1	STUDY OF PRESCRIPTION PATTERN IN PATIENT WITH
2	ACID PEPTIC DISEASE ATTENDING MEDICINE
3	OUTPATIENT DEPARTMENT IN A GOVERNMENT TERTIARY
4	CARE HOSPITAL
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7	Abstract
8 9 10 11	Background : Acid peptic diseases are common conditions present in daily clinical practice and, as a result of their chronicity, represent a significant healthcare cost. APD influences the quality of life and productivity of afflicted patients and are common and important causes of morbidity and mortality.
12 13 14	Aim : The objectives of the study were to evaluate the drug prescribing pattern in patients with acid peptic disease attending an outpatient department in a government tertiary care hospital.
15 16 17 18 19	Methods : Cross-sectional observational study in 1000 newly diagnosed acid-peptic disease patients attending medicine outpatient department during study period. Patient's prescription sheet will be evaluated on the basis of patient profile, duration of chief complaints, diagnosis, co-morbidities, name of the drug, details of drug administered, and WHO drug prescribing indicators.
20 21 22 23 24 25 26 27 28 29	Results : Out of 1000 patients, 588 (58.8%) were males and 412 (41.2%) were female who belonged to the age group of 31 to 40 years, which constituted 33.4% of the total study population, followed by the age group of 41 to 50 years (32%). Total 1750 anti-peptic ulcer drugs were prescribed for these patients, among which 1005 (57.43%) drugs were prescribed using generic names and 745 (42.57%) drugs were prescribed using brand names. 26 (2.6%) prescriptions included antibiotics, which were prescribed for treatment of certain infectious diseases. Out of the total drugs prescribed, 1610 (92%) drugs were given by oral route, and only 140 (8%) were given by parenteral routes. The most common class of anti-peptic ulcer drugs prescribed was proton pump inhibitors, followed by H2 blockers, antacids and then sucralfate.
30 31 32	Conclusion : The study provides an insight into the demographic profile, various drugs prescribed, and prescription pattern in acid peptic disease patients. The data on drug utilization pattern was fairly comparable to other studies conducted in various parts of India.
33	Keywords: Acid peptic disease, NSAIDs, PPI, Antacids, H2 blockers, Prescription pattern
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Introduction

Acid Peptic Disease (APD) arises from distinct but often overlapping mechanisms, including excessive acid secretion and diminished mucosal defence. The condition is primarily driven by acid and pepsin activity in gastric secretions, leading to mucosal damage.(1) APD encompasses a range of conditions such as gastroesophageal reflux disease (GERD), gastric and duodenal peptic ulcers, NSAID-induced mucosal injury, and stress-related mucosal disease. These conditions occur when aggressive factors like acid, pepsin, and bile overpower the protective mechanisms of the gastrointestinal mucosa, such as mucus and bicarbonate secretion, prostaglandins, blood flow, and tissue repair.(2)

APD is commonly encountered in clinical practice and has significant implications for public health. The chronic nature of these conditions contributes to substantial healthcare costs, adversely affects the quality of life and productivity of patients, and represents a leading cause of morbidity and mortality (3). Besides physiological factors, smoking, excessive alcohol consumption, emotional stress, and psychological conditions also play critical roles in the development and exacerbation of APD (4).

