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Research Article

Test Preferences for the Diagnosis of Helicobacter pylori Infection in Developing Countries: a Systematic Review

Elmas Pinar Kahraman*, İmdat Kılbaş, and İhsan Hakkı Çiftci

Department of Medical Microbiology, Sakarya University, Turkey

***Corresponding author**

Elmas Pınar Kahraman, Department of Microbiology, Sakarya University, Korucuk Neighborhood, Konuralp Boulevard, 81/1 Sakarya, Turkey, Tel: 90-552-239-5794; Email: elmas.kahraman@ogr.sakarya.edu.tr

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Keywords

- Helicobacter pylori/H. pylori/HP; Diagnosis/ identification; Clinical test; Developing countries

Abstract

Study Aims: The purpose of this study was to evaluate the test preferences for Helicobacter pylori detection in developing countries.

Patients and methods: A systematic search of PubMed, Web of Science, EMBASE, ClinicalTrials.Gov, OVID, and the Cochran Library databases was performed to identify relevant review articles, editorials, and original studies published in the English language using the following.

Results: Sufficient information was available to pool data from 67 randomized trials for meta-analyses. Non-invasive diagnostic methods, including the stool antigen test, were used in three studies to determine H. pylori infection. Another 64 (96%) studies were designed with invasive tests to address diagnoses related to H. pylori infection. The enzyme-linked immunosorbent assay method was used in 21 (32.3%) studies. Diagnostic processes in another 44 studies were performed with endoscopic biopsy specimens. Culture results were reported only in two studies with histopathology, and molecular test results were discussed in six studies, whereas histopathology results were given in only six studies. A significant difference in H. pylori positivity was found among countries.

Conclusions: In light of these results, it will be important to address the following question: Which test is best for H. pylori diagnosis in developing countries? This is a complicated question, but changing H. pylori testing policies in developing countries is urgently needed to grant better access to service. Future studies should focus on clarifying which test is more appropriate for patients with an H. pylori infection while taking into account clinical characteristics, pre-infection status, and availability and cost.

INTRODUCTION

Helicobacter pylori infection is one of the most common chronic infections worldwide [1]. It is also responsible for deaths from peptic ulcers. Moreover, H. pylori-related gastric cancer causes more than one million deaths per year worldwide [2], making it a serious public health concern. The main burden of this disease in developing countries can be ascribed to overcrowding and poor hygiene. Infection due to H. pylori is common in developing nations, and basic research continues to expand our knowledge but presents new challenges. The prevalence of infection ranges from 20% in developed/industrialized countries to more than 90% in the developing world [3- 5]. Helicobacter pylori can be diagnosed by non-invasive or invasive methods. The choice of the appropriate diagnostic technique may vary depending on the clinical setting, laboratory infrastructure, and the presence of specialists. Non-invasive tests include the 13C-urea breath test (UBT), stool antigen test (SAT), and serology. The UBT is a readily available test with an accuracy rate of >97% [6,7]. The SAT is reported to have a sensitivity of 76–81% and a specificity of 80–93% [8,9]. Both the UBT and SAT can be used for infection follow-up after eradication therapy because of their ability to detect an active infection [10].

Serological tests are widely used and inexpensive; however, the diagnostic accuracy is variable, and only validated IgG tests should be used [11]. Positive serology may indicate a past infection and thus cannot be used for infection follow-up after eradication [12,13]. Moreover, serology is helpful in patients with a low bacterial load (e.g., use of antimicrobial or antisecretory agents, bleeding, and the presence of malignant lesions) and therefore remains the only type of test that is not affected by local changes in the stomach [14].

Invasive techniques requiring endoscopy are usually preferred in patients with a higher prevalence of gastrointestinal disorders, as well as for their superiority in analyzing the severity of gastritis and detecting premalignant lesions [11].

The purpose of this article is to review the most important results of various established diagnostic tests and to discuss new perspectives on managing this complex and interesting infection in developing countries.

