Widespread Pain and Low Widespread Pain Index Scores among Fibromyalgia-positive Cases Assessed with the 2010/2011 Fibromyalgia Criteria

Frederick Wolfe, Niklaus Egloff, and Winfried Häuser

ABSTRACT. ***Objective.*** Widespread pain is no longer required for fibromyalgia (FM) diagnosis according to the American College of Rheumatology (ACR) 2010 preliminary diagnostic criteria and its 2011 modification, but its absence may be of concern. We investigated whether the widespread pain definition was satisfactory and the consequences of having a small number of painful regions or of not satisfying the widespread pain criterion.

Methods. We studied 5011 patients who satisfied the 2011 criteria. FM was identified using the Widespread Pain Index (WPI) and the Symptom Severity Scale (SSS): WPI ≥ 7 and SSS ≥ 5 or WPI 3–6 and SSS ≥ 9. Widespread pain was 4 quadrants plus axial pain, according to the 1990 ACR FM criteria.

Results. There were 4700 patients (93.8%) who satisfied the ACR 1990 widespread pain criterion. Using a new strict definition for 5 pain regions based on the WPI sites, a modified widespread pain criterion requiring 4 of 5 regions identified 98.8% of criteria-positive patients. Patients without widespread pain or those in the low WPI/high SSS group had milder FM and no evidence of increased psychological or physical distress.

Conclusion. In usual clinical and epidemiological studies, the 2011 and 2010 criteria work well, but are not as effective in patients with asymmetrical or regional pain who do not satisfy a widespread pain criterion. A ≥ 4-pain region widespread pain definition will eliminate regional pain false-positives and will identify 98.8% of current 2011 cases. Future revisions of the 2010/2011 criteria should consider incorporating the ≥ 4-region requirement to avoid misclassification. (First Release July 1 2016; J Rheumatol 2016;43:1743–8; doi:10.3899/jrheum.160153)

Key Indexing Terms:
FIBROMYALGIA WIDESPREAD PAIN CRITERIA

Among the changes brought about by the 2010 American College of Rheumatology (ACR) preliminary diagnostic criteria for fibromyalgia (FM; ACR 2010, FM 2010)[1] and its 2011 self-report modification for research use (FM 2011)[2] were the abandonment of both tender points and the specific requirement for the presence of widespread pain. The latter was first defined in the ACR 1990 FM classification criteria and thought by many to be a central component of the FM concept[3,4,5]. The change in definition from 1990 to 2010 recognized the increased importance of FM symptoms and noted that there was a small proportion of patients whom clinicians diagnosed as having FM but who did not satisfy the 1990 criteria because of having either < 11 tender points or slightly less than the full ACR 1990 definition of widespread pain. The loosening of the widespread pain requirement addressed this second group.

According to the 1990 criteria, pain was widespread if an appropriate distribution and a sufficient number of body quadrants and axial skeleton had pain. The 2010 and 2011 criteria sets substituted a count of painful body regions, the Widespread Pain Index (WPI), for the simpler widespread pain requirement, noting that a continuous scale count of painful regions provided more information than the simple widespread pain determination. In addition, the WPI was also highly correlated with the 1990 tender point count in the setting of experienced rheumatologists, a finding that described a link between the physical examination of tender regions and self-reported pain[1]. For FM symptoms, the criteria sets defined a Symptom Severity Scale (SSS) as composed of graded common FM symptoms. FM diagnosis was satisfied by either of 2 definitions: WPI ≥ 7 and SSS

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≥ 5, or WPI 3–6 and SSS ≥ 9. The 2011 criteria, in contradistinction to the 1990 and 2010 criteria, were self-reported and did not require an examiner, which may be satisfactory for epidemiologic and some research purposes, but had limitations for clinical use.

