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Original article

New guidelines for the diagnosis of fibromyalgia

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ABSTRACT

Objective: To establish guidelines based on scientific evidence for the diagnosis of fibromyalgia.

Material and methods: Evidence collection was performed based on 9 questions regarding the diagnosis of fibromyalgia, structured using the Patient, Intervention or Indicator, Comparison and Outcome (P.I.C.O.), with searches in the main, primary databases of scientific information. After defining the potential studies to support the recommendations, they were graded according to evidence and degree of recommendation.

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Novas diretrizes para o diagnóstico da fibromialgia

Palavras-chave:
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RESUMO

Objetivo: Estabelecer diretrizes baseadas em evidências científicas para o diagnóstico da fibromialgia.

Material e métodos: A coleta de evidências foi elaborada a partir de nove questões sobre diagnóstico da fibromialgia, estruturadas por meio do PICO (Paciente, Intervenção ou Indicador, Comparação e *Outcome*), com busca nas principais bases primárias de informação científica. Após definir os estudos potenciais para sustentação das recomendações, esses foram graduados pela força da evidência e grau de recomendação.

Resultados e conclusões: As questões resultaram em nove recomendações para o diagnóstico da fibromialgia com base nas evidências de literatura e na opinião dos experts que participaram do trabalho.

Introduction

Considered one of the most common clinical rheumatologic conditions, fibromyalgia (FM) has variable epidemiological data. In studies performed in the USA and in Europe, the prevalence found was up to 5% in the general population,[1–5] surpassing 10% of visits in rheumatology clinics.[6] In Brazil, FM is present in up to 2.5% of the general population, predominantly among women, especially from 35 to 44 years of age.[7,8]

FM is certainly not a new syndrome, as corroborating reports have been published since 1592.[9] The term "fibromyalgia" was first used in a review by Hench[10] in 1976, although its recognition as a syndrome occurred after the publication of a study by Yunus et al. in 1981,[11] who described and characterized the clinical pattern of FM. However, its diagnosis in the daily routine and the choice of patients for clinical studies were challenging due to the lack of an objective clinical or laboratory marker. To minimize the subjectivity of clinical judgment, several diagnostic criteria were elaborated from 1980, though without unanimity, which generated more diagnostic confusion. In 1990, the American College of Rheumatology (ACR) prepared classification criteria that were accepted by the scientific community,[12] substantially helping to homogenize the diagnosis of FM and to promote studies on FM.

Despite advances in the use of these criteria, many criticisms have appeared over the years, especially regarding overvaluing widespread pain above symptoms such as fatigue, sleep disorders and morning stiffness, among others. Counting and searching for tender points became another reason for discussion because many physicians lacked adequate training to recognize them.

In response to these criticisms, in 2010, the ACR prepared new preliminary diagnostic criteria, which included several symptoms and excluded palpation of tender points. These criteria were subsequently changed and are still under analysis by the rheumatologic medical community.[13,14]

Given the variety in clinical patterns and the inexistence of laboratory markers or characteristic imaging examination, the diagnosis of FM is based on clinical judgment and varies with the experience of each physician.

Material and methods

This guideline followed a systematic review pattern, retrieving evidence based on the evidence-based medicine movement, in which clinical experience is integrated with the capacity to critically analyze and rationally apply scientific information, thus improving the quality of medical care.

Nine clinical questions relevant to the diagnosis of FM were elaborated, with the participation of all members of the Committee for Pain, Fibromyalgia, and Soft-Tissue Rheumatism of the Brazilian Society of Rheumatology (Sociedade Brasileira de Reumatologia). The formulation structure of each question is summarized by the P.I.C.O. acronym, wherein P corresponds to Patient – with Fibromyalgia; I to intervention – diagnostic criteria or ACR criteria, widespread pain, tender points, sleep disorders, fatigue, thermography; C to Comparison – clinical evaluation and other diagnostic criteria; and O to Outcome – diagnostic accuracy.[15] Thus, the descriptors to be used in the search strategies for scientific evidence were obtained. Searches were performed from August 2015 to September 2016 in the main primary databases of scientific information (Medline/PubMed, Embase, Lilacs/Scielo, Cochrane Library, Premedline via OVID), in addition to a manual search in the Brazilian Digital Library of Theses and Dissertations (Biblioteca Digital Brasileira de Teses e Dissertações – BDTD) of the Brazilian Institute for Information in Science and Technology (Instituto Brasileiro de Informação em Ciência e Tecnologia – IBICT; Table 1).

