A Questionnaire Using the Modified 2010 American College of Rheumatology Criteria for Fibromyalgia: Specificity and Sensitivity in Clinical Practice

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ABSTRACT. ***Objective.*** To determine the specificity and sensitivity of the Modified 2010 American College of Rheumatology (ACR) Diagnostic Criteria for Fibromyalgia (given as a self-administered questionnaire) in clinical practice.

Methods. A cohort of patients with widespread pain, referred by primary care physicians to rheumatologists, completed the questionnaire for the Modified ACR 2010 criteria. Prior to completion of the questionnaire, patients were diagnosed by at least 1 rheumatologist as either having fibromyalgia (FM) or not having FM, using the rheumatologist's clinical assessment as the gold standard for diagnosis of FM. The Modified ACR 2010 criteria were then applied to determine whether a diagnosis of FM was satisfied by the criteria. Sensitivity and specificity were determined, using the rheumatologist's clinical assessment as the gold standard. A score ≥ 12 on the Modified ACR 2010 criteria questionnaire was also tested as the criterion to satisfy a diagnosis of FM, and subsequently to determine sensitivity and specificity. We examined the effect of using a cutoff score ≥ 13, as previous research indicated that this may be a more useful cutoff value.

Results. A total of 451 subjects completed the questionnaire: 174 with an *a priori* diagnosis of FM by a rheumatologist and 277 with widespread pain who did not have an *a priori* clinical diagnosis of FM by a rheumatologist. The Modified ACR 2010 criteria were satisfied by 90.2% of patients with an *a priori* diagnosis of FM, and by 10.5% of subjects who had widespread pain, but were not diagnosed with FM when previously assessed by a rheumatologist. Thus, sensitivity and specificity are 90.2% and 89.5%, respectively, using the Modified ACR 2010 criteria. A score ≥ 12 on the Modified ACR 2010 criteria was observed in 97.4% of patients with an *a priori* diagnosis of FM, and 14.8% of subjects who had widespread pain, but were not diagnosed with FM when previously assessed by a rheumatologist. Thus, the sensitivity and specificity are 97.4% and 85.2%, respectively, using a cutoff score ≥ 12. Using a score of ≥ 13, however, the sensitivity was 93.1% and the specificity was 91.7%.

Conclusion. The Modified ACR 2010 criteria questionnaire can be used in primary care as a tool to assist physicians in the diagnosis of FM with high specificity and sensitivity. Calculating the total score on a Modified ACR 2010 criteria questionnaire, and setting the value of ≥ 13 as the cutoff for a diagnosis of FM appears to be the most effective approach. The Modified ACR 2010 criteria may reduce the need for rheumatology referral simply for the diagnosis of FM. (First Release July 1 2013; J Rheumatol 2013;40:1590–5; doi:10.3899/jrheum.130367)

Key Indexing Terms:
FIBROMYALGIA WIDESPREAD PAIN SPECIFICITY SENSITIVITY CRITERIA

While the pathophysiology of fibromyalgia (FM) continues to be debated, the diagnostic term itself is now generally accepted as useful, and it is no longer a diagnosis of exclusion. The 2012 Canadian Guidelines for the Diagnosis and Management of Fibromyalgia Syndrome[1] emphasize that the responsibility for the diagnosis and management of FM should be shifted from the specialist and concentrated in the primary care setting. The guidelines further emphasize that a diagnosis made in the primary care setting is an earlier diagnosis (i.e., not awaiting a referral to a specialist), which in turn avoids lengthy, costly, and unnecessary investigations, a cause for patient uncertainty that will prolong healthcare seeking behaviors and foster medicalization[2,3,4]. An early diagnosis will allow attention toward symptom management, attainment of optimal health, and maintenance or improvement of function.

There are a number of problems in achieving this goal. First, the gold standard for the diagnosis of FM has always been the rheumatologist's diagnosis, by whatever method that rheumatologist used. That is, the original 1990 American College of Rheumatology Criteria (1990 ACR

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criteria) for the diagnosis of FM were developed on the basis of assessment of patients diagnosed with FM by a select group of rheumatologists, using whatever criteria that collection of rheumatologists had then used to make this diagnosis. As a result, at least 20% of patients diagnosed by rheumatologists as having FM failed to meet the 1990 ACR criteria[5]. Despite this, the rheumatologist's diagnosis remains the gold standard. The 1990 ACR criteria were, in fact, not intended for use in clinical practice.