The presence of a low WPI definition (WPI 3–6 and SSS ≥ 9) raised concerns because a WPI of 3 would only rarely satisfy the 1990 widespread pain criterion; in addition, the SSS ≥ 9 presaged a diagnostic process that selected for symptoms that might often be found in patients with psychological distress[4]. In addition, these authors noted the ratio of WPI (7.0) to SSS (9.0) to be 0.78, an indication that non-pain symptoms were more prominent than pain symptoms in their tertiary pain clinic setting. Results from the 2010 criteria study showed that the ACR 1990 widespread pain criterion was present in 93%–94% of cases[1], and an epidemiologic study from the German general population that used the 2011 criteria showed that widespread pain was present in 83% of FM cases[6]. Recently, however, Egloff, *et al* reported that only 46% of FM-positive cases had widespread pain in a tertiary pain clinic[4]. Egloff, *et al*'s data were worrisome because they suggested that in some pain populations, the 2010 and 2011 criteria did not work as intended.

To illuminate widespread pain and its relation to the WPI and to associated somatic and psychological variables in FM, our report analyzed widespread pain among 2011 FM-positive cases in a large rheumatic disease databank while asking the following questions: What is the relation of the WPI to widespread pain? Is the definition of widespread pain satisfactory? How can widespread pain be defined for clinical and epidemiology studies? What are the consequences of having a low WPI/high symptom severity score (WPI 3–6 and SSS ≥ 9) or not satisfying the widespread pain criterion on somatic and psychological symptom burden and disability? Finally, are the FM criteria performing as expected? And if not, would the addition of a widespread pain measure improve the criteria? Because the WPI and widespread pain issue is the same when using the 2010 as when using the 2011 criteria, it is probable that the results of our study could be extended to the 2010 criteria.

MATERIALS AND METHODS

We studied a random sample of 17,385 participants from the National Data Bank for Rheumatic Diseases (NDB) longitudinal study of rheumatic disease outcomes using questionnaires completed between July 2009 and December 2014. Participants were volunteers recruited from the practices of US rheumatologists, who completed mailed or Internet questionnaires about their health at 6-month intervals. They were not compensated for their participation. The clinical rheumatic disease diagnoses were made by the patient's rheumatologist or confirmed by the patient's physician in the small number of cases that were self-referred. The NDB uses an open-cohort design in which patients are enrolled continuously. About 8% of patients discontinued participation per year[7]. The characteristics of the NDB have been reported previously[8].

We determined the patients' current research FM status using the 2011 research criteria for FM, a modification of the preliminary ACR 2010 criteria[2]. The 2011 criteria are for research, not for individual patient diagnosis. Only patients who were positive for the 2011 FM criteria (n = 5011) were included in our study. We had no data on whether study participants met the 1990 FM criteria at any time. In our study, FM was identified when levels of the WPI and SSS were sufficiently high (WPI ≥ 7 and SSS ≥ 5, or WPI 3–6 and SSS ≥ 9). The WPI is a 0–19 count of painful nonarticular body regions and the SSS is a 0–12 measure of symptom severity that includes fatigue, sleep, and cognitive problems. The polysymptomatic distress (PSD) score, a measure of FM severity, was calculated by summing the WPI and SS score for each patient. The PSD scale is also called the FM severity scale, and how it should be called is a matter of controversy[9]. We considered patients who satisfied the criteria with WPI 3–6 and SSS ≥ 9 to be in the "low" WPI group and those who satisfied it by WPI ≥ 7 and SSS ≥ 5 to be in the "high" WPI group.

To determine the presence of widespread pain, we used the following definition from the ACR 1990 criteria[3]: "Pain is considered widespread when all of the following are present: pain in the left side of the body, pain in the right side of the body, pain above the waist, and pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present. In this definition, shoulder and buttock pain is considered as pain for each involved side. 'Low back' pain is considered lower segment pain." The 1990 definition, however, is inexact because it does not state which body areas should be included in the body pain assessment. In addition, rare patients who otherwise met the 1990 criteria could satisfy the ACR widespread pain definition with pain in only 3 areas. For example, in the presence of axial pain, low back pain and pain in the right hand and left foot would qualify as widespread pain. This occurs because pain in a single site can be expanded to include 2 regions, as when right hand pain is scored for right side and for upper extremity. A recent detailed review of widespread pain reported that 24 studies had used the ACR 1990 definition, but did not report on areas assessed, probably because that information was not given in the study reports[10]. Because the first author of the 1990 study is also the first author of our current report, we want to indicate that it was not the intention of the 1990 criteria group to include the head, chest, or abdomen in the widespread pain definition, and we have not done so in any of our subsequent reports[11]. Further, meeting the 1990 widespread pain criterion with only 3 sites was rarely a problem in the 1990 classification criteria because of the simultaneous requirement to have at least 11 tender points. But when the widespread pain definition was used in circumstances other than the 1990 criteria, the 1990 widespread pain definition was problematic and was not a good measure of widespread pain.

