

# Fibromyalgia Diagnosis: Moving Beyond Tender Points

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**F**ibromyalgia (FM) is a disabling, widespread pain disorder affecting 3.4% of women and 0.5% of men in the United States.<sup>1</sup> Despite its prevalence and the availability of effective treatments, 75% of people in the general population with FM remain undiagnosed.<sup>1</sup> New FM diagnostic criteria promise to simplify diagnosis and improve patient recognition.<sup>2</sup>

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The word *diagnosis* is derived from Greek, meaning to discern or distinguish. As it pertains to medicine, diagnosis is the process of determining the cause of signs or symptoms experienced by a patient. Diagnosis is typically made by a combination of patient history, physical examination, and various other evaluations (eg, laboratory, imaging, and electrical tests). Given the wide array of expensive and potentially toxic treatments available in modern medicine, accurate diagnosis is vital for providing cost-effective and safe therapy that effectively manages patient symptoms. Although technological advances have simplified the identification of many disorders, diagnosis of FM remains challenging for many providers. Like depression, FM is a subjective disorder and no objective diagnostic tests exist to aid patient identification.

FM diagnosis is dependent on careful evaluation by a clinician familiar with the pattern of signs and symptoms characteristic of the disorder. However, diagnosis is complicated because as a group, patients with FM are heterogeneous and individual patients often present with different symptoms. Also, these patients often have difficulty relaying their symptoms in a coherent framework that allows clinicians to form the correct diagnosis. Further complicating diagnosis is the fact that FM rarely occurs in isolation and patients commonly suffer from multiple other related conditions that can obfuscate diagnosis (eg, migraine headaches, temporomandibular joint syndrome, irritable bowel syndrome, and chronic fatigue syndrome).

## A Brief History of FM Diagnosis

Although descriptions of the complex symptoms now termed FM have existed since earliest recorded history, the terminology used to refer to the condition has changed numerous times. The first specific term, *muscular rheumatism*, was used in the early 19th century by surgeon William Balfour to describe a condition comprising disturbed sleep, fatigue, stiffness, and pain for which there was no explanation.<sup>3</sup> Balfour later described anatomic tender points accompanying the disorder that could be used in identification. In 1880, neurologist George Beard coined a new term, *neurasthenia*, characterized by a combination of symptoms including fatigue, widespread pain, and anhedonia.<sup>4</sup> In 1904, Gowers renamed the disorder *fibrositis* due to his incorrect belief that the disorder was caused by inflammation in muscle fascia.<sup>5</sup> Despite subsequent evidence that FM was not an inflammatory condition, *fibrositis* was used to refer to the condition until Yunus coined the modern term *fibromyalgia* in his seminal 1981 article that proposed a combination of historical symptoms and tender points that could discriminate patients with FM from normal controls.<sup>6</sup> In 1983, Campbell et al proposed a symptom questionnaire to differentiate these two groups.<sup>7</sup>

Wolfe stressed the importance of using tender points to discriminate FM from other musculoskeletal diseases in his work during the same time period.<sup>8,9</sup> In his 1987 article in the *Journal of the American Medical Association*, Goldenberg combined the work of Yunus and Wolfe with his own to propose FM diagnostic criteria that included 3 obligatory criteria:

1. Chronic, generalized aches, pains, or stiffness involving 3 or more anatomic sites for at least 3 months.
2. The presence of multiple tender points at characteristic locations.
3. The absence of another systemic condition that could account for the symptoms.

These were considered along with some combination of 6 characteristic minor criteria:

1. Disturbed sleep.
2. Generalized fatigue or tiredness.
3. Subjective swelling and numbness.
4. Pain in the neck and shoulders.
5. Chronic headaches.
6. Irritable bowel symptoms.<sup>10</sup>

## 1990 ACR Classification Criteria

By 1990, numerous criteria for defining FM had been proposed but agreement on a standard had not been reached. The 1990 American College of Rheumatology (ACR) FM classification criteria were designed to standardize patient populations for research to ensure reproducibility between studies.<sup>11</sup> The study that defined the classification criteria differed from many previous studies because rather than comparing patients with FM with normal healthy controls, FM patients were compared with patients who had other painful rheumatic conditions, including inflammatory diseases such as rheumatoid arthritis and lupus. This had important implications for the results because, despite a very high percentage of patients with FM in the study having symptoms of fatigue and poor sleep quality, the differences in symptom prevalence between these patients and patients with other rheumatic conditions was not sufficient to differentiate them. In addition to the requirement that patients with FM have pain that was both chronic ( $\geq 3$  months duration) and widespread (occurring on both sides of the body both above and below the waist and including the axial skeleton), the criteria that best differentiated patients with FM was the presence of pain with examiner palpation of 4 kg/cm<sup>2</sup> force on at least 11 of 18 standardized tender points arrayed symmetrically from the base of the skull to just above the knees. Although never intended for diagnostic use, the ACR FM classification criteria went on to become the most common method for identifying patients with FM in the clinic (Table 1).

