Positivity Rate of Stool Antigen of Helicobacter Pylori in Upper Gastrointestinal Endoscopy Duodenitis in Dyspepsia Patients- An Observational Study

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ABSTRACT

Introduction: Helicobacter pylori (H. pylori), Gram Negative bacilli, is implicated in diseases such as chronic duodenitis, peptic ulcer, and gastric cancer. While most infected individuals remain symptoms free, a less percentage of individuals may develop peptic ulcer or gastric cancer after prolonged infection, contributing significantly to global morbidity and mortality.In this study we are discussed about the positivity rate of stool antigen of Helicobacter Pylori in upper gastrointestinal endoscopy duodenitis in dyspepsia patients.

Objective: To detect the positivity rate of stool antigen of helicobacter pylori in upper gastrointestinal endoscopy duodenitis in dyspepsia patients. To find the sensitivity, specificity, positive predictive value, negative predictive value, disease prevalence and correlation between duodenitis and stool antigen test positivity.

Materials And Methods: In this observational study, we included 242 dyspeptic patients and performed an Upper GI endoscopy and Stool Antigen Test (SAT) using Stool Antigen Test kit,H. pylori antigen is detected for all the patients. Patients who are on Proton pump inhibitors and Any Antibiotic therapy within one month are excluded from this study. Results: In this observational study, by Comparing the age distribution gastritis was more commonly seen in elderly patients > 50yrs and Duodenitis was most commonly seen in middle age group 30-50yrs. Our study has demonstrated results of sensitivity of 96.5% and specificity of 96.1%. Statistically it also shows positive predictive value of 96.5% and negative predictive value of 96.9%, with the disease prevalence of 46.69%. while assessing the chi square value which is 207.225 and p value of 0.0001(<0.05), there is an association between duodenitis and stool antigen test of h.pylori positivity. We have compared our study results with various researches results regarding stool antigen test sensitivity and specificity.

Conclusion: Detecting H. pylori infection and resistance for antibiotics are crucial for preventing various gastro-duodenal diseases, including gastric cancer. Stool antigen test was more Efficient , Non invasive and Cost effective and less time consuming than duodenal biopsy in diagnosing H. Pylori infection. Hence H. Pylori treatment could be started at the earliest with this test

1. INTRODUCTION

Helicobacter pylori (H. pylori), Gram Negative bacilli, is implicated in diseases such as chronic duodenitis, peptic ulcer, and gastric cancer (1). While most infected individuals remain symptoms free, a less percentage of individuals may develop peptic ulcer or gastric cancer after prolonged infection, contributing significantly to global morbidity and mortality. Approximately 50% of the global population is infected with H. pylori, increasing the risk of GI malignancy (2). Hereby a quick, precise, and easily available diagnostic methods are crucial for early detection & primary prevention of gastric cancer.

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Diagnostic tools for H. pylori are categorized into invasive (such as histology, culture, and rapid urease test) and non-invasive methods (like urea breath test, stool antigen test, serological test, and polymerase chain reaction). Non-invasive methods are preferred in clinical practice due to their ease and patient comfort, particularly stool antigen tests, which are effective in several studies and paediatric diagnosis of H. pylori infection (3). In this study we are discussed about the positivity rate of stool antigen of Helicobacter Pylori in upper gastrointestinal endoscopy duodenitis in dyspepsia patients

AIMS

To detect the positivity rate of stool antigen of helicobacter pylori in upper gastrointestinal endoscopy duodenitis in dyspepsia patients.

OBJECTIVES:

To find the sensitivity, specificity, positive predictive value, negative predictive value, disease prevalence and correlation between duodenitis and stool antigen test positivity.

STUDY DESIGN :

An Observational Study

PLACE OF STUDY:

S.R.M. Medical College Hospital and Research Centre period of study: 3 months

STUDY POPULATION:

All patients admitted in S.R.M. hospital during study period.

INCLUSION CRITERIA:

1. All patients- age18 years above of both genders admitted with symptoms of dyspeptic and epigastric pain at S.R.M. medical college hospital.

2. Planned for an upper GI endoscopy.

3. Patients consented for inclusion in the study according to designated proforma.

EXCLUSION CRITERIA:

1. Patients who are on Proton pump inhibitors.

2. Any Antibiotic therapy within one month.

2. METHODOLOGY

All patients planned for an upper GI Endoscopy in an elective setting with informed written consent.

