

H. Pylori ED Screening Trial with Bedside Serologic Test: Estimation of H. Pylori Prevalence in Patients Presenting with Epigastric Pain

Victor Scali¹, Kenyon W. Sprankle², James Espinosa^{3*}

¹Department of Emergency, Emergency Medicine Residency, Rowan University SOM, Stratford, NJ, USA.

²Department of Emergency, Emergency Medicine Residency, Rowan University SOM [Deceased].

³Department of Emergency Medicine, Rowan University SOM Kennedy University Hospital, Stratford, NJ, USA.

Corresponding Author: James Espinosa, Department of Emergency Medicine, Rowan University SOM Kennedy University Hospital, 18 East Laurel Road, Stratford, NJ 08084, USA, **Tel:** +1 646 241 5695; **Email:** jim010@aol.com

In Memoriam: Dr. Kenyon W Sprankle, DO. Friend and fellow emergency physician.

Received Date: 27 Dec 2016

Copyright © 2017 Espinosa J

Accepted Date: 19 Jan 2017

Citation: Scali V, Sprankle KW and Espinosa J. (2017). H. Pylori ED Screening Trial with Bedside Serologic Test: Estimation of H. Pylori Prevalence in Patients Presenting with Epigastric Pain. M J E-Med. 2(1): 020.

Published Date: 24 Jan 2017

ABSTRACT

Helicobacter pylori (H. pylori) is a gram-negative bacterium, found worldwide, associated with duodenal ulcers, gastric ulcers, gastric lymphoma and gastric cancer.

Several testing methods are commonly used to detect H. pylori. Some are based on endoscopic biopsy urease testing, histology, and culture of tissue. All of the aforementioned are, of course, invasive. Several noninvasive tests exist. Patients frequently present to the Emergency Department with a chief complaint of upper abdominal pain. Scali et al performed a study of the use of a bedside commercial point of care serology test for H. pylori.

The purpose of this research report is to present the results of this previously unpublished data. A total of 75 patients presenting to the ED with epigastric abdominal pain were studied using a bedside test for H. pylori that was commercially available at the time of the study. 30 of the 75 patients (40%) tested positive by the bedside test. 45 of the 75 patients (60%) tested negative by the bedside test. The two proportions were significantly different. [Test for difference of two proportions $p = 0.012$, Fischer's exact test: $= 0.022$] Thus, the prevalence estimate in this study was 40% in patients with epigastric abdominal pain. Of the 30 patients who tested positive, 20 were lost to follow-up, 6 did not fill the prescription provided, and 4 filled the prescription. Of the 4 patients who completed their treatment, 2 were symptomatically improved, with one patient ultimately having endoscopically documented gastritis and the other patient an endoscopically proven duodenal ulcer.

Since the time of this study, it appears that there has been a movement away from similar bedside serological tests, perhaps due to a relatively low positive predictive value. However, the data appear to support the proposition that H.pylori testing, if practical and cost-effective would be helpful to patients presenting to the ED with upper abdominal pain. Non-invasive tests hold the promise of a more rapid diagnosis at a lower cost than endoscopic histological testing. Any strategy to diagnose and treat H. pylori would need to be studied in reference to cost effectiveness of competing strategies-and would need to take into account H. pylori prevalence. Comparative effectiveness of the most current eradication therapy regimes would also need to be studied.

KEYWORDS

Non-Invasive Testing for H. Pylori; Emergency Department Diagnosis of H. Pylori; Estimation of H. Pylori Prevalence in Emergency Department Patients with Abdominal Pain; Abdominal Pain and H. Pylori Prevalence.

INTRODUCTION

Helicobacter pylori (H. pylori) is a gram-negative bacterium, found worldwide, associated with duodenal ulcers, gastric ulcers, gastric lymphoma and gastric cancer [1, 2]. H. pylori infects the stomach lining of 60% of the world’s population [3]. Patients frequently present to the Emergency Department with a chief complaint of upper abdominal pain. As noted by Meltzer et al, one of the major causes of upper abdominal pain is peptic ulcer disease (PUD) [4]. The annual cost of PUD to the healthcare system in the United States is considerable as high as 10 billion dollars per year with 500,000 new patients diagnosed with PUD per year in the United States [5].

