Validation of New Symptom-Based Fibromyalgia Criteria for Irritable Bowel Syndrome Co-morbidity Studies

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Background/Aims
There is significant co-morbidity between irritable bowel syndrome (IBS) and fibromyalgia syndrome (FMS). However, FMS is diagnosed by physical examination, which limits the conduct of co-morbidity studies in a large population-based study. The purpose of this study was to determine the diagnostic validity of a new symptom-based criteria in patients with FMS and/or IBS using the American College of Rheumatology (ACR) criteria as a gold standard.

Methods
The study participants consisted of women with FMS (n = 30), IBS (n = 27) and controls (n = 28). A new symptom-based diagnostic criteria for FMS comprised a regional pain scale and a visual analogue scale for fatigue. All subjects underwent a physical examination for FMS (ACR criteria) and structured questionnaires of regional pain scale and visual analogue scale for fatigue. A fibromyalgia intensity score was calculated and thresholds of tenderness were determined by a dolorimeter.

Results
The number of participants diagnosed with FMS in the entire study population (n = 85) was 31 by the new criteria. Compared to the ACR, the sensitivity of the new criteria was 82.9%, specificity 96.0%, positive predictive value 93.5% and negative predictive value 88.9%. In addition, new criteria were useful for the diagnosis of FMS among the subjects with IBS. A fibromyalgia intensity score was significantly correlated with the threshold of tenderness (r = -0.62, \( P < 0.001 \)).

Conclusions
The new symptom-based diagnostic criteria for the diagnosis of FMS can be used in large-scale clinical and epidemiological co-morbidity studies, in which physical examination is unfeasible. Gastroenterologists investigating the effects of co-morbid FMS in IBS patients can use these new criteria with confidence.

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Key Words
Comorbidity; Fibromyalgia; Irritable bowel syndrome; Physical examination

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Introduction

Irritable bowel syndrome (IBS) and fibromyalgia syndrome (FMS) are common functional disorders that share many characteristics. The prevalence of FMS among IBS patients ranges from 30% to as high as 70% in published studies.1-3 Our group reported that 32.4% of IBS patients met the American College of Rheumatology (ACR) diagnostic criteria for FMS and 32% of FMS patients met the Rome II diagnostic criteria for IBS.3 We also found that patients with both disorders have more severe IBS symptoms, more psychopathology, lower health-related quality of life4 and a lower score on the sense of coherence questionnaire for coping skills5 than patients with only one of these disorders. FMS is a soft tissue disorder characterized by diffuse musculoskeletal pain and specific tender points on physical examination. FMS is diagnosed in accordance with the ACR criteria of 1990,6 namely widespread pain in combination with tenderness of 11 or more of the 18 specific tender point sites on physical examination.

Since many IBS and FMS patients have concomitant functional disorders in other body systems, eg, the chronic fatigue syndrome, the possibility of a common pathogenesis has been raised.7-11 Large-scale clinical studies and epidemiological surveys could advance our understanding of these associations in terms of pathogenesis, the impact on symptom severity, health-related quality of life and patient care.

The diagnosis of IBS is symptom-based12 and is established mostly by the Rome criteria questionnaire.13 In contrast, the diagnosis of FMS requires physical examination by a trained examiner. This situation makes research into co-morbidity between FMS and other functional disorders, such as IBS, difficult, time consuming and inconvenient for the patient and the investigator. In effect, large-scale clinical or epidemiological studies of co-morbidity between FMS and IBS are not feasible due to this limitation. Wolfe and Michaud14,15 developed and validated new criteria to diagnose FMS without requiring physical examination. The criteria are a composite score of their regional pain scale (RPS) and a visual analog scale (VAS) for chronic fatigue (for details see the Methods section below). In a validation study of 12,799 patients with rheumatic disease, Wolfe14 found a concordance rate of 73% between the ACR criteria and the new criteria. The authors concluded that the new criteria are useful for the diagnosis of FMS and have the advantage of not requiring physical examination.

The purpose of this study was to determine the test characteristics of the new diagnostic criteria in a population of IBS and FMS patients, as well as healthy controls, using the ACR criteria as the gold standard. The expectation is that the new criteria could be used in the future to facilitate studies of co-morbidity between IBS, FMS and other functional disorders.

Materials and Methods

Study Groups

The study population was comprised of women with FMS, women with IBS and female controls. The IBS patients and the controls were matched by age to the FMS patients. The women were recruited from the FMS and Gastroenterology clinics in the Soroka Medical Center, Beer-Sheva, Israel between January 2007 and March 2008. The FMS patients were recruited and tested first. IBS patients and controls were then matched by age (± 3 years) to the FMS group. The study group was comprised of women because this is a female-predominant disorder and we wanted to avoid potential confounders in this initial applicability study. The study was approved by the Helsinki committee (Internal Review Board) of the Soroka Medical Center. After receiving detailed information about the design of the study and its objectives and providing signed informed consent, each participant completed the survey questionnaire and underwent a physical examination to diagnose FMS, including palpation of tender points and determination of tenderness thresholds.

Diagnostic Criteria

American College of Rheumatology criteria for fibromyalgia syndrome (1990)

The ACR classification criteria of 1990 served as the gold standard. The ACR criteria are defined as:

Widespread pain has been present for at least 3 months. Pain is considered widespread when it is: (1) in both sides of the body and (2) above and below the waist. In addition, axial skeletal pain (cervical spine, anterior chest, thoracic spine or low back pain) must be present. Low back pain is considered lower segment pain. Finally, pain on digital palpation must be present in at least 11 of 18 defined tender point sites.

New composite score criteria for fibromyalgia syndrome

The diagnosis of FMS using the new criteria was based on a composite score of a survey questionnaire (RPS) and a VAS for fatigue, as follows:

Regional pain scale. This questionnaire is comprised of a