Republic of Yemen

Emirates International University

Faculty of Medicine and Health Science

Department of Laboratory Medicine

Seroprevalence and Associated Risk Factors of *Helicobacter pylori* Infection Among Medicine and Health Sciences Students in Emirates International University, Sana'a City, Yemen

A graduation project submitted to the Faculty of Medicine and Health Science

As a partial fulfillment for the requirement of a bachelor degree in laboratory medicine

Submitted by:

1- Abdalkreem Ahmed Qosilah

2- Abdullah Ali Mohammed Qaid Munasser

3- Aisha Habib Nasser Al-Ansi

4-Aliya Sami Qaid Abdulmalek

5-Khlood Khalid Hassan Al-Rainee

6-Marwa Abdulkareem Ganem Al-Dubai

7-Ziyad Abdulqawi Ali Mohsen Aldhbiaina

8-Zidane Abdulhadi AL-Srouri

Supervisor

Dr. Taha Abdul-Aziz Saeed Al-Nassari

Assistant professor of Microbiology and Medical Immunology

Faculty of Medicine and Health Sciences

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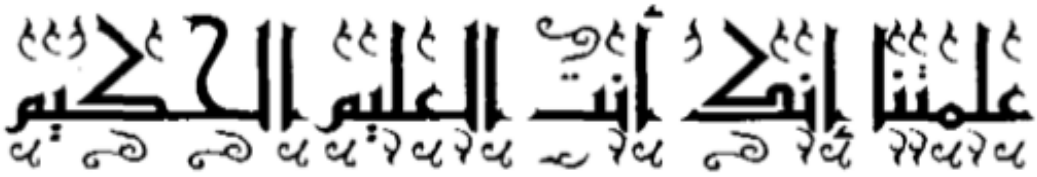

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Dedication

This work is dedicated to our beloved country where we live, grow and study.

To our parents and families who want to see us as doctors.

Special people in our life; our sisters and our brothers.

To our doctors who taught us and who have made us doctors.

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LIST OF ABBREVIATIONS

H. pylori : ***Helicobacter pylori***

IARC : International Agency for Research on Cancer.

PUD : Peptic ulcer disease.

GERD : Gastro Esophageal Reflux Disease.

PCR : Polymerase Chain Reaction.

HE : Hematoxylin And Eosin.

RUT : Rapid Urease Test.

UBT : Urea Breath Test.

EIA : Enzyme Immunoassay.

PPIs : Protons Pump Inhibitors

HpSA : *Helicobacter pylori* Stool Antigen

SPSS : Social Package of Statistical Science

ABSTRACT

Background: *Helicobacter pylori* is the leading cause of peptic ulcer and stomach cancer. The present study aims to determine the seroprevalence and risk factors associated with *helicobacter pylori* infection among medicine and health science students in Emirates International University in Sana'a city, Yemen.

Methods: This is a cross-sectional study carried out on 300 university students randomly selected, aged of 18-30 years old in Emirates International University in Sana'a city, Yemen.

Results: About 20.33% of university students in Emirates International University had been exposed to infection with *helicobacter pylori.*

Conclusion: The study concluded that the prevalence of *helicobacter pylori* is still high in our country. The prevalence was higher among females than in males, but we found no significant difference between the genders and *helicobacter pylori infections.* The results may be due to difference in lifestyle.

Chapter One

1.INTRODUCTION

Helicobacter pylori, previously known as ***Campylobacter pylori***, is gram-negative spiral (helical) bacterium (Alfarouk KO, 22 February 2019) first identified by the Australian researchers Professor Marshall, 54, and Dr. Warren, 68, in 1982 **(Watts, 2005)**. It is part of the *Helicobacteraceae* family. It grows in microaerophilic conditions and is often identified through positive catalase, H2S, Oxidase, urease, glucose-fermentation and motility test results (**Aryal**, 2022). It is found in natural environment and as a pathogen in human stomach.

H. pylori has been the number one leading cause of peptic ulcers and stomach cancer **(Meurer & Bower, 2002)**. The important clinical ***H. pylori*** infections are chronic gastritis, peptic ulcer disease and gastric cancer (Chang & Parsonnet, 2010). Other clinical infections are dyspepsia, anemia, duodenal ulcers, and gastric polyps (Suerbaum & Michetti, 2002). It produces a pore-forming toxin that enhances its ability to colonize the stomach and contributes to the pathogenesis of gastric adenocarcinoma and peptic ulcer disease **(Foegeding, et al., 2016).**

The CagA gene code is responsible for one of the major ***H. pylori*** virulence proteins **(Broutet, et al., 2001).** This gene is associated with the ability to cause ulcers. Another gene that plays a major role in the pathogenesis of ***H. pylori*** is the serine protease HtrA. It enables the bacterium to transmigrate across the epithelium of the host cell, and it's also needed for the translocation of CagA (Zawilak-Pawlik, et al., 2019). Another ***H. pylori*** virulence protein is vacA gene which has four main subtypes (s1/m1, s1/m2, s2/m1, and s2/m2. s1/m1 and s1/m2). These subtypes are known to cause an increased risk of gastric cancer (**Miehlke, et al.,** 2001).

About 50% of the population is infected with ***H. pylori*** while the other 50% is a carrier for the organism (Mladenova, 2021). Several antibiotics have been developed for the treatment of the organism, but till this very day the ideal treatment

remains evasive. So far, triple therapy, which consists of proton pump inhibitors (PPIs), bismuth subsalicylate and histamine (H-2) blockers, has been used to treat ***H. pylori*** (**Malfertheiner, et al., 2012)**.

Chapter Two

2. AIM OF THE PROJECT

2.1. General objective

The present study aims to determine the seroprevalence and risk factors associated with ***Helicobacter pylori*** infection among Medicine and Health Sciences students in Emirates International University in Sana'a city, Yemen.

2.2. Specific objectives

1. To determine the seroprevalence rate of ***H. pylori*** among Medicine and Health Sciences students.
2. To determine the distribution of ***H. pylori*** infection among Medicine and Health Sciences students according to certain population characteristics.
3. To study the risk factors associated with ***H. pylori*** infection among Medicine and Health Sciences students.

2.3. "PROJECT QUESTION "

Is the prevalence of *H. pylori* among medical students decreased?

2.4. "PROJECT HYPOTHESIS "

Is the prevalence of *H. pylori* among medical students increased?

Chapter Three

3. REVIEW OF LITERATURE

3.1. History of *H. pylori:*

H. pylori was first discovered in the stomachs of patients with gastritis and stomach ulcers in 1982 by Dr. Barry Marshall and Dr. Robin Warren of Perth, Western Australia. At the time the conventional thinking was that no bacterium could live in the human stomach as the stomach produced extensive amounts of acid of strength to the acid found in a car battery **(Warren and Marshall, 1983)**.

However, The Italian researcher Giulio Bizzozero described similarly shaped bacteria living in the acidic environment of the stomach of dogs in 1893. Professor Walery Jaworski of the Jagiellonian University in Krakow investigated sediments of gastric washings obtained from humans in 1899. Among some rod-like bacteria, he also found bacteria with a characteristic spiral shape, which he called Vibrio rugula. He was the first to suggest a possible role of this organism in the pathogenesis of gastric diseases.

3.1.1. Microbiological characteristic of *H. pylori*:

H. pylori is a bacterial species, which belongs to the genus of *Helicobacter*, family of *Helicobacteraceae* and order of *Campylobacterales*. is a slow-growing, microaerophilic, spiral shaped multi flagellated, gram-negative bacterium, about 3 micrometers long with a diameter of about 0.5 micrometers, whose surface is coated with 12–15 nm ring-shaped aggregates of urease and heat shock protein.

The urease enzyme and the heat shock protein B are located almost exclusively within the cytoplasm in the fresh log-phase cultures of *H. pylori.* In subcultures, urease and heat shock protein B become associated with the bacterial surface, suggesting bacterial autolysis leading to release of protein and adsorption into the bacterial surface.

Some of the lipopolysaccharide of the organism mimics the Lewis blood group antigens in structure. This molecular mimicry also helps in the continued existence

of *H. pylori* in the unfavorable gastric environment. This bacterium colonizes gastric mucosa and elicits both inflammatory and immune lifelong responses, with release of various bacterial and host dependent cytotoxic substances **(Peterson *et al*., 1998)**.

