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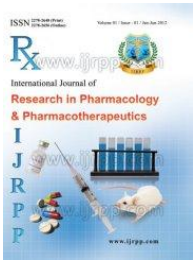

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A study on appropriateness and cost comparison of prescription of proton pump inhibitors at a tertiary care hospital

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ABSTRACT

Proton pump inhibitors (PPIs) are frequently used in patients who do not meet the criteria for appropriate use. Reducing inappropriate prescribing of PPIs in the inpatient and outpatient settings can minimize potential for adverse events, and can also help in controlling cost expenditure. The objective of the study is to determine the appropriateness and compare the cost of prescriptions of PPIs. A prospective observational study was conducted at a 750 bedded tertiary care teaching hospital in Coimbatore. The data were collected during regular ward rounds. The appropriateness was analyzed using the FDA guidelines. A total of 209 patients was included in the study as per the inclusion criteria. In the study population pantoprazole was the most frequently prescribed in 144 (68.89%) patients, followed by esomeprazole in 46 (22.01%) patients, rabeprazole in 17 (8.13%) patients and omeprazole in 2 (0.95%) patients. Out of 209 patients 115 (55.02%) prescriptions were found to be appropriate and 94 (44.98%) prescriptions were found to be inappropriate as per the guidelines. The majority of the inappropriate prescriptions contained pantoprazole followed by esomeprazole and rabeprazole. The cost of treatment can be reduced in 94 patients who have been prescribed with PPIs inappropriately. The results revealed that interventions made by the pharmacist avoided the inappropriate use of PPI at the study site. Most of the inappropriate prescriptions were consisting increased frequency of dosing and utilizing PPIs for prophylactic use. The need for PPI use in the individual patient must be evaluated by the pharmacist and if any possible alternatives are found to be effective the same can be reported to the physician. The regular monitoring of prescription of PPI by clinical pharmacist is the need of the hour.

Keywords: PPIs, Appropriateness, Cost comparison, FDA guidelines

INTRODUCTION

Peptic Ulcer Disease (PUD) is common among adults in modern society. Although the prevalence of PUD is decreasing in many communities, it still affects approximately 10% of adults at some point in their lives. The prevalence is seen to increase with age [1]. According to the latest World Health Organization published data in May 2014, PUD deaths in India reached 85,487 [2]. PPIs signifies a

revolutionary development in gastroenterology. PPIs has emerged as the chief treatment for GERD and peptic ulcer disease due to their effectiveness and low toxicity in treating these conditions. PPIs are also indicated as a simultaneous medication to prevent NSAID and aspirin related ulcers in high-risk patients. Prescriptions for PPIs have increased extremely over the last decade [3]. The effectiveness of PPIs has led to overutilization in multiple treatment areas, exposing patients to an increasing number of potential risks. PPI overutilization in the inpatient setting is often a result of inappropriate stress ulcer prophylaxis in non-intensive care unit patients, and failure to discontinue prior to hospital discharge [4]. A potential consequence of prolonged PPI therapy is the potential for long term hyper-gastrinemia and parietal cell hypertrophy. The potential risks associated with long-term use include vitamin B12 deficiency, spontaneous bacterial peritonitis in cirrhotic patients with ascites, increased risk of community-acquired pneumonia, diarrhoea due to Clostridium difficile and gastroenteritis due to Campylobacter jejuni. Iron deficiency anemia has been reported in patients with atrophic gastritis or gastric resection [5]. Even though the indications for PPI prescription are well defined by U.S Food and Drug Administration (FDA), these indications are often ignored [2]. As the use of PPIs continues to rise, appropriate prescribing of PPIs is important to reduce adverse events in patients. Even in patients with appropriate indications for PPI use, this drug class has been related to several adverse events and risks to patient health [6]. Pharmacists play a unique role in improving the appropriate use of PPIs within the hospital setting [7]. Thus, the present study is an attempt to evaluate the appropriateness in the usage of PPIs in the study site and to signify the role of pharmacist in reducing the use of PPIs.

