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Drug Utilization Review of Pantoprazole in Inpatients of a Tertiary Care Hospital

Wafa Awadh O. Basalib[1]Pharm.D, Balakeshwa Ramaiah[2]M.Pharm, Ph.D.
Karnataka College of Pharmacy, Bengaluru - 560064 , Karnataka, India.

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ABSTRACTS

Background: Drug utilization review (DUR) is an approved, structured, ongoing review of prescriptions, administering (dispensing), and utilization of medications. DUR helps to promote the rational use of medications, by ensuring that prescriptions for outpatient and inpatient drugs are for the right indications, medically necessary, and will not result in adverse medical effects. Proton pump inhibitors (PPIs) such as pantoprazole are one of the most prescribed classes of medications globally. However, irrational use of pantoprazole is high because of their high efficacy and easy availability.

Aim: This study is aimed to identify the problems associated with the inappropriate use of pantoprazole and to promote it rational use.

Methodology: A prospective-observational study was carried out at the Bangalore Baptist Hospital (BBH) – Hebbal, Bengaluru. 167 inpatients were enrolled for the study after signing the informed consent form. The patients' case sheet containing prescriptions with pantoprazole included were reviewed and relevant data were extracted in a suitable designed data collection form.

Results: Out of the 167 patients, 115 (68.86%) were males and 52 (31.6%) were females. The most predominant age group was 41-50 years (22.60%) and 61-70 years (30.77%) for male and female participants respectively. Pantoprazole was mostly prescribed for patients in the general medicine (50 patients; 29.94%), cardiology (39 patients; 23.35%) and nephrology (22 patients; 13.1%) departments. The major clinical indication for pantoprazole was drug induced ulcer (146 patients; 87.42%), with 40 mg (152 patients; 91.01%) and once daily (127 patients; 76.05%) as the major dose and frequency of pantoprazole. Irrational prescription was observed in 38 (22.75%) patients, which is due to wrong indications or multiple drug administration at the same time (polypharmacy). The main route of administration was IV administered to 100 (59.88%) patients, and pantoprazole was mostly prescribed with NSAIDs (114 patients), antibiotics (106 patients), with abdominal pain (11 patients; 6.58%), nausea and vomiting (8 patients; 4.79%) being the major adverse effects observed in the patients.

Conclusion: Pantoprazole should be used when there is well justifiable clinical evidence, thereby promoting the rational use of pantoprazole, improving patient quality of life and reducing the healthcare burden on the patient. The study is also expected to promote more pharmacovigilance studies on the rational use of pantoprazole and other proton pump inhibitors (PPIs).

Keywords: Drug utilization review, proton pump inhibitors, pantoprazole, inpatients, rational drug use.

I. INTRODUCTION

Drug utilization review (DUR) is defined as an approved, structured, ongoing review of prescriptions, administering (dispensing), and utilization of medications. Drug utilization review programs helps to promote the rational use of medications, thereby ensuring that prescriptions for outpatient and inpatient drugs are for the right indications, medically necessary, and not likely to result in adverse medical consequences (1).

The World Health Organization (W.H.O.) defines drug utilization research as; "the marketing, distribution, prescription and use of drugs in a society with special emphasis on the resulting medical, social, and economic consequences"(2).

Drug utilization focuses on the various medical (risks and benefits of drug therapy , social (inappropriate use of drugs), and economic aspects (cost of drugs and treatments for patients and society at large) of drug use.

Drug Utilization Review (DUR), is also reffered to as Drug Utilization Evaluation (DUE) or Medication Utilization Evaluation (DUE).

DUR is classifidied in three categories: Prospective (evaluation of a patient's drug therapy before medication is dispensed), concurrent

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(ongoing monitoring of drug therapy during the course of treatment) and retrospective (review of drug therapy after the patient has received the medication).

Proton pump inhibitors (PPIs) are a group of drugs that cause noticeable and long-lasting reduction of gastric acid production. They are most potent gastric acid suppressing drugs currently in clinical use (3), and have emerged as the choice of treatment for gastric acid related disorders (4). PPIs irreversibly inhibit the gastric H^+-K^+ATPase pump (proton pump), thereby decreasing basal and stimulated gastric output.

The discovery, development of PPIs took place in early 1970s (5). Omeprazole was the first PPI available in the market to treat gastric acid reflux(6), pantoprazole was the first PPI to be availablein both oral and intravenous (IV) forms(7).

The PPIs available in India currently are omeprazole, esomeprazole, pantoprazole, rabeprazole and lansoprazole. PPIs are used therapeutically in peptic ulcer disease, Zollinger-Ellison syndrome (ZES), gastro-esophageal reflux disease (GERD) associated with a history of erosive esophagitis, gastro-intestnal bleeding,prevention of non-steroidal anti-inflammatory drugs (NSAIDs)induced ulcer and as an adjunctive therapy with antibiotics (metronidazole, clarithromycin or amoxicillin) for Helicobacter pyloritreatment in patients without history of antibiotic resistance (8). PPIs are also given prophylactically along with NSAIDs or steroids in patients with known history of peptic ulcer disease (PUD), previous gastrointestinal bleeding(9).

