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In the Clinic®

Fibromyalgia

Pathophysiology and Risk Factors

Diagnosis

Treatment

Practice Improvement

Fibromyalgia is characterized by chronic, widespread musculoskeletal pain and associated fatigue, sleep disturbances, and other cognitive and somatic symptoms. For many patients, these symptoms persist for years and lead to frequent health care use; for some, fibromyalgia and its symptoms can be debilitating. Although many treatments are available, management remains challenging. This article highlights the clinical features of fibromyalgia, discusses diagnostic criteria and their evolution, and reviews treatment options.

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Fibromyalgia is a common disorder whose cardinal manifestation is chronic, widespread pain (1). Prevalence estimates can vary 4-fold depending on the diagnostic criteria applied (2). Fibromyalgia affects approximately 2% to 4% of the general population (2), and the prevalence exceeds 15% in selected clinical samples (3).

Fibromyalgia is costly, and the economic burden to society from lost productivity and impairment is substantial. People with fibromyalgia are frequent users of health care, similar to patients with diabetes mellitus and hypertension. On average, persons with fibromyalgia make 10 outpatient medical visits per year (4).

Fibromyalgia is underdiagnosed, but newer criteria have been developed to facilitate diagnosis in clinical settings. Nonpharmacologic therapies (supervised and graded exercise programs and cognitive behavioral interventions) are the mainstays of treatment, and pharmacologic therapies are adjunctive for symptom relief. Fibromyalgia is best managed as a chronic disease in which the primary care physician provides comprehensive care and continuous management and facilitates coordination with specialty care or ancillary services if needed.

Pathophysiology and Risk Factors

What causes fibromyalgia?

The cause of fibromyalgia is unclear. For decades, there was considerable dissent among medical professionals about its cause, and some viewed it as a psychogenic condition. This outdated view has been refuted by more recent research characterizing it as a disorder of pain regulation and central sensitization.

Brain imaging studies using functional magnetic resonance imaging and other research have shown several perturbations of pain processing and regulation that amplify pain (5) or decrease pain inhibition in persons with fibromyalgia. Some of these perturbations include greater neuronal activity in pain-processing brain regions, exaggerated pain responses to experimental stimuli (sensitization), changes in brain morphology, regulation of peripheral or brain receptors, and altered levels of pain-related neuropeptides and neurotransmitters (for example, substance P, brain-derived neurotrophic factor, glutamine, and dopamine). These changes may extend to processing of other sensory input, potentially explaining other bothersome symptoms, such as fatigue, sleep disruption, cognitive problems, and depression (1).

What are the risk factors?

Nonmodifiable risk factors include genetic factors, female sex, and the presence of other painful conditions. Twin studies have estimated the heritability of chronic widespread pain at approximately 50% (6). Fibromyalgia diagnosed according to the 2010 American College of Rheumatology (ACR) criteria has an approximately 2:1 female-to-male predominance, which is more pronounced (6:1 to 9:1 female-to-male ratio) in clinical versus population-based studies. Prior painful conditions are also strongly associated with fibromyalgia, perhaps due to secondary central sensitization. For example, studies report fibromyalgia in 20% to 30% of patients with inflammatory conditions, including rheumatoid arthritis and systemic lupus erythematosus (7). In a study of patients with early in-

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flammatory arthritis, the cumulative incidence of new-onset fibromyalgia was 6.8 per 100 person-years in the first year and 3.6 per 100 person-years in the second year (8). Mental health symptoms and pain severity—but not inflammatory markers, such as erythrocyte sedimentation rate or C-reactive protein level—predicted onset of fibromyalgia. Mental health conditions, such as depression and anxiety, may be present in 25% to 65% of patients with fibromyalgia (9). Fibromyalgia also commonly coexists with other chronic symptomatic illnesses that may have similar central mechanisms, such as chronic back pain, irritable bowel syndrome, and temporomandibular disorders.

In the general population, potentially modifiable risk factors include sleep disturbances, physical inactivity, and overweight or obesity. In a longitudinal, community-based study of Norwegian women, insomnia symptoms approximately doubled the risk for new-onset fibromyalgia, whereas high levels of physical activity were protective (10). Women who were overweight or obese were 60% to 70% more likely than women with normal weight to develop fibromyalgia (10, 11).

Pathophysiology and Risk Factors... The cause and pathophysiology of fibromyalgia are not completely understood. However, several strands of research suggest abnormal central pain processing as the primary pathophysiologic mechanism. Prevalence of fibromyalgia is twice as high in women than in men. Regular physical activity, weight loss, and treatment of mood and sleep disturbances may be protective against fibromyalgia and other chronic pain conditions.

CLINICAL BOTTOM LINE

Diagnosis

What are the characteristic clinical features?

