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EVALUATION OF DRUG UTILIZATION PATTERN AND RISK FACTORS AMONG PATIENTS WITH ACID PEPTIC DISEASE IN A MULTI-SPECIALITY HOSPITAL

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ABSTRACT

Background: The physical morbidity and economic incapacity associated with Acid peptic disease; makes interest in its epidemiology. Hence, this study was designed to provide insight into the prescription pattern of drugs used in Acid peptic disease. **Aims and Objective:** To understand and analyze the prescribing pattern of drugs and to calculate the prevalence of acid peptic disease. **Materials and Methods**: A prospective observational study was carried out in a multi-speciality Hospital, Mysuru, Karnataka, India. Data were analyzed by the WHO core prescription indicators to know about the prescription pattern and related risk factors associated with the disease. **Results:** Out of the 85 study subjects, 38.82% were male and 61.17% were female. The majority of patients were in the age group of 1-30 years (29.41%). In this study, the most commonly prescribed class of drugs were Electrolytes and antibiotics, and PPI with 24.84% (n=162) and 14.26% (n=93) respectively. The important risk factor found in this study includes Occupation, marital status, and age. The prevalence of acid peptic disease was found to be 16.6%. **Interpretation and Conclusion:** Antibiotics and PPI were the most commonly prescribed drugs. The percentage of drugs prescribed by generic name and from essential drug list is less and needs efforts to improve the situation.

KEYWORDS: Acid Peptic Disease, Drug Utilization, Risk factors, Prevalence.

INTRODUCTION

Acid peptic diseases, also known as acid peptic disorders are a collection of diseases involving acid production in the stomach and nearby parts of the gastrointestinal tract it is a collective term that is used to describe many conditions such as gastro-oesophageal reflux disease (GERD), gastritis, gastric ulcer, duodenal ulcer, oesophageal ulcer, Zollinger Ellison Syndrome (ZES) and acute gastroenteritis.[1]

Peptic ulcer disease: Peptic ulcer disease (PUD) is ulcer formation in the lining of the upper GI tract due to excess and high concentration of pepsin that affect mainly the mucosal lining of the stomach, duodenum, or esophagus.[2] In the general population of Kashmir, India, the prevalence of peptic ulcer disease was determined by an endoscopy in a randomly selected sample population of 2763 adults aged 18 years and above who were interviewed using a questionnaire. The point prevalence of peptic ulcer was 4.72% and the lifetime prevalence was 11.22%.[4] Risk factors include for developing peptic ulcer disease include H. pylori infection, NSAID uses, alcohol and tobacco consumption, non-steroidal, and Zollinger–Ellison syndrome (ZES). The most significant risk factors for peptic ulcer disease are H. pylori infection and NSAID use.[3] A triple therapy consisting of a proton pump inhibitor (PPI) and two antibiotics, such as clarithromycin plus amoxicillin or metronidazole given for seven to 14 days is considered the standard first-line therapy for H. Pylori eradication. The recommended standard first-line therapy is either a bismuth-containing quadruple therapy for 14 days (PPI, a bismuth salt, tetracycline, and metronidazole) or 14-day concomitant therapy for patients who cannot tolerate bismuth (PPI, clarithromycin, amoxicillin, and metronidazole); both the regimens have the higher eradication rates (more than 90%).[2]

Patients hospitalized at Virginia Mason Hospital the average treatment cost to manage patients' hospitalization with a peptic ulcer disease is approximately $5000 per patient in a series of 30 patients. there are 150,000 peptic ulcer cases per year in the United States and, the total hospital cost can be estimated to be $750 million.[5]

GERD: Gastroesophageal reflux disease (GERD) is a chronic and relapsing condition in which prolonged reflux of hydrochloric acid, pepsin, and bile salt in the esophagus, oral cavity, and respiratory system occurs that leads to esophagitis.[7] Epidemiological data conducted in the United States indicate a prevalence of GERD of up to 27.8% and 25.9% in Europe. The prevalence of GERD in Japanese adults is as low as 11.6%.[6] The risk factor includes Obesity, high fat diet, hiatus hernia, tobacco smoking, alcohol consumption,

helicobacter pylori infection, pregnancy, genetics, certain medications NSAID, tetracycline, clomipramine, quinidine, etc. Other risk factors include the Consumption of coffee, spicy foods, carbonated beverages, chocolate, citrus products, and tomato products could increase GERD risk.[6]

