



2016 Revisions to the 2010/2011 fibromyalgia diagnostic criteria

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ABSTRACT

Objectives: The provisional criteria of the American College of Rheumatology (ACR) 2010 and the 2011 self-report modification for survey and clinical research are widely used for fibromyalgia diagnosis. To determine the validity, usefulness, potential problems, and modifications required for the criteria, we assessed multiple research reports published in 2010–2016 in order to provide a 2016 update to the criteria.

Methods: We reviewed 14 validation studies that compared 2010/2011 criteria with ACR 1990 classification and clinical criteria, as well as epidemiology, clinical, and databank studies that addressed important criteria-level variables. Based on definitional differences between 1990 and 2010/2011 criteria, we interpreted 85% sensitivity and 90% specificity as excellent agreement.

Results: Against 1990 and clinical criteria, the median sensitivity and specificity of the 2010/2011 criteria were 86% and 90%, respectively. The 2010/2011 criteria led to misclassification when applied to regional pain syndromes, but when a modified widespread pain criterion (the “generalized pain criterion”) was added misclassification was eliminated. Based on the above data and clinic usage data, we developed a (2016) revision to the 2010/2011 fibromyalgia criteria. Fibromyalgia may now be diagnosed in adults when all of the following criteria are met:

- (1) Generalized pain, defined as pain in at least 4 of 5 regions, is present.
- (2) Symptoms have been present at a similar level for at least 3 months.
- (3) Widespread pain index (WPI) ≥ 7 and symptom severity scale (SSS) score ≥ 5 OR WPI of 4–6 and SSS score ≥ 9 .
- (4) A diagnosis of fibromyalgia is valid irrespective of other diagnoses. A diagnosis of fibromyalgia does not exclude the presence of other clinically important illnesses.

Conclusions: The fibromyalgia criteria have good sensitivity and specificity. This revision combines physician and questionnaire criteria, minimizes misclassification of regional pain disorders, and eliminates the previously confusing recommendation regarding diagnostic exclusions. The physician-based criteria are valid for individual patient diagnosis. The self-report version of the criteria is not valid

Abbreviations: FM, fibromyalgia; FS, FS scale, fibromyalgia severity, fibromyalgia severity scale; NDB, National Data Bank for Rheumatic Diseases; PSD, polysymptomatic distress; SSS, symptom severity scale; WPI, widespread pain index.

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for clinical diagnosis in individual patients but is valid for research studies. These changes allow the criteria to function as diagnostic criteria, while still being useful for classification.

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Introduction

Purpose

In 1990, the American College of Rheumatology (ACR) first approved criteria for fibromyalgia, “The American College of Rheumatology 1990 criteria for the classification of fibromyalgia” [1]. In 2010, the ACR endorsed the “The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity” as “an alternative method of diagnosis” [2], but indicated that “This criteria set has been approved by the American College of Rheumatology (ACR) Board of Directors as Provisional. This signifies that the criteria set has been quantitatively validated using patient data, but it has not undergone validation based on an external data set. All ACR-approved criteria sets are expected to undergo intermittent updates.” However, in 2015 the ACR altered its view of diagnostic criteria, writing that “the ACR will provide approval only for classification criteria and will no longer consider funding or endorsement of diagnostic criteria” [3]. Since the publication of the 2010/2011 criteria, multiple studies have been performed with respect to validation. In addition, extensive research and clinical use of the criteria have identified areas for update. In this article we review validation and clinical data, combine the 2010/2011 criteria into a single set, provide clarifying modifications to the criteria, and describe how the new (2016) combined criteria should be used. In these respects we follow the original 2010 recommendations of the ACR for intermittent updates.

Background

A detailed description of the history of fibromyalgia criteria is available [4]. Modern criteria for fibromyalgia arose in 1977 from the observations and criteria of Smythe and Moldofsky [5]. These authors first proposed a tender point count and a requirement of “widespread aching.” In 1981, Yunus et al. [6] formally proposed criteria that included tender points and the “presence of generalized aches and pains involving 3 or more anatomic sites” In an effort to standardize fibromyalgia criteria, a multi-center study was organized that resulted in the ACR 1990 classification criteria for fibromyalgia [1]. The criteria fixed the number of tender points at 11 out of a possible 18 and added the requirement for widespread pain—defined as 4-quadrant plus axial pain. The widespread pain criterion was not an essential part of the criteria, as the criteria worked just as well in terms of accuracy without the widespread pain requirement [1]. Defined widespread pain was an *ad hoc* measure added only to aid in epidemiologic screening. However, with the passage of time, the widespread pain definition became an essential element and central part of the fibromyalgia definition, even though it was not part of pre-1990 criteria definitions.

There is no gold standard for fibromyalgia diagnosis. The 1990 criteria were based on the consensus of unblinded rheumatology physician investigators in the 1990 study regarding the degree of symptom severity and how many tender points were needed to diagnose fibromyalgia. The 1990 criteria were widely accepted by the research community, but generally ignored by most physicians for reasons that included the difficulty non-rheumatologists had in performing the tender point examination. Although there are few data on this point, it is likely that most diagnoses in the

community were made by physicians who used symptoms rather than the tender point examination and the absolute widespread pain requirement. Using 2012 US National Health Interview Survey (NHIS) data [7], Walitt et al. [8] have recently reported that more 70% of persons reporting a diagnosis of fibromyalgia do not satisfy NHIS (surrogate) fibromyalgia criteria.

Partly in response to the tender point difficulty, the 2010 criteria dropped the tender point and widespread pain requirements, replacing them with a count of 19 painful regions and a series of fibromyalgia symptom assessments. These changes altered the case definition of fibromyalgia somewhat. Practically, the 2010 criteria study found that there was $\geq 85\%$ agreement in diagnosis when using the 1990 and 2010 criteria set definitions, and that 93–94% of 2010 positive individuals satisfied the 1990 widespread pain criterion—a level the 2010 authors considered satisfactory [2].

The 1990 classification and 2010 diagnostic criteria were developed among rheumatology patients and were physician based, meaning that the physician evaluated the patient by interview and used usual medical examinations to consider other diagnostic possibilities. The 1990 criteria assessment also required the physician to perform a tender point examination. The 2010 criteria required no specific physical examination. Instead, it depended on the number of reported painful body regions, as assessed by the widespread pain index (WPI), and the severity of symptoms, as measured by the symptom severity scale (SSS). In 2011, the authors of the 2010 criteria published a modification of the 2010 criteria that allowed diagnosis to be accomplished entirely by self-report. In recognition of the problems with self-report diagnosis, the 2011 authors cautioned that the modified criteria should be used only for research and not for clinical diagnosis. The 2011 criteria also introduced a fibromyalgia severity (FS) score—the sum of the WPI and SSS—which permitted a quantitative measurement of the severity of fibromyalgia symptoms.¹ This scale can also be used with the 2010 criteria as the WPI and SSS are part of both criteria sets. In the text that follows we often refer to the “2010/2011” criteria when we want to address the 2010 as well as the 2011 criteria, as both sets are extremely similar.

