# Review

# Fibromyalgia syndrome: under-, over- and misdiagnosis

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**ABSTRACT**

*Fibromyalgia syndrome (FM) is an enigma. During the past three decades, with the gradual acceptance of the validity of FM, it is variously under-, over and misdiagnosed. Evidence-based interdisciplinary guidelines have suggested a comprehensive clinical assessment to avoid this diagnostic conundrum. Every patient with chronic pain should be screened for chronic widespread pain (pain in four of five body regions) (CWP). Those with CWP should be screened for presence of additional major symptoms of FM: unrefreshed sleep and fatigue. A complete medical (including drug) history and complete physical examination is mandatory in the evaluation of a patient with CWP in order to consolidate the diagnosis of FM or identify features that may point to some other condition that may have a presentation similar to FM. Limited simple laboratory testing is recommended to screen for possible other diseases. The 2016 criteria may be used to further confirm the clinical diagnosis of FM. In consideration of the differential diagnosis of FM, attention should be paid to the presence of other chronic overlapping pain conditions and of mental disorders. FM as a stand alone diagnosis is however rare, as most patients with FM meet criteria for other chronic overlapping pain conditions or mental disorders. The severity of FM should be assessed in order to direct treatment approaches and help inform the likely outcome for an individual patient.*

## Introduction

Despite substantial interest and investigation over the past 30 years, fibromyalgia syndrome (FM) continues to provoke debate and raise challenges at many levels (1, 2). Fibromyalgia wars (3, 4) are fought on a number of fronts: the legitimacy and clinical usefulness of the diagnostic label FM, the nosological classification, diagnostic criteria, suggested aetiology and pathophysiology, "ownership", the preferred treatment options and long-term outcome (5-7). Even in this past decade physicians still report uncertainties about how to diagnose FM (8, 9). This medical uncertainty translates into patient stressors, frustration and even dissatisfaction (10). The time to establish a definitive diagnosis of FM often extends to many years, with innumerable clinic visits, investigations and specialist consultations, all contributing to the personal and societal burden of FM. (9-11).

A definitive diagnosis of FM has several advantages for an individual patient: the diagnostic label legitimises the subjective symptoms and provides reassurance; patients are better able to cope with their health status (9), patients are able to access guidelines-based treatments (12). In contrast, there is increasing recognition of both misdiagnosis of FM (13-15), and overdiagnosis of FM (16). These controversies and uncertainties may contibute to the poor view of FM by physicians, with Norwegian physicians ranking FM on two separate occasions in 2002 and 2014 as the disease with the lowest prestige of 38 low ranking conditions (17).

The aims of this narrative overview are to outline the prevalence and potential reasons for the under-, over- and misdiagnosis of FM and to give a clinical guidance to enable the clinician to achieve a more accurate diagnosis of FM and thereby to improve the prestige of this condition.

The recommendations towards better accuracy in the diagnosis of FM are based on recent German (12), Canadian (18) and European League Against Rheumatism (19) guidelines on FM.

## Underdiagnosis of FM

The true rate of underdiagnosis of FM is difficult to estimate. Anecdotally, in the clinic, patients with FM often report

that other family members experience symptoms compatible with FM, but without a definite clinical diagnosis. It is also possible that the media may contribute to an increased awareness of FM in some countries, whereas other populations may be less aware of this condition, and merely accept the constellation of symptoms without question or consultation. Discrepancies between the administrative and epidemiological prevalence might be a signal of underdiagnosis of FM in some countries. For example, only 2.5% of Japanese persons meeting the 2011 criteria were reported to be diagnosed with fibromyalgia (20). According to data from a German health insurance company with 7 million insured persons, the one year prevalence of persons identified with FM defined by at least one billing ICD 10 code for fibromyalgia was 0.3% (21). In contrast, the prevalence of potential FM cases according to the 2011 criteria (22) was 2.1% in the general German population (23).

