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CLINICAL AUDIT TO ASSESS WHETHER THE CURRENT USE OF PROTON PUMP INHIBITORS IN A GENERAL PRACTICE CONFORMS TO STANDARD GUIDELINES

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Article History

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Abstract

Introduction: Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. The present clinical audit identifies the patients who are on Proton Pump Inhibitor (PPI) therapy and assess whether their indication for proton pump indicators is appropriate as per the standard guidelines. The data is collected by the personal interview of patients or their attenders and filled information in the questionnaires and results are analysed. Effective interventions are made and then a second phase audit is conducted. Again data is collected and results are analysed. Proton pump inhibitors (PPIs) are a group of drugs that cause pronounced and long-lasting reduction of gastric acid production. PPIs are frequently prescribed for inappropriate indications or for indications where their use offers little benefit. Inappropriate PPI use is a matter of great concern, especially in the elderly, who are often affected by multiple comorbidities and are taking multiple medications, and are thus at an increased risk of long-term PPI-related adverse outcomes as well as drug-to-drug interactions. Our audit aimed to assess whether the current use of proton pump inhibitors in a general practice conforms to standard guidelines. Results: Out of 205 patients, appropriate use was found in 176 cases, and inappropriate use of PPIs was found in 29 cases in phase I audit. After intervention, Phase II audit is conducted and results are evaluated. Out of 250 patients, appropriate use was found in 248 cases, and inappropriate use of PPIs was found in 2 cases in phase II audit. The inappropriate use of proton pump inhibitors was decreased in the Phase II by around 14.2%, when compared to the Phase I audit. Conclusion: The present clinical audit showed the usage pattern of PPIs in a wide range of indications. PPIs should be used only when there is valid documented evidence and when their use is clinically justified. This clinical audit has strongly highlighted that there is inappropriate use of PPI as add on drug for corticosteroids. Various efforts should be made to reduce the unnecessary use of PPIs to minimize drug interactions, related risks, adverse effects and health care costs.

Keywords: Clinical audit, proton pump inhibitors, appropriate use, standard guidelines, adverse effects.

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Introduction

Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.

Proton pump inhibitors (PPIs) are a group of drugs that cause pronounced and long-lasting reduction of gastric acid production. PPI's represent the "gold-standard" therapy in acid-related disorders. 1Effective gastric acid suppressive therapy has dramatically improved the therapy and outcome of acid-related disorders. The introduction of proton pump inhibitors (PPIs) in clinical practice has significantly changed the medical management of upper gastrointestinal disorders [1, 2]. They are the most potent inhibitors of acid secretion available for clinical use. PPIs irreversibly inhibit the gastric H+-K+ ATPase pump also known as proton pump and reduce both basal and stimulated gastric output [3].

Proton pump inhibitors have been demonstrated to be safe and well tolerated drugs but short term adverse effects like headache, dizziness, diarrhea, fatigue, rashes and abdominal pain have been reported in 5%of the patients taking proton pump inhibitors. Chronic therapy of PPIs carries an increased risk of bacterial enteritis due to decreased gastric acidity allowing colonization of ingested pathogens and also infection with clostridium difficile. Long term use of PPIs have also been associated with increased risk of hip fractures, and community acquired

pneumonia. In setting with low rate of such infections benefit of PPI therapy outweighs the risk developing it. Poly pharmacy can also make the elderly patients more likely to confuse their use of medication schedule. Such risks are worth taking for life saving drugs that are clearly indicated, but prescribing PPIs that may not be clinically necessary can put patients at risk of complications [4].

PPIs are frequently prescribed for inappropriate indications or for indications where their use offers little benefit. Inappropriate PPI use is a matter of great concern, especially in the elderly, who are often affected by multiple comorbidities and are taking multiple medications, and are thus at an increased risk of long-term PPI-related adverse outcomes as well as drug-to-drug interactions [5].

Audit Plan

This clinical audit identifies the patients who are on Proton Pump Inhibitor (PPI) therapy and assess whether their indication for proton pump indicators is appropriate as per the standard guidelines. The data is collected in the questionnaires and results are analyzed. Effective interventions are made and then a second phase audit is conducted. Again data is collected and results are analyzed.

