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Prescription Pattern and Adverse Drug Reactions Associated with Proton Pump Inhibitors in a Tertiary Care Teaching Hospital: A Prospective Observational Study

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Abstract: Background: Proton pump inhibitors (PPIs) are among the most commonly prescribed medications worldwide for acid-related gastrointestinal disorders. Despite their proven efficacy, inappropriate prescribing and long-term use have raised concerns regarding adverse drug reactions (ADRs) and unnecessary healthcare expenditure.**Aim:** To evaluate the prescription pattern of PPIs and assess associated adverse drug reactions in patients attending a tertiary care teaching hospital.**Materials and Methods:** A prospective observational study was conducted in the Department of Pharmacology in collaboration with the Departments of Medicine and Gastroenterology at a tertiary care teaching hospital over a period of 12 months. A total of 320 patients receiving PPIs were enrolled after informed consent. Data regarding demographic profile, indication, type of PPI prescribed, duration, route of administration, concomitant medications, and ADRs were recorded using a predesigned case record form. Causality assessment of ADRs was performed using the WHO-UMC scale. Statistical analysis was done using descriptive statistics and chi-square test.**Results:** Out of 320 patients, 186 (58.1%) were males and 134 (41.9%) females. Mean age was 46.8 ± 15.2 years. Most common indication for PPI prescription was gastroesophageal reflux disease (GERD) (34.4%), followed by gastritis (26.3%) and peptic ulcer disease (18.1%). Pantoprazole was the most frequently prescribed PPI (54.7%), followed by omeprazole (21.6%), rabeprazole (14.4%), and esomeprazole (9.3%). Injectable PPIs were used in 29.1% patients. Inappropriate indications were identified in 22.5% prescriptions. ADRs were observed in 52 patients (16.3%), with headache (30.8%), diarrhea (23.1%), nausea (17.3%), abdominal pain (13.5%), and dizziness (9.6%) being common. Most ADRs were mild and categorized as “probable” or “possible.”**Conclusion:** Pantoprazole was the most commonly prescribed PPI. A significant proportion of prescriptions lacked appropriate indications. ADRs were generally mild but notable. Periodic prescription audits and rational prescribing strategies are recommended to optimize PPI use.

Keywords: Proton pump inhibitors, prescription pattern, adverse drug reactions, pantoprazole, pharmacovigilance, drug utilization study

INTRODUCTION

Proton pump inhibitors (PPIs) are potent suppressors of gastric acid secretion and are widely used in the treatment of acid peptic disorders such as gastroesophageal reflux disease (GERD), peptic ulcer disease, Zollinger-Ellison syndrome, and for prevention of NSAID-induced gastropathy. Since their introduction, PPIs have largely replaced H2

receptor antagonists due to superior efficacy and tolerability.

Commonly prescribed PPIs include omeprazole, pantoprazole, rabeprazole, lansoprazole, and esomeprazole. These agents irreversibly inhibit the H+/K+ ATPase pump in gastric parietal cells, resulting in prolonged acid suppression. Although generally safe, increasing evidence suggests that long-term or irrational use may be associated with adverse outcomes such as headache, diarrhea, hypomagnesemia, vitamin B12 deficiency, fractures, Clostridium difficile infection, and drug interactions.

In clinical practice, PPIs are often prescribed empirically, continued without reassessment, or used prophylactically without clear indications. Drug utilization studies are useful tools to assess prescribing trends, identify irrational use, and improve patient safety. Monitoring adverse drug reactions is equally important for safer pharmacotherapy.

Hence, the present study was undertaken to evaluate the prescription pattern and ADR profile associated with PPIs in a tertiary care teaching hospital.

Materials and Methods

Study Design
Prospective observational study.

Study Setting
Department of Pharmacology in collaboration with the Departments of General Medicine and Gastroenterology at a tertiary care teaching hospital.

Study Duration
12 months.

Study Population
Patients receiving any proton pump inhibitor in outpatient or inpatient departments.

Sample Size
320 patients.

Inclusion Criteria

- Patients aged ≥18 years.
- Patients prescribed any PPI during study period.
- Patients willing to provide informed consent.

Exclusion Criteria

- Patients unwilling to participate.
- Critically ill patients unable to provide history.
- Patients with incomplete prescription records.

Data Collection

Relevant data were collected using a structured case record form:

- Age, gender
- Diagnosis/indication
- Type of PPI prescribed
- Dose, frequency, route, duration
- Concomitant medications
- Whether indication was appropriate as per standard guidelines
- Adverse drug reactions during follow-up

ADR Assessment
Reported ADRs were assessed using WHO-UMC causality scale and categorized as certain, probable, possible, unlikely, or unclassified.

Statistical Analysis
Data were entered in Microsoft Excel and analyzed using SPSS version 20. Results expressed as percentages, mean ± SD. Chi-square test used for categorical variables. $p < 0.05$ considered statistically significant.