Initially, the studies were selected by title, then by abstract, and lastly by full text, which was subjected to critical evaluation and extraction of results on outcomes. The retrieved evidence was considered eligible if meeting the PICO method criteria. Observational studies (cross-sectional or cohort) or before-and-after studies were preferentially considered, without time or language restrictions and with available full text. The critical evaluations of the cohort studies were performed using the Newcastle-Ottawa Scale (NOS)[16] and the cross-sectional studies using Quadas.[17]

Studies that failed to address a population with FM or diagnosis; that used intermediate outcomes; that were narrative

Table 1 – Search strategies and articles retrieved and selected according to each guideline question.

Question	Strategy	Result
1. Are the 1990 ACR criteria essential for the diagnosis of FM?	Fibromyalgia AND (ACR OR American College of Rheumatology) AND (sensitiv*[Title/Abstract] OR sensitivity and specificity[MeSH Terms] OR diagnos*[Title/Abstract] OR diagnosis[MeSH:noexp] OR diagnostic* [MeSH:noexp] OR diagnosis,differential[MeSH:noexp] OR diagnosis[Subheading:noexp])	Retrieved: 283 Selected: 5
2. Is widespread pain essential for the diagnosis of FM?	((Fibromyalgia AND Pain AND widespread AND (sensitiv*[Title/Abstract] OR sensitivity and specificity[MeSH Terms] OR diagnos*[Title/Abstract] OR diagnosis[MeSH:noexp] OR diagnostic* [MeSH:noexp] OR diagnosis,differential[MeSH:noexp] OR diagnosis[Subheading:noexp])) OR (Fibromyalgia AND Pain AND specificity[Title/Abstract])))	Retrieved: 382 Selected: 6
3. Should tender points be considered in the diagnosis of FM?	(tender point* OR pressure OR pain threshold) AND Fibromyalgia AND (sensitiv*[Title/Abstract] OR sensitivity and specificity[MeSH Terms] OR diagnos*[Title/Abstract] OR diagnosis[MeSH:noexp] OR diagnostic* [MeSH:noexp] OR diagnosis,differential[MeSH:noexp] OR diagnosis[Subheading:noexp])	Retrieved: 588 Selected: 13
4. Are sleep disorders, fatigue disorders and cognitive disorders also considered?	(sleep OR fatigue OR mental disorders OR cognitive OR cognition OR stress) AND Fibromyalgia AND (sensitiv*[Title/Abstract] OR sensitivity and specificity[MeSH Terms] OR diagnos*[Title/Abstract] OR diagnosis[MeSH:noexp] OR diagnostic* [MeSH:noexp] OR diagnosis,differential[MeSH:noexp] OR diagnosis[Subheading:noexp])	Retrieved: 1419 Selected: 6
5. Can the 2010 criteria be considered in the diagnosis of FM?	Fibromyalgia AND (sensitiv*[Title/Abstract] OR sensitivity and specificity[MeSH Terms] OR diagnos*[Title/Abstract] OR diagnosis[MeSH:noexp] OR diagnostic* [MeSH:noexp] OR diagnosis,differential[MeSH:noexp] OR diagnosis[Subheading:noexp]) Limits: published in the last 3 years Sort by: PublicationDate	Retrieved: 659 Selected: 7
6. Is thermography indicated in the diagnosis of FM? Note: use in complex pain, almost nothing on FM	(Fibromyalgia AND (thermography OR temperature OR thermo test OR capillaroscopy OR heat OR hot OR cold OR sensory OR thermal OR somatosensory) OR (thermograph* OR telethermography) AND (pain OR trigger OR tender))	Retrieved: 857 Selected: 10
7. When should we request polysomnography for the diagnosis of FM? Note: the question of sleep complements	Fibromyalgia AND (Polysomnography* OR Circadian Rhythm)	Retrieved: 62 Selected: 4
8. Is the diagnosis of FM a diagnosis of exclusion? Note: The answer to this question can naturally arise with the other answers	Fibromyalgia AND (exclu* OR differential)	Retrieved: 766 Selected: 7
9. Should we assess mood disorders in patients with FM? How?	(Mood Disorders OR depression OR depressive) AND Fibromyalgia AND (sensitiv*[Title/Abstract] OR sensitivity and specificity[MeSH Terms] OR diagnos*[Title/Abstract] OR diagnosis[MeSH:noexp] OR diagnostic* [MeSH:noexp] OR diagnosis,differential[MeSH:noexp] OR diagnosis[Subheading:noexp])	Retrieved: 617 Selected: 9

