Original Article

Drug Utilization Evaluation of Pantoprazole in Inpatients of Tertiary Care Hospital

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ABSTRACT

Objectives: To review Pantoprazole drug use, prescribing patterns and promote appropriate pantoprazole use. **Methods:** The study is prospective and observational conducted in inpatients of a tertiary care teaching hospital [MGM hospital]. A total of 1012 cases were enrolled according to our plan of work i.e., inpatients who were under pantoprazole therapy were enrolled in two phases, phase-I (before intervention) and phase-II (after intervention) as we assessed inappropriate use of drug, intervention was developed and implemented and therefore pertinent use of drug is increased. **Results:** Inappropriate use of drug was found in phase-I and appropriateness in terms of rational use for indication, dose, dosing interval was improved in phase-II, this may be due to implementation of intervention. **Conclusion:** Rational use of pantoprazole in accordance with appropriate drug for indication, appropriate dose, dosing interval, duration of therapy for specific indication and particular individual was found to be low in phase-I and rational use was improved after intervention in phase-II by implementing criteria and standards rational drug therapy can be achieved. Rational use of pantoprazole should be increased.

Key words: Drug Utilization Evaluation, Pantoprazole, Proton pump inhibitors, Intervention, Indication, Rational use, Criteria and Standards.

INTRODUCTION

Drug Utilization Evaluation (DUE) is a system of ongoing, systematic, criteria-based evaluation of drug use that will help ensure that medicines are used appropriately (at the individual patient level). It involves a comprehensive review of a patient's medication and health history before, during and after dispensing in order to attempt to achieve appropriate therapeutic decision-making and positive patient outcomes. Pharmacists participating in DUE programs can directly improve the quality of care for patients, individually and as populations, by striving to prevent the use of unnecessary or inappropriate drug therapy, prevent adverse drug reactions and improve overall drug effectiveness.[1,2] It is an ongoing empowered and organized quality improvement process, designed to

1. To amend drug use by developing criteria and standards.

2. To audit drug use.

3. To interpret prescription pattern.

Steps involved in Drug Utilization Evaluation is depicted in Figure 1.

DUE cycle

Pantoprazole is a first-generation proton pump inhibitor that constrain the activity of proton pump and are used to constrain gastric acid secretions in the treatment of ulcers and gastroesophageal reflux, preventing ulcer complications related to use of NSAIDs and corticosteroids, managing gastroesophageal reflux diseases and ulcer bleeding, prophylaxis of stress ulcer and preventing gastrointestinal risks in patients receiving anticoagulants.[3] Some other conditions where this drug is used include Helicobacter Pyloric eradication, Pyrosis [Heartburn], dyspepsia [OTC], Zollinger-

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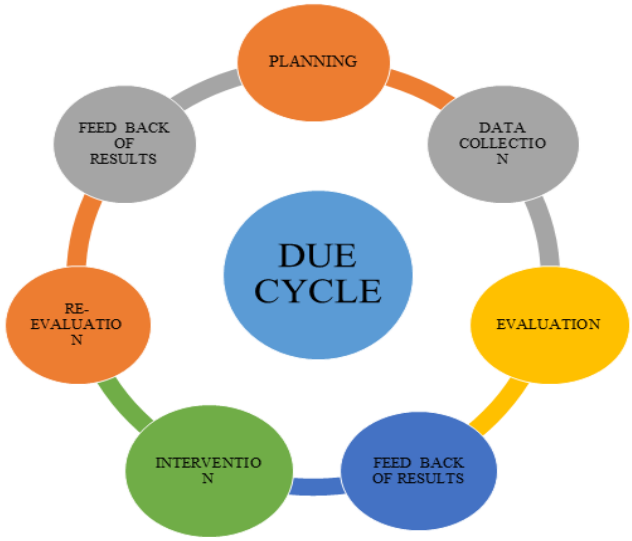

Figure 1: Due Cycle.