**Table 1. Fibromyalgia Diagnostic Criteria: Physician Assessment**

Criteria			
A patient satisfies diagnostic criteria for fibromyalgia if the following 3 conditions are met:			
1) Widespread pain index (WPI) $\geq 7$ and symptom severity (SS) scale score $\geq 5$ or WPI 3-6 and SS scale score $\geq 9$ .			
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 explain the pain.			
Ascertainment			
1) 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, left	Hip (buttock, trochanter), left	Jaw, left	Upper back
Shoulder girdle, right	Hip (buttock, trochanter), right	Jaw, right	Lower back
Upper arm, left	Upper leg, left	Chest	Neck
Upper arm, right	Upper leg, right	Abdomen	
Lower arm, left	Lower leg, left		
Lower arm, right	Lower leg, right		
2) SS scale score:			
Fatigue			
Waking unrefreshed			
Cognitive symptoms			
For each of the 3 symptoms above, indicate the level of severity over the last 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			
Considering somatic symptoms in general, indicate whether the patient has: <sup>a</sup>			
0 = no symptoms			
1 = few symptoms			
2 = a moderate number of symptoms			
3 = a great deal of symptoms			
The SS scale score is the sum of the severity of the 3 symptoms (fatigue, waking unrefreshed, cognitive symptoms) plus the extent (severity) of the somatic symptoms in general. The final score is between 0 and 12.			

<sup>a</sup>Somatic symptoms that might be considered are: muscle pain, irritable bowel syndrome, fatigue/tiredness, trouble thinking or remembering problem, muscle weakness, headache, pain/cramps in the abdomen, numbness/tingling, dizziness, insomnia, depression, constipation, pain in the upper abdomen, nausea, nervousness, chest pain, blurred vision, fever, diarrhea, dry mouth, itching, wheezing, Raynaud's phenomenon, hives/welts, ringing in ears, vomiting, heartburn, oral ulcers, loss of/change in taste, seizures, dry eyes, shortness of breath, loss of appetite, rash, sun sensitivity, hearing difficulties, easy bruising, hair loss, frequent urination, painful urination, and bladder spasms.

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## FM Diagnostic Criteria: Physician Assessment

Although the requirement for patients with FM to have chronic and widespread pain was universally accepted, the tender point exam has been controversial since its inception.<sup>12</sup> The exam is difficult to perform and, even when done correctly, fails to identify nearly half of clinically diagnosed patients with FM.<sup>13</sup> The tender point criteria are particularly problematic in identifying men with FM because they typically experience fewer painful tender points than women.<sup>14</sup> Tender points also have questionable specificity, as at least 11 painful tender points can be found in 5% of the healthy population and appear to be an indicator for general distress levels and not a specific indicator of FM.<sup>15,16</sup> For these and other reasons, an alternative to the tender point exam for FM diagnosis was developed and has been provisionally accepted by the ACR.<sup>2</sup>

These diagnostic criteria are symptom-based and do not require a physical examination. In the development study for the diagnostic criteria, patients with FM were compared with age- and gender-matched controls with non-inflammatory and non-neurologic pain conditions (eg, degenerative disk disease, osteoarthritis, and tendonitis). Patients with inflammatory rheumatic disorders or neuropathic pain were excluded from the study. These exclusions may be the reason that symptom-based criteria were able to differentiate patients in the diagnostic criteria study but not in the classification study as that study included control patients with inflammatory conditions and did not exclude patients with nerve pain.

