Project On

“Adverse Effects Of Proton Pump Inhibitors By Irrational Uses Of These Drugs”

Submitted To

The Department of Pharmacy,

Faculty of Allied Health Sciences,

Daffodil International University.

[In the partial fulfillment of the requirements for the degree of Bachelor of Pharmacy]

Submitted By

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A P P R O V A L

This project on **"Adverse Effects Of Proton Pumps Inhibitors By Irrational Uses Of These Drugs"** submitted to the Department of Pharmacy,Faculty of Allied Health Sciences, Daffodil International University,has been accepted as satisfactory for the partial fulfillment of the requirements for the degree of Bachelor of Pharmacy and approved as to its style and contents.

BOARD OF EXAMINERS

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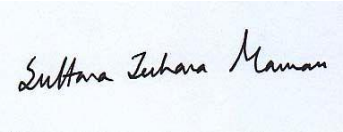
Examiner

D E C L A R A T I O N

I, Ratri Saha , hereby declare that, this project is done by me under the guidance of S u l t a n a J u h a r a M a n n a n , Assistant Professor, Department of Pharmacy, Daffodil International University, in partial fulfillment of the requirements for degree of Bachelor of Pharmacy. The results embodied in this project have not been submitted to any other university or institute for the award of any degree or bachelor.

Guidance by:



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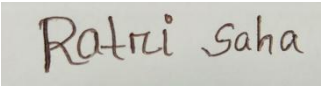

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ACKNOWLEDGEMENT

Firstly, I'd like to express my heartfelt gratitude to GOD, the All-Powerful, for providing me with the ability to complete my project work and the opportunity to focus on this topic.

I'm also grateful to my honorable project advisor, Sultana Juhara Mannan , Assistant Professor, Department of Pharmacy, Daffodil International University, for her brilliant guidance and steady supervision, as well as for providing critical information about the challenge and her assistance in completing it.

I would like to express my humble regards to Dr. Muniruddin Ahmed, Professor and Head, Department of Pharmacy, Daffodil International University. I also wish to offer my respect to all of the teachers of Pharmacy Department, Daffodil International University and I am thankful to other members for their excellent cooperation.

Finally, I'd like to show my thankfulness to my family members for their unwavering support and motivation in helping me complete this project.

Abstract

Proton pump inhibitors (PPIs) have slowly taken over as the cornerstone of treatment for illnesses associate with excess acidity since the release of omeprazole in 1989. Whether links between PPI use and probable side effects are causative is debatable. The combined epidemiological and mechanistic evidence of the adverse effects of PPI use is reviewed in the current study. My primary goal is to find out the adverse effects of proton pump inhibitors by irrational use of these drugs. The data were collected utilizing a self-administered questionnaire which was created by different journal studies. Around 117 individuals have taken an interest here. Data was imported into MS Excel and descriptive statistics were used to examine it. In this study, I found 24.8% of people used proton pump inhibitors regularly,54.7% of people sometimes used proton pump inhibitors,15.4% were used rarely and only 5.1% of people did not use proton pump inhibitors.

Key words: Proton Pump Inhibitors, gastrin, renal disease, adverse effects Fracture risk.

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CHAPTER

01 INTRODUCTION

1.1.Proton pump inhibitors:

By covalently interacting with the cysteine residues of the proton pump, proton pump inhibitors block the gastric H+/K+-ATPase. All proton pump inhibitors must accumulate acid in the parietal cell through protonation, and then be activated via a second protonation at the parietal cell's active secretory canaliculi[1].A substituted pyridine with a primary pKa of around 4.0, which permits selective accumulation in the secretory canaliculi of the parietal cell, and a benzimidazole with a second pKa of about 1.0 make up proton pump inhibitors (PPIs), weak bases. PPIs are acid-activated prodrugs that become sulfenic acids or sulfenamides when exposed to an acid, which then react covalently with one or more cysteines that are accessible from the luminal surface of the ATPase. Its inhibitory effects continue significantly longer than their plasma half-life because of covalent binding. However, the drug's short half-life in the blood and need for acid activation limit its effectiveness in acid control, especially at night. Longer half-lives for PPIs indicate improved acid suppression. All PPIs provide effective peptic ulcer repair.[2]

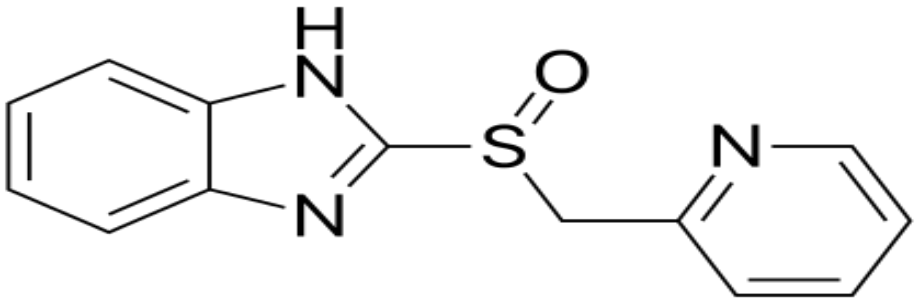

Fig: Structure Of Proton pump inhibitors

The most typical factor leading to stomach cancer is an infection with Helicobacter pylori. The risk at the time of cure determines whether eradicating H. pylori lowers or completely eliminates the risk of gastric cancer. In people who have mucosal injury and hypochlorhydria, getting rid of H. pylori can make their acid secretion return. After H. pylori treatment, proton pump inhibitor (PPI) therapy can significantly reduce acid secretion. After H. pylori has been eradicated, the impact of PPIs on the risk of stomach cancer remains uncertain. [3]

