Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March 2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1117
Original Article

RAPID UREASE TEST POSITIVITY BY ENDOSCOPY IN ADULT PATIENTS WITH DYSPEPSIA IN A TERTIARY CARE HOSPITAL: A CROSS-SECTIONAL STUDY.

Dr. Deepak[1], Dr. Pankaj Kumar[1], Dr. Manish Kumar*[2], Dr. Ranjeet K Sinha[3], Dr. Amit Kumar[2], Dr. Saurav Raj[2]
[1] Senior Consultant, Gastroenterology,
[2] DrNB Resident, Gastroenterology, BIG Apollo Spectra Hospital, Patna,
[3] Department of Community Medicine, PMCH, Patna

ABSTRACT

Background

Dyspepsia, a common gastrointestinal complaint among adults, necessitates efficient diagnostic methods for tailored treatment. The Rapid Urease Test (RUT) during endoscopy offers a cost-effective and prompt approach to identifying *H. pylori* infection, a prevalent cause of gastritis. This study evaluates the diagnostic value and clinical utility of RUT in adults with dyspepsia.

Methods

A cross-sectional study was conducted, enrolling 500 adult patients undergoing upper gastrointestinal tract endoscopy. Demographic data, indications for endoscopy, and endoscopic findings were collected. The RUT was performed using the RUT Test kit. Random positive samples were subjected to histopathological examination to see the accuracy of the kit and the significance of test accuracy was judged by statistical analyses.

Results

In this study of 500 adult dyspeptic patients, a gender distribution (54% vs 46%) with a preponderance of rural background (66.7%) was observed. Common indications for endoscopy were pain abdomen, RUQ pain, and epigastric burning, with multifocal and mild antral gastritis being predominant endoscopic findings providing insights into dyspepsia and diagnostic methods. Other notable findings included esophageal and duodenal abnormalities, a history of hepatitis (25.6%), and chronic liver disease (15.5%). *H. pylori* infection was detected in 32.4% of cases on RUT. Sedation was administered in 39.1% of cases.

Conclusion

The RUT during endoscopy is a valuable diagnostic tool for *H. pylori*-associated gastritis in dyspeptic patients. Its high sensitivity and specificity enable prompt and early targeted therapy for better outcomes. RUT during endoscopy for dyspeptic patients should be considered, especially in populations with a high prevalence of *H. pylori* infection.

Recommendations

The study highlights the effectiveness of the RUT for diagnosing *H. pylori* in dyspeptic patients during endoscopy. Given its accuracy and cost-effectiveness, RUT is recommended for routine use in regions with high *H. pylori* prevalence.

Keywords: *Dyspepsia, Rapid Urease Test, Helicobacter pylori, Endoscopy.*
Submitted: 2024-03-28 Accepted: 2024-03-30

Corresponding author: *Dr. Manish Kumar**
Email: *medico.manish@gmail.com*
Dr. NB Resident, Department of Gastroenterology, BIG Apollo Spectra Hospital, Patna.

INTRODUCTION

The Rapid Urease Test (RUT), conducted during endoscopy, is a significant diagnostic tool for adult patients experiencing dyspepsia. Dyspepsia, characterized by chronic or recurrent discomfort centered in the upper abdomen, is a prevalent gastrointestinal complaint among adults [1]. Its multifactorial etiology demands efficient diagnostic methods to tailor appropriate treatments. The RUT emerges as a frontline diagnostic method due to its simplicity, cost-effectiveness, and rapid results [2].

This test, performed during an endoscopic procedure, involves obtaining gastric mucosal biopsies from patients. These biopsies are then exposed to a urea-containing medium. *H. pylori*, if present, produces urease, an enzyme

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March 2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1117
Original Article

that hydrolyzes urea, resulting in a rapid change in the pH of the medium. This change is visually detectable, often within minutes, providing a prompt and direct indication of *H. pylori* infection [3].

The diagnostic value of the RUT lies in its high sensitivity and specificity, particularly in populations with a high prevalence of *H. pylori* infection. Its immediate results enable clinicians to initiate targeted therapy without delay, an important aspect in managing dyspeptic symptoms efficiently [4].

This study aims to evaluate whether *H. pylori* infection is a common cause among adults presenting with dyspepsia and symptoms similar to dyspepsia.

