WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 13, Issue 21, 712-722. Research Article ISSN 2277–7105

A PROSPECTIVE STUDY TO ASSESS DRUG UTILISATION OF PROTON PUMP INHIBITORS AMONG PATIENTS IN A TERTIARY CARE HOSPITAL

Satish S.[1*], Sayanth S.[2*] and Ramakrishna Shabaraya A.[3]

[1]Department of Pharmacy Practice, Srinivas College of Pharmacy, Manglore-574143.

Article Received on
03 September 2024,

Revised on 25 Sept. 2024,
Accepted on 15 October 2024

DOI: 10.20959/wjpr202421-34223

***Corresponding Author**
Sayanth S.
Department of Pharmacy Practice, Srinivas College of Pharmacy, Manglore-574143.

ABSTRACT

Proton-pump inhibitors (PPIs) cause a profound and prolonged reduction of stomach acid production used to treat different acid related gastrointestinal disorders. However, concerns about PPI interaction, overprescribing of PPIs and side effects, have increased in recent years. The objectives of this study were to assess the PPI utilization by implementing Drug utilization Research. Drug utilization research is a multidisciplinary activity that is increasingly recognized as an important part of quality assurance wherever medications are used. Monitoring factors like DDD (Define daily dose), DDC (Define daily cost) and DUI (Drug utilization index) has been used. Ethical clearance was obtained, and data were collected regarding the PPI utilization over a period of 6 months at tertiary care hospital. Individual aged≥18 years with at least one dispensing PPIs were identified as PPI users and included in the study. Data were collected using data forms from patient medical records and analyzed using Microsoft Excel, Student T Test. The results revealed a PPI prescribing trend, allowing us to conduct drug utilization study. A DUI result of less than one indicates that the drug was administered appropriately. Apart from Rabeprazole (0.53) all PPI's DUI values were more than 1, indicating that Rabeprazole was only given reasonably among research participants. The DDD value was determined to be highest in Pantoprazole and lowest in Lansoprazole. According to pharmacoeconomic analysis, DDC value was high for Omeprazole and low for Pantoprazole, resulting in increased use of it among the study population. To conclude with keeping in consideration the aim and objective, this study provided an insight into drug utilization research of Proton pump inhibitors in a tertiary care hospital. The data pattern of drug

utilization was largely comparable to other studies conducted. It has been found the Proton pump inhibitors which is commonly used in heath sector has been prescribed irrationally which leads to increase in risk of adverse effects. Efforts should be made to limit PPI treatments to appropriate indications and ensure the choice of suitable PPIs promoting rational use.

KEYWORDS: *PPI, DUI, DDD, DDC Rational.*

INTRODUCTION

Proton-pump inhibitors (**PPIs**) are a class of medications that cause a profound and prolonged reduction of stomach acid production. They do so by irreversibly inhibiting the stomach's proton pump.[7] They are the most potent inhibitors of acid secretion available. Proton pump inhibitors are class of drugs which are used to treat different acid related gastrointestinal disorders acid reflux or gastroesophageal reflux disease (GERD), PUD, GI bleeding, H Pyloric infection.[7] The primary mechanism of action of proton pump inhibitorsis to act on the gastric parietal cells to lower down the stomach's acidity. Gastric parietal cells are found in the gastric lining and are responsible for secreting hydrochloric acid.

Proton pump inhibitors (PPIs) are currently favored over other gastric acid suppressive medications because of their high efficacy, good tolerance, safety profile, and affordable costs with both original and generic preparations.[3] Thus, they have been adopted worldwideamong primary care providers and their presence is ubiquitous within the armamentarium of the modern gastroenterologist.[2] PPIs as a class of medication also have a high prevalenceof being prescribed for poorly defined reasons or for conditions where PPIs have not beenshown to be beneficial.[4]

Hence, there is a requirement for Drug use studies have proven critical in the prescribing pattern of proton pump inhibitors. Drug utilization research is a multidisciplinary activity that is increasingly recognized as an important part of quality assurance wherever medications are used.[11] It will be evaluated using prescription numbers, proportions, and economic indicators. The analysis was conducted using monitoring criteria such as DDD (Define daily dosage), DDC (Define daily cost), and DUI (Drug Utilization Index). The WHO defines DDD as an average maintenance dose for drugs that are not indicated but provide a standardized unit for comparative reasons.[11]

