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Original Research Article

Prevalence of Helicobacter Pylori Infection in Children and Diagnostic Evaluation of Helicobacter Pylori Stool Antigen (HpSA) Test Kit

Avanesh Singh[1], R. Sujatha[2], V.K. Tandon[3], Desh Nidhi Singh[4], Khutija Sarah[5], Suneet Kumar Yadav[5], Deepak Sameer Bind[6], Vikas Kumar[7]*

[1]PG Student, Department of Microbiology, Rama Medical College, Hospital & Research Centre, Kanpur, U.P.

[2]Professor & Head, Department of Microbiology, Rama Medical College, Hospital & Research Centre, Kanpur, U.P.

[3]Professor & Head, Department of Paediatrics, Rama Medical College, Hospital & Research Centre, Kanpur, U.P.

[4]Professor, Department of Microbiology, Rama Medical College, Hospital & Research Centre, Kanpur, U.P.

[5]Assistant Professor, Department of Microbiology, Rama Medical College, Hospital & Research Centre, Kanpur, U.P.

[6]Demonstrator, Department of Microbiology, Rama Medical College, Hospital & Research Centre, Kanpur, U.P.

[7]Associate Professor, Department of Microbiology, Sarojini Naidu Medical College, Agra, U.P.

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Corresponding author: Vikas Kumar

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Abstract:

Background: Helicobacter pylori has been recognized as principal cause of peptic ulcer and the risk factor responsible for gastric cancer. The infection is usually acquired in early childhood. Invasive techniques used for the diagnosis required endoscopy which is expensive. Thus we have aimed to evaluate easy to perform noninvasive H. pylori stool antigen (HpSA) test Kit.

Materials and Methods: Total 50 children (37 female and 13 male) who have undergone upper gastrointestinal endoscopy due to recurrent abdominal pain, diarrhea, vomiting, gastritis and antral erythema were included in this study. The performance of HpSA test has been evaluated with reference to the result of endoscopy diagnostic procedure.

Result: The HpSA was detected in 8 (16%) cases. The HpSA positivity was more in male (62.5%) as compare to females (37.5%). Diarrhea (50%) and abdominal pain (37.5%) were the most common symptoms of H. pylori. Gastritis (50%) was the most common clinical diagnostic and antral erythema (25%) was the most common endoscopic findings. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of HpSA test were as 100%, 97.6%, 87.5%, 100% and 98% respectively.

Conclusion: Present study concludes that HpSA test is a non invasive and cost effective diagnostive test for H. pylori with high sensitivity and specificity.

Keywords: H. pylori, HpSA test, sensitivity, specificiy, accuracy.

Helicobacter pylori has been recognized as the principal cause of peptic ulcer disease and the main risk factor for development of gastric cancer [1]. Infected patients may develop chronic active gastritis, peptic ulcer disease, gastric cancer and is also present with mucosa-associated lymphoid tissue lymphoma [2]. All these complications occur in their vast majority in adulthood [3].

The infection is less common in developed countries as compare to developing countries like in India. The infection is more prevalent in adults than in children and may also vary in a geographic area [4]. The highest rates have been found in Nigeria, Serbia, South Africa, Nicaragua and Colombia with and the lowest in Yemen, Indonesia, Belgium, and Ghana [5].

H. pylori may play role in some extraintestinal disease like unexplained iron deficiency anemia (IDA), immune thrombocytopenic purpura (ITP), Henoch-Schoenlein purpura, bronchial asthma, other allergic diseases and inflammatory bowel disease (IBD) which may cause improper growth of children [6,7]. Thus the early diagnosis of H. pylori in children is the main goal of doctors specially pediatricians.

There are various diagnostic methods ranging from non-invasive to invasive. In children the diagnosis is confirmed through invasive methods and is limited to patients in whom benefits are expected like in gastro-duodenal ulcer and erosive gastritis, refractory IDA in which other causes have been ruled out and when investigating causes ITP [8]. The diagnosis is confirmed by the culture and if culture is not available or is negative than two invasive methods like histology and some molecular method like PCR or FISH can be used where biopsy is required. If culture is not available or it is negative and only histological examination is available, some non-invasive method likes Urease Breath Test (UBT) or Stool Antigen Test (SAT) can be used [9]. The decision to investigate and treat H. pylori infection in children should be based on specificity of the test and non-invasive procedure. SAT is noninvasive method thus we have taken the present study to know the prevalence of H. pylori infection among population by SAT in and around Rama Medical College, Hospital & Research Centre, Kanpur (U.P.).

