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Research Article

A Cross-sectional Observational Study to Analyse Prescription Pattern of Proton Pump Inhibitors in a Tertiary Care Teaching Hospital

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ABSTRACT

The approved indications of proton pump inhibitors (PPIs) do not include generalized acid suppression. Rather these agents should be used for various forms of gastroesophageal reflux disease (GERD), patients receiving non-steroidal anti-inflammatory drugs (NSAIDs) with high bleeding risk. Several reports are available which show that chronic inappropriate use of PPIs results in severe adverse effects. Recent systemic reviews and meta-analyses studying the prescription pattern of PPIs in India over the last two decades revealed that the PPIs are being overprescribed, and prescribed for indications other than the approved indications. With this background, the current study was planned to explore the prescription and usage pattern of PPIs in a tertiary care teaching hospital.

The present study was a cross-sectional observational study conducted at the punjab institute of medical sciences, Jalandhar after obtaining Institutional Ethics Committee (IEC) approval. The prescriptions received at the pharmacy department of the hospital from different open publication distribution system (OPDs) were screened.The data regarding demographics of the patient (gender, age), the prescribing department, and the total number of drugs prescribed per prescription was collected. Further, the prescriptions were analysed according to World Health Organization (WHO) prescribing indicators.

It was observed that every second prescription received in the pharmacy department was of PPIs. In total 1000 prescriptions were screened and 500 prescriptions were for PPIs. 63% of the prescriptions were from female patients and the rest of the prescriptions were from male patients. The majority of the patients (58.4%) were in the age group of 18 to 40 years. 95.2% of the prescriptions contained PPIs in fixed-dose combination (FDCs) formulation. The most frequently prescribed PPI as a mono drug was pantoprazole (2.4%).The second active pharmaceutical ingredient (API), in all the FDCs, was observed to be a prokinetic agent, either domperidone or itopride. Only 4.8% of the prescriptions were from the gastroenterology clinic. The analysis of the prescription using WHO prescribing criteria showed that the average number of drugs prescribed per encounter was 4.63 and only 0.4% of the drugs were prescribed from National List of Essential Medicines (NLEM). The drugs prescribed by generic name were 81.4% against the optimal level of 100%. It can be concluded that PPIs are being prescribed without appropriate indication in most cases. These findings suggest the need for sensitization programs for practitioners for prescribing practices and appropriate use of PPIs.

Introduction

Drug utilization research (DUR) as defined by the WHO is the right prescription and utilization, right marketing and distribution, of a drug in public with specific attention on the resultant medical, social and economic consequences. The DUR aims to identify if the drug therapy for managing a disease is appropriate and according to the clinical guidelines. It also helps in identifying appropriate prescribing practices like frequency, duration of drug therapy, therapeutic dose, symptom quality and the result of drug use.[1]

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Table 1: Demographics of study participants.

Demographics	*Frequency*	*Relative frequency (%)*
Female	315	63.00
Male	185	37.00
Age<18 years	5	1.00
Age 18–40 years	292	58.40
Age 41–65 years	176	35.20
Age >65 years	27	5.40

Gastrointestinaldiseases are one of the most common disorders affecting people across countries. PPIs are a commonly prescribed class of anti-secretory drugs in acid-related gastric disorders.[2] PPIs were launched in the market at the end of the 1980s.[3] Since then,PPIs are widely prescribed drugs worldwide.[4] Drugs belonging to PPI class include omeprazole, esomeprazole, lansoprazole,dexlansoprazole, pantoprazole and rabeprazole. PPIs are prescribed for efficient long-lasting acid suppression. These drugs suppress acid production by inhibiting the action of the H^+/K^+ATPase pump.[5] Many factors have contributed to making PPIs one of the most selling drugs worldwide. The major contributing factors include high prescription rate, availability of generic products and over-the-counter status.[6]

However, more than 60% of the PPI prescriptions are for unjustified indications.[7] Improper utilization of antacids as such has been observed worldwide in various hospitals but among antacids, PPIs are prescribed more due to their high level of efficacy, easy availability and expanded indications.[8] The people are not aware of their adverse effects due to the long-term or overuse of PPI. The cessation of PPI therapy afterlong-term use is associated with rebound acid secretion.[9] Chronic administration of PPIs is associated with an increase in the risk of fractures, and nosocomial and intestinal infections.[10] The extended administration of PPIs, after *H. pylori* eradication, has been reported to increase the risk of gastric cancer.[11] PPIs are also associated with the occurrence of tubulointerstitial nephritis[12] and acute renal failure.[13] Continued PPIs

Table 2: Use pattern of proton pump inhibitors prescribed as a single active pharmaceutical ingredient.

