The Spanish version of the 2010 American College of Rheumatology Preliminary Diagnostic Criteria for fibromyalgia: reliability and validity assessment

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ABSTRACT

Objective. *To investigate the reliability and validity of the Spanish version of the 2010 American College of Rheumatology (ACR) Preliminary Diagnostic Criteria for Fibromyalgia (FM) in patients with chronic pain.*

Methods. *The 2010 ACR Preliminary Diagnostic Criteria for FM were adapted to a Spanish version following the guidelines of the Rheumatology Spanish Society Study Group of FM. Based on the 1990 ACR classification criteria for FM, patients with chronic pain were initially divided into two groups: A FM group and another group of non-FM individuals. Patients from the FM group were evaluated by tender points (TP) examination, Fibromyalgia Impact Questionnaire (FIQ), Widespread Pain Index (WPI), and Symptom Severity Scale (SSS). The non-FM (control) group included patients with rheumatoid arthritis (RA) and osteoarthritis (OA). They were evaluated by WPI and SSS.*

Results. *We included 1,169 patients divided into two groups: FM group (n=803; 777 women and 26 men) and non-FM group (n= 366; 147 patients with RA, and 219 with OA). The median value of TP and FIQ in the FM group was 16 and 74, respectively. The preliminary 2010 ACR criteria were met by 665 (82.8%) FM patients and by 112 (30.6%) patients from the non-FM group (p<0.0001). Statistically significant differences in the number of TP (p<0.03), FIQ (p<0.0001), WPI (p<0.0001) and SSS (p<0.0001) were observed when FM patients fulfilling the 2010 ACR criteria were compared with the remaining FM patients who did not fulfill these criteria. Sensitivity of the Spanish version of the 2010 ACR criteria was 85.6% (95%CI: 83.1–88.1), specificity 73.2% (95%CI: 68.4–78), positive predictive value 87.7% (95%CI: 85.3–90.1) and negative predictive value 69.4% (95%CI: 64.5–74.2).*

Conclusion. *Our results indicate that the 2010 ACR Preliminary Diagnostic Criteria for FM may be useful to establish a diagnosis of FM in Spanish individuals with chronic pain.*

Introduction

Fibromyalgia (FM) is a chronic disorder of unknown aetiology characterised by widespread pain, frequently accompanied by fatigue, sleep disturbances, anxiety, and psychological distress. Clinical diagnosis is usually performed following the 1990 classification criteria established by the American College of Rheumatology (ACR). It requires a history of widespread pain for at least 3 months along with tenderness in at least 11 of 18 specific tender points (TP) (1). Widespread pain was defined as axial pain, both left and right sided and with upper and lower segment pain lasting for at least 3 month. Using this definition, the prevalence of FM in Spain is 4.2% in women and 0.2% in men over 20 years (2).

Nonetheless, the 1990 ACR classification is fraught with inconsistencies and controversy. In this regard, the tender point test lies in measuring the pain felt when an equal pressure of 4 kg is applied accurately to a tender point each time and, therefore, in some cases this test may be inconsistent. Moreover, besides widespread pain this syndrome causes many other symptoms that were not considered in the 1990 ACR classification criteria.

The 2010 ACR Preliminary Diagnostic Criteria for FM were designed to improve these shortcomings. This clinical criteria set integrates variations in

symptoms with a severity scale, (3). According to them, a patient is considered to have FM whether the following three conditions are met: 1- Widespread Pain Index (WPI) ≥7, and Symptom Severity Score (SSS) ≥5, or WPI of 3 – 6 and SSS ≥9., 2- the symptoms have been present at a similar level for at least three months, and 3- the patient does not have any disorder that may otherwise explain the pain. Noteworthy, the ACR preliminary criteria 2010 excluded the TP's examination. These criteria have been successfully validated in Japanese individuals. In this regard, the Japanese version of the ACR Preliminary Diagnostic Criteria for FM reached high reliability and validity and it was found to be very useful for assessing FM in Japanese populations with chronic pain (4). It was also the case when they were validated in Iranian patients with chronic pain (5). Moreover, preliminary results indicate that these criteria may be a useful tool to screen for FM in an adolescent population with juvenile FM (6).

The combination of the 1990 ACR criteria and the 2010 modified ACR diagnostic criteria was recommended for FM diagnosis in a Spanish population (7). However, in assessing 100 patients with widespread pain Oncu *et al*. (8) found that the 2010 modified ACR criteria were more sensitive than the 1990 ACR criteria, both at diagnosis and after 1 year of follow-up. A 0-31 Fibromyalgia Symptom Scale, developed by adding the WPI to the modified SSS scale, has recently been proposed to be used in epidemiologic and clinical studies without the need of having an examiner. This scale may also be used to replace the "widespread pain" variable in these studies (9).

