



Original Research Article

A study to determine the presence of *H. pylori* in patients with ear dischargeSantosh UP¹, Arfan Nasser^{1*}, Monica Shre A¹, Vikram Gattu¹¹Dept. of Otorhinolaryngology JJM Medical College, Davangere, Rajiv Gandhi, University of Health Sciences, Karnataka, India.

Abstract

Introduction: *Helicobacter pylori* (*H. pylori*) a gram-negative bacterium is primarily recognized for its involvement in gastrointestinal diseases, including gastritis, peptic ulcers, and gastric cancer. But new research indicates that *H. pylori* might not be limited to the gastrointestinal system alone and might also play a role in extra-intestinal infections, such as those that impact the ear, nose, and throat area.

One of the most prevalent clinical signs of ear infections, such as otitis media and chronic suppurative otitis media (CSOM), is ear discharge, also known as otorrhea. Researchers have conjectured about *H. pylori*'s possible involvement in ear infections, especially when chronic or persistent ear discharge is present, after finding the bacteria in the middle ear in certain instances

Aim and Objective: This study aims to determine the presence of *H. pylori* in ear discharge using the rapid urease test.

Materials and Methods: A prospective descriptive study was conducted on 100 patients with ear discharge. Samples were collected and tested for *H. pylori* using the rapid urease test.

Result: Out of 100 tested samples, 70 (70%) were positive for *H. pylori*, suggesting a potential role of this bacterium in ear infections

Conclusion: The findings indicate a significant presence of *H. pylori* in ear discharge, warranting further investigation into its pathogenic role and clinical implications.

Keywords: Ear discharge, *Helicobacter pylori*, Rapid urease test kit

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1. Introduction

Helicobacter pylori is a gram-negative, microaerophilic bacterium that was first identified in the gastric mucosa of individuals suffering from gastritis. This bacterium is not harmless, as it causes gastritis, characterized by the presence of both acute and chronic inflammatory cells. It is estimated that around 50% of the world's population is infected with *H. pylori*. With incidence in developing countries like India to be as high as 80%.¹ The bacterium is primarily believed to be transmitted through the oral route. While some researchers suggest that it spreads via the orofecal route, there is also a possibility that it migrates from the stomach to the mouth due to gastro esophageal reflux. A significant number of individuals with gastro esophageal reflux disease are also infected with *H. pylori*, making it likely that the bacterium could travel from the stomach to the middle ear through gastro esophageal reflux.²

Otitis media with effusion (OME) is characterized by the accumulation of fluid in the middle ear without the typical signs and symptoms of acute inflammation observed in acute otitis media. This condition can have various causes, including allergies, autoimmune responses, gastro esophageal reflux disease, bacterial and viral infections, and eustachian tube dysfunction. In chronic OME cases, *Haemophilus influenzae* is the most commonly detected pathogen, while *Streptococcus pneumoniae* and *Moraxella catarrhalis* are also frequently implicated. Recent research has explored a possible link between OME and the presence of *H. pylori* in the middle ear.^{3,4}

The urease test, also referred to as the Campylobacter-like organism (CLO) test, is the most widely used method by gastroenterologists globally for detecting *H. pylori*.⁵ The RUT is a simple, sensitive, and highly specific test with high Sensitivity, positive predictive value, negative predictive

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value, of 93%, 75%, 95%, 94%, 86% and 0.831 respectively with a lower specificity of 75%.^{6,7}

Since *H. pylori* has been found in anatomical locations like the adenoids, which are close to the eustachian tube, it is reasonable to suggest that this bacterium could be involved in middle ear infections.⁸

2. Materials and Methods

2.1. Source of data

Patients of either sex who presented with complains of ear³. discharge in out-patient department of Otorhinolaryngology and Head and Neck Surgery at Chigateri District Hospital and Bapuji Hospital, teaching hospitals attached to J.J.M. Medical College, Davangere, Karnataka were included. The selection of these patients was based on specific inclusion and exclusion criteria, ensuring a thorough screening process after obtaining approval from the institutional ethical committee

2.2. Study of design

Prospective Descriptive study

2.3. Study duration

September 2024 TO December 2024

2.4. Samplesize

100

2.5. Inclusion criteria

- 1. Patients with ear discharge.
- 2. Either sex.
- 3. Age between 8-65 years.

