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A Study to Determine the Prevalence of Helicobacter Pylori in Saliva of Patients with Symptoms of Gastroesophageal Reflux Disease

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ABSTRACT

Introduction: Gastroesophageal reflux disease (GERD) is a widespread condition that places a heavy financial burden on healthcare systems globally. GERD is characterized by upward flow of stomach contents into the esophagus. The diagnosis of Helicobacter pylori infection can be confirmed through the encapsulated urea breath test and analysis of microbiological analysis of gastric biopsy samples taken from the antrum and corpus during gastroduodenoscopy or using a rapid urease test. The aim of this study is to determine the presence of Helicobacter pylori in saliva of patients with symptoms of gastroesophageal reflux disease by Rapid Urease Test.

Methodology: This study included 100 patients with symptoms of GERD whose Saliva were collected using sterile swabs and tested for Helicobacter pylori using a Rapid Urease Test kit. Color changes from yellow to pink/red were recorded as positive, and yellow after 6 hours was recorded as negative. No readings were taken after 6 hours.

Result: 65(65%) patients tested positive for H. pylori in saliva, while 35(35%) of them tested negative.

Conclusion: Testing for Helicobacter pylori using a Rapid Urease Test kit is recommended for diagnosis in suspected GERD cases. The rapid urease test is a valuable tool for the quick diagnosis of GERD in outpatient settings, offering a low-cost, fast-result method that allows for the prompt initiation of treatment. However further studies are needed

Keywords: *Gastroesophageal reflux disease ; Helicobacter pylori; Rapid Urease Test.*

INTRODUCTION

Gastroesophageal reflux disease (GERD) is a widespread esophageal condition, and its prevalence is rising globally, placing significant strain on healthcare systems and leading to high costs.[1]Gastroesophageal reflux disease (GERD) is a common condition, where stomach contents flow back into the esophagus and mouth due to a weakened muscle at the bottom of the esophagus.3*Helicobacter pylori* is a gram-negative bacterium that has long been associated with various gastrointestinal diseases, including peptic ulcers and gastric cancer. Studies have suggested a potential link between Helicobacter pylori infection and gastroesophageal reflux disease (GERD). It is characterized by symptoms such as heartburn and regurgitation.[2]

When the stomach is colonized by H. pylori, the bacteria may be regurgitated into the saliva in the oral cavity. The salivary microbiota in individuals with gastroesophageal reflux disease has not been extensively studied or characterized[3]

There are several ways to diagnose *Helicobacter pylori*infections. These diagnostic methods are generally grouped into two categories: invasive and non-invasive.

Invasive tests involve performing an upper endoscopy to collect a biopsy from the stomach lining for analysis. Non-invasive tests, on the other hand, do not require endoscopy. These include immunological tests such as blood antibody tests and stool antigen tests.

Another common non-invasive method is the C-urea breath test, which detects the presence of H. pylori by analyzing exhaled air. 4

This study aims to investigate the presence of *Helicobacter pylori* in the saliva of patients presenting with symptoms of gastroesophageal reflux disease (GERD) using the Rapid Urease Test, and to evaluate its potential as a non-invasive diagnostic alternative for the detection of *H. pylori*.

OBJECTIVES

To determine the presence of Helicobacter pylori in saliva of patients with symptoms of gastroesophageal reflux disease by Rapid Urease Test.

METHODOLOGY

The patients presenting with symptoms of gastroesophageal reflux disease in the out-patient department were be selected for study in hospitals attached to J.J.M Medical College, Davangere from November 2024 to February 2025 based on the fulfilment of inclusion and exclusion criteria along with their willingness to participate in the study. The exclusion criteria for the study include patients under the age of 18, pregnant women, and those with a history of gastric or esophageal surgeries. Informed as well as written consent will be taken formall patients participatingin the study. A sample size of 100 was estimated.