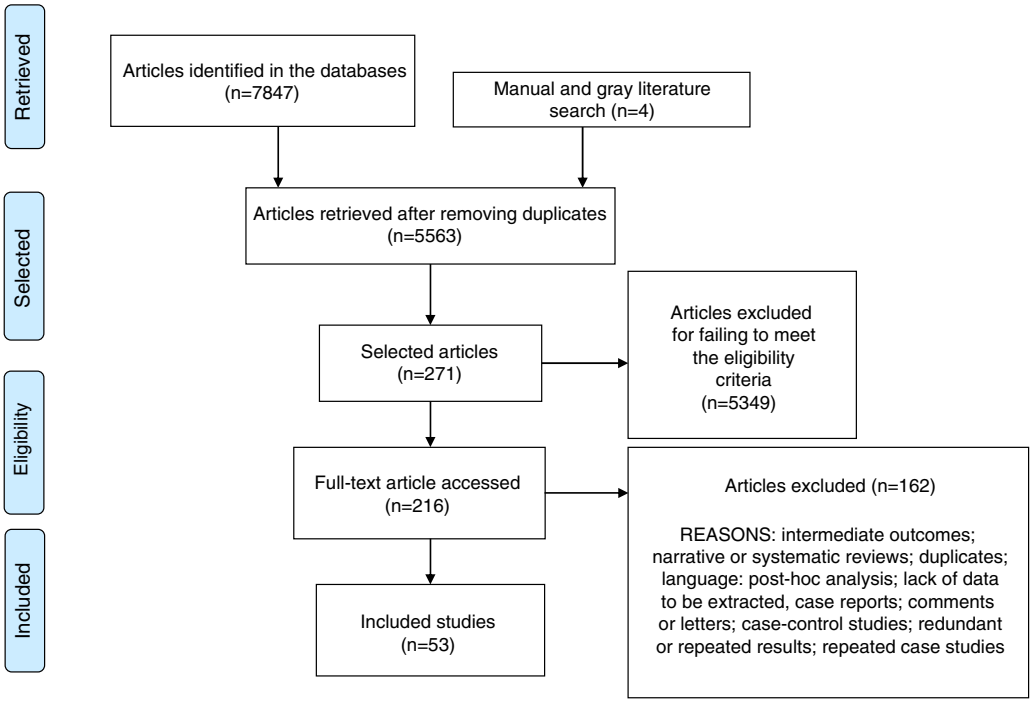

Fig. 1 – Flowchart.

or systematic reviews; that were post hoc analyses, comments or letters, case reports, or case-control studies; that had redundant or repeated results; that were duplicates; that were repeated case studies; or that where not conducive to data extraction were excluded.

After defining the potential studies supporting the recommendations, they were selected based on evidence and degree of recommendation according to the Oxford classification.[18] The recommendations were then written and re-evaluated by all participants during 4 videoconference meetings held between January 2015 and July 2016 and were approved by at least 70% of participants. Questions without this level of agreement were subjected to new questioning and correction sessions via the Internet until they were accepted by at least 70% of the members.

Fig. 1 shows the search and selection stages of the articles for these guidelines.

Guidelines for the diagnosis of fibromyalgia

Are the 1990 ACR criteria essential for the diagnosis of fibromyalgia (FM)?

