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Inappropriate Long-Term Proton Pump Inhibitor Use in a General Medicine Outpatient Department: A Cross-Sectional Study

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KEYWORDS

Proton pump inhibitors; Inappropriate prescribing; Deprescribing; Long-term use; Polypharmacy; Medication review; Outpatient; India

ABSTRACT:

Introduction: Proton pump inhibitors (PPIs) are among the most commonly prescribed medications worldwide, yet inappropriate long-term PPI use is increasingly recognized as a global clinical problem.

Objectives: To determine the prevalence and patterns of inappropriate long-term PPI use, assess documentation quality, identify associated factors, and evaluate patient awareness in a general medicine outpatient department.

Methods: A cross-sectional observational study of 120 adult patients receiving long-term PPI therapy (≥8 weeks) was conducted at a tertiary care hospital in India. PPI use was classified as appropriate or inappropriate using evidence-based guideline criteria by two independent reviewers.

Results: Of 120 patients, 70 (58.3%; 95% CI, 49.1%–67.0%) had inappropriate long-term PPI use. Common inappropriate indications were nonspecific dyspepsia without diagnostic confirmation (35.7%), undocumented indication (28.6%), and prophylaxis without risk factors (21.4%). Documentation quality was poor; only 32.5% had a recorded indication. Factors independently associated with inappropriate use included prescription by general physicians (OR, 3.8), polypharmacy (OR, 2.9), therapy duration >1 year (OR, 4.2), and self-prescription (OR, 5.6). Potential adverse effects were identified in 35% of patients.

Conclusions: Inappropriate long-term PPI use affects more than half of patients in general medicine outpatient settings. Systematic interventions including prescriber education, electronic decision support, and structured deprescribing protocols are urgently needed.

1. INTRODUCTION

Proton pump inhibitors (PPIs), introduced in the late 1980s with omeprazole, have become among the most widely prescribed medications globally, ranking in the top 10 most dispensed drugs in many countries.1,2 By irreversibly inhibiting the gastric H^+/K^+-ATPase enzyme, PPIs achieve potent suppression of gastric acid secretion by up to 90–95%, making them highly effective for managing acid-related disorders.3 Currently available PPIs include omeprazole, pantoprazole, lansoprazole, rabeprazole, and esomeprazole, all demonstrating comparable efficacy across approved indications.4

Evidence-based indications for PPI therapy include gastroesophageal reflux disease (GERD), peptic ulcer disease, Helicobacter pylori eradication therapy, Zollinger-Ellison syndrome, stress ulcer prophylaxis in critically ill patients, and prevention of NSAID-induced gastropathy.5,6 Current clinical practice guidelines recommend short-term PPI therapy, typically 4–8 weeks for most conditions, with continuation beyond this period only when clearly indicated and regularly reassessed.7,8

Despite these recommendations, inappropriate long-term PPI use has emerged as a significant clinical concern. International studies report that 25–70% of PPI prescriptions lack appropriate indication, and up to two-thirds of patients continue therapy beyond guideline-recommended durations without systematic reassessment.9-11 Contributing factors include empirical initiation for nonspecific gastrointestinal symptoms, inadequate medication review, prescription inertia, fear of symptom recurrence, and poor documentation of indication and planned duration.12,13

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The clinical significance of inappropriate long-term PPI use extends beyond unnecessary medication exposure. Accumulating evidence associates prolonged PPI therapy with Clostridioides difficile infection, community-acquired pneumonia, chronic kidney disease, hypomagnesemia, vitamin B12 and iron deficiency, osteoporosis-related fractures, and small intestinal bacterial overgrowth.14-18 Although many of these associations derive from observational studies and causality remains debated, they underscore the importance of judicious prescribing and regular medication review.19,20

In India, data characterizing PPI prescribing appropriateness remain limited despite high consumption rates. Factors including high patient volumes in outpatient clinics, over-the-counter availability of PPIs, and variable adherence to clinical guidelines may influence prescribing patterns.21,22 Recent Indian studies have reported inappropriate PPI use rates ranging from 54% to 62%, with significant gaps in documentation and medication review practices.23-25

This study aimed to determine the prevalence of inappropriate long-term PPI use among adult patients attending a general medicine outpatient department at a tertiary care hospital, characterize patterns of inappropriate prescribing, assess documentation quality, identify associated factors, and evaluate patient awareness regarding PPI therapy.