Troublesome symptoms can be managed with medications, and many of the medications can be available without a prescription. Medications for GERD include **1. PPIs:** ex-Pantoprazole, omeprazole, lansoprazole. **2. Antacids and alginate:** ex- Sodium bicarbonate, Calcium carbonate, Magnesium carbonate, Aluminum hydroxide, Magnesium hydroxide, and sodium alginate. **3. Histamine H2 receptor antagonists (H2RAs):** ex-cimetidine, ranitidine, famotidine.[6]

Gastroesophageal reflux disease (GERD) symptoms can increase complication and morbidity and can contribute to substantial medication use and treatment costs worldwide. In the United States (US) alone, the overall cost of GI diseases is estimated to be $142 billion (in 2009 US dollars) per year in direct and indirect costs. GERD accounts for approximately $15–20 billion of these direct and indirect costs.[6]

Acute Gastroenteritis: Gastroenteritis is inflammation of the stomach, small intestine, or large intestine that results in problems like abdominal pain, diarrhea, cramping, nausea, and vomiting. Acute gastroenteritis can usually last fewer than 14 days.[8] Out Of 175 articles included, the pooled prevalence of norovirus in 187 336 patients with acute gastroenteritis was 18% (95% CI 17–20).[3] Acute gastroenteritis can be caused by many infectious agents, it can be Viral, Bacterial, and Parasitic. About 50% -70% of cases were caused due to Viral infections, examples include Norovirus, Rotavirus, Enteric adenovirus types 40 and 41, Astrovirus, Coronavirus, and Some picornaviruses. Symptoms include anorexia, abdominal pain, malaise, watery diarrhea, cramping, nausea and vomiting, and low-grade fever. Symptoms may progress to colitis, and bloody diarrhea.[13]

Acute GE can be diagnosed using Stool cultures for those patients with persisting symptoms like prolonged illness, bloody diarrhea, and fever.[3]

Treatment includes acute GE, **1. Fluid replacement therapy:** It treats symptomatic relief. This Intravenous hydration is necessary for the setting of dehydration. **2. Antibiotics**: They can shorten the treatment course for about 1-2 days. Ciprofloxacin 500mg (OD or BD) is

most commonly prescribed. **3. Antimotility agents:** They can decrease stool frequency but they cannot alter the course of infection. It is avoided in case of rectal bleeding and fever. Loperamide or diphenoxylate are common antimotility agents. **4. Probiotics:** Lactobacillus GG can relieve diarrhea in travelers' gastroenteritis.[8]

Gastritis: Gastritis in simple terms defined as the inflammation of the stomach lining. Which is usually caused due to use of an NSAIDS drug or by certain types of bacteria.[9] There are two types of gastritis acute and chronic. Acute gastritis has noticeable stomach and bowel problems, that can go away on their own within a few days to a week. Chronic gastritis is another one where the symptoms may go unnoticed. The symptoms of acute gastritis include- Abdominal pain, Heartburn, Nausea, Vomiting, Decrease food intake, and Belching.[9] People with chronic gastritis only have mild symptoms or not having any symptoms The prevalence for acute gastritis is estimated to be 2% to 5%, however, this data are not specific. The overall prevalence of chronic gastritis is depending on the geographical region. It is estimated that the prevalence of chronic gastritis is approximately 69% in Africa, 78% in South America, and 51% in Asia.[10]

The causes of gastritis include H.pylori infection, use of NSAIDS, or steroids, tobacco smoking, consumption of alcohol, increased serum anti-parietal and anti-intrinsic factor antibodies and leads to chronic atrophic gastritis, presence of subepithelial collagen deposition with mucosal inflammatory infiltrate.[10]

Depending on the type and severity of the symptoms, the following drugs can be used**:** **Proton pump inhibitors (PPIs)** like omeprazole or pantoprazole reduce the production of stomach acid. **H2 blockers** such as ranitidine and famotidine also reduce acid production. **Antacids** like aluminum hydroxide or magnesium hydroxide neutralize the acid already in your stomach. If the gastritis is caused by a Helicobacter infection, proton pump inhibitors are combined with two or three antibiotics.[9]

MATERIAL AND METHODS

Study design: It is a Prospective Observational study.