MATERIALS AND METHODS

The study was conducted in a 750 bedded multi-specialty hospital in the General Medicine department located in South India. A prospective observational study was conducted among 209 patients for ten months from November 2015 to August 2016. The study was carried out after obtaining the consent from the hospital authorities and patients.

Inclusion criteria

- Patients above 18 years old
- Patients prescribed with oral or intravenous PPI
- Patients willing to participate in the study

Exclusion criteria

- Patients not willing to participate in the study
- Patients with insufficient data in their records

The demographic data of the patients were obtained during ward rounds. The data from the medical chart were recorded in customized data entry form. The data were analyzed to evaluate the appropriateness and to compare the cost of prescriptions. The FDA approved guidelines was used to assess the appropriateness in the prescription of PPIs [2].

RESULTS & DISCUSSION

A total of 209 patients who met the inclusion criteria were included in the study. The study result revealed that there is not much difference in prescription pattern of PPIs between males and females. The age categorization was analyzed. The majority of patients, i.e., 84 (40.19%) was in the age group >60 years. A similar study was conducted by Blesson M et al 2015 [8] which reported that 42.16% comprised of patients in the age group of 60-80 years.

The study population was categorized under different risk groups based on the number of risks. The different risks in the study population were found to be age, stress related profession, use of alcohol, smoking and chronic NSAID users. The patients were categorized into 4 main groups, i.e. no risk, moderate risk, high risk and very high risk categories. The majority of the patients 83 (39.71%) came under the moderate risk category, followed by 64 patients (30.62%) in the low risk category, 52 patients (24.88%) in the high risk category and 10 patients (4.79%) in the very high risk categories [Table 1].

From the results it is observed that antibiotics are the most concomitantly prescribed with PPIs in the study population. It is observed that as the number of drugs prescribed increases, there is more chance for prescribing PPI for prophylactic prevention of PUD or gastric irritation.

Among the 209 PPIs prescribed in the study population pantoprazole were the most frequently prescribed in 144 (68.89%) patients, followed by esomeprazole in 46 (22.01%) patients, rabeprazole in 17 (8.13%) patients and omeprazole in 2 (0.95%) patients [Table 2]. A similar study was conducted by Anton P, et al 2016 [9] in which 82% patients were prescribed pantoprazole. A study by Jungnickel P W 2000 [10] stated that pantoprazole has low potential for drug interactions compared to other PPIs. Thus, prescribing pantoprazole more is found to be beneficial, which avoids the risk of drug interactions.

Assessment of dosing frequency of PPIs prescribed revealed that in 95 prescriptions twice daily dosing of pantoprazole was prescribed and in 49 prescriptions once daily dosing of pantoprazole was prescribed [Table 3]. As per FDA guidelines twice daily dosing of pantoprazole is inappropriate, once daily dosing is sufficient to produce desired effects. Thus, twice daily dosing of pantoprazole in the study department was changed to once daily dosing through necessary intervention with a physician.

Appropriateness of prescription of PPIs in the study population was analyzed using the FDA guidelines, out of 209 patients 115 (55.02%) prescriptions were found to be appropriate and 94 (44.98%) prescriptions were found to be inappropriate. Similar results were found out by Nirajan K, et al 2015 [11], which reported that 76.93% patients had an appropriate prescription of PPI and 23.07% patients had an inappropriate prescription of PPIs. In the present study, the PPIs were prescribed very less in case of PUD. The number of patients were prescribed with PPIs for the prevention of ulcer rather than treating ulcer. Thus the prophylactic use of PPIs can be evaluated and if alternatives are available, that can be utilised in order to lower the risk involved with PPI use.

The inappropriate prescriptions with PPIs were analyzed and it was found that inappropriateness in prescriptions may be due to several reasons, i.e. wrong frequency, wrong dosage form, H_2 blockers is recommended, chronic use of PPIs, inappropriate indication and occurrence of adverse events. The reasons for inappropriate events were identified [Table 4]. The inappropriateness identified was documented and the management measures were taken to prevent an inappropriate prescription through proper intervention.

