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## RESEARCH ARTICLE

### AN OBSERVATIONAL STUDY ON EFFECTIVENESS OF H.PYLORI ERADICATION THERAPY AND UTILIZATION OF ACID SUPPRESSANT MEDICATIONS IN PATIENTS WITH PEPTIC ULCER DISEASE

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#### ABSTRACT

It remains unknown whether successful H. Pylori eradication therapy leads to a relief of dyspepsia and subsequent arrest or reducing the acid suppressants use. Aim of the study is to assess H. Pylori eradication therapy and utilization of acid suppressant medications in patients with peptic ulcer disease. The eradication of helicobacter pylori is recommended for patients with peptic ulcer. In the present study out of 280 patients consulted 82 had H. Pylori positive result. Among these 60 patients undergone eradication therapy successfully. This result in the arrest of acid suppressant medication and attain complete cure during the follow up period. The remaining patients are still on maintenance therapy with acid suppressants. This study also finds out whether the use of acid suppressants is inappropriate and is prescribed for justified indication. Around 60% of patients is taking acid suppressant for non justified cases. This will lead to the long term use of medications and increases economic burden to the patients.

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## INTRODUCTION

Peptic ulcer broadly refers to a group of disorder characterized by the presence of ulcer in any portion of GIT exposed to acid. Acid suppressant drugs is used for the treatment of peptic ulcer (De Boer *et al.*, 2008). Repeat prescription of acid suppressants represent an important burden on health care resources. it leads to inappropriate use of drugs in turn leading to possible damage to patients health. (1) Eradication is the treatment of choice in patients with H. Pylori positive in peptic ulcer. (2) Cure of healing accelerates healing, prevents ulcer bleeding, improves quality of life and significantly reduce ulcer relapse. H. Pylori eradication was defined as the inability to detect evidence of infection on examination such as serology test, endoscopic examination etc atleast 4 weeks after eradication therapy (Abu-Mahfouz *et al.*, 1997; Bell *et al.*, 1993). Few patients with a history of peptic ulcer are treated by their general practitioners, for H. Pylori infection, even though theoretical evidence supports such an approach. (3) However special attention should be taken when approaching a patients with PUD otherwise it will lead to complicated disease and overburden to patients both quality and economic aspects (Borody *et al.*, 1992).

## MATERIALS AND METHODS (Bodger *et al.*, 1996; El-Omar *et al.*, 2004)

### Study Design

This is an observational based prospective study.

### Study Period

Study is conducted between May 2012 to February 2013.

### Study Population

Total number of population taken is 370. From that 90 patients are excluded with various reason. Finally 280 patients profile is taken for the study.

### Designing of Data Collection Form

A suitable data collection form was designed to collect and document the data. Data collection form includes Demographic details of the patients, past medical history, drugs prescribed by generic name, laboratory data, social status and improvement of GI symptoms. It includes a question about the patients satisfaction to the cost of acid suppressant drugs they used. Time taken to complete the question is around 4 minutes.

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## Study Procedure

Initially a data collection form was prepared according to the study going to be conducted. Patients case histories are randomly collected contains patients with a history of peptic ulcer documented by endoscopy or serology and who were still taking acid suppressants to control symptoms such as dyspepsia. And also noted the patient prescription sheet containing ASMs for unjustified indication in the GE department. This is done based on the ASHP therapeutic guidelines and FDA approved prescribing information. Another important factors noted is the duration time, side effects and category of ASMs used. All this information is filled in data collection form. Identification of patients was done when they requested a repeat prescription for acid reducing drugs from pharmacy records or computer search during consultation. Drug prescription were used to identify continuous usage of ASMs after discharge from hospital. Patients were excluded when aged <15 years or when it was documented that ulcer had been induced by NSAIDs or aspirin.

Patients were divided into two categories according to the endoscopic and serology report for the easy assessment of the study. One group having HP+ve result and others having HP-ve report. Case histories are then consulted to find out whether they undergone H.Pylori eradication therapy or they still on maintenance ASMs therapy. Data regarding the H.Pylori eradication therapy are consulted to evaluate the effectiveness of therapy<sup>6</sup>. Follow up also noted for 6 months. Cure rate is described as at least 6 weeks after cessation of therapy, all patients were endoscoped to test for cure or blood samples are collected before and after 6 months follow-up treatment. Success was defined if the test shows H. Pylori negative. Patients were asked to answer the question prior to, and at 6 weeks and 6 months after treatment. Some are refused to participate in the study. A gastric symptoms list was used to obtain more detailed information about dyspeptic complaints at the initial, 6 weeks and 6 month follow up visit. Use of antacids and ASMs was reported prior to antibiotics (Eom *et al.*, 2011).

