

## A PROSPECTIVE AND OBSERVATIONAL STUDY ON RATIONAL USE OF PROTON PUMP INHIBITORS AND THEIR ECONOMIC BURDEN

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### ABSTRACT

The study aimed to evaluate the rational use of proton pump inhibitors and their crucial economic impact. A prospective observational study was performed on 102 in-patient wards at tertiary hospital. The handling of inpatient prescriptions was carried out and assessed to determine the prescribing pattern associated with it. The case sheets of the patients were reviewed for PPIs prescription and relevant data was taken Out of 102 patients Pantoprazole was prescribed in 92.1% patients, Rabeprazole in 5.2% patients, Esomeprazole in 2.1% patients. Most commonly prescribed ppi in the study was pantoprazole. Moving to dose prescribed, out of 102 patients, 6 were prescribed with optimal dose of ppi and 96 patients were prescribed with higher dose of ppi. The PPI usage for off-label indication was identified as 34.3%, whereas as 16.6% were having indications. Further, the prevalence of Non-Indicated Prescriptions of PPIs was determined to be 49.01%. A high proportion of non-indicated PPI use results in a high economic burden. This burden regarding percentage is 3.4% /patient. The outcomes demonstrate the challenges of PPI use was accompanied by unapproved indications, frequent inappropriate co-prescription with GCs and excessive dosages. Efforts should be paid to promote rational use and guarantee the decision of appropriate PPI therapy in the future. High proportion i.e., 49.1% of PPI non-indicated use was seen in high economic burden. 353.9 is the cost burden observed /patient/hospitalization Hence, the use of PPI without a proper indication was the most common type of non-indicated use observed in the study.

**KEYWORDS:** Proton Pump Inhibitors, Rabeprazole, Pantoprazole, esomeprazole, Cost Economic Analysis (CEA).

### INTRODUCTION

Proton-pump inhibitors (PPIs) A group of drugs termed (PPIs) can significantly and permanently reduce the fabrication of digestive -juice by suppressing the H<sup>+</sup>/K<sup>+</sup> ATPase proton pump.<sup>[1]</sup> They work by permanently blocking the stomach's H<sup>+</sup>/K<sup>+</sup> ATPase proton pump. They are the most intense inhibitors of acid secretion and are available over the counter. Although they are very effective, using them has some risks, especially if used for an extended period.<sup>[2]</sup> PPIs should be prescribed appropriately to enhance outcomes, reduce hazards, and ease the fiscal burden on the healthcare system.<sup>[3]</sup> The inappropriate use of PPIs has become alarming and needs to be controlled.<sup>[4]</sup> If the application of medicines is not as per the FDA-approved indications or guidelines it is considered as "irrational" or "inappropriate" use of medicines. A healthcare system may not invariably be relevant to cost-effectiveness analysis. Decision makers frequently adopt new treatments without their cost-effectiveness being known. Decision-makers could disagree with the findings or be unable to understand the facts, even in cases when cost-effectiveness has been

researched.<sup>[5]</sup> The World Health Organization (who) noted a majority of medicines are improper in prescription.<sup>[6]</sup> The FDA in the US has proposed that over-the-counter PPIs, such as Prilosec OTC, be used in no more than three 14-day treatment courses within 12 months.<sup>[7]</sup>

### METHODOLOGY

**Aim:-** To evaluate the rational use of proton pump inhibitors. and their economic burden.

### OBJECTIVE

- To assess the prescribing pattern of proton pump inhibitors (PPI with FDA approved indications, Off-label indications, and inappropriate use)
- To identify the economic burden problems associated with the use of PPIs and to make necessary interventions to improve it.

### MATERIALS AND METHODS

This study will be conducted in inpatient wards.

- Study design

A prospective observational study.

- Study period: 6 months
- Inclusion criteria

Patients of age greater than 18 years, who were prescribed with PPI's.

- Exclusion criteria

Pediatrics and Patients in critical condition, who were prescribed with PPI's. Patients with mental illness and cognitive impairments.

Patients who do not yet turn eighteen.<sup>[18]</sup>

## METHOD OF DATA COLLECTION

To carry out the investigation, A data collecting form has been used to gather the patient's information. The demographic information about the patient—name, age, gender, literacy level, place of residence, employment, previous health records, family background, and socioeconomic history, history of presenting illness, and drug use—has all been recorded. This information includes the drug name, dosage, dosage form, frequency, duration, treatment indication, and concurrent medications. The foundation for our assessment of PPI prescriptions is based on NICE recommendations, NHS guidelines, and FDA-approved indications.