During the study the selected patients underwent detailed history taking along with systemic and local examination. Using tongue depressor to depress anterior two-thirds of tongue, saliva was taken using sterile swab sticks from junction of anterior two-third and posterior one third of tongue and tested for the presence of Helicobacter pylori with Rapid Urease Test kit and an initial color read at 0 min. Subsequent color changes were read at 30min and 6 hours. Any color change from the initial yellow color to either pink or red was recorded as positive. Any test well that remained yellow after 6 hours was recorded as negative. No readings were taken after 6 hours. All the data was recorded in proforma.

STATISTICAL ANALYSIS

Statistical analyses were performed using IBM SPSS v28 for Windows. Categorical data were represented in the form of frequency and percentage. Association of variables was assessed using Chi-Square Test. Quantitative data was represented as mean and standard deviation. *P*-value less than 0.05 was considered to be statistically significant.

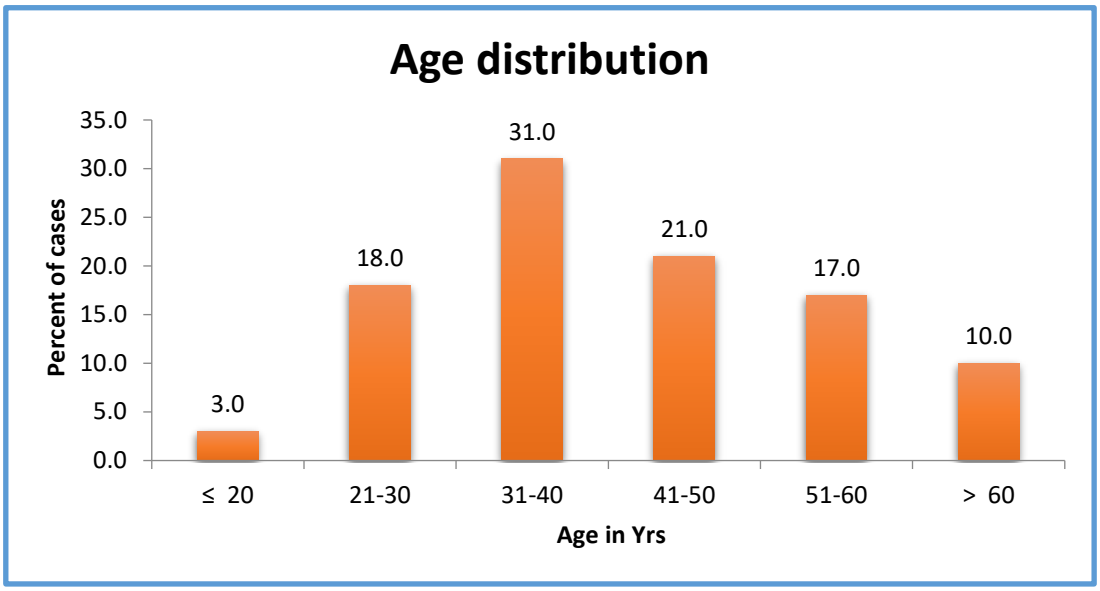
RESULTS

The study included 100 participants ranging in age from below 20 to over 60 years. The majority of cases (31%) were in the 31–40 age group, followed by 21% in the 41–50 age group. Participants aged 21–30 and 51–60 each made up 18% and 17% of the sample, respectively. Those above 60 years accounted for 10%, while the least represented group was individuals aged 20 or below, comprising only 3% of the total. The mean age of the participants was 42.4 years with a standard deviation of 12.9 years.