Aim

To assess whether the current use of proton pump inhibitors in a general practice conforms to standard guidelines.

Objectives

- To evaluate the appropriate use of Proton pump inhibitors.
- To find out prescriptions without justified indication for PPIs.
- To avoid irrational use of proton pump inhibitors.
- To avoid the adverse effects caused by the unnecessary use of PPIs.
- To educate the patients, other people and staff regarding the appropriate use of PPIs and adverse effects caused by PPIs on chronic use

Methodology

Study Design

The present audit was a prospective observational study.

Study Area

This audit was conducted in Pinnacle hospitals, India which is a tertiary care hospital.

Study Period

This audit is conducted in two phases, in the month of January 2023 (Phase I) and April 2023 (Phase II).

Sample Size

The number of patients depends on the admissions taken place in the specified month of audit i.e. January and April.

Identifying Eligible Patients

Patients of either sex, admitted into the inpatient wards of Pinnacle hospitals, India, between the age group of 20-80 years who were on proton pump inhibitors were included in the study.

Inclusion and Exclusion Criteria

Inclusion criteria

All the patients who had been prescribed proton pump inhibitors.

Exclusion criteria

Patients for whom PPI has not been prescribed.

Pregnant patients.

Collection of Data

The demographic data and the detailed history of patient regarding past, present, personal and drug history was taken. The other details like the present diagnosis, reason for the present admission, any present complaints of gastrointestinal discomforts and other prescribed drugs were noted.

A questionnaire was designed for data collection to assess appropriate use of PPIs. This questionnaire was filled by personal interview of the patient on inclusion in the study.

Data Analysis

The information filled in the questionnaire was analyzed and results were drawn. The percentage of the appropriate and inappropriate indications of the proton pump inhibitors were calculated and graphs were plotted.

Plan of Work

Phase-I

Step 1: Approval from head of the department and hospital authorities.

Step 2: Literature review.

Step 3: Designing data collection form.

Step 4: Identification of patients with PPI therapy and recording the data.

Step 5: Evaluating the recorded data.

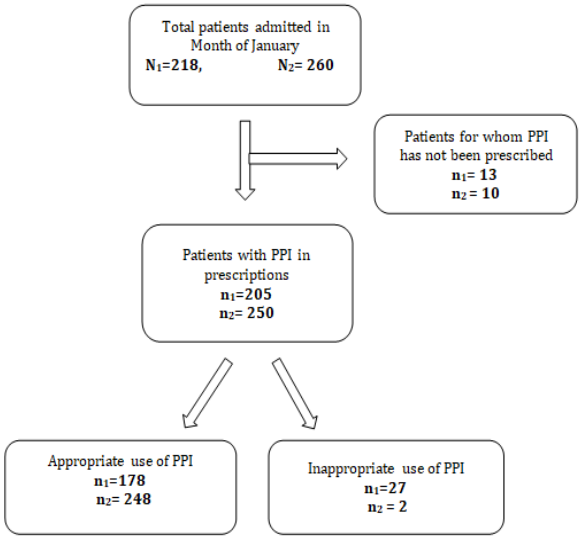
Phase-II

Step 6: Develop and implement intervention for appropriate use of PPIs.

Step 7: Identification of patients with PPI therapy and recording the data.

Step 7: Re-evaluation of the results.

Algorithm of Identifying Appropriate Use of Proton Pump Inhibitors- Phase I& II



Results

PHASE I:

Out of 205 patients, appropriate use was found in 176 cases, and inappropriate use of PPIs was found in 29 cases.

Among appropriate indication for proton pump inhibitors, cases with gastrointestinal disorders are 17, NSAIDS are 24, antibiotics are 93, anticoagulants are 6, antiplatelet are 24, corticosteroids + NSAIDS are 11 and cancer 1.

Among inappropriate indication for proton pump inhibitors cases with only corticosteroids without NSAID, cases with no

gastric disorders, drugs with no potential for causing gastric disorders are found.