Several testing methods are commonly used to detect H. pylori. Some are based on endoscopy biopsy (e.g. biopsy urease testing, histology testing and culture of tissue biopsy specimens.) All of the aforementioned are, of course, invasive. Several non-invasive tests exist. Serology is convenient but cannot be used in early follow up of treatment testing. Some commercial kits are less than ideally accurate. A breath test is available (13C urea breath test (UBT)) and is useful for early follow up of treatment. Breath tests are more accurate than currently available serology testing kits. However, breath testing generally requires fasting and is not as convenient as stool or blood testing. A stool antigen test is slightly less accurate than the breath test, can be used in follow up of treatment testing and can be used in the pediatric population [6].

A recent article by Meltzer et al. reports their experience with using the UBT in patients presenting to an ED with a complaint of upper abdominal pain, in which there was a clinical suspicion for peptic ulcer disease. They note that to their knowledge, “no one has investigated the prevalence of active H. pylori infection among patients who present to and emergency department with abdominal pain.” One of the purposes of their study was to estimate the prevalence of H. pylori in an ED population with abdominal pain [4].

Scali et al performed a study of the use of a bedside commercial point of care serology test for H. pylori. The data provides an estimation of prevalence, since point of care testing has the potential for false positive results. This data has been unpublished. The purpose of this research report is to present the results of this previously unpublished data.

MATERIALS AND METHODS

The Scali et al. study was prospective in design, designed to look at the rate of H. pyloric positive results in a cohort of ED patients presenting with epigastric abdominal pain. Inclusion criteria included age greater than 18 years of age, not pregnant with epigastric pain.

The study was approved the Institutional Review Board (IRB) and all patients provided written consent after the procedure was explained. The study was performed over a 1.5 year period, beginning in January of 1998. The setting was the three ED community hospital/University affiliated EDs of the Kennedy Health System. The bedside test used (FlexSure HP, SmithKline Diagnostic) was a finger stick bedside method which provided a colorimetric (pink line positive) results in 4 minutes. Residents in Emergency Medicine performed the procedure using Universal Precautions. Patients were otherwise evaluated in the normal ED manner and standard of care. However, patients who tested H. pylori positive were offered one of three options, clearly discussed as part of the consent process: 1) antibiotic treatment with metronidazole, tetracycline, ranitidine and bismuth subsalicylate for 14 days 2) antibiotic treatment with clarithromycin, omeprazole and metronidazole for 10 days or 3) no specific anti-H. pylori treatment. All patients, treated or untreated for H. pylori, were provided follow instructions to see their primary care physician and/or gastroenterologist on call, as per patient preference. An attempt was made to make follow up contact with all treated patients and their treating primary physician and/or gastroenterologist in order to ascertain the patient’s clinical course and final diagnosis.

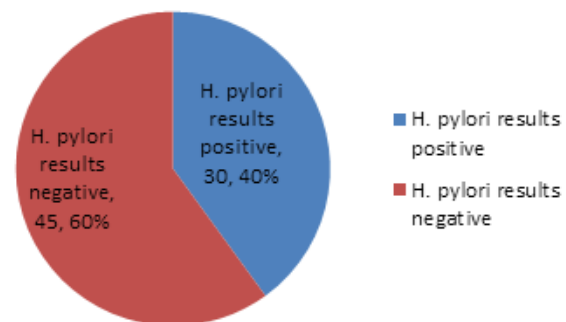
RESULTS

A total to 75 patients were studied. 30 of the 75 patients (40%) tested positive by the bedside test. 45 of the 75 patients (60%) tested negative by the bedside test [Table 1, Figure 1].

H. pylori results	N	%
positive	30	40%
negative	45	60%
Total	75	100%

Table 1: H. pylori results.

Figure 1: Pie Chart, H. pylori results.



The estimate for the difference was -0.2 (-20%) The 95% CI for the difference was -0.356, -0.043. The two proportions are significantly different. [Test for difference of two proportions p = 0.012, Fischer’s exact test: = 0.022].