Objectives of the study

- Evaluate the prevalence of *H. pylori* infection among adults presenting with dyspepsia or similar symptoms.
- Assess the diagnostic reliability and clinical utility of the RUT when performed during endoscopy in patients with indications for the procedure.

METHODOLOGY

Study design

A cross-sectional diagnostic study

Study setting

The study was conducted at Big Apollo Spectra Hospital, Agam Kua, Patna, Bihar, India, over a period from '1st January 2024 to 15th March 2024.

Participants

The total number of participants in the study was 500.

Inclusion criteria

Adult patients over 18 years, presenting with dyspepsia and dyspepsia-like symptoms indicated for upper gastrointestinal tract endoscopy were included in the study.

Exclusion criteria

Patients having pregnancy, breastfeeding, refusal or contraindication to undergo endoscopy, gastric malignancy findings, and recent consumption of antibiotics, NSAIDs, or proton pump inhibitors were excluded.

Study size

To calculate the sample size for this study, the following formula was used for estimating a proportion of a population:

$$n = \frac{Z^2 \times p \times (1-p)}{E^2}$$

Where:

- n = sample size
- Z = Z-score corresponding to the desired level of confidence
- p = estimated proportion in the population
- E = margin of error

Bias

There was a chance that bias would arise when the study first started, but it was avoided by giving all participants identical information and hiding the group allocation from the nurses who collected the data.

Variables

Key variables included patient demographics, clinical indications, and endoscopic and histopathological results.

Data collection

Participants underwent endoscopic examination under sedation, if needed, with biopsies taken for the RUT and histopathological examination in random positive cases to crosscheck the reliability of the kit. The RUT was performed using the RUT Test kit, with results interpreted after 40 minutes.

The study data on demographics (age, sex), indications for endoscopy, endoscopic findings, presence of *H. pylori*, and other variables like rural/urban background, co-morbidities, and complications, were collected on a predesigned proforma and entered into MS Excel spreadsheet.

Statistical Analysis

Sensitivity, specificity, PPV, NPV, and LR of the RUT were calculated, incorporating data from the Excel sheet. A p-value of <0.05 was considered significant.

Ethical Considerations

The study was conducted by the ethical standards of the institutional research committee. Informed consent was obtained from all individual participants included in the study.

RESULT

In this study, a total of 520 individuals were initially identified as potentially eligible for participation. Upon further examination of eligibility criteria, 510 were confirmed eligible. Out of these, 500 agreed to participate and were included in the study after providing informed consent. All 500 participants completed the study and their data was included in the final analysis. The reasons for non-participation among the 10 who were confirmed eligible but did not participate included personal reasons and discomfort

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March 2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1117
Original Article

with undergoing an endoscopic procedure. Additionally, 10 individuals were excluded after the initial assessment due to reasons such as recent antibiotic use, pregnancy, or other contraindications to endoscopy.

Table 1.1: Demographic characteristics of the study population

Parameter	Frequency (Number)	Percentage (%)
Total Participants	500	100%
Sex		
- Female	271	54%
- Male	229	46%
Age (Mean)	42.6 years ± 21.6	
Residence		
- Rural	333	66.7%
- Urban	167	33.3%

Table 1.2: Endoscopic characteristics of the study population

Parameter	Frequency (Number)	Percentage (%)
Indication for Endoscopy		
- Pain Abdomen	176	35.3%
- RUQ Pain	80	15.9%
- Epigastric Burning	68	13.5%
Endoscopic Findings		
- Multifocal Gastritis	199	39.8%
- Mild Antral Gastritis	194	38.%
- Erosive Gastritis	53	10.6%
H. pylori Infection	162	32.4%
Other Endoscopic Findings		
- Prominent Veins (Esophagus)	31	6.3%
- Esophagitis	21	4.8%
- Duodenal Ulcers	43	8.7%
- Varices (Grade 3)	14	2.9%
History of Hepatitis	128	25.6%
Chronic Liver Disease (CLD)	77	15.5%
Complications		
- Reflux Esophagitis	10	1.9%
- Duodenitis	5	1.0%
- Candidiasis	5	1.0%
- Achalasia Cardia	2.5	0.5%
Sedation Administered	196	39.1%
Residence		
- Rural	333	66.7%
- Urban	167	33.3%

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March 2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1117
Original Article