The nature of fibromyalgia criteria

Both the 1990 and the 2010/2011 criteria separate cases and non-cases based on severity. The 2010/2011 criteria discriminate based on the levels of WPI and SSS, but can easily and appropriately be modeled by the 0–31 FS score. By criteria definition, it is impossible to satisfy the 2010/2011 criteria with an FS score < 12 . The overall accuracy of an FS classification using an FS cut point of 12–13 depends on the distribution of FS scores, but has been shown to be about 92–96% (see discussion below and Ref. [9]). The 1990 criteria require the presence of widespread pain (4-quadrant pain), but once that is present, all persons with ≥ 11 tender points satisfy the fibromyalgia criteria. Approximately 10–12% of the general population report widespread pain [10]. The tender point count depends not only on the intrinsic decrease in pain threshold

¹ The name, FS score or scale, has also been called the polysymptomatic distress scale (PSD), a term that has been vigorously contested and defended elsewhere.

but also on the self-report of the patient and the performance and interpretation of the physician examiner. The tender point count is highly correlated with patient symptoms, but the dolorimetry measure of pain threshold, which may be considered a semi-objective measure of pain threshold, is not. Gracely et al. [11] called the tender point count “some unspecified combination of tenderness and distress”; it has also been called “a sedimentation rate for distress” [12].

Measurement error and criteria assessment

The absence of a gold standard to identify fibromyalgia confounds evaluation of fibromyalgia criteria. This problem begins with the arbitrary nature of 1990 caseness and extends to measurement issues in the 1990 and 2010/2011 criteria. For the 1990 criteria, measurement error, difficulty in the performance of the tender point examination, and subjective contribution of physicians and patients leads to reduced reliability and validity. However, except for concern about circularity expressed after the publication of the 1990 criteria [13], there has been almost no criticism of the validity or reliability of the 1990 criteria. The few data available show reliability coefficients ≤ 0.71 [14–17]. The tender point count appears to work best when there is unspoken interaction between doctors and patients who take clues from each other and adjust their examinations and response, as fibromyalgia symptoms are always on the minds of the physician and patient. One could argue that during the clinical interview for 1990 criteria diagnosis, elements of the 2010/2011 criteria are almost always included. However, no study has examined that possibility.

In the evaluation of 2010/2011 criteria, the 1990 criteria have been used as a reference standard, with the result that inherent measurement error in the 1990 criteria will be carried over to the 2010/2011 criteria. The idea that valid sensitivity and specificity can be derived from comparisons with the 1990 criteria is only partially true, as the 1990 criteria examination will often be unreliable. A second major factor in any disagreement between the 1990 and 2010/2011 criteria is that the 2010 criteria deliberately altered the definition of fibromyalgia slightly by explicitly giving more emphasis to symptoms by the use of the SSS. Thus, in evaluating external data that includes the 1990 criteria, a level of 85% agreement, as observed in the 2010 study [2], can be interpreted as very close agreement.

In accordance with ACR criteria committee’s recommendation in 2010 regarding external validation and intermittent updates, the purpose of this report is to evaluate published data relating to external validation of the 2010/2011 criteria, examine published and unpublished problems with the criteria, and to update the criteria to address problems that have been noted. In addition, we further propose to combine the 2010 and 2011 criteria sets and clarify definitions that would enable the combined 2016 revision to function as diagnostic and classification criteria.

Methods

Studies

We evaluated studies of adults primarily with respect to sensitivity/specificity, fibromyalgia severity (FS), and study methodology, and we sought reports regarding problems with the 2010/2011 criteria in Figure 1. All published reports that evaluated either 2010 criteria or 2011 criteria are included in Table 1 if they were comparison studies and provided sufficient information for evaluation. We also included information from databanks or epidemiology studies if the studies provided FS scores. A single study from Fitzcharles provided reliability data, but not comparison or FS data

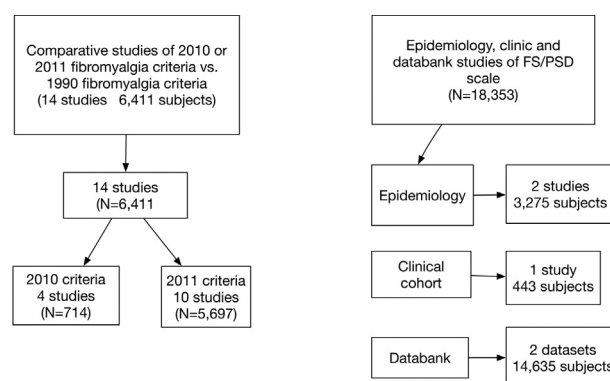


Fig. 1. Flow chart of fibromyalgia studies.

and was, therefore, not included in Table 1 [18]. In addition, we included data from surveys that assessed the prevalence of fibromyalgia in previously diagnosed clinical populations [19], as well as one that used 2011 criteria to estimate fibromyalgia prevalence among patients in a tertiary pain clinic [20].

We included unpublished data from the original ACR 2010 study [2]. The ACR 2010 preliminary criteria differed from the 2011 self-report survey criteria by being based on physician-obtained variables. However, all of the patient self-report variables were also available in the 2010 criteria set, but had not been reported previously. We used these variables to form 2011 survey criteria variables. As described in the ACR 2010 report [2], we compared ACR 1990 positive patients with controls. As defined by the 2010 study, controls consisted of (1) patients who previously were diagnosed with fibromyalgia but did not meet criteria at the time of the study (“prior fibromyalgia”) and (2) patients with arthritis-related pain disorders who never had a fibromyalgia diagnosis. In one analysis (ACR partial) we excluded prior fibromyalgia and in another analysis we included this group (ACR all). By including prior fibromyalgia we added controls with FS scores closer to 1990 fibromyalgia positive patients. The intent of these analyses was to examine the 2011 criteria against usual pain controls and also against “more difficult” pain controls, as was done in the 2010 ACR criteria report. These data, coming from the primary 2010 criteria study, form a kind of gold standard by which to evaluate other studies included in this report. We included new ACR study data because they had not been reviewed or presented previously, and their use allowed for a direct examination of 2011 variables in a setting where 2010 data had been reliably collected.

We also included data from patients who had participated in the National Data Bank for Rheumatic Diseases longitudinal study of rheumatoid arthritis and osteoarthritis [21]. Patients included had physician diagnoses of rheumatoid arthritis or osteoarthritis. As these patients were not referred because of fibromyalgia, they constitute representative patients with these disorders and provided useful information concerning the distribution of FS scores and fibromyalgia diagnosis.