1.2 Generation of proton pump inhibitors:

First-generation PPIs (omeprazole, pantoprazole, and lansoprazole) have noteworthy drawbacks despite their well-documented efficacy and safety. These medications' pharmacokinetics show a lot of interpatient variation and they could interact with other medicines in a big way. The timing of doses and the consumption of meals may also have an impact on the pharmacokinetics of these medications and their capacity to reduce stomach acid secretion. The effectiveness of first-generation PPIs in on-demand GORD therapy may be constrained by their comparatively sluggish beginning of pharmacological action, several doses needed to achieve maximum acid suppression, and symptom alleviation. Even with twice-daily doses, nocturnal acid breakthroughs can still happen with first-generation PPIs that fail to achieve 24-hour suppression of gastric acid. As a result of gastric acid suppression, both first- and second-generation PPIs may be linked to unfavorable events, however newer PPIs may be able to circumvent several important pharmacokinetic, pharmacodynamic.[4]When omeprazole, lansoprazole, and pantoprazole, two of the older PPIs in this class, are contrasted with the two most recent PPIs, rabeprazole and esomeprazole, the latter offers several significant advantages over the former, particularly when it comes to the treatment of gastro-oesophageal reflux disease. Compared to previous treatments, rabeprazole and esomeprazole effectively and quickly reduce acid secretion, and they maintain this suppression to regulate acid and relieve symptoms for up to 24 hours. Rabeprazole's balanced hepatic metabolism, which includes both cytochrome P450 (CYP)-mediated and non enzymatic liver responses, appears to provide it an edge over previous PPIs in that CYP2C19 genetic variants have no effect on the drug's clearance and, possibly, clinical effectiveness. CYP2C19 is similarly involved in the metabolism of esomeprazole, however the pharmacokinetic[5].Omeprazole and two antibiotics have been the standard treatment up till now for Helicobacter pylori eradication. Only a few studies have compared omeprazole and double-dose new-generation proton pump inhibitors (PPI). As a result, we carried out a randomized, prospective trial to assess variations in H. pylori eradication rates according to PPI type.[6]

1.3Mechanism of action proton pump inhibitors:

To bind to the CYSs of the ATPase, PPIs must be activated, and the rate of this activation varies with their structures. Some PPIs must be made with an enteric coating because they are weak bases that are acid labile and need to withstand gastric acid breakdown in order to allow absorption in the more alkaline environment of the small intestine. By adding two protons to the nitrogens on either side of the sulfinyl group, the PPI is activated. The proton pump has a number of CYSs that the PPI can bind to. The CYS(s) it will bind depends on how quickly these two activation events take place. The proton transporter's CYS813 is found on the acidic lumenal side, and all PPIs bind to it to prevent proton transfer. PPIs can attach to this site with ease, but reducing agents like glutathione and dithiothreitol can also access there to release the PPI and restart the transporter. The PPIs that are activated more slowly, such as pantoprazole and tenatoprazole, react with the CYS at position 822, which is deep within the sixth transmembrane segment of the ATPase. As reducing agents have a difficult time accessing CYS822, the disulfide bonds formed by the PPI. The above-mentioned acidic activation of the proton pump requires that the PPI reach the acidic site of action within the parietal cell when the proton pump is operating. The PPI's pharmacokinetics, which start with inactive form absorption, distribution, metabolism by cytochrome P450 (CYP) 2C19 or CYP3A4, and elimination, dictate the concentration at the site of action. Accurate estimation of these rates is complicated by the fact that genetic and developmental factors both influence metabolic rate.[7]

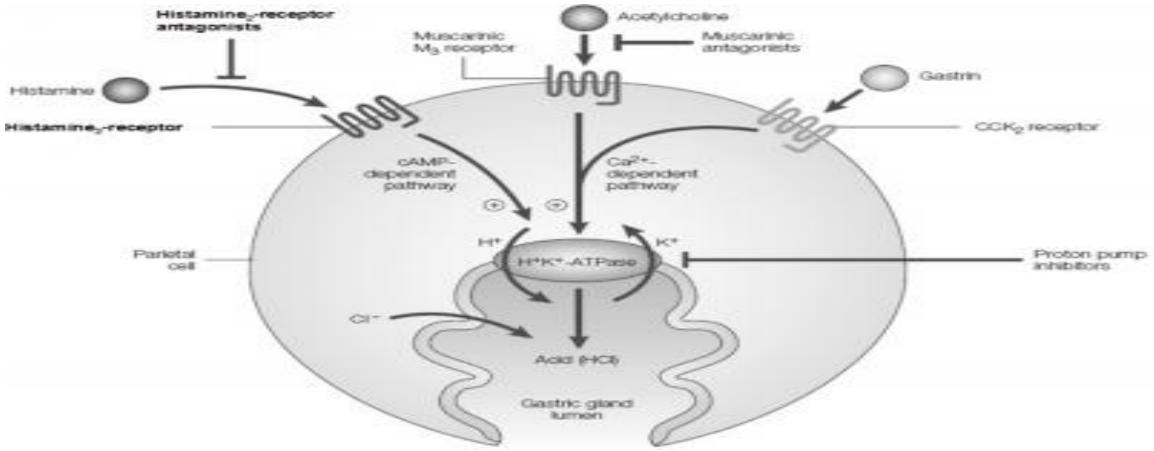

Fig: Mechanism of action (PPI)

1.4.Beneficial uses of proton pump inhibitors:

Proton pump inhibitors (PPIs) are commonly used for treating acid-related disorders, such as gastroesophageal reflux disease and secondary prevention of aspirin/NSAID-induced ulcers. They potently reduce gastric acid secretion[8].They have been demonstrated to have therapeutic benefits beyond treating disorders caused by stomach acid. PPIs may have anti-inflammatory and antioxidant properties. PPIs have also been linked to antifibrotic and antiproliferative qualities.[9]

1.5.Adverse effects of proton pump inhibitors:

☐Gastric polyps:

The growth of fundic gland polyps has been linked to PPI long-term treatment. Patients with familial adenomatous polyposis (FAP) frequently develop these polyps, though they can also appear randomly. Histologically, they are made up of dilated glands that are localized in the stomach's body and fundus and are surrounded by healthy oxyntic mucosa cells. They have occurred in connection with PPI use for more than a year. [10]

☐Gastric cancer:

At several levels, the topic of the danger of stomach cancer in individuals receiving long-term PPI therapy has been discussed. The debate began with hypergastrinemia. In addition, patients with pernicious anemia have been shown to have a higher chance of developing gastric adenocarcinoma. Gastrin has a trophic impact on the gastrointestinal mucosa and has been linked to gastric and colonic carcinomas. It is unclear if patients with pernicious anemia have a higher chance of developing stomach cancer.[10]

☐Bone fracture:

