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Abstract

Background: About one-half of the world population has been affected with *Helicobacter pylori* (*H. pylori)* and it is very prevalent in developing countries. The expanded risk of infection due to precarious hygiene standards, crowded households and incomplete sanitation associated with this portion of the world. *H. pylori* is known as gram-negative, spiral shaped, flagellated organism uniquely adjust to colonize the gastric mucous layer.

Objective: To determine the relation between *H. pylori* infection in patients with various of gastrointestinal and respiratory symptoms in Taiz city, Yemen, based on stool and serological diagnostic tests.

Methods: In the present study, a cross-sectional study for a total of 178 patient's antigen and antibody sample diagnosis for *H. pylori* were

conducted. One hundred thirty-eight outpatients are from hospitals and clinic centers with different gastrointestinal (GI) and respiratory (R) symptoms, and 40 individuals as control (patients without symptoms). The samples were collected during the period of September 2017 to May 2018. Two samples were used to detect *H. pylori*; the blood sample to detect the presence antibodies (Ab) and stool sample to detect antigens (Ag) of *H. pylori*. The data analysis was conducted by the SPSS version 24.0.

Results: The current study results showed a statistically significant distribution of *H. Pylori* infection among the outpatients according to demographic, clinical data, symptoms and diagnostic method. Out of 178 outpatients 65 (37%) male and 113 (63%) females, age ranging from 9 to 63 years. The accompanying symptoms were associated with Gl and respiratory symptoms and infection. The Ag test identified 42 positive cases out of 69 (60.9%; $p<0.05$) while the Ab test detected 33 positive cases out of 69 (47.8%; $p<0.05$) patients. Similarly, for respiratory symptoms, the Ag test identified 8 positive cases out of 9 (88.9%; $p<0.05$), and the Ab test detected 6 positive cases out of 9 (66.7%; $p<0.05$). The data in this study was analyzed by a Chi-square analysis with a significant p-value of < 0.05.

Conclusions: This study highlights a significant association and prevalence of *H. pylori* infection among outpatients with gastrointestinal and respiratory symptoms. The antigen test was found to be a more effective diagnostic method for detecting current infection compared to the serum antibody test. Early diagnosis using appropriate methods could improve patient outcomes and reduce the burden of associated diseases.

Keywords*:* *Helicobacter pylori*, Taiz city, gastrointestinal symptoms, respiratory symptoms

Introduction:

Though the *Helicobacter pylori* (*H. pylori)* infection is widespread in the world, it is usually acquired during childhood, and often related to low socio-economic class (McColl et al., 2010). *H. pylori*, is one of the most studied bacteria related to gastrointestinal microorganism. The network of interactions that *H. pylori* have constituted with its host is closely linked to all systems of the organism (Linz et al., 2007). Based on many of systemic illnesses including hematological, neural, cardiovascular, dermatological, and allergic diseases are associated with *H. pylori* (Parsonnet et al., 1994; Suerbaum et al., 2002).

Respiratory diseases are considered as a leading cause of global morbidity and mortality, the World Health Organization (WHO) has declared their prevention, control, and treatment as a top priority in global health policy (Levine, 2022). Out of them, the association between *H. pylori* infection and the risk of allergic diseases is becoming better known and is of some concern to the general public. The relation of the human immune system and environmental factors lead to allergic diseases, and given the radical regional heterogeneity of these diseases. It is likely that environmental factors play an important role in their etiology (Cooke et al., 2005). As outcome, increasing evidence from research demonstrating a linked between early *H. pylori* exposure and allergic diseases may act as a preventative factor in the expansion of allergic disease (Levine et al., 2007).

Nevertheless, only a few number of studies have described the immune response to *H. pylori* and its association with gut microbial. Which explored the linked of *H. pylori* infection with asthma in expression of immunity and gut microbiota; in addition, the use of *H. pylori* and its related components in the treatment of asthma, and the most recent developments in the association among *H. pylori* infection and allergic diseases.

The approach of *H. pylori* transmission is unknown however it is thought to be mainly through oral-oral, the fecal-oral route and waterborne transit are other modes (Al-Moagel et al., 1990). *H. pylori* infection is a common and has connect to disorders of the gastrointestinal tract (Graham et al., 1991).

