Journal of Psychosomatic Research 78 (2015) 546–552

Contents lists available at ScienceDirect

Journal of Psychosomatic Research

Construct validity and clinical utility of current research criteria of DSM-5 somatic symptom disorder diagnosis in patients with fibromyalgia syndrome

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ARTICLE INFO

Article history:
Received 28 January 2015
Received in revised form 22 March 2015
Accepted 23 March 2015

Keywords:
fibromyalgia syndrome
somatic symptom disorder
validity
clinical utility
anxiety
depression

ABSTRACT

Objective: The validity and clinical utility of current research criteria of the DSM 5 category somatic symptom disorder (SSD) needs to be tested outside the setting of psychiatry.
Methods: Consecutive patients with an established diagnosis of fibromyalgia syndrome (FMS) were evaluated by medical examination, psychiatric interview and self-report questionnaires in an outpatient pain medicine center. The diagnosis of SSD was established using published research criteria. The discriminative concurrent criterion validity of SSD was tested by comparing FMS-patients with and without SSD as to the amount of impairment and of health care seeking. Two clinicians blinded as to the purpose of the study, assessed the medical reports of patients after the evaluation for the determination of the need for psychotherapy based on the German FMS — guideline recommendations (clinical utility).
Results: 25.6% of 156 patients met the criteria of SSD. Patients meeting SSD criteria scored significantly higher in a self-report measure of disability. There were no significant differences in the number of patients on sick leave or applying for disability pension and in self-reported doctor visits and physiotherapy in the previous six months. 95.0% of patients with SSD and 71.6% of patients without SSD met the criteria of a current anxiety or depressive disorder as assessed by the psychiatric interview. 80.0% of patients with SSD and 66.7% of patients without SSD received a recommendation for psychotherapy.
Conclusions: The construct validity and clinical utility of current research criteria of DSM 5 category SSD were limited in German patients with FMS.

Introduction

One of the most important changes in the Diagnostic and Statistical Manual of Mental Disorders (DSM) 5 [1] involved a reconceptualization of the somatoform disorders and the creation of a newly defined disorder, the somatic symptom disorder (SSD) [2]. SSD replaced the former DSM 4 diagnoses of somatization disorder, undifferentiated somatoform disorder and pain disorder. The diagnosis of SSD may be made when there are persistent (i.e., typically longer than six months) somatic symptoms that are distressing and/or significantly disrupt daily life (criteria A and C) that are accompanied by excessive and disproportionate symptom-related thoughts, feelings, and behaviors regarding these symptoms (criteria B) [1]. The DSM 5 SSD workgroup postulated that clinicians should diagnose and treat SSD because successful treatment options (psychotherapy, psychotropic drugs) are available [2].

Early US studies provided evidence concerning feasibility [3], reliability [4], validity [5–7] and clinical utility [5,7,3] of the SSD diagnostic category. A gold standard method of diagnosis, a structured interview of the SSD criteria, does not yet exist. Preliminary research criteria have been developed by recent studies [5–7]. These validation studies were conducted in psychiatry or psychosomatic medicine centers with patients who were previously diagnosed with somatoform disorders [5–7]. Developers of the SSD category stressed the necessity of further studies on the validity and clinical utility of SSD diagnosis when applied in other settings [2], e.g., internal or pain medicine.

The diagnosis of somatoform disorders was rarely used by non-psychiatrists [8]. Somatic symptoms that suggested a general medical condition and were not fully explained by a general medical condition,

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http://dx.doi.org/10.1016/j.jpsychores.2015.03.151
0022-3999/

by the direct effects of a substance, or by another mental disorder, are usually considered by non-psychiatrists to be functional disorders and functional somatic syndromes (FSSs) respectively [9]. Whether FSS such as irritable bowel syndrome or fibromyalgia syndrome (FMS) should be diagnosed as a somatoform disorder, in accordance with DSM 4, has been a matter of debate [10,11]. Not surprisingly, a discussion started on the application of the SSD diagnostic category to FSS [12]. .

Given the uncertainties on the prevalence of SSD in FSS and the validity and usefulness of SSD diagnosis in patients with FSS, we assessed how many patients diagnosed with FMS in a pain medicine setting met the current research criteria of a SSD. Furthermore we tested the construct validity and clinical utility of current research criteria of SSD in these patients.

Methods

Setting

All examinations and interviews with the patients were conducted by the first author (WH) in an outpatient ambulatory health care center (secondary care level) for pain medicine. Patients were referred by rheumatologists or general practitioners or made an appointment by their own.

