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Patient Health Questionnaire 15 as a generic measure of severity in fibromyalgia syndrome: Surveys with patients of three different settings

Winfried Häuser [a,b,*], Elmar Brähler [c], Frederick Wolfe [d,e], Peter Henningsen [b]

[a] Department Internal Medicine I, Klinikum Saarbrücken, Saarbrücken, Germany
[b] Department Psychosomatic Medicine, Technische Universität München, München, Germany
[c] Department of Medical Psychology and Medical Sociology, Universität Leipzig, Germany
[d] National Data Bank for Rheumatic Diseases, Wichita, KS, United States
[e] University of Kansas School of Medicine, Wichita, KS, United States

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ABSTRACT

Objective: Graduated treatment of patients with functional somatic syndromes (FSS) and fibromyalgia syndrome (FMS) depending on their severity has been recommended by recent guidelines. The Patient Health Questionnaire 15 (PHQ 15) is a validated measure of somatic symptom severity in FSS. We tested the discriminant and transcultural validity of the PHQ 15 as a generic measure of severity in persons with FMS.
Methods: Persons meeting recognized FMS-criteria of the general German population (N = 98), of the US National Data Bank of Rheumatic Diseases (N = 440), and of a single German pain medicine center (N = 167) completed validated self-report questionnaires on somatic and psychological distress (Polysymptomatic Distress Scale, Patient Health Questionnaire 4), health-related quality of life (HRQOL) (Short Form Health Survey 12 or 36) and disability (Pain Disability Index). In addition, self-reports of working status were assessed in the clinical setting. Overall severity of FMS was defined by PHQ 15 scores: mild (0–9), moderate (10–14) and severe (15–30).
Results: Persons with mild, moderate and severe FMS did not differ in age and gender. Irrespective of the setting, persons with severe FMS reported more pain sites, fatigue, depressed mood, impaired HRQOL and disability than persons with moderate or mild FMS. Patients with severe FMS in the NDB and in the German clinical center reported more work-related disability than patients with mild FMS.
Conclusion: The PHQ 15 is a valid generic measure of overall severity in FMS.

Introduction

The definition and content of fibromyalgia syndrome (FMS) have changed repeatedly in the last 100 years [1]. The most important change was the requirement for multiple tender points and chronic widespread pain that arose from the fibromyalgia classification criteria of the American College of Rheumatology [2]. By 2010, a second shift occurred with the preliminary American College of Rheumatology (ACR) diagnostic criteria [3] and the research criteria of fibromyalgia [4] that excluded tender points and placed reliance on patient-reported symptoms with chronic widespread pain, fatigue and cognitive difficulties ('fibro fog') as main and abdominal pain, depression and headache as minor symptoms. The new diagnostic criteria [3,4] indexed FMS into functional somatic syndromes (FSS), which are defined by a typical cluster of chronic somatic symptoms and the exclusion of somatic diseases sufficient to explain the symptoms [5]. FSS are frequently associated with each other (e.g. FMS and irritable bowel syndrome) and with anxiety and depressive disorders [6,7].

Recent evidence-based guidelines on FSS [8] and on FMS [9,10] recommended a graduated treatment approach based on severity. Clinical criteria for severity are based on the amount of somatic and psychological distress, disability and health care use [8–10]. However, the lack of an internationally accepted instrument for severity grading of FSS and FMS is one major obstacle in their definition and management [10,11]. The Polysymptomatic Distress Scale (PSD) [4] and the Fibromyalgia Impact Questionnaire (FIQ) [12] have been proposed as disease-specific measures of FMS-severity. However, cut-off values of the PSD have not been determined and the FIQ is difficult to analyze in routine clinical care.

The Patient Health Questionnaire (PHQ 15) is an easy to use measure of somatic symptom intensity. It provides cut-off scores for mild, moderate and severe somatic intensity. In 6000 unselected primary care patients, higher PHQ-15 scores were strongly associated with worsening function on all six Short Form Health Survey-20 scales as well as increased disability days and health care utilization [13,14]. Recently, population-based cross-sectional studies demonstrated that the total somatic symptom score measured by the PHQ 15 was a valid

* Corresponding author at: Klinikum Saarbrücken gGmbH, Winterberg 1, D-66119 Saarbrücken, Germany. Tel.: +49 681 9632020; fax: +49 681 9632022.
E-mail address: whaeuser@klinikum-saarbruecken.de (W. Häuser).

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predictor of health status and healthcare use over and above the effects of anxiety, depression and general medical diseases [15]. The PHQ 15 has been proposed for the grading of severity of somatic symptom disorder (SSD) by the Diagnostic and Statistical Manual of Psychiatric Diseases DSM V [16]. Therefore the total score of the PHQ 15 might be suited as a generic measure of overall severity of patients diagnosed with FSS, including those with FMS.

We tested if the cut-off scores for mild, moderate and severe somatic intensity measured by PHQ 15 provide a valid grading of overall severity of FMS. We hypothesized that FMS-specific measures of severity such as number of pain sites and fatigue as well as psychological distress and disability would increase with PHQ 15-defined severity (discriminant validity) and that these findings could be demonstrated in patients of different settings and countries (transcultural validity).

