

Research Article**RETRO - PROSPECTIVE OBSERVATIONAL COMPARATIVE STUDY ON DRUG UTILISATION OF PROTON PUMP INHIBITORS vs H₂ RECEPTORS BLOCKERS****Thelkar Venkata Durga Vinoothna^{1*}, Shaik Riyazuddin², Chigurupati Madhav Kalyan³, Unnava Naga Sai Vyshnavi Sugatri¹, Dr.Vutukuri Suresh⁴**¹ Pharm.D (IV Year), Department of Pharmacy Practice, Hindu College of Pharmacy, Amaravati Road, Guntur – 522002, A.P, INDIA.² Asst Professor, Department of Pharmacy Practice, Priyadarshini Institute of Pharmaceutical Education & Research, Guntur - 522 017, A.P, INDIA.³ Pharm.D (Intern), Department of Pharmacy Practice, Hindu College of Pharmacy, Amaravati Road, Guntur – 522002, A.P, INDIA.⁴ MBBS, MS, MCh Gastro, AIIMS (Delhi), Gastroenterologist, Vutukuri Hospital, Kothapeta, Guntur - 522001, A.P, INDIA.**Received on: 24-09-2019; Revised and Accepted on: 18-11-2019****ABSTRACT**

Aim of Study: The objective of the study was to assess the retrospective observational comparative study on drug utilisation of Proton Pump Inhibitors (PPI) vs H₂Receptor Blockers (H₂RB).

Methodology: 150 patients are included in the study. All the patients were undergoing proton pump inhibitors and H₂ receptor blockers therapy and /or co-morbidities were included in the study. The study was conducted in General Medicine Unit (IPD), Intensive Care Unit, Surgery, Orthopaedic and all other departments in a multi-speciality tertiary care hospital. The patient's demographic status like name, age, gender, occupation, IP number, date of admission, etc., was collected. The appropriateness of PPIs and H₂RBs drugs like dose, dosage form, duration of treatment, route and frequency of administration with standard guidelines was also recorded.

Result: Results of patient population included in the study are 150, out of males are 98(65%) and female are 52(35%) are using Anti-Ulcer drugs. In total study population based on dose and dose frequency Pantoprazole (PPI) 40mg, OD is prescribed in 17% of prescriptions and Ranitidine (H₂RB) 150mg, BD is prescribed in 14% of prescriptions.

Conclusion: Gender, Age, Social habits, Occupation and Education status influence the occurrence of GIT problems. Based on this study, in our area, PPIs are prescribed more often than H₂RBs. In PPIs Pantoprazole (PPI) 40mg was the highest prescribed as prophylaxis to GIT damage than Ranitidine (H₂RB) 150mg.

KEYWORDS: Proton Pump Inhibitors (PPIs), H₂ Receptor Blockers (H₂RBs), NSAID Prophylaxis, Anti-Ulcer drugs.

INTRODUCTION

Rational use of drugs is defined by World Health Organisation (WHO) as "Patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, at the lowest cost to them and their community" [1].

The increased number of medicines and treatment

options serves to increase the irritational medicine treatment encounters that ultimately lead to poor patient outcome and significant wastage of money and resources [2].

Drug Utilization Review is the process by which the quality of drug prescribing is measured by organising important predetermined criteria. DUE studies are designed to assess the appropriateness of the usage of various medications [4].

DUE is defined by WHO as "The marketing, distribution, prescription and use of drugs in society, with special emphasis on their suiting medical, social and economic consequences" [7].

H₂RBs reduce the production of stomach acid. This makes the stomach less acidic so that any stomach juice that gets into oesophagus is less irritating which relieves the symptoms and allows the oesophagus to heal. They include Ranitidine, Cimetidine, Burimamide, etc., [10].

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PPIs are a group of drugs whose action is a pronounced reduction of gastric acid production. These are the most widely sold drugs in the world. They include Pantoprazole, Rabeprazole, Omeprazole, Lansoprazole, etc.,^[12].

The indications for the use of these drugs are GERD, NSAID induced UGI complications, Peptic ulcers, Helicobacter pylori infection, etc.,^[10-12].

PPIs are superior to H₂RBs in standard doses for the prevention of ulcers (gastric and duodenal)^[18].

