

Sociodemographic factors in fibromyalgia: results from the Italian Fibromyalgia Registry

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Abstract Objective

Fibromyalgia (FM) is a chronic musculoskeletal pain syndrome of unknown aetiopathogenesis. Its development and maintenance are related to the interplay of biological, psychological, and contextual factors. Among the contextual factors, sociodemographic aspects are poorly elucidated. This study aimed to evaluate the relationships between sociodemographic/clinical factors and symptom severity measures using a web-based registry of patients with FM.

Methods

Adult patients with an ACR 2010/2011 diagnosis of FM underwent a clinical evaluation and were asked to complete questionnaires covering their sociodemographic data (gender, age, marital status, educational level), and disease-specific measures (the revised Fibromyalgia Impact Questionnaire (FIQR), and the Polysymptomatic Distress Scale (PDS)).

Results

Data relating to 3,221 patients (3001 women and 220 men) was collected. The ANOVA showed significant difference in mean FIQR scores when the five marital conditions (cohabiter, married, separated/divorced, single, widowed) were compared ($F 3.321, p < 0.01$). While males and females were found to have comparable FIQR scores, the interaction between gender and marital status indicated that separated/divorced males have higher FIQR scores ($F 5.684, p = 0.001$). The multiple regression analysis demonstrated that patients who reported lower educational level experienced more severe FM symptoms, as scored with FIQR ($p < 0.0001$).

Conclusion

Our results indicated that being male and separated/divorced is associated to higher severity of FM symptoms, as rated with FIQR. Furthermore, a relationship between educational level and FIQR scores has been detected. This study supports the importance of collecting simple SES measures to identify environmental risk factors for FM severity.

Key words

fibromyalgia, gender, sociodemographic factors

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Introduction

Fibromyalgia (FM) is a chronic syndrome characterised by a broad pattern of symptoms that heavily impact patients' daily lives and wellbeing. The core features are musculoskeletal pain, fatigue, and impaired sleep, often associated with cognitive and psychological disturbances (1). The aetiopathogenesis of FM is still unclear, but research suggests the involvement of the so-called central sensitisation, an amplification of neuronal signal within the central nervous system that leads to an enhanced perception of pain (2).

The development of FM is related to the complex interplay of biological, psychological, and contextual factors, all contributing to a different extent to the onset, maintenance, and exacerbation of symptoms, as well as to the treatment response in the single patient (3, 4).

In the last decades, our view of disease causation has broadened, to include socioeconomic status (SES) among the contextual factors involved in the development and outcome of several medical conditions. For example, low SES has been consistently associated with increased rates of cardiovascular diseases (5, 6), and stroke (7), more strongly in women than in men.

SES, usually measured at the individual level by determining educational background, occupation, family members and living areas, has been reported to influence development, clinical presentation and outcome of pain-related syndromes, such as chronic widespread pain (CWP) and arthritis. In earlier studies, low education and low socioeconomic status have been linked to new onset CWP, higher pain frequency and perception of disability due to pain (8, 9). Among the different explanations proposed for this association, research has supported job overcommitment and physical demand (10), high "job strain" (high demand/low control) and effort-reward imbalance at work (11) or mediation through psycho-social factors and poor mental health status (9, 12). Similarly, SES-related aspects, such as educational background (13-15), personal income (16), and occupation (17) influence the rheumatoid arthritis (RA) risk and disease activity (18).

The role of SES in RA was confirmed using an alternative housing-based measure of SES (summed z-score for housing value, square footage and number of bedrooms and bathrooms). This novel measure further supports the association of lower SES with both the risk of developing RA and higher mortality rate after RA (19).

Socio-demographic factors have also an impact on the effectiveness of pain syndromes treatment. De Rooij showed that male gender and higher level of education are associated with the success of multidisciplinary treatments in patients with CWP (20), in addition to less anxiety, pain, fatigue, and stronger beliefs in personal control. In patients with FM, higher education is one of the main independent variables that predicted an improvement in a variety of measures after a treatment programme (21).

Despite the number of studies supporting the influence of socio-demographic factors on the development and outcome of several pain-related diseases, only few of them have focused so far on patients with FM. For this reason, it seems worthwhile to evaluate the relationship of socio-demographic factors with the severity of symptoms using data from a web-based registry of a large multicentre cohort of patients with FM.

Materials and methods

Subjects

The study included adult patients recruited between November 2018 and April 2019 at 19 Italian rheumatology centres. All the patients underwent a complete physical examination and those laboratory tests specified in the revised European League Against Rheumatism (EULAR) recommendations for the management of FM (22).