Underdiagnosis of FM as a comorbid condition may also occur in patients with some other primary disease. This concept of comorbid FM has recently been highlighted in a review in which the authors found substantial rates of patients meeting FM-criteria, especially for those with inflammatory rheumatic diseases. However FM is also now recognised to occur in diseases in which chronic pain is not a major symptom such as heart failure, primary immunodeficiency or Parkinon's disease (24). Unfortunately, the studies of comorbid FM have not reported whether FM was a preexisting condition, or occured concomitant with the specific medical condition described.

There may be a number of reasons to explain this impression of an underdiagnosis of FM: a) Physicians may be poorly knowledgeable in the recognition and diagnosis of FM (8); b) Some physicians may be reticent to assign a diagnosis of FM in view of the stigmatisation that still associates with FM, *e.g.* male patients being labelled as having a condition most commonly associated with females, or a condition that can be viewed as malingering (25, 26); c) Physicians are attuned to using objective abnormalities on examination or biomarkers on laboratory testing to confirm clinical diagnoses, a scenario completely lacking in the diagnosis of FM. Outside of psychosocial and pain medicine, there are uncertainties and reluctance to use symptom-based diagnosis. Other so-called non-specific, functional, and somatoform disorders such as FM or irritable bowel syndrome (IBS) remain underdiagnosed in general and specialist care (27); d) There remains the notion amongst some health care professionals that FM "does not exist" and are therefore reluctant to use the diagnostic code "FM" (12). For example, psychiatrists may choose to use the diagnostic codes of masked depression, whereas specialists in clinical psychology and psychosomatic medicine may preferably use the diagnostic code for a somatoform pain disorder or a physical symptom disorder, rather than the specific label of FM (28). Another choice may be the diagnosis of post-traumatic stress disorder (PTSD). PTSD is a mental disorder that can develop after a person has been exposed to a traumatic event, characterised by a specific set of symptoms including re-experiencing of the event, avoidance and numbing and arousal (29, 30).

**Overdiagnosis of FM**

Overdiagnosis of FM can occur when regional pain conditions are wrongly diagnosed as FM. This fallacy may be partly attributed to rigid adherence to the American College of Rheumatology FM classification criteria(31) that allowed for a diagnosis of FM when only three body locations were painful. Although it is possible that some regional pain conditions may evolve into a more widespread pain condition, implications for outcome and treatment differ for regional pain differ from that for FM. An incorrect diagnostic label of FM, a condition that is expected to be lifelong, has considerable personal and social consequences. Patients may believe that a condition that is potentially self limited will result in long standing poor health; there could be the mental anguish of the prospect of living with a chronic illness; and there is also the risk that a perception of chronic illness may lead to sickness behaviour and disablement. In some cases physicians may leap to a quick diagnostic label of FM in a busy clinical setting and thereby limit the consultation time, especially when the encounter can be rapidly terminated by provision of a drug prescription.

We are aware of only one US study which found a signal of overdiagnosis of FM on a population level. In the National Health Interview Survey 2012, 73.5% of the 1.8% of respondents who reported doctor-diagnosed FM did not meet the 2011 criteria as their symptoms were not sufficiently severe. This has led the authors to conclude that the diagnosis of FM may be assigned too freely in the clinical setting, and that physicians have not adhered to use of diagnostic criteria in establishing a diagnosis, a conclusion that is debatable (18). In contrast, 85.5% of the 1661 participants of the German Fibromyalgia consumers report (with a self-reported diagnosis of FM that was established by a physician) met the 2011 FM criteria at the time of the study (32). In view of the signals of underdiagnosis of FM in Germany and Japan, more studies in different countries are needed to assess if overdiagnosis of FM is solely an US or an international phenonemon. Furthermore, the misdiagnosis of FM in some case series of rheumatology centres in patients with inflammatory rheumatic diseases (see below) may also be regarded as a signal of overdiagnosis.

**Misdiagnosis of FM**

There are a number of clinical scenarios that are associated with CWP. It is therefore encumbant on the physician to always consider a differential diagnoisis when evaluating a patient with a diffuse pain syndrome. The differential diagnosis of CWP has been examined in detail in a recent review titled appropriately "diagnostic confounders of chronic widespread pain" (33). Broadely speaking, conditions that may be confounded with FM can be categorised into rheumatic, neurologic, non-rheumatic medical conditions, mental health disorders and drug related adverse effects.