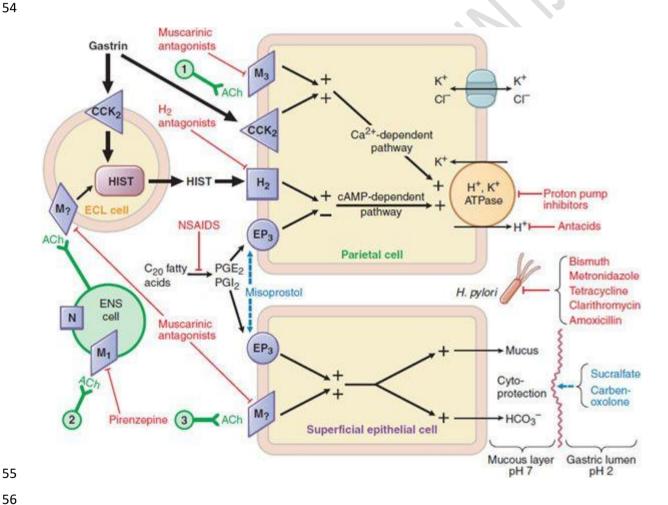


Figure 1: Pharmacologist's view of gastric secretion and its regulation: the basis for therapy of acid-peptic disorders. Shown are the interactions among an enterochromaffin-like (ECL) cell that secretes histamine, a ganglion cell of the enteric nervous system (ENS), a parietal cell that secretes acid, and a superficial epithelial cell that secretes mucus and bicarbonate. Physiological pathways, shown in solid black, may be stimulatory (+) or inhibitory (-). 1 and 3 indicate possible inputs from postganglionic cholinergic fibers; 2 shows neural input from the vagus nerve. Physiological agonists and their respective membrane receptors include acetylcholine (ACh), muscarinic (M), and nicotinic (N) receptors; gastrin, cholecystokinin receptor 2 (CCK₂); histamine (HIST), H₂ receptor; and prostaglandin E₂ (PGE₂), EP₃ receptor. A red indicates targets of pharmacological antagonism. A light blue dashed arrow indicates a drug action that mimics or enhances a physiological pathway. Shown in red are drugs used to treat acid-peptic disorders. NSAIDs are nonsteroidal anti-inflammatory drugs, which can induce ulcers via inhibition of cyclooxygenase.

- 67 Management strategies primarily involve the use of anti-peptic ulcer drugs (APUDs), which
- 68 include proton pump inhibitors (PPIs), H2-receptor antagonists, antacids, synthetic
- 69 prostaglandins, and cytoprotective agents. These medications have transformed treatment
- 70 approaches in general practice, gastroenterology, and other specialties. However, overuse of
- 71 APUDs is a growing concern, especially among patients receiving concomitant medications
- 72 like antiplatelets, NSAIDs, corticosteroids, or anticoagulants (5).
- 73 **Proton pump inhibitors (PPIs)** are particularly pivotal in managing acid-related disorders,
- 74 but their prolonged use has been linked to increased susceptibility to enteric infections and
- other adverse effects (6). The safety of long-term acid suppression with PPIs has been a
- 76 matter of debate, with studies suggesting an association with renal impairment, bone
- fractures, and micronutrient deficiencies (7). Furthermore, guidelines for the prevention of
- 78 NSAID-related ulcer complications emphasize the importance of balancing benefits and risks
- 79 when prescribing these medications (8).
- 80 **H2-receptor antagonists** offer an alternative approach to acid suppression but may not
- 81 provide the same efficacy in severe conditions, making them less favored in specific clinical
- scenarios (9). Meanwhile, the use of antacids and cytoprotective agents remains limited
- 83 to symptomatic relief or specific indications, such as peptic ulcer prevention during NSAID
- 84 therapy. Synthetic prostaglandins, although effective, often come with gastrointestinal side
- 85 effects that limit their use.
- The overuse of APUDs among patients on concomitant medications like NSAIDs,
- 87 corticosteroids, or anticoagulants underscores the necessity of cautious prescribing
- 88 practices. Adverse effects such as increased risks of enteric infections, hypochlorhydria-
- 89 related complications, and potential drug-drug interactions further stress the need for
- 90 appropriate indication and duration of therapy (10). For instance, the Montreal consensus on
- 91 GERD emphasizes evidence-based use of acid-suppressive therapies, tailoring treatment to
- 92 the severity of the condition and individual patient risk factors (9).
- 93 Drug utilization research, as highlighted by World Health Organization (WHO) guidelines, is
- vital to promoting rational drug use. These studies evaluate the efficacy, safety, convenience,
- and economic impact of medications across all levels of healthcare (11). They also provide
- 96 insights into prescribing trends, help identify inappropriate drug use, and assess correlations
- 97 between medications and adverse drug reactions (ADRs) (12). Such studies are particularly
- 98 crucial in optimizing healthcare systems by ensuring the effective allocation of resources and
- 99 minimizing the risks associated with irrational prescribing. Despite the widespread
- 100 prescription of APUDs, few studies have documented their utilization patterns in Asian
- 101 countries. Existing research often focuses on specific drug classes or specialized settings
- like gastroenterology or critical care units (13).
- Drug utilization studies not only support evidence-based practices but also aim to enhance
- the quality of care by minimizing irrational drug use. For example, studies have shown that
- 105 excessive and inappropriate prescribing of proton pump inhibitors (PPIs) contributes to
- increased healthcare costs and potential adverse events (14). Furthermore, global
- prescribing trends emphasize the need for country-specific evaluations, as cultural,
- economic, and healthcare system differences influence drug usage patterns (15). Research
- in Asian countries has pointed out significant gaps in rational prescribing practices for
- 110 APUDs, particularly regarding overuse in primary care settings (16).

