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ABSTRACT. ***Objective.*** To develop a fibromyalgia (FM) survey questionnaire for epidemiologic and clinical studies using a modification of the 2010 American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia (ACR 2010). We also created a new FM symptom scale to further characterize FM severity.

Methods. The ACR 2010 consists of 2 scales, the Widespread Pain Index (WPI) and the Symptom Severity (SS) scale. We modified these ACR 2010 criteria by eliminating the physician's estimate of the extent of somatic symptoms and substituting the sum of 3 specific self-reported symptoms. We also created a 0–31 FM Symptom scale (FS) by adding the WPI to the modified SS scale. We administered the questionnaire to 729 patients previously diagnosed with FM, 845 with osteoarthritis (OA) or with other noninflammatory rheumatic conditions, 439 with systemic lupus erythematosus (SLE), and 5210 with rheumatoid arthritis (RA).

Results. The modified ACR 2010 criteria were satisfied by 60% with a prior diagnosis of FM, 21.1% with RA, 16.8% with OA, and 36.7% with SLE. The criteria properly identified diagnostic groups based on FM severity variables. An FS score ≥ 13 best separated criteria+ and criteria– patients, classifying 93.0% correctly, with a sensitivity of 96.6% and a specificity of 91.8% in the study population.

Conclusion. A modification to the ACR 2010 criteria will allow their use in epidemiologic and clinical studies without the requirement for an examiner. The criteria are simple to use and administer, but they are not to be used for self-diagnosis. The FS may have wide utility beyond the bounds of FM, including substitution for widespread pain in epidemiological studies. (First Release Feb 1 2011; J Rheumatol 2011;38:1113–22; doi:10.3899/jrheum.100594)

Key Indexing Terms:
FIBROMYALGIA CRITERIA DIAGNOSIS

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The publication of American College of Rheumatology (ACR) preliminary diagnostic criteria for fibromyalgia (FM) in 2010 (ACR 2010)[1] eliminated the tender point examination, thus making it possible to study FM in survey and clinical research. The diagnostic criteria for FM are satisfied if the following 3 conditions are met: (1) the Widespread Pain Index (WPI) ≥ 7 and the Symptom Severity Score (SS) ≥ 5, or the WPI is 3–6 and the SS ≥ 9; (2) symptoms have been present at a similar level for at least 3 months; and (3) the patient does not have a disorder that would otherwise explain the pain.

The ACR 2010 study found that about 25% of clinic patients with FM did not satisfy ACR 1990 classification criteria[2]. The study group developed the SS scale so that patients who improve and do not satisfy criteria could be followed for the severity of FM symptoms. This scale could also be used in patients with other rheumatic and nonrheumatic diagnoses to determine the extent to which someone may also have comorbid FM symptoms. In addition, some patients with other rheumatic diseases will also satisfy dichotomous (i.e., yes or no) FM criteria when tested for

it[3,4,5,6,7,8,9]. From such data it is likely that an important proportion of patients with FM in observational studies would not satisfy 1990 or 2010 FM criteria, while many patients with other rheumatic diseases would satisfy the ACR 2010 criteria had they been queried about symptoms of FM.

A major limitation in understanding FM prevalence and characteristics is the difficulty imposed by the requirement for a physician examination. Even the ACR 2010 requires at least an interviewer. Because most of the ACR 2010 items can be obtained by self-administration, we modified the criteria so that complete self-administration would be possible. While this eliminates special skills that an interviewer might have, it allows administration in survey research and settings where the use of interviews would be difficult or prohibitively expensive.

We describe here the development and performance of modified ACR 2010 criteria and a new Fibromyalgia Symptom scale (FS) formed by the combination of the WPI and SS scales. We examined how the ACR 2010 SS scale could be best modified for survey research, and we applied the modified ACR 2010 criteria to patients surveyed in a longitudinal databank. We examined the rate of modified ACR 2010 positivity in patients diagnosed by rheumatologists as having FM at entry to the study, and in patients with other rheumatic disorders. Finally, we examined the performance and distribution of the FS scale across different rheumatic disorders. This scale has also been called the fibromyalgianess scale[10,11].

MATERIALS AND METHODS

Patients and diagnoses. We studied participants in the US National Data Bank for Rheumatic Diseases (NDB) longitudinal study of rheumatic disease outcomes[12]. Participants are volunteers, recruited from the practices of US rheumatologists, who complete mailed or Internet questionnaires about their health at 6-month intervals. They are not compensated for their participation. Diagnoses are made by the patient's rheumatologist or confirmed by the patient's physician in the small number of cases that are self-referred. The NDB uses an open cohort design in which patients are enrolled continuously[12].

In July of 2009, we administered FM criteria items to 7233 patients who were completing a comprehensive 28-page semiannual survey, including 729 whose diagnosis was FM at entry to the NDB study, 855 with osteoarthritis (OA) or with other noninflammatory rheumatic conditions, 439 with systemic lupus erythematosus (SLE), and 5210 with rheumatoid arthritis (RA). The mean age and percentage of men who participated was 63.3 years (SD 12.5; 17.3%) for all patients; 59.1 (SD 12.2; 3.6%) for patients with FM; 70.1 (SD 10.7; 17.4%), for patients with OA; 54.1 (SD 12.4; 5.5%) for patients with SLE; and 63.8 (SD 12.0; 19.2%) for patients with RA. To distinguish between FM classification in the NDB, which was based on physician diagnosis, and classification based on the modified ACR 2010 criteria, we call FM as diagnosed by physicians and categorized in the NDB, "NDB fibromyalgia."