Under unfavorable circumstances it can become coccoidal, a nonculturable form with debatable viability. The bacterium is a microaerophilic and capnophilic organism, slowly growing with rigorous culture demands **(Mégraud and Lehours, 2007)**.

Several virulence factors for gastric colonization, tissue damage, and survival have been identified in *H. pylori* (**Figure 1**). Flagella, urease, and adhesions are all essential factors for *H. pylori* to colonize the gastric mucosa. Mutants of *H. pylori* without flagella or without urease are unable to colonize the gastric mucosa in laboratory animals **(Eaton *et al*., 1991)**.

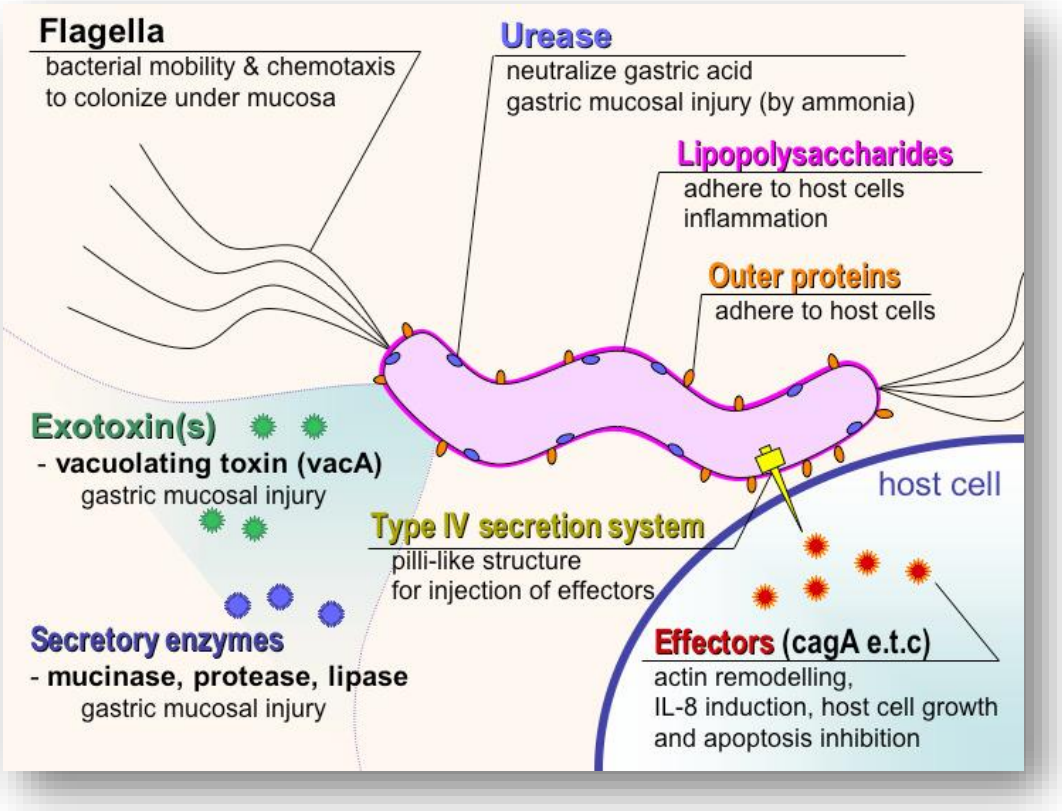

Figure 1: Components of *H. pylori* with biological activity

3.1.2 Route of transmission of *H. pylori*

H. pylorus is contagious, although the exact route of transmission is not known **(Smoot, 1997).** Person-to-person transmission by either the oral-oral or fecal oral route is most likely. Consistent with these transmission routes, the bacteria have been isolated from feces, saliva and dental plaque of some infected people. Findings suggest *H. pylori* is more easily transmitted by gastric mucus than saliva **(Yamoka, 2008).** Transmission occurs mainly within families in developed nations, yet can also be acquired from the community in developing countries.

H. pylori may also be transmitted orally by means of fecal matter through the ingestion of waste-tainted water, so a hygienic environment could increase the risk of *H. pylori* infection **(Yamoka, 2008)**.

Iatrogenic spread through contaminated endoscopes has been documented as rout of transmission **(Dunn *et al*., 2001)**.

3.1.3. The Global Burden of *H. pylori:*

H. pylori remain a major global health problem. It causes ill-health among millions of people each year and ranks as the fires leading cause of cancer from an infectious disease worldwide.

Most infections are believed to be acquired during childhood and appear to persist for decades. *H. pylori* is known to be the most important causal agent of human gastritis, gastric and duodenal ulcers, and has recently been classified as a first-class human carcinogen by IARC (International Agency for Research on Cancer) **(Anonymous, 1994).**

Medline and Pub Med databases were searched on epidemiology of *H. pylori* for the period of April 2013–March 2014. Several studies have shown that the prevalence of *H. pylori* is still high in most countries. In north European and North American populations, about one-third of adults are still infected, whereas in south and east Europe, South America, and Asia, the prevalence of *H. pylori* is often higher than 50%. *H. pylori* remain highly prevalent in immigrants coming from countries with high prevalence of *H. pylori*. However, the lower prevalence of infection in the younger generations suggests a further decline of *H. pylori* prevalence in the coming decades. Low socioeconomic conditions in childhood are confirmed to be the most important risk factors for *H. pylori* infection. Although the way the infection is transmitted is still unclear, interpersonal transmission appears to be the main route. Finally, *H. pylori* recurrence after successful eradication can still occur, but seems to be an infrequent event **(Eusebi LH *et al*, 2014)**. The prevalence of *H. pylori* infection among students in Hawler Medical University was 55.8%, which is lower than in neighboring countries e.g. Kuwait 81%, Jordan 82% and Turkey 63 % (**Bashdar M. Hussen et al, 2013**)

3.2. Pathogenesis of *H. pylori* infection:

Several virulence factors for gastric colonization, tissue damage, and survival have been identified in *H. pylori*. The primary disorder, which occurs after colonization with *H. pylori*, is chronic active gastritis. This condition can be observed in all *H. pylori* -positive subjects. The intragastric distribution and severity of this chronic inflammatory process depend on a variety of factors, such as characteristics of the colonizing strain, host genetics and immune response, diet, and the level of acid production. *H. pylori* -induced ulcer disease, gastric cancer, and lymphoma are all complications of this chronic inflammation; ulcer disease and

gastric cancer in particular occur in those individuals and at those sites with the most severe inflammation.

3.3 *H. pylori and* disease*:*

Infection with *H. pylori* results in an acute pangastritis often associated with achlorhydria. This gastritis may be symptomatic with nausea, vomiting and abdominal pain. Although the infection can be cleared in some patients it mostly results in an active, chronic, antrum predominant gastritis. This chronic gastritis is asymptomatic in the majority of cases, but in about 10% it leads to PUD **(Cats et al., 1998).**

Furthermore, the infection may cause atrophy and intestinal metaplasia of the mucosa leading to gastric adenocarcinoma in a minority. *H. pylori* infection has also been related to rare disorders such as gastric MALT lymphoma and hypertrophic gastropathy of Ménétrier. Finally, it has been suggested that *H. pylori* infection may be one of the causes of functional dyspepsia, but this is still a much-debated topic **(Laheij et al., 1998)**.

Recently it was suggested that *H. pylori* infection can also be beneficial as the microorganism may protect against gastroesophageal reflux disease (GERD) and its potential sequelae: Barrett's esophagus and adenocarcinoma of the esophagus.
Several arguments support this hypothesis. First, several epidemiological studies show that the decrease in the prevalence of *H.pylori* and PUD was accompanied by a Simultaneous increase in the prevalence of adenocarcinoma of the esophagus. Second, in some studies the prevalence of *H.pylori* was lower in patients with GERD than in controls (24,25). Finally, a study by Labenz et al. suggested an increase in GERD after *H.pylori* eradication in patients with peptic ulcer disease (26).

The factors that determine the outcome of the chronic *H.pylori* infection are largely unknown. Most likely, bacterial factors (such as the virulence factors discussed above), host factors (for example blood group and parietal cell mass), and environmental factors (for example age of acquisition of the infection and smoking) closely interact and determine the clinical outcome of the infection.