Aims and Objectives

To Study the prevalence of H. pylori infection among children in and around Rama Medical College, Hospital & Research Centre, Mandhana, Kanpur.

Material and Methods

The present observational prospective study was conducted in the Department of Microbiology at Rama Medical College, Hospital & Research Centre from January 2021 to December 2021. Total 50 children less than 18 years having recurrent abdominal pain that persists for more than 3 months and affects normal activity, living in Kanpur and surrounding area were recruited for the study. The patients below 18 year of both genders who were suffering from recurrent abdominal pain and diarrhea were included in the study and patient who were receiving antibiotics, H2 antagonists, or proton pump inhibitors within the preceding 3 months were excluded.

Information of suspected patients was collected in a predesign patient proforma after taking their guardian's consent. Stool samples of selected patients were collected and sent to the Microbiology laboratory and subjected to rapid stool antigen test (SD Biosensor, Figure-1&2) following standard collection, transportation, storage and test method. The test results were interpreted according to the kit literature using controls. Variables of the study were collected in Microsoft excel sheet. Data

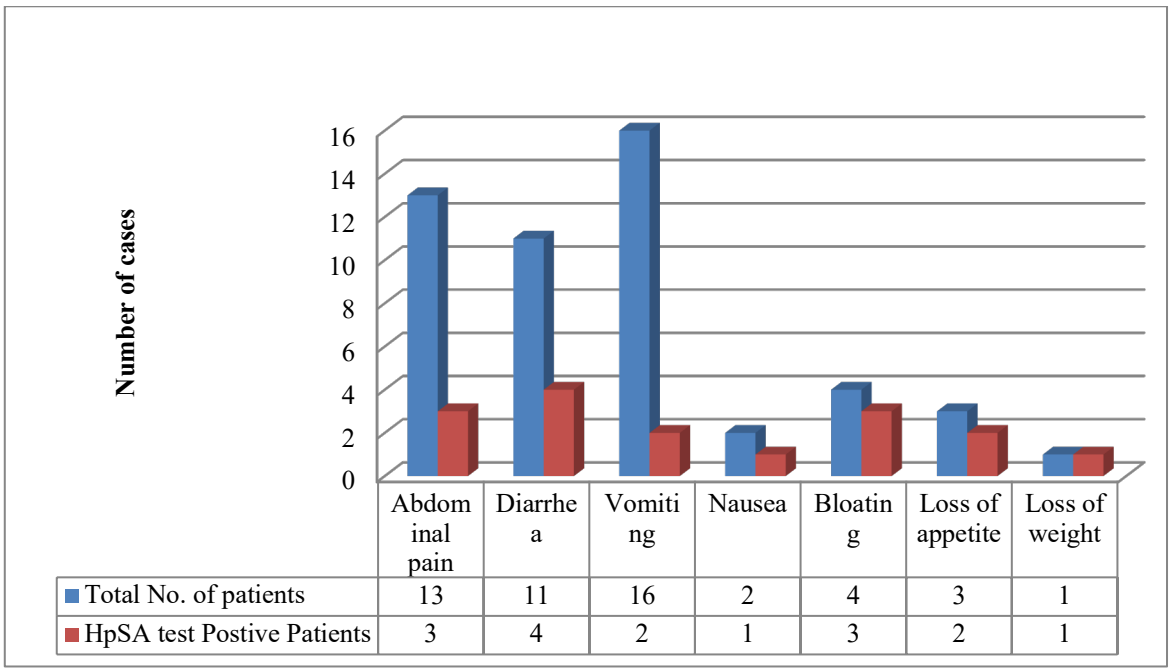
were analyzed by descriptive statistical analysis using suitable statistical tools available in Microsoft excel 2021. The study was approved by the Ethics Committee of Rama Medical College, Hospital & Research Centre, Kanpur, U.P. India.

