A New Approach to the Assessment of the Treatment Effects of Somatoform Disorders

WINFRIED RIEF, PH.D.
WOLFGANG HILLER, PH.D.

A new 53-item instrument for the evaluation of treatment effects in somatoform disorders, the Screening for Somatoform Symptoms—7 (SOMS-7), is presented. It covers all somatic symptoms mentioned as occurring in somatization disorder, according to DSM-IV and ICD-10. A group of 325 patients was assessed at the beginning and end of treatment to compute scores of reliability and validity. The new scale showed high internal consistency (alpha = 0.92) and revealed two composite indices: somatization symptom count and somatization severity index. These indices discriminated patients fulfilling complete criteria for somatoform disorders, patients with somatization syndrome, and patients with other mental and psychosomatic disorders. The instrument confirmed symptom reductions between admission and discharge, while in another group composed of wait-listed patients, no significant decrease in symptoms was observed. In sum, the SOMS-7 seems to be a comprehensive, reliable, and valid instrument for the evaluation of treatment effects in patients with somatoform disorders.

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Physical complaints not fully explained by organic reasons are a common phenomenon. About 10% of the general population report multiple and persisting physical symptoms, with subsequent visits to physicians not finding an organic explanation for the complaints.1 Multiple somatic symptoms are a predictor of persistency and bad outcome.2 These patients represent about one-fifth of the patients defined as high users of health care services.3 Therefore, effective management and treatment strategies are needed that may help reduce the symptoms, the disability, and the treatment costs for patients in the health care system.

Treatment studies of patients with somatoform disorders should use evaluation instruments that allow assessment of the different aspects of outcome. However, to date, an adequate instrument to assess outcome of somatoform symptoms is lacking. There are some scales that assess trait aspects of somatization, such as the Screening for Somatoform Symptoms (SOMS)4,5 or the WHO screening scales.6,7 However, these instruments were not developed to assess change but to define groups at high risk for somatoform disorders. Other instruments, such as the somatization scale of the symptom checklist SCL-90-R8 and the hypochondriasis scale of the MMPI,9 contain questions regarding a few physical symptoms; however, their suitability for assessing changes in somatoform disorders is questionable. The lists of somatoform symptoms in somatization disorder according to ICD-10 and DSM-IV as well as in somatoform autonomic dysfunction comprise 53 physical complaints; therefore, SCL-90-R and MMPI exclude the majority of these symptoms. Moreover, for the assessment of somatoform disorders, patients should be instructed not to endorse symptoms that have evaluated organic causes. Other measures with comparable shortcom-
ings are the Symptom Questionnaire\textsuperscript{10} and the Bradford Somatic Inventory.\textsuperscript{11}

Studies of patients with unexplained physical symptoms have frequently used symptom counts, according to standardized interviews.\textsuperscript{12} Other groups used self-developed rating scales for the assessment of change or symptom diaries.\textsuperscript{13} In a pharmacological treatment trial,\textsuperscript{14} the somatic items of the Hamilton Anxiety Rating Scale have been used. Hiller and Janca\textsuperscript{15} summarized different ways of assessing multiple somatoform symptoms by using interviewing and self-rating strategies and emphasizing that there is a need for instruments assessing syndrome severity. Suitable scales for the assessment of hypochondriasis exist,\textsuperscript{16,17} but for somatization syndrome, most of the instruments mentioned do not assess the intensity of symptoms, and validity data are still missing.

A psychometric instrument used to measure symptoms of somatoform disorders should fulfill the following criteria:

1. Objectivity: Most self-rating scales fulfill this criterion.
2. Comprehensiveness: All 53 physical symptoms mentioned in DSM-IV and ICD-10 for somatization should be covered.
3. Reliability: The instrument should have sufficient internal consistency to allow the aggregation of symptoms to form total scores.
4. Validity: 1) Associations of total somatization scores should be higher with other somatization scores than with other psychopathology indices. 2) Somatization scores should be higher in patients with somatization disorder than in patients with other psychological disorders. 3) The instrument should reveal no differences in patient groups without treatment (on a waiting list) but significant differences in patient groups receiving an effective treatment. 4) Not only total scores but also scores for single items should be sufficiently sensitive to demonstrate treatment changes. 5) Difference scores of somatization, indicating treatment success, should be associated with other difference scores of psychopathology and well-being.

We tested whether a newly developed scale for the assessment of somatoform disorders could fulfill these criteria. The basis of our new scale was the symptom list of the SOMS, which includes all 53 physical symptoms mentioned in the somatoform disorders categories of DSM-IV and ICD-10 (items or symptoms of the SOMS-7). To improve the sensitivity to change, the answer categories were modified from dichotomy to a 5-point Likert scale, ranging from 0 (not at all) to 4 (very severe). Furthermore, the time frame that should be considered for the answers was reduced to 7 days, which should give a good basis for the assessment of treatment effects.

### METHOD

#### Subjects

Subjects were patients applying for treatment at the behavioral medicine treatment center in Prien, Germany. We included 325 subsequently admitted patients. Patient characteristics are shown in Table 1. Data were obtained from most patients at discharge (N = 285). For the analyses of temporal stability during periods of no intervention, we used another group of patients (N = 34) who filled out the self-rating scale about 4 months before admission and at admission. This group had elevated scores for somatization and was therefore acquired for another study. Other characteristics of that second group were comparable to those of the main group.

#### Treatment

For all these patients, an intensive treatment program was administered, including individual and group cognitive behavior therapies, relaxation training, symptom-specific interventions, such as panic management or depression management in group therapy or psychopharmacotherapy, if indicated, and other medical and psychological interventions. Since this treatment is covered by all health care insurance companies in Germany, a socioeconomic selection bias was not present. However, persistence of the symptoms as well as comorbidity of multiple disorders are common features of the patients referred to the center.

#### Psychological Assessment

All patients were interviewed after admission with a structured interview (the International Diagnostic Check Lists for ICD-10 and DSM-IV\textsuperscript{18}) to obtain valid diagnoses according to DSM-IV, then the SOMS-7 was administered. This instrument reveals two variables. The somatization symptom count is the number of all items that have been confirmed from the patients, even in a mild form. This score should allow estimations of the number of symptoms, which may be relevant for classification. The other variable
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