INTRODUCTION

Symptoms of upper gastrointestinal distress are of worldwide interest and very common in the general population. Dyspepsia represents a cluster of symptoms characterized by chronic or recurrent pain in the upper abdomen, upper abdominal fullness, and feeling full earlier than expected with eating. Globally, the prevalence of dyspepsia ranges from 20% to 30% and is a major cause of morbidity and economic loss in community.

Dyspepsia may be associated with peptic ulcer disease, gastroesophageal reflux disease (GERD), and gastric cancer. However, the most frequent type is functional (non-ulcer) dyspepsia. According to ROM III criteria, functional dyspepsia (FD) is defined as presence of one or more dyspepsia symptoms that are considered to originate from gastroduodenal region, in the absence of any organic, systemic or metabolic disease that is likely to explain the symptoms. The precise pathophysiology of this condition remains unclear, but it is thought to result from a combination of visceral hypersensitivity, gastric motor dysfunction, psychological factors and presence of Helicobacter pylori infection causing gastroduodenal mucosal inflammation.
H. pylori is helical shaped, Gram-negative, microaerophilic human pathogen. Approximately 50% of the world’s population is believed to be infected with it. Most infections are probably acquired in childhood, but geographic locale, age, race, socioeconomic status, and hygiene seems to play roles in the prevalence of H. pylori. Several methods have been developed to detect H. pylori infection which include invasive tests that require endoscopy to obtain tissue biopsies, such as rapid urease test, culture, histological examination, and polymerase chain reaction and non-invasive tests such as urea breath test or stool antigen test.6

The reported prevalence of H. pylori in patients with FD ranges from 39% to 87%, but it remains unclear whether H. pylori infection actually causes symptoms or is just an associated finding.7,8 Many trials evaluating the role of H. pylori in FD and efficacy of H. pylori eradication on symptomatology of FD have been published in past, but most of these have given conflicting results.9 Therefore, this study was conducted to find out the prevalence of H. pylori in FD using both invasive and non-invasive methods of diagnosis of infection.

METHODS

The study was conducted in a tertiary care teaching hospital of Nagpur. The study protocol was approved by Institutional Ethics Committee and written informed consent was obtained from all the patients after explaining them the nature and purpose of the study. Patients of either sex within age group 18-60 years, with any dietary habit attending medicine out-patient department over a period of 2 years, with presenting complaints of dyspepsia diagnosed according to ROME III criteria were enrolled in the study. Detailed history, complete general and systemic examination, basic investigations such as hemoglobin %, total leukocyte count, differential leukocyte count, erythrocyte sedimentation rate, random blood sugar, liver function tests, kidney function tests, and urine examination were done to rule out any other disease. Patients having evidence of GERD, esophagitis, gastric or duodenal ulcer on endoscopy, with history of previous gastric surgery, with concomitant diseases such as gallstones which might be the cause of dyspeptic symptoms and who were taking any medication with a possible influence on dyspeptic symptoms such as NSAIDs were excluded from the study.

A total of 142 patients were included and assessed by seven-point global overall symptom (GOS) scale to measure the severity of dyspepsia symptoms.10 Subjects were asked to rate the overall severity of their dyspepsia symptoms during the previous 1 month on seven-point as: (1) no problem, (2) minimal problem (can be easily ignored without effort), (3) mild problem (can be ignored with effort), (4) moderate problem (cannot be ignored but does not affect daily activities), (5) moderately severe problem (cannot be ignored and occasionally limits daily activities), (6) severe problem (cannot be ignored and often limits concentration on daily activities), and (7) very severe problem (cannot be ignored, markedly limits daily activities and often requires rest). Patients were then screened for H. pylori infection by endoscopic biopsies (invasive) and C-14 urea breath test (noninvasive). Endoscopy findings were noted and mucosal biopsy from antrum was taken from 3 sites and was immediately transported in 0.2 ml normal physiological saline for further processing.11

Rapid urease test

A volume of 0.5 ml freshly prepared unbuffered 10% urea solution in distilled water with 1% phenol red, pH adjusted at 6.8-7.2 was used as a medium. Color change from yellow to pink indicates a positive test.12

Gram-staining

A smear was prepared from the tissue homogenate fixed with 95% ethanol, which was stained with Jensen’s modification of Gram-stain using carbol fuchsin (0.2%) for better visualization of bacteria. Weakly stained rods with unique curvature were seen.13

Culture

Biopsy sample was homogenized, inoculated on brucella agar which was made selective for H. pylori by addition of Skirrow’s supplement and incubated at 37°C in a candle jar with a pad of cotton soaked in water placed at the bottom to provide a humidified microaerophilic environment.13 Culture plate was examined on 3rd, 5th and 7th day. Characteristic colonies were identified by Gram staining, urease, catalase, and oxidase tests.14

C-14 urea breath test

Patients were also tested for H. pylori infection by C-14 urea breath test (using heliprobe system of Kibion, Sweden) at radioisotope laboratory of Department of Pharmacology. This test has 95% sensitivity, 100% specificity, and 98.4% accuracy.15 Patients having two or more of the above diagnostic methods positive were regarded as H. pylori positive. Data was entered and analyzed by using Microsoft Excel 2007.

RESULTS

Of total 142 patients, 90 were H. pylori positive giving a prevalence rate of 63.38%. Demographic characteristics of the study participants are shown in Table 1. Among 90 H. pylori positive patients assigned for the study, 50 (56%) were male and 40 (44%) were female. Maximum patients were in 31-40 years age group with a mean age of 38.53. Presenting complaints and GOS score are shown in Figures 1 and 2. Mild gastritis was the most common endoscopic finding, other are denoted in Figure 3. Regarding H. pylori diagnosis, rapid
urease test, Gram-staining, culture and C-14 urea breath test were positive for 81, 77, 7, and 90 patients, respectively. All the patients were given anti-\textit{H. pylori} treatment.