Result:

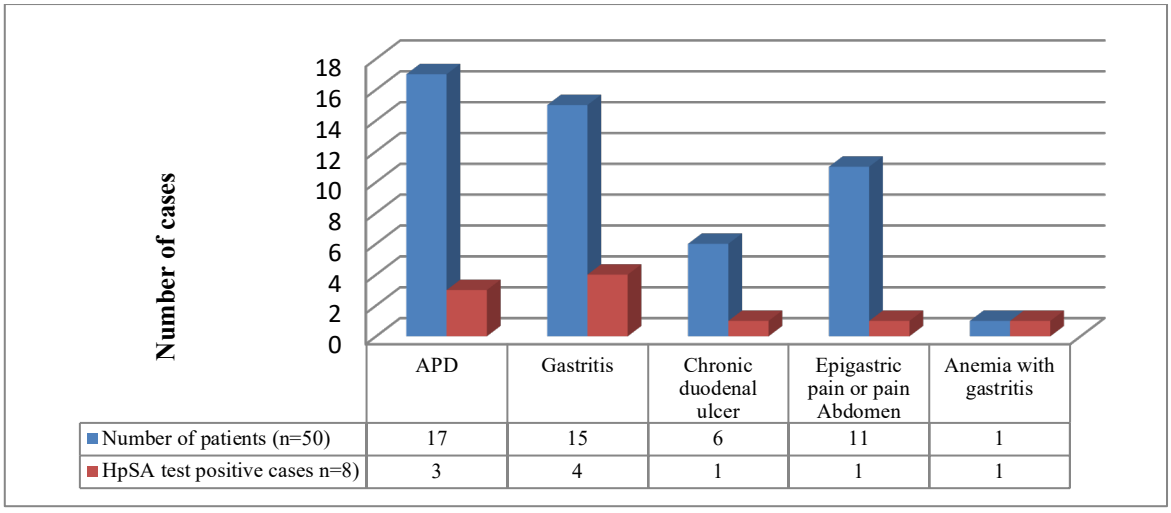
Maximum number 19 (38.0%), of suspected H. pylori was observed in age group of 11–14-year with a mean 11.2 years and Standard Deviation ± 3.9 years.

Females were 37 (74%) more affected than males 13 (26%). The female to male ratio was 2.8:1. Out of 74 female HpSA test were positive in 3 participants whereas out of 13 males HpSA test were positive in 5 participants. As compare to female HpSA test positivity was more in males.

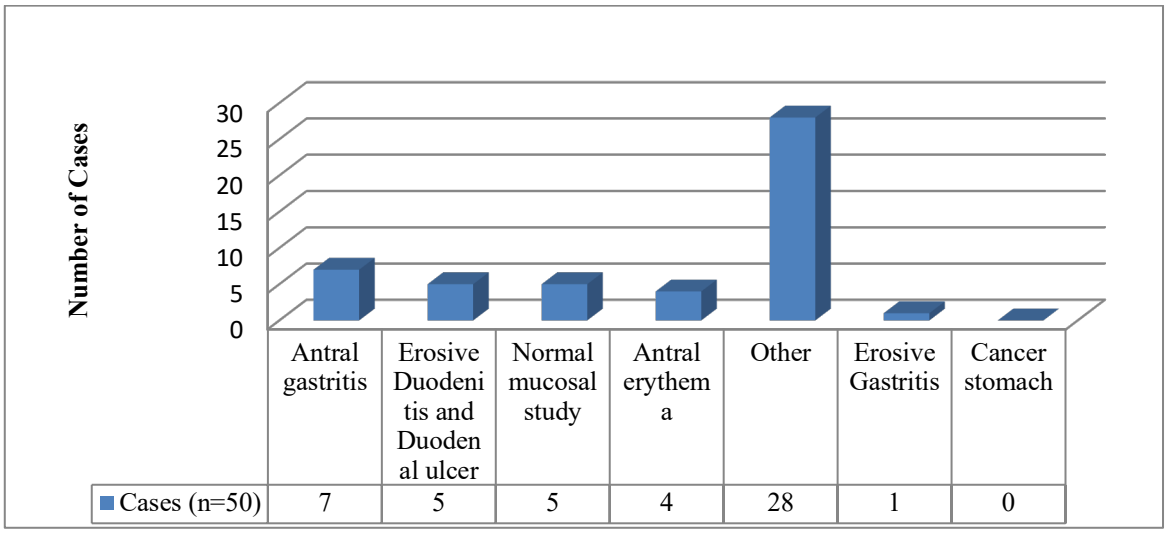
Helicobacter pylori stool antigen was detected in 8 (16%) cases. The HpSA positivity was more in male (62.5%) as compare to females (37.5%). Diarrhea (50%) and abdominal pain (37.5%) were the most common symptoms of H. pylori (Graph-1). Gastritis (50%) was the most common clinical diagnostic and antral erythema (25%) was the most common endoscopic findings (Graph-2). The Demographic profile of H. pylori showed that three fourth HpSA positive cases (n=6; 75%) were from rural area and one third positive cases (n=2; 25%) were from urban area. Among positive HpSA cases of H. pylori infected patients, antral erythema was observed in 25 percent (n=2) cases according to Endoscopic diagnosis (Graph-4).



