Prevalence of fibromyalgia and associated factors in Spain

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ABSTRACT

Objective. *The prevalence of fibromyalgia (FM) differs depending on the population studied. The main objective of the EPISER2016 study was to estimate the prevalence of FM in adults in Spain. The secondary objective was to evaluate the association with sociodemographic and anthropometric characteristics and smoking.*

Methods. *This is a population-based cross-sectional multicentre study. The random selection was based on multistage stratified cluster sampling. The final sample comprised 4916 persons aged ≥20 years. Participants were contacted by telephone for completion of a screening survey. Investigating rheumatologists evaluated positive results (review of medical records and/or telephone interview, with medical visit if needed) to confirm the diagnosis. Prevalence and 95% confidence interval were calculated, taking into account the sample design. Weighing was applied based on age, sex, and geographic origin. Predictive models were constructed to analyse which sociodemographic, anthropometric and lifestyle variables in the call centre questionnaire were associated with the presence of FM.*

Results. *602 subjects (12.25%) had a positive screening result for FM, of which 24 were missing (3.99%). A total of 141 cases of FM were recorded. The estimated prevalence was 2.45% (95% CI, 2.06-2.90). Female sex was the variable most associated with FM, with an odds ratio (OR) of 10.156 (95% CI, 5.068-20.352). Peak prevalence was at 60-69 years (p=0.009, OR=6.962). FM was 68% more frequent in obese individuals (OR, 1.689; 95% CI, 1.036-2.755).*

Conclusion. *The prevalence of FM in adults in Spain barely changed between 2000 and 2016 and it is similar to that observed in Europe as a whole.*

Introduction

Fibromyalgia (FM) is a syndrome characterised by the presence of chronic pain affecting the musculoskeletal system. The pain can affect several sites, its aetiology is unknown, and it usually occurs alongside with other symptoms, such as fatigue, digestive and kidney-urinary abnormalities, and psychiatric disorders. Its diagnosis has traditionally required diffuse pain not to be associated with other conditions that can cause it and to have been present for more than 3 months. In addition, physical examination must reveal tender points at 11 or more of 18 previously established sites (1, 2, 3).

One of the main approaches to the syndrome was the report on psychogenic rheumatism by Rotés-Querol (4). The 1980s and 90s saw the development of a systematic description and the use of tender points in the physical examination. Various signs and symptoms were also described, the main ones being fatigue, non-reparative sleep, cognitive disorders, headache, depressive symptoms, lower abdominal pain or contractions, pruritus, dry eye, and irritable bowel syndrome (5).

Two key publications addressing the diagnosis of FM were headed by Wolfe *et al.* (1, 6) under the auspices of the American College of Rheumatology (ACR). The classification criteria for FM were published in 1990 and brought together patients who could be classified as having the disease, although they recommended taking into account other signs and symptoms in the clinical history, for example, those related to psychiatric disorders, irritable bowel syndrome, and various types of neuralgia (1). The

patient had to have diffuse chronic pain with demonstration of pain on palpation at ≥11 of 18 points (based on a statistical analysis showing the most common points affected in chronic musculoskeletal pain). New ACR criteria for the classification of FM were published in 2010 (6). The criteria did not require examination of tender points, but stressed the presence of diffuse chronic pain (more than 3 months), by areas. The criteria also established indexes for the severity of symptoms, both in terms of intensity of pain and of the presence of concomitant symptoms.

Generalised or extensive chronic musculoskeletal pain is very prevalent and thought to affect around 10% of the general population, often without fulfilling the criteria for classification of fibromyalgia. The prevalence of FM differs depending on the population studied. It also differs depending on whether the patients studied are from a tertiary hospital and on whether they have comorbid conditions or associated diseases. For example, the prevalence is higher in patients with systemic lupus erythematosus (SLE) or rheumatoid arthritis (RA) than in the general population. Studies carried out in the general population have revealed a prevalence of 2% in North America and 2.37% in Spain (estimated in the previous EPISER study, in 2000), with clearly higher values in women (5-9).

