Original Article

Non-Prescription Use of Proton-Pump Inhibitors for Self - Treating Frequent Heartburn

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ABSTRACT

Objective: Determine the Prescription Patterns of Proton Pump Inhibitors (PPI) at the outpatient department (OPD) of a tertiary care hospital of Sindh.

Study Design: Retrospective study

Place and Duration of Study: This study was conducted at the Department of Pharmacologhy and Medicine, Peoples University of Medical and Health Sciences for Women from February 2019 to August 2020.

Materials and Methods: Previous records of 300 outpatient department (OPD) subjects were checked during the study period. OPD sample was selected by probability non – purposive convenient sampling. Age, gender and GI symptoms PPI used for were entered in proforma. PPI class, duration of use, frequency of use, and prescription or non-prescription patterns were noted. Data variables were saved in a pre – structured proforma. Data was analyzed on SPSS (version 21.0) and Microsoft Excel sheet. Data was presented as tables showing frequency and % of variable.

Results: Omeprazole was used by 31% followed by dexlansoprazole 29%, esomeprazole 21%, pantoprazole 7.3%, lansoprazole 7.6% and rabeprazole by 4% of subject's respectively (table - 2). PPI were being used as long durations as >5 years noted in 18.6% on irregular basis (35.6%) and without prescription (63.0%).

Conclusion: We found injudicious use of proton pump inhibitors on irregular basis without prescription that needs to be controlled by the health authorities.

Key Words: Proton Pump inhibitors, Injudicious Use, Non - prescription

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INTRODUCTION

Proton pump inhibitors (PPIs) are one of widely used drug agents primarily indicated for the acid peptic disorders. It is the widely purchased by prescription but more so non-prescription as over the counter drugs that is illegal. PPIs are prescription sold drug agents only despite this is available freely.[1,2] Although PPIs are an excellent drug of its class but injudicious use has created problem of toxicity and adverse drug reactions. PPIs are indicated for the acid peptide disorders, gastro-esophageal reflux disease (GORD), gastric and duodenal ulcers, Zollinger – Ellison syndrome (ZES), esophageal ulceration, and Barrett's esophagus. Maintenance low dose PPIs prevents the recurrence of acid related disorders of upper GI system. PPIs have shown promising results in the eradication of H.pylori. PPIs are now over-prescribed and over – used for gastric acid disorders. PPIs are also indicated as co-therapy for nonsteroidal anti-inflammatory drug (NSAID) and aspirin. Injudicious uses are frequent for the functional dyspepsia, mild gastric problems, and un-investigated dyspepsia without making a proper diagnosis. Non-ulcer dyspepsia (NUD) or with mild dyspepsia are often not benefited from PPIs but still people are using without prescription.[2,3] It has noted the majority of patients attending the OPDs have already used a variety of PPIs before reaching to the medical officers. Masses are using the high dose PPIs for poorly defined gastric problems or as digestant after hot spicy foods that has become a public dilemma. Such inappropriate and injudicious PPIs use has accelerated adverse effects that are unnoticed and not understood

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properly creating new health problems and are threatening normal health of public. Currently, the PPIs are the over used by prescription and non-prescription.[4-5] Many subjects are taking the drug as self-determined regimen on irregular basis.[6,7] Although intermittent therapy with H_2- blockers is ideal and considered safe but is denied. In general, a pressure is developed by the pharmaceutical industry on the general practitioners (GPs) to prescribe the PPIs to each of the patient 'inappropriately'.[8] PPIs have side effects as diarrhea, gut upset, headache and malabsorption. Headache and diarrhea are noted in up to 10% subjects. PPIs use is linked to increased risk of malabsorption, vitamin and iron deficiency, bacterial growth, community acquired pneumonia, C – difficile colitis and C – jejuni gastroenteritis.[7,8] PPIs interact with vitamin, mineral, calcium supplements and occasionally cause adverse drug reactions resulting in hepatic, renal, bone marrow, skin and even anaphylaxis.[9-11] Data is lacking on the injudicious use of PPIs, patterns of its use, duration and side effects. National data is seriously lacking although the problem has deep rooted. In this context, the present observations study was conducted on the dose and duration of proton pump inhibitors in the general patient population. The present study determined the clinical and practice use on PPIs use, duration of uses, dosing frequency and prescription patterns in patients attending the OPD of our tertiary care hospital.