Patients and methods

Our study period was taken into account between Januay 1998 to December 2016. This Meta analysis was carried out in according to the Declaration of Helsinki [15].

Literature search

A systematic search of PubMed, Web of Science, EMBASE, ClinicalTrials.Gov, OVID and the Cochran Library databases were made to identify relevant review articles, editorials, and original studies published using the following key words: Helicobacter pylori/H. pylori/HP, diagnosis/identification, clinical test, developing countries [16]. (Such as Korea, Turkey, México, etc.) in English language. Data were independently extracted from each study by two of the authors working independently and using a predefined form; disagreements were resolved by discussion with other investigator.

Inclusion and exclusion criteria

Published reports were selected for inclusion in the systematic review according to the following criteria: English language publication; studies of testing positive for the presence of H. pylori prior to treatment and eradication of the infection documented by histopathology, culture, ELISA, stool antigen, carbon (C) 14 urea breath test (UBT) or 13 C-UBT and molecular tests. Studies not meeting these criteria, those without data for retrieval, and duplicate publications were excluded from the meta-analysis. (Figure1)

Quality assessment

The quality of included studies was assessed using the Risk of Bias table outlined in the Cochrane Reviewer's Handbook 5.0.1 [17].

Data extraction

The data extracted from each study included the following: general article information (author, publication date, journal name, etc.); data to calculate the value of the total effect (positivity, negativity, etc.); clinical heterogeneity of the study (sex, age, concurrent disease, etc.); methodological heterogeneity of the study (design type, randomized, blinded, follow-up, quantity of and processing methods for specimens, and methodology). Studies were reviewed and data extracted by two independent reviewers with knowledge of clinical medicine, epidemiology, and medical statistics, with discrepancies resolved through discussion. The proportional distributions of positive results were made for the country, year and method. This process for data extraction was repeated to ensure accuracy.

Statistical Analysis

Statistical analyses were performed with SPSS 21.0 (SPSS Inc., Chicago, IL, USA) Results were given as mean ± standard deviation, and frequencies for categorical variables. Comparisons were performed with one-way ANOVA test, and two-tailed and a p value of <0.05 was accepted as statistically significant.

RESULTS

Study Choice

There were 1174 publications retrieved from the search and 1063 were excluded because they were not randomized trials, had inappropriate comparators, or both (Figure 1). Of the 111 potential studies, 44 were excluded because they have inadaptable data, contained ineligible comparators, and were duplicate samples. There were 67 trials included with 114604 patients that met eligibility criteria and were included in this systematic review. Sufficient information was available to pool data from 67 randomized trials for meta-analyses.

The selection of study included in the Meta analysis is described in a flow chart in (Figure 1). Included studies were divided into 11 groups according to the country, 5 groups according to test and 3 groups according to years. The distributions of incorporated study were as follow: 5 Argentina (n=2262), 7 Brazil (n=5685), 5 China (n=3752), 6 India (n=1491), 5 Indonesia (n=4037), 12 Iran (n=6586), 5 Korea (n=76105), 5 Malaysia (n=1664), 1 Rusia (n=3149), 5 South Africa (n=966) and 11 Turkey (n=8907). When the H. pylori diagnoses of the 68384 (59,66%) patient were evaluated,39,2±12,6 Argentina, 39,7±20,6 Brazil, 56,4±10,1 China, 45,8±25,3 India, 39,6±27,1 Indonesia, 45,6±17,2 Iran, 31,2±14,9 Malaysia, 87,1±NA Rusia, 61,7±17,4 South Africa, 47,9±18,1 South Korea and 55,2±17,7 Turkey. (Figure 2) There was statistically significant difference among the countries for H. pylori positivity (p<.001).