The misdiagnosis of FM most likely

occurs in the setting of early undiagnosed rheumatic diseases before the appearance of objective abnormalities on physical examination or laboratory testing. Preclinical rheumatoid arthritis may present with body pain, fatigue and even muscle weakness in the months preceeding onset of appreciable joint swelling (34). Similarly, the early stages of inflammatory spondyloarthritis, especially in the setting of mutltiple sites of enthesopathy, may appear as a more ill-defined pain syndrome (35). Polymyalgia rheumatica should always be considered in an older person presenting with a new onset of diffuse pain, although there is usually prominent stiffness and complaints are more focussed towards the limb girdle regions. Non-inflammatory musculoskeletal conditions include myofascial pain syndromes and hypermobility syndrome.

In the category of other medical illnesses, consideration of the following conditions should be given: endocrine disease or metabolic disorder (hypothyroidism, hyperparathyroidism, acromegaly, vitamin D deficiency), gastrointestinal disease (celiac and non-gluten sensitivity), infectious diseases (Lyme disease, hepatitis C and immunodeficiency disease) and the early stages of a malignancy such as multiple myeloma, metastatic cancer and leukaemia/lymphoma (33).

Neurological diseases with an important pain component include multiple sclerosis, Parkinson's disease and peripheral neuropathy. Spinal stenosis, although most commonly associated with claudicant type pain, can present in a more ill-defined way, and may be difficult for a patient to clearly describe. Although weakness is the most common symptom of a myopathy, this may be less prominent than diffuse pain in some patients. Some case series have reported on the misdiagnosis of FM in patients with myopathies (36).

As noted above, a medication history is always required in the setting of diffuse pain, with an ever increasing list of drugs causing myalgias and arthralgias. The most well recognised drugs are the statins, opioids, chemotherapeutic agents, aromatase inhibitors and bisphosphonates (33).

**Table I.** Steps in the clinical encounter in assessing chronic widespread pain (29, 33).

1. Pain history
   a. Location( may use pain diagram)
   b. Timing of onset
   c. Aggravating and alleviating factors
2. Associated symptoms history
   a. Fatigue and unrefreshed sleep (may use fibromyalgia symptom questionnaire)
   b. Other organ system symptoms
   c. Systemic symptoms (weight loss, reduced appetite, fever)
3. Past medical (including drug) history
4. Examination
   a. Full physical examination with specific attention to:
      i. Assessment of body tenderness or allodynia
      ii. Examine for joint swelling, spinal stiffness and enthesis tenderness
      iii. Neurological examination
5. If fibromyalgia is suspected
   a. Limited laboratory testing (full blood count, ESR, CRP, CK, TSH, Calcium)
6. History of other chronic pain syndromes
7. Psychiatric history (Anxiety, depression, ongoing family and /or professional problems)

ESR: erythrocyte sedimentation rate; CRP: C-reactive protein; TSH: thyroid stimulating hormone.

## Appropriate diagnosis of FM

The foundation for evaluating a patient with CWP is a comprehensive history and physical examination, which may be followed by specifically directed investigations as indicated (37) (Table I).

*History*

As a first step, the location of chronic pain can be assessed by means of a pain diagram. CWP can be recognised at a glance using a pain diagram completed by the patient (Fig. 1-2). In case of CWP, further questioning regarding associated symptoms of unrefreshed sleep and fatigue should be pursued. Positive responses in the setting of CWP would identify the condition as a FM-type syndrome. Attention must be given to timing of onset and evolution of symptoms, report of any triggering event, as well as alleviating or aggravating factors. In the context that there is a familial association of FM, a family history of first degree relatives should be documented. Some "yellow flags" in the history and physical evaluation can point towards FM (Table II).

