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THE PREVALENCE OF HELICOBACTER PYLORI INFECTION IN PATIENTS WITH DYSPEPSIA IN THE CENTRAL RURAL REGION OF SAUDI ARABIA

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Abstract:

Background: *Helicobacter pylori (H. pylori) is one of the strongest risk factors for gastric cancer, and infects more than half of the world population. Globally, the prevalence of H. pylori in patients with an ulcer or non-ulcer dyspepsia is high. Similarly, Kingdom of Saudi Arabia (KSA) is suffering from a challenging prevalence of H. pylori in patients with dyspepsia. In south-west Saudi Arabia, the prevalence of H. pylori infection has been reported to be 54.9%. This paper determines the prevalence of H. pylori infection in patients with dyspepsia in the central rural region of KSA. This study will assist in formulating appropriate healthcare policies at the national level to eradicate H. pylori from the KSA population, relieving sufferers of cumbersome upper abdominal discomfort.*

Methodology: *This prospective study was conducted in the period from May 2016 to November 2017. A total of 686 patients were included. The authors utilized the ROME IV criteria for dyspepsia to screen patients who might have an H.pylori infection, and confirmed the infection using the urea breath test. This prospective study was conducted in the outpatient section of the gastroenterology clinic at Prince Sattam bin Abulaziz University (PSAU) and King Khaled Hospital (KKH). The primary aim of this study was to investigate the frequency of H. pylori infection in patients with dyspepsia in the central rural region of Saudi Arabia.*

Results: *686 patients fulfilled the ROME IV criteria for dyspepsia and went on to undergo urea breath testing. The male to female ratio of patients was 1.25:1. 39.5% of all patients who were ROME IV positive for dyspepsia, turned out to have an H. pylori infection.*

Conclusions: *The results warrant an evaluation of risk factors associated with the high prevalence of H. pylori in the urban population of KSA in order to reduce upper GIT discomfort and the incidence of gastric cancer. Therefore, it is recommended that further studies be carried out with a specific focus on evaluating the risk factors associated with H. pylori infection in the urban population of KSA.*

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INTRODUCTION

Helicobacter pylorus (H. pylori) is one of the strongest risk factors of gastric cancer, and infects more than half the world's population [1]. It is a ubiquitous organism, found to be positive in 4.4 billion individuals globally. Although the prevalence of H. pylori infection is highly variable across the world, it is reported to be as high as 80% or more in developing countries, due to low socio-economic status and poor hygiene [2, 3]. H. pylori is responsible for more than 90% and 80% duodenal and gastric ulcers, respectively [4]. It lives and grows in the gastrointestinal tract (GIT), causing local inflammation resulting in chronic gastritis, peptic ulcer disease (PUD), intestinal metaplasia and gastric adenocarcinoma [1]. Unfortunately, it is the most common cause of infection-related cancers, posing a real burden on the global healthcare system [5]. Similarly, the Kingdom of Saudi Arabia (KSA) is not free of H. pylori infection. In patients with different biopsy-proven conditions of GIT, such as gastritis, PUD and gastric cancer, the prevalence of H. pylori infection in KSA is 71.33%, with a slight female predominance [6].

H. pylori is a gram-negative microaerophilic flagellated bacterium that infects the epithelial lining of the GIT, with the stomach and duodenum being the most common sites. The pathogenesis of H. pylori infection depends upon the host and bacterial and environmental factors. The organism survives by neutralizing the hostile acidic environment of the stomach using the urease enzyme, which hydrolyzes urea into ammonia [7]. Motile flagella help the organism to move toward gastric epithelial cells, interacting with host cell receptors through bacterial adhesions. Subsequently, H. pylori releases several proteins and toxins, while the host activates its innate immunity through cytokines, leading to clinical manifestation of gastritis and ulcers [7]. Having a high prevalence across the world, H. pylori eradication is mandatory in order to prevent atrophic gastritis, PUD and gastric cancer. Unfortunately, therapies to eradicate H. pylori are becoming ineffective due to the emergence of antibiotic resistance [8]. In this context, bacterial resistance against Metronidazole and Clarithromycin has reached an alarming point [9, 10]. However, triple and quadruple eradication therapies are still effective against H. pylori.

