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RESEARCH ARTICLE

Assessment of Awareness, Knowledge and Behaviour Regarding the Misuse of Proton Pump Inhibitors Among the General Population in the Selected Areas of Kalaburagi City

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Abstract: Proton Pump Inhibitors (PPIs) are highly effective for acid-related disorders, but their widespread availability has led to significant overuse and self-medication, escalating the risk of long-term adverse effects. This misuse is frequently linked to insufficient public awareness regarding their appropriate use and potential risks. This study aimed to assess the baseline knowledge, awareness, and behaviors (KAP) concerning PPI use within the general population of Kalaburagi city and to determine the impact of a structured educational intervention. A prospective, quasi-experimental, controlled study was conducted over nine months. Five hundred participants were allocated into an intervention group (n=250), which received pharmacist-led counseling and a patient information leaflet (PIL), or a control group (n=250), which received only the PIL. A validated KAP questionnaire was administered at baseline and again two months post-intervention. Data were analyzed using paired and independent t-tests. The intervention group demonstrated a substantial and statistically significant improvement in mean KAP scores, rising from a baseline of 9.44 ± 1.75 to 13.83 ± 2.05 ($p < 0.001$). While the control group also showed a minor significant increase, from 9.63 ± 1.71 to 10.26 ± 1.85 ($p < 0.001$), the magnitude of change in the intervention group was vastly superior. The main baseline deficits were identified in knowledge of administration timing and long-term complications. These results confirm that pharmacist-led educational initiatives can markedly improve public knowledge and promote more rational medication-use behaviors, mitigating the risks associated with PPI misuse.

Keywords: Proton Pump Inhibitors; Rational Drug Use; Health Education; Patient Knowledge; Medication Misuse

1. Introduction

Proton Pump Inhibitors (PPIs) are a cornerstone in the management of acid-peptic disorders. This class of drugs, which includes omeprazole, pantoprazole, lansoprazole, and their derivatives, exerts its therapeutic effect through the potent and irreversible inhibition of the H^+/K^+-ATPase enzyme system (the "proton pump") located in the gastric parietal cells [1]. This action is the final step in the pathway of gastric acid secretion, and its blockade results in a more profound and sustained suppression of gastric acid compared to other agents, such as H_2-receptor antagonists [2]. Consequently, PPIs are widely indicated and highly effective for the treatment of gastroesophageal reflux disease (GERD), peptic ulcer disease (PUD), the eradication of *Helicobacter pylori* (in combination regimens), and for ulcer prophylaxis in high-risk patients receiving non-steroidal anti-inflammatory drugs (NSAIDs) [3].

Despite their clear therapeutic benefits, the high efficacy and increasing over-the-counter (OTC) availability of PPIs have contributed to their extensive use, often outside of established guidelines [4]. They are frequently prescribed for inappropriate durations, for functional dyspepsia without a clear diagnosis, or as unnecessary prophylaxis in low-risk patients [5]. This pattern of overuse is compounded by widespread self-medication, driven by the public perception of PPIs as simple "antacids" with a benign safety profile [6]. This irrational consumption places a large population at risk of unnecessary drug exposure and subsequent complications.

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While generally well-tolerated in the short term, a substantial body of evidence has emerged detailing significant risks associated with long-term and high-dose PPI use. The profound acid suppression disrupts normal physiological processes, leading to a spectrum of adverse outcomes. These include micronutrient malabsorption, most notably Vitamin B12 and magnesium, which can manifest as hematological or neurological symptoms and hypomagnesemic tetany, respectively [7, 8].

Moreover, the alteration of gastric pH is believed to compromise the gut's natural barrier against pathogens, increasing susceptibility to enteric infections, including a significantly elevated risk of *Clostridium difficile*-associated diarrhea [9]. Other documented concerns include an increased risk of community-acquired pneumonia and a potential association with bone fractures, particularly of the hip, linked to possible effects on calcium absorption and osteoclast function [10]. More recent, though less conclusively established, concerns have highlighted potential links to renal complications, such as acute interstitial nephritis and the progression of chronic kidney disease [11].

A critical factor contributing to PPI misuse is the documented low level of public awareness regarding these potential adverse effects and the correct parameters for their use [12]. Many individuals are unaware of the importance of taking PPIs 30-60 minutes before a meal for optimal efficacy or the fact that they are intended for a finite duration unless otherwise directed by a physician. Given the public health implications of widespread PPI misuse, interventions aimed at improving patient knowledge are essential. Therefore, this study was designed to assess the baseline knowledge, awareness, and behaviors related to PPI use in the general population of Kalaburagi, Karnataka, and to evaluate the effectiveness of a pharmacist-led educational intervention in promoting rational use.