For a person presenting with CWP, especially as a new symptom, a medication history must be explored to ensure that medication adverse effect is not the cause of the pain complaint. Medications that should be considered include lipid lowering agents in the category of statins, aromatase inhibitors, bisphosphonates and paradoxically even opioids. Therefore a history of current medication use is obligatory.

*Physical examination*

A physical examination is required specifically to examine for evidence of structural joint abnormality, muscle weakness, neurological abnormality or evidence of endocrine disease. The physical examination should be within normal limits for the patient's age. Clues that may point to a diagnosis of FM are soft tissue and generalised body tenderness. Although the tender point examination was used in the past to establish a diagnosis of FM, this finding is no longer incorporated into the physical examination in view of poor validity and poor reproducibility. Some patients may demonstrate dysaesthesia on light touch, or myofascial induration, or joint hypermobility.

*Additional testing*

No confirmatory blood tests (biomarkers), imaging or histological analysis are available for FM. A limited number of laboratory tests will allow for screening for medical conditions that can mimic FM symptoms.

A summary of conditions that should be considered in the differential diagnosis of a patient presenting with CWP, as well as "red flags" characteristic for each, and suggested specific testing are detailed in Table III (33).

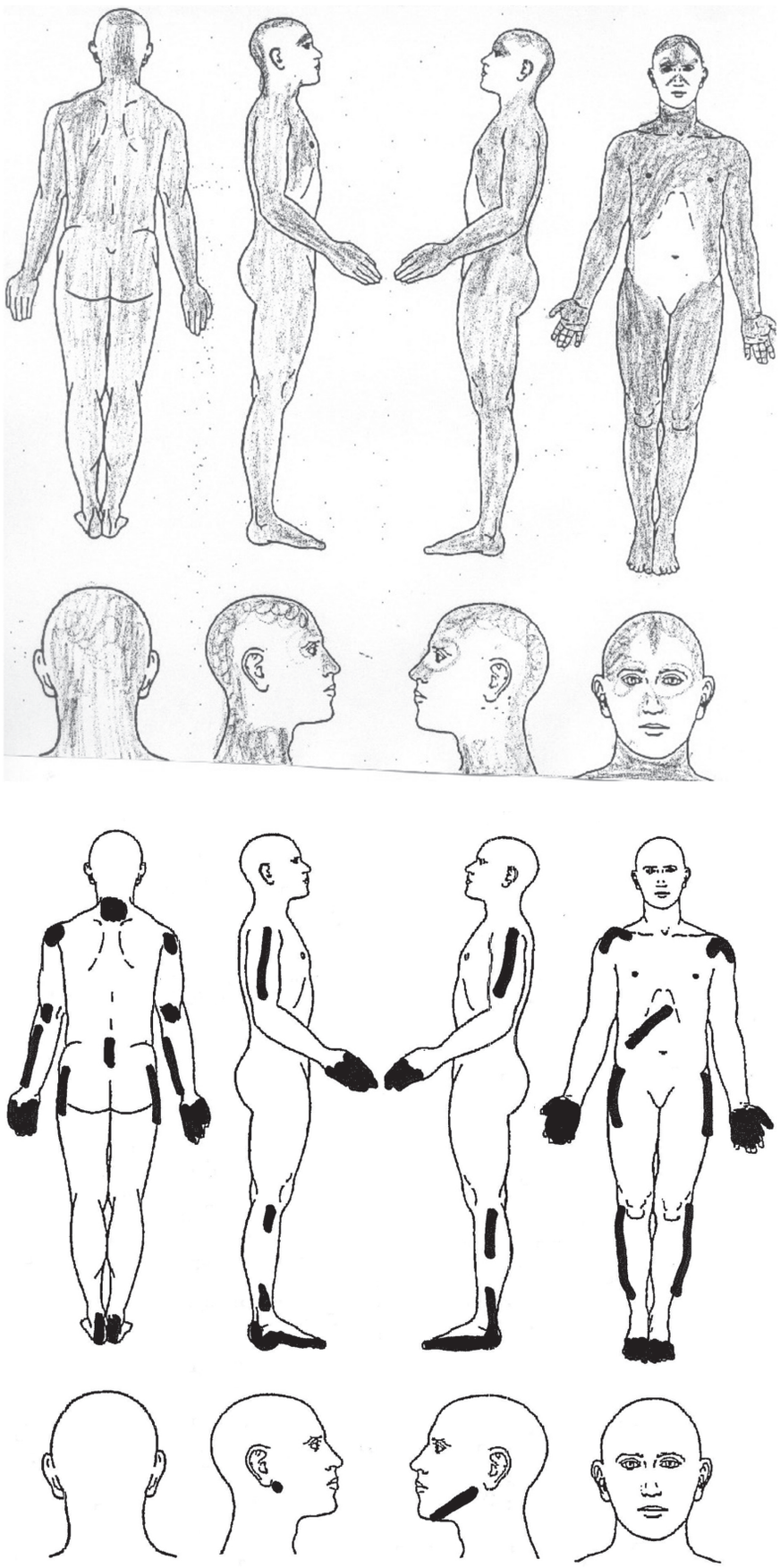

**Fig. 1.** Pain diagrams of patients with fibromyalgia syndrome.

*Definite diagnosis*

To reassure the clinician regarding a clinical diagnosis of FM, reference may be made to one of the published classification or diagnostic FM-criteria. The authors recommend that the 2016 criteria may be used to complement the clinical evaluation in establishing a diagnosis of FM. The 2016 criteria require a widespread pain index (WPI) of between 4 (2011 required 3) and 6 pain sites and a symptom severity (SS) score of ≥9. In addition, generalised pain as defined by pain occurring in at least four of five body regions (four quadrants and axial) except the face and the abdomen should be present (38).

The Fibromyalgia Survey Questionnaire (also called polysymptomatic distress scale, PSD) capturing the 2011 (22) and 2016 (38) diagnostic criteria of FM, can be completed by the patient to further complement the clinical assessment, and can be used to give some indication of severity of the condition.

