Frequency Scale for the Symptoms of GERD Score for Gastroesophageal Reflux Disease in Koja Hospital

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ABSTRACT

Background: The frequency scale for the symptoms of GERD (FSSG) was a specific questionnaire to gastroesophageal reflux disease (GERD), which has been validated against the endoscopic findings in Japan. The high score FSSG is one of the factors related to failure of proton pump inhibitor (PPI) mono therapy. The purpose of this study is to determine FSSG score in patients with GERD at Koja hospital, in order to predict the need for combination therapy of PPI with pro-kinetic drug or PPI only.

Method: Dyspeptic patients which had have heartburn and/or regurgitation were collected in the period of March until July 2010. The FSSG score was obtain containing 12 questions which consisted of seven questions for reflux symptoms and five questions for dysmotility/dyspeptic symptoms.

Result: There were 129 patients, 51 (39.5%) males and 78 (60.5%) females, mostly in the age group of < 40 years (55.8%), body mass index of most patients (66.6%) were normal, only 12.4% were overweight. FSSG score revealed the mean of total score of 17.6 \pm 6.9. From 129 dyspepsia patients who complained heartburn and or regurgitation, obtained 121 (94%) met criteria for GERD with cutoff eight. The mean of reflux score was 7.4 \pm 4.6 while the mean of dyspeptic/dysmotility score was 10.1 ± 4 . Thus from 129 patients studied, the symptoms of dyspeptic/dysmotility more dominant than symptoms of reflux.

Conclusion: GERD patients in Koja hospital have a high mean FSSG score, whereas dysmotility symptoms was proved to be more dominant than acid reflux.

Keywords: GERD, FSSG, dyspeptic/dysmotility score, reflux score

INTRODUCTION

Gastroesophageal reflux is a normal physiological phenomenon commonly experienced by most people, particularly after meals.¹ Gastroesophageal reflux disease (GERD) is defined as a pathological condition when the amount of gastric contents reflux into the esophagus exceeds the normal limit, with a variety of symptoms caused.^{1,2} It was known that reflux into the esophagus can lead to symptoms to extra-esophageal or esophagus itself, besides severe complications such as stricture, Barrett's esophagus or even adenocarcinoma of the cardio and esophagus.^{1,2} The prevalence of GERD in Asia, including Indonesia, is relatively lower compared to

Western countries. In America, nearly 7% of the populations have a heartburn complaint, and 20-40% of them are estimated to suffer from GERD. Prevalence of esophagitis in the West ranged from 10-20%, while in Asia only 3-5%, with the exception of Japan and Taiwan (13-15%).^{2,3} There is no gender predilection on GERD, in which men and women have the same risk, but the incidence of esophagitis in males was higher (2:1-3:1), likewise the incidence of Barrett's esophagitis is also higher (10:1).¹ GERD can also occur in all age groups, but the prevalence increased in age over 40 years.¹

Pathogenesis of GERD involves a balance between offensive factors namely reflux materials and defensive factors. The defensive factors include the anti-reflux dividing factor of lower esophageal sphincter (LES), the clearance of acid from the lumen of the esophagus, and the esophageal epithelial resistance.² Typical clinical symptoms of GERD are heartburn (burning sensation in the chest

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accompanied by pain) and regurgitation (sour and bitter taste on the tongue).3,4 Gold standard for diagnosis of GERD according to the Montreal Consensus in 2006 is 24-hour esophageal pH monitoring.5 However Armstrong et al have reported in Canadian digestive diseases week (CDDW) 2008⁶ that health practitioners in the United States are still difficult to perform esophageal pH monitoring for GERD diagnosis, because of the constraints of facilities and skills, and they generally prefer upper gastrointestinal endoscopy. The National Consensus 2004 for gastro-esophageal reflux disease treatment in Indonesia,³ has agreed on the basic standards of diagnosis is the upper gastrointestinal endoscopy, which is found of mucosal breaks in the esophagus as its result. However, endoscopic examination of the upper gastro-intestinal tract is not easy to be implemented as the facilities and experts are not always available and it is often less comfortable for patients. Besides, repeat the procedure of the endoscopic examination for the purpose of treatment's evaluation is not practically to do. Hence, there is a scoring system has been developed for the screening and evaluation of GERD therapy.7 Currently, a scoring system called the frequency scale for the symptoms of GERD (FSSG) has been developed in Japan to evaluate GERD symptoms. This questionnaire specific to GERD, which contains 12 questions consisted of seven questions for reflux score and five questions to score the dysmotility or dyspeptic.8 FSSG score has been validated against the endoscopic findings in Japan with the cut-off score (cut points) at 8, showed sensitivity of 62%, specificity 59% and accuracy of $60\%.^{9,10}$

Miyamoto et al found that high score FSSG is one of the factors related to failure of proton pump inhibitor (PPI) monotherapy, in addition to female, alcohol consumption and obesity. Thus, GERD with a high FSSG score requiring PPI combination therapy with pro-kinetic drug for a more satisfactory outcome. The purpose of this study is to determine FSSG score in patients with GERD at Koja hospital, in order to predict the need for combination therapy of PPI with pro-kinetic drug or PPI monotherapy only.