The defined daily cost (DDC) value which is a pharmacoeconomic indicator will be calculated by the total sales of PPIs divided by the DDD value. DUI (Drug utilization Index) is another parameter to evaluate the rationality of PPI use, indication has been done with margin of 1, DUI value exceeding 1 indicates that the Prescribed drug is not rational which emphasize need to focus on the prescribing patten of PPI.[1] The defined daily cost (DDC) value, a Pharmacoeconomic measure, is determined by dividing total PPI sales by the DDD value. DUI (Drug Utilization Index) is another parameter used to assess the rationality of PPI usage.[1] Indication has been done with a margin of one; a DUI value greater than one shows that the prescribed drug is not rational, emphasizing the need to focus on the prescription pattern of PPI.[1]

METHODOLOGY

MATERIALS AND METHOD

- **Study design:** Prospective study and interventional study will be carried out to assess proton pump inhibitor utilization and analysis among in-patients in a tertiary care hospital. Individual aged 18 years or above in in-patient service with at least one dispensing for PPIs were identified as PPI users and were included in the study. Data will be collected from samples using convenient sampling method between January- June 2023.
- **Study site**: Srinivas Institute of Medical Science & Research Centre, Mukka
- **Study Duration**: 6 months.
- **Sample Size**: 171[4]
- **Ethical Clearance**: Ethical clearance will be obtained from the Institutional **Ethics Committee**: [IEC] of Srinivas Institute of Medical science and Research Centre [SIMS & RC], Mangalore.
- **Inclusion Criteria**

✓ Individuals aged 18 years or above

✓ New user (patient not on PPI past 1year)

✓ Patients prescribed with oral PPI

- **Exclusion Criteria**

✓ Patient with parenteral PPI

Source of Data Collection:

Patient and Medical records

The study period is divided into 3 phases.

PHASE I

(A) Preparation for the study

1) Preparation of Patient's Data Collection form: Data collection form includes the patient's demographic details and the list of PPI medicines that they take and duration of the PPI and even the Indication for which the PPI was been prescribed.

(B) Institutional Ethics committee approval: Ethical Clearance was obtained from the Institutional Ethics Committee (IEC) of Srinivas Institute of Medical Science and Research Centre (SIMS & RC), Mangalore.

PHASE II

- **Patient selection**: The patients for the study was selected based on the inclusion and exclusion criteria.
- **Obtaining inform consent**: During the hospital visit, we explained the patients about the study and obtained the patient consent for collecting data. The data was collected by personal discussion with the patient.
- Based on the data collected we categorized the patients

PHASE III

The data collected was analyzed using Microsoft Excel

Data Analysis: Statistical Analysis involves collecting and scrutinizing every data sample in a set of items from which samples can be drawn and a suitable statistical test will be applied to analyze the data. ✓ The collected data will be analyzed using Microsoft Excel.

RESULTS

1. PRESCRIBING PATTERN OF PROTON PUMP INHIBITOR (PPI) THERAPY

In the current study it was observed that Pantoprazole was the most widely prescribed PPI accounting for the 68.42% of the total PPI prescription (Male 42.6% and 57.3% Female) majority of them were seen in 18-60yr age group, followed by Rabeprazole (15.2) (Male 53.8% and 46.15% Female), Esomeprazole 8.18% (Male 57.145%), Omeprazole 7.01% (male 58.33) and Lansoprazole 1% (male 100%). Majority of the utilization of PPI were observed in 18-60yr (78%) age group compared to >60yr (22%) age group.

This data is essential for comprehending the utilization of diverse PPI medications in a tertiary care hospital. It enables the assessment of preferred PPI medications, examination of age-related prescription disparities, exploration of gender-based variations in treatment choices, identification of trends among new PPI users and their reasons for initiation, and customization of PPI therapy guidelines according to patient demographics. Ultimately, this data guides clinical decisions and enhances PPI usage at the hospital, offering valuable insights into treatment trends within this specific patient group.

