FSSG Scale System in Comparison with GERD Questionnaires in Predicting Endoscopic Findings with Reflux Esophagitis

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ABSTRACT

Background: *Gastroesophageal reflux diseases (GERD) frequently manifests in varied symptoms other than its classics (heartburn and regurgitation), this variation might hinder its diagnostic effort. Several questionnaires based on symptoms filled by the patients themselves may help in diagnosing GERD without previous endoscopic examination. This study objects to compare endoscopic findings in patients which previously asked to fill the questionnaires (frequency scale for the symptoms of GERD (FSSG)) and GERD questionnaire (GerdQ) in pursuit of reliable and valid instrument to detect GERD before endoscopic approaches.*

Methods: *This study was conducted in cross-sectional design involving 72 patients in Adam Malik Hospital, Medan with symptomps of upper abdominal pain or discomfort with or without heartburn/regurgitation. Subjects were asked to fill both FSSG and GerdQ and underwent endoscopy. Diagnoses made were classified as reflux esophagitis, functional dyspepsia, or other diagnoses. Subsequently we conduct a comparison analysis of both questionnaires' specificity and accuracy using receiver operator curve (ROC) by analyzing the area below the curve.*

Results: *According to endoscopic findings from 72 subjects, we ascertained the following results: 52.8% gastritis, antral ulcer, and esophageal hiatal hernia, 37.5% functional dyspepsia, and reflux esophagitis in 9.7% cases. GerdQ is concluded to be superior in terms of specificity and accuracy compared with FSSG with the following percentages in terms of sensitivity, specificity, accuracy, and p value, respectively: 100%, 23.1%, 61.5%, 0.318 vs. 100%, 73.8%, 86.9%, 0.001.*

Conclusion: *GerdQ is superior compared to FSSG in diagnosing GERD based on clinical symptoms in daily practice.*

Keywords: *reflux esophagitis, GERD, FSSG, GerdQ, endoscopy, Los Angeles classification, heartburn.*

ABSTRAK

Latar belakang: *Penyakit refluks gastroesophageal (PRGE) sering bermanifestasi dengan gejala yang beragam selain gejala klasik (rasa panas/terbakar di dada dan regurgitasi) sehingga timbul kesulitan dalam penegakan diagnosa akurat. Beberapa kuesioner berdasarkan gejala yang dinilai oleh pasien itu sendiri dapat membantu diagnosis PRGE tanpa pemeriksaan endoskopi sebelumnya. Penelitian ini bertujuan untuk membandingkan gambaran endoskopi dengan frequency scale for the symptoms of GERD (FSSG) dan GERD questionnaire (GerdQ) pada pasien PRGE untuk mengetahui kuesioner mana yang lebih baik.*

Metode: *Penelitian ini dilakukan secara potong lintang yang melibatkan 72 pasien di Rumah Sakit Adam Malik Medan dengan gejala nyeri/tidak enak di perut bagian atas dengan atau tanpa heartburn/regurgitasi. Pasien penelitian mengisi kuesioner FSSG dan GerdQ serta menjalani prosedur pemeriksaan endoskopi. Diagnosis pada pasien dikelompokkan menjadi refluks esofagitis, dispepsia fungsional dan diagnosis lainnya. Kemudian dilakukan perbandingan antara sensitivitas, spesifisitas serta akurasi FSSG dan GerdQ menggunakan receiver operator curve (ROC) dengan menganalisis area di bawah kurva.*

Hasil: *Berdasarkan hasil gambaran endoskopi dari 72 subyek maka dilakukan pengelompokkan yaitu gastritis, ulkus antrum dan hiatal hernia esofagus 52.8%, dispepsia fungsional 37.5%, dan refluks esofagitis 9.7%. Diketahui bahwa GerdQ lebih baik dalam hal spesifisitas dan akurasi dibandingkan dengan FSSG dimana sensitivitas, spesifisitas, akurasi dan nilai p FSSG vs. GerdQ berturut-turut yaitu 100%, 23.1%, 61.5%, 0.318 vs 100%, 73.8%, 86.9%, 0,001.*