S. no.	*PPI prescribed as single API*	*Formulation prescribed*	*Number of prescriptions (%)*	*PPI included in NLEM (2015)*	*PPI included in WHO essential medicines (2021)*
1	Esomeprazole	Tablet	2 (0.40)	No	No
		Syrup	8 (1.60)	No	No
2	Pantoprazole	Tablet	8 (1.60)	No	No
		Capsule	1(0.20)	No	No
		Syrup	3 (0.60)	No	No
3	Omeprazole	Capsule	2 (0.40)	Yes	Yes

Table 3: DCG(I) and WHO approval status of prescribed fixed-dose combinations.

S. no.	*Prescribed fixed-dose combination*	*API strength*	*Number of prescriptions (%)*	*DCG (I) approval status*	*DCG (I) approved indication*	*WHO approval status*
1	Pantoprazole+ Domperidone	40 mg + 30 mg	210 (42.00)	Yes	GERD not responding to pantoprazole alone	No
2	Rabeprazole+ Domperidone	20 mg + 30 mg	252 (50.40)	Yes	GERD not responding to rabeprazole alone	No
3	Rabeprazole+ Itopride	20 mg + 150 mg	130 (26.00)	Yes	GERD	No
4	Esomeprazole+ Domperidone	40 mg + 30 mg	6 (1.20)	Yes	GERD not responding to esomeprazole alone	No
5	Omeprazole+ Domperidone	20 mg + 10 mg	8 (1.60)	Yes	GERD not responding to omeprazole alone	No

Table 4: Department-wise frequency of proton pump inhibitor prescriptions.

S. no.	*Prescribing department*	*Number of prescriptions*	*Relative frequency (%)*
1	Medicine (General medicine+ Cardiology+ Gastroenterology)	196	39.2
2	All Others (Obstetrics and Gynaecology+ Psychiatry + Dermatology + ENT+ Orthopaedics + Dental + Ophthalmology+ Chest and TB + paediatrics)	304	60.8
3	Medicine (General medicine)	155	31
4	Medicine (Gastroenterology)	24	4.8
5	Medicine (Cardiology)	17	3.4

use may result in vitamin B12, iron, and magnesium deficiency.[14]

Prescribing is an important tool used by doctors in the treatment of a disease, improving symptoms and controlling future disease.[15] There is a need to undertake prescribing pattern analysis and drug utilization research, to judge the appropriateness of the initiative for prescribing PPIs and to promote the judicious use of PPIs. The study by Liu *et al.*[16] showed that 50% of the PPI prescriptions were for inappropriate indications. Another study reported that inappropriate and misuse of PPIs is related to the increased economic burden of the patients.[17] A study conducted in a tertiary care hospital in Karnataka also reported misuse of PPIs without appropriate indications.[18] With this background, the current drug utilization study was planned to evaluate PPIs prescription patterns and prescription rationality in a tertiary care teaching hospital in Jalandhar, Punjab.

Materials and Methods

Study Design

The current study was a cross-sectional observational study. The study was carried out at the Punjab Institute of Medical Sciences (PIMS), Jalandhar, Punjab. The study plan was assessed and approved by the IEC of Punjab Institute of Medical Sciences (PIMS), Jalandhar, Punjab (IEC/21/66). The study was conducted between February 2021 to June 2021.

Data Collection

The prescriptions received at the pharmacy department of the hospital were screened for the presence of PPIs. The demographic data of the patients receiving PPIs was collected. In addition to demographic data, data was also collected as mentioned in the sections below.