FM study variables. The widespread pain questionnaire asks patients to indicate whether they have had pain or tenderness over the previous week in the shoulder girdle, hip, jaw, upper back, lower back, upper arm, upper leg, chest, neck, abdomen, lower arm, and lower leg. They were asked to grade the right and the left side of the body separately. Each item was scored 0 or 1. The minimum total score was 0 and the maximum total score was 19. This scale represented the widespread pain index (WPI). The WPI is a part of the ACR 2010 and the modified ACR 2010 criteria.

The symptom scale questionnaire asked patients to indicate the severity over the previous week of several items, 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; and 3, severe, continuous, life-disturbing problems. The items were fatigue, trouble thinking or remembering, and waking up tired (unrefreshed). Patients also were asked to answer yes/no whether they had had pain or cramps in the lower abdomen, depression, or headache during the previous 6 months. When summed, these items result in a score between 0 and 12. This score represents the SS scale of the modified ACR 2010 criteria. It differs from the SS scale of the ACR 2010.

Other study variables. Patients also completed the Medical Outcomes Study Short-Form 36 (SF-36), version 1, from which the physical component summary score (PCS) was calculated[13,14]. The primary time period of the SF-36 questionnaire was 4 weeks. The SF-36 mental health scale was transformed to a 0–10 mood scale, with higher numbers indicating worse mental health. To measure functional status, we used the Health Assessment Questionnaire Disability Index (HAQ)[15], and fatigue, disturbed sleep, and pain were assessed by visual analog scales (VAS). Patients also reported on the presence of somatic symptoms, similar to those reported in the ACR 2010 diagnostic criteria study[1], and a count of somatic symptoms (0–37) was obtained. We also calculated the Symptom Intensity Scale (SI) by summing the WPI and VAS fatigue scale scores[16]. The SI scale is similar to the FS scale of our report.

Criteria modification. The ACR 2010 criteria used a 4-item SS that included 1 item that asked the physician to indicate whether the patient had no, few, moderate, or many somatic symptoms. As that evaluative question to physicians appeared to lack face validity if presented to patients, we modified the SS by substituting for the somatic symptoms item a 0–3 item that represented the sum of 3 items: the presence or absence of headaches, pain or cramps in lower abdomen, or depression symptoms during the previous 6 months, as described. We used a 6-month timeframe rather than a 1-week timeframe because we wanted a 6-month prevalence rather than a point prevalence as a measure of somatic symptoms. We also asked patients to report areas of "pain or tenderness" for the WPI. In the ACR 2010 study we asked only physicians to determine areas of pain. We made this change to be sure that patients understood that tenderness in regions should be counted for the WPI. The change in the somatic question, the WPI clarification, and the method of administration are the essential differences between ACR 2010 and modified ACR 2010 criteria. The modified criteria are not ACR criteria, but are modified from the official ACR criteria.

The sum of these 3 new symptom items (mini-somatic scale) correlated with a count of somatic symptoms in the study subjects at 0.668 (Spearman correlation). The mean number of somatic symptoms at each level of the 3-symptom item scale was 0: 4.7; 1: 9.6; 2: 14.7; and 3: 20.6, suggesting that the scale functions as a surrogate for the somatic symptoms item.

The modification we describe, the creation of a modified 4-item SS scale, was only one of several other possible modifications. Other possible modifications included deletion of the ACR 2010 somatic symptoms question, which would have resulted in a 3-item SS scale, or the use of a different 4-item scale based on the determination of multiple somatic symptoms. The advantage of using a 4-item scale was that the modified ACR 2010 criteria and the ACR 2010 criteria would have the same scale length for the SS scale. In the statistical analyses for this report, we compared the performance of the ACR 2010 modified 4-item scale with a 3-item scale that omitted the ACR 2010 somatic question. We also evaluated the addition of a count of 37 symptoms to a diagnostic regression model that included the WPI and the modified 4-item scale. In logistic regression simulation analyses comparing NDB FM with NDB OA, we determined that the addition of the somatic symptom scale increased the percentage correct by 0.3% and the area under the receiver-operating characteristic (ROC) curve by 0.005.

Given the practical difficulty of constructing and using a multiple somatic symptom scale, and the extremely slight improvement that it might afford, we concluded that a simpler scale performed adequately, and we did not include a multiitem somatic symptom scale in the modified ACR 2010 criteria.

The modified ACR 2010 criteria are a WPI ≥ 7 and an SS ≥ 5 or the WPI is 3–6 and the SS ≥ 9, provided symptoms have been present at a similar level for at least 3 months and the patient does not have a disorder that would otherwise explain the pain. As noted, the modified ACR 2010 criteria are almost the same as the ACR 2010 diagnostic criteria with the exception that the 4-item SS scale is modified as described.

We also developed an FS scale. This scale represented the sum of the 0–19 WPI and the modified 4-item (0–12) SS scale. Its range is 0–31. This scale is also known as the fibromyalgianess scale[10,11].

Statistical methods. To describe the univariate associations of NDB FM diagnoses with the study variables, we calculated Somers' D and its 95% CI (Table 1). Multivariable models comparing a 3-item SS scale with a 4-item SS scale used logistic regression in bootstrapped simulation models (100 repetitions). Models were evaluated with the Akaike Information Criterion (AIC), the Bayesian Information Criterion (BIC), the area under the ROC curve, and the percentage of patients correctly classified. We compared the SI and FS scales using the Pearson correlation coefficient and Lin's concordance coefficient[17]. Data were analyzed using Stata version 11.0 (Stata Corp., College Station, TX, USA).

RESULTS

Entry characteristics. Table 1 displays the entry characteristics of participants, according to NDB diagnosis. The long duration of illness reflects that patients entered the NDB at a younger age and had been participants in the NDB for 6.5 (SD 4.82) years prior to the development of the FM study questionnaires. Patients with FM had more abnormal scores for all study variables.

