



Original Article

The Observational, Cross-Sectional Study of Drug Utilization (DU) 90% of Proton Pump Inhibitors (PPIS) in the Patient at Private Hospital, in Nashik

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Background: This study was designed to identify how much PPIs are co-prescribed with other drugs. The observational and cross-sectional study was conducted at the private hospital OPD, Nashik, Maharashtra. Proton pump inhibitors (PPI) are one of the most frequently prescribed classes of drugs.

Objectives: To determine and calculate DU 90% of Proton Pump Inhibitors in OPD patients.
Material & Methods: The Study was conducted with ICH GCP, Schedule 'Y' guidelines and Indian regulatory requirements. Approval of Institutional ethics committee was taken. Providing to subject a patient information sheet and informed consent form before screening. Then signed dated written informed consent was taken and also observed a Prescription and taken information required from it. Analysis from the whole data, appropriate statistical methods applied according to the objectives.

Result: Total 245 prescriptions were screened and among the patients selected for study 55.5% were male and 44.5% females. Total 600 drugs prescribed during this research. Out of this 600 drugs 55.5% drugs were prescribed by essential drug list. And 44.5% drugs were prescribed by general drugs name.

Conclusion: We found that DU 90% is achieved in private hospital, Nashik. Proton pump inhibitors were used in 54% of in patients. Proton pump inhibitors were prescribed to patient not specific indication. The use of PPIs is extensive and increased rapidly than other drugs. Rabeprazole mostly prescribed PPIs.

Keywords: Drug Utilization 90%, Proton Pump Inhibitors (PPI's), DDD.

1. INTRODUCTION

The drug utilization research started in late 1960s.¹ Drug Utilization (DU) research was defined by WHO in 1997 as "The marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social, and economic consequences" (Introduction to drug utilization research- WHO).²

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The irrational use of drugs is a major problem of a present day medical practice and its consequences include ineffective treatment, unnecessary prescription of drugs, development of resistance to antibiotics, adverse effects and economic burden on patients and society. In spite of extensive programs on rational use of drugs and the Essential Medicine List (EML) of WHO, There is need of mass awareness amongst physicians and consumers about the concept of essential medicines, advantages of generic drug prescription and use of rational combinations.³

Proton pump inhibitors (PPIs) are a group of drugs that cause pronounced and long-lasting reduction of gastric acid production. They are most potent gastric acid suppressing drugs currently in clinical use.⁴ The proton pump inhibitors are major drugs used to control APD (Acid Peptic Disorders). The use of corrosive drugs is common e.g. NSAIDs, Anti-microbial agents. PPI plays important role in prevention of APD especially iatrogenic APD. Cellular medium inside the cell is alkaline, acid is not produced in parietal cells of stomach but is produced outside and is produced by addition of H⁺ and Cl⁻ ions secreted by different surfaces of parietal cells of stomach. PPI block the H⁺ secretion and only Cl⁻ ions get secreted. HCL will not formed.⁵ Available proton pump inhibitors are Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole and Esomeprazole. However because of their High efficacy & easy availability irrational use and unnecessary exposure is high. Moreover Parenteral PPIs are costly thereby increasing the economic burden on the patients.⁶

Drug utilization 90% is one of the pattern of drug utilization used in application of quality indicators to compare actual use to national prescription guidelines or local drug formularies. The DU 90% segment reflects the number of drugs that account for 90% of drug prescriptions and adherence to the local or national prescription guidelines to obtain a rough estimate of the quality of prescribing. Drug utilization 90% calculated for the description of the drug use patterns. The rationale behind the development of DU 90% rest on an assumption that a low number of products prescribed is associated with more rational prescribing practice.⁷

The defined daily dose (DDD) concept represents a method for the quantification of drugs. The DDD of a drug refers to the assumed daily dose in adults for its main indication. Sales or prescription data complained and represented as number of DDD per 1000 inhabitants per day may provide a rough estimate of drug exposure with a community.⁸ DDD were assigned for drugs that already have an ATC code. Doses for individual patients and patient groups will often differ from the DDD and were necessarily have to be based on individual characteristics (e.g. Age, weight etc.) and pharmacokinetic considerations.⁹

DU 90% study have various advantages. Present study is design to calculate DDD, achieve Drug Utilization 90%,

rational use of PPIs, and also observed how much drugs prescribed by essential drug list.