Simpulan: *Kuesioner GerdQ diketahui lebih sesuai dibandingkan dengan kuesioner FSSG dalam menegakkan diagnosis PRGE berdasarkan gejala klinis dalam praktik sehari-hari.*

Kata kunci: *refluks esofagitis, PRGE, FSSG, GerdQ, endoskopi, klasifikasi Los Angeles, rasa panas/terbakar di dada*

INTRODUCTION

Gastroesophageal reflux disease (GERD) defined as pathological condition marked by reflux of gastric contents to esophagus causing various esophageal and extraesophageal manifestations, even severe complications such as Barrett's esophagus, strictures, adenocarcinoma of esophagus and gastric cardia.[1,2] Studies of general population reveals tendency towards increment of GERD prevalence in Asia. Population in Southeast Asia also shows similar phenomenon. GERD prevalence in Singapore is 10.5%, while in Malaysia its incidence increases from 2.7% (1991-1992) to 9% (2000-2001), however no epidemiological data documented in Indonesia up to date.[3,4] GERD frequently manifests in various symptoms aside its classical presentations (heartburns and regurgitations) causing difficulties in accurately diagnose its presence in daily clinical practice. For that purpose, researchers have developed several questionnaires, i.e., questionnaire for the diagnosis of reflux esophagitis (QUEST), frequency scale for the symptoms of GERD (FSSG), reflux questionnaire (ReQuest), reflux disease questionnaire (RDQ), and the recently developed 2009, GerdQ questionnaires.[5-12]

FSSG scale system was developed in Japan[7] and used in several countries outside Japan. FSSG comprised of 12 questions which related with the most frequent symptoms suffered by patients, not only heartburn and acid taste, but also other dyspepsia symptoms such as excessive full sensation, especially after meals.[8] Study by Ndraha in Koja Hospital, Jakarta in 2010 using FSSG revealed high mean of FSSG results, in which dismotility symptoms is found to be more predominant than its reflux counterpart.[13]

GerdQ questionnaires developed by Jones et al also including new questionnaires modified from RDQ, gastrointestinal symptom rating scale (GSRS) dan gastroesophageal reflux disease impact scale (GSIS). GerdQ comprised of 6 simple questions including reflux symptoms, dyspepsia, and drugs to alleviate symptoms. The study results show the potentials of GerdQ as diagnostic tool for general practitioner with similar sensitivity as if the diagnoses were made by gastroenterologists.[12] In this study, we try to compare FSSG and GerdQ in terms of sensitivity and specifity and its relationship with endoscopic findings.

METHOD

Cross-sectional survey was conducted in Adam Malik Hospital, Medan between October until December 2011. Study population is defined as all patients with dyspepsia-related symptomps with or without heartburn and/or regurgitations. Study sample is defined as all subjects which underwent endoscopic procedure. Inclusion criteria are stated as the followings, i.e., male or female aged ≥ 18 years old, patients with dyspepsia related symptoms with or without heartburn or regurgitations, willing to be recruited in the study, and signed the informed consent. While the exclusion criteria defined as subjects with liver and kidney disorders, upper gastrointestinal (GI) bleeding, severe hematologic malignancies (e.g. aplastic anemia), severe heart disease (e.g. myocardial infarct and other heart disease), malignancy, pregnancy, surgical history of upper GI, postoperative reflux esophagitis, and patients in NSAIDs therapy.

Before data collection phase was heralded, all the subjects were asked to sign informed consent paper. Thereafter we collected patients identity, history taking, and physical examination, also the laboratory tests (i.e., routine hematology, liver and kidney function tests, blood glucose level, and abdominal ultrasonography). Subsequently, all the subjects were evaluated using the FSSG and GerdQ questionnaires and underwent esophagogastroduodenoscopy examination.

FSSG questionnaires contain 12 questions comprised of 5 acid reflux related symptoms and 7

dyspepsia or dismotility-related symptoms (expressed as never, once, sometimes, frequent, and always suffered). In the aftermath, the FSSG total score was calculated, the cut-off points defined as 8.[11]

GerdQ questionnaires contain 6 questions, including reflux symptoms, dyspepsia, and medications used to alleviate the symptoms. GerdQ evaluated using the symptoms frequency score, stated in days (0 day, 1 day, 2-3 days, 4-7 days). The cut-off points defined as 8.[12]

Both Indonesian version of the questionnaires have not been officially validated by experts as its Japanese, Chinese, Italian, Spanish, and French versions. For the purpose of the study, the authors translated both the questionnaires into Indonesian language.