In our current report, we evaluated 2 definitions of widespread pain. First, we determined widespread pain using the 1990 definition of body segments and sides. Second, based on 4 quadrants plus axial pain used in the 1990 definition, we created a separate 0–5 variable ("widespread pain regions") that was the sum of pain (0 or 1) in each of the 5 regions. In these analyses, we used pain regions specified in the WPI[1,2]. The axial region included the neck, upper back, and lower back. The upper regions (left and right) included the shoulder girdle, upper arm, and lower arm. The lower regions (left and right) included the hip (buttock, trochanter), upper leg, and lower leg. The WPI did not include the wrist, ankle, and foot. The jaw, chest, and abdomen were not included in our 5-region definition in our report or in our determination of the ACR 1990 pain criterion. In our report, we compared the 2011 criteria without a widespread pain criterion to the 2011 criteria that used the 1990 definition, as well as to the 2011 criteria at various levels of the variable of 0–5 widespread pain regions.

The 2 consequences of the definitions of widespread pain can be seen in Table 1. Of the 5011 patients who were positive for the FM 2011 criteria, 93.8% satisfied the 1990 criteria, including those who had pain only in 3 sites — because of the site expansion described above. Using the "widespread pain regions" of our current study, Table 1 shows that 93.8% of those with 5 regions positive and 98.8% (93.8% + 5.0%) of those with at least 4 regions would satisfy an alternative widespread pain criterion.

To determine the relationship of widespread pain and the WPI group to clinical status, we evaluated a series of clinical variables. Pain and global severity were assessed using 0–10 visual analog scales. Functional status

Table 1. Categories of WS pain and pain regions according to fibromyalgia criteria categories. Values are n (%).

Variables	WPI 3–6 and SSS ≥ 9	WPI ≥ 7 and SSS ≥ 5	Total
Group			
All patients	343 (6.8)†	4668 (93.2)†	5011 (100)
Patients with ACR 1990 WS pain	177 (51.6)* (3.8)†	4523 (96.9)** (96.2)†	4700 (93.8)
Patients with non-ACR 1990 WS pain	166 (48.4)* (53.4)†	145 (3.1)** (46.6)†	311 (6.2)
WS pain regions (% of all patients in column)			
≤ 1	1 (0.3)	0 (0.0)	1 (0.02)
2	11 (3.2)	0 (0.0)	11 (0.2)
3	49 (14.3)	1 (0.02)	50 (1.0)
4	105 (30.6)	144 (3.1)	249 (5.0)
5	177 (51.6)	4523 (96.9)	4700 (93.8)

* Percent of "low" (WPI 3–6 & SSS ≥ 9) cases (n = 343). ** Percent of "high" (WPI ≥ 7 & SSS ≥ 5) cases (n = 4668). † Percent of cases in group. WS pain: widespread pain; WPI: Widespread Pain Index; SSS: Symptom Severity Scale; ACR: American College of Rheumatology.

was measured using the Health Assessment Questionnaire (HAQ)-Disability Index[12]. We also calculated the physical (PCS) and mental component summary (MCS) scores from the Medical Outcomes Study Short Form-36[13]. To evaluate depression and anxiety, we used the Patient Health Questionnaire (PHQ) 2 and Generalized Anxiety Disorder 2 scales. "When used together, they are referred to as the PHQ-4, a 4-item screening measure which ranges from a score of 0 to 12, and serves as a good measure of 'caseness' (i.e., the higher the score, the more likely there is an underlying depressive or anxiety disorder)," according to Kroenke, *et al*.[14]

We used the PHQ-15 to determine somatic symptom severity. The PHQ-15 contains 15 somatic symptoms. Each symptom is scored from 0 (not bothered at all) to 2 (bothered a lot). PHQ-15 scores of 5, 10, and 15 represent cutoff points for low, medium, and high somatic symptom severity, respectively. The usefulness of the PHQ-15 in screening for somatization syndromes and in monitoring somatic symptom severity in clinical practice and research has been demonstrated in numerous studies[15]. The PHQ-15 and PHQ-4 only became available toward the end of study and were completed by 2387 and 2260 subjects, respectively.