Sociodemographic and lifestyle changes in Spain during the last 16 years may have had an influence on the prevalence of FM. These changes involve an increase in the percentage of people aged >64 years (10), increase in the frequency of obesity and overweight (11, 12), and changes associated with smoking (lower values for men in all age groups, decreases in women aged 15–34 years and increases in those aged 35–64 years) (13).

The main objective of the present study was to estimate the prevalence of FM in adults in Spain. The secondary objective was to evaluate the association with sociodemographic, anthropometric and lifestyle characteristics.

Methods

The present study is part of the EPISER2016 study, promoted by the Spanish Society of Rheumatology to estimate the prevalence of selected rheumatic diseases, whose methodology and sample characteristics have been described elsewhere (14, 15). Briefly, it was a population-based cross-sectional multicentre study. Assuming a Poisson distribution, we estimated that a sample of 4000 subjects would enable us to obtain a 95% confidence interval of 0.30–0.77 for a prevalence of 0.5% (expected prevalence of RA) and 0.14–0.54 for a prevalence of 0.3% (expected prevalence of psoriatic arthritis [PsA]). Given estimated missing values of 20%, it would be necessary to include a sample of 5000 persons.

Random selection was based on multistage stratified cluster sampling. The participants in each selected municipality were contacted by telephone for completion of a survey to screen for the study diseases. The random selection of telephone numbers in each municipality and the screening interviews were both performed by an external social research company (Ipsos España) with a call center and experience in the field of health.

The final sample comprised 4916 persons aged ≥20 years living in 78 municipalities in all the autonomous communities in Spain. Given the sample size reached and the limited magnitude of the differences with the general population for the characteristics analysed, the sample obtained could be considered representative of the general population aged ≥20 years in Spain for estimation of the prevalence of rheumatic diseases (15).

Screening followed 2 complementary pathways. On the one hand, participants were asked if they had already been diagnosed with fibromyalgia; on the other, screening was based on symptoms (Fig. 1).

If the participant reported having been diagnosed with any of the study diseases, he/she was asked to give his/her consent for the investigating rheumatologists at the local reference hospital to confirm the diagnosis based on the review of the clinical history. Participants who reported not having been diagnosed but who had a positive result in symptom-based screening received a second telephone call from the investigating rheumatologist to evaluate the suspicion by means of a second questionnaire (Fig. 2). Participants for whom the suspicion remained after the second telephone call were given an appointment at their reference hospital to complete the diagnostic confirmation process (physical examination and additional tests) according to the ACR 1990 criteria for classification of FM (criteria used in EPISER2000) (Supplementary material) (1, 5).

These criteria were applied to confirm cases that had not been diagnosed before the study. In the case of previously diagnosed participants, there was no request to actively verify that they fulfilled the criteria according to their clinical history. Clearly identified diagnoses were accepted, regardless of the criteria used.

Cases where the subject completed the interview from the call center with a positive screening result for FM and the rheumatologist could not confirm or rule out the diagnosis were considered missing.

We requested oral informed consent from all participants during the first telephone call. We also requested written informed consent from all those participants who came to the participating centres to undergo the physical examination and additional tests. The study was approved by the Research Ethics Committee (REC) of Hospital Universitario de Canarias, which acted as the reference REC, and by the RECs of those participating centres who wished to approve the study locally.

Statistical analysis

Prevalence and 95% confidence interval were calculated taking into account the sample design; weights were calculated depending on the probability of selection at each of the sampling stages, taking as a reference the distribution of the Spanish population according to data from the census of the Spanish National Statistical Institute. Weighing was applied based on age, sex, and geographic origin (3 areas were established: North [Galicia + Asturias + Cantabria + Basque Country + Navarra

Do you feel pain over most of your body? ❑ Yes ❑ No
If the answer to this question is "Yes":

1. Have you had the pain for at least 3 months? ❑ Yes ❑ No
If the answer to question 2 is "Yes":

2. Is it painful because of an accident or injury? ❑ Yes ❑ No

The result is considered to be positive if the patient reports pain affecting most of the body for at least 3 months and the pain is not associated with an accident or injury.

