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Original Research Article

A study on appropriate use and stewardship of proton pump inhibitors

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ABSTRACT

Objective: To analyze the prescribing pattern of use of PPI with respect to "FDA-Approved Indications and Doses for PPI Therapy."

Materials and Methods: After obtaining approval from the Institutional Ethics Committee, a cross-sectional study was carried out among 400 inpatients in a tertiary care hospital in Bangalore. The data were collected from the patient case profile and prescriptions and noted in a self-designed data collection form. The statistical analysis of the collected data was performed using SPSS software and Excel.

Results: The study, conducted on 400 patients, revealed a male majority (60%) and a female representation of 40%. Proton Pump Inhibitors (PPIs), mainly Pantoprazole (74.70%), were frequently prescribed, notably in General Medicine (220 patients). PPI use was generally appropriate: indication (99%), dose (97%), frequency (92.8%), and duration (91.8%). However, irrational prescriptions were noted: indication (1%), dose (3%), frequency (7.3%), and duration (8.3%). 139 drug interactions were identified, categorized into Major (39.6%), Moderate (46%), and Minor (14.4%). For example, Ondansetron and tramadol exhibited a major interaction. Among PPI combinations, 93.75% could affect CYP2C19 metabolism, and 6.3% had additive/synergistic toxicity potential.

1. Introduction

Proton Pump Inhibitors (PPIs) have become a cornerstone in managing acid-related gastrointestinal conditions, yet their widespread use has raised concerns regarding responsible stewardship in modern healthcare. Stewardship entails ensuring appropriate, safe, and effective medication usage, going beyond prescription to encompass monitoring, optimization, and discontinuation when necessary. While PPIs offer relief from distressing symptoms, their long-term and unnecessary use poses risks.

Evidence suggests PPIs are often overprescribed or misused, linked to adverse effects such as increased infection susceptibility, bone fractures, and nutrient deficiencies. The study delves into prescribing patterns, clinical outcomes, and areas for improvement to advocate for judicious PPI use. Mechanistically, PPIs reduce stomach acid secretion by targeting the proton pump enzyme in parietal cells. However, their prolonged use has been associated with hypomagnesemia, rebound acid secretion, and vitamin deficiencies. [1–9]

Administration of PPIs involves various formulations designed to resist premature activation by stomach acid. They are typically taken before meals to maximize effectiveness, with delayed onset compared to other acid-reducing drugs. Side effects include hypomagnesemia, rebound acid secretion, and vitamin deficiencies, while potential associations with osteoporosis and fractures require further investigation.

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Monitoring of magnesium and vitamin B12 levels is advised, particularly in long-term PPI users. Toxicity may result in adverse reactions such as headaches and gastrointestinal disturbances. An interprofessional team approach is essential to ensure optimal patient outcomes, with physicians prescribing, nurses monitoring for side effects, and pharmacists reviewing interactions.[10–13]

Prescribing pattern monitoring studies (PPMS) are crucial for assessing drug use trends and promoting rational medicine use. PPIs are indicated for various acid-related disorders and are FDA-approved for specific conditions such as GERD and peptic ulcers. However, caution is warranted in patients with hypersensitivity or severe liver disease due to potential drug interactions.

Adverse effects, while relatively rare, can be severe and include hypomagnesemia, rebound acid secretion, and vitamin deficiencies. Monitoring for complications and adherence to treatment plans are paramount. Adverse outcomes may result from interactions with other drugs or inappropriate dosage, highlighting the importance of careful prescribing and monitoring.

In conclusion, responsible stewardship of PPIs is imperative to balance therapeutic benefits with potential risks. Through careful monitoring, optimization, and interprofessional collaboration, healthcare providers can ensure the appropriate use of PPIs, thereby enhancing patient care and safety in acid-related disorders.[14–19]

2. Materials and Methods

2.1. Sources of data and materials

Patient case sheet, Medication chart, Laboratory data

2.2. Method of collecting data

1. A Patient data was collected from medical records.
2. Collected data was recorded in self-designed patient data collection form.
3. This is a cross sectional study, the patient who are satisfying the inclusion criteria were enrolled into the study with the help of patient consent form. All patients admitted in the ward were reviewed on daily basis. Patient demographic details such as name, age, gender, education level, lifestyle, economic status, occupation, date of admission, reasons for admission, history of previous illness, social history were collected.
4. Information of vitals (blood pressure, temperature, pulse rate and respiratory rate), laboratory data (hematology test, blood sugar test, liver function test, urine analysis, renal function test such as serum creatinine, blood urea etc.), final diagnosis, current treatment drug regimen and other relevant data was collected from case sheets of patients. All the above-mentioned data were entered into the patient data collection form. The results of collected data was analyzed using statistical analysis, frequencies, percentages and mean values were calculated.