All the cases with appropriate and inappropriate indication for proton pump inhibitors are recorded and percentage is calculated.

TABLE:I

PHASE I					
Sl. No.	Total cases	Number of appropriate indications	Percentage of appropriate indications	Number of inappropriate indications	Percentage of inappropriate indications
1.	205	176	85%	29	15%

Table: II

Sl. NO.	INDICATION FOR PPI	TOTAL NO. OF CASES (PHASE I)
1.	GASTROINTESTINAL DISORDERS	17
2.	NSAIDs	24
5.	ANTIBIOTICS	93
6.	ANTICOAGULANTS	6
7.	ANTIPLATELETS	24
8.	CORTICOSTEROIDS+NSAIDs	11
9.	CANCER	1

In the phase I audit, we found that there are 29 patients with inappropriate use for the PPIs. Thus we made an intervention and action plan was designed. After implementation of the action plan we had conducted Phase II audit.

Action Plan

- PPIs are not routinely indicated as add on drug for corticosteroids unless patients taking concomitant NSAID therapy or have a peptic ulcer disease.
- A circular was issued by the medical directed to all the consultants stating to avoid usage of proton pump inhibitors as add on therapy for corticosteroids unless needed.
- The doctors, clinical pharmacists and the other medical professionals should work together for the rational use of PPIs by making interventions like the educational programs on guidelines of rational use of PPIs, adverse effects for chronic use of PPIs.
- Institutional specific guidelines should be developed and implemented to reduce the usage of PPIs in the inpatients and given to all consultants and this aims to promote rational use of proton pump inhibitors.
- By educating patients to avoid use of proton pump inhibitors without a proper indication and also about the adverse effects caused by proton pump inhibitors on chronic use.

Sl. NO.	INDICATION FOR PPI	TOTAL NO. OF CASES (PHASE I)	TOTAL NO. OF CASES (PHASE II)
1.	GASTROINTESTINAL DISORDERS	17	31
2.	NSAIDs	24	106
3.	ANTIBIOTICS	93	54
4.	ANTICOAGULANTS	6	14
5.	ANTIPLATELETS	24	26
6.	CORTICOSTEROIDS+NSAIDs	11	17
7.	CANCER	1	0

Actions Recommended

To verify the rational use of proton pump inhibitors in the next phase after 2 months.

PHASE II

Out of 250 patients, appropriate use was found in 248 cases, and inappropriate use of PPIs was found in 2 cases.

Among appropriate indication for proton pump inhibitors, cases with gastrointestinal disorders are 31, NSAIDS are 106, antibiotics are 54, anticoagulants are 6, antiplatelet are 26, corticosteroids + NSAIDS are 17.

Among inappropriate indication for proton pump inhibitors cases with no gastric disorders or symptoms were given PPI.

All the cases with appropriate and inappropriate indication for proton pump inhibitors are recorded and percentage is calculated.

Table III:

PHASE II					
Sl. No.	**Total cases**	**Number of appropriate indications**	**Percentage of appropriate indications**	**Number of inappropriate indications**	**Percentage of inappropriate indications**
1.	250	248	99.2%	2	0.8%

Table IV

Sl. NO.	INDICATION FOR PPI	TOTAL NO. OF CASES (PHASE II)
1.	GASTROINTESTINAL DISORDERS	31
2.	NSAIDs	106
3.	ANTIBIOTICS	54
4.	ANTICOAGULANTS	14
5.	ANTIPLATELETS	26
6.	CORTICOSTEROIDS+NSAIDs	17
7.	CANCER	0

Results of Phase II Audit

After intervention, Phase II audit is conducted and results are evaluated. The inappropriate use of proton pump inhibitors was decreased in the Phase II by around 14.2% , when compared to the Phase I study. Proton pump inhibitors are used as add on drug for corticosteroid, only if there is a concomitant use of corticosteroids with NSAIDs or if any

gastric disorders persists. The patients were educated regarding the appropriate use of proton pump inhibitors and the adverse effects caused by the proton pump inhibitors on chronic use. The results of both phases are tabulated and graphs are plotted as below.