METHOD

This study used cross-sectional design, with the population of all outpatients who visited Department of Internal Medicine Koja hospital in the period of March until July 2010. Samples were taken by using non probability sampling that is consecutive sampling.

The inclusion criteria were the presence of heartburn (burning sensation in the chest accompanied by pain) and/or regurgitation (acid taste and bitter to the tongue). Patients would be excluded if they refused the interview or could not speak Indonesia. Data was taken from all patients who met the inclusion criteria and the FSSG score was obtain containing the following questions:

- Do you get heartburn? (reflux/acid-related symptoms)
- 2. Does your stomach get bloated? (dyspeptic/dysmotility symptoms)
- 3. Does your stomach ever feel heavy after meals? (dyspeptic/dysmotility symptoms)
- 4. Do you sometimes subconsciously rub your chest with your hand? (reflux/acid-related symptoms)
- 5. Do you ever feel sick after meals? (dyspeptic/dysmotility symptoms)
- 6. Do you get heartburn after meals? (reflux/acid-related symptoms)
- 7. Do you have an unusual (e.g. burning) sensation in your throat? (reflux/acid-related symptoms)
- 8. Do you feel full while eating meals? (dyspeptic/dysmotility symptoms)
- 9. Do some things get stuck when you swallow? (reflux/acid-related symptoms)
- 10. Do you get bitter liquid (acid) coming up into your throat? (reflux/acid-related symptoms)
- 11. Do you burp a lot? (dyspeptic/dysmotility symptoms)
- 12. Do you get heartburn if you bend over? (reflux/acid-related symptoms)

Seven questions (number 1, 4, 6, 7, 9 and 12) were related to acid reflux, and 5 questions (number 2,3,5,8 and 11) were related to dyspeptic/dysmotility disorder. For each question in FSSG scale, patients had given 5 choices answer: never (for score = 0), occasionally (for score = 1), sometomes (for score = 2), often (for score = 3), and always (for score = 4). Thus, the score for reflux/acid-related symptoms was ranged between 0-28, the score for dyspeptic/dysmotility symptoms was ranged between 0-20, and total score was ranged between 0-48.

All the data was recorded in the entry form, and further organized using descriptive statistics, presented as mean \pm SD for numerical data, and proportion (%) for the categorical data.

RESULTS

Study has been done on patients with dyspepsia who met the inclusion criteria, which are heartburn or regurgitation, or both. There were 129 patients, 51 (39.5%) males. The mean age of 39.6 \pm 15.5 years, mostly in the age group of < 40 years (55.8%), followed by the 40-60 years age group (38.8%) and only 5.4% at age over 60 years. Body mass index (BMI) of most patients (66.6%) were normal, overweight (BMI 25-30 kg/m²) was found in 12.4% patients, 21% met the criteria of underweight (BMI < 18.5 kg/m²), and there

is no patients who meets the criteria of obese (BMI $> 30 \text{ kg/m}^2$).

A total of 47 (36.4%) patients complained of heartburn, regurgitation was found in 70 (54.3%) patients, whereas 12 (9.3%) patients had both heartburn as well as regurgitation. FSSG score that was conducted on 129 patients, revealed the mean of total score of 17.6 ± 6.9 with the lowest score was 5 (found in 2 patients), and the highest score was 47 (found in one patient). When used the cut off 8 as proposed by Kusano et al, then from 129 of dyspepsia patients who complained heartburn and or regurgitation, obtained 121 (93.8%) met criteria for GERD with cut off 8 (figure 1). The rest is only 8 (6.2%) who do not qualify for GERD FSSG score.

Table 1. Patients characteristic

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Characteristic	Mean ± SD	n (%)
Sex		_
Male		51 (39.5)
Female		78 (60.5)
Age (years old)	39.6 ± 15.5	
< 40		72 (55.8)
40-60		50 (38.8)
> 60		7 (5.4)
Body mass index (kg/m²)		
Underweight (< 18.5)		27 (21)
Normal weight (18.5-24.9)		86 (66.6)
Overweight (25-30)		16 (12.4)
Chief complaint		
Heartburn		47 (36.4)
Regurgitation		70 (54.3)
Heartburn + regurgitation		12 (9.3)
FSSG score	17.6 ± 6.9	
Reflux score	7.4 ± 4.6	
Dyspeptic score	10.1 ± 4	