In Yemen many environmental factors including the low socioeconomic level, association with poor personal hygienic exercise, needed waste disposal system, crowded people conditions and many lack of clean and safe

water are contributing in *H. pylori* infection. Recently, many of our populations are predisposed to diverse risk factors of *H. pylori* infection, so the prevalence and the epidemiological patterns of *H. pylori* infection are changed within community and geographical locations. On a large status, our study of *H. pylori* infection distribution and its determinant and aptitude risk factors are associated in order to recognize priorities for support the health services at local community.

Therefore, this study explored the association of *H. pylori* infection with different of gastrointestinal and respiratory symptoms in Taiz city, Yemen, as well as the more reliable method used for *H. pylori* diagnosis. It also introduced the most developments in the association linked to *H. pylori* infections and demographic data.

Materials and Methods:

Outpatients and selection criteria:

A conducted across-sectional study for the outpatient clinical sections was conducted during the period of September 2017 to May 2018. The sample consisted of 138 outpatients with gastrointestinal and respiratory symptoms from three hospitals, and two clinics at Taiz city, as well as 40 individuals as control (patients without symptoms) from UST campus in Taiz city.

Our study included 138 patients with gastrointestinal and respiratory symptoms. Inclusion criteria was clinical outpatients with gastrointestinal and respiratory symptoms who were voluntary participants in this study. The exclusion criteria was other outpatients participate associated with characteristics such as pregnancy women, childs age below 9 years, and patients with viral hepatic. The samples collection (Stool and blood) continued till accomplishment of the needed sample size from patients with clinical gastrointestinal and respiratory symptoms.

Data collection and processing:

Socio-demographic variables data like name, age, sex, specialty, location was identified as well as other relevant clinical data such as history of *H. pylori* history of gastrointestinal illness, nutrition, habits of smoking, symptoms, GERD, pervious infection and earlier treatment, the participants' patient all data were collected using as interviews questionnaire, and sample collection. The written consent forms or were collected from all patients as well as the form of the personal, pickings, and present illness of histories.

Diagnosis:

Specimens Collection and Processing

The diagnosis of H. pylori was performed using a rapid, visual, qualitative test kit from HEALGEN Products, TX, USA. The test is designed to detect the antibodies of H. pylori in human serum, plasma, or whole blood samples. The method is based on immunochromatography and the results can be obtained within 20 minutes. According to the manufacturer's specifications, it has a high sensitivity and specificity of 94.88% and 95.21%, respectively. The procedures followed the manufacturer's instructions.

Antigen test (Ag) for H. pylori was conducted using an immunochromatographic assay supplied by HEALGEN Products, TX, USA in patient feces sample. The test is used to obtain a visual, qualitative result with a high sensitivity 98.4% and specificity of 98.6% as per manufacturer's specifications and *H. pylori* test result interpretation (Rafeey et al., 2007).

Data Analysis and Interpretation:

Statistical analysis was conducted using the SPSS Version 24.0, where the results frequency and percentages were reported. To identify the factors association with *H. pylori*, the Chi square was applied and followed by multi-variant analysis. The data presentation was show by tables. To evaluate the association of *H. pylori* infection and diagnostic method Odds Ratios (ORs) and their 95% Confidence Intervals (95% CIs) was used. In addition, logistics regression was used to determine the impact of independent variables on the *H. pylori* infection prevalence. The study case a 95% Confidence Intervals was used with p. value is less than 0.05 was considered statistically significant.

Ethical Issue:

This study work was approved by the university department of Medical Laboratory, Faculty of Health Sciences, Taiz Branch, UST, Yemen.

Results:

Baseline distribution of demographic and clinical data of the outpatients:

The baseline characteristics of the patients and controls of study samples are shown in Table (1). It is shows the 178 outpatient's diagnosis of *H. pylori* infection; 138 outpatients out of them from hospitals and clinic

centers with different gastrointestinal and respiratory symptoms and 40 individuals as control (patients without symptoms), during the period of September 2017 to May 2018. All the frequencies of demographic and clinical data showed significant differences in distribution based on $p \leq 0.05$.

