

**TO ANALYSE THE RISK FACTOR AND DRUG UTILIZATION  
REVIEW OF PEPTIC ULCER DISEASE IN A TERTIARY CARE  
HOSPITAL**

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**ABSTRACT**

Peptic ulcer disease is defined as disruption of the mucosal integrity of the stomach or duodenum thereby resulting in a defect or excavation occurring locally due to the presence of an active inflammation.<sup>[1]</sup> About 10% of people develops a peptic ulcer at some point in their life.<sup>[3]</sup> A prospective observational study was conducted among both inpatients and outpatients (both male and female) in general medicine and gastroenterology of a Tertiary Care Hospital, Erode. A total number of 110 patients were enrolled in the study. Informed consent forms were taken from every patient after the procedure is being explained. The study aims to identify risk factors for PUD and estimate their relative impact on ulcer incidence in patients and to evaluate the drug utilization pattern of anti peptic drugs. From the study it may be concluded that the mostly prescribed anti-peptic ulcer agent in our hospital is Pantoprazole (54.61%) and Food habits (47.44%) are the main risk factor in peptic ulcer disease.

**KEYWORDS:** Peptic ulcer disease, Risk factor, Drug Utilisation Evaluation, Anti peptic ulcer drugs.

## INTRODUCTION

Peptic ulcer disease is defined as disruption of the mucosal integrity of the stomach or duodenum thereby resulting in a defect or excavation occurring locally due to the presence of an active inflammation.<sup>[1]</sup> Two types of PUD include duodenal and gastric ulcers. Mucosal Erosion could be equal to or greater than 0.5cm. Duodenal ulcers dominate in Western populations while gastric ulcers are more frequent in Asia.

The most common symptoms of Peptic Ulcer include waking at night with upper abdominal pain or upper abdominal pain that improves with eating. The pain can be either burning or dull ache. Other symptoms include belching, vomiting, weight loss, or poor appetite.<sup>[2]</sup> Complications may include bleeding, perforation, and blockage of the stomach. Bleeding occurs in 15% of people. About 10% of people develop a peptic ulcer at some point in their life.<sup>[3]</sup> According to the latest WHO data published in 2017 Peptic Ulcer disease Deaths in India reached 57,658 or 0.66% of total deaths. Although it is generally accepted that the aetiology of peptic ulcer disease (PUD) is multifactorial, data on the relative impact of single risk factors are scarce. *Helicobacter pylori* (*H. pylori*) infection and usage of Non-Steroidal Anti Inflammatory Drugs (NSAID s) have been considered to be the most important causative factors in the development of PUD.<sup>[4]</sup> The strongest indication for eradication of *H. Pylori* is in patients with duodenal ulcer; 90-95% of Indian subjects with duodenal ulcer are positive for *H. Pylori* compared to 80% of asymptomatic healthy individuals in the community.<sup>[5]</sup>

A meta-analysis suggested that 95% of all hospitalised ulcer cases in the USA were attributable to *H pylori* infection, use of non-steroidal anti-inflammatory drugs (NSAIDs), and tobacco smoking.<sup>[6]</sup>

Anti Peptic Ulcer Drugs (APUDs) like proton pump inhibitors, H<sub>2</sub>-receptor antagonists, antacids, synthetic prostaglandins, and cytoprotective agents are widely used nowadays and have changed the physician's treatment patterns in general practice, gastroenterology as well as specialized clinics. The use of these drugs has been extended beyond prevention and treatment of peptic ulcers; to other disease and symptoms such as non-ulcer dyspepsia, heartburn, prevention of side effects caused by drugs etc.<sup>[7]</sup>

Drug Utilization Evaluation (DUE) is a system of ongoing, systematic, criteria-based evaluation of drug use that will help to ensure that medicines are used appropriately (at the

individual patient level). It is drug or disease specific and can be structured so that it will assess the actual process of prescribing, dispensing or administering a drug (indications, dose, drug interactions, etc.). DUE is also known as Drug Use Evaluation. The goal of DUE is to promote optimal medication therapy and ensure that drug therapy meets current standards of care. DUE is designed to review drug use and/or prescribing patterns, provide feedback of results to clinicians and other relevant groups, develop criteria and standards which describes optimal drug use, and enhance appropriate drug use through education and other interventions. For the individual patient, the rational use of drugs implies the prescription of well documented drug at an optimal dose, together with correct informations on frequency and duration of therapy. Hence the inappropriate use of drugs represents a potential hazard to patients and may leads extended hospital stay and as well as the expense of the therapy. This necessitates the periodic review of patterns of drug use in a health care facility to ensure safe and effective use of drugs.<sup>[8]</sup>

Risk factor assessment is a scientific process of evaluating the adverse effects caused by a substance, activity, lifestyle, or natural phenomenon.<sup>[8]</sup> The study aims to identify risk factors for PUD and estimate their relative impact on ulcer incidence in patients and to evaluate the drug utilization pattern of anti peptic drugs.