Results of Phase II Audit

Sl. NO.	INDICATION FOR PPI	TOTAL NO. OF CASES (PHASE I)	TOTAL NO. OF CASES (PHASE II)
1.	GASTROINTESTINAL DISORDERS	17	31
2.	NSAIDs	24	106
3.	ANTIBIOTICS	93	54
4.	ANTICOAGULANTS	6	14
5.	ANTIPLATELETS	24	26
6.	CORTICOSTEROIDS+NSAIDs	11	17
7.	CANCER	1	0

Table V: Showing Combined Results Of Phase I & II

SL.NO	PHASES	TOTAL NO. OF CASES	APPROPRIATE INDICATION	INAPPROPRIATE INDICATION
1.	Phase I	206	176	29
2.	Phase II	250	248	2

Graph 1

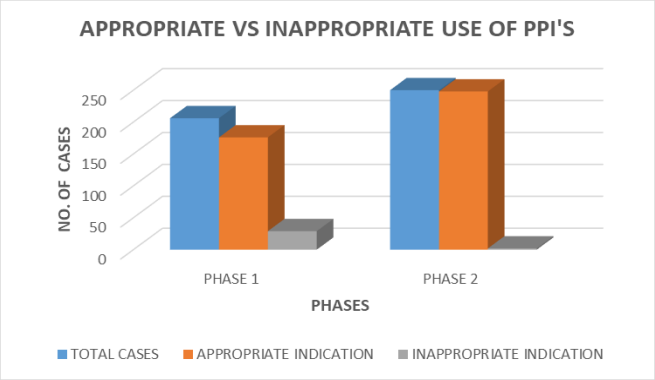
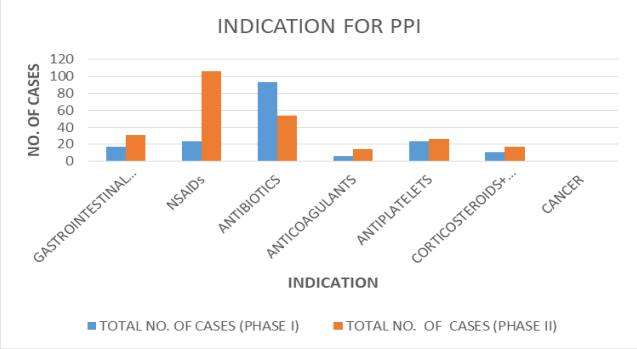


Table VI Showing Indications for PPI

Graph: 2



Discussion

Clinical Audit

Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria [6].

Using the Method

Clinical audit can be described as a cycle or a spiral (see Figure 1). Within the cycle there are stages that follow a systematic process of establishing best practice, measuring care against criteria, taking action to improve care, and monitoring to sustain improvement. The spiral suggests that as the process continues, each cycle aspires to a higher level of quality [6].

Audit Cycle:

Proton Pump Inhibitors

The present clinical audit is on the appropriate use of the proton pump inhibitors. In this audit we evaluate PPI use on medical patients and determine whether this use was appropriate and conforms to standard guidelines or not.

Proton Pump Inhibitors (PPIs) are one of the most commonly prescribed category of drugs that cause pronounced and long-lasting suppression of gastric acid production by inhibiting the Hydrogen-Potassium Adenosine Triphosphates Enzyme system.

Short-term PPI therapy appropriate
- Healing of erosive esophagitis (Los Angeles grade A and B)
- *Helicobacter pylori* eradication (in combination with antibiotics)
- Functional dyspepsia
- Peptic ulcer disease
- Acute upper gastrointestinal bleeding
- Stress-ulcer prophylaxis in high-risk patients
- Eosinophilic esophagitis

Long-term PPI appropriate
- Barrett's esophagus
- Severe erosive esophagitis (Los Angeles grades C and D)
- Zollinger-Ellison syndrome
- Idiopathic peptic ulcer disease
- Gastroprotection in high-risk patients (long-term nonselective NSAID-users)
- Anti-platelet therapy in patients at high risk for upper GI complications
- PPI-responsive Eosinophilic esophagitis