Patients with fibromyalgia have chronic (>3 months) pain that is generalized; occurs in multiple sites; and is associated with fatigue, sleep problems, and cognitive or somatic symptoms (see the Box: Symptoms and Signs of Fibromyalgia). A chief complaint of "I hurt all over" should alert the clinician to a possible diagnosis of fibromyalgia. Pain may be generalized initially or may be localized to a specific site or region, such as the lower back or neck. The diagnosis may be missed when a broader pain history is not considered in the evaluation of seemingly isolated symptoms. In addition to widespread pain, patients frequently present with fatigue and sleep disturbances (1). Fatigue is often reported as moderate to severe (12) and is chronic. Some patients report cognitive problems affecting their memory, attention, and ability to focus or concentrate; these are sometimes informally referred to as "fibro fog." Somatic symptoms (headaches, abdominal pain, bloating, nausea, diarrhea, jaw pain, dizziness, and paresthesias) are frequently reported and are included in current diagnostic frameworks.

The diagnosis of fibromyalgia should be considered in any patient with widespread or multisite pain lasting longer than 3 months. Although the diagnosis is typically based on clinical eval-

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Table 1. **Comparison of Diagnostic Criteria**

Criteria	*2010/2011 American College of Rheumatology Criteria With 2016 Proposed Changes (13)*	*ACTTION–American Pain Society Pain Taxonomy Initiative (12)*
Core criteria		
Duration of symptoms	≥3 mo at similar level	≥3 mo for both multisite pain and fatigue/sleep
Pain location	Generalized pain: ≥4 of 5 body regions (upper left, upper right, lower left, lower right, axial)	Multisite pain: ≥6 of 9 body regions (head, left arm, right arm, chest, abdomen, upper back, lower back/buttocks, left leg, right leg)
Fibromyalgia scale score	WPI score ≥7 and SSS ≥5 *or* WPI score of 4–6 and SSS ≥9	Not applicable
Fatigue/sleep	Not applicable	Moderate to severe sleep problems *or* fatigue
Additional criteria/comments	A diagnosis of fibromyalgia is valid regardless of other diagnoses	Additional features that are not required but support the diagnosis include tenderness, cognitive problems, musculoskeletal stiffness, environmental hypersensitivity, and hypervigilance

ACTTION = Analgesic, Anesthetic, and Addiction Clinical Trial Translations Innovations Opportunities and Networks; SSS = Symptom Severity Score; WPI = Widespread Pain Index.

uation, various criteria have been developed, tested in population-based studies, and disseminated to aid in clinical diagnosis (**Table 1**). The ACR has published multiple iterations of criteria for classification or diagnosis of fibromyalgia (13). The 1990 ACR classification criteria included widespread pain occurring both above and below the waist and affecting both the right and the left side of the body, as well as the presence of at least 11 of 18 defined tender points on physical examination. Potential limitations of this approach included omission of nonpain symptoms and questionable specificity and practicality of the tender point requirement.

The ACR issued updated diagnostic criteria in 2010 (14). These criteria dropped tender point requirements, added a somatic symptom requirement, and established 2 brief assessment scales: the Widespread Pain Index, which assesses the number of pain locations from a list of 19, and the Symptom Severity Score, which assesses fatigue, sleep disturbances, cognitive symptoms, and the number of somatic symptoms. A 2011 modification created a patient self-report form (13) to facilitate diagnosis. Proposed revisions to the 2010/2011 ACR diagnostic criteria were published in 2016 (13) (**Table 1**) and added the requirement of generalized pain in at least 4 of 5 regions to reduce misclassification of regional pain disorders. This iteration also clarified that the diagnosis of fibromyalgia "is valid irrespective of other diagnoses."

In 2018, an international working group sponsored by the ACTTION (Analgesic, Anesthetic, and Addiction Clinical Trial Translations Innovations Oppor-

Symptoms and Signs of Fibromyalgia

- Chronic (>3 mo) widespread or multisite pain
- Fatigue
- Sleep disturbances
- Cognitive problems
- Other somatic symptoms (headaches, abdominal pain or bloating, dizziness, paresthesias)
- Diffuse and significant soft tissue tenderness on examination

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tunities and Networks)–American Pain Society Pain Taxonomy (AAPT) initiative suggested new diagnostic criteria for fibromyalgia (12) as part of a larger project to develop a diagnostic system across chronic pain disorders. The AAPT working group defined the core features of fibromyalgia as multisite pain (**Table 1**) and fatigue or sleep problems. Other features, including generalized soft tissue tenderness, cognitive symptoms, stiffness, and environmental sensitivity, are considered supportive but are not required for diagnosis. Despite their differences, current criteria identify similar patients and may be useful for guiding diagnosis.

What should the physical examination include?

A thorough physical examination should be performed, with particular attention paid to the joints and soft tissues. The primary goals are to identify widespread soft tissue tenderness and to evaluate for other conditions (osteoarthritis, rheumatoid arthritis, and systemic lupus erythematosus) that may present with similar symptoms. Palpation of multiple soft tissue sites (muscles, ligaments, and tendons) and joints should be performed to assess for signs of synovitis or inflammation of soft tissues. Generally, multiple soft tissue sites may be tender with palpation and application of modest pressure. Patients with fibromyalgia frequently report paresthesias, necessitating a neurologic examination. If soft tissue or joint inflammation or erythema is present, other conditions need to be considered. Likewise, focal neurologic findings should be evaluated further.