Prior to the development of PPI, hypochlorhydria was thought to affect the gut's ability to absorb calcium. Without a suitable acid environment, calcium may be retained in food, reducing its absorption. This could lead

increased parathyroid hormone levels, which could accelerate bone resorption, skeletal turnover, and finally increased risk of bone fractures. HCl is thought to be an important mediator of calcium absorption in the small intestine .[10]

□Infections outside of the digestive system:

Except for H. Pylori, the stomach is typically clear of microorganisms. A bacterial overgrowth in the upper gastrointestinal tract and microbial colonization of the stomach may result with acid suppression medication. This condition may make it easier for people who are being mechanically ventilated to develop pneumonia. A sizable cohort research was carried out by Laheij et al. to assess how PPI use affected the emergence of community-acquired pneumonia. Few cases of pneumonia were identified.[10]

□Lack of vitamin B12 and hypomagnesaemia:

Gastric acid and pepsin are needed for the first stage of cobalamin absorption, which involves the vitamin's release from food proteins. The R-protein that is released by the parietal and salivary cells binds to free cobalamin at that point. The R-protein-cobalamin complexes are broken down by pancreatic enzymes in the duodenum, allowing the intrinsic factor released by gastric parietal cells to bind to free cobalamin. The cobalamin-intrinsic factor complex is then taken up by the ileum.[10]

CHAPTER

02

LITERATURE REVIEW

2.1.Fossmark R, Martinsen TC, Waldum HL. Adverse Effects of Proton Pump Inhibitors-Evidence and Plausibility. Int J Mol Sci. 2019 Oct 21;20(20):5203. doi: 10.3390/ijms20205203. PMID: 31640115; PMCID: PMC6829383.

Proton pump inhibitors (PPIs) lessen acid output by permanently inhibiting the stomach H+K+ATPase in parietal cells. Although PPIs have a brief plasma half-life, they bind to proton pumps irreversibly, so new proton pumps must be produced before acid secretion can be resumed. PPIs have been used for a long time to treat gastrointestinal conditions that are caused by excess acid, such as peptic ulcer disease and gastroesophageal reflux disease (GERD).PPIs' immediate effects are fairly well understood, but long-term profound acid inhibition's effects are less well understood since epidemiological studies' observation periods are sometimes too brief to uncover disorders that take years to manifest. The possibility of unmeasured confounding factors being present by default is another issue with epidemiologic investigations. As a result, we have placed an emphasis on crucial translational research as well as mechanistic investigations that could support findings in epidemiological studies. More importantly, compared to the relatively large, but brief, epidemiological studies of patients using PPIs, mechanistic investigations of long-term PPI usage may be more important. This is crucial when researching chronic diseases like cancer that have a long latency period.

2.2.Thong BKS, Ima-Nirwana S, Chin KY. Proton Pump Inhibitors and Fracture Risk: A Review of Current Evidence and Mechanisms Involved. Int J Environ Res Public Health. 2019 May 5;16(9):1571. doi: 10.3390/ijerph16091571. PMID: 31060319; PMCID: PMC6540255.

Patients with gastroesophageal reflux disease are using proton pump inhibitors (PPIs) at a higher rate. PPIs and the risk of fracture, particularly hip fractures, have been linked in several studies, however the connection is still debatable. This review sought to examine the longitudinal studies on PPIs and fracture risk that have been published in the previous five years. It was also investigated how this relationship came to be. PPIs were generally shown to be positively linked with increased fracture risk across studies (n = 14), although some research found no significant association (n = 4). The two main factors that impact bone remodeling, mineral absorption, and muscular strength and raise the risk of fracture in PPI users are increased gastrin production and hypochlorhydria. In conclusion, there may be a connection between fracture and PPIs.

2.3.Cunha N, Machado AP. Proton pump inhibitors and the risk of severe adverse events - A cardiovascular bombshell? Rev Port Cardiol (Engl Ed).2018Oct;37(10):859863.English,Portuguese.doi:10.1016/j.repc.2017.10.012. Epub 2018 May 24. PMID: 29804887.

Given their efficiency and safety profile, which has up until now been viewed favorably, proton pump inhibitors are currently one of the most commonly prescribed pharmaceutical classes in industrialized countries. But in recent years, a number of articles that link prolonged use of these medications with a variety of negative side effects have been published, raising concerns about their safety. Cardiovascular events are more likely, which is one of the negative impacts mentioned.

Because proton pump inhibitors interfere with cytochrome P450 2C19 and cause clopidogrel to be converted to its active metabolite, this link was initially identified in patients who had experienced acute coronary syndrome. The usage of antiplatelet medications that do not rely on cytochrome P450 2C19 activation has also been linked to this association in more recent investigations. Inhibition of the physiological enzyme dimethylarginine dimethylaminohydrolase, which raises plasma concentrations of the latter enzyme and causes a decrease in nitric oxide levels, is the hypothesized mechanism. The authors of this article review the link between prolonged use of proton pump inhibitors and an increased risk of cardiovascular and cerebrovascular events in an effort to raise awareness among medical professionals about the potential side effects of these medications and urge the establishment of a moratorium on their continued use.

2.4.Lodato, F., Azzaroli, F., Turco, L., Mazzella, N., Buonfiglioli, F., Zoli, M., & Mazzella, G. (2010). Adverse effects of proton pump inhibitors. Best practice & research Clinical gastroenterology, 24(2), 193-201.

Acid-related diseases are treated mostly with proton pump inhibitors (PPI), which are very effective medications. Concern has been expressed in recent years about their excessive use in benign conditions such gastroesophageal reflux disease. The other presumed adverse consequences, with the exception of the example of Helicobacter Pylori (H. Pylori) positive patients, in whom long-term acid suppression resulted in the development of corpus prominent atrophic gastritis, a precursor to cancer; have never been proven in prospective investigations. Instead of worrying about PPI side effects, the focus should shift to the proper prescription of PPI.In fact, based on their safety profile, PPI are frequently administered in clinical practice to individuals who do not already have a specific acid-related condition.

2.5.In fact, based on their safety profile, PPI are frequently administered in clinical practice to individuals who do not already have a specific acid-related condition. The main unfavorable effects of long-term PPI use are the main topic of this review.