Association of criteria-related clinical variables with NDB FM diagnosis. Before studying the modified ACR 2010 criteria, we examined the ability of variables to identify NDB FM compared with OA, and NDB FM compared with all patients. We separately examined OA because OA is a noninflammatory comparison group, similar to the control group in the 2010 FM diagnostic criteria study. Table 2 shows that the strongest univariate correlations in the OA and all-patients group analyses included the 4-item SS score and the WPI. The highest-ranking variable was the composite FS variable that represented the sum of the 4-item SS score and the WPI. Other important differentiating variables were the number of somatic symptoms and the presence of tender muscles.

Because the 4-item SS scale was modified from the 2010 ACR scale, we examined its predictive ability. We performed a series of multivariable regression analyses using the WPI and the 3- item and 4-item SS scales as predictor variables to determine whether the 4-item SS scale performed better than the 3-item scale in distinguishing NDB patients with FM from non-NDB patients with FM, as suggested by Table 2. In analyses performed in all patients and separately against the OA subset, the 4-item scales fit the data better than the 3-item scale as measured by the Akaike Information Criterion and the Bayesian Information Criterion. Classification was also slightly better with the 4-item scale. For example, in the evaluation of NDB FM versus OA, the area under the ROC was 0.77 versus 0.76, respectively, and the percentage correctly classified was 71.0% versus 70.3%.

Prevalence of FM according to survey FM criteria. We applied the modified ACR 2010 criteria to NDB groups. By diagnosis at entry into the NDB, 10.1% of NDB patients carried the diagnosis of FM. By modified ACR 2010 criteria, the percentage with FM was 25.4% (Table 3). Among patients with RA, 21.1% had FM by modified ACR 2010 criteria; and 16.8% of patients with OA and 36.7% of patients with SLE satisfied the criteria. However, among patients carrying the FM diagnosis in the NDB, only 60% satisfied the modified ACR 2010 criteria. These data indicate that many patients diagnosed with FM in the past do not currently satisfy modified ACR 2010 criteria, and that many patients with non-FM criteria do satisfy the modified ACR 2010 criteria.

Characteristics of patients satisfying and not satisfying

Table 1. Characteristics of study patients by National Data Bank for Rheumatic Diseases (NDB) diagnosis.

Variable	Fibromyalgia, n = 729	SLE, n = 439	RA, n = 5210	OA, n = 855
Age, yrs (SD)	59.1 (12.2)	53.2 (12.4)	63.8 (12.0)	68.9 (12.0)
Sex, % men	3.6	6.2	19.9	18.4
Disease duration, yrs (SD)	18.9 (11.6)	17.4 (11.5)	18.2 (11.5)	18.3 (11.4)
Widespread pain index (0–19)	10.0 (5.3)	6.3 (5.3)	5.3 (4.8)	5.3 (4.4)
4-item modified SS score (0–12)	6.4 (2.8)	5.3 (3.0)	3.8 (2.7)	3.4 (2.5)
Fibromyalgia symptom scale (0–31)	16.4 (7.2)	11.6 (7.5)	9.0 (6.7)	8.7 (6.3)
Fatigue (0–10)	6.0 (2.7)	4.9 (3.1)	3.9 (3.0)	3.5 (2.8)
Sleep disturbance (0–10)	5.4 (3.0)	4.5 (3.3)	3.7 (3.0)	3.4 (2.9)
Mood (0–10)	3.4 (2.1)	3.0 (2.0)	2.4 (1.8)	2.2 (1.7)
Muscle tenderness, %	79.0	44.9	27.2	30.3
Symptom count (0–37)	13.2 (6.5)	12.3 (7.7)	7.3 (5.7)	7.3 (5.5)

SLE: systemic lupus erythematosus; RA: rheumatoid arthritis; OA: osteoarthritis; SS: Symptom Severity Score.

Table 2. Somers' D correlations of fibromyalgia and study variables.

Variable	Osteoarthritis (855)	All Patients (7233)
Fibromyalgia symptom scale (0–31)	0.573 (0.527, 0.619)	0.542 (0.508, 0.576)
4-item modified SS score (0–12)	0.559 (0.513, 0.605)	0.493 (0.457, 0.530)
3-item Short SS score (0–9)	0.511 (0.463, 0.559)	0.442 (0.405, 0.480)
Symptom count (0–37)	0.511 (0.463, 0.559)	0.495 (0.460, 0.531)
Widespread pain index (0–19)	0.494 (0.445, 0.544)	0.492 (0.456, 0.528)
Tender muscles (0–1)	0.489 (0.445, 0.532)	0.507 (0.476, 0.539)
VAS Fatigue scale (0–10)	0.483 (0.434, 0.533)	0.394 (0.357, 0.432)
3-item symptom scale	0.458 (0.410, 0.507)	0.423 (0.385, 0.461)
Muscle pain (0–1)	0.446 (0.403, 0.489)	0.459 (0.430, 0.489)
Unrefreshed sleep severity (0–3)	0.455 (0.406, 0.503)	0.391 (0.353, 0.429)
Fatigue severity (0–3)	0.417 (0.368, 0.466)	0.332 (0.295, 0.370)
Cognitive symptom severity (0–3)	0.391 (0.341, 0.440)	0.371 (0.333, 0.409)
Mood (0–10)	0.365 (0.312, 0.418)	0.291 (0.250, 0.333)
VAS sleep problem severity (0–3)	0.361 (0.308, 0.415)	0.320 (0.279, 0.361)
VAS pain scale (0–1)	0.348 (0.295, 0.402)	0.398 (0.361, 0.435)
Memory/thinking problems (0–1)	0.333 (0.285, 0.380)	0.336 (0.299, 0.373)
Headaches (0–1)	0.319 (0.272, 0.366)	0.295 (0.257, 0.333)
Depression symptoms (0–1)	0.273 (0.229, 0.318)	0.241 (0.204, 0.279)
Pain or cramps in lower abdomen (0–1)	0.220 (0.177, 0.263)	0.213 (0.177, 0.249)
HAQ disability (0–3)	0.138 (0.081, 0.196)	0.131 (0.090, 0.171)