2.6. Exclusion criteria

- 1. Patients below 8 ears and above 65 years of age
- 2. Previously diagnosed and treated for H pylori infection.
- 3. Patients with other ear pathologies
- 4. Patients with diabetes or other immunocompromised status

2.7. Data collection method

- 1. The patients presenting with features of ear discharge in the out-patient department will be selected based on the fulfilment of inclusion and exclusion criteria along with the willingness to participate in the study. Informed written consent will be taken from all patients participating in the study.
- 2. During the study the selected patients would undergo detailed history taking along with systemic and local examination.

- 3. Under endoscopic guidance, discharge from the middle ear cavity was taken using sterile swab sticks and tested for the presence of H.pylori with Rapid Urease Test kit and an initial colour read at 0 min. Subsequent colour changes were read at 30min and 6 hours. Any colour change from the initial yellow colour 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

Categorical data will be represented in the form of frequency and percentage. Association between variables will be assessed with Chi Square Test.

Quantitative data will be represented as Mean & Sd. A p-value of <0.05 will be statistically significant. Data was analyzed with IBM SPSS Version 28 for windows.

4. Results

This study included 100 patients who met inclusion and exclusion criteria. Out of 100 tested samples, 70 (70%) were positive for *H. pylori*, suggesting a potential role of this bacterium in ear infections. The distribution of *H. pylori* infection varies across age groups, with the highest percentage of positive cases in the 31-40 age group (27.14%) as shown in **Table 1**, The results even though was found to be not statistically significant was still interesting with a high positivity rate. A higher percentage of females (73.33%) were *H. pylori*-negative compared to males (26.67%) as shown in **Table 2**.

H. pylori was isolated more frequently detected in right ear discharge (58.57%) compared to left ear discharge (41.43%) which was found to be statistically significant as shown in **Table 3**.

Table 1: The distribution of *H. pylori* positive and negative cases across different age groups, along with the results of a chi-square test.

Age	<i>H. pylori</i> positive		<i>H. pylori</i> negative		Chi Square Test
	No	%	No	%	
≤ 10	1	1.43	2	6.67	χ ² Value=8.159, P value=0.227, Not Sig
11-20	15	21.43	5	16.67	
21-30	12	50	4	13.33	
31-40	19	27.14	6	20.00	
41-50	9	12.86	8	26.67	
51-60	8	11.43	3	10.00	
> 60	6	8.57	2	6.67	
Total	70	100.00	30	100.00	

Table 2: shows the distribution of *H. pylori* positive and negative cases by gender, along with the results of the chi-square test.

Gender	<i>H. pylori</i> positive		<i>H. pylori</i> negative		Chi Square Test
	No	%	No	%	
Male	35	50.00	8	26.67	χ^2 Value=4.665, P value=0.03, Sig
Female	35	50.00	22	73.33	

Table 3: shows the distribution of *H. pylori* positive and negative cases based on the site of ear discharge (right ear vs left ear), along with the results of the chi-square test.

Site	<i>H. pylori</i> positive		<i>H. pylori</i> negative		Chi Square Test
	No	%	No	%	
Right Ear Discharge	41	58.57	10	33.33	χ^2 Value=5.353, P value=0.021, Sig
Left Ear Discharge	29	41.43	20	66.67	
Total	70	100.00	30	100.00	

5. Discussion

H. pylori is a spiral-shaped, gram-negative bacterium widely recognized for its involvement in gastric diseases such as gastritis, peptic ulcers, and even gastric cancer. However, recent studies indicate that *H. pylori* may also colonize sites beyond the stomach, including the middle ear, where it may contribute to conditions like OME and persistent ear infections.