Table 1: Prescribing Pattern of Proton Pump Inhibitor.

PPI	Overall(n=171) n (%)	18-60years (n=135)n (%)			>60 years (n=36)n (%)			New user	Males	Females
		M	F	Total	M	F	Total			
Pantoprazole	117(68.42)	57	35	92(78.63)	16	9	25(21.37)	42	24	18
Rabeprazole	26(15.2)	8	11	19(73.06)	6	1	7(26.94)	9	5	4
Esomeprazole	14(8.18)	6	7	13(92.85)	1	0	1(7.15)	6	2	4
Omeprazole	12(7.01)	5	5	10(83.33)	0	2	2(16.67)	2	0	2
Lansoprazole	2(1.16)	0	1	1(50)	0	1	1(50)	0	0	0

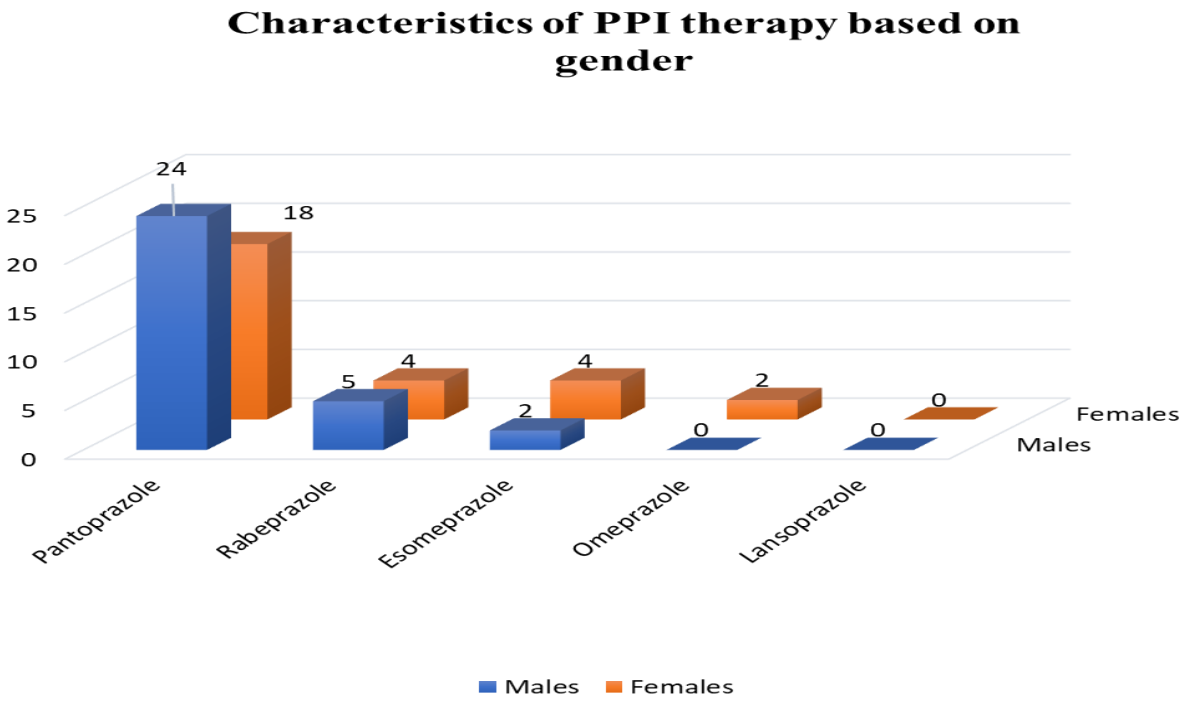

Fig 1: Characteristic Of PPI therapy based on gender.

