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Validation and regulatory acceptance on novel toxicological test methods

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ABSTRACT— To study the prevalence of Helicobacter Pylori (H. pylori) infection, according to ethnicity, gender and endoscopic findings among the patients underwent the oesophago-gastro-duodenoscopes (OGDS) at gastroenterology endoscopy unit, Hospital Serdang, Selangor, Malaysia. The database of all whom underwent OGDS at the gastroenterology endoscopy unit, Hospital Serdang from 1st August 2010 to 31st July 2012 was collected and assessed, retrospectively. A total of 924 patients who underwent OGDS were analyzed for the H. pylori infection by using Campylobacter-like organism (CLO) test. 130 (14.07%) tested positive, and their data were further studied according to gender, ethnicity, age group, initial indication for OGDS and endoscopic finding. The prevalence rate among males was 15.15% (70/462), while it was 12.99% (60/462) among females. In terms of ethnics, H. pylori infection was commonly found among Indian and Chinese with prevalence rate of 25.13% (50/199) and 17.41% (51/293) respectively. These figures are significantly higher than the 6.01% (25/416) for Malays. The age group (31-50 years old) had the highest prevalence rate of H. Pylori infection, which is of 18.55% (41/221). No significant difference was observed among initial indications for OGDS. Erosions were the commonest finding in H. pylori positive group with rate of 51.54% (67/130). However, erosions were not uncommon in H. pylori negative group as well with the rate of 48.61% (386/794). H. pylori infection rate among Malaysians was generally low, with the highest rate in Indians, followed by Chinese and relatively low in Malays. No significant difference between the prevalence rate of H. pylori infection in male and that in female was found. Erosions were equally common in either H. pylorus positive or H. pylori negative group.

KEYWORDS: Oesophago-gastro-duodenoscopes (OGDS), Helicobacter Pylori, Malaysia.

1. INTRODUCTION

Helicobacter pylori (H. pylori) is a common transmissible bacterial human pathogen. H. pylori infection is well recognized as a major causative organism for peptic ulcer disease and gastric cancer in human beings [1], [2]. The prevalence of H. pylori infection varies worldwide being lower in developed countries than of many developing countries [3], [4]. There is great difference in its prevalence among different ethnic groups, even within the same country [5]. Malaysia is a multiracial country, composed of three major ethnic groups, namely Malay, Chinese and Indian.1 Each ethnic group has their own unique lifestyle, religious and cultural practice. Quite a number of studies conducted in Malaysia have consistently shown a higher prevalence of H. pylori infection among non-Malays than in Malays [6- 8]. Few countries reported declines in H. pylori infection over the past few decades. Nakajima et al. reported a drop in H. pylori seroprevalence among the subjects undergoing annual health checks from 70.5% to 52.7% over a 17-year period [9]. While a U.S. study had concluded the declining endoscopic H. pylori prevalence in their rural locality over the past decade [10]. Low socioeconomic status associated with high-density living and inferior hygienic conditions are believed to be main factors causing the transmission of H. pylori. A UK study found that the ethnic origin was significantly associated with H. pylori infection, in which the rate for non-UK birth (69%) was markedly higher if compared with (40%) UK birth [1], [11]. In Israel, the H. pylori prevalence rate among Arab Isrealis living in three villages in northern Israel coherent with the socioeconomic status of the

village, although they are from the same ethnic group [12]. H. pylori infection is thought to be commoner in elders. Several epidemiologic studies on elderly people, with a mean age of approximately 70 years, reported a prevalence of nearly 60% in asymptomatic subjects [13], [14] and more than 70% among the most elderly patients with gastrointestinal diseases [15], [16]. The H. pylori infection transmission mechanism is oral-oral or fecal-oral, as well as through contaminated water [17] because of poor socioeconomic and hygienic conditions H. pylori is strongly linked to the development of chronic gastritis, and peptic ulcer disease. Moreover, H. pylori is well recognized as a class I carcinogen by the International Agency for Research on Cancer (IARC) because chronic gastric mucosal inflammation and atrophy can further bring to malignant transformation [18], [19]. The aim of this study is to elucidate the prevalence of H. pylori infection, according to ethnicity, gender, age group, initial indication for OGDS and endoscopic finding in 924 patients attending oesophago-gastro-duodenoscopes (OGDS) at gastroenterology endoscopy unit, Hospital Serdang.

2. PATIENTS AND METHODS

This study was approved by the Ethics Committee of both Universiti Putra Malaysia and Hospital Serdang (Ministry of Health). The Demographic variables (the patient's gender/age/race), the indication for OGDS, the endoscopic finding, and the result of Rapid Urease Test for H. pylori Infection were collected from the gastroenterology endoscopy unit, Hospital Serdang, retrospectively. All endoscopies were performed by experienced endoscopists using the Olympus GIF video endoscope. Campylobacter-like organism (CLO) test was used as a Rapid Urease Test for H. pylori infection. Endoscopic mucosal biopsies from stomach (2 samples from the antrum, and 2 samples from the corpus) were inoculated into the medium which contained urea and phenol red, a dye that turns pink in a pH of 6.0 or greater (The pH will rise above 6.0 when HP presents as H. pylori metabolizes urea to ammonia). The test was read at 24 H. A total of 924 patients that attended for OGDS with CLO test at the gastroenterology endoscopy unit, Hospital Serdang during the period from 1st August 2010 till 31st July 2012 were studied. All of the patients were categorized to age group as $\leq$ 30, 31-50, 51-70, and $\geq$ 71 years old of age Ethnic group were arranged as Malay, Chinese, Indian and others (Sikh, Bumiputra including both Sabahan and Sarawakian, and foreigners). Indications for OGDS were grouped to dyspepsia (epigastric pain/bloatness/reflux syndrome), anemia and others (to rule out malignancy/to assess portal hypertension/to assess ulcer healing/for endoscopic procedure). OGDS findings were subdivided into erosions (oesophagitis/gastritis/duodenitis), ulcer disease (esophageal/ gastric/duodenal ulcer), growth lesion (polyp/tumour/malignancy), normal and other findings (portal hypertensive gastropathy/oesophageal or fundal varices/angiodysplasia/hiatus hernia). All the data collected above were further compared between those with CLO test positive and those with CLO test negative.

3. RESULTS

The 924 patients comprised 416 Malays, 293 Chinese, 199 Indians and 16 others were analyzed for the H. pylori infection by using CLO test. Among 924 patients, 130 (14.07%) tested positive for CLO test, and their data were subsequently studied according to gender, ethnicity, initial indication for OGDS and endoscopic finding. These consisted of 70 males and 60 females.

Table 1: H. pylori infection rates in relation to gender

Gender	Total	*H. pylori* positive (%)	*H. pylori* negative (%)	Significance
Male	462	70/462 (15.15)	392/462 (84.85)	P >0.05, not significant
Female	462	60/462 (12.99)	402/462 (87.01)	

4. CONCLUSION

H. pylori infection rate among Malaysians is low and declining. H. pylori infection prevalence rates vary among ethnic groups in Malaysia, being highest in Indians followed by Chinese and lowest in Malays. In this study, we found that the age group 31-50 years old of age has the highest prevalence rate of H. pylori infection. Gender is not a significant risk factor for H. pylori infection. No significant difference between prevalence rate of either erosion or ulcer disease in both H. pylori positive group and H. pylori negative group was discovered. The limitations of this study include insufficient details of the patients with regards to drugs consumed and several endoscopists were involved in reporting the endoscopic findings. More studies are required to obtain a clearer understanding of the role of other important co-factors affecting risk such as dietary factors, co morbidities, co medication and host genetic predisposition in the Malaysian population.

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