Prior to anaesthasia induction during surgery, intravenous pantoprazole may be administered to reduce gastric volume and output as well as for pulmonary aspiration prophylaxis, as well as been administered in post surgery to reduce the amount of acid produced by the stomach. In joint replacement surgery it is prescribed to prevent ulcers associated with the use of non-steroidal anti-inflammatories and aspirin.

The proton pump inhibitors (PPIs) are better therapeutically than histamine receptor antagonists (H2RAs) for reducing the adverse effects of gastro-intestinal bleeding (10) and provide long term maintainance of stomach acidity pH levels of>6 (11,12)

Pantoprazole is a substituted benzimidazole derivative, and appears as a white crystalline powder, that is weakly basic and acidic. It is freely soluble in water, and very slightly soluble in phosphate buffer at pH 7.4 and insoluble in n-hexane (4).

It inhibits the final step in gastric acid secretion, it alters the absorption of drugs such as digoxin, ampicillin, diuretics, iron salts, antifungals (ketoconazole, itraconazole) whose bioavailability is determined by gastric pH 7, and the drug is usually administered on empty stomach (13,14).

The dosages and strengths for pantoprazole are as follows; 40mg/packet given as oral suspension, 40mg/vial and 20mg given as powder for injection, 40mg for tablet and delayed-release(15).

The Pantoprazole for injection may be administered intravenously through delicate line or Y-site for a duration of about 15 minutes. Parenteral routes of administrationother than Intravenous are not recommended for pantoprazole. The intravenous line should be flushed before and after administration of intravenous pantoprazole either by using 5% dextrose injection USP or 0.9% sodium chloride injections or Ringers lactate Injection USP. Administration of pantoprazole should be stopped immediately if precipitation or discoloration occurs during administration through the Y-site (16).

Adverse effects associated with the use of pantoprazole includes; abdominal pain, constipation, flatulence, leukopenia, nausea, vomiting, thrombophlebitis, angioedema, jaundice, and urticaria(17).

The Proton pump inhibitors, including pantoprazole sodium for injection are contraindicated in patients receiving rilpivirine-containing products and patients with known hypersensitivity (4).

An understanding of the Drug Utilization Review of pantoprazole prescribed to inpatients in a tertiary care hospital is important to ensure the rational use of pantoprazole thereby limiting the drugs' side effects, overuse, adverse drug reactions, treatment failures, thereby improving patient quality of life(18). Hence this drug utilization review study will form the basis for advocacy, regulation, and health policy review for health promotion programs.

Aim: The study was aimed to assess the drug utilization review of pantoprazole in a tertiary care teaching hospital including the pharmacokinetics and pharmacodynamics properties of pantoprazole.

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Objectives

- To assess the indications for pantoprazole in inpatients
- To find out percentage of irrational prescriptions with pantoprazole (inappropriate prescriptions without justified indications)
- To assess the frequency of usage pantoprazole along with their dosage and interval
- To assess the safety, efficacy and cost effectiveness of pantoprazole

II. METHODOLOGY

Study design: This was aprospective, observational study.

Study site: The study was conducted in the in-patient units of general medicine department, cardiology department, nephrology department, pulmonology department, neurology department, gastroenterology department, urology department, orthopaedic department and intergrated liver care units of the Bngalore Baptist Hospital (BBH), Hebbal, Bangalore, India.

Study period: Study was carried out from January 2022 to March 2023.

Study Criteria: Study included in-patients of any gender at the study site receiving pantoprazole as drug treatment for peptic ulcer, gastritis, gastro-esophageal reflux disorder (GERD), or as a prophylactic drug in concomitant administration with non-steroidal anti-inflammatory drugs (NSAIDs), antibiotics, steroids. Children, pregnant patients, lactating mothers, psychiatric patients, patients allergic to proton pump inhibitors (PPIs), uncoscious and comatose patients as well as patients unwilling to participate in the study were excluded from the study.

Institutional Ethical Committee (IEC) approval: All patients who filled the informed consent form and accepted to participate in the study were included. The study was approved by the Institutional Ethical Committee of Bangalore Baptist Hospital (IEC-BBH) Bangalore, and a certificate of clearance for the study was issued.

Study procedure: Eligible patients were enrolled after administering the informed consent forms which was prepared in English and translated versions in Hindi and Kannada. The Informed Consent Form was designed as per the requirements of the Indian Council of Medical Research (ICMR) Ethical Guidelines for biomedical research on human subjects.

Relevant data such as demographic details of the patient, social habits, current medication, past medical and medication history, provisional and final diagnosis, laboratory investigations, and other relevant data were collected from patients' progress records, treatment charts, laboratory reports and entered in a suitably designed structured data collection form.

The collected data was subjected for checking of drug-drug interactions and adverse drug reactions (ADRs) reporting using primary (Micromedex), secondary and tertiary resources which are available in the clinical pharmacy department of the Bangalore Baptist Hospital (BBH).

Data analysis: The collected data were entered into Microsoft Excel Spreadsheet for easy calculations and retrieval followed by the assessment with the help of SPSS software version 25.0 (licensed to BBH).

Descriptive statistical analysis was carried out using P value of <0.05 as statistical significant with 95% confidence interval (CI). Predictors for the prescription of pantoprazole was calculated in percentages (%) and expressed using charts and graphs.