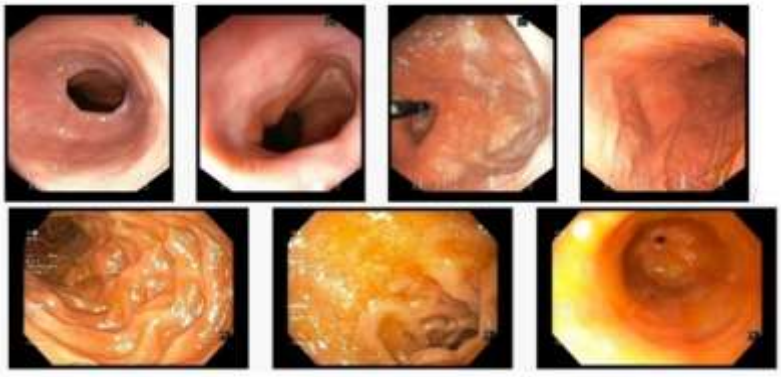
Table 1.3: Clinical characteristics of the study population

Parameter	Frequency (Number)	Percentage (%)
History of Hepatitis	128	25.6%
Chronic Liver Disease (CLD)	77	15.5%
Complications		
- Reflux Esophagitis	10	1.9%
- Duodenitis	5	1.0%
- Candidiasis	5	1.0%
- Achalasia Cardia	2.5	0.5%
Sedation Administered	196	39.1%

A total of 500 adult patients with dyspepsia were included in the study. Among them, 54% were females, and 46% were males. The ages of the participants ranged from 6 to 80 years, with a mean age of 42.6 years. Sedation was administered in 39.1% of endoscopic procedures for various reasons. Additionally, 66.7% of the participants were from rural areas, while 33.3% were from urban areas.

The most common indication for endoscopy among the participants was pain abdomen (35.3%), followed by RUQ (right upper quadrant) pain (15.9%) and epigastric burning (13.5%). The predominant endoscopic findings were multifocal gastritis (51.7%), mild antral gastritis (27.1%), and erosive gastritis (10.6%). *H. pylori* infection was detected in 32.4% of the cases**.** Out of the positive RUT cases it was distributed 35 out of 194 (18%) in Mild antral gastritis were positive for RUT, 63 out of 199 (31.6%) in Multifocal gastritis 12 out of 53 (22.6%), 14 out of 77 (18.1%) patients of CLD**.** The sensitivity and specificity of the RUT Test Kit were found to be 84% and 91%, respectively. The positive predictive value and negative predictive value were calculated to be 78% and 95.4%.

Figure 1: Showing Negative results of RUT done for *H. pylori*



Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March 2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1117
Original Article

Figure 2: Showing Positive results of RUT done for *H. pylori*

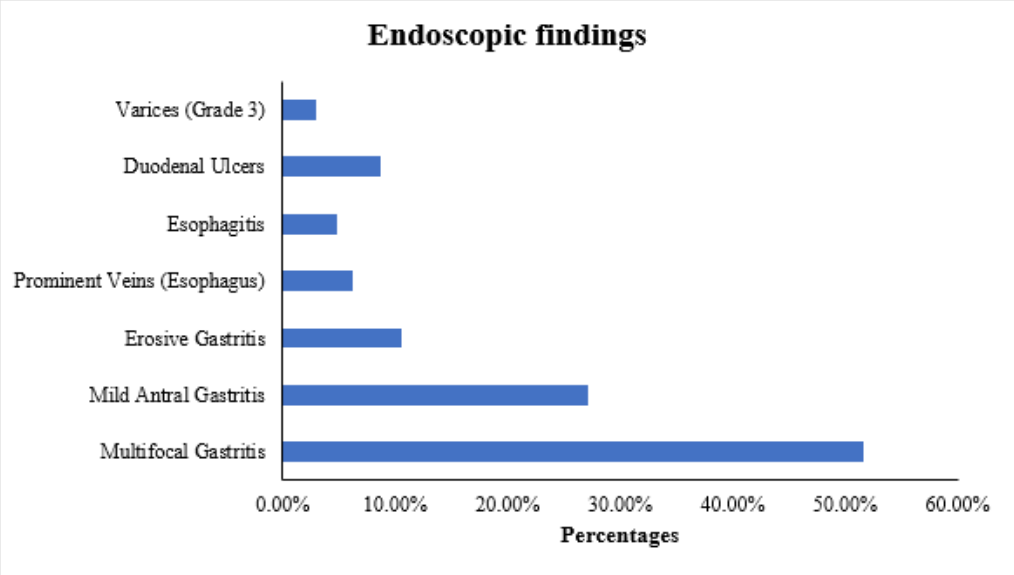


Figure 3: Endoscopic findings of the study population

Regarding other endoscopic findings, prominent veins in the esophagus were observed in 6.3% of cases, and esophagitis was present in 4.8% of cases. Duodenal ulcers were found in 8.7% of patients, and varices (grade 3) were observed in 2.9% of cases.

