Clinical manifestations and diagnosis of fibromyalgia in adults

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INTRODUCTION

Fibromyalgia (FM) is the most common cause of chronic widespread musculoskeletal pain, often accompanied by fatigue, cognitive disturbance, psychiatric symptoms, and multiple somatic symptoms [1,2]. The etiology of the syndrome is unknown, and the pathophysiology is uncertain [1,2]. Despite symptoms of soft tissue pain affecting the muscles, ligaments, and tendons, there is no evidence of inflammation in these tissues.

FM, like many other common chronic pain syndromes, has been a controversial condition [1,2]. Patients look well, there are no obvious abnormalities on physical examination other than widespread soft tissue tenderness, and laboratory and radiologic studies of musculoskeletal structures are normal. Thus, the role of organic illness had been questioned, and FM has often been considered by some to be psychogenic or psychosomatic. However, ongoing research suggests that FM is a disorder of pain regulation, often classified as a form of central sensitization [3]. (See "Pathogenesis of fibromyalgia".)

FM is often associated with other conditions that may cause musculoskeletal pain, disruption of sleep, or psychiatric symptoms; features of these conditions may also mimic FM, and the presence of such disorders should be considered in the diagnostic evaluation. (See "Differential diagnosis of fibromyalgia".)

The clinical manifestations and diagnosis of FM will be reviewed here. The differential diagnosis of FM is discussed in detail separately, as are the presentation and impact of chronic widespread pain (CWP) in other musculoskeletal diseases, the possible pathogenic mechanisms and treatment of FM in adults, and the clinical manifestations, diagnosis, and

treatment of FM in children and adolescents. (See "Differential diagnosis of fibromyalgia" and "Overview of chronic widespread (centralized) pain in the rheumatic diseases" and "Pathogenesis of fibromyalgia" and "Initial treatment of fibromyalgia in adults" and "Treatment of fibromyalgia in adults not responsive to initial therapies" and "Fibromyalgia in children and adolescents: Clinical manifestations and diagnosis" and "Fibromyalgia in children and adolescents: Treatment and prognosis overview".)

EPIDEMIOLOGY

Fibromyalgia (FM) is a common cause of chronic pain and the most common cause of generalized, musculoskeletal pain in women between ages of 20 and 55 years; in the United States and in other countries, the prevalence is approximately 2 to 3 percent and increases with age [4-7]. Initially termed fibrositis, FM was described in France and England in the mid-19th century. By the end of the 20th century, many rheumatologists recognized FM as a discrete syndrome, and diagnostic classification criteria were proposed, evaluated, and then validated. FM is more common in women than men and occurs in both children and adults [4-8]. It is six times more common in women in reports from specialty clinics, although the female predominance is not as striking in the community and when using survey criteria that do not require a tender point examination [6].

The diagnosis may be under-recognized in clinical practice. Prevalence estimates vary greatly with the specific diagnostic criteria applied. The prevalence of FM was much higher using surveys with standardized criteria than estimates based upon medical record documentation of the diagnosis (6.4 versus 1.1 percent) [4]. Prevalence studies in adolescents have been very similar to those in adults [8]. A United Kingdom population study found a prevalence of chronic widespread pain (CWP) of 14 percent and FM of 5 percent [9]. In a National Health Service electronic health records survey in the United Kingdom, there was an increase in the diagnosis of FM for the period 2001 to 2013 compared with 10 years earlier [10].

Ten to 15 percent of the general population have CWP and do not have any specific disease or structural abnormality to account for the pain [7,9,11]; there is no clear boundary separating those who meet criteria for FM from the larger pool of people with CWP (figure 1) [7,9,11]. FM, also termed by some as CWP, as well as conditions such as chronic low back pain, may be conceived as diseases in their own right, termed "chronic primary pain" according to the new International Classification of Diseases (ICD-11) [12].

CLINICAL MANIFESTATIONS

Fibromyalgia (FM) is characterized by widespread musculoskeletal pain, accompanied by other somatic symptoms, particularly fatigue and sleep disturbances, as well as cognitive

and psychiatric disturbances (table 1) [1,2,5,7,13] (see 'Symptoms' below and 'Other common symptoms' below). Physical examination reveals tenderness in multiple soft tissue anatomic locations (see 'Physical findings' below). Laboratory testing is normal in the absence of other illnesses. (See 'Laboratory testing and other studies' below.)

Some disorders are seen in greater frequency in patients with FM than in the general population. Certain of these conditions may cluster with FM and have some common pathophysiologic features, such as irritable bowel syndrome (IBS) and migraine. Additionally, certain features of other commonly associated disorders may simulate or exacerbate the symptoms of FM, such as musculoskeletal pain in patients with chronic forms of arthritis; and sleep disturbance and fatigue in patients with depression, obstructive sleep apnea, or restless legs syndrome. (See 'Coexisting disorders' below and "Overview of chronic widespread (centralized) pain in the rheumatic diseases".)

Symptoms — The core symptoms of FM are generalized pain, fatigue, and sleep disturbances, present for at least three months and not explained by any other medical condition (table 1) [13].

- **Widespread musculoskeletal pain** – The cardinal manifestation of FM is chronic widespread pain (CWP), also termed multisite pain (MSP) [5-8,13]. A 2018 report from an expert working group suggested using MSP rather than CWP to define pain in FM (figure 2) [13]. Typically, at least six sites are involved in patients with FM, which may include the head, each arm, the chest, the abdomen, each leg, the upper back and spine, and the lower back and spine (including the buttocks).

  Sometimes the pain may initially be localized, often in the neck and shoulders. Common patient descriptions include "I feel as if I hurt all over" or "It feels as if I always have the flu." Patients typically describe pain predominantly throughout the muscles, but often state that their joints hurt, and sometimes describe joint swelling, although synovitis is not present on examination [1,2,13].

- **Fatigue and sleep disturbances** – Moderate to severe persistent fatigue and sleep disturbances are core features of the FM diagnosis [13]. Seemingly minor activities aggravate the pain and fatigue, although prolonged inactivity also heightens symptoms. Patients are stiff in the morning and feel unrefreshed, even if they have slept 8 to 10 hours. The morning stiffness may be difficult to differentiate from that of rheumatic diseases such as in rheumatoid arthritis (RA) or polymyalgia rheumatica [13]. Patients with FM characteristically sleep "lightly," waking frequently during the early morning and have difficulty getting back to sleep. A common quote is "No matter how much sleep I get, it feels like a truck ran me over in the morning." Fatigue may be a sense of ongoing physical and/or emotional exhaustion.

