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Original Article

Indications for the Usage of Proton Pump Inhibitors in Medicine, Surgery, and Gastroenterology Ward of Dhaka Medical College Hospital

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Bidhan Krishna Sarker[1*], Sangita Devi[2], Sonia Akter[3], Sharmin Jahan Khan[4], Asim Kumar Saha[5]

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*Corresponding Author

ABSTRACT

Introduction: *The landscape of treating acid-related diseases has undergone a profound transformation with the introduction of proton pump inhibitors (PPIs) into clinical practice.The strong evidence supporting PPI efficacy and a favorable safety profile has led to the overuse of these drugs both in hospitals and in primary care settings. This study aimed to assess appropriateness in the indication of proton pump inhibitors in medicine, surgery, and gastroenterology wards of Dhaka Medical College Hospital.* ***Methods & Materials:*** *This cross-sectional observational study was conducted at the Department of Pharmacology and Therapeutics, Dhaka Medical College, Dhaka, from July 2019 to June 2020. Data were analyzed using descriptive statistics. Analysis of data was carried out by using Statistical Package for Social Science (SPSS) 22.0 for Windows.* ***Result:*** *Among 521 patients, who were prescribed PPIs, 255 (48.9%) patients were given PPIs for appropriate indications, whereas in 266 (51.1%) patients indications were not appropriate for prescribing PPIs. There was a significant difference ($p<0.05$) inappropriateness in the usage of PPIs in different departments of Dhaka Medical College Hospital. Among the three departments, for prescribing PPIs appropriate indications were followed mostly in the gastroenterology department (59; 59.6%), followed by the medicine department (93; 49.5%), and were lowest (103; 44%) in the surgery department.* ***Conclusion:*** *This study concludes that most of the patients' PPI prescriptions do not follow appropriate indications recommended by reference guidelines and inappropriate usage is most common in the surgery department, followed by the medicine department.*

Keywords: *Proton Pump Inhibitor, Indication, Prophylaxis, Guideline*

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1. *Lecturer, Department of Pharmacology and Therapeutics, Sylhet MAG Osmani Medical College, Sylhet, Bangladesh*
2. *Consultant, Department of Gynaecology and Obstetrics, Jaintapur Upazila Health Complex, Sylhet, Bangladesh*
3. *Assistant Professor, Department of Pharmacology and Therapeutics, Ashiyan Medical College, Dhaka, Bangladesh*
4. *Lecturer, Department of Pharmacology, Mugda Medical College, Dhaka, Bangladesh*
5. *Senior Consultant, Department of Gynaecology and Obstetrics, District Sadar Hospital, Narsingdi, Bangladesh*

INTRODUCTION

The advent of proton pump inhibitors (PPIs) has brought about a remarkable transformation in the treatment of acid-related ailments. Omeprazole, the inaugural PPI introduced in 1989, has revolutionized the management of conditions such as peptic ulcers and gastroesophageal reflux disease (GERD)[1]. Considering USFDA approved indications, National Institute for Health and Care Excellence (NICE) guidance recommendations and the systematic review by Scarpignato, et al. recommendations, there are several clinical scenarios where PPI therapy is appropriate [1,2,3]. It is to be noted here that the world literature provides ample evidence for the efficacy of PPIs in many usages for which there are no USFDA or NICE approvals. In the study by Scarpignato, et al., committees on behalf of three Italian scientific societies, named the Italian Society of Pharmacology (SIF), the Italian Association of Hospital Gastroenterologists (AIGO), and the Italian Federation of General Practitioners (FIMMG) collaborated with impressive panels of expert international reviewers to address 13 clinical scenarios in which uncertainty exists about usage of PPIs and their misuse[1]. Taking into consideration the above-mentioned recommendations, PPI therapy is indicated in GERD, Barrett's esophagus, eosinophilic esophagitis, Helicobacter pylori (H. pylori) eradication, non-H. pylori-related PUD, functional dyspepsia, NSAID-gastropathy, Zollinger-Ellison syndrome, prophylaxis of PUD for patients taking corticosteroid, anti-platelet therapy, anticoagulant therapy, PU bleeding, prevention and/or treatment of esophageal ulcers after