We compare FSSG and GerdQ using receiver operator curve (ROC) and hypothesis test (student T-test and Mann-Whitney U test). If p < 0.05 defined as statistically significant. We analyze the data with SPSS statistical program version 15.0.

RESULTS

Results of the study show from 72 patients, we found 27 (37.5%) patients with normal endoscopy result, 7 subjects with reflux esophagitis (9.7% comprise of 5.5% grade A, 4.2% grade B), and other diagnoses in 38 patients (52.8%). Other diagnoses including antral ulcer, gastritis, and esophageal hiatal hernia. In group of subjects with esophagitis, we found 2 subjects aged less than 40 years old and 5 subjects more than 40 years old. Female patients are more commonly found in group with esophagitis and normal endoscopic findings. Baseline characteristics of the patients are illustrated below.
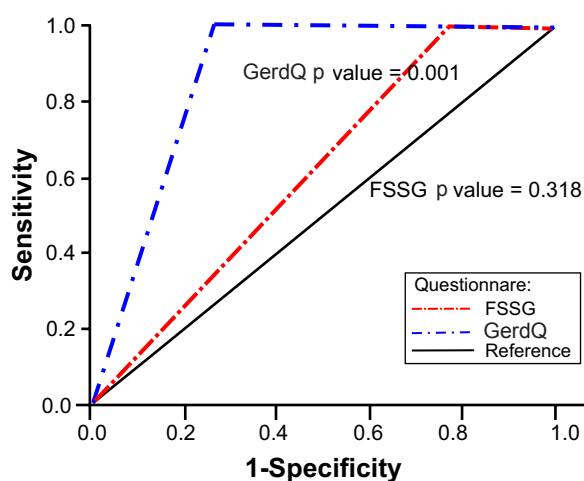

Figure 1. ROC curve showed comparison between FSSG and GerdQ questionnares in predicting reflux esophagitis related endoscopic findings

Based on analysis study using ROC test, we concluded that GerdQ is superior than FSSG in diagnosing reflux esophagitis (p = 0.001 vs. 0.318) with 100% sensitivity, 73.8% specificity, and 86.9% accuracy (Table 2 and Figure 1).

Table 1. Baseline characteristics of the subjects

Variables	Normal	Esophagitis	Others*	Total
n	27 (37.5%)	4 (5.5%) grade A 3 (4.2%) grade B Total: 7 (9.7%)	38 (52.8%)	72 (100%)
Sex				
Male	11 (40.7%)	3 (42.9%)	20 (52.6%)	34 (47.2%)
Female	16 (59.3%)	4 (57.1%)	18 (47.4%)	38 (52.8%)
Age (years old)				
≤ 40	7 (25.9%)	2 (28.6%)	10 (26.3%)	26.4%)
> 40	20 (74.0%)	5 (71.4%)	28 (73.7%)	53 (73.6%)
Education				
Elementary school	1 (3.70%)	1 (14.3%)	6 (15.8%)	8 (11.1%)
Junior high school	8 (29.6%)	2 (28.6%)	7 (18.4%)	17 (23.6%)
Senior high school	8 (29.6%)	2 (28.6%)	14 (36.8%)	24 (33.3%)
University graduates	10 (37.0%)	2 (28.6%)	11 (28.9%)	23 (31.9%)
Occupations				
Civil servants	12 (44.4%)	3 (42.9%)	13 (34.2%)	28 (38.9%)
Housewifes	9 (33.3%)	0 (0.0%)	9 (23.7%)	18 (25.0%)
College student	0 (0.0%)	1 (14.3%)	0 (0.0%)	1 (1.4%)
Entrepreneur	6 (22.2%)	3 (42.9%)	16 (42.1%)	25 (34.7%)
Ethnics				
Bataknese	12 (44.4%)	2 (28.6%)	15(39.50%)	29 (40.3%)
Karonese	5 (18.5%)	2 (28.6%)	6 (15.8%)	13 (18.1%)
Mandailingnese	4 (14.8%)	1 (14.3%)	2 (5.26%)	7 (9.7%)
Malays	1 (3.70%)	1 (14.3%)	5 (13.16%)	7 (9.7%)
Javanese	3 (11.1%)	1 (14.3%)	5 (13.16%)	9 (12.5%)
Minangs	2 (7.40%)	0 (0.00%)	3 (7.90%)	5 (6.9%)
Niasians	0 (0.00%)	0 (0.00%)	2 (5.26%)	2 (2.8%)