The following factors influence how PPIs are prescribed, and a patient's use of PPIs should be assessed according to.

- The patients' age and gender.
- The PPI kinds that are advised.
- The dosing schedule, how often, and how long to use it.
- The classification of illnesses is based on diagnosis for which PPIs are recommended.
- Any more medications that are given in addition to PPIs.

## RESULTS AND DISCUSSION

### TYPE OF PROTON PUMP INHIBITORS

Table 1: Distribution According To Type Of Proton Pump Inhibitors.

TYPE OF PROTON PUMP INHIBITORS	NO. OF PATIENTS	PERCENTAGE (%)
PANTOPRAZOLE	94	92.1
RABEPRAZOLE	6	5.8
ESOMEPRAZOLE	2	2.0

- The method used to give PPIs.

Rational use of prescription can be evaluated according to criteria. The assessment of PPI prescriptions is divided into the subsequent groups.

Appropriate: Prescriptions which follow FDA guidelines.

Inappropriate: Prescriptions that do not follow the guidelines.

Off-label: prescription with unapproved indication or in unapproved age groups, dosage, or route of administration.

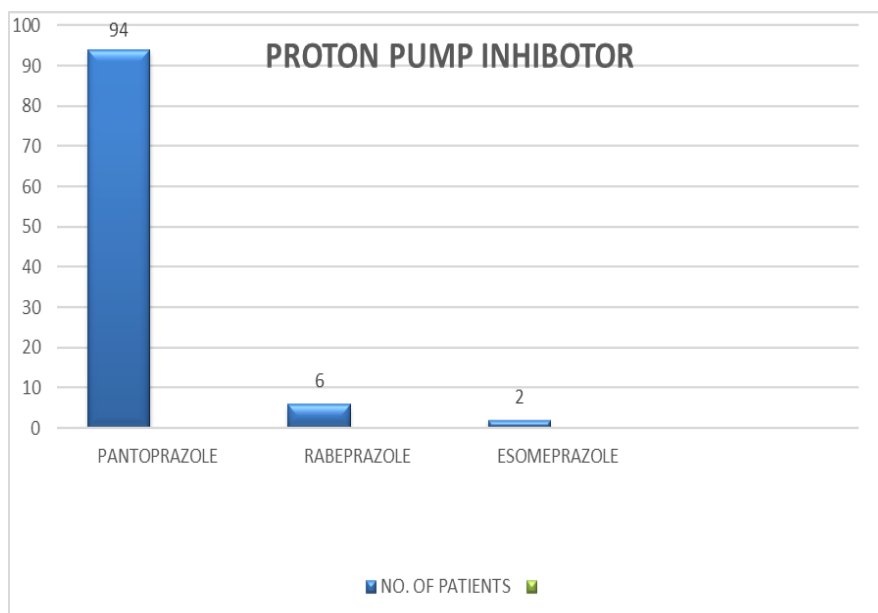
Unclear: Lack of clear indication for the prescription of PPI's.

## STATISTICAL ANALYSIS

Microsoft Excel will be used to enter the acquired data, and SPSS V-21 should be used for statistical analysis. The data should be analyzed for percentage computations, standard derivation, and mean.

## RESULTS

The patient Performa of 102 patients were evaluated for PPI prescription. Significant data was captured, in which Pantoprazole was prescribed in 92% of patients, Rabeprazole in 5% patients, Esomeprazole in 1% of patients. The most prescribed PPI during the analysis was pantoprazole. The PPI usage for off-label indication was identified as 34.3%, whereas as 16.6% were having indications. Further, the prevalence of Non-Indicated Prescriptions of PPIs was determined to be 49.01 %. A high proportion of non indicated PPI use resulting in a high economic burden. This burden regarding percentage is 3.4% /patient. **Conclusion:** The increase in the utilization of PPIs across countries elevates the issues regarding their appropriate prescription globally. The rapid growth of the PPI market has raised important obstacles for regulatory authorities because of the rising costs of therapy and increased risks for patients. To achieve optimal outcomes and reduce risks including cost in the healthcare system, it is important to prescribe (PPIs) as per specified guidelines.