Proton pump inhibitors (PPIs) have been used widely for about 20 years now, raising concerns among doctors and the general public that these benefits may come with a number of hazards that, up until recently, had not received much attention. A variety of adverse drug reactions (ADRs) have been identified as likely or probably linked with PPI therapy, mostly on the basis of observational research.Concerns regarding the dangers of bone fractures, higher susceptibility to infections, and consequences of altered stomach function are the most prevalent connections of ADRs with long-term PPI medication.

CHAPTER

03

GoAL oF MY study

The aim of my study is :

√To see which ages people are mostly using PPI?

√To find out ,Is everyone knowing about rational uses of PPI?

√To see which areas people are well known about PPI?

√To find which medicine is nowadays popular as PPI?

√Finally, evaluate if everybody knows the side effects of PPI.

√Creation of awareness among the people.

CHAPTER

04

METHoDoLogY

Methodology:

4.1.Study Design:

The examination starts with a study, which has 18 appropriate questions. There are about 117 people that are interested in this. I physically collected data from the city & rural area. I compile all of their evaluations into one survey and use them in my research. I want to learn what people think about proton pump inhibitors and evaluating Consciousness between Educated and Untaught people. Evaluating which ages people mostly take PPI. Finally, Creating a data Percentage of irrational uses PPI.

4.2.Inclusion Criteria:

People who took PPI met the inclusion criteria.

4.3.Exclusion Criteria:

People who refused to take part in the trial were not included.

4.4.Survey questionnaires:

- Age
- Gender
- Location
- Do you know about proton pump inhibitors?
- Are you taking PPI?
- At what time are you taking PPI?
- For what purpose are you taking PPI?
- Are you taking PPI from a medicine shop?
- Are you taking rabeprazole or pantoprazole?
- If you are taking Rabeprazole or Pantoprazole, are you taking this by
- How much dosage do you take regularly?
- Are you taking two or more proton pump inhibitors at once ?
- Do you have any idea about the proper dosage of these medicines?
- Which medicine are you taking as normally as PPI?
- How long have you been taking PPI?
- After taking PPI, are you facing any problems like
- Do you have any idea about the adverse effects of PPI?
- Do you know which PPIs are safest during pregnancy?

CHAPTER

05

RESULT AND DISCUSSION

5.1.Age:

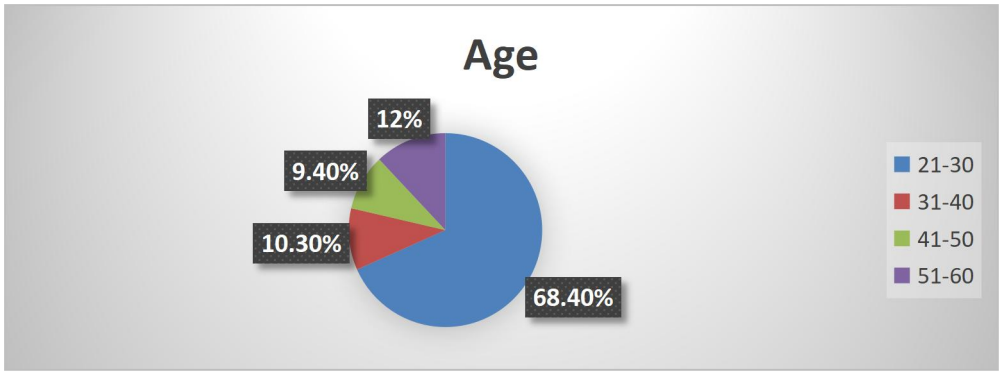

Fig1: Age

Discussion: A total of 117 people participate in this study. Among them were people aged 21 to 60 years. Here people aged 21-30 years were the most with a percentage of 68.40% & the lowest is 41-50 years were 9.40%.Among other patients, patients aged 31-40 years were 10.30% & 51-60 years were 12%.

5.2.Gender:

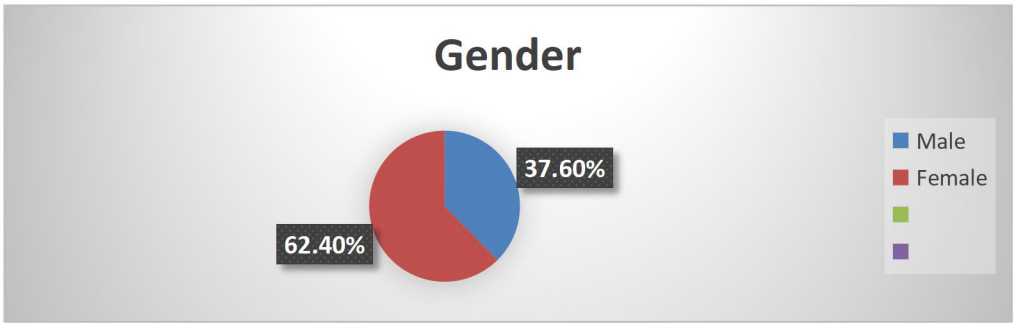

Fig4:Gender

Discussion: According to this survey, 62.40% female & 37.60% male are participated.

5.3.Location :

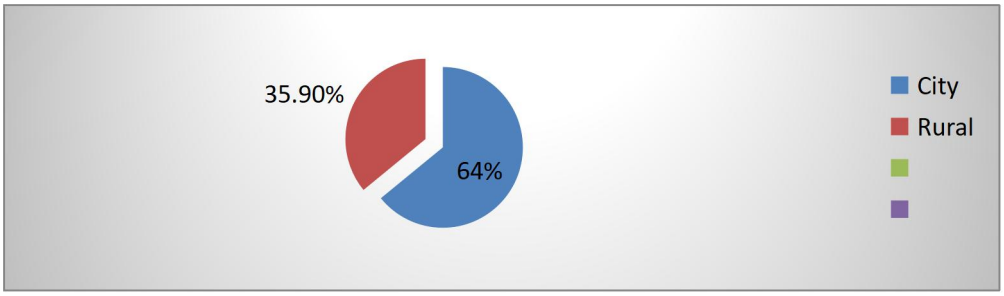

Fig5. Location

Discussion: Among all the people, 64% people from rural areas & 35.09% are from city areas participated in this study.