Patients

All consecutive patients who presented to the first author from January 2, 2013 to December 31, 2014, for the evaluation and/or management of chronic widespread pain/FMS were screened for eligibility for the study. The inclusion criteria were as follows: 1. Medical testing according to the German guideline on FMS [13] to exclude somatic diseases fully explaining the symptoms was performed. Patients with somatic diseases which could explain a part of pain sites (e.g., osteoarthritis) were included. 2. Patients were designated as having criteria positive fibromyalgia if they satisfied research criteria for fibromyalgia [14,15]. 3. Patients were informed either by physicians and/or by information seeking by their own that FMS is a) a disease with a normal life expectancy and b) not a progressive illness that leads to inability to function (e.g., to need a wheel chair). The exclusion criteria were as follows: 1. Patients with a duration of FMS-diagnosis <6 months, 2. Patients with concomitant FMS in inflammatory rheumatic diseases under immunosuppressive treatment (e.g., biologicals, corticosteroids, methotrexate). To our clinical experience, FMS-related fears of these patients cannot be disentangled from fears regarding the course of the inflammatory rheumatic disease and/or side effects of immunosuppressive therapies, 3. Patients in which FMS was diagnosed for the first time by the author or which had not been informed on the normal life expectancy and lack of progress to inability to function in FMS. The German guideline on the management of FMS recommends as a first of therapy after establishing the diagnosis of FMS for the first time, that patients should be educated on these issues to reduce potential symptom-related anxieties [13], and 4. Patients who were unable to properly complete the questionnaires due to language or intellectual barriers.

A battery of questionnaires was used by the first author for routine clinical assessment. The questionnaires were sent to the patient before the first appointment for completion at home. During the first appointment the results of the questionnaires were discussed with the patients and additional questions, e.g., on longer symptom duration than indicated in the self-report questionnaires were asked. The completed questionnaires were kept apart from medical charts in a separate room only accessible to the first author. In addition, at the first appointment patients were required to present records of medical diagnostic and treatment relating to their symptoms.

Measures

Polysymptomatic distress scale (PSD)

The Widespread Pain Index (WPI) is a 0–19 count of painful body regions. The Symptom Severity Score (SSS) is the sum of the severity (0–3) of the three symptoms (fatigue, waking unrefreshed, cognitive symptoms) plus the sum of the number of the following symptoms occurring during the previous six months: headaches, abdominal pain, and depression (0 = no, 1 = yes). The final score is between 0 and 12. For fatigue, waking unrefreshed, and cognitive problems, scoring is 0 No problem; 1 Slight or mild problems, generally mild or intermittent; 2 Moderate, considerable problems, often present and/or at a moderate level; and 3 Severe: continuous, life-disturbing problems. The 0–19 widespread pain index and the 0–12 symptom severity score can be combined by addition into a 0–31 PSD index. The PSD scale is a measure of the intensity of FMS symptoms and correlates with all general measures of distress [14].

Patient Health Questionnaire-15

We used the Patient Health Questionnaire (PHQ) as a measure of somatic symptom burden [16] and as a generic measure of FMS severity [17] with scores of 5, 10, and 15 representing cutoff points for low, medium, and high somatic symptom (FMS) severity, respectively. We used the validated German version of the PHQ 15 [18].

Patient Health Questionnaire-4

The 4-item Patient Health Questionnaire-4 (PHQ-4) comprises two DSM-IV criteria of major depression as "0" (not at all) to "3" (nearly every day) and two DSM-IV criteria of general anxiety disorder [19]. The total score of the PHQ- 4 (Minimum 0, Maximum 12) is a validated measure of psychological distress [20]. We used the validated German version of the PHQ-4 [20].

Whiteley Index

The Whiteley Index (WI) is a widely used instrument for measuring hypochondriacal worries and beliefs. Fourteen questions can be answered in a dichotomic format (yes/no) [21]. We used the validated German version of the WI [22].

Pain Catastrophizing Scale

The Pain Catastrophizing Scale (PCS) includes 13 items. Participants are asked to indicate on a 5-point Likert scale the degree to which they experience various thoughts and feelings on a painful experience. The total score, indicating the degree of pain catastrophizing, ranges from 0–42. There are no validated cut-off scores of the PCS available neither for chronic pain patients as a whole nor for fibromyalgia patients as a subgroup. The authors of the PCS suggest that a total PCS score of 30 represents clinically relevant level of catastrophizing. In addition we defined an additional cut-off score by the 75th percentile of the study sample. The reliability and validity of the PCS have been demonstrated in samples of clinical institutions and of the general population [23,24]. We used the validated German version of the PCS [25].

Pain Disability Index

The Pain Disability Index (PDI) measures impairment by pain in seven areas of daily living (family/home responsibilities, recreation, social activities, occupation sexual behavior, self-care, life-support activity) on an 11 point Likert scale. The total score of the PDI ranges from 0–70. Psychometric evaluations of the PDI in outpatients and inpatients with chronic pain found high internal consistency, test–retest reliability and good convergent validity in reference to pain characteristics and pain behavior [26]. The validated German version of the PDI was used [27].