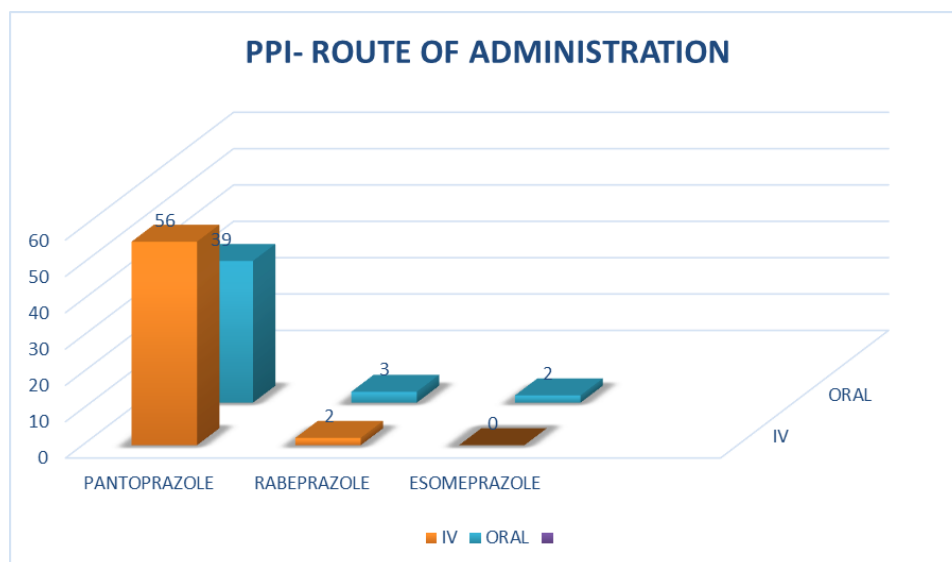
**Figure 1: Type of Proton Pump Inhibitor.**

- In this study, most of the participants were prescribed with Pantoprazole followed by esomeprazole and rabeprazole.

#### ✚ TYPE OF PROTON PUMP INHIBITOR WITH ROUTE OF ADMINISTRATION

**Table 2: DISTRIBUTION ACCORDING TO PPI WITH ROUTE OF ADMINISTRATION.**

PPI	IV	ORAL
PANTOPRAZOLE	56	39
RABEPRAZOLE	2	3
ESOMEPRAZOLE	0	2



**Figure 2: PPI – Route of Administration.**

- In this research, PPIs were administered in both oral and IV route of administration.

#### APPROPRIATENESS

**Table 3: DISTRIBUTION ACCORDING TO APPROPRIATENESS.**

APPROPRIATENESS	NO. OF PATIENTS	PERCENTAGE (%)
INDICATED	17	16.7
NON-INDICATED	50	49.0
OFF-LABEL	35	34.3

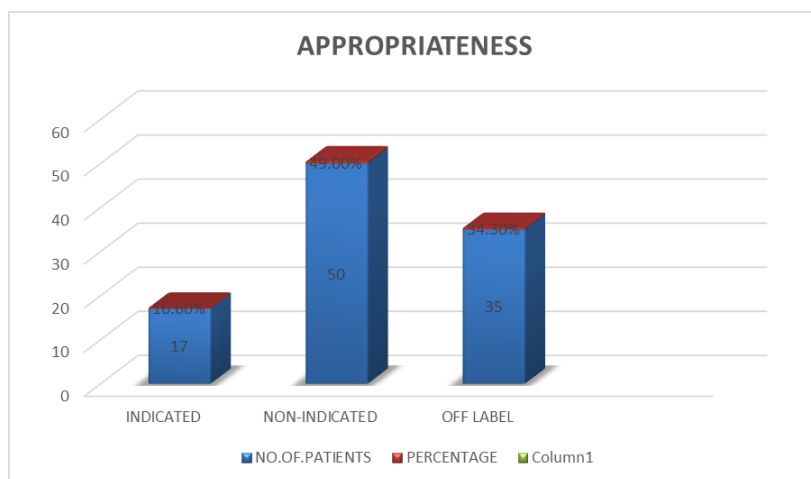


Figure 3: AppropriatenesS.

○ In this study, only 17 patients out of 102 were determined to be appropriate for PPI usage. PPI was given with an off-label indication for 35 patients. 50 patients were not indicated for PPI use according to their condition. Out of the 102 patients in the current study, 49.0% of patients are using PPIs incorrectly (prescribed inappropriately).