5.4.Do you know about proton pump inhibitors:

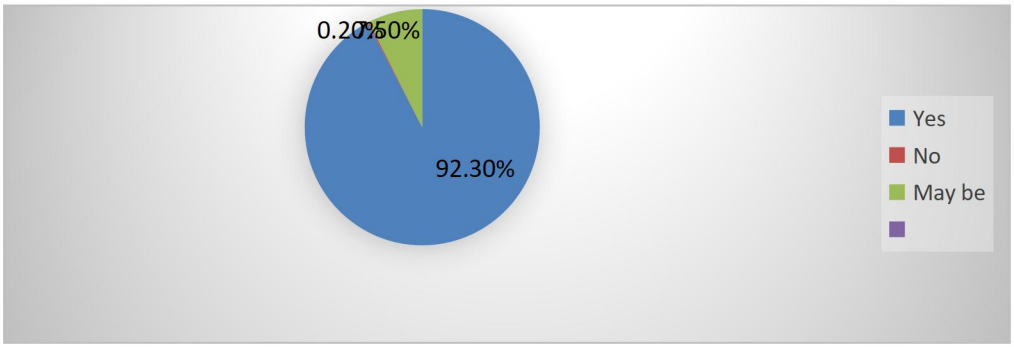

Fig6: Do you know about proton pump inhibitors

Discussion: From this report, it was identified that 92.3% of people know about PPI & up to 10% people are confused & they are not sure about PPI. But only less than 0.1% of people have no idea about PPI.

5.5.Are you taking PPI?

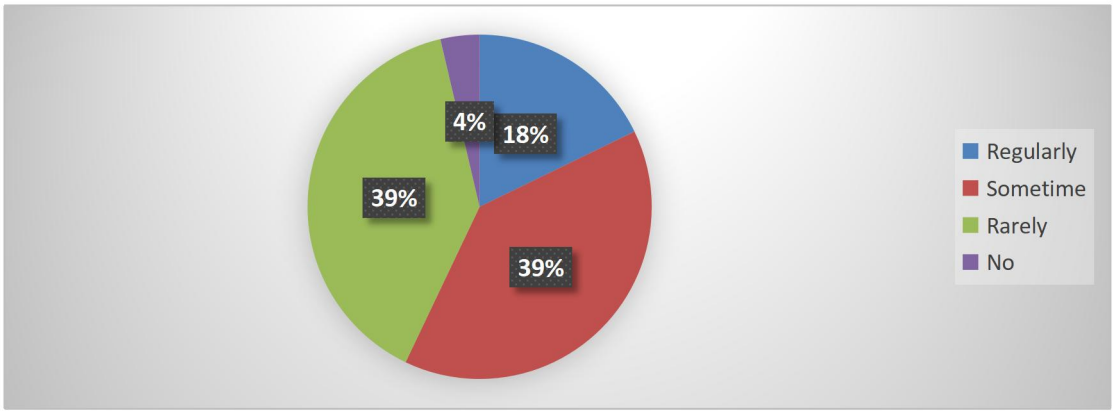

Fig7: Are you taking PPI

Discussion: Here, we see that maximum people are sometimes taking PPI. These percentage rates are 54.7% & only 5.1% people are not taking PPI. Besides, 15.4% people are taking PPI rarely & 54.7% taking it regularly.

5.6.At what time are you taking PPI?

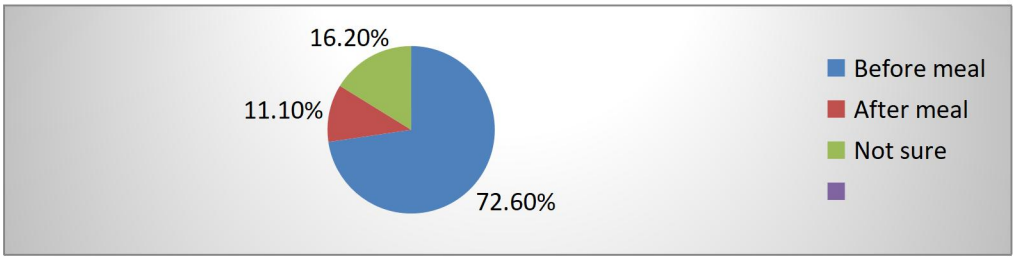

Fig8: At what time are you taking PPI

Discussion: According to these reports, most people are taking PPI before their meal. The percentage of these people is 73%. But some people are not sure which time they should take PPI. These percentage rate 16% & 11% people are taking PPI after their meal time.

5.7. For what purpose are you taking PPI?

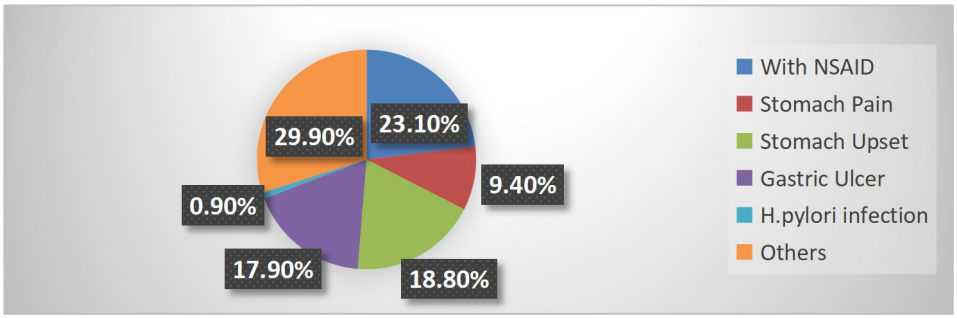

Fig10: For what purpose are you taking PPI

Discussion: The percentage rate of taking PPI with NSAID 23.01%. People taking PPI for the purpose of stomach pain & upset. These rates are 9.40% & 18.80%. For the purposes of Gastric ulcer & H.pylori infection people are also taking PPI. Only 0.9%of people are taking PPI for the reason of H.pylori infection. Besides, people take PPI for different purposes that are not specific. And these other purposes of taking PPI rate is 29.90%.