Methods

Patients and settings

We analyzed the data of three different settings:

a. FMS-cases within a cross-sectional survey of the general German population conducted between May and June 2008 [17].
b. 2012 survey of the US National Data Bank of Rheumatic Disease (NDB) longitudinal study of rheumatic diseases outcomes [18]. Participants were volunteers, recruited primarily from the practices of US rheumatologists, who complete mailed or Internet questionnaires at 6-month intervals. They were not compensated for their participation.
c. Consecutive FMS-patients of a German center of pain and psychosomatic medicine between January 2011 to December 2013.

Questionnaires

Demographic questionnaires

Age and sex were assessed in all surveys. The NDB study determined work disability by self-report. Self-report for disability rather than receipt of a disability pension was used as all patients are not eligible for a pension because of age or previous work history limitations. Duration of chronic widespread pain, time since FMS-diagnosis, partnership and professional status were assessed in the patients of the German clinical setting study. Long-term sick leave was defined as sick leave >four weeks.

Patient Health Questionnaire 15 (PHQ 15)

The PHQ-15 contains 13 somatic and 2 psychological (fatigue, sleep problems) symptoms. Each symptom is scored from 0 (not bothered at all) to 2 (bothered a lot). PHQ-15 scores of 5, 10, and 15 represent cutoff points for low, medium, and high somatic symptom severity, respectively. The usefulness of the PHQ-15 in screening for somatization syndromes and in monitoring somatic symptom severity in clinical practice and research has been demonstrated in numerous studies [13,14].

Polysymptomatic Distress Scale (PSD)

The PSD includes the Widespread Pain Index (WPI) and the Symptom Severity Score (SSS). The WPI is a 0–19 count of painful body regions. The SSS is the sum of the severity (0–3) of the 3 symptoms (fatigue, waking unrefreshed, cognitive symptoms) plus the sum of the number of the following symptoms occurring during the previous 6 months: headaches, abdominal pain, and depression. The final score is between 0 and 12. For fatigue, waking unrefreshed, and cognitive problems, scoring was 0 No problem; 1 Slight or mild problems, generally mild or intermittent; 2 Moderate, considerable problems, often present and/or at a moderate level; 3 Severe: continuous, life-disturbing problems. Soon after the publication of the 2010 ACR criteria, it was suggested that the 2 components of the 2010 criteria, the 0–19 Widespread Pain Index and the 0–12 Symptom Severity Score, could be combined by addition into a 0–31 index, termed the "Polysymptomatic Distress" Scale (PSD) [4]. We used the validated German version of the PSD [19].

Regional Pain Scale (RPS)

The RPS includes the WPI and 0–10 Visual Analog Scale [20]. We used the validated German version of the RPS [21].

The Short Form Health Survey SF is a generic measure of health related quality of life (HRQOL). Physical and mental health composite scores (PCS, MCS) are computed using the scores of twelve questions and range from 0 to 100, where a zero score indicates the lowest level of health measured by the scales and 100 indicates the highest level of health. The reliability and validity of the SF-36 and SF-12 had been proved in numerous studies [22,23]. We used the validated German version of the SF-12 [23] in the survey of the general German population.

The Pain Disability Index (PDI) measures disability 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 to 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 [24]. We used the validated German version of the PDI [25].

PHQ 4

The 2-item depression scale of the 4-item Patient Health Questionnaire-4 (PHQ-4) which scores two DSM-IV criteria of major depression as "0" (not at all) to "3" (nearly every day) was used to screen for a potential depressive disorder. With reference to the Structured Clinical Interview for DSM-IV (SCID), a score of 3-or-greater on the depression subscale had a sensitivity of 87% and a specificity of 78% for major depression disorder and a sensitivity of 79% and a specificity of 86% for any depressive disorders [26]. We used the validated German version of the PHQ 4 [27]. We did not use the PHQ 9 [28] which could overestimate depression in FMS because of the inclusion of key symptoms of FMS (fatigue, sleeping and concentration problems).

Self-reports of mental disease

Patients of the NDB also self-reported current and lifetime "mental illness" (not defined further in the questionnaire), and the presence now and ever of "depression" and "drug or alcohol abuse." We classified a patient as having a "psychiatric illness" (current or past) if any "mental illness," "depression" or "drug or alcohol abuse" was endorsed.

Structured psychiatric interview

Patients of the single center German study underwent a structured psychiatric interview for current anxiety and depressive disorder using the International Classification of the World Health Organization checklist [29].

Diagnoses

a. Persons of the general German population: FMS-cases were defined by the Katz criteria (>=8 pain sites in the WPI and fatigue score >= 6 on VAS 0–10 during last week) [30]. The setting of the study excluded a medical examination.
b. NDB: Diagnoses of the NDB-patients were made by the patient's rheumatologist or confirmed by the patient's physician in cases that were self-referred [18]. However, to be classified as FMS patients they were required to satisfy research criteria for fibromyalgia. The research criteria [4] were a modification of the 2010 American College of Rheumatology preliminary diagnostic criteria for fibromyalgia [3] to allow the use of self-report questionnaires for research. For patients to be diagnosed with fibromyalgia they had to have either a Widespread Pain Index(WPI) $\geq$7 and Symptom Severity