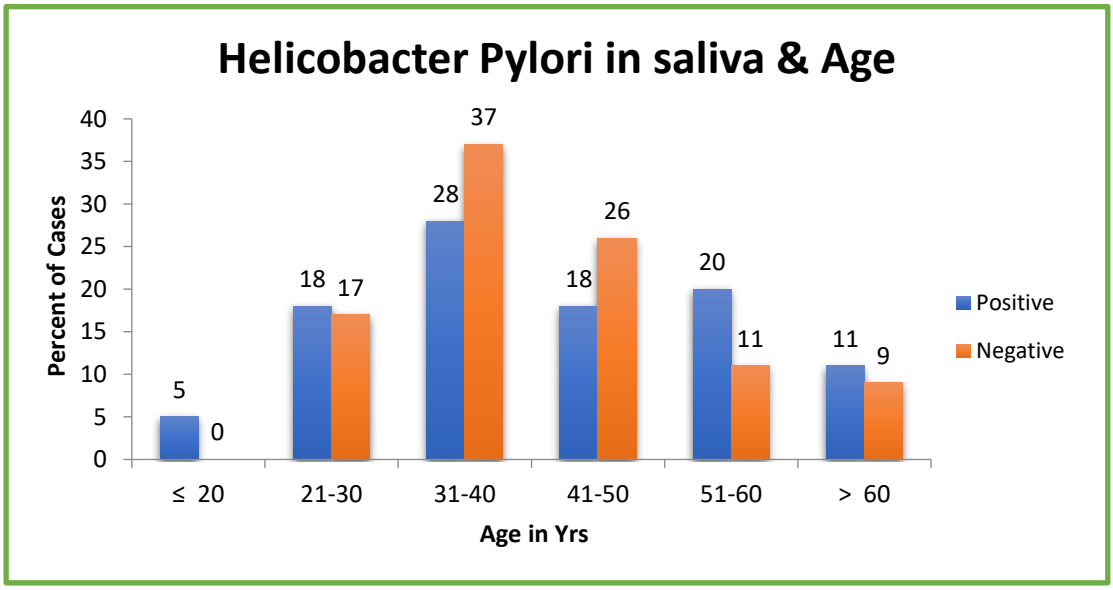
The study population had a nearly equal gender distribution: 48% were male and 52% were female.

Out of the 100 participants, Helicobacter pylori was detected in the saliva of 65 individuals, accounting for 65% of the cases, while 35 participants (35%) tested negative.

In our study, Helicobacter pylori was detected in saliva across all age groups, with the highest proportion of positive cases in the 31–40 age group. However, statistical analysis using the Chi-square test showed no significant association between age and H. pylori positivity ($p = 0.556$).Among the study participants, Helicobacter pylori was detected in 51% of males and 49% of females. The Chi-square test showed no significant association between gender and the presence of H. pylori in saliva ($p = 0.45$), indicating that infection rates were similar between males and females.



Graph 1:Age distribution of participants



Graph 2: Age wise distribution of RUT positive and negative cases

Table1: Gender wise distribution of RUT positive and negative cases

Gender	Helicobacter Pylori in saliva				Chi Square Test	
	Positive		Negative			
	No	%	No	%	χ^2 Value	P Value
Male	33	51	15	43	0.571	0.45
Female	32	49	20	57		
Total	65	100	35	100		

DISCUSSION

Gastroesophageal reflux disease (GERD) manifests as the regurgitation of stomach contents into the esophagus, causing symptoms and potential complications. It involves the backflow of stomach contents into the esophagus, resulting in troublesome symptoms and potential complications. Globally, the prevalence of gastroesophageal reflux disease (GERD) and GERD symptoms vary depending from country to country and region to region. Defining GERD and pinpointing its prevalence are problematic due to its diagnostic issues. However, understanding the differences in prevalence will help us identify the differences in associated risk factors, such as genetics and diet, that lead to an individual's susceptibility to suffering from GERD and its symptoms.

In India, according to a study done by - DrRai S, DrKulkarni A, DrGhoshal UC - Prevalence and risk factors for gastroesophageal reflux disease in the Indian population: A meta-analysis and meta-regression study. Indian J

Gastroenterol. 2021-GERD exhibits a prevalence of approximately 15.6%, with higher rates observed in urban areas compared to rural regions.

There are a few things that need to be clarified while creating a noninvasive technique for identifying Helicobacter pylori in saliva.

The first and foremost is whether H. pylori in dental plaque is equivalent to H. pylori in the stomach. The use of several sample techniques, including urease tests, polymerase chain reaction (PCR) techniques, immunoassays, cytology, and culture, to identify the bacteria in dental plaque may account for this large range.