MATERIALS AND METHODS

The present retrospective study took place at the Department of Pharmacology and Medicine, Peoples University of Medical and Health Sciences for Women from February 2019 to August 2020. Study protocol was discussed in detail by the researchers. Hundreds of patients were screened as per inclusion criteria. Inclusion criteria were records of drug prescriptions, laboratory investigations, outpatient department (OPD) patients, complete clinical history, PPIs intake irrespective of duration, and age 40 – 60 years. Finally, 300 patients qualified the inclusion criteria and were included in the study protocol. Patients were selected according to the convenient sampling. Patients with major systemic disease such as; chronic liver diseases, chronic lung disease, chronic valvar cardiac disease, chronic malabsorption syndrome, pulmonary tuberculosis, etc. were excluded. Patients without proper records and prescription slips were also excluded. Volunteers were interviewed that the participation is on personal willingness, and there will be no extra expenses of any investigations. They were taken into confidence that if they are not willing, it will not affect their therapy. Patients with proofs of PPIs intake of different symptoms and durations were further screened. Symptoms of PPIs intake were confirmed by interviews and from prescription records. Clinical history of epigastric pain, heart burn, dyspepsia, nausea, vomiting, hematemesis, indigestion, bloating and retching (34.3%) was taken in detail. Age, gender, PPIs class, duration of PPIs, frequency of PPIs (regular or irregular intake) use, and prescription or non – prescribed, were noted in a pre – structured proforma. Type of PPIs taken was enquired and checked from prescriptions and included; omeprazole, esomeprazole, pantoprazole, dexlansoprazole, lansoprazole and rabeprazole. PPIs intake details were saved in the proforma. Saved data in proforma was kept confidential. The data was copied and pasted on Microsoft Excel Sheet. Statistical analysis was performed on Statistical Package for Social Sciences (SPSS) 21.0 (ver.) (Microsoft Windows Release) (IBM, Inc., Chicago, IL, USA) using Student`s t – test and Chi – square testing. Result output of continuous data was presented as mean±SD. And results of Categorical data were presented as frequency and %. Analysis of significance was calculated at 95% CI ($P \leq 0.05$).

RESULTS

Table –1 show age distribution and gender patterns of study subjects (n=300). 21 (7%) subjects belonged to 2nd decade, 53 (17.6%) to 3rd decade, 67 (22.3%) to 4th decade, 45 (15%) to 5th decade, 77 (25.6%) to 6th decade and 37 (12.3%) to ≥6 decade. Mean±SD age was noted as 47.1±10.5 years. Male to female ratio was 1:1, comprised 150 of each gender.

Table No.1: Age and gender distribution of study groups (n=300)

Age (years)	Frequency	%	P
- 12 – 19.9	21	7.0	0.001
- 20 – 29.9	53	17.6	
- 30 – 39.9	67	22.3	
- 40 – 49.9	45	15	
- 50 – 59.9	77	25.6	
- ≥60	37	12.3	
Gender			
- Male	150	50%	0.91
- Female	150	50%	

Table No.2: Frequency of GI symptoms (n=300)

	Frequency	%
Epigastric pain	239	79.6
Heart burn	287	95.6
Dyspepsia	132	44.0
Nausea	39	13.0
Vomiting	76	25.3
Hematemesis	89	29.6
Indigestion	197	65.6
Bloating	53	18.6
Retching	103	34.3

PPI were being used for the epigastric pain (79.6%), heart burn (95.6%), dyspepsia (44%), nausea (13%), vomiting (25.3%), hematemesis (29.6%), indigestion (65.6%), bloating (18.6%) and retching (34.3%).

Omeprazole was used by 31% followed by dexlansoprazole 29%, esomeprazole 21%, pantoprazole 7.3%, lansoprazole 7.6% and rabeprazole by 4% of subject's respectively (table - 2). PPI were intake for long durations as >5 years noted in 18.6% (Table - 3) on irregular basis (35.6%) and without prescription (63.0%).