III. RESULTS

Out of the 178 patients screened for the study, 167 patients met the study criteria and were enrolled into the study. The reporting plan for the study is discussed below;

Gender distribution of study population: Among 167 enrolled patients, 108 (64.67%) were male, 59 (35.33%) were female as shown in table 01 and figure 01 below.

Table 01: Gender distribution

Gender	NO. of Patients	Percentage
MALE	108	64.67%
FEMALE	59	35.33%

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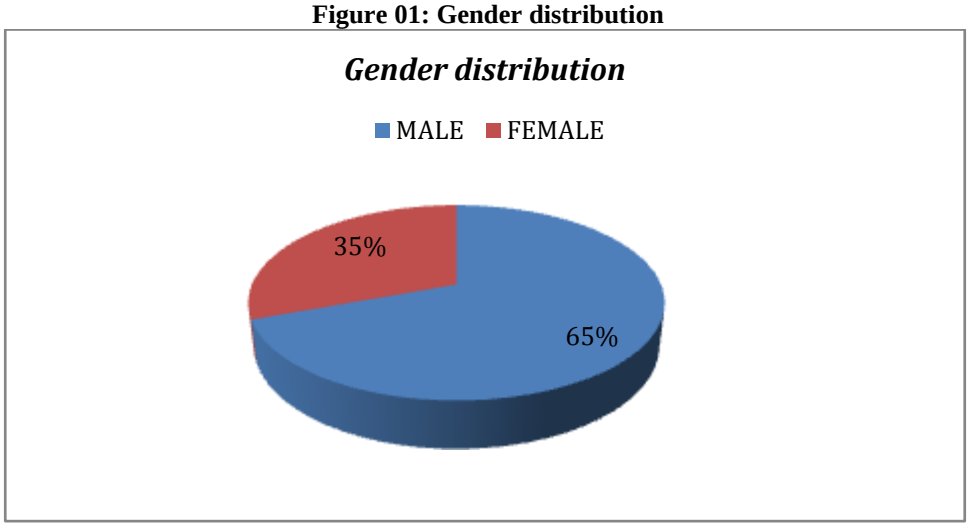
Figure 01: Gender distribution



Age distribution of study population: Among 167 enrolled patients, the patients in age range of 41-50 years (22.22%) were most predominantly receiving pantoprazole for the male population, and the age group of 61-70 years (25.43%) for the femaale population. The least age group are patients greaterthan 80 years for both male (1.85%) and female (6.78%) receiving pantoprazole as shown in table 02 and figure 02 below.

Table 02: Age distribution

AGE	MALE	FEMALE	MALE PERCENTAGE %	FEMALE PERCENTAGE %
20-30	9	11	8.33 %	18.64%
31-40	13	13	12.03%	22.03%
41-50	24	7	22.22%	11.86%
51-60	22	4	20.37%	6.78%
61-70	19	15	17.59%	25.43%
71-80	16	5	14.81%	8.47%
>80	2	4	1.85%	6.78%

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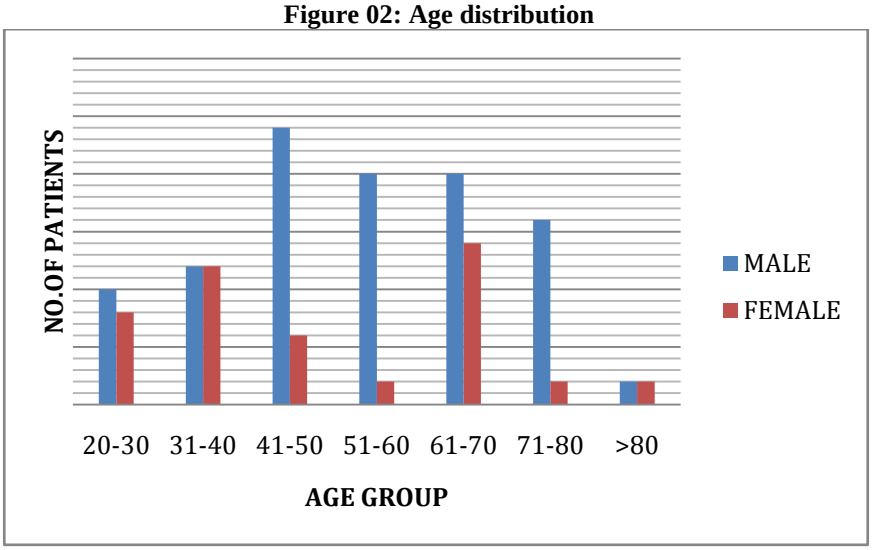
Figure 02: Age distribution