SD: standard deviation

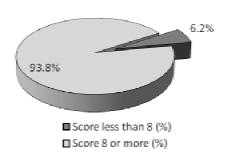


Figure 1. Proportion of GERD according FSSG score in 129 patients

From the total score of 17.6 ± 6.9 , a mean reflux score is 7.4 ± 4.6 with range of lowest value 0 and the highest 21 was obtained. The mean of dyspeptic/dysmotility score was 10.1 ± 4 with a range second lowest and the highest 20. Mean score of reflux (7.4) represents 26.5% of the total score of reflux (total score 28), while the mean of dyspeptic/dysmotility score was (10.1 ± 4) is 50.6% of the total score of dyspeptic/dysmotility (total score 20). Thus from 129 patients studied, the symptoms of dyspeptic/dysmotility more dominant than symptoms of reflux.

DISCUSSION

Most of the patients studied in present study were female (60.5%). Some authors in Western countries reported that gender differences did not influence the incidence of GERD. However, this study found that female patients with GERD are dominant compare to male (60.5%, with a ratio of 1:1.5). Mantynen et al, examined 3,378 patients with GERD, and got the ratio of male: female was 1:1.3. In Japan, Miyamoto studied 163 patients with GERD, 99 (60.7%) were female. According to Miyamoto, female gender is a factor associated with failure of PPI mono therapy. Thus, from the point of gender this study showed that probability of failure of PPI mono therapy is higher. Gender predominance of female in this study was also more in line with Asian populations. 6

BMI of most patients (66.6%) were normal, overweight (BMI 25-30 kg/m²) was found in only 12.4 patients, 21% met the criteria of underweight $(BMI < 18.5 \text{ kg/m}^2)$, and there is no patients who meets the criteria of obese (BMI $> 30 \text{ kg/m}^2$). These findings were not in accordance with the literature that states obesity is a major risk GERD. 1,4,12 Malekzadeh et al reported some significant risk factors for the occurrence of GERD, such as obesity, high fat diet, too much eating, spicy food, smoking, tight clothing, emotional stress, regular fast food, tea and coffee, pregnancy, drugs, and habit of laying down immediately after eating. Among all of these factors, it is considered that obesity and high fat diet play an important role in GERD.⁴ This lack of conformity which may be obtained because the study sample was small, or also because of confounding factors in this study such as age, smoking, alcohol, educational level, and the use of NSAIDs, were not controlled.

The main clinical GERD complaint is heartburn and regurgitation.^{3,4} In this study, 47 (36.4%) patients had heartburn and 70 (54.3%) patients had a regurgitation complaint, whereas 12 (9.3%) patients had both heartburn as well as regurgitation. In the FSSG, heartburn and regurgitation were classified into the reflux score (corresponding to the questions number 1, 4 and 6). From 129 patients, this study has proved more dominant regurgitation from heartburn complaints (54.3% vs. 36.4%). In this study, if complaints related to reflux compared with those related to dysmotility, dysmotility symptoms was proved to be more dominant than acid reflux $(7.4 \pm 4.6 \text{ vs. } 10.1 \pm 4)$.

When used FSSG score as a screening, by using the cut off number of 8,9,10 it turns out from 129 patients were diagnosed based on a complaint heartburn and regurgitation, as many as 94% did meet a score of GERD according to the FSSG. The mean FSSG score in this study was quite high, that was

 17.6 ± 6.9 . According to the study of Miyamoto et al, this high score became a factor associated with failure of PPI monotherapy. In his study, Miyamoto et al found that a group that failed with PPI monotherapy had a mean FSSG score of 17.4, and then that group was given a combination therapy of PPI with prokinetic.⁸ Miyamoto proposed that pretreatment FSSG scores can be used to predict the need for the addition of a prokinetic agent to PPI therapy prior to treatment.⁸ Japanese physicians usually add prokinetic agent to the standard dose of a PPIs instead of doubling the dose of the PPI for cases refractory to PPI monotherapy.

PPIs are unstable at a low pH dysmotility will slow down gastric emptying, resulting in retention of PPIs. Retention of PPIs inside the stomach for a long time may result in an impaired acid suppressive effect, so rapid transit of the PPIs to the upper intestine will be of benefit. Based on this, then combination of PPIs with prokinetic will improve the effect of PPIs.⁸

CONCLUSION

GERD patients in Koja hospital have a high mean FSSG score, whereas dysmotility symptoms were proved to be more dominant than acid reflux.

SUGGESTION

Based on the findings in this study, combination therapy is recommended. In this group, the use of prokinetic combination therapy with PPI is considered more effective than PPI therapy alone. Further study is needed to assess the FSSG score improvement in patients receiving combination therapy PPIs with prokinetic compared to PPIs monotherapy alone.

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