2.3. Statistical analysis

The data was collected and entered in Microsoft Excel software 2019 and interpreted by descriptive statistics that were presented to analyze and express the report as counts and percentages in the form of tables, charts, and graphs. The statistical analysis of the collected data was performed using IBM SPSS version 26 statistical software. A p-value of >0.05 was taken as significant.

2.4. Ethical consideration

Confidentiality was maintained throughout the study. Written informed consent was obtained from all the participants. There is no physical harm to the participants, as there is no intervention.

2.5. Ethical clearance

The study was submitted for ethical clearance to the ethical committee of the Sapthagiri Institute of Medical Sciences and Research Center. This study was based on the analysis of approved surveillance data.

3. Results

3.1. Patient's age wise categorisation

Out of 400 cases, the patients are divided into 8 categories according to their age. Patients who are aged between 51-60 have high percent for being admitted to the hospital. A total of 198 patients were above 50 years of age, while 202 were below 50 years of age. In the current study, the dominant gender was male (240) and remaining was filled by female gender (160).[20–23]

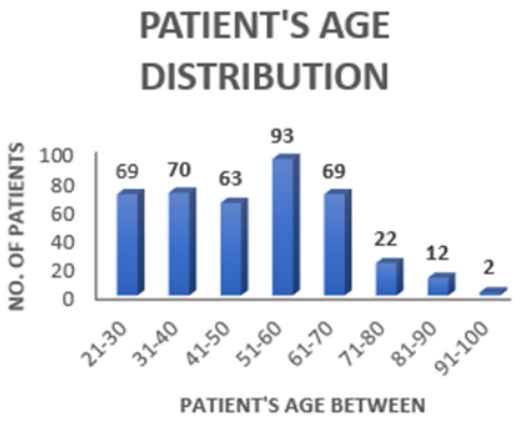

Figure 1: Patient'sage wise categorization

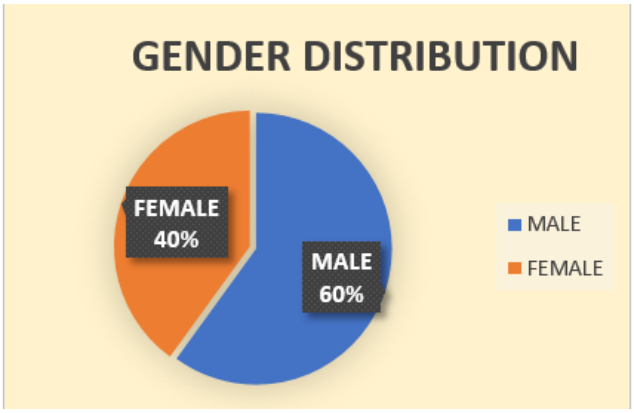

Figure 2: Gender distribution

4. Total Number of Departments

Among 400 patients, most proton pump inhibitors were prescribed to the following departments:

General medicine: 220 patients Orthopedics: 41 patients and so on to the other departments as follows.

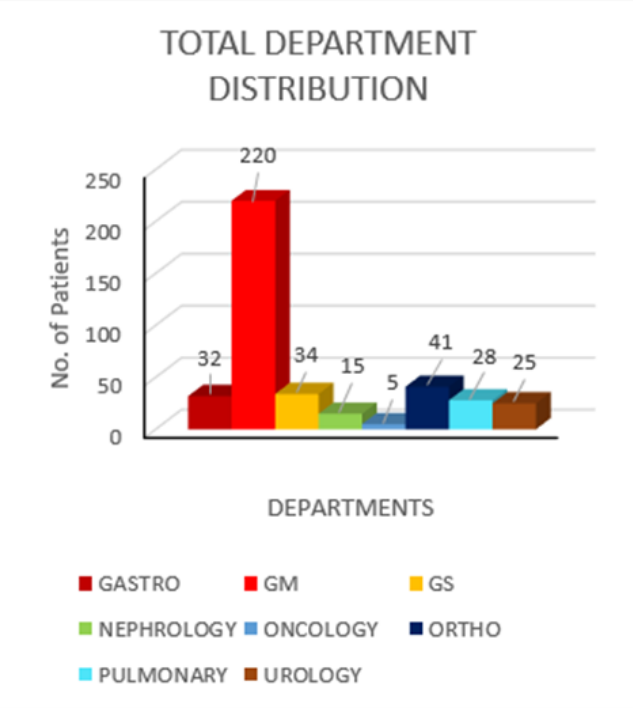

Figure 3: Total departments distribution

5. Number of Times Proton Pump Inhibitiors Prescribed

The study reports that 74.70 percent of prescriptions were prescribed by the drug Pantoprazole which comes under the class of Proton pump inhibitors. Rabeprazole comes in the second highest prescribed drug among Proton pump inhibitors with a percentage of 6.83.