Other common symptoms

- **Cognitive disturbances** – Cognitive disturbances are present in the majority of patients. The cognitive disturbances are often referred to as "fibro fog." Patients typically describe problems with attention and difficulty doing tasks that require rapid thought changes. Neuropsychological testing reveals abnormalities that are somewhat different than those found in psychiatric disorders [14]. However, subjective cognitive deficits are much more common than changes on objective measures, either by brain imaging or validated instruments [15]. A meta-analysis of 23 case-control studies found significant cognitive impairment in FM patients compared with healthy controls that were explained in part by levels of pain and depression [16].

- **Psychiatric symptoms** – Depression and/or anxiety are present in 30 to 50 percent of patients at the time of diagnosis [17-21]. In a Canadian general population sample of 127,000, those 1635 subjects with FM were three times more likely to have depression compared with subjects without FM [17]. Twenty-two percent of the FM group had concurrent major depression. Depression in that group correlated with younger age, female sex, unmarried status, food insecurity, number of chronic conditions, and limitations in activities. Two-fifths of those with depression and FM had not discussed mental health concerns with any health professionals in the previous year (see 'Coexisting disorders' below). A meta-analysis of 11 studies of the prevalence of depression in FM found that one-fourth of FM patients had current major depression and that one-half had a lifetime history of major depression [18]. Anxiety disorders, bipolar disorder, posttraumatic stress disorder (PTSD), and traits such as catastrophizing and alexithymia are more common in patients with FM than in the general population [19-21]. In a systematic review, 50 percent of FM patients had a lifetime history of depression, and one-third had a lifetime history of bipolar disorder, panic disorder, or PTSD [21].

- **Headache** – Headaches are present in more than 50 percent of patients with FM and include migraine and muscular (tension) types [22,23]. In an ambulatory tertiary headache clinic, FM was present in 174 of 889 patients (20 percent), including 44 percent of those with chronic, tension-type headaches [22]. FM comorbidity correlated with frequency of headaches, anxiety, pericranial tenderness, poor sleep, and physical disability. FM is especially common in patients with episodic migraine [23].

- **Paresthesias** – Patients also often report paresthesias, including numbness, tingling, burning, or creeping or crawling sensations, especially in both arms and both legs. However, unless a concurrent neurologic disorder, such as carpal tunnel syndrome or a cervical radiculopathy, is present, a detailed neurologic evaluation or formal electrophysiologic testing is usually unremarkable. (See 'Physical findings' below.)

- **Other symptoms and disorders** – Patients also may have a variety of poorly understood pain symptoms, including abdominal and chest wall pain; symptoms suggestive of IBS; and pelvic pain and bladder symptoms of frequency and urgency suggestive of the interstitial cystitis/painful bladder syndrome (formerly female urethral syndrome) [13]. (See "Clinical manifestations and diagnosis of irritable bowel syndrome in adults" and "Interstitial cystitis/bladder pain syndrome: Clinical features and diagnosis".)

  Although IBS is the most common gastrointestinal syndrome associated with FM, gastroesophageal reflux disease (GERD) is also more common in FM than in the general population [24].

  Symptoms of autonomic nervous system (ANS) dysfunction, dry eyes, and Raynaud phenomenon (RP) are common in FM. Orthostatic hypotension and altered heart rate variability are common manifestations of ANS dysfunction in FM [25]. Dry eye syndrome is 1.4-fold higher in FM compared with the general population [26]. RP is common in FM, although the thermographic and microvascular abnormalities seen in primary RP are not present in RP reported in FM patients [27]. Hearing loss was four- to fivefold more often reported in patients with FM than in the general population [28].

  Some individuals report that particular weather conditions or changes in the weather may aggravate symptoms, but consistent effects of such conditions upon daily pain or fatigue have not been found in most studies [29]. As an example, a detailed study of the influence of weather on symptoms of pain and fatigue involving 403 women with FM found a statistically significant but small effect of weather upon either pain or fatigue [29]. Such symptoms may be part of what has been described as environmental hypersensitivity, including to sounds and lights [13].

Physical findings — In patients with FM, the one finding that is usually present on physical examination is tenderness, sometime marked, on modest palpation in multiple soft tissue sites, particularly (but not exclusively) in those tender point locations previously described in the 1990 American College of Rheumatology (ACR) classification criteria. These were located at the upper mid-trapezius muscle, the lateral epicondyle (the so-called tennis elbow location), the second costochondral junction (the site of costochondritis), the greater trochanter (the site of trochanteric bursitis of the hip), and other locations. By contrast, patients are not as tender over joints, and FM does not cause swelling or erythema of soft tissue or joints. (See '1990 ACR classification criteria' below.)

The neurologic evaluation sometimes reveals minor sensory and motor abnormalities in the absence of another condition [30]. A subset of FM patients meet criteria for a small-fiber neuropathy, and some of these patients may have subtle findings suggesting a peripheral neuropathy [31,32].

Laboratory testing and other studies — FM does not cause any abnormalities in routine clinical laboratory testing (eg, complete blood counts [CBCs], acute phase response measures, and blood chemistries) or imaging. However, abnormalities that reveal distinctions between patients with FM and control subjects have been identified in research studies using specialized neuroimaging (eg, functional magnetic resonance imaging [MRI]) and other techniques.

Research studies have also found that a subset of patients with FM have abnormalities on skin biopsies suggestive of small-fiber neuropathic changes; the meaning of these findings is uncertain, and a small-fiber skin biopsy is not warranted in routine clinical practice [31,32]. (See "Pathogenesis of fibromyalgia", section on 'Central nervous system altered pain processing' and "Pathogenesis of fibromyalgia", section on 'Peripheral pain mechanisms'.)

DIAGNOSIS

Fibromyalgia (FM) should be suspected in patients with chronic pain of at least three months' duration without another identified cause. The diagnosis of FM is symptom-based (table 1) [11]. FM can generally be diagnosed based upon symptoms of widespread pain in multiple sites, often accompanied by moderate to severe problems with sleep or fatigue, also of at least three months duration; other symptoms may also be present. Although widespread tenderness is present at multiple sites, there is an absence of joint swelling or other inflammatory changes on physical examination. (See 'Clinical manifestations' above and 'Diagnostic evaluation' below and 'Additional evaluation' below.)

As with many of the most common illnesses in clinical practice, including depression, migraine, and irritable bowel syndrome (IBS), the diagnosis rests on documenting a number of subjective symptoms and excluding other conditions that could account for those symptoms. There are no confirmatory tests or biomarkers. Therefore, the clinician's familiarity with the diagnosis and a comprehensive clinical encounter are pivotal in making a timely diagnosis.