Follow up of positive results

Of the 30 patients who tested positive, 20 were lost to follow-up. 6 did not fill the prescription provided. 4 filled the prescription [Table 2].

<i>H. pylori positive</i>	
lost to follow up	20
did not fill prescription	6
filled prescription	4
<i>total</i>	30

Table 2: 4 filled the prescription.

Of the 4 patients who completed their treatment, 2 were symptomatically improved. One patient ultimately had endoscopically documented gastritis and one patient had an endoscopically documented duodenal ulcer.

DISCUSSION

Despite the increased availability and significant advances made in diagnostic imaging currently used in the Emergency Department, abdominal pain often remains a difficult and elusive diagnosis in a significant number of patients. In 2006, abdominal pain accounted for 7 % of all visits to the emergency department, and misdiagnosis continues to pose additional medical legal risk for the emergency physician. Once trauma and life threatening surgical abdominal emergencies, such as abdominal aortic aneurysm, ischemic bowel, perforated hollow viscus, ruptured appendicitis, ascending cholangitis and bowel obstruction have been ruled out by CT and ultrasound imaging, the emergency physician is often left with a diagnosis of abdominal pain of unknown etiology [7].

In a study of 264 consecutive patients presenting to tertiary care center in India, 26.9% of patients characterized their pain as upper abdominal [8]. Furthermore delay in diagnosis by endoscopy and subsequent treatment of peptic ulcer disease with biopsy proven H. Pylori infection may put the patient, particularly the elderly, at higher risk of perforation [9].

With this clinical conundrum in mind and observed by the multitude of emergency physicians treating undifferentiated abdominal pain daily in the ED, our study attempted to further define an important potential diagnosis, PUD and/or gastritis in a cohort of patients whose chief complaint was epigastric pain and negative ED workup.

A total to 75 patients were studied. 30 of the 75 patients (40%) tested positive by the bedside test. 45 of the 75 patients (60%) tested negative by the bedside test.

Thus the prevalence estimate in this study was 40% in patients with epigastric abdominal pain. In Meltzer’s study, 24% of patients with upper abdominal pain tested positive for H. pylori.

This difference may be attributable to a difference population, different testing method, or a change in the prevalence in H. pylori. In addition, in the Meltzer study, patients were excluded who had active treatment for gastritis, included patients taking protein pump inhibitors [4].

Since the time of this study, it appears that there has been a movement away from similar bedside serological tests, perhaps due to a relatively low positive predictive value [10].

Of the 30 patients who tested positive, 20 were lost to follow-up. 6 did not fill the prescription provided. 4 filled the prescription.

Of the 4 patients who completed their treatment, 2 were symptomatically improved. One patient ultimately had endoscopically documented gastritis and one patient had an endoscopically documented duodenal ulcer.

This would appear to support the proposition that H.pylori testing would be helpful to patients presenting to the ED with upper abdominal pain if practical and available at the point of care. Noninvasive tests hold the promise of a more rapid diagnosis at a lower cost than endoscopic histological testing [11, 12]. It was not the purpose of this study to compare costs of testing strategies. Any strategy to diagnose and treat H. pylori would need to be studied in reference to cost effectiveness of competing strategies-and would need to take into account H. pylori prevalence [13]. Comparative effectiveness of the most evidence based eradication therapies would also need to be studied [14].

CONCLUSIONS

A total to 75 patients presenting to a community teaching hospital ED with epigastric abdominal pain, in which peptic ulcer disease might be in the differential diagnosis, were studied using a bedside test for H. pylori that was commercially available at the time of the study. 30 of the 75 patients (40%) tested positive by the bedside test. 45 of the 75 patients (60%) tested negative by the bedside test. The two proportions were significantly different. [Test for difference of two proportions $p = 0.012$, Fischer’s exact test: $= 0.022$]

Thus the prevalence estimate in this study was 40% in patients with epigastric abdominal pain. Of the 30 patients who tested positive, 20 were lost to follow-up, 6 did not fill the prescription provided, and 4 filled the prescription. Of the 4 patients who completed their treatment, 2 were symptomatically improved. One patient ultimately had endoscopically documented gastritis and one patient had an endoscopically documented duodenal ulcer.