Where appropriate, we compared groups by Student t tests or chi-square tests. Data were analyzed using Stata, version 14.0[16].

Ethics and Institutional Review Board (IRB) approval. This study was conducted in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 1983. No financial support was received for this study. The study was approved by the Via Christi IRB, Wichita, Kansas, USA.

RESULTS

What is the extent of non-widespread pain in patients satisfying the 2011 research definition for FM? We evaluated 5011 patients who participated in the NDB and who satisfied the 2011 FM research criteria. Of these FM criteria-positive participants, widespread pain according to the ACR 1990 criteria was present in 95.3% with FM (n = 961), 90.8% of 566 with systemic lupus erythematosus, 93.9% of 3023 with rheumatoid arthritis, and 93.9% of 461 referred with other noninflammatory rheumatic diseases. Overall, 4700 (93.8%) satisfied the widespread pain criterion of the 1990 criteria and 311 (6.2%) did not have widespread pain (Table 1).

Of the 311 without widespread pain (Table 1), 145 (46.6%) came from the 343 patients in the high WPI group (WPI 3–6 and SSS ≥ 9) and 166 (53.4%) from the 4668 patients in the low WPI group (WPI ≥ 7 and SSS ≥ 5). The relationship of widespread pain to the WPI is shown in Figure 1. The graph shows that both the high WPI and low WPI groups contribute to the widespread/non-widespread pain categories.

As noted, the ACR 1990 widespread pain criterion expands to 5 regions with pain (4 quadrants plus axial) if the 1990 rules are followed, even if fewer than 5 sites are involved. Table 1 shows that 311 (6.2%) of 2011 FM-positive patients did not meet the ACR 1990 criterion. Using the widespread pain regions method shown at the bottom of Table 1, 4700 (93.8%) of 2011-positive subjects had 5-region widespread pain and 4949 (98.8%) had ≥ 4-region widespread pain. Thus, if ≥ 4 regions were used to designate widespread pain instead of 5 regions, only 1.2% of 2011-positive patients would not have widespread pain.

FM and severity measure according to widespread pain and criteria categories. Table 2 shows (under "All") the overall FM and severity scores for all patients who satisfied the research FM criteria. The mean WPI score was 12.3 and the ratio of the WPI to the SSS was 1.6.

Because the low WPI group (column 2) and the group without widespread pain (column 6) were both variables of the decreased WPI scores, the PSD was consequently lower and the SSS higher compared with the comparison groups (columns 3 and 6; Table 2). However, consistent with the lower PSD scores, the HAQ, pain, global, and PCS were less abnormal than in the comparison groups. The MCS scores were inconsistent [more abnormal in column 2 (low WPI and high SSS), but less abnormal in column 5 (WS Pain)]. The PHQ-15 scores were at the same level in the low WPI group and reduced nonsignificantly in the non-widespread pain group. The PHQ-4 scores were slightly but not significantly increased. These data indicated that, in general, more painful regions and widespread pain were associated with more severe symptoms, as shown by the WPI, SSS, and PSD.

To compare the low and high groups under equivalent conditions, we compared the groups only in patients who had SS scores ≥ 9 and who differed, thereby, only in the high or