2. MATERIALS AND METHODS

2.1. Study Design and Setting

This cross-sectional observational study was conducted at the Department of General Medicine, Chettinad Hospital and Research Institute, Kelambakkam, Tamil Nadu, India, between January 2025 and June 2025. The hospital is a 1,200-bed tertiary care teaching institution. The study protocol was approved by the Institutional Human Ethics Committee (IHEC-I/039/01/2026) and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants.

2.2. Study Population

Adult patients (aged ≥18 years) currently taking any PPI for ≥8 weeks with regular follow-up (at least 2 visits in the preceding 6 months) were consecutively screened. Exclusion criteria included active GERD requiring optimization, active peptic ulcer disease confirmed endoscopically within 8 weeks, ongoing H. pylori eradication, Zollinger-Ellison syndrome, postgastrointestinal surgery requiring long-term acid suppression, Barrett esophagus, severe esophagitis (Los Angeles grade C/D), high-risk chronic NSAID therapy with documented gastropathy, cognitive impairment, critically ill patients, and refusal to participate.

2.3. Sample Size

Using $p = 0.58$ (Indian studies), $z = 1.96$, and $E = 0.09$, minimum sample size was calculated at 116, increased to 120 for protocol deviations.

2.4. Data Collection

All patients underwent comprehensive evaluation including structured history, physical examination, medical record review, and patient interview using a standardized case record form. Documentation quality was graded as adequate (indication, duration, and review plan all recorded) or inadequate. Patient awareness was assessed via structured questionnaire. Laboratory data from routine investigations within 3 months were recorded.

2.5. Appropriateness Classification

PPI use was classified as appropriate or inappropriate based on evidence-based guideline criteria.7,8,26,27 Appropriate use required documented indications such as endoscopically confirmed GERD with esophagitis, high-risk NSAID use, Barrett esophagus, recurrent peptic ulcer disease, post-gastrectomy status, or Zollinger-Ellison syndrome. Inappropriate use was defined by absence of documented indication, nonspecific dyspepsia without diagnostic confirmation, GERD symptoms controlled yet continuing >8 weeks without reassessment, prophylaxis without risk factors, resolved initial indication with continued therapy, or use beyond guideline-recommended duration without clinical justification. Two investigators (A.K.G. and M.K.) independently reviewed each case; disagreements were resolved by consensus. Inter-rater reliability was assessed using Cohen kappa.

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2.6. Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 28.0. Continuous variables are expressed as mean (SD) or median (IQR). Comparisons used Student's t test, Mann-Whitney U test, and chi-square or Fisher exact tests as appropriate. Factors associated with inappropriate use were evaluated using univariable and multivariable logistic regression. Variables with P<0.10 in univariable analysis were included in the multivariable model. Results are expressed as odds ratios (ORs) with 95% confidence intervals (CIs). A two-sided P<0.05 was considered statistically significant.

3. RESULTS

3.1. Patient Characteristics

During the 6-month study period, 487 patients were screened; 367 were excluded (158 not meeting inclusion criteria, 124 meeting exclusion criteria, 85 declining participation), yielding a final cohort of 120 patients (Fig. 1). The mean (SD) age was 56.8 (12.4) years; 68 patients (56.7%) were female. Common comorbidities included hypertension in 54 patients (45.0%), type 2 diabetes mellitus in 42 (35.0%), chronic kidney disease in 18 (15.0%), and coronary artery disease in 16 (13.3%). Polypharmacy (≥5 concurrent medications) was present in 64 patients (53.3%).