The epidemiology studies that we included generally had few fibromyalgia positive subjects owing to the low prevalence in the general population. The Olmsted County study had 44 cases [22]. Owing to non-response in this study, the authors stated, “Limitations of our study include the low participation rate in the survey of the Olmsted County population over-all (27.7%), with a very low rate (16.2%) in the 21–39-year age category. Because of this low participation rate and the unexpectedly high FM rate in this category, our estimates of FM in the general population are likely biased.” A German population study included 52 cases [23]. Another population based study identified 27 2011 cases and 7 2010 cases. No data on FS scales were reported so we excluded that report [24,25]. That study also compared 1990, 2010, and 2011

Table 1
Published studies of 2010 and 2011 fibromyalgia criteria

Author	Criteria	Type	Sens (%)	Spec (%)	FS ACR+	FS ACR–	FS FM+ 2010/2011	FS FM– 2010/2011	WPI 2010–2011	SSS 2010–2011	WSP in FM + cases (%)	Current 1990 Dx	PT TP count	Cntrl TP count	Number of examiners	Sample size
ACR 2011 all [2]	2011	C	81	79	19.1	8.9	20.3	6.9	12.1	8.2	93.8	Yes	13.1	4.6	30	514
ACR 2011 part ^a [2]	2011	C	81	87	19.1	7.4	20.3	3.6	12.1		93.8	Yes	13.1	4.2	30	447
ACR 2010 all ^a [2]	2010		83	84												
ACR 2011 part [2]	2010		83	92												
Bennett et al. [29]	2011	C	83	67	19.7	11.0			12.4	7.3		Mixed			8	321
Bidari et al. [30]	2010	C	59	93	15.2	5.6			8.3	6.6		Clinical (No)	16.1	10.4	≥ 7	278
Carrillo-de-la-Peña et al. [44]	2011	C	80	97	22.4	4.7			13.1	9.3		Yes	13.7	6.0	1	139
Egloff et al. [40]	2011	C	84	60	17.0	9.0	17.0	9.0	8.0	9.0	46	Yes			Multiple	300
Ferrari et al. [45]	2011	C	90	90	17.7	10.6					100 ^b	Clinical (?)			2	451
Häuser et al. ^a [46]	2011	Surv	96						11.6	8.3		Clinical (?)				1651
Kim et al. [31]	2010	C	92	100	19.3	17.9			10.9	8.4			13.7	8.2		98
Marcus et al. [47]	2011	C	76	82								Clinical (?)	14.6	3.1	Multiple	337
Moyano et al. [48]	2010	NC	87									Yes				206
Segura-Jiménez et al. [27]	2011	C	88	92	21.0	6.0			13	8		Clinical (?)	15.0	3.0		844
Usui et al. [49]	2011	C	64	96	16.7	3.7						Yes			2	693
Yanmaz et al. [50]	2010		96	22.6					13.4	9.3			16.2			132
Mean of sens/spec (N = 14/11)			82.6	85.6	18.7	8.5			11.2	8.1			14.2	5.6		6411
Median of sens/spec (N = 14/11)			85.7	90.0	19.1	8.2			12.1	8.2			13.7	4.6		6411
Wolfe et al. [23]	2011	Epi						3.0 ^c	8.9	7.4	83				Multiple	2445
Vincent et al. [22]	2011	Epi					16.7		8.0	8.6					N.A.	830
<i>Clinical studies</i>																
Brummett et al. [20]	2011	Surv					17.2	8.5								443
<i>Databank studies</i>																
NDB OA All	DB	Surv					9.0		5.3	3.7	45.0					2359
NDB OA FM+	DB	Surv					19.3		11.8	7.6	94.1					442
NDB OA FM–	DB	Surv					6.6		6.6	2.8	33.7					1917
NDB RA All	DB	Surv					10.0		5.7	4.2	45.7					12,276
NDB RA FM+	DB	Surv					20.0		12.3	7.6	93.8					3135
NDB RA FM–	DB	Surv					6.6		3.5	3.1	29.5					9141

Type, type of study; sens, sensitivity; spec, specificity; WPI, widespread pain index; WSP%, percent with ACR 1990 defined widespread pain; prior 1990 Dx, No = current examination, Yes = prior examination, and mixed = undetermined prior and current; clin, clinical diagnosis-AXR criteria not stated; PT TP count, tender point count criteria+; cntrl TP count, tender point count criteria–.

FS ACR+/- = FS scores for patients for patients positive or negative for ACR 1990 criteria or other comparison criteria.

FS FM+/- 2010/2011 = FS scores for patients for patients positive or negative by 2010 or 2011 criteria.

^a Not included in mean/median calculation.

^b All subject required by study criteria to satisfy 1990 widespread pain criterion.

^c Combines positive and negative cases.

criteria in a small number of cases (1990, $n = 11$; 2010, $n = 7$; and 2011, $n = 27$) and provided limited explanatory data. We considered that the study did not provide sufficient information for evaluation, and we did not include these results in [Table 1](#). A 10-year follow-up epidemiology study of 1719 young adults who were recruited in their teens used the 2011 criteria, but did not provide FS scales on cases and controls was also excluded [\[26\]](#).

Results

Characterizations in Table 1

We categorized each study by type: whether they evaluated 2010, 2011, or were databank or epidemiology studies. Based on the comparison of the 2010 or 2011 study with 1990 or clinical criteria, we reported sensitivity, specificity, FS, WPI, SSS, and tender point counts, when available. Clinical criteria were defined as those criteria based on the investigator or clinician's experience or intuition. We categorized studies according to whether the FM 2010/2011 criteria study used FM 1990 "ACR criteria" or "clinical criteria" as the comparison group, according to the methods reported in the study. ACR 1990 criteria were further classified as to whether 1990 status was determined at the time of the study ($Y = \text{Yes}$) or ($N = \text{No}$) if 1990 status was defined by examination prior to the reported study. We characterized criteria as "mixed" if some of the study subjects had contemporaneous 1990 status determined and some relied on prior data. Because 1990 positive status can be lost, but not usually gained, over time, studies that are "Yes" as to prior diagnosis are more likely to have lower sensitivity, as cases may include false positives.

Some studies did not use the 2010/2011 criteria, but instead used cut points of the FS scale for diagnosis. For those studies, we listed the cut point at which the classification was positive. In the study of Segura-Jiménez et al. [\[27\]](#), the authors tested and reported the optimum cut point, but did not use it for classification.

