

Diagnosis of *Helicobacter Pylori* infection correlation between clotest (Urease enzyme) and gastric mucosal histology

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Summary

Background: There are few histopathologists in West African region. Histology results on gastric mucosal biopsies for *Helicobacter pylori* (HP) usually take between one to two weeks to be out. On the other hand, clo-test results for *Helicobacter pylori* can be read between 5 minutes to 24 hours. Is one justified to commence therapy based on the clo-test ahead of the histology result? Where there is no histopathology services as in many centers in West Africa can one rely on clo-test alone?

Aim: To evaluate the correlation between clo-test (urease) and histological findings of gastric mucosal biopsies.

Design: Prospective study

Setting: Endoscopic unit of Obafemi Awolowo University Teaching Hospital Complex, Ile-Ife, Nigeria

Patients: Twenty duodenal ulcer (DU) patients seen consecutively in the endoscopy unit.

Intervention: Upper gastrointestinal tract endoscopy, antral biopsies for the clo-test and histopathology.

Result: There was 100% correlation between the clo-test and histological findings among all the 20 patients.

Conclusion: Clo-test (urease) is reliable enough to be used to commence therapy aimed at ulcer healing and HP eradication.

Keywords: *Helicobacter pylori*, Clo-test and Gastric mucosa biopses

Résumé

Introduction: Il y a peu d'histopathologistes dans la région de l'ouest africaine. D'habitude, il faut environ une ou deux semaines avant d'avoir les résultats de l'histologie sur les biopsies du muqueux gastrique pour l'hélicobacter pylori (HP).

D'autre part, on peut noter les résultats du clo-test pour l'hélocobacter pylori entre 5 minutes à 24 heures. Est-elle fondée à commencer la thérapie basée sur le clo-test avant le résultat de l'histologie? Là où il n'y a pas de services histopathologies comme en est le cas dans beaucoup de centre en Afrique de l'Ouest est-ce qu' on peut avoir confiance sur clo-test seulement?

But: Evaluer la corrélation entre clo-test (urée) et des résultats histologique les biopsies du Muqueux gastrique.

Plan: Étude en perspective.

Cadre: Département d'endoscopique complexe hospitalier universitaire d'Obafemi Awolowo, Ile-Ife, Nigeria.

Patients: Vingt patients atteints d'ulcère duodénal vu consécutivement au département d'endoscopie.

Intervention: L'endoscopie de voie gastrointestinale supérieure, antra-biopsies pour le clo-test et l'histopathologie.

Résultat: Il y avait 100% corrélation entre le clo-test et les résultats histologiques chez tous les 20 patients.

Conclusion: Le clo-test (urease) est assez fiable d'être utilisé pour commencer une thérapie visée à soigner l'ulcère et dans l'éradication de HP.

Introduction

The discovery of *Helicobacter pylori* (HP) associated with peptic ulcer diseases has revolutionized the diagnosis and treatment of peptic ulcer diseases.¹⁻³ Ninety percent of duodenal ulcer (DU) patients have *Helicobacter pylori* (HP) infection and the eradication of this organism is followed by rapid healing of the DU.^{1,4} Owing to this significant risk association, all patients discovered at upper Gastrointestinal Track (GIT) endoscopy to have DU, have their antral mucosal biopsies taken to look for HP. In our center, we commonly subject the specimen to urease enzyme (Clo)⁵ test or histological examination depending on which is available.

Histology facilities are not available in many health institutions in the West African subregion. Moreover the histology results only come out between 1 and 2 weeks. On the other hand, the urease enzyme (clo-test) may begin to be positive within five minutes, though the mildly positive ones may take up to 24hrs to show up.^{6,7} Despite this apparent advantage, clo-test which depends on P^H is not as absolute as histological findings. We decide to test out the reliability of clo-test against histology to see the correlation between the two of them.

Patient and method

The study was carried out at the gastro-intestinal tract endoscopy unit of the Obafemi Awolowo University Teaching Hospitals Complex (OAUTHC) Ile-Ife, Nigeria within a period of 24 months from September 1998 to September 2000.

Twenty patients were recruited into the studies. The criteria used were endoscopy diagnosis of DU plus informed oral consent to participate in the study. Any patient who was already on anti ulcer or *anti-Helicobacter pylori* treatment at the time of diagnosis was automatically excluded from the study.

