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Comparative Study of 2 Different Questionnaires in Japanese Patients: The Quality of Life and Utility Evaluation Survey Technology Questionnaire (QUEST) Versus the Frequency Scale for the Symptoms of Gastroesophageal Reflux Disease Questionnaire (FSSG)

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Background/Aims

The aim of this study was to examine the convenience of the quality of life and utility evaluation survey technology (QUEST) questionnaire and the frequency scale for the symptoms of gastroesophageal reflux disease (FSSG) questionnaire as self-assessment diagnostic instrument.

Methods

This was a two-way crossover study conducted over 6 weeks from September 2010 to November 2010. The subjects were 60 consecutive patients admitted to the Hiratsuka city hospital with a gastrointestinal condition, regardless of the coexistence of heartburn. They were assigned to fill in both the QUEST and FSSG questionnaires in random order. We analyzed the time taken to complete the questionnaires, whether subjects asked any questions as they filled in the questionnaire, and the questionnaire scores.

Results

Comparison of the QUEST and the FSSG revealed significant differences in the completion time (196.5 vs. 97.5 seconds, respectively; $P < 0.0001$) and in whether subjects asked any questions (37 vs. 15 subjects, respectively; $P < 0.0001$). Completion time in QUEST scores of ≥ 4 was lower than < 4 (170.5 vs. 214.0 seconds, respectively; $P = 0.022$), and the QUEST score was significantly higher without questions than with question (3 vs. 1 points, respectively; $P = 0.025$).

Conclusions

This study revealed that the FSSG questionnaire may be easier for Japanese subjects to complete than the QUEST questionnaire. (*J Neurogastroenterol Motil* 2013;19:54-60)

Key Words

Comparative study; Gastroesophageal reflux; Questionnaires

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Author contributions: Takashi Nonaka, Takaomi Kessoku, Yuji Ogawa and Shogo Yanagisawa performed the research. Yusuke Sekino, Hiroshi Iida, Hiroki Endo, Yasunari Sakamoto, Tomoko Koide and Hirokazu Takahashi analyzed the data. Takashi Sakaguchi, Kazuhiro Atsukawa and Hisao Takahashi drafted the manuscript. Shin Maeda, Atsushi Nakajima and Eiji Gotoh conducted the study. Takashi Nonaka and Masahiko Inamori designed the research study and wrote the paper.

Introduction

Questionnaires are extremely important aid to rapidly reach to an accurate diagnosis, assisting in the selection of suitable treatment, and monitoring the therapeutic response without expensive investigations. In addition, they are an essential component of clinical trials which aim to comprehensively evaluate pharmacotherapies for chronic diseases such as gastroesophageal reflux disease (GERD), functional dyspepsia and irritable bowel syndrome.

A number of questionnaires, such as the gastrointestinal symptom rating scale,¹ the medical outcomes study 36-item short form,² the quality of life and utility evaluation survey technology (QUEST) questionnaire,³ and the frequency scale for the symptoms of gastroesophageal reflux disease (FSSG) questionnaire,⁴ have been designed and applied to evaluate digestive symptoms. However, no questionnaires are widely used in clinical settings for various reasons, including complicated questionnaires. Some comparisons of different questionnaires focusing on their validity, reliability and responsiveness, have been published,^{5,6} but few studies have addressed questionnaire simplicity, ease of understanding and convenience in clinical settings.⁷

In this study, we compared the convenience of the QUEST and FSSG questionnaires, both major diagnostic instruments for GERD in Japan, for Japanese patients hospitalized with a gastrointestinal condition, regardless of coexistence of GERD.

Materials and Methods

Subjects

The subjects were 60 consecutive patients hospitalized with a gastrointestinal condition (Table 1) in Hiratsuka City Hospital between September and November 2010. We excluded potential subjects aged less than 20 years, those who did not consent to participate, and those who had previously completed either the QUEST or the FSSG, or were unable to complete the questionnaires by themselves. On hospitalization, 25 subjects were taking acid-suppressive medications for some reason, of whom 12 were taking histamine type 2 receptor antagonists and the others proton pump inhibitors. During the study period, 39 subjects underwent upper gastrointestinal endoscopy, of whom 6 were found to have erosive esophagitis.