## **MATERIALS AND METHODS**

This was a prospective observational study approved by the Institutional Ethics Committee (Ref No: EC/PHARM D/2017-3). In this study a total number of 110 peptic ulcer patients, including both inpatient and outpatients (both male and female) in general medicine and gastroenterology of a Tertiary Care Hospital, Erode. During the period of January 2017 to June 2017, and the data were collected in a self designed data collection form, updated timely and were analysed according to the needs of the study. All the patients above the age of 18 and diagnosed with PUD were included in this study. Written informed consent was obtained from the prescribing doctors and patients for viewing their prescriptions.

## RESULTS AND DISCUSSION

Table 1: Demography of study participants.

Variable	Number (n=110)	Percentage (%)
<b>Gender</b>		
Male	67	60.90%
Female	43	39.09%
<b>Age</b>		
Adolescent	4	3.63%
Young Adult	72	65.45%
Middle Age	28	25.45%
Older Adult	6	5.45%
<b>Employment status</b>		
Employed	85	77.27%
Unemployed	25	22.72%

Demographic characteristics of study participants were shown in Table 1. More than a half of patients with PUD in both healthcare facilities were males (60.90%). It revealed that males suffer more from peptic ulcer disease (PUD) than females in the hospital. This is similar to a study conducted by Arul *et al.*<sup>[8]</sup> The prevalence of peptic ulcer disease has shifted from predominance in males to similar occurrences in males and females. The lifetime prevalence is approximately 11-14% in men and 8-11% in women.<sup>[9]</sup> The young adult age groups had the highest percentage of PUD patients in the hospital. This may be due to the hyperactivity and exposure to stress of this age group. In 70 percent of patients it occurs between the ages of 25 and 64 years.<sup>[10]</sup> Peptic ulcer disease is a worldwide common disease, but the incidence of peptic ulcer disease in different countries and regions is obviously different. This may be the reason for variation in the ratio. The group of patients that suffered most from PUD because a lot of them are not educated, not empowered economically and may suffer from lack of proper sanitation, of safe drinking water, and of basic hygiene, as well as poor diets and overcrowding, all play a role in determining the overall prevalence of PUD.

## SOCIAL DEMOGRAPHIC DATA

Table 2: Social demographic data.

	SMOKER			ALCOHOL			TOBACCO		
	Non-Smoker	Past	Current	Non-Drinker	Social	Current	Non User	Past	Current
<b>Number</b>	78	11	21	45	51	14	107	1	2
<b>Percentage</b>	70.90%	10%	19.09%	40.90%	46.36%	12.72%	97.27%	0.90%	1.81%

Out of 110 patients, 19.09% were smokers and 70.90% were non-smokers. 12.72% were alcoholic and 40.90% were non-alcoholics. 1.81% of patients were tobacco users and 97.27%

were non-tobacco users. Cigarette smoking is also considered to be one of the major contributors to ulcer diseases. According to clinical observations, cigarette smokers are more likely to develop ulcers which are more difficult to heal.<sup>[11]</sup> The risk of peptic ulcers also increases in smokers who have a large daily intake of tobacco compared with never smokers.<sup>[12]</sup> However, cigarette smoking is not an independent ulcerogenic. It adversely affects the gastroduodenal mucosal protective mechanisms and increases the risk of *H. pylori* infection.<sup>[11]</sup> Consumption of alcohol and smoking are risk factors. Chronic alcohol disturbs gastric mucosal barrier by inhibiting COX 1 receptor enzymes which reduce the production of cytoprotective prostaglandin. Cigarette smoking causes reduction of circulating epidermal growth factor and increase free radical production in gastric mucosa.<sup>[13,14]</sup>

### RISK FACTOR ASSESSMENT DATA

**Table 3: Risk factor assessment data.**

SL NO	Risk Factors	Number (n=110)	Percentage (%)
1	NSAIDS	5	4.5%
2	Current Smoker	15	13.63%
3	Heavy Drinker	10	9.09%
4	Food Habits	53	47.44%
5	Other Diseases	27	24.54%