Ellision syndrome.[4] The maximum recommended treatment duration for many of these indications is 4-8 weeks.[3] The feasibility of adverse reactions to pantoprazole also increases with polypharmacy and is higher in patients with chronic disease.[5] Due to increasing reports of potentially serious adverse effects and drug-drug interactions the possible widespread use of this drug in hospitalized patients require further examination.[3] adverse effects of pantoprazole Headache, diarrhea, constipation, abdominal pain, flatulence, fever, vomiting, nausea, rash.[6] proton pump inhibitors may increase the risk of clostridium difficile infection of the colon, high doses and long-term use may increase the risk of osteoporosis related, wrist or spine. Prolonged use cause, reduction in absorption of Vitamin B_{12}, low levels of magnesium increased risk of heart attacks.[7]

This study may be advantageous for physicians and to lessen Pantoprazole prescription in patients with no probable indications.

MATERIALS AND METHODS

Study Design

The study is hospital based prospective and observational study conducted in inpatients of a tertiary care teaching hospital [MGM hospital].

Inclusion criteria are patients who are suffering with acid disorders and prescribed in polypharmacy Inpatients of both gender and age group for more than 15 years, prescribed with PPI's were included for the study and exclusion criteria are Patients who denied to participate, Pregnancy and Lactating mothers, ICCU, causality and Pediatric population.

Data Collection

The patient data collection form was designed as per the need of study. The patients were reviewed as per inclusion criteria, voluntarily informed consent was taken and necessary data were collected. Which includes the age, gender, social history, social history, past medical history, family history, history of PPI's, laboratory data and medication charts (name of drug, dosage form, frequency, route of administration and duration of treatment).

Plan of work Phase-I

Step 1: Approval from head of the department and hospital authorities.

Step 2: Literature review.

Step 3: Designing data collection form.

Step 4: Identification of patients with pantoprazole therapy and recording the data.

Step 5: Evaluating the recorded data.

Step 6: Feedback of results to physicians.

Phase-II

Step 7: Develop and implement and intervention for appropriate use of pantoprazole.

Step 8: Reevaluation of the results.

Step 9: Feedback of results to physicians and other health care professionals.

RESULTS

Off the 1012 subjects screened, 1012 fulfilled the selection criteria and were randomized -506 to group A (Phase I) and 506 to group B (Phase II). The consort chart has been shown in Figure 2.

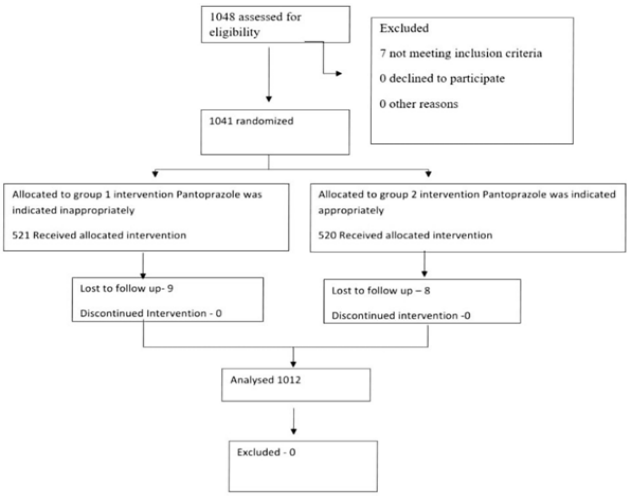

Figure 2: CONSORT Flow Diagram.

Gender wise distribution of study population

In 1012 enrolled patients, 746 (74%) male patients were administered with pantoprazole and 265 (26%) were female patients Figure 3.

Age distribution of study population

Among 1012 enrolled patients, patients in between age group of 55-64 years are most predominantly prescribed with pantoprazole followed by 45-54 years and other age groups Figure 4.

Clinical diagnosis of study population

As our study was done in two phases i.e., Phase-I and Phase-II variability of number of patients in respective wards was occurred due to development and implementation of intervention in Phase-II. The highest number of patients were found in cardiovascular disorders (24.3%) in phase-I and gastrointestinal disorders (34.7%) in Phase-II (Table 1).