Dyspepsia refers to acute, chronic or recurrent discomfort, bloating and nausea originating from the upper abdomen [11]. Specifically, it presents with postprandial fullness, early satiation and epigastric pain or a burning sensation [12]. It affects 15% of the adult population, and up to 80% of the general population in KSA experiences dyspeptic symptoms at some point in their life [13, 14]. Fortunately, most people suffering from dyspepsia do not have serious problems or any organic cause. Important etiologies of dyspepsia include food or drug intolerance, functional dyspepsia, GIT dysfunction, H. pylori infection, pancreatic or biliary tract disease, diabetes mellitus, thyroid disease and malignancies [13]. In KSA, H. pylori, smoking and the use of painkillers are reported to be risk factors for dyspepsia [15].

Globally, the prevalence of H. pylori in patients with ulcer or non-ulcer dyspepsia is high. Similarly, KSA is suffering from a challenging prevalence of H. pylori in patients with dyspepsia [16]. In south-west Saudi Arabia, the prevalence of H. pylori infection has been reported to be 54.9% [17]. In Taif, 66.1% of the city's population suffers from non-ulcer dyspepsia, with a slight female predominance [15]. Moreover, the prevalence of H. pylori has been reported to be higher in younger age groups of women [18]. In fact, KSA is considered to be hyper-endemic for H. pylori infection. Unfortunately, studies conducted in the cities of Jeddah and Riyadh have also reported a high prevalence of H. pylori infection among children [19]. The high prevalence of H. pylori infection in children indicates a heavy burden on the healthcare services, and complications of this infection may lead to lethal outcomes in the form of atrophic gastritis, PUD and cancer, especially if left undiagnosed and untreated.

In KSA, no studies have been conducted in rural regions on the prevalence of H. pylori infection. Therefore, there is an urgent need for studies to be conducted in the rural areas of KSA, as various risk factors such as poor socio-economic status, smoking, lack of healthcare facilities, and poor hygiene exist in these areas, which may affect the actual prevalence in the country [20]. This paper determines the prevalence of H. pylori infection in patients with dyspepsia in the central rural region of KSA. This study will help to formulate appropriate healthcare policies at the national level to eradicate H. pylori from the KSA population, relieving sufferers of cumbersome upper abdominal discomfort.

METHODOLOGY:

The primary aim of this study was to investigate the frequency of H. pylori infection in patients with dyspepsia in the central rural region of Saudi Arabia. This study was a prospective study conducted in the period from May 2016 to November 2017.

The authors utilized the already validated ROME IV criteria [21] for dyspepsia to screen patients who may have an H. pylori infection, and confirmed the infection using the urea breath test. The study was conducted in the outpatient section of the gastroenterology clinic at Prince Sattam bin Abulaziz University (PSAU) and King Khaled Hospital (KKH), which is an associated hospital of PSAU. It serves a population of over 600,000 in the region of Al-Kharj. Patients who presented with symptoms of dyspepsia had their files reviewed by the authors. There was a logistical challenge of using the urea breath test to objectively diagnose patients who were screened with the ROME IV criteria, as neither KKH nor PSAU could make provisions for this specialized test. Hence, patients who were deemed likely to have dyspepsia, based on the ROME IV criteria, were referred to the Al-Taawin Medical Clinic (ATMC) – a private clinic, for the urea breath test to confirm H. pylori infection.

The gold standard for diagnosis of H. pylori infection is by polymerase chain reaction; however this is an invasive method that relies on the use of endoscopy to obtain samples for DNA analysis [22]. PCR not only detects the H. pylori bacterium, but characterizes genes which confer pathogenicity as well as mutations which contribute to antimicrobial resistance of the bacterium. The sensitivity and specificity of PCR has been reported to be 100% [23]. In contrast, the urea breath test has a reported sensitivity of 75%-100% and a reported specificity of 77%-100% [22]. Despite the superiority of PCR as a diagnostic test for H. pylori infection, we chose to adopt the urea breath test in view of its inexpensive and non-invasive nature.

Statistical power analysis required that this prospective study recruit at least 382 patients keeping 5% as margin error and confidence interval (CI) of 95%, using the Clopper-Pearson formula. The recruitment of patients was mediated through non-probability convenience sampling. A total of 800 patients were recruited for this study. Inclusion and exclusion criteria were strictly adhered to by the authors to ensure the integrity of the sample size, as well as the credibility of the data collected. The inclusion criteria were as follows – male and female genders, all ages, provision of informed consent, living in Saudi Arabia who present with dyspepsia symptoms. The exclusion criteria were as follows – known current H. pylori infection, currently on antibiotic therapy, recent antibiotic therapy in the preceding 4 weeks, failed ROME IV criteria for dyspepsia, known gastric bacterial overgrowth, known small intestinal bacterial overgrowth, current hospitalization and minors who failed to provide legal guardian consent to take part in the study.