At the same time, the presentation of patients with FM may be confusing, sometimes with a single principal symptom and sometimes with a multitude. Symptom severity typically waxes and wanes over time. Patients with FM often report symptoms such as joint swelling that are not objectively apparent to the physician, and yet may raise the concern of the possibility of inflammatory arthropathy, needing confirmation by a specialist. In addition, while the 1990 ACR Criteria for FM have long been available, and have increasingly been used in clinical practice, they require the identification of tender points, an examination that is difficult to standardize[5].

Publication of the ACR preliminary diagnostic criteria for FM (ACR 2010 criteria) eliminated the tender point examination as a criterion[6]. This greatly facilitates the diagnostic process by eliminating the uncertainty surrounding the tender point examination. Yet the 2010 ACR criteria remain complex — they require an assessment of presence of symptoms and symptom severity by an interviewer, as well as determination of the number of regions of the body with pain. Using the 2010 ACR criteria, a diagnosis of FM is satisfied when the following 3 conditions are met: (1) the Widespread Pain Index is ≥ 7 and the Symptom Severity Score is ≥ 5, or the Widespread Pain Index is 3–6 and the Symptom Severity Score is ≥ 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. Beyond having to combine different scales, concerns have been raised by Wolfe, *et al* that "many patients with other rheumatic diseases would satisfy the ACR 2010 criteria had they been queried about symptoms of fibromyalgia," even though a rheumatologist would not label them as having FM[7].

To simplify this diagnostic process further, eliminating even the need for an interviewer, and to allow epidemiologic studies with no physician, a modification of the 2010 ACR criteria was made[7]. These modified criteria (Modified 2010 ACR criteria) eliminated the physician assessment of extent of somatic symptoms and allowed subjects to instead rate 3 specific self-reported symptoms. The criteria further create a total scale score (a Fibromyalgia Score; FS) that ranges from 0 to 31, by combining the Widespread Pain Index and the Symptom Severity Score. Researchers mailed out the questionnaire for the Modified 2010 ACR criteria to cohorts of patients with FM (diagnosed by a rheumatologist as the gold standard), osteoarthritis and other noninflammatory rheumatic conditions, systemic lupus erythematosus, and rheumatoid arthritis (RA). Although the Modified 2010 criteria for a diagnosis of FM could be satisfied when a score ≥ 12 was obtained, it was found that an FS ≥ 13 (out of a possible 31) provided a specificity of 91.8% and a sensitivity of 96.6% for a diagnosis of FM (using the rheumatologist's clinical assessment as the gold standard)[7]. This is impressive, given that this can be achieved through a self-administered questionnaire, and a diagnosis of FM can be made, for example, by a primary care practitioner based on this score alone, with assurance that a rheumatologist would concur with that diagnosis at least 92% of the time. The FS scale has been renamed the polysymptomatic distress scale[8], a reference to a broad use of this term by others to refer to a variety of clinical syndromes[9]. The term polysymptomatic distress scale (PDS) will be used in this report.

Because the study of specificity and sensitivity above was determined through a mail-out survey, it remains important to assess how well the Modified 2010 ACR criteria work in clinical practice. As well, it is important to determine whether simply using a total score cutoff of 12 or 13 from the PDS of the Modified 2010 ACR criteria is as effective, in terms of maintaining a high sensitivity and specificity for the diagnosis of FM. That is, instead of specifically ensuring that the Widespread Pain Index is ≥ 7 and the Symptom Severity Score is ≥ 5, or the Widespread Pain Index is 3–6 and the Symptom Severity Score is ≥ 9, as required by the Modified 2010 ACR criteria, one could simply look at the combined scores of the Widespread Pain Index and the Symptom Severity Score. If the total reaches a cutoff value of, for example, 12, one could also determine the sensitivity and specificity of this total score for the diagnosis of FM, regardless of how the total arises (i.e., how each of the Widespread Pain Index and the Symptom Severity Score contributes to the total score).