*Others including HHO, gastritis, and antral ulcers

Table 2. Sensitivity and specificity of FSSG and GerdQ questionnaires with endoscopic findings

Variable	Normal	Esophagitis	Others
Sensitivity*			
FSSG	70.4%	100%	81.6%
GerdQ	29.6%	100%	23.7%
Specificity*			
FSSG	15.6%	23.1%	23.5%
GerdQ	64.4%	73.8%	55.9%
Positive predictive value			
FSSG	33.3%	12.3%	54.4%
GerdQ	33.3%	29.2%	37.5%
Negative predictive value			
FSSG	53.3%	0.0%	46.7%
GerdQ	39.6%	0.0%	60.4%
Accuracy*			
FSSG	43%	61.5%	52.6%
GerdQ	47%	86.9%	39.8%
p value			
FSSG	0.320	0.318	0.710
GerdQ	0.675	0.001*	0.137

*Sensitivity, specificity, and accuracy tests were conducted using ROC test; FSSG: *frequency scale for the symptoms of* GERD; GerdQ: GERD questionnaire
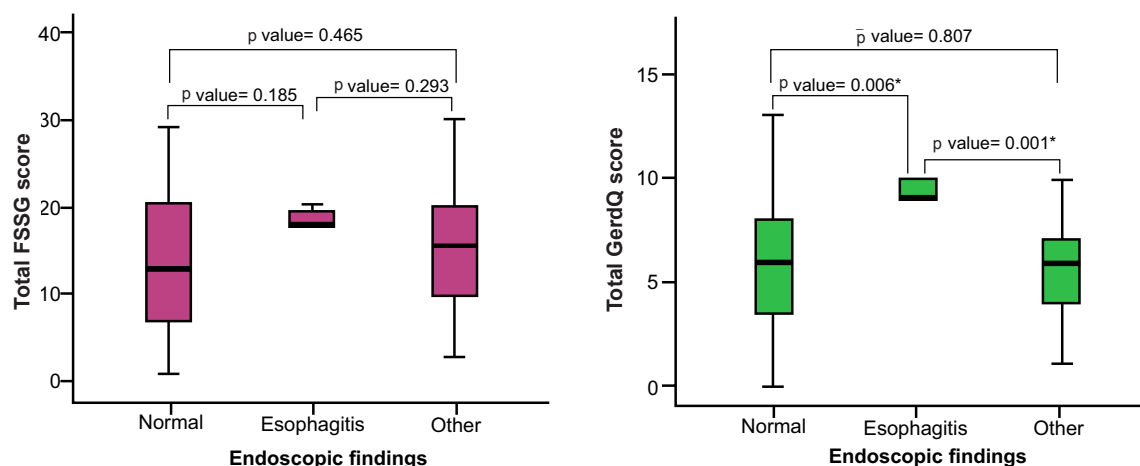
Figure 2. Comparison of endoscopic findings with FSSG and GerdQ questionnaires score

Values of significance between normal group and others were tested using T-test while between normal vs. esophagitis groups and others vs. esophagitis groups were evaluated using Mann-Whitney U test with significant values defined as results with $p < 0.05$.

DISCUSSION

GERD may occur in diverse points of age spectrum, eventhough its prevalence is recently found prominent in people aged more than 40 years old.[14] In this study, group with reflux esophagitis predominantly comprised of subjects more than 40 years old, 5 subject. In previous studies conducted in Western countries there are no differences of incidence rate between male and female subjects.[14] However in one study conducted in Asia, female predominates the incidence.[15] In this study, from total 7 subjects, we found similar results with female predominance, 4 subjects.

