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Original Research Article

Comparative study of rapid urease test and histopathological examination for detection of *H. pylori* infection

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ABSTRACT

Background: Aims and objectives of the study was to study the incidence of *H. pylori* infection in our Hospital. To find out the sensitivity and specificity of rapid urease test (RUT) and histopathological examination for the detection of *H. pylori* on gastric biopsy. To study the effect of anti *H. pylori* drugs by performing follow-up endoscopy in terms of positive or negative Rapid Urease Test and Histopathological Examination report.
Methods: The study was conducted at Dr. D. Y. Patil Medical College and Hospital, DPU University, for a period of 2 years (from July 2012-September 2014) and is a prospective and comparative randomized type of study using 100 patients. The study was approved by the Institute's Ethics Committee.
Results: Data analysis showed that: In our study 84 patients (84%) were detected positive by RUT method. In our study 83 patients (83 %) were detected positive by HPE method. There was an association between RUT and HPE finding in study group with the sensitivity being 96.38 % and specificity being 74.47 %, PPV was 95.24% and NPV was 81.25%. At the time of follow up after taking anti *H pylori* treatment, 79 patients were RUT negative and 8 were RUT positive who were defaulters (not taken complete dose) and again started on treatment with the accuracy of the drug being 98.85 %. At the time of follow up after taking anti *H pylori* treatment 78 patients were HPE negative and 9 were HPE positive who were defaulters (not taken complete dose) and again started on treatment. There was an association between RUT and HPE finding at follow up with the sensitivity being 88.89 % and specificity being 100%, PPV was 100% and NPV was 98.73%.
Conclusions: Our study reveals that RUT is accurate for the diagnosis of *H. pylori* infection and its use will serve as a good alternative to histology in management of patients with dyspepsia in resource poor environments, except in patients who need histology for reasons other than *H. pylori* diagnosis.

Keywords: Anti *H. Pylori* treatment, *H. Pylori*, RUT

INTRODUCTION

Helicobacter pylori (*H. pylori*) infection is very common throughout the world, occurring in 40-50% of the population in developed countries and 80-90 % of population in developing regions. Since the discovery of *H. pylori* by Marshall and Warren in 1983, overwhelming evidence has accumulated to confirm that *H. pylori* infection plays a significant role in the development of chronic active gastritis and peptic ulcer.[1] *H. pylori* is the etiologic agent of acute and chronic gastritis, peptic ulcer disease and two forms of gastric cancer.[2]

Up to 80% of gastric carcinomas and 92% of low grade gastric mucosa-associated lymphoid tissue lymphomas are *H. pylori* associated.[3] Every method for detection of H Pylori has its own inherent advantages and disadvantages. Rapid Urease Test (RUT), with its high sensitivity and specificity, is considered to be a quick and reliable test for the initial diagnosis of *H. pylori* infection and is simple and inexpensive.[4]

The present study is done for evidence of *H. pylori* infection in our set up and detection of *H. pylori* from Gastric biopsy specimen using Rapid Urease Test and Histopathological examination and the efficacy of the anti *H. pylori* treatment by doing the follow up endoscopy and diagnostic test.

In this study, we aim: to study the incidence of *H. pylori* infection in our Hospital. And to find out the Sensitivity and Specificity of Rapid Urease Test and Histopathological Examination for the detection of *H. pylori* on gastric biopsy. Also, to study the effect of anti *H. pylori* drugs by performing follow-up Endoscopy in terms of positive or negative Rapid Urease Test and Histopathological Examination report.

METHODS

The study was conducted at Dr. D. Y. Patil Medical College and Hospital, DPU University, for a period of 2 months (from July 2012-September 2014) and is a prospective and comparative randomized type of study using 100 cases. The study was approved by the Institute's Ethics Committee.

Inclusion criteria

- Age- 18-75 years
- All patients with upper abdominal pain more than 6 month.

Exclusion criteria

- Alcoholic Patients
- Patients taking NSAIDS[5]
- Acute Abdominal pain
- Immunocompromised patient
- Active TB.

In our study, 100 patients with history of epigastric pain for more than 6 months, burning sensation in epigastric region, were admitted and evaluated. Patients taking NSAIDS and PPIs were advised to stop taking the drugs at least 5 days prior to endoscopy. HIV and HbSAg status was done.