#### PREVALENCE CALCULATOR OF NON-INDICATED PPI's

In the field of epidemiology, the percentage of a given population afflicted by a disease, risk factor, or other result under investigation is referred to as prevalence, or prevalence rate. This can be monitored over a predetermined length of time, or at a specific moment in time.

$$\bullet \text{ Prevalence (\%)} = \frac{\text{number of people with disease}}{\text{number of people in the population}} \times 100\%$$

Fig-4.

○ In this study, Only 17 patients out of 102 were determined to be appropriate for ppi usage. PPI was given with an off-label indication for 35 patients. 50

patients were not indicated for PPI use according to their condition.

#### Prevalence Calculator

Number of Cases

Population Size

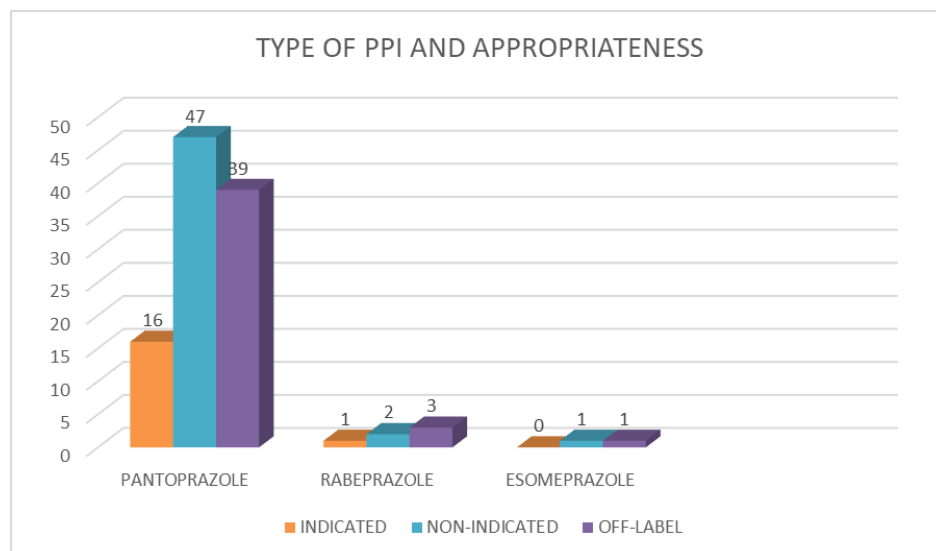
Prevalence (%)

Fig 5.

○ The prevalence of Non-Indicated Prescription of PPI's was found to be 49.01 %

**TYPE OF PPI AND APPROPRIATENESS****Table 4: Distribution According To Type Of Ppi And Appropriateness.**

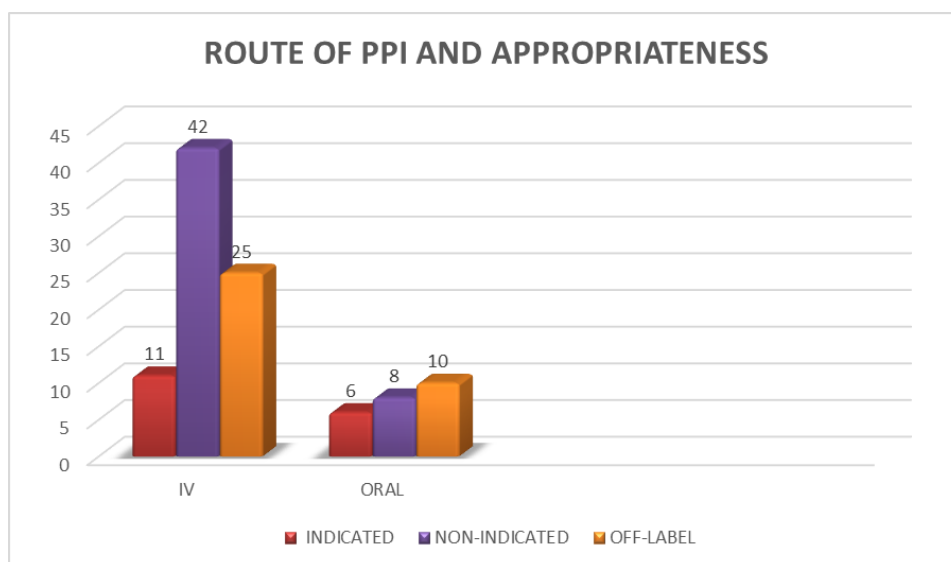
TYPE OF PPI / APPROPRIATENESS	INDICATED	NON-INDICATED	OFF-LABEL
PANTOPRAZOLE	16	47	39
RABEPRAZOLE	01	2	3
ESOMEPRAZOLE	0	1	1

**Figure 6: Type of PPI and Appropriateness.**

- In this study, among the individuals who have with PPI Indicated were prescribed with pantoprazole
- Among the individuals who have with PPI Non- Indicated were prescribed with pantoprazole.
- Among the individuals who have with PPI Off Label were prescribed with pantoprazole.