**DISCUSSION**

Dyspepsia is a common complaint among individuals seeking medical care as well as in general population.\textsuperscript{16} It is diagnosed in presence of symptoms thought to originate from gastroduodenal region and if there is no organic cause to explain dyspeptic symptoms on upper gastrointestinal endoscopy, the patient is labeled as FD.\textsuperscript{17}

\textit{H. pylori} is associated with several upper gastrointestinal diseases. Various invasive and non-invasive tests are available for its diagnosis. The choice of test is determined by clinical indication, pretest probability of infection, as well as availability, cost, sensitivity, and specificity of the test. \textit{H. pylori} can now be diagnosed using simple, cheap, and non-invasive techniques such as C13 or C-14 urea breath test or serologic assay for anti-\textit{H. pylori} antibodies. Thus, it has been suggested that it would be more cost effective to screen dyspeptic patients for \textit{H. pylori} by these non-invasive tests prior to referral for endoscopy.

The association of FD with \textit{H. pylori} infection has been widely reported, however, whether this association is casual or causal remains debatable. Hence, in present prospective study 142 FD patients were enrolled out of which 90 were found \textit{H. pylori} positive giving a prevalence of 63.38%. Rates have been suggested to be higher in developing than in developed countries in previous studies.\textsuperscript{18} However, recently even in developed countries like Northeastern Mexico high \textit{H. pylori} prevalence (67.8\%) in symptomatic patients has been suggested, it was more common in patients with peptic ulcer (77.8\%) than with non-ulcer dyspepsia (43.2\%).\textsuperscript{19}

\begin{table}
\centering
\begin{tabular}{|c|c|}
\hline
\textbf{Categorical variables} & \textbf{n (\%)} \\
\hline
\textbf{Age (years)} & \\
18-20 & 9 (10) \\
21-30 & 13 (14.14) \\
31-40 & 31 (34.44) \\
41-50 & 20 (22.22) \\
51-60 & 17 (18.9) \\
\hline
\textbf{Gender} & \\
Male & 50 (56) \\
Female & 40 (44) \\
\hline
\textbf{Dietary habits} & \\
Vegetarian & 42 (46.67) \\
Non-vegetarian & 48 (53.33) \\
Excess chilies and spicy food & 40 (44.44) \\
Excess tea/coffee and beverages addiction & 33 (36.67) \\
Tobacco chewing/smoking/snuff & 20 (22.22) \\
Alcohol/alcoholic beverages & 18 (20) \\
\hline
\textbf{Socioeconomic status} & \\
Upper & 16 (17.78) \\
Middle & 48 (53.33) \\
Lower & 26 (28.89) \\
\hline
\textbf{Occupation} & \\
Office work & 37 (41.11) \\
Housewife & 29 (32.22) \\
Business & 14 (15.56) \\
Students & 10 (11.11) \\
\hline
\end{tabular}
\caption{Demographic characteristics of participants (n=90).}
\end{table}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{Figure1.png}
\caption{Presenting complaints of 90 patients.}
\end{figure}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{Figure2.png}
\caption{Severity of global overall symptom score among 90 patients.}
\end{figure}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{Figure3.png}
\caption{Endoscopic findings of 90 patients.}
\end{figure}
The prevalence recorded in our study appears to be similar in comparison to the recent studies from various parts of India, whereas contrary to this lower prevalence (34.71%) has been observed in Jammu region.

Of the 90 cases analyzed, 56% were male. The youngest *H. pylori* positive patient was 18 years old and the eldest aged 60 years, 58.89% patients were below 40 years. Higher rate of infection tend to occur at a younger age in developing countries compared to developed countries and in regions characterized by lower socioeconomic status and higher density living.

Pain in the epigastric region was the most frequent presenting complaint in 44% patients followed by early satiation, bothersome postprandial fullness, and epigastric burning. Endoscopic and histopathological examination of *H. pylori* positive patients revealed mild gastritis 50% followed by antral gastritis 30%, esophagitis 5.5%, and normal in 14.44% patients.

Patients were assessed by 7-point GOS scale to measure the severity of dyspepsia symptoms. GOS has been demonstrated to be satisfactory scale and it fulfills the properties of reproducibility, responsiveness, and validity. In our study, GOS score was in the range of 5-7 (mean 6.01±0.64). Dyspepsia was not related to the quantity of spices consumed or to the type of diet (vegetarian or non-vegetarian). Dyspepsia was more prevalent in subjects who abused tobacco and alcohol.

In our study, *H. pylori* was seen commonly in middle socio-economic class (53.33%) followed by low socioeconomic patients (28.89%). Similar finding was reported in the survey evaluating epidemiology of dyspepsia in an urban population of Mumbai city. The prevalence of *H. pylori* infection in adult varies in different parts of world depending on social and economic standards of the population.

**CONCLUSIONS**

The present study revealed 63.38% prevalence of *H. pylori* in FD patients of central India and more predominance in males, 31-40 years age group and middle socio-economic class. Pain in the epigastric region was the most frequent symptom and on endoscopy mild gastritis was the most common presentation.

The results of the present study suggest that *H. pylori* infection is an important causative factor for dyspeptic symptoms in a subset of patients with FD. Early detection of *H. pylori* and its complete eradication may help in significant reduction in usage of acid suppression drugs and would also lead to improvement in severity of dyspeptic symptoms and overall quality of life. Thus, all the FD patients must be investigated for *H. pylori* and treated properly. Considering the high prevalence of FD in the Indian population, socio-economic burden of this disease in our country is expected to be enormous. Hence, more studies are needed on this issue in Indian population.

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