Proton Pump Inhibitor Use Pattern

Data were collected regarding the type of PPI prescribed, and whether PPI was prescribed as a single active pharmaceutical ingredient (API) or as a FDC. The collected information was analysed to compute the relative frequency of the prescriptions with a single API and prescriptions with FDCs. Further analysis was done to determine the second API along with PPI in FDC. Then the prescriptions were analyzed to determine if the specific PPI prescribed and the prescribed formulation of PPI is included in the National List of Essential Medicines[19]and WHO Model List of Essential Medicines.[20] The approval status of the FDCs recorded in the data was checked from the DCG(I) approved list issued in the year 2019 and subsequent updates.[21] The prescribed FDCs approval was checked to see if the APIs in FDC are approved and the approved indication of the FDCs.The data was collected to compute the relative frequency of the PPI prescriptions department-wise. Further, the analysis was done to evaluate the relative frequency of PPI prescription as a single API or as FDC department-wise.

Prescription Analysis Using WHO Indicators

The collected prescriptions were analysed according to prescribing indicators given by WHO.[22] The core prescribing indicators can be used as such without national adaptation. The prescribing indicators point out various issues in the prescribing practices so that targeted measures can be taken to resolve such issues.

Data Analysis and Presentation

The recorded data were tabulated for analysis. Analysis was done by using descriptive statistics. After analysis, data was presented in the form of frequency and relative frequency. For analysis, MS excel and SPSS software version 24 were used.

Results

Demographics of Study Participants

In total 1000 prescriptions were received at the pharmacy department, of the patients vising the various outpatient departments of PIMS, Jalandhar was screened to identify prescriptions with proton pump inhibitors. It was observed that every second prescription contained PPI. Out of the 1000 prescriptions screened 500 prescriptions had PPIs. The gender-wise analysis of the PPI prescription pattern showed that 315 prescriptions were for female patients and the remaining 185 for male patients (Table1). The average age of the study participants was 39.25 ± 14.20 years. The highest PPI prescriptions, 58.40%, were from patients in the age group 18 to 40 years followed by 35.20% prescriptions in the age group 41 to 65 years.

Table 5: Prescription analysis using WHO prescribing indicators.

S. no.	*Indicator*	*Observed value*	*Optimal value*
1	The average number of drugs per encounter	4.63	1.6–1.8
2	Percentage of drugs prescribed by generic name	81.4%	100%
3	Percentage encounters with an antibiotic	2.8%	20.0–26.8%
4	Percentage encounters with an injection	None	13.4–24.1%
5	Percentage drugs from the essential drugs list	0.4%	100%

Only 5.40% of the prescriptions were in the age group more than 65 years.

Proton Pump Inhibitors use Pattern

The prescription analysis showed that 4 different types of PPIs were prescribed. The prescribed PPIs were omeprazole, esomeprazole, pantoprazole and rabeprazole. In the majority of prescriptions, PPIs were prescribed as FDCs (95.2%) and in only 24 (4.8%) prescriptions PPIs were prescribed as mono-drug. Overall rabeprazole was the most frequently prescribed PPI when both single API and FDC prescriptions were considered together. Rabeprazole was prescribed 252 times (50.4%) followed by pantoprazole with 222 (44.4%) prescriptions, esomeprazole with 16 (3.2%) prescriptions and omeprazole with 10 (2%) prescriptions.

Among the PPIs prescribed as a single API, pantoprazole was the most frequently prescribed. Pantoprazole was prescribed in 12 (2.4%) prescriptions, followed by esomeprazole in 10 (2%) prescriptions and omeprazole in 2 (0.4%) prescriptions (Table 2). The formulations of esomeprazole prescribed were tablets and syrup. Pantoprazole formulations prescribed were capsule, syrup and tablet. The formulation of omeprazole prescribed was as a capsule. The NLEM 2015 issued by DCG(I), the Government of India does not include esomeprazole. The list includes omeprazole in doses of 10, 20 and 40 mg as capsule and powder for oral liquid in the dose of 20 mg. Whereas, pantoprazole 40 mg injection is the only formulation included in NLEM, 2015. In the present study, all the pantoprazole prescriptions were with formulations other than parenteral preparations. The WHO model list of essential medicines issued in 2021 includes only omeprazole as a capsule, powder for injection and powder for the oral liquid.

