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The Evidence Landscape of Fibromyalgia

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Abstract

This article compares the 2010 and 2016 fibromyalgia criteria, a sleep-measurement study in adults with comorbid fibromyalgia and insomnia, an FIQR validation study, and a scoping review of QST. The evidence shows that widespread pain and the burden of sleep, fatigue, and cognitive symptoms are repeatedly assessed together, while function and responses to evoked stimuli form separate measurement layers. Sleep methods can produce different estimates, however; FIQR convergence is a group-level result between questionnaires; and QST protocols are highly heterogeneous. The current evidence therefore does not establish causal order among domains, a single mechanism, or an individual diagnostic biomarker. The next study needs to measure symptoms, sleep, activity and function, and sensory responses repeatedly in the same participants along a connected timeline.

Keywords: fibromyalgia evidence · widespread pain · sleep measurement · fatigue · cognitive symptoms · functional impairment · FIQR · quantitative sensory testing

Different Observations Under One Name

The single label “pain syndrome” is not enough to describe fibromyalgia. The 2010 American College of Rheumatology preliminary criteria combined the Widespread Pain Index (WPI), a count of painful areas during the previous week, with a Symptom Severity (SS) scale covering fatigue, unrefreshing sleep, cognitive symptoms, and overall somatic symptom burden. The 2016 revision retained this structure and added a requirement that pain be present in at least four of five regions. ^[1, 2]

This structure reflects the judgment that pain alone does not adequately represent the clinical pattern. But the inclusion of these domains in the same criteria does not establish that pain causes disrupted sleep, that fatigue causes cognitive difficulties, or that all of these phenomena arise from a single biological pathway. The criteria define which features and thresholds to assess together; they are not a study that tests a causal model linking those features. ^[1, 2]

The evidence landscape therefore has at least four layers: the symptom pattern assessed by the criteria; sleep as measured by sleep diaries, actigraphy, and polysomnography; the impact on daily life recorded by questionnaires; and responses to evoked stimuli measured by quantitative sensory testing. ^[1, 2, 3, 4, 5] Even when applied to the same person, these layers answer different questions.

How to Read the Map

This article does not combine different forms of research into a single effect size. Two diagnostic-criteria papers show which combination of symptoms is classified as a fibromyalgia pattern.^[1,2] One sleep study compared three measurement methods in 113 adults with both fibromyalgia and insomnia.^[3] A validation study examined the FIQR questionnaire structure of function, overall impact, and symptoms,^[4] while a scoping review of quantitative sensory testing mapped the methods used in 126 studies.^[5]

Here, “consistent” does not mean that every study proved the same mechanism. We need to distinguish whether multiple sources repeatedly measure the same phenomenon, whether corresponding scales converge within one study, and whether different methods produce the same values. Repeated inclusion of a domain in diagnostic criteria, correlation between two measurements, change after treatment, and individual diagnostic accuracy represent different levels of evidence.

The blank spaces are also part of the map. This evidence set contains no study that repeatedly measured all six domains in the same participants at the same intervals. It therefore cannot establish whether the domains improve or worsen together, which change comes first, or which combinations occur in which people.^[1,2,3,4,5]

The Firmest Common Ground: Pain Distribution and Symptom Burden

In the 2010 criteria, the WPI records the number of 19 areas that were painful during the previous week, producing a score from 0 to 19. The SS scale records fatigue, unrefreshing sleep, cognitive symptoms, and overall somatic symptom burden on a scale from 0 to 12. The criteria required $WPI \geq 7$ and $SS \geq 5$, or $WPI 3-6$ and $SS \geq 9$, with symptoms present at a similar level for at least three months.^[1]

The 2016 revision combined $WPI \geq 7$ and $SSS \geq 5$, or $WPI 4-6$ and $SSS \geq 9$, and added pain in at least four of five regions.^[2] The recurring common ground across the two editions is that widely distributed pain and the burden of multiple symptoms are considered together. A single site of localized pain or one fatigue score alone does not define the fibromyalgia pattern.

The criteria themselves, however, were not tested against an independent biological standard. The 2010 paper noted that no independent gold-standard case definition existed when the fibromyalgia criteria were developed.^[1] The 2016 authors also distinguished criteria applied by a physician as part of an overall medical evaluation from a self-report version intended for research. A self-scored result alone should not be used to establish an individual clinical diagnosis.^[2]

Sleep, Fatigue, and Cognition: Assess Them Together Without Making Them the Same

Unrefreshing sleep, fatigue, and cognitive difficulties have been explicitly assessed together in the criteria since 2010. ^[1,2] That is strong documentary consistency. Their contribution to the same score, however, does not make them interchangeable. Sleep duration, time awake after falling asleep, feeling refreshed in the morning, and daytime fatigue are different observations.