The classification of FM according to the 1990 ACR criteria (1990 ACR) primarily depends on the presence of widespread pain (axial plus upper and lower segments plus left- and right-sided) and on the physical examination of tender points.[12]

These criteria were exclusively prepared to include patients in scientific studies. The 2010 ACR preliminary diagnostic criteria of FM are based on the number of tender areas of the body and on the presence and severity of fatigue, non-restorative sleep, cognitive difficulties, and the extent of somatic symptoms (D).[12,13,19]

Over time, it became evident that tender points have not been used or have been erroneously assessed by untrained physicians in clinical practice, particularly in primary care, causing failures in the final diagnosis. Therefore, the diagnosis was often evaluated only based on patient complaints.[20]

The 1990 ACR criteria, when positive, in a population with 49% pre-test probability for FM (prevalence), made a definitive diagnosis in 92% cases (post-test probability) (B).[12,21]

FM diagnosis using the 1990 ACR criteria had 25% false negatives when compared with clinical diagnosis. The use of the Widespread Pain Index (WPI >7) combined with the Symptom Severity Scale (SS >5), both based on patient symptoms (pain, fatigue, sleep, cognition, and somatic symptoms), enabled a 90.8% diagnostic accuracy (90.9% sensitivity and 85.9% specificity) when compared with the 1990 ACR criteria (B).[13]

At 49% pre-test probability, combining the positivity of the 1990 and 2010 ACR criteria enabled diagnostic certainty in 99% cases (B).[13,21]

Recommendation

FM diagnosis may be performed without using the 1990 ACR criteria, although its application with the 2010 criteria increases the diagnostic accuracy.

Is widespread pain is essential for the diagnosis of FM?

It is estimated that defining FM based on the presence of 11 of 18 tender points (ACR 1990) identifies only 20% of patients with widespread pain (D).[22]

The 1990 ACR criteria consist entirely of signs and symptoms of widespread pain, whereas 56% of the 2010 ACR criteria are linked to musculoskeletal pain.[23]

The WPI (0–19), with a cut-off point >8, enabled an FM diagnosis with 83.2% sensitivity, 87.6% specificity, and 85.4% accuracy. Based on a 49% FM prevalence (pre-test probability), the presence of WPI >8 increased the diagnostic probability to 86% (B).[21]

The symptoms and impact related to widespread pain, as measured using the instruments the Fibromyalgia Impact Questionnaire (FIQ), the Multidimensional Pain Inventory (MPI), the SF-36 Health Survey Short Form (SF-36), and the Pain Processing Inventory (PPI), in patients with an average of 15 tender points, were significantly more frequent than in patients with an average of 6 tender points (B).[24]

The WPI in patients with FM was significantly higher than in other clinical conditions, including Systemic Lupus Erythematosus, Osteoarthritis, and Rheumatoid Arthritis. The WPI of patients diagnosed with FM and with positive 2010 ACR criteria was significantly higher, on average, than that of patients with negative criteria. Among the patients with positive 2010 ACR criteria for FM, 93.7% met the widespread pain criterion (according to the 1990 ACR). Of the 2010 ACR patients negative for FM, 32.8% were positive for the widespread pain criterion (B).[14]

In 2016, a review of the 2010/2011 criteria was proposed to correct classification errors observed in patients with regional pain by adding a complementary criterion of widespread pain (B).[25]

Recommendation

The presence of widespread pain is essential for the diagnosis of patients with suspected FM.

Should tender points be considered in the diagnosis of FM?

Over time, it became evident that in primary care clinical practice, tender points have not been used or, at least, have been used inadequately by untrained physicians, impairing the final diagnosis. Therefore, the diagnosis is often evaluated only based on patient complaints.[20]

The incidence rates of the presence of tender points at a higher number than 11 were 22.4%, 24.7% and 89.9% in patients with Rheumatoid Arthritis, Osteoarthritis, and FM, respectively, with a linear association between the number of tender points and the Rheumatology Distress Index (RDI) (B).[26]

Regardless of the diagnostic method used to define FM (clinical or through a questionnaire combining evaluation of regional pain and fatigue), a substantial number of positive diagnoses occurred at tender point counts ranging from 6 to 18, and the diagnosis was strongly negative at values lower than 2–3 (B).[21]

Patients with FM were identified through tender points (more than 11) with 84% sensitivity and 87% specificity, which provided 84% diagnostic certainty when positive (B).[27]

Regardless of the FM diagnosis, 70% of elderly patients older than 70 years, with widespread pain, had at least 1 positive tender point, 41.5% had more than 3 tender points, and less than 10% had more than 10 tender points. Furthermore, 10% of patients without widespread pain had >3 positive tender points. A tender point count higher than 3 was already associated with the decreased physical performance of patients, as measured by the Short Physical Performance Battery (SPPB) (B).[28]