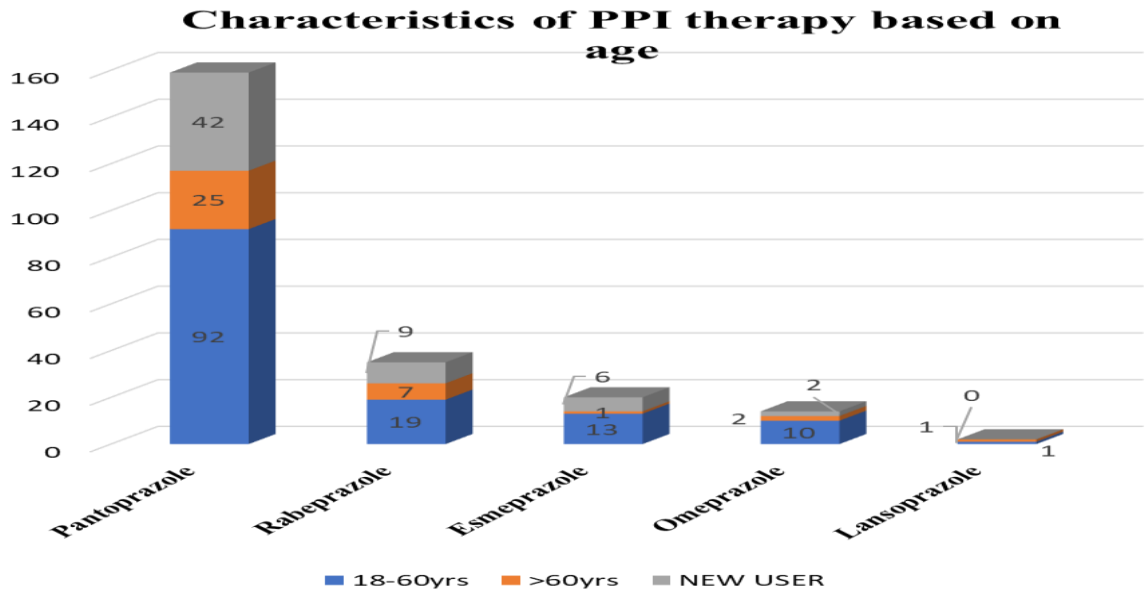

Fig. 2: Characteristic of PPI therapy based on age.

2. DEFINE DAILY DOSE [DDD]

The Define daily dosage of proton pump inhibitors among study participants from a tertiary care hospital is summarized in Table no.2. The calculation of DDD involves dividing the total prescription dosage of proton pump inhibitors by the standard dose. After analyzing the data, it was found that Lansoprazole had the lowest DDD value and Pantoprazole had the highest DDD value.

Table No. 2: Define Daily Dose of Proton Pump Inhibitors among study participants.

PROTON PUMP INHIBITORS	STANDARD DOSE (mg)	MEDICATION DAYS	TOTAL DOSES (mg)	DDD (mg)
PANTOPRAZOLE	40	3532	2,25,702	5642.5
RABEPRAZOLE	20	949	35,760	1788
OMEPRAZOLE	30	493	25,140	838
ESOMEPRAZOLE	20	387	14,720	736
LANSOPRAZOLE	30	213	12,780	426