SS: symptom severity scale; VAS: visual analog scale; HAQ: Health Assessment Questionnaire.

modified ACR 2010 criteria. As shown in Table 4, application of the modified ACR 2010 criteria to FM and non-FM NDB (entry) groups resulted in FM+ and FM– modified ACR 2010+ groups that were very similar in FM symptoms, but with perhaps a very slight increase in severity in the FM+ entry group. The FM– modified ACR 2010 group had the least abnormal score, and the FM+ modified ACR 2010 group had scores between the modified ACR 2010+ and the modified ACR 2010– just described.

Table 3. Fibromyalgia (FM) databank prevalence according to entry diagnosis and modified ACR 2010 diagnostic criteria.

Entry Diagnosis (N)	FM by NDB Entry Diagnosis, %	FM by Modified ACR 2010 Criteria, %
All patients (7233)	10.1	25.4
Fibromyalgia (729)	100.0	60.0
RA (5210)	0.0	21.1
OA (855)	0.0	16.8
SLE (439)	0.0	36.7

The FS scale. The 2010 ACR FM diagnostic criteria created an SS scale that was used together with the WPI to diagnose FM. We summed the 0–19 WPI and 0–12 modified 4-item SS scores to create the FS. Using all study patients, the WPI and SS scale were correlated at r = 0.587 and each had nearly equal predictive ability for NDB FM diagnosis. When combined, this scale was the best univariate predictor of NDB FM (Table 2). An FS score ≥ 13 best separated modi-

Table 4. Fibromyalgia (FM)-related characteristics according to entry and diagnostic criteria. FM+ and FM– refer to clinical diagnosis at time of databank entry. Criteria+ and Criteria– refer to results of the modified ACR 2010 diagnostic criteria.

Variable	FM (+), Criteria+, mean or %	FM+, Criteria–, mean or %	FM–, Criteria+, mean or %	FM–, Criteria–, mean or %
Widespread pain index (0–19)	12.9	5.6	11.7	3.6
4-item modified SS score (0–12)	8.0	4.0	7.4	2.8
Fibromyalgia symptom scale (0–31)	20.9	9.6	19.0	6.5
Fatigue (0–10)	7.2	4.2	7.1	3.1
Sleep disturbance (0–10)	6.5	3.8	6.1	3.0
VAS pain (0–10)	6.3	3.8	5.9	2.7
Mood (0–10)	4.0	2.6	3.8	2.0
Muscle tenderness (%)	89.7	63.0	65.7	18.6
Symptom count (0–37)	16.1	8.8	14.5	5.7

ACR: American College of Rheumatology; SS: symptom severity scale; VAS: visual analog scale.

fied ACR 2010 criteria+ and criteria– patients, classifying 93.0% correctly, with a sensitivity of 96.6% and a specificity of 91.8% in the study population. Figure 1 shows the distribution of the FS scale of modified ACR 2010-positive and 2010-negative patients. Figure 2 shows the distribution of the FS scale among NDB patients with FM and patients with RA. Among patients who satisfy modified ACR 2010 criteria, the FS has these characteristics: mean 19.5 (SD 4.8), median 19, range 12–31.

The FS is similar to the SI[16], and has also been called the fibromyalgianess scale. Although the SI scale combines a VAS fatigue scale with the WPI and the FS scale combines the WPI with the 4-item SS scale, the 2 scales are effectively the same in terms of performance. When the SI scale is transformed to the same scale length (0–31), the Pearson correlation coefficient of the scales is 0.963 and Lin's concordance coefficient is 0.956. The 4-item SS scale is correlated with the FS at 0.817 and with SI at 0.746.

To further characterize the relationship between study variables and new scales, we determined Pearson correlations for the all-patient groups and ranked the coefficients according to their strength of association with the FS scale (Table 5). As expected, the single-item components of the minisomatic scale were the least associated with the study composite scales.

To understand how well the FS and SS scales performed, we studied correlations between the scales and the individual SF-36 domains (Table 6). In column 4 of Table 6, we show similar correlations for the revised Fibromyalgia Impact Questionnaire (FIQ) total score[18]. In general, the FS and SS scales have correlations with the SF-36 domains that are at least as strong as correlations between the FIQ and SF-36 scales, with the exception that the FIQ is more strongly related to SF-36 physical functioning. This is expected, because the FIQ contains 9 physical function items and the FS and SS scales by design do not contain any such items.