This study was conducted in accordance with the Declaration

of Helsinki. Each subject was provided with information on the scientific purposes of the study, and gave their written informed consent. The study protocol using the QUEST and the FSSG was approved by the Ethics Committee of Hiratsuka City Hospital and Yokohama City University Hospital.

Questionnaire

The QUEST and the FSSG are self-administered questionnaires and major diagnostic instruments of GERD in Japan. Japanese versions of both were used in this study. A QUEST score ≥ 4 was considered to indicate probable GERD³ and similarly an FSSG score ≥ 8 was considered to indicate probable GERD.⁴

Study Design

This randomized, 2-way crossover study was conducted between September and November 2010 at Hiratsuka City Hospital. None of the subjects had ever completed either the QUEST or the FSSG previously. Subjects were randomly assigned to complete the QUEST first and the FSSG second, or the FSSG first and the QUEST second, by themselves. We analyzed the time required to complete the questionnaire, whether

Table 1. Summary of Admission Diagnoses

Gastrointestinal	Gastrointestinal hemorrhage (7) (gastric ulcer 2/duodenal ulcer 1/hemorrhagic colitis 1/other 1) Acute gastroenteritis (6) Ischemic colitis (3) Colonic diverticulitis (2) Crohn's disease (3)
Liver	Chronic hepatitis (2) Liver cirrhosis (3) Liver abscess (1)
Biliary	Choledocholithiasis (1) Cholecystolithiasis (2)
Pancreas	Acute pancreatitis (2) Chronic pancreatitis (2)
Neoplasms	Granular cell tumor of the esophagus (1) Esophageal cancer (1) Gastric cancer (7) Colorectal polyp (2) Colorectal cancer (2) Hepatocellular carcinoma (7) Cholangiocarcinoma (1) Pancreatic ductal carcinoma (3)
Other	Other diseases (2)

subjects asked any questions as they filled in the questionnaire, and the questionnaire scores.

Statistical Methods

Statistical evaluations were performed using the Wilcoxon signed-rank test, the χ^2 test, and the Mann-Whitney U test. The level of significance was set at $P < 0.05$. Statistical analyses were performed using Stat View software (SAS Institute, Cary, NC, USA).

Results

All 66 completed the study. The subjects' demographics

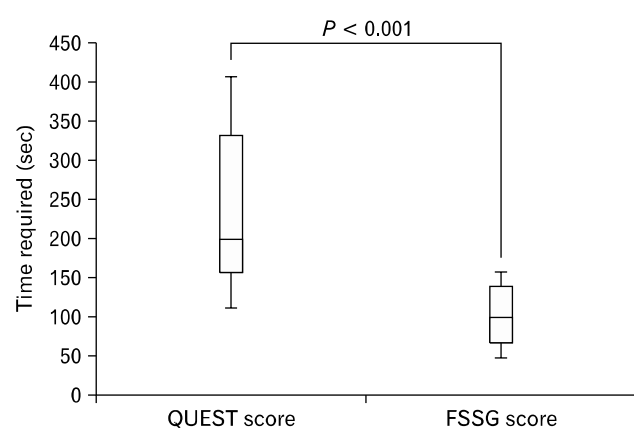


Figure 1. Comparison between the QUEST and the FSSG questionnaires revealed a significant difference in the completion time. QUEST, quality of life and utility evaluation survey technology; FSSG, frequency scale for the symptoms of gastroesophageal reflux disease.