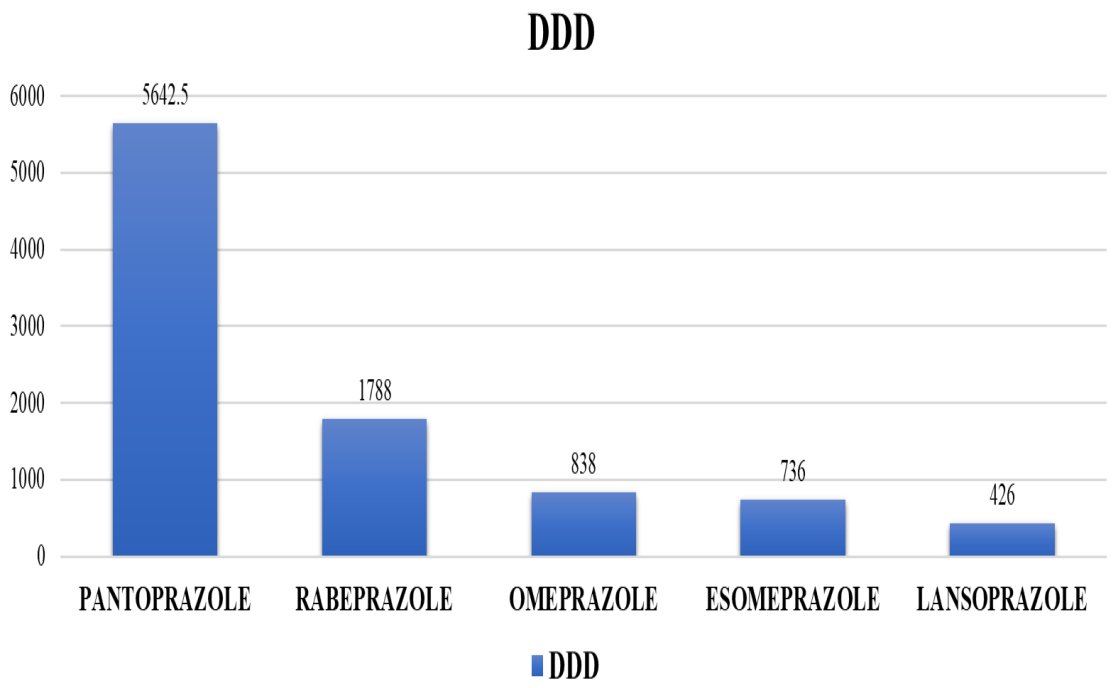

Fig. 3: Define Daily Dose of Proton Pump Inhibitors among study participants.

3. DEFINE DAILY COST [DDC]

The Define daily cost of proton pump inhibitors among study participants at a tertiary care hospital has been summarized in Table no3. Total sales are divided by the DDD value to get DDC. Multiplying the cost per PPI unit by the total number of PPI units yields the total sales. Following analysis, it was shown that Pantoprazole had the lowest DDC and Omeprazole had the highest.

PROTON PUMP INHIBITORS	DDD	TOTAL SALES	DDC
PANTOPRAZOLE	5642.5	1,14,800	20.34
RABEPRAZOLE	1788	44,308	24.7
OMEPRAZOLE	736	66,360	75.6
ESOMEPRAZOLE	838	63.360	90.16
LANSOPRAZOLE	426	26,700	62.67

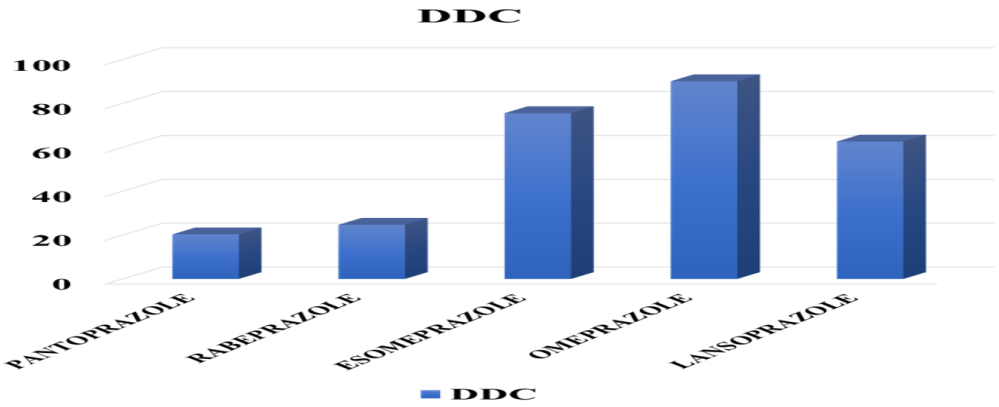

Fig. 4: Define Daily Cost of Proton Pump Inhibitors among study participants.

4. DRUG UTILISATION INDEX (DUI)

Overview of the Drug Utilization Index for proton pump inhibitors among research participants from a tertiary care institution has been provided in Table no.4. DUI value gives information on whether a medicine is prescribed rationally. A DUI value of less than 1 suggests that the medication is prescribed rationally. Apart from Rabeprazole, all DUI values were found to be more than 1, after analysis. It demonstrates that among study participants Rabeprazole was only prescribed rationally.