The inclusion criteria were: a) age from 18 to 80 years; b) diagnosis of FM based on the 2010/2011 criteria of the American College of Rheumatology (ACR) (23), made by a rheumatologist with at least 10 years of experience. The exclusion criteria were: a) cardiovascular disease; b) moderate/severe chronic lung disease; c) uncontrolled hypertension; d) uncontrolled thyroid disorders;

Competing interests: none declared.

e) orthopaedic or musculoskeletal conditions prohibiting moderately intense exercise; f) inflammatory rheumatic conditions or other connective tissue diseases; and g) significant psychiatric conditions that would interfere with the assessment of FM, including severe depression and psychosis.

Ethical approval

All the participants gave their written informed consent to the study. The protocol and the patient information sheet and consent form were approved by the Ethics Committee of the Università Politecnica delle Marche, Ancona, Italy (Comitato Unico Regionale, ASUR Marche, no. 1970/AV2), and the review boards of all the study centres. The study protocol did not require any medical intervention.

Measurements

All patients were asked to complete a package of questionnaires about their sociodemographic data (age, sex, marital status, education and BMI), disease-related variables, their quality of life, and the type(s) of pharmacological and non-pharmacological treatments currently received.

The data and measures were electronically entered into the web-based Italian Fibromyalgia Registry (IFR) by physicians working at those 19 Italian rheumatology centres.

Two disease-specific questionnaires were used for the clinical evaluation in this study: the Revised Fibromyalgia Impact Questionnaire (FIQR) and the Polysymptomatic Distress Scale (PDS).

Revised Fibromyalgia Impact Questionnaire (FIQR)

The FIQR is the updated version of the Fibromyalgia Impact Questionnaire (FIQ) (24). It consists of 21 items, 11-point numerical rating scales (0-10) that investigate three main domains in relation to the previous week: FM symptoms (10 items), physical function (9 items), and overall impact (2 items). The final score may range from 0 to 100 (higher scores indicate more severe disease) and is calculated as the algebraic sum of the symptom domain divided by two, plus the physical func-

Table I. Clinical characteristics of the sample, divided by gender.

	Females (n=3001)		Males (n=220)	
	Mean	SD	Mean	SD
Age	53.17	11.52	50.69	12.07
FIQR overall	11.50	5.95	9.84	6.13
FIQR function	16.76	7.53	12.40	8.01
FIQR symptoms	32.07	10.88	27.59	11.72
FIQR total	60.28	22.61	49.84	23.53
PDS	19.08	7.10	16.57	7.28
SSS	7.85	3.29	6.78	3.37
WPI	11.23	4.86	9.79	5.02

Table II. Mean and standard error of FIQR scores categorised by gender and marital status.

Gender	Marital status	n.	Mean	Std. Error	95% confidence interval
Females	Cohabiter	414	59.0314	1.1110	56.8531 to 61.2097
	Married	1817	61.3016	0.5303	60.2618 to 62.3414
	Separated-Divorced	257	57.3385	1.4101	54.5738 to 60.1033
	Single	444	59.0180	1.0728	56.9146 to 61.1215
	Widowed	69	60.2029	2.7214	54.8671 to 65.5387
Males	Cohabiter	35	51.6000	3.8210	44.1081 to 59.0919
	Married	114	46.0614	2.1172	41.9102 to 50.2126
	Separated-Divorced	11	70.4545	6.8158	57.0908 to 83.8183
	Single	58	51.0345	2.9682	45.2146 to 56.8543
	Widowed	2	87.0000	15.9845	55.6592 to 118.3408

tion domain divided by three, plus the two items of the overall impact domain (25).

Polysymptomatic Distress Scale (PDS)

The PDS is derived from the variables used in the 2010/2011 ACR diagnostic criteria for FM (23). The PDS score is obtained by summing the scores of the widespread pain index (WPI), a 0–19 count of painful non-articular body regions, and the symptom severity scale (SSS), a 0–12 measure of the severity of the three symptoms of fatigue, sleep, and cognitive problems. PDS ranges from 0 to 31, with higher scores indicating more severe disease.

Statistical analysis

All the data was entered into a Microsoft Excel data management database, and were analysed using 64-bit MedCalc®, v. 19.0.1.0 (MedCalc Software, Mariakerke, Belgium). The patients were stratified according to their marital status in the following categories: cohabiter, married, separated/divorced, single, widowed. Normal data distribution was verified using the Shapiro-Wilk test.

First, to determine the effects of gender

and marital status on FIQR scores, a two-way analysis of variance (ANOVA) was conducted, with gender and marital status as the factors. Subsequently, Bonferroni post-hoc test was carried out for pairwise comparisons. The resultant *p*-values less than 0.05 were considered statistically significant.

