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Comparative Evaluation of Gastrointestinal Symptoms among Adult users of Pantoprazole and Omeprazole: A Community Survey with WHO VigiAccess Context

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Abstract

Background: Proton pump inhibitors (PPIs), including pantoprazole and omeprazole, are commonly used to treat acid-related disorders. Gastrointestinal symptoms may occur during treatment, but patient-reported symptoms do not necessarily establish an adverse drug reaction.

Methods: This cross-sectional observational community survey included 100 adults from Bengaluru, comprising 50 physical proformas and 50 digital responses. The sample included 74 pantoprazole users and 26 omeprazole users. Demographic information, medicine use and reported gastrointestinal symptoms were summarized using descriptive frequencies and percentages. The dissertation also recorded global spontaneous-reporting counts for selected gastrointestinal events from WHO VigiAccess.

Results: New or suspected gastrointestinal discomfort was recorded in 27.0% of pantoprazole users and 23.1% of omeprazole users. In the pantoprazole group, the dissertation's symptom summary recorded abdominal pain/cramping (9.5%), bloating/gas/flatulence (6.8%), diarrhoea/loose stools (6.8%) and nausea (1.4%). In the omeprazole group, bloating/gas/flatulence and diarrhoea/loose stools were each recorded in 7.7%, nausea in 3.8%, and abdominal pain was not recorded. The VigiAccess extraction log listed 24,546 gastrointestinal disorder reports for pantoprazole and 38,702 for omeprazole.

Conclusion: Symptoms were reported in both groups, but the descriptive design, unequal group sizes and absence of diagnostic testing do not establish causality, statistical significance or comparative risk. VigiAccess report counts are not incidence rates.

Keywords: *Pharmacovigilance; Pantoprazole; Omeprazole; Gastrointestinal symptoms; Adverse drug reactions; VigiAccess*.

I. INTRODUCTION

Acid-peptic disorders include gastroesophageal reflux disease, peptic ulcer disease and functional dyspepsia. These conditions involve an imbalance between aggressive gastric factors, particularly hydrochloric acid and pepsin, and the protective mechanisms of the gastrointestinal mucosa [6-10]. Proton pump inhibitors are widely used because they inhibit the gastric H+/K+-ATPase enzyme, the final step in acid secretion [11,12].

Omeprazole is an established PPI commonly administered at a standard adult dose of 20 mg once daily. It is metabolized mainly through CYP2C19 and to a lesser extent through CYP3A4, which contributes to its potential for drug interactions [14,15]. Pantoprazole is commonly used at 40 mg once daily and has a different metabolic profile, including a sulfation pathway, which may reduce some CYP-mediated interaction potential [13,16].

Although PPIs are effective for acid-related disorders, prolonged acid suppression may alter the gastric environment and influence gastrointestinal microbial composition. Previous literature has discussed possible associations between PPI use, intestinal microbial changes and symptoms such as bloating, diarrhoea and abdominal discomfort [21-30]. These symptoms are not, by themselves, proof of small intestinal bacterial overgrowth (SIBO) or dysbiosis.

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Pharmacovigilance supports the detection and assessment of suspected adverse drug reactions after medicines enter routine use. WHO VigiAccess provides public access to aggregated reports from the global VigiBase system. Spontaneous-reporting counts are affected by under-reporting and the absence of exposure denominators; therefore, they cannot be interpreted as incidence rates [36,37,42-44]. The present study used a community survey to describe gastrointestinal symptoms reported by adult users of pantoprazole and omeprazole, with VigiAccess data included only as global reporting context.

II. MATERIALS AND METHODS

Study design and setting

A cross-sectional, prospective observational study was conducted in Bengaluru, Karnataka. Primary data were collected over a 45-day period from adult patients approached at the outpatient pharmacy and waiting areas of Aster Hospital, Whitefield, and community pharmacies in Hebbal and Mariyanapalya. A total of 100 participants were included: 50 completed physical proformas and 50 submitted digital responses.

Study population and eligibility

Eligible participants were adults aged 18 years or older, of any gender, with a history of pantoprazole 40 mg or omeprazole 20 mg use, including short-term and maintenance users, within the preceding six months. Patients using concurrent medicines likely to alter gastrointestinal motility (such as domperidone or levosulpiride), broad-spectrum systemic antibiotics, multiple PPIs or concurrent H2-receptor antagonists were excluded. Patients with a diagnosed history of severe inflammatory bowel disease or major gastrointestinal surgical resection were also excluded.

Data collection

For the physical survey, the study purpose was explained to eligible patients in their preferred language (Kannada, Hindi or English), and written informed consent was obtained before the questionnaire was administered. The proforma recorded demographic information, PPI molecule, duration and pattern of use, and patient-reported gastrointestinal symptoms. Participants were asked to distinguish symptoms present before treatment from new symptoms noticed after starting continuous PPI therapy.

For digital data collection, the questionnaire was converted into a Google Form with a mandatory electronic consent step and controls intended to reduce duplicate submissions. The digital link was circulated through community networks in Bengaluru. Physical and digital records were merged into a single dataset, checked for incomplete or internally inconsistent responses, and anonymized before analysis.

WHO VigiAccess data extraction

The dissertation recorded global VigiAccess report counts for pantoprazole and omeprazole under the MedDRA System Organ Class 'Gastrointestinal disorders'. Counts for nausea, diarrhoea, abdominal pain and flatulence were documented for each medicine. These aggregated spontaneous-reporting counts were not combined with the community survey as patient-level data and cannot be interpreted as incidence rates. The source dissertation does not state the exact date on which the VigiAccess counts were accessed; the authors should add the original extraction date, if available, before submission.