Ethical Approval
Study approved by Institutional Ethics Committee prior to initiation.

Results

Demographic Profile
A total of 320 patients receiving proton pump inhibitors were included in the study. Among them, 186 (58.1%) were males and 134 (41.9%) were females, showing a male predominance. The mean age of the study population was 46.8 ± 15.2 years.

Variable	Number (%)
Male	186 (58.1)
Female	134 (41.9)
Total	320

Mean age = 46.8 ± 15.2 years

Indications for PPI Prescription
The most common indication for prescribing PPIs was gastroesophageal reflux disease (GERD), accounting for 110 (34.4%) cases, followed by gastritis in 84 (26.3%) patients. Peptic ulcer disease was observed in 58 (18.1%) patients, while NSAID prophylaxis and dyspepsia accounted for 38 (11.9%) and 18 (5.6%) cases respectively. Other miscellaneous indications were noted in 12 (3.7%) patients.

Indication	Number (%)
GERD	110 (34.4)
Gastritis	84 (26.3)
Peptic ulcer disease	58 (18.1)
NSAID prophylaxis	38 (11.9)
Dyspepsia	18 (5.6)
Others	12 (3.7)

Pattern of PPI Use

Pantoprazole was the most frequently prescribed proton pump inhibitor, used in 175 (54.7%) patients. Omeprazole was prescribed in 69 (21.6%) cases, followed by rabeprazole in 46 (14.4%) and esomeprazole in 30 (9.3%) patients. Regarding route of administration, oral PPIs were prescribed in 227 (70.9%) patients, whereas injectable formulations were used in 93 (29.1%) patients.

Drug	Number (%)
Pantoprazole	175 (54.7)
Omeprazole	69 (21.6)
Rabeprazole	46 (14.4)
Esomeprazole	30 (9.3)

Route of Administration	Number (%)
Oral	227 (70.9)
Injectable	93 (29.1)

Appropriateness of Prescription

Out of 320 prescriptions analyzed, 248 (77.5%) were considered appropriate according to standard treatment guidelines, whereas 72 (22.5%) were categorized as inappropriate. Common examples of irrational prescribing included routine stress ulcer prophylaxis in low-risk patients and continuation of therapy without reassessment.

Category	Number (%)
Appropriate indication	248 (77.5)
Inappropriate indication	72 (22.5)

Adverse Drug Reactions

A total of 52 patients (16.3%) experienced adverse drug reactions during the study period. Headache was the most commonly reported ADR in 16 (30.8%) patients, followed by diarrhea in 12 (23.1%) patients. Nausea, abdominal pain, dizziness, and rash were also reported.

ADR	Number (%)
Headache	16 (30.8)
Diarrhea	12 (23.1)
Nausea	9 (17.3)
Abdominal pain	7 (13.5)
Dizziness	5 (9.6)
Rash	3 (5.7)

Severity of ADRs

Most ADRs were mild in nature and observed in 39 (75.0%) patients. Moderate reactions were seen in 11 (21.2%) patients, while severe ADRs were uncommon and reported in only 2 (3.8%) patients.

Severity	Number (%)
Mild	39 (75.0)
Moderate	11 (21.2)
Severe	2 (3.8)

WHO-UMC Causality Assessment

Based on WHO-UMC causality assessment scale, 24 (46.2%) ADRs were categorized as probable, 22 (42.3%) as possible, and 6 (11.5%) as unlikely.

Category	Number (%)
Probable	24 (46.2)
Possible	22 (42.3)
Unlikely	6 (11.5)

DISCUSSION

The present study demonstrated that pantoprazole was the most commonly prescribed PPI, similar to previous Indian studies due to its favorable safety profile, lower interaction potential, and availability in injectable form. GERD and gastritis were the most common indications.

A notable finding was that 22.5% prescriptions were inappropriate. Overuse of PPIs has been reported globally, especially for prophylactic purposes in patients without clear risk factors. Such irrational use increases cost burden and risk of adverse effects.

The incidence of ADRs in our study was 16.3%, with headache and diarrhea being the most common, consistent with established literature. Most ADRs were mild and self-limiting. Serious reactions were rare.

This study highlights the importance of regular prescription audits, guideline-based therapy, and pharmacovigilance systems.

Limitations

1. Single-center study.
2. Moderate sample size.
3. Long-term complications such as fractures and micronutrient deficiency were not assessed.
4. Follow-up duration limited.

CONCLUSION

Pantoprazole was the most frequently prescribed PPI in this tertiary care hospital. Though PPIs were largely prescribed appropriately, a substantial proportion lacked justified indications. Adverse drug reactions were mostly mild, with headache and diarrhea being common. Rational prescribing practices, deprescribing when unnecessary, and active pharmacovigilance are essential to improve patient safety.

Recommendations

1. Use PPIs only for evidence-based indications.
2. Review necessity during follow-up visits.
3. Avoid prolonged empirical use.
4. Encourage ADR reporting.
5. Conduct regular prescription audits.

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