5.8.Are you taking PPI from a medicine shop:

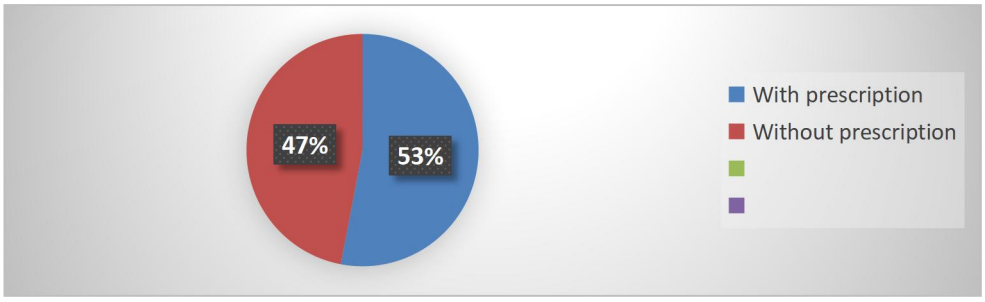

Fig11: Are you taking PPI form a medicine shop

Discussion: Most people are taking PPI with a prescription. These rates of people are 53%. And 47% of people are taking PPI without Prescription.

5.9. Are you taking rabeprazole or pantoprazole?

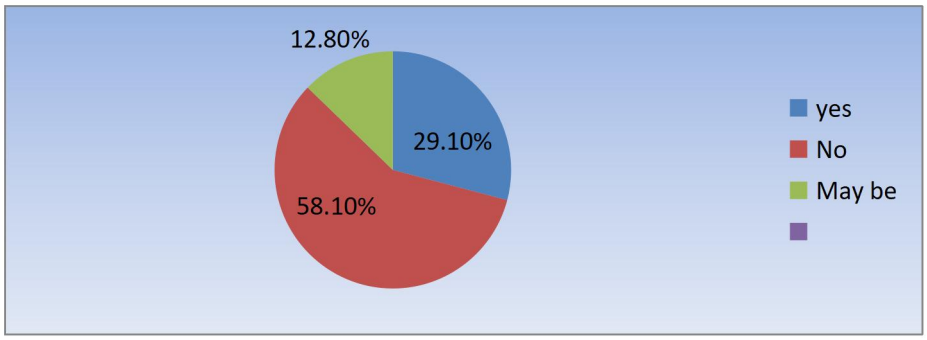

Fig12: Are you taking rabeprazole or pantoprazole

Discussion: Here, Among all people maximum are not taking pantoprazole or rabeprazole .These percentage rate are 58.10%.Besides, 29.10% are not taking rabeprazole or pantoprazole. And 12.80% of people are not sure if they are taking it or not.

5.10. If you taking rabeprazole & pantoprazole, are you taking this by:

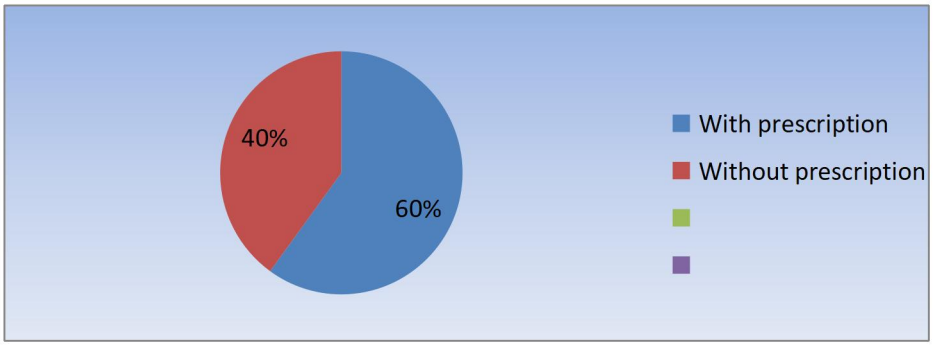

Fig13: If you are taking rabeprazole or pantoprazole,are you taking these by

Discussion: This graph described 60% people are taking these drugs with prescription and 40% people are taking without prescription.

5.11. How much dosage do you take regularly :

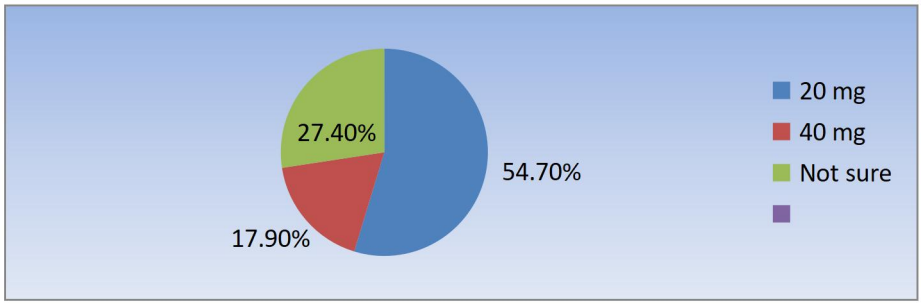

Fig14: How much dosage do you take regularly

Discussion: From this chart, we see that most people are taking 20 mg per day. Other-sides,17.90% are taking 40 mg. And 27.40% are not sure how much dosage they are taking or not.

5.12. Are you taking two or more proton pump inhibitors at once :

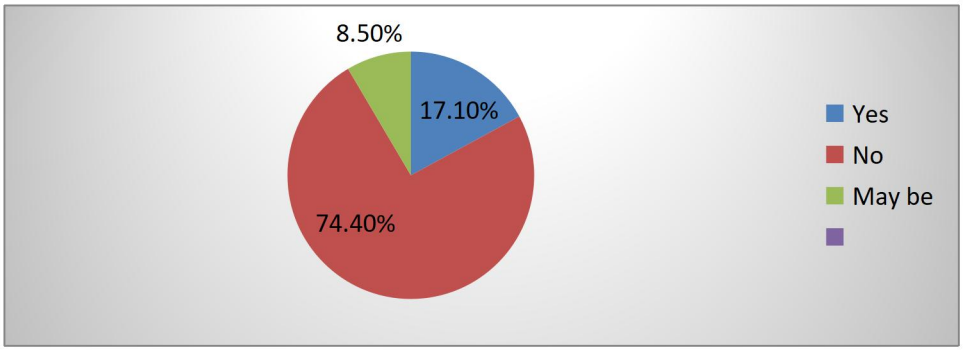

Fig15:Are you taking two or more proton pump inhibitors at once

Discussion: This graph shows 74.40% people are not taking PPI twice or more at one time. 17.10% of people are taking twice or more dosages at one time. And 8.50% of people are not sure.