3.4. Diagnosis of *H. pylori* infection:

Currently, there are several popular methods for detecting the presence of *H. pylori* infection, each having its own advantages, disadvantages, and limitations. Basically, the tests available for diagnosis can be separated according to whether or not endoscopic biopsy is necessary. Histological evaluation, culture, polymerase chain reaction (PCR), and rapid urease tests are typically performed on tissue obtained at endoscopy. Alternatively, simple breath tests, serology, and stool assays are sometimes used, and trials investigating PCR amplification of saliva, feces, and dental plaque to detect the presence of *H. pylori* are ongoing.

3.4.1 Invasive methods to detect *H. pylori* infection

3.4.1.1 Histology:

As the standard method to diagnose *H. pylori* infection, histological examination provides critical information related to the mucosa (*e.g.*, presence and severity of inflammation, intestinal metaplasia, glandular atrophy, dysplasia, and neoplasia). Several studies have recommended that both antrum and corpus biopsies be collected **(Tonkic et al., 2012)**.

To detect *H. pylori* in biopsy samples, a routine hematoxylin and eosin (HE) stain is usually sufficient. When the results of this stain are inconclusive, special stains, such as Warthin-Starry, Giemsa, toluidine blue, acridine orange, McMullen, Genta, Dieterle, and Romanouski stains, or immunochemical methods can be used. Present guidelines suggest that at least 2 different stain techniques be used on biopsied tissue: HE to evaluate inflammatory cells, and Giemsa or Genta stain to detect *H. pylori.* Although the Genta stain is able to visualize both inflammatory cells and *H. pylori* by combining a silver stain, HE, and Alcian blue, it is technically complex. In contrast, the Giemsa stain is technically simple, highly sensitive, and inexpensive. Thus, the Giemsa stain is the preferred method in clinical practice. All other methods are used specifically for research proposes **(Lan *et al.*, 2012)**.

3.4.1.2 Culture:

A recently obtained gastric biopsy specimen is the ideal specimen for culturing *H. pylori* because no notable amount of commensal bacterial flora is expected (except in patients with reduced gastric acid production, in whom an overabundance of commensal bacteria is possible). Procedures that are less invasive than biopsy collection include gastric juice sampling or the string test. Specimens from gastric juice samples or the string test can also be used for culture; however, the sensitivity is lower than when biopsy specimens are used. Culturing typically has a sensitivity greater than 90% and a specificity of 100% when performed under optimal conditions **(Hirschl et al., 2007**).

However, lower sensitivity values have been reported (85.4%) with a confirmed 100% specificity, and a culture sensitivity of 40.0% was reported in bleeding patients **(Choi *et al.*, 2012).**

3.4.1.3 Polymerase chain reaction:

PCR allows researchers and clinicians to identify *H. pylori* in small samples that have few bacteria present. It does not require any special processing supplies or transportation, and it can be performed on samples obtained by both invasive and noninvasive methods. Moreover, PCR can be performed faster than many other diagnostic methods, used to identify diverse bacterial genotypes, and employed in epidemiological studies. A considerable drawback of PCR is that it can detect DNA segments of dead bacterium in the gastric mucosa of patients after treatment; consequently, it can produce false-positive results (**Rimbara *et al.*, 2013).**

Molecular detection of *H. pylori* using PCR is possible in materials obtained by non- or minimally invasive procedures, such as gastric juice, gastric content, saliva, stools, *etc*. Thus, molecular methods can be easily applied to specimens obtained by string tests or orogastric brushes. Molecular testing may be of particular value for samples that can no longer be successfully cultured because of prolonged transport or in cases where isolation of *H. pylori* is not feasible as a result of contamination **(Duś *et al.*, 2013)**.

3.4.1.4 Rapid urease test:

The RUT utilizes the ability of *H. pylori* to produce large quantities of urea as the basis for diagnosing infection. Biopsies obtained during endoscopy are placed in a medium containing urea and a pH indicator. If urease is present, the urea is broken down into carbon dioxide and ammonia, which increases the pH of the medium and causes a subsequent color change in the pH indicator. The RUT produces a result in a range of minutes up to 24 h, depending on the number of bacteria in the biopsy. The RUT is inexpensive, rapid, widely available, and highly specific.

Low sensitivity and specificity of the RUT have been reported in the presence of blood. When results from RUTs performed on individual gastric antrum and corpus tissue specimens and on combined specimens were compared to histology results (as the gold standard), combining the tissues increased *H. pylori* detection from 64% in separate specimens to 69.2% commercial RUTs have specificities above 95% to 100%, but their sensitivity is slightly less (approximately 85%-95%). Commercially available RUTs include gel- (CLOtest, HpFast) and paper-based tests (PyloriTek, ProntoDry HpOne) (**Moon *et al.*, 2012)**.

3.4.2 Noninvasive methods to detect an infection

3.4.2.1 Urea Breath Test (UBT):

Few studies were carried out on UBT this year. When comparing the 14C-UBT using encapsulated (which previously recommended) versus non-encapsulated urea, Pathak et al. favored the latter. They presented dynamic scintiscan images showing a possible incomplete resolution of the capsule in the stomach. showed a better sensitivity, 97.2% versus 91.8%, respectively, after 15 minutes in a series of 100 dyspeptic patients **(Pathak *et al.*, 2014)**.

3.4.2.2 Serology:

Several types of tests have been used to identify antibodies against *H. pylori.* The enzyme immunoassay (EIA) test has been the most prevalently used. Most commercial EIA tests are based on detecting IgG, with sensitivity and specificity values ranging from 60% to 100%. Critical factors important in evaluating the quality of serology tests for the detection of active *H. pylori* infection include the prevalence of infection, variations in geography, and characteristics of the study populations. Local validation of a serology test is necessary, and it is imperative to

make adjustments to cut-off levels for specific populations. In general, tests containing complex antigen mixtures of various strains show the highest sensitivity **(Harris *et al.*, 2005)**.

Numerous characteristics should be considered when determining whether a serology test should be used as the method of choice. In particular, a serology test should be considered in patients with a recent use of antibiotics or PPIs, bleeding ulcers, or gastric atrophy. Neither office-based whole-blood tests nor antibody detection in urine or saliva show similar reliability to laboratory-based tests, and they are not recommended to diagnose *H. pylori* infection (**Malfertheiner *et al*., 2007)**.

3.4.2.3 Stool Antigen Test

There are several SATs using either monoclonal or polyclonal antibodies and available as ELISAs on immunochromatographic tests (ICTs). Recently, new tests for *H. pylori* infection have been developed that rely on the detection of specific antigens in the stools of infected individuals. The *H. pylori* Stool Antigen test (HpSA) is an enzyme immunoassay. The initially developed stool antigen test was a polyclonal antibody test (Premier Platinum HpSA test; Meridian Diagnostic Inc., Cincinnati, OH, USA) and was found to have variable sensitivities and specificities for the diagnosis of *H. pylori* infection. The development of a new ELISA test using monoclonal antibodies (Femtolab *H. pylori*; Connex, Martinsried, Germany) gave a new dimension and greater precision for stool antigen testing. In comparative studies, stool antigen test using monoclonal antibodies showed a higher sensitivity than the polyclonal test **(Korkmaz *et al*., 2013)**.

A nice review on the interest of the SAT for the management of *H. pylori* infection was published by Shimoyama **(Shimoyama *et al*., 2013**). Furthermore, *H.*

pylori SAT (easy One-Step Test, Firstep Bioresearch, Taiwan) was added to the fecal occult blood tests used for colorectal cancer screening, in order to detect upper gastrointestinal (GI) lesions, mostly due to *H. pylori*, in a program in Taiwan. Of 31,721 participants, the prevalence of upper GI lesions was higher in those with a positive *H. pylori* SAT (34.6%) than in those with a positive guaiac-based test (24.7%) **(Lee *et al*., 2013)**.

H. pylori antigen detection in stool is a rapid, non-invasive, easy to perform test that can be used to detect active infection, monitor effectiveness during therapy and to confirm cure after antibiotic use **(Vaira *et al*., 2002).**

3.5. TREATMENT OF *H. PYLORI* INFECTION

Once *H. pylori* were detected in a person with a peptic ulcer, the normal procedure is to eradicate it and allow the ulcer to heal. The standard first-line therapy is a one-week "triple therapy" consisting of proton pump inhibitors such as Omeprazole and the antibiotics Clarithromycin and amoxicillin.

Variations of the triple therapy have been developed over the years, such as using a different proton pump inhibitor, as with Pantoprazole or Rabeprazole, or replacing amoxicillin with Metronidazole for people who are allergic to penicillin. Such a therapy has revolutionized the treatment of peptic ulcers and has made a cure to the disease possible. Previously, the only option was symptom control using antiacids, H -antagonists or proton pump inhibitors alone **(Malfertheiver*et al*., 2007)**.

