

The Value of a Structured Questionnaire in Diagnosis of Gastroesophageal Reflux Disease in Thai Patients with Dyspepsia

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ABSTRACT

Background: There is no gold standard test for diagnosis of gastroesophageal reflux disease (GERD), imprecise definitions and overlapping of symptoms between GERD and dyspepsia leading to the skepticism of the true value of symptom based diagnosis. In previous study by R. Carlsson using structural questionnaire for the diagnosis of GERD showed the sensitivity of 92% but a specificity of 19%. There is no data regarding the value of structural questionnaire in the diagnosis of GERD in Thai patients. The aim of this study is to determine usefulness of Carlsson-Dent questionnaire in diagnosis of GERD in Thai patients compared with endoscopy or 24 hr pH monitoring as gold standard.

Methods: One hundred patients with dyspepsia by Rome II criteria and patients with heartburn and/or regurgitation were recruited from May 2007 to January 2008. All patients completed Carlsson-Dent questionnaire and underwent endoscopic examination of upper gastrointestinal tract. Those with negative endoscopic examination and questionnaire score equal to or more than four have 24 hr pH monitoring performed.

Result: There were 11 patients with significant abnormal endoscopic examination, 3 (3%) LA class B esophagitis, 6 (6%) LA class A esophagitis, 1 (1%) gastric ulcer, and 1 (1%) duodenal ulcer. There were 21 with insignificant endoscopic findings and 68 patients (68%) with normal finding. There were 41 with negative endoscopy and score equal to or more than four underwent 24 hr pH monitoring. When endoscopic esophageal mucosal breaks and 24 hr pH monitoring was used as criteria for diagnosis of GERD, the Carlsson-Dent questionnaire positive was confirmed in 11 of 44 (25%). The sensitivity of the questionnaire for GERD diagnosis in the group with abnormal endoscopic findings was 33% (3/9).

Conclusion: Carlsson-Dent questionnaire had a low sensitivity in picking up GERD. It over diagnosed GERD if the score of 4 or greater was used as positive test compared to endoscopic esophagitis or abnormal acid reflux as assessed by 24 hr pH monitoring.

Key words : gastroesophageal reflux disease, GERD, dyspepsia, Thailand

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INTRODUCTION

Gastroesophageal reflux disease is a common problem in primary and secondary care setting. In the western countries, depending on definition, the prevalence of reflux symptoms ranges from 10-29%⁽¹⁾. In Thailand, the reported prevalence of esophagitis detected by endoscopy is about 5% and the prevalence based on questionnaire survey of the motility club is 7.5%. There is no gold standard for the diagnosis of GERD. Symptom based diagnosis using typical reflux symptoms such as heartburn and acid regurgitation has a high positive predictive value for diagnosis of GERD, but its sensitivity is low⁽²⁾. Empirical acid suppression with a proton-pump inhibitor (PPI) has a reasonably sensitivity but a poor specificity⁽³⁻⁶⁾. The identification of esophagitis with upper gastrointestinal endoscopy is highly specific (90-95%)⁽⁷⁾ but has a sensitivity of only around 50%⁽⁸⁾.

Ambulatory esophageal pH monitoring provides strong supportive evidence when abnormally high level of esophageal acid reflux is present, but a normal pH dose not exclude the diagnosis.^(9,10) Furthermore this investigation is expensive, invasive, technically demanding and not readily available.

Heartburn and acid regurgitation are the most common symptoms of gastroesophageal reflux disease. Heartburn has been shown to correlate with abnormal esophageal acid exposure when dominant⁽¹¹⁾ and is specific for gastroesophageal reflux disease. However, due to imprecise definitions of these symptoms and some patients with GERD have overlapping epigastric pain with the symptoms of dyspepsia, so diagnosis based on symptom will not recognize some patients.

Some structural questionnaires were developed to standardize the symptom based diagnosis of GERD. The studies evaluating the validity of these types of questionnaires have conflicting results^(12,13). Dent and colleagues developed a reflux-specific questionnaire (Carlsson-Dent questionnaire) with a sensitivity of 92% and a specificity of 19% in diagnosis of GERD compared with endoscopic esophagitis and 24 hour pH monitoring as standard.

In Thailand, there is no specific term for heartburn, patients' term for heartburn in Thai implying different symptoms and interpretation of the term by the physicians varies enormously among the clinicians. Using structural questionnaire may help to minimize this problem in symptom based diagnosis of GERD. The aim of this study is to assess the usefulness of the

Carlsson-Dent questionnaire in diagnosis of GERD in Thai patient with dyspepsia.

MATERIALS AND METHODS

Patients with dyspepsia as defined by Rome II criteria and patients with heartburn and regurgitation with age more than 18 years were recruited from May 2007 to January 2008 at Songkhlanakarin Hospital. Exclusion criteria include the presence of any alarming symptoms (unintentional weight loss, vomiting, dysphagia, hematemesis, melena, fever, jaundice or other symptoms or signs suggesting serious or malignant disease), a previous history of documented peptic ulcer disease by endoscopy or radiology, a past history of gastroesophageal reflux disease documented by endoscopy or 24 hr esophageal pH monitoring, clinical diagnosis of irritable bowel syndrome, hepatobiliary tract disease, the presence of significant medical disease that would complicate the evaluation of outcome (eg. Unstable diabetes mellitus or malignancy), pregnancy or lactation, treatment with steroid, NSAIDs usage within 1 month or continuous usage prior to endoscopy, and patients unwilling to participate in the study.