This observational study was conducted to find the extent of usage of PPIs and H₂RBs in patients with different conditions.

Need of the Study:

PPIs and H₂RBs are undoubtedly effective agents, studies of their prescribing pattern in practice suggest overuse prior to endoscopy, use in patients who don't fit approved criteria, and prescribing for indications in which less potent agents should have been sufficiently effective for patient's symptoms.

Also, PPIs and H₂RBs are not completely benign medications as there are a lot of associated ADRs.

Understanding the DUE and adherence rates of patients with PPIs and H₂RBs might conform the trend in published studies as to other treatment guidelines are influential in health care practice.

The study may improve management of GI disorders through analysing, prescribing patterns might be identified effects of acid in GIT more efficiently.

Aim and Objectives:

To observe the drug utilization evaluation of Proton Pump Inhibitors (PPI) and H₂ Receptor Blockers (H₂RB) in In patient department patients at St. Joseph General Hospital, Guntur, Andhra Pradesh.

To compare and observe the drug utilization evaluation of proton pump inhibitors and H₂ receptor blockers in the given hospital.

To assess relationship between patient demographics and drug utilization evaluation.

METHODOLOGY

Study Design: It was retrospective observational study of the drug utilization evaluation of PPIs and H₂RBs in In patient department patients at St. Joseph General Hospital, Guntur, Andhra Pradesh.

Study Duration: 150 patients were observed during the study period commencing from January 2018 to May 2019.

Inclusion Criteria:

- Age group – 18yrs and above
- All the patients were undergoing proton pump inhibitors and H₂ receptor blockers therapy and /or co-morbidities were included in the study. The study was conducted in General Medicine Unit (IPD), Intensive Care Unit, Surgery, Orthopaedic and all other departments in a multi-speciality tertiary care hospital.

Exclusion Criteria:

- Patients below the age of 18yrs.
- Terminally ill patients
- Pregnant patients
- Paediatric patients

All the patients undergoing PPIs and H₂RBs therapy and or with some comorbidities were included in the study. The study was conducted in study. The study was conducted in General Medicine Unit (IPD), Intensive Care Unit, Surgery, Orthopaedic and all other departments in a multi-speciality tertiary care hospital, St. Joseph General Hospital, Guntur, Andhra Pradesh.

The patient's demographic status like name, age, gender, occupation, address, IP number, date of admission, etc., were collected.

The patient's lifestyle profile was collected by individual patients by direct interaction with the patients or with their care takers for any lifestyle modifications.

The patient's PPIs and H₂RBs prescribed by the physician, along with the dosage were recorded. The appropriateness of like dose, dosage form, duration of treatment, route and frequency of administration with standard guidelines was recorded.

Whether the medication given was polytherapy or monotherapy was taken into consideration.

How well the medication helped lowering GI complications or symptoms to its target was analysed and whether the monotherapy or polytherapy was more efficient in achieving the target was analysed.

RESULTS

Data collection process for this project was started in January 2016 and continued till May 2016. A Retrospective observational study of the prescribing pattern of Proton Pump Inhibitors and H₂ receptor blockers agents in IPD (In – Patient Department) patients in a multispecialty tertiary care hospital, ST.JOSEPH hospital. A total of 150 patients, who qualified the inclusion criteria, were included in the study.

Gender Distribution of the patients included in the study:

The study shows that the total number of patients included in the study was 150 out of which 98 patients were male (65%) and 52 patients were female (35%), indicating 30% higher prevalence of male population in the study.

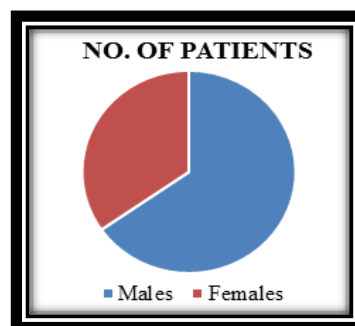


Fig. 1: Relation between No. of Male and Female Patients

Table No. 1: Based on Sex

S.No.	Type of Patient	No. of Patients	% of Patients
1	Males	98	65%
2	Females	52	35%
Total		150	100%

Food habits of the patients included in the study that were prescribed with PPI VS H2RB medication:

It is clearly seen that patients are non-vegetarians mostly and the % of non-vegetarians patients who are mostly prescribed with PPI & H2RB medications as follows

- Males 94%
- Females 85%
- Total population 91%

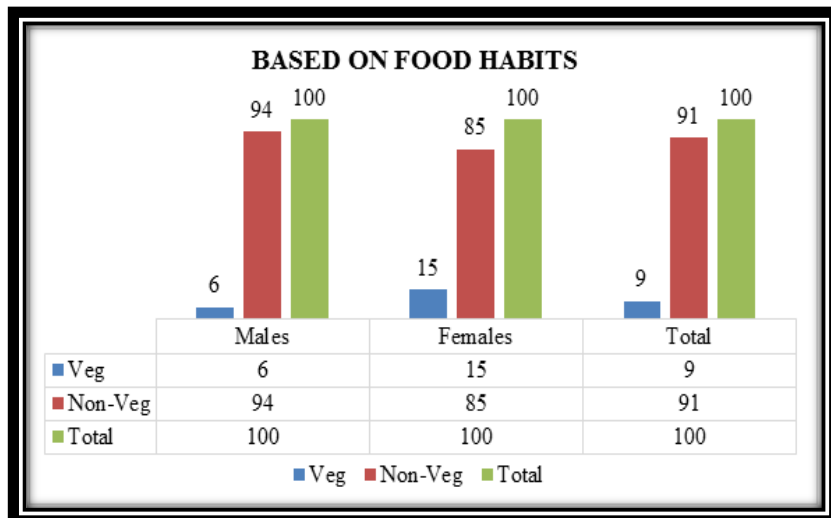


Fig. 2: Relation between No. of Vegetarians, Non-Vegetarians in Male and Female Patients

Social habits of the patients included in the study that were prescribed with PPI & H2RB medications:

It is clearly seen that male patients are alcoholic mostly and prescribed with PPI & H2RB medications more than the non-alcoholic but the as the non-alcoholics are more in the female it gave impact over the total populations based

on alcoholic habit and the % of alcoholic patients who are on PPI & H2RB medications are as follows

- Males 59%
- Females 0%
- Total population 39%

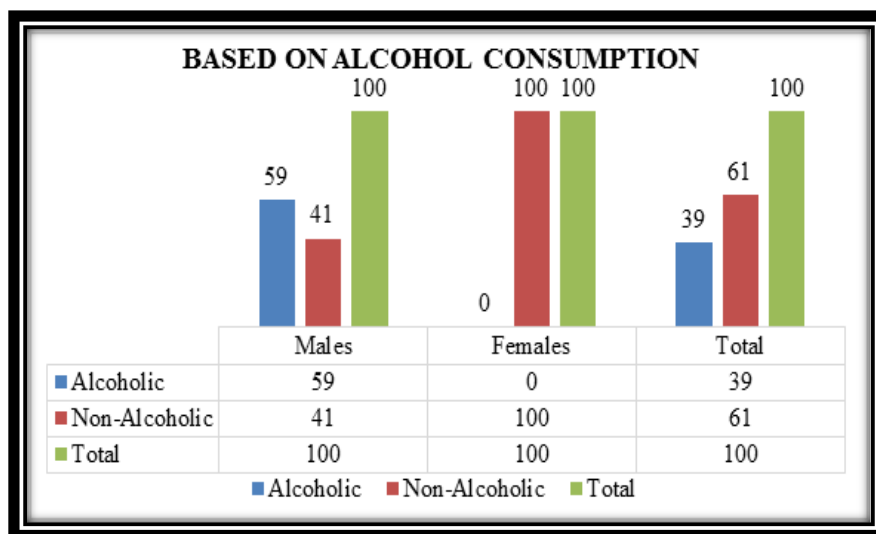


Fig. 3: Relation between No. of Alcoholics, Non- Alcoholics in Male and Female Patients