Outcomes

In three studies non-invasive diagnostic methods such as stool antigen were used to determine H. pylori infection. In a study conducted in Brazil, 363 eligible individuals were studied with 13C-UBT. The prevalence rate of H. pylori infection was 63.4% (95%CI 59.3%–69.3%) [24]. In another prospective study, fecal samples of 59 dyspeptic patients who underwent endoscopy was evaluated for H. pylori gaita antigen. In 22 (91.7%) of the 59 patients who participated in this study, H. pylori stool antigen test was found to be positive. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy were 91.7%, 100%, 100%, 94.6% and 96.6%, respectively [30]. Other 64 (96%) studies were designed with invasive tests to address diagnosis related to H. pylori infections. The ELISA method was used 21 (32%) studies, diagnostic process in other 44 (68%) study were performed with endoscopic biopsy specimens. When used tests detailed; culture results were reported only two studies with histopathology, and molecular test results were discussed in 6 study, histopathology results were given with 6 study. Histological examination of 90 patients who underwent rapid urease test showed H. pylori in 67.8% (n=61) of the biopsy specimens. In this study, the sensitivity and specificity of urease test were found as 65.9% and 100%, respectively [84]. The antral biopsies taken from 1298 patients in a retrospective study in Turkey; Helicobacter pylori were positive in 918 (71%) patients, in 379 (29%) patientswas found to be negative. The prevalence of males and females was similar. The frequency of Helicobacter pylori was found to be 73.2%, 71.5%, 68.6% and 70.4% in the 14-30 years, 31-45 years, 46-60 years, 61-88 age groups, respectively [34]. In a study conducted with a total of 1022 patients in China, 71.7% of patients were found positive for H. pylori by ELISA test. Helicobacter pylori infection was equally common in all age groups [48]. In a study with UBT in Iran, 60 children who met the Rome III criteria of dyspepsia were included. Of the 60 patients, 28 (46.7%) were found positive H. pylori and 32 (53.3%) negative results. Negative pathology was detected in 12 (42.9%) patients. The sensitivity and specificity of C13-UBT for detection of H. pylori infection were 76.2% and 69.2%, respectively [73].

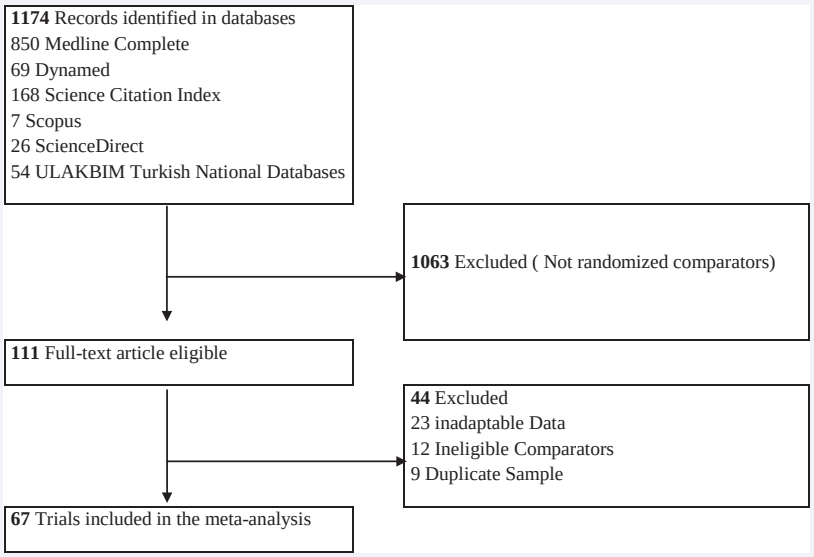

Figure 1 Flowchart diagram of the selection of included studies.