We calculated the FS score for 1990 or clinical criteria when available (FS ACR+ and FS ACR−). If the study reported FS scores for those meeting or not meeting the 2010 or 2011 criteria, we reported these values (FS FM+ 10/11 and FS FM− 10/11). WPI and SSS, based on ACR 1990 or clinical data, were reported if available. The proportion of subjects meeting the 1990 widespread pain criterion was reported if available. Similarly, we reported tender point counts for the 1990 or clinically characterized subjects. When available, we reported the number of examiners. It was not always clear what the role of these examiners was, but most performed the tender point examination or participated in the ACR 2010 criteria assessment. The sample size reported was the sum of cases and controls.

Diagnostic problems. Diagnosis of fibromyalgia cases for 2010/2011 and 1990 comparison studies

Because diagnostic criteria are evaluated at the time of testing, current criteria status cannot be established reliably by a past diagnosis. A consequence of this to validation of the 2010/2011 criteria is that if patients who previously met 1990 criteria are assumed to still meet 1990 criteria, but are not reexamined and are then compared to 2010/2011 candidates, misclassification of putative 1990 cases will occur and sensitivity can be reduced substantially. For example, if only 80% of 1990 cases are still 1990 positive and 2011 criteria are 100% accurate in diagnosis, then the observable sensitivity of the 2010/2011 criteria will appear to be 80%. But we know from the FM 2010 study that because of changes in the case definition of fibromyalgia, only about 85% of 2010 positive patients will satisfy 1990 criteria. Combining these results, we can expect 2011 FM to have an approximate sensitivity of 85% if the

1990 examination is current and ($80\% \times 85\%$) and 68% if previous 1990 status is used.

Ascertainment of diagnosis for 1990 cases or non-fibromyalgia cases was less than optimum

For studies in [Table 1](#), one study performed tender point examinations only if they had not been done previously, resulting in a mixed diagnosis group. Four of the 10 studies did not report tender point counts. No study reported the time between the establishment of diagnosis by examination and the current study date. Two studies performed the tender point count using a dolorimeter rather than digital examination. One study used clinical diagnosis and did not perform new tender point examinations. No study reported on the reliability of the tender point examination. Three studies used the "cut point" of the fibromyalgia symptom scale to diagnose fibromyalgia. As we discussed above, this method always leads to misclassification, but only 1 (Ferrari) of the 3 studies provided used both the criteria and the cut point criteria, allowing measurement of the effect of the cut point strategy. Overall, the effect of attenuated diagnostic methodology or "clinical examination" could be to reduce the sensitivity of the 2010/2011 criteria because false positives would have been entered into the gold standard "true positive" group. Unfortunately, there is no way to assess the extent of these problems, although based on prior observations, this was almost certain to have occurred.

Diagnosis of fibromyalgia in controls and comparison group subjects

Assessment is much more complex in this group. While diagnosis of fibromyalgia cases is not affected by the selection process, control or non-fibromyalgia cases are very sensitive to a number of issues. Less than perfect specificity (true negatives/(true negative + false negatives)) depends primarily on misclassifying patients with 2010/2011 fibromyalgia as not having fibromyalgia using the 1990 definition. One important determinant of such misclassification and the consequent reduced specificity is the level of the fibromyalgia symptom scale—the severity of control or comparison subjects. The further away a patient or study is from the cut point of 12 (having a higher score), the less likely there is to be misclassification, while the closer to the cut point the more likely misclassification is [\[28\]](#). For example, the mean fibromyalgia symptom scale value of the Bennett study in non-fibromyalgia cases is 11.0 (S.D. = 6.0) [\[29\]](#), and there will, therefore, be many patients with $FS \geq 12$. Studies that have a methodologically valid method of recruitment and report specific details of subject recruitment are less likely to have a biased sample. For example, recruiting serial patients or "all patients," screening for subjects with a specific diagnosis can reduce bias. Convenience samples are likely to be biased.

Overall results

A total of 6411 subjects were evaluated. The 2010/2011 criteria had mean and median unweighted sensitivities of 83% and 86% and specificities of 86% and 90% in the 14 comparative studies of [Table 1](#). The results are shown graphically in [Figure 2](#). For reasons described below, we also considered the data after the excluding results of Bidari et al. [\[30\]](#) and Kim et al. [\[31\]](#). Reanalyses of the revised summary scores in [Table 1](#) showed small changes: the sensitivity changed to 84% (mean) and 84% (median) and specificity changed to 83% and 87%.

Tender points

Six studies contributed tender point data, but Marcus's study did not report FS data. There was a strong association between ACR

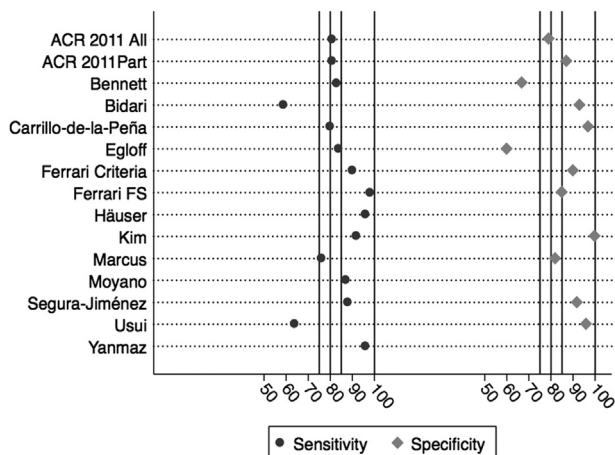


Fig. 2. Sensitivity and specificity of 2010/2011 fibromyalgia criteria compared with ACR 1990 or clinical criteria. See Table 1 for additional details.

1990 tender point levels in cases and controls, and among 2010/2011 FS scale results. “All” data from the ACR 2010 study [2] indicated the correlation between tender points and FS scale was 0.781.

The 5 studies with tender point data are presented in Figure 3 and Table 1. In Figure 2, study data above the 12 unit horizontal line can be thought of as representing FM 2010/2011 positive cases. Study data to the right of the 11 tender point count line can be thought of as representing positive FM 1990 cases. In Figure 3 several points appear to be outliers, Kim control and Bidari FM cases and controls. The Kim control FS value is very high and inconsistent with control subjects where an FS ≥ 12 generally identifies fibromyalgia cases; and the Kim control tender point count is moderately high. The Bidari control tender points mean (10.4) is very high for control subjects and, as it is a mean value, suggests many individual counts must have exceeded 11 tender points, in which case there would be misclassification with respect to ACR 1990 criteria. In addition, the Bidari FM positive tender points are higher than expected. Compared with the 4 other studies that had control and FM tender point data, Bidari tender points were highest in each of the 2 categories. Bidari used dolorimetry-based tender points rather than digital tender points. In addition, of the 4 examiners, 2 were internal medicine residents and 2 were general practitioners who were trained to be evaluators for this study [30].