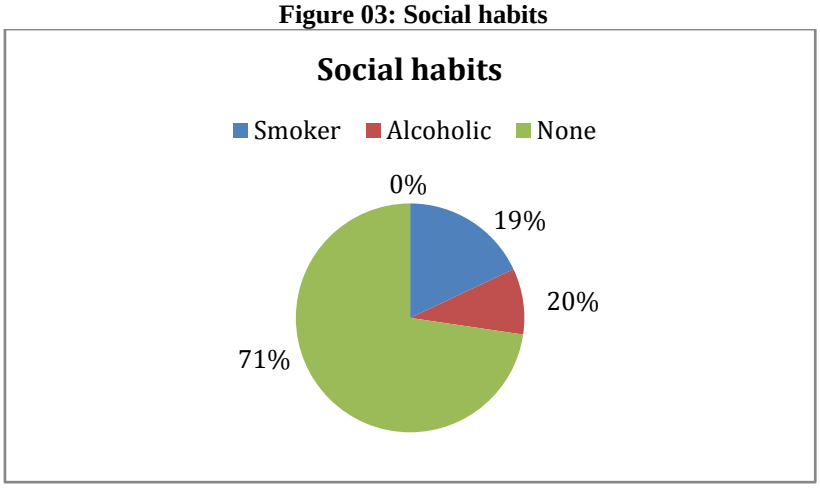


Social habits of study population: Among 167 enrolled patients, 32 patients (19.16%) are smokers, 34 patients (20.40%) patients are alcoholics, 17 patients (10.18%) are both smokers and alcoholics, where as 118 patients (70.66%) are neither smokers nor alcoholics as shown in table 03 and figure 03 below.

Table 03: Social habits

S. N	SOCIAL FACTORS	NO. OF PATIENTS	% OF PATIENTS
1	SMOKERS	32	19.16%
2	ALCOHOLIC	34	20.40%
3	NONE	118	70.66%

Figure 03: Social habits



Use of pantoprazole in different departments: The highest number of patients enrolled in the study were found in the general medicine department with 49 patients (29.35%), followed by cardiology department with 37 patients (22.16%), nephrology department with 21 patients (12.57%), urology department with 14 patients (8.39%), where as the least number of patients were from

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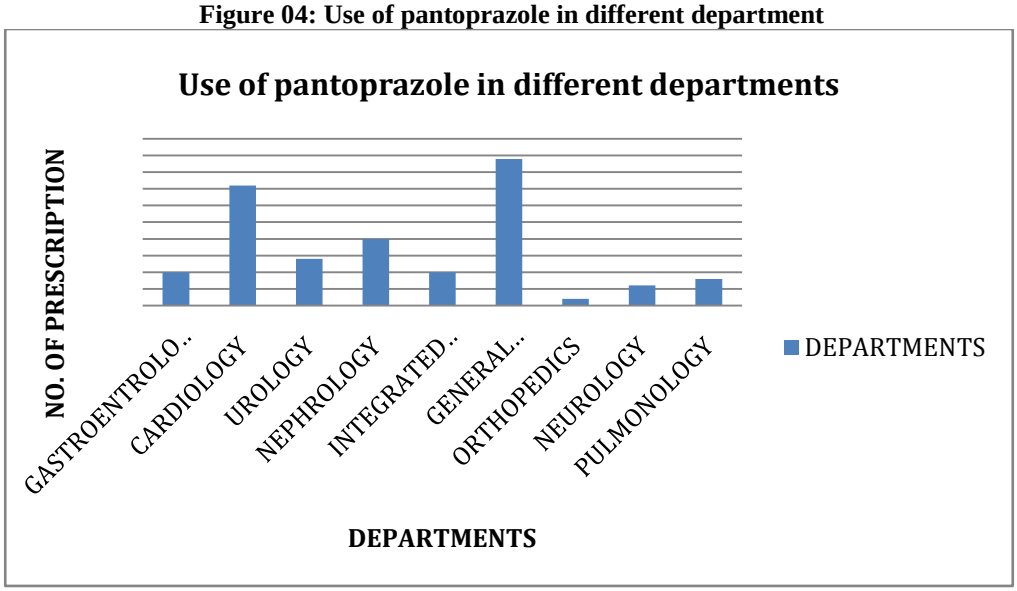
pulmonology and orthopedics departments with 7 (4.20%) and 4 (2.40%) patients respectively. This is shown in table 04 and figure 04 below.

Table 04: Use of pantoprazole in different departments

DEPARTMENTS	NO: OF PATIENTS	PERCENTAGE %
GASTROENTROLOGY	13	7.78%
CARDIOLOGY	37	22.15%
UROLOGY	14	8.38%
NEPHROLOGY	21	12.57%
INTEGRATED LIVER CARE UNITS	12	7.18%
GENERAL MEDICINE	49	29.34%
ORTHOPEDICS	4	2.39%
NEUROLOGY	8	4.79%
PULMONOLOGY	7	4.19%

Figure 04: Use of pantoprazole in different department



Clinical indications of pantoprazole: Out of 167 prescriptions containing pantoprazole, 138 (82.63%) prescriptions were given for the treatment of drug induced ulcer (most clinical diagnosis), where as the least diagnosis were crohn's disease and GERD (gastro-esophageal reflux disorders) with 5 (3.00%) prescriptions each as shown in table 05 and figure 05 below.