The most frequently prescribed FDCs were those with rabeprazole as PPI API. In total 252 (50.40%) prescriptions of rabeprazole as FDC were recorded. Pantoprazole was second on the list with 210 (42.00%) prescriptions, followed by omeprazole with 8 (1.60%) prescriptions and esomeprazole with 6 (1.20%) prescriptions. The most common second API was domperidone irrespective of the PPI as API. FDCs of rabeprazole and domperidone prescribed were 122 (24.40%), prescriptions with pantoprazole and domperidone as APIs were 210 (42.00%), and prescriptions with omeprazole and domperidone as APIs were 8 (1.60%) and prescriptions with esomeprazole and domperidone as API were 6 (1.20%). The prescriptions with rabeprazole and itopride as APIs were 130 (26.00%) in number. The DCG(I), Government of India issues the approved list of fixed-dose combinations. Such a list was issued in the year 2019 and subsequent updates in the year 2020 and 2021 were consulted. The list was checked to see whether the FDCs prescribed in the current study were among the approved list. It was observed that the prescribed FDCs are included in the approved list issued by DCG(I) (DCG(I) approved FDCs, 2019, 2020, 2021). The DCG(I) approval mentions that the combination of PPI and domperidone are for GERD not responding to PPI alone adequately (Table 3). The WHO model list of essential medicines 2021 does not include any FDC with PPI and prokinetic agents as APIs.

Department Wise Proton Pump Inhibitor Prescription Frequency

The PPI prescriptions analysed in the study were received from all the OPD of PIMS, Jalandhar. The OPD-wise analysis of the prescriptions showed that the maximum number of prescriptions were from medicine OPD, which was 196 (39.20%), followed by obstetrics and gynaecology with 152 (30.40%) prescriptions (Table 4). Prescriptions from all the other OPDs were below 100. The prescription frequency was orthopaedics 55 (11.00%), psychiatry 50 (10.00%), ENT 12 (2.40%), chest and TB 12 (2.40%), dermatology 11 (2.20%), surgery 7 (1.40%), 2 (0.40%) each from paediatrics and dental department and 1 (0.20%) from ophthalmology OPD. The prescriptions of the medicine OPD were further bifurcated into general medicine, gastroenterology and cardiology. Among these the maximum 153 prescriptions were from general medicine (30.6%), followed by gastroenterology 24 (4.8%) and cardiology 17 (3.4%).

Since the combination of PPI and a prokinetic agent is indicated for patients not responding adequately to PPI alone we analyzed the prescriptions to explore the prescription of FDCs department-wise. The results showed that 100% of the prescriptions from ophthalmology, dental, paediatrics, surgery, dermatology, ENT, chest and TB and psychiatry OPDs had FDC of PPI plus prokinetic agent. 98.2% of the prescriptions from orthopaedics and 94.7% of the prescriptions from obstetrics and gynaecology were of PPI FDCs.

Prescription Analysis using WHO Criteria

The drug use indicators described by WHO intend to describe the prescribing behaviour of healthcare providers. The WHO indicators help in identifying the potential problem so that focused plans can be formulated to improve healthcare in a setting. The prescribing indicators are core indicators and do not require to be adopted nationally and are generic indicators that can be used for any kind of drug use studies (WHO 1993). The results of the analysis of the prescriptions according to WHO prescribing indicators are depicted in Table 5.

The average number of drugs prescribed per encounter in the current study was observed to be 4.63 which was way high than the WHO-recommended optimal level.The percentage of drugs prescribed from the essential drugs list was observed to be only 0.4% whereas the optimal level is that 100% of the drugs should be from NLEM. The drugs prescribed by generic name were 81.4% against the optimal level of 100%.

Discussion

The high prescription rate of PPIs observed in our study is similar to previous studies reporting high prescription rates in Indian patients[23] and even in studies conducted outside India.[8] PPIs are the most frequently prescribed class of drugs among antisecretory drugs. In India, PPIs were ranked the fourth most prescribed drugs in the year 2016 and the sixth most prescribed drugs in the USA.[24] Several studies in the literature report a high prescription rate of PPIs and a significant number for inappropriate indications.[17,23]