2. MATERIALS AND METHODOLOGY

This was observational cross sectional study. Study was conducted in compliance with the protocol, ICH GCP, Schedule 'Y' guidelines and Indian regulatory requirements. Approval of Institutional ethics committee was taken prior to initiation of study. Enrolment of patient was done as per inclusion and exclusion criteria. Before collecting the data or observing a prescription, signed dated written informed consent was taken from all subjects after providing them with patient information sheet and informed consent form before screening. It was the study of prescriptions among the (PPIs) Proton Pump Inhibitors. Data from prescriptions was collected at the general OPD, private Hospital Nashik, Maharashtra, from the patients of age group above 18-60 years.

Total 245 prescriptions were collected from the patient and data from prescription were recorded in Case Record Form with the help of interview of patient. The data collected from each prescription were summarized. Analysis from the whole data, appropriate statistical methods applied according to the objectives. Prescriptions were studied and analysis was done as per WHO drug utilization study guidelines. After obtaining the Statistical analysis discussion & conclusion were drawn. Core indicators were also studied, with help core indicators we can make out the pattern of drug use.

OBJECTIVES:

Primary objective:

To determine and calculate DU 90% of Proton Pump Inhibitors (PPIs) in OPD patients

Secondary objective:

How much Proton Pump Inhibitors (PPIs) are co-prescribed with other drugs

Statistical plan:

Data analysis will be done by calculating the following prescription core indicator

1. $DDD/1000/day = \frac{\text{Total no. of dosage units prescribed} \times \text{strength of each dose} \times 100}{DDD (ATC) \times \text{duration of study in weeks} \times \text{total sample size}}$
2. $DDD\% = \frac{DDD/1000/day \text{ of particular drug} \times 100}{\text{Sum of } DDD/1000/day \text{ total drugs}}$

3. RESULT

Total 245 prescriptions were screened for the use of PPIs. And Among the patients selected for study 55.5% were male and 44.5% females, Show in table no. 1, Out of 245 patients on proton pump inhibitors majority of them 28.9% were between 51-60 years age group, then 24.8% were age group of 31-40 years, 23.2% were age group of 18-30 and 22.8% were belong to 41-50 age group. Show in the fig. no.1 and table no.2.

Table 1: Ratio of male and female

Male %	Female %
55.510	44.489

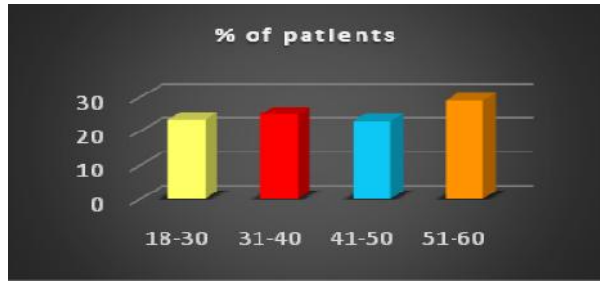


Fig 1: No of Percentage in Age Group Wise

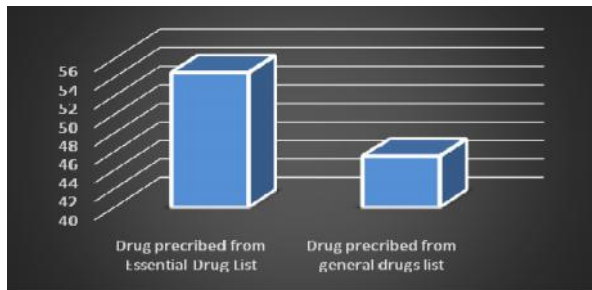


Fig 2: Percentage of Essential and General Drug

Total 600 drugs prescribed during this research. Out of this 600 drugs 55.5% drugs were prescribed by essential drug list. And 44.5% drugs were prescribed by general drugs name. Show in fig. no.2.

