wjpmr, 2021,7(1), 217-220

SJIF Impact Factor: 5.922

WORLD JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.wjpmr.com

Research Article

ISSN 2455-3301

WJPMR

PHARMACOVIGILANCE STUDY ON PROTON PUMP INHIBITORS IN ACUTE MEDICAL WARD AT CIVIL HOSPITAL

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DOI: https://doi.org/10.17605/OSF.IO/UDKR9

Article Received on 20/11/2020 **Article Revised on 10/12/2020** **Article Accepted on 30/12/2020**

ABSTRACT

Proton Pump Inhibitors (PPIs) are mostly used in almost all the cases due to patients may suffer with hospital induced excess acid, Medication induced acid production or Disease itself causing excess acid production. These Proton Pump Inhibitors help in reducing the excess acid production by blocking the H, K-ATPase. But, these drugs though they have good safety profile they may also cause few Adverse Drug Reactions (ADR's). So, we have conducted a Prospective Observational study for a period of one year and found 152 ADR's related to PPIs and found mostly prescribed drug among PPIs is Pantoprazole (51%) followed by Omeprazole (34%). Most common ADR found was Urticaria (36.2%) followed by angioedema (21.8%). We have done the severity and preventability assessment and found that most of the ADRs are Mild (51.3%) and Probably Preventable (63%). Based on all these findings we can conclude that Hypersensitivity reactions are commonly occurring due to PPIs. So, Proper monitoring in the initial stage of therapy can reduce the suffering of the patient.

KEYWORDS: Proton Pump Inhibitors (PPIs), ADR's, Pantoprazole, Omeprazole, Hypersensitivity reactions.

INTRODUCTION

Pantoprazole, Omeprazole, Lansoprazole, Esomeprazole and Rabeprazole are the most widely used Proton Pump Inhibitors (PPIs) in most of the cases to reduce excess acid production physiologically and also hospital acquired excess acid production.[1] These drugs act on the gastric pump and inhibit the gastric acid secretion by blocking the H,K-ATPase.[2] The gastric H,K-ATPase are majorly found in parietal cells of stomach followed by renal medulla. This enzyme at resting state of parietal cell found in cytoplasmic tubular membranes and in stimulated state of parietal cell found in microvilli of expanded secretory canaliculus. If the enzyme found in canaliculus, acid is being secreted by the enzyme by exchange of extracellular potassium with cytoplasmic hydronium. By the help of these PPIs we can block the H,K-ATPase and thereby reduce the excess acid production.[3] These drugs to be given 30 minutes before meals, as it is important to protect them from acid protection prior to administration.[4]

There is no direct toxicity for these drugs, but they also posses some adverse drug reactions.[2] Like hypersensitivity reactions (Immediate, Delayed)[4] gastric neoplasia, Kidney disease, dementia, liver disease and fractures.[6]

Aim

The main aim of this study is to monitor the adverse drug reactions of PPIs in patients admitted in Acute Medical Ward at Civil Hospital.

MATERIALS AND METHOD

This is a Prospective Observational study conducted in Acute Medical Ward, Civil Hospital, Karimnagar, India for about one year from 2019 January to 2020 January. In this duration the observed patient prescription was 1010.

Inclusion criteria

- Adults from age group (>18 years).
- Patients admitted to Acute Medical Ward
- Patients who accepted the Informed consent form

Exclusion Criteria

- Patients who did not accept the Informed Consent Form
- Pregnancy and Lactating women
- Children (<18 years)

Study Procedure

After obtaining the informed consent form from the patients. The case sheet of the patient is collected and age, gender, diagnosis, ADR's was recorded. Then the observed ADR's where evaluated using WHO-UMC

casualty assessment scale where they are classified into Possible, Probable and Certain. Then Severity assessment of those ADR's were done using Modified Hartwig Siegel Scale where they are classified into Sever, Moderate and Mild reactions. Then Preventability assessment of those ADR's was done using Criteria of Schumock and Thornton where they are categorized into preventable or not preventable. Finally, by using CDSCO Adverse Drug Reaction Reporting Form all the recorded ADR's were reported to the Adverse Drug Reaction Monitoring Centre (AMC) located in Civil Hospital, Karimnagar.