Chapter Four

4. SUBJECTS AND METHODS

4.1. Subjects:

4.1.1 Chemicals and Reagents

- Test Cassettes - Disposable specimen droppers
- Package insert - Buffer
- Specimen collection container - Centrifuge (for plasma only)
- Timer - Tips

***H. pylori* blood antibody test by Lateral Flow Immunoassay**: (device kit)**:**

The *H. pylori* Antibody Rapid Test Cassette (ACON laboratories, Inc, San Diego, USA) is a qualitative membrane based on lateral flow chromatography immunoassay for the detection of *H. pylori* antibodies in whole blood, serum, or plasma within 10-min.

4.2 Methods:

4.2.1 Protocol of study:

This is a cross-sectional study that will be carried out on 300 university students randomly selected, aged 18-30 years-old, in Emirates International University, **Sana'a City**, the study will be conducted during February of 2023.

Written informed questioner will be obtained from all students after explaining the purpose and nature of the study.

Inclusion criteria:

Patients included in the study fulfilled the following criteria:

1. Medical student of Emirates International University.
2. Agree to participate in the study.

Exclusion criteria:

1. Any students not in the factually of Medicine and Health Sciences of Emirates International University.
2. Patients who have undergone partial or complete gastrectomy.
3. Patients treated with any antibiotics within the last 4 weeks.
4. Patients treated with any colloidal bismuth compounds, proton pump inhibitors (PPI), or H2 blocker within the last 4 weeks.
5. Not agree to participate in the study.

4.2.2 Sample Size Calculation:

The sample size (n) was estimated using the formula:

$$\mathbf{n = (1.96)^2 pq / d^2}$$

Where;

n = required sample size,

p = proportion of the population having *H. pylori* infection from previous study,

q = 1 - p and

d = the degree of precision

For the calculation, a 95% confidence interval, a p value of **0.865**, i.e., a prevalence rate of **86.5%** from previous study by **Ejilude *et al*.** [11] and margin of error (d) set

at **0.05** was used to determine the minimum sample size required. To minimize errors arising from the likelihood of non-compliance, 10% of the sample size was added giving a final sample size of **220**.

4.2.3 Sample Collection and Processing:

4.2.3.1 Blood sample Collection

About 5-ml blood samples will be collected from medical students into pre-labeled glass test tubes. Sera were separated after blood clotting by centrifugation at 3,000 rounds per minute for 10 minutes. Sera were then preserved at 4-8oC until the performance of serological investigations. If the test was not done immediately, sample was stored at -20

4.2.4 Assay procedure for detection of *H. pylori* Abs in Blood:

According to manufacturer instructions, specimens were tested using the whole blood, serum, or plasma test according to the manufacturer's instructions (94.9%-100% sensitivity and 95.1-100% specificity, according to the manufacturer). Briefly, small samples of serum vigorously agitated and after two minutes of resting the tube, dropping around two to three drops into the round window of the test cassette. Reading was made after 10 minutes of incubation at room temperature, and based on the appearance of colored lines across the central window of the cassette, two lines, C (control) and T (test), indicated positive test, only one line in C indicated negative result. A pale colored line in T was also considered positive.

4.2.5 Statistical Analysis:

The **SPSS24.0** (Social Package of Statistical Science) computer program by IBM Technologies; Inc. **USA** (**2014**) will be used to analyze the data. The significant

interrelationships between parameters were analyzed by Pearson correlation and chi-squire test. ***P*-value** will be considered statistically significant

4.2.6. Ethical aspects

The protocol of the present study was approved by the Medicine and Health Sciences of Emirates International University, Sana'a (Annex I). Written informed consent was obtained from all participants in the study after explaining to them the goal of the study. Their participation was on a voluntary basis. Confidentiality of patients was assured.

Chapter Five

5.RESULTS

1. Sociodemographic characteristics of the studied among university students

Table (4.1) shows that the majority of university students in Emirates university in Sana'a city were males (66.3%; 135/300), aged 22 years or older (61.3%; 184 /300), with a mean age of 22.13± 2.96 years (range: 18–30).

The majority of university students in Emirates university were urban residents (85.7%; 287/300), whereas those coming from rural areas represented 4.3%. On the other hand, the majorities of Emirates university students were unemployed (84.0%), and unmarried (11.7%).

Table (4.1): Sociodemographic characteristics of university student in Emirates university, Sana'a (2023)

Characteristic	Frequency (%)
Gender	
Male	199 (66.3)
Female	101 (33.7)
Age (years)	
Mean ± SD	22.13± 2.96
<21	184 (61.3)
≥ 21	116 (38.7)
Residence	
Rural	13 (4.3)
Urban	287 (85.7)
Marital status	
Married	35 (11.7)
Unmarried	265 (88.3)
Occupational	
Unemployed	252 (84.0)
Employed	18 (16.0)

* Total number of students participating in the study was 300.

2. Prevalence of *H. pylori* infection among university student

Figure (4.1) shows that about a 61(20.33%) of university students in Emirates University had been exposed to infection with *H. pylori*, where anti-*H. pylori* IgG antibodies were prevalent among 20 % (93/300) of university students.

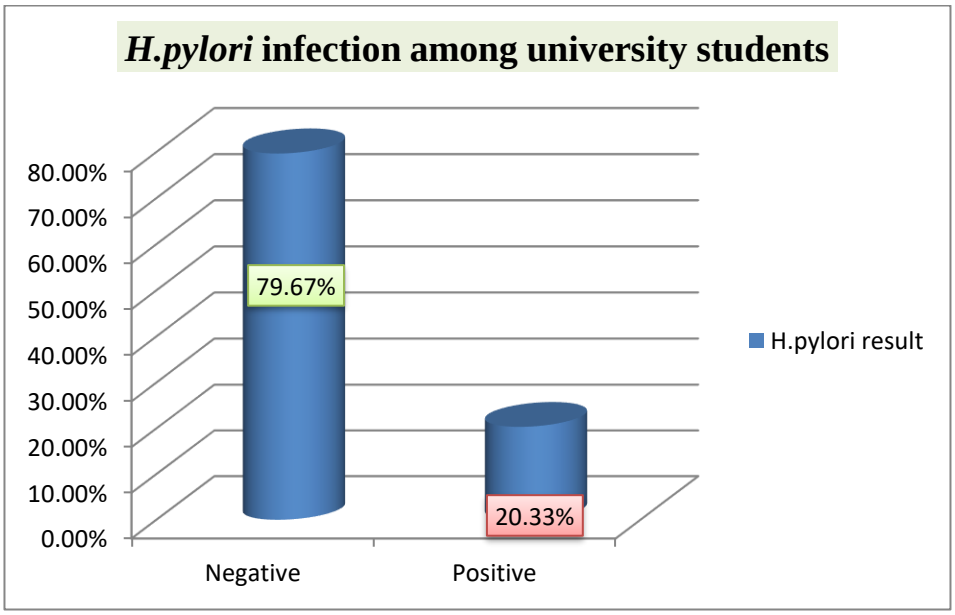

Figure (4.1): Seroprevalence of anti-*Helicobacter pylori* IgG antibodies among university student in Emirates University, Sana'a (2023)

3. Association of Gender of university student with *Helicobacter pylori* infection

Our study showed that H. pylori was positive in 61(20.3%) students, 17 (22.1%) of them were female and 44 (16.8%) were male (Table 4.2)

Table (4.2): Gender and *H.* pylori infection

Gender	*H. pylori* test				Total		*P*
	Positive		Negative				
	N	%	N	%	N	%	
Female	**17**	**22.1%**	**84**	**77.9%**	**101**	**100.0%**	***X*** ^{2}***=1.153***
Male	**44**	**16.8%**	**155**	**83.2%**	**199**	**100.0%**	***P =0.283***
Total	**61**	**20.3%**	**239**	**79.7%**	**300**	**100.0%**	

4. Association of age of university student with *Helicobacter pylori* infection

H. pylori infection was higher (22.4%) among students aged more than 22 years old than those students aged less than 22 (19.0%) (Table 4.3).

