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In May 2010, the American College of Rheumatology (ACR) released new criteria for the clinical diagnosis of Fibromyalgia (FM). The proposed criteria are provisional and will still need to be intermittently updated. For the last 20 years, besides having widespread pain on both sides of the body for at least 3 months, a patient needed to have pain (not just 'tenderness') present in 11 out of 18 specific tender point sites in order to be diagnosed with FM.

The new preliminary criteria recommend that the tender point examination be replaced with a combination of a wide pain index (WPI) and severity scale of symptoms (SS) as the revised standards for the diagnosis of FM.

The study supporting the revised criteria was published in the May 2010 issue of Arthritis Care & Research journal titled, The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity. The authors of the revised criteria are Frederick Wolfe, Daniel J. Clauw, Mary-Ann Fitzcharles, Don L. Goldenberg, Robert S. Katz, Philip Mease, Anthony Russell, I. Jon Russell, John B. Winfield, and Muhammad B. Yunus.

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Why new diagnostic criteria were needed

This major revision of the diagnostic criteria was precipitated by numerous shortcomings of the 1990 ACR standards. Dr. Robert M. Bennett of Portland, Oregon, one of the FM specialists who helped to create the original criteria, discussed some of these problems in a recent FM publication. Dr. Bennett stated that considerable skill is needed to correctly check for a patient's

tender points (i.e., digital palpation that is done with certain amount of applied pressure), yet this technique is not typically taught at most medical schools.

Many primary care physicians have been avoiding tender point examinations, or if the exams were performed, they might often have been done incorrectly. It is thought that a percentage of patients who likely have FM have not been diagnosed with it, either due to poor examination of their tender points or not having the minimum number of required tender points. As a result, physicians had already started to rely on symptoms commonly found in FM patients (i.e., sleep problems, decreased mental clarity, forgetfulness, and impaired function during daily activities) when making a diagnosis of FM, but with no consistent standards in place.

Other specialists mentioned in their criticisms: the excessive focus on tender points, which had not improved overall medical knowledge about the cause of pain in FM; that the examination of tender points also did not accurately measure the effectiveness of treatments (i.e., treatments which might help FM patients may not cause any changes to their tender points); that the fluctuation of pain and presence of many other symptoms had been long overlooked; and, that studies of FM were disproportionately limited to females.

One of the study authors, Dr. Robert S. Katz, a rheumatologist at Rush University Medical Center, elaborated on this discrepancy in a June 2010 issue of Science Daily, "The tender point test also has a gender bias because men may report widespread pain, but they generally aren't as tender as women. Fibromyalgia may be under-diagnosed in both men and women because of the reliance on 11 tender points, rather than considering other central features of the illness."

However, most researchers felt the old criteria had helped to bring the science and recognition of FM to where it stands today.

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The new criteria for FM diagnosis

The new criteria for FM diagnosis were developed during a 2010 study intended to create a simple, efficient and uniform standard that would be used in the clinical diagnosis of FM, and that would also be easy to use in primary and specialty care settings.

The new standards were designed to:

- eliminate the use of a tender point examination
- include a severity scale by which to identify and measure characteristic FM symptoms
- utilize an index by which to rate pain

Taking into consideration the amount of data that was analyzed at great length by the authors in the original research article, details for various statistics, tables and figures, and in-depth discussions were omitted from this report. A link to the full text of this report is provided at the end of this article (see More Resources). It may be worthwhile for patients to tell their doctors about this study and/or to print a copy of the article and review the new criteria with them. One chart in particular, Table 4 on page 607, provides a “snapshot” of the new fibromyalgia diagnostic criteria. This page could serve as a helpful reference sheet.

In short, the study concluded that the most significant diagnostic variables were the “widespread pain index” (WPI) and the categorical scales for cognitive symptoms, unrefreshing sleep, fatigue, and other somatic symptoms. These categorical scales were added up to create the “symptom severity score” (SS) scale.

