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# Is it necessary to strictly diagnose fibromyalgia syndrome in patients with chronic widespread pain?

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**Abstract** The applicability of the American College of Rheumatology (ACR) 1990 and 2010 criteria for the diagnosis of fibromyalgia syndrome (FMS) was determined in 284 patients with chronic widespread pain (CWP) including those with regional and systemic painful disorders. On the basis of initial evaluation, patients were classified into three groups. Group 1, those without any comorbid disease ( $N=105$ ), group 2, those having regional non-inflammatory painful disorders ( $N=104$ ), and group 3, those with a diagnosis of an inflammatory rheumatic disease ( $N=75$ ). Overall, 65 % of the patients fulfilled the 1990 criteria, while 94 % of them fulfilled the 2010 criteria. Almost all of the patients (97 %) with CWP did meet at least one of the criteria set, regardless of whether they have accompanying painful disorders. Widespread pain index (WPI), symptom severity scale (SS), and fibromyalgia impact questionnaire (FIQ) scores were found to be significantly higher in the patients who satisfied the 1990 criteria than those who did not ( $P<0.001$ ). Tender point counts were found to be significantly correlated with WPI, SS, FIQ, and Beck depression inventory (BDI) scores ( $P<0.001$ ). **The findings of the study support the suggestion that FMS is just a continuum of CWP, rather than a distinct diagnostic entity. As treatment of FMS is usually identical with that of CWP, strict diagnosis of FMS will provide little or no significance** from

the viewpoint of clinical practice. We suggest that future research should be directed toward classification of CWP to provide guidance to clinicians in selecting effective therapies.

**Keywords** Fibromyalgia · Pain · Rheumatoid arthritis · Soft tissue rheumatism

## Introduction

Fibromyalgia syndrome (FMS) is a chronic widespread pain (CWP) syndrome, which is associated with a series of somatic and cognitive symptoms such as fatigue, sleep disturbance, anxiety, and depression. CWP is the hallmark of FMS, being the entry point of clinical pathways suggested for FMS [1]. Although CWP has been recognized for centuries, various terms have been used to strictly define chronic pain syndromes, including FMS. However, because of the lack of a specific clinical sign or an objective diagnostic indicator, it has been a challenging disorder to diagnose, and the concept of FMS as a distinct entity has been questioned by many authors.

The American College of Rheumatology (ACR) 1990 classification criteria (1990 criteria) has been the sole diagnostic criteria for FMS until recently [2]. A patient with CWP must have a positive clinical examination for tender point (TP) counts to meet the 1990 ACR criteria for FMS. Although these criteria have made the FMS a discrete disease, use of TPs has drawn a number of criticisms regarding their validity, specificity, and usability in diagnosing FMS [3]. Population-based studies demonstrated linear associations between features of psychological distress and the TP count in patients meeting the 1990 ACR criteria, suggesting that FMS may be the extreme end of a continuum of pain and rather than a discrete entity [4, 5]. More recent studies have shown that the relationship between FMS and distress is not solely due

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to TPs, as CWP alone is somewhat associated with distress [6]. This view was reinforced by more recent research, providing evidence that CWP can be a manifestation of a more general process of somatization [7].

Considering these issues, ACR recently provided symptom-based preliminary diagnostic criteria (2010 criteria) that eliminate the TP criterion, with the aim to simplify the diagnosis of FMS and to recognize the importance of the extent of CWP and associated symptoms in making the diagnosis [8]. Modification of 2010 criteria to be used for surveys without need of physician evaluation was reported in 2011 [9]. By using these new criteria, CWP has been increasingly seen as a spectrum, with FMS representing the most severe manifestation of CWP, rather than a distinct diagnostic entity [1]. On the other hand, this newest definition of FMS has been questioned by some authors as it discounts the only objective finding of the syndrome [10]. Exclusionary regulation of the new criteria has also been criticized by some authors, as the presence of a second clinical disorder that would otherwise explain CWP excludes the diagnosis of FMS [11]. Thus, it is not clear whether these criteria can differentiate an FMS patient from among a broad spectrum of patients with CWP. For example, the association of FMS and rheumatologic disorders may pose diagnostic dilemmas. Moreover, there is no standardized way to determine which disorders would otherwise explain the CWP. Based on these inferences, some authors have claimed that clinical criteria for FMS have little or no significance from the viewpoint of clinical practice and that the ACR 2010 criteria should be revised in order that they would be used for all patients [12].