SAMPLE SIZE :

P- Prevalence (62%)

α - Type I error(1.96)

L- Relative precision(15% of Prevalence)

Z - Critical value of the normal distribution

 n - Sample size

Based on parent article,

$$n= \frac{(Z_{1-\alpha/2})^2 \times P(1 - P)}{(L)^2}$$

$$n= \frac{(1.96)^2 \times 0.62 \times 0.38}{(0.09)^2}$$

$$n= \frac{(3.84)(0.2356)}{(0.0081)}$$

$$n= \frac{0.9041}{0.0081}$$

n= 112.

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Procedure :

In this study, we included 242 dyspeptic patients and performed an Upper GI endoscopy and Stool Antigen Test (SAT) for all the patients.

- After making the patient for overnight fasting, patient was taken for Upper GI endoscopy.
- Oesophagus, Stomach (Fundus, Body, Antrum, Pylorus), Duodenum (1st and 2nd part) visualised for an ulcer, growth, erosion and inflammation.
- Morning Stool samples are collected for Stool antigen test.
- Using Stool Antigen Test kit, H. pylori antigen is detected.

3. RESULTS

After performing Upper GI endoscopy and Stool antigen test for all the 242 patients in our study group. The following outcomes evaluated and showed sensitivity, specificity, positive predictive value, negative predictive value and p value for stool antigen test in an Upper endoscopy duodenitis/ duodenitis patients.

1. Age distribution
2. Gender distribution
3. Site of endoscopic abnormalities
4. Correlation of endoscopic abnormalities with stool antigen.

OUTCOMES MEASURED:

1) AGE DISTRIBUTION:

- In computing the age distribution, it is found that Gastritis is found in most common in >50yrs of age group, gastritis with duodenitis most common in 30-50yrs of age group and duodenitis most common in 30-50yrs of age group.
- Overall pathology was most commonly seen in 30-50yrs of age group.
- Among the patients included in the study 40%(96) had a diagnosis of gastritis followed by duodenitis 25%(62) and gastritis with duodenitis 21%(52). [Table/Fig. 1]

2). GENDER DISTRIBUTION:

- Among the 242 patients, 62%(151 patients) were males and 38 %(91 patients) were females. This statistics shows that dyspepsia is more common in males than females at the ratio of 1.6: 1. [Table/Fig. 2]

3). SITE OF ENDOSCOPIC ABNORMALITIES:

- Among the 242 patients for whom upper gastro endoscopy done, it showed Normal findings for 32 patients(13%), 96 patients had Gastritis(39.7%), 52 patients had Duodenitis(25.7%), 62 patients had Gastritis with Duodenitis(21.6%). As our study aims in proving the efficacy of stool antigen for h.pylori in patients having duodenitis. Among 242 dyspepsic patients, Patients who had duodenitis and gastritis with duodenitis were 114 patients, who had prevalence of duodenitis. [Table/Fig. 3]

4). EFFICACY OF STOOL ANTIGEN FOR H.PYLORI:

Sensitivity of Stool antigen test – 96.5%

Specificity of Stool antigen test - 96.1%

Positive Likelihood ratio of Stool antigen test- 24.89

Negative Likelihood ratio of Stool antigen test- 0.04

Disease prevalence- 46.69%

Positive Predictive Value of Stool antigen test – 95.6%

Negative Predictive Value of Stool antigen test – 96.9% [Table/Fig. 5]

Where Chi square value is 207.225 and P value is <0.05 (p=0.0001) [Table/Fig. 5]

There is an association between Duodenitis and Stool antigen test of h.pylori positivity. Since the significance value 0.0001 which is <0.05 and chi square vale is 207.225. so, we reject the null hypothesis.

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Table 1- Age Distribution

Age Distribution	Normal	Gastritis	Gastritis with duodenitis	Duodenitis	Total
18-30yrs	17(7%)	11(4%)	16(6%)	17(7%)	61(25%)
30-50yrs	13(5%)	33(13%)	31(12%)	29(11%)	106(44%)
>50yrs	2(0.8%)	52(21%)	5(2%)	16(2%)	75(31%)
Total	32(13%)	96(40%)	52(21%)	62(25%)	242

Table. 2- Gender Distribution

Gender distribution	Normal	Gastritis	Gastritis with duodenitis	Duodenitis	Total
Male	20(8%)	53(22%)	31(13%)	47(19%)	151(62%)
Female	12(5%)	43(18%)	21(9%)	15(6%)	91(38%)
Total	32(13%)	96(40%)	52(21%)	62(25%)	242

Table.3- Site of Endoscopic Abnormality

Site of Abnormalities	Study Population	Percentage
Normal	32	13 %
Gastritis	96	39.7 %
Duodenitis	52	25.7 %
Gastritis with duodenitis	62	21.6 %
Total	242	100 %

