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ABSTRACT: Fibromyalgia syndrome (FMS) has been fraught with ambiguity in diagnosis, uncertainty in understanding of its pathophysiology, and difficulties for physicians in managing it competently. In 1990, classification criteria were published that emphasized a tender point examination requiring evaluation by specialists. Also, an erroneous impression that FMS is a “peripheral musculoskeletal disease” was created. Since then, there has been increasing recognition of central pain sensitization as the underlying neurobiological basis that explains most of the cardinal systemic symptoms. In 2010, the American College of Rheumatology (ACR) published new FMS diagnostic criteria suitable for the primary care setting that incorporated both peripheral pain and somatic symptoms. More recently, the ACR 2010 criteria have been further simplified to a survey format for use in epidemiological studies. (J Musculoskel Med. 2012;29:13-15)

Fibromyalgia syndrome (FMS)—a chronic pain condition that affects at least 2% of the adult population in the United States and other regions—has been fraught with ambiguity in diagnosis, uncertainty in understanding of the pathophysiology behind its myriad symptoms, and difficulties that physicians face in managing it competently. Chronic widespread pain used to be its defining feature, but patients also may exhibit a range of other symptoms, including sleep disturbance, fatigue, irritable bowel syndrome, headache, and mood disorders. The American College of Rheumatology (ACR) classification criteria, developed in 1990, helped galvanize research on FMS. The criteria required the presence of widespread pain in combination with 11 or more of 18 specific tender point sites. Widespread pain was defined as “3 out of 4 quadrant” pain, including left- and right-sided and upper- and lower-segment pain, and axial pain.

The 1990 ACR criteria required tender point examination—found to be a barrier in the primary care setting. Also, they created the erroneous impression that FMS is a peripheral musculoskeletal disease with the pathology centered on the tender points. Since then, understanding about the underlying pathophysiology of this complex pain syndrome has evolved and the need to develop new diagnostic criteria has grown.

This is the third in a series of articles that describe new or modified classification and diagnostic criteria for various rheumatologic conditions. The first article (“New Classification Criteria for RA,” The Journal of Musculoskeletal Medicine, November 2011, page 422) discussed recent revisions in rheumatoid arthritis classification criteria. The second article (“New Axial and Peripheral Spondyloarthritits Classification Criteria,” The Journal of Musculoskeletal Medicine, December 2011, page 454) reviewed the new classification criteria for the spondyloarthropathies. In this article, we discuss the new ACR diagnostic criteria for FMS and their modification as survey criteria.

The Use of New Criteria
Diagnosis of FMS is performed mostly in the primary care setting. However, tender point examination rarely is performed in this setting, and when it is performed, it often is done incorrectly. The 2010 ACR criteria were aimed at simplifying the diagnosis of FMS and being suitable for use in primary care practice without requiring a tender point examination. Another objective was to recognize the importance of the numerous nonpain symptoms of FMS, such as perceived cognitive impairment (“fibrofog”), fatigue, and sleep disturbance, in making the diagnosis. Also, the new diagnostic criteria were meant to objectively assess disease severity and to develop a method of longitudinally monitoring patients who subsequently may not satisfy classification criteria. These goals were not achievable with the older classification criteria.

The Process of Developing New Diagnostic Criteria
To develop the new criteria, Wolfe and colleagues conducted a 2-phase, case-control, multicenter study that involved more than 600 and 300 patients in phases 1 and 2, respectively. Cases were...
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defined as patients with a previous diagnosis of FMS. Diagnosis could be made on clinical grounds by a physician or by the 1990 classification criteria or both. Controls were age- and sex-matched patients with noninflammatory painful disorders, such as degenerative back pain and other regional pain syndromes, without a previous diagnosis of FMS. Of note, patients with inflammatory conditions, such as rheumatoid arthritis (RA), and those with other known painful conditions, such as cancer, fractures, and neuropathic pain, were excluded from the study.

Phase 1 evaluated an extensive set of FMS symptoms as study variables. Evaluating physicians were chosen randomly from a list of 113 ACR members, and 5 known experts in the field were added. The study variables included painful body areas and somatic symptoms. Phase 2 was designed to develop a practical questionnaire shortened from the long list of phase 1 variables.