The data collected by the authors was analyzed anonymously, and the confidentiality of all participants was respected. Collated data were entered manually by the authors independently into Microsoft Excel, and SPSS 22.0 was used for statistical analysis. Cross-tabulation and Fisher's test were performed to show the statistical significance of urea breath test among males and females. Fisher's exact test was performed to establish statistical significance of nationality and urea breath test. The Mann Whitney test was performed to evaluate statistical significant between age and a positive urea breath test. The statistical significance was deemed by the authors to be 0.05 or less.

RESULTS:

A total of 800 patients presented to PSAU and KKH between May 2016 and November 2017 with symptoms suggestive of dyspepsia. Of these, 686 (86%) fulfilled the ROME IV criteria for dyspepsia and went on to undergo urea breath testing at ATMC. The demographic breakdown of these 686 patients can be referenced in Table 1 and 2. The male to female ratio of these 686 patients was 1.25:1. 69% of the ROME IV positive patients were of Saudi Arabian nationality. Of the 686 patients who were ROME IV positive, 271 tested positive for the urea breath test. In other words, 39.5% of all patients who were ROME IV positive for dyspepsia turned out to have an H. pylori infection.

Based on this, the authors concluded that the prevalence of H. pylori in patients with dyspepsia in the Al-Kharj region was 39.5%. Taking gender into account, the prevalence of H. pylori in males with dyspepsia was 40.3%, whereas it was 38.5% for females. However, this difference was not significant statistically (p=0.068).

The mean age of all 686 patients was 32.68 years. The mean ages for those who tested positive and negative for the urea breath test were 32.5 and 32.79 respectively. However, there was no statistically significant relationship between age and a positive urea breath test (p>0.05). The exact age breakdown of all 686 patients can be referenced in Figure 1 below.

Regarding the nationality, 69.1% were Saudi Arabian, while 30.9% were non-Saudi participants. For patients who had a proven H. pylori infection through a positive urea breath test, 67.15% were Saudi Arabian. For patients who had a negative urea breath test, 70.3% were Saudi Arabian. A cross-tabulation showed that Saudi nationals were less likely to have a positive urea breath test. However, statistically this relationship was not significant (p=0.398).

DISCUSSION:

From a global perspective, the present study reveals a high prevalence of H. pylori infection (39.5%) among patients with dyspepsia living in central rural region of KSA. However, the prevalence of H. pylori infection among dyspeptic patients is surprisingly low, compared to that previously reported in urban areas and cities in KSA. Globally, the prevalence of uninvestigated dyspepsia ranges from 7% to 45% [24] while the reported prevalence of H. pylori infection among uninvestigated dyspeptic patients is 38.4% [25]. However, the prevalence of H. pylori infection in patients with functional dyspepsia, or non-ulcer dyspepsia, is controversial due to conflicting results [26]. Recently in Poland, a study evaluated 148 patients with dyspepsia using urea breath test, reporting a prevalence of 35.8% of H. pylori infection [27]. In Turkey, a cross sectional study was conducted including 4622 random participants (irrespective of dyspeptic symptoms) in order to determine the prevalence of H. pylori infection among adult population. ^{13}C-urea breath test was performed to identify the H. pylori infection and reported a high prevalence of 82.5% [28].

A varied prevalence of H. pylori infection among dyspeptic patients in different regions of KSA has been reported. A cross-sectional study was conducted at Riyadh Armed Forces Hospital including 352 consecutive patients (aged 17-69 years) with dyspepsia that were referred for gastroscopy to the to determine the prevalence of H. pylori infection [29]. Typical gram-negative bacteria were identified in 61.64% of patients, with the highest incidence of H. pylori infection in patients with duodenal ulcer. This shows that the prevalence of H. pylori in dyspeptic patients in the present study is significantly low. Similarly, a cross sectional study was conducted in Makkah City, KSA including 314 school students presenting with recurrent pain abdomen [30]. Urea Breath Test was used to identify H. pylori infection, reporting positive test in 27.4% school students with pain abdomen. This prevalence of H. pylori is low as compared to other cities of KSA such as Riyadh [28]. In another prospective study, 208 patients (median age 38.2 years) with dyspepsia underwent endoscopic gastric biopsy and a rapid urease test at Asir Central Hospital, Abha (southern Saudi Arabia) [31]. They reported that 82.2% of patients were positive for H. pylori – a very high prevalence compared to that reported in the present study.