These ambiguous aspects of the FMS criteria have been the starting point of our study. We aimed to examine fulfillment of both the ACR 1990 and 2010 criteria in patients with CWP, regardless of whether they have an accompanying painful disorder, in order to determine the applicability of these criteria for the diagnosis of FMS in patients with CWP.

## Materials and methods

### Subjects

The patients were selected from March to December 2012, among those admitted to physical medicine and rehabilitation, algology, and rheumatology clinics at a university setting. Patients aged 17–70 years were included if they had CWP regardless of prior patient diagnosis. CWP was defined using the definition of the ACR in their 1990 criteria [2]. According to this definition, the patient must have pain on both sides of the body both above and below the waist including the axial skeleton, and this pain must be present for at least 3 months. The patients were excluded if they had serious cognitive and psychiatric disorders, severe neurological disorders (i.e.,

multiple sclerosis, motor neuron disorders, stroke, spinal cord injury, etc.), uncontrolled endocrine disorders (i.e., hyper-/hypothyroidism and diabetes), cardiopulmonary disorders, malignancy, and severe organ deficiencies. The study was approved by the local Institutional Review Board for the Protection of Human Subjects and a written informed consent from all the patients.

A total of 300 outpatients with CWP were consecutively assessed for eligibility. Because 16 subjects did not meet inclusion–exclusion criteria, a total 284 patients were included into the study.

### Assessments

After the detailed medical histories were taken by a single physician, a targeted exam of the musculoskeletal system, as well as a systemic exam for comorbid diseases, was carried out by the same physician (DA). Laboratory or imaging studies (i.e., complete blood count, biochemical tests, direct radiographies, ultrasound, and magnetic resonance imaging) were performed if clinically indicated. On the basis of this information, patients were classified into three groups: group 1, the patients not having any comorbid disease ( $N=105$ ), group 2, the patients having regional non-inflammatory painful disorders ( $N=104$ ; low back pain in 48, neck pain in 32, osteoarthritis in 28, tendinitis in 26, and multiple regional disorders in 22), and group 3, the patients who had been diagnosed previously as having an inflammatory rheumatic disease ( $N=75$ ; rheumatoid arthritis in 55, systemic lupus erythematosus in 12, and scleroderma in 8).

All patients were evaluated using the ACR 1990 and 2010 criteria for FMS, by a single physician (DA) at the same time. A patient satisfied the 1990 criteria if pain was present with examiner palpation of about 4 kg/cm<sup>2</sup> force on at least 11 of 18 standardized TPs [2]. A diagnosis according to the 2010 ACR criteria was given when the first and second diagnosis criteria were satisfied [8]. All included patients had already satisfied the second criterion, as they had been suffering from widespread pain for 3 months or more. The patients satisfied the first diagnosis criterion, when the widespread pain index (WPI) score which represents a subjective number from the 19 whole-body pain areas is greater than or equal to 7 and the symptom severity (SS) score is greater than or equal to 5 or when the WPI score is from 3 to 6 and the SS score is greater than or equal to 9. The third diagnosis criterion which requires the absence of other incidents or diseases related to the symptoms was only satisfied by the patients in groups 1 and 2 but not by those in group 3.

The patients were also asked to answer the fibromyalgia impact questionnaire (FIQ) [13] to assess the impact of FMS and the Beck depression inventory (BDI) [14] to assess the severity of depression affect.