## Ethical Committee Approval

Ethical committee approval for the study was obtained from the institutional ethics committee. Confidentiality and anonymity of the patient's information were maintained during and after the study. The patients were asked for oral consent to participate in the study before filling the form

## Data Analysis and Processing

All data were coded, entered and analysed using statistical package. Result was expressed in mean, standard deviation, in percentage, 95% confidence interval and p-value was determined.

## RESULTS

### Age Wise Distribution

In the present study it was shown that the acid suppressant drug use increases with increase in age. The proportion of drug users increases significantly from 5% to 71%. Acid

suppressant drug use seen mostly in elderly people say above 65 years old.

**Table 1. Proportion of drug users according to age**

Age distribution (in years)	Number of patients (N = 280)	Percentage (%)
15 – 44	14	5%
44 – 65	68	24%
> 65	198	71%

N= total no of patients.

Current study shows 5 % patients comes under the age group 15-44, 24% comes under 44- 65 age group and 71 % comes under more than 65 years old group. (5) This is because as age increases mucosal protective mechanism is not sufficient to meet the extra acid formed.

### Step- Up Therapy and Step Down Therapy

Step-down therapy is evaluated by the initial prescribing of PPIs for peptic ulcer disease may be changed to H2RAs and similarly step up is evaluated by the initial prescribing of H2RAs for peptic ulcer disease may be changed to PPIs. Table 3 shows the ratio of step-up and step-down therapy.

**Table 2. Ratio of step up and step down therapy**

Step down therapy (N)	Percentage(%)	Step-up therapy (N)	Percentage(%)
185	66	130	46

N= total no of patients.

### Duration of ASMS Therapy

Table 3 indicates the duration of acid suppressant medications prescribed by physicians. The maximum recommended treatment duration for acid suppressant medications is 4 to 8 weeks.

**Table 3. Duration of ASMs prescribed in patients**

Duration of ASMs Therapy	No of patients (N)	Percentage(%)
1-3 Months	208	74%
3-6 Months	68	24%
6-12 Months	12	4%
More than 1 years	2	0.7%

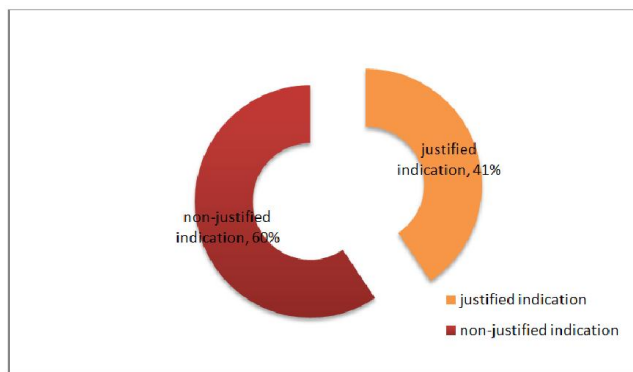
74% patients prescribed ASDs for 1- 3 month, 24% physicians prescribed acid suppressant drugs for 3-6 month, 4% patients prescribed acid suppressant medication for 6 -12 month and some would prescribe ASMs for more than 1 year in the treatment of acid peptic disorders which is negligible

### Percentage of Cost Adherence by Patients

Table 4 shows the percentage of cost adherence by patients using acid suppressant drugs. Total of 80 patients enrolled in the study.

**Table 4. Percentage of cost adherence by patients**

Cost satisfaction by patients	No of patients (n=80)	Percentage (%)
Affordable	52	64%
Costly	30	38%
Cheap	5	6%



(Total no of patients (n) =280).  
justified indication(n) = 114  
non-justified indication(n) = 166