RESULTS

In this present study 1010 patients have been included those met the inclusion criteria among them 152 ADRs have be recorded of which females were 84(55.2%) and males were 68 (44.8%). Age wise distribution, Most the ADR's observed in the 31-40 years age were 67 (44%), followed by 41-50 years age with 30 ADRs's (19.7%), followed by 20-30 years age with 26 ADR's (17.2%), 51-60 years age group and >61 years age group, 17 (11.2%) and 12 (7.9%) ADR's were observed respectively (Table 1).

Table 1: Distribution of Demographic Details.

Characteristics	Number of ADRs (%)
Gender	
Female	84 (55.2)
Male	68 (44.8)
Age (years)	
20-30	26 (17.2)
31-40	67 (44)
41-50	30 (19.7)
51-60	17 (11.2)
>61	12 (7.9)

Among the ProtonPump Inhibitors Pantoprazole 77(50.7%) was the most frequently used followed by Omeprazole 52 (34.2%) and Esomeprazole 23 (15.1%) (Figure.1).

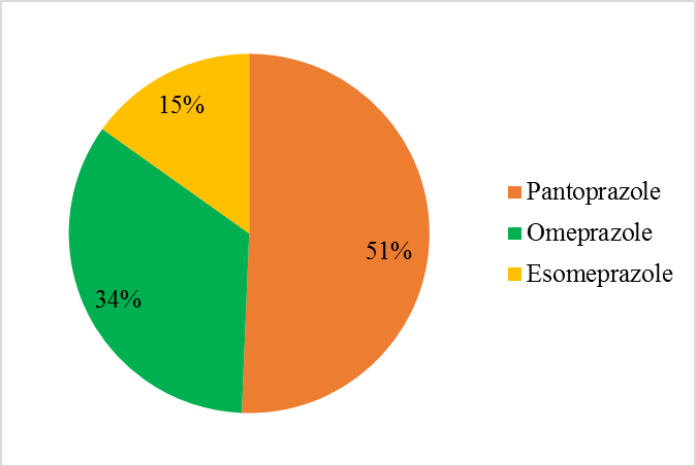

Figure-1: Distribution of Proton Pump Inhibitors.

Out of 152 ADR's most observed is Urticaria 55(36.2%) followed by Angioedema 33 (21.8%), Nausea and vomiting 25 (16.4%), Dyspnea 17 (11.1%), Asthenia 15 (9.9%), Gastric neoplasia 5 (3.3%), Dementia 2(1.3%) (Figure-2).

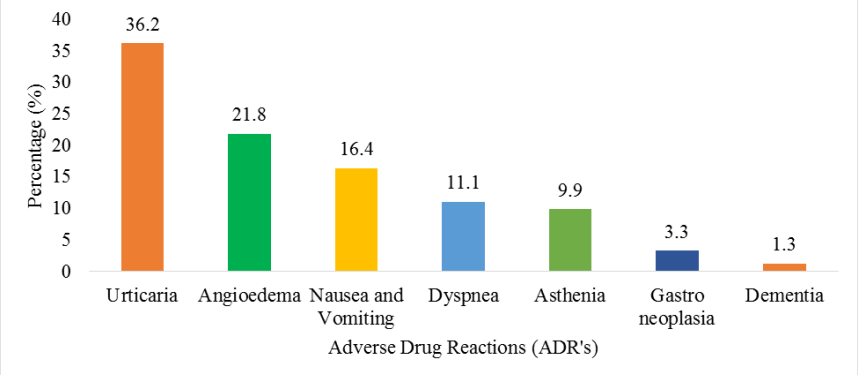

Figure-2: Distribution of Adverse Drug Reactions

Based on the WHO-UMC causality assessment most of the ADRs fell under category possible 81(53.3%) which means it can't be explained by disease or drug, followed by Probable 40 (26.3%) which means withdrawal of the

drug is responsible and Certain was found to be 31 (20.4%) which means withdrawal and re-challenge of the drug is done (Table 2).