Table. 4- Efficacy of stool antigen for H.pylori

	Stool antigen +	Stool antigen -	Total
Duodenitis +	109	5	114
Duodenitis -	4	124	128

Total	113	129	242

Table. 5- Chi square test for efficacy of stool antigen for H.pylori

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	207.225	1	.0001
N of Valid Cases	242		

Table 6- Comparing Sensitivity, Specificity of stool antigen for H.pylori with other studies

References	Patients (Total-13253)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
In this study	**242**	**96.5**	**96.1**	95.6	**96.9**
Javier P Glisbert (10)	10858	91	93	92	87
Laure et al (11)	100	88.6	39.3	53.4	81.5
Dino vaira (12)	84	94	97	100	91
Kimitoshi kubo (13)	1055	97.3	99	-	-
Shadi kazemi (14)	94	96	83	98	96
Masami sato et al (15)	111	100	100	-	-
Lea veijola (16)	185	93	88.7	94	86.9
Rea krausse (17)	52	72.7	80	72.7	80
Yoram Elitsur (18)	121	67	99	86	97
Huseyin Korkmaz (19)	162	51.6	96	88.8	76.1
Mei-Jyh Chen et al(20)	189	92.9	95.8	-	-
Weighted mean		86.7	88.9		

4. DISCUSSION

Helicobacter pylori (H. pylori), a Gram Negative bacilli, is implicated in diseases such as chronic duodenitis/ duodenitis, peptic ulcer disease & GI malignancy. Rapid, accurate, and convenient diagnostic methods are crucial for early detection and primary prevention of gastric cancer. The stool antigen test (SAT) detects H. pylori antigen directly from faecal samples. Yan et al. found that stool antigen tests (SATs) maintain diagnostic accuracy in patients who have undergone distal gastrectomy, similar to those without surgical intervention (4). In Comparing the age distribution gastritis was more commonly seen in elderly patients > 50yrs. In a study done at Institute for Quality and Efficiency in Health Care, Gastritis is more common in people over 65, and the risk increases with age (5). Gastritis with duodenitis was most commonly seen in middle age group 30-50yrs. Ramakrishnan K study shows that, between 25 and 64, 70% of people have peptic ulcer disease (6). Duodenitis was most commonly seen in middle age group 30-50yrs. Ocasio study shows that Any age can develop duodenal ulcers. Men over women are more likely to be diagnosed with them between 20 and 45 (7). This goes as par with our study which also shows male preponderance. Our study shows gastritis (39.7 %) is the most common cause of dyspepsia followed by duodenitis (25.7 %) which is in concordance with a similar study done by Abdeljawad K which shows the most common endoscopic abnormalities were nonerosive gastritis (29.7%) and duodenitis (7.2%) (8) in his study with a sample size of 650 patients. Researchers have shown significant interest in comparing the diagnostic efficacy of various

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stool antigen tests. According to the guidelines for managing Helicobacter pylori infection in Japan, stool antigen testing demonstrates excellent diagnostic accuracy, with sensitivity ranging from 95% to 100% and specificity from 97% to 100% prior to eradication (9). Our study has demonstrated similar results of sensitivity of 96.5% and specificity of 96.1%. Statistically it also shows positive predictive value of 96.5% and negative predictive value of 96.9%, with the disease prevalence of 46.69%. while assessing the chi square value which is 207.225 and p value of 0.0001(<0.05), there is an association between duodenitis and stool antigen test of h.pylori positivity. We have compared our study results with various researches results regarding stool antigen test sensitivity and specificity [Table/Fig. 6]. In conclusion, stool antigen tests (SATs) offer several advantages for detecting H. pylori infection. Collecting stool samples non-invasively facilitates mass screening in communities, including children. Stool samples can be stored at freezing temperatures for long-term storage or at ambient temperature for immediate transport when using commercial detection kits. SATs are cost-effective compared to other non-invasive methods like urease breath tests, as they do not require expensive chemicals or specialized equipment.

5. CONCLUSION

Detecting H. pylori infection and resistance for antibiotics are crucial for preventing various gastro-duodenal diseases, including gastric cancer. Stool antigen test was more Efficient , Non invasive and Cost effective and less time consuming than duodenal biopsy in diagnosing H. Pylori infection. Hence H. Pylori treatment could be started at the earliest with this test.

LIMITATIONS OF THIS STUDY:

Availability of the stool antigen test

Cost effectiveness.

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