Pantoprazole was the most frequently prescribed PPI (62 patients [51.7%]), followed by omeprazole (32 [26.7%]), esomeprazole (16 [13.3%]), rabeprazole (8 [6.7%]), and lansoprazole (2 [1.7%]). The median (IQR) PPI therapy duration was 18 (10–36) months. PPIs were initiated by general physicians in 78 patients (65.0%), gastroenterologists in 28 (23.3%), and were self-prescribed in 14 (11.7%). Baseline characteristics stratified by appropriateness are shown in Table 1.

3.2. Prevalence and Patterns of Inappropriate PPI Use

Based on evidence-based appropriateness criteria, 70 patients (58.3%; 95% CI, 49.1%–67.0%) had inappropriate long-term PPI use (Table 2). Inter-rater reliability was excellent (κ = 0.89; 95% CI, 0.82–0.96). Among 50 patients (41.7%) with appropriate use, documented indications included GERD with esophagitis (22 [44.0%]), high-risk NSAID use (14 [28.0%]), Barrett esophagus (6 [12.0%]), maintenance therapy for recurrent peptic ulcer disease (5 [10.0%]), and post-gastrectomy status (3 [6.0%]).

Among the 70 patients with inappropriate use, common categories included nonspecific dyspepsia without diagnostic confirmation (25 [35.7%]), no documented indication (20 [28.6%]), prophylaxis without appropriate risk factors (15 [21.4%]), GERD controlled but continuing beyond 8 weeks without reassessment (8 [11.4%]), and resolved initial indication with continued therapy (2 [2.9%]). The median (IQR) duration of inappropriate PPI therapy was 24 (14–42) months, significantly longer than appropriate therapy (12 [8–24] months; P=0.004).

3.3. Documentation Quality

Documentation quality was suboptimal across the cohort (Table 3). Only 39 patients (32.5%) had a clear PPI indication documented in medical records. Planned duration was specified in 28 patients (23.3%), and review plans in only 18 patients (15.0%). Documentation was significantly better for PPIs initiated by gastroenterologists than general physicians (indication documented: 71.4% vs. 24.4%; P<0.001). Among appropriate users, indication, duration, and review plan documentation rates were 68.0%, 48.0%, and 32.0%, respectively, compared with 7.1%, 5.7%, and 2.9% among inappropriate users (all P<0.001).

3.4. Patient Awareness

Patient awareness regarding PPI therapy was poor (Table 4). Only 34 patients (28.3%) could accurately state their PPI indication; 22 (18.3%) were aware of planned duration; and 18 (15.0%) had knowledge of potential adverse effects. Previous discussion about discontinuation had occurred in 24 patients (20.0%). When queried about willingness to consider discontinuation under medical supervision, 86 patients (71.7%) expressed openness. Patients with appropriate PPI use demonstrated higher awareness (56.0% could state indication) compared with inappropriate users (8.6%; P<0.001).

3.5. Factors Associated With Inappropriate PPI Use

Multivariable logistic regression identified prescription by general physicians vs. gastroenterologists (adjusted OR, 3.8; 95% CI, 1.6–9.2; P=0.003), polypharmacy (adjusted OR, 2.9; 95% CI, 1.3–6.5; P=0.009), therapy duration >1 year (adjusted OR, 4.2; 95% CI, 1.8–9.8;

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P<0.001), and self-prescription (adjusted OR, 5.6; 95% CI, 1.4–22.3; P=0.015) as independent risk factors (Table 5). The model demonstrated good fit (Hosmer-Lemeshow χ^2=6.42; P=0.60; Nagelkerke R^2=0.48).

3.6. Potential PPI-Related Adverse Effects

Potential PPI-related adverse effects were identified in 42 patients (35.0%) (Table 6). The most common were anemia in 18 patients (15.0%), chronic kidney disease (eGFR <60 mL/min/1.73 m²) in 14 (11.7%), self-reported fractures since PPI initiation in 6 (5.0%), and hypomagnesemia (<1.8 mg/dL) in 4 of 52 patients (7.7%) who had magnesium levels measured. Anemia prevalence was significantly higher among inappropriate vs. appropriate users (21.4% vs. 6.0%; P=0.02), as was CKD prevalence (17.1% vs. 4.0%; P=0.03).