There are reasons for using criteria that are not based solely on tender point counts. Although there is a standardized protocol for counting tender points, it is not used in clinical practice, and its examination is susceptible to the variable pressure exerted by the examiner in most research studies. The need for involving a multidisciplinary team in FM is another obstacle related to the capacity to measure tender points. Thus, the relevance and specificity of tender points in the diagnosis of FM are limited (B).[29]

The manual count of tender points was correlated with stress or depression variables, as measured using the scales the Brief Symptom Inventory (BSI), the Global Severity Index (GSI), and the Beck Depression Inventory (BDI), defining a linear relationship between the number of positive tender points and the stress intensity and/or depression (B).[30]

The mean number of tender points in patients diagnosed with FM may be 3–4 times higher than that in healthy people. Using a dolorimeter, with a 4.0 kg/cm^2 cut-off point for pain threshold, each tender point will provide good sensitivity and specificity significant for the diagnosis of FM. The combined use of each positive tender point may increase the post-test probability of the diagnosis of FM (B).[31]

A study showed that most tender points examined in FM could be trigger points, observed through spontaneous intramuscular electrical activity. Therefore, a significant correlation was detected between the intensity of spontaneous widespread pain and the total number of active trigger points and tender points pre-determined in FM (B).[32]

The tender point count and the result from the visual analog pain scale, the BDI in the evaluation of depression, and the FIQ in the evaluation of disease severity were correlated in patients with FM and a mean of 15 positive tender points (B).[33]

Patients with widespread pain and less than 11 tender points had lower disease severity, fewer sleep disorders and somatic symptoms, and lower risk for anxiety and depression (the Duke Anxiety-Depression (Duke-AD) score) (B).[34]

In six months of follow-up, 32% patients diagnosed with atypical FM (number of tender points ranging from 6 to 10) developed numbers of tender points >11. In the same period, 36% patients initially diagnosed with typical FM (numbers of tender points >11) were diagnosed with atypical FM. Symptoms related to sleep quality, anxiety, depression, and total FIQ score may initially be increased in patients with numbers of tender points >11 when compared with patients with 6–10 tender points. After 6 months of follow-up, that difference may disappear. These symptoms improved in both types of patients after 6 months of follow-up, albeit with further therapeutic improvement in patients with numbers of tender points >11 (B).[35]

Pain-related symptoms, measured by the SF-36 scores (bodily pain, pain intensity, fatigue, and morning tiredness) were significantly worse in patients with numbers of tender points ≥11 than in patients with numbers of tender points <11. Motor skills were significantly reduced (an Assessment

of Motor and Process Skills score <1.5) in patients with widespread pain and numbers of tender points ≥11 (B).[36]

Recommendation

Tender points may be useful for the diagnosis of fibromyalgia when evaluated in combination with other functional disorders covered in the 2010 criteria. The tender point count may be correlated with the intensity of some symptoms, particularly emotional stress.

Are sleep disorders, fatigue, and cognitive symptoms also important for diagnosis?

Patients with FM have higher risks for somatic symptoms (67%), depression (55%), panic syndrome (35%), and agoraphobia (30%) than patients with rheumatoid arthritis. Furthermore, they have worse pain, sleep quality, and quality of life indices (B).[37]

In patients with FM, pain intensity and worse sleep quality are associated with high fatigue scores. Daily pain is a more important predictor of daily fatigue than depression or sleep quality. There is a cyclical and dysfunctional pattern of intensified pain and non-restorative sleep underlying the experience of fatigue in FM (B).[38]

In patients diagnosed with FM, in a one-year follow-up, sleep quality was permanently low when measured using the Pittsburgh Sleep Quality Index. Sleep quality and pain intensity at the beginning of the diagnosis may predict pain intensity after one year (B).[39]

The evaluation of patients with FM using the measuring instruments FIQ, the Hospital Anxiety and Depression Scale, the Brief Pain Inventory, the Fatigue Assessment Scale, the Health Assessment Questionnaire, the General Health Questionnaire, the Chronic Pain Coping Inventory, the Arthritis Self-efficacy Scale, and the Sleep Quality Scale may identify 4 factors associated with active disease (with the presence of a clinical impact on daily life)[40]:

1. Emotional aspects (33.7% variation) regarding anxiety, depression, and social elements;
2. Physical activity (15% variation), including pain, fatigue, sleep quality, and functional capacity;
3. Decision-making capacity or the ability to deal with situations (9% variation) involving active coping and expectations about the disease; and
4. Passive coping (6.3% variation), which includes inactivity or external help request (B).[40]