What other diagnoses should clinicians consider?

The diagnosis of fibromyalgia is challenging because the differential diagnosis is large (**Table 2**) and there is significant heterogeneity of clinical presentations and overlapping conditions. In broad categories, the differential diagnosis includes rheumatologic, neurologic, infectious, and endocrine disorders. Many conditions, especially other rheumatologic conditions, can present with musculoskeletal pain, fatigue, sleep disturbances, cognitive problems, and psychiatric symptoms that can mimic or coexist with fibromyalgia (1). For example, widespread pain and fatigue may be seen in patients presenting with a viral syndrome or acute hepatitis, but these symptoms typically do not last for more than 3 months. A thorough history and physical examination is usually sufficient to distinguish fibromyalgia from other conditions in the differential diagnosis.

Fibromyalgia often coexists with other chronic, painful conditions generally classified as functional somatic syndromes. These include migraine or tension headaches, irritable bowel syndrome, myalgic encephalomyelitis/chronic fatigue syndrome, interstitial cystitis (painful bladder syndrome), chronic pelvic pain, and temporomandibular joint disorder (12). These disorders are not only more prevalent in patients with fibromyalgia but are also believed to have common central nervous system mechanisms and tend to cluster in affected patients. The recognition and management of these comorbid disorders can help toward achieving treatment goals.

What is the role of laboratory testing?

No specific laboratory abnormalities are diagnostic for or characteristic of fibromyalgia. Thus, laboratory testing has a limited role in the evaluation and should be kept to a minimum (1, 12). The primary goal of laboratory testing

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Table 2. **Differential Diagnosis***

Condition, by System	*Characteristics/Distinguishing Features*
Rheumatologic	
Mechanical spinal pain and soft tissue	Pain, stiffness, and tenderness localized to a specific body area (low back, neck, shoulder, jaw); tenderness over tendon (tendinitis) or bursa (bursitis); radiographic or imaging findings
Rheumatoid arthritis	Symmetrical, small joint polyarthritis, systemic symptoms (fever, weight loss), elevated inflammatory markers (ESR, CRP), morning stiffness lasting >1 h
Spondyloarthritis	Spinal pain predominance (cervical, thoracic, lumbar), limited range of motion of the spine, radiographic findings, inflammatory markers (ESR, CRP)
Osteoarthritis of multiple joints	Joint stiffness, periarticular pain, joint line tenderness, joint space narrowing or osteophyte formation on radiographs
Polymyalgia rheumatica	Shoulder and hip girdle pain, elevated inflammatory markers, good response to corticosteroid treatment, stiffness more prominent than pain, more common in older adults
Systemic lupus erythematosus	Systemic manifestations (dermatitis, nephritis), photosensitivity, elevated inflammatory markers, positive result on antinuclear antibody test
Polymyositis	Proximal muscle weakness, possible muscle tenderness, generalized pain not present, elevated creatine kinase levels, characteristic histopathology on muscle biopsy
Neurologic	
Neuropathy	Paresthesias, sensory and/or motor deficits on physical examination, widespread pain unusual, electromyographic evidence of neuropathy
Multiple sclerosis	Vision changes, dysarthria, brain MRI abnormalities, widespread pain unusual
Infectious	
Lyme disease	Endemic area, recent tick bite, rash (erythema migrans), joint synovitis, confirmatory serologic testing
Hepatitis	Abdominal pain, elevated liver enzyme levels, positive result on hepatitis serologic testing

CRP = C-reactive protein; ESR = erythrocyte sedimentation rate; MRI = magnetic resonance imaging.
** Fibromyalgia is not a diagnosis of exclusion and may coexist with any of the conditions listed in this table.*

is to evaluate for other conditions with a similar symptom profile. Experts recommend obtaining only a complete blood count and either an erythrocyte sedimentation rate or a C-reactive protein level for initial testing to assess for an underlying inflammatory condition.

Screening or routine serologic tests (rheumatoid factor or antinuclear antibody) are not recommended unless there is clinical suspicion for an inflammatory rheumatologic condition based on history and physical examination. These tests often show positive results in healthy patients and have poor predictive value. If hypothyroidism or inflammatory myopathies are considered, thyroid-stimulating hormone or creatine kinase testing can be done to differentiate them from fibromyalgia. Blood chemistry tests and viral serologic tests are not helpful.

What imaging studies should be ordered?

Fibromyalgia has no characteristic radiographic findings, so radiographic or imaging studies should not be ordered. Although findings from research using functional neuroimaging are consistent with abnormal central nervous system processing of sensory input, neuroimaging is not

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currently useful for clinical diagnostic or prognostic purposes.

What additional testing may be needed?

Additional testing can be considered to evaluate for associated conditions that are clinically suspected. In patients with suggestive symptoms, a formal sleep study can be done to evaluate such sleep disorders as obstructive sleep apnea, restless legs syndrome, and periodic limb movements, given that prevalence of obstructive sleep apnea and restless legs syndrome is relatively high in patients with fibromyalgia (15, 16). A psychological assessment may be useful (7) to uncover undiagnosed depression or anxiety, which commonly coexist with fibromyalgia.