A wide variety of PPIs are available in the study site and the cost of each PPI also varied. Analysis of the cost of different parenteral PPIs, oral PPIs and H_2 receptor antagonists (H_2RAs) available was carried out. The result of the cost comparison showed that among IV PPIs injection Esomac (Esomeprazole) was the most costly (Rs. 92.5) and injection Pantocid (Pantoprazole) was the least costly (Rs. 43.38) drug. Among oral PPIs tablet Pantocid L (Pantoprazole) was the most costly (Rs. 18.12) and tablet Omez (Omeprazole) was the least costly (Rs. 3.49). The cost of H_2RAs was also analyzed and it is found that the H_2RAs are cheaper than PPIs. Wherever possible the use of H_2RAs is recommended instead of the more costly PPIs. The cost of treatment can be reduced in 94 patients who have been prescribed with PPIs inappropriately. Among these 94 patients, 71 patients were identified with H_2RAs as an alternate drug instead of PPI by which the cost of treatment will be reduced. The possibility of alternate and reducing the cost of treatment was reported to the study department and immediate interventions were implicated.

Table 1: Risk Categorization (N=209)

Sl. No.	Risk Categories	Number (N)	Percentage (%)
1.	No Risk (No risk factors)	64	30.62
2.	Moderate Risk (1 risk factor)	83	39.71
3.	High Risk (2 risk factors)	52	24.88
4.	Very High Risk (more than 2 risk factors)	10	4.79

Table 2: PPIs prescribed (N=209)

Sl. No.	PPIs	Number (N)	Percentage (%)
1.	Pantoprazole	144	68.89
2.	Esomeprazole	46	22.01
3.	Rabeprazole	17	8.13
4.	Omeprazole	2	0.95

Table 3: Dosing Frequency of PPIs Prescribed (N=209)

Sl. No.	PPIs Prescribed	Frequency		
		O.D	B.D	T.I.D
1.	Pantoprazole	49	95	-
2.	Esomeprazole	15	30	1
3.	Rabeprazole	8	9	-
4.	Omeprazole	-	2	-

Table 4: Categorization of Inappropriate Use of PPIs

Sl. No.	PPIs involved in Inappropriate Prescribing	Inappropriateness Identified	Number (N)
1.	Pantoprazole	1. Wrong Frequency	23
		2. Wrong Dosage Form	10
		3. H_2 blockers are recommended	42
		4. Chronic Usage of PPIs	31
		5. Inappropriate Indication	22
		6. Occurrence of Adverse Event	14
2.	Esomeprazole	1. Wrong Dosage Form	4
		2. H_2 blockers are recommended	16
		3. Inappropriate Indication	8
		4. Chronic Usage of PPIs	11
		5. Occurrence of Adverse Event	11
3.	Rabeprazole	1. H_2 blockers are recommended	13
		2. Inappropriate Indication	11
		3. Occurrence of Adverse Event	9

CONCLUSION

In the present study it can be observed that a high degree of appropriateness is seen in the use of PPIs in the study department. The possible reason of inappropriateness was identified and reported to the study department. Most of the inappropriate prescriptions were consisting increased frequency of dosing and utilizing PPIs for prophylactic use. The results signified the importance of the role of the clinical pharmacist in monitoring the prescriptions with PPIs. The present study suggests that physicians and clinical pharmacist should work together to increase appropriate use of PPIs. The inappropriate use of PPIs must be prevented through proper interventions. The development of guidelines for PPI usage will avoid irrational prescription of PPIs and reduce cost of therapy. The need for PPI use in the individual patient must be evaluated by the pharmacist and if any possible alternatives are found to be effective the same can be reported to the physician. There is no established Indian guideline regarding the use of PPIs. Hence, in future, it is necessary to prepare institutional guideline for the use of PPI and evaluation can be done based on the new implemented guideline in different setup. The impact and risk involved with overuse of PPI has not been thoroughly revealed, so studies which focus on the impact of chronic use of PPIs are necessary to determine the risk associated with long term use of PPIs. Even though there are no major risks seen in the study population by the use of PPI but rational prescribing of PPI will reduce overall cost of therapy as well as improves the patient safety.

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