Table (4.3): *H. pylori* infection in relation to age

Age	*H.pylori test*		Total	P
	Positive	Negative		
<22	35 (19.0%)	149 (81.0%)	184(61.3%)	$X^2=1.153$
>22	26 (22.4%)	90(77.6%)	116(38.7%)	$P=0.283$
Total	61(20.3%)	239(79.7%)	300(100%)	

5. Association of the residency of university student with *Helicobacter pylori* infection

Table (4.4) and Figure (4.2) shows that from 300 patients, 287 live in urban areas and 13 in rural areas. From the 300 patients who lived in Urban areas 58 (20.2%) had *H. pylori* while patients who lived in Rural areas 3 (23.1%) had *H. pylori*. (P-value =0.802).

Table (4.4): *H. pylori* infection rates in relation to the residency

Residency	*H.pylori* test		Total	*P*
	Positive	Negative		
Rural	3 (23.1%)	10 (76.9%)	13 (4.3%)	***X²=0. 063***
Urban	58 (20.2%)	229 (79.8%)	287 (95.7%)	***P =0. 802***
Total	61(20.3%)	239(79.7%)	300(100%)	

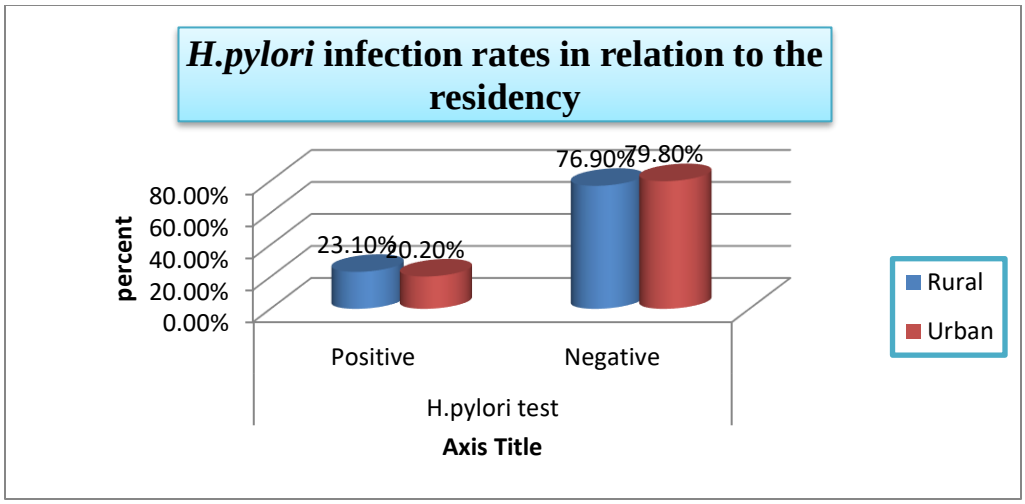

Figure (4.2): *H. pylori* infection rates in relation to the residency among university student in Emirates University, Sana'a (2023)

6. Association of the income levels of university student with *Helicobacter pylori* infection

Table (4.5) shows that regarding the income level, most of the seropositive participants (20.9%) were from **medium income** social class (*P value* = 0.715).

Table (4.5): *H. pylori* infection in relation to the income level among university student in Emirates University, Sana'a (2023)

Income level	*H.pylori* test		Total	P
	Positive	Negative		
Low	1 (11.1%)	8 (88.9%)	9 (3.0%)	$X^2 = 0.672$
Medium	57 (20.9%)	216 (79.1%)	273 (91.0%)	$P = 0.715$
High	3 (16.7%)	15(83.3%)	18(6.0%)	
Total	61(20.3%)	239(79.7%)	300(100%)	

7. Association of Departments of university student with *Helicobacter pylori* infection

Table (4.6) and Figure (4.3) shows that *H. pylori* infection was higher (25.0%) among Medicine students than Laboratory Medicine (23.7%) and Dentistry students (17.8%), and there were no significant difference found between them (P. value = 0.345) (Table 6).

Table (4.6): *H. pylori* infection in relation to Departments

Departments	***H.pylori* test**		**Total**	***P***
	Positive	Negative		
Laboratory Medicine	18 (23.7%)	58 (76.3%)	76(25.3%)	$X^2 = 3.323$
Clinical Pharmacy	11 (14.7%)	64 (85.3%)	75 (25.0%)	$P = 0.345$
Dentistry	13(17.8%)	60 (82.2%)	73 (24.3%)	

Medicine	19(25.0%)	57(75.0%)	76(25.3%)	
Total	61(20.3%)	239(79.7%)	300(100%)	

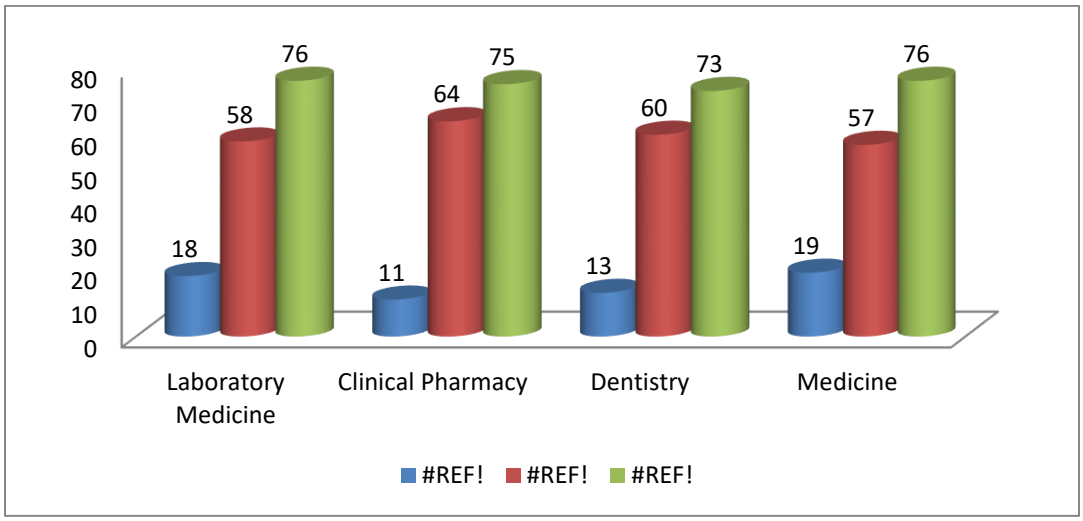

Figure (4.3): *H. pylori* infection rates in relation to the Departments among university student in Emirates University, Sana'a (2023)

8. Association between levels of university student with *Helicobacter pylori* infection

Table (4.7) shows that *H. pylori* infection was higher (25.0%) among 3rd Level and 4th Level (23.7%) than the primary and secondary level, and there was no significant difference found between them (P value=0.405)

Table (4.7): Association between levels of university student with *Helicobacter pylori* infection

Study level	*H.pylori* test		Total	P
	Positive	Negative		
1st Level	**12 (15.0%)**	68 (85.0%)	**80(26.7%)**	***X 2= 2.916***

2nd Level	**15(18.8%)**	65 (81.3%)	**80(26.7%)**	***P = 0.405***
3rd Level	**16 (25.0%)**	48 (75.0%)	**64(21.3%)**	
4th Level	**18 (23.7%)**	58 (76.3%)	**76(25.3%)**	
Total	**61 (20.3%)**	79.7(53.7%)	**300(100%)**	

9. Risk factors associated with *H. pylori* among University Students

University Students who chew qat and consume tea, coffee and have an Infection in the family had more *H. pylori* infection rates than those who consumed Cola and smoked. On the other hand, bivariate analysis showed that none of the other studied factors were significant predictors with *H. pylori* infection rates among University Students (Table 8).

Table (4.8): *H. pylori* infection rates in relation to risk factors (drinks, smoking and family infection)

Risk Factors		***H. pylori* test (Positive) N (%)**	**Risk Estimate OR (95% CI)**	***P***
Cola consumption	Yes	38 (18.0%)	0.630(0.349-1.137)	0.157
	No	23 (25.8%)		

Tea consumption	Yes	57 (21.4%)	2.045(0.692-6.045)	0.258
	No	4(11.8%)		
Coffee consumption	Yes	44 (21.5%)	1.254(0.673-2.335)	0.539
	No	17 (17.9%)		
Smoking	Yes	18 (19.4%)	0.915(0.495-1.692)	0.877
	No	43 (20.8%)		
Infection in family	Yes	9 (25.7%)	0.915(0.495-1.692)	0.877
	No	52(19.6%)		

OR, odds ratio; CI, confidence interval; *p=0.05*

10. Association of Blood groups of university students with *Helicobacter pylori* infection

Table (4.9) shows that *H. pylori* infection was higher (57.4%) among medical students who had O blood group than A blood group (32.8%), B blood group (6.6%), and AB blood group (3.3%) but there is no significant difference found between them (P value=0.414).