**Statistics**

Statistical analyses were performed with the 15.0 Statistical Package for the Social Sciences (SPSS). Frequency analysis, cross tabulation, and Pearson chi-square test were performed for comparison of the categorical variables. For continuous variables, normality distribution was first assessed using the one-sample Kolmogorov–Smirnov test to determine the most appropriate statistical method for analyzing across-group comparisons and associations between variables. Normally distributed data were expressed with the mean values and standard deviations and compared using one-way analysis of variance (ANOVA) and multiple comparison procedure (post hoc Tukey test). Data that were not normally distributed were expressed with the median and minimum–maximum values and analyzed using Kruskal–Wallis ANOVA. The mean values of two groups of normally distributed data were compared by independent-samples *t* test. The median values of the data that were not normally distributed were compared with the Mann–Whitney rank-sum test. For measuring the strength of associations between variables, Pearson correlation analysis was used for normally distributed data, and Spearman correlation analysis was used when the data were not normally distributed. *P* value below 0.05 was considered to indicate statistical significance.

**Results**

Demographic variables of the patient groups are seen in Table 1. The patients in group 1 were significantly younger than those in the other two groups (one-way ANOVA, post hoc Tukey; *P*<0.001), but the percentage of males did not differ among the three groups (Pearson chi square test, *P*>0.05).

Table 2 shows the cross tabulation of the fulfillment of 1990 and 2010 criteria in the patients included. Overall, 184 out of 284 patients (65 %) fulfilled the 1990 criteria, while 267 (94 %) fulfilled the 2010 criteria. Of all patients, 92 (32 %) fulfilled only the 2010 criteria, while 9 (3 %) fulfilled only the 1990 criteria. Of the 17 patients who did not meet the 2010 criteria, 9 (53 %) satisfied the 1990 criteria, meaning that 276 patients (97 %) did meet at least one of the criteria set. Of the 184 patients satisfying the 1990 criteria, 175 (95 %) satisfied the 2010 criteria as well. This rate was 93 % for group 1 and

96 % for group 2 and group 3. Among 267 patients satisfying the 2010 criteria, 92 (34 %) did not satisfy the 1990 criteria. This rate was 46 % in group 1, 26 % in group 2, and 29 % in group 3. The percentage of patients that fulfilled the 1990 criteria did differ by the study groups (54 % in group 1, 72 % in group 2, and 69 % in group 3; Pearson chi square test, *P*<0.05). The percentage of participants that fulfilled the 2010 criteria did not show statistically significant difference between the study groups (93 % in group 1 and 94 % in the other groups; Pearson chi square test, *P*>0.05).

We found that only one patient had no TP, and 100 patients (35.2 %) had 1–10 TPs. As seen in Table 3, mean TP counts and WPI scores were significantly lower in group 1, comparing to those in the other groups (one-way ANOVA, post hoc Tukey; *P*<0.001 and *P*<0.05, respectively). There were no statistically significant differences among the three groups regarding the SS scale (Kruskal–Wallis ANOVA, *P*>0.05) and BDI scores (one-way ANOVA, *P*>0.05).

WPI, SS, and FIQ scores were found to be significantly higher in the patients who satisfied the ACR 1990 TP criterion comparing to those who did not (Mann–Whitney rank-sum test for WPI and SS, *P*<0.001, independent-samples *t* test for FIQ, *P*<0.001) (Table 4). Although BDI scores also tended to be higher in patients satisfying the TP criterion than those not satisfying this criterion, the difference did not reach statistical significance (independent-samples *t* test, *P*>0.05).

TP counts were found to be strongly correlated with WPI, SS, BDI, and FIQ scores (Spearman correlation analysis; *R* 0.510, 0.385, 0.198, and 0.374, respectively, *P*<0.001 for all).