4. DISCUSSION

This cross-sectional study of 120 patients receiving long-term PPI therapy in a general medicine outpatient setting revealed that inappropriate use was highly prevalent, affecting 58.3% of patients. Common inappropriate indications included nonspecific dyspepsia without diagnostic confirmation, lack of documented indication, and prophylaxis without appropriate risk factors. Documentation quality was poor, with only one-third having clear indication documented. Factors independently associated with inappropriate use included prescription by general physicians, polypharmacy, therapy duration exceeding 1 year, and self-prescription. Patient awareness regarding PPI therapy was strikingly low, and potential adverse effects were identified in over one-third of patients.

Our findings align with international literature reporting inappropriate PPI use rates of 25–70%.9-11 The 58.3% prevalence is consistent with recent Indian studies reporting rates of 54–62%.23-25 Nevertheless, direct comparisons should be interpreted cautiously given varying definitions of appropriateness, study populations, and healthcare settings across studies.

The preponderance of nonspecific dyspepsia as an inappropriate indication (35.7% of inappropriate users) reflects a common clinical scenario wherein PPIs are empirically initiated for vague gastrointestinal symptoms without adequate diagnostic evaluation. Current guidelines recommend limiting PPIs for uninvestigated dyspepsia to 4–8 weeks, followed by reassessment.7,8 The finding that 28.6% of patients had no documented indication highlights deficiencies in medical record keeping and incomplete medication reconciliation.

Poor documentation quality emerged as a critical issue. Documentation rates were significantly better for PPIs initiated by gastroenterologists than general physicians (71.4% vs. 24.4%), possibly reflecting differences in specialty training, time availability, or perceived importance of documentation. Inadequate documentation impedes clinical decision-making, contributes to prescription inertia, and complicates medication review. Electronic health record systems with structured prescribing templates requiring mandatory indication entry may help address this issue.28,29

Prescription by general physicians was independently associated with inappropriate use (adjusted OR, 3.8). This finding should not be interpreted as reflecting inadequate competence but rather likely reflects differences in case mix, time pressures in busy general medicine clinics, and less focused attention on gastroenterology-specific prescribing guidelines. General physicians manage diverse conditions and may prioritize other clinical issues over detailed PPI reassessment, highlighting the need for targeted educational interventions and clinical decision support tools.

Polypharmacy emerged as an independent risk factor (adjusted OR, 2.9). Patients on multiple medications face challenges with medication management, and clinicians may be hesitant to discontinue medications in complex patients despite lack of clear indication. Deprescribing interventions addressing polypharmacy have shown promise.30,31

Patient awareness regarding PPI therapy was alarmingly low, with only 28.3% able to state their indication. This knowledge gap has important implications for shared decision-making, as uninformed patients may continue obtaining refills without questioning necessity. Structured patient education should be incorporated into clinical practice.32

The identification of potential adverse effects in 35.0% of patients, including significantly higher anemia and

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CKD prevalence among inappropriate vs. appropriate users, underscores the clinical relevance of prolonged unnecessary PPI exposure.14-18 Although our cross-sectional design precludes establishing causality, these associations warrant attention.

Several practical implications emerge. Systematic medication review protocols, electronic prescribing decision support alerts, prescriber education initiatives, patient education materials, and PPI deprescribing protocols should be implemented. A systematic review reported successful PPI discontinuation in 40–62% of patients identified with inappropriate use, with most experiencing no significant symptom recurrence.33

Limitations

This study has several limitations. The cross-sectional design precludes establishing temporal relationships or causality between PPI use and adverse effects. Single-center design may limit generalizability. The relatively small sample size (n=120) limited statistical power for some subgroup analyses. Appropriateness classification, while based on evidence-based criteria with high inter-rater reliability, involves some subjectivity for borderline cases. Laboratory data derived from routine clinical care were incompletely available for some parameters. Patient-reported outcomes relied on recall and may be subject to recall bias. We did not assess outcomes following deprescribing. Finally, some patients classified as inappropriate users may have had valid undocumented reasons for continuation.