Patients and controls in the diagnostic criteria study were evaluated by questioning to determine scores on a widespread pain index (WPI) and a symptom severity (SS) scale. The WPI quantified the extent of bodily pain on a 0 to 19 scale by asking patients if they had pain or tenderness in 19 different body regions (shoulder girdle, hip, jaw, upper arm, upper leg, lower arm, and lower leg on each side of the body, as well as upper back, lower back, chest, neck, and abdomen) over the past week, with each painful or tender region scoring 1 point. The SS scale quantified symptom severity by scoring problems with fatigue, cognitive dysfunction, and unrefreshed sleep over the past week, each on a scale from 0 (*no problem*) to 3 (*severe problem*) and summing these along with a measure of the physician's impression of the number of somatic symptoms the patient had on a scale from 0 (*no symptoms*) to 3 (*a great deal of symptoms*) to yield a 0 to 12 score. A patient was diagnosed with FM if:

1. The WPI was at least 7 and the SS scale score was at least 5 or the WPI was 3 to 6 and the SS scale score was at least 9.
2. The symptoms had been present at a similar level for at least 3 months.

3. The patient did not have another disorder that would otherwise explain his or her pain (Table 1).<sup>2</sup>

## FM Diagnosis: Patient Self-Assessment Questionnaire

Although the FM diagnostic criteria do not require a physical examination, symptom severity in the validation study was scored by a physician. However, because FM is a subjective disorder, patients are the ultimate source of information on the severity of their symptoms. Physicians tend to underestimate patient symptom severity,<sup>17</sup> and physician scoring of symptom severity could therefore lead to underdiagnosis. By their nature, the FM diagnostic criteria are amenable to administration as a patient self-report questionnaire that could limit underdiagnosis and speed clinical evaluation because patients could complete the assessment prior to entering the exam room.

Such a self-administered patient questionnaire based on the FM diagnostic criteria has been shown to accurately identify patients with FM (Table 2).<sup>18</sup> This questionnaire was divided into 3 sections. Section 1 assessed the distribution of bodily pain using the same 19 body areas as in the WPI, with patients marking each area yes or no to indicate the presence of pain or tenderness in that area over the past week. Patients received 1 point for each painful or tender body area, yielding a self-report WPI score between 0 and 19 (analogous to the WPI score in the physician-assessed diagnostic criteria). Section 2 separately evaluated the severity of problems with daytime fatigue, restorative sleep, and dyscognition (trouble thinking and remembering) on a scale from 0 (*no problem*) to 3 (*a severe problem*). Section 3 asked patients whether they had experienced pain or cramps in the lower abdomen, depression, or headache during the past 6 months, with patients scoring 1 point for each positive symptom. Scores from the second and third sections were summed to yield a 0 to 12 SS scale score analogous to the SS scale score in the physician-assessed diagnostic criteria. As in the physician-assessed diagnostic criteria, the patient was diagnosed with FM using the patient self-assessment scale if:

1. The WPI was at least 7 and the SS scale score was at least 5 or the WPI was 3 to 6 and the SS scale score was at least 9.
2. Symptoms had been present at a similar level for at least 3 months.
3. The patient did not have another disorder that would otherwise explain his or her pain.

Additionally, a 0 to 31 FM symptom (FS) scale was calculated by summing the WPI and SS scale scores. The FS scale accurately quantified the global severity of FM symptoms and scores of at least 13 were highly correlated with a diagnosis of FM.

**Table 2. Patient Self-Report Questionnaire for FM Diagnosis<sup>18</sup>**

**Below is a list of body areas. Please check Yes or No to indicate whether or not you have had PAIN or TENDERNESS in each area OVER THE PAST WEEK. ANSWER ALL AREAS YES OR NO.**

Right Side	Yes (1)	No (0)	Trunk	Yes (1)	No (0)	Left Side	Yes (1)	No (0)
Jaw			Neck			Jaw		
Shoulder			Upper back			Shoulder		
Upper arm			Chest			Upper arm		
Lower arm			Abdomen			Lower arm		
Hip/buttock			Low back			Hip/buttock		
Upper leg			OFFICE USE ONLY:  Widespread Pain Index (WPI) (0-19) _____ Lower leg			Upper leg		
Lower leg								

**Please circle the number that best indicates the severity of each symptom OVER THE PAST WEEK**  
**where 0 = no problem; 1 = slight or mild problem, generally mild or intermittent;**  
**2 = moderate, considerable problem, often present and/or at a moderate level; and**  
**3 = severe, continuous, life-disturbing problem.**