Somatic symptoms, the feeling of waking up tired and other sleep problems, cognitive decline, fatigue, and mood disorders are variables strongly correlated with tender point count and the WPI in patients with FM (B).[13]

Patients with FM and sleep disorders have significantly higher tender point counts than patients with no sleep impairment. Those patients also have higher associations with other symptoms, such as fatigue and reduced function and energy (B).[41]

Recommendation

Sleep disorders and changes in cognition and fatigue should be considered in the diagnosis of FM. They should also be considered in the assessment of severity of patients with FM.

Can the 2010 criteria be considered in the diagnosis of FM?

The 2010 ACR criteria eliminate tender point counts, essential for diagnosis using the 1990 ACR criteria, assessing symptoms often reported by patients in the clinical evaluation and enabling inclusion of patients without widespread pain, who are excluded by the 1990 ACR criteria.[42]

Patients with suspected diagnosis of FM are evaluated using the following three methods:

(1) Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften – AWMF; widespread chronic pain defined as axial pain and pain in the 4 extremities and/or data on sleep disorders and fatigue and/or the feeling of swelling or stiffness in the hands or feet or face in the previous 3 months, with a Z1/10 score in a numerical scale assessed using a questionnaire);
(2) Survey (Regional Pain Score – RPS Z8/19 and Z6/10 Fatigue Score on a visual analog scale in the previous week); and
(3) ACR (ACR 1990) – (widespread chronic pain defined by the ACR and pressure stiffness of at least 11/18 tender points).

In conclusion, 71% of patients are diagnosed with FM using these three methods; the AWMF and the 1990 ACR were concordant in 86.6% cases, and the Survey and the 1990 ACR were concordant in 79.5% cases. Patients positive in the three methods had higher levels of depression and somatic symptoms than patients positive in the AWMF and 1990 ACR criteria; positive cases according to only one of these criteria were identified at percentages of 1.4%, 3.1%, and 2.0% in the AWMF, the Survey and the 1990 ACR criteria, respectively (B).[29]

In a population of patients with a prevalence of 68% FM, the use of the 2010 ACR instrument (with a widespread pain score ranging from 0 to 19) and the cut-off point at the score of 10 to differentiate positive (>10) from negative (<10) patients enabled the diagnosis of FM at 94% sensitivity and 91% specificity, leading to post-test diagnostic probabilities of 96% for positive results and 87% for negative results (B).[43]

The 2010 ACR diagnostic criteria, combining chronic pain (WPI > 7) and severity scale (SS > 5) or chronic pain (WPI 3–6) and severity scale (SS > 9), had 88.1% accuracy in the diagnosis of FM (B).[13]

Modification of the ACR 2010 ACR criteria, eliminating the estimate of somatic symptoms, replacing the sum of 3 specific symptoms reported by the patient using a scale of FM symptoms ranging from 0 to 3, and adding the WPI to the modified severity scale (SS scale), when administered to patients with and without FM, using a score ≥13 as the cut-off point for positive and negative diagnosis, enabled a 93.0% correct diagnosis, with 96.6% sensitivity and 91.8% specificity (B).[14]

The 2010 ACR criteria are more useful for diagnosis because they use physician-administered and patient self-administered questionnaires, increasing the percentage of

correct diagnoses. Conversely, the 2010 ACR criteria modified in 2011 are more suitable for research because they are easily administered (self-administered) and, therefore, reach a higher number of patients.[42]

The ease of use of the 2010 ACR criteria indicates their application mainly to primary care because the diagnosis covers the main patient complaints and assesses the severity of the clinical symptoms and the patient follow-up.[20]

Recommendation
We recommend using the 2010 ACR criteria for the diagnosis of fibromyalgia. The modifications published in 2011 are more appropriate for epidemiological research.

Is thermography indicated for the diagnosis of FM?

The diagnosis of FM syndrome is based on clinical characteristics. Thermography is not included in the 1990, 2010, or 2011 diagnostic criteria or in the 2016 review.[12,13,25]

Few controlled studies on the use of thermography in the FM syndrome, for both diagnosis and assessment of the efficacy of a treatment, have been published.