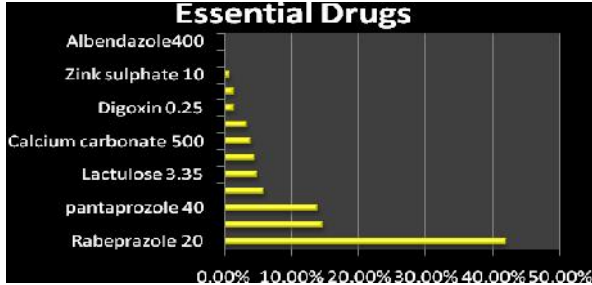


Fig 3: Drugs Which Are Prescribed By Essential Drug List

In fig.no.3 it shows that the percentage of drugs which prescribed by essential drug list. According to fig. no 4 there is Rabeprazole is 42.01%, Pantoprazole is 14.20%, Aspirin 6.16%, Metformin 14.84%, Digoxin is 1.68%, Telmisartan is 1.68%, Amoxicillin is 4.76%, Calcium Carbonate is 4.20%, Clopidogrel is 0.28%, Zink Sulphate is 1.12%, Thyroxin is 3.64%, Albendazole is 0.28% and Lactulose is 5.04%.

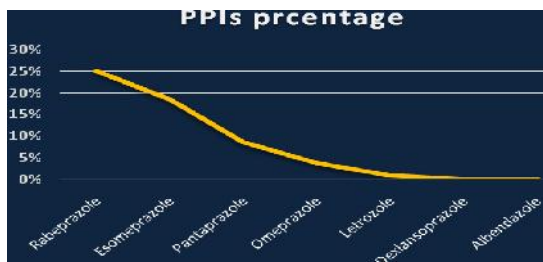


Fig 4: Proton Pump Inhibitor in Percentage

Total no of 600 drugs are prescribed out of these 342 drugs are proton pump inhibitor (PPIs) i.e. 57% of total drugs. The Rabeprazole is prescribed by 25%, Esomeprazole is prescribed by 18.5%, Pantoprazole is prescribed by 8.5%, Letrozole is prescribed by 0.8%, Omeprazole is prescribed by 3.8%, Dexlansoprazole is prescribed by 0.1% and Albendazole is prescribed by 0.1%. Show in fig. no. 4.

Table 2: DU 90% for proton pump inhibitors

Name of Drugs	ATC Code	ATC Dose	DDD/1000/day	DDD%
Rabeprazole 20	A02BC04	10	153.0612	32.296
Esomeprazole 40	A02BC05	20	111.2245	23.469
Pantoprazole	A02BC02	20	52.04082	10.981
Domeperidone 30A03FA03	30		33.67347	7.1052
Cyanocobalamin				
15	B03BA01	1	30.61224	6.4592
Aspirin 75	N02BA01	75	11.22449	2.3684
Rosuvastatin 10	C10AA07	10	10.71429	2.2607
Letrozole 10	L02BG04	2.5	10.20408	2.1531
Omeprazole 10	A02BC01	20	5.867347	1.238
Clonazepam 0.5	N03AE01	3	4.506803	0.9509
Metformin 500	A10BA02	2000	4.209184	0.8881
Total			427.3384	90.1696

90%

Name of drug utilized for Ischemic heart diseases, ATC code of drugs, DDD / 1000 / Day of each drug and then calculated DDD%. Table no.2, stated that total 69 drugs studied in DU 90% for proton pump inhibitors. All drugs were studied and calculate DDD/1000/day and DDD% for each drug. And we achieved DU 90%.

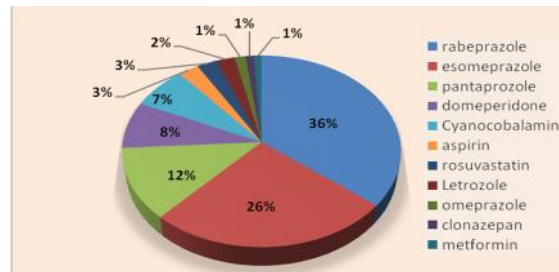


Fig 5: Define Daily Dose in percentage which achieved DU90%

Following drugs were included in DU 90%. DU 90% achieved by drugs Rabeprazole 32.29%, Esomeprazole 23.46%, Pantoprazole 10.98%, Doneperidone 7.10%, Cyanocobalamin 6.45%, Aspirin 2.36%, 2.26%, Letrozole 2.15%, Omeprazole 1.23%, Clonazepam 0.95%, Metformin 0.88%.