FM will continue to be a controversial diagnosis because of a lack of clinically apparent objective changes, and there has been controversy regarding the utility of the diagnosis of FM. Although some have argued that providing a diagnostic label to everyday symptoms increases illness behavior, there are now more studies suggesting that patients improve after a diagnosis and there is significant saving of health care dollars [33].

Diagnostic evaluation — The diagnostic evaluation includes a thorough history and physical examination, together with limited laboratory testing to exclude other conditions (table 1). The diagnostic evaluation is usually straightforward and should never be a "fishing" expedition to exclude every potential cause of pain and fatigue (table 2) [1,2,13].

- **History** – A thorough medical history should be obtained. Particular attention should focus on:

  - **Pain characteristics** – The cardinal symptom of FM is chronic widespread pain (CWP) or multisite pain (MSP), present for at least three months (see 'Symptoms' above). The location of pain (figure 2), as well as the duration, quality, and severity of pain should be documented. Two instruments that are recommended for such documentation are available, respectively, from the American Pain Society (APS) and the US Food and Drug Administration (FDA), called Analgesic, Anesthetic, and Addiction Clinical Trial Translations Innovations Opportunities and Networks (ACTTION)-APS Pain Taxonomy (AAPT) (figure 2) [13] and from the American College of Rheumatology (ACR) (figure 3A-B) [34]. These can easily be embedded in the medical records.

  - **Sleep, fatigue, and other associated symptoms and disorders** – Patients should be asked detailed questions about sleep, mental and physical energy, cognitive disturbances, mood disorders and other psychiatric conditions, and other conditions that overlap with FM and may be considered to be part of the diagnostic spectrum. These include symptoms of chronic migraine or other headache disorders, IBS, chronic pelvic and/or bladder pain, and chronic temporomandibular pain.

  - **Other disorders and differential diagnosis** – A history of other conditions that may cause musculoskeletal pain and coexist with or mimic FM, including inflammatory rheumatologic disorders (eg, rheumatoid arthritis [RA], systemic lupus erythematosus, spondyloarthritis), noninflammatory rheumatic diseases (eg, osteoarthritis), localized pain syndromes, and thyroid disease. (See 'Differential diagnosis' below and 'Coexisting disorders' below and "Overview of chronic widespread (centralized) pain in the rheumatic diseases".)

- **Physical examination** – A thorough physical examination should be performed, with particular attention to a careful joint and neurologic examination to identify generalized widespread soft tissue tenderness and to exclude other illness presenting with similar symptoms. The examination should include palpating multiple soft tissue and joint sites, and a joint examination should always be done, looking for any synovitis and also palpating for tenderness over the joints themselves. Generally, many soft tissue sites are very tender with modest palpation and are more tender than the joints. There should be no soft tissue or joint swelling or redness.

  We no longer recommend palpating specific "tender point" locations or enumerating the number of tender points but rather estimating widespread or multisite soft tissue tenderness. The presence of such tender points was part of the 1990 ACR classification

criteria. These tender points were located at the upper mid-trapezius muscle, the lateral epicondyle (the so-called tennis elbow location), the second costochondral junction (the site of costochondritis), the greater trochanter (the site of trochanteric bursitis of the hip), and other sites. However, performing such a tender point examination has proven to be impractical in clinical practice [13].

- **Laboratory testing** – There is no diagnostic laboratory test or radiographic or pathologic finding, and testing should be kept to a minimum; frequently only a complete blood count (CBC) and either an erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) are required. Often, subspecialty referral is more cost-effective than ordering multiple laboratory and imaging studies if another condition or type of disorder is suspected. Testing is done primarily to exclude an associated disease or another illness that may mimic FM (table 2 and table 1) because FM itself does not cause any abnormalities in laboratory testing or routine imaging. We use the following approach to laboratory testing:

  - We obtain a CBC and a measurement of the ESR or a CRP for initial laboratory evaluation. Since FM is not an inflammatory condition, normal acute phase reactants immediately provide confidence that an occult inflammatory disorder is unlikely.

  - Serologic tests, such as antinuclear antibody and rheumatoid factor, should be obtained only if the history and physical examination suggest an inflammatory, systemic rheumatic disease. These tests are often positive in otherwise healthy people and have very poor predictive value unless there is significant clinical suspicion of a systemic rheumatic disease [35]. (See "Measurement and clinical significance of antinuclear antibodies", section on 'Clinical limitations of ANA testing'.)

  - In patients with any suspicion of thyroid disease or inflammatory muscle disease, we order thyroid function tests or a creatine kinase (CK), respectively. In 375 subjects with suspected FM, 7.5 percent had an elevated CK, 3.5 percent an elevated thyroid-stimulating hormone (TSH), and 1.4 percent a low TSH [36]. However, these abnormal tests did not lead to identification of alternative diagnoses for the patient's presenting symptoms other than FM.

  - There is no evidence that ordering viral tests such as antibodies to the Epstein-Barr virus or ordering vitamin D levels are helpful in the diagnosis of FM. Low vitamin D levels are common in patients with chronic pain, but most reports have not found a correlation with the diagnosis of FM [37].

Additional evaluation — Findings on the initial evaluation will determine what additional evaluation may be needed. As examples:

- Patients with symptoms of obstructive sleep apnea and restless legs or repetitive limb movements should be referred for a formal sleep evaluation, which may include an overnight polysomnogram [38,39]. Sleep apnea has been observed more often in males with FM [39]. (See "Clinical presentation and diagnosis of obstructive sleep apnea in adults" and "Clinical features and diagnosis of restless legs syndrome and periodic limb movement disorder in adults".)

- Patients suspected of an undiagnosed psychiatric disorder, such as depression or anxiety, should undergo further evaluation and treatment by an expert experienced in these conditions [17,18]. (See "Unipolar depression in adults: Assessment and diagnosis" and "Bipolar disorder in adults: Assessment and diagnosis" and "Generalized anxiety disorder in adults: Epidemiology, pathogenesis, clinical manifestations, course, assessment, and diagnosis".)

- Autonomic nervous system (ANS) dysfunction, which may present with symptoms of orthostasis, tachycardia, or palpitations, has been noted in patients with FM [40]. This may be especially prominent in the subset of FM patients who meet criteria for a small-fiber neuropathy [31]. However, there are no appropriate screening tests other than blood pressure and heart rate readings when patients are recumbent and standing. In selected individuals who exhibit these findings, referral to an expert, such as a cardiologist or neurologist, is indicated for further evaluation and, if needed, more formal tests such as tilt table testing. (See "Upright tilt table testing in the evaluation of syncope", section on 'Tilt table testing procedure' and "Postural tachycardia syndrome" and "Mechanisms, causes, and evaluation of orthostatic hypotension" and "Sinus tachycardia: Evaluation and management" and "Evaluation of palpitations in adults".)