PPI use - no benefit
- Corticosteroid treatment (unless used in combination with NSAIDs)
- Acute pancreatitis (no benefit form acid inhibition)
- Hypertensive gastropathy (no need for acid suppression)
- Chronic pancreatitis (standard dose of PPI only in patients with steatorrhea, refractory to enzyme replacement treatment)
- Stress ulcer prophylaxis in noncritically ill hospitalized patients and low risk for upper GI complications
- Anticoagulant therapy (no need for gastroprotection unless used in combination with NSAIDs)

PPI, proton pump inhibitor; NSAID, nonsteroidal anti-inflammatory drug; GI, gastrointestinal.

As we all know PPIs are an efficient therapy. Although validated indications of PPIs are well known, numerous studies consistently show that PPIs are being overprescribed and this is associated with possible side effects [9,10]. Previous reports have estimated that over 60% of all PPI prescriptions in Ireland are generated from within the hospital setting [11], and multiple studies have documented wide spread in appropriate use of PPIs with in hospitals.

Studies have shown that the incidence of irrational use of PPIs ranges for 40-70% 12

In contrast to our work, the work done by D'Souza, Anisha Marita et.al, out of 170 patients, appropriate use was found in 64% and inappropriate use was found in 36% of the cases.13

In contrast to our present study, the study done by Muhammad Haroon et.al, during the audit period, 205 consecutive medical inpatients were assessed. Seventy-nine percent (162 out of 205) of the studied patients were found to be using PPI. For 45% (*n* = 73) of patients, there was no documentation of valid indication for being on PPI. 14

In contradictory to our work, the work done by S.L .Lim et.al, in the phase 1 audit 52% of patients were appropriately prescribed PPI and in re audit there was a slight increase in percentage to 57%. 15

Conclusion

The present clinical audit showed the usage pattern of PPIs in a wide range of indications. PPIs should be used only when there is valid documented evidence and when their use is clinically justified. This clinical audit has strongly highlighted that there is inappropriate use of PPI as add on drug for corticosteroids. Intervention is required to tackle this issue and should focus in enhancing prescribers' knowledge as well as patient knowledge. Various efforts should be made to reduce the unnecessary use of PPIs to minimize drug interactions, related risks, adverse effects and health care costs.

As PPI use continues to grow every year, concerns regarding their safety have arisen. Although once thought of as safe options, PPI usage in recent years has raised concerns, evidenced by numerous studies and reviews exploring a diverse range of adverse outcomes associated with PPI use. Below is the list of PPI-associated adverse events caused by and mechanisms. So it is paramount for clinicians to reassess their individual patients' need for continuation of PPI therapy long term, taking into account adverse events and cost.

Sl. no	PPI associated adverse event	Potential or believed mechanism
1.	Hypo magnesia	Increased gastric pH alters magnesium transport and absorption.
2.	Vitamin B12 deficiency	Increased gastric pH alters absorption, potential for microbial overgrowth that utilize cobalamin
3.	Clostridium difficile infection	Alteration of gut microbiome
4.	Community acquired pneumonia	Alteration of gut microbiome
5.	Bone fracture	Reduction in calcium absorption due to increased gastric Ph.
6.	Myocardial infarction	Unknown, believed to be related to impairment of endothelial nitric oxide synthase
7.	Dementia	Increased production and degradation of amyloid and binding to tau. Decreased availability of other nutrients.
8.	Acute interstitial nephritis	Cell and humoral mediated drug hypersensitivity.

Our results suggest that PPIs are overprescribed in hospital practice. As use of PPIs is costly and is associated with side effects, doctors should be better educated in guidelines for its use. And even the patients should be educated regarding the rational use of the PPI and their adverse effects by proper patient counseling.