Dagli, M, Eryilmaz et al² studied the presence of *H.pylori* in the middle ear of individuals with CSOM. Findings revealed that 53% of middle ear mucosa samples from 41 patients tested positive for *H. pylori*, while the 14C UBT test showed a 79.1% positivity rate in the patient group. Additionally, the study explored the connection between gastric *H. pylori* and its presence in the middle ear, suggesting that the stomach may be the primary source of the bacterium. While the results indicate an association between *H. pylori* and CSOM, they do not establish a causal relationship. Further clinical research is necessary to clarify the bacterium's role in the pathogenesis of chronic ear infections.

Mohammad Ali Damghani, et al³ study revealed a significant presence of *H.pylori* in the middle ear of children with chronic OME, suggesting that *H. pylori* may play a role in OME pathogenesis.

Agirdir, B. Vet al⁵ study employing CLO testing identified the presence of *H.pylori* in middle ear effusions,

indicating its potential role in the etiopathogenesis of OME. Fancy, T., Mathers et al⁸ study confirms the presence of *H.pylori* in the nasopharynx and middle ear. However, they mentioned their results do not support a role for this bacterium in the pathogenesis of OME. Nader Saki, et al⁹ studied colonization of *H. pylori* in adenoid tissue and middle ear might have a role in pathogenesis of ear infection. For OME cases resistant to medical treatment, it might be meaningful to evaluate the patient for *H. pylori*.

Yılmaz et al¹⁰ studied the presence of *H. Pylori* in the middle ears of children with chronic OME, suggesting that *H.Pylori* may play a role in the pathogenesis of OME.

Khasawneh, L. et al¹¹ concluded that although one-third of OME cases are associated with reflux, *H.pylori* does not appear to have a role in the pathophysiology of OME, as it is absent in endo-tympanic exudate. In a study by Karlidag, T. et al¹² *H. pylori* was identified in the middle ear effusion of certain OME patients, which could have intriguing implications for its potential role in OME.

However there have also been studies by Thirumurthi S et al.¹ and Jeyakumar, A et al¹³ which have also shown zero positive cases which *H. pylori* positivity in middle ear effusion samples. Similar result was also found in a study by Pitkäranta, A et al¹⁴ in which they failed to establish any correlation between *H. pylori*, recurrent upper respiratory tract infection and otitis media from the adenoidectomy samples they had tested.¹⁵

In addition, further research is necessary to clarify whether the bacterium reaches the middle ear through gastroesophageal reflux, direct transmission, hematogenous spread, or translocation.⁵

Numerous studies have reported association between *H.pylori* and ear discharge/ middle ear effusions. Our study reaffirmed these findings, demonstrating a high rate of positivity of *H.pylori* in middle ear effusions. Further larger population studies may be needed to substantiate this finding.

6. Conclusion

This study suggests that *H. pylori* is present in ear discharge, with a significant association with site of discharge, particularly in the right ear. However, age and gender did not influence the prevalence of *H. pylori*. In cases of chronic middle ear infections that have been repeatedly treated but remain resistant to therapy, testing for *H. pylori* is recommended due to its multidrug-resistant nature. Further research is needed to better understand the mechanisms of *H. pylori* colonization in ear discharge and its clinical implications.

7. Source of Funding

The authors have no relevant financial or non-financial interest to disclose.

8. Conflicts of Interest

The Authors declare that there is no conflict of interest.

9. Availability of Data and Material

The data used in this study was not used/published in any other publications.

10. Code Availability

The data was compiled and analyzed using IBM SPSS STATISTICS version 28 for Windows.

11. Authors' Contribution

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed Dr Vikram, Dr Monica and Dr Santosh U P. The first draft of the manuscript was written by Dr. Vikram and Dr Arfan, and all other authors commented on previous version of the manuscript. All authors read and approved the final manuscript.

12. Consent to Publication

All authors have reviewed the manuscript and approved the version to be published.

13. Ethics Approval

The study was conducted after obtaining approval from the Institutional Ethics Committee of JJM Medical College, Davangere, Karnataka, India, in accordance with the ethical standards of the institutional and/or national research committee.

14. Consent to Participate

Written informed consent was taken from all the patients.

15. Source of Funding

None.

16. Conflict of Interest

None.

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