CLASSIFICATION AND PROPOSED DIAGNOSTIC CRITERIA

Various classification criteria for fibromyalgia (FM) have been developed and tested in an attempt to provide some homogeneity in patient populations for clinical studies; such classification criteria are most useful for clinical research and epidemiologic studies. In general, they have not been validated for individual patient diagnosis. Particularly in symptom-based diagnosis, the experience of the clinician and the details of the clinical encounter are paramount to rendering an accurate diagnosis [11].

In efforts to design diagnostic criteria for FM, it gradually became apparent to clinicians and investigators that the tender point examination, an important element of the 1990 criteria (see '1990 ACR classification criteria' below), should not be used for diagnosis of FM and that

the presence of somatic symptoms, such as sleep disturbances and fatigue, must be included in any diagnostic criteria.

Both the 2010 ACR preliminary diagnostic criteria (2010 criteria) for FM and the AAPT diagnostic criteria for FM are designed to aid in diagnosis (see '2010 ACR preliminary diagnostic criteria' below and 'AAPT criteria' below). They both can be quickly documented and the 2010 criteria are especially useful for following symptom severity (SS) over time (figure 2 and figure 3A-B). Nevertheless, these criteria need to be further tested and compared with clinician diagnosis. Furthermore, these criteria have not been evaluated in FM patients with concurrent rheumatic or medical conditions.

1990 ACR classification criteria — The American College of Rheumatology (ACR) classification criteria for FM were published in 1990 and have been used in most clinical and therapeutic trials [41].

The ACR criteria were based upon expert rheumatologists' opinions regarding the optimal historical and physical findings that could differentiate patients with FM from those with other rheumatic diseases and forms of chronic pain. These criteria were then field-tested in a number of academic rheumatology clinics and office practices.

The final 1990 ACR FM classification criteria included:

- Symptoms of widespread pain, occurring both above and below the waist and affecting both the right and left sides of the body
- Physical findings of at least 11 of 18 defined tender points

These simple criteria had greater than 85 percent sensitivity and specificity for differentiating patients with FM from those with other rheumatic diseases. However, these initial FM criteria were not intended for use in clinical practice. They focused on specific tender point locations despite the evidence that FM is a central pain disorder. It became clear over time that a tender point examination would be impossible to standardize in primary care and was not being performed, even by rheumatologists. Most importantly, these initial criteria neglected the multiple somatic symptoms in FM.

2010 ACR preliminary diagnostic criteria — The 2010 American College of Rheumatology (ACR) preliminary diagnostic criteria (2010 criteria) for FM (figure 3A-B) do not require a tender point examination and provide a scale for measurement of the severity of symptoms that are characteristic of FM [34]. Importantly, these criteria were based upon patient self-reporting.

According to these 2010 preliminary criteria (figure 3A-B), a patient satisfies FM diagnostic criteria if the following three conditions are met:

- Widespread pain index (WPI) >7 and symptom severity (SS) scale >5 or WPI 3 to 6 and SS scale >9
- Symptoms have been present for at least three months
- There is no other disorder that would explain the patient's symptoms

The WPI is a measure of the number of painful body regions from a defined list of 19 areas. The SS score includes an estimate of the degree of fatigue, waking unrefreshed, and cognitive symptoms, and the number of somatic symptoms in general (figure 3A-B). In contrast to the initial 1990 classification criteria, these 2010 criteria were formulated to be used for diagnosis, hence the term the 2010 ACR preliminary diagnostic criteria.

The 2011 modification of the 2010 ACR preliminary criteria slightly modified a few questions from the 2010 criteria so that they can be self-administered [42]. These criteria are to be used primarily for epidemiologic studies.

Applying the 1990, the 2010, or the 2011 modified FM criteria changed estimates of the prevalence of FM as much as fourfold [6]. The prevalence of FM was 1.7 with the 1990 criteria and 1.2 with the 2010 criteria, but 5.4 with the 2011 modified criteria. These modified criteria identified a greater proportion of men with FM and were more influenced by somatic symptoms than by pain [6].

In 2016, further modification of the 2010 criteria suggested using a generalized pain criterion, which decreased misclassification of regional pain syndromes [43]. These criteria require that FM patients have pain in 4 of 5 regions, termed multisite pain (MSP), in contrast to the 1990 definition of chronic widespread pain (CWP). In general, there was good agreement between physician- and patient-based FM diagnostic criteria, especially for research [43].

[44]

AAPT criteria — In 2013, the Analgesic, Anesthetic, and Addiction Clinical Trial Translations Innovations Opportunities and Networks (ACTTION) public-private partnership with the US Food and Drug Administration (FDA) and American Pain Society (APS) initiated the ACTTION-APS Pain Taxonomy (AAPT) in an attempt to develop a diagnostic system that would be clinically useful and consistent across chronic pain disorders, including FM. In 2019, the FM working group suggested new AAPT diagnostic criteria for FM [13]. These FM core diagnostic criteria are (figure 2):

- MSP defined as six or more pain sites from a total of nine possible sites
- Moderate to severe sleep problems or fatigue
- Both one and two must have been present for at least three months

According to the AAPT FM diagnostic criteria, the presence of another pain disorder or related symptoms does not exclude the diagnosis of FM, but a clinical assessment must fully evaluate any condition that could account for the patient's symptoms.

Role of classification and proposed diagnostic criteria in office practice — Classification criteria are essential for epidemiologic studies and clinical trials but have limited utility in clinical practice. They provide a window for quantifying symptoms that are present on a spectrum of severity, such as chronic pain. For clinicians who are inexperienced or uncomfortable with the diagnosis of FM, we consider it appropriate to utilize either the 2010 criteria or the AAPT diagnostic criteria to help guide the diagnosis, despite some limitations to their use for this purpose [45]. (See 'Classification and proposed diagnostic criteria' above and '2010 ACR preliminary diagnostic criteria' above and 'AAPT criteria' above.)

However, such diagnostic guidelines cannot replace clinical judgment, the diagnostic gold standard of symptom-based diagnosis [11]. Because of the importance of excluding other conditions and recognizing comorbid disorders, clinicians unfamiliar with these disorders may need to refer patients identified by use of such criteria to a clinician familiar with these conditions and with FM for confirmation of the diagnosis.