2. Materials and Methods

2.1. Study Design and Setting

A prospective, quasi-experimental, controlled intervention study was conducted in various community areas and colonies within Kalaburagi city, Karnataka, India. The study employed a pre-test and post-test design with a non-equivalent control group. The study was conducted over a nine-month period, from January 2023 to September 2023.

2.2. Study Population and Sampling

A total of 510 participants were initially enrolled. Participants who failed to complete the follow-up assessment (n=10) were excluded, resulting in a final sample size of 500. Participants were allocated into two groups: an intervention (test) group (n=250) and a control group (n=250).

2.3. Inclusion and Exclusion Criteria

The study included individuals of either gender, aged 18 years and above, who were able to communicate in English or Kannada. Participants were required to have a diagnosis of gastritis, GERD, ZES, or PUD, or to have a history of purchasing PPIs for self-medication. All participants provided written informed consent. Individuals below 18 years of age and those unwilling to participate or unable to provide consent were excluded from the study.

2.4. Intervention and Data Collection

2.4.1. Baseline Assessment

At enrollment, all 500 participants completed a structured Knowledge, Awareness, and Behavior (KAP) questionnaire, which served as the pre-test data.

2.4.2. Intervention Phase

Intervention Group (n=250): Participants in this group received a pharmacist-led educational intervention. This included one-on-one counseling on the appropriate use of PPIs, correct administration timing, the importance of adherence, lifestyle modifications, and detailed information on potential long-term adverse effects. This counseling was supplemented with a Patient Information Leaflet (PIL).

Control Group (n=250): Participants in this group did not receive active counseling but were provided with the same PIL.

2.4.3. Follow-up Assessment

After a two-month interval, the same KAP questionnaire was re-administered to both the intervention and control groups to gather post-test data.

2.5. Data Collection Tool

A structured KAP questionnaire was developed by the research team based on a review of existing literature and clinical guidelines. The questionnaire was validated for content and clarity by senior pharmacy practice faculty. It was translated into the local language (Kannada) and back-translated into English to ensure accuracy and consistency. The questionnaire collected demographic details and included specific questions to assess participants' awareness of PPIs, knowledge of their use (e.g., timing, duration), and self-reported behaviors (e.g., self-medication, dose escalation).

2.6. Ethical Factors

The study protocol (Approval No: IEC/HKE/OBS/NOV2024/11) received formal approval from the Institutional Ethics Committee (IEC) of HKES's Matoshree Taradevi Rampure Institute of Pharmaceutical Sciences, Kalaburagi. The research was conducted in strict adherence to the ethical principles outlined in the Declaration of Helsinki and the National Institute for Health and Care Excellence (NICE) guidelines. Written informed consent was obtained from each participant prior to any data collection or intervention.

2.7. Statistical Analysis

Collected data were coded, entered into Microsoft Excel, and analyzed using statistical software. Descriptive statistics (frequencies, percentages, mean ± standard deviation [SD]) were used to summarize demographic data and baseline KAP scores. A paired-samples t-test was employed to compare the pre-intervention and post-intervention KAP scores *within* each group (intervention and control). An independent-samples t-test was used to compare the post-intervention scores *between* the two groups. A p-value of < 0.05 was considered statistically significant.

3. Results

3.1. Demographic Characteristics

A total of 500 participants completed the study and were divided equally into the intervention (n=250) and control (n=250) groups. The demographic analysis revealed that the participant cohort was predominantly composed of young adults; individuals in the 18-25 age group constituted the largest segment, accounting for 48% (n=240) of the total sample. In terms of educational attainment, the majority of participants (48.6%, n=243) held an undergraduate qualification. Students represented the most common occupation, comprising 38% (n=190) of the participants.

Table 1. Demographic Profile of Study Participants

Characteristic	Category	Intervention Group (n=250) n (%)	Control Group (n=250) n (%)	Total (N=500) n (%)
Age Group	18-25	120 (48.0%)	120 (48.0%)	240 (48.0%)
	26-40	75 (30.0%)	78 (31.2%)	153 (30.6%)
	41-60	45 (18.0%)	42 (16.8%)	87 (17.4%)
	> 60	10 (4.0%)	10 (4.0%)	20 (4.0%)
Gender	Male	130 (52.0%)	128 (51.2%)	258 (51.6%)
	Female	120 (48.0%)	122 (48.8%)	242 (48.4%)
Education Level	High School or less	60 (24.0%)	62 (24.8%)	122 (24.4%)
	Undergraduate	121 (48.4%)	122 (48.8%)	243 (48.6%)
	Postgraduate	69 (27.6%)	66 (26.4%)	135 (27.0%)
Occupation	Student	95 (38.0%)	95 (38.0%)	190 (38.0%)
	Employed	102 (40.8%)	100 (40.0%)	202 (40.4%)
	Homemaker	33 (13.2%)	35 (14.0%)	68 (13.6%)
	Other/Unemployed	20 (8.0%)	20 (8.0%)	40 (8.0%)