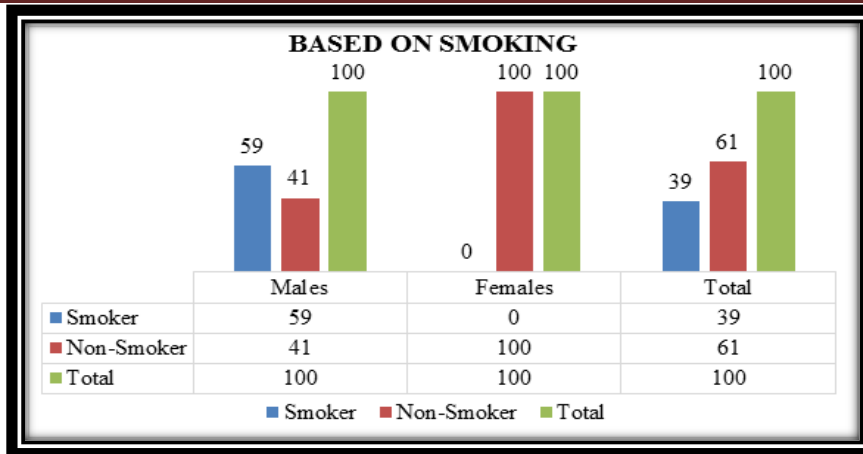


Fig. 4: Relation between No. of Smokers, Non-Smokers in Male and Female Patients

Details about Prescribed PPI & H₂RB:

Based on Drug dose and frequency it is clearly seen that patients mostly prescribed with PPI & H₂RB medications were

- Inj. Pantoprazole 40 mg O.D was mostly prescribed in 17 prescriptions accounting 17 %.
- In H₂RB Tab. Ranitidine 150 mg B.D were mostly prescribed in 21 prescriptions accounting 14%.

Table No. 2: Details about Dose and Frequency of Drugs in Total

Dose and Frequency Of Drugs		Total
Inj. Pantoprazole - 40mg	OD	17
	BD	14
Tab. Pantoprazole - 40mg	OD	14
	BD	19
Inj. Rabeprazole - 20mg	OD	1
	BD	0
Tab. Rabeprazole - 20mg	OD	10
	BD	20
Cap. Rabeprazole - 20mg	OD	2
	BD	0
Cap. Omeprazole - 20mg	OD	8
	BD	7
Inj. Ranitidine - 150mg	OD	0
	BD	6
Tab. Ranitidine - 150mg	OD	1
	BD	21
Tab. Famotidine - 40mg	OD	10
	BD	0

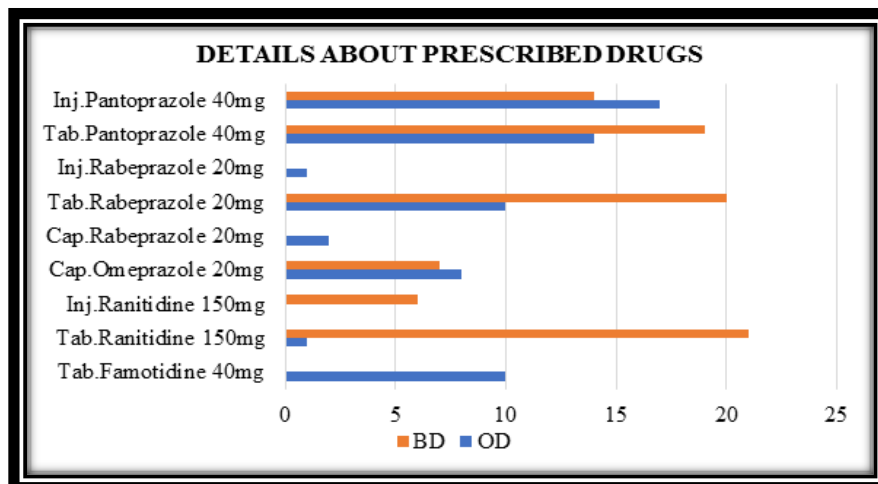


Fig. 5: Details about doses and frequency of drugs in total

DISCUSSION

The present study is done 150 cases who are prescribed with PPIs and H₂RBs, of all 98 were male and 52 were female patients indicating 30% higher prevalence of male population in the study. Which is on par with Milan.R et al (Oct,2001) observation of PPIs and H₂RBs in different GIT condition and NSAID ulcers which composed of 140 case study, of which 105 male patients taking PPIs and H₂RBs prescribed in different GI problems and NSAID ulcers.