**Fig. 1. Ratio of justified and unjustified indications**

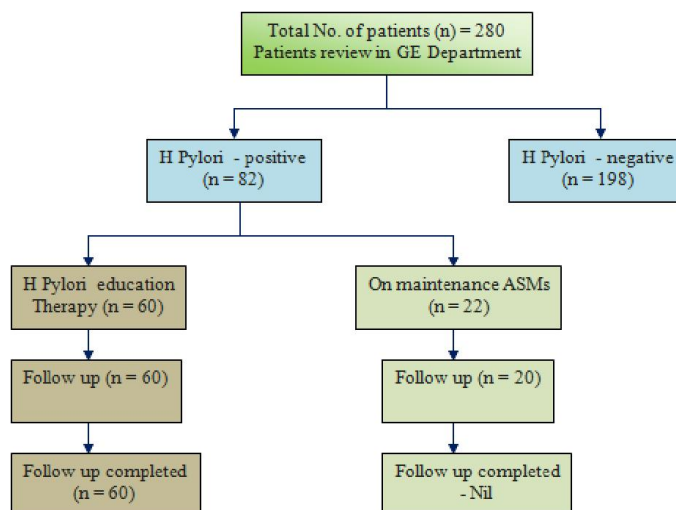
Among them patients indicated costly and 6 % of patients indicated the use of ASMs was cheap. Studies shows that curing an ulcer with antibiotics take less time and less cost. In this table it shows that 64 % affordable in the acid suppressants cost. This is because among them mostly undergone H. pylori eradication therapy.

Therapeutic Guidelines on stress ulcer prophylaxis, Food and Drug Administration (FDA) approved prescribing information and strong literature evidence for the use of ASMs in certain patients.

**Improvement of Gastric Symptoms**

Improvement of gastric symptoms after the H. Pylori eradication therapy is noted here. Percentage of patients suffering from gastric complaints before, after 6 weeks and after 6 months of therapy is taken into consideration. At baseline more than 50 % of patients had epigastric pain during daytime, heartburn, bloating and belching, 45% complained about epigastric pain during night and 35% of postprandial epigastric pain. After 6 months of therapy, compared to the baseline data, only 19% of patients suffered from epigastric pain during the day (p <0.001), 11% during night (p <0.001) and 14% postprandial (p <0.01), significant improvement could also be reported for heartburn (p <0.001), bloating (p <0.001), early satiety (p <0.001) and belching (p <0.01). It means that H.pylori eradication therapy almost completely cure the gastric symptoms. In these studies the treatment endpoints are often symptoms and quality of life scales and the intake of acid suppressant drugs during follow up was used as an endpoint.

**Summary of Patients at Different stages of their Medical Record Review**



**Table 5. Number and percentage of patients with gastric symptoms pre-treatment and at 6 weeks and 6 months post treatment**

Gastrointestinal symptoms	Pre-treatment (N)	%	After 6 Weeks therapy	%	After 6 months therapy	%	P value
Epigastric pain during day	27	61	11	26	8	19	<0.001
Epigastrical pain during night	22	45	4	9	5	11	<0.001
Epigastrial pain postprandial	17	35	3	7	6	14	<0.01
Pyrosis	24	54	9	20	11	25	<0.001
Nausea	13	28	7	16	8	19	=0.29
Bad breath	10	21	4	10	9	21	<0.1
vomiting	4	15	3	7	1	2	=0.11
Bloating	28	63	15	33	16	37	<0.001
Belching	32	69	21	48	19	46	<0.01
Early satiety	21	46	4	9	11	25	<0.001

\*p value <0.001 is significant.  
N= no of patients.

**Ratio of Justified and Unjustified Cases**

Justification for the usage of acid suppressants was based on the American Society of Health- system Pharmacists (ASHP)

**DISCUSSION**

From this study it is found that uncomplicated peptic ulcer disease patients treated with maintenance acid suppressant

drugs in primary care largely benefit from H. pylori eradication. Successful H. Pylori eradication in these patients results in a dramatic decrease in the use of acid suppressant drugs. Tapering the acid suppressant drugs gradually prior to the follow up period is presumably important in reaching this successful outcome. Only a few patients continued to use acid suppressant drugs, be at low level, whereas those who experienced some mild dyspeptic complaints were able to neutralize these symptoms with low dose antacids. More over it is very important to select a proper therapy for patients.

These findings support the need for the development and implementation of evidence based guidelines regarding the usage of acid suppressant in medical in-patients and out patients. And the need for restricting the use of acid suppressants as over the counter medicine. Interventions such as educational programs or institution specific guidelines or both for use may be developed and implemented to help decrease the use of PPIs in the patient population.

We know that around 80% of peptic ulcers are caused by an infection with the bacterium, *Helicobacter pylori* and not by stress or spicy foods as previously thought. Curing the infection with antibiotics shortens ulcer healing time and significantly reduces the ulcer recurrence rate compared with traditional ulcer therapies such as acid-reducing medications. *H. pylori* infection can usually be cured with a two-week regimen of antibiotics. In more than 80 percent of patients, the ulcer is cured and does not recur. Antibiotic therapy has a much greater effect on lowering the overall cost of peptic ulcer disease.

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