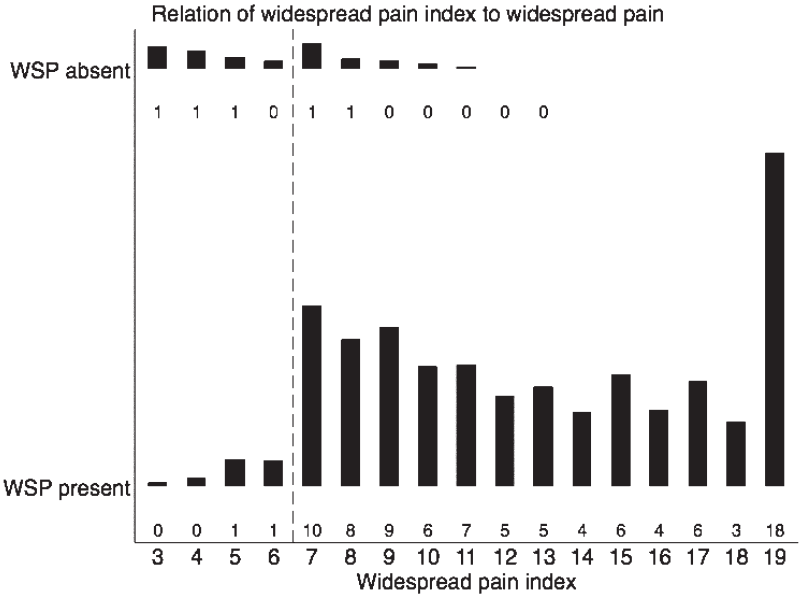

Figure 1. The relation of WSP to the WPI. The low WPI group (WPI 3–6 and SSS ≥ 9) is shown to the left of the dashed line, and the high WPI group (WPI ≥ 7 and SSS ≥ 5) is shown to the right of the line. The numbers below the bars are the percent of all patients and would add to 100%, except for rounding. WSP: widespread pain; WPI: Widespread Pain Index; SSS: Symptom Severity Score.

Table 2. Fibromyalgia and severity measures according to WS pain and criteria categories. Values are mean (SD) unless otherwise specified.

Variables	WPI 3–6 and SSS ≥ 9	WPI ≥ 7 and SSS ≥ 5	All	WS Pain	Not WS Pain
Subjects in category, n	343	4668	5011	4700	311
WPI	4.6 (1.1)	12.9 (4.3)	12.3 (4.7)	12.8 (4.5)	6.0 (2.3)
SSS	9.7 (0.8)	7.7 (2.0)	7.8 (2.0)	7.8 (2.0)	8.5 (1.9)
PSD	14.3 (1.4)	20.6 (5.2)	20.2 (5.3)	20.5 (5.2)	14.5 (2.1)
Age, yrs	52.3 (12.6)	56.0 (13.0)	55.8 (13.0)	55.9 (13.1)	53.4 (12.6)
Male, %	7.3	10.6*	10.4	10.5	8.7*
College graduate, %	33.8	30.6*	30.8	30.6	35*
HAQ, 0–3	1.2 (0.6)	1.5 (0.6)	1.5 (0.6)	1.5 (0.6)	1.2 (0.6)
Pain, 0–10	5.7 (2.5)	6.4 (2.2)	6.3(2.2)	6.4 (2.2)	5.5 (2.6)
Global severity, 0–10	5.6 (2.2)	5.9 (2.1)	5.9 (2.1)	5.9 (2.1)	5.3 (2.2)
PCS, SF-36	32.7 (8.3)	28.9 (7.8)	29.1 (7.9)	28.9 (7.7)	32.5 (8.9)
MCS, SF-36	34.6 (10.6)	39.5 (11.5)	39.1 (5.0)	39.3 (11.5)	37.5 (11.2)
PHQ-15	13.5 (3.1)	13.5 (4.7)*	13.5 (4.6)	13.5 (4.6)	12.4 (3.8)*
PHQ-4 score	5.1 (3.6)	4.3 (3.5)*	4.4 (3.5)	4.4 (3.6)	4.9 (3.5)*

The low WPI and high WPI groups (columns 2 and 3) are significantly different from each other at $p < 0.5$, except where flagged with asterisks (*). WS Pain and Not WS Pain groups (columns 5 and 6) are significantly different from each other at $p < 0.5$, except where flagged with asterisks (*). WS pain: widespread pain; WPI: Widespread Pain Index; SSS: Symptom Severity Scale; PSD: Polysymptomatic Distress Scale; HAQ: Health Assessment Questionnaire; PCS: physical component summary; SF-36: Medical Outcomes Study Short Form-36; MCS: mental component summary; PHQ-15: Patient Health Questionnaire 15; PHQ-4: Patient Health Questionnaire 4.

low WPI grouping. As can be seen in Table 3, patients in the low WPI group had less severe symptoms for almost all study variables. These observations suggest that even in patients with high SSS, it is the level of widespread pain that influences symptom severity, probably because patients satisfying the 2011 criteria with high SSS have low WPI scores.