113 114	centre. The findings will contribute to a better understanding of prescribing practices and help inform strategies for optimizing the use of these medications in clinical practice.
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116	Materials and methods
117	Study setting
118 119 120 121 122 123	The study was conducted in the Medicine Outpatient Department (OPD) of a government tertiary care hospital in Maharashtra, India, using a cross-sectional observational design. The population included all newly diagnosed acid-peptic disease patients attending the OPD during the study period from January 2019 to June 2020. Aim is to evaluate the drug prescribing pattern in patients with acid peptic disease attending outpatient department in a government tertiary care hospital.
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125	Data collection
126 127 128 129 130 131	Inclusion criteria consisted of newly diagnosed patients with acid-peptic disease, while patients unwilling to participate or presenting with complications such as perforation, bleeding, or cancer were excluded. Data collection involved reviewing patients' prescription sheets to gather information on patient profiles (reference number, initials, age, gender, occupation), duration of complaints, diagnosis, co-morbidities, and detailed drug information, including name, formulation, dose, duration, frequency, and adverse effects.
132 133 134 135	Additionally, WHO drug prescribing indicators were evaluated, such as the average number of drugs per encounter, percentage of drugs prescribed by generic name, rates of antibiotic and injection prescriptions, and the proportion of drugs prescribed from the essential drug list or formulary.
136	Data analysis
137 138 139 140 141 142 143	The analysis will utilize descriptive statistics to summarize and interpret the collected data effectively. Key measures such as frequencies, percentages, means, and standard deviations will be calculated to provide an overview of patient demographics, clinical characteristics, and prescribing patterns. These statistical methods will help identify trends, highlight prescribing practices, and assess compliance with WHO prescribing indicators. The findings will enable a comprehensive understanding of the treatment approaches for acid-peptic disease in the study population.
145	Ethical consideration
146 147	Ethical approval was obtained from the Institutional Ethics Committee on research, and informed consent was obtained from all the study participants.
148	
149	Results

This study aims to address these gaps by evaluating APUD utilization in a tertiary care

In the present study data were collected from 1000 patients, of whom 588 (58.8%) were males and 412 (41.2%) were females. The majority of patients were aged 31–40 years (33.4%), followed by 41–50 years (32%), with males being more affected than females in all age groups. A total of 1750 drugs were prescribed, of which 1005 (57.43%) were generic and 745 (42.57%) were brand-name drugs. Among the prescriptions analysed, 69% contained only generic names, 22% contained only brand names, and 9% included both. Antibiotics were prescribed in 2.6% of the prescriptions, while 8% of the total drugs were injectables, which were administered in 14% of the prescriptions.

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Age Group	No. of Males	No. of females	Total	Percentage
< 20 years	25	15	40	4
21-30 years	96	69	165	16.5
31-40 years	201	133	334	33.4
41-50 years	176	144	320	32
51-60 years	50	18	68	6.8
61-70 years	34	31	65	6.5
>70 years	6	2	8	0.8
Total	588	412	1000	100

Table no.- 1 Demographic characteristics of the study population





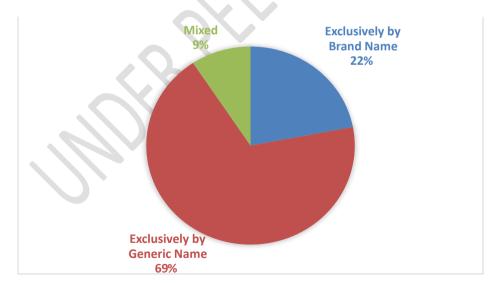


Figure 2: Prescription pattern in terms of brand name / generic name

Oral administration was predominant, accounting for 92% of the drugs, with capsules being the most common form (668), followed by tablets (522), and liquid preparations (420).

Notably, 78.51% of the drugs were from the National List of Essential Medicines (NLEM) 2015, and 77.82% were included in the hospital formulary. Lifestyle and dietary modifications were also emphasized, with patients being advised to abstain from alcohol, tobacco, and smoking alongside their prescribed medications. The study also highlighted the importance of evaluating differences between the prescribed daily dose (PDD) and the defined daily dose (DDD) in drug utilization analyses. These findings provide insights into prescribing patterns and the integration of lifestyle interventions in the management of acid-peptic disease.

