

RAPID COMMUNICATION

Evaluation of the use of rapid urease test: Pronto Dry to detect *H pylori* in patients with dyspepsia in several cities in Indonesia

AF Syam, M Abdullah, AA Rani, S Nurdjanah, P Adi, A Djumhana, P Tarigan, IDN Wibawa

AF Syam, M Abdullah, AA Rani, Division of Gastroenterology, Department of Internal Medicine, Dr. Cipto Mangunkusumo Hospital, Faculty of Medicine, University of Indonesia, Jakarta 10430, Indonesia

S Nurdjanah, Division of Gastroentero-Hepatology, Department of Internal Medicine, Dr. Sardjito Hospital, Faculty of Medicine, Gajah Mada University, Yogyakarta, Indonesia

P Adi, Division of Gastroenterology, Department of Internal Medicine, Dr. Sutomo Hospital, Faculty of Medicine, Airlangga University, Surabaya, Indonesia

A Djumhana, Division of Gastroentero-Hepatology, Department of Internal Medicine, Dr. Hasan Sadikin Hospital, Faculty of Medicine, Padjajaran University, Bandung, Indonesia

P Tarigan, Division of Gastroentero-Hepatology, Department of Internal Medicine, H. Adam Malik Hospital, Faculty of Medicine, Sumatera Utara University, Medan, Indonesia

IDN Wibawa, Department of Internal Medicine, Sanglah Hospital, Faculty of Medicine, Udayana University, Denpasar, Indonesia

Correspondence to: Dr. Ari Fahrial Syam, Division of Gastroenterology, Department of Internal Medicine, Dr. Cipto Mangunkusumo Hospital, Faculty of Medicine, University of Indonesia, Jakarta 10430, Indonesia. ari_syam@hotmail.com

Telephone: +62-21-3153957 Fax: +62-21-3142454

Received: 2006-04-28 Accepted: 2006-06-14

Abstract

AIM: To evaluate Pronto Dry examination in patients with dyspepsia.

METHODS: The study was conducted in patients with dyspepsia who underwent endoscopic examination in several endoscopic centers of several cities in Indonesia from January 2003 until April 2004. Biopsies for histopathologic examination were fixed with formalin and sent to Histopathologic Department to be analyzed and confirm the presence of *H pylori* infection. If *H pylori* was found positive, the density was calculated semi quantitatively. Histopathologic examination from gastric biopsy samples was interpreted based on the updated Sydney system classification.

RESULTS: Of 550 patients, 309 (56%) were male and 241 (44%) were female with ages ranging from 15 to 82 years. Mean age was 44.98 ± 14.46 years. Mean age of male patients was 44.35 ± 13.85 years and mean age of female patients was 45.78 ± 15.19 years. Evaluation of endoscopic results showed gastric ulcer in 36 cases (6.5%) and duodenal ulcer in 20 cases (3.6%). Normal endoscopic finding was found in 45 cases (8.2%) and

minimal disorder of gastritis and duodenitis were found in 246 cases (44.7%). One case of gastric cancer was identified. Of 56 cases which were positive based on the criteria used, 39 patients were positive with Pronto Dry and 17 patients were negative with Pronto Dry. Overall sensitivity and specificity of Pronto Dry were 69.7% and 95.7% respectively. Positive predictive value was 66.1% and negative predictive value was 96.4% and overall accurate rate was 92.9%.

CONCLUSION: Pronto Dry seems promising as a diagnostic tool to detect *H pylori* more rapidly and accurately.

© 2006 The WJG Press. All rights reserved.

Key words: Rapid urease test; Pronto Dry; *H pylori*; Dyspepsia

Syam AF, Abdullah M, Rani AA, Nurdjanah S, Adi P, Djumhana A, Tarigan P, Wibawa IDN. Evaluation of the use of rapid urease test: Pronto Dry to detect *H pylori* in patients with dyspepsia in several cities in Indonesia. *World J Gastroenterol* 2006; 12(38): 6216-6218

<http://www.wjgnet.com/1007-9327/12/6216.asp>

INTRODUCTION

H pylori is a microaerophilic, gram negative, slowly growing, and pathogenic bacterium which produces urease enzyme^[1]. *H pylori* may cause chronic gastritis and predispose to gastric and duodenal ulcer. Recently, *H pylori* has been classified as gastric carcinogen class 1^[2,3].