Importantly, we noted in Table 1 that the Bidari study had the lowest sensitivity, 59%, and low FS scores for FM positive and

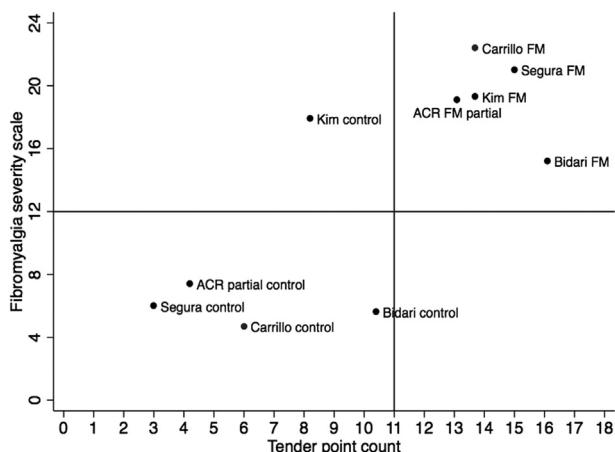


Fig. 3. Mean tender point counts vs. the fibromyalgia severity (FS) scale for studies reporting such data.

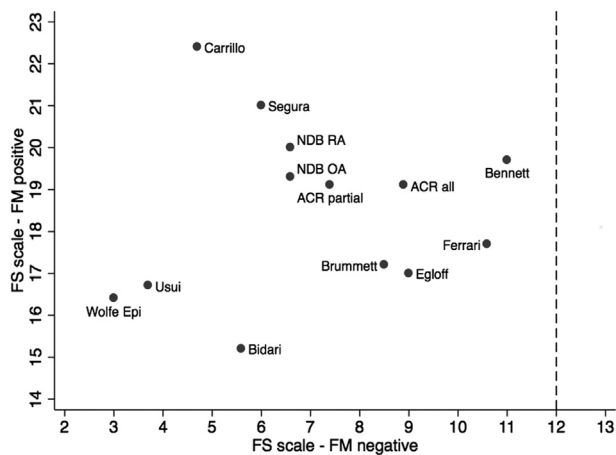


Fig. 4. Plot of FM positive versus FM negative FS scores. Data from Kim with FS+/FS- values of 19.3/17.9 is not shown.

negative subjects (Figure 4). Bidari indicates, “The study physicians were free to diagnose FM in each way they were satisfied in their usual practice, and neither the ACR 1990 classification criteria nor the ACR 2010 preliminary criteria were considered as a requirement for their diagnosis. All 3 physicians, however, used their clinical methods with an extremely brief, if any, tender point examination for diagnosing FM.” Furthermore, Bidari indicates that when using “expert diagnosis” as the gold standard, the ACR 1990 criteria had a sensitivity of 71.4%. In a previous report in 2009 they stated “This study showed the ACR 1990 criteria was not able to consistently classify affected patients with FM syndrome within a group of patients having nonspecific body pain and multiple tender points over 6 months of follow-up” [32]. We conclude that the Bidari studies may not utilize an appropriate “expert definition” diagnosis, and this results in uninterpretable validation data. Overall, for the 3 remaining studies ($N = 1430$) the relationship between tender points to the FS scale is strong, and it mirrors results from ACR 2010 of Figure 3 where the correlation between tender points and the FS scale was 0.781.

FS scores

The mean and median FS scores were 18.7 and 19.1 among positive ACR and clinical cases and were 8.5 and 8.2 among controls. Several studies had FS score results that were substantially different from average values. FS scores provide insight into the severity of symptoms among patients and controls. As fibromyalgia cannot occur with FS < 12, examining these scores in fibromyalgia cases and controls enable us to better understand the nature of the comparisons being made. The distribution of FS mean scores is shown in Figure 4. FS scores are low in the general population (Wolfe Epi) in those without fibromyalgia, averaging 3.0 in fibromyalgia-negative subjects, as shown in Wolfe Epi in Table 1 and in the “healthy” controls (4.7) of Carrillo-de-la-Peña. However, Usui (Table 1) had a mean FS score of 3.7 among pain controls with rheumatoid arthritis and osteoarthritis. By comparison, in the NDB the FS score among 12,276 RA and 2359 OA patients without fibromyalgia, at a random observation, is 6.6 and 6.6, respectively, and FS among controls in Bennett and Egloff are 11.0 and 9.0, respectively. In addition, Usui had an unexpectedly low sensitivity (64%) among ACR 1990 positive subjects. The Usui study is meticulously described and carried out and it is unclear why there are low values like these. One explanation offered by Usui is “cross-cultural differences in expression or rating of symptoms.” We note that the Usui data are strikingly at variance with other data in this report, and this finding appears to be

related to lower FS scores for ACR (+) and ACR 1990 (–) patients. The Usui FS-positive and negative scores of 16.7 and 3.7 resemble the general population data of Wolfe–Häuser (16.4 and 3.0, respectively). If Bidari and Usui are not included in the sensitivity determination, the mean and median sensitivity becomes 84% and 84%, not 83% and 86 as shown in Table 1.

FS control scores and lowered specificity

Low specificity indicates that cases classified as fibromyalgia positive by 2010/2011 criteria are classified as fibromyalgia negative by ACR or clinical criteria. Several studies had results with low specificity, and these studies raise important issues. Bennett reported specificity of 67%, Egloff reported specificity of 60%, and Marcus reported specificity of 76%. FS data were not available in the Marcus study. Marcus also collected data for and was a coauthor of the Bennett study. Bennett's mean FS in controls was 11.0 (S.D. = 6.0), one point removed from the 12 cut point, and Egloff's value of 9 is also high. By contrast, in clinical populations, the ACR studies had FS control values of 3.6 and 6.9, NDB OA of 6.6, NDB RA of 6.6, and the Brummitt pain clinic data of 8.5 (2.8) [33].

One other high FS value comes from Ferrari (10.6). However, Ferrari's study entry criteria required controls to satisfy the 1990 widespread pain criterion, but not be diagnosed as fibromyalgia positive. Ferrari's high FS scores in controls is, therefore, an artifact of his control definition and screening methods. Because Ferrari's controls seemed like a useful but unusual set of controls, we used the NDB to obtain FS levels on rheumatoid arthritis patients who met the ACR 1990 widespread pain criterion but did not meet 2011 criteria to evaluate the Ferrari data. The value of FS in 3167 NDB rheumatoid arthritis patients was 10.9, confirming Ferrari's scores.