Out of 178 patients with high rate of females comprising of the 113 (63%) sample compared to 63(37%) males. The majority of patients was housewives (35%) and students (32%) with significant difference among specialties (p = 0.005). Age distribution was also significant, with the largest group being 20-30 years old (39%), followed by 31-41 years (27%) (p = 0.000). The indicator to *H. pylori* previous history test was (27%) and the undergone treatment was 26% respectively; both showing significant differences (p = 0.000). Also, 22% of participants were reported having gastroesophageal reflux disease (GRED). The nutrition status significantly different, with; 57% as weak, 36% as good, and 7% as poor with a p = 0.002.

Table (1)

Baseline demographic and data of 178 Patients included in the study.

Demographic and data	Categories	Frequency (*n*=178)	Percentage (%)	*P.* value
Gender	Male	65	37	0.000
	Female	113	63	
	Total	178	100	
Specialty	Free work	39	22	0.005
	Student	56	32	
	Farmer	11	5	
	Doctor	10	6	
	Housewife	62	35	
	Total	178	100	
Age	9-19	14	8	0.000
	20-30	70	39	
	31-41	49	27	
	42-52	21	12	
	53-63	10	6	
	63	14	8	
	Total	178	100	
Residence	Village	22	12	0.000
	City	156	88	
	Total	178	100	

Demographic and data	Categories	Frequency (*n*=178)	Percentage (%)	*P*. value
Smoking	Yes	42	24	0.000
	No	136	76	
	Total	178	100	
Previous *H. pylori* test	Yes	49	27	0.000
	No	129	73	
	Total	178	100	
Previous *H. pylori* treatment	Yes	47	26	0.000
	No	131	74	
	Total	178	100	
GRED	Yes	39	22	0.000
	No	139	78	
	Total	178	100	
Nutrition status	Good	63	36	0.002
	Weak	102	57	
	Poor	13	7	
	Total	178	100	

Note: GRED = Gastroesophageal reflux disease; *P*≤ 0.05 was considered statistically significant.

GI and respiratory symptoms distribution of the outpatients:

The distribution of various gastrointestinal and respiratory symptoms of the outpatients for *H. pylori* test in term of their frequency is shown in Table (2). The highest symptoms that dominating this outpatient population of gastrointestinal tract are heartburn, inflammation of abdominal, and regurgitation with 60 (42.8%), 57 (40.7%), and 51 (36.4%) respectively, while the clinical symptoms of respiratory tract are higher number of chest pain 39 (27.8 %) followed by asthma 20 (14%). These results show that the symptoms in gastrointestinal outpatient represented the most significant concerns comparing to the respiratory tract.

138 out of 178 participants were participated in the investigate the prevalence of *H. pylori* infection and its link with either gastrointestinal or respiratory symptoms or combination of both symptoms. The majority of participants 69 (39%) were reported due to the gastrointestinal (GI) symptoms, while 60 (34%) were due to both gastrointestinal and respiratory (GI+RT) symptoms. Respiratory symptoms alone are less common reported by only 9 (5%) of participants.

A significant proportion of the sample 40 (22%) is categorized as healthy (H) indicating no reported symptoms. There were no statistically significant differences in distribution of symptoms across the categories and p. value was ≥ 0.05. The results confirm that the more symptoms are due to the gastrointestinal outpatient comparing to respiratory tract as showed in Table (3).

Table (2)

Predominant GI and RT symptoms and related frequencies in 138 patients.

Symptoms	Frequency	%
Cough	17	12.1
Pharyngitis	16	11.4
Asthma	20	14.2
Dental erosion	9	6.4
Excessive burping	22	15.7
Heartburn	60	42.8
Regurgitation	51	36.4
Chest pain	39	27.8
Early satiety	17	12.1
Dolor epigastric	11	7.8
Distension abdominal	18	12.8
Inflammation abdominal	57	40.7
Constipation	26	18.5
Diarrhea	30	21.4

Table (3)

Distribution of outpatient's symptoms in the study sample.