**Discussion**

To our knowledge, this is the first study investigating the fulfillment of the old and new diagnostic criteria for FMS in patients presenting with CWP, including those with inflammatory disorders. The main finding of this study is that almost all patients with CWP may be diagnosed as FMS by using the 2010 criteria, regardless of whether they have an accompanying painful disorder or have been diagnosed as FMS based on the 1990 criteria. We also found that as many as 46 % of patients with CWP who have satisfied the 2010 criteria did not satisfy the 1990 criteria. From another point of view, 92 % of the patients with CWP who did not fulfill the 1990 criteria were newly identified by the 2010 criteria. These findings

**Table 1** Demographic variables of the patients included in the study

	Group 1 (n=105)	Group 2 (n=104)	Group 3 (n=75)	Total (n=284)	<i>P</i> value
Age (mean±SD)	37.9±9.7	49.3±10.1	50.7±9.5	45.8±11.4	<0.001
Gender					
Women, <i>n</i> (%)	94 (89.5)	99 (95)	70 (93.3)	263 (92.6)	0.282
Men, <i>n</i> (%)	11 (10.5)	5 (5)	5 (6.7)	21 (7.4)	

**Table 2** Cross tabulation of the fulfillment of the 1990 and 2010 criteria

		2010 criteria		Total	P value
		-	+		
<b>Group 1</b>					
1990 criteria	-	3 (3 %)	45 (43 %)	48 (46 %)	0.023*
	+	4 (4 %)	53 (50 %)	57 (54 %)	
Total		7 (7 %)	98 (93 %)	105 (100 %)	
<b>Group 2</b>					
1990 criteria	-	3 (3 %)	26 (25 %)	29 (28 %)	0.927**
	+	3 (3 %)	72 (69 %)	75 (72 %)	
Total		6 (6 %)	98 (94 %)	104 (100 %)	
<b>Group 3</b>					
1990 criteria	-	2 (3 %)	21 (28 %)	23 (31 %)	0.927**
	+	2 (3 %)	50 (66 %)	52 (69 %)	
Total		4 (6 %)	71 (94 %)	75 (100 %)	
<b>Overall</b>					
1990 criteria	-	8 (3 %)	92 (32 %)	100 (35 %)	0.927**
	+	9 (3 %)	175 (62 %)	184 (65 %)	
Total		17 (6 %)	267 (94 %)	284 (100 %)	

The values in parentheses represent percentage of a whole in each group

\*The percentage of patients that fulfilled the 1990 criteria showed statistically significant difference between the study groups

\*\*The percentage of patients that fulfilled the 2010 criteria did not show statistically significant difference between the study groups

may simply be attributed to the lack of specificity of the 2010 criteria or to the lack of sensitivity of the 1990 criteria. However, as there is no gold standard in diagnosing FMS, fulfillment of 1990 or 2010 criteria does not purport to have FMS and it is difficult to form a correct inference from these findings. On the other hand, these findings may also reflect that most patients with chronic painful disorders complain of additional somatic and psychological symptoms that were assessed in the 2010 criteria; thus, these symptoms are not FMS specific. Then, other questions arise as to whether FMS is just a continuum CWP rather than a distinct diagnostic

entity and whether FMS identified with the new criteria is considerably different from FMS identified with the old criteria.

CWP is the main determinant of FMS. The prevalence of CWP has been reported to be around 10–11 % in the general population [15]. Our understanding of how and why chronic pain develops in the presence of minimal and undetectable tissue damage has been improved during the last decades, and many studies provided evidence for central sensitization as a likely etiology of CWP. FMS shares common pathogenetic mechanisms with other CWP syndromes [16], and much of our understanding of the pathogenesis of CWP has been gained through pieces of research into FMS. Substantial amount of neural plasticity within the nociceptive system and comparable levels of augmented pain processing as seen in FMS patients have been demonstrated even in patients representing with chronic regional pain [17–19]. As FMS and other chronic widespread and regional pain syndromes share common mechanisms, they also share the associated clinical symptoms, such as fatigue, memory difficulties, poor sleep, irritable bowel syndrome, painful bladder, migraine, and tension headache [20, 21]. This clustering of somatic symptoms in the population gives rise to overlapping of chronic pain syndromes, presenting with similar symptomatology [22]. Our study lends powerful support to these observations, as the severity of symptoms assessed in the SS scale was found to be considerably high in our patients regardless of whether they have an accompanying regional or systemic painful disorder. We also found that our patients had moderate level of depression as measured by BDI. It was not a surprising finding since the symptoms of fatigue, trouble in thinking or remembering, awakening tired, abdominal pain, depression, and headache represent depression as much as FMS; in fact, four of the six symptoms are part of the BDI [10]. Moreover, associations between CWP and symptoms of psychological distress have been well documented. Depression is also highly prevalent in patients with rheumatic diseases and has been partly attributed to the levels of pain experienced [23]. Thus, our finding further supports the suggestions that the symptoms assessed in the SS scale are a