SR NO	NAME OF DRUG	ROUTE OF DRUG ADMINISTRATION	WHO DDD	DRUG USE IN CURRENT STUDY	PRESCRIBED DAILY DOSE (PDD)	RATIO OF PDD/DDD
1.	Omeprazole	Oral	20 mg	3920	0.04	2
2.	Pantoprazole	Oral	40 mg	3836	0.08	2
3.	Inj. Pantoprazole	Injection	40 mg	140	0.04	1
4.	Rabeprazole	Oral	20 mg	1358	0.02	1
5.	Domperidone	Oral	30 mg	1358	0.03	1
6.	Ranitidine	Oral	0.3 g	1736	0.3	1
7.	Magnesium hydroxide	Oral	3 g	444.25	1.6	0.53
8.	Aluminium Hydroxide	Oral	Not defined	-	-	-
9.	Sucralfate	Oral	4 g	441	4	1
10.	Simethicone	Oral	0.3 g	444.25	0.16	0.53

Table no. 2: Drugs prescription analysis using PDD/DDD system

Discussion

 In this study, a total of 1000 prescription sheets from acid peptic disease (APD) patients attending the medicine outpatient department (OPD) at a government tertiary care hospital were analyzed to evaluate prescribing patterns and drug use. The demographic characteristics of the study population revealed that the majority of patients were from the 31–40 years age group (33.4%), followed by the 41–50 years age group (32%). This pattern is consistent with the findings of Hatila et al. (17), where 39.84% of patients were in the 31–40 year age group. However, this differs from the study by Jha et al., where the majority (28%) of patients were aged between 51 and 60 years (18). This variation in age groups can likely be attributed to regional differences in the patient populations, as regional lifestyle, diet, and environmental factors may influence the prevalence of APD in different age groups.

The gender distribution in this study showed that males (58.8%) were more commonly affected by APD than females (41.2%). This finding aligns with similar studies, including the ones by Jha et al. (55.75% males and 44.25% females) and Hatila et al. (66.16% males and

- 33.84% females) (17, 18). The higher prevalence of APD in males can be attributed to
- lifestyle factors, such as increased consumption of alcohol, tobacco, and smoking, which are
- known risk factors for APD. Additionally, male patients may be more likely to seek medical
- care for such conditions, contributing to the higher observed prevalence.

Drug Prescribing Pattern

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- The study analysed a total of 1750 drugs prescribed during the study period. The average
- number of drugs per prescription was 1.8, with the number of drugs per prescription ranging
- from 1 to 4. A significant portion of the prescribed drugs (57.5%) was generic, with 42.5%
- 200 prescribed by their brand names. The preference for generic drug prescription is especially
- important in a developing country like India, where generic drugs provide a cost-effective
- alternative to branded medications. However, despite the potential cost savings, the
- relatively low prescription rate for generics can be attributed to a lack of awareness among
- both physicians and patients, as well as the misconception that generic drugs may not be as
- 205 effective as branded ones. This issue underscores the need for increased awareness about
- the safety and efficacy of generic medicines (19).
- Among the total prescriptions, 86% involved oral medications, which is consistent with
- 208 typical prescribing patterns in outpatient settings, where oral drugs are preferred due to their
- 209 ease of administration and better patient compliance. Only 14% of prescriptions included
- 210 injectables, which is lower than might be expected for conditions requiring more aggressive
- treatments. This lower percentage is likely due to the study's focus on outpatient care, where
- injectable therapies are less commonly needed.
- 213 The most frequently prescribed anti-peptic ulcer drugs in the study were proton pump
- 214 inhibitors (PPIs), with Pantoprazole being the most commonly prescribed drug, followed by
- Omeprazole and Rabeprazole. These findings are in line with studies by Dhande PP and
- 216 Patel HR, where PPIs (71%) were the most commonly prescribed class of anti-peptic ulcer
- drugs, followed by H2 blockers (19%) and antacids (7%) (20). In the current study, the most
- common combination therapies included Rabeprazole and Domperidone (36%), followed by
- H2 blockers and PPIs (34%). A smaller proportion (22%) of prescriptions included
- 220 combinations of antacids and sucralfate with PPIs.

Adherence to Essential Medicine Lists

- In terms of drug selection, the study found that 70% of prescribed drugs were from the
- National Essential List of Medicines (NELM) 2015, and 20% were from the WHO Model List
- of Essential Medicines. The high percentage of drugs prescribed from these lists indicates
- adherence to essential medicine guidelines, promoting safe, effective, and rational use of
- 226 medicines. Drugs from these lists are generally well-regarded for their efficacy, safety, and
- cost-effectiveness, and their use in clinical practice supports the rational use of medicines,
- optimizes healthcare resources, and ensures that patients have access to essential
- medications.