Statistical analysis and ethics

Descriptive statistics were used. Frequencies and percentages were calculated for demographic characteristics, medicine utilization, treatment duration and reported gastrointestinal symptoms. No inferential comparison or formal causality assessment was reported. The dissertation describes voluntary participation, informed consent for physical and digital responses, and removal of identifying information from the analysis dataset. However, it does not provide an institutional ethics committee approval number or a formal exemption statement. The authors must confirm the applicable ethics review/approval or exemption with their institution and insert the documentation before journal submission.

III. RESULTS

Participant characteristics

The study included 100 participants, with equal numbers recruited through physical and digital methods. The digital cohort predominantly included younger adults, while the physical cohort consisted of participants aged 41 years or older. This difference indicates that age and collection method were confounded in the sample

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Age group	Physical (n=50)	Digital (n=50)	Total (N=100)
18–25 years	0	37	37 (37.0%)
26–40 years	0	10	10 (10.0%)
41–60 years	37	3	40 (40.0%)
>60 years	13	0	13 (13.0%)

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Gender	Physical	Digital	Total
Male	16	29	45 (45.0%)
Female	15	18	33 (33.0%)
Prefer not to say	19	3	22 (22.0%)

PPI utilization and duration

Pantoprazole was used by 74 participants (74.0%), while 26 participants (26.0%) used omeprazole. Acute use of less than one week was recorded in 39 participants (39.0%). Chronic use exceeding six months was reported by 25 participants (25.0%).

Treatment duration	Pantoprazole (n=74)	Omeprazole (n=26)	Total
Acute (<1 week)	31 (41.9%)	8 (30.8%)	39
Short-term (1–4 weeks)	14 (18.9%)	5 (19.2%)	19
Medium-term (1–6 months)	10 (13.5%)	7 (26.9%)	17
Chronic (>6 months)	19 (25.7%)	6 (23.1%)	25

Patient-reported gastrointestinal symptoms

New or suspected gastrointestinal discomfort was reported by 27.0% of pantoprazole users and 23.1% of omeprazole users. The symptom-specific frequencies are presented in Table 3. The source dataset also noted one 'other' symptom entry in each medicine group; the symptom details were not specified in the summary table.

Symptom	Pantoprazole (n=74)	Omeprazole (n=26)
Abdominal pain/cramping	7 (9.5%)	0 (0.0%)
Bloating/gas/flatulence	5 (6.8%)	2 (7.7%)
Diarrhoea/loose stools	5 (6.8%)	2 (7.7%)
Nausea	1 (1.4%)	1 (3.8%)

WHO VigiAccess reporting context

The global report counts recorded in the thesis are shown in Table 4. These are absolute spontaneous-reporting counts and do not represent the number or proportion of all patients exposed to either medicine.

Gastrointestinal event	Pantoprazole reports	Omeprazole reports
All gastrointestinal disorder reports	24,546	38,702
Nausea	4,066	6,877
Diarrhoea	3,703	5,630
Abdominal pain	2,181	3,283
Flatulence/bloating	1,686	1,423

IV. DISCUSSION

In this 100-participant community survey, new or suspected gastrointestinal discomfort was reported by 27.0% of pantoprazole users and 23.1% of omeprazole users. The most frequently recorded symptom in the pantoprazole group was abdominal pain/cramping (9.5%), whereas bloating/flatulence and diarrhoea were each reported by 7.7% of omeprazole users. These percentages describe the responses in this sample and should not be interpreted as proof that one medicine has a higher gastrointestinal risk.

Both medicines belong to the PPI class and suppress gastric acid by inhibiting the H+/K+-ATPase pump [11,12]. Literature has proposed that sustained acid suppression may influence intestinal microbial ecology and may be associated with gastrointestinal symptoms [21-30]. However, the present survey did not include breath testing, microbiological analysis or another diagnostic method to confirm SIBO or dysbiosis. The symptoms were therefore treated as patient-reported experiences only.

The WHO VigiAccess counts provide a broader pharmacovigilance context. The omeprazole totals were higher for several recorded events, while flatulence/bloating reports were higher for pantoprazole in the dataset extracted by the project. These raw totals cannot be compared as rates because the number of exposed patients, reporting patterns and other factors are unknown [36,37,44]. They should not be used to validate or contradict the local survey.

Several limitations affect interpretation. The study was cross-sectional and used convenience sampling without a formal sample-size calculation. The medicine groups were unequal (74 pantoprazole and 26 omeprazole users), and many participants were short-term users. Data relied on self-report and may be affected by recall bias. There was no control group or baseline symptom tracking, and underlying disease severity and lifestyle factors were not controlled. Age was strongly associated with the collection method:

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the digital survey captured mostly younger participants, while the physical survey captured older participants. No formal causality algorithm, such as the Naranjo scale, or diagnostic testing for SIBO was performed. These limitations prevent causal or statistically significant comparative conclusions.

V. CONCLUSION

Gastrointestinal symptoms, including abdominal pain, bloating/flatulence, diarrhoea and nausea, were reported by adult users of both pantoprazole and omeprazole in this community survey. New or suspected discomfort was reported by 27.0% of pantoprazole users and 23.1% of omeprazole users. The findings are descriptive and do not establish causality, statistical significance or a difference in comparative risk between the medicines. SIBO and dysbiosis were not clinically confirmed. WHO VigiAccess counts provide global spontaneous-reporting context but cannot be interpreted as incidence rates. Larger, controlled prospective studies with baseline symptom assessment and appropriate diagnostic methods are needed to evaluate comparative gastrointestinal tolerability.

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Conflicts of Interest
The source dissertation does not include a conflict-of-interest declaration. Each author must confirm and approve the final declaration before submission.

Data Availability
The participant-level survey dataset is not included in the manuscript. The authors should state whether anonymized data can be shared, and under what conditions, in accordance with participant consent and institutional requirement.

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