**Table 3** Comparison of TP counts and WPI, SS, and BDI scores between the groups

	Group 1	Group 2	Group 3	P value
TP count (mean±SD)	10.6±3.6	12.6±3.4	12.4±3.8	<0.001*
WPI score (mean±SD)	11.0±4.1	12.5±3.8	12.9±3.9	0.02**
SS scale (median–range)	8 (2–12)	9 (2–11)	8 (4–12)	0.437
BDI score (mean±SD)	19.5±10.5	19.4±9.3	19.6±9.8	0.660

TP tender point, WPI widespread pain index, SS symptom severity, BDI Beck depression index

\*post hoc Tukey test: statistically significant difference between group 1 and group 2 ( $P<0.001$ ) and between group 1 and group 3 ( $P=0.003$ )

\*\*post hoc Tukey test: statistically significant difference between group 1 and group 2 ( $P=0.013$ ) and between group 1 and group 3 ( $P=0.004$ )

**Table 4** Comparison of WPI, SS, and FIQ scores between the patients satisfying the TP criterion of ACR 1990 and those who had 0–10 TPs

	TP counts		<i>P</i> value
	0–10 TPs ( <i>N</i> =101)	≥11 TPs ( <i>N</i> =183)	
WPI score, median (range)	9 (3–17)	14 (1–19)	<0.001
SS scale, median (range)	7 (3–11)	9 (2–12)	<0.001
BDI score, mean±SD	18.1±9.8	20.4±9.8	<0.001
FIQ, mean±SD	56.5±17.7	67.9±16.2	0.056

common set of variables in most patients with chronic painful disorders, rather than FMS-specific symptoms [10].

In our study, the rate of fulfillment of the 1990 criteria in the patients with CWP without any known comorbidity (54 %) appears to be higher than the previous population-based study [24]. This difference may be contributed to the different criteria used to define CWP in this study. We also found that the 2010 criteria correctly classified 93 % of cases classified by the 1990 criteria in this subgroup of patients. This rate was also slightly higher than the 88 % rate reported by previous studies [8]. The finding that as many as 46 % of patients satisfying the 2010 criteria did not satisfy the 1990 criteria was an important one. This rate seems to be higher than the other comparison studies [8, 25]. This difference should be attributed to the differences in the study population. Previous studies comparing both criteria were carried out on “clinically diagnosed” patients, while we assessed the patients who had CWP. This may also be associated with the health-care-seeking behavior of the patients, as psychological and psychiatric comorbidities have been shown to be higher in the studies that originated from tertiary care centers [26]. We were unable to compare the fulfillment rates of both criteria in our patients with concomitant painful disorders with the previous studies, as—to our knowledge—no study has investigated these rates so far. However, the rates of fulfillment of the 1990 criteria were even higher in our patients with concomitant painful disorders, while the rate of fulfillment of the 2010 criteria was similar. This finding suggests the significance of the number of TPs in assessing patients with CWP. This issue has been controversial since it was introduced [3]. TPs have been considered to represent the areas of increased nociceptor activation, leading to symptoms of hyperalgesia or allodynia. However, they have been suggested to be interpreted as representing a measure of general distress, rather than part of the classification criteria [4, 5]. In accordance with the previous studies, we found that TP counts were significantly correlated with the WPI and SS scale as well as with BDI scores and that WPI, SS, and FIQ scores were significantly higher in the patients who had satisfied the TP criterion of the ACR 1990 comparing to those who had not. These findings lend a powerful support to the suggestion that the patients satisfying the 1990 criteria are those who are at the upper end of a continuum of CWP, characterized by increased pain

sensitivity and high levels of distress [4, 5]. However, the cutoff value at which TPs and symptoms of CWP occur concurrently would be difficult to define. This concern has been raised repeatedly [3–7]. Indeed, 27 of our patients had 10 TPs, thus did not satisfy the TP requirement for the 1990 criteria. Of these patients, 23 satisfied the 2010 criteria. On the other hand, 9 patients who had 11 or more TPs did not meet the 2010 criteria. If FMS represents a clinical continuum of widespread pain, then we may fail to identify the patients with symptoms of CWP, though with fewer TPs by using the 1990 criteria. The opposite issue is also true for the patients having the requisite number of TP but not having enough symptoms to meet the 2010 criteria.

