Patient-Reported Outcomes and Fibromyalgia

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KEYWORDS

• Fibromyalgia • Diagnosis • Phenotyping • Multimodal assessment • Self-report • Pain

KEY POINTS

- Physicians and/or patient-reported outcomes (PROs) remain the most sensitive and specific means of diagnosing fibromyalgia (FM) in clinical or research settings.
- The primary uses of PROs for FM include diagnostics, disease monitoring, phenotyping/characterization, and as outcomes for clinical trials.
- FM is a multifaceted condition requiring a multifaceted assessment if the complexity of the condition is to be represented in a reliable and valid manner.

INTRODUCTION

Fibromyalgia (FM) is considered to be a chronic pain condition characterized by chronic widespread pain along with accompanying symptoms of fatigue, sleep difficulties, diminished physical functioning, mood disturbances, and cognitive

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dysfunction that can include problems with memory, concentration, and mental clarity.[1,2] Globally, the mean prevalence of FM is 2.7% with females having a global mean prevalence of 4.2% and males having a mean prevalence of 1.4% (female to male ratio of 3:1).[3] Individuals with FM often report diminished quality of life,[4] diminished functional status,[5] and greater than expected health care use.[6]

FM is currently considered to be a central pain state suggesting that, although peripheral input may be playing a role, central factors (eg, central sensitization) likely account for much of the symptomatology.[7] In FM, aberrant activity in both central afferent[8] as well as descending modulatory mechanisms[9] contribute to symptoms and can be targeted therapeutically with some success.[10–12]

Currently, self-report measures, increasingly referred to as patient-reported outcomes (PROs), remain the best method for characterizing the multiple facets of FM. Although numerous attempts to identify biomarkers have produced mixed results (eg, genetics, autoantibodies, cytokines, hematologic findings, oxidative stress, neuroimaging, neuropathology),[13] pathophysiologic indices with sufficient sensitivity and specificity to serve as an FM biomarker remain elusive.[14] The use of PROs in the context of FM can take several forms, depending on the purpose of assessment: (a) diagnostics, (b) symptom monitoring, (c) phenotyping/characterization, and (d) as outcomes for clinical trials. The remainder of this paper focuses on these 4 uses of PROs for FM and describes instruments that can be used to support each use.

DIAGNOSTICS

In 1990, the American College of Rheumatology developed research classification criteria so that standardized selection of individuals likely to have FM could be identified in support of conducting research on the condition. These criteria required the presence of tender points and widespread pain over a prolonged period of time.[15] Although the American College of Rheumatology 1990 criteria were useful in promoting research, the tender point concept was flawed as a means of identifying FM.[16] Women generally report more musculoskeletal tenderness compared with men and thus defining FM by tenderness lead to the erroneous conclusion that FM was predominantly a “female” condition. When tenderness was replaced with widespread pain, the distribution still favored females but not nearly as much.[17]

In 2010, the American College of Rheumatology released for the first time their Clinical Diagnostic Criteria for FM. These new criteria retained the need to have widespread pain, but eliminated the tender point concept for the reasons discussed. The new diagnostic criteria included other symptoms in addition to pain that are commonly experienced by people with FM, such as cognitive dysfunction, fatigue, and sleep problems. These new criteria also require a physician to rule out a number of other diagnoses that could account for the symptoms.[18]

Again, in the interest of conducting research on FM with the new clinical criteria, a PRO survey containing most of the diagnostic criteria was published in 2011.[19] There are a number of practical differences between the actual diagnostic criteria and the survey criteria in that the survey can be mailed to people, completed online via an Internet-based platform, and/or completed in a research setting without a physician present. The survey criteria also permit the calculation of a continuously scaled Fibromyalgia Score (0–31) allowing an individual to have a lot or a little of FM, consistent with the experience reported by individuals with FM that FM tends to be variable over time and with the observation that some individuals have greater disease (symptom) burden compared with others. Scores on this continuous measure can provide