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sclerotherapy or variceal band ligation in cirrhosis and steatorrhea refractory to enzyme replacement therapy in chronic pancreatitis. The recent literature review has demonstrated the risk for adverse drug reactions and drug interactions with inappropriate use of PPIs[4]. Over recent years evidence has emerged showing some previously unrecognized toxicities of PPIs[5]. The various mild and self-limiting side effects of PPIs are nausea, loose stool, headache, abdominal pain, muscle and joint pain, and dizziness[6]. Long-term effects include fracture, *Clostridium difficile* infection, pneumonia, acute interstitial nephritis, chronic kidney disease, hypomagnesemia, vitamin B12 deficiency, cardiovascular events, subacute cutaneous lupus erythematosus, cancer, and higher mortality[7]. PPIs get metabolized through hepatic P450 cytochromes and lead to drug interactions by increasing their half-life and thus causing harmful systemic effects[6]. So, PPI therapy needs to be evidence-based. Decisions on initiation or continuation of PPI therapy should be sound and PPIs should only be prescribed when there is an appropriate clinical indication. However, in the current situation, PPI consumption is overwhelming worldwide, which invites studies to be carried out to examine the prescribing pattern of PPIs in hospitalized patients. The aim of the study is to assess appropriateness in the indication of proton pump inhibitors in the medicine, surgery, and gastroenterology ward of Dhaka Medical College Hospital.

METHODS & MATERIALS

This cross-sectional observational study was conducted at the Department of Pharmacology and Therapeutics, Dhaka Medical College, Dhaka, from July 2019 to June 2020, including all patients admitted to the medicine, surgery, and gastroenterology wards of Dhaka Medical College Hospital, with a total of 600 patients selected using purposive sampling based on specific inclusion and exclusion criteria. Inclusion criteria encompassed patients admitted for ≥ 2 days, aged ≥ 18 years, and willing to give consent, while exclusion criteria included those admitted for < 2 days, aged < 18 years, or unwilling to consent. Data were collected using a specially designed form, reviewing patients' clinical history, laboratory data, medication charts, and other relevant information, focusing on the frequency and indications of PPIs, guided by USFDA (2014) approved indications, NICE (2014) guidance recommendations, and the systematic review by Scarpignato et al. (2016). Descriptive statistics were used for analysis, with continuous data expressed as mean ± SD and nominal data as percentages, performed using SPSS 22.0 for Windows, and results presented in tables and charts. Ethical approval was obtained from the ethical committee of Dhaka Medical College, and informed written consent was taken from all participants.

RESULTS

Table – I: Distribution of respondents by their age in years (*n*=600)

Age group (years)	n	%	Mean ± SD (range)
≤ 20	6	1.0	44.8±13.5 (18 – 80)
21-40	258	43.0	
41-60	267	44.5	
61-80	69	11.5	
Total	600	100.0	

The highest number of respondents (267 patients) were in the age group 41-60 years, followed by the age group 21-40 years (258 patients) and the lowest number of respondents (6 patients) were in the age group ≤20 years. The mean age of our patients was 44.8±13.5 years. [Table I]

Table – II: Gender distribution of the study patients (*n*=600)

Gender	n	%	Male: Female ratio
Male	341	56.8	1.3: 1
Female	259	43.2	
Total	600	100.0	

The above table shows that in this study male patients were more than female patients with a ratio of 1.3:1. Males were 341 (56.8%) and females were 259 (43.2%) in number. [Table II]

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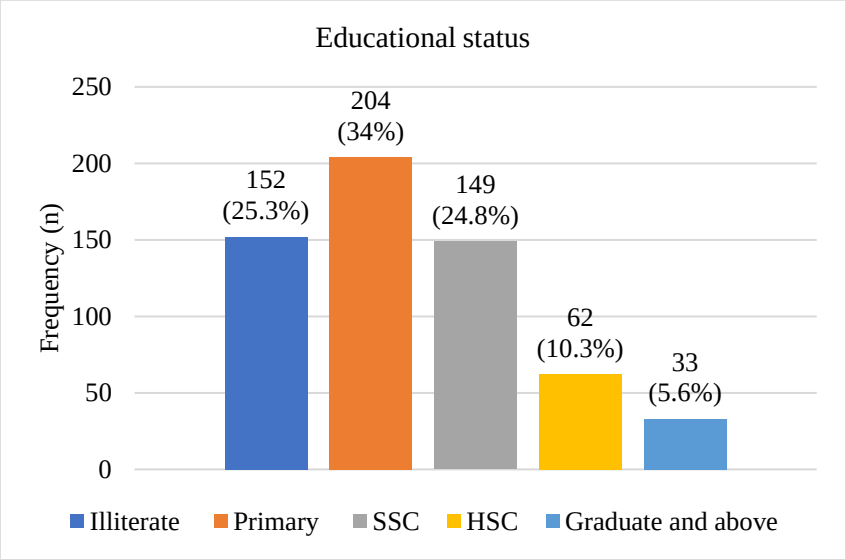

Figure – 1: Bar diagram showing the distribution of the study respondents by educational status (*n*=600)