3.2. Knowledge, Awareness, and Behavior (KAP) Scores

The primary outcome of the study was the change in the mean composite KAP score from baseline to the two-month follow-up. At baseline, both groups demonstrated comparable scores, with the intervention group at 9.44 ± 1.75 and the control group at 9.63 ± 1.71.

Following the intervention period, the intervention group, which received pharmacist-led counseling and a PIL, exhibited a substantial and statistically significant increase in their mean KAP score to 13.83 ± 2.05. This represents a 46.5% improvement from baseline ($t=52.16$, $p < 0.001$).

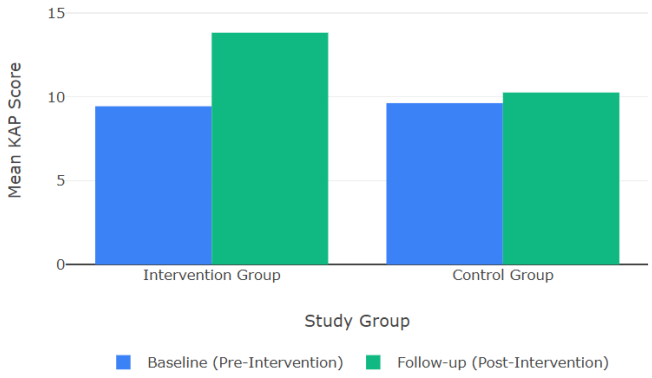

Figure 1. Mean KAP Scores Before and After Intervention

Conversely, the control group, which received only the passive PIL, showed a minor, though statistically significant, increase in their mean score to 10.26 ± 1.85 ($t=9.34$, $p < 0.001$). The magnitude of improvement in the intervention group was significantly greater than that observed in the control group.

Table 2. Comparison of Mean KAP Scores Before and After Intervention

Group	Time Point	Mean KAP Score ± SD	Mean Difference (Post - Pre)	p-value*
Intervention Group (n=250)	Baseline (Pre)	9.44 ± 1.75	4.39	< 0.001
	Follow-up (Post)	13.83 ± 2.05		
Control Group (n=250)	Baseline (Pre)	9.63 ± 1.71	0.63	< 0.001
	Follow-up (Post)	10.26 ± 1.85		

SD = Standard Deviation; KAP = Knowledge, Awareness, and Behavior.
**p-value calculated using a paired-samples t-test for the within-group change from baseline to follow-up. A separate independent-samples t-test confirms the post-intervention scores between the two groups were significantly different ($p < 0.001$).*

3.3. Analysis of Specific KAP Domains

3.3.1. Knowledge of PPI Indications and Administration

At baseline, awareness of correct PPI indications (e.g., acidity, heartburn) was moderate in both the intervention (48.0%, n=120) and control (52.0%, n=130) groups. Post-intervention, this awareness rose dramatically to 84.4% (n=211) in the intervention group, while remaining virtually unchanged at 52.8% (n=132) in the control group.

A more significant deficit was noted in the knowledge of appropriate administration timing. At baseline, only 40.0% (n=100) of the intervention group and 38.0% (n=95) of the control group knew the correct timing. The educational counseling resulted in a marked improvement, with 86.0% (n=215) of the intervention group demonstrating correct knowledge at follow-up. The control group's knowledge saw only a marginal increase to 40.0% (n=100).