It seems clear that the reason that there is lower specificity in the Bennett study is that their control FS mean is very close to the positive FS case cut point and has a standard deviation that overlaps with the FS cut point definition (FS mean/SD = 10.98/6.02) [29]. As discussed above, the closer cases and controls resemble each other, the more difficult it is to distinguish them. In addition, even if we were to accurately place patients on either side of the cut point, measurement error is sufficient to introduce clinically important misclassification [28]. It is difficult to know for certain why the Bennett controls have much higher FS scores, but one explanation could be the selection process. Their patients were “recruited” from the practices of 5 rheumatologists, 2 pain specialists, and 1 psychologist. The requirements for recruitment are not explicitly stated except that “adult patients ≥ 18-year-old were enrolled as a convenience sample with individual investigators inviting patients to participate if they had one or more of the specified diagnoses agreed upon during the development of the study. Enrollment was not restricted by sex, comorbidities, medications, or disease severity. All physicians used the 1990 ACR classification criteria for the diagnosis of FM; only if the subject was being seen for the first time was another tender point evaluation performed. Given the usual new to return patient ratio, it would seem that the great majority of patients were “return patients” and did not have a repeat tender point examination. Given the control FS scores are higher than those in all other studies except Kim, but including ACR, epidemiologic, NDB data-bank, and clinical studies, it seems likely that the selection process for controls subjects led to more controls of greater severity being selected.

Egloff, by contrast, “collected data on 300 consecutive in-patients with a diagnosis of a functional pain syndrome at a tertiary university centre for multi-modal pain therapy” The term comprises diagnoses such as FM, chronic tension headache, chronic temporomandibular joint disorder, chronic atypical facial pain, chronic low back pain, chronic atypical chest pain, the group

Table 2
Effect of changing criteria—NDB data (N = 17,385)

Criteria/alternates	Positive (%)	Misclassification (%)
2010/2011 Criteria	28.8	0.0
2010/2011 + 1990 Widespread pain criterion	27.0	1.8
2010/2011+ Pain in 4–5 regions (generalized pain criterion)	28.5	0.4

NDB, National Data Bank for Rheumatic Diseases; SSS, symptom severity score.

of functional gastrointestinal pain disorders (e.g., irritable bowel syndrome, functional dyspepsia, and functional abdominal pain, and the group of chronic pelvic pain syndromes (e.g., chronic non-inflammatory prostatitis, painful bladder syndrome, and female urethral syndrome).”

He reported that “An analysis of the pain distribution pattern in patients according to the ACR 2010 criteria showed that less than half of all patients (46%) suffered from pain in all 4 quadrants. Whereas 10.4% of FM 2010 patients suffered from unilateral pain syndromes, in 9.6% pain were limited to the head and trunk or to the upper part of the body; 10.4% of FM 2010 patients had local pain syndromes affecting just 1 or 2 quadrants. The remainder showed other forms of ‘incomplete’ distribution patterns.” By contrast, in the ACR 2010 study 93.8% had widespread pain, 83% had it in the Wolfe–Häuser epidemiology study, 93.8% in the NDB OA study and 94.1% in the NDB RA study. The essential difference between the Egloff study and all other reports is that Egloff conducted his study in a specialized restricted population, with a high frequency of regional disease and psychological symptoms. In addition, the ratio of SSS to WPI exceeded 1 in this population compared with ~0.75 in the other studies. Egloff concluded that “By dropping the requirement of “generalized pain,” these criteria result in a blurring of the distinction between FM and more localized functional pain syndromes.”

In response to this finding, Wolfe, Egloff, and Häuser analyzed factors associated with misclassification and widespread and non-widespread pain. Using 17,385 mixed NDB rheumatic disease patients, they showed that the use of a modified widespread pain criterion (called “generalized pain” to distinguish it from the 1990 widespread pain criterion) that required having pain in 4 of 5 pain regions (4 quadrants + axial) eliminated misclassification of regional pain syndromes as fibromyalgia (Table 2). The 5 regions are shown in Table 3. By requiring at least 4 regions, the criterion “... WPI of 3–6 and SSS score ≥ 9” becomes “WPI of 4–6 and SSS score ≥ 9” because the use of 4 regions mandates a minimum WPI score of 4.

Summarizing all studies, when compared with 1990 and clinical criteria the 2010/2011 criteria had good sensitivity and specificity. The use of a “generalized pain” criterion eliminates misclassification of regional pain syndromes as fibromyalgia. The FS scale provides a means for measuring fibromyalgia symptom severity in population and clinical studies.

Discussion

At the time of diagnosis, fibromyalgia in adults may be seen as a syndrome of moderate-to-severe symptoms and findings that usually include widespread pain and point tenderness, together with fatigue, sleep disturbance, cognitive complaints, and a general increase in somatic complaints. In populations, the symptoms exist as a continuum, cornucopia-like—from few to many and from

Table 3
Fibromyalgia criteria—2016 revision

Criteria		
A patient satisfies modified 2016 fibromyalgia criteria if the following 3 conditions are met:		
(1) Widespread pain index (WPI) ≥ 7 and symptom severity scale (SSS) score ≥ 5 OR WPI of 4–6 and SSS score ≥ 9 .		
(2) Generalized pain, defined as pain in at least 4 of 5 regions, must be present. Jaw, chest, and abdominal pain are not included in generalized pain definition.		
(3) Symptoms have been generally present for at least 3 months.		
(4) A diagnosis of fibromyalgia is valid irrespective of other diagnoses. A diagnosis of fibromyalgia does not exclude the presence of other clinically important illnesses.		
Ascertainment		
(1) WPI: note the number of areas in which the patient has had pain over the last week. In how many areas has the patient had pain? Score will be between 0 and 19		
<i>Left upper region (Region 1)</i>	<i>Right upper region (Region 2)</i>	<i>Axial region (Region 5)</i>
Jaw, left ^a	Jaw, right ^a	Neck
Shoulder girdle, left	Shoulder girdle, right	Upper back
Upper arm, left	Upper arm, right	Lower back
Lower arm, left	Lower arm, right	Chest ^a
		Abdomen ^a
<i>Left lower region (region 3)</i>	<i>Right lower region (Region 4)</i>	
Hip (buttock, trochanter), left	Hip (buttock, trochanter), right	
Upper leg, left	Upper leg, right	
Lower leg, left	Lower leg, right	
(2) Symptom severity scale (SSS) score		
Fatigue		
Waking unrefreshed		
Cognitive symptoms		
For the each of the 3 symptoms above, indicate the level of severity over the past week using the following scale:		
0 = No problem		
1 = Slight or mild problems, generally mild or intermittent		
2 = Moderate, considerable problems, often present and/or at a moderate level		
3 = Severe: pervasive, continuous, life-disturbing problems		
The symptom severity scale (SSS) score: is the sum of the severity scores of the 3 symptoms (fatigue, waking unrefreshed, and cognitive symptoms) (0–9) plus the sum (0–3) of the number of the following symptoms the patient has been bothered by that occurred during the previous 6 months:		
(1) Headaches (0–1)		
(2) Pain or cramps in lower abdomen (0–1)		
(3) And depression (0–1)		
The final symptom severity score is between 0 and 12		
The fibromyalgia severity (FS) scale is the sum of the WPI and SSS		

The FS scale is also known as the polysymptomatic distress (PSD) scale.