Among the patients, 25.6% had a history of hepatitis, and 15.5% had chronic liver disease (CLD). Complications such as reflux esophagitis, duodenitis, candidiasis, and achalasia cardia were identified in a subset of patients.

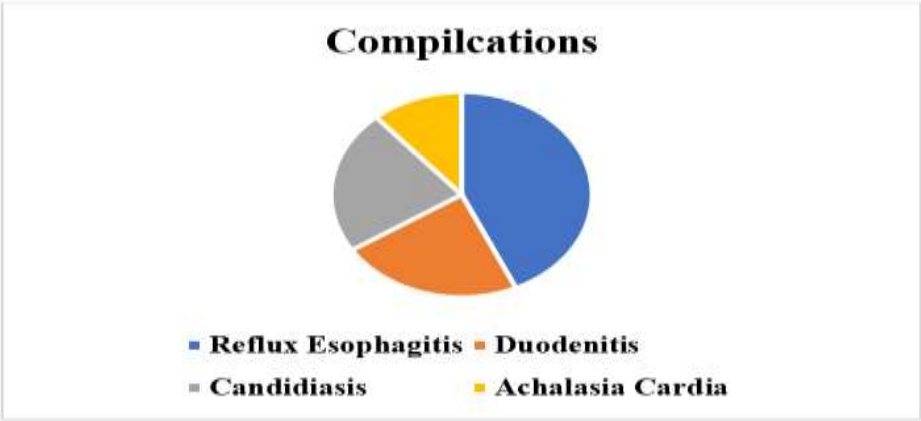


Figure 4: Complications observed in the study population

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March 2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1117
Original Article

Table 2: Endoscopic and Histopathological Findings

Findings in Endoscopy	N (%)
Esophagus Inspection Results	
- Unremarkable	159 (31.88%)
- Esophagitis, Grade A	152 (30.43%)
- Esophagitis, Grade B	36 (7.25%)
- Esophagitis, Grade C	29 (5.80%)
- Esophagitis, Grade D	5 (0.97%)
- Miscellaneous Findings	14 (2.90%)
Gastric Examination Outcomes	
- Normal Condition	19 (3.86%)
- Gastric Atrophy	5 (0.97%)
- Gastritis with Lesion	14 (2.90%)
- Gastritis Coexisting with Ulcer	24 (4.83%)
- Gastric Lesion and Ulcer	10 (1.93%)
- Isolated Gastric Ulcer	10 (1.93%)
Duodenal Scope Findings	
- No Abnormality Detected	290 (58.10%)
- Duodenitis Alone	68 (13.57%)
- Duodenitis with Erosion	14 (2.90%)
- Duodenitis and Ulcer Present	14 (2.90%)
- Erosion and Ulcer in Duodenum	10 (1.93%)
- Sole Duodenal Ulcer	19 (3.86%)
- Duodenal Mass Identified	10 (1.93%)

Among the participants, 66 individuals (31.88%) had unremarkable esophageal findings, while 152 (30.43%) showed signs of Esophagitis, Grade A. Esophagitis, Grade B was observed in 36 cases (7.25%), followed by Esophagitis, Grade C, which was present in 29 cases (5.80%). Only 5 individuals (0.97%) exhibited signs of Esophagitis, Grade D. Miscellaneous findings were noted in 14 cases (2.90%).

In the gastric examination, 19 participants (3.86%) had a normal gastric condition, while 5 individuals (0.97%) showed signs of gastric atrophy. Gastritis with lesions was found in 14 cases (2.90%), while 24 participants (4.83%) exhibited gastritis coexisting with an ulcer. A combination of gastric lesions and ulcers was observed in 10 individuals (1.93%), and isolated gastric ulcers were seen in 10 cases (1.93%).