Table 1: Distribution based on the number of times ppi's prescribed.

Name of drugs	Frequency	Percentage %
Dexlansoprazole	18	3.61
Esomeprazole	22	4.42
Lansoprazole	20	4.02
Omeprazole	32	6.43
Pantoprazole	372	74.70
Rabeprazole	34	6.83
Grand total	498	100.00

6. Class of Drugs Prescrib

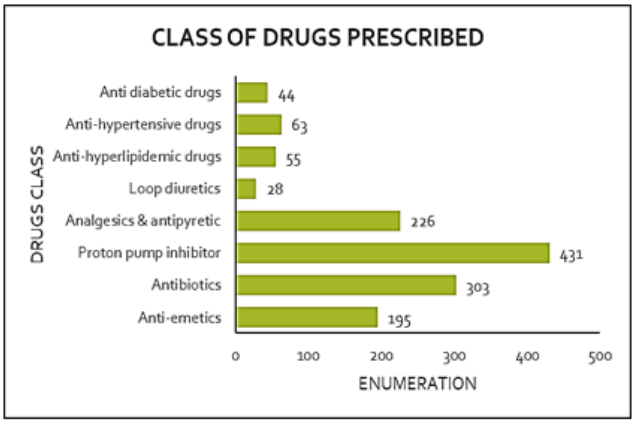

Figure 4: Class of drugs prescribed

For 400 patients diagnosed with various disorders from every department, the classes of drugs prescribed are enlisted on the table below. The major portion belongs to Proton Pump Inhibitors (431) followed by Antibiotics (303). The least prescribed class of drug is Loop diuretics (with only 28). The data is given on the table and chart below.

7. Rational Use of Proton Pump Inhibitors

In the study on analyzing the rational use of Proton Pump Inhibitors. It was observed that the overall appropriateness of Proton Pump Inhibitors with respect to Indication was 99.0%. For dose, it was 97.0%. With reference to frequency and duration 92.8% and 91.8% were observed.

8. Irrational Use of Proton Pump Inhibitors

From the study it was observed that 1.0 percent of Indications were irrational. With reference to Dose and frequency 3.0 and 7.3 percentiles were noted. In terms of duration of treatment 8.3 percent of inappropriateness was found.

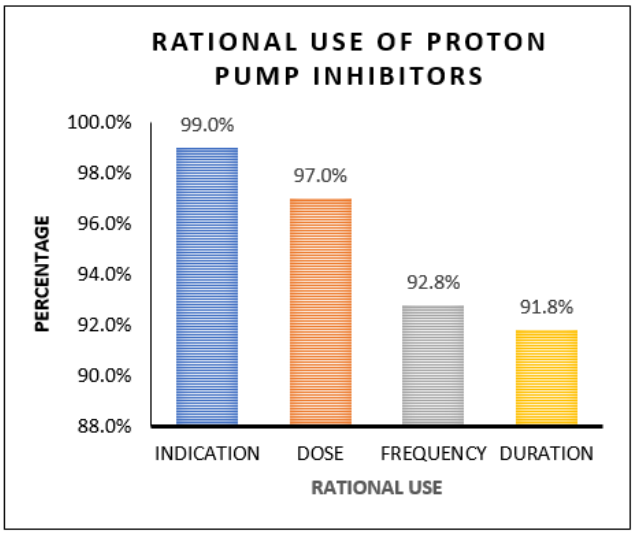

Figure 5: Distribution for rational use of proton pump inhibitors.

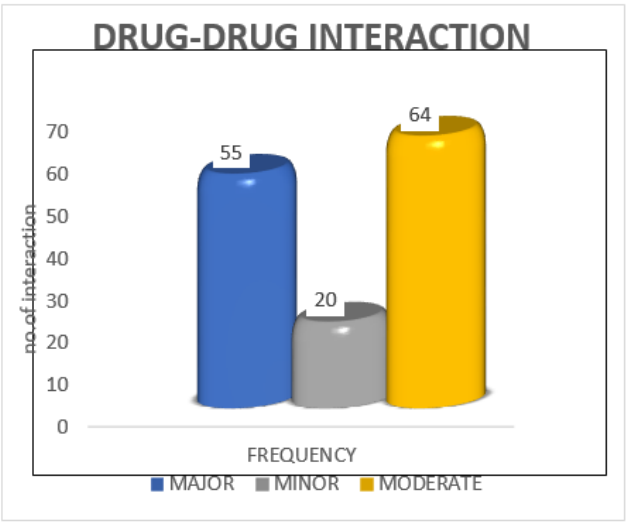

Figure 7: Distribution of potential drug- drug interactions.