^a Not included in generalized pain definition.

mild to severe, and may be recognized by plotting the FS scale against specific symptoms [23].

Fibromyalgia may be diagnosed when the level of symptoms, or the point on the continuum, is sufficiently high (widespread pain plus 11 of more tender points in 1990 criteria or high levels of WPI, SSS, or FS scale in the 2010/2011 criteria). The boundaries of fibromyalgia, however, are not well defined [34]. At the mid-portion of the continuum, where the symptoms increase to blend into the named syndrome, problems with inter-rater reliability (measurement error) make distinguishing cases and non-cases difficult, as is the case in many disorders that depend on dichotomizing a continuum. In addition, the nature of the fibromyalgia symptom continuum makes differences in severity at the borderline of diagnosis problematic, for patients on different sides of the cut point are much more similar than they are different [35].

Among patients meeting 1990 or 2010/2011 criteria, those with fibromyalgia cannot be clearly distinguished from others with illnesses like chronic fatigue and irritable bowel syndrome if such patients also satisfy fibromyalgia criteria. Some observers see this syndrome overlap as an overlap between different but similar comorbid conditions, while other observe that the conditions are the same, but that they are named differently. In non-rheumatic disease specialities, fibromyalgia has been given many names, including somatoform disorder, functional somatic syndrome, and bodily distress syndrome, among many other names [36–38]. For the purposes of diagnosis, we take overlap with this type

of similar condition to be the identification of the same illness, but named differently. That is, for example, the presence of chronic fatigue in patients who satisfy fibromyalgia criteria is not a misclassification of fibromyalgia or chronic fatigue. Both exist in the same symptom and diagnostic space.

More problematic is the presence of fibromyalgia among other, distinctly different painful conditions that are not usually considered to be “functional somatic syndromes.” The 1990 criteria stated “A diagnosis of fibromyalgia remains a valid construct irrespective of other diagnoses” [1]. The 2010/2011 criteria stated that fibromyalgia could be diagnosed provided “The patient does not have a disorder that would otherwise explain the pain” (2010) and “The patient does not have a disorder that would otherwise sufficiently explain the pain” (2011). Although the 2010/2011 authors have attempted to clarify the instructions by indicating that no difference was intended between the 1990 and 2010/2011 recommendations, the 2010/2011 recommendations were seen as unclear and led to misunderstandings about what the criteria meant [39]. Therefore, in this revision of the 2010/2011 criteria, we specifically endorse and accept the original 1990 recommendation that “fibromyalgia remains a valid construct irrespective of other diagnoses” [1]. This status has an important effect on the idea of specificity because anyone who satisfies fibromyalgia criteria can be held to have the disorder—there is no possibility of misclassification. There can be fibromyalgia *and* another disorder, but not fibromyalgia *or* another disorder—as long as fibromyalgia criteria are satisfied.

Table 4
2016 Changes to modified ACR fibromyalgia diagnostic criteria

<p><i>This revision makes the following changes to the fibromyalgia criteria shown in Table 3.</i></p> <p>(1) Changes criterion 1 to “widespread pain index (WPI) ≥ 7 and symptom severity scale (SSS) score ≥ 5 OR WPI 4–6 and SSS score ≥ 9” (WPI minimum must be ≥ 4 instead of previous ≥ 3).</p> <p>(2) Adds a generalized pain criterion (criterion 2), and one that is different from the 1990 widespread pain definition. The definition is: “Generalized pain is defined as pain in at least 4 of 5 regions. In this definition, jaw, chest, and abdominal pain are not evaluated as part of the generalized pain definition.”</p> <p>(3) Standardizes and makes 2010 and 2011 criterion (criterion 3) wording the same: “Symptoms have been generally present for at least 3 months.”</p> <p>(4) Removes the exclusion that regarding disorders that could (sufficiently) explain the pain (criterion 4) and adds the following text: “A diagnosis of fibromyalgia is valid irrespective of other diagnoses. A diagnosis of fibromyalgia does not exclude the presence of other clinically important illnesses.”</p> <p>(5) Adds the fibromyalgia symptom (FS) scale as a full component of the fibromyalgia criteria.</p> <p>(6) Creates one set of criteria instead of having separate physician and patient criteria by replacing the physician estimate of somatic symptom burden with ascertainment of the presence of headaches, pain or cramps in lower abdomen, and depression during the previous 6 months.</p> <p>Forms and pain maps to aid in ascertainment are available at (https://medicine.umich.edu/sites/default/files/content/downloads/MBM%20w%20SSI%202016.pdf) (Michigan Pain Map) and (https://www.arthritis-research.org/sites/default/files/editor/FM%20Diagnostic%20Criteria%20Survey%20Questionnaire%20282013%29.pdf) National Data Bank for Rheumatic Diseases (NDB) fibromyalgia diagnosis form.</p>

The fibromyalgia symptom (FS) scale is also known as the polysymptomatic distress (PSD) scale.

The absence of exclusion criteria does not mean that *post hoc* exclusions cannot be added for research studies and clinical trials. For example, one may wish to exclude fibromyalgia positive subjects who have serious somatic diseases and mental disorders, or who are receiving certain treatments. In this respect, fibromyalgia is no different from other rheumatic illness where exclusions are applied.

We noted problems with the 2010/2011 criteria with respect to misclassifying a small fraction of patients who did not have generalized pain. For example, when 2010/2011 criteria were applied to patients in a tertiary pain clinic, fibromyalgia positivity was noted in some with regional pain disorders [40]. Misclassification occurs because the WPI, while indicating the number of painful sites, does not consider the spatial distribution of the sites. This problem can be obviated by imposing the requirement of meeting a widespread pain criterion, such as the 1990 criterion. However, the 1990 widespread pain criterion is often very restrictive. We found that by requiring that patients with fibromyalgia have pain in 4 out of 5 regions, rather than 5 of 5 regions, we excluded regional disorders while imposing only very slight changes in the 2010/2011 case definition [41]. As shown in Table 2, only 0.4% of 2010/2011 classified patients would be reclassified by this change [41]. Therefore, the proposed criteria modifications now require the presence of what we have called “generalized pain,” to distinguish it from the 1990 definition of widespread pain (Table 3).