Variables	Categories	Frequency (n=178)	%	*P. value*
Symptoms	GI	69	39	0.268
	R	9	5	
	GI+R	60	34	
	H	40	22	
	Total	178	100	

GI = gastrointestinal R = respiratory H = Healthy $p \leq 0.05$

H. pylori prevalence associated with GI and respiratory symptoms and diagnostic method:

Compared to positive and negative *H. pylori* patients in relation to GI and respiratory symptoms as showed in Table (4). Our results showed that the higher number of *H pylori* infection was linked more to GI than respiratory

symptoms 42 and 8 based on antigen (Ag) test and 33 and 6 based on antibody (Ab) detection, respectively.

The data reveal significant associations between *H. pylori* infection and both GI and respiratory symptoms, p-values ($p < 0.001$) for both diagnostic methods.

For GI symptoms, the antigen test identified 42 positive cases out of 69 (60.9%), while the antibody test detected 33 positive cases out of 69 (47.8%). Similarly, for respiratory symptoms, the antigen test identified 8 positive cases out of 9 (88.9%), and the antibody test detected 6 positive cases out of 9 (66.7%). The combined GI and respiratory symptoms group (GI+R) showed 40 positive cases out of 60 (66.7%) with the antigen test and 40 positive cases out of 60 (66.7%) with the antibody test. In contrast, the control group (H) had significantly lower positivity rates, with 9 out of 40 (22.5%) for the antigen test and 4 out of 40 (10%) for the antibody test, highlighting the link of *H. pylori* with symptomatic cases. The relative risk (RR) and odds ratio (OR) further support the strong association among *H. pylori* infection and symptoms. For the antigen test, the RR was 4.253, and the OR was 9.489 (95% CI: 3.916–25.397). For the antibody test, the RR was 5.720, and the OR was 12.063 (95% CI: 4.065–35.723). Both diagnostic methods showed statistically significant results ($p < 0.001$), indicating that *H. pylori* infection is strongly associated with both GI and respiratory symptoms, and both antigen and antibody diagnostic methods are effective in detecting the infection with *H. pylori* (Table 5).

Table (4)

Prevalence of H. pylori in associated to GI and R symptoms and diagnostic method.

Symptoms	(Ag) Diagnostic					(Ab) Diagnostic				
	Pos^{+}	Neg^{-}	Total	Chi^{2}	*P.* Value	Pos^{+}	Neg^{-}	Total	Chi^{2}	*P.* Value
GI	42	27	69	30.061**	0.000	33	36	69	32.737**	0.000
R	8	1	9			6	3	9		
GI+R	40	20	60			40	20	60		
H (control)	9	31	40			4	36	40		
Total	99	79	178			83	95	178		

Pos^{+}=Positive Neg^{-}-=Negative. P* value the GI and R symptoms consider significant as $p \leq 0.05$

Table (5)

The association between H. pylori diagnostic methods and patient's symptoms.

Symptoms	Diagnosis type	(RR) %	(OR) %	CI 95%	*P.* value
	Antigen (Ag)	4.253	9.489	(3.916 - 25.397)	0.000
	Antibody (Ab)	5.720	12.063	(4.065 - 35.723)	0.000

RR: Risk Ratio CI 95%: 95% confidence Interval. OR: odds ratio.

H. pylori distribution based on stool & blood samples of outpatients:

The detection of *H. pylori* infected at outpatients with was difference according to the samples were collected, from *H. pylori* positive the antigen test had a higher proportion of positive results 99 (56%) of the 178 compared to the antibody test 83 (47%), which reflect the prevalence of *H. pylori* in our populations regardless of sex Table (6), however this differences were not statistically significant.

Table (6)

Appearance of positive and negative cases based on diagnosis method

Diagnosis	Categories	Frequency (n)	(%)	*P. value*
Antigen (Ag)	Positive	99	56	0.134
	Negative	79	44	
	Total	178	100	
Antibody (Ab)	Positive	83	47	0.370
	Negative	95	53	
	Total	178	100	

H. pylori infection in outpatients' clinics based on demographic data and diagnostic method:

The results of this study revealed that there was no statistically significant association between *H. pylori* infection and gender based on the diagnostic method used (Ag; p=0.302; Ab; p=0.112). Similarly, no significant relationship was found with occupation (p= 0.895 for stool antigen (Ag) and p= 0.166 for blood antibody (Ab), age groups (p=0.740; p=0.786), residence location (p=0.545; p=0.194), smoking status (p=0.340; p=0.530), or nutrition status (p=0.773; p=0.634). These factors were not significant influences on the clinical association of demographic data with *H. pylori* diagnosis in outpatients, as shown in Table 7.