The number of "hotspots" found using this imaging method is considered by some as a key instrument in the diagnosis of various diseases, including FM syndrome. In a study, the number found was higher in patients with FM than in healthy individuals, thereby concluding that more than seven "hotspots" could predict sensitivity in 11 or more of the 18 specific anatomical pain sites, termed tender points.[44]

Based on the "hotspot" count, 74.2% of 252 individuals (161 FM, 71 with widespread pain and <11 tender points, and 20 healthy controls) were correctly diagnosed in another research study. Although the intra-evaluator repeatability of the "hotspot" count was acceptable, its inter-evaluator reproducibility was weak.[45]

In an Austrian study, thermographic investigation of FM showed a diagnostic accuracy of only 60% of the so-called "hotspots" for tender points.[46]

Conversely, a study conducted in Italy found no differences in heat distribution patterns in 156 patients with FM compared with patients with osteoarthritis of the spine. The authors concluded that thermography could not be a diagnostic instrument for FM syndrome.[47]

A study aimed at assessing the neurogenic response to pressure stimuli applied to the dorsal areas of 16 patients with FM and to 16 healthy controls suggested a lower thermographically measured skin temperature at rest in patients with FM. The authors proposed that such a finding would result from increased adrenergic sympathetic activity at rest. No significant differences were found between the groups after the stimuli.[48]

A study used stimulation with cold water and subsequent thermographic evaluation to examine potential differences between the autonomic nervous systems of patients with FM and healthy controls. No significant differences were identified between the groups.[49]

A study involving 23 women with FM and 15 healthy controls observed that patients with FM showed lower tolerance to cold water than participants in the control group. Conversely, the temperature recovery patterns were similar in both groups.[50]

In summary, the studies revealed no pattern of thermographic changes in FM syndrome. There are no consistent data evaluating the use of thermography in patients with FM, and the few published studies fail to support the use of thermography as a diagnostic method for FM.

Recommendation
There is no scientific evidence to recommend using thermography for the diagnosis of FM.

When should we request polysomnography for the diagnosis of FM?

Sleep disorders are among the main manifestations of FM. However, the role of these changes in their pathophysiology is still controversial.

Mork and Nilsen showed that sleep problems among young women were associated with the risk for developing FM. The risk increased proportionally to the intensity of the sleep problems and with the increase of the patient age group (B).[51]

Sleep disorders occur in FM regardless of the assessment instrument. The symptoms vary, but the most frequent complaints are poor quality sleep, insufficient sleep, and light and fragmented sleep (with a high number of awakenings). However, current evidence does not permit confirmation of the importance of sleep for the pathogenesis and maintenance of FM symptoms, according to Diaz-Pietra (B).[52]

In polysomnographic assessments, both patients with FM and patients with primary insomnia showed decreased total sleep times and increased latency to persistent sleep and times of awakenings after starting sleeping when compared with normal people. Patients with FM had a higher number of short waves, lower latency to persistent sleep, and a higher frequency of night awakenings than patients with primary insomnia. The authors concluded that those changes suggest that patients with FM have a higher inability to maintain continuous sleep than cases of primary insomnia (B).[53]

The cyclical alternating pattern (CAP) is a neurophysiological marker of sleep instability observed in electrophysiological studies in both normal and pathological conditions. It expresses a condition of instability at the level of vigilance and leads to brain fatigue in sleep preservation and regulation. The CAP index (total CAP time/non-rapid eye movement (REM) sleep time) is increased in FM and is correlated with the severity of clinical symptoms (tender points) and with the decrease in sleep efficiency, with an increased ratio of non-REM sleep and twice as many awakenings per hour of sleep (B).[54]

Recommendation
We do not recommend using polysomnography for the diagnosis of FM.

Is the diagnosis of FM a diagnosis of exclusion?