Site of study: The study was carried out in a Multi-specialty tertiary care hospital, in Mysuru.

Study population: 85 patients.

Study period: This study was conducted over six months in the department of the General medicine ward from March 2022 to August 2022.

Department selected for study: The study was conducted in the department of General medicine which includes both Inpatients ad Outpatients.

Sources of data: All the relevant and necessary data were collected from, Patient case records, Inpatient case sheets, Treatment charts, Interviews with the patients and caretaker, Communicating with concerned clinicians and healthcare professionals.

Inclusion Criteria: Patients of age 18 years of both genders, Patients diagnosed with an acid peptic disease, and Subjects who are willing to participate in the study.

Exclusion Criteria: Incomplete case sheets, Incomplete medical or medication information, Patient with pregnancy or breastfeeding conditions, and Patients who are not willing to participate in the study.

Study Tools

a. **Informed Consent Form:** An informed consent form was designed to incorporate all the vital information about the study. The informed consent form was prepared in English and the same was also translated into the local language (Kannada) and the patient was explained clearly about the study.
b. **Information to participant sheet:** It consists of a detailed explanation in both English and the local language (Kannada), about the information regarding the study such as the title, the purpose, the procedure, and possible risks and benefits. This form is converted to the local language (Kannada) and attested by a reliable authority.
c. **Patient Data Collection Form** It includes the demographics of the patients such as age, literacy, occupation, and socio-economic status and also consists of I.P number, Chief complaints, Past medical history, Past medication history, Current medication, Relevant laboratory details, Date of admission, and department.

RESULT

DEMOGRAPHIC DETAILS OF THE STUDY POPULATION

Out of 85 subjects, female [61.17%, n=52] patients are majorly seen as affected with Acid peptic Disease than Males [38.82%, n=33]. The average age of the patients was 30 years while the majority [n=25, 29.41%] of them were in the age group of 18-30 years followed by [n=23, 27.05%] in 31-40 years, [n=12, 14.11%] in 41-50 years, [n=11, 12.94%] in 61-70 years, [n=9, 10.58%] in 51-60 years, and the least [n=6, 7.05%] in 71-90 years category.

[79.9%] are Literate among these [16.4%] are Primary, [20.5%] are PUC, and [47.05%] are Graduated. [8.23%] are from the Higher class, [91.76%] are from Middle-class families. Data suggested that [69.41%] are Non-vegetarians and [30.58%] are Vegetarians. A total of 68 [79.9%] patients were literate and with low socio-economic status [n=78, 91.76%]. Data also showed that [17.64%] patients were Smokers and [18.82%] are Alcoholic. History of medical comorbidity was observed in 21.9% (n=17) of patients, among these, [8.2%] Hypertensive with Diabetic, [4%] Hypertensive, [4%] Diabetic, [1%] Hypertensive, Diabetic and Ischemic Heart Disease, [1%] Diabetic with Hypothyroidism, [1%] Hernia,1%] Menopause at 22 years age. and a majority of study subjects are married (77.64%).

Table 1: Demographic Details Of The Study Population.

Demographics		**Number (%)**
Age group	18-30 years 31-40 years 41-50 years 51-60 years 61-70 years 70-90 years	25(29.41%) 23(27.05%) 12(14.11%) 9(10.58%) 11(12.94%) 6(7.05%)
Gender	Male Female	33(38.82%) 52(61.17%)
Literacy	Illiterate High school Graduate	17(20%) 28(32.94%) 40(47.05%)
Occupation	Employed Unemployed Agriculture	33(38.82%) 49(57.64%) 3(3.52%)
Diet	Vegetarian Non-vegetarian	26(30.58%) 59(69.41%)
Marital Status	Married Single	66(77.64%) 19(22.35%)
Socio-economic status	Low and Middle class High class	78(91.76%) 7(8.23%)
Smoking status	Smoker Non-smoker	15(17.64%) 70(82.45%)
Alcoholic status	Alcoholic Non-alcoholic	16(18.82%) 69(81.17%)
Comorbidities	Present Absent	17(20%) 68(80%)

Table 2: Details of Drugs Utilization Pattern.