Route of administration

In 1012 patients, 64.9% of the prescription of pantoprazole were given by intravenous route followed by 34.9% were given by oral route (Table 2).

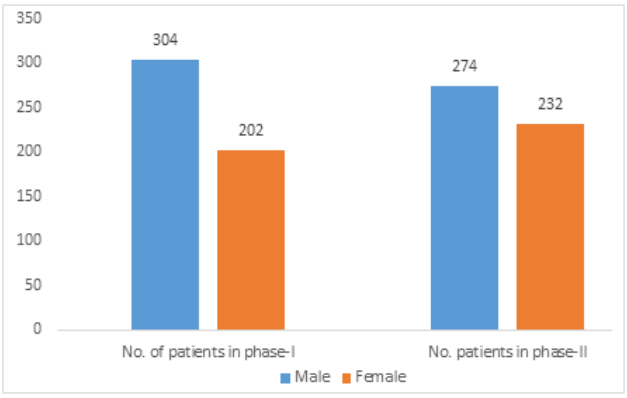

Figure 3: Gender distribution.

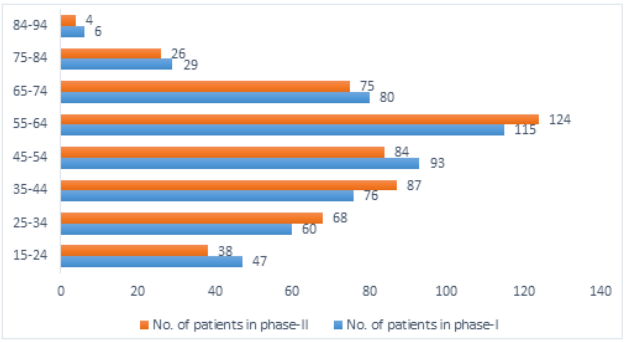

Figure 4: Age distribution.

Indication

Among 1012 patients enrolled in the study as depicted in Table 3, prophylactic therapy was more in Phase-I than in Phase-II and prescribing for actual treatment was also improved in Phase-II i.e., after intervention

Adverse effects

Among 1012 enrolled patients in the study incidents of adverse effects was decreased in Phase-II as the intervention is developed and implemented (Table 4).

Table 1: Clinical diagnosis.

S. No.	Diagnosis	No. of patients in Phase-I	No. of patients in Phase-II
1.	Cardiovascular disorders	123	114
2.	Surgery	117	96
3.	Gastrointestinal disorders	53	176
4.	Liver disorders	34	37
5.	Neurological disorders	33	29
6.	Acute febrile illness	30	9
7.	Respiratory tract infections	25	3
8.	Blood disorders	10	0
9.	Diabetes	10	4
10.	Gall bladder	9	4
11.	Poisoning	8	10
12.	Skin disorders	8	
13.	Thyroid disorders	6	0
14.	Seizures	5	0
15.	Psychiatry	4	0
16.	Renal diseases	4	3
17.	Urinary tract infections	4	2
18.	Others	23	19

Table 2: Route of administration.

S. No.	Route of administration	No. of patients in Phase-I	No. of patients in Phase-II
1.	Intravenous	329	352
2.	Oral	177	154

Table 3: Indication.

S. No.	Category	No. of patients in Phase-I	No. of patients in Phase-II
1.	Prophylaxis	227	126
2.	Empirical	146	134
3.	Treatment	133	246

Table 4: Incidence of adverse effects.

S. No.	Incidence of adverse effect	No. of patients in Phase-I	No. of patients in Phase-II
1.	Positive	167	58
2.	Negative	339	448

Table 5: Commonly occurred adverse effects.

S. No.	Adverse effect	No. of patients in Phase-I	No. of patients in Phase-II
1.	Abdominal pain	70	24
2.	Joint pains	42	16
3.	Vomiting	18	10
4.	Numbness	15	02
5.	Headache	07	02
6.	Vitamin B12 deficiency	06	0
7.	Diarrhea	03	02
8.	Hypomagnesaemia	03	0
9.	Hypernatremia	03	0

Commonly occurred adverse effects

In 1012 patients' adverse effects of pantoprazole were seen in 225 patients among these most commonly occurred adverse effects were (Table 5).