Since the time of this study, it appears that there has been a movement away from similar bedside serological tests, perhaps due to a relatively low positive predictive value. [Elizur,

1997] However, the data appear to support the proposition that H. Pylori testing were it practical, would be helpful to patients presenting to the ED with upper abdominal pain. Non-invasive tests hold the promise of a more rapid diagnosis at a lower cost than endoscopic histological testing. It was not the purpose of this study to compare costs of testing strategies. Any strategy to diagnose and treat H. pylori would need to be studied in reference to cost effectiveness of competing strategies-and would need to take into account H. pylori prevalence. Comparative effectiveness of newer eradication therapy would also need to be studied concurrently.

REFERENCES

1. Kuipers EJ and Blaser MJ. (2012). Acid Peptic Disease. In Goldman L and Schafer A (Eds.), *Goldman's Cecil Medicine*. Philadelphia, PA: Elsevier Saunders. 1: 887-895.
2. Chey WD, Wong BC and Practice Parameters Committee of the American College of Gastroenterology. (2007). American College of Gastroenterology guideline on the management of *Helicobacter pylori* infection. *Am J Gastroenterol*. 102(8): 1808-25.
3. Azevedo NF, Huntington J and Goodman KJ. (2009). The epidemiology of *Helicobacter pylori* and public health implications. *Helicobacter*. 14 (1): 1-7.
4. Meltzer AC, Pierce R, Cummings DA, Pines JM, et al. (2013). Rapid (13)C Urea Breath Test to Identify *Helicobacter pylori* Infection in Emergency Department Patients with Upper Abdominal Pain. *West J Emerg Med*. 14(3): 278-82.
5. Hess JM and Lowell MJ. (2014). Esophagus, Stomach and Duodenum. In JA. Marx (Ed.), *Rosen's Emergency Medicine: Concepts and clinical practice*. Philadelphia, PA: Saunders. 1: 180-1181
6. Atherton J and Blaser M. (2012). *Helicobacter pylori* Infections. In D. Longo (Ed.), *Harrison's Principles of Internal Medicine* New York, NY: McGraw-Hill. 1: 1261-1265.
7. Macaluso CR and McNamara RM. (2012). Evaluation and management of acute abdominal pain in the emergency department. *Int J Gen Med*. 5: 789-97.
8. Chanana L, Jegaraj MA, Kalyaniwala K, Yadav B, et al. (2015). Clinical profile of non-traumatic acute abdominal pain presenting to an adult emergency department. *J Family Med Prim Care*. 4(3): 422-5.
9. Lyon C and Clark DC. (2006). Diagnosis of acute abdominal pain in older patients. *Am Fam Physician*. 74(9): 1537-44
10. Elitsur Y, Neace C and Triest WE. (1997). Comparison between a rapid office-based and ELISA serologic test in screening for *Helicobacter pylori* in children. *Helicobacter*. 2(4): 180-184.
11. Hahn M, Fennerty MB, Corless CL, Magaret N, et al. (2000). Noninvasive tests as a substitute for histology in the diagnosis of *Helicobacter pylori* infection. *Gastrointest Endosc*. 52(1): 20-26
12. Pourakbari B, Ghazi M, Mahmoudi S, Mamishi S, et al. (2013). Diagnosis of *Helicobacter pylori* infection by invasive and noninvasive tests. *Braz J Microbiol*. 44(3):795-8.
13. Vakil N, Rhew D, Soll A and Ofman JJ. (2000). The cost-effectiveness of diagnostic testing strategies for *Helicobacter pylori*. *Am J Gastroenterol*. 95(7): 1691-1698
14. Ford AC, Delaney BC, Forman D and Moayyedi P. (2004). Eradication therapy for peptic ulcer disease in *Helicobacter pylori* positive patients. *Cochrane Database Syst Rev*. 19(2): CD003840.