Table No. 4: Drug Utilization Index of Proton Pump Inhibitors among study participants.

PROTON PUMP INHIBITORS	MEDICATION DAYS	DDD	DUI
PANTOPRAZOLE	3532	5642.5	1.597
RABEPRAZOLE	949	1788	0.53
OMEPRAZOLE	493	736	1.69
ESOMEPRAZOLE	387	838	1.90
LANSOPRAZOLE	213	426	1.99

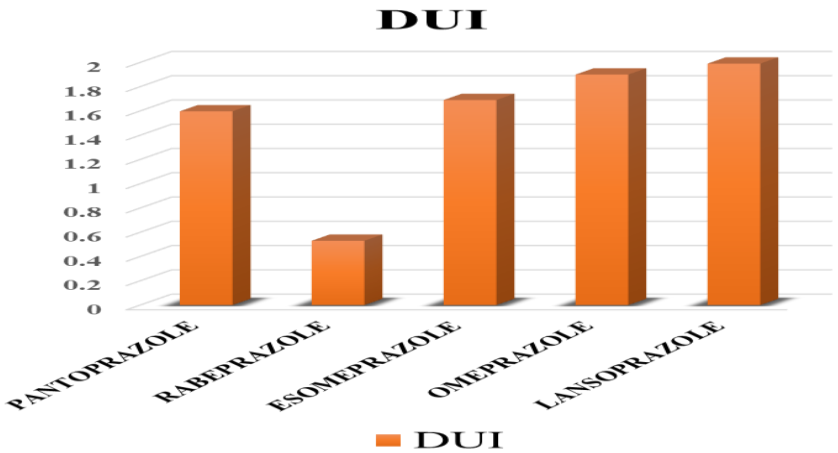

Fig. 5: Drug Utilization Index of Proton Pump Inhibitors among study participants.

DISCUSSION

PPIs are among the most frequently prescribed drugs worldwide, and their overuse has beenon the rise in recent years. According to a study from the USA, in 2017, PPIs were prescribedin moderate number of outpatient visits, but this number increased in 2019.[8] The current study provides valuable insights into the utilization patterns of PPI users., the present study revealed a high prevalence of PPI utilization among male patients particularly those in middle age. This finding contradicts the results of the study by Hoteit M *et al.*, where utilization of PPI was observed more in Females.[9]

The current study also explored the specific proton pump inhibitors (PPIs) prescribed to patients. The results indicated that Pantoprazole had the highest prescription rate among all PPIs, making up a significant portion of the total PPI prescriptions. Most of these prescriptions were within the 18-60-year age range Which aligned with the findings of Haroon M *et al.*[3] Following closely behind Pantoprazole was Rabeprazole, with a lower prescription rate compared to Pantoprazole, and it was followed by Esomeprazole, Omeprazole, and Lansoprazole in that order.

The majority of PPI usage was observed in the 18-60-year age group, in contrast to the >60-year age group (Due to less percentage of participants). Despite numerous guidelines and extensive published reports highlighting the importance of appropriate use of PPIs and the potential disadvantages of inappropriate usage, the inappropriate prescribing of PPIs has persisted in clinical practice. For instance, Giannini *et al.*,[12] reported that PPIs were inappropriately prescribed for approximately high proportion of outpatients, and an even higher rate of inappropriate PPI use was observed in patients by the findings Thomas Y *et al.*[11]

Drug utilization research was assessed using the prescription number, proportional and economic indicators. The study revealed that the assumed average dose (DDD) recommended was highest for Pantoprazole, this observation aligns with the findings of etal. Lowest DDD values was observed in Lansoprazole which contradicted the findings of Liu y *et al.*[1] where Esomeprazole has the lowest value.

