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CLINICAL PHARMACIST ROLE IN RATIONAL USE OF PROTON PUMPINHIBITORS

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ABSTRACT

The practice of clinical pharmacy embraces the philosophy of pharmaceutical care, blending a caring orientation with specialized therapeutic knowledge, experience, and judgment to ensureoptimal patient outcome. As a discipline, clinical pharmacy also has an obligation to contribute to the generation of new knowledge that advances health and quality of life. Proton pump inhibitors(PPIs) are a group of drugs that cause pronounced and long-lasting reduction proton of gastric acid production. They are most potent gastric acid suppressing drugs currently in clinical use PPIs irreversibly inhibit the gastric H+-ATPase pump also known as proton pump and reduce both basal and stimulated gastric output. The setting for the study was the multihospital setting. A standard proforma was used to perform a survey of the prescription charts of all patients in a hospital from a questionnaire. The proforma included details of patient age and sex, department, indication for PPI use, type of PPI prescribed chief complaints, duration of therapy and details of other prescribed medications. study with 710patient populations takes us to the fact that rationaluse of ppis were shown to be 40% of the studypopulation have shown to be with a definitive while 54.59% shown with a prophylactic use.

KEYWORDS: 1.Peptic ulcers 2.Proton pump inhibitors 3.Gastrointestinal bleeding 4.Gastrointestinal esophageal reflux disease 5.Patient care.

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INTRODUCTION

Clinical pharmacy is a health science discipline in which pharmacists provide patient care that optimizes medication therapy and promotes health, and disease prevention. The practice of clinical pharmacy embraces the philosophy of pharmaceutical care, blending a caring orientation with specialized therapeutic knowledge, experience, and judgment to ensure optimal patient outcome. As a discipline, clinical pharmacy also has an obligation to contribute to the generation of new knowledge that advances health and quality of life. It also includes the community practice, hospital practice, and public health. It can be defined as that area which embraces the acquisition and preparation of medications and their distribution to the public.

Clinical pharmacy is a key area of the pharmacy profession. Future pharmacists should be concerned with advancing the profession as a whole. The practice of pharmacy in the presence of patients whether they are hospitalized or ambulatory outpatients visiting their community pharmacy or neighbourhood health care centre. It is defined as the services provided by the pharmacist in an attempt to promote rationaldrug therapy i.e. safe, appropriate and cost effective.

1 Pharmacist Role In Patient Care

The pharmacist with clinical background can make a helpful contribution in medication selection process on matters like medication formulation, dosage schedules, absorption, distribution, metabolism, excretion patterns, side effects, interactions, contra indications, alternative dosage forms, stability and storage products, requirements, as well as relative costs of different products. From considerations of these factors and their interplay with each other, the range of possible suitable medications suitable for achieving the therapeutic objectives can be narrowed down to few suitable alternatives Functions of clinical pharmacist.

The clinical pharmacist must be competent to develop and provide patient oriented services. It is the responsibility of the director of pharmacy services in eachhospital to develop and maintain appropriate clinical services as a component f apharmacy services within the hospital. Some of the clinical functions of pharmacist, based on recommendation of.

"American society of hospital pharmacist" are as follows

- 1. Patient education and counseling
- 2. Preparation of patient medication histories through patient admission and discharge interviews and from

patient database and medical records.

- 3. Monitoring drug therapy, including routineanalysis of patient drug therapy, medical problems, laboratory data and special procedures. The pharmacist correlate this analysiswith direct patient observation and communicates his observation to clinical responsible for the patient care.
- 4. Provision of written consultation in such areas as total parenteral nutrition, intravenous therapy, clinical pharmacokinetics, selection of drug therapy and determination of therapeutic endpoints.
- 5. Management of patients with chronic diseases with diabetes, hypertension, arthritis, chronic obstructive pulmonary disease and cancer in cooperation with medical staff.

Responsibilities of clinical pharmacist

Pharmacist have a professional responsibility to communicate significant advances in the development and delivery of clinical pharmacy services to the professional community through appropriate publications presentations and programs.

Responsibilities of clinical pharmacist inhospitals patient care areas

Direct patient care areas: (wards)

Pharmacist's role in patient care at thetime of admission and discharge.

1.3- Role of clinical pharmacist inrationalising drug therapy

A clinical pharmacist can play a multidisciplinary approach to the promotion of the rational use of medicines by providing proper information, and instruction regarding the adverse drug reactions, dosage schedule of drugs to the patients and warning them about the unwanted effects of medicines and monitoring such unwanted effects. In collaboration with other health care professionals the clinical pharmacist can play a key role in educating the patient abouthazards of self- medication, over use of drugs, polypharmacy. The clinical pharmacist will play an important role in the management of drug procurement, storage and distribution that ensureadequate use of medicines. Incoordination with healthcare team, clinical pharmacists can establish a common approach to the rational use of drugs by giving advice and information to patient regarding the proper use of drugs. Hence, proper role and involvement of a clinical pharmacistin safe use of medicines and overall health care becomes very crucial. Clinical Pharmacist helps in achieving the goal of rational use of drugs by following good pharmacy practices. Thus we can conclude that promoting the rational use of medicines results in improved quality of life for the patient in particular and for the community in general.