SYMPTOM	No problem	Moderate	Severe
Fatigue or tiredness throughout the day	0	2	3
Waking up tired or unrefreshed	0	2	3
Trouble thinking or remembering	0	2	3

**Please check Yes or No to indicate whether or not you have experienced any of the following symptoms OVER THE PAST 6 MONTHS. ANSWER ALL SYMPTOM QUESTIONS YES OR NO.**

SYMPTOM	Yes (1)	No (0)
Pain or cramps in the lower abdomen		
Depression		
Headache		

OFFICE USE ONLY:  
 Symptom Severity (SS) Scale (0-12) \_\_\_\_\_ FS Scale (WPI + SS Scale) (0-31) \_\_\_\_\_

WPI ≥7 and SS Scale ≥5 or WPI 3-6 and SS Scale ≥9. Symptoms present at similar level for ≥3 months. No other disorder that would explain the pain.

Adapted from Wolfe F, et al. *J Rheumatol.* 2011;38(6):1113-1122.

### Table 3. Differential Diagnosis of Fibromyalgia<sup>2</sup>

**Psychological disorders:** major depressive disorder, generalized anxiety disorders, bipolar disease, somatoform disorders

**Hematologic disorders:** anemia, leukemia, lymphoma, sickle cell disease

**Endocrinologic disorders:** thyroid disease, hyperparathyroid disease, Paget's disease, Cushing's disease, diabetes

**Autoimmune disorders:** polymyalgia rheumatica, rheumatoid arthritis, systemic lupus erythematosus, Sjogren's syndrome, Behcet's disease, sarcoid, vasculitides

**Infectious diseases:** HIV, hepatitis, parvovirus, Lyme disease, Epstein-Barr virus, cytomegalovirus, urinary tract infection

**Neurologic disorders:** multiple sclerosis, myasthenia gravis, peripheral neuropathy

**Miscellaneous conditions:** obstructive sleep apnea, periodic limb movement disorder, restless legs syndrome, cancer, renal disease, vitamin deficiencies (eg, B<sub>12</sub>, folate, D), celiac disease (sprue), Chiari malformation, drug and alcohol abuse

### The Importance of Differential Diagnosis

The new FM diagnostic criteria differ from the prior classification criteria in that they define FM as a diagnosis of exclusion; they do not allow FM to be diagnosed if the patient has another disorder that could otherwise explain his or her pain. This exclusionary requirement is very important, as many other disorders can mimic FM and the need to rule out other causes is the reason patient self-diagnosis is not allowed under the new criteria. The differential diagnosis of widespread pain is broad and includes numerous psychological, hematologic, endocrinologic, autoimmune, infectious and neurologic disorders; cancer; and vitamin and mineral deficiencies (Table 3).<sup>2</sup> Patients under evaluation for FM should be subjected to a thorough history and physical examination along with a laboratory evaluation appropriate for their symptoms. A typical laboratory evaluation includes a complete metabolic panel with liver function testing, a complete blood count with differential, thyroid function tests, 25 hydroxyvitamin D level, magnesium, B<sub>12</sub>, folate, and

iron studies (including iron, total iron-binding capacity, percent iron saturation, and ferritin). Although an erythrocyte sedimentation rate (ESR) often is recommended, given that the upper limit of normal for women is one half their age and non-inflammatory conditions can increase the ESR (including obesity, which is common in patients with FM), the ESR is usually only helpful in ruling out an inflammatory condition rather than as evidence for one. Patients also should be screened for the presence of psychological disorders that could cause or exacerbate FM symptoms, including depression, anxiety, and bipolar disorder, as well as sleep disorders such as obstructive sleep apnea and restless legs syndrome/periodic limb movement disorder. Finally, because cancer can present with widespread pain, patients should have all appropriate cancer screenings.<sup>19</sup> However, it is important to realize that effective treatment of a discovered condition often will not improve pain, and if a possible cause of symptoms is treated and the patient remains symptomatic, FM should be diagnosed and treated.

### Conclusion

FM is a common, but underdiagnosed, widespread pain disorder. New FM diagnostic criteria simplify diagnosis because a tender point exam is no longer required. Patients can be diagnosed under the diagnostic criteria either by direct physician evaluation or through use of a self-report questionnaire. However, because of the large number of mimicking disorders, FM remains a diagnosis of exclusion and a thorough evaluation for other conditions should be performed before patients are diagnosed and treated symptomatically for FM.

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