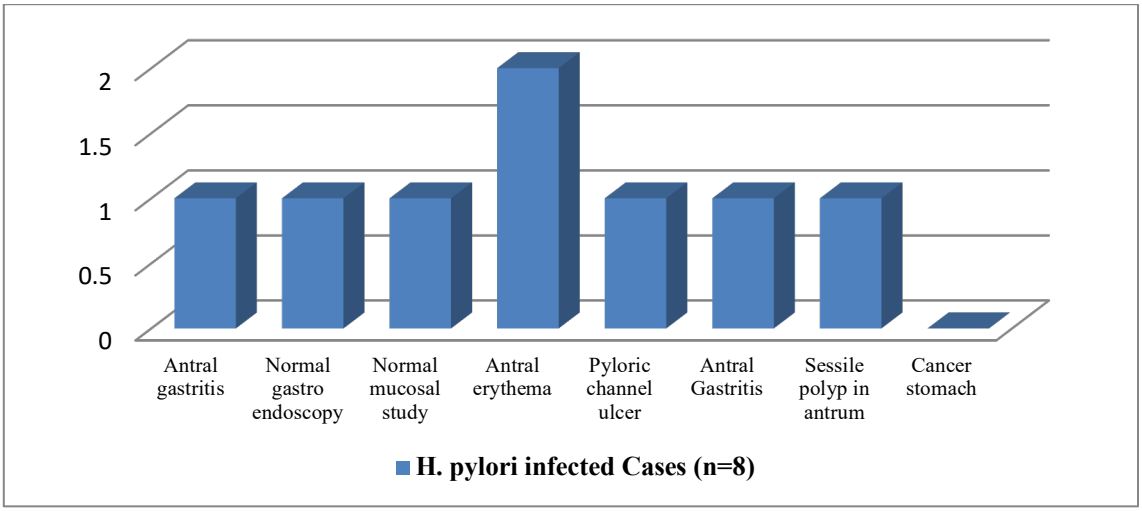
Graph 1: Distribution of suspected cases according to Signs and symptoms



Graph 2: Distribution of patients according to clinical findings in suspected cases of H. pylori



Graph 3: Distribution of Patients according to Endoscopic diagnosis in suspected cases of H. pylori (n=50)



Graph 4: Distribution of H. pylori infected Patients according to Endoscopic diagnosis in cases

Table 1: Age wise distribution of cases

Age Group	Total Number of cases	Number of H. pylori by HpSA test Positive
0-5	05	0
6-10	16	1
11-14	19	3
15-18	10	4
Total	**50**	**8**

Table 2: Comparison of Endoscopy tests v/s H. Pylori Stool Antigen Test

Test		Endoscopy (Gold Standard Test)		Total
		Positive	Negative	
H. pylori Stool Antigen Test	Positive	7	1	**8**
	Negative	0	42	**42**
Total		**7**	**43**	**100**