DISCUSSION

There is a disconnect between the WPI that measures the number of painful sites and the 5 regions in the 4 quadrants plus axial definition of widespread pain of the 1990 FM criteria. The disconnect occurs because each of the pain regions can contain more than 1 WPI site. Thus, as shown in

Table 3. Fibromyalgia and severity measures according to WS pain in patients with SSS ≥ 9. Values are mean (SD) unless otherwise specified.

Variables	WPI 3–6 and SSS ≥ 9	WPI ≥ 7 and SSS ≥ 9
Subjects in category, n	343	1538
WPI	4.6 (1.1)	14.2 (4.2)
SSS	9.7 (0.8)	10.1 (1.0)
PSD	14.3 (1.4)	24.3 (4.6)
Age, yrs	52.3 (12.6)	52.1 (11.8)
Male, %	7.3	7.9*
College graduate, %	33.8	28.2*
HAQ, 0–3	1.2 (0.6)	1.7 (0.6)
Pain, 0–10	5.7 (2.5)	7.2 (1.9)
Global severity, 0–10	5.6 (2.2)	6.8 (2.0)
PCS, SF-36	32.7 (8.3)	27.5 (7.1)
MCS, SF-36	34.6 (10.6)	33.5 (10.4)*
PHQ-15	13.5 (3.1)	16.4 (4.7)
PHQ-4 score	5.1 (3.6)	6.5 (3.5)

Comparisons are significantly different at $p < 0.05$, except where flagged with asterisks (*).WS pain: widespread pain; SSS: Symptom Severity Scale; WPI: Widespread Pain Index; PSD: Polysymptomatic Distress Scale; HAQ: Health Assessment Questionnaire; PCS: physical component summary; SF-36: Medical Outcomes Study Short Form-36; MCS: mental component summary; PHQ-15: Patient Health Questionnaire 15; PHQ-4: Patient Health Questionnaire 4.

Figure 1, it is possible, though very rare, to have a WPI as high as 12 and still not satisfy the widespread pain criterion. While 145 of those in the high WPI group failed to satisfy the widespread pain criterion, the majority of patients (53.4%, n = 166) with non-widespread pain came from the low group. Although fewer patients from the high WPI group (3.1%) had non-widespread pain, the absolute number of patients in the group was substantial because most patients with FM satisfied the high WPI group requirements.

Despite the concern that satisfying the FM criteria through the low WPI group is harmful, we found no evidence that patients selected by having a low WPI or no widespread pain reported more somatic and psychological symptoms (Table 2 and Table 3), and this was true regardless of how we compared WPI groups or widespread pain categories. In fact, those in the low WPI groups or without widespread pain seemed to have slightly less severe illness symptoms. Thus, the use of the low WPI/high SSS group and the inclusion of 6.2% of patients with non-widespread pain do not appear to cause problems in rheumatic disease cohorts. This is supported by the WPI to SSS ratio of 1.6, and is in contradistinction to the ratio of 0.78 reported by Egloff, *et al*[4].

One consequence of not meeting the widespread pain criterion is the violation of the idea that FM required widespread pain to be a valid concept or was a part of widespread pain-associated illnesses. However, most of the non-widespread pain patients in our study had pain in 4 out of 5 pain regions, a result that is consistent with the idea of generalized pain and which, if accepted as widespread pain, would reduce the 2011 criteria-positive non-widespread pain group to 1.2%. Approaches to handle what might seem to be a non-problem could include (1) excluding the 6.2% of patients without widespread pain, (2) treating all patients with 4 or more pain regions as having widespread pain, or (3) ignoring the widespread pain issue. For research purposes, where diagnosis is not applicable to individual patients, one approach would be to determine whether the non-widespread pain proportion is sufficiently high to be of concern and if so, then to report essential data with 1 of the "corrections" noted above.