**ROUTE OF PPI AND APPROPRIATENESS****Table 5: Distribution According to Route of Ppi and Appropriateness.**

ROUTE OF PPI / APPROPRIATENESS	INDICATED	NON-INDICATED	OFF-LABEL
IV	11	42	25
ORAL	6	8	10

**Figure 7: Route of PPI and Appropriateness.**

- In this study, most of the patients with PPI Indicated were prescribed with IV route.
- Most of the patients with PPI Non- Indicated were prescribed with IV route.
- Most of the patients with PPI Off Label were prescribed with Oral route.

#### DEPARTMENT AND APPROPRIATENESS

Table 6: Distribution According to Department and Appropriateness.

DEPARTMENT / APPROPRIATENESS	INDICATED	NON-INDICATED	OFF-LABEL
GENERAL MEDICINE	0	9	2
CARDIOLOGY	0	7	15
DERMATOLOGY	0	3	1
GASTROENTEROLGY	17	0	2
ENDOCRINOLOGY	0	3	0
GYNECOLOGY	0	4	0
EMERGENCY	0	3	0
NEPHROLOGY	0	3	3
NEUROLOGY	0	6	3
OBSTETRICS	0	1	0
ORTHOPEDIC	0	0	1
ICU	0	0	1
PULMONOLOGY	0	11	5
UROLOGY	0	0	1

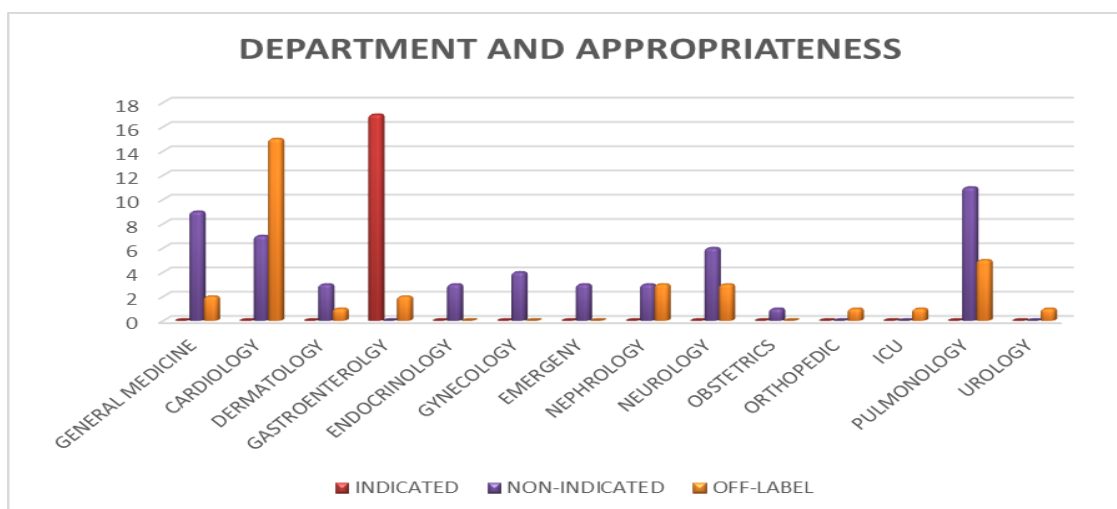


Figure 8: Department and Appropriateness.

- In this study, most of the patients with PPI Indicated were under Gastroenterology department.
- Most of the patients with PPI Non- Indicated were prescribed with the pulmonology department.
- Most of the patients with PPI Off Label were prescribed with cardiology department.