Proton Pump Inhibitors (PPIS)

Proton pump inhibitors (PPIs) are a group of drugs that cause pronounced and long- lasting reduction proton of gastric acid production. They are most potent gastric acid suppressing drugs currently in clinicaluse.

PPIs irreversibly inhibit the gastric H+- ATPase pump also known as proton pump and reduce both basal and stimulated gastric output. Inhibition of the proton pump in the parietal cells has been established as the main therapeutic principle in the treatment of acid-related diseases, such as peptic ulcer and gastro- oesophageal reflux. They accumulate in the target cell and are activated by acid and bind strongly to the specific target the proton pump. The clinical superiority of the1proton pump inhibitors is due not only to their high efficacy but also to the long duration of the acid inhibition in comparison with other anti-secretory drugs. Currently the PPIs available in India are omeprazole, esomeprazole, pantoprazole, rabeprazole and lansoprazole.

PPIs are used the rapeutically in active ulcers, Zollinger-Ellison syndrome, Gastrooesophageal Reflux Disease(GERD), GI bleeding, dyspepsiafrom NSAID's and along with antibiotics for helicobacter pylori. PPIs are also given prophylactically along with NSAID's or Steroids in patients with history of peptic ulcer / previousGI bleed / elderly patients.

Symptoms relief agents other than PPIs will provide greater patient satisfaction and better clinical outcomes. The prescriptions for the PPIshave increased consistently over the past years. Many drug utilization studies have reported widespread use of PPIs and that are outside the current prescribing guidelines. The incidence of improper use of PPIs varies from 40-70% in various studies. The significance of rational use of drugs can be described by WHO definition which states that rational use of drugs require that, patients receive medications appropriate to their clinical needs in doses that meet their own individual requirement for an adequate period of time at lowest cost to them and their community. Hence in this present scenario, where the use of PPIs is overwhelming, the present study is planned to know the rational use of PPIs in the in patients from various departments of a rural tertiary carehospital.

Examples

Medically used proton pump inhibitors

- Omeprazole (OTC in the USA)
- Lansoprazole
- Dexlansoprazole
- Esomeprazole
- Pantoprazole
- Rabeprazole

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• Ilaprazole (not FDA approved as of May 2017)

Mechanism of action

Proton pump inhibitors act by irreversibly blocking the hydrogen/potassium adenosine triphosphatase enzyme system (the $H^+/K^+ATPase$, or, more commonly, thegastric proton pump) of the gastric parietal cells.^[22] The proton pump is the terminal stage in gastric acid secretion, being

directly responsible for secreting H^+ ions into the gastric lumen, making it an ideal target for inhibiting acid secretion.

Targeting the terminal step in acid production, as well as the irreversible nature of the inhibition, results in a class of drugs that are significantly more effective than H2 antagonists and reduce gastric acid secretion by up to 99%. Decreasing the acid in the stomach can aid the healing of duodenal ulcers and reduce the pain from indigestion and heartburn. However, stomach acids are needed to digest proteins, vitamin B12, calcium, and other nutrients, and toolittle stomach acid causes the condition hypochlorhydria.

The PPIs are given in an inactive form, which is neutrally charged (lipophilic) and readily crosses cell membranes intointracellular compartments (like the parietal cell canaliculus) with acidic environments. In an acid environment, the inactive drug is protonated and rearranges into its active form. As described above, the active form will covalently and irreversibly bind to the gastric proton pump, deactivating it.

Medicinal uses

Proton pump inhibitors are used for the prevention and treatment of acid-related conditions such as:

- Esophageal duodenal and stomach ulcers.^[23]
- NSAID-associated ulcer.^[24]
- Barret esophagus.^[25]
- Gastroesophageal reflux disease (GERD).^[26]
- Zollinger-Ellison syndrome.^[27]

Adverse effects

The most common side effects of proton pump inhibitors are

- Diarrhea
- Constipation
- Abdominal pain
- Flatulence
- Fever
- Vomiting
- Rash.^[29,30,31]

Questionnaire For Patient Interview.

3. AIMS AND OBJECTIVES

Aim: Assessing the appropriate indication andutilisation of PPIs in multidepartment hospital setting.

OBJECTIVES

- The overall goal of the study is to evaluate the PPIs usage pattern.
- To compare usage of PPIs in variousdepartments.
- To find out percentage of irrational.

prescriptions	with	PPIs	(Improper
prescriptions		with-out	justified
indication).			