Table No.3: Information of PPI use (n=300)

PPI Class	Frequency	%
- Omperazole	93	31.0
- Esomeprazole	63	21.0
- Dexlanzoprazole	87	29.0
- Pantoprazole	22	7.3
- Lansoprazole	23	7.6
- Rabeprazole	12	4.0
Duration		
- <1 months	32	10.6
- <6 months	31	10.3
- < 1 years	67	22.3
- 1- 2 years	53	17.6
- >2 years	61	20.3
- >5 years	56	18.6
Frequency of Use		
- Daily	193	64.3
- Irregular	107	35.6
Prescribed Use		
- Prescribed	111	37.0
- Non – prescribed	189	63.0

DISCUSSION

The present observational study was conducted for PPIs use and duration, dosing frequency and prescription patterns in patients in patients attending the out patients department of a tertiary care hospital. In present study, the mean±SD age was noted as 47.1±10.5 years. The findings are in agreement with previous studies.[12-14] Madi et al[12] found the age of participants was 40–59 years that is highly comparable to our present study. Age finding of present is also consistent with previous studies.[13,14] Of 300 study participants, 150 were male and female each showing male to female ratio 1:1. The findings are inconsistent of a recent study[12] that reported majority of patients were male. Reason could be different sample size, different study settings, geographical patterns of health provision and data collection. Equal ratio of male to female is because of although the male the only bread earners, and are tolerating the major stress of life in the setting of economic crisis of corona virus pandemic but female have been at risk of anxiety by staying at home due to financial crisis equally. Peptic ulcer disease is the major indication of PPIs, but the erupting tense financial crisis has created much worry and anxiety that begot the hyperacidity due to stress. In present study, the PPIs were being used for the epigastric pain (79.6%), heart burn (95.6%), dyspepsia (44%), nausea (13%), vomiting (25.3%), hematemesis (29.6%), indigestion (65.6%), bloating (18.6%) and retching (34.3%).The findings are in keeping with previous studis[12-14] that had mentioned similar acid related gastric problems. In present study, the omeprazole was frequently used PPI found in 31% followed by dexlansoprazole 29%, esomeprazole 21%, pantoprazole 7.3%, lansoprazole 7.6% and rabeprazole by 4% of subject's respectively (table - 2). The findings are in line with previous studies.[12-16] Madi et al[12] reported omeprazole was frequent prescribed PPIs followed by esomeprazole and pantoprazole. In present study, the dexlansoprazole was found in 29% second to omperazole; that is because of its new entry as a magical pill that captured major share of PPIs market being new addition to the already available pool of PPIs. Madi et al[12] found 65% use of esomeprazole and pantoprazole that is in contrast to present study. In present study the rabeprazole accounts for 4% prescriptions that are in contrast to only 1% in a previous study.[12] Currently, the burden of PPIs has increased in the society because of stressful life full of financial constraints putting the pocket open to extra expenses. Patterns of PPIs use noted in present study is in agreement with previous studes.[15-19] However, Pendhari et al[14] has produced inconsistent results as they found high use of rabeprazole that is in contrast to present and previous studes.[12-19] In present study, the PPIs were intaken for long durations as for as >5 years noted in 18.6% (Table - 3) on irregular basis (35.6%) and without prescription (63.0%). This is a crucial state of serious concerns. A previous study[12] reported using PPIs for >1 years in 8% of participants. Hence findings are supporting the present study. In presnet study the without prescription PPIs were found in 63.0% on irregular basis in 35.6% participants that is an alarming situation. A previous study[21] reported the stress ulcer prophylaxis was major indication in 77% of the patients who were prescribed PPIs for >1 year. Using PPIs for more than 5 years as noted in present study is beyond the recommended duration of any of medical indications. It is reported the adverse effects of PPIs are substantially increased when PPIs are used for >1 year.[12] The findings are consistent with previous studies.[17-21] In light of evidence based finding of present study supported by previous literature, it is an alarming situation of PPIs over – and injudicious use that must be condemned. Institutional pharmacovigilance programs and awareness seminars should be arranged for the medical practitioners and non-prescription sale of drugs must be stopped immediately for overcoming the adverse drug reactions of proton pump inhibitors.

CONCLUSION

The present study shows proton pump inhibitors were being used for long durations as >5 years (18.6%) on irregular basis (35.6%) and without prescription

(63.0%). The injudicious use of proton pump inhibitors on irregular basis without prescription needs to be controlled by the health authorities urgently. Further studies on the patterns of proton pump inhibitors use are warranted.

Author's Contribution:

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Conflict of Interest: The study has no conflict of interest to declare by any author.

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