Table 3: Evaluation of Helicobacter pylori stool antigen test

Sensitivity	Specificity	PPV	NPV	Accuracy	Prevalence
100%	97.67%	87.5%	100%	98%	16%

Figure 1: H. pylori stool Ag rapid kit

Figure 2: H. pylori kitinsert in SD Biosensor

Discussion

Detection of H. pylori infection in children today mostly depends on the endoscopy, biopsy of the gastric tissue which is an invasive method performed for rapid urease test, histology, and culture [10]. These methods have been recognized as gold standard. In pediatric patients, however, invasive procedures have major disadvantages such as risk of anesthesia, discomfort, and terrifying the patients and their parents. For this reason, common use of those procedures in children is limited [11]. Therefore, a noninvasively, practical, and sensitive diagnostic test for the detection of H. pylori infection is desirable [12].

The most common noninvasively tests are

serology and UBT [11]. Serology is based on the detection of specific IgG and IgA antibodies by using the ELISA method in patients infected by H. pylori [13]. It is not solely used in diagnosis of the infection but particularly used for epidemiological or screening studies [14]. Serological methods are not reliable in children and fail in the diagnosis and in monitoring the success of anti-H. pylori therapy [15]. Up to the present, UBT is the favorite diagnostic tool in children for the diagnosis of H. pylori infection because it avoids upper gastrointestinal endoscopy [16].

The accuracy of noninvasively UBT in diagnosing H. pylori infection has also been evaluated in children with reference to histology and culture [17]. UBT is based on the stable isotope technique and combines the advantages of non-invasiveness, excellent sensitivity and specificity [16]. However, there are some disadvantages of the test including its requirement of a mass spectrometer device which is very expensive and its wrong results due to lack of cooperation of young children for performing the inhalation and exhalation exercises [11].

HpSA is a newly developed noninvasively FIA. It is not time-consuming and is cheaper than the UBT. The analytical technique of the immunoassay in stool samples can be performed easily in any laboratory. Faces can be obtained easily, even in new-born children. Spot samples of the stool are sufficient; homogenization of the stool is not required [12]. This new test utilizes polyclonal anti-H. pylori capture antibody that is adsorbed to microwells and shows good performance characteristics [12].

In the present study male (62.5%) were more affected than female (37.5%). The finding was in accordance with Houria Kasmi et al and was in contrast with Ari Fahrial Syam et al.

In the Present study the sensitivity and specificity correlated with the study of Yao-Kuang Wang etal.

In the present study, results of HpSA were compared with H. pylori status. Positive H. pylori status and positive HpSA results were consistent in 7 patients, while negative H. pylori status and negative HpSA results were consistent in 42 patients. We observed one false-positive stool test result, but there was no false-negative test result. Therefore, the sensitivity, specificity, and positive and negative predictive values, accuracy of HpSA in untreated children were 100%, 97.67%, 87.5%, and 100%, 98%, respectively. Other investigators have reported similar high sensitivities (86.9-100%) and specificities (92-100%) of HpSA in untreated children. Positive and negative predictive values have been found similarly high in these studies [11,12,19]

Besides, it has been claimed that HpSA can be used for monitoring treatment success and that successful eradication of H. pylori can be confirmed after treatment [19]. The accuracy of HpSA has been confirmed in children, and this may be the optimal test to confirm the success of eradication therapy [11]. HpSA has been found to be a useful method for post-treatment eradication testing of H. pylori infection in children [20]. However, some investigators have reported that results of HpSA reveal an unsatisfactory sensitivity after treatment [19].

Conclusion

Our study concludes that Helicobacter pylori stool antigen test a noninvasive diagnostic test for H. pylori is a rapid test also cost effective. With a high sensitivity and specificity this test can be used for detecting H. pylori infection in children with recurrent abdominal pain. Our results are comparable to those reported elsewhere in children and demonstrate that the Helicobacter pylori stool antigen test can replace endoscopy and biopsy for detecting H. pylori infection. Helicobacter pylori stool antigen may be useful particularly in

selection of the cases requiring endoscopic examination, in monitoring the response to treatment and in epidemiological studies.

Limitation of the study: Due to cost constraints only 50 samples were processed.

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