The most common risk factor was the Food Habits (47.44%) followed by other diseases (24.54%) and smoking (13.63%). Other Risk factors include Alcoholic consumption and NSAIDs. The acid-increasing foods such as tea, coffee, alcohol, cayenne pepper, etc. are contributed to ulcers. Foods that are spicy, oily, fatty and acidic in nature can aggravate the ulcer by irritating the mucosal lining. At the same time poor eating habits are associated with ulcers, which are as follows –Irregular meal timings, overeating, loss of appetite. Skipping of meals allows gastric acid to directly act on surface mucosa of the stomach causing irritation which ultimately leads to gastric ulcers. Gastric ulcers cause abdominal pain which aggravate with meals.<sup>[15]</sup> Stress due to serious health problems such as those requiring treatment in an intensive care unit is well described as a cause of peptic ulcers, which are termed stress ulcers.<sup>[16]</sup>

### CLASSIFICATION OF ANTI - PEPTIC ULCER DRUGS PRESCRIBED

**Table 4: Classification of anti-peptic ulcer drugs prescribed.**

Sl no	Prescribed pud drugs	(n=110)	Percentage (%)
1	H2 Receptor Antagonist	10	9.09%
2	Proton Pump Inhibitors	96	87.27%
3	Antacid	104	94.54%

Proton Pump Inhibitor were the most prescribed ulcer healing drugs category with the utilization frequency more in tertiary healthcare facilities (87.27%). Kadiri et al., found out that Proton pump inhibitors were the most prescribed ulcer healing drugs category with the utilization frequency more in tertiary compared to secondary healthcare facilities (91.3% and 74.8%, tertiary and secondary healthcare facility respectively) in north central Nigeria.<sup>[17]</sup>

Antacid utilization (94.54%) in the study center was high as it is given to patients with other anti peptic ulcer drugs. To date, no drug meets all goals of therapy. Drug treatment of peptic ulcers is targeted at either counteracting aggressive factors or stimulating the mucosal defense. Drugs that inhibit or neutralize gastric acid secretion include histamine H<sub>2</sub>-receptor antagonists, Proton pump inhibitors, anticholinergics, prostaglandins, and antacids.<sup>[18]</sup>

### ANTI –PEPTIC ULCER DRUGS PRESCRIBED

**Table 5: Anti-peptic ulcer drugs prescribed.**

Sl No	Drugs Prescribed	Number	Percentage
1	Pantoprazole	142	54.61%
2	Pantoprazole + Domperidone	1	0.38%
3	Pantoprazole+Levosulpride	1	0.38%
4	Omeprazole + Domperidone	2	0.76%
5	Esomeprazole	3	1.15%
6	Omeprazole	1	0.38%
7	Ranitidine	1	0.38%
8	Ranitidine+Domperidone	4	1.53%
9	Rabeprazole	1	0.38%
10	Sodium Alginate+Calcium Carbonate+Sodium Bicarbonate	99	38.07%
11	Sucralfate	5	1.92%

The most commonly prescribed PPI in our study subjects was found to be Pantoprazole followed by Sodium Alginate + Sodium Bicarbonate + Calcium Carbonate Oral Suspension (38.07%). Omeprazole (0.38%) and Rabeprazole (0.38%) was found to be the least prescribed drug among the proton pump inhibitors. Priti et al., found out that most common class of anti-peptic drug ulcer prescribed was Proton Pump Inhibitors (71%) followed by H<sub>2</sub> blockers (19%) and Antacids (7%).<sup>[19]</sup>

**TYPES OF FORMULATION OF ANTI –PEPTIC ULCER THERAPY****Table 6: Types of formulation of anti-peptic ulcer therapy.**

Sl no	Types of formulation	Number (n=110)	Percentage
1	Injection	43	16.53%
2	Tablet	107	41.15%
3	Syrup	104	40.00%
4	Capsule	6	2.30%

In our study, the most commonly used formulation were tablets which accounts for 41.15% followed by syrup (40%) and the least prescribed formulation were capsule (2.30%). Priti et al., reported that majority (86%) of anti-peptic ulcer drug formulations prescribed were oral solid formulations – tablets or capsules.<sup>[19]</sup>

**PRESCRIPTION PATTERN OF ANTI – PEPTIC ULCER DRUGS****Table 7: Prescription pattern of anti-peptic ulcer drugs.**

Sl no	Pattern of prescription	Number	Percentage
1	Frequency not mentioned	49	44.54%
2	Frequency mentioned	61	55.45%

Out of 110, frequency mentioned prescriptions were 55.45% and prescriptions with frequency not mentioned were 44.54%.

**CONCLUSION**

Proton Pump Inhibitors are the most common anti peptic ulcer drugs prescribed. From the above studies it may be concluded that the mostly used Anti-peptic ulcer agent in our hospital was Pantoprazole, and food habits were the main risk factor in peptic ulcer. Clinical Pharmacist can provide patient education and management of risk factors associated with peptic ulcer development and recurrence. Importance of adherence and counseling on proper administration of drug therapy is also an important part of treatment success.

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