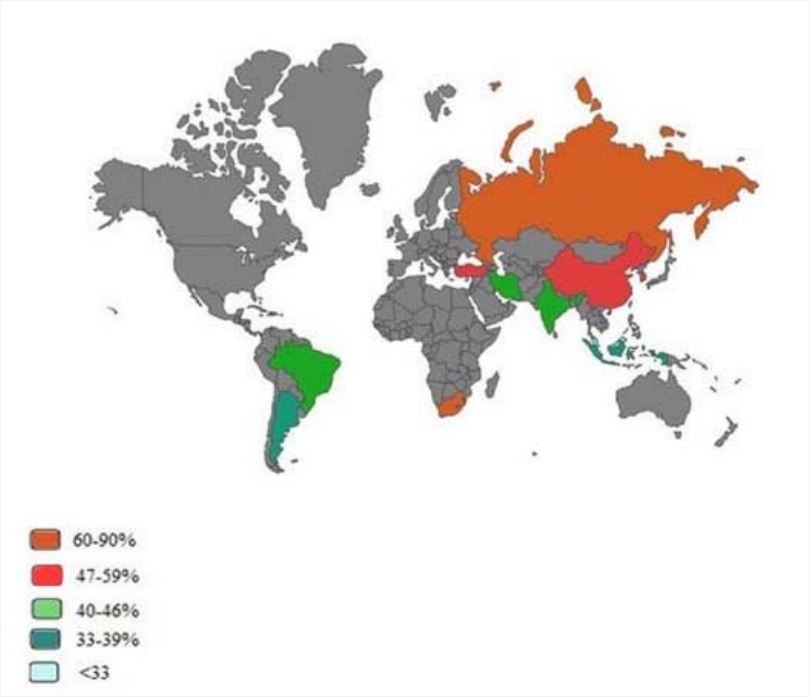

Figure 2 *H.pylori* prevalance rate according to countries.

There was no statistically significant difference between the tests groups about H. pylori positivity (p=0,235), other data were summarized in (Table 1). Additionally, statistical significant differences for H. pylori prevalence were not found among the years which the study was conducted.

DISCUSSION

Helicobacter pylori is the most efficient human pathogen infecting more than half of the global population. Non-invasive tests are carried out in patients with dyspepsia to assess whether H. pylori is present; if it is found, the infection is then treated. These procedures thus avoid the costs, inconvenience, and discomfort of endoscopy [11,86]. As the name implies, this strategy is used to determine the existence of H. pylori and enable its subsequent eradication when a positive result is obtained. Moreover, symptomatic treatment can be performed with non-infected patients with H. pylori. However, it is believed that such an approach is not appropriate in developing countries where the prevalence of H. pylori is high in the normal population. The test and scope strategy tests all patients for H. pylori detection;

Table 1: Prevalence rate of *H. pylori* according to different parameters.

Parameters		n		Mean	Minimum	Maximum	p**
		Study	Sample				
Countries	Argentina	5	2262	39,2±12,6	25,1	57,5	>.001
	Brazil	7	5685	39,7±20,6	22,1	63,4	
	China	5	3752	56,4±10,1	49,0	71,7	
	India	6	1491	45,8±25,3	7,0	80,0	
	Indonesia	5	4037	39,6±27,1	8,2	68,0	
	Iran	12	6586	45,6±17,2	26,00	78,9	
	Malaysia	5	1664	31,2±14,9	15,2	51,0	
	Russia	1	3149	87,1± NA	NA	87,1	
	South Africa	5	966	61,7±17,4	39,4	84,8	
	South Korea	5	76105	47,9±18,1	26,4	70,9	
	Turkey	11	8907	55,2±17,7	29,6	78,4	
Total		**67**	**114604**	**49,9±18,1**	**7,0**	**87,1**	
Parameters		**Study**	**Number of Positive Samples (n)**	**Mean Positivity Rate (%)**	**Minimum Positivity Rate (%)**	**Maximum Positivity Rate (%)**	**p****
Tests***	Stool Antigen [20,22,30]	3	835	1,24±13,2	29,6	40,6	0,235
	Molecular Method [21, 25, 26, 35, 58, 76]	6	972	1,45±13,1	30	84,7	
	Histopathology [60, 70, 73, 82, 83, 85]	6	2998	4,47±10,9	26,6	87,1	
	ELISA [27, 31, 37, 41, 47, 48, 49, 50, 56, 60, 61, 62, 66, 68, 74, 75, 77, 79, 81, 82]	21	57586	86±46,6	7	87,1	
	Urease [19, 23, 24, 29, 32, 33, 35, 39, 40, 42, 44, 46, 50, 51, 52, 53, 54, 55, 57, 59, 63, 64, 65, 67, 70, 72, 78, 80, 85]	29	4537	6,77±9,3	26,6	73	
Total		**65**	**66928**		**7**	**87,1**	
Years***	1998-2003	6	60352	70,2±13,8	35,7	70,9	0,551
	2004-2010	33	20173	45,2±17,9	15,2	80,0	
	2011-2016	19	11195	52,4±23,8	9	87,1	
Total		**58**	**91720**	**62,6±19,3**	**9**	**87,1**	