In other gulf countries, the prevalence of H. pylori infection among patients with dyspepsia is also varied. In Kuwait, a prospective study was conducted including 362 patients with dyspepsia, to determine the prevalence of H. pylori infection [32]. Using the 13C-Urea breath test, they reported a positive H. pylori rate in 42.6% of Kuwaitis, with slight male predominance. Similarly, a retrospective study of 366 gastric biopsies was conducted to determine the prevalence of H. pylori infection (age: 47.87±19 years males, and 45.21±17.56 years females) in patients presenting with gastritis at the College of Medicine and Health Sciences, Sultan Qaboos University, Oman [33]. The authors reported a prevalence of H. pylori in 30.05% of patients, with female predominance; the highest incidence was reported to be in the age group of 26-44 years. A retrospective study was conducted in the United Arab Emirates (UAE) which included 480 patients with a variety of symptoms, i.e. dyspepsia, heartburn and abdomen pain. They reported H. pylori infection in 100% cases, which were tested by either a urea breath test, H. pylori stool antigen, or gastric biopsy. Hence, in Oman the prevalence of H. pylori is lower, while in UAE and Kuwait it is high, compared to that reported in the present study.

In previous studies conducted in KSA, H. pylori infection has been reported to be predominant among females [6, 15]. In contrast, the present study reports a higher rate of H. pylori infection in males, although the difference is not statistically significant. Similarly, another study supports the male predominance [32]. The strengths of the study

include prospective study design, a valid sample size, and being the pioneer study on the given subject, among the patients in rural Saudi Arabia. The limitations of the study include the use of urea breath test only, as the addition of histological demonstration of H. pylori might have improved the results.

CONCLUSION:

From global perspective, prevalence of H. pylori is high in the rural regions of KSA. Comparing with the prevalence of H. pylori reported in previous studies that were conducted in urban areas of the KSA, prevalence of H. pylori is lower in rural areas like central rural region of KSA. Overall, high prevalence of H. pylori infection among KSA population warrants the evaluation and prevention of certain risk factors. Therefore, it is recommended that further studies should be carried out with a specific focus on evaluating the risk factors associated with H. pylori infection in the both urban and rural population of KSA.

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Tables and figures

Table1:Demographic breakdown of data

Table 1: Demographic breakdown of data

	Donor project Budget figures in MTEF	**Frequency**	**Percentage %**
Gender	**Male**	382	55.7
	Female	304	44.3
Nationality	**Saudi**	474	69.1
	Non- Saudi	212	30.9
H Pylori Test Result	**Positive**	271	39.5
	Negative	415	60.5

Table 2: Age, Gender and Nationality In relation to H .pylori test results

Table 2: Age, Gender and Nationality In relation to H. pylori test results					
			Result		**Total**
			Positive	**Negative**	
Age		Mean	32.50	32.79	32.68
		N	271	413	684
		Std. Deviation	11.676	11.819	11.755
		P value	0.696	-	-
A Mann Whitney test showed that there was no statistically significant correlation of the result with age (p>0.05).					
Gender	**Male**	Count	154	228	382
		% within G	40.3%	59.7%	100.0%
	Female	Count	117	187	304
		% within G	38.5%	61.5%	100.0%
	Total	Count	271	415	686
		% within G	39.5%	60.5%	100.0%
A cross-tabulation showed that males are more likely to have positive results. However, Fisher's exact test showed this relation was not statistically significant (p=0.638).					
Nationality	**Saudi**	Count	182	292	474
		% within N	38.4%	61.6%	100.0%
	Other	Count	89	123	212
		% within N	42.0%	58.0%	100.0%
	Total	Count	271	415	686
		% within N	39.5%	60.5%	100.0%
A cross-tabulation showed Saudi nationals are less likely to have positive results. However, Fisher's exact test showed this relation was not statistically significant (p=0.398).					

Figure 1: Age Categorization (Years)