Patients were kept Nil by Mouth (NBM) 4-6 hrs. prior to Endoscopy. Four biopsies were taken from different sites (Antrum and Pylorus). Two biopsies were sent to the Pathology department in plain bulb containing 1:10 mixture of distilled water and formalin after the endoscopy for examination, and other two biopsies were subjected to RUT and result was seen within 1-2 hrs.

Specific preparation

Patients were instructed not to eat or drink for 4-6 hours before endoscopy. Patients with gastric outlet or oesophageal obstruction were kept NBM for a longer period.

Pre-endoscopy preparation

IV access was obtained for giving IV fluids and SOS Injectable Antispasmodics.

Premedication

Premedication consists of local oral anaesthesia by lidocaine topical aerosol (LOX 10% oral spray).

Examination

All patients were kept NBM for 6 hrs prior to endoscopy and after bringing the patient to endoscopy room LOX 10% spray was sprayed on the both tonsillar pillars, posterior pharyngeal wall and after waiting for 5 minutes, patient was kept in left lateral position with the head on a small pillow flexed forward and mouth tilting downward to facilitate drainage of saliva and a pulse oximeter was attached to the patient and endoscope was introduced after placing a mouth gag.

The scope was passed through the oropharynx and nudged through cricopharynx under vision with the voluntary swallowing movement of the patient. The scope was rapidly passed through the esophagus doing a rough scanning and leaving the detailed mucosal examination to be done during withdrawal.

As per the endoscopic finding a total of 4 biopsies were taken. 2 of the biopsy samples were taken for the RUT and rest for the Histopathological Examination. After confirming haemostasis, the scope was removed after deflating the stomach.

2 biopsies were placed on yellow paper of RUT kit after removing the plastic cover and a single drop of distilled water was placed on yellow paper and then plastic cover was again sealed with its own adhesive and results were observed after 1- 2 hrs. Change of colour of yellow paper to pink indicates an *H. pylori* infection.

2 biopsies were sent for histopathological examination, in a plain bulb containing 1:10 of formalin and water mixture to the pathology department, for Giemsa stain.

The patient was advised to start oral diet after 1 hour of procedure. Negative PPI Started immediately. The anti *H. pylori* therapy included: a Lansoprazole (PPI) 30 mg,

clarithromycin 500 mg, and Tinidazole 500 mg for a duration of 14 days.

Table 1: Algorithm.

RUT	Histopathological examination	Remark
Positive	Positive	Anti *H. Pylori* therapy started Immediately
Positive	Negative	Anti *H. Pylori* therapy started Immediately
Negative	Positive	PPI Started immediately and Anti *H. Pylori* therapy after HPE report.
Negative	Negative	PPI Started immediately

Follow up

H. pylori positive patients were advised for follow up endoscopy after 6 weeks of completion of the treatment. Patient was again assessed by doing follow up endoscopy and taking biopsies for RUT and HPE.

RESULTS

The Table 2 showing that 84 patients out of 100 are RUT positive and 16 patients are RUT negative.

Table 2: RUT wise distribution of cases in study group.

RUT	No of cases	Percentage
Positive	84	84
Negative	16	16
Total	100	100

The Table 3 showing that Total 83 patients shows presence of *H. pylori* positive in HPE.

Table 3: HPE finding wise distribution of cases in study group.

HPE finding	No of cases	Percentage
Positive	83	83
Negative	17	17
Total	100	100

Table 4: Association between RUT and HPE finding in study group.

RUT	HPE		Total
	Positive	Negative	
Positive	80	4	84
Negative	3	13	16
Total	83	17	100

Chi-square=55.73, P<0.0001, Sensitivity=96.38%, Specificity=74.47%, PPV=95.24%, NPV=81.25%, Accuracy=93%.

This Table 4 showing total no. of cases positive for both RUT and HPE positive is 80 RUT positive and HPE negative is 4 and HPE positive and RUT negative is 3 and both negative is 13.

Table 5: Treatment wise distribution of cases in study group.

Treatment	No of cases	Percentage
Anti *H pylori*	87	87
PPI	13	13
Total	100	100

The Table 5 showing that 87 patients were treated with anti h pylori treatment and rest with PPI.

