8	-

FIQ-R: Revised-Fibromyalgia Impact Questionnaire; FSS: Fibromyalgia Survey Score; IQR: interquartile range; SD: standard deviation; WPI: Widespread Pain Index; SSS: symptom severity scale.
*Significance of the between-group difference (chi-square or Mann-Whitney U-test). Bold indicates $p<0.05$.

symptoms may often resemble those reported by patients with shoulder diseases such as adhesive capsulitis (22).

In our study population, the ratio between the number of females compared to the number of males was 11:1; this result confirms what is already available in the literature about the higher prevalence of FM syndrome in the female sex, although this ratio is more than three times higher than the one reported in the literature in the general population (21). However, due to the small number of patients fulfilling the FM syndrome criteria it is difficult to interpret the data properly.

Finally, patients who tested positive for FM syndrome criteria were in their 60s, in line with previous reports (23).

Another relevant aspect of this study is the correlation between FM and the presence of other rheumatological diseases. Our data confirm the already available literature on this topic (5). Many authors demonstrated a higher prevalence of FM in patients suffering from rheumatological conditions such as rheumatoid arthritis, spondyloarthritis, or psoriatic arthritis. The concomitant presence of FM could lead to problems in the management of these conditions. For example, the persistence of arthralgia despite adequate treatment may be attributed to a lack of efficacy of a drug, whereas it may be due to the concomitant presence of FM syndrome, often underdiagnosed (12, 24). Patients who fulfilled the FM syndrome criteria had a greater tendency to use painkillers. In particular, 3 out of 4 patients with FM syndrome criteria reported using NSAIDs. However, the EULAR guidelines do not recommend the use of NSAIDs for the management of FM syndrome.

Therefore, this finding highlights how a misdiagnose of FM syndrome leads to inadequate pharmacological management not compliant with proper guidelines, leading to the use of drugs that do not have a proven efficacy on the disease while exposing the patient to undesirable effects (25). In addition, FM is often overlooked during preoperative assessment, with a high risk of misdiagnosis of this disease, which often coexists in patients with other pathological conditions such as cuff tears or osteoarthritis (26, 27). Consequently, medical or surgical options are often performed with unsatisfactory results, considering that several studies found that FM patients may require different postoperative pain management. In particular, there is evidence of a higher opioid consumption in these patients undergoing lower-extremity joint replacement or hysterectomy (28-30).

The main limitation of this study is the inclusion of patients with different shoulder diseases, such as adhesive capsulitis or glenohumeral osteoarthritis. In future studies, the inclusion of patients with a specific diagnosis could lead to more accurate information on the impact of FM in patients with shoulder pain. In addition, the evaluation of central sensitisation should be included in future studies as it can be part of a shoulder pain syndrome even in the absence of FM (31). Another limitation of this study is the lack of data on the influence of FM on the outcomes of shoulder surgery. The authors are planning to analyse this impact in an ongoing study in order to gain insights to inform personalised management to achieve satisfactory post-surgical outcomes.

In conclusion, FM syndrome is a common disease in patients that refer to orthopaedic outpatient clinics due to shoulder pain, with a prevalence rate double than that of the general population.

This syndrome could be underestimated in clinical practice, leading to ineffective treatments and inappropriate surgical indications or worse post-surgical outcomes. Orthopaedic surgeons should take into consideration the high prevalence of FM syndrome in the clinical setting and reckon its influence on symptoms related to capsular or ligament diseases in the decision-making process.

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