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Rapid communication

Development and evaluation of FSSG: frequency scale for the symptoms of GERD

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Background. The aim of this study was to produce a simplified questionnaire for evaluation of the symptoms of gastroesophageal reflux disease (GERD). ***Methods.*** A total of 124 patients with an endoscopic diagnosis of GERD completed a 50-part questionnaire, requiring only "yes" or "no" answers, that covered various symptoms related to the upper gastrointestinal tract, as well as psychosomatic symptoms. The 12 questions to which patients most often answered "yes" were selected, and were assigned scores (never = 0; occasionally = 1; sometimes = 2; often = 3; and always = 4) to produce a frequency scale for symptoms of GERD (FSSG). Sensitivity, specificity, and accuracy of the FSSG questionnaire were evaluated in another group of patients with GERD and non-GERD. The usefulness of this questionnaire was evaluated in 26 other GERD patients who were treated with proton pump inhibitors for 8 weeks. ***Results.*** When the cutoff score was set at 8 points, the FSSG showed a sensitivity of 62%, a specificity of 59%, and an accuracy of 60%, whereas a cutoff score of 10 points altered these values to 55%, 69%, and 63%. The score obtained using the questionnaire correlated well with the extent of endoscopic improvement in patients with mild or severe GERD. ***Conclusions.*** This new questionnaire is useful for the objective evaluation of symptoms in GERD patients.

Key words: frequency scale for the symptoms of GERD (FSSG), gastroesophageal reflux disease, questionnaire

Introduction

The initial diagnosis of gastroesophageal reflux disease (GERD) is based on the history or on questionnaires such as questionnaire for the diagnosis of reflux disease (QUEST), produced by Carlsson et al.,[1] as well as the findings at upper gastrointestinal endoscopy. Other diagnostic modalities for GERD include 24-h esophageal pH monitoring and the proton pump inhibitor (PPI) test, which is a therapeutic diagnostic method.[2] Because diagnosis on the basis of the history is the simplest and quickest method, placing no demands on the patient, it is favored by general practitioners.

Evaluation of the response to treatment of GERD is usually performed by asking patients about the extent of improvement of their symptoms, but there is no questionnaire available that provides an accurate and objective assessment of therapeutic efficacy. A higher QUEST score only signifies that an event is more typical of gastroesophageal reflux than of other conditions, so changes in the score for this questionnaire cannot be used to assess the severity of GERD or the response to treatment. Repeat endoscopy is often performed for assessment of the therapeutic response of GERD, but if organic disease other than esophagitis has already been excluded by the initial examination, it seems unnecessary to perform further endoscopy just to evaluate the esophageal mucosa.

With the aim of formulating a questionnaire to evaluate the response of GERD symptoms to medical therapy, we first analyzed the characteristic symptoms of GERD, and then produced a frequency scale for the symptoms of GERD (FSSG) that scored the frequency of each symptom. We also investigated the clinical usefulness of the FSSG.

Subjects and methods

Subjects

With the aim of determining the characteristic symptoms of GERD, we surveyed 124 patients who first attended the Gastroenterology Outpatients Clinic at

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Gunma University Hospital, or one of three associated hospitals, between April 1999 and March 2000, and who were diagnosed as having GERD by endoscopy. Informed consent was obtained from all of the patients, in accordance with the Helsinki Declaration of the World Medical Association. The Los Angeles classification[3] of the endoscopic features of GERD was modified by the addition of grade O (healed mucosal breaks),[4] and grade M (minimal change), which was defined as prominent erythema without clear demarcation of whitish cloudiness of the lower esophageal mucosa obscuring the longitudinal blood vessels.[3,5] Subjects with findings of grade M or grades A–D were diagnosed as having GERD. Among the 124 subjects, 39 were grade M (19 men and 20 women, with an average age of 59.7 years), 74 were grades A or B (48 men and 26 women, with an average age of 60.3 years), and 11 were grades C or D (4 men and 7 women with an average age of 65.1 years).