[18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 85].
p**; One-Way ANOVA, NA; Non Aplicated, ***; Calculations were conducted according to data compatibility, incompatible studies excluded.

endoscopy is not considered useful in patients who are infected only. Therefore, this strategy is not preferred in clinical practice [87,88].

In this meta-analysis, the H. pylori positivity rates differed significantly by country; this may be attributed to socioeconomic conditions, a factor that has been documented for H. pylori and other infections [89]. Additionally, hygiene and accessibility to water play important roles in the high rate of H. pylori positivity [90]. Because the data obtained from the publications used in the meta-analysis were disjointed, it is difficult to generalize the worldwide dynamics of infection.

A number of different invasive and non-invasive diagnostic methods are currently available. Invasive tests such as histological examinations are considered highly specific, but their sensitivity is partly dependent on the biopsy procedure used and they are both time-consuming and require specialized laboratory facilities. For these reasons, several non-invasive diagnostic tests for H. pylori detection have been developed and are in widespread use. Laboratory serologic assays, the UBT, and the fecal antigen test are common non-endoscopic diagnostic methods for H. pylori infection [91, 92]. At present, there is no single non-invasive test for H. pylori. Clinical conditions, experience, availability, and cost should be taken into consideration when choosing a suitable test in developing countries.

The methods used in these studies were ranked according to World Gastroenterology Organization global guidelines based

on their sensitivity (high to low) as follows: rapid urease test, histopathology, molecular methods, 13C/14C UBT, SAT, culture, and antibody-based methods [93]. However, there is no single test that is accepted as the gold standard for H. pylori infection for multicomponent disorders. However, UBT and SAT are probably considered to be the best non-invasive methods for detecting the presence of infection.

The prevalence rate of H. pylori infection between 1998 and 2003 was 70.2%; that between 2004 and 2010 was 45.2%; and that between 2011 and 2016 was 52.4%. It is difficult to compare positivity rates because of the diversity of the tests mentioned above and different approaches.

Because of the heterogeneity among the articles included in our analysis, our results should be interpreted with this heterogeneity in consideration. Additionally, several studies featured small populations. Consequently, some results may not have achieved statistical significance due to the small sample size. Studies including a larger number of individuals are needed. Hence, there is a need for better designed and larger datasets to obtain more reliable and accurate results.

Which test is best for H. pylori diagnosis in developing countries? This is a complicated question, but changes to the H. pylori testing policies in developing countries are urgently needed to grant better access to service; waiting for test results and bureaucratic obligations represent the major barriers to be removed. Reliable and cheaper testing may be the best approach to offer new opportunities, although the testing approach may need to be changed for newly diagnosed people. Another important question that remains is: Is there a minimal guideline for H. pylori epidemiologic publications? The available data show insufficient evidence for managing H. pylori infections in developing countries. Furthermore, there is no proposed algorithm for how to present epidemiological studies of H. pylori infection. Our study can be considered a well-intentioned effort in an unknown background. Therefore, the data obtained herein may reflect the risk group positivity rate and the positivity rate for persons with health insurance.

In conclusion, future epidemiological studies of H. pylori infection should focus on clarifying which test is more appropriate for patients while taking into account their clinical characteristics, pre-infection status, availability, and cost.

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