An important consequence of this change is that one previous criterion for diagnosis, WPI of 3–6 and SSS ≥ 9 is not entirely correct since is now impossible to satisfy our modification with a WPI < 4 . Therefore we have changed the criterion to WPI of 4–6 and SSS ≥ 9 (Table 3). The proposed generalized pain criterion is easier to use than the 1990 widespread pain, as it requires only a quick look by the clinician to decide if the patient meets the criterion. In addition, we have provided detailed rules for calculating generalized pain (Tables 3 and 4). The 1990 widespread pain definition required the presence of pain above and below the waist, and pain on the left and right sides of the body. The exact pain locations to be assessed, however, were not clearly defined [42], but were not intended to include headache or facial pain (F. Wolfe, personal communication); and the widespread pain index that is used in the 2010/2011 criteria assesses several areas that are problematic for a quadrant or region definition, including jaw, chest, and abdominal pain. Therefore, in the current (2016) revision of the criteria (Table 3) these areas and headache and facial pain should not be included in the quadrant or region definition of generalized pain.

Finally, with this revision we combine the physician-based 2010 criteria with the self-report version of the 2011 criteria as one set

of criteria with 2 methods of administration, by altering the physician-based question about multiple symptoms and replacing that question with 3 short-symptom questions, as per the 2011 criteria. We made this change because data from Table 1 and, in particular, the comparative analysis of patient and physician assessments in the ACR 2010 study indicated a high level of agreement. The physician-based criteria are valid for individual patient diagnosis, and should always be accompanied by a full medical evaluation at the time of initial diagnosis. The self-report version of the criteria is not valid for clinical diagnosis in the individual patients, but is valid for research studies. The use of a self-report questionnaire for research has several advantages. First, it does not require interview and examination by a physician, thereby enabling survey and epidemiology research that would otherwise be heavily burdened. Second, it reduces classification error by having multiple assessors (the patients) compared with physician examinations which usually rely on a single or few examiners.

The use of the FS scale

Each of the symptom criteria items (SSS) of the 2016 modification (Table 3) can vary in severity, as can the WPI. When applied in populations, the WPI and SSS, combined into the FS score, ranges from 0 (no symptoms) to 31 (most severe symptoms). Because of the way fibromyalgia criteria are determined, a patient with a score < 12 cannot satisfy the criteria, but most (92–96%) of those with scores ≥ 12 will satisfy criteria. Therefore use of the FS score can provide an approximate guide to fibromyalgia criteria status. In persons who satisfy criteria, the FS score can also provide an approximate measure of fibromyalgia severity. In persons not satisfying criteria the role of FS scores is less clear. For those who have received a previous fibromyalgia diagnosis, a subsequent score < 12 might be used as a measure of improvement or of current status. For persons not satisfying fibromyalgia criteria or to those whom criteria classification has not been applied, the FS score may serve as a measure of the level of fibromyalgia type symptoms. Because the FS score is easy to determine and is always measured when criteria are assessed, we recommend that the FS score always be reported.

Diagnosis and the use of fibromyalgia criteria

Clinical diagnosis

Diagnosis or the confirmation of diagnosis occurs in different clinical and research settings, and at different points in the life course of patients and illnesses. Only in epidemiological or population research, where available medical information may

be limited, should criteria be applied without the gathering of additional information. Otherwise, criteria should never be applied without the gathering of essential medical and social information. Criteria are to be used after diagnostic possibilities have been narrowed through medical evaluations. The extent of new medical information to be gathered depends on the setting, the patient, and the information already available.

Assuming that the purpose of the medical encounter in the clinical setting is to understand, diagnose and treat a patient with chronic pain, all (undiagnosed) patients should receive a detailed interview, physical examination, and laboratory studies as required prior to establishing a final diagnosis of fibromyalgia. Information should be gathered regarding possible diagnoses, alternative diagnoses and comorbid illnesses. The requirement for generalized pain (pain in 4 of 5 regions) provides an efficient screening tool. If fibromyalgia is considered a reasonable possibility, diagnostic criteria may then be applied. Diagnosis may not be possible if the illness is of short duration (< 3 months as required by the fibromyalgia criteria), or symptoms are changing or unclear. Under such circumstances, diagnosis may be deferred.

Fibromyalgia occurs frequently among persons with musculoskeletal disorders and may be seen with almost any other medical condition, as well as in persons with psychological disorders. If such patients have symptoms consistent with fibromyalgia and satisfy fibromyalgia criteria, they may be diagnosed as having fibromyalgia using fibromyalgia criteria: the current criteria definition of fibromyalgia does not exclude patients with coexistent conditions. A diagnosis of fibromyalgia does not mean it is the patient's only diagnosis or even the most important diagnosis. It is only an acknowledgement that the patient has symptoms of fibromyalgia and satisfies fibromyalgia criteria. It is for the clinician to decide the meaning and importance of the clinical findings. Finding that a patient satisfies fibromyalgia criteria is not, *ipso facto*, sufficient to define the entirety of the patient's medical conditions.

Criteria and research

In research, criteria may be physician based, but more often are questionnaire based because of feasibility issues. When criteria are used in persons with a previous diagnosis of fibromyalgia, the purpose of the criteria is to be certain patients have fibromyalgia. Therefore complex diagnostic work-ups are not required. In addition, the research study can exclude persons with concomitant illness or limit the study based on gender or other characteristics, depending on the purpose of the study as long as the exclusions are well documented. Exclusions are common in pharmaceutical studies.

When research criteria are used in surveys and epidemiologic studies where the diagnosis is not known, *post hoc* exclusions are possible only when information about coexistent diseases is available. Exclusions based on age, gender, race, and other demographic characteristics are always possible. Epidemiology and prevalence studies may capture a small number of cases that are incompletely classified because of incomplete information.

The use of the fibromyalgia symptom scale

When fibromyalgia is approached as continuum rather than a discrete disorder, the FS scale is appropriate and helpful. It measures the magnitude and severity of fibromyalgia symptoms in those satisfying and not satisfying criteria. It has been shown to predict adverse outcomes, even in those not satisfying fibromyalgia criteria [9,20,43,44]. If the name, "Fibromyalgia," is removed from the scale, it can be useful in any group of patients with musculoskeletal pain, where it can serve as an evaluative as well as a screening instrument. As noted above, the FS scale has sometimes been described as the polysymptomatic distress scale.

Summary

With more than 5 years of experience, the 2010/2011 criteria have been shown to be useful and valid in multiple settings. We have now combined the ACR 2010 criteria set and the 2011 modified criteria into a single set of dual purpose criteria (2016 modified criteria—Table 4). These criteria can continue to serve as diagnostic criteria when used in the clinic, but also as classification criteria when used for research. The combined criteria introduce several changes based on experience in clinical and research settings with the 2010 and 2011 criteria. These changes include (1) the use of a generalized pain criterion to insure that regional pain syndromes are not captured by the criteria, (2) the return to original 1990 recommendation that "fibromyalgia remains a valid construct irrespective of other diagnoses," (3) the recommendation for the use the fibromyalgia symptom scale (FS scale), and (4) the combination of the ACR 2010 "physician" based criteria with the 2011 modified "patient" criteria into a single set of criteria that can be used by physicians or patients.

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