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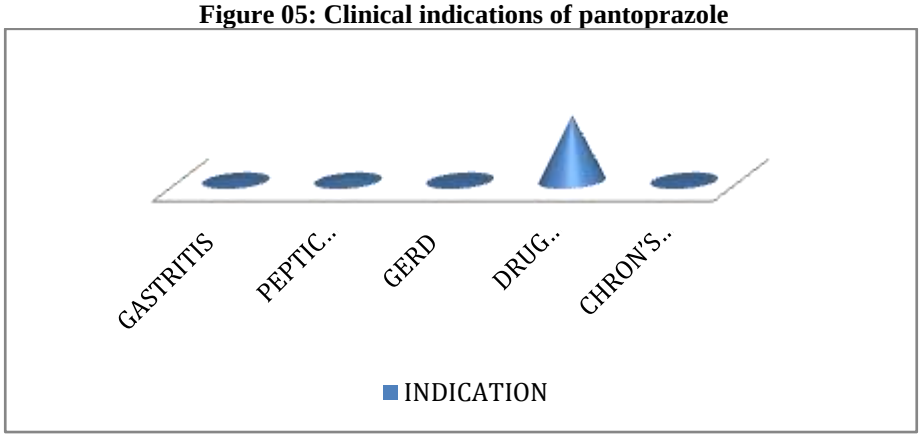
Table 05: Clinical indications of pantoprazole

S. NO	INDICATION	NO. OF PRESCRIPTION	PERCENTAGE
1.	GASTRITIS	8	4.80%
2.	PEPTIC ULCER	11	6.59%
3.	GERD	5	3.00%
4.	DRUG INDUCED ULCER	138	82.63%
5.	CROHN'S DISEASE	5	3.00%

Figure 05: Clinical indications of pantoprazole



Dose and frequency of pantoprazole: Out of 167 patients, 149 (89.22%) patients were prescribed pantoprazole 40 mg, where as 20 mg of pantoprazole was prescribed to 18 (10.80%) patients. Pantoprazole was prescribed once daily (OD) to 124 (74.26%) patients and twice daily (BD) to 43 (25.76%) patients. These results are shown in tables 06, 07, and figures 06, 07 below.

Table 06: Dose of pantoprazole

DOSE	NO. OF PRESCRIPTIONS	PERCENTAGE± SD
20 MG	18	10.80% ± 1.7
40 MG	149	89.22% ± 1.07

Figure 06: Dose of pantoprazole

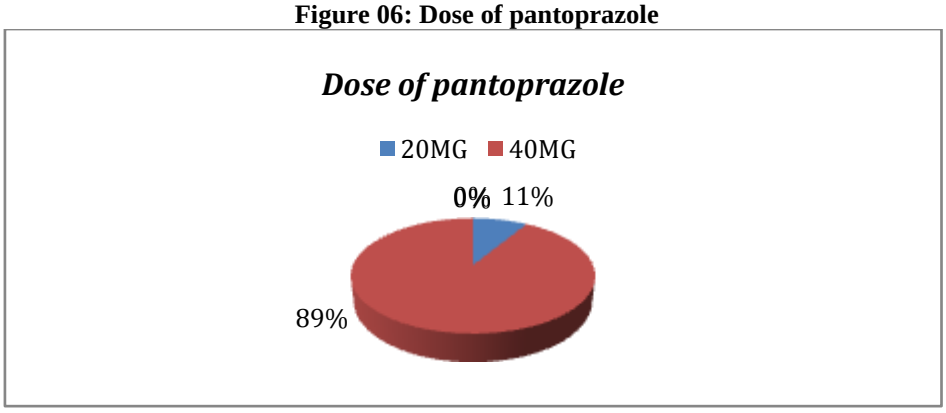


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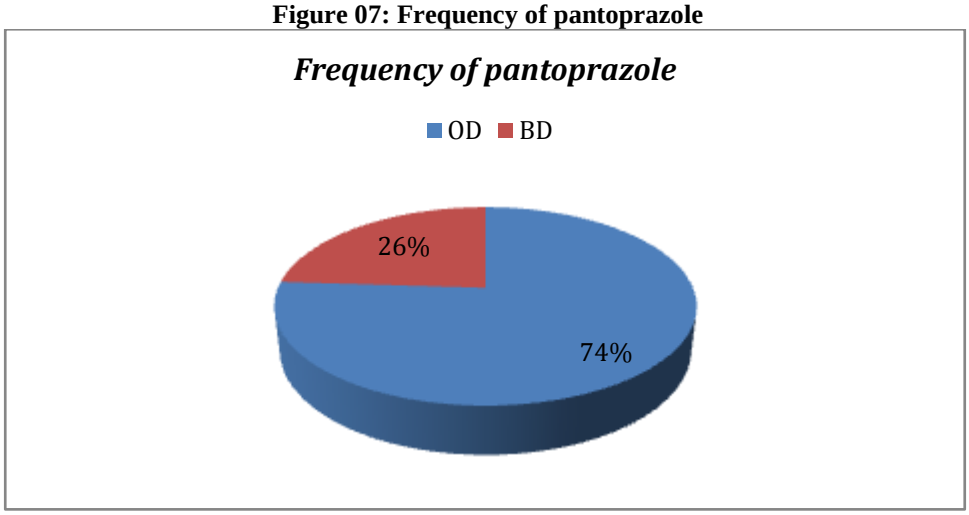
Table 07: Frequencey of pantoprazole

FREQUENCY	NO. OF PATIENTS	PERCENTAGE (%)± SD
OD	124	74.26% ± 0.05
BD	43	25.75% ± 0.05

Figure 07: Frequency of pantoprazole



Rational prescription: Out of 167 prescriptions, 129 (77.24%) prescriptions where rational, where as 38 (22.75%) prescriptions were irrational as shown in table 08 and figure 08 below.