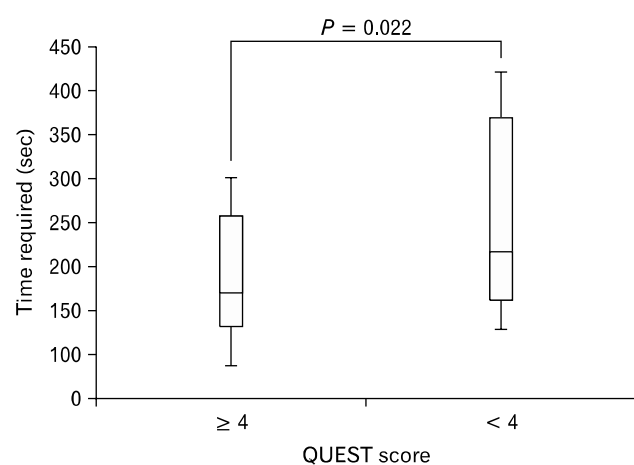


Figure 2. Significant differences were seen in the quality of life and utility evaluation survey technology (QUEST) completion time between QUEST scores of ≥ 4 and < 4 .

were male/female ratio of 37/23; median age of 66 years (range, 20-88 years). Their physical characteristics were: median height 158.7 cm (range, 135.0-183.6 cm); median weight 55.8 kg (range, 35.0-83.3 kg); median body mass index 22.16 (range, 14.21-27.78).

Time Required to Complete the Questionnaire: Completion Time

Comparison between the QUEST and the FSSG revealed a significant difference in the completion time (196.5 [54.0-661.0] vs. 97.5 [27.0-225.0] seconds, respectively; $P < 0.0001$ using the Wilcoxon signed-rank test) (Fig. 1).

Whether the Subjects Asked Any Questions As They Filled in the Questionnaire (Questions During Completion)

Comparison between the QUEST and the FSSG revealed a significant difference in the proportion of subjects asking questions (37 [61.7%] vs. 15 [25.0%] subjects, respectively; $P < 0.0001$ using the χ^2 test).

Score and Completion Time

There were 22 subjects with a QUEST score of ≥ 4 , and 29 subjects with an FSSG score of ≥ 8 .

A significant difference was seen in QUEST completion time between subjects with a QUEST score of ≥ 4 and < 4 (170.5 [54.0-366.0] vs. 214.0 [109.0-661.0] seconds, respectively; $P = 0.022$ using the Mann-Whitney U test) (Fig. 2).

On the other hand, comparison between subjects with an

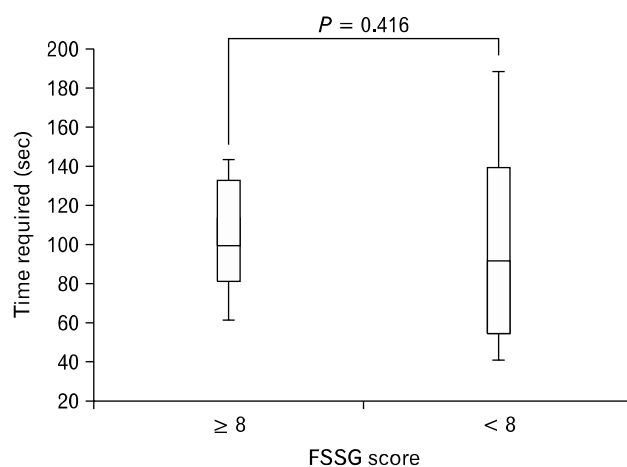


Figure 3. No significant difference was seen in the frequency scale for the symptoms of gastroesophageal reflux disease (FSSG) completion time between FSSG scores of ≥ 8 and < 8 .

FSSG score of ≥ 8 and < 8 revealed no difference in completion time (91.0 [27.0-225.0] vs. 100.0 [36.0-165.0] seconds, respectively; $P = 0.416$ using the Mann-Whitney U test) (Fig. 3).

In comparisons of the completion time under a QUEST score of ≥ 4 or < 4 vs. an FSSG score of ≥ 8 or < 8 , there were significant differences in all conditions (Table 2). That is, the completion time for the FSSG was shorter than for the QUEST regardless of GERD patients with questionnaire scores.