Table (4.9): Association between Blood groups with *Helicobacter pylori* infection

Blood group	***H. pylori* test**		**Total**	***P***
	Positive	**Negative**		
A	20(32.8%)	85(35.6%)	105 (35.0%)	$X^2 = 2.860$

B	4(6.6%)	32(13.4%)	36(12.0%)	***P = 0.414***
AB	2(3.3%)	6(2.5%)	8(2.7%)	
O	35(57.4%)	116 (48.5%)	151 (50.3%)	
Total	61(20.3%)	239(79.7%)	300(100%)	

11. *H. pylori* infection rates in relation to Water drinks

Table (4.10) shows that the majority of university students were drinking filtrated water (95.2%; 277/300) than Government Water (4.3%; 12/300) and well water (3.2%; 11/300). *H. pylori* infection rate was higher among medical students who are drinking well water (25.0%; 3/11.) than filtrated water (20.2%; 56/277). But there is no significant difference found between them (P value =0.907)

Table (4.10): *H. pylori* infection rates in relation to Water drinks

Water drinking	***H. pylori* test**	**Total**	***P***

	Positive	**Negative**		
well water	3(25.0%)	9(75.0%)	11(3.2%)	0.416
government water	2(18.2%)	9 (81.8%)	12(4.3%)	
filtered water	56(20.2%)	221(79.8%)	277(95.2%)	
Total	61(20.3%)	239(79.7%)	300(100%)	

Chapter Six

6. DISCUSSION

H. pylori remain a major global health problem. It is known to be the most important causal agent of human gastritis, gastric and duodenal ulcers, and ranks as the fires leading cause of cancer from an infectious disease worldwide **(1).** The prevalence of *H. pylori* infection shows large geographical distribution especially in low developing countries.

The present study aimed to determine the seroprevalence and risk factors associated with *Helicobacter pylori* infection among Medicine and Health Sciences students in Emirates International University in Sana'a city, Yemen. Also aims to correlate between *H. pylori* infection and some risk factors associated with infection.

Our results show that the majorities of university student in Emirates International university were males (66.3%; 135/300), aged 22 years or older (61.3%; 184 /300), with a mean age of 22.13± 2.96 years (range: 18–30). The majority of them were urban residents (85.7%; 287/300), whereas those coming from rural areas represented 4.3%. On the other hand, the majorities of Emirates university students in University were unemployed (84.0%), and unmarried (11.7%).

In our present study, the prevalence of *H. pylori* among medical students was 20.3% (61/300). These findings indicate that *H. pylori* infection is highly prevalent in Emirates International, Yemen, which is lower than in neighboring countries e.g., Iraq 55.8% Kuwait 81%, Jordan 82%, and Turkey 63% **Bashdar M. Hussen*et al.* (2013)**. (123)

The prevalence was higher in female than in male. Our study showed that *H. pylori* was positive in 61(20.3%) students, 17 (22.1%) of them were female and 44 (16.8%) were male. This was in contrary to study obtained in Iraq by **Bashdar M. Hussenet *al.* (2013)** and others found no gender-related difference in the prevalence of *H. pylori* infection. But there was no significant correlation between *H. pylori* infection and gender. This was an agreement with the result obtained in Egypt by **Manal*et al* (2007),** and other studies by **Huang *et al* (2004)**.in Malaysia. The results were agreeable to **Mirghani *et al* (2007).** And his workers in Sudan; they found no significant difference between gender and *H. pylori* infection. The difference of results may be due to the different in the lifestyle.

H. pylori infection was higher (22.4%) among students aged more than 22 years old than those students aged less than 22 (19.0%). This was in agreement with the results obtained by **Malik et al., 2007; Abu Ahmad et al., 2010),** these studies showed that the prevalence of infection increase with the age.

H. pylori infection was higher (25.0%) among Medicine students than Laboratory Medicine (23.7%) and Dentistry students (17.8%), and there was no significant difference found between them (P. value = 0.345). Also, the infection rate was higher (25.0%) among 3rd Level and 4th Level (23.7%) than the primary and secondary level, and there was no significant difference found between them.

Regarding the income level, most of the seropositive participants (20.9%) were from medium income social class (P value = 0.715). This was in agreement with the result obtained by **Bashdar M. Hussenet al**. (2013).

From 300 patients, 287 live in urban areas and 13 in rural areas. From the 300 patients who lived in Urban areas 58 (20.2%) had *H. pylori* while patients who lived in Rural areas 3 (23.1%) had *H. pylori*. (P-value =0.802). Moreover, several factors related to residence have been found to be associated with the infection. Indeed, living in a rural area **(Hanafi** et al., 2013), in crowded homes **Dorjiet al., 2014)** (128) and having contaminated sources of drinking water were risk factors for *H. pylori* infection.

Our study showed that University students who chewed khat and smoked had more *H. pylori* infection rates than those who consumed tea, coffee, Cola and had an infection in the family. On the other hand, bivariate analysis showed that none of the other studied factors were significant predictors with *H. pylori* infection rates among University Students. There are studies that viewed correlation between smoking and *H. pylori* positivity**, (A-Ameri and Alkadasi, 2013).** Also, there are studies that

disagree with our finding **(Tanih et al., 2010; Abo-Shadi et al., 2013).** WHO reported that no significant difference between positive and negative *H. pylori* cases and smoking status.

Our study showed that *H. pylori* infection was higher (57.4%) among medical students who had O blood group than A blood group (32.8%), B blood group (6.6%), and AB blood group (3.3%) but there is no significant difference found between them (P value=0.414); Our results are in agreement with the results of **Fayez Muhammad, 2015**, who found that subjects with AB type of blood groups are more resistant to infection with *H. pylori* while those with A, O type; B types are at high risk of the infection. Aspholm-Hurtig et al. (2004), showed that Lewis B antigen acts as a receptor for *H. pylori* attachment, which assists in microbial adhesion to the gastric epithelium and enhances bacterial colonization (in contrast to the current research). Other studies have revealed no association between the ABO blood groups and *H. pylori* serological status either in healthy (**Klaamas et al., 1994; Robertson et al. 2003)**, or in symptomatic subjects (**Moges et al., 2006; Wu et al. 2003)**.

The majorities of university students were drinking filtrated water (95.2%; 277/300) than Government Water (4.3%; 12/300) and well water (3.2%; 11/300). *H. pylori* infection rate was higher among medical students who are drinking well water (25.0%; 3/11.) than filtrated water (20.2%; 56/277). But there is no significant difference found between them (P value =0.907). Our result is in agreement with the result of **Dorjiet al., 2014)**, who found that contaminated sources of drinking water were a risk factor for *H. pylori* infection.

In conclusion, Data from our study showed that the prevalence of *H. pylori* infection is still high in our country. The prevalence was higher in female than in male, but we found no significant difference between gender and *H. pylori* infection. The difference of results may be due to the difference in the life style. Also *H. pylori*

infection was higher among Medicine students than Laboratory Medicine and Dentistry students. It also showed that there is a correlation between *H. pylori* infection and some risk factors associated with infection like chewing khat and smoking were more *H. pylori* infection rates than consumption of tea, coffee, Cola and Infection in family. The results of this study suggest that: students with AB type of blood groups are more resistant to infection with *H. pylori* while those with A, O types are more susceptible to this infection; B types are at high risk of the infection. Also, the infection rate was high in students how drinking well water then Government Water had.

Chapter Seven

7.SUMMARY AND CONCLUSION

In conclusion, data from our study showed that the prevalence of *H. pylori* infection is still high in our country. The prevalence was higher in female than in male, but we found no significant difference between gender and *H. pylori* infection. The difference of results may be due to the difference in the life style. Also, *H. pylori* infection was higher among Medicine students than Laboratory Medicine and Dentistry students. It also shows that there is a correlation between *H. pylori*

infection and some risk factors associated with infection like chewing khat and smoking were more *H. pylori* infection rates than consumption of tea, coffee, Cola and Infection in family. The results of this study suggest that: students with AB type of blood groups are more resistant to infection with *H. pylori* while those with A, O types are more susceptible to this infection; B types are at high risk of the infection. Also, the infection rate was high in students how drinking well water then Government Water had.