4. METHODOLOGY

The setting for the study was the multihospital setting. A standard proforma was used to perform a survey of the prescription charts of all patients in a hospital from a questionnaire. Theproforma included details of patient age and sex, department, indication for PPI use, type of PPIprescribed chief complaints, duration of therapyand details of other prescribed medications.

- 1) On what purpose PPI's are prescribed?
- 2) Since when the medication is being taken and how often?
- 3) Are the medications taken even after the problem has been resolved ? Yes No
- Does the problem resolve soon after taking the drug? Yes No
- 5) Do you typically take the medication at the same time of the day (at what time)?Yes No
- 6) Are there any rebound symptoms? Yes No
- 7) Do you feel comfortable taking the drug? Yes No
- 8) Did doctor prescribe you the drug?Yes No
- 9) Are you satisfied with the drug? Yes No

Indications for PPI Therapy

The clinical indications for PPI therapy specified in the study proforma were those published in the Monthly Index of Medical Specialities (MIMS) of May, 2001 (4). The indications included

- (a) treatment of GERD;
- (b) treatment of duodenal ulcer and benign gastric ulcer;
- (c) Healing and prophylaxis of NSAID- associated benign gastric and duodenal ulcer;
- (d) Helicobacter pylori eradication in peptic ulcer disease;
- (e) Relief of associated dyspeptic symptoms;
- (f) Prophylaxis of acid aspiration; and
- (g) Zollinger–Ellison syndrome.

Patients on PPI therapy were identified using thestudy proforma. Informed consent was then obtained from these patients who were interviewed and their hospital case notes werereviewed.

Study Period

Study is being conducted randomly from June 2021 to November 2021.

Study Design

It is a prospective observational cohort study.

Study Method

The study is being conducted in a secondarycare hospital.to meet the study eligibility criteria data is being collected and assessed on the indication and utilization of PPIs.

Inclusion Criteria

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All ages above 18yrs who are on PPI.

Exclusion Criteria

Less than 18 yrs of age

People who are not willing to participate inthisstudy.

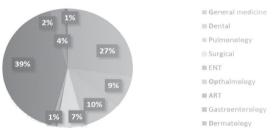
5. RESULTS

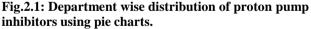
In a total of 710 patients, 392 (55.2%) patients were on ppis, of which 107(27.2%) patients are from general medicine and 35(8.92%) from dental department, 38(9.69%) frompulmonology, 26(6.6%) from surgical, 2(0.5%) from ENT, 4(1%) from ophthalmology, 2(0.5%)from ART. 153(39.03%) from gastroenterology, 8(2.04%) from dermatology, 14(3.57%) orthopaedics, 3(0.76%) from from gynaecology. From the above results upon statistical analysis chisquare value obtained is 174 and degree of freedom value is 1. Upon statistical application p value is obtained as (0.00001) and alpha significance value is (0.05).

 Table 2: Department wise distribution of patient on proton pump inhibitors.

Department	No of pa- tients on ppis	Patientson ppis (%)	
General Medicine	107	27.2%	
Dental	35	8.92%	
Pulmonology	38	9.69%	
Surgical	26	6.6%	
ENT	2	0.5%	
ART	2	0.5%	
Gastroentermology	153	39.13%	
Dermtology	8	2.04%	
Orthopaedics	14	3.57%	
Gynaecology	3	0.76%	

Department wise distribution





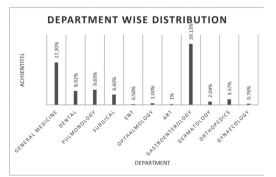
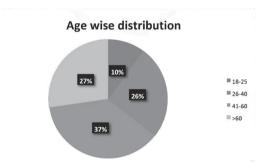


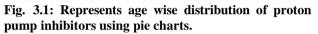
Fig.2.2: department wise distribution of proton pump inhibitors using bar graphs.

Out of 392 patients on ppis there are 39 patients under age group 18-25(9.94%),100 patients under age group 26-40(25.5%), 146 patients under age group 41-60(37.24%),107 patients under age group above 60 years (27.29%) and 61.98% were males and 39.01% females shownin Table 2 and Table 3.

Table 3: Age wise distribution of patients on protonpump inhibitors.

Age	% of patients
18-25	9.94%
26-40	25.5%
41-60	37.2%
Above 60	27.2%





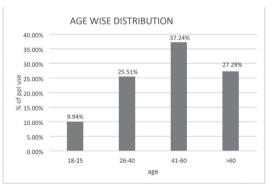


Fig. 3.2: Represent age wise distribution of proton pump inhibitors using bar graphs.

Table 4: Gender wise distribution of patients onprotonpump inhibitors.