DRUGS	NUMBERS (n)	PERCENTAGE (%)
Analgesics	80	12.26
Antibiotics	93	14.26
Antiparasitic	13	1.99
PPI	85	13.03
Antiemetics	79	12.11
Probiotics	54	8.28
Antidiarrheals	49	7.51
Ulcer protective agents	8	1.22
Vitamins	29	4.44
Electrolytes	162	24.84
TOTAL	652	100

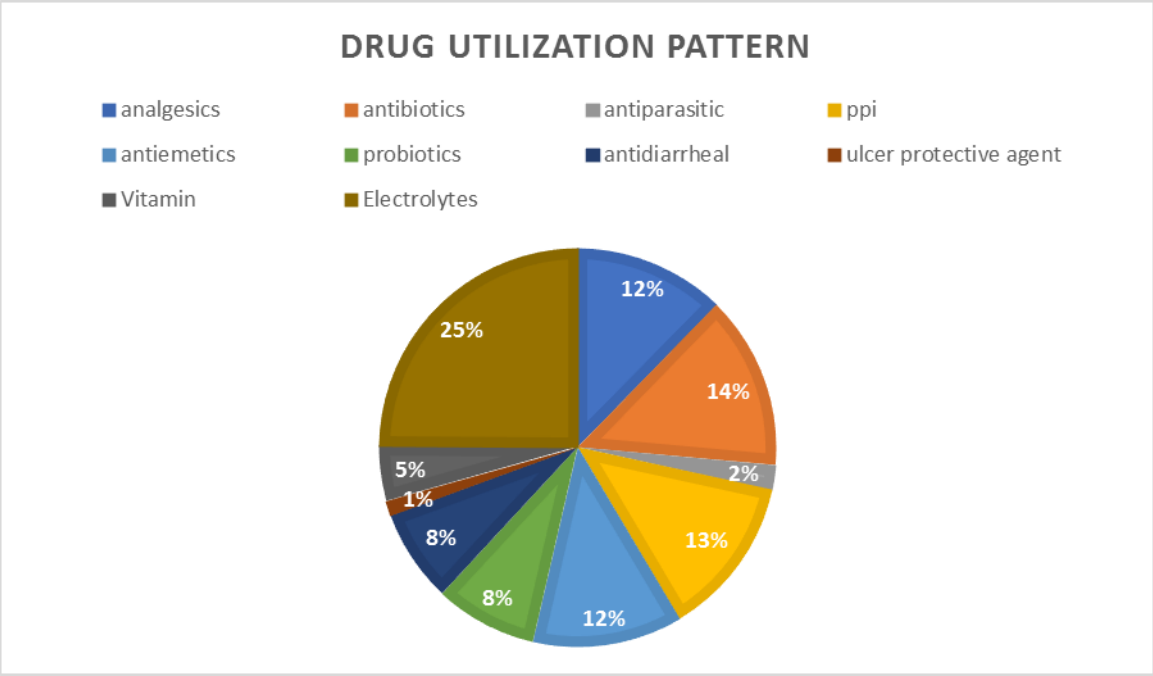

Figure 1: Showing the distribution of Drug Utilization Pattern.

Among 85 patients, a total of 652 drugs were prescribed and the average number of drugs prescribed per prescription was found to be 7.67.

In this study, the most commonly prescribed class of drugs was Electrolytes, Antibiotics and PPI with 24.84%, 14.26% and 13% respectively, followed by Analgesics and Antiemetic drugs with 12.26% and 12.11% respectively.

Table 3: Risk Factor Analysis For Acid Peptic Disease.

A. Risk factor analysis in acute GE.

Factors	Demographics data			P value
Age	18-50 years 50-90 years	43 18	16 8	0.73
Gender	Male Female	21 37	12 15	0.47
literacy	Literate Illiterate	47 14	20 4	0.52
Occupation	Workers Non-workers	29 32	19 5	0.008*
diet	Veg Non-veg	18 43	8 16	0.73
Marital status	Married Unmarried	52 9	14 10	0.007*
Smoking	Smokers Non-smokers	9 52	6 18	0.26
Alcohol	Alcoholic Non-alcoholic	10 51	6 18	0.36