5. CONCLUSION

Inappropriate long-term PPI use affects more than half of patients in general medicine outpatient settings. Poor documentation, inadequate medication review, and low patient awareness contribute to this problem. Systematic interventions are needed at multiple levels including prescriber education, electronic health record modifications, structured medication review, patient education, and implementation of deprescribing protocols. Future prospective studies should evaluate long-term outcomes and effectiveness of deprescribing interventions in diverse Indian healthcare settings.

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AUTHOR CONTRIBUTIONS

A. Kumar G.: study concept and design, data collection, data analysis and interpretation, drafting of the manuscript. K. Mayilananthi: study design, appropriateness classification, critical revision of the manuscript. V.R. Mohan Rao: study design, supervision, critical revision of the manuscript. M. Balajinathan: critical revision, administrative support. C. Ramakrishnan: critical revision of the manuscript. K. Centhil: critical revision of the manuscript. D. Krishnan: critical revision of the manuscript. All authors approved the final version of the manuscript.

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FIGURE LEGEND

Figure 1. Flow diagram of patient enrollment. Of 487 patients screened, 367 were excluded: 158 did not meet inclusion criteria, 124 met exclusion criteria, and 85 declined participation. The final cohort comprised 120 patients; 50 (41.7%) had appropriate long-term PPI use and 70 (58.3%) had inappropriate long-term PPI use. PPI, proton pump inhibitor.

TABLES

Table 1. Baseline Characteristics of Study Participants by PPI Use Appropriateness

Characteristic	Total (N=120)	Appropriate Use (n=50)	Inappropriate Use (n=70)
Age, mean (SD), y	56.8 (12.4)	58.2 (11.8)	55.8 (12.7)
Female sex, No. (%)	68 (56.7)	26 (52.0)	42 (60.0)
Comorbidities, No. (%)			
Hypertension	54 (45.0)	24 (48.0)	30 (42.9)
Type 2 diabetes	42 (35.0)	20 (40.0)	22 (31.4)
Chronic kidney disease	18 (15.0)	6 (12.0)	12 (17.1)

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Coronary artery disease	16 (13.3)	9 (18.0)	7 (10.0)
Polypharmacy (≥5 medications), No. (%)	64 (53.3)	18 (36.0)	46 (65.7)
PPI type, No. (%)			
Pantoprazole	62 (51.7)	28 (56.0)	34 (48.6)
Omeprazole	32 (26.7)	12 (24.0)	20 (28.6)
Esomeprazole	16 (13.3)	6 (12.0)	10 (14.3)
Rabeprazole	8 (6.7)	3 (6.0)	5 (7.1)
Lansoprazole	2 (1.7)	1 (2.0)	1 (1.4)
PPI duration, median (IQR), mo	18 (10–36)	12 (8–24)	24 (14–42)
Prescriber, No. (%)			
General physician	78 (65.0)	22 (44.0)	56 (80.0)
Gastroenterologist	28 (23.3)	22 (44.0)	6 (8.6)
Self-prescribed	14 (11.7)	6 (12.0)	8 (11.4)

IQR, interquartile range; PPI, proton pump inhibitor; SD, standard deviation.

Table 2. Categories of Inappropriate PPI Indications (n=70)

Indication Category	No. (%)	Median Duration (IQR), mo
Nonspecific dyspepsia without diagnostic confirmation	25 (35.7)	26 (16–48)
No documented indication	20 (28.6)	28 (18–52)
Prophylaxis without risk factors	15 (21.4)	18 (12–36)
GERD controlled but continued >8 weeks without reassessment	8 (11.4)	14 (10–22)
Initial indication resolved	2 (2.9)	20 (16–24)
Total	70 (100)	24 (14–42)

GERD, gastroesophageal reflux disease; IQR, interquartile range; PPI, proton pump inhibitor.