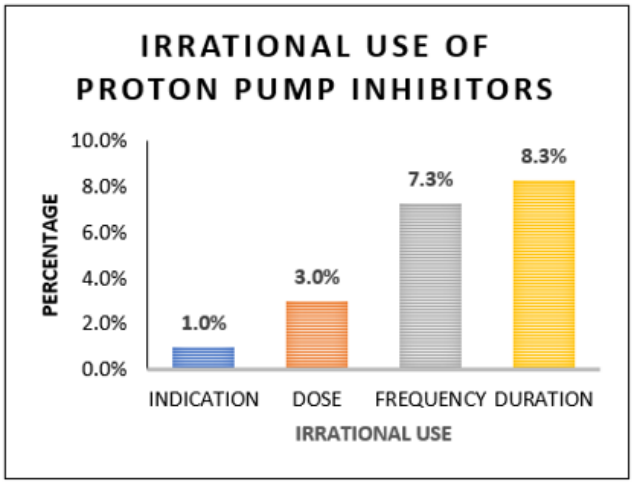

Figure 6: Distribution for irrational use of proton pump inhibitors.

9. Potential Drug - Drug Interactions

Out of 400 cases 139 drug interactions were found from the study. In that 55 (39.6%) cases Major interactions were noted. Moderate drug interactions were found in 64 Cases (46%) and Minor interaction in 20 cases (14.4%).

10. Discussion

Among the 400 cases collected for our study, we found that majority of patients aged between 51-60 (23.25%) having more percentage of being admitted in the hospital. Total of 198 were above 50 years of age and 202 were below 50 years of age. The study found out to be consistent with the study conducted by Shivani Juneja conducted a cross sectional observational study on "Appropriateness of Proton Pump Inhibitor Use in Hospitalized Patients". (Figure 1)

Out of 400 cases, Majority were males 240 (60%) and females were 160 (40%).(Figure 2)

Among 400 patients, most proton pump inhibitors were prescribed to the following departments: General medicine: 220 patients, Orthopedics 41 patients, General Surgery(GS) 34, Gastro 32 Patients, Urology 25 Patients, Pulmonary 28 Patients, Nephrology 15 Patients and Oncology 5 Patients. (Figure 3)

Out of 400 patients, the study reports that 74.70% of prescriptions were prescribed by the drug Pantoprazole which comes under the class of Proton pump inhibitors. Rabeprazole comes in the second highest prescribed drug among Proton pump inhibitors with a percentage of 6.83% and the Omeprazole is 6.43% and Esomeprazole is 4.42% and Lansoprazole is 4.02% and Dex lansoprazole is 3.61%. (Table 1)

Among 400 patients diagnosed with various disorders from each department, the classes of drugs prescribed as follows. The major portion belongs to Proton Pump Inhibitors was 431 (32%) followed by Antibiotics was 303 (22.5%), Analgesics and Antipyretic drugs 226 (16.8%), Anti emetics drugs was 195 (14.5%), Anti-hypertensive drugs was 63 (4.7%), Anti hyperlipidemic drugs 55 (4.1%), Anti diabetic drugs 44 (3.3%). The least prescribed class of drug was Loop diuretics 28 (2.1%).(Figure 4)

In the study on analyzing the rational use of Proton Pump Inhibitors, it was observed that the overall appropriateness of Proton Pump Inhibitors with respect to Indication was 99.0%.

For dose it was 97.0%. With reference to frequency and duration 92.8% and 91.8% were observed. (Figure 5)

From the study it was observed that 1.0 percent of Indications were irrational. With reference to Dose and frequency 3.0 and 7.3 percentiles were noted. In terms of

duration of treatment 8.3 percent of inappropriateness was found. (Figure 6)

Out of 400 cases 139 drug-drug interactions were found from the study. In that 55 (39.6%) cases Major interactions were noted. Moderate drug interactions were found in 64 Cases (46%) and Minor interaction in 20 cases (14.4%). (Figure 7)

11. Conclusion

The study reported that the overall PPI use with respect to indication was high, at 99%. This indicates that in a majority of cases, PPIs were prescribed appropriately based on the clinical indications. The 400 cases were analyzed, out of 35 proton pump inhibitors combinations 30 (93.75%) drug combinations could exhibit on by affecting hepatic enzyme CYP2C19 metabolism followed by 2 (6.3%) drug combinations with a capability of inducing an additive/synergistic toxicity. The presence of ADRs raises concerns about patient safety and the need for careful monitoring of medication regimens.

12. Acknowledgment

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13. Source of Funding

None.

14. Conflict of Interest

None.

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