A number of studies have reported the percentage of subjects satisfying the 2011 (or 2010) criteria by the low WPI category, including 4.4% of 1411 patients with FM in a German clinical study[17], 15.5% of 71 patients in a Korean clinical study[18], 2.7% of 80 patients in a Spanish population[19], 17% of 52 cases in a German population study[6], 6–7% of 514 patients in the ACR 2010 criteria study[1], 6.2% in our current report, and 25.9% in a 27-subject Scottish population survey[20]. It should be noted that in the German population study, widespread pain estimate included chest, head, and abdominal pain in the widespread pain calculation. One study, however, was a distinct outlier. Egloff, *et al*'s observation that only 46% of FM-positive cases had widespread pain in a tertiary pain clinic raised several important issues[4]. They reported that "10.4% of FM 2010 patients suffered from unilateral pain syndromes, in 9.6% pain was 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 one or two quadrants. The remainder showed other forms of 'incomplete' distribution patterns." We would advise 2 approaches to Egloff, *et al*'s type of data. If one is screening for FM with the diagnostic criteria in clinical or research settings where regional disorders are common, it makes sense to impose a widespread pain filter, either at 4 or 5 regions, and then to review carefully what the data show (Table 4). At the level of the individual patient, one needs to suspect that the patient may have the disorder being tested for before applying criteria. However, because the cost of imposing a filter of ≥ 4 pain regions is very small and identifies 98.8% of unfiltered cases, we suggest that future revisions of 2010/2011 criteria sets include this additional criterion regardless of the study setting. When we applied this filter to the German population data in which 17% of FM categorized cases met the old widespread pain criterion, only 7.7% did not meet the ≥ 4-region widespread pain criterion; and FM population prevalence changed from 2.1% to 2.0%.

Classification accuracy depends upon the prevalence of FM in the population under study. Under usual circumstances of clinical and epidemiological studies, the 2011 (and 2010) criteria should work well. Under circumstances where the population is unusual, with an overrepresentation of regional disease, it may be necessary to test that the widespread pain criterion or at least the 4 regions of the widespread pain assessment are met before having confidence in the data. At

Table 4. Possible criterion addition to the ACR (2010) diagnostic criteria and the modified ACR survey criteria (2011) for FM.

Variable	ACR (2010)	Modified ACR (2011)	Possible Criterion Addition for 2010/2011 Criteria
Criteria	WPI 3–6 and SSS ≥ 9, or WPI ≥ 7 and SSS ≥ 5	WPI 3–6 and SSS ≥ 9, or WPI ≥ 7 and SSS ≥ 5	
Assessment method	Physician assessment	Patient self-report	
Symptoms assessed, 0–12	Fatigue, 0–3	Fatigue, 0–3	
	Sleep disturbance, 0–3	Sleep disturbance, 0–3	
	Cognitive problems, 0–3	Cognitive problems, 0–3	
	Somatic symptom reporting, 0–3	Abdominal pain, 0–1, headache, 0–1, depression, 0–1	
WPI, 0–19	19 sites	19 sites	
WS pain regions, 0–5			5 regions
≤ 1	Not used	Not used	Excludes FM
2	Not used	Not used	Excludes FM
3	Not used	Not used	Excludes FM
4 or 5	Not used	Not used	Required for FM

The 5 WS pain regions are derived from sites specified in the WPI. The axial region includes the neck, upper back, and lower back. The upper regions (left and right) include the shoulder girdle, upper arm, and lower arm. The lower regions (left and right) include hip (buttock, trochanter), upper leg, and lower leg. The WPI does not include the wrist, ankle, and foot. The jaw, chest, and abdomen are not included in the 5-region definition. The number of regions with pain is the sum of axial, left upper, right upper, left lower, and right lower regions. ACR: American College of Rheumatology; FM: fibromyalgia; WPI: Widespread Pain Index; WS pain: widespread pain; SSS: Symptom Severity Scale.

the clinical patient care level, one should always apply the diagnostic criteria only when there is a reasonable suspicion of FM. We suggest adding a ≥ 4-pain region filter to future revisions of FM criteria sets because that would eliminate the misclassification of regional pain syndromes.