Table 08: Rational prescription

USES	NO. OF PATIENTS	PERCENTAGE (%)± SD
RATIONAL	129	77.24% ± 1.42
IRRATIONAL	38	22.75% ± 2.13

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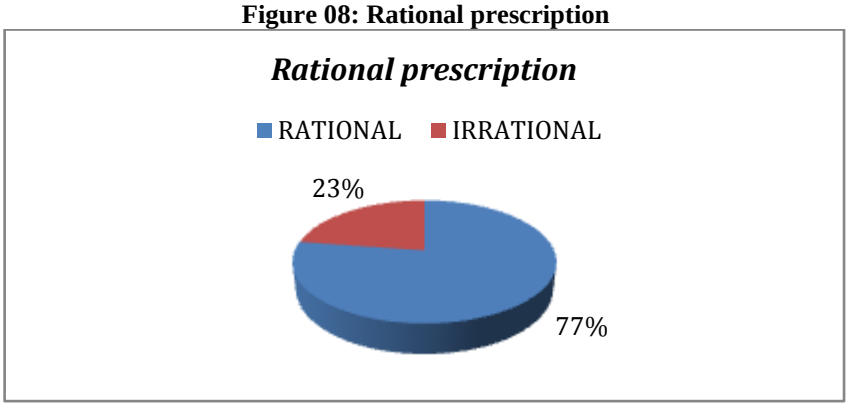
Figure 08: Rational prescription



Route of administration and switching of therapy: Out of the 167 patients enrolled for the study, 98 (58.70%) patients were administered I.V pantoprazole therapy, where as 69 (41.32%) patients weregiven oral pantoprazole therapy. Inthe I.V therapy administered, 24 (24.49%) was later switched to oral therapy. These results are shown in table 09,10, and figure 09 and 10 below.

Table 09: Route of drug adminstration

S. N.	ROUTE OF ADMINISTRATION	PRESCRIPTIONS	PERCENTAGE± **SD**
1	I.V.	98	58.70% ± 2.38
2	ORAL	69	41.32% ± 2.20

Figure 09: Route of drug administration

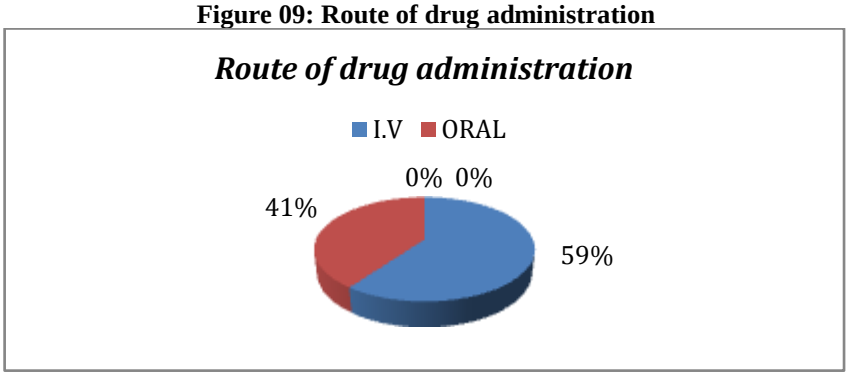


Table 10: Pantoprazole I.V. therapy switched to oral therapy

S. N	PRESCRIPTIONS	NUMBER OF PRESCRIPTION	PERCENTAGE± **SD**
1	FULL IV THERAPY	74	75.51% ± 3.915
2	IV SWITCHED TO ORAL THERAPY	24	24.49% ± 2.38

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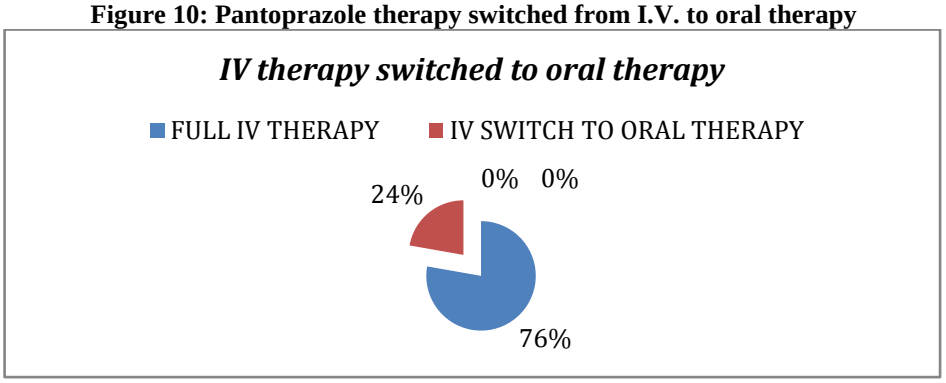
Figure 10: Pantoprazole therapy switched from I.V. to oral therapy



Concurrent drugs prescribed with pantoprazole: Out of the 167 prescriptions from the 167 enrolled patients, the most prescribed drugs along with pantoprazole were NSAIDS (non-steroidal anti-inflammatory drugs), antibiotics and antiemetics with 114, 106 and 67 prescriptions respectively. The least prescribed medications were antimalarial medications and iron products with 6 and 5 prescriptions respectively as shown in table 11 and figure 11 below.