Creation of the FSSG questionnaire

The 124 subjects were asked to respond to a questionnaire requiring "yes" or "no" answers, comprising 50 questions about a number of symptoms related to the upper gastrointestinal tract, and psychosomatic symptoms. The 50 questions consisted of 10 questions related to gastroesophageal reflux (such as, "Do you get heartburn?" and "Do you usually get heartburn after meals?"), 12 questions related to dysmotility-like dyspepsia (such as, "Does your stomach get bloated?" and "Does your stomach ever feel heavy?"), 6 questions related to ulcer-like symptoms (such as, "Do you get pain in the stomach at night?" and "Do you get pain in the stomach after you eat?"), 11 questions related to psychosomatic symptoms (such as, "Are you always anxious?" and "Do you feel sick?"), and there were 11 other questions. The subjects were asked to fill out a questionnaire on the day of endoscopy before they underwent the procedure. No explanation was provided, but replies were given if questions were raised by the subjects.

The 12 questions to which the subjects with GERD most often answered "yes" were: "Do you feel full while eating meals?" (60%), "Do you get heartburn after meals?" (50%), "Do you get heartburn?" (47%), "Do you ever feel sick after meals?" (42%), "Does your stomach get bloated?" (37%), "Does your stomach ever feel heavy after meals?" (37%), "Do you have an unusual sensation in your throat?" (31%), "Do you sometimes subconsciously rub your chest with your hand?" (30%), "Do you get bitter liquid coming up into your throat?" (26%), "Do you burp a lot?" (26%), "Do you get heartburn if you bend over?" (23%), and "Do some things get stuck when you swallow?" (19%).

The FSSG questionnaire (Fig. 1) was devised from these 12 questions, which were scored to indicate the frequency of symptoms, as follows: never = 0; occasionally = 1; sometimes = 2; often = 3; and always = 4.

Evaluation of the FSSG questionnaire

The sensitivity, specificity, and accuracy of the FSSG questionnaire were evaluated in another group of patients with GERD and non-GERD. The subjects comprised 42 GERD patients (12 grade M, 26 grade A or B, 4 grade C or D) and 67 non-GERD patients (23 with peptic ulcers, 29 with gastritis, and 15 with other diagnoses) who attended the Gastroenterology Outpatients Clinic at Gunma University Hospital. A diagnosis of peptic ulcer (gastric or duodenal ulcer) was made if lesions with definite plaque were present. Endoscopic gastritis was classified as erosive (erosions present), superficial (redness, edema, and adherent gastric mucus in the gastric body), or atrophic (distal migration of the border between the pyloric glands and fundic glands of the gastric body, as well as clearly visible vasculature).

The clinical usefulness of the FSSG questionnaire was evaluated in 26 consecutive new patients with GERD at Gunma University Hospital. These subjects were 15 men and 11 women, with an average age of 61.3 years, who were treated with PPI therapy (rabeprazole, 10–20 mg/day; omeprazole, 20 mg/day; or lansoprazole, 30 mg/day). All patients were assessed endoscopically and by using the FSSG questionnaire before treatment and after 8 weeks of PPI treatment.

Statistical analysis

FSSG scores were compared using Student's paired *t*-test, and $P < 0.05$ was taken as the indicator of statistical significance.

Results

When the cutoff score was set at 8 point, the FSSG showed a sensitivity of 62%, a specificity of 59%, and an accuracy of 60%, whereas a cutoff score of 10 points altered these values to 55%, 69%, and 63%.

Endoscopic improvement was detected in 24 of the 26 subjects. The FSSG score increased in 1 subject with endoscopic improvement and was increased or unchanged in 2 subjects with unchanged endoscopic findings. Significant reduction of the FSSG score was seen, however, in patients with both mild and severe GERD (Fig. 2).

Do you have any of the following symptoms? If so, please circle the appropriate response below.