Plausible explanation of lower specificity and accuracy percentages in FSSG group (23.1% and 61.5%, respectively) is the complexity of FSSG questions, which evaluated to be more difficult to be understood by subjects (FSSG contains 12 questions including 7 reflux-related questions and 5 dismotility-related questions which are more in detail than the simpler GerdQ). Difficulty in differentiating between reflux- and dismotility-related symptoms by patients might also explain this result, as the same subject might experience overlapped symptoms of both reflux and dismotility symptoms.

Alongside the above mentioned possibilities, the frequency of each symptom in FSSG assessed to be less definitive and distinct to be differentiated by subjects (*rarely* vs. *sometimes*; *often* vs. *always*); these options might confuse subjects and further make the effort to obtain accurate frequency quite more formidable.

Whilst GerdQ questionnaires consists of 6 simpler questions pertaining to reflux and dismotility-type. The frequency also stated in more definitive unit of measurement i.e., number of days in 1 week (0-7 days). When T-test and Mann-Whitney U tests were tested against each total FSSG and GerdQ scores, we found a confirming result as revealed from ROC test in which GerdQ found to be more superior than FSSG instrument. This result hoped to validate the use of GerdQ to diagnose reflux esophagitis without endoscopy.

In a study of 475 subjects in Japan, no differences in terms of sensitivity, specifity, and accuracy between FSSG and QUEST instruments in diagnosing GERD and other GI disorders. Other study confirmed that FSSG is more reliable to reflect GERD severity found endoscopically, which justify its use to evaluate the symptoms or response of patients towards GERD therapeutic agents.[11] Upper GI endoscopy has been justified as the gold standard in diagnosing GERD in Indonesia as published in 2004 Indonesian National Guidelines of GERD Management.[16] Whilst according to Montreal Consensus in 2006, the gold standard of GERD ideally shall be esophageal pH 24-hour monitoring.[1] Several studies show a better efficacy of pH monitoring using wireless capsule compared with traditional 24-hour monitoring using transnasal catheter. This better efficacy was concluded from its capability to identify more patients with acid reflux, more data related to subjects mucosal characteristics, and better tolerated by patients.[17-19] In a study in Lebanon and US involving 180 patients, it was found that GerdQ only shows moderate sensitivity and specificity (66% and 48% respectively) compared with 48-hour esophageal pH capsule monitoring. Therefore

this study does not recommend its use in GERD screening. It also stated that higher GerdQ scores related to higher occurrence of abnormal esophageal pH in subjects not consuming PPI previously.[20]

Several limitations of this study are small sample size, and not all grades of esophagitis are obtained. Therefore relationship between FSSG and GerdQ total scores with the severity confirmed in endoscopy examination are not able to be analyzed, which make it impossible to decide which is the more reliable questionnaire to evaluate response to therapy of reflux esophagitis.

Since the study is using Los Angeles Classification which does not include GERD M grade (minimal changes), this study might lose some abnormal (GERD M grade) endoscopic findings which underestimated as normal findings.

The last limitations might be defined by many unadjusted confounding factors such as age, education levels, and occupations in this study.

CONCLUSION

GerdQ questionnaire is superior compared with FSSG in terms of specificity and accuracy to diagnose reflux esophagitis in Adam Malik Hospital.

REFERENCES

1. Vakil N, van Zanten SV, Kahrilas P, Dent J, Jones R; Global Consensus Group. The Montreal definition and classification of gastroesophageal reflux disease: a global evidence-based consensus. Am J Gastroenterol 2006;101:1900-20.

2. Makmun D. Penyakit refluks gastroesofageal. In: Sudoyo AW, Setyohadi B, Alwi I, Simadibrata M, Setiati S, eds. 5th ed. Buku Ajar Ilmu Penyakit Dalam. Jakarta: Pusat Penerbitan Departemen Ilmu Penyakit Dalam FKUI 2009.p.481-95.

3. Jung HK. Epidemiology of gastroesophageal reflux disease in Asia: a systematic review. J Neurogastroenterol Motil 2011;17:14-27.