DIFFERENTIAL DIAGNOSIS

The multiple nonspecific symptoms of fibromyalgia (FM) can mimic many other conditions, and consideration of the differential diagnosis is important in making the diagnosis of FM. The history and physical examination, as well as limited laboratory testing, are usually sufficient to differentiate FM from these other conditions, such as systemic inflammatory arthropathies, spondyloarthritis, systemic autoimmune ("connective tissue") disorders, polymyalgia rheumatica, inflammatory myopathy, and hypothyroidism (table 3). A detailed discussion of the differential diagnosis of FM is presented separately. (See "Differential diagnosis of fibromyalgia".)

COEXISTING DISORDERS

Several groups of disorders may occur in association with fibromyalgia (FM) more often than expected by chance alone. Some features of these conditions may simulate or exacerbate the symptoms of FM, such as musculoskeletal pain in patients with chronic forms of arthritis; and sleep disturbance and fatigue in patients with depression, obstructive sleep apnea, or restless legs syndrome. Recognition and effective treatment of these comorbidities can potentially contribute to symptomatic relief in patients with FM. These conditions include:

- **Functional somatic syndromes and related disorders** – FM is often present in patients together with other common functional somatic syndromes, including irritable bowel syndrome (IBS) [46]; chronic fatigue syndrome (CFS), also known as myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) [47]; migraine and tension-type headaches [48,49]; as well as chronic bladder and pelvic pain syndromes [50,51] and temporomandibular disorders [52]. The prevalence of FM in each of these disorders varies from 20 to 50 percent, and 30 to 70 percent of patients with FM meet criteria for CFS and IBS [51,52]. This aggregation of related clinical conditions has been termed chronic overlapping pain conditions (COPCs) [53].

  Demographic, clinical, and potential pathophysiologic characteristics of CFS, IBS, and other functional somatic syndromes are very similar to those of FM, and patients with FM may receive multiple diagnoses according to subspecialty referral patterns, if the clinicians caring for the patient are diagnostic "splitters" (ie, those who prefer to divide what others might consider as one entity into multiple distinct entities). On the other hand, the exact label may be less important if these functional illnesses are considered as part of a spectrum. Each of these conditions is diagnosed using criteria based upon the patients' symptoms when other diseases have been excluded, and they tend to be controversial because of the absence of a specific diagnostic test or of objective pathophysiologic abnormalities. Screening questions that can be useful in determining whether additional evaluation for one of them is warranted include [52]:

  - CFS – Have you had unexplained, persistent, or relapsing fatigue for at least six months? (See "Clinical features and diagnosis of myalgic encephalomyelitis/chronic fatigue syndrome".)

  - IBS – Have you had abdominal discomfort or pain accompanied or affected by constipation or diarrhea for three or more months in the past year? (See "Clinical manifestations and diagnosis of irritable bowel syndrome in adults".)

  - TMD – Have you had recurrent facial/jaw pain and/or limitation in jaw opening occurring in the past six months? (See "Temporomandibular disorders in adults".)

  - Tension and migraine headache – Have you had recurrent headaches (at least 5 for migraine, at least 10 for tension-type) lasting 30 minutes occurring in the past six months? (See "Chronic daily headache: Associated syndromes, evaluation, and management".)

  - Chronic bladder and pelvic pain syndromes – Have you had symptoms for over nine months of bladder pain, urinary urgency and frequency (voiding more than eight times during the day or more than two times during the night), and a negative urine

culture? (See "Interstitial cystitis/bladder pain syndrome: Clinical features and diagnosis".)

Have you experienced unexplained pelvic/vaginal pain frequently during the past six months? (See "Chronic pelvic pain in adult females: Evaluation" and "Vulvar pain of unknown cause (vulvodynia): Clinical manifestations and diagnosis".)

- **Psychiatric disorders** – Psychiatric disorders, including depressive disorders, anxiety disorders, and posttraumatic stress disorder (PTSD), are more prominent in FM than in other rheumatic diseases, such as rheumatoid arthritis (RA). Approximately 25 percent of patients with FM have concurrent major depression, and 50 percent have a lifetime history of depression [54-56].

  An informal evaluation for psychiatric illness should be part of the initial evaluation of any patient with FM, with a more formal assessment by a mental health professional in selected patients. (See "Unipolar depression in adults: Assessment and diagnosis" and "Generalized anxiety disorder in adults: Epidemiology, pathogenesis, clinical manifestations, course, assessment, and diagnosis" and "Posttraumatic stress disorder in adults: Epidemiology, pathophysiology, clinical manifestations, course, assessment, and diagnosis".)

  As further examples, in one report, 47 percent of FM patients had a mood or anxiety disorder and 13 percent had a personality disorder [56]. More than 50 percent of these patients were suffering from sexual dysfunction. Bipolar disorder was present in 15 percent of FM subjects [56].

- **Sleep disorders** – Most patients with FM have nonrestorative sleep as a characteristic of their illness; sleep disturbances are also very common in patients with FM, although the most common is a nonspecific interruption in stage 4 sleep [57]. Nonrestorative sleep abnormalities correlate with severity of FM symptoms and quality of life [58]. However, primary sleep disturbances, including sleep apnea, restless leg syndrome, and periodic limb movement disorders (PLMD), are also quite common [59]. A 2017 systematic review and meta-analysis of case-control studies found lower sleep quality and sleep efficiency, longer wake time after sleep onset, and a short sleep duration [59]. Subjective sleep disturbances were more prominent than objective evidence of disturbed sleep.

  The associated sleep disorders can contribute significantly to the symptoms of fatigue and nonrestorative sleep experienced by patients with FM, and symptom relief in patients with these comorbidities requires recognition of these conditions and appropriate treatment interventions. Thus, a careful sleep history should be obtained in patients with FM symptoms. Patients with possible sleep apnea or PLMD (also

termed nocturnal myoclonus) should be referred to a sleep clinic for further evaluation and treatment. (See "Clinical presentation and diagnosis of obstructive sleep apnea in adults" and "Clinical features and diagnosis of restless legs syndrome and periodic limb movement disorder in adults".)

- **Inflammatory rheumatic diseases** – The prevalence of FM is increased in patients with chronic inflammatory arthritis and systemic autoimmune rheumatic diseases, including RA, psoriatic arthritis, and spondyloarthritis, systemic lupus erythematosus, and Sjögren's syndrome, and in osteoarthritis and regional pain disorders. This association, which may impact assessment and attribution of symptoms and evaluation of disease activity, has implications for management, and can influence patient outcomes, is discussed in detail separately. (See "Overview of chronic widespread (centralized) pain in the rheumatic diseases".)