5.13.Do you have any idea about the proper dosage of these medicines :

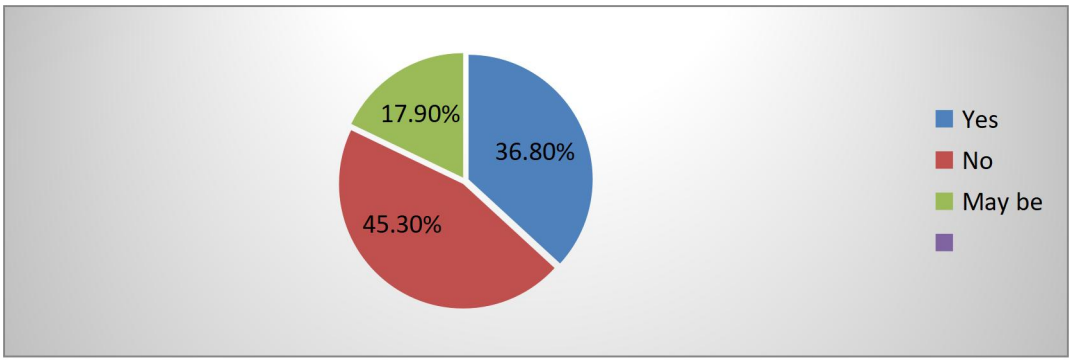

Fig16:Do you have any idea about the proper dosage of these medicines

Discussion: Most people have no idea about proper dosage of PPI. 36.80% of people have idea about proper dosage of PPI. Besides, 17.90% of people are confused about these topics.

5.14.Which medicine are you taking as normally as PPI?

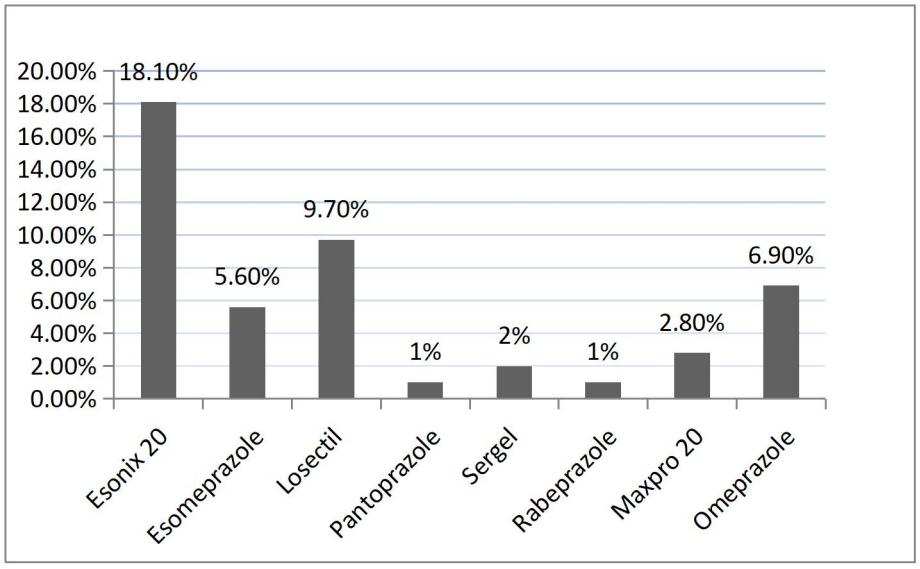

Fig17: Which medicine are you taking as normally as PPI

Discussion: Most people are taking Esonix 20 mg. This percentage rate is 18.10%. And the lowest number of people are taking Pantoprazole & Rabeprazole.These rate of percentage 1%. Some people are taking Esomeprazole.They do not mention brand name.These rates of percentage are 5.60%.Besides,9.70% taking losectil,6.90% taking omeprazole,2.80% percentage people taking Maxpro 20 mg.

5.15.How long have you been taking PPI?

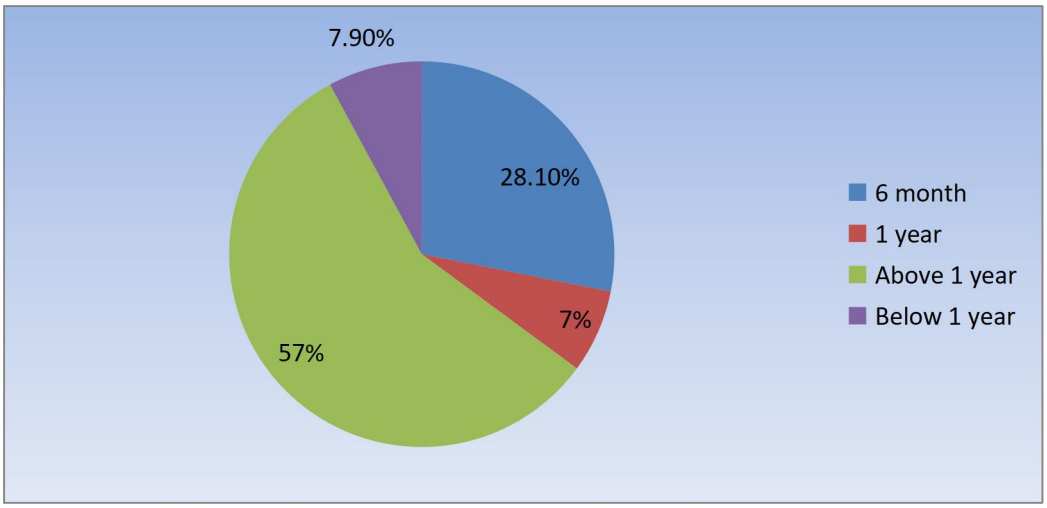

Fig18:How long have you been taking PPI

Discussion: Here,I identified that most people take PPI above 1 year. This percentage level is 57%.Besides,28.1% of people are taking PPI probably 6 months of time. 7% people PPI taking duration of time 1 year & 7.9% taking time above than 1 year.