Chapter Eight

8.RECOMMENDATION

Based on this study results the following recommendations are to be considered:

1. Further study to detect exactly the prevalence of *H. pylori* in Yemen by increasing the target population (sample size) and using advanced techniques to ensure more accurate result.

2. Further study to detect the other Risk Factors for *Helicobacter pylori* Infection

3. Health education about the *H. pylori* infection, transmission and how to take precaution**.**

4. New vaccination strategies against *H. pylori* need to induce the immunity and decrease the prevalence.

Chapter Nine

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الملخص بالعربي

تمثل بكتريا الجرثومة المعدية (*الهيلكوبكتربيلوري*) مشكلة صحية عالمية لملايين الاشخاص خلال العام. حيث انها تسبب التهابات و تقرحات في المعدة و الاثني عشر مصاحبة لأعراض في الجهاز الهضمي العلوي, وقد صنفتها منظمة الصحة العالمية على انها السبب الاول لسرطان المعدة و تظهر الدراسات السابقة ان معدل انتشارها مرتفع و خاصة في البلدان النامية.

لذلك هدفت هذه الدراسة الى تحديد معدل انتشار هذه البكتيريا في طلاب كلية الطب و العلوم الطبية في الجامعة الإماراتية الدولية في العاصمة صنعاء – اليمن و كذلك تحديد العوامل المساعدة على الامراضية.

شملت الدراسة 300 طالب و طالبة من جميع التخصصات الطبية (الصيدلة السريرية, الطب المخبري, و الطب) من جميع المستويات تتراوح أعمارهم ما بين ال18 و ال30 سنة, منهم 199 من الذكور و 101 من الاناث. تم عمل لهم فحص الفصائل الدموية و الاجسام المضادة في عينة السيروم باستخدام كاست يحتوي على الانتيجينات لهئه البكتيريا.

ومن خلال النتائج التي حصلنا عليها من دراستنا اظهرت ان معدل انتشار هذه البكتريا كان بنسبة 20.3% لازال مرتفع في طلاب الجامعة وخاصة في صنعاء. وكانت الاصابة عند الذكور اكثر من الاناث وهذا يدل على الاختلاف بنمط المعيشة بين الطرفين. وهنالك علاقة ارتباط بين الاصابة بهذه البكتريا وبعض العوامل المساعدة على الاصابة مثل شرب المشروبات الغازية والاصابة في العائلة والتدخين وطبيعة السكن. مقارنةً مع الفصائل O وBوأظهرت الدراسة أن معدل الاصابة بالجرثومة أعلى عند الطلبة الذين فصيلة دمهم الدموية الاخرى وكذلك عند الطلبة الذين يشربون الماء من الآبار أكثر من الطلبة الذين يشربون المياه الأُخرى.

وقد اوصت الدراسة بما يلي:

1. عمل دراسة اخرى يكون فيها حجم العينة أكبر واستخدام أكثر من طريقة من اجل التأكد من دقة النتائج.
2. عمل دراسة اخرى لمعرفة العوامل الاخرى المساعدة على الاصابة.
3. التثقيف الصحي حول كيفية الاصابة بهذه البكتريا, طرق انتقالها و كيفية الوقاية منها.
4. استراتيجية جديدة للتطعيم ضد هذه البكتريا من اجل تحفيز الجهاز المناعي للوقاية منها وتقليل مدى انتشارها.

Appendix I

Republic of Yemen
Emirates International University
College of Medicine & Health Sciences
Section: - Medical Laboratories

الجمهورية اليمنية
الجامعة الإماراتية الولية
كلية الطب والعلوم الصحية
القسم: مختبرات طبية

Questionnaire

Prevalence and associated risk factors of *Helicobacter pylori* infection among Medicine and Health Sciences students in Emirates International University, Sana'a City, Yemen

معدل الانتشار والمخاطر المرتبطة بعدوى بكتيريا جرثومة المعدة (*الهليكوبكتربيلوري*) بين طلاب الطب والعلوم الصحية في الجامعة الإماراتية الدولية في مدينة صنعاء، اليمن

Questionnaire No: ……..….**Date :** / / **2023**

Informed consent

Dear student: we are a graduated research students in the Faculty of Medicine and Health Sciences –Emirates International University- department of Medical Laboratories. We are performing a Graduation project in the field of the Microbiology that aims to assess the prevalence and associated risk factors of *Helicobacter pylori* infection among Medicine and Health Sciences students in Emirates International University, Sana'a City, Yemen.

Participation in this study is voluntary and the information that we will take from you will be subject to strict confidentiality in accordance with the ethics of scientific research, and the identity of the participant will not be known to anyone. Thank you for giving us your time.

The consent

Do you agree to participant in the thesis?

- Yes, I agree to complete participation ( )
- No, I do not agree ( )

Prevalence and associated risk factors of *Helicobacter pylori* infection among Medicine and Health Sciences students in Emirates International University, Sana'a City, Yemen

Sample collection form

Student name: sample number:

Gender:	male ☐	female ☐	
Age:			
Residence:	Urban ☐	Rural ☐	
Marital status:	married ☐	not married ☐	
Department:	Medicine ☐	Medical laboratory ☐	Dentistry ☐

Pharmaceutical ☐

Level: first second ☐ third ☐ forth ☐

Pathological symptoms: Acidity ☐ Vomiting ☐ Diarrhea ☐ Anxious ☐

Abdominal pain ☐ Others: ☐

Occupation: Employed ☐ Unemployed ☐

Risk factors:

Income level: High ☐ Medium ☐ Low ☐

Infection in family: Yes ☐ No ☐

Father ☐ Mother ☐ Sister ☐ Brother ☐

Smoker: Yes ☐ No ☐

Coffee Drinking: Yes ☐ No ☐

Tea Drinking: Yes ☐ No ☐

Cola Drinking: Yes ☐ No ☐

Qat chewing: Yes ☐ No ☐

Water drinking: Government water ☐ Well water ☐ Filtered water ☐

Blood grouping: A ☐ B ☐ AB ☐ O ☐

H.pylori test: Positive ☐ Negative ☐

Signature:

الجمهورية اليمنية
الجامعة أ
كلية الطب والعلوم الصحية
القسم:- مختبرات طبية

Republic of Yemen
University A
College of Medicine & Health Sciences
Section: - Medical Laboratories

استبيان

Prevalence and associated risk factors of *Helicobacter pylori* infection among medical students in Emirates International University، Sana'a City، Yemen

معدل الانتشار والمخاطر المرتبطة بعدوى بكتيريا جرثومة المعدة (*الهليكوبكتربيلوري*) بين طلاب الطب في الجامعة الإماراتية الدولية في مدينة صنعاء، اليمن

رقم الاستبيان: تاريخ : / /2023

موافقة مسبقة

عزيز الطالب: نحن طلبة باحثين متخرجين في كلية العلوم الطبية ـ الجامعة الاماراتية العالمية ـ قسم المختبرات الطبية. نحن نقوم بتنفيذ مشروع التخرج في مجال علم الأحياء الدقيقة الذي يهدف إلى تقييم مدى انتشار وعوامل الخطر المرتبطة بعدوى (الهليكوبكتربيلوري) بين طلاب الطب في الجامعة الاماراتية الدولية في مدينة صنعاء؛ اليمن.
المشاركة في هذه الدراسة تطوعية والمعلومات سنأخذها منك ستخضع للسرية التامة وفقا لأخلاقيات البحث العلمي، ولن تكشف هوية المشارك لأي شخص. شكراً على إعطائنا وقتكم.