According to Vaira D, Holton J, Cairns S, et al Urease tests for Campylobacter pylori: care in interpretation.2016 (Journal of Clinical Pathology) - Compared to research employing other techniques, the prevalence rate observed in urease test studies was higher. Because H. pylori is present in dental plaque in the metabolically active but unculturablecoccoid form, microbial culture has been shown to have the lowest detection rate (typically less than 20%). There has been discussion on the use of urease assays to find H. pylori in dental plaque. The reason for this dispute is that, despite H. pylori being the sole urease-positive microbe found in the stomach, several urease-positive bacterial species, including Streptococcus, Haemophilus, and Actinomyces species, can be found as a typical component of the oral flora. However, it has been reported that only H. pylori produces large amounts of urease, such that a positive urease test can occur within 20 minutes, while other urease-producing bacteria are not positive within 1 hour. The PCR technique for detection of H. pylori provides the advantage of detecting even small numbers of the target species and detecting the target DNA in spite of the viability of the bacteria. The results of utilizing PCR techniques have been variable, ranging from 0% to 100%.

Secondly, does the presence of H. pylori in saliva match the presence of H. pylori in the stomach? According to.Namavar F, Roosendaal R, Kuipers EJ, de Groot P, van der Bijl MW, Pe~ na AS, et al. Presence of Helicobacter pylori in the oral cavity, oesophagus, stomach and faeces of patients with gastritis - The detection rate in saliva was generally less than in dental plaque (usually < 50%). However, when compared to studies that utilised PCR, the prevalence rate was significantly lower in those that used culture to detect H. pylori. The reason for this could be that dental plaque forms a biofilm that enables the bacteria to stick to solid surfaces, and the constant flow of saliva may lower the bacterial load, making detection challenging. Similar to dental plaque, researchers' views on the importance of finding H. pylori in saliva have been divided.

After reviewing the aforementioned issues, we understand the reason why Khadir et al's study showing that a low detection of H. pylori antigens in saliva compared to the presence of this bacterium in gastric mucosa, and Yang et al's study revealing that a one-step H. pylori saliva test exhibited a low specificity in H. pylori detection, although the saliva test is a sample noninvasive test for H. pylori detection.

In our studies, 65(65%) patients tested positive for H. pylori in saliva, while 35(35%) of them tested negative. And thus the rapid urease test is a valuable tool for the quick diagnosis of GERD in outpatient settings, offering a low-cost, fast-result method that allows for the prompt initiation of treatment. However further studies are needed

In conclusion, although H. pylori has been detected in the oral cavity for > 10 years, the clinical significance remains controversial. If the oral cavity is an important extragastric reservoir of H. pylori, then this finding may have a principal impact because the oral cavity can serve as both a route of transmission and a source of reinfection. Thus, it is imperative to identify the role of saliva and dental plaque in H. pylori infection. Once these factors are clearly understood and the fact that the oral cavity is a major extragastric reservoir of H. pylori is confirmed, then a new diagnostic method, especially using saliva as a sample, could be useful in the future.

CONCLUSION

Rapid Urease Testing of saliva for *H. pylori* offers a non-invasive, rapid, and economical diagnostic tool in patients with suspected GERD. However, more extensive studies employing confirmatory methods like PCR and bacterial culture are required to validate these findings and understand the role of oral *H. pylori* in gastrointestinal pathology.

This study reinforces the idea that salivary detection of *H. pylori* using RUT has potential clinical value, particularly in early identification and triage of GERD patients. While not intended to replace invasive or molecular diagnostics, the RUT method in saliva could serve as a preliminary screening tool that informs further investigation or early intervention in symptomatic individuals.

In conclusion, incorporating salivary RUT into routine outpatient diagnostic workflows could enhance patient care by facilitating quicker clinical decisions. However, to fully validate its use, further studies incorporating larger sample sizes, diverse patient cohorts, and comparison with gold-standard diagnostics (like gastric biopsy or PCR) are essential. The integration of such non-invasive testing may ultimately contribute to more personalized and efficient management of GERD and associated *H. pylori* infections.

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