This paper describes the development and testing of a new self-report measure, the Dyspepsia Symptom Severity Index (DSSI), for assessing the severity of symptoms commonly associated with dyspepsia. The instrument was based on the literature, focus groups, and feedback from gastroenterologists; 48 patients and 24 controls participated in testing. Patients completed the DSSI and a symptom diary to test concurrent validity; one-week reproducibility was evaluated in 21 stable patients. Three subscales comprise the 20-item DSSI, representing reflux-, ulcer-, and dysmotility-like symptoms. Subscale internal consistency levels ($\alpha$) were high (0.84–0.89), total score $\alpha$ levels were very good (0.76, 0.80), and scores were reproducible (ICC = 0.90–0.92). Correlations between the DSSI and diary were moderate to strong ($r$ = 0.33–0.77; $P < 0.05$). Patients reported significantly more severe symptoms than controls ($P < 0.001$). Results indicate the DSSI is a reliable and valid tool for evaluating symptom severity in patients with functional dyspepsia.

**KEY WORDS:** dyspepsia; symptoms; questionnaire; measurement; outcome measure; patient-reported measure.

Dyspepsia is defined as persistent or recurrent abdominal pain or discomfort characterized by postprandial fullness, early satiety, and nausea (1). It is a common disorder, affecting approximately 25% of the US population (2). While dyspepsia symptoms may be caused by an identified underlying disease such as cholecystitis, duodenal or gastric ulceration, gastric carcinoma, or gastroesophageal reflux, the diagnosis of functional dyspepsia is based on patient-reported symptoms and the exclusion of other nonfunctional gastrointestinal disorders (3).

Dyspepsia is considered a symptom complex, rather than a diagnosis *per se*, characterized by reflux-like, ulcer-like, and dysmotility-like symptoms (4, 5). Over half of patients with dyspepsia experience the refluxlike symptoms of heartburn (6) or regurgitation (3, 4, 7, 8). Epigastric pain and nocturnal or fasting pain are identified as ulcerlike symptoms and have been reported by over 45% of those with dyspepsia (1, 3, 4, 8, 9). Dysmotility-like symptoms include bloating, early satiety, distension, postprandial fullness, abdominal discomfort, and vomiting (3, 4, 10). In a study of over 3000 dyspeptic patients in Scotland and Holland, 40% reported they had bloating (9).

There is considerable debate as to the extent to which the three symptom clusters reflect distinctive underlying pathologies or describe groups who respond differentially to specific types of treatment (6). Clearly, the clusters are not useful for discriminating among patients with dyspepsia, due in large part to substantial overlap in symptoms (11–13). In a study of the one-year prevalence of dyspepsia, most patients
(64%) experienced ulcerlike symptoms, with 31% reporting dysmotility-like and 38% refluxlike dyspepsia (2). However, nearly half (43%) of subjects experienced symptoms from more than one cluster. Further, symptomatic improvement with treatment can also cross symptom clusters. A study of the effectiveness of prokinetic therapy in patients with dyspepsia, for example, found improvements in abdominal pain, early satiety, nausea, vomiting, anorexia, and heartburn (14). Thus, while it may not be useful to classify patients into symptom groups, the symptom clusters provide a logical framework for evaluating the severity of symptoms associated with dyspepsia and the symptomatic outcomes of treatment.

Clinicians and investigators must rely on patients’ assessments of their symptoms for managing functional dyspepsia and evaluating treatment effectiveness (1). Despite its importance, there is no “gold standard” for this evaluation. Most studies to date have used individual symptoms as outcome indicators; others have used total symptom scores based on instruments that have not been systematically developed or empirically validated (8, 15, 16). The purpose of this paper is to describe the development and empirical evaluation of the Dyspepsia Symptom Severity Index (DSSI), a new self-report measure to quantify the severity of dyspepsia symptoms in clinical practice and research.

MATERIALS AND METHODS

Part I: Instrument Development

The items and the response structure for the instrument were based on an extensive review of the published literature, results of focus groups with patients, and feedback from gastroenterologists.

Published Literature. In the first stage of the development process, we examined the relevant literature on dyspepsia to identify the words and phrases experts used to describe dyspeptic symptoms. Subjects were recruited through the data bank of active participants in a marketing research program. All participants were between 18 and 70 years of age, spoke English, and were experiencing abdominal discomfort and at least three of the following symptoms for a minimum of three months and over the past two weeks: nausea, vomiting, bloating, fullness, or early satiety (1). Groups were stratified according to type of care received. Group 1 comprised people who had consulted or were being seen by a gastroenterologist for symptom relief; group 2 consisted of people who had not consulted a physician but had dyspepsia symptoms; people who were seen by a primary care or general practitioner for diagnosis comprised group 3; and group 4 had no restrictions with regard to type of care. Approval to conduct the study was obtained from the Essex Review Board (Lebanon, New Jersey). All subjects provided informed consent prior to participating in the study.

Focus groups were conducted in New York (two groups) and Philadelphia (two groups) in March 1996. Eight to 10 people participated in each group, with each session lasting approximately 90 min. Each discussion began with descriptions of the symptoms participants experienced, ie, their nature, intensity, and antecedent conditions. Each group also addressed the following issues: predictability and frequency of symptoms, duration and severity of symptoms, treatment for symptom relief, and impact on quality of life. During the group interviews, patients described both the spectrum and the gradations of symptoms they associated with their dyspepsia, the frequency of these symptoms, associated factors, and the relative weighting of symptoms in terms of awareness and treatment efficacy. Patients described the symptoms characteristic of dyspepsia, including feeling full after meals, and the inability to complete normal-sized meals. They also discussed their experiences with symptoms characteristic of the three symptom clusters of dyspepsia, including heartburn, pain, bloating, and nausea.