Table 3. Quality of PPI Documentation in Medical Records

Documentation Component	Total (N=120)	Appropriate Use (n=50)	Inappropriate Use (n=70)
Indication documented, No. (%)	39 (32.5)	34 (68.0)	5 (7.1)
Duration specified, No. (%)	28 (23.3)	24 (48.0)	4 (5.7)
Review plan documented, No. (%)	18 (15.0)	16 (32.0)	2 (2.9)
Adequate documentation,[a] No. (%)	16 (13.3)	14 (28.0)	2 (2.9)

[a]*Adequate documentation defined as all three components documented. All P<0.001 for appropriate vs. inappropriate comparisons.*

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Table 4. Patient Awareness and Understanding of PPI Therapy

Patient Awareness Component	Total (N=120)	Appropriate Use (n=50)	Inappropriate Use (n=70)
Can state PPI indication, No. (%)	34 (28.3)	28 (56.0)	6 (8.6)
Aware of planned duration, No. (%)	22 (18.3)	18 (36.0)	4 (5.7)
Knows potential adverse effects, No. (%)	18 (15.0)	12 (24.0)	6 (8.6)
Ever discussed discontinuation, No. (%)	24 (20.0)	16 (32.0)	8 (11.4)
Willing to consider discontinuation, No. (%)	86 (71.7)	38 (76.0)	48 (68.6)

PPI, proton pump inhibitor. P values from chi-square or Fisher exact test.

Table 5. Factors Associated With Inappropriate Long-Term PPI Use

Variable	Univariable OR (95% CI)	P Value	Multivariable OR (95% CI)	P Value
Age, per 10-y increase	0.9 (0.7–1.2)	.48	—	—
Female sex	1.4 (0.7–2.8)	.39	—	—
Polypharmacy (≥5 medications)	3.4 (1.6–7.0)	.001	2.9 (1.3–6.5)	.009
Duration >1 year	4.8 (2.2–10.5)	<.001	4.2 (1.8–9.8)	<.001
Prescriber (vs gastroenterologist)				
General physician	5.1 (2.3–11.4)	<.001	3.8 (1.6–9.2)	.003
Self-prescribed	6.2 (1.7–22.8)	.006	5.6 (1.4–22.3)	.015
Hypertension	0.8 (0.4–1.6)	.58	—	—
Type 2 diabetes	0.7 (0.3–1.4)	.33	—	—

Multivariable model included variables with P<.10 in univariable analysis. CI, confidence interval; OR, odds ratio.

Table 6. Potential PPI-Related Adverse Effects

Adverse Effect	Total (N=120)	Appropriate Use (n=50)	Inappropriate Use (n=70)
Any adverse effect, No. (%)	42 (35.0)	12 (24.0)	30 (42.9)
Anemia,[a] No. (%)	18 (15.0)	3 (6.0)	15 (21.4)
CKD (eGFR <60),[b] No. (%)	14 (11.7)	2 (4.0)	12 (17.1)
Hypomagnesemia,[c] No./total No. (%)	4/52 (7.7)	2/24 (8.3)	2/28 (7.1)
Self-reported fractures, No. (%)	6 (5.0)	1 (2.0)	5 (7.1)
Vitamin B12 deficiency,[d] No./total No. (%)	3/38 (7.9)	1/18 (5.6)	2/20 (10.0)

[a]Anemia: hemoglobin <13 g/dL in males, <12 g/dL in females. [b]CKD: eGFR <60 mL/min/1.73 m². [c]Hypomagnesemia: serum magnesium <1.8 mg/dL. [d]Vitamin B12 deficiency: <200 pg/mL. CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; PPI, proton pump inhibitor.