After that, we estimated ordinary least squares (OLS) regression coefficients for the full sample, showing the relationships between age, marital status, education level, BMI, WPI and SSS scores, and FIQR.

Results

The data relating to 3,221 patients (3001 women and 220 men with a mean age of 52.3±10.7 years at the time of enrolment) was entered into the IFR between November 2018 and December 2020. The clinical characteristics of the sample, divided by gender, are shown in Table I.

Mean and standard error of FIQR scores categorised by gender and marital status are shown in Table II.

Since in the majority of cases normality and equal variance criteria were not fulfilled, non-parametric two-way ANOVA test was applied.

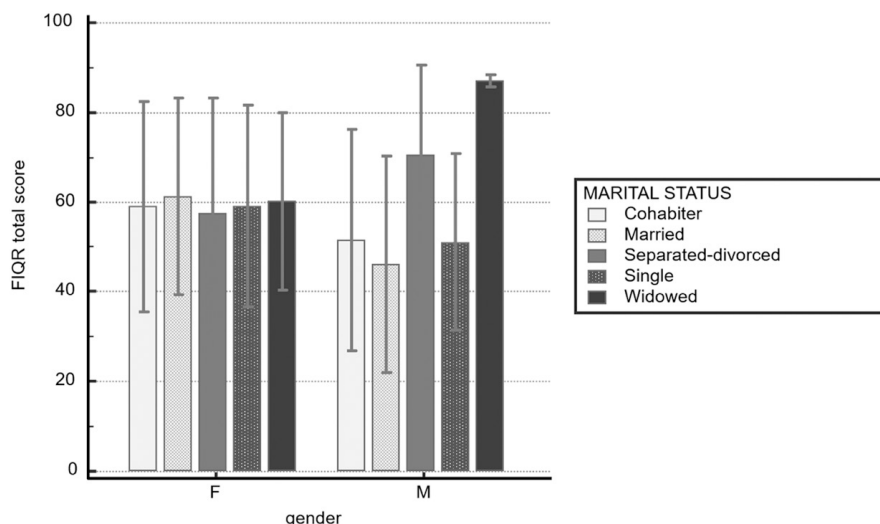


Fig. 1. Interaction between marital status and gender.

Table III. Multiple regression analyses of the association of clinical and socioeconomic markers with FIQR scores.

Independent Variables	coefficient	std. error	t	p	tpartial	tsemipartial
(Constant)	17.0663					
BMI	0.01189	0.01584	0.750	0.4532	0.01323	0.009012
Education	-1.5052	0.3506	-4.294	<0.0001*	-0.07552	0.05158
Marital-status	0.08299	0.2340	0.355	0.7229	0.006255	0.004260
Age	0.05022	0.02488	2.018	0.0436	0.03558	0.02424
SSS	3.7226	0.09618	38.705	<0.0001*	0.5638	0.4649
WPI	1.3193	0.06539	20.177	<0.0001*	0.3353	0.2424

*Statistically significant values.

The ANOVA results showed significant difference in mean FIQR scores when the five marital conditions were compared ($F 3.321, p < 0.01$). By contrast, men and women were found to have comparable FIQR scores ($F 0.251, p = 0.617$). The interaction between the factors was significant ($F 5.684, p = 0.001$) indicating that separated-divorced males have higher FIQR scores (Fig. 1).

The multiple regression analysis demonstrated that the level of education ($p < 0.0001$), SSS scores ($p < 0.0001$), WPI scores ($p < 0.0001$) and age ($p < 0.05$) were significantly associated with FIQR scores. Patients who reported lower educational level experienced more severe FM symptoms, as scored with FIQR. Neither marital status nor BMI were significantly associated with FIQR scores (Table III).

Discussion

Our results indicated that being male and separated/divorced is associated

to higher severity of FM symptoms, as rated with FIQR. This finding agrees with the sex-role theory, developed in the 1970's for mental illness (26), stating that marriage is advantageous for men's mental health but disadvantageous for women. Accordingly, Klose and Jacoby (27) showed that separated, divorced or widowed men have a higher risk of having a mood disorder or a somatoform disorder, including FM, compared to the female counterpart.

Our data does not support an independent effect of gender and marital status on FM symptom severity. This result agrees with a recent study on 668 patients with FM (28) that did not show an association between gender and overall FM symptom severity as indicated by an increased FIQR total score. By contrast Wolfe, in an unselected sample of RA patients studied for the presence of FM, found slightly higher values of pain and symptom severity in women compared to men (29).