The duodenal scope findings revealed that the majority, 290 participants (58.10%), had no abnormalities detected in the duodenum. Duodenitis alone was noted in 68 cases (13.57%), while 14 individuals (2.90%) had duodenitis with erosion. Similarly, 14 participants (2.90%) exhibited duodenitis along with an ulcer. Erosion and ulcers in the duodenum were identified in 10 cases (1.93%), and sole duodenal ulcers were present in 19 individuals (3.86%). Additionally, 10 participants (1.93%) had a duodenal mass identified during the endoscopic examination.

DISCUSSION

In the study, the mean age of participants was 42.6 years, with a gender distribution of 54% females and 46% males. This demographic information is crucial for understanding the prevalence of gastrointestinal issues in this age group. Comparatively, the study [5] also underscores the significance of age and gender in endoscopic findings, indicating that patients over 60 years and males tend to have longer transit times and higher positive findings rates. This comparison highlights the importance of age and gender as significant factors in endoscopic diagnostics in diverse populations.

The study identified pain in the abdomen, RUQ pain, and epigastric burning as the primary indications for endoscopy, aligning with findings from the study [6]. This consistency emphasizes the universal nature of these gastrointestinal symptoms as primary motivators for endoscopic examination across different geographical regions.

The findings, including multifocal gastritis, mild antral gastritis, and erosive gastritis, are noteworthy. These results are consistent with the study [7], which discusses the detection of gastrointestinal diseases using endoscopic techniques and assessment of *H. Pylori* infection positivity by Rapid Urease Test in various conditions. The prevalence of gastritis-related findings in both studies underscores the common occurrence of these conditions in patients undergoing endoscopy.

Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol. 5 No. 3 (2024): March 2024 Issue
https://doi.org/10.51168/sjhrafrica.v5i3.1117
Original Article

Notably, 32.4% of the study participants tested positive for *H. pylori*, indicating its significance in various gastrointestinal diseases. Important findings of the study included those patients with MAG have a significant percentage of *H. Pylori* Positivity (%) compared with other significant endoscopic findings. A good percentage of CLD patients were positive for RUT suggesting possible involvement in the progression of the disease. The RUT Test Kit test's sensitivity and specificity in detecting *H. pylori* were 84% and 91%, respectively, highlighting its reliability as a diagnostic tool. This aspect underscores the importance of accurate diagnostic methods in managing gastrointestinal diseases.

The study reveals a significant link between *H. pylori* infection and chronic liver disease since these patients are highly prone to Hepatic Encephalopathy and ammonia metabolism is an important precipitating factor emphasizing the infection's role in potentially worsening liver conditions.

Early detection of *H. Pylori* infection may aid in the treatment and favorable outcome of the disease and prevent the progression of Hepatic encephalopathy. It suggests that treating and eradicating *H. pylori* could markedly improve outcomes for liver disease patients, offering a new pathway for enhancing care. Furthermore, the research highlights the Rapid Urease Test's effectiveness and efficiency in diagnosing *H. pylori*, proposing its use as a tool to refine clinical decision-making and patient outcomes. This discovery paves the way for further investigation into *H. pylori* targeted treatments within liver disease management, promising to improve strategies for patient care and disease control.

Generalizability

To assess the generalizability of the study results, future research could focus on replicating the study in diverse populations with varying demographics, disease spectra, H. pylori prevalence rates, and healthcare infrastructures. Comparative studies across different healthcare settings and regions can further validate the external validity of the findings and guide the applicability of RUT testing in clinical practice globally.

CONCLUSION

This study explores the use of the Rapid Urease Test (RUT) for diagnosing *H. Pylori* infection in adults with dyspepsia during endoscopy, uncovering surprising findings. Notably, *H. Pylori* was found in seemingly normal mucosa, challenging expectations, while some expected positive cases of Multifocal Gastritis tested negative. Furthermore, a considerable number of Chronic Liver Disease (CLD) patients at risk for Hepatic Encephalopathy were *H. Pylori* positive, suggesting early treatment could prevent disease progression.

The research advocates for RUT's integration into dyspepsia diagnostics, highlighting its cost-effectiveness, reliability, and patient-friendly nature. RUT proves to be a key tool in dyspepsia management, enabling personalized treatment plans and providing insights into gastrointestinal health. With high sensitivity and specificity, RUT is recommended for clinicians, especially where *H. Pylori* is prevalent, ensuring medication history is considered for accurate results. This study positions RUT as a transformative approach in gastrointestinal diagnostics, promoting proactive and patient-centric healthcare. The only limitation of this study includes the non-feasibility of culturing samples to directly confirm the presence of *H. pylori*. The reliance on the Rapid Urease Test, while effective for immediate diagnosis, precludes the possibility of performing culture-based confirmation, which may affect the comprehensive understanding of *H. pylori* prevalence and its strain-specific characteristics within the study population.