Table 11: Concurrent drugs prescribed with pantoprazole

S. N	DRUG	NO. of PRESCRIPTION
1	ANTIBIOTICS	106
2	NSAIDS	114
3	ANTIEMETIC	67
4	ANTIDIABETIC	28
5	DIURETICS	50
6	ANTIHYPERTENSIVE	47
7	VITAMINS	22
8	STATINS	33
9	CORTICOSTERIODS	17
10	ANTICONVULSANTS	28
11	ANTIANGINAL	8
12	ANTI ALLERGIC	17
13	ANTIPLATELETS	28
14	ANTIASTHMATIC	28
15	THYROID DRUG	11
16	ANTICOAGULANTS	39
17	ANTACIDS	25
18	IRON PRODUCTS	5
19	ANTIMALARIAL	6
20	INSULIN	17

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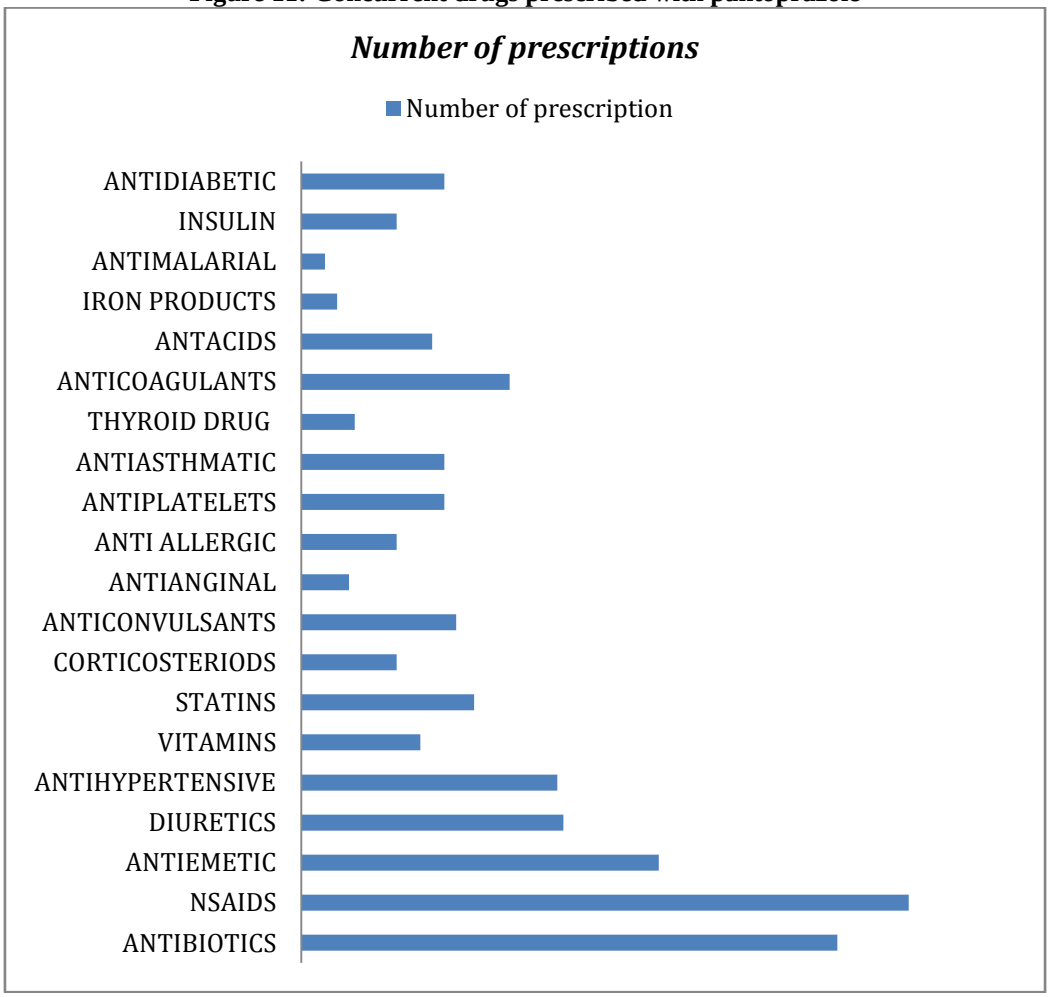
Figure 11: Concurrent drugs prescribed with pantoprazole



Commonly occurred adverse effects: Among the 167 patients, adverse effects of pantoprazole were experienced by 31 patients (18.56%), for which the most common adverse effects were abdominal pain experienced by 11 patients (6.58%), and nausea with vomiting experienced by 8 patients (4.79%). The least adverse effects were diarrhoea and joint pain, experienced by 4 (2.39) and 3 (1.79%) patients respectively as shown in table 12 below

Table 12: Reported adverse effects of pantoprazole

S.No.	Adverse effects	No. of patients	Percentage
1	Abdominal pain	11	6.58%
2	Nausea and vomiting	8	4.79%
3	Headache	5	2.99%
4	Diarrhea	4	2.39%
5	Joint pain	3	1.79%

IV. DISCUSSION

According to our study which examined 167 in-patients being administered pantoprazole in a tertiary care hospital (Bangalore Baptist hospital), pantoprazole was prescribed more to males (108, 64.67%) when compared to female participants (59, 35.33%). This result is similar to a study conducted by Ghorbani and Nagaraju. (4). The major age group being administered pantoprazole are 41-50 (22.22%) years for males, and 61-70 (25.43%) years for females.