The purpose of our study was thus to determine the specificity and sensitivity of the Modified 2010 ACR criteria for the diagnosis of FM, specifically in patients with widespread pain referred to rheumatologists by primary care physicians. Further, we determined the specificity and sensitivity of using either the total ≥ 12 or ≥ 13 from combining the Widespread Pain Index and the Symptom Severity Score. Doing so is a step in determining the usefulness of the Modified 2010 ACR criteria for the diagnosis of FM in primary care. As well, comparing the sensitivities and specificities from these 3 ways of applying the Modified 2010 ACR criteria will act as a further guide to clinicians.

MATERIALS AND METHODS

Subject recruitment. During a 6-month period, subjects were recruited from 2 rheumatologists' practices in Edmonton, Alberta. The subjects were from referrals made by primary care practitioners, and these patients were typically referred with widespread pain. Subjects were typically referred

with questions about the diagnosis management, investigation, and treatment for the pain problem. Some patients had preliminary labels or queries of FM, and others did not.

Procedure. Upon referral, patients with widespread pain were diagnosed by the rheumatologists as either having FM or not. The rheumatologists' diagnosis of FM as the gold standard was conducted as per previous studies[5,6], according to each rheumatologist's individual methodology. After each patient with widespread pain was assessed and diagnosed by the rheumatologist, regardless of diagnosis, they were asked to complete the Modified 2010 ACR criteria questionnaire. The rheumatologist's diagnosis of FM (or not) was made independent of the questionnaire scores and was not subsequently modified by the scores. The diagnosis was not in all cases made at the first visit, but was nevertheless made independent of the scores from the Modified 2010 ACR criteria questionnaire. The questionnaires were given to the subjects after each consultation and collected and scored as a group several weeks after study completion. No attempt was made to determine interrater reliability for the diagnosis of FM among the 2 rheumatologists.

Instrument. The Modified 2010 ACR criteria questionnaire consists of 3 parts[1]. The first part asks the subject to use a scale from 0 to 3 to rate the symptoms (in the last week) of Fatigue, Trouble thinking or remembering, and Waking up tired (unrefreshed). The scores 0–3 correspond to no problem, slight or mild problems, moderate problems, and severe problems, respectively. The second part asks the subjects if, during the last 6 months, they have had any of "pain or cramps in lower abdomen," "depression," or "headache." The options are "yes" or "no," scored as "1" or "0," respectively. The third part of the questionnaire asks the subject to indicate in a list of regions of the body where they have had pain or tenderness over the past week. A total of 19 body regions, if any, may be selected. Combining these 3 parts, there can be a score range of 0–31 (maximum score 9 from part 1, maximum score 3 from part 2, and maximum score 19 from part 3). The instrument is self-administered on paper.

Inclusion/exclusion criteria. Following an initial assessment by history and physical examination, the authors screened all consecutively referred subjects for inclusion/exclusion criteria before having them complete the Modified 2010 ACR criteria questionnaire. Inclusion criteria included age over 18 years and referred with a pain disorder of > 3 months' duration. Exclusion criteria included unable to read English; less than grade 8 level education; suspected or known malignancy, vasculitis, bone disease causing bone pain, polymyositis; recent major surgery; objective neurologic signs (e.g., diminished or absent reflexes, muscle atrophy, muscle weakness); pain < 3 months' duration; and pain not meeting definition of widespread pain as per criterion I of the 2010 ACR criteria[5]. The diseases above were exclusions because they were not "benign" pain, and in many cases the patients were undergoing treatment that was likely to resolve their widespread pain. Subjects were not excluded if they had multiple diagnoses (e.g., both RA and FM diagnosed by a rheumatologist), because the objective of the study was to determine whether the Modified ACR 2010 criteria questionnaire would identify subjects labeled with FM (regardless of other diagnoses) and whether, equally, subjects lacking a diagnosis of FM would meet the criteria (i.e., measures to determine sensitivity and specificity, respectively). We repeated the above analysis for a cutoff ≥ 12 and ≥ 13, to ascertain how this affected the sensitivity and specificity, as an effect of increasing specificity was demonstrated in a mail-out survey when a cutoff score ≥ 13 was used[7].