Overall, we noted none of demographic variables analyzed in the current study were significantly associated with *H. pylori* infection based on either

diagnostic method in outpatient's clinical samples. The used of Chi-Square test (X^2) was used to calculate the *p.* value, where this values were more than 0,05 indicated not statistically significant.

Table (7)

H. pylori infection rates among outpatients' clinics based on demographic data using stool Ag and blood Ab diagnostic methods

Demographic Variables	Group	(Ag) Diagnostic			(Ab) Diagnostic			(Ag) Diagnostic		(Ab) Diagnostic	
		Pos+	Neg-	Total	Pos+	Neg-	Total	Chi^2	*P.* value	Chi^2	*P.* value
Gender	Male	34	31	65	26	39	65	0.455	0.302	1.883	0.112
	Female	65	48	113	57	56	113				
	Total	99	79	178	83	95	178				
Specialty	Free work	21	18	39	12	27	39	1.097	0.895	6.483	0.166
	Student	30	26	56	29	27	56				
	Farmer	5	6	11	8	3	11				
	Doctor	6	4	10	5	5	10				
	House wife	37	25	62	29	33	62				
	Total	99	79	178	83	95	178				
Age	9-19	9	5	14	9	5	14	2.748	0.740	2.440	0.786
	20-30	41	29	70	30	40	70				
	31-41	23	26	49	22	27	49				
	42-52	12	9	21	10	11	21				
	53-63	5	5	10	5	5	10				
	63 <	9	5	14	7	7	14				
	Total	99	79	178	83	95	178				
Residence	Village	12	10	22	13	9	22	0.012	0.545	1.167	0.197
	City	87	69	156	70	86	156				
	Total	99	79	178	83	95	178				
Smoking	Yes	25	17	42	19	23	42	0.340	0.344	0.011	0.530
	No	74	62	136	64	72	136				
	Total	99	79	178	83	95	178				
Nutrition status	Good	33	30	63	29	34	63	0.516	0773	0.911	0.634
	Weak	58	44	102	50	52	102				
	Poor	8	5	13	4	9	13				
	Total	99	79	178	83	95	178				

Discussion:

H. pylori infection is recurring worldwide and the greatest number of cases are reported in the developing countries. To the best of our knowledge, information concerning the links of *H. pylori* with GI and R symptoms of participants' outpatients at Taiz city, Yemen is not carried out yet. Out of the 178 outpatients were involved in this study of the most frequent symptoms we complained was with gastrointestinal symptoms heartburn and inflammation of abdominal 60 (42.8%) and 57 (40.7%) respectively, while for the clinical symptoms of respiratory tract were highest with chest pain 39 (27.8 %) followed by asthma 20 (14%).

The results showed that more symptoms were present in gastrointestinal outpatient compare to respiratory tract, many earlier studies detected that *H. pylori* has the ability for affecting GI and extra-intestinal organs producing diseases and symptoms (Tan et al., 2011).

Baseline distribution of demographic data that studied the relationship of *H. pylori* infection in terms of gender, specialist, age, location, smoking, previous *H. pylori* infection and test, GRED, nutrition status. and it was noted that the infection with female more than males, female 113 (63%) while males 65 (37%). Hamrah et al., (2018) reported that there was no link between *H. pylori* infection and other factors, including age, sex, and status of education.

The patient’s residence from the city 156 (88%), while 22 (12%) living in the village was enrolled in the current study. At this point, we can conclude that the incidence of infection in the city is higher than the countryside. Ahmed et al., (2007)) have also reported similar results, showing that the prevalence of *H. pylori* can vary among urban and rural populations within the same country.