Due to the study, the new case definition of Fibromyalgia will be made on the following criteria:

1. The values and ranges allowed for the WPI and the SS scales should meet one of the combinations: WPI >7 AND SS >5 or WPI 3–6 AND SS >9.
2. Symptoms have persisted at this level for the past 3 months.
3. Patient does not have any other disorder or cause to explain the pain

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How the new criteria were developed

The data for the creation of these criteria was attained through a multicenter study totaling 829 patients, which was conducted in two stages. Patients labeled as the FM group needed to have a previous diagnosis of FM and the control group were patients who had various non-inflammatory pain disorders. All patients in the study underwent physicals and interview assessments, and their pain levels were measured using a “widespread pain index” (WPI). Their symptoms were identified (from a predetermined list) and scored for severity (SS).

The first phase was designed to gather and examine a more extensive set of patient and physician variables and it served as the basis for the second phase. Phase 1 analysis used 3 groups of “classifier” variables: a short set, an intermediate set and a complete set.

Phase 1 of the study—data provided by patients. The first phase of the study started out with 610 patients, but 96 of these were rejected due to various protocol violations. Therefore, the first stage consisted of 514 patients and controls. Patients had to complete multiple forms with information about their pain and other symptoms, by specific categories, along with ratings for these symptoms based on what they had experienced during the preceding week (i.e., the data reflects what patients experienced for the duration of one week).

The summary below highlights the type of data provided directly by the patients:

- Which of 19 locations where they had pain during that particular week and also the rating of the pain according to a given scale—this is defined as the “widespread pain index” (WPI)

- Ratings on 4 visual analog scales for four key symptoms during that particular week such as the severity of pain that they had, how much of a problem had fatigue been, how much of problem had sleep been, and, how much of a problem waking up unrefreshed had been
- A Health Assessment Questionnaire II functional disability scale
- The number of medications they had used in the last month to control pain and to what extent they had experienced morning stiffness
- How many symptoms they had experienced in the last 3 months, from 56 designated, that are characteristic of FM

Phase 2 of the study—data provided by physicians. For the second phase, 315 patients and controls were added to the study group following the same methods and rules. In this phase, patients did not complete any questionnaires. Phase 2 forms were simplified and were completed only by the physicians. This was to determine if shorter forms and assessments would be as effective as the more detailed ones used in Phase 1. Information about the patients’ overall pain was scored by the physicians using the WPI, but the individual regions were not scored.

The summary below highlights the information that physicians had to provide for Phase 2:

- Information from tender point examinations which were required in this phase
- Whether these 3 distinctive symptoms were present or absent: muscle pain, muscle tenderness and/or irritable bowel syndrome
- Rating of the patients’ somatic symptoms (from a list of 41 symptoms)
- The categorical scales for 4 key symptoms: sleep disturbance, unrefreshing sleep, cognitive problems, and fatigue

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Results of the study

Results of study found that approximately 25% of FM patients did not meet the American College of Rheumatology (ACR) 1990 criteria.

This study was able to show that the new, simple clinical case definition of FM had correctly classified 88.1% of cases which had met the previous ACR criteria, without physical or tender

point examination.

An interesting discovery was that the 19 locations identified as probable areas of pain did not include any joints as sites for pain. The list of somatic symptoms made no mention of joint pain nor problems having to do with joints.

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Reaction by patients and physicians

The new case definition has been generating mixed reaction from patients and physicians. Initial reaction by patients was captured in a survey conducted by the Fibromyalgia Network. This survey revealed two major concerns that patients had: the amount of pain that someone would need to experience in a given area to result in a positive WPI value; and confusion caused by the dual approaches for symptom evaluation and rating.

For example, muscle pain or tenderness is rated by patients on the pain side of the equation. Almost 89 percent of the 4,500 participants in this independent survey felt they were able to meet the new criteria whereas 11 percent found themselves excluded, even though they had met the older ACR criteria. Some reasons for this discrepancy were that patients were receiving effective medical treatment or that patients already knew their triggers and had better coping skills.

While some patients with FM were left out, it was discovered that individuals who do not have FM were able to meet the new criteria. This raises an obvious concern about incorrect diagnosis of FM. Physicians are urged not to rely primarily on the measurement of symptoms without doing a thorough physical exam. Dr. Bennett strongly recommends that “a carefully structured physical examination should be part of any criteria for FM.”

The authors of this study agree that it has a number of limitations/shortcomings, and have recommended a follow-up study of patients with other rheumatic conditions in the primary care setting in order to narrow down the rate of misclassification when using this criteria.

Lilly Research Laboratories had funded this study, though it is reported that they did not participate in the design of the study.

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More resources

Full text of the article (PDF)

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