الموافقة

هل توافق على المشاركة في الرسالة:

- نعم، أوافق على المشاركة ( )
- لا، لا أوافق على المشاركة ( )

انتشار وعوامل الخطر المرتبطة بعدوى الملوية البوابية بين طلاب الطب في الجامعة الامارتية، مدينة صنعاء، اليمن

استمارة جمع العينات

اسم الطالب: رقم العينة:

الجنس: ☐ انثى ☐ ذكر

العمر:

السكن: ☐ حضري ☐ ريفي

الحالة الاجتماعية: ☐ متزوج ☐ غير متزوج

القسم: ☐ المختبرات الطبية ☐ طب بشري ☐ طب اسنان ☐ صيدلة

المستوى: الأول ☐ الثاني ☐ الثالث ☐ الرابع ☐

الأعراض المرضية: ☐ حموضة ☐ إسهال ☐ التقيؤ ☐ وجع بطن ☐ قلق أخر:

العمل: ☐ يعمل ☐ عاطل عن العمل

عوامل الخطر:

مستوى الدخل: ☐ عالي ☐ وسط ☐ قليل

العدوى في الأسرة: ☐ نعم ☐ لا

☐ الأب ☐ الأم ☐ أخ ☐ أخت

التدخين: ☐ نعم ☐ لا

شرب القهوة: ☐ نعم ☐ لا

شرب الشاي: ☐ نعم ☐ لا

شرب المشروبات الغازية: ☐ نعم ☐ لا

مضغ القات: نعم ☐ لا ☐

شرب الماء: ☐ المياه الحكومية ☐ مياه الابار ☐ مياه مصفاي

فصيلة الدم: ☐ O ☐ AB ☐ B ☐ A

H.pylori test: Positive ☐ Negative ☐

توقيع المريض: توقيع الطبيب:

Appendix II

ACON®

H. pylori Antibody Rapid Test Cassette (Serum/Plasma/Whole Blood) Package Insert

REF L031-10621 | English

A rapid test for the qualitative detection of antibodies to Helicobacter pylori (H. pylori) in whole blood, serum, or plasma
For professional in vitro diagnostic use only

INTENDED USE

The *H. pylori* Antibody Rapid Test Cassette (Serum/Plasma/Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to *H. pylori* in whole blood, serum, or plasma to aid in the diagnosis of *H. pylori* infection.

SUMMARY

H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis.[1,2] Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease. Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining.[3] Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods.[4,5] Individuals infected with *H. pylori* develop antibodies which correlate strongly with histologically confirmed *H. pylori* infection.[6,7,8]
The *H. pylori* Antibody Rapid Test Cassette (Serum/Plasma/Whole Blood) is a simple test that utilizes a combination of *H. pylori* antigen coated particles and anti-human IgG to qualitatively and selectively detect *H. pylori* antibodies in whole blood, serum, or plasma.

PRINCIPLE

The *H. pylori* Antibody Rapid Test Cassette (Serum/Plasma/Whole Blood) is a qualitative membrane based immunoassay for the detection of *H. pylori* antibodies in whole blood, serum, or plasma. In this test procedure, anti-human IgG is immobilized in the test line region of the test. After specimen is added to the specimen well of the Cassette, it reacts with *H. pylori* antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-human IgG. If the specimen contains *H. pylori* antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not

- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test result.

MATERIALS

Materials Provided

- Test Cassettes
- Package insert
- Disposable specimen droppers
- Buffers

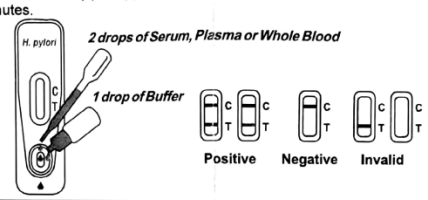
Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for plasma only)
- Timer

DIRECTIONS FOR USE

Allow the test, specimen, and buffer to reach room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible.
2. Place the test cassette on a flat surface. Hold the dropper vertically and **transfer 2 drops of serum, plasma, or whole blood** (approximately 50 µL) into the Specimen Well of the test cassette, then **add 1 drop of buffer** (approximately 40 µL) and start the timer. Avoid air bubbles. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes**. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)
POSITIVE:* Two distinct colored lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the

concentration of *H. pylori* antibodies present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct sample application to the specified specimen well.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The *H. pylori* Antibody Rapid Test Cassette (Serum/Plasma/Whole Blood) is for *in vitro* diagnostic use only. The test should be used for the detection of *H. pylori* antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in *H. pylori* antibody concentration can be determined by this qualitative test.
2. The *H. pylori* Antibody Rapid Test Cassette (Serum/Plasma/Whole Blood) will only indicate the presence of *H. pylori* antibodies in the specimen and should not be used as the sole criteria for the diagnosis of *H. pylori* infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *H. pylori* infection.

EXPECTED VALUES

The *H. pylori* Antibody Rapid Test Cassette (Serum/Plasma/Whole Blood) has been compared with ELISA method, demonstrating an overall accuracy of 97.2%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

6. Ansorg, R, Von Recklinghausen, G, Pomarius, R and Schmid, EN. *Evaluation of techniques for isolation, subcultivation and preservation of Helicobacter pylori.* J. Clin. Micro. (1991), 29:51-53.
7. Pronovost, AP, Rose, SL, Pawlak, J, Robin, H and Schneider, R. *Evaluation of a new immunodiagnostic assay for Helicobacter pylori antibody detection: Correlation with histopathological and microbiological results.* J. Clin. Micro. (1994), 32: 46-50.
8. Megraud, F, Bassens-Rabbe, MP, Denis, F, Belbouri, A and Hoa, DQ. *Seroepidemiology of Campylobacter pylori infection in various populations.* J. Clin. Micro. (1989), 27: 1870-3.

Index of Symbols

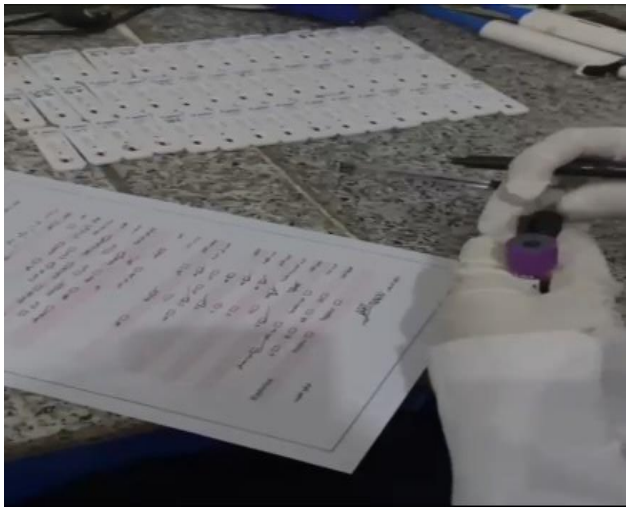
	Manufacturer	Σ	Tests per kit	30°C / 2°C	Store between 2-30°C
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Consult instructions for use	LOT	Lot Number	REF	Catalog #
EC REP	Authorized Representative				

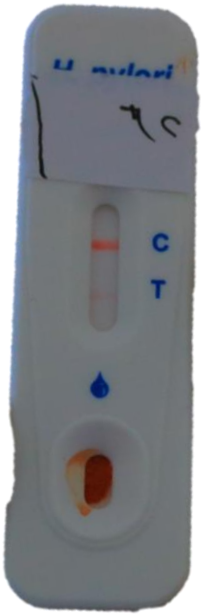
***ACON* Laboratories, Inc.**
10125 Mesa Rim Road,
San Diego, CA 92121, USA

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150957901
Effective date: 2017-11-17


REDMI NOTE 8
AI QUAD CAMERA




C
T


Anti-D IgG/IgM
BGD00010
DD-2110-1/4
2023 / 11
Anti-B Monoclonal
BGB00010
BB-2207-1/9
2026 / 03
Anti-A Monoclonal
BGA00010
AA-2207-1/9
2025 / 02
IVD


NO. 1 GLOVE
SLIDES
FIRST AID PLASTER

الجمهورية اليمنية

وزارة التعليم العالي والبحث العلمي

الجامعة الإماراتية الدولية

كلية الطب والعلوم الصحية

قسم الطب المخبري

معدل الانتشار المصلي وعوامل الخطر المرتبطة بعدوى الجرثومة المعدية (*الهيلكوبكتربيلوري*) بين طلاب الطب والعلوم الصحية في الجامعة الإماراتية الدولية، صنعاء-اليمن

مشروع تخرج مقدم لكلية الطب والعلوم الصحية كمتطلب للحصول على درجة البكالوريوس في الطب المخبري

مقدم من:

1-عبد الكريم احمد قصيلة
2-عبد الله على محمد قائد منصر
3-عائشة حبيب ناصر العنسي
4-علياء سامي قائد مطهر
5-خلود خالد حسن الرعيني
6-مروة عبد الكريم غانم الدبعي
7-زياد عبدالقوي على محسن الضبياني
8-زيدان عبد الهادي السروري

تحت إشراف

الدكتور. طه عبد العزيز سعيد النصاري

أستاذ مساعد في علم الاحياء الدقيقة والمناعة الطبية

كلية العلوم الطبية

2023-1445