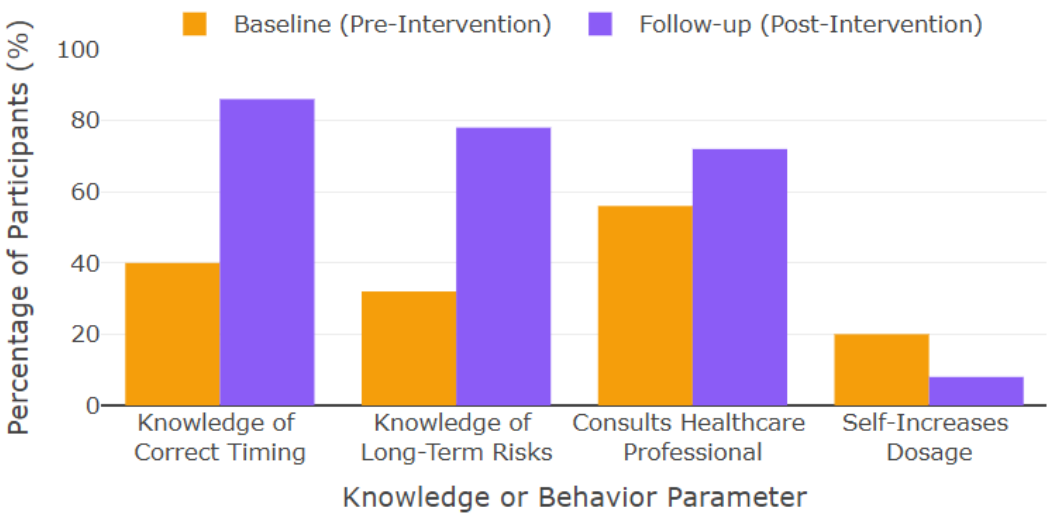

Figure 2. Impact of Intervention on Specific Knowledge & Behavior

Table 3. Comparison of Correct Responses to Knowledge-Based Questions

Knowledge Parameter *(Correct Responses)*	**Intervention Group (n=250) n (%) Baseline**	**Control Group (n=250) n (%) Post-Intervention**
1. Awareness of correct PPI indications (e.g., acidity, heartburn)	120 (48.0%)	211 (84.4%)
2. Knowledge of appropriate administration timing (e.g., 30-60 min before food)	100 (40.0%)	215 (86.0%)
3. Knowledge of long-term risks (e.g., nutrient deficiencies)	80 (32.0%)	195 (78.0%)
4. Knowledge of potential drug interactions	100 (40.0%)	200 (80.0%)

3.3.2. Knowledge of Long-Term Adverse Effects

Baseline knowledge regarding potential long-term complications, such as nutrient deficiencies, was poor across the entire cohort (32.0%, n=80 in the intervention group; 30.0%, n=75 in the control group). The intervention successfully addressed this gap, with 78.0% (n=195) of the intervention group reporting awareness of these risks post-counseling. In contrast, the control group's awareness increased minimally to 35.2% (n=88). Similarly, awareness of potential drug interactions improved from 40.0% (n=100) to 80.0% (n=200) in the intervention group, while stagnating in the control group (42.0% to 43.2%).

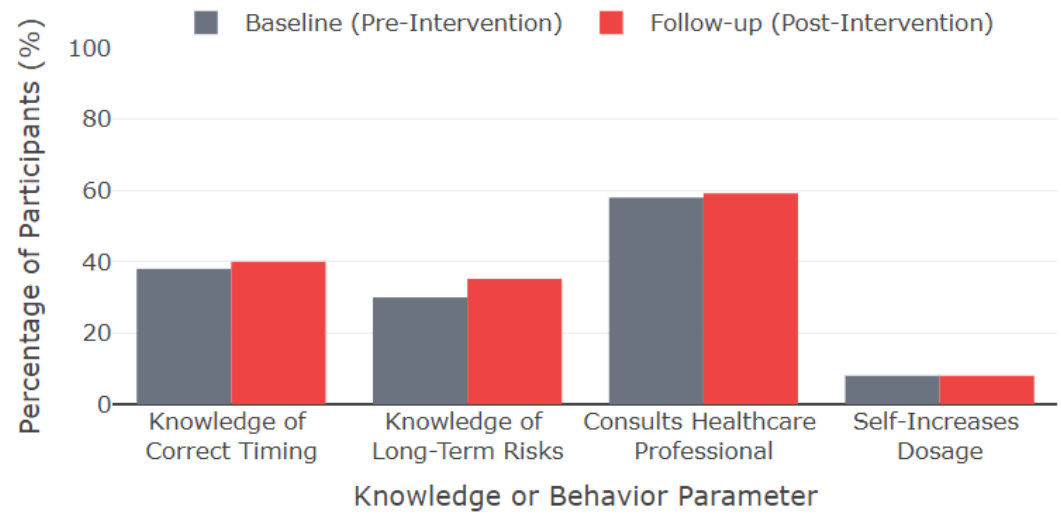

Figure 3. Specific Knowledge & Behavior (Control Group)

3.3.3. Self-Reported Medication-Use Behaviors

Behavioral practices also showed positive changes following the intervention. The proportion of participants in the intervention group who reported consulting a healthcare professional before using PPIs increased from 56.0% (n=140) to 72.0% (n=180). This behavior saw negligible change in the control group (58.0% to 59.2%).