In most cases, a definite diagnosis can be effectively established based on the history, a physical examination that demonstrates general tenderness (muscle, joints, tendons), and the absence of some other pathology that could explain pain and fatigue, and with normal basic laboratory tests. According to the standards of good medical practice, the physician must always consider a differential diagnosis for any patient presenting with a diffuse pain complaint. This has been covered in the section on misdiagnosis of FM.

*FM may co-exist with other pain syndromes*

Patients with a diagnosis of FM may also experience other pain conditions that are mostly distinct from FM and are generally classified as overlapping pain conditions. It is notable that the 2011 (22) and 2016 (38) criteria include headache and abdominal pain into the somatic symptom score, thereby increasing the probability that patients with migraine or tension headaches, or irritable bowel syndrome will meet FM criteria. Even when the ACR 1990 classification criteria (31) are used for diagnosis, many patients with FM meet criteria of some other functional

**Table II.** Clues for FMS by history (33).

- Family history of early chronic pain, *e.g.* low back pain, "rheumatism", etc.
- Personal history of pain (head, abdomen, joints) in childhood and adolescence.
- Long history of local pain.
- Onset of widespread pain related to physical and/or psychosocial stress.
- Pain characteristics that include .
  - Variable in location and intensity.
  - Neuropathic-like pain quality (burning pain).
  - Aggravated by weather changes, tension, poor sleep, stress.
- General hypersensitivity to touch, smell, noise, taste.
- Hypervigilance.
- Multiple somatic symptoms (gastrointestinal, urology, gynecology, neurology) with previous diagnosis of functional dyspepsia, irritable bowel syndrome, painful bladder syndrome, tension headache, migraine, temporomandibular disorder.
- High symptom-related emotional strain.

somatic syndrome (also called chronic overlapping pain conditions) (39). Although many treatment options for various functional somatic syndromes are identical, such as aerobic exercice, cognitive-behavioural therapies and antidepressants (40), there are some treatments that specifically address focussed organ symptoms such as gut-directed hypnosis and antispasmodics for those with irritable bowel syndrome (IBS). It is notable that a recent study has demonstrated that treatment of visceral pain comorbidities (endometriosis, IBS, primary dysmenorrhea) reduced FM-pain (41). Therefore, FM patients should be screened for other pain syndromes, *e.g.* by questions about headache and abdominal pain and /or a questionnaire that captures somatic symptom burden such as the Patient Health Questionnaire (PHQ) 15 (42).