Score and Questions During Completion

The QUEST score was significantly higher in subjects not asking questions during completion than in those asking questions (3 [-2-13] vs. 1 [-2-13] points, respectively; $P = 0.025$ using the Mann-Whitney U test) (Fig. 4).

There was no significant difference in the FSSG score between subjects not asking questions during completion and those asking questions (8 [0-33] vs. 5 [0-19] points, respectively; $P =$

Table 2. The Comparisons of Completion Time Under QUEST Score of ≥ 4 or < 4 vs. FSSG Score of ≥ 8 or < 8

(sec)	FSSG ≥ 8	FSSG < 8
QUEST ≥ 4	191.0 [54-366] vs. 100.0 [43-151], $P < 0.0004$	125.0 [60-339] vs. 51.0 [27-140], $P < 0.028$
QUEST < 4	178.0 [109-435] vs. 98.0 [36-165], $P < 0.002$	247.0 [116-661] vs. 97.0 [32-225], $P < 0.0001$

QUEST, quality of life and utility evaluation survey technology; FSSG, frequency scale for the symptoms of gastroesophageal reflux disease.

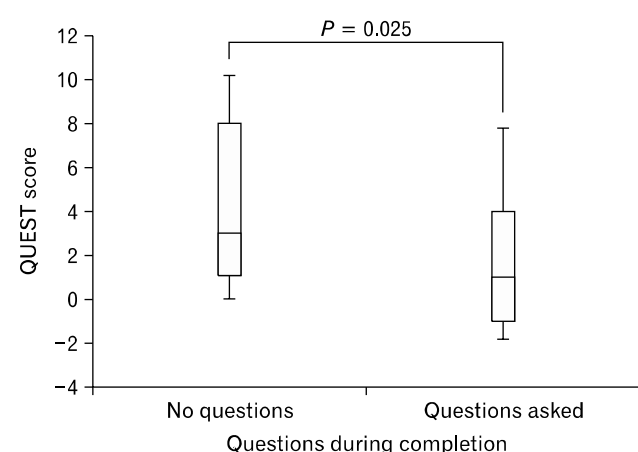


Figure 4. Significant differences were seen in QUEST scores between subjects asking questions during completion and those not asking questions. QUEST, quality of life and utility evaluation survey technology.

0.222 using the Mann-Whitney U test) (Fig. 5).

Discussion

GERD is a very common disease. GERD occurs when the reflux of gastric contents into the esophagus leads to troublesome symptoms, with or without mucosal damage and/or complications.⁸ Symptom assessment, endoscopy, 24-hour esophageal pH monitoring, and the proton pump inhibitor test are used for the diagnosis of GERD.⁸ However, there is no gold standard for the diagnosis of this condition. Symptom assessment using a questionnaire is a simple, readily available, noninvasive, and inexpensive method to diagnose GERD. When a questionnaire is to be used as a self-assessed instrument, it requires usability, comprehensibility, and a short completion time, apart from accurate identification as a matter of course. Accordingly, we investigated the convenience of the QUEST and FSSG questionnaires, both major diagnostic instruments for GERD in Japan, focusing on the time required to complete the questionnaire, whether subjects asked any questions as they filled in the questionnaire, and any correlations with questionnaire scores.