The subjectivity of FM symptoms considerably expands the possibilities of differential diagnosis to be considered by the physician. Widespread chronic pain, the preponderance in

women, and the lack of objective imaging data and laboratory tests are some of the characteristics that may generate diagnostic confusion because these symptoms are present in a high number of other diseases (D).[55,56]

In patients with diagnostic suspicion of FM, Sheyfer et al. showed that the rheumatologist confirms the clinical diagnosis in 71% cases. Non-specific arthralgia and rheumatoid arthritis were the main differential diagnoses in this study. When assessed by a family physician, agreement with the diagnosis of the rheumatologist was 87% (B).[55]

The 1990 ACR Diagnostic Criteria showed high sensitivity and specificity when widespread chronic pain and tender point counts were present. FM should be considered a clinical syndrome with specific characteristics without requiring excluding other conditions that might be part of its differential diagnosis according to the authors of that study. FM should not be classified into primary or secondary types but instead into isolated or associated FM (B).[12]

In the study reporting the 2010 preliminary criteria for the diagnosis of FM, the composition of the criteria used 2 indices: the WPI (0–19) and the SS scale (0–12). In this study, the authors recommended excluding other diseases that may be confused with FM (B).[13]

Similarly, Goldenberg DL listed clinical situations that should be part of the differential diagnosis of FM and that may be ruled out through laboratory or imaging tests, citing rheumatoid arthritis, systemic lupus erythematosus, polymyalgia rheumatica, myopathies, ankylosing spondylitis, hypothyroidism, and peripheral neuropathies (D).[57]

The presence of common symptoms associated with the functional nature of various conditions led Yunus MB into grouping them into so-called central sensitivity syndromes, which include chronic fatigue syndrome, irritable bowel syndrome, migraine, and temporomandibular joint dysfunctions, in addition to FM (B).[58]

A recent review of the 2010/2011 criteria proposed the validity of the FM diagnosis independent from other diagnoses (B).[25]

Recommendation

FM should not be considered a diagnosis of exclusion, although we suggest always considering differential diagnoses with other syndromes or diseases with similar symptoms, as recommended by the 2010 ACR criteria.

Should we evaluate mood disorders in patients with FM? How?

The role of psychiatric disorders in FM is still controversial in the literature. Although several studies have shown that there were high frequencies of psychiatric diagnoses, especially depression and anxiety, other authors have disputed this statement (B).[37,59]

Psychological variables, including depression and anxiety, were associated with the perception of increased disease severity and worsened functional capacity (B).[60]

The severity of psychiatric symptoms should be a potential prognostic factor for FM to be considered in therapeutic interventions (B).[61]

The possibility of establishing subgroups of patients based on the presence of psychological changes has been discussed in the literature. The study by Giesecke et al. showed that patients with FM may be classified based on psychosocial domains (depression/anxiety), cognitive domains (pain catastrophizing/control), and neurobiological domains (pain) using instruments such as the Center for Epidemiologic Studies Depression Scale [for depression], the State-Trait Personality Inventory (for anxiety-related symptoms), the Visual analog scale (VAS), dolorimetry and pressure-pain applied at suprathreshold values, and the Coping Strategies Questionnaire (CSQ) [inattention, feeling of pain, coping, prayer or hope, and pain catastrophizing] (B).[62] The first subgroup of patients was characterized by moderate indices of mood changes, moderate levels of pain catastrophizing, and control and low levels of pain. A second subgroup showed high values in the mood disorder evaluations, the highest values in the pain catastrophizing scale, and the lowest values of pain control with high levels of pain. The third subgroup had normal mood indices, very low levels of pain catastrophizing, and the highest level of pain control, despite the high levels of pain (B).[62]

The literature indicates that the evaluation of psychiatric comorbidities or psychological variables in patients with FM may be conducted using several specific instruments or components of generic instruments, including the following cited instruments and components: the Structured Clinical Interview for DSM-III-R (SCID) for axial components; the BDI, the Beck Anxiety Inventory (BAI); the SF-36, the NEO Personality Inventory-Revised (NEO PI-R); the Barsky Amplification Scale; and the Whitely Index of Hypochondriasis (B).[63,64]

In patients with chronic pain, depression and anxiety have been measured using various validated instruments, including the Centers for Epidemiological Studies Depression Scale (CES-D), the Profile for Mood States (POMS), and the BDI. However, their administration in outpatient primary care settings becomes impractical due to the time required to fill them out. Other instruments, such as the Patient Health Questionnaire – 9 (PHQ-9), are more appropriate for primary care physicians in identifying and measuring depression (B).[65,66]

Recommendation

We suggest the systematic measurement of mood disorders using validated instruments suitable to the healthcare level in which they are administered because they are highly important when assessing the severity of patients with FM.

Conflicts of interest

The authors declare no conflicts of interest.

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