Table 2: Based on WHO-UMC causality assessment scale.

WHO-UMC Scale	N (%)
Certain	31 (20.4%)
Probable	40 (26.3%)
Possible	81 (53.3%)

Based on Modified Hartwiig and Siegel's scale severity assessment was done where "Mild" (level-1 and level-2) was found to be 78(51.3%) which means ADR is occurred but no change in treatment or withdraw of drug is done. Then followed by "Moderate" (level 3 and level 4) was found to be 49 (32.3%) which means discontinuation of drug or an antidote is given and finally "Severe" (level-5,6 and 7) was found to be 25 (16.4%) which means there is a permanent harm/ death to the patient either directly or indirectly (Table 3).

Table 2: Based on Modified Hartwig and Siegel's severity assessment scale.

Modified Hartwig and Siegel's Scale	N (%)
Mild	78 (51.3)
Moderate	49 (32.3)
Severe	25 (16.4)

Based on the Modified Schumock and Thornton Preventability assessment was done where Probably preventable was found to be 95(62.5%) followed by 35 (23%) Definitely preventable and 22 (14.5%) Not preventable (Figure 3).

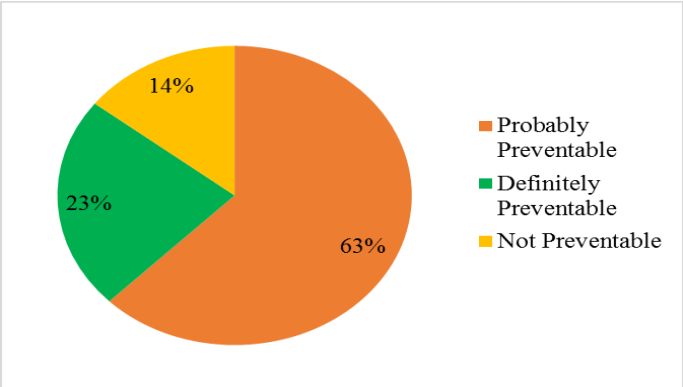

Figure 3: Based on Modified Schumock and Thornton Preventability assessment scale.

DISCUSSION

In this study Adverse Drug Reactions associated with different Proton Pump Inhibitors have been observed.

Females (55.2%) are mostly affected compared to man (44.8%) this might be due to women are more prone to stress which lead to excess acid production and usage of the medication is also more among them[7]. More number of ADR's among age group 31-40 years (44%). Age is also one of the factor for increase in acid secretion told be Goldschemidat et al[8].

In this study Pantaprazole (50.7%) was the most frequently used drug followed by Omeprozole (34.2%). Where marco et.al. study showed Pantaprazole (42%) followed by Esomeprazole (25%).[2] In this study most affected ADR was Urticaria (36.2%) followed by angioedema (21.8%). Similar results have been observed with the Marco et.al study where Urticaria (42%) followed by Angioedema (33%).[2]

Till now there is no preventability assessment and severity assessment on the ADR's for Proton Pump Inhibitors alone. This is the first study which assessed the severity and preventability of ADR's among Proton Pump Inhibitors. Based on severity assessment most of the ADR's fell under Mild (51.3%) and Based on the Preventability assessment most of the ADR's were found to be Probably Preventable (63%).

CONCLUSION

Most the ADR's were found to be hypersensitivity reactions which occur immediately. So, patients receiving PPIs should be monitored carefully in the initial stages of treatment to observe any hypersensitivity reactions occurring. By early detection prevention of ADRs can be easy.

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