The association between CWP and FMS diagnosis is more complicated in patients with inflammatory disorders. CWP is also a common feature in these disorders and FMS is frequently coexpressed [27–31]. Although the mechanisms of development of CWP in inflammatory arthritis are not well understood, alterations in central pain regulatory mechanisms are likely responsible for the widespread reductions in pain thresholds [32]. In a recent study, the prevalence of CWP was found to be 34 % in patients with early RA [27]. Similar to our study, CWP was defined according to self-reported pain duration and distribution by using the definition of the ACR [2]. To the best of our knowledge, no study investigated the prevalence of FMS diagnosis among a group of patients with inflammatory arthritis who had CWP. In our study, we have found that 69 % of the patients with inflammatory disorders (*N*=52) who had CWP met the 1990 criteria for FMS. Normally, the 2010 criteria cannot be applied to these patients because of the exclusionary regulation of these criteria. Then, what do we do when the other 31 % of patients represent with CWP and associated symptoms and what should we call them? Indeed, we found that, of the remaining 23 patients who did not fulfill the 1990 criteria, 21 (92 %) were diagnosed as FMS by using the new criteria. Should we call them just as CWP, or do they remain undiagnosed? Thus, application of FMS classification criteria may identify a subgroup of patients with the most abnormal pain processing but may conceal patients in whom similar pain mechanisms make an important contribution to their symptoms [32]. However, if coexpression of CWP/FMS is unrecognized, it may cause overestimation of disease activity that may

adversely affect treatment decision [29, 30, 33]. More importantly, diagnosis of concomitant FMS and/or CWP is of vital importance so that adequate treatment may be instituted.

There are some limitations of this study that prevent generalization of the findings to the broader community. The first limitation was the relatively small sample size. The second one was that the patients included in the study were only those admitted to a tertiary care center. This may be responsible for overdiagnosis of FMS based on the diagnostic criteria. Another limitation of the study may be that fulfillment of both criteria were evaluated by the same physician. However, as the items of the 2010 criteria are based on a validated questionnaire, it is unlikely to cause an information bias and misclassification. On the other hand, the performance of the TP examinations by an experienced physician was a strong feature of our study.

Although it is important for clinical research studies to make distinction between FMS and CWP, the findings of this study deserve special attention because of their relevance for clinical practice. Our findings strongly support the recent suggestions that there seems to be no rationale for diagnosing FMS as a discrete disorder in patients presenting with CWP [34, 35]. To characterize patients with CWP as having or not having FMS by using rigid diagnostic criteria, we may miss many patients with CWP who need treatment. Moreover, as treatment of FMS is usually identical with that of chronic widespread or local pain throughout the world [34], such a differentiation will provide little or no significance regarding the choice of effective and safe therapies. It would be appropriate to apply general principles of CWP treatment in these patients [1] which include evaluation and consideration of the entire range of symptoms and psychological comorbidities. In this case, strict diagnosis criteria for FMS seem to be arbitrary. These criteria can provide guidance in defining and monitoring the symptoms associated with CWP, thus in formulating an effective treatment plan. This does not mean to ignore TPs entirely, as they may represent abnormal pain sensitivity and distress. However, validated measurements of various aspects of distress, various pain scales, and new diagnostic methods would be more useful for evaluating disordered central pain processing, as well as psychological components of CWP. Thus, we suggest that future research should be directed toward classification of CWP based on these approaches, in an attempt to formulate effective treatment strategies.

**Disclosures** None.

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