Each patient underwent gastro-duodenoscopy after an overnight fast. Premedication with intravenous midazolam (2 - 5mg) as well as hyosine butyl bromide (40mg) and Topical pharyngeal anaesthetic spray with lignocain were administered. At endoscopy multiple antral mucosal biopsies were taken, one specimen was subjected to the clo-tests, while the remaining three were later sent to histology for detection of *Helicobacter pylori*. The result of the two groups were compared and level of significance analysed by chi square test and that of coefficient significant.

The biopsies were directly inoculated into semi-solid urease medium (commercially available clo-test kit from Delta West Australia), immersing each biopsy in the middle of the

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semi-solid medium with the aid of a sterile needle and sealed up. After inoculation, it was kept close to the body (e.g. in a laboratory coat breast pocket) until the result was read every 5 - 15min or 30 minutes. A positive result was shown by a pink colouration of the medium from the original yellow colour.

The study was approved by the research and ethical committee of the OAUTHC, Ile-Ife.

Results

Twenty adult patients were recruited. There were 12 males and 8 females. The ages ranged between 21 and 59 years. (42.75years mean).

All the 20 patients (100%) tested positive for urease enzyme and all the histology specimen showed *Helicobacter pylori* organism. There was thus a 100% correlation between the clo-test and histological findings (Table 1).

Severity of mucosal infection compared well with reaction to clo-test. The severity of infection was based on the density of intraepithelial neutrophils.⁸

All those with immediate positive clo result (60%) showed

Table 1 Endoscopic: Clo-test and histology fundings in the 20 DU patients

Patients			CLO (Urease Enzyme) Tests	Histology for <i>Helicobacter pylori</i>
S/N	Sex	Age (Yrs)		
1.	M	42	++	+++
2.	F	31	++	+++
3.	F	38	++	+++
4.	M	20	+	++
5.	M	47	++	+++
6.	M	50	+	+++
7.	FM	45	++	+++
8.	M	30	+	+++
9.	M	50	+	+++
10.	M	24	+	+
11.	F	58	++	+++
12.	M	26	++	+++
13.	M	30	++	+++
14.	F	40	++	+++
15.	M	44	++	+++
16.	M	55	++	++
17.	M	60	+	++
18.	F	35	+	++
19.	F	40	+	+++
20.	F	56	++	+++

N. B. For Clo-test + Indicates delayed clo-test
 ++ Indicates immediate positive clo-test
 Histology For *H. pylori* (i) + indicates mild infection
 (ii) ++ indicates moderate infection
 (iii) +++ indicates severe infection

evidence of severe infection by *Helicobacter pylori* organisms in their histological examination. Only 3 (15%) patients with delayed reaction showed evidence of severe infection. Four patients (20%) with delayed clo-test showed histological evidence of moderate infection while only one with delayed reaction also had few numbers of *Helicobacter pylori* demonstrated in the histological examination. The above picture indicates that the intensity of clo-test reaction is directly proportional to the severity of infection demonstrated

by histological finding.

Discussion

The high association of *Helicobacter pylori* infection with peculiar erosive ulcerative and malignant changes in the duodenum and/or stomach still gives much concern to the gastroenterologist.^{5,7,11} The eradication of *Helicobacter pylori* is therefore the immediate concern of most gastroenterologist worldwide.^{12, 13} Many eradication strategies and various regimens are currently been administered.^{13, 15} For a hopefully successful therapy, it is only rational that treatment be based on direct or indirect demonstration of presence of *Helicobacter pylori* in the affected organ. This will obviously require some diagnostic aids. We used clo-test and histology in our present work.

Histological examination is the only known method that can show the extent of *Helicobacter pylori* infection as well as the degree of mucosal damage.¹⁶ Urease enzyme tests on the other hand is rapid and quite specific but sensitivity can be poor in the post treatment period.⁹ Our study however has been able to demonstrate though with a small number of patients that the urease enzyme tests are comparable to histological examination, before treatment.

Although similar findings have been reported by several workers,⁷ this present work emphasizes a handy alternative to histology, particularly in the West African subregion where there is chronic paucity of histopathology facilities. The study result therefore suggests that clo-test is reliable for diagnosis of *Helicobacter pylori* infection and treatment can therefore be instituted with out much delay. Also clo-test kits are recommended for the screening and early diagnosis of *Helicobacter pylori* infection in this environment.

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