Diagnosis of *H pylori* may be made by invasive or non invasive methods. During the invasive method patients would undergo endoscopic examination and gastric tissue biopsy. Samples and biopsies are examined to detect the presence of *H pylori* by histopathologic examination, rapid urease test or culture^[4,5]. Culture examination is the gold standard test. Culture examination is not simple because transport media and biopsy samples for observation of the growth of the bacteria need special preparation procedures.

Non invasive methods include the rapid urease test, serologic and *H pylori* examination of the feces (*H pylori* stool antigen)^[6]. Rapid urease test is frequently done in

endoscopic centers in patients with dyspepsia to detect the presence of *H pylori*. This method is rapid and easy to perform in the endoscopic room. Currently, there are various kinds of rapid urease test in the market such as CLO, MIU or Pyloric test and a recent one called Pronto Dry. The advantage of this method is that it is not necessary to keep the sample in the refrigerator, a rapid result may be obtained only in 1 h, and it is easy to read the color changes. Previous studies have shown this test has good sensitivity and specificity^[7,8].

The aim of the present study was to evaluate Pronto Dry examination in patients with dyspepsia in several endoscopic centers in Indonesia including Jakarta, Bandung, Surabaya, Denpasar, Yogyakarta and Medan.

MATERIALS AND METHODS

Research subjects

The study was conducted in patients with dyspepsia who underwent endoscopic examination in the endoscopic centers of several cities in Indonesia which were as follows: RSCM Jakarta, RS Hasan Sadikin Bandung, RS Sardjito Yogyakarta, RS Soetomo Surabaya, RS Adam Malik Medan, and RS Sanglah Denpasar. The study period was from Jan 2003 until Apr 2004.

Inclusion criteria were patients who had been diagnosed dyspepsia and would undergo upper gastrointestinal endoscopic examination, with age more than 15 years old. Patients were not taking antibiotics, H₂ receptor antagonists or proton pump inhibitors during 7 d prior to the examination.

Patients who had fulfilled inclusion criteria had endoscopic examination and biopsy samples were taken two in the antrum and two more in the corpus. Pronto Dry (Medical Instruments Corporation, Solothurn, Switzerland) was performed according to standard procedure and interpretation was read in 1 h after examination.

Biopsies for histopathologic examination were fixed with formalin and sent to Histopathologic Department to be analyzed and confirm the presence of *H pylori* infection. If *H pylori* was found positive, its density would be read semi quantitatively. Histopathologic examination of gastric biopsy samples was interpreted based on the Updated Sydney system classification.

Statistical analysis

The values are expressed as mean \pm SD. Statistical calculation to test sensitivity, specificity, positive predictive value, negative predictive value, and the accuracy was done using statistics software. $P < 0.05$ was taken as significant.

RESULTS

This multicentre study was conducted in 6 endoscopic centers. Each unit collected various numbers of cases and most were obtained from endoscopic room in RSCM, Jakarta. The number of patients included in the study was 550 consisting of 320 (58.2%) patients from RSCM Jakarta, 40 (7.3%) patients from RS Adam Malik Medan, 60 (10.9%) patients from RS Sutomo Surabaya, 37 (6.7%) patients from RS Sardjito Yogyakarta, 43 (7.8%) patients

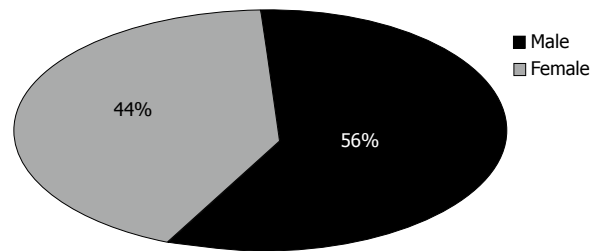


Figure 1 Distribution of patients based on gender.