Data collection. In addition to the instrument used, data were gathered regarding age and sex. For our study, no data were gathered on treatment or total duration of symptoms (beyond 3 months, a mandatory consideration for chronic widespread pain). Tender point count was not recorded.

Ethics approval was obtained from the College of Physicians and Surgeons of Alberta.

Data analysis. Mean, range, and SD were calculated for age, and sex distribution was noted for 2 resulting cohorts: an FM cohort who were diagnosed by the rheumatologists *a priori* as having FM and a non-FM cohort, determined *a priori* to not have FM when assessed by the rheumatologist. Specificity and sensitivity of the Modified 2010 ACR criteria score for the diagnosis of FM were determined using the rheumatologists' *a priori* diagnosis of FM as the gold standard, and determining the percentages of subjects who met the criteria for a diagnosis of FM set out in the Modified 2010 ACR criteria. That is, a diagnosis of FM is made through the Modified 2010 ACR criteria if the Widespread Pain Index is ≥ 7 and the Symptom Severity Score is ≥ 5, or the Widespread Pain Index is 3–6 and the Symptom Severity Score is ≥ 9. Examining the numbers of false positives and negatives arising, as compared to the gold standard diagnosis, allows for a determination of specificity and sensitivity of the Modified 2010 ACR criteria.

As there is a single score, the PDS score, that arises out of the Modified 2010 ACR criteria questionnaire, it is possible to determine the specificity and sensitivity of a PDS score for the diagnosis of FM. We thus determined the number of subjects with an *a priori* diagnosis of FM who also had a PDS ≥ 12 (true positives), as well the number of subjects without an *a priori* diagnosis of FM who had a PDS ≥ 12 (false positives). In calculating the sensitivity, the numerator was the number of subjects who had both a gold standard diagnosis of FM and a PDS score ≥ 12, while the denominator was all subjects with a gold standard diagnosis of FM. In calculating the specificity, the numerator was the number of subjects in the non-FM group who had a PDS score < 12, while the denominator was the number of subjects with a gold standard diagnosis of not having FM, as assessed by the rheumatologist. The above analysis was repeated for a cutoff score of ≥ 13.

RESULTS

Over the study period, a total of 515 patients with presumed widespread pain were seen by the 2 rheumatologists; 64 patients were excluded for the following reasons: 23 could not read English or had an education below grade 8; 22 failed to meet the definition for widespread pain according to criterion I of the 2010 ACR criteria[5]; 3 had metastatic disease, 1 polymyositis, 2 suspected systemic vasculitis, and 8 had objective neurological findings. Finally, an additional 5 subjects were excluded because they did not complete the instrument fully. Thus, a total of 451 subjects completed the Modified 2010 ACR criteria questionnaire.

Of the 451 subjects, 174 were given an *a priori* diagnosis of FM by the rheumatologist, 70 had an *a priori* diagnosis of RA without FM, and 207 had an *a priori* diagnosis of osteoarthritis and other noninflammatory rheumatic conditions (including whiplash-associated disorder grade 2[10]). Two of the subjects with RA also had a diagnosis of FM, and these were included in the group of 174 subjects with FM. Thus, the 2 groups comprised 174 with FM and 277 without FM. The FM group had a similar mean age to those in the previously studied group[7], and being predominantly female, are likely a representative sample of patients with FM.

Subject characteristics. The mean age and sex distribution of the subjects are shown in Table 1, with the cohort of 451 subjects divided into the FM and non-FM groups. As expected, the FM group was predominantly female. The mean PDS scores and range for each group are also shown.

Of 174 subjects with an *a priori* gold standard diagnosis of FM, 157 met the Modified 2010 ACR criteria, with either the Widespread Pain Index being ≥ 7 and the Symptom

Table 1. Demographics and fibromyalgia scores (per the 2010 Modified American College of Rheumatology Criteria questionnaire) for the fibromyalgia (FM) and nonfibromyalgia (non-FM) groups, determined by the rheumatologist's clinical assessment as the gold standard.