When considering cost-effective prescribing, the DDC results showed that Omeprazole had the highest cost, while Pantoprazole had the lowest. This implies that patients using Omeprazole spend more on PPI utilization compared to other PPIs. However, the lower DDC

value of Pantoprazole indicates that it is more affordable but also potentially contributes to a higher frequency of overutilization compared to other PPIs.[6]

Rationality of Proton Pump inhibitors was assessed in terms of DUI (Drug Utilization Research). A DUI value exceeding 1 suggests the presence of inappropriate and irrational usage. From the study it was observed that only DUI value of Rabeprazole (0.53) was less than 1, remaining all forms of PPI has the DUI value exceeding 1. Which point outs that among the PPI's only Rabeprazole is Prescribed rationally in current study. Highest value of DUI (Higher irrationality) was observed in Lansoprazole. These findings contradict the results of Liu y *et al* where Esomeprazole was found to be rationally prescribed among other PPI's.[1]

CONCLUSION

To conclude with keeping in consideration the aim and objective, this study provided an insight into drug utilization research of Proton pump inhibitors in a tertiary care hospital. The data pattern of drug utilization was largely comparable to other studies conducted. It has been found the Proton pump inhibitors which is commonly used in heath sector has been prescribed irrationally which leads to increase in risk of adverse effects. Efforts should be made to limit PPI treatments to appropriate indications and ensure the choice of suitable PPIs promoting rational use. The educational activities would be useful to address concerns of PPI indication, adverse effects, and novel indication. Healthcare practitioners should assess the risk and benefit while prescribing the PPIs to identify the actual need and

ACKNOWLEDGEMENTS

Authors would like to extend deepest gratitude to Srinivas College of Pharmacy and would like to extend our thanks and appreciation to the study participants for smooth completion.

REFERENCES

1. Liu Y, Zhu X, Li R, Zhang J, Zhang F. Proton pump inhibitor utilization and potentially inappropriate prescribing analysis: insights from a single-centred retrospective study. BMJ open., 2020; 10(11).
2. Strand DS, Kim D, Peura DA. 25 Years of Proton Pump Inhibitors: A Comprehensive Review, Gut Liver., 2017; 11: 27–37.
3. Haroon M, Yasin F, Gardezi SK, Adeeb F, Walker F. Inappropriate use of proton pump inhibitors among medical inpatients: a questionnaire-based observational study. JRSM

short reports, 2013; 4(8).

4. Batuwitage BT, Kingham JGC, Morgan NE. Inappropriate prescribing of proton pump inhibitors in primary care. Postgrad Med J., 2007; 83: 66–68.
5. Shaheen NJ, Hansen RA, Morgan DR, et al. The burden of gastrointestinal and liver diseases, 2006. Am J Gastroenterol., 2006; 101: 2128–2138.
6. Thomas L, Culley EJ, Gladowski P. Longitudinal analysis of the costs associated with inpatient initiation and subsequent outpatient continuation of proton pump inhibitor therapy for stress ulcer prophylaxis in a large managed care organization. J Manag Care Pharm., 2010; 16: 122–9.
7. Eusebi LH, Rabitti S, Artesiani ML, Gelli D, Montagnani M, Zagari RM, et al. Proton pump inhibitors: risks of long-term use. Journal of gastroenterology and hepatology, 2017; 32(7): 1295-302.
8. WHO Model List of Essential Medicines 2011. Available from: http://www.whqlibdoc.who.int/. (Last cited on 2012 Dec 30; Last access date: 2013 Dec31).
9. Hoteit M, Mattar E, Allaw R, Abou Rached A. Epidemiological study assessing the overuse of proton pump inhibitors in Lebanese population. Middle East Journal of Digestive Diseases., 2020; 12(4): 265.
10. Heidelbaugh JJ, Kim AH, Chang R, Walker PC. Overutilization of proton-pump inhibitors: what the clinician needs to know. Therapeutic advances in gastroenterology, 2012; 5(4): 219-32.
11. WHO Collaborating Centre for Drug Statistics Methodology. ATC/ DDD index. Available from: URL. http://www.whocc.no/atcddd/ 2005.
12. Giannini EG, Crespi M, Djahandideh A. Appropriateness of proton pump inhibitors treatment in clinical practice: prospective evaluation in outpatients and perspective assessment of drug optimization. Dig Liver Dis., 2020; 52: 862–8.