The number of outpatient who smoked 42 (24%) were smokers, 136 (76%) were non-smoker, we observed a higher prevalence of *H. pylori* antigen than seropositivity among smokers and to individuals who had never smoked table (7). Our results in agreement with Hamrah et al., (2018) who reported that smokers had higher rates of *H. pylori* than nonsmokers. The clinical characteristics of 178 outpatients with GERD were analyzed. Of these patients, 39 (22%) had previously been tested for *H. pylori*, while

49 (27%) had received treatment (Table 1). The prevalence of *H. pylori* in this outpatient population was 47% and 53%, based on the diagnostic method used as exhibited in Table (6). Our findings also indicate a highly significant relationship between certain clinical characteristics and *H. pylori* infection. Table 6 provides details on the diagnostic methods used to determine the prevalence of *H. pylori*.

Xiang Liu et al., (2023) reported in their study the *H. pylori* infection was affects gastric acid secretion as well association of the infection with gastroesophageal reflux disease (GERD), Barrett's esophagus (BE), and esophageal adenocarcinoma (EAC) have been conducted but remain controversial studies, Dour results are not compatible with this study.

In terms of GI and respiratory symptoms of participants' outpatients and association with *H pylori* infection, our results showed that the higher infection *H. pylori* was more associated with GI rather than respiratory symptoms 60 (39%), 6(5%) and for both GI and R symptoms 60 (40%) based on the Ag and Ab test. Our results were agreement with Vinagre et al., (2015).

Table (4) showed prevalence of *H. pylori* in associated with GI and respiratory (R) symptoms and diagnostic methods. Our results showed that, in patients with both GI and respiratory symptoms (GI+R), the positivity rates were 66.7% for both diagnostic methods, indicating a strong association between *H. pylori* and multisystemic involvement. This aligns with the hypothesis that *H. pylori* infection may have systemic effects beyond the GI tract, potentially mediated by inflammatory or immune mechanisms (Franceschi et al., 2014).

In our study, we found a significant association of *H. pylori* infection among patients' symptoms, for detecting the patients infected with *H. pylori*, based on samples were collected, the higher number was positive in stool sample compared to blood sample 42 and 33 out of 69 outpatients with GI symptoms regardless the sex. This difference in prevalence could be due to difference in diagnostic testing methods and variations in the socio-economic level of the study population (Ndip et al., 2004), which is compatible with our study.

Many gastroenterological associations did not recommend regular usage of antibody blood test for diagnosis of *H. pylori* infection or even for

following up the response of treatment, because this test has not been to distinguish the present infection from the previous one. When the result of this blood test is negative, this means that the person is unlikely to have *H. pylori* infection. However, if it is positive, stool antigen or breath test should be used for confirmation of the presence of a current *H. pylori* infection (Malfertheiner et al., 2022).

The results of this study explain a significant association between *H. pylori* infection and both gastrointestinal (GI) and respiratory (R) symptoms, as detected by antigen (Ag) and antibody (Ab) diagnostic methods. The results align with existing literature, which suggests that *H. pylori* infection is a major contributor to GI disorders, including gastritis, peptic ulcers, and gastric cancer, and may also play a role in respiratory conditions such as chronic bronchitis and asthma (Franceschi et al., 2014).

Regarding the distribution of positive cases for *H pylori* infection according to the age group, most of the earlier studies are various reports on the relationship between age of patients and prevalence of *H. pylori.* A study conducted in China by Zhang et al., (2013) documented identical prevalence with no statistically significant difference among age groups. However, Alizadeh et al. (2009) found out that the prevalence of *H. pylori* increased with age. In this study, there was an increase in the prevalence of *H. pylori* with age groups 20-30 and 31-41 years, the number of *H. pylori* infection in outpatients at this age group diagnosed by Ag (41 and 23) and Ab (30 and 22) *H. pylori* positive respectively, Table (7). As well statistically significant association was found for age frequencies and distribution Table (1).

Conclusion:

The results of this study demonstrate that there is a lack of awareness relating to the symptoms, diagnostic and treatment established for *H. pylori* infection. Therefore, this study focus on the significant association between *H. pylori* infection and both GI and respiratory symptoms. The findings support the use of antigen and antibody diagnostic methods for detecting *H. pylori* in symptomatic patients. Early diagnosis and treatment of *H. pylori* infection could have important implications for improving patient outcomes and reducing the burden of associated diseases, especially in the developing countries such as Yemen.

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