	FM Group, n = 174	Non-FM Group, n = 277
Age, mean yrs ± SD (range)	47.4 ± 10.6 (22–69)	44.9 ± 14.9 (18–85)
Sex (% females)	93.0	58.8
FM score, mean ± SD (range)	17.7 ± 4.0 (11–28)	10.6 ± 2.7 (5–21)

Severity Score being ≥ 5, or the Widespread Pain Index being 3–6 and the Symptom Severity Score being ≥ 9. This yields a sensitivity of 90.2% (157/174). However, of the 277 subjects without an *a priori* diagnosis of FM, 29 met the Modified 2010 ACR criteria stated above. This yields a specificity of 89.5% (248/277) for the diagnosis of FM (Table 2).

Of the 174 subjects with an *a priori* gold standard diagnosis of FM, 170 had a PDS score ≥ 12 (range 12–28), for a sensitivity of 97.7% (170/174). However, of the 277 subjects without an *a priori* diagnosis of FM, 41 had a PDS ≥ 12 (range 12–20). This yields a specificity of 85.2% (236/277) for the diagnosis of FM, using the Modified 2010 ACR criteria with a score ≥ 12 as the cutoff for diagnosis of FM (Table 3).

Table 2. Numbers of subjects in the fibromyalgia* (FM) and non-fibromyalgia* (non-FM) groups who met and did not meet the 2010 Modified American College of Rheumatology criteria** for FM, respectively.

Met the Criteria	FM Group, n = 174	Non-FM Group, n = 277
Yes	157	29
No	17	248

* Determined by the rheumatologist's clinical assessment as the gold standard. ** Widespread Pain Index is ≥ 7 and Symptom Severity Score is ≥ 5, or Widespread Pain Index is 3–6 and Symptom Severity Score is ≥ 9.

Table 3. Numbers of subjects in the fibromyalgia* (FM) and non-fibromyalgia* (non-FM) groups who met and did not meet the polysymptomatic distress scale (PDS) cutoff score of ≥ 12, respectively.

PDS Score	FM Group, n = 174	Non-FM Group, n = 277
≥ 12	170	41
< 12	4	236

* Determined by the rheumatologist's clinical assessment as the gold standard.

We repeated the above analysis with a PDS cutoff score ≥ 13 as the cutoff for a diagnosis of FM. Of the 174 subjects with an *a priori* gold standard diagnosis of FM, a total of 162 had a PDS score ≥ 13 (range 13–28), for a sensitivity of 93.1% (162/174). Of the 277 subjects without an *a priori* diagnosis of FM, 23 had a PDS ≥ 13 (range 13–20). This yields a specificity of 91.7% (254/277) for the diagnosis of FM using the Modified 2010 ACR criteria with a score ≥ 13 as the cutoff for a diagnosis of FM (Table 4).

DISCUSSION

In our study of a cohort of subjects with widespread pain referred from primary care physicians to rheumatologists, the specificity of the Modified 2010 ACR criteria for the diagnosis of FM (using a rheumatologist's assessment as the gold standard) was 89.5% and the sensitivity was 90.2%. In other words, if the primary care physician had used the Modified 2010 ACR criteria for diagnosis, his or her diagnosis of FM would agree with a rheumatologist's assessment 89.5% of the time. Alternatively, if a rheumatologist were to diagnosis FM, a primary care physician could expect that administration of the Modified 2010 ACR criteria would lead to the same diagnosis 90.2% of the time. Using a PDS score ≥ 13 as the cutoff, however, improved the specificity and sensitivity.

It is thus noteworthy that, in a sample of patients with widespread pain, if one simply totals the scores of the 2 scales of the Modified 2010 ACR criteria, and determines whether this sums to 13 or more, one achieves a specificity and sensitivity of 90.6% and 93.1%, respectively, for the diagnosis of FM. It is not necessary to specifically address whether the Widespread Pain Index is ≥ 7 and the Symptom Severity Score is ≥ 5, or the Widespread Pain Index is 3–6 and the Symptom Severity Score is ≥ 9. Doing the latter is more cumbersome, and indeed produces a lower sensitivity and specificity in our sample population. Calculating the total PDS score (the combined values of the Widespread Pain Index and the Symptom Severity Score) is simpler and may be more helpful than applying specific number limits to components of the Modified ACR 2010 criteria. This further raises the issue of whether a patient could be diagnosed with FM if they had numerous and severe somatic symptoms (i.e., achieved the maximum score of 12 on the Symptom

Table 4. Numbers of subjects in the fibromyalgia* (FM) and non-fibromyalgia* (non-FM) groups who met and did not meet the polysymptomatic distress scale (PDS) cutoff score of ≥ 13, respectively.

