Editorial

Is it time to review the 2016 American College of Rheumatology diagnostic criteria for fibromyalgia?

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For nearly 35 years, I have studied fibromyalgia (FM) primarily through daily clinical practice and clinical research. Over time, I have increasingly focused on critical issues emerging from the routine evaluation of FM patients, particularly the accurate identification of individuals truly affected by this syndrome.

The initial consultation is always a challenge, aimed at determining whether other medical conditions might mimic FM features or whether the patient has one or more rheumatologic diseases coexisting with FM. Most importantly, I strive to optimally use diagnostic tools, avoiding simplistic or hasty conclusions based on superficial evaluations or over-reliance on potentially misleading questionnaires. Differential diagnosis is essential. Assigning a diagnosis of FM carries significant responsibility, considering the personal, familial and social implications.

The 1990 American College of Rheumatology (ACR) classification criteria were a significant innovation, providing a foundation for more accurate FM study (1). However, these criteria quickly became a practical yet often misleading diagnostic tool. At the time, chronic widespread pain lasting at least three months was the defining criterion, including axial, left/right, and upper/lower segment pain. Tender point count (TPC) was mandatory. Later, the first author of the 1990 criteria opposed using tender points in clinical practice, as stated in a 2003 editorial titled "Stop using the ACR Criteria in the clinic" (2).

In 2010, new ACR criteria, defined as both preliminary and diagnostic, addressed limitations of tender points by introducing the Widespread Pain Index (WPI) and the Symptom Severity Scale (SSS) (3). These emphasised that FM is not merely a pain syndrome but involves a constellation of associated symptoms. The concept of widespread chronic pain was redefined, but without a precise definition.

Although initially well-received, these criteria led to an increase in FM diagnoses. While this benefited male patients, many authors raised concerns about excessive emphasis on the SSS (4). The revised criteria allowed a diagnosis with a WPI as low as 3 if the SSS was ≥9, regardless of specific pain sites.

The 2016 revisions to the 2010/2011 criteria defined generalised pain more clearly, requiring its presence in at least four of five regions. The minimum WPI for diagnosis increased to 4. The list of somatic symptoms was also simplified for practical use (5).

A recurring debate concerns whether comorbid medical conditions should exclude FM diagnosis. The 2010 criteria allowed potential exclusion, while the 2016 revision stated that FM diagnosis is valid regardless of other conditions. However, recent studies show that SSS disproportionately influences the Polysymptomatic Distress (PSD) score, potentially leading to misdiagnosis in cases where fatigue, cognitive impairment, and sleep disturbances outweigh pain distribution (6).

In my own study, many prior FM diagnoses lacked adherence to ACR 2016 criteria. Only 53.5% met the criteria at evaluation; 22.3% had borderline findings; 24.1% did not meet FM criteria. Often, pain-related diseases like inflammatory arthritis explained symptoms, alone or with FM (7). Assessing symptoms over the past week (WPI and SSS) may not reflect the fluctuating nature of FM and conflicts with the requirement of pain persistence over three months. Thus, the timing of the evaluation is critical.

The WPI measures the number of painful areas experienced. However, it lacks clarity on two critical aspects: the type

of pain and the anatomical site. It remains ambiguous whether the pain should be muscular, joint-related, neuropathic, or otherwise. More importantly, the criteria do not clarify whether certain anatomical regions, such as the extremities, including hands and feet, should be included in the WPI count. For example, is toe or finger pain valid for inclusion? What about localised joint pain in the wrist, ankle, or sternoclavicular joint? In my clinical practice, I exclude pain arising from conditions such as osteoarthritis or tendinopathy if they fully explain the symptomatology. The lack of definition risks inflating the WPI score, particularly in patients with comorbid conditions, leading to potential overdiagnosis.

Such ambiguity can significantly alter WPI scores, especially in borderline cases or when local pain is treated. Moreover, the WPI lacks grading of pain intensity and differentiation between day/night or spontaneous/mechanical pain. In my experience, FM pain is mainly muscular, diurnal, and non-articular.

The SSS evaluates three core domains, fatigue, waking unrefreshed and cognitive difficulty, alongside a range of additional symptoms, including headache, lower abdominal pain and depression. However, these domains are vulnerable to significant subjectivity and conceptual misunderstanding. For instance, 'fatigue' is often confused with general tiredness, despite representing a distinct clinical phenomenon: a persistent, debilitating lack of energy not alleviated by rest.

Equally problematic is the interpretation of additional symptoms. Is a single, transient episode of headache or abdominal discomfort over a six-month period truly sufficient to assign a score of 1? And what weight should be given to self-reported depressive symptoms in the absence of formal psychiatric evaluation? Finally, assigning severity levels to these symptoms requires a high degree of clinical discernment. Even minor inconsistencies in interpretation may significantly alter the overall score, affecting diagnostic classification and treatment decisions. Cultural and semantic differences further complicate accurate scoring.

The validity of FM diagnosis independent of other conditions remains controversial. Including pain from conditions like early arthritis risks overdiagnosis. If successful treatment of arthritis reduces WPI below threshold, the FM diagnosis was likely incorrect. Correct timing of diagnostic questionnaires is essential (7, 8).

FM, rooted in central sensitisation, differs from mechano-degenerative, muscular, inflammatory, or neuropathic conditions (9, 10). The TPC, though not diagnostic, remains a useful clinical tool to assess pain threshold, but it may be present in other pathological conditions. Notably, gender differences have been observed in pain sensitivity and tender point prevalence. Women tend to report more tender points and experience greater pain intensity at these sites compared to men. This disparity may contribute to the underdiagnosis of FM in male patients, as traditional diagnostic criteria and assessments may not fully capture the male presentation of the syndrome (7-11).

Conclusions

Diagnosing FM is complex, even with validated 2016 ACR criteria. Current criteria may not capture all cases. Mistimed assessments or imbalanced scoring (WPI *vs*. SSS) risk overdiagnosis. Coexisting conditions further complicate interpretation. Inaccurate diagnoses lead to inappropriate treatment strategies. Each FM diagnosis must be made with care, using validated criteria, and the PSD score calculated with accuracy and clinical judgement. TPC should no longer serve as a diagnostic basis but can remain a helpful clinical indicator.

Suggestions for improvement

1. Clearly define what constitutes a 'pain area' in the WPI, including distinctions between muscular, articular, and neuropathic pain.
2. Introduce a minimal pain intensity threshold for each area included in the WPI.
3. Balance the influence of WPI and SSS within the diagnostic algorithm to reduce the risk of overdiagnosis based solely on symptom severity.
4. Extend the symptom evaluation window beyond the past week to better reflect symptom fluctuation and chronicity.
5. Provide clearer guidance on excluding pain caused by other defined musculoskeletal or inflammatory conditions from the WPI.
6. Encourage clinical integration of objective findings (*e.g*. pain threshold assessment, physical examination) into the diagnostic process.
7. Promote culturally adapted versions of the criteria that consider semantic and contextual differences in symptom reporting.

Finally, in my opinion, it is time to reconsider and refine the diagnostic criteria to enhance diagnostic accuracy and reduce misdiagnosis.

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