Although paresthesias are frequently reported by patients with fibromyalgia, formal electromyography is usually not indicated. In 2 recent studies, a subset of patients with fibromyalgia had skin biopsy evidence of a small fiber neuropathy (17), yet the clinical significance of these abnormalities is questionable. Some patients may present with orthostatic symptoms, tachycardia, or palpitations, possibly representing autonomic nervous system dysfunction.

When should clinicians consider consulting a rheumatologist?

Referral to a rheumatologist may be considered to confirm a diagnosis, evaluate for other suspected inflammatory conditions, or clarify the diagnosis when fibromyalgia symptoms occur in a patient with known rheumatologic disease. Referral may be more cost-effective than ordering multiple laboratory and imaging studies if another condition is suspected.

Diagnosis... Diagnosis of fibromyalgia is based primarily on a history and physical examination, with limited laboratory testing to exclude other conditions that can present with widespread pain. Screening for rheumatologic and other diseases with a battery of laboratory tests or radiographic imaging is not recommended unless a specific disorder is suspected. Available diagnostic criteria, especially the ACR and AAPT criteria, can be used to help guide the evaluation and diagnosis.

CLINICAL BOTTOM LINE

Treatment

What is the overall approach to treatment?

The overall approach to treating fibromyalgia should focus on maintaining or improving function, improving quality of life, and managing symptoms. To achieve these goals, guidelines recommend an individualized and multimodal treatment approach. Early in treatment, each patient should receive education about their diagnosis; basic pathophysiology; and treatment options, including an introduction to and discussion of self-management strategies. These strategies may include stress management; sleep hygiene; a balanced diet; regular physical activity, including aerobic exercise; weight reduction; activity pacing; and maintenance of an overall healthy lifestyle. Coexisting conditions, such as sleep disorders and major depressive disorder, should be identified

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promptly and treated concurrently.

Active nonpharmacologic therapies (supervised and graded exercise programs and cognitive behavioral interventions) are the mainstay of treatment (18). Although medications are often used first due to practice patterns that rely more on pharmacologic management than nonpharmacologic therapies, they are associated with adverse effects and clinical trials show modest benefits in patients. When treatments are initiated, patients should be counseled about reasonable expectations for benefits, reassessment should be scheduled, and treatments should be discontinued if benefits are not evident after a reasonable trial period. Because no single treatment improves function and minimizes all symptoms, a combination of treatments will likely be needed. Treatment guidelines recommend that the initial management of patients with fibromyalgia can and should be carried out in the primary care setting (18, 19).

What should clinicians recommend regarding physical activity?

Engagement in regular physical activity is imperative for effective management of fibromyalgia. In the 2017 European League Against Rheumatism recommendations for management of fibromyalgia, the only treatment receiving a "strong" recommendation was exercise (18). Aerobic exercise may also improve sleep (20) and may lessen depression and anxiety symptoms in patients with fibromyalgia (21). Even modest increases in daily physical activity can improve a patient's level of functioning (22). The most effective interventions are supervised exercise and physical activity programs that include low-impact aerobic exercise, such as walking, swimming, water aerobics, or biking (20, 23). In a 2017 systematic review of aerobic exercise, Bidonde and colleagues (24) found moderate-quality evidence for improved health-related quality of life and low-quality evidence for pain relief and increased physical function. Programs were relatively intense, involving supervised exercise that averaged 35 minutes per session and occurred 2 to 3 times per week. Water exercises and swimming were also found to be effective (23). Other potentially effective forms of exercise include strength and resistance training (25) and mind–body options, such as tai chi or yoga (26).

Although these types of exercise are generally well tolerated and are associated with minimal and infrequent adverse effects, adherence is a significant challenge. Exercise programs can be difficult to initiate and maintain. Patients may worry and perceive that exercise will worsen their pain and fatigue. To improve adherence, graded exercise programs are recommended that gradually and incrementally increase the amount and intensity of exercise that is tolerated by patients. Exercise programs that are aggressively implemented and advanced may lead to exercise-induced pain and myalgias, which can decrease adherence.

Clinicians should understand that there is no "one-size-fits-all" approach to exercise for patients with fibromyalgia. To optimize adherence, an exercise program should be individualized, account for patient preferences, and assess for concerns and adherence barriers. Ang and colleagues (27) found that a motivational interviewing intervention in patients with fibromyalgia promoted adherence to an exercise program, improved symptoms,

and increased self-reported physical activity. Physical therapists or exercise physiologists with expertise in fibromyalgia treatment can help prescribe an exercise program and provide ongoing support, coaching, and supervision that facilitates adherence (1). If adherence is optimized, benefits can be sustained in the long term.

What is the role of psychological and behavioral therapies?