The Carlsson-Dent questionnaire, a self-administered questionnaire, with seven items was translated to Thai version and back translation from Thai to English to ensure validity.

1. Which one of these four statements BEST DESCRIBES the main discomfort you get in your stomach or chest?

- (5) A burning feeling rising from your stomach or lower chest up toward your neck
- (0) Feelings of sickness or nausea
- (2) Pain in the middle of your chest when you swallow
- (0) None of the above, please describe below:

2. Having chosen one of the above, please now choose which one of the next three statements BEST DESCRIBES the timing of your main discomfort?

- (-2) Any time, not made better or worse by taking food
- (3) Most often within 2 hours of taking food
- (0) Always at a particular time of day or night without any relationship to food

3. 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"/>

4. Which one of the following BEST DESCRIBES the effect of indigestion medicines on your main discomfort?

- (0) No benefit
- (3) Definite relief within 15 minutes
- (0) Definite relief after 15 minutes
- (0) Not applicable (I don't take indigestion medicines)

5. Which of the following BEST DESCRIBES the effect of lying flat, stooping, or bending on your main discomfort?

- (0) No effect
- (1) Brings it on or makes it worse
- (-1) Gives relief
- (0) Don't know

6. 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?

- (0) No effect
- (1) Brings it on or makes it worse
- (-1) Gives relief
- (0) Don't know or this does not apply to me

7. If food or acid-tasting liquid returns to your throat or mouth what effect does it have on your main discomfort?

- (0) No effect
- (2) Brings it on or makes it worse
- (0) Gives relief
- (0) Don't know or this does not apply to me

Carlsson-Dent questionnaire

The study flow is shown in algorithm depicted in Figure 1. Eligible patients were asked to complete self-administered Carlsson-Dent questionnaire and baseline characteristic (age, gender, BW, height, smoking history, drinking history, predominate symptom, and period of symptom) before endoscopy. The en-

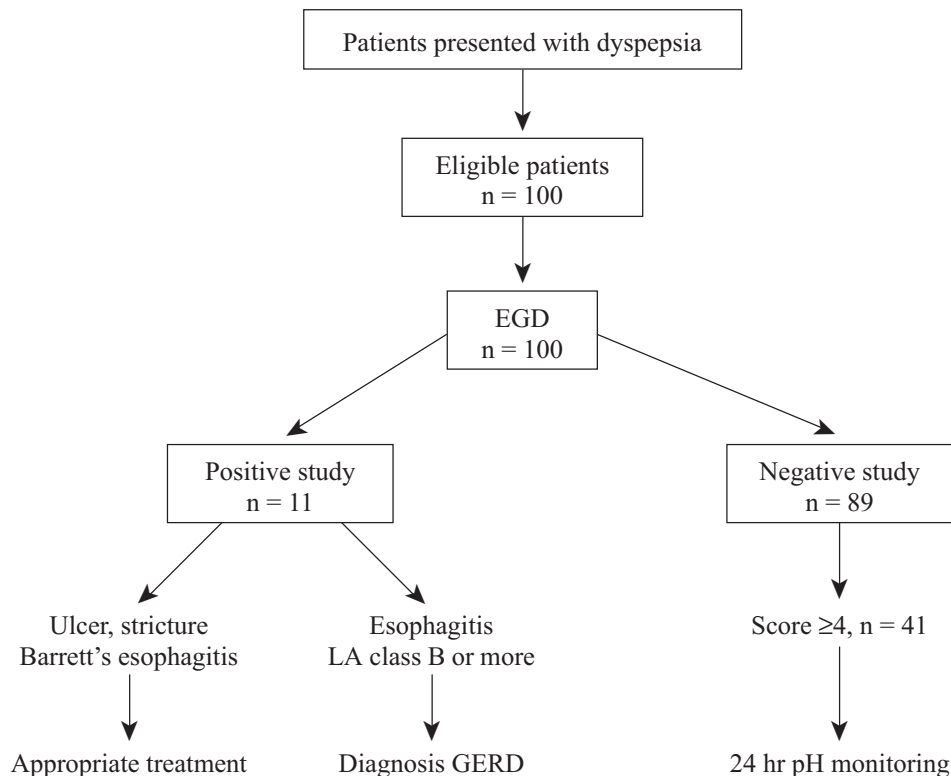


Figure 1. Flow diagram study design

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Endoscopic diagnosis of esophagitis is based on grading in accordance with the Los Angeles Classification. Endoscopic diagnosis of esophagitis was defined as LA class B or more. Hiatal hernia was defined as the length from esophagogastric mucosal junction (Z line) to the crus of diaphragm is 3 cm or more. Peptic ulcers were defined as mucosal breaks in the stomach and/or duodenum >0.5 cm in diameter. Clinically significant findings were defined as the presence of esophagitis, peptic ulcer, esophageal and gastric cancer. Only patients with the score of 4 or more and endoscopy with normal finding or non significant finding proceed to have 24 hr pH monitoring performed in standard manner. Acidic or sour drinks and alcohol were not allowed during the monitoring period. A positive diagnosis of GERD was defined by distal esophageal pH below 4 for more than 4% of 24 hr period.