- 230 Moreover, the study found that 77.82% of the prescribed drugs were from the hospital
- formulary, highlighting that the hospital's drug formulary is adequate and well-utilized. This
- 232 suggests that the hospital's drug procurement system is effective in maintaining a well-
- 233 stocked inventory of medications, allowing prescribers to make cost-effective choices while
- ensuring that the drugs are appropriate for patient care. A hospital formulary, which lists the
- 235 drugs recommended by a formulary committee, helps standardize treatment practices,
- 236 reduces prescribing variability, and ensures that only safe and cost-effective drugs are
- 237 prescribed.

Drug Utilization: ATC/DDD Classification

- The study also evaluated drug use patterns based on the ATC (Anatomical Therapeutic
- 240 Chemical) and DDD (Defined Daily Dose) classification systems. The ATC classification is
- an international system for classifying drugs according to their therapeutic, pharmacological,
- 242 and chemical properties. This system helps compare drug utilization across different
- 243 countries and healthcare systems.
- The prescribed daily doses (PDD) and the DDD for the most commonly prescribed drugs
- were calculated. A PDD/DDD ratio of 1 suggests optimal dosing, and in the current study,
- 246 drugs like Ranitidine, Rabeprazole, and Pantoprazole (IV) showed a PDD/DDD ratio of 1,
- indicating appropriate dosing. However, the PDD/DDD ratio for drugs like Omeprazole and
- 248 Pantoprazole (oral) was greater than 1, indicating that these drugs were potentially
- overdosed. On the other hand, the PDD/DDD ratio for antacids was less than 1, suggesting
- 250 underdosing. These variations can be attributed to differences in therapeutic practices and
- 251 patient needs, highlighting the importance of ensuring that prescribed doses align with
- 252 recommended guidelines.

Adverse Drug Reactions (ADRs)

- The study found that adverse drug reactions (ADRs) were not recorded in the prescription
- sheets, raising concerns about the potential underreporting or oversight of ADRs. Non-
- serious ADRs, such as nausea, headache, and gastrointestinal disturbances, may have
- been overlooked by physicians or not documented in the medical records. This is a common
- issue in clinical practice, and improving ADR reporting and documentation is essential for
- 259 patient safety and for assessing the long-term effects of drug therapies.

Strengths and Limitations

The strengths of this study include its comprehensive analysis of prescribing patterns using 261 various metrics like the ATC/DDD classification, PDD, and WHO prescribing indicators. The 262 use of prescription sheets and electronic medical records helped minimize bias and allowed 263 for a thorough evaluation of drug utilization in acid peptic disease patients. Despite these 264 strengths, the study has limitations. The data was collected from a single institution, which 265 may limit its generalizability to other regions or populations. Additionally, the study relied on 266 WHO core prescribing indicators, which may not fully reflect local prescribing practices. The 267 underreporting of ADRs is another limitation, as non-serious adverse effects may not have 268 been documented or recorded.

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Conclusion

- 272 In conclusion, the present study offers valuable insights into the prescription patterns and
- 273 drug utilization in patients with acid peptic disease (APD) attending the outpatient
- 274 department of a tertiary care hospital. The demographic profile revealed a higher prevalence
- of APD in males (58.8%), with the majority of patients falling within the 31-40 year age
- group. A significant portion of drugs were prescribed using generic names (57.43%),
- 277 highlighting a trend toward cost-effective prescribing practices, although branded drug
- 278 prescriptions were still prevalent. The study also found a preference for oral medication
- 279 (92%) over parenteral routes (8%), with proton pump inhibitors (PPIs), particularly
- 280 Pantoprazole, being the most commonly prescribed class of drugs for APD. Furthermore, a
- 281 large proportion of prescribed drugs were included in the National List of Essential Medicines
- 282 (70%) and the hospital formulary (77.82%), supporting rational drug use practices.

- The analysis of drug utilization using the ATC/DDD classification system showed optimal
- dosing for most drugs, though certain drugs, such as omeprazole and pantoprazole (oral),
- indicated potential overdosing. The absence of reported adverse drug reactions (ADRs) in
- the prescription sheets raises concerns about possible underreporting of non-serious ADRs,
- 287 which warrants further attention in future studies. Overall, the drug prescribing trends in this
- study align with other studies conducted in India, suggesting consistency in prescribing
- 289 practices for APD management.

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