

Validation and Comparison of A New Biopsy Urease Test: Pronto Dry Vs the Clo Test in The Diagnosis of Helicobacter Pylori Infection

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Background

The gastric biopsy urease test is the mainstay of diagnosis of *Helicobacter pylori* (*H. pylori*) infection in routine GI endoscopy practice. In Malaysia up to recently, only one commercial biopsy urease test is available: the CLO test. Some large endoscopy units use their own "homemade" unbuffered rapid urease test for this purpose which has been shown to be highly accurate.

Objective

To compare the accuracy and reaction time of a new biopsy urease test, Pronto Dry (Medical Instruments Corporation, Solothurn, Switzerland) and the CLO test (Ballard Medical Products, Utah, U.S.A.) in the diagnosis of *H. pylori* infection.

Methods

Consecutive patients from August 2001 to January 2002 presenting with dyspepsia to the endoscopy unit, University of Malaya Medical Centre were recruited for the study. Patients who were previously treated for *H. pylori* infection or who had received antibiotics, PPIs or bismuth compounds in the preceding 2 weeks were excluded. *H. pylori* diagnosis was made based on the rapid urease test and histological examination of gastric biopsies. Four antral and four corpus biopsies were taken from all patients. A diagnosis of *H. pylori* infection was made when both rapid urease test and histology were positive in either the antral or corpus biopsies. A negative diagnosis of *H. pylori* was made when both tests from both antral and corpus biopsies were all negative. Another two antral and two corpus biopsies were taken for the Pronto Dry and CLO tests. All tests were carried out and read by an investigator who was blinded to the endoscopic diagnosis and the *H. pylori* status of the patients.

Results

Two hundred and eight patients were recruited in the study. 86 of the patients were males and 122 patients were females. The mean age was 46.3 years, range 15-82 years. Although the specificity and positive predictive values were similar for Pronto and CLO test but Pronto test has higher sensitivity and negative predictive values than CLO test (table 1). All the patients had the positive reaction time within 60 minutes with the Pronto test (range: 1-54 min)(table 2). On the other hand, 17 patients had positive reaction time more than 60 minutes with the CLO test (range: 61-345 min).

Table 1 (at 60 min.):

	Pronto		CLO	
	Results	95% CI	Results	95% CI
Sensitivity	104/106 (98.1%)	93.4, 99.8	87/106 (82.1%)	74.8, 89.4
Specificity	102/102 (100%)	96.4, 1.0	102/102 (100%)	96.4, 1.0
PPV <i>Positive Predictive</i>	104/104 (100%)	96.5, 1.0	87/87 (100%)	95.8, 1.0
NPV <i>Value</i>	102/104 (98.1%)	93.2, 99.8	102/121 (84.3%)	77.8, 90.8
Diagnostic accuracy	206/208 (99.0%)	96.6, 99.9	189/208 (90.9%)	86.1, 94.4

Table 2:

t (min)	Pronto n=106 n (%)	CLO n=106 n (%)
5	33 (31.1)	17 (16.0)
10	69 (65.1)	26 (24.5)
15	81 (76.4)	41 (38.7)
20	87 (82.1)	60 (56.6)
25	94 (88.7)	70 (66.0)
30	102 (96.2)	75 (70.8)
35	103 (97.2)	76 (71.7)
40	104 (98.1)	82 (77.3)
45	104 (98.1)	86 (81.1)
50	105 (99.1)	86 (81.1)
55	106 (100)	88 (83.0)
60	106 (100)	89 (84.0)
>60	106 (100)	106 (100)

Conclusions

The Pronto Dry test was more accurate than the CLO tests for the diagnosis of *H. pylori* infection. The positive reaction time was much quicker with the Pronto Dry compared to the CLO test. Furthermore, colorimetric changes were more obvious with the Pronto Dry test.