Among 600 patients, 152 (25.3%) patients were illiterate, 204 (34.0%) patients were educated by primary education, 149 (24.8%) patients were SSC and 62 (10.3%) patients were HSC and 33 (5.6%) patients were graduate and above. [Figure 1]

Table – III: Distribution of the study patients by department (*n*=600)

Department	n	%
Gastroenterology	139	23.2
Medicine	220	36.6
Surgery	241	40.2
Total	600	100.0

The above table shows that among 600 patients, 241 (40.2%) patients were from the surgery department, 220 (36.6%) patients were from the medicine department and 139 (23.2%) patients were from the gastroenterology department. [Table III]

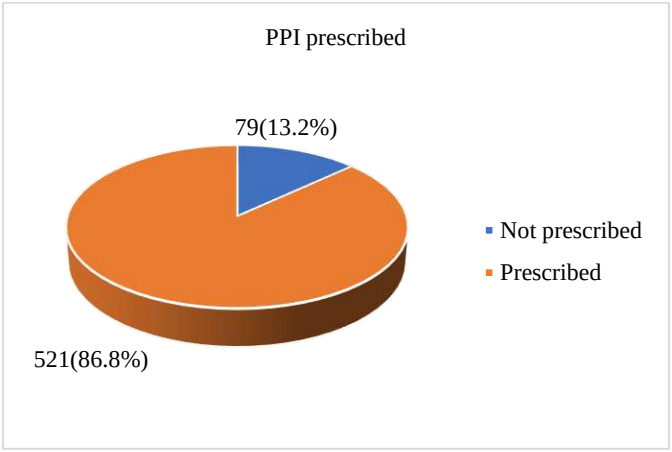

Figure – 2: Pie diagram showing the distribution of the study patients by PPIs prescribed (*n*=600)

The pie diagram shows that most of the patients (521; 86.8%) were prescribed PPIs, whereas only 79 (13.2%) patients were not prescribed PPIs in our study.

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Table – IV: Distribution of the study patients by appropriateness of PPIs (*n*=521)

Appropriateness of PPIs	*n*	%
Yes	255	48.9
No	266	51.1
Total	521	100.0

Among 521 patients, who were prescribed PPIs, 255 (48.9%) patients were given PPIs for appropriate indications, whereas in 266 (51.1%) patients indications were not appropriate for prescribing PPIs. [Table IV]

Table – V: Distribution of the study patients by department basis PPI usage (*n*=521)

Appropriate Indications	Department			p-value
	Gastroenterology (n=99) No. (%)	Medicine (n=188) No. (%)	Surgery (n=234) No. (%)	
Appropriate	59(59.6%)	93(49.5%)	103(44.0%)	0.034[s]
Not appropriate	40(40.4%)	95(50.5%)	131(56.0%)	
Total	99(100.0%)	188(100.0%)	234(100.0%)	

Chi-squared Test (χ^2) was done to analyze the data.

s = significant

There was a significant difference (p<0.05) in appropriateness in the usage of PPIs in different departments of Dhaka Medical College Hospital. Among the three departments, for prescribing PPIs appropriate indications were followed mostly in the gastroenterology department (59; 59.6%), followed by the medicine department (93; 49.5%) and were lowest (103; 44%) in surgery department. [Table V]

Table – VI: Distribution of the study patients by trade name of individual PPI used (*n*=521)

Trade name of Individual PPI used	*n*	%
Maxpro	36	6.9
Omep	33	6.3
Omenix	12	2.3
Sergel	10	1.9
Nexcap	7	1.3
Pantonix	6	1.2
PPI	6	1.2
Esotid	4	.8
Rabe	4	.8
Progut	3	.6
Esonix	2	.4
Nexum	2	.4
Nexum Mups	2	.4
Omeprol	2	.4
OP	2	.4
Seclo	2	.4
Emep	1	.2
Ometid	1	.2
Xeldrin	1	.2
No trade name	385	73.9
Total	521	100.0

In this series, no trade name was mentioned in most patients (73.9%). As a trade name, Maxpro (trade name for esomeprazole) was mentioned in the highest number of patients (6.9%), followed by Omep (trade name for omeprazole) (6.3%). [Table VI]