Tabel 1 Results of upper gastrointestinal endoscopy of patients with dyspepsia

Endoscopic diagnosis	n	%
Normal	45	8.2
Gastritis and or duodenitis	246	44.7
Gastric ulcer	36	6.5
Duodenal ulcer	20	3.6
Mild erosive gastritis	83	15.1
Esophagitis	85	15.5
Gastric cancer	1	0.2
Mild erosive gastritis/Esohagitis	2	0.4
Severe erosive gastritis	16	2.9
Gr. B Esophagitis/Mmoderate gastritis	6	1.1
Barrett's esophagus	2	0.4
Esophagitis, gastric ulcer	1	0.2
Esophagitis, pangastritis, duodenal ulcer	1	0.2

from RS Sanglah Denpasar Bali and 50 (9.1%) patients from RS Hasan Sadikin Bandung.

Of 550 patients included in this study, 309 patients (56%) were male and 241 patients (44%) were female (Figure 1) with age ranging from 15 years to 82 years. Mean age was 44.98 ± 14.46 years. Mean age of male patients was 44.35 ± 13.85 years and of female patients was 45.78 ± 15.19 years.

Evaluation of endoscopic results showed gastric ulcer was found in 36 cases (6.5%) and duodenal ulcer in 20 cases (3.6%). Normal endoscopic finding was found in 45 cases (8.2%) and minimal disorders of gastritis and duodenitis were found in 246 cases (44.7%). In addition, one case of gastric cancer was identified (Table 1).

Diagnosis of *H pylori* infection

Based on definition determined at the beginning of the study, *H pylori* infection was considered positive if histopathologic examination showed the presence of *H pylori*. Of 550 cases studied, *H pylori* was found positive in 56 (10.2%). The highest prevalence of *H pylori* was found in patients from Yogyakarta (30.6%) and the lowest was in patients from Jakarta (8%).

Of 550 patients, 25 did not have histopathologic examinations. Furthermore, analysis on sensitivity and specificity was done with only 525 patients because they had complete examination with both histopathology and Pronto Dry. Of 56 cases which were positive based on the criteria used, 39 were positive with Pronto Dry and 17 were negative with Pronto Dry. Overall sensitivity and specificity of Pronto Dry were 69.7% and 95.7%, respectively. Positive predictive value was 66.1% and

negative predictive value was 96.4% and overall accurate rate was 92.9%. If we calculated the sensitivity and specificity of each endoscopic center, results were varied (Table 2).

DISCUSSION

To date, the rapid urease test is still needed to detect the presence of *H pylori*. This test is relatively easy and rapid and thus appropriate therapy is possible if diagnosis of *H pylori* is confirmed. In addition, upper gastrointestinal endoscopic examination is still a reliable procedure to investigate the cause of dyspepsia.

Our result indicated that endoscopic examination of patients with uninvestigated dyspepsia showed various underlying disorders. Almost 45% of endoscopic results showed organic disorders such as esophagitis, peptic ulcer and erosive gastritis. In addition, 1 of 550 cases in this study was found to be gastric carcinoma. This result indicated that endoscopy is very important in evaluating upper gastrointestinal disorder in patients with dyspepsia. Rapid urease test has become indispensable in patients having the indication for endoscopic procedure.

Of all patients with dyspepsia who had undergone endoscopic examination, *H pylori* infection was positive in only 10.2% of cases. This figure was lower than the result of multicentered study in Europe published in 1999. In that study involving 501 patients with dyspepsia, 55.7% were found to have positive result of *H pylori*. Another study conducted in Jakarta found that 9.5% patients with dyspepsia were positive for *H pylori* infection by endoscopic examination^[9].

The sensitivity, specificity, positive and negative predictive values, and overall accurate level were 69.6%, 95.7%, 66.1%, 96.4%, and 92.9%, respectively. A study conducted by Said *et al* in Malaysia to evaluate Pronto Dry found better sensitivity (98.1%) and specificity (100%)^[8]. However, if we compared the result of studies in Jakarta and Bandung, similar results to the study in Malaysia were obtained. The study in Jakarta found a sensitivity of 95.7% and specificity of 98.3%, while the study in Bandung found both sensitivity and specificity of 100%. The difference of the results might be due to different histopathologic evaluation criteria adopted by different centers. This, however, could be overcome by standardization of appropriate biopsy location, standardised type of biopsy instrument and samples size and results read by same pathologists.