Limitations

The study limitations include the sample size's potential selection bias and limited generalizability due to its single-center nature. Variations in H. pylori prevalence and diagnostic test accuracy could also impact findings, alongside incomplete clinical data and limited follow-up information. These factors suggest cautious interpretation and highlight the need for larger, multicenter studies with standardized protocols and comprehensive data collection for more robust conclusions.

Recommendations

The study highlights the effectiveness of the RUT for diagnosing *H. pylori* in dyspeptic patients during endoscopy. Given its accuracy and cost-effectiveness, RUT is recommended for routine use in regions with high *H. pylori* prevalence.

Acknowledgment

We are thankful to the patients; without them, the study could not have been done. We are thankful to the supporting staff of the hospital who were involved in the patient care of the study group.

List of abbreviations

RUT: Rapid Urease Test
H. pylori: Helicobacter pylori
NPV: Negative Predictive Value
PPV: Positive Predictive Value
NSAIDs: Nonsteroidal Anti-Inflammatory Drugs
LR: Likelihood Ratio
SD: Standard Deviation

RUQ: Right Upper Quadrant
MAG: Mild antral gastritis
CLD: Chronic liver disease

Source of funding
No funding was received.

Conflict of interest
The authors have no competing interests to declare.

REFERENCES
1. Talley NJ, Zinsmeister AR, Schleck CD, Melton III LJ. Dyspepsia and dyspepsia subgroups: a population-based study. Gastroenterology. 1992 Apr 1;102(4):1259-68.
2. Vijay N. *Diagnostic Role of Endoscopy in Upper Gastrointestinal Diseases* (Doctoral dissertation, Rajiv Gandhi University of Health Sciences (India)). 2018
3. Kulkarni DP, Sreeramulu PN, Natrajan A, Srinivasa D, Kumar YR. Comparative Study of Endoscopic Rapid Urease Test with Serology of Helicobacter Pylori Infection in Acid Peptic Disease. International Journal of Health Sciences. 2022, (III):3305-14.
4. Aftab H, Yamaoka Y, Ahmed F, Khan AA, Subsomwong P, Miftahussurur M, Uchida T, Malaty HM. Validation of diagnostic tests and epidemiology of Helicobacter pylori infection in Bangladesh. The Journal of Infection in Developing Countries. 2018 May 31;12(05):305-12.
5. Hausmann J, Tal A, Gomer A, Philippe M, Moog G, Hohn H, Hesselbarth N, Plass H, Albert J, Finkelmeier F. Colon Capsule Endoscopy: Indications, Findings, and Complications - Data from a Prospective German Colon Capsule Registry Trial (DEKOR). Clin Endosc. 2021 Jan;54(1):92-99. doi: 10.5946/ce.2020.049. Epub 2020 Jun 18. PMID: 32549533; PMCID: PMC7939783.
6. Egea Valenzuela J, Sánchez Martínez A, García Marín AV, Alberca de Las Parras F. Influence of demographic and clinical features of the patient on transit times and impact the on the diagnostic yield of capsule endoscopy. Rev Esp Enferm Dig. 2019 Jul;111(7):530-536. doi 10.17235/reed.2019.5971/2018. PMID: 31140286.
7. Kamran M, Fawwad A, Haider SI, Hussain T, Ahmed J. Upper gastrointestinal endoscopy; A study from a rural population of Sindh, Pakistan. Pak J Med Sci. 2021 Jan-Feb;37(1):9-14. doi: 10.12669/pjms.37.1.3297. PMID: 33437243; PMCID: PMC7794160.

Publisher details:

SJC PUBLISHERS COMPANY LIMITED

Category: Non-Government & Non-profit Organisation
Contact: +256775434261(WhatsApp)
Email: admin@sjpublisher.org, info@sjpublisher.org or studentsjournal2020@gmail.com
Website: https://sjpublisher.org
Location: Wisdom Centre Annex, P.O. BOX. 113407 Wakiso, Uganda, East Africa.