A 2013 Cochrane review (28) concluded that cognitive behavioral therapy (CBT) provides small, incremental benefits compared with control interventions in alleviating pain, improving mood, and reducing disability at the end of treatment and during long-term follow-up. A more recent systematic review (29) found that psychological interventions may be effective in improving physical function, pain, and mood compared with usual care, but the strength of evidence was low. In this same review, the effectiveness of biofeedback, mindfulness, movement therapies, and relaxation-based therapies was unclear due to low or very low quality of evidence (29).

Even if treatment benefits are modest, psychological therapies are clearly safer than pharmacologic agents and are likely associated with lower costs. In a cost–utility analysis, CBT was more cost-effective than combination therapy with pregabalin plus duloxetine and usual care (30). Another analysis of economic outcomes in functional somatic syndromes, including fibromyalgia, found significant short- and long-term cost savings with a CBT group intervention compared with enhanced usual care (31).

Potential barriers to psychological therapies include limited access to therapists with expertise in managing patients with fibromyalgia or reluctance among patients to see a mental health provider. To improve access, telephone-based and technology-delivered interventions have been developed and tested. For example, an Internet-based self-management program (32) and an Internet-delivered CBT course (33) both provided benefits (reduced pain, improved depression, and increased satisfaction) for patients with fibromyalgia. The importance and use of psychological and behavioral therapies should be emphasized, given their effectiveness, safety, and cost advantages.

What should clinicians recommend regarding sleep hygiene?

All patients with fibromyalgia should be educated about the importance of sleep in moderating pain, fatigue, and cognitive symptoms. Basic sleep hygiene advice is appropriate for patients who do not have chronic insomnia. Patients should be evaluated for sleep disorders, including sleep apnea and insomnia, because specific therapies beyond basic sleep hygiene are needed for those with sleep disorders. For patients with insomnia, CBT for insomnia (CBT-I) is the first-line treatment (34). When individual or group CBT-I is not feasible, self-help CBT-I delivered via books or Web- or app-based programs is also effective (35). Use of over-the-counter or prescription sedative-hypnotics should generally be avoided.

How should clinicians approach pharmacologic treatment?

After initiation of nonpharmacologic treatments, several classes of medications (**Table 3**) may be tried to alleviate fibromyalgia symptoms. Tricyclic antidepressants (TCAs), especially amitripty-

61. Peterson K, Anderson J, Bourne D, et al. Effectiveness of models used to deliver multimodal care for chronic musculoskeletal pain: a rapid evidence review. J Gen Intern Med. 2018;33:71-81. [PMID: 29633140]

Table 3. **Pharmacologic Treatments**

Drug Class	*Dose*	*Advantages*	*Disadvantages and Adverse Effects*
Tricyclic antidepressants	Amitriptyline: start at 10 mg at bedtime; 20–30 mg maintenance Cyclobenzaprine (alternative): 5–20 mg at bedtime	Widely available Inexpensive Extensively studied Effective for pain and sleep	Need to titrate slowly Anticholinergic and antihistamine adverse effects are common (dry mouth, constipation, urine retention, sedation, concentration problems) Cardiotoxicity
Serotonin–norepinephrine reuptake inhibitors	Duloxetine: start at 20–30 mg in morning; 60 mg maintenance Milnacipran: start at 12.5 mg in morning; 50–100 mg twice-daily maintenance	Efficacy shown in multiple clinical trials (except for venlafaxine) May be helpful for patients with comorbid depression Better tolerated than tricyclic antidepressants	Headaches, nausea, dry mouth, diarrhea (duloxetine), and constipation (milnacipran) are common
Gabapentinoids	Pregabalin: start at 25–50 mg at bedtime; 300–450 mg/d maintenance Gabapentin: start at 100 mg at bedtime; 1200–2400 mg (divided doses) maintenance	May improve pain and sleep	Dizziness, dry mouth, somnolence, weight gain, peripheral edema, and cognitive problems (pregabalin)
Simple analgesics: acetaminophen, nonsteroidal anti-inflammatory drugs	–	Possible to use as an adjunct with other treatments May be helpful for coexisting conditions (e.g., osteoarthritis)	No evidence of benefit, but limited formal studies of acetaminophen
Tramadol	–	Improved pain and quality of life in the short term Possible role in patients who have severe pain and are refractory to other treatments	May be misused or abused (Drug Enforcement Administration schedule IV) Unknown long-term effects
Topicals	Capsaicin gel: apply several times a day	May provide some pain relief Safe	Associated with mild burning sensation when applied to skin

line, have been used in clinical practice for decades as an initial therapy, and systematic reviews (36, 37) have reported their effectiveness. Potential adverse effects can be minimized by initiating low doses of amitriptyline at night and titrating doses upward slowly. Other TCAs, such as nortriptyline and desipramine, may be tried, but these are not as well studied. Cyclobenzaprine has traditionally been classified as a skeletal muscle relaxant, but it is structurally and functionally similar to a TCA.