Overall, our findings mirror those coming from studies on mental health. A recent prospective cohort survey demonstrated that being single or divorced is associated with depressive symptoms and lower self-esteem quite consistently throughout the 30-year-long study period, especially in men (30). Consistently, a cross sectional general population Canadian surveys supported our finding that the effect of marital status on health differs depending on gender. This study highlighted the role of gender in modifying the association of marital status with the odds ratio for major depression, showing that single, widowed and divorced women, compared to those who are married, are less vulnerable to develop depression than men (31).

The role of marital status per se has been scarcely investigated in patients with FM, and research preferentially focused on the quality of marital relationship. Reich (32) found that in FM patients, in contrast to the osteoarthritis ones, lower partnership satisfaction was related to higher average pain and poorer physical functioning. Additionally, the quality of FM patients' relationship with their spouses was significantly associated with mental quality of life, while no significant association was found with physical quality of life (33). Finally, in FM patients, a poor marital adjustment is associated to suicidal ideation and related variables, such as higher suicidal risk, higher depression, perceived burdensomeness, thwarted belongingness, and sleep disturbance scores, as compared with patients with good marital adjustment or without a partner (34).

Although these studies support the need of considering the level of adjustment or distress in the relationship when assessing the environmental agents of FM, the simple use of marital status may be an informative indicator of the risk of a more severe illness course.

The finding of a relationship between the educational level and the FIQR scores in our population of FM patients adds to the bulk of research supporting the role of formal education in rheumatic disease. Our results agree with those of Kang and colleagues

(35) who showed that FM patients with lower SES, as indexed by unemployment, lower educational levels and income, had more severe symptoms and poorer function compared to those with higher SES. Higher educational level is among the main independent variables that predicted treatment success after a 12-week intervention programme for patients with FM (36). Similarly, more years of education with college or graduate degree, in addition to higher baseline FIQ depression score, lower tender point count, and absent abuse history, were all associated with a positive response to a brief interdisciplinary fibromyalgia treatment programme (21).

A relationship between educational level and disease development/outcome was observed in other pain conditions such as RA and osteoarthritis (OA). An association of formal education with morbidity and mortality in RA was initially observed in a cohort studied from 1973 to 1982. Overall, 79% of grade-school educated, 43% of high-school educated, and 20% of college-educated patients had either died or declined more than 50% in functional capacity (37). Later, a Danish case-control study demonstrated that the level of education was significantly inversely associated with risk of RA, with a 2-fold lower risk of RA among those with the highest level of formal education compared with those having the lowest one (14). Equally, lower educational levels were associated with higher self-reported pain and impaired physical function in clinical (38,39) and community-based samples (40) of individuals with hip OA.

It is thought that formal educational levels provide a composite marker that reflect several psychological, biological and environmental aspects related to competence in self-care, problem solving, access to and use of medical facilities.

In particular, lower educational attainment is associated with higher prevalence of smoking (41), obesity (42), depression (43), sedentary lifestyle (44), and unhealthy diets (45). All these clinical and behavioural aspects were described as contributors to the severity of FM symptoms.

Studies converged to suggest that tobacco use is associated with greater global pain severity and functional difficulties in patients with FM (46-48). Similarly, several investigations showed that being overweight and obese correlated with greater pain sensitivity (49-51). Conversely, other studies did not find, as in our sample, any correlation between BMI and fibromyalgia symptoms severity measures (47).

In patients with FMS the severity of depression was found significantly correlated with FIQ (52) and FIQR (53) scores, and sedentary time (ST) has been associated with pain, worsened physical and social function in a sample of 407 women with FM (54).

Finally, recently growing evidence suggested a potential beneficial impact of nutritional strategies highlighting the centrality of a healthy diet in the treatment of FM. In particular, low-calorie, low fermentable oligo-, di- and monosaccharides, alcohols and polyols (FODMAPs), gluten-free, vegetarian, and Mediterranean diets are associated to a reduction of FM symptoms (55, 56). Formal educational levels are a parameter easy to measure and poorly influenced by diseases with onset in adulthood, unlike other socioeconomic variables such as income and occupation. Our results suggest that it should be a parameter routinely determined in both clinical and research approach to FM.

A number of limitations can be described for this study. Firstly, its cross-sectional design precludes elucidating the direction of the relationships between SES-related measures and the severity of FM symptoms. Secondly, our patients came from tertiary care clinics and our findings may not apply to all patients with FM. Thirdly, the study did not analyse the role of the factors described above that can mediate the relationship between SES-related measures and severity of FM symptoms, such as smoking, unhealthy diet, depression and sedentary lifestyle.

In conclusion, our findings support the routine evaluation of SES-related measures, in particular educational background and marital status as simple indicators of the risk of developing severe FM symptoms.

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