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Our study shows that 32 (19.16%) patients are smokers, 34 (20.40%) patients are alcohol consumers, 17 (10.18%) patients are smokers and alcoholics, which are major risk factors for various acute and chronic diseases, and 118 (70.66%) patients are neither smokers nor alcoholics.

Pantoprazole was mostly prescribed in general medicine (49 patients; 29%), cardiology (37 patients, 22%) and nephrology (21 patients; 13%) departments for the various clinical indications, for which drug induced ulcer (138 patients; 82.63%) was the most clinical indication. This is similar to the studies conducted by Patil et al., (20)(14) (19) and Nousheen et al., (20)(16) (20). This shows that pantoprazole is the drug of choice as gastroprotective agents alone or in combination with antibiotics and NSAIDs. Thus pantoprazole decreases the gastrointestinal side effects (adeverse effects) of NSAIDs, and some antibiotics, but prolong admistration will give rise to some adverse effects such as abdominal pain, nausea and vomiting, headache, diarrhoea and joint pain, and this is in accordance with the study conducted by Shabhir et al., (21), tadvi et al., (22) and Airee et al., (23).

Pantoprazole was mostly prescribed once daily (124 patients; 74.26%), as compared to twice daily (43 patients, 25.75%). This is based on the pharmacokinetic, pharmacodynamic properties of the drug, and the disease severity of the patients (1) (24)

Among the 167 patients, 98 (58.70%) patients were on IV pantoprazole, where as 69 (41.32%) patients where on oral pantoprazole. Based on the stability of the patients, 24 (24.49%) pattients on IV therapy where later switched to oral therapy, where as the remaining 74 (75.51%) patients were maintained on IV therapy.

Only in-patients were enrolled for this study as many inpatients may be suffereing from multiple ailments and pantoprazole is mostly prescribed emperically (for a particular diagnosis) and synergistically with other drugs (1) (24).

V. CONCLUSION

Ethical guidelines should be followed to promote the rational use of pantoprazole in inpatients, which includes; indication for use, appropriate dose and interval, duration of therapy for different indications, there by reducing the unwanted effects of irrational use of pantoprazole such as hypersensitivity reactions and prolong duration of treatments, as well as increased cost of treatment.

This study shows that majority of the indication for pantoprazole was appropriate, but more satisfactory results can be reached by the healthcare professionals (physicians, pharmacists, nurses) promoting adherence to the guidelines for administration of pantoprazole. We recommend there should be a drug therapeutic committee in each hospital to promote the rational use of drugs, thereby promoting patient quality of life, as well as reducing the adverse effects and economic burden caused by the inappropriate use of medications.

More DUR studies should be conducted in the future to promote the pharmaco-economic and rational use of pantoprazole and other gastroprotective agents.

Our study also proves that pantoprazole and other PPIs are prescribed by physicians majorly to produce gastro-protective effects, especially when NSAIDs or some antimicrobials are administered simultaneously. However, continuous pharmacovigilance studies should be carried out to reduce the adverse effects of these medications.

Study limitations: The limitation of our study are; a small sample size of only 169 patients, the study being carried out in a single tertiary care center (BBH), DUR was done only for inpatients prescribed pantoprazole, and the duration of our study was short.

Competing financial and/or non-financial interests: The authors have no competing interests that may perceive to influence the results and/or discussion reported in this paper.

ABREVIATIONS

PPIs = Pron pump inhibitors
DUR = Drug utilization review
NSAIDs = Non-steroidal anti-inflammaroy drugs
PUD = Peptic ulcer disease
OD = Once daily
BD = Twice daily
ZES = Zollinger Ellison syndrome

DECLARATIONS

Ethics approval and consent to participate: All patients who filled the informed consent form and accepted to participate in the study were included. The study was approved by the Institutional Ethical Committee of Bangalore Baptist Hospital (IEC-BBH) Bangalore, and a certificate of clearance for the study was issued. The guidelines for the study was in accordance to the Indian Council of Medical Research (ICMR) guidelines for biomedical

research and also in accordance with Helsinki Declaration for research on biomedical sciences.

Consent for publication: Information provided for this study can be made known to the public through publication and further information can be gotten from the corresponding author via emails.

Availability of data and materials: The tables, figures and other data are original and if part is extracted from a journal paper, the papers/authors has been listed in the references.

Competing interests: The authors have no competing interests that may perceive to influence the results and/or discussion reported in this paper.

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