Rapid urease test using Pronto Dry which is relatively new is found to have good specificity although the sensitivity is lower than specificity. Studies in several cities

Table 2 Sensitivity, specificity, positive predictive value and negative predictive value by Pronto Dry examination at each endoscopic centre

Endoscopic centre	Sensitivity (%)	Specificity (%)	Negative predictive value (%)	Positive predictive value (%)	Accurate level (%)
Jakarta	95.7	98.3	99.7	81.5	98.2
Bandung	100.0	100.0	100.0	100.0	100.0
Medan	100.0	59.4	100.0	38.1	67.5
Surabaya	33.3	98.1	93.0	66.7	91.6
Yogyakarta	10.0	100.0	75.0	100	75.7
Bali	25.0	94.1	84.2	50.0	81.0

have shown that Pronto Dry has very good sensitivity and specificity level above 95%. If we compare with the other rapid urease test, Pronto Dry can give result in only 1 h. This test seems very promising as a diagnostic tool to detect *H pylori* more rapidly and accurately.

REFERENCES

- 1 **Weeks DL**, Scott DR, Volland P, Marcus EA, Athman C, Melchers K, Sachs G. The urease system of *Helicobacter pylori*. In: Hunt RH, Tytgat GNJ, eds. *Helicobacter pylori* basic mechanisms to clinical cure 2000. Dordrecht-Boston, London: Kluwer Academic Publishers, 2000: 15-24
- 2 **Lee A**. *Helicobacter pylori* is pathogenic flora. In: Hunt RH, Tytgat GNJ, eds. *Helicobacter pylori* basic mechanisms to clinical cure 2000. Dordrecht-Boston, London: Kluwer Academic Publishers, 2000: 31-35
- 3 **Blaser MJ**. The amphibolic relationship of *Helicobacter pylori* and humans. In: Hunt RH, Tytgat GNJ, eds. *Helicobacter pylori* basic mechanisms to clinical cure 2000. Dordrecht-Boston, London: Kluwer Academic Publishers, 2000: 25-30
- 4 **Goodwin CS**, Mendall MM, Northfield TC. *Helicobacter pylori* infection. *Lancet* 1997; **349**: 265-269
- 5 **Suerbaum S**, Michetti P. *Helicobacter pylori* infection. *N Engl J Med* 2002; **347**: 1175-1186
- 6 **Vaira D**, Malfertheiner P, Mégraud F, Axon AT, Deltenre M, Hirschl AM, Gasbarrini G, O'Morain C, Garcia JM, Quina M, Tytgat GN. Diagnosis of *Helicobacter pylori* infection with a new non-invasive antigen-based assay. HpSA European study group. *Lancet* 1999; **354**: 30-33
- 7 **Morio O**, Rioux-Leclercq N, Pagenault M, Corbinais S, Ramee MP, Gosselin M, Bretagne JF. Prospective evaluation of a new rapid urease test (Pronto Dry) for the diagnosis of *Helicobacter pylori* infection. *Gastroenterol Clin Biol* 2004; **28**: 569-573
- 8 **Said RM**, Cheah PL, Chin SC, Goh KL. Evaluation of a new biopsy urease test: Pronto Dry, for the diagnosis of *Helicobacter pylori* infection. *Eur J Gastroenterol Hepatol* 2004; **16**: 195-199
- 9 **Syam AF**, Rani AA, Abdullah M, Manan C, Makmun D, Simadibrata M, Djojoningrat D, Sato T. Accuracy of *Helicobacter pylori* stool antigen for the detection of *Helicobacter pylori* infection in dyspeptic patients. *World J Gastroenterol* 2005; **11**: 386-388

S- Editor Pan BR L- Editor Zhu LH E- Editor Bi L