Fig. 1. Call centre questionnaire to screen for symptoms of fibromyalgia.

1. According to the questionnaire administered on (*date of the interview from the call centre*), you have felt pain affecting most of your body for at least 3 months. Is this the case? ❑ Yes ❑ No

If the answer to question 1 is "Yes", continue with:

2. Do you feel pain in your shoulders, arms, or hands? ❑ Yes ❑ No

3. On which side? ❑ Right ❑ Left ❑ Both

4. Do you feel pain in your hips, legs, or feet? ❑ Yes ❑ No

5. On which side? ❑ Right ❑ Left ❑ Both

6. Do you feel pain in your neck, chest, or back? ❑ Yes ❑ No

7. What score would you give to your pain on a scale of 0 to 10, where 0 is no pain and 10 the worst pain imaginable?
0 1 2 3 4 5 6 7 8 9 10

8. Does it hurt because of an accident or injury? ❑ Yes ❑ No

Taking into account the previous answers:

9. Result of fibromyalgia screening[1] ❑ Positive ❑ Negative

10. Do you still suspect fibromyalgia? ❑ Yes ❑ No

11. Reason for not suspecting fibromyalgia (state whether you no longer suspect fibromyalgia in the case of a positive screening result according to the criteria of the scientific committee):
[1]In accordance with the criteria of the Scientific Committee, the suspicion will be maintained if the patient reports having generalised pain (on the right and left side of the body + pain above and below the waist + pain in the axial skeleton) for at least 3 months with an intensity greater than 1 on a scale of 0 (no pain) to 10 (worst pain imaginable) that is not the result of an accident or injury.

Fig. 2. Telephone questionnaire to assess the suspicion of fibromyalgia by the rheumatologist.

+ La Rioja], Mediterranean and Canary Islands [Catalonia + Comunidad Valenciana + Balearic Islands + Murcia + Andalusia + Canary Islands], and Centre [Comunidad de Madrid + Castilla y León + Aragón + Castilla-La Mancha + Extremadura]).

Finally, predictive models were constructed to analyse which sociodemographic, anthropometric and lifestyle variables in the call center questionnaire were associated with the presence of FM. First, a bivariate analysis of the association between the disease and each of the variables was performed. Then, multivariate logistic regression models were constructed based on variables with a p-value <0.2 in the bivariate analysis (age and sex were included in the model, regardless of the p-value in the bivariate analysis). Statistical significance was set at $p<0.05$.

The analyses were performed using IBM SPSS Statistics v. 22.

Results

The final sample comprised 4916 persons. After the interview from the call centre, 602 subjects (12.25% of interviewees) had a positive screening result for FM, of which 24 were missing (3.99%).

A total of 141 cases of FM were recorded; of these, 95 cases (67.38%) had already been diagnosed before EPISER2016. The diagnostic criteria were not available in 24 cases.

The estimated prevalence was 2.45% (95% CI, 2.06–2.90). As for distribution by sex, prevalence was 4.49% in women (95% CI, 3.76–5.35) and 0.29% in men (95% CI, 0.14–0.60).

Of the 578 patients with a positive screening result who completed the study, 140 had fibromyalgia. The positive predictive value of the screening for FM by the call center was 24.22%. The remaining case was evaluated by the investigating rheumatologist at the local centre after positive screening for another of the study diseases (screening was positive for all the diseases except FM, RA, and PsA, although only FM was eventually confirmed).

The negative predictive value (NPV) for FM of the entire call center questionnaire was 99.52%, that is, 1 case from 209 subjects who participated in the NPV assessment. These participants were selected at random from among subjects with a negative result in the screening for all the diseases studied in EPISER2016. The patient had been diagnosed before EPISER2016 and reported having given a false answer in the initial screening questionnaire.

Table I shows the results of the bivariate analysis of the association between sociodemographic variables, physical characteristics, and lifestyle variables included in the call centre questionnaire and the presence of FM. Table II shows the results of the multivariate analysis.

Age, female sex, educational level ($p<0.001$), and body mass index ($p=0.036$) were significantly associated with the presence of FM.