The co-existence of FM with some other medical condition that could act as a pain generator, may influence outcome of the other condition in particular, and the global health outcome in general. There are two considerations when FM co-exists with some other condition: firstly the underlying condition should be treated according to best practice, *e.g.* for osteoarthritis or mechanical back pain; and secondly there must be an appreciation that concomitant FM may affect the outcome of the underlying condition. This has been shown for surgical outcome which is less favourable for patients with osteoarthritis of the knee and comorbid FM (43).

*FM may co exist with mental health disorders*

Depression is another FM symptom identified in the somatic symptom scale of the Fibromyalgia Symptom Questionnaire. Depending on the clinical setting, up to 80% of FM patients meet the criteria of depressive and/or anxiety disorder. The severity (number and intensity of symptoms and degree of disability) of FM is substantially determined by comorbid mental disorders (44). A screening of FM patients for psychological distress either by questions such as "Over the last 2 weeks, how often have you been feeling down, depressed, or hopeless", "Feeling nervous, anxious or on edge" or questionnaires (*e.g.* PHQ 4) (45) is recommended by some FM guidelines. Severe comorbid mental disorders require the inclusion of a mental health specialist in the management of FM (19, 46).

*Severity of FM as a continuum disorder*

Patients with full expression of FM are at the end of a continuum of multiple pain sites and other somatic and psychological symptoms (47). As for other diseases which are defined by continuous variables such as hypertension, diabetes or depression, there is currently no absolute point that defines where FM begins. Cut-off points for the diagnosis of continuum disorders are defined by expert consensus and based on clinical studies. The higher the cut-off point for a diagnosis, the lower is the prevalence of that diagnosis. The 2016 diagnostic criteria for FM (38) increased the requirements needed to meet the widespread pain criterion compared to those of the 2011 diagnostic criteria (38). Thus, the prevalence of potential FM-cases in the general German population decreased from 2.1% (21) to 1.9% (Wolfe 2018, submitted). In addition, longitudinal studies of patients with CWP and or fibromyalgia have demonstrated that some patients report fluctuation in symptoms over time and thus oscillate around the cut-off points; at times being FM positive or FM negative (48, 49). The waxing and waning nature of FM might explain some discepancies between the prevalence of criteria identified FM versus clinical FM.

There is no internationally accepted grading of the severity of FM, but clinical wisdom requires the treating physician to make an assessment of severity in order to direct treatment options (50). Most gradings suggest a distinction between mild, moderate and severe forms of FM, based on the intensity of symptoms and the degree of limitation in daily functioning (51). It therefore follows that a stepwise management approach can be based on the severity of FM. Mild forms require primarily education and advice (regular physical and social activities) with perhaps the occasional use of drug therapy for episodes of exacerbation, and can be managed in primary care. More severe forms require multicomponent (exercise, psychological therapies, drugs) and multidisciplinary therapies (12, 18). Therefore, for the follow-up of patients diagnosed with FM, a "continuum" assessment, *e.g.* by questions about general well-being (*e.g.* on a 0-10 scale, or a Likert scale of "the same", "better" or "worse") or by symptom questionnaires such as the PSD (23) or the PHQ 15 (42) might be more appropriate (47) than determination of whether a patient meets FMS criteria or not at a particular time point (38, 45).

