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Research report

Validation of patient health questionnaire (PHQ) for major depression in Chinese outpatients with multiple somatic symptoms: A multicenter cross-sectional study

Nana Xiong [a], Kurt Fritzsche [b], Jing Wei [a,*], Xia Hong [a], Rainer Leonhart [c], Xudong Zhao [d], Lan Zhang [e], Liming Zhu [f], Guoqing Tian [g], Sandra Nolte [h,i], Felix Fischer [h,j]

[a] Department of Psychological Medicine, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Shuaifuyuan 1, Dongcheng District, Beijing 100730, PR China
[b] Department of Psychosomatic Medicine and Psychotherapy, University Medical Centre Freiburg, Freiburg, Germany
[c] Institute of Psychology, University of Freiburg, Germany
[d] Department of Psychosomatic Medicine, Dongfang Hospital, School of Medicine, Tongji University, Shanghai, PR China
[e] Mental Health Centre, West China Hospital, Sichuan University, Chengdu, Sichuan, PR China
[f] Department of Gastroenterology, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, PR China
[g] Department of Traditional Chinese Medicine, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, PR China
[h] Medical Clinic for Internal Medicine, Department of Psychosomatic Medicine, Charité - Universitätsmedizin Berlin, Germany
[i] Population Health Strategic Research Centre, School of Health and Social Development, Deakin University, Burwood, Australia
[j] Institute for Social Medicine, Epidemiology and Health Economics, Charité - Universitätsmedizin Berlin, Germany

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ABSTRACT

Background: Despite the high co-morbidity of depressive symptoms in patients with multiple somatic symptoms, the validity of the 9-item Patient Health Questionnaire (PHQ-9) has not yet been investigated in Chinese patients with multiple somatic symptoms.
Methods: The multicenter cross-sectional study was conducted in ten outpatient departments located in four cities in China. The psychometric properties of the PHQ-9 were examined by confirmative factor analysis (CFA). Criterion validation was undertaken by comparing results with depression diagnoses obtained from the Mini International Neuropsychiatric Interview (MINI) as the gold standard.
Results: Overall, 491 patients were recruited of whom 237 had multiple somatic symptoms (SOM+ group, PHQ-15 $\geq$ 10). Cronbach's α of the PHQ-9 was 0.87, 0.87, and 0.90 for SOM+ patients, SOM− patients, and total sample respectively. All items and the total score were moderately correlated. The factor models of PHQ-9 tested by CFA yielded similar diagnostic performance when compared to sum score estimation. Multi-group confirmatory factor analysis based on unidimensional model showed similar psychometric properties over the groups with low and high somatic symptom burden. The optimal cut-off point to detect depression in Chinese outpatients was 10 for PHQ-9 (sensitivity=0.77, specificity=0.76) and 3 for PHQ-2 (sensitivity=0.77, specificity=0.74).
Limitations: Potential selection bias and nonresponse bias with applied sampling method.
Conclusions: PHQ-9 (cut-off point=10) and PHQ-2 (cut-off point=3) were reliable and valid to detect major depression in Chinese patients with multiple somatic symptoms.

1. Introduction

Many patients seek for help repeatedly because of a variety of symptoms without identifiable somatic correlate, including pain, fatigue, dizziness or shortness of breath, leading to a disproportionate consumption of health care (Barsky et al., 2005). However, there is much confusion and inconsistencies in the diagnosis and classification of such phenomena. Common definitions of these phenomena include "medically unexplained symptoms (MUS)" or "somatization", as well as "somatoform disorders", following the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (DSM-IV) (APA, 1994) and "somatic symptom disorder" following DSM-5 (APA, 2013).

Recently, a multicenter, cross-sectional study in Chinese outpatients detected that 28.1% of all patients showed multiple somatic

* Corresponding author. Tel.: +86 1069156066; fax: +86 1069151493.
E-mail address: weijing@pumch.cn (J. Wei).

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symptoms (Schaefert et al., 2013). Several studies have shown a correlation between the high number and severity of somatic symptoms and adverse psycho-behavioral and functional characteristics (Korber et al., 2011; Schaefert et al., 2013). Moreover, persistent high somatic symptom severity predicted impaired health status 12 months later (Creed et al., 2012). Further, there was a high co-morbidity (50–79.6%) of somatoform disorders/somatization with depression and anxiety (Henningsen et al., 2005; Lowe et al., 2008).

Research has shown that somatic symptoms are not only common in general medical practice but also in tertiary medical settings, especially in neurology, gastroenterology, psychiatry, and rheumatology (Kroenke, 2003). Traditional Chinese Medicine (TCM) is a special structural feature of the Chinese healthcare system (Hougaard et al., 2011) and might be more appealing to Chinese patients with multiple somatic symptoms due to own preference, encouragement by family members, poor treatment effects of western medicine, and doctor transferal. Therefore, such context might be unique in Chinese samples and is worth investigating.