The QUEST questionnaire was developed by Carlsson et al³ in 1998 as a self-administered questionnaire for the diagnosis of GERD. The QUEST questionnaire has 7 items that focus on the nature of symptoms and precipitating, exacerbating, and relieving factors. Each response is assigned a score of positive, neutral or negative, and the score for each item is weighted (Fig. 6). The QUEST questionnaire has a reported sensitivity of 70% and

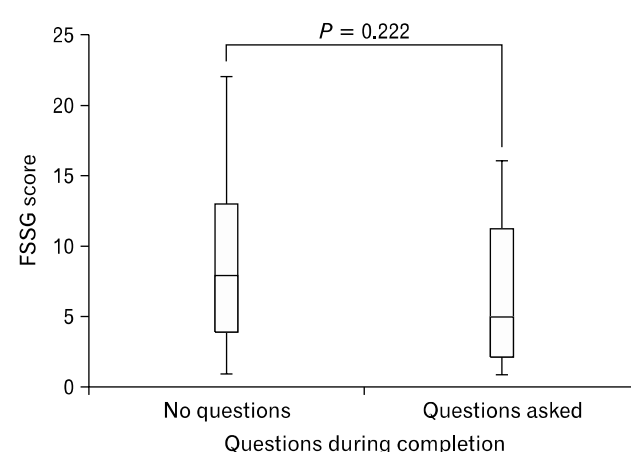


Figure 5. No significant difference was seen in FSSG scores between subjects asking questions during completion and those not asking questions. FSSG, frequency scale for the symptoms of gastroesophageal reflux disease.

Please answer the following questions by ticking one box only, except for question 3, where you must tick one box for each statement.

- Which one of these four statements BEST DESCRIBES the main discomfort you get in your stomach or chest?
 - ☐ A burning feeling rising from your stomach or lower chest up towards your neck
 - ☐ Feelings of sickness or nausea
 - ☐ Pain in the middle of your chest when you swallow
 - ☐ None of the above, please describe below:
- Having chosen one of the above, please now choose which one of the next three statements BEST DESCRIBES the timing of your main discomfort?
 - ☐ Any time, not made better or worse by taking food
 - ☐ Most often within 2 hours of taking food
 - ☐ Always at a particular time of day or night without any relationship to food
- How do the following affect your main discomfort?

	Worsens	Improves	No effect/Unsure
Larger than usual meals	(1) <input type="checkbox"/>	(-1) <input type="checkbox"/>	(0) <input type="checkbox"/>
Food rich in fat	(1) <input type="checkbox"/>	(-1) <input type="checkbox"/>	(0) <input type="checkbox"/>
Strongly flavored or spicy food	(1) <input type="checkbox"/>	(-1) <input type="checkbox"/>	(0) <input type="checkbox"/>
- Which one of the following BEST DESCRIBES the effect of indigestion medicines on your main discomfort?
 - ☐ No benefit
 - ☐ Definite relief within 15 minutes
 - ☐ Definite relief after 15 minutes
 - ☐ Not applicable (I don't take indigestion medicines)
- Which of the following BEST DESCRIBES the effect of lying flat, stooping or bending on your main discomfort?
 - ☐ No effect
 - ☐ Brings it on or makes it worse
 - ☐ Gives relief
 - ☐ Don't know
- Which of the following BEST DESCRIBES the effect of lifting or straining (or any other activity that makes you breath heavily) on your main discomfort?
 - ☐ No effect
 - ☐ Brings it on or makes it worse
 - ☐ Gives relief
 - ☐ Don't know or this does not apply to me
- If food or acid-tasting liquid returns to your throat or mouth what effect dose it have on your main discomfort?
 - ☐ No effect
 - ☐ Brings it on or makes it worse
 - ☐ Gives relief
 - ☐ Don't know or this does not apply to me

Figure 6. The QUEST questionnaire. QUEST, quality of life and utility evaluation survey technology.

F-scale

F.S.S.G (Frequency Scale for the Symptoms of GERD)

Date:

*Do you have any of following symptoms?

If so, please circle the appropriate response below.

Name	(ID;)	Age	
		Gender	M•F

Question		Fill-in space				
		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 (eg, 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 lean over?	0	1	2	3	4
Please describe any other symptoms you experience.		<div>Sum points</div> <div> <input type="text"/> + <input type="text"/> + <input type="text"/> + <input type="text"/> = <input type="text"/> </div>				

Total point

Acid reflux related symptom = Points

Dyspeptic (Dysmotility) symptom = Points

Figure 7. The FSSG questionnaire. FSSG, frequency scale for the symptoms of gastroesophageal reflux disease. GERD, gastroesophageal reflux disease.

specificity of 46% for reflux esophagitis when the cut-off score is set at 4 points. In this connection, it was reported that the sensitivity decreased to 54% and specificity increased to 60% when the cut-off score was set at 6 points.