In patients who have contraindications, do not respond, or have intolerable side effects to TCAs, a serotonin–norepinephrine reuptake inhibitor (SNRI) can be considered. SNRIs, especially duloxetine and milnacipran, have been shown to be beneficial in several trials. A 2014 systematic review (38) showed that duloxetine was more likely than placebo to achieve the primary outcome of a 50% reduction in pain (relative risk, 1.57), with a number needed to treat of 8 (38). Although there are few long-term trials of SNRIs, duloxetine was found to be safe and effective at 1-year follow-up (39) and may be a good choice in patients with severe fatigue or comorbid depression. Milnacipran has been shown to be more effective than placebo for pain relief, global well-being, and physical function (40) and may be an alternative to duloxetine. Häuser and colleagues (41) found that duloxetine and milnacipran were superior to placebo in reducing pain and fatigue (but not sleep problems). However, it led to higher dropout rates due to adverse events.

Gabapentinoids (gabapentin and pregabalin) have been shown to benefit patients with fibromyalgia (42). In a meta-analysis of 5 randomized placebo-controlled trials (4 of pregabalin and 1 of gabapentin), they significantly reduced pain and improved sleep and quality of life (43). Few

studies have tested gabapentin, but it may be considered as an alternative to pregabalin. Although a trial by Arnold and colleagues (44) showed gabapentin to be superior to placebo, a recent systematic review concluded that "there is insufficient evidence to support or refute the suggestion that gabapentin reduces pain in fibromyalgia" (45).

Simple analgesics, such as acetaminophen and nonsteroidal anti-inflammatory drugs, are often prescribed as adjuncts to relieve pain (46) but have not been found to be effective in fibromyalgia. Tramadol has been studied in fibromyalgia and may be appropriate for some patients with severe pain (47). A review of topical capsaicin (48) included 2 trials of 153 participants and showed benefits in terms of pain relief but inconsistent findings for other outcomes. Although the data are inconclusive due to small sample sizes and methodological limitations, capsaicin gel is considered safe and may be a reasonable treatment option.

How should clinicians approach use of opioids?

Other than tramadol, which may be beneficial because of its serotonin and norepinephrine reuptake inhibition effects rather than its weak opioid agonist effects, opioids do not have evidence of efficacy in fibromyalgia. Research suggests patients with fibromyalgia have alterations in the endogenous opioid system and may even have improvement in pain when treated with low doses of the opioid antagonist naltrexone (49). Although opioids are unlikely to benefit patients with fibromyalgia, epidemiologic studies indicate that long-term opioid therapy is commonly prescribed for them (47). Clinicians should work with patients currently treated with long-term opioids to engage them in gradual tapering of doses. Unless patients desire more rapid dose reduction, tapering may need to occur over many months or years to optimize outcomes. Although fibromyalgia is not considered an appropriate indication for opioid therapy, abrupt tapering or discontinuation should be avoided because it may worsen symptoms, increase risk for opioid-related harm, and disrupt therapeutic relationships.

Are acupuncture, chiropractic manipulation, or other manual therapies effective?

Randomized controlled trials of manual acupuncture and electroacupuncture suggest benefit for pain, fatigue, and well-being, although trials are small and mostly short-term. A Cochrane review concluded that acupuncture was superior to no treatment or standard treatment but was not superior to sham acupuncture (50). A more recent systematic review found moderate-quality evidence (10 trials) that acupuncture was more effective than sham acupuncture and very-low-quality evidence (2 trials) that acupuncture was more effective than medications (51). For manual therapies, such as chiropractic manipulation, massage, and myofascial release, evidence is very limited and does not suggest substantial benefit in fibromyalgia (18, 26).

What is the role of dietary modification in treating or preventing flares?

Despite significant interest among patients in "anti-inflammatory" and other popular diets, evidence is lacking to support any particular nutritional intervention for fibromyalgia. A recent review found that 7 clinical trials of different diets (low-calorie, vegetarian, and low-

FODMAP) had similar positive results, but all studies were small and had substantial risk of bias (52). Given the low quality of the evidence, appropriate dietary guidance for patients with fibromyalgia may be similar to that for the general population, including reducing calories for weight loss when appropriate.

How should clinicians monitor patients?

Patients with fibromyalgia should be followed regularly for assessment of symptom severity and functioning, response to treatment, adherence, and adverse effects. The number of visits per year should be tailored depending on disease severity at diagnosis, comorbidity burden, symptom severity, changes in the treatment plan, adverse effects of treatment, and patient preferences. These factors and tracking of progress toward treatment goals are best assessed and addressed longitudinally rather than at a single clinic visit. An ideal chronic disease management approach takes time to find the most effective treatment or combination of treatments for each patient. Assessing response to different treatments in a stepwise fashion requires trial and reevaluation. More frequent office visits may be necessary at the time of diagnosis and after initiation of new treatments (19), as well as to manage flare-ups, encourage patients with suboptimal adherence, support patients who are overwhelmed by their condition, provide ongoing education, and emphasize self-management strategies. Furthermore, greater outpatient engagement has been found to protect against suicide in patients with fibromyalgia (53).

What is the prognosis?