Table 3: Core Indicators

Indicators	Results
Average no of drugs per prescription	2.44
Percentage of drug prescribed by generic name	00%
Percentage of Drugs from Essential drug list	54.5%
Percentage of general drug prescribed	44.5%

Table no 3. Shows the core indicators which we founded. The average number of drugs peer prescription was 2.44, percentage of drugs prescribed by generic name was 00%, percentage of drugs from essential drug list was 54.5%, percentage of general drug prescribe was 45.5%.

4. DISCUSSION

The PPIs have become one of the most commonly prescribed drugs in India. The present study shows that 245 patients were received proton pump inhibitors for Medication i.e. 57%, during the study period. The used of PPIs was more prescribed in male than female. Male enrolled this observational study is 55.5% and female was 44.5%. This is in accordance with the previous study by Mayet AY9. According to CDSCO publication National Formulary of India- 2011, indications for the use of PPIs are Benign gastric and duodenal ulcers, Zollinger Ellison syndrome, gastric acid reduction during gastric surgery, GERD, NSAID- induced ulcer, prophylaxis during NSAIDs treatment in patients with high risk for peptic ulceration, as preoperative medication, eradication of *H. pylori*, systemic mastocytosis and in patients not responsive to H2 blockers.

Total 245 subjects enrolled in this study. Case Record form filled with the help of prescribed drugs & interview of subjects. Name of drug utilized for Ischemic heart diseases, ATC code of drugs, DDD / 1000 / Day of each drug and then calculated DDD%. Total 69 drugs studied in DU 90% of Proton Pump Inhibitors. All drugs were studied and calculate DDD/1000/day and DDD% for each drug¹⁰⁻¹⁵.

Core indicators also studied. DU 90% achieved by drugs Rabeprazole 32.29%, Esomeprazole 23.46%, Pantoprazole 10.98%, Doneperidone 7.10%, Cyanocobalamine 6.45%, Aspirin 2.36%, 2.26%, Letrozole 2.15%, Omeprazole 1.23%, Clonazepam 0.95%, Metformin 0.88%. Average no. of drug per prescription was 2.44, Percentage of drug prescribed by generic name was 0% and 54.5% drugs prescribed from essential drug list. Percentage of general drugs prescribed was 44.5%. Brand name drugs are more costly than the generic name drugs. It's also cause burden on patients which treated in sahyadri hospital.

The proton pump inhibitors was more prescribed than other drugs. Sahyadri hospital was show rational prescribed pattern with proper examination as well as consultation of patients. Total no of 600 drugs are prescribed out of these 342 drugs are proton pump inhibitor (PPIs) i.e. 57% of total drugs. The Rabeprazole is prescribed by 25%, esomeprazole is prescribed by 18.5%, pantoprazole is prescribed by 8.5%, letrozole is prescribed by 0.8%, Omeprazole is prescribed by 3.8%, Dexamprazole is prescribed by 0.1%, and Albendazole is prescribed by 0.1%. The percentage of drugs which prescribed by essential drug list is 54.5%. there is Rabeprazole is 42.01%, Pantoprazole is 14.20%, Aspirin 6.16%, Metformin 14.84%, Digoxin is 1.68%, Telmisartan is 1.68%, Amoxicillin is 4.76%, Calcium Carbonate is 4.20%, Clopidogrel is 0.28%, Zink Sulphate is 1.12%, Thyroxin is 3.64%, Albendazole is 0.28% and Lactulose is 5.04%.

Out of 245 patients on proton pump inhibitors majority of them 28.9% were between 51-60 years age group, then 24.8% were age group of 31-40 years, 23.2% were age group of 18-30 and 22.8% were belong to 41-50 age group.

Proton pump inhibitors was more prescribed in 51-60 age group.

Most drugs were prescribed with the knowing indication of drugs i.e. relevant to symptoms and diagnosis of patients. The dose of drug, frequency, route of administration and duration of medication was clearly mentioned in prescription. Present study showed there was need to improve the prescription writing. That means prescribe drugs with their generic name as compare to brand name, which is help to reduce burden of cost and it is also beneficial and safe to patients as well as society.

5. CONCLUSION

We found that DU 90% is achieved in private Hospital, Nashik. Proton pump inhibitors were used in 54% of inpatients in this study. Consideration of study was age, sex, drug name, contains, doses these factors estimate rational Drug Utilization pattern in PPIs. Proton pump Inhibitors were prescribed to the patients without any specific indications. The use of PPIs is extensive and increased rapidly than other drugs. Rabeprazole was the most prescribed drug

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