DISCUSSION

In this series, a majority of male patients as compared to female patients i.e. 341 (56.8%) and 259 (43.2%) respectively with a ratio of 1.3:1. Similar findings were found in a study done by Mathew, et al., where they showed male and female patients were 646 (55.59%) and 516 (44.4%) respectively[8]. In this study, majority of the patients belonged to the age group 41-60 years (267, 44.5%), 258 (43%) patients were of age between 21-40 years, and 69 (11.5%) patients were of age between 61-80 years. The mean age of this study population was 44.8±13.5 years. Similar results were reported by Airee, et al., where they found most of the patients (47%) were in the age group 40-60 years and 10% of patients were in the age group of >60 years[4]. Considering the department basis distribution of study patients, we found that the majority of patients were from the surgery department (241; 40.2%) followed by medicine (220; 36.6%) and the gastroenterology department (139; 23.2%). Unlike my study, another study reported out of 214 patients, more patients (113) were from the medical department as compared to the surgery department (101)[9]. Again, in another study conducted by Mathew et al. majority of the patients (42.34%) were from the

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general medicine department, whereas 20.47% of patients were from the general surgery department [8]. In this study, out of 600 patients, 521 (86.8%) patients were prescribed PPIs, whereas only 79 (13.2%) patients were not given PPIs. A similar result was found by Haroon, et al., where out of 205 consecutive medical inpatients 162 patients (79%) were prescribed PPIs[10]. The present study showed that out of 521 patients, who were prescribed PPIs, the majority of the patients (266, 51.1%) were prescribed PPIs without a proper indication. Whereas 255 (48.9%) patients were given PPIs with an appropriate indication. Similar results were reported by Nousheen, Tadvi, and Shareef [9], where 58% of patients were prescribed PPIs without any valid indication, and only 42% of patients were given PPIs according to the criteria of rationality. This follows the study by Michelon, et al., who reported 62.5% of PPI prescriptions without an appropriate indication, but less than the study by Akram, et al., where 81.2% of patients were prescribed PPIs without any valid documented indications[11,12]. In contrast, my observations were more than the study by Kunwar, et al., D'Souza, et al., and Mathew, et al., where 23.07%, 36%, and 39.58% PPI prescriptions respectively were in appropriate[6,8,13]. We found a significant difference ($p<0.05$) in the appropriateness of the usage of PPIs in different departments. I observed that in the gastroenterology, medicine, and surgery department, out of 99, 188, and 234 patients, 59 (59.6%), 93 (49.5%), and 103 (44%) patients respectively were prescribed PPIs with an appropriate indication. So, among the three departments, for prescribing PPIs appropriate indications were not followed mostly in the surgery department (56%), followed by the medicine (50.5%) and gastroenterology (40.4%) department. In the present study, the most commonly prescribed brand for PPIs was Maxpro (Esomeprazole) in 36 (6.9%) prescriptions, followed by Omep (Omeprazole) in 33 (6.3%) prescriptions. No trade name was mentioned in 385 (73.9%) prescriptions. Dissimilar to this study, Airee, et al. reported that the most commonly prescribed brand for PPIs was Apan (Pantoprazole) in 28% of prescriptions, followed by Omez (Omeprazole) in 12% of prescriptions[4]. In this study, out of 255 patients, who were prescribed PPIs for an appropriate indication, most of the patients (88; 34.51%) were given PPIs as a prophylaxis for NSAID, followed by prophylaxis for steroid and PUD (41; 16.08%). Other indications were Prophylaxis for antiplatelet (12.55%), EVL (8.63%), chronic pancreatitis (7.45%), Functional dyspepsia (3.14%), GERD (3.14%), Stress ulcer prophylaxis (2.75%) and Prophylaxis for anticoagulant (2.35%). This is following the study by Nousheen, Tadvi, and Shareef and Mathew, et al., who have found a high incidence of PPI prescriptions at 32% and 38.6% respectively as prophylaxis for NSAID[8,9]. However, these results were contrary to the study done by Kunwar, et al., where 73.85% of PPI prescriptions were indicated as a prophylaxis for NSAID[13]. Therefore, implementing PPI stewardship programs is essential to encourage the appropriate use of PPIs based on indication and duration[14]. Moreover, GPs should carefully assess hospital recommendations and their medication before admission to avoid over- and under-prescribing[15].

Limitations of The Study

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community. Moreover, adverse drug reactions, drug interaction, and cost evaluation were not done due to the limited time frame.

CONCLUSION

This study concludes that in most of the patients PPI prescriptions are not following appropriate indications recommended by reference guidelines and inappropriate usages are most common in the surgery department, followed by the medicine department.

RECOMMENDATION

To conduct further study and to ensure appropriate prescribing of a PPI some recommendations are proposed, the study should be conducted with large sample size, the duration of the study period should be increased, the study should be done at different levels of hospitals, additional relevant parameters like adverse drug reaction, drug interaction, and cost evaluation should be considered for further study, the decision on initiation or continuation of PPI therapy should be sound, appropriate prescribing of a PPI national or institutional specific guidelines should be developed.

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