  Proposed diagnostic criteria for FM have not been tested in patients with concurrent rheumatic or other musculoskeletal disorders (see 'Classification and proposed diagnostic criteria' above). However, other than the presence of the comorbid musculoskeletal disorder, the same characteristics can be used to make a clinical diagnosis of FM in patients with or without another such condition. There appears to be no distinction between the formerly termed primary and secondary FM [60].

FIBROMYALGIA AND PRIMARY CARE

Fibromyalgia (FM) continues to be a difficult diagnosis for many primary care clinicians [61]. They typically refer patients to rheumatologists, but most rheumatologists, as shown in a study of Canadian physicians, do not provide primary care for FM, and some do not see patients with FM [62]. Many Canadian rheumatologists in another study did not utilize published FM diagnostic criteria to make the diagnosis in their practices [63].

Impediments to establishing the diagnosis — The diagnosis of FM, like that of headaches, chronic low back pain, and depression, can generally be made in the primary care setting, although many barriers exist for a timely diagnosis of FM in primary care. Despite improved awareness among primary care clinicians, many continue to be uncomfortable with a diagnosis of FM. There are no objective physical, laboratory, or imaging abnormalities, and the diagnosis is based on subjective reporting of symptoms.

In one study, FM patients rated receiving a diagnosis as somewhat difficult on average and had difficulties communicating their symptoms to the physician [64]. Most patients rated their chronic widespread pain as moderate or severe, and FM symptoms were on average "fairly" to "very" disruptive and had a "moderate" to "strong" impact on patients' lives. However, patients waited on average almost a year after experiencing symptoms before

presenting to a clinician, and before receiving a diagnosis of FM there was an average duration of 2.3 years and patients presenting to 3.7 different clinicians. In a study of general practice patients, FM was commonly misdiagnosed as a psychiatric illness [65]. In large population database studies, the FM diagnosis varied greatly based on demographic and social factors more than on symptom severity (SS) [66].

Benefits of establishing the diagnosis — Recognition and diagnosis of FM leads to a decrease in resource use, including subsequent testing and overall health care costs, despite concerns that diagnostic labels such as FM would promote illness behavior and drive up health care costs. This was shown in a study involving more than 2000 patients, 81 percent women, who were newly diagnosed with FM [33]. During the 10 years before diagnosis, the patients with FM had considerably higher mean annual rates of visits, medication prescription, and testing, compared with controls (25 versus 12 visits and 11 versus 4.5 prescriptions). Following an FM diagnosis, visits for most symptoms and health care usage declined, although within two to three years visit levels rose.

A decrease in costs as compared with the predicted trend has also been observed in the four years after diagnosis [67]. Costs before diagnosis were used in a trend analysis to predict later costs, assuming the diagnosis had never been made, and these predicted costs were compared with the observed costs after diagnosis. The average difference between the predicted and observed cost in the primary care population in the United Kingdom that was studied was £66.21 per six months per patient. Another report described both improved quality of life and decreased cost of health care after a diagnosis of FM, suggesting a need for early diagnosis and treatment [68].

Potential diagnostic tools — Earlier detection of FM in primary care may be advanced with new diagnostic tools [69,70]. The FibroDetect includes 14 questions assessing patients' pain and fatigue, personal history and attitudes, symptoms, and impact on lives. The predictive accuracy of the tool increased to 0.86 for FM and non-FM patient detection, with a sensitivity of 90 percent and a specificity of 67 percent for a cutoff of 6 on the score. Using self-report Multidimensional Health Assessment Questionnaire scores, a Fibromyalgia Assessment Screening Tool (FAST) was developed and correctly identified FM patients [70]. However, these screening diagnostic questionnaires have not been widely adopted for use in clinical practice settings. Electronic medical records have been used to identify variables associated with the diagnosis of FM [71]. Significant differences between the FM and no-FM cohorts were observed for nearly all the demographic, clinical, and health care resource variables. These results support the use of electronic medical records data in clinical research for identifying variables associated with FM.

Proposed diagnostic criteria may also help to guide and confirm an FM diagnosis and assess severity of symptoms as discussed above (see 'Role of classification and proposed diagnostic

criteria in office practice' above and 'Classification and proposed diagnostic criteria' above). FM survey criteria (figure 3A-B) have also been used to identify patients with spine pain or undergoing joint replacement who meet FM criteria [72,73]. Those subjects meeting the FM criteria had more pain and poorer outcome.

The diagnosis of FM, like that of every medical condition lacking a diagnostic gold standard, is based on clinical judgment [74]. Rheumatologists should be consulted when there is diagnostic uncertainty. Eighty-seven percent of rheumatologists, compared with 53 percent of primary care physicians, describe themselves as confident in making a diagnosis of FM [74].

SOCIETY GUIDELINE LINKS

Links to society and government-sponsored guidelines from selected countries and regions around the world are provided separately. (See "Society guideline links: Fibromyalgia".)

INFORMATION FOR PATIENTS

UpToDate offers two types of patient education materials, "The Basics" and "Beyond the Basics." The Basics patient education pieces are written in plain language, at the 5th to 6th grade reading level, and they answer the four or five key questions a patient might have about a given condition. These articles are best for patients who want a general overview and who prefer short, easy-to-read materials. Beyond the Basics patient education pieces are longer, more sophisticated, and more detailed. These articles are written at the 10th to 12th grade reading level and are best for patients who want in-depth information and are comfortable with some medical jargon.

Here are the patient education articles that are relevant to this topic. We encourage you to print or e-mail these topics to your patients. (You can also locate patient education articles on a variety of subjects by searching on "patient info" and the keyword(s) of interest.)

- Basics topic (see "Patient education: Fibromyalgia (The Basics)")
- Beyond the Basics topic (see "Patient education: Fibromyalgia (Beyond the Basics)")

SUMMARY AND RECOMMENDATIONS

- **Clinical manifestations** – Fibromyalgia (FM) is characterized by widespread (multisite) musculoskeletal pain, accompanied by other somatic symptoms, particularly fatigue and sleep disturbances, as well as cognitive and psychiatric disturbances (table 1).

Physical examination reveals tenderness in multiple soft tissue anatomic locations. Laboratory testing is normal in the absence of other illnesses. (See 'Clinical manifestations' above.)