The multivariate analysis showed that female sex was the variable most associated with fibromyalgia, with an odds ratio (OR) of 10.156 (95% CI, 5.068–20.352). As for age, peak prevalence was at 60-69 years ($p=0.009$, OR=6.962). FM was 68% more frequent in obese individuals than in those with a normal body mass index (OR, 1.689; 95% CI, 1.036-2.755).

Living in a rural setting was not associated with FM (p=0.389). The positive association between the area of Spain and FM (p=0.027) observed in the bivariate analysis was not confirmed in the multivariate analysis, although an association close to statistical significance was observed, with lower frequency in the center of the country. Smoking was not significantly associated with FM.

Discussion

In the present study, we found the prevalence of FM in adults in Spain to be 2.45% (95% CI, 2.06–2.90%). Of note, a considerable percentage of the cases detected (32.62%) had not been diagnosed before the study.

The prevalence of FM in EPISER2016 is consistent with that reported in EPISER2000 (2.37%) and in a recent meta-analysis of 65 studies covering a total of 3,609,810 persons, in which the prevalence of FM in the general population worldwide was 1.78% (7, 16). While prevalence was greater in Europe (2.64%) than in America (2.41%) or Japan and Korea (1.62%), the confidence interval did not reveal statistically significant differences between the different regions of the world. Of note, as in EPISER2016, most studies included in the meta-analysis used the criteria of the ACR to define cases of FM, with estimated prevalence values similar to those of EPISER2016.

Female sex was the variable most associated with FM. The prevalence was 4.49% in women compared with 0.29% in men. These data are very similar to those reported in EPISER2000 (4.2% in women and 0.2% in men) (7).

As for the age, peak prevalence was found at 60–69 years, which was almost 7 times greater than that observed at 20–29 years. In EPISER2000, the highest prevalence was found for persons aged 40-49 years; this group continued to have a high frequency of FM in EPISER2016 (OR, 4.925; 95% CI, 1.159–20.922%) (7).

The association between educational level and FM is clear, with a higher prevalence among persons with the lowest educational level. This observation is consistent with data from other

Table I. Association between the presence of fibromyalgia and sociodemographic, anthropometric and lifestyle variables. Bivariate analysis.

Variable	FM cases	Subjects without FM	p-value
Age			<0.001
20-29	1.4%	13.0%	
30-39	5.0%	19.9%	
40-49	23.4%	21.4%	
50-59	23.4%	16.8%	
60-69	30.5%	13.4%	
70-79	11.3%	9.3%	
80-	5.0%	6.1%	
Sex, female	93.6%	53.2%	<0.001
Area of Spain			0.027
North	27.7%	28.8%	
Mediterranean and Canary Islands	51.8%	41.6%	
Centre	20.6%	29.6%	
Educational level			<0.001
Basic	63.8%	36.4%	
Intermediate	16.3%	26.4%	
Higher	19.9%	37.2%	
Body mass index			0.019
Normal weight (18.5 ≤BMI <25)	35.6%	44.8%	
Underweight	0%	1.2%	
Overweight (25 ≤ BMI < 30)	41.7%	39.5%	
Obesity (BMI ≥30)	22.7%	14.5%	
Smoking			0.080
Never smoker	53.9%	48.9%	
Former smoker	21.3%	27.0%	
Smoker	24.8%	24.1%	
Birth abroad	6.4%	7.0%	0.781
Residence in an urban municipality	74.5%	77.5%	0.389

FM: fibromialgia.

Table II. Variables associated with the presence of fibromyalgia. Multivariate analysis.