#### MEAN COST AND TYPE OF PROTON PUMP INHIBITORS

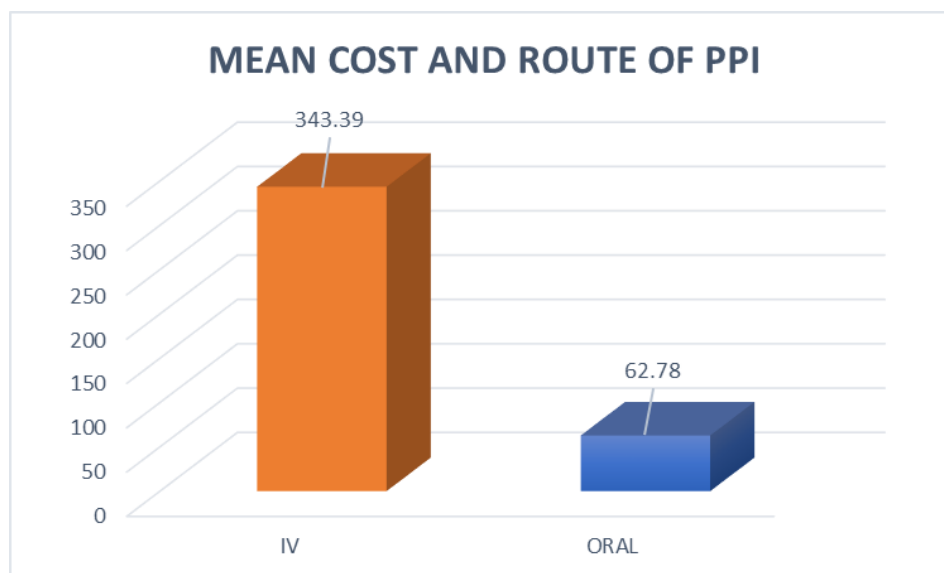
Table 7: Distribution According to Mean Cost and Type of Ppi.

TYPE OF PPI	MEAN COST	STD.DEV
PANTOPRAZOLE	235.48	275.35
RABEPRAZOLE	292.96	312.80
ESOMEPRAZOLE	263.7	333.04

#### MEAN COST AND ROUTE OF PROTON PUMP INHIBITORS

Table 8: Distribution According to Mean Cost and Route Of Ppi.

ROUTE OF PPI	MEAN COST	STD.DEV
IV	343.39	301.01
ORAL	62.78	40.47



**Figure 9: Mean Cost and Route of PPI.**

- In this study, mean cost of the PPIs in IV Route prescribed patients was found to be 343.39.
- Mean cost of the PPIs in Oral Route prescribed patients was found to be 62.78.
- Mean Cost of the PPI's in IV route is high when compared to oral route.

#### **ECONOMIC BURDEN OF PATIENT PER HOSPITALIZATION**

TOTAL COST OF NON-INDICATED/NO. OF NON-INDICATED PATIENT

$$\frac{17697.2}{50} = 353.9\%$$

High proportion i.e., 49.1 % of PPI non-indicated use was seen in high economic burden. 353.9 is the cost burden observed /patient / hospitalization Hence, the use of PPI without a proper indication was the most common type of non-indicated use observed in the study.

#### **CONCLUSION**

- The main indications for PPI use include treating gastroesophageal reflux disease, eradicating *H. pylori* infection, healing and preventing NSAID-associated gastric ulcers, controlling upper digestive bleeding, and treating Zollinger-Ellison Syndrome. However, the increasing use of PPIs raises concerns about their appropriate prescription globally.
- The increasing use of PPIs in both Western and Eastern countries makes one wonder about their appropriate prescription globally.
- PPIs should be taken by GERD patients for the whole prescribed term to minimize needless medical burden and to optimize efficacy, safety, and economic considerations.
- The rapid growth of the PPI market has presented substantial obstacles for regulatory authorities due to the rising costs of therapy and increased risks for patients.
- The importance of reassessing the appropriate

indications for proton pump inhibitors (PPIs) among general practitioners and specialists, to ensure their correct and evidence-based use in clinical practice. It suggests that PPIs should be prescribed more sparingly, and hospital physicians should be educated about this to enhance patient care without incurring significant expenses.

- To achieve optimal outcomes and reduce risks and costs in the healthcare system, it is important to prescribe proton pump inhibitors (PPIs) appropriately. The misuse of PPIs is a concerning issue that requires regulation and control.
- There is a high economic burden due to a significant amount of non-indicated use of PPIs, particularly the use of PPIs without a proper indication. Therefore, it is necessary to develop a national policy on PPI usage to address this issue and reduce the economic burden.

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