- **Diagnosis** – The diagnosis of FM should be considered in any patient with greater than three months of widespread or multisite pain (MSP) and when there is no evidence for another condition to account for that pain (table 2 and table 1). Core symptoms include fatigue and sleep disturbances. Diagnostic criteria for FM are available and can be used to help guide diagnostic evaluation and confirm clinical decision-making but have not been validated for individual patient diagnosis (figure 2 and figure 3A-B). (See 'Diagnosis' above.)

- **Role of laboratory testing** – Testing should be kept to a minimum since there are no diagnostic laboratory tests for FM. We advise obtaining a complete blood count (CBC) and either an erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), to exclude systemic inflammatory disease. Additional laboratory testing should be based upon clinical suspicion of a specific disorder, such as a thyroid-stimulating hormone (TSH) test or a creatine kinase (CK), if hypothyroidism or inflammatory myopathy are suspected, respectively. (See 'Diagnostic evaluation' above.)

- **Indications for additional evaluation** – Additional evaluation should be considered for associated conditions if clinically suspected, including sleep disorders, such as obstructive sleep apnea or restless legs syndrome, and psychiatric disorders, such as depression or anxiety. (See 'Additional evaluation' above.)

- **Avoidance of unnecessary testing** – There is a broad differential diagnosis (table 3), but screening for rheumatologic and other diseases with multiple serologic tests, laboratory studies, and invasive testing is not recommended. Excluding other conditions that may mimic FM is best accomplished with early subspecialty referral. This is especially important in FM patients with coexisting rheumatic disorders. (See 'Diagnostic evaluation' above and 'Additional evaluation' above and 'Role of classification and proposed diagnostic criteria in office practice' above and 'Differential diagnosis' above and 'Coexisting disorders' above.)

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Topic 5624 Version 43.0

GRAPHICS

Prevalence of fibromyalgia (FM) and chronic widespread pain (CWP) in general population studies

FM: fibromyalgia; CWP: chronic widespread pain.

Graphic 120689 Version 1.0

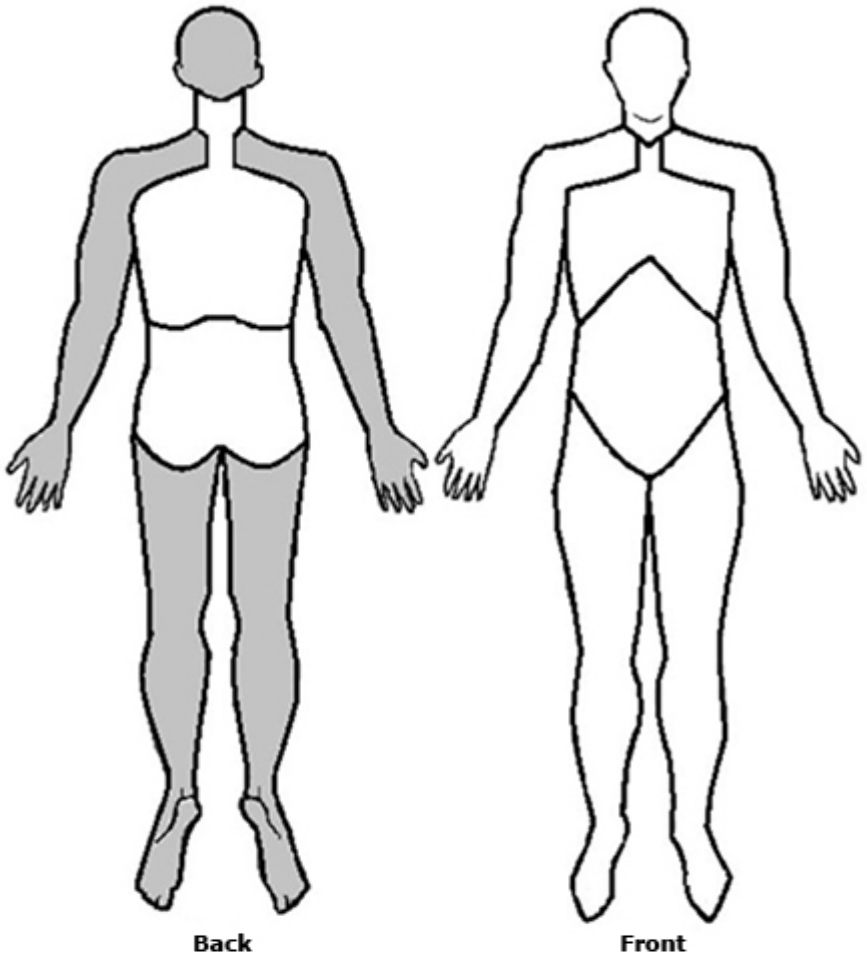
Characteristic features and diagnostic evaluation for fibromyalgia

History
Widespread (multisite) pain
Present for at least 3 months
Fatigue, sleep disturbances
Other symptoms, such as cognitive disturbances, headaches, bowel irritability
Physical examination
Widespread (multisite) tenderness
Absence of joint swelling, inflammation
Laboratory testing
Normal acute phase reactants (ESR/CRP)
Normal CBC
In selected cases, muscle enzymes, thyroid testing

ESR: erythrocyte sedimentation rate; CRP: C-reactive protein; CBC: complete blood count.

Graphic 120702 Version 1.0

AAPT diagnostic criteria for fibromyalgia



Number of painful body sites:

- ☐ Head
- ☐ Left arm
- ☐ Right arm
- ☐ Chest
- ☐ Abdomen
- ☐ Upper back and spine
- ☐ Lower back and spine, including
- ☐ Left leg
- ☐ Right leg

FM core diagnostic criteria:

1. MSP defined as 6 or more pain sites from a total of 9 possible sites
2. Moderate to severe sleep problems **or** fatigue
3. MSP plus fatigue or sleep problems must have been present for at least 3 months

NOTE: The presence of another pain disorder or related symptoms does not rule out a diagnosis of FM. However, a clinical assessment is recommended to evaluate for any condition that could fully account for the patient's symptoms or contribute to the severity of the symptoms.

FM: fibromyalgia; MSP: multisite pain.