Variables		p-value	OR	95% CI	
				Lower	Upper
Age, yrs	20-29[1]				
	30-39	0.518	1.686	0.346	8.224
	40-49	0.031	4.925	1.159	20.922
	50-59	0.050	4.299	0.999	18.489
	60-69	0.009	6.962	1.614	30.035
	70-79	0.163	2.985	0.641	13.888
	≥ 80	0.183	3.071	0.589	16.017
Sex	Female	<0.001	10.156	5.068	20.352
Area of Spain	North[1]				
	Mediterranean (+ Canary Islands)	0.484	1.160	0.765	1.760
	Centre	0.086	0.643	0.388	1.065
BMI	Normal weight[1]				
	Overweight	0.096	1.420	0.940	2.144
	Obesity	0.036	1.689	1.036	2.755
Educational level	Basic[1]				
	Intermediate	0.001	0.436	0.262	0.725
	Higher	0.003	0.484	0.300	0.782
Smoking	Never smoker[1]				
	Prior smoker	0.713	0.917	0.578	1.455
	Smoker	0.138	1.408	0.896	2.214

BMI: body mass index.
[1]Reference category.

Table III. Prevalence of fibromyalgia in most relevant studies.

ID	First Author	Publication Year	Age	Sample size	Prevalence	Criteria and tools of diagnosis	Region
1	Mas AJ	2008	-	2192	2.37	ACR	Europe
2	Topbas	2005	-	1930	3.60	ACR	Europe
3	Rusu	2015	-	59101	1.50	Questionnaire self-made	America
4	Wolfe	2013	50.20	2445	2.10	ACR	Europe
5	Walit	2015	46.60	8446	1.75	ACR	America
6	Vincent	2013	55.70	1115	1.13	ACR	America
7	Kim	2012	-	1077	1.70	ACR	Asia
8	Toda	2009	-	539	1.48	ACR	Asia

studies, in which the prevalence of FM increased as educational level decreased. A similar association has been observed with socioeconomic status, namely, the lower a person's income is, the greater the prevalence of FM (17-19). In EPISER2000, the association with educational level was not confirmed in the multivariate analysis (7).

The positive association between obesity and FM is consistent with data from other national and European publications, in which a negative association between body mass index and quality of life and a positive association with intensity of pain and fatigue have been found in persons with FM. The main mechanisms proposed to explain this association include low physical activity, sleep disorders, and depression, as well as thyroid dysfunction or disorders of the somatotropic axis (20, 21).

EPISER2016 revealed no associations between FM and living in a rural setting, in contrast with data from EPISER2000, where the prevalence of FM was higher in rural than in urban settings, although the difference was not significant (7). This difference could be accounted for by differences in the geographic distribution of the municipalities studied: the rural municipalities in EPISER2000 were in Aragón, Catalonia and the Balearic Islands; in EPISER2016 they were more widely distributed (Galicia, Castilla y León, Navarra, and Valencia).

In EPISER2016, the area of Spain (variable not studied in EPISER2000) did in fact seem to be associated with FM(p=0.027 in the bivariate analysis), although this was not confirmed in the multivariate analysis. While no statistically significant differences were observed between living in the Centre, Mediterranean (+ Canary Islands), or the North, an association close to statistical significance (p=0.086) was found, with a lower frequency in the center of the country.

While smoking was not statistically significantly associated with the presence of fibromyalgia, the disease was 1.4 times more common in smokers than among people who had never smoked. Even though the difference was not significant, the wide confidence interval (95% CI, 0.896-2.214) leads us to believe that a larger sample would enable significance to be reached. Other studies show an increased prevalence of FM in smokers (20), as well as an association between smoking and symptoms such as more intense pain, greater interference from pain, paresthesia, overall severity, and functional difficulties in patients with FM (23-25).

The main strength of EPISER2016 is that its sample is sufficiently broad and representative of the general population in Spain to enable us to estimate prevalence with acceptable accuracy (15). Furthermore, the percentage of missing values was low, and the NPV of the initial questionnaire was high.

The study is limited by the fact that we do not know the diagnostic criteria used in 24 of the cases diagnosed before EPISER2016. However, we did contact the investigating rheumatologists in these cases in order to confirm that there was no recording error on the case report form and that the diagnosis was correct.

In conclusion, the present study shows that the prevalence of FM in adults in Spain barely changed between 2000 and 2016 and it is similar to that observed in Europe as a whole. FM is more frequent in women, between 60 and 69 years of age, and in persons with a lower educational level. There is also a positive association between FM and obesity. No association was found with smoking. These data confirm those present in the literature.

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