DISCUSSION

As the study is generalized patients who are taking pantoprazole are recruited in our work despite of condition they are on.

On the basis of our study majority of the patients were prescribed with pantoprazole for one to two weeks even after discharge for inappropriate indication.[8,9] Pantoprazole was prescribed in patients with viral fever, COPD, Bronchial asthma, Hyperparathyroidism during the first day of hospitalization for which there was no valid documented evidence and this accounted for the irrelevant use. This suggest that pantoprazole is safe and effective, it should be used only when there is standard evidence of a gastrointestinal disorder that cannot be treated with an H_2 receptor blocker.[10,11] Majority of the patients were prescribed by pantoprazole in inpatients wards, as inpatients may suffer from multiple disease, there may not be clear-cut indications for being prescribed pantoprazole and this drug is mostly used empirically synergistically with other drugs.

It was prescribed once daily in all patients calculated based on pharmacokinetic characteristic of this drug. In about 40% of patients the provisional and final diagnosis was different, although most final diagnosis were not needed in therapy of patients.[12] The frequency of pantoprazole on once daily basis was reported in 88.2% patients, twice daily basis in 10% patients and both once daily and twice daily basis in only 1.8% patients.[8,11] The maximum number of pantoprazole was prescribed for one week after the discharge. The reason of this was most of the pantoprazole was prescribed with NSAIDs for one week.[10] The results of this study show that prolonged use of pantoprazole irrationally had a chance of transpiring adverse effects.

According to our plan of work patients under pantoprazole therapy were taken in 2 phases: Phase-I (before intervention); Phase-II (after intervention)

Phase-I

In Phase-I, most of the patients admitted to the inpatient were in the age group of 55-64 years (22.7%).[8] The percentage of male patients (60%) in the study was more compared to female patients (39.9%).[8,13] In the present study majority of the patients were prescribed with intravenous (65%) and oral therapy (34.9%).[10] Most of the pantoprazole was prescribed on a once daily basis as this was enough to produce the therapeutic effect in the patients.[8,11]In this study pantoprazole was given as one of the category among prophylactic, empirical and treatment. As prophylactic (44.8%) it is given to prevent the side effect caused by polypharmacy. As empirical treatment (28.8%) it is given to the patient as provisional and final diagnosis was different, although were not needed in therapy of patient.[12,13] As treatment (26.2%) it is given for the appropriate indication and therefore incidence of adverse effects (33%) are more in phase-I than phase-II. As long-term use of this drug leads to adverse effects the intervention was developed and implemented.

Phase-II

In Phase-II patients were recorded after implementing the intervention. In this phase most of the patients admitted to the inpatient were in the age group of 55-64 (24.5%). The percentage of male patients (54.1%) in this study was more compared to female patients (45.8%). In the present study majority of patients were prescribed with intravenous (69.5%) and oral therapy (30.4%).

As compared to patients of phase-I prophylactic therapy (24.9%) and empirical (26.4%) is less than actual treatment (48.6%) and therefore incidence of adverse effect (11.4%) decrease with usage of drug for appropriate indication.

Our study is theoretical further study can be done by showing physiological evidences for prevalence of adverse effects.

CONCLUSION

Rational use of pantoprazole in accordance with appropriate drug for indication, appropriate dose, dosing interval, duration of therapy for specific indication and particular individual was found to be low in phase-I and rational use was improved after intervention in phase-II by implementing criteria and standards rational drug therapy can be achieved. Rational use of this drug should be increased.

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CONFLICT OF INTEREST

The authors declare no Conflict of interest.

ABBREVIATIONS

NSAIDs: Non-Steroidal Anti-Inflammatory Drugs; **MGMH:** Mahatma Gandhi Memorial Hospital; **DUE:** Drug Utilization Evaluation; **HCP:** Health Care Professionals; **OTC:** Over- the- counter; **PPI:** Proton Pump Inhibitors; **ICCU:** Intensive Coronary Care Unit.

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