The sleep measurement study makes this difference concrete. The 113 adults with both insomnia and fibromyalgia underwent one night of polysomnography and two weeks of sleep-diary and actigraphy measurement. At baseline, the objective measures estimated shorter sleep-onset latency and greater total sleep time and sleep efficiency than the diaries did. Actigraphy and polysomnography also produced different estimates of sleep-onset latency and time awake during the night. ^[3]

The repeated-measures analysis included 15 participants from the cognitive behavioral therapy for insomnia group. In this small subset, diaries and actigraphy detected improvement in some sleep measures, while polysomnography did not detect a significant change. ^[3] This finding supports the conclusion that measurement methods may differ in their time windows and sensitivity to change, not that one method invariably reveals the “true value.” It cannot be generalized to every person with fibromyalgia who does not have insomnia or used to establish an individual's sleep mechanism.

Functional Impairment Asks a Different Question from Symptom Count

The Revised Fibromyalgia Impact Questionnaire (FIQR) records function, overall impact, and symptoms over the previous seven days in 21 items. Its symptom domain includes not only pain and fatigue but also memory, tenderness, balance, and environmental sensitivity. ^[4] This structure creates a place to record the fact that the same pain score can have different effects on work, mobility, and everyday tasks.

In the 2009 validation study, the three FIQR domains correlated 0.69–0.88 with the corresponding domains of the earlier FIQ. ^[4] This is group-level evidence that the new questionnaire's domains moved with the related domains of the earlier instrument. It does not mean that FIQR scores agree with sensory-testing results or polysomnography, nor does it identify the cause of functional impairment.

The validation also had limits. The study did not directly assess test-retest reliability among online participants, included only 12 male participants, and did not estimate responsiveness to change or a minimum clinically important difference. ^[4] A single total score can summarize the impact of the previous week, but it cannot stand in for variation within a day, worsening after activity, or a long-term trajectory of change.

The Laboratory Language of Sensory Amplification

Quantitative sensory testing (QST) applies controlled mechanical or thermal stimuli and measures the response.^[5] This differs from counting self-reported painful areas with the WPI or asking about daily impact with the FIQR. Pain thresholds, responses to repeated stimuli, and inhibitory responses under a conditioning stimulus show how the sensory system responds under experimental conditions.

The 2025 scoping review screened 2,512 records and included 126 studies.^[5] The number of studies shows that sensory response is an important research subject. But the review reported that common protocols were not used consistently and that test sites and modalities varied. This heterogeneity limits the synthesis of results across studies and the interpretation of QST as a fibromyalgia biomarker.^[5]

Temporal summation and conditioned pain modulation are often linked to central sensitization, but the review noted that the peripheral nervous system also contributes to these measures and that each study must define the parameters used to analyze sensitization.^[5] A heightened response observed at the group level is therefore an association worth studying, not a conclusion about an individual's cause of pain, diagnosis, or the validity of their symptoms.

Where the Evidence Overlaps and Where It Diverges

The points of overlap are clear. The clinical pattern of fibromyalgia is described more fully when sleep, fatigue, cognitive symptoms, and functional impact are recorded alongside widespread pain.^[1,2,4] Sensory testing adds a separate observational layer: responses to evoked stimuli.^[5]

The points of divergence are equally clear. In the sleep study, baseline estimates and detection of change differed by method;^[3] the FIQR validation correlations represented group-level convergence between questionnaires;^[4] and heterogeneity in QST protocols constrained biomarker interpretation.^[5] None of these sources permits the conclusion that all six domains are joined by one mechanism within an individual.

Nor does disagreement among measurements invalidate any one experience. A diary records the night as experienced by the participant, actigraphy estimates sleep from movement, and polysomnography records physiological signals during one night.^[3] FIQR and QST likewise record daily impact and responses to evoked stimuli, respectively.^[4,5] When values differ, the first question should be whether the methods measured the same target over the same time window.

The Spaces the Map Still Leaves Blank

The current evidence makes three points most reliably. Fibromyalgia criteria consider widespread pain together with the burden of sleep, fatigue, and cognitive symptoms.^[1,2] A functional questionnaire distinguishes symptoms from their impact on daily life.^[4] QST measures responses to controlled stimuli, but substantial methodological heterogeneity prevents a direct move from those results to a single biomarker or an individual's mechanism.^[5]

The links among these domains are less certain. Differences among sleep measurement methods and correlations between questionnaire domains are group results from particular samples.^[3,4] This evidence cannot show the sequence in which pain distribution, sleep, fatigue, cognition, function, and sensory response change within the same person, or whether those trajectories distinguish subgroups.

The gap for the next study to fill is not another set of cross-sectional scores but a connected timeline. Symptom diaries, sleep, activity and function, and quantitative sensory testing need to be measured repeatedly in the same participants, with treatment and life context recorded alongside them. Only then can research move from a group-level map of what “occurs together” toward trajectories that show “what changes first, and for whom.” This is not a conclusion established by the current research. It is the next question derived from the gaps in the present evidence.^[1,2,3,4,5]

Declarations

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Ethics	Only public literature was used; no individual patient data or clinical intervention was involved. Any future human-participant research requires separate ethics review before it begins.

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