Fibromyalgia symptoms may begin after physical trauma, surgery, infection, or significant psychological stress. In other cases, symptoms gradually develop and accumulate over time, with no single triggering event. Most patients will continue to have persistent pain and fatigue with intermittent fluctuations in their symptoms over time. Wolfe and colleagues (54) found that pain, fatigue, sleep disturbances, anxiety, and depression were essentially unchanged over 8 years of follow-up among patients seen in 6 tertiary referral centers. In a more recent observational study, only 1 out of 4 patients followed for up to 11 years reported at least moderate pain improvement (55). In contrast, Fitzcharles and colleagues found that only 35% of patients still had widespread pain 2 years after their initial assessment (56).
Of note, patients treated by community-based primary care clinicians have a better prognosis than those seen in tertiary referral centers, and almost all large long-term outcome studies have involved tertiary care center patients.

Work disability is common in patients with fibromyalgia. Wolfe and colleagues (57) found that 41.5% of patients with fibromyalgia received Social Security disability compared with 36.8% and 23.7% of those with rheumatoid arthritis and osteoarthritis, respectively. Of note, this was a registry study with a nonrepresentative sample, so it may not accurately reflect population prevalence of disability.

Prognosis is related to certain demographic, behavioral, and psychological factors. Female sex, low socioeconomic status, and unemployment status are

associated with poorer outcomes (58). Other important prognostic factors include depression, abuse history, catastrophizing, excess somatic concern, and obesity (59). Patients with fibromyalgia have increased risk for suicide (60) and should thus be monitored for symptoms of depression.

How should clinicians educate patients about fibromyalgia?

Patient education is important to validate the illness experience, reduce symptom-related anxiety, and provide a rationale for self-management and recommended therapies. To optimize the likelihood of treatment success, clinicians should provide ongoing support for lifestyle changes (for example, sleep hygiene, exercise, and weight reduction) and participation in active nonpharmacologic therapies. Patients should be educated that symptom exacerbations (flares) are common and should be taught several possible strategies (keeping a symptom log and noting triggers, reducing stress, using relaxation exercises, engaging in pleasant activities, and resting) to prevent and manage them. Key educational points are summarized in the Box.

Key Educational Points

- Pathophysiology: Fibromyalgia is a disorder of pain processing. The nervous system signaling is amplified or turned up so that people feel more pain and fatigue than would be expected under the circumstances.
- Diagnosis: A checklist of symptoms can accurately identify fibromyalgia. Patients with fibromyalgia usually have normal physical examination findings and do not have abnormalities in blood or routine imaging tests.
- Prognosis: Fibromyalgia is a chronic disease, meaning it can be managed but not cured. The overall approach to treating fibromyalgia should focus on maintaining or improving function, improving quality of life, and managing symptoms. This is best achieved through an active collaboration between the physician and the patient. Encouraging patients to be physically active and acknowledging their efforts toward reaching their treatment goals can give them the confidence and optimism needed to manage their disease over time. The prognosis of fibromyalgia is better when it is managed in primary care, and patients are more likely to attain remission.
- Treatment: Active treatments for fibromyalgia work by retraining the brain and nervous system to make them less sensitive. Medications often help to relieve symptoms. Most people need combined approaches to address different aspects of fibromyalgia.

When should clinicians consider specialist consultation?

Fibromyalgia treatment should be multimodal and multidisciplinary, using a combination of exercise, behavioral, and medication therapies. The ability to provide integrated care and longitudinal follow-up is probably more important than the specialty of the physician responsible for coordinating care. However, in patients who have not responded to initial, optimal management, consultation with a rheumatologist, a pain specialist, a physiatrist, and a mental health provider should be considered. Although the evidence base for any particular treatment model is limited, systematic reviews and clinical trials have identified collaborative and interdisciplinary care models (for example, nurse- or pharmacist-led care management, stepped care,

algorithm-guided treatment, and multidisciplinary treatments) that improve function, pain, and other outcomes in chronic musculoskeletal pain (61). For patients with substantial functional limitations or disability due to fibromyalgia, referral to an interdisciplinary chronic pain rehabilitation program is indicated.

Treatment... Fibromyalgia treatment should focus on maintaining or improving function, improving quality of life, and managing the most prominent or bothersome symptoms. To achieve these goals, sleep hygiene, active self-management, and regular physical activity should be emphasized at each clinic visit. Optimal treatment is tailored to the patient and involves a multimodal approach that includes both nonpharmacologic and pharmacologic therapies. Among nonpharmacologic therapies, graded exercise programs and cognitive behavioral interventions have the highest-quality evidence supporting their use. There are several pharmacologic treatments that can be used to relieve the pain of fibromyalgia and its associated symptoms.

CLINICAL BOTTOM LINE

Practice Improvement

What do professional organizations recommend regarding diagnosis and management?

Professional organizations in Canada, Europe, Israel, and Japan have published guidelines on the diagnosis and management of fibromyalgia. The 2 most commonly cited guidelines were issued by the Canadian Pain Society and Canadian Rheumatology Association in 2013 (19) and the European League Against Rheumatism in 2017 (18). Each used systematic reviews with or without meta-analyses to identify the highest level of evidence to inform their recommendations. Both guidelines endorsed that initial management should emphasize education about the condition and should focus on nonpharmacologic therapies. If initial management is ineffective, the recommended next step is adding pharmacologic therapies targeted to the most problematic symptoms.