The widespread pain criterion. The presence of widespread pain, a criterion of the 1990 ACR FM classification criteria, has been used extensively in epidemiological research. Among patients positive for the modified ACR 2010 criteria, 93.7% satisfied the widespread pain criterion. Among those who were negative for the modified ACR 2010 criteria, 32.8% were positive for the widespread pain criterion. Further insight into the important relationship between the FS and widespread pain can be seen in Figure 3. As widespread pain has been associated with increased mortality, we evaluated HAQ and PCS values in patients with widespread pain who did and did not satisfy modified ACR 2010 criteria. HAQ and PCS are important predictors of mortality and patient outcomes. HAQ and SF-36 PCS values for modified ACR 2010 patients with widespread pain were 1.5 (SD 0.6) and 29.0 (SD 7.8), respectively, compared with 1.0 (SD 0.7)

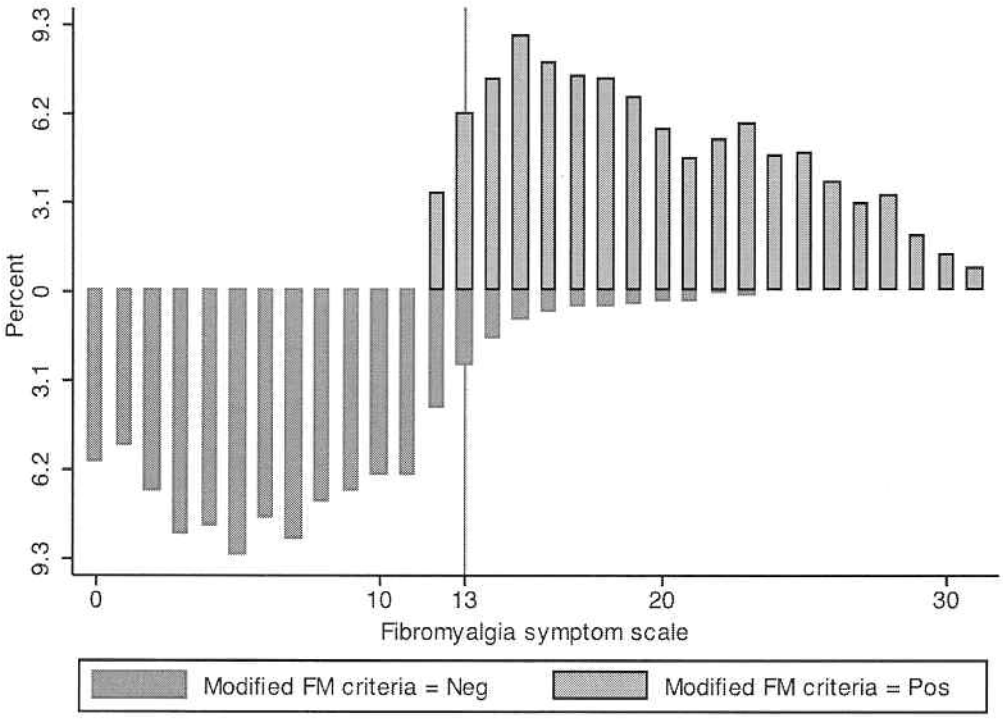

Figure 1. The distribution of fibromyalgia symptom scores in all patients according to whether they satisfy modified American College of Rheumatology 2010 criteria. Percentages separately reflect criteria+ and criteria– patients. There is a wide distribution of scores for each. The vertical line at 13 represents the optimum cutpoint that separates criteria+ and criteria– patients.

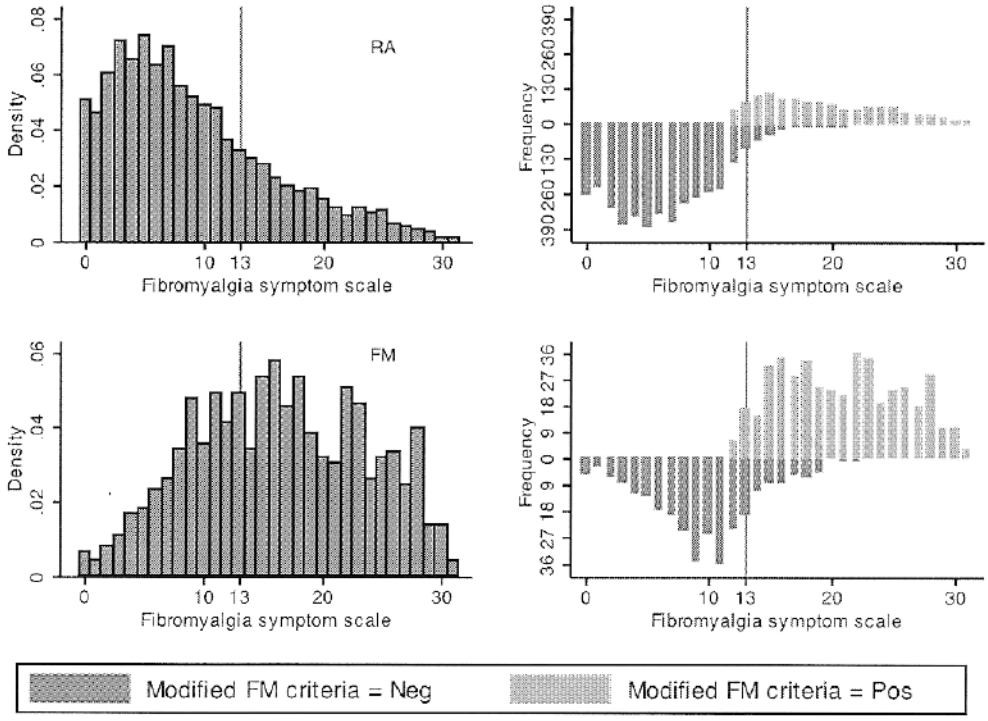

Figure 2. Fibromyalgia symptom scores in rheumatoid arthritis (above) and National Data Bank fibromyalgia (below). The vertical line at 13 represents the optimum cutpoint that separates criteria+ and criteria– patients.

Table 5. Pearson correlations between key study variables for all patients.