Statistical analysis

Baseline descriptive data were expressed as means and standard deviation for continuous variables and as percentages and frequencies for categorical variables. Sensitivity was defined as proportion of patients with positive diagnosis of GERD who had score equal 4 or more, as endoscopic results as a gold standard.

RESULTS

There were 100 patients (68 female and 32 male) with the mean age of 45.6 ± 12.4 years with a range of 25-78 years enrolled in the study. The predominant symptoms were heartburn in 37 patients (37%), upper abdominal pain in 25 (25%), nausea/vomiting 9 (9%) and acid regurgitation in 4 (4%). The endoscopic examinations were normal in 68 patients (68%). There were 11 with significant lesions, 9 with erosive esophagitis with Los Angeles grade A in 6 and grade B in 3, 1 with gastric ulcer, and 1 with duodenal ulcer. There were 21 patients with insignificant lesions, 12 with gastritis, 4 with duodenitis, 4 with hiatus hernia and 1 with gastric polyp. None of the patients had Barrett's esophagitis or cancer. (Table 1)

All patients had completed self-administered Carlsson-Dent questionnaire. There were 44 cases with positive score of more than 4, 3 of which the esophagitis was confirmed by endoscopy, of the remaining 41 patients (41%) with negative endoscopic examination 24 hr pH monitoring were performed and 8 patients had positive 24 hr pH monitoring test. Overall,

Table 1. The predominant symptoms, duration of symptoms and endoscopic findings.

Predominate symptom (n, %)	
Heartburn	37 (37%)
Regurgitation	4 (4%)
Upper abdominal pain	25 (25%)
Nausea/vomiting	9 (9%)
Other symptom	25 (25%)
Duration of symptoms prior to presentation (n, %)	
<1 month	8 (8%)
1 month to 1 year	50 (50%)
>1 year	42 (42%)
Endoscopic finding (n, %)	
Reflux esophagitis	
Grade A	6 (6%)
Grade B	3 (3%)
Grade C	0 (0%)
Grade D	0 (0%)
Duodenal ulcer	1 (1%)
Gastric ulcer	1 (1%)
Gastritis	12 (12%)
Duodenitis	4 (4%)
Gastric polyp	1 (1%)
Normal findings	68 (68%)

the diagnosis of GERD as picked up by Carlsson-Dent questionnaire was confirmed in 11 of 44 (25%) using endoscopy and pH monitoring.

In 11 patients with significant endoscopic lesions, the diagnosis of GERD was quite certain since the organic causes of the symptoms were identified. Eventhough, the esophagitis by LA grade A may have some inter-observer variation, by including these patients into the GERD group, the Carlsson-Dent questionnaire can identify 3 of 9 cases with GERD so the sensitivity of the test was 33%.

DISCUSSION

The endoscopic diagnosis of these 100 Thai patients presenting with dyspepsia was different from other reports in Thailand (personal communication) with the prevalence of esophagitis of 5% and peptic ulcer of 10-20% with 2% cancer of stomach (unpublished data from the stomach research club). The prevalence of esophagitis of 9% (6 in LA class A, 3 in LA class B) in our study is almost double the reported prevalence above, while the prevalence of peptic ulcer

was as low as 2% which was almost ten times lower than previous data. The differences in result are likely to be due to a combination of factors. First, the patient selection may play a major role in this study which was conducted in tertiary care center, secondly the number of patients recruited in this study was small and thirdly the wide spread practice of *Helicobacter pylori* eradication in our community leading to the declining prevalence of peptic ulcer in our population.

This is the first study in Thailand on the usage of structural questionnaire to help identifying GERD. When the Carlsson-Dent diagnostic score more than or equally 4 for diagnosis of GERD is used, only 11 out of 44 patients with positive results were confirmed by endoscopy or 24 hr pH monitoring. When the group of patients with significant endoscopic lesions were analysed due to rather firm diagnosis was achieved, the sensitivity of the questionnaire was 33%. These data were much different from previous study by R. Carlsson. J. Dent M 1998 reported the sensitivity of test questionnaire in identifying patients with esophagitis was 70%, using a cut off score of 4 or higher for a positive test⁽¹²⁾. The difference result are likely due to a small number of the subjects and low prevalence of GERD in Thai patient. However, there is one study by Numans *et al.* reported in 2003 showed the poor diagnostic performance of this version of the Carlsson-Dent questionnaire.⁽¹³⁾

There were 33 patients with positive score from the questionnaire where 24 hr pH monitoring did not show reflux. Based on endoscopy and pH monitoring as a standard, the questionnaire reported over diagnosed of GERD in our population. This is implying that even with structural questionnaire is not good enough to make the diagnosis of GERD and in clinical practice without standardize questionnaire the clinical diagnosis of GERD may be more over diagnosed.

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