References

1. László Herszényi, Tamás Bakucz, Loránd Barabás, Zsolt Tulassay; Pharmacological Approach to Gastric Acid Suppression: Past, Present, and Future. Dig Dis 22 January 2020; 38 (2): 104–111. https://doi.org/10.1159/000505204
2. Roland Nnaemeka Okoro https://orcid.org/0000-0002-6391-5000 Kasim Abdullahi, and Dauda Ayuba DayarView all authors and affiliations, Assessment of proton-pump inhibitor use at a tertiary teaching hospital in Nigeria, sage journals, https://doi.org/10.1177/23992026211062729
3. Nirajan Kunwar, M. Kumaraswamy, Surendra Shrestha, Saroj Paudel, Bipin Kafle, Thakur Pokharel, and Jamuna TR, A study on proton pump inhibitors in general medicine unit of tertiary care teaching hospital, World Journal of Pharmaceutical Research, SJIF Impact Factor 5.990, Volume 4, Issue 6, 1519-1534. Research Article ISSN 2277– 7105.
4. NousheenTadvi NA, Shareef SM, Use of proton pump inhibitors in general practice: Is it rationale? March 2014 International Journal of Medical Research & Health Sciences 3(1) DOI:10.5958/j.2319-5886.3.1.008
5. Scarpignato C, Gatta L, Zullo A, Blandizzi C; SIF-AIGO-FIMMG Group; Italian Society of Pharmacology, the Italian Association of Hospital Gastroenterologists, and the Italian Federation of General Practitioners. Effective and safe proton pump inhibitor therapy in acid-related diseases - A position paper addressing benefits and potential harms of acid suppression. doi: 10.1186/s12916-016-0718-z. PMID: 27825371; PMCID: PMC5101793.
6. Ross Scrivener, Clare Morrell, Principles for best practice in clinical audit, https://www.uhbristol.nhs.uk/files/nhs-ubht/best_practice_clinical_audit.pdf
7. Yadlapati R, Kahrilas PJ. When is proton pump inhibitor use appropriate? BMC Med. 2017 Feb;15(1):36.
8. 8.Freedberg DE, Kim LS, Yang YX. The risks and benefits of long-term use of proton pump inhibitors: Expert review and Best Practice Advice From the American Gastroenterological Association. Gastroenterology. 2017 Mar;152(4):706–15.

9. . Sheen E, Triadafilopoulos G. Adverse effects of long-term proton pump inhibitor therapy. Dig Dis Sci. 2011;56(4):931-50.
10. . Xie Y, Bowe B, Li T, Xian H, Balasubramanian S, Al-Aly Z. Proton Pump Inhibitors and Risk of Incident CKD and Progression to ESRD. J Am Soc Nephrol. 2016;27(10):3153-63.
11. 11.. Mat Saad AZ, Collins N, Lobo MM, O'Connor HJ. Proton pump inhibitors: a survey of prescribing in an Irish general hospital. Int J Clin Pract. 2005;59(1):31-4. 4. Ladd AM, Panagopoulos G, Cohen J, Mar N, Graham R
12. D'Souza, Anisha Marita; Shastry, C S; Mateti, Uday Venkat; Kabekkodu, Shamaprakash; Chand, Sharad, Drug Utilization and Evaluation of Proton Pump Inhibitors in General Medicine Ward of a Tertiary Care Hospital, Journal of Pharmaceutical Sciences and Research; Cuddalore Vol. 11, Iss. 6, (Jun 2019): 2174-2179.
13. 13..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 Rep. 2013 Jun 25;4(8):2042533313497183. doi: 10.1177/2042533313497183. PMID: 24040498; PMCID: PMC3767067.
14. S.L. Lim, N.A. Mohd Yunus, M.M. Tan, E. Mageswaren, Clinical audit on appropriateness of proton pump inhibitor (PPI) prescription in medical wards in hospital Tengku Ampuan Rahimah (HTAR), Klang, Malaysia Topic 03 : Data for improvement Identifier: PO084DO - 10.13140/RG.2.2.18856.39682
15. Gupta R, Marshall J, Munoz JC, Kottoor R, Jamal MM, Vega KJ. Decreased acid suppression therapy overuseafter education and medication reconciliation. Int J Clin Pract. 2013;67:60-65.