Variable	FS	WPI	SS (4)	Sleep	Fatigue	Symp (3)	Cog	Muscle Tenderness	Headache	Depression	Ab pain
FS	1.000	0.946	0.817	0.693	0.680	0.623	0.599	0.562	0.469	0.451	0.403
WPI	0.946	1.000	0.587	0.489	0.483	0.477	0.413	0.521	0.364	0.322	0.327
SS (4)	0.817	0.587	1.000	0.862	0.841	0.710	0.762	0.480	0.525	0.555	0.424
Sleep	0.693	0.489	0.862	1.000	0.717	0.448	0.539	0.403	0.334	0.367	0.246
Fatigue	0.680	0.483	0.841	0.717	1.000	0.410	0.525	0.374	0.304	0.344	0.218
Symp (3)	0.623	0.477	0.710	0.448	0.410	1.000	0.403	0.411	0.764	0.698	0.662
Cog	0.599	0.413	0.762	0.539	0.525	0.403	1.000	0.333	0.269	0.361	0.226
Muscle tenderness	0.562	0.521	0.480	0.403	0.374	0.411	0.333	1.000	0.324	0.273	0.275
Headache	0.469	0.364	0.525	0.334	0.304	0.764	0.269	0.324	1.000	0.276	0.283
Depression	0.451	0.322	0.555	0.367	0.344	0.698	0.361	0.273	0.276	1.000	0.203
Ab pain	0.403	0.327	0.424	0.246	0.218	0.662	0.226	0.275	0.283	0.203	1.000

FS: Fibromyalgia Symptom scale (0–31); WPI; Widespread Pain Index; SS (4): 4-item symptom severity scale; Sleep: unrefreshed sleep (0–3); Symp (3): 3-item symptom count scale composed of headache (0–1), self-reported depression (0–1), and pain or cramps in lower abdomen (colon; 0–1); Fatigue: fatigue severity scale (0–3); Cog: cognitive dysfunction severity scale (0–3); Muscle tenderness (0–1); Headache (0–1); Depression: self-reported depression (0–1); Ab pain: pain or cramps in lower abdomen (colon; 0–1).

and 35.6 (SD 9.8) for modified ACR 2010-negative patients with widespread pain.

DISCUSSION

The criteria presented in the Appendix permit FM to be identified and studied in survey research without the necessity of a physician examiner. We modified the ACR diagnostic criteria for fibromyalgia to be applicable to survey research and then applied the modified criteria to patients with rheumatic disease who were enrolled in a longitudinal observational study. Based on previous research, we expected to find that many patients with rheumatic disease would satisfy FM criteria and many patients with FM would not, and that is what we found.

Most estimates of FM in RA range from 12% to 15%[3,4,5,19], with 1 study reporting a prevalence of 57%[6]. A

Table 6. Pearson correlation between FM symptom scale, severity scale, and FIQR and individual FIQR domains.

Variable	FM Symptom Severity Scale	Severity Scale (SS)	FIQR[18]
All Patients			
FM Symptom Severity scale	1.000	0.817	
Severity scale	0.817	1.000	
Bodily pain (SF-36)	–0.668	–0.602	–0.68
Vitality – energy (SF-36)	–0.647	–0.723	–0.53
Social functioning (SF-36)	–0.624	–0.642	–0.54
General health (SF-36)	–0.568	–0.571	–0.57
Physical role (SF-36)	–0.559	–0.547	–0.54
Physical function (SF-36)	–0.533	–0.472	–0.71
Emotional health (SF-36)	–0.499	–0.577	–0.46
Emotional role (SF-36)	–0.460	–0.494	–0.39
NDB fibromyalgia patients			
FM Symptom Severity scale	1.000	0.768	
Severity scale	0.768	1.000	
Bodily pain SF-36)	–0.636	–0.560	–0.68
Vitality – energy (SF-36)	–0.567	–0.556	–0.53
Social functioning (SF-36)	–0.563	–0.649	–0.54
EQ-5D	–0.554	–0.550	
General health (SF-36)	–0.552	–0.610	–0.57
Physical role (SF-36)	–0.495	–0.499	–0.54
Physical function (SF-36)	–0.484	–0.420	–0.71
Emotional health (SF-36)	–0.433	–0.469	–0.46
Emotional role (SF-36)	–0.420	–0.500	–0.39

FM: fibromyalgia; SF-36: Medical Outcomes Study Short-Form 36; FIQR: Fibromyalgia Impact Questionnaire Revised; EQ-5D: EuroQol health measurement instrument.

prior study from the NDB using different criteria noted FM in 17.1%[7]. FM is "very common" in SLE[8], with 1 estimate as high as 40%[9]. With the modified ACR 2010 criteria, we identified FM in 21.1% of patients with RA and 36.7% of those with SLE. We found that 60% of patients with an NDB diagnosis satisfied the modified ACR 2010 criteria for FM. In the ACR diagnostic criteria FM study, about 25% of clinic patients diagnosed with FM did not meet the ACR 1990 FM classification criteria[1]. Although the overall course of patients diagnosed with FM is not clear, chronicity is often assumed, but considerable improvement may occur[20].

While the prevalence rates we found are consistent with other studies, observed prevalence depends not only on case selection, but on the specific criteria as well. The FS scale provides further insight into this issue. As shown in Figure 2, upper left panel, in "non-fibromyalgia" patients, the FS scale represents a continuum. The best cutpoint that separated FM-positive and FM-negative cases was 13, using the modified ACR 2010 criteria. The ACR 2010 diagnostic criteria increased the sensitivity to FM clinicians' diagnosis by about 18% compared with the ACR 1990 criteria[1]. In that study, 38% of patients satisfied ACR 1990 classification criteria and 45% satisfied the ACR 2010 diagnostic criteria. The change in diagnostic sensitivity is probably also reflected in the prevalence estimates in the NDB determined by modified ACR 2010 criteria.