## Conclusions

FM is now firmly established as a real and valid condition. Most patients with FM experience considerable suffering and

**Table III.** Clues to some other conditions presenting as chronic widespread pain (29).

| Condition | History | Examination | Specific testing |
|---|---|---|---|
| **Systemic inflammatory rheumatic diseases** | Defined time of onset<br>Progressive increase symptoms<br>Morning stiffness>1 hour<br>Constitutional symptoms (fever, decreased appetite, weight loss)<br>Pain focussed to joints or enthesis sites<br>Skin rash/psoriasis, vasculitis, sun sensitivity, Raynaud's phenomenon<br>Dry mucosal surfaces<br>Bowel symptoms suggesting inflammatory bowel disease<br>Family history of systemic inflammatory rheumatic diseases | Pallor, low BMI<br>Adenopathy<br>Skin rash/nodules<br>Joint tenderness<br>Limited spinal mobility | ESR, CRP, RF, ant-CCP, ANA, HLA-B27<br>Joint ultrasound<br>Radiographic imaging |
| **Non rheumatic musculoskeletal conditions** | Pain focussed to regions (neck, shoulders, back)<br>Joint dislocations<br>Family history of hypermobility | Trigger points<br>Hypermobile joints<br>Skin hyper elasticity<br>Skin fragility (bruising, atrophic scarring) | Genetic testing if Ehlers-Danlos other than hypermobility type is suspected |
| **Non rheumatic medical conditions** | | | |
| **Endocrine/metabolic** | Weight gain<br>Constipation<br>Change size hands/feet<br>Poor sun exposure<br>Family history thyroid disease | Pallor<br>Thickened hair<br>Waddling gait | TSH<br>PTH<br>Vitamin D |
| **Gastrointestinal** | Weight loss<br>Bloating, diarrhoea | | Colonoscopy<br>Transglutaminase antibody |
| **Infectious diseases** | Risk factors for Hepatitis c (intravenous drugs)<br>Erythema migrans | | Anti-HCV |
| **Malignancy** | Prominent systemic symptoms<br>Bone pain<br>Night pain | | Blood count; ESR |
| **Neurological diseases** | Any neurological symptoms<br>Increase muscular tone<br>Slow gait<br>Tremor | Discrete neurological abnormality<br>Tremor<br>Rigidity<br>Positive glabellar tap | Nerve conduction studies, evoked potentials |
| **Spinal stenosis/myelopathy** | Older age<br>Previous spinal pain<br>Claudicant pain especially buttocks and thighs<br>Pain related to posture | Spinal examination may be normal for age | Radiographic imaging studies as indicated |
| **Myopathy/myositis** | Family history of myopathy<br>Difficulty climbing stairs/arising from seated position unaided<br>Exercise induced muscle symptoms<br>Skin rash<br>Raynaud's phenomenon<br>Muscle tenderness<br>Muscle cramping<br>Symptoms related to carbohydrate intake | Heliotrope facial rash<br>Mechanics hands<br>Skin tightening<br>Exercise or food induced muscle symptoms<br>Muscle weakness/tenderness | Creatine kinase<br>Immunological and genetic testing as indicated<br>Exercise testing<br>Electromyography<br>Magnetic resonance imaging<br>Muscle biopsy |
| **Mental health disorders** | Personal and family psychosocial history | Patient Health Questionnaire 4 (screening for anxiety and depression) | Psychiatric interview |

ESR: erythrocyte sedimentation rate; CRP: C-reactive protein; RF: rheumatoid factor; anti-CCP: anti-cyclic citrullinated peptide; ANA: antinuclear antibody; HLA-B27: human leucocyte antigen-B27; TSH: thyroid stimulating hormone; PTH: parathyroid hormone.

quality of life (52) is adversely affected leading physician groups worldwide to establish guidelines for appropriate diagnosis and treatment. In the context of subjective symptoms, without any clinical or biomarker, the accurate diagnosis of FM is based on symptoms (FM 2016 criteria met by medical history) and the exclusion of somatic diseases better explaining CWP, unrefreshed sleep and fatigue (medical history; physical examination; technical investigations if required). Alternately FM can be under-, over- and misdiagnosed. This overview has addressed these specific problems and provided clarification on common areas of clinical challenge in order to assist physicians towards diagnostic accuracy. Furthermore, the co-existence of FM with other pain syndromes and mental health disorders is described. In order to promote best clinical care and facilitate treatment, physicians should assess the of severity of FM symptoms in an individual patient and understand that FM is a continuum disorder that is likely lifelong.

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