For comparison, patients were divided into 3 groups: “current FMS” (ACR classification positive, physician FMS diagnosis positive); “prior FMS” (ACR classification negative, physician diagnosis positive); and “controls” (ACR classification negative, physician diagnosis negative). Study variables were analyzed in short, intermediate, and complete lists to devise a suitable-length questionnaire with an acceptable level of misclassification rates.

TABLE 1

ACR 2010 fibromyalgia diagnostic criteria

The misclassification rate for symptom variables when collected by a physician was 6% to 10%, compared with 13% with self-reported or patient-obtained data. It was decided that the ACR 2010 diagnostic criteria should be physician-assessed and not patient self-reported.

The model with an intermediate number of variables and categorical widespread pain index (WPI) value represented the best practical model; it had the lowest error rate, 7.3%. With the use of this model, a WPI value of 7 or higher best identified FMS cases and values of 6 or lower best identified noncases.

The most important diagnostic variables were WPI and categorical scales for cognitive symptoms, unrefreshed sleep, fatigue, and number of somatic symptoms. The categorical scales were summed to create a symptom severity (SS) scale value of 0 to 12. The SS scale and the WPI were then combined to form a new case definition of FMS: WPI of 7 or higher and SS of 5 or higher or WPI of 3 to 6 and SS of 9 or higher (Table 1).

Using the 1990 ACR classification criteria as the gold standard, the new 2010 ACR diagnostic criteria made the correct diagnosis in 83% of cases. However, about 9% of controls satisfied the new criteria, compared with 2% satisfying the old classification criteria. Overall, the FMS rate among all of the study patients increased from 38% to 45%.

Conceptual Differences From the Old Classification Criteria

The new diagnostic criteria shifted the FMS definition from a “peripheral pain”–defined disease to a “systemic symptoms”–based disease. In the new criteria, the somatic symptoms of FMS are accorded appropriate importance by the provision of the SS scale, which also provides a measurement of disease severity. Thus, these criteria may be satisfied by a high level of symptoms even if the WPI is not high.

Advantages Over the Old Classification Criteria

The new diagnostic criteria are a simple tool for use in the primary care setting. The older classification criteria involved a tender point count performed by an expert physician in specialty clinics and has been useful in achieving patient homogeneity for clinical trials. However, they have not been embraced widely in primary care.

The new case definition of FMS correctly classifies about 83% of cases without a physical or a tender point examination. This rate almost equals the 84% rate achieved by a physician diagnosis. The previous classification criteria did not have a provision for assessing severity or monitoring patients.
with a previous diagnosis of FMS. The SS scale allows for assessment of severity in patients with current or previous FMS and monitoring the disease course over time. TABLE 2

FMS survey criteria

Limitations of the New Diagnostic Criteria

The finding that as many as 25% of patients with physician-diagnosed FMS did not satisfy the 1990 ACR classification criteria was an important one. The new criteria do not solve this problem. Because inflammatory and other painful disorders were excluded, the new criteria cannot be applied to patients with RA, systemic lupus erythematosus, or other conditions.

The new criteria do not distinguish between primary and secondary FMS. The performance of these criteria in the primary care setting has not been validated by prospective studies. It could be argued that making a diagnosis of a condition without physical examination probably will miss important physical findings and other potential causes for patients’ symptoms. In addition, these criteria still rely on clinical grounds and do not incorporate any objective laboratory or imaging data in making the diagnosis, although currently no objective parameters are widely accepted for routine use in clinical practice.

2011 Modification of the ACR 2010 Diagnostic Criteria

To develop an FMS model for use in surveys and epidemiological studies, the same authors further modified the 2010 criteria to make it completely patient-driven, avoiding the need for physicians’ input. In essence, they eliminated the physician’s estimate of the extent of somatic symptoms (point B in Table 1), substituting it with the sum of 3 specific self-reported symptoms (Table 2). In addition, they created a 0 to 31 FMS symptom scale (FS) by adding the WPI to the modified SS scale, which measures what the authors call the overall “fibromyalgianess” of a patient. The FS scale was found to be the best univariate predictor of FMS. An FS score of 13 or higher best separated modified ACR 2010 criteria–positive and criteria–negative patients, classifying 93% correctly, with a sensitivity and specificity of more than 90% each.

Removing the physician from the diagnosis-making process and relying on patients to fill out questionnaires to self-diagnose a condition has its own problems. Therefore, these criteria warrant further epidemiological and clinical studies to assess their acceptance, reliability, and validity.

References:

REFERENCES


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