The ACR 2010 FM diagnostic criteria introduced a

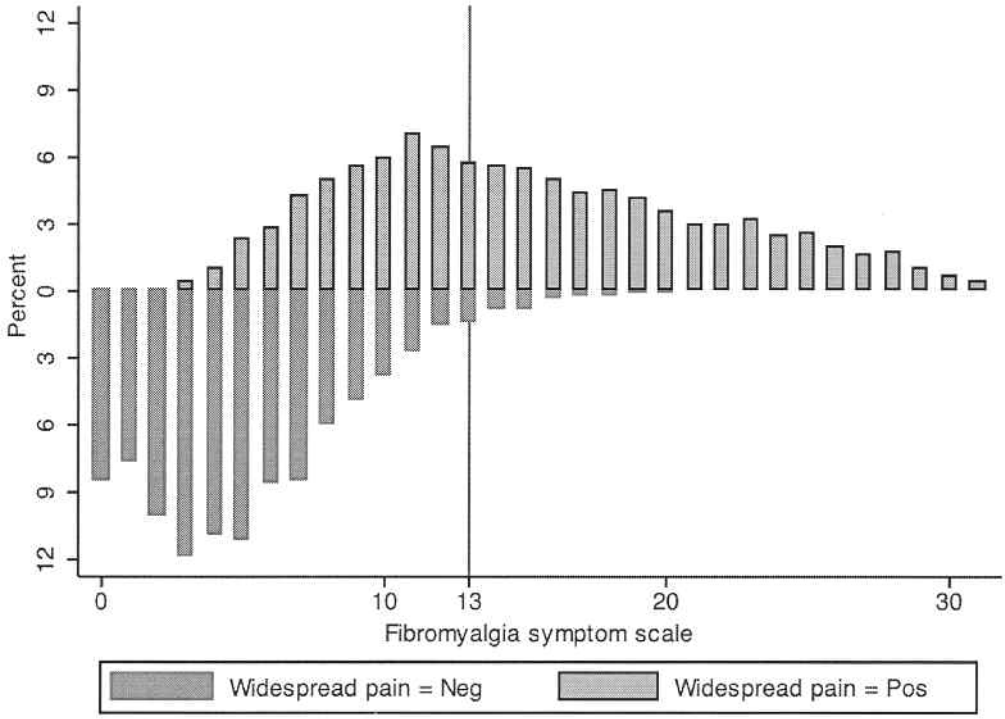

Figure 3. The distribution of fibromyalgia symptom scores in all patients according to whether they satisfy the American College of Rheumatology 1990 classification criteria for widespread pain. Percentages separately reflect widespread pain+ and widespread pain– patients. The vertical line at 13 represents the optimum cutpoint that separates the patients positive for widespread pain from the patients negative for widespread pain.

severity scale as part of FM diagnosis, and as a measure to evaluate symptom severity. The data of our study show that the modified 4-item scale of the modified ACR 2010 criteria works better than a 3-item scale; and by adopting the 4-item scale we allow the modified ACR 2010 criteria and the ACR 2010 SS scales to have the same scale length. We have suggested taking this scale further by combining the SS scale with the WPI. As shown in Table 3, the FS effectively measures the severity of the different clinical groups after the application of the modified ACR 2010 criteria. It also identifies differences among patients with FM (Figure 2, bottom) and among patients with RA (Figure 2, top right panel). This scale is similar to the SI that was based on the WPI and a VAS fatigue scale[16]. Wolfe and Rasker[16] reported that the SI scale was the best identifier of symptoms associated with FM content, including an increase in general medical symptoms. SI scale elevations were associated with increases in cardiovascular disorders, hospitalization, work disability, and death. Persons with socioeconomic disadvantage by reason of sex, ethnicity, household income, marital status, smoking, and body mass had increased SI scores. It appears that either conceptualization of FM symptoms will work. For research purposes and the understanding of pain syndromes, the FS offers the advantage of a continuous scale that is representative of the ACR 2010 diagnostic criteria.

The FS can also be applied directly to FM severity, enabling measurement within the group of FM-diagnosed patients. The median score among modified ACR 2010 criteria+ patients is 19, a value that could be a benchmark for FM severity. Other categorizations of the scale in modified ACR 2010+ patients are possible. If the FS is used without regard for FM diagnosis, it gives a broad picture of FM symptoms that spans the FM dichotomy and integrates such symptoms into rheumatic diseases and medicine generally as a measure of physical and psychological symptom intensity.

The FS and the 4-item severity scales can be compared to the FM-specific revised Fibromyalgia Impact Questionnaire (FIQR)[18]. As shown in Table 6, correlations between the FS, SS, FIQR, and the SF-36 domain scales were similar. The FS and SS scales might be more useful generally because they are not restricted to FM use, as is the FIQR. The FIQR total score is more strongly associated with the SF-36 physical function scale because the FIQR contains 9 functional questions and the FS and SS contain none. We strongly agree with the importance of functional status, but omitted it because our scales were designed primarily for aiding in diagnosis. We recommend the use of a functional scale such as the HAQ when comprehensive assessments are required.

The scales we have developed are not designed for assessment in clinical trials, where responsive questionnaires that access multiple domains are available[21,22].

The idea of FM as a part of a continuum has recently gained additional support from the work of Häuser and colleagues[23], who performed a detailed face-to-face population study of 2524 subjects that used the regional pain scale (WPI), comprehensive assessments of patient health, psychological distress, social support, and health-related quality of life. They found that the primary symptoms of FM existed in a continuum. They reported that the markers of physical and psychological distress were continuously distributed among the general population, and that FM is a clinical entity at the end of a continuum of biopsychosocial distress (i.e., physical and psychological symptom intensity). FS can be a way to characterize that continuum[23].