5.16.After taking PPI, are you facing any Problem like

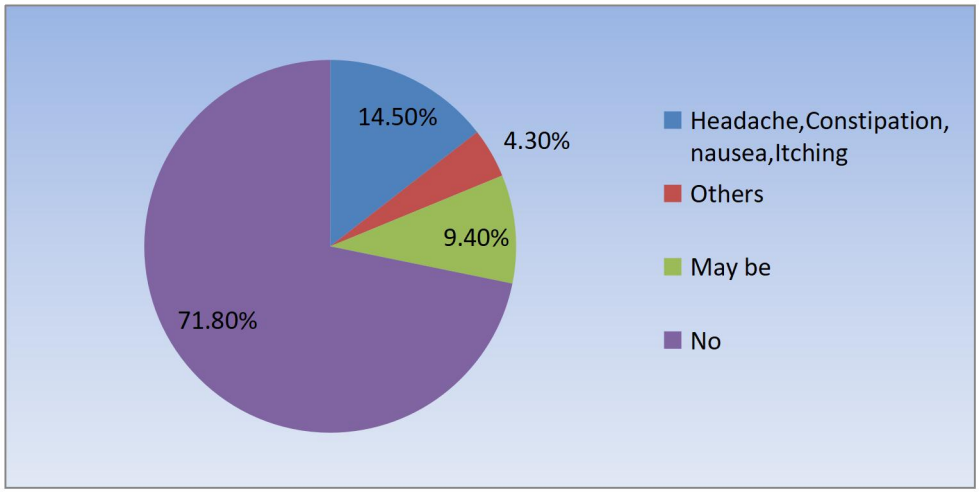

Fig19:After taking PPI,are you facing any problem like

Discussion: Among 118 people surveyed most of them are not facing any problem after taking PPI. But some people are facing some problems like constipation, nausea, itching & headache. The rate is 14.50% of people.Besides, 4.30 % people are facing some unidentified other problem & some are confused about facing the problem or not.

5.17.Do you have any idea about the adverse effects of PPI?

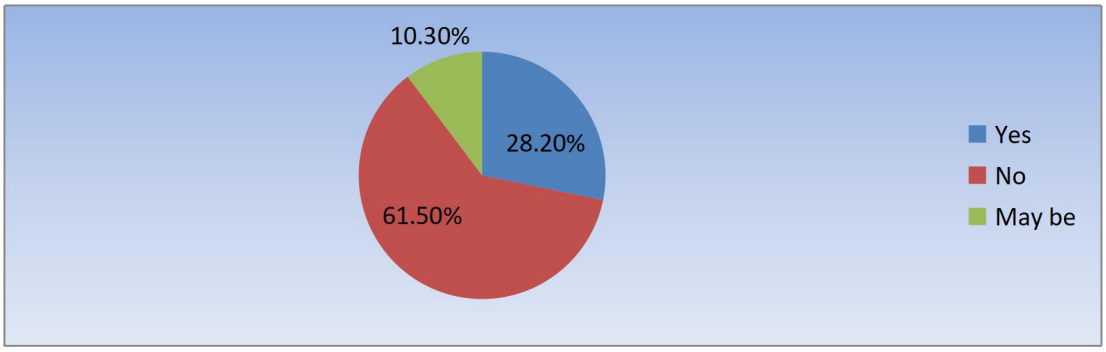

Fig20: Do you have any idea about adverse effects of PPI

Discussion: Most people are unconscious about the adverse effects of PPI. About 61.5% of people are not aware about adverse effects of PPI. 28.2% of people have ideas about adverse effects of PPI. And 10.3% of people are confused about these topics.

5.18. Do you know which PPIs are safest during pregnancy :

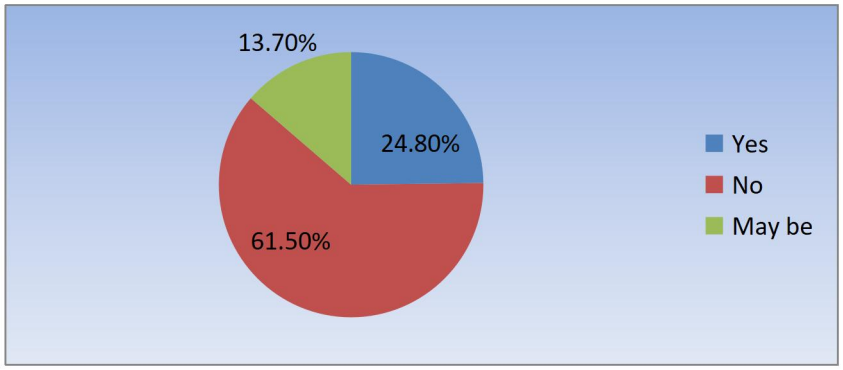

Fig21: Do you know which PPIs are safest during pregnancy

Discussion: Most people have no idea about which PPI is safest in pregnancy. The rate of percentage is 61.50%. 24.80% of people have an idea about which PPI is safest in pregnancy. And 13.70% of people are confused and they are not sure.

CHAPTER

06

CoNCLUsIon

Conclusion:

Though current conditions of adverse effects of proton pump inhibitors are not severe, day by day these problems are increasing. These problems are mainly increasing because of irrational uses of these drugs. And the irrational uses of these drugs are increasing for not only public unawareness but also for easy availability. Campaigns for general people education and counseling, in my opinion, have a beneficial, long-lasting effect on the level of awareness. From the research, it can be partially understood that the current status of adverse effects of proton pump inhibitors in Bangladesh and how much they know about proton pump inhibitors and the number of persons who are affected by adverse effects of proton pump inhibitors in Bangladesh can be obtained through this research-work. From the point of view of our country, it can be seen that there is very little idea about proton pump inhibitors and its adverse effects. They do not have much idea about proper dosage of proton pump inhibitors. There are many people who do not know the basic concept of proton pump inhibitors but they are suffering from this problem and they are taking irrational doses of PPI. The survey shows that the number of females is more than male.Doctors in the country are also to blame for this lack of awareness about proper dosage of proton pump inhibitors. Because the doctors of the country are prescribing medicine but without creating any awareness among them, without giving any idea about the disease. They should provide proper information to the patients about his medicine . Through this research work, it has been possible to create some awareness among the peoples. While taking information from the people, the people have some idea about the information about uses of proton pump inhibitors, which will lead to their future while they are taking proton pump inhibitors. There should be more research about proton pump inhibitors which will create more awareness among the people and people of our country about adverse effects of proton pump inhibitors. If more awareness is created, it will be possible to treat irrational uses of proton pump inhibitors. So that it will be possible to reduce the adverse effects of proton pump inhibitors.

CHAPTER

07

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