PDS Score	FM Group, n = 174	Non-FM Group, n = 277
≥ 13	162	23
< 13	12	254

* Determined by the rheumatologist's clinical assessment as the gold standard.

Severity Score) and 1 or 2 sites of pain. The Modified ACR 2010 criteria stipulate, however, that widespread pain is a criterion. A patient who has widespread pain, by definition, would score at least a 5 on the Widespread Pain Index. That is, they must have multiple sites of pain as well to have a diagnosis of FM.

By whatever method the Modified ACR 2010 criteria are used, the results are impressive, given that one is relying on a single measure, given at one point in time, with no consideration of further history, physical examination, or laboratory investigation. The Modified 2010 ACR criteria, like the original 2010 ACR criteria, do not require tender point assessment or laboratory investigation. The 2012 Canadian Guidelines for the Diagnosis and Management of Fibromyalgia Syndrome do suggest that FM should be diagnosed as a clinical construct, without any confirmatory laboratory test, and with testing limited to simple blood testing including a full blood cell count, erythrocyte sedimentation rate, C-reactive protein, creatine kinase, and thyroid-stimulating hormone. Indeed, it may be that adding the results of this additional assessment to the Modified 2010 ACR criteria will give primary care physicians the further confidence to avoid unnecessary referrals simply for diagnostic confirmation. Whether the use of laboratory testing (expected to be normal) would affect the specificity and sensitivity of the Modified 2010 ACR criteria, however, remains to be determined.

There are limitations to this study, including that the sample came from only 2 rheumatology practices. However, these 2 rheumatologists receive referrals throughout the catchment area of Edmonton, Alberta, and do not triage or restrict their practices (i.e., general rheumatology). An additional limitation, which has always been an issue in the development of criteria for the diagnosis of FM, is that the gold standard is the rheumatologist's diagnosis, which, although it may be similar among rheumatologists, is difficult to standardize. Nevertheless, what is clear is that if the Modified 2010 ACR criteria are used in primary care practice, the primary care physician will likely label patients as having FM or not, much as a rheumatologist would. The 1 proviso is that this can only be said to be true if the primary care physician used the questionnaire on a group of patients with widespread pain, as we have done. Note, however, that individuals without widespread pain are likely to have lower PDS scores, all else being equal, and thus, had we included them in our study we would have found an even greater specificity to the questionnaire for the diagnosis of FM. Indeed, although not reported above, when we applied the questionnaire to 32 subjects with regional pain syndromes, not a single subject of those 32 had a score above 11.

The use of the Modified 2010 ACR criteria may provide primary care physicians with greater confidence in diagnosis, and obviate the need for referral for diagnosis in most cases, as recommended in the 2012 guidelines[1]. Confirmation of the specificity and sensitivity of the questionnaire for a diagnosis of FM in the primary care setting will require studies conducted in primary care centers, with each case of a patient with widespread pain being evaluated by a primary care physician (using the Modified 2010 ACR criteria), and then subsequently evaluated by a rheumatologist as the gold standard. Future studies should also evaluate whether addition of the typically negative results of limited investigation to the Modified 2010 ACR criteria or additional questions concerning symptoms or symptom severity or depressive scales may further increase the specificity and sensitivity of these proposed criteria in primary care. Finally, despite the impressive specificity and sensitivity of this questionnaire for a diagnosis of FM, this should not detract from the need for a history and physical examination in patients with widespread pain, as indeed the 2010 Modified criteria require the physician to substantially understand the patient's symptoms, documenting the severity of symptoms and extent of pain. Physicians should not rely on the questionnaire alone for a diagnosis, and indeed they do not have to, given that they will have access, in most cases, to a great deal more historical, physical examination, and possibly laboratory data. Notably, the questionnaire does perform well on its own as a diagnostic tool. The diagnosis of FM is not always straightforward, but this questionnaire does provide a useful tool to assist the primary care physician. Further, FM may coexist and need to be managed alongside other pain conditions, another reason to screen for it in these other pain conditions, a task for which a questionnaire based on the Modified 2010 criteria is well suited[1].

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