The FSSG is another self-administered questionnaire developed by Kusano M et al⁴ in 2004, based on Japanese studies of the clinical signs and symptoms of GERD. The FSSG comprises 12 items to which patients with GERD most often answered "yes". Each response is assigned a score for the frequency of each symptom, as follows: 0, never; 1, occasionally; 2, sometimes; 3, often; and 4, always (Fig. 7). With a cut-off score of 8 points, the FSSG showed a sensitivity of 62% and specificity of 59% for reflux esophagitis based on endoscopic examination. It was also reported that raising the cut-off score to 10 points yielded 55% sensitivity and 69% specificity.

In a comparative study of the QUEST and the FSSG focusing on sensitivity, specificity and accuracy, no differences in these parameters were shown.⁹ However, no attempt to compare questionnaires in terms of their convenience in clinical use has ever been tried. Previously, we conducted a comparative study of the QUEST and the FSSG questionnaires with healthy volunteers, focusing on their convenience.⁷ We concluded that the FSSG was easier to complete and more suitable for clinical use than the QUEST. The results of this study with patients with gastrointestinal disorders are consistent with our previous results with healthy volunteers.

In this study, we demonstrated that the completion time for the FSSG was shorter than for the QUEST. The shorter completion time for the former is potentially attractive in the clinical setting. The QUEST questionnaire is comprised of 795 Japanese characters, whereas the FSSG of 381 Japanese characters. The difference in the number of characters to be read may affect the completion time. The QUEST questionnaire used in this study is a form translated into Japanese sentence, which might account for large number of Japanese characters and difficulty of understanding for Japanese patients. Furthermore, the FSSG is comprised of 12 questions concerning acid reflux-related symptoms and dyspepsia/dysmotility symptoms, and the response to each question is chosen from the frequency scale in a similar manner, such as never, occasionally, sometimes or always. On the other hand, the QUEST contains 7 questions related to the characteristics of GERD, and the response to each question is chosen from three or four alternatives, so the patient has to read a total of 26 possible responses, contributing to a longer completion time.

The proportion of subjects asking questions while they filled

in the questionnaire was lower for the FSSG than for the QUEST. This consequence implies that the FSSG is easier to understand for patients than the QUEST. The majority of questions the subjects asked in the QUEST is related to the first question, "Which 1 of these 4 statements BEST DESCRIBES the main discomfort you get in your stomach or chest?" A limitation of this study is that it included a variety of subjects irrespective of the co-existence of GERD. Therefore, subjects without discomfort in their stomach or chest may hesitate over which response to choose for this first question.

Interestingly, the completion time was significantly shorter for subjects with QUEST scores of ≥ 4 than those with a score of < 4 . The majority of QUEST scores of ≥ 4 include subjects with reflux esophagitis, from the viewpoint of sensitivity of the QUEST questionnaire. Furthermore, QUEST scores were significantly higher for subjects not asking questions during completion than in those asking questions. In other words, the QUEST is an easy questionnaire to complete for a patient with reflux esophagitis. For the FSSG questionnaire, no correlations were seen between FSSG scores, completion times and questions during completion. This suggests that the FSSG is easy to complete for anyone, whether the reflux esophagitis is present or not.

We concluded that the FSSG is more convenient for clinical use than the QUEST. The clinical implications of our results remain unclear, however, we showed in this study that the completion time for the FSSG was shorter for the QUEST. In fact, at present no questionnaire is widely used in daily clinical practice. We anticipate the development of a more suitable questionnaire that combines convenience and accurate identification in the near future.

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