We also evaluated the relation between the modified ACR 2010, the FS, and widespread pain (Figure 3). A series of important pain studies have used the widespread pain criterion that was part of the ACR 1990 classification criteria[24,25,26,27,28,29,30]. Widespread pain, as a variable, has a substantial advantage over the ACR 1990 criteria because it can be used in epidemiologic research without requiring an examiner. In addition, its use does not require the acceptance of the ACR concept of FM[31,32]. Our study shows that adding the FS scale from the modified ACR 2010 criteria to the widespread pain criteria identifies patients who are at higher risk for adverse outcomes. The use of the modified ACR 2010 criteria study variables should allow additional refinement for studies based on widespread pain.

Among the limitations of our study was that we did not evaluate the possibility that patients might have had another disorder that could have caused their pain. However, all patients in the study had well characterized rheumatic diseases. It is important to note that rheumatic diseases do not usually cause pain that could be confused with FM; instead they most often coexist with FM. We also did not specifically inquire whether the patients' symptoms had been present for more than 3 months. However, patients entered the NDB study because they had ongoing symptoms.

The modification that we made to the ACR 2010 diagnostic criteria was to substitute a count of 3 symptoms for the physician's (0–3) evaluation of the extent of somatic symptom intensity. We did this because it was not reasonable to have patients evaluate their own degree of somatic symptom intensity. While it was possible to provide patients with checklists of many symptoms, this would have complicated the questionnaire. In addition, analysis of checklist data did not support such a method. The exact questions that we added — headache, pain or cramps in lower abdomen, and depression symptoms — were based on results from the ACR 2010 diagnostic criteria study and from suggestions in the literature[33,34]. While these items were not assessed for severity, their addition provided the measure of somatic symptom intensity. The exact wording of the depression question could be a matter of concern. In the context that we used the word depression, it meant depressive symptoms, feelings of depression, or depressed mood. It was not meant

APPENDIX. Fibromyalgia criteria modified from American College of Rheumatology diagnostic criteria.

Criteria

A patient satisfies modified ACR 2010 fibromyalgia diagnostic criteria if the following 3 conditions are met: (1) Widespread Pain Index ≥ 7 and Symptom Severity Score ≥ 5 or Widespread Pain Index between 3–6 and Symptom Severity Score ≥ 9. (2) Symptoms have been present at a similar level for at least 3 months. (3) The patient does not have a disorder that would otherwise sufficiently explain the pain.

Ascertainment

1). Widespread Pain Index (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.

Shoulder girdle, Lt.	Hip (buttock, trochanter), Lt.	Jaw, Lt.	Upper Back
Shoulder girdle, Rt.	Hip (buttock, trochanter), Rt.	Jaw, Rt.	Lower Back
Upper Arm, Lt.	Upper Leg, Lt.	Chest	Neck
Upper Arm, Rt.	Upper Leg, Rt.	Abdomen	
Lower Arm, Lt.	Lower Leg, Lt.		
Lower Arm, Rt.	Lower Leg, Rt.		

2). Symptom Severity Score: Fatigue; Waking unrefreshed; Cognitive symptoms.

For the each of these 3 symptoms, 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 Score is the sum of the severity of the 3 symptoms (fatigue, waking unrefreshed, and cognitive symptoms) plus the sum of the number of the following symptoms occurring during the previous 6 months: headaches, pain or cramps in lower abdomen, and depression (0–3). The final score is between 0 and 12.

to indicate a medical diagnosis of depression. The use of a single-item depression questionnaire has been reviewed and used in RA[35]. In that report we indicated that as evidence of validity, self-reported depression was significantly associated with the SF-36 mood and mental component summary score (MCS). The area under the ROC curve for mood was 0.826. The area under the ROC curve for the MCS scale was 0.823. Clinicians and investigators using these criteria should select words related to depression that capture the intent of the criteria in their assessment questionnaire.

The ACR 2010 diagnostic criteria and the modified ACR 2010 indicate that symptoms should be present for at least 3 months. The ACR 2010 criteria items, however, specify a shorter period of evaluation (7 days). Except for the 3 somatic symptoms, the modified ACR 2010 criteria also use the period of 7 days. This period was chosen because memory of pain and symptoms deteriorates with time. Importantly, Häuser and colleagues have shown that concordance of FM diagnosis according to survey criteria[36] after 8 weeks was 97.5% (test-retest reliability) in patients presenting with chronic pain in departments of rheumatology and pain medicine[37]. The survey criteria in that report were based on the WPI and a VAS fatigue scale[36]. These data offer support for the use of a 7-day frame for WPI assessment in patients presenting with chronic pain.

Survey criteria may be used in many different settings and circumstances, and it is not always possible or necessary to include criteria items 2 and 3 as specific questions: symptoms have been present at a similar level for at least 3 months, and the patient does not have a disorder that would otherwise sufficiently explain the pain. But is important to be sure that the questionnaire does not address a transitory condition. Where appropriate and needed, a question such as this might be added: "Have your problems with pain and symptoms been present for 3 months or more?" Such a question, of course, would not be needed if patients with a chronic disorder (e.g., RA) were being surveyed.

We have shown that a modification to the ACR 2010 FM diagnostic criteria will allow their use in epidemiologic and clinical studies without the requirement for a tender point examination. The criteria are simple to use and administer, but they are not to be used for self-diagnosis or as a substitute for a physician's diagnosis. In addition, we describe an FM symptom scale that appears to have wide utility beyond FM. For the time being, investigators can use the modified criteria or the ACR 2010 or 1990 criteria for diagnosis. Future studies should assess the acceptance, reliability, and validity of the modified ACR FM diagnostic criteria in epidemiologic and clinical studies in different levels of care.

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