Taking together these considerations, we aimed to assess the reliability and validity of the Spanish version of the 2010 ACR Preliminary Diagnostic Criteria for FM in a large series of patients with chronic pain.

Table I. Demographic and clinical characteristics of the group classified as having fibromyalgia (FM) according to the ACR 1990 criteria and the control (non-FM) group of patients with chronic pain (RA and OA).

Group	FM (n=803)	Non-FM (n=366)	
		RA (n=147)	OA (n=219)
Age (years), median (IQR)	52 (45-58)	50 (43-57)	57 (50-64)
Sex (female), n (%)	781 (97.2)	143 (97.2)	214 (97.7)
FIQ, median (IQR)	74 (64-87)	-	-
Tender Points, median (IQR)	16 (14-18)	-	-
FM symptoms (years), median (IQR)	13 (13-22)	-	-
Patients fulfilling the ACR 2010 criteria, n (%)	665 (82.8)	20 (13.6)	91 (41.5)
WPI, median (IQR)	15 (11-18)	5 (4-6)	7 (5-14)
SSS, median (IQR)	8 (6-10)	4 (3-5)	5 (3-8)

ACR: American College of Rheumatology; FIQ: Fibromyalgia Impact Questionnaire; FM: Fibromyalgia; IQR: Interquartile range; n: number; OA: Osteoarthritis; RA: Rheumatoid Arthritis; SSS: Symptom Severity Scale; WPI: Widespread Pain Index.

Table II. Patients diagnosed with FM according to ACR 1990 classification criteria: Comparison between the patients who also fulfilled the 2010 ACR criteria for FM and those who did not meet the ACR 2010 preliminary diagnostic criteria for FM.

Fibromyalgia group*	Fulfilling the ACR 2010 criteria	Not fulfilling the ACR 2010 criteria	*p*-value
FM symptoms (years), median (IQR)	14 (7-22)	7 (5-10)	<0.0001
FIQ, median (IQR)	77 (67-88)	55 (45-65)	<0.0001
Tender Points, median (IQR)	16 (14-18)	16 (14-17)	0.03
WPI, median (IQR)	15 (11-18)	5 (4-8)	<0.0001
SSS, median (IQR)	8 (6-10)	4 (3-5)	<0.0001

ACR: American College of Rheumatology; FIQ: Fibromyalgia Impact Questionnaire; FM: Fibromyalgia; IQR: Interquartile range; SSS: Symptom Severity Scale; WPI: Widespread Pain Index.
*All of them met the 1990 ACR criteria for FM.

Patients and methods

Translation and cultural adaptation process of the 2010 ACR Preliminary Diagnostic Criteria for FM was adjusted to a Spanish version by the Rheumatology Spanish Society Study Group of Fibromyalgia, with the authors' permission (3). Herein, we performed a multicenter study: for this purpose we recruited two groups of patients; firstly, FM patients diagnosed by a Rheumatologist, who met the previously proposed 1990 ACR criteria for FM and did not have severe psychiatric disorders according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) (10). Secondly, as a control group, we assessed patients with diseases associated with chronic pain, such as rheumatoid arthritis (RA) and osteoarthritis (OA), and who had not been diagnosed with FM. RA and OA were diagnosed according to the 2010 RA classification criteria (11) and de ACR criteria for classification and reporting of osteoarthritis of the hand (12), hip (13) and knee (14), respectively. Informed consent was obtained for all the participants and the Ethical Committees approved the study protocol. In FM patients, the number of TP, Fibromyalgia Impact Questionnaire (FIQ) in the Spanish validated version (15), WPI and SSS were evaluated. In RA and OA patients from the control group, WPI and SSS were analysed.

Statistical analysis

Results were expressed as median and interquartile range (IQR) and compared with the Mann-Whitney U-test. Sensitivity, specificity, positive and negative predictive values and the area under the receiver-operating characteristics (ROC) curve (along with 95% confidence intervals- CI) were calculated. A *p*-value <0.05 was considered statistically significant. Analyses were conducted using SPSS15.0.

Results

One thousand and one hundred and sixty-nine patients, divided into the FM group that fulfilled the 1990 ACR criteria (n=803) and the non-FM group of patients with chronic pain (n=366; 147

Table III. Clinimetric properties of the Spanish version of the 2010 ACR preliminary diagnostic criteria for fibromyalgia.

Parameter	Value	95% Confidence intervals
Sensitivity, %	85.6	83.1-88.1
Specificity, %	73.2	68.4-78.0
Positive predictive value, %	87.7	85.3-90.1
Negative predictive value, %	69.4	64.5-74.2
Area under ROC curve	0.79	0.76-0.81

ROC: Receiver Operating Characteristic.

patients with RA, and 219 with OA), were included in the study. Baseline demographic and clinical characteristics of both groups are shown in the Table I. In this regard, the median of TP and FIQ in the FM group were 16 and 74 respectively.