In the Clinic
Tool Kit

Fibromyalgia

Patient Information

www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Fibromyalgia

www.rheumatology.org/I-Am-A/Patient-Caregiver/Enfermedades-y-Condiciones/Fibromialgia

Patient information on fibromyalgia in English and Spanish from the American College of Rheumatology.

https://medlineplus.gov/fibromyalgia.html

Patient information and handouts on fibromyalgia in English and other languages from the National Institutes of Health's MedlinePlus.

www.niams.nih.gov/health-topics/fibromyalgia

www.niams.nih.gov/es/informacion-de-salud/fibromialgia

Resources for patients on fibromyalgia in English and Spanish from the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Information for Health Professionals

www.sciencedirect.com/science/article/abs/pii/S0049017216302086

2016 revisions to the 2010/2011 American College of Rheumatology preliminary diagnostic criteria for fibromyalgia.

www.jpain.org/article/S1526-5900(18)30832-0/fulltext

Proposed diagnostic criteria for fibromyalgia from the ACTTION-American Pain Society Pain Taxonomy Initiative.

https://ard.bmj.com/content/76/2/318

2017 revised recommendations for management of fibromyalgia from the European League Against Rheumatism.

https://rheum.ca/resources/publications/canadian-fibromyalgia-guidelines

Guidelines for the diagnosis and management of fibromyalgia from the Canadian Rheumatology Association.

https://nccih.nih.gov/health/providers/digest/fibromyalgia

https://nccih.nih.gov/health/providers/digest/fibromyalgia-science

Mind and body practices for fibromyalgia from the National Center for Complementary and Integrative Health.

WHAT YOU SHOULD KNOW ABOUT FIBROMYALGIA

What Is Fibromyalgia?

Fibromyalgia is a chronic condition that causes pain and tenderness all over the body for longer than 3 months. It can make you feel very tired, even after sleep, and can also cause a range of other symptoms. Research shows that people with fibromyalgia are extra-sensitive to pain signals and process them differently. Symptoms may begin after physical trauma, surgery, infection, or significant stress. Sometimes, there is no triggering event, and symptoms develop gradually over time.

Am I at Risk?

Risk factors include:

- Being female (twice the risk)
- Having a history of other inflammatory conditions, like rheumatoid arthritis or lupus
- Having a family member with fibromyalgia
- Insomnia or other sleep problems
- A history of depression and/or anxiety
- Not being physically active
- Excess body weight

What Are the Symptoms?

- Tenderness and pain all over the body
- Extreme tiredness
- Trouble sleeping
- Problems with concentration and memory
- Numbness or tingling in the hands and feet
- Other physical symptoms, such as headaches, abdominal pain, nausea, jaw pain, diarrhea, and dizziness

How Is It Diagnosed?

- A checklist of symptoms and their duration can identify fibromyalgia.
- Your doctor will perform a thorough history and physical examination to rule out other potential causes of your symptoms. The doctor will apply pressure to your muscles, joints, and tendons to see where there is tenderness.
- Because there is no test to diagnose fibromyalgia, laboratory and imaging tests should be kept to a minimum.
- When another condition is suspected, your doctor may order additional tests.

How Is It Treated?

Fibromyalgia is a chronic disease. The goals of treatment are to improve your function and quality of life and manage your most bothersome symptoms. Doctors and patients should work together to come up with a treatment plan. Exercise is essential for all patients with fibromyalgia because research shows it improves health-related quality of life, pain, function, sleep, depression, and anxiety. Low-impact exercise, such as walking, swimming, or yoga, is best. Usually, a combination of several treatments is needed, which may include:

- Getting enough sleep
- Managing stress
- Eating a balanced diet and losing weight if you have obesity or overweight
- Treating other conditions, such as sleep disorders or depression
- Cognitive behavioral therapy
- Acupuncture

In addition to these self-management strategies, your doctor may suggest medication to help with persistent symptoms. Several medications are available that may reduce pain and improve sleep. However, most have only modest benefits and may have side effects. Most opioid pain medications do not work for patients with fibromyalgia and have serious side effects. Talk to your doctor about the benefits and risks.

Because fibromyalgia is a chronic condition, you should have regular visits with your doctor to check in about your treatment plan and how your symptoms are improving.

Questions for My Doctor

- How can I manage my symptoms and address flare-ups?
- Would you help me create a self-management plan?
- Do I need to take medicine?
- What are the side effects of the medicines?
- How can exercise improve my symptoms?
- How often do I need to follow up?
- Do I need to see other medical specialists?
- What alternative treatments should I try?

For More Information

ACP℠
American College of Physicians
Leading Internal Medicine, Improving Lives

MedlinePlus
https://medlineplus.gov/fibromyalgia.html

National Fibromyalgia & Chronic Pain Association
https://fibroandpain.org

Patient Information