4. Goh KL, Wong CH. Gastrooesophageal reflux disease: an emerging disease in Asia. J Gastroenterol Hepatol 2006;2:118-23.

5. Stanghellini V, Armstrong D, Monnikes H, Bardhans KD. Systematic review: do we need a new gastro-oesophageal reflux disease questionaire? Aliment Pharmacol Ther 2004;19:463-79.

6. Carlsson R, Dent J, Bolling-Sternevald E, Johnsson F, Junghard O, Lauritsen K, et al. The usefulness of a structured questionnaire in the assessment of symptomatic gastroesophageal reflux disease. Scand J Gastroenterol 1998;33:1023-9.

7. Kusano M, Shimoyama Y, Sugimoto S, Kawamura O, Maeda M, Minashi K, et al. Development and evaluation of FSSG: frequency scale for the symptoms of GERD. J Gastroenterol 2004;39:888-91.

8. Bardhan KD, Berghofer P. Look-but also listen! Request™: an assay on a new validated scale to access the outcome of GERD treatment. Digestion 2007;75(Suppl 1):87-100.

9. Shaw M, Talley NJ, Beebe T, Rockwood T, Carlsson R, Adlis S, et al. Initial validation of a diagnostic questionnaire for gastroesophageal reflux disease. Am J Gastroenterol 2001;96:52-7.

10. Shaw M, Dent J, Beebe T, Junghard O, Wiklund I, Lind T, et al. The reflux disease questionnaire: a measure for assessment of treatment response in clinical trials. Health and Quality Life Outcomes 2008;6:31.

11. Danjo A, Yamaguchi K, Fujimoto K, Saitoh T, Inamori M, Ando T, et al. Comparison of endoscopic findings with symptom assessment systems (FSSG and QUEST) for gastroesophageal reflux disease in Japanese centres. J Gastroenterol Hepatol 2009;24:633-8.

12. Jones R, Junghard O, Dent J, Vakils N, Halling K, Wernersson B, et al. Development of the GerdQ, a tool for the diagnosis and management of gastroesophageal reflux disease in primary care. Aliment Pharmacol Ther 2009;30:1030-8.

13. Ndraha S. Frequency scale for the symptoms of GERD score for gastroesophageal reflux disease in Koja Hospital. Indones J Gastroenterol Hepatol Dig Endosc 2010;2:75-8.

14. Fisichella PM, Patti MG. Gastroesophageal reflux disease [serial online] 2011 [cited 2011 Oct 8]. Available from: URL: http://www.emedicine.medscape.com/article/176595-overview

15. Armstrong D, Gittens S, Vakil N. The Montreal consensus and the diagnosis of gastroesophageal reflux disease (GERD): a Central American need analysis. CDDW 2008 [cited 2011 Oct 8]. Available from: URL: http://www.pulsus.com/cddw2008/abs/195.htm.

16. Kelompok studi GERD Indonesia. Konsensus nasional penatalaksanaan penyakit refluks gastroesofageal (Gastroesophageal Reflux Disease/GERD) di Indonesia 2004. Perkumpulan Gastroenterologi Indonesia 2004.

17. Lacy BE, Weiser K, Chertoff J, Fass R, Pandolfino JE, Richter JE, et al. The diagnosis of gastroesophageal reflux disease. Am J Med 2010;123:583–92.

18. Wong WM, Bautista J, Dekel R, Malagon IB, Tuchinsky I, Green C, et al. Feasibility and tolerability of transnasal/peroral placement of the wireless pH capsule vs. traditional 24-h pH monitoring-a randomized trial. Aliment Pharmacol Ther 2005;21:155-63.

19. Wenner J, Johnsson F, Johansson J, Oberg S. Wireless esophageal pH monitoring is better tolerated than the catheter-based technique: results from a randomized cross over trial. Am J Gastroenterol 2007;102:229-45.

20. Lacy BE, Chehade R, Crowell MD. A prospective study to compare a symptom-based reflux disease questionnaire to 48-h wireless pH monitoring for the identification of gastroesophageal reflux (revised 2-26-11). Am J Gastroenterol 2011;106:1604-11.

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