Food habits also effects the regular bowel movements and increase secretion of HCl in stomach region. This information obtained from Akbar, D.H. et al., 2006 which describes that the spicy foods non vegetarians, fats food consumers will be at greater risk of developing the GI problems. In the present study among 150 patients, 14 patients were found to be vegetarians and 136 were non-vegetarians. So, the patients are in agreement with Akbar, D.H. et al., 2006 study.

Alcohol can interfere with production of HCl, which will cause the epithelium tissue damage, thus leading to the ulcers and other GI problems. This information is taken from Melander et al., study on the effects of alcoholism on the GI tract damage. In the present study among 150 patients, 58 patients were found to be alcoholic and 92 were non-alcoholic. By this info one cannot come to the assumption that the non-alcoholic are at a high risk of developing the GIT problems because most of the Indian women are non-alcoholic so their impact will be there on total study.

Smoking has effect on epithelium damage on GI tract, Bertelsen & Hegdus, (1994; bartalena et.AL.) observed in a 100 case study on smoking effects on GIT problems 75 patients are smokers, in which most patients 68% are having GI pain, and acidity problems. In the present study among 150 patients, 58 patients were found to be smokers in which the gender is totally male remaining 92 patients are non-smokers. By this info, one cannot come to the assumption that the non-smokers are at a high risk of developing the GIT problems because most of the Indian women are non-smokers so their impact will be there on total study.

CONCLUSION

In the 150 prescriptions, PPIs Pantoprazole 40mg and H₂ RAs Ranitidine 150mg were the highest prescribed to NSAID induced GI damage.

Gender had always influence over the disease in our study. Males are found to be more vulnerable to GIT problems than females leading to higher percentage of hospitalizations.

Mostly the age group of middle age people are firstly influenced by the pathological conditions and that will continue to occur throughout their life.

Food habits like spicy, non-vegetarian, fast food consuming people, smoking, alcoholics were at more risk in developing GIT problems and other pathological conditions leading to hospitalization.

ACKNOWLEDEMENTS

We take this opportunity to express our deep sense of gratitude to our esteemed guide G. Sadasiva Rao, Head of the

department, Department of Pharmacy Practice, Hindu College of Pharmacy, Guntur for his valuable contributions, suggestions and constructive criticisms in the most appropriate way. We would like to specially thank our supervising doctor at Vutukuri Hospital, Dr. Vutukuri Suresh – MBBS, MS, MCh Gastro, AIIMS (Delhi), Gastroenterologist for his excellent co-operation and for all the opportunities we were given to conduct our research. We extend our sincere thanks to the Principal Dr. R. Govindarajan, M. Pharm, Ph.D; Dr. A. Suneetha, M. Pharm, Ph.D and Pharm. D Director Sri. P. Seetharamaiah, M. Pharm, (PhD); Hindu college of pharmacy, Guntur for providing necessary facilities. We take this chance to express our sincere thanks to Chairman Sri. Jupudi Rangaraju, B.Com, LLB, Vice-Chairman Dr. S. Madhusudhan Rao, MBBS, Hindu college of pharmacy, Guntur for providing dexterities to carry out this work.

REFERENCES:

1. Amanda LG, Hans V H, Flora MH. Intervention research in rational use of drugs: a review Health Policy Plan **1999**;89-102.
2. Koren G. Trends of medication errors in hospitalized children. J Clin Pharmacol **2002**;42: 707-10.
3. Brewer T, Colditz GA. Post-marketing surveillance and adverse drug reactions: current perspectives and future needs. JAMA **1999**;281:824-9.
4. Lisa KP, Susan ET. Drug utilization review across jurisdictions – a reality or still a distant dream. Eur J Clin Pharmacol **2006**;62:97-06.
5. The US pharmacopeia drug utilisation review panel. Rug Utilization review: mechanisms to improve its effectiveness and broaden its scope. J Amer Pharmacist Assoc **2000**;40: 538-44.
6. World Health Organisation. The World Health Report. Geneva, **1996**.
7. 4. Jadhav PR, Moghe VV, Deshmukh YA. Drug utilization study in ophthalmology outpatients at a tertiary care teaching hospital. ISRN Pharmacol **2013**(22):768-792
8. World Health Organisation. The World Drug Situation. Geneva, **1988**.
9. Ramakrishnan K, Salinas RC. Peptic ulcer disease. Am Fam Physician **2007**;1005-1012.
10. Leontiadis GI, Sreedharan A, Dorward S, et al. Systematic reviews of the clinical effectiveness and cost-effectiveness of proton pump inhibitors in acute upper gastrointestinal bleeding. Health Technol Assess **2017**;11(51):1-164.
11. Comparative effectiveness of PPIs, Therapeutic initiative. 28, June, 2016; Retrieved 14, July **2016**.
12. De Giorgi F, Palmiero M, Esposito I, Mosca F, Cuomo R. Pathophysiology of gastro-oesophageal reflux disease. Acta Otorhinolaryngol Ital **2006**;26:241-246.
13. Dean, Laura (1 October 2010) Comparing PPIs. Pubmed Health; Retrieved 16 July, **2016**.
14. Kowalsky SF, Hamilton RA, Figge HL. Drug usage evaluation:H₂-receptor antagonist use in 30 hospitals. Hospital Formulary **1991**;26(90):725-6,732,734-6.
15. Wang WH, Huang J Q, Zheng GF, et al. Head-to-head comparison of H₂-receptor-antagonists and proton pump inhibitors in the treatment of erosive esophagitis: a metaanalysis. World J Gastroenterol **2005**;135(4)4067-4077.
16. Falk GW. Refractory GERD: further insights into the cause of symptoms. Gastroenterol **2008**;132(4):1414-1415.
17. Ritcher JE. Gastroesophageal reflux disease. Best Pract Res Clin Gastroenterol **2007**;21: 609-631.

18. Bhatt DL, Scheiman J, Abraham NS, et al. ACCF/ACG/AHA 2008 expert consensus document on reducing the gastrointestinal risks of antiplatelet therapy and NSAID use. A Report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents. *Circulation* **2008**;118(18):1894-1909.
19. Laine L, Takeuchi K, Tarnawski A. Gastric mucosal defence and cytoprotection: bench to bedside. *Gastroenterol* **2008**;135:41-60.
20. Makola D, Peura DA, Crowse SE. Helicobacter pylori infection and related gastrointestinal diseases. *J Clin Gastroenterol* **2007**;41:548-558.
21. Milan R, et al (Oct,2001) observation of PPIs and H₂RBs in different GIT condition and NSAID ulcers which composed of 140 case study, of which 105 male patients taking PPIs and H₂RBs prescribed in different GI problems and NSAID ulcers. *Gastroenterol* **2004**; 21:1220-758.
22. Nauton M, Peeterson GM, Bleasel MD. Overuse of proton pump inhibitors. *J Clin pharm Ther* **2000**;25(5):333-40.
23. Ntaios G, Chatziniolaou A, Savopoulos C, Hatzitolios A, Karamitsos D Evaluation of use of proton pump inhibitors in Greece. *Eur J Intern Med.* **2009**;20(2):171-3.
24. Philips JO et al. A prospective study of simplified omeprazole suspension for the prophylaxis of stress-related mucosal damage. *Crit Care Med* **1996**;24:1793-1800.
25. Levy MJ et al. Comparison of omeprazole and ranitidine for stress ulcer prophylaxis. *Dig Dis Sci* **1997**;42:1255-9.
26. Tryba M, Cook D. Current guidelines on stress ulcer prophylaxis. *Drugd.* **1997**;54(4):581-96.
27. Thaakur SR, Deepthi V, Sowjanya N, Maheswari E, Saraswathy GR. Study of utilization pattern of antimicrobials in paediatric out patients. *Ind J Pharm Sci* **2007**;6(2):104-107.
28. Introduction to drug utilization research. WHO international working group for drug statistics methodology, WHO collaborating center for drug statistics methodology, WHO collaborating center for drug utilization research and Clinical Pharmacological services; 2003; Geneva, Switzerland: WHO; **2003**.

How to cite this article:

T.V.D. Vinoothna, et al. RETRO - PROSPECTIVE OBSERVATIONAL COMPARATIVE STUDY ON DRUG UTILISATION OF PROTON PUMP INHIBITORS vs H₂ RECEPTORS BLOCKERS. *J Pharm Res* 2019;8(8):698-703.

Conflict of interest: The authors have declared that no conflict of interest exists.

Source of support: Nils