The preliminary 2010 ACR criteria were met by 665 (82.8%) FM patients and by 112 (30.6%) patients from the non-FM group ($p<0.0001$).

As shown in Table II, statistically significant differences in the number of TP ($p<0.03$), FIQ ($p<0.0001$), WPI ($p<0.0001$) and SSS ($p<0.0001$) were observed when FM patients fulfilling the 2010 ACR criteria were compared with the remaining FM patients who did not fulfill the 2010 ACR criteria.

Sensitivity of the Spanish version of the 2010 ACR preliminary diagnostic criteria was 85.6%, specificity 73.2%, positive predictive value 87.7% and negative predictive value 69.4%. These clinimetric properties are shown in the Table III. ROC analysis was performed to compare the FM group with de non-FM group. The area under the curve was 0.79.

Discussion

The present study included the largest series of patients with chronic pain ever assessed for the validation of the 2010 ACR Preliminary Diagnostic Criteria for FM.

The former 1990 ACR FM classification criteria were found to be useful for the diagnosis of this syndrome in patients attending clinics especially focused on FM. On the other hand, the limitation derived from the need of having at least 11 out of 18 TP may lead to a failure to make a diagnosis of FM in some patients with other typical manifestations of this syndrome. Because of that, the search for new diagnostic criteria for FM is of potential interest. With respect to this, the use of WPI, which strongly correlated with TP count, and the SSS to quantify FM symptom severity may represent a practical solution to this problem.

The initial 2010 ACR preliminary diagnostic criteria for FM and the measurement of symptom severity correctly classified 88.1% of cases that also met the 1990 ACR classification criteria (3). Other studies have found similar results, suggesting that the 2010 ACR criteria may be a sensitive tool to classify FM patients (16). In our study, the sensitivity of the Spanish version of the modified 2010 ACR criteria for FM was 85.6%. Therefore, the sensitivity was slightly lower than that found using the 1990 ACR classification criteria (88.4%) and the observed in an initial multicenter study on 829 previously diagnosed FM patients who were assessed by the combination of WPI and SSS (88.1%) (3).

The sensitivity and negative predictive value (69.4%) results of the validation of the 2010 ACR criteria for FM in our series of Spanish patients with chronic pain yielded similar results to those found in the Japanese version of the 2010 ACR preliminary classification criteria (82% and 70%, respectively) (4). However, the specificity (73.2%) and positive predictive value (87.7%) in the Spanish cohort was lower than in the Japanese study (specificity 91% and positive predictive value 95%) (4). In contrast, in an Iranian multicenter prospective study on 168 FM patients and 110 controls that compared the 2010 ACR preliminary criteria for FM with the expert diagnosis as the gold standard test, the authors found greater specificity (92.8%) but lower sensitivity (58.9%) of the 2010 ACR than in our study. We feel that cross-cultural differences in the expression or rating scale of symptoms may explain the different results in terms of sensitivity, specificity and predictive values among different populations. With respect to this, it would be interesting to establish if the modification of the 2010 ACR preliminary criteria proposed by Wolfe *et al.*, that suggested removing 38 of 41 somatic symptoms from the original symptom severity score (9), might minimise such differences. These authors created the Fibromyalgia Symptom Scale adding the WPI to the new SSS (FS). The sensitivity and specificity of a questionnaire based on these modified 2010 ACR (mACR) criteria, using for this purpose a FS cut-off score ≥13, in a cohort of 451 patients with widespread pain were 93.1% and 91.7%, respectively, (17). A Japanese version of these 2010 mACR criteria (18) that was tested in 462 FM patients and 231 controls with RA and or OA yielded a sensitivity of 64%, specificity of 96%, positive predictive value of 97%, and negative predictive value of 56%. However, these results cannot be compared with our data since we did not use the 2010 mACR criteria in our assessment.

There are a number of potential limitations in our study. Firstly, our findings may not be applicable to patients with spondyloarthritis or connective-tissue diseases because these patients were not included in our control group. Secondly, we did not study the performance of these criteria in patients from a primary care setting. Nevertheless, the large series of patients included in our assessment constitutes a major strength of the present study. In addition, our patients were exhaustively studied as they were patients attending rheumatology clinics. A recent study has shown that age, educational level and the impact of FM are explanatory variables of the discrepancies observed between the objective and subjective measures in women with this syndrome (19). Because of that, further studies including primary care patients and individuals from different ethnicities and countries as well as studies focused on specific age and educational level groups are required

to determine cross-cultural and ethnic differences in the expression or rating of FM symptoms.

In conclusion, we have assessed the reliability and validity of Spanish version of the 2010 ACR Preliminary Diagnostic Criteria for FM in a large series of patients with chronic pain. Our results indicate that this set of criteria may be useful to establish the presence of FM in Spanish individuals with chronic pain.

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