Graphic 120690 Version 2.0

Hints for early and cost-effective diagnosis of fibromyalgia

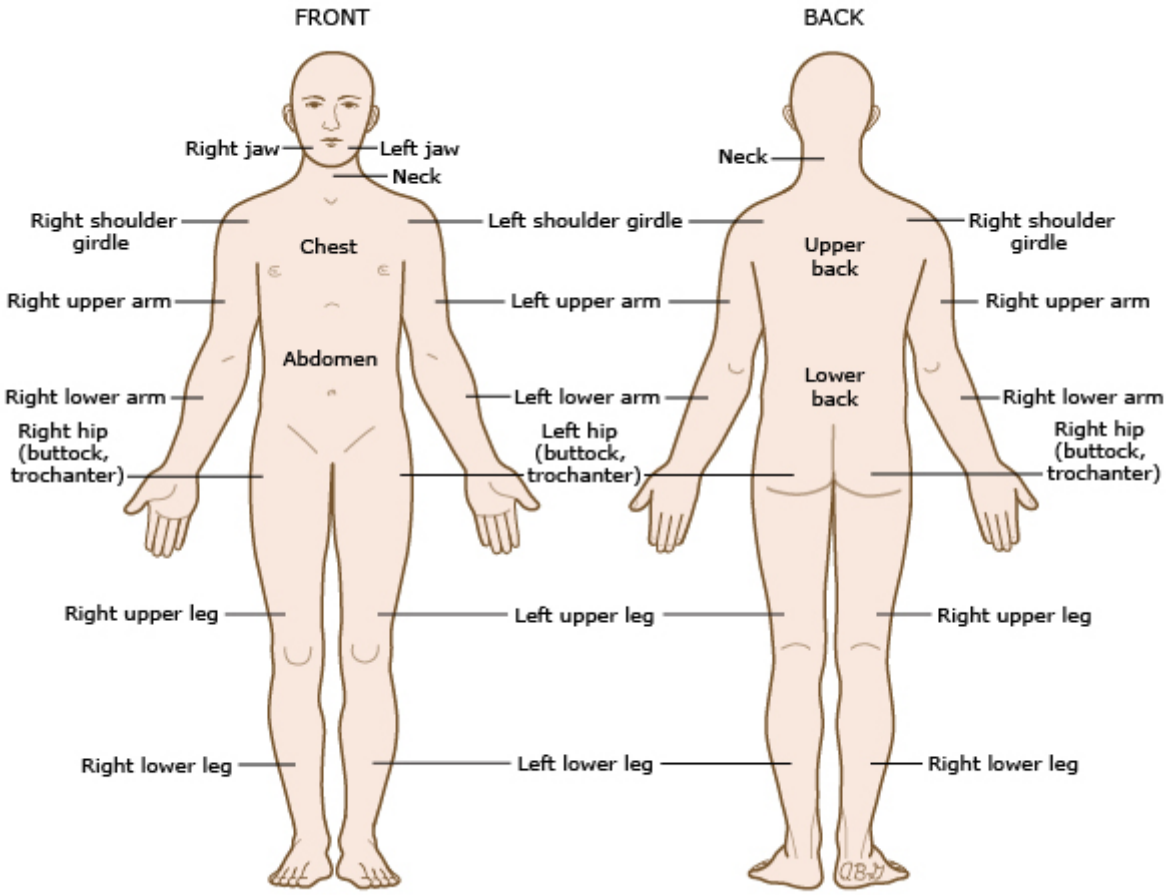
Chronic widespread musculoskeletal pain for ≥3 months
Absence of other systemic condition accounting for pain
Excess tenderness in soft tissues
Characteristic symptoms:
• "I hurt all over"
• "It feels like I always have the flu"
• Fatigue, sleep and mood disturbances
• IBS, irritable bladder, multiple other somatic complaints
Exclusion of structural or systemic disease
• Not a "fishing" expedition
• Avoid "screening" rheumatology tests
• Most efficient with early subspecialty referral

IBS: irritable bowel syndrome.

Courtesy of Don L Goldenberg, MD.

Graphic 63893 Version 4.0

Regions for scoring of widespread pain index



The total number of the 19 noted anatomic regions in which the patient has had pain over the last week equals the widespread pain index.

Modified from:

1. *Wolfe F. Pain extent and diagnosis: development and validation of the regional pain scale in 12,799 patients with rheumatic disease. J Rheumatol 2003; 30:369.*
2. *Wolfe F, Clauw DJ, Fitzcharles MA, et al. The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. Arthritis Care Res (Hoboken) 2010; 62:600.*
3. *Wolfe F, Clauw DJ, Fitzcharles MA, Fibromyalgia criteria and severity scales for clinical and epidemiological studies: a modification of the ACR Preliminary Diagnostic Criteria for Fibromyalgia. J Rheumatol 2011; 38:1113.*

Graphic 120698 Version 1.0

American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity

Criteria
A patient satisfies diagnostic criteria for fibromyalgia if the following 3 conditions are met:
1) Widespread pain index (WPI) ≥7 and symptom severity (SS) scale score ≥5 or WPI 3 to 6 and SS scale 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 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.
Neck
Jaw, left
Jaw, right
Shoulder girdle, left
Shoulder girdle, right
Upper arm, left
Upper arm, right
Lower arm, left
Lower arm, right
Chest
Abdomen
Upper back
Lower back
Hip (buttock, trochanter), left
Hip (buttock, trochanter), right
Upper leg, left
Upper leg, right
Lower leg, left
Lower leg, right
2) SS scale score
For the each of the 3 symptoms below, 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
- Fatigue (0 to 3)			
- Waking unrefreshed (0 to 3)			
- Cognitive symptoms (0 to 3)			
How many of the following has the patient had in the past 6 months?			
- Pain or cramps in lower abdomen			
- Depression			
- Headache			
The SS scale score is the sum of the severity of the 3 symptoms (fatigue, waking unrefreshed, cognitive symptoms) plus the number of the itemized symptoms present. The final score is between 0 and 12.			

Reference:

1. *Wolfe F, Clauw DJ, Fitzcharles M, et al. Fibromyalgia criteria and severity scales for clinical and epidemiological studies: A modification of the ACR preliminary diagnostic criteria for fibromyalgia. J Rheumatol 2011; 38:1113.*

Graphic 81631 Version 7.0

Differential diagnosis of fibromyalgia

Diagnosis	Helpful features
Rheumatoid arthritis or lupus	Symmetrical polyarthritis, systemic features (dermatitis, nephritis), elevated erythrocyte sedimentation rate, serologic abnormalities (rheumatoid factor, anti-DNA antibodies)
Polymyalgia rheumatica	Elderly, elevated erythrocyte sedimentation rate, stiffness>pain, responds well and quickly to steroids
Myositis	Muscle weakness, elevated muscle enzymes
Hypothyroidism	Abnormal thyroid function tests
Hyperparathyroidism	Hypercalcemia
Neuropathies	Clinical and electrical evidence of neuropathy

Graphic 50712 Version 1.0

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Conflict of interest policy

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