As one of the most common self-rated screening tools for depression, the 9-item Patient Health Questionnaire (PHQ-9) has demonstrated acceptable screening efficacy in many populations including Chinese patients in primary care settings (Chen et al., 2010; Yu et al., 2012; Zhang et al., 2013). The 2-item Patient Health Questionnaire (PHQ-2), containing the first 2 items of the PHQ-9, has also performed well as a depression screening tool with comparable performance to the PHQ-9 (Chen et al., 2010; Liu et al., 2011; Arroll et al., 2010). Both exploratory factor analysis (EFA) and confirmative factor analysis (CFA) approaches have been used to test the construct validity of the PHQ-9. EFA with principal component factor method yielded the expected 1-factor structure, accounting for a total of 35.8–69.8% of the variance (Yu et al., 2012; Liu et al., 2011; Gelaye et al., 2013). However, results of CFA differed. In addition to a 1-factor solution, with all 9 items loading onto a single depression factor, as suggested by studies among the general population and patients with spinal cord injury (Yu et al., 2012; Graves and Bombardier, 2008), 2-factor models have also been shown to fit well. In these studies, different latent factors – usually resembling the cognitive/affective and somatic aspects of depression – and different numbers of items have shown good model fit (Krause et al., 2010, 2011; Chilcot et al., 2013). In contrast, the factor structure of the PHQ-9 has not been investigated in Chinese patients with multiple somatic symptoms. Such patients are generally believed to express their mental distress by physical discomforts and it is unclear whether comorbid multiple somatic symptoms would influence the accuracy of the PHQ-9 in diagnosing depressive disorders.

The aim of this study is twofold: a) to evaluate the reliability and to explore the factor structure of the PHQ-9 in Chinese patients with multiple somatic symptoms; b) to explore the validity and optimal cut-off value of the PHQ-9 as well as the PHQ-2 as a screening tool for depression in Chinese patients with multiple somatic symptoms.

2. Methods

2.1. Study design and setting

This is a secondary data analysis of data collected within a multicenter cross-sectional study (Zhang et al., 2014), which was conducted in 10 outpatient clinics (Neurology, Gastroenterology, TCM, and Psychosomatic Medicine) in Beijing (Peking Union Medical College Hospital), Shanghai (Shanghai Tongji Hospital, Shanghai Mental Health Centre, and Dong Fang Hospital), Chengdu (West China Hospital of Sichuan University), and Kunming (Red Cross Hospital). On randomly assigned days, all patients who entered one of above departments were consecutively informed about the study and invited to participate by research assistants. Data were collected between February 1, 2011, and October 30, 2012.

All participants were screened using the somatic symptom scale of the Patient Health Questionnaire (PHQ-15), assessing the presence of bothersome somatic complaints during the last four weeks. A cut-off score of 10 points for PHQ-15 was identified as optimal for predicting the diagnosis of a somatoform disorder with a sensitivity of 80.2% and a specificity of 58.5% (Korber et al., 2011). Using results of the PHQ-15, we split the sample into patients with (SOM+) and without (SOM-) multiple somatic symptoms respectively. Recruitment continued until a sample size of $n=25$ SOM+ (PHQ-15 ≥ 10) and $n=25$ SOM- (PHQ-15 < 10) patients in each department were enrolled. After filling out the self-report questionnaires, including the PHQ-9, all participants were invited to participate in the Mini International Neuropsychiatric Interview (MINI, version 5.0.0).

2.2. Subjects

The inclusion criteria for the study were as follows: 18 years or above, seeking treatment voluntarily for their own problems, and being able to read and sign the informed consent form. The exclusion criteria included language barriers, limited writing skills, cognitive impairment/organic brain disorder/dementia, psychosis, and acute suicidal tendency. All patients were registered, including those who denied participation with their reasons. The above criteria were ensured to be fulfilled by both research assistants (medical students) and clinical doctors. Chinese TCM practitioners in public hospitals underwent basic western medicine education which ensures appropriate transfer in case of serious health conditions (such as organic brain syndromes).

Written informed consent was obtained from all eligible participants. For data analysis, all questionnaires were copied and sent to the study center located at the medical center of the University of Freiburg where all data were entered, analyzed, and stored. The study was approved by the ethics committee of the medical center of the University of Freiburg.

2.3. Assessment instruments

The PHQ-9 was used to measure depression severity, with one item for each of the nine depressive symptoms. Respondents were asked to rate perceived symptom burden during the past two weeks between 0 (not at all) and 3 (nearly every day), resulting in a total score ranging from 0 to 27. To screen major depressive disorder in the general population using the PHQ-9, a cut-off value of 10 has been validated, with respective sensitivity of 0.88 and specificity of 0.88 (Kroenke et al., 2001).

The PHQ-15 includes 15 most prevalent somatic symptoms that account for more than 90% of the physical complaints in primary care (Kroenke et al., 2002). It has become one of the most common and brief instruments for assessing somatic symptoms severity. Studies in both Western and Chinese populations have shown that the PHQ-15 exhibited satisfactory reliability and validity (Korber et al., 2011; Lee et al., 2011; Schaefert et al., 2013). We used a cut-off point of 10 as criterion for the allocation of patients in SOM+ and SOM−, respectively.

The MINI is a brief structured interview for the diagnosis of major Axis I psychiatric disorders according to the DSM-IV diagnostic criteria (Sheehan et al., 1998). It was used as the gold standard to diagnose major depression by a face-to-face interview in this study. The Chinese version of the MINI has been shown to have good reliability and validity (Si TM, 2009).

2.4. Statistical procedures

Descriptive data are presented as means and standard deviations for continuous variables and absolute and relative frequencies for