The majority of the prescribed PPIs in the present study were in FDCs formulation with domperidone as the second API. The study conducted by Biswas *et al.*[25] in a tertiary care hospital also reported the highest prescription frequency of pantoprazole+ domperidone fixed-dose combination. Authors also reported that domperidone was the most common API combined with PPI. However, the WHO model list of essential medicines 2021 does not include any FDC with PPI and prokinetic agents as APIs. In literature, several studies are available that show that a combination of PPI with domperidone is more effective in patients suffering from unresponsive GERD than PPI monotherapy.[26] Even the various guidelines advocate the combination of PPIs with prokinetic agents only in a patient refractory to PPIs monotherapy. Japanese guidelines recommend the use of prokinetics as third-line therapy in the algorithm of PPI failure.[27] The U.S. guidelines published in the year 2018 did not recommend the use of prokinetic agents.[28] The PPI FDC prescribed in the current study is included in the approved list issued by DCG(I).[21] Nevertheless, the DCG(I) approval mentions that the combination of PPI and domperidone are for GERD patients not responding to PPI alone adequately. The information regarding non-responsiveness to PPIs was not available to draw any conclusion as to why combination was prescribed over monotherapy. The regulatory authorities worldwide from time to time have issued warnings and restricted the use of prokinetic agents including domperidone due to adverse cardiac effects.[29]

The approved indications of PPIs include GERD, acid-related: erosive esophagitis, peptic stricture, uncomplicated GERD: for patients responding to short-term PPIs, Barrett oesophagus and symptomatic GERD, asymptomatic Barrett oesophagus, patients taking NSAIDs who are at high risk for ulcer bleeding. The PPIs have specific indications rather than generalized use. As observed in the current study, the majority of prescriptions (60.8%) were from departments other than medicine and only 39.2% of the prescriptions were from the medicine department. Within the medicine department, only 24 prescriptions were from the gastroenterology clinic. This observation raises a concern as to whether a clear-cut indication for the prescription of PPIs was there or not. The inappropriate use of PPIs has been reported several times in countries worldwide. The study conducted by Venkataraman *et al.*[18] in a tertiary care teaching hospital in Karnataka, reported that less than 45% of the PPI prescriptions were for approved indications. The authors also reported that more than 50% of the prescriptions did not have a clear indication for PPI use. Savarino *et al.*[30] reviewed clinical trials, systemic reviews and meta-analyses published between 1997–2017 to evaluate the use of PPIs as acid suppressant therapy. The authors analysed the appropriate use of PPIs in hospital settings and primary care settings separately. In the hospital settings, the inappropriate use of PPIs for indications other than FDA-approved indications ranged between 50 to 69%. The main reasons cited by the authors for inappropriate use of PPIs in primary care settings include continued use of PPIs by patients after hospital discharge and the absence of a periodic review of PPI prescriptions by the doctor. The consequences of inappropriate and chronic use of PPIs pose a serious health risk to the patients and add to the economic burden of the patient. A study conducted by Thomas *et al.*[31] concluded that a global expense of approximately 3,000,000 dollars is incurred due to misuse of PPIs after hospital admission. The adverse drug reaction rate of PPIs is between 1 to 3% if prescribed appropriately. The rate complies with the acceptance rate of adverse drug reactions with pharmacological interventions.[32] However, with chronic use PPIs are associated with hypomagnesemia, *Clostridium difficile* infections and acute renal disorders like idiosyncratic interstitial nephritis.[33]

The average number of drugs prescribed per encounter in the current study was observed to be 4.63 which was way high than the WHO-recommended optimal level. This indicator measures the degree of polypharmacy. The findings of the current study are in line with a recently published meta-analysis. The study explored the prevalence of polypharmacy in different regions of India. The result of the analysis showed that pooled prevalence of polypharmacy was 49%, hyperpolypharmacy was 31% and potentially inappropriate medication use prevalence was 28%. Region-wise polypharmacy was highest in the Northeast region (65%). Hyperpolypharmacy was highest in South India (33%).[33] As the number of drugs prescribed per encounter increases, it increases the risk of unwanted effects and drug interactions.[22]

Conclusion

It can be concluded that PPIs are being prescribed without appropriate indication in most cases. The use of PPI and the prokinetic agent is reserved for PPI refractory cases but it was observed that FDCs are being used routinely without appropriate indication. The trend of polypharmacy indicates that practitioners were managing the patients symptomatically rather than specifically managing the underlying disease condition. The practitioners were also not following the NLEM. These findings suggest the need

for sensitization programs for practitioners for prescribing practices and appropriate use of PPIs.

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