Critically, a key behavior associated with misuse—self-increasing PPI dosage without medical advice—was significantly impacted. At baseline, 20.0% (n=50) of the intervention group reported engaging in this practice. After the educational session, this proportion was reduced by 60%, to only 8.0% (n=20). This behavior remained constant in the control group, with 8.0% (n=20) reporting it at both baseline and follow-up.

Table 4. Comparison of Self-Reported Behavioral Practices

Self-Reported Behavior	Intervention Group (n=250) n (%) Baseline	Control Group (n=250) n (%) Post-Intervention
1. Reports consulting a healthcare professional before PPI use	140 (56.0%)	180 (72.0%)
2. Reports self-increasing PPI dosage without medical advice	50 (20.0%)	20 (8.0%)

4. Discussion

The findings of this study demonstrate a significant deficiency in the general public's knowledge and self-reported behaviors concerning the rational use of PPIs. At baseline, a substantial portion of the population in Kalaburagi was unaware of critical information, such as correct administration timing and the potential for long-term adverse effects, particularly nutrient deficiencies. These knowledge gaps are a likely contributor to the widespread PPI misuse and self-medication reported in broader literature [12].

The primary finding of this investigation is the pronounced efficacy of a pharmacist-led, active educational intervention. The intervention group, which received direct counseling, achieved a 46.5% improvement in mean KAP scores. This was vastly superior to the minimal change observed in the control group, which received only a standard Patient Information Leaflet (PIL). This discrepancy strongly suggests that passive information dissemination (PILs alone) is insufficient to produce meaningful changes in patient knowledge or behavior. This observation aligns with extensive research in medication adherence and health literacy, which indicates that active, dialog-based patient counseling is essential for translating information into practice [13, 14].

The intervention was particularly effective in addressing specific, high-risk knowledge deficits. For instance, knowledge of administration timing, which is critical for PPI bioavailability and efficacy, improved from 40% to 86% in the intervention group. Likewise, awareness of long-term risks, a key factor in discouraging indefinite, non-prescribed use, increased from 32% to 78%. These improvements in knowledge correlated with positive shifts in self-reported behaviors. The reduction in self-escalation of PPI dosage (from 20% to 8%) in the intervention group is a clinically relevant outcome, as this practice is directly associated with an increased risk of adverse effects.

The results highlight the essential public health role of pharmacists and other healthcare professionals as active educators. The minimal change in the control group underscores that mere access to information does not equate to comprehension or behavioral modification. The active counseling provided by the pharmacist allowed for clarification, reinforcement, and a tailored discussion, which proved decisive in improving the rational use of PPIs.

This study has several limitations. The quasi-experimental design, while practical, lacks the robust control of a randomized controlled trial (RCT). The reliance on self-reported data for behavioral outcomes introduces the possibility of social desirability bias, where participants may have reported more "correct" behaviors after the intervention. Moreover, the study was conducted in a single urban setting, which may limit the generalizability of these findings to rural populations or other regions with different healthcare access and literacy levels. The two-month follow-up period is sufficient to demonstrate short-term knowledge retention but cannot be used to determine the long-term sustainability of the behavioral changes.

5. Conclusion

This study confirms that baseline knowledge regarding the safe and appropriate use of Proton Pump Inhibitors is inadequate among the general population in Kalaburagi. This information deficit, particularly concerning administration timing and long-term risks, fosters an environment of medication misuse and self-dosing. The results conclusively indicate that a structured, pharmacist-led educational intervention, combining verbal counseling with written materials, is a highly effective strategy for improving patient knowledge and promoting rational medication-use behaviors. The minimal impact of passive information leaflets alone highlights the necessity of active patient engagement by healthcare providers. Utilizing such educational protocols into routine pharmacy practice and community health programs is essential to mitigate the public health risks associated with the irrational consumption of PPIs.

Compliance with ethical standards

Acknowledgements

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Conflict of interest statement

The authors declare that they have no conflict of interest.

Statement of ethical approval

The study protocol (Approval No: IEC/HKE/OBS/NOV2024/11) received formal approval from the Institutional Ethics Committee (IEC) of HKES's Matoshree Taradevi Rampure Institute of Pharmaceutical Sciences, Kalaburagi. The research was conducted in strict adherence to the ethical principles outlined in the Declaration of Helsinki and the National Institute for Health and Care Excellence (NICE) guidelines.

Statement of informed consent

Written informed consent was obtained from all individual participants included in the study.

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