Table 6: RUT at follow up wise distribution of cases in study group.

RUT	No of cases	Percentage
Positive	8	9.20
Negative	79	90.80
Total	87	100

This Table 6 showing that 9.20% cases were positive RUT at the time of follow up after treatment and rest that is 90.80 % were RUT negative.

Table 7: HPE finding at follow up wise distribution of cases in study group.

HPE finding	No of cases	Percentage
Positive	9	10.34
Negative	78	89.66
Total	87	100

This Table 7 shows that 10.34 % cases were positive in HPE at the time of follow up and rest were negative.

This Table 8 showing total number of cases positive for both RUT and HPE were 8 and RUT positive and HPE negative were 0 and both RUT and HPE negative were 78 and HPE positive and RUT negative were 1.

It shows that RUT is 88.89 % sensitive and 100 % specific and accuracy of treatment was 98.85 %.

Table 8: Association between RUT and HPE finding at follow up in study group.

RUT at follow up	HPE at follow up		Total
	Positive	Negative	
Positive	8	0	8
Negative	1	78	79
Total	9	78	87

Chi-square=66.08, P<0.0001, Sensitivity=88.89%, Specificity=100%, PPV=100%, NPV=98.73%, Accuracy=98.85%.

DISCUSSION

RUT results at first presentation

In our study 84 patients were detected positive by RUT method. This is comparable with study conducted by Jemilohun et al found RUT is accurate for the diagnosis of *H. pylori* infection. Its use will serve as a good alternative to histology in management of patients with dyspepsia in resource poor environments, except in patients who need histology for reasons other than H. Pylori diagnosis.[6]

HPE results at first presentation

In our study 83 patients (83 %) were detected positive by HPE method. This is comparable with study conducted by MDU Islam, SHZ Rahman et al found culture, RUT and HPE all are high sensitive and specific to diagnose H. pylori infection.[7]

Association between RUT and HPE finding in study group

The sensitivity was 96.38 % and specificity was 74.47 %, PPV was 95.24% and NPV was 81.25%. This is comparable with study conducted by Jemilohun et al found sensitivity, specificity, PPV and NPV was 93.33%, 75.6 %, 80.76 % and 91.17 % respectively.[6]

Treatment for H. pylori infection

We have given triple drug therapy (Lansoprazole 30mg, Clarithromycin 250 mg, Tinidazole 500mg or Metronidazole 400mg) for 14 days with patients with *H. pylori* gastritis and PPI for nonspecific gastritis. This is comparable with study conducted by Yesim Ozen Alahdab et al and found that triple drug therapy remains an appropriate first line therapy in areas of low clarithromycin resistance.[8]

RUT results at the time of follow up

At the time of follow up after taking anti *H. pylori* treatment, 79 patients are RUT negative and 8 are RUT positive which are defaulters (not taken complete dose) and again started on treatment with the accuracy of the drug being 98.85 %.

HPE results at the time of follow up

At the time of follow up after taking anti *H. pylori* treatment, 78 patients are HPE negative and 9 are HPE positive which are defaulters (not taken complete dose) and again started on treatment.

Association between RUT and HPE finding at follow up

The sensitivity was 88.89 % and specificity was 100%, PPV was 100% and NPV was 98.73%. This is comparable with study conducted by Megraud F. found sensitivity, specificity, PPV and NPV was 93.33%, 100 %, 80.76 % and 91.17 % respectively.[9] According to Islam MDU, Shamsuzzaman SHZ et al, a comparative study among different invasive methods for the diagnosis of *H. pylori* was done and it was concluded that comparing among culture, rapid urease test, and histopathology methods all are highly sensitive and specific to diagnose *H. pylori* infection.10

CONCLUSION

The results support the view that RUT is accurate for the diagnosis of *H. pylori* infection as it is as sensitive to HPE examination. Main disadvantage of this procedure is that it is an invasive procedure. In our population the OMA regimen shows 99 % sensitivity which was proven by follow up biopsy with RUT and HPE. To conclude, our study reveals that RUT is accurate for the diagnosis of *H. pylori* infection and its use will serve as a good alternative to histology in management of patients with dyspepsia in resource poor environments, except in patients who need histology for reasons other than H. pylori diagnosis.

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