Question		Frequency				
		Never	Occasionally	Sometimes	Often	Always
①	Do you get heartburn?	0	1	2	3	4
②	Does your stomach get bloated?	0	1	2	3	4
③	Does your stomach ever feel heavy after meals?	0	1	2	3	4
④	Do you sometimes subconsciously rub your chest with your hand?	0	1	2	3	4
⑤	Do you ever feel sick after meals?	0	1	2	3	4
⑥	Do you get heartburn after meals?	0	1	2	3	4
⑦	Do you have an unusual (e.g. burning) sensation in your throat?	0	1	2	3	4
⑧	Do you feel full while eating meals?	0	1	2	3	4
⑨	Do some things get stuck when you swallow?	0	1	2	3	4
⑩	Do you get bitter liquid (acid) coming up into your throat?	0	1	2	3	4
⑪	Do you burp a lot?	0	1	2	3	4
⑫	Do you get heartburn if you bend over?	0	1	2	3	4

Fig. 1. The FSSG questionnaire: frequency scale for the symptoms of gastroesophageal reflux disease (GERD)

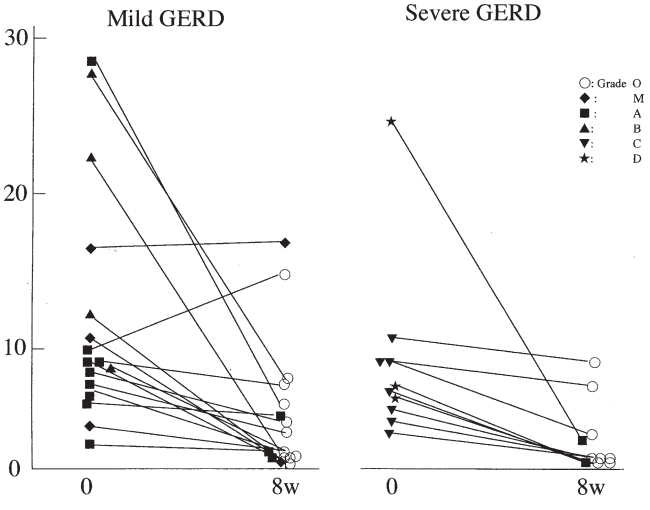

Fig. 2. Changes of FSSG scores in GERD patients on proton pump inhibitor therapy. *W*, weeks

Discussion

We produced a questionnaire, to score GERD symptoms, which combined questions about symptoms commonly experienced by GERD patients with a score for the frequency of each symptom. The FSSG score showed a good correlation with the extent of endoscopic improvement, indicating that this questionnaire is useful for objectively evaluating the therapeutic response of GERD.

When an attempt is made to evaluate symptoms objectively, it is usual to classify symptoms as mild, moderate (discomfort sufficient to interfere with normal activities, such as work or sleep), or severe (incapacitating, leading to inability to perform normal activities). Such scoring of severity may be inappropriate in Japan, however, where patients with mild GERD are relatively common.[6] There have also been attempts to evaluate the effects of treatment for GERD through changes in quality of life (QOL), using questionnaires such as the Psychological General Well-Being Index (PGWB)[7] and the Gastrointestinal Symptom Rating Scale (GSRS).[8] The PGWB includes questions related to anxiety and depression that do not necessarily reflect changes in gastrointestinal symptoms. The GSRS resembles our questionnaire in that it scores gastrointestinal symptoms using a four-grade scale from 0 to 3, but it was originally produced for evaluating therapeutic efficacy in irritable bowel syndrome and peptic ulcer disease. Accordingly, it contains seven questions related

to bowel motions and flatus, so it is not particularly well suited to the evaluation of the therapeutic response in GERD patients.

With our questionnaire, subjects had no difficulty in rating their symptoms as occurring occasionally (around 30% of the time), sometimes (50%), often (70%), or always (100%). To accurately assess the frequency of symptoms, it is necessary to determine how often heartburn, etc. occurs during a day or a week by completing a symptom diary, but the decision to include or exclude each individual event is necessarily subjective. To perform a subjective evaluation of symptoms, the method we devised using the FSSG is considerably simpler for the patient.

Actual evaluation of the therapeutic response of GERD has often been performed endoscopically, but if organic disease other than esophagitis has been excluded by the initial endoscopy, repeat examination is undesirable in terms of medical costs and the burden on the patient. The results of our questionnaire correlated strongly with the endoscopic findings, suggesting that it may be possible to evaluate therapeutic efficacy in GERD patients without repeated endoscopy. Use of the FSSG questionnaire may allow objective assessment of the therapeutic effect of various PPIs, including on-demand therapy. By following the same procedure as that used to create this questionnaire, it should also be possible to apply our technique to the evaluation of supraesophageal manifestations of GERD in the respiratory and otorhinolaryngology fields.

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