***** *P-value: ≤ 0.05 indicates the significant level*

B. Risk factor analysis in gastritis.

Factor	Demographics data			P value
Age	18-50 years 50-90 years	14 5	45 21	0.64
Gender	Male Female	10 9	23 43	0.15
literacy	Literate Illiterate	16 3	51 15	0.51
Occupation	Workers Non-workers	16 3	32 34	0.005*
diet	Veg Non-veg	5 14	21 45	0.64
Marital status	Married Unmarried	11 8	55 11	0.018*
Smoking	Smokers Non-smokers	5 14	10 56	0.26
Alcohol	Alcoholic Non-alcoholic	5 14	11 55	0.34

***** *P-value: ≤ 0.05 indicates the significant level*

C. Risk factor analysis in GERD

Factor	Demographics data			P value
Age	18-50 years 50-90 years	0 3	59 23	0.007*
Gender	Male Female	0 3	33 49	0.15
literacy	Literate Illiterate	2 1	65 17	0.59
Occupation	Workers Non-workers	1 2	47 3	0.40
diet	Veg Non-veg	2 1	24 58	0.16
Marital status	Married Unmarried	3 0	63 19	0.34
Smoking	Smokers Non-smokers	0 3	15 67	0.41
Alcohol	Alcoholic Non-alcoholic	0 3	16 66	0.39

***** *P-value: ≤ 0.05 indicates the significant level*

In the risk factor analysis, we found that for Acute GE, Occupation (P-value: 0.008) and Marital status (P-value: 0.007) was the significant factor. For GERD, Age (P-value: 0.007) was found to be the risk factor. For Gastritis, Occupation (P-value: 0.005) and Marital status (P-value: 0.018) was the significant factor.

PREVALENCE

Out of 512 study populations, 16.6% were diagnosed with the acid peptic disease (n=85).

DISCUSSION

Data regarding the demographic details of patients in our study showed that the majority of patients admitted for the acid peptic disease were female subjects. The percentage of female subjects included in our study was 61.17% which was found similar to the study conducted were Among the total study participants, 246 (67.6%) were females, while 118 (32.4%) were males and in contrast to the study conducted by **Arun Gupta, Darpan Bansal, Manan s Malhotra,** et al where the subjects 80.5% were more in male compared to female.[11]

Our study also revealed that the risk factor associated with this acid peptic disease were, Occupation, marital status, and age, which was found slightly similar to the study conducted by **Manohar Shankarrao Chavan, M. Bhaktavatsalam,** et al, where the significant risk factors were found to be age, lower social class, alcohol use, tea, and use of NSAID.[12] The most commonly prescribed class of drugs was Electrolytes and antibiotics and PPI with 24.84% (n=162) and 14.26% (n=93) respectively, followed by Analgesics and Antiemetic drugs with 12.26% (n=80) and 12.11% (n=79) respectively which was found to be similar in the study conducted **by Schmutz, C., Bless, P.J., Mäusezahl, D. *et al*,** where Symptomatic treatment included probiotics (45.9%, 95% CI 39.1–52.8), antiemetics (45.4%, 95% CI 40.5–50.4), antidiarrheals (28.8%, 95% CI 23.6–34.6), analgesics (16.3%, 95% CI 12.8–20.5).[13]

CONCLUSION

In our study, antibiotics, PPI, and analgesics, drugs are the most commonly used drug classes in acid peptic disease. Acute GE is the most common indication for admissions. The average number of drugs per prescription was high reflecting polypharmacy. The percentage of drugs prescribed by generic name and from the essential drug list was found to be moderate. This study helps in evaluating the existing drug use pattern, Calculating the prevalence of acid peptic disease in India, identifying the risk factor associated with this disease, and making appropriate interventions required to provide optimum healthcare services to the community. This survey helps to estimate the important risk factor like Occupation, marital status, and age, which can provide public awareness about this disease. Out of 512 study population, 16.6% were diagnosed with the acid peptic disease.

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ABBREVIATIONS

ABBREVIATIONS	EXPANSIONS
WHO	World Health Organisation
GERD	Gastro-Oesophageal Reflux Disease
PUD	Peptic Ulcer Disease
ZES	Zollinger Ellison Syndrome
NSAID	Nonsteroidal anti-inflammatory drugs
PPI	Proton Pump Inhibitor
H2RA	Histamine H2 receptor antagonists
GE	Gastroenteritis

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