REFERENCES

1. Wolfe F, Clauw DJ, Fitzcharles MA, Goldenberg DL, Katz RS, Mease P, et al. The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. Arthritis Care Res 2010;62:600-10.
2. Wolfe F, Clauw DJ, Fitzcharles MA, Goldenberg DL, Häuser W, Katz RS, et al. Fibromyalgia criteria and severity scales for clinical and epidemiological studies: a modification of the ACR preliminary diagnostic criteria for fibromyalgia. J Rheumatol 2011;38:1113-22.
3. Wolfe F, Smythe HA, Yunus MB, Bennett RM, Bombardier C, Goldenberg DL, et al. The American College of Rheumatology 1990 criteria for the classification of fibromyalgia. Report of the Multicenter Criteria Committee. Arthritis Rheum 1990;33:160-72.
4. Egloff N, von Känel R, Müller V, Egle UT, Kokinogenis G, Lederbogen S, et al. Implications of proposed fibromyalgia criteria across other functional pain syndromes. Scand J Rheumatol 2015;44:416-24.
5. McBeth J, Mulvey MR. Fibromyalgia: mechanisms and potential impact of the ACR 2010 classification criteria. Nat Rev Rheumatol 2012;8:108-16.
6. Wolfe F, Brähler E, Hinz A, Häuser W. Fibromyalgia prevalence, somatic symptom reporting, and the dimensionality of polysymptomatic distress: results from a survey of the general population. Arthritis Care Res 2013;65:777-85.
7. Wolfe F, Michaud K. Assessment of pain in rheumatoid arthritis: minimal clinically significant difference, predictors, and the effect of anti-tumor necrosis factor therapy. J Rheumatol 2007;34:1674-83.
8. Wolfe F, Michaud K. The National Data Bank for rheumatic diseases: a multi-registry rheumatic disease data bank. Rheumatology 2011;50:16-24.
9. Littlejohn GO, Guymer EK. In clinical practice, the term "central sensitivity score" is more useful than the term "polysymptomatic distress scale": comment on the editorial by Wolfe. Arthritis Rheumatol 2015;67:2553.
10. Mansfield KE, Sim J, Jordan JL, Jordan KP. A systematic review and meta-analysis of the prevalence of chronic widespread pain in the general population. Pain 2016;157:55-64.
11. Wolfe F. Pain extent and diagnosis: development and validation of the regional pain scale in 12,799 patients with rheumatic disease. J Rheumatol 2003;30:369-78.
12. Fries JF, Spitz P, Kraines RG, Holman HR. Measurement of patient outcome in arthritis. Arthritis Rheum 1980;23:137-45.
13. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473-83.
14. Kroenke K, Spitzer RL, Williams JB, Löwe B. An ultra-brief screening scale for anxiety and depression: the PHQ-4. Psychosomatics 2009;50:613-21.
15. Kroenke K, Spitzer RL, Williams JB. The PHQ-15: validity of a new measure for evaluating the severity of somatic symptoms. Psychosom Med 2002;64:258-66.
16. Stata. Stata statistical software: release 14.0. College Station: Stata Corporation; 2015.
17. Häuser W, Jung E, Erbslöh-Möller B, Gesmann M, Kühn-Becker H, Petermann F, et al. Validation of the Fibromyalgia Survey Questionnaire within a cross-sectional survey. PLoS One 2012;7:e37504.
18. Kim SM, Lee SH, Kim HR. Applying the ACR preliminary diagnostic criteria in the diagnosis and assessment of fibromyalgia. Korean J Pain 2012;25:173-82.
19. Carrillo-de-la-Peña MT, Triñanes Y, González-Villar A, Romero-Yuste S, Gómez-Perretta C, Arias M, et al. Convergence between the 1990 and 2010 ACR diagnostic criteria and validation of the Spanish version of the Fibromyalgia Survey Questionnaire (FSQ). Rheumatol Int 2015;35:141-51.
20. Jones GT, Atzeni F, Beasley M, Flüß E, Sarzi-Puttini P, Macfarlane GJ. The prevalence of fibromyalgia in the general population: a comparison of the American College of Rheumatology 1990, 2010, and modified 2010 classification criteria. Arthritis Rheumatol 2015;67:568-75.