Gender	% of patients
Male	61.98%
Females	39.01%

Gender wise distribution

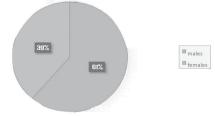


Fig. 4.1: Represents gender wise distribution of proton pump inhibitors using pie charts.

GENDER WISE DISTRIBUTION



Fig. 4.2: Represents gender wise distribution of proton pump inhibitors using bar graphs.

In either of the departments ppisareprescribed in 28% of patients with gastritis, 5% of patients for gastro esophageal reflux (GERD), 48% H. Pylori, 5% for gastric ulcer, 8% for duodenal ulcer, 2% for ieal ulcer, 1% for oesophageal ulcer, 4% forgastro enteritis.

Table5:Indicationsforprescribingppisingastroenterology department.

Disease	% of patients
Gastritis	28%
GERD	4%
H.Pylori	48%
Gastric ulcer	5%
Duodenal ulcer	8%
Ileal ulcer	2%
Oesophageal ulcer	1%
Gastroenteritis	4%

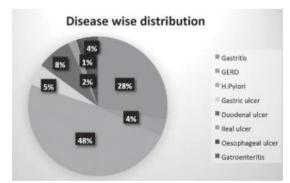


Fig.5.1 Represents disease wise distribution of proton pump inhibitors using pie charts.

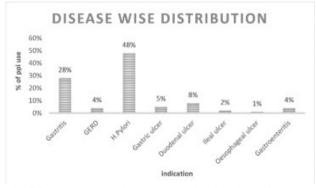


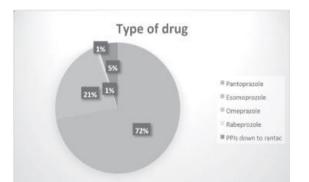
Fig.5.2 Represents disease wise distribution of proton pump inhibitors using bar graphs.

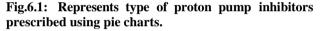
Among the usuage of ppis 71.9% were pantoprazole, 21.4% Esmoprazole, 0.7% Omeprazole, 0.7% Rabeprazole, 5.1% ppis downto rantac.

Table 6: Proton pump inhibitors used in this study.

Drug	% of patients
Pantoprazole	71.9%
Esmoprazole	21.4%
Omeprazole	0.7%
Rabeprazole	0.7%
Ppis down torantac	5.1%

40.8%	of	patients	were	on	ppis	with	definitive
indicatio	n 54	.59% were	on prop	hyla	cticand	14.59%	misuse.





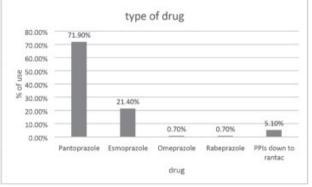


Fig.6.2: Represents type of proton pump inhibitorbeing prescribed using bar graphs.

Table 7: Usage of PPI's in this study.

Usage	% of patients
Definitive	40.8%
Prophylactic	54.59%
Misuse	4.59%

95.4% of drug use is rational and 4.59% drug is irrational.

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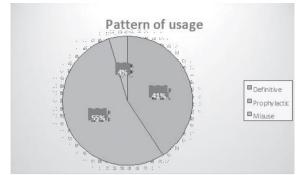


Fig.7.1: Represents usage pattern of proton pump inhibitors using pie charts.

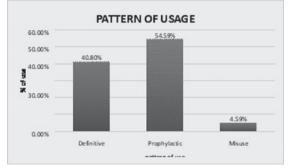


Fig.7.2: represents usage pattern of proton pump inhibitors using bar graphs.

 Table. 8: Rationality of drug use in this study.

Rationality of drug use	% of patients
Rational	95.4%
Irrational	4.59%

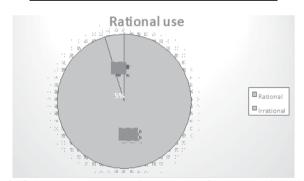


Fig.8.1: Represents rational use of drugs using pie charts.

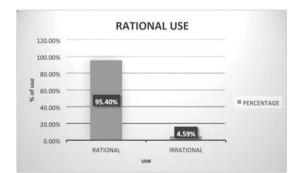


Fig. 8.2: Represents rational use of drugs using bar graphs.

7. CONCLUSION

A substantial number of patients who apparently do not meet prescription suitability condition can be identified, but among non PPIusers on the contrary it is possible to identify equal no of patients for whom prescription would be suitable. Thus there is scope for appropriate use of PPIs by adhering to criteria. Hence 40% of the study population have shown to be with a definitive while 54.59% shown with a prophylacticuse. From the above findings it is concluded that there is no irrational drug prescribing for PPIs. Prophylactic utilization of PPI is much higher than its definitive indication. According to the results obtained it is clear that males are more prescribed with PPIs in comparision with females. Majority of the population are from the age group 41-60 years for whom PPIs prescription is more comparitively with agegroups.

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