

**CLINICAL PROFILE AND PRESCRIBING PATTERNS OF PROTON PUMP
INHIBITORS IN PATIENTS WITH LIVER CIRRHOSIS: A CROSS-SECTIONAL
OBSERVATIONAL STUDY****Sahithi Yallamelli^{1*}, Koriche Umesh², Mounica Vattikuti Pilli³**¹Assistant Professor, Department of Doctor of Pharmacy, Koringa College of Pharmacy, Korangi, Andhra Pradesh, India.²Associate Professor, Department of Pharmacy Practice, Oxbridge College of Pharmacy, Bangalore, Karnataka, India.³Assistant Manager, Coquitlam, Canada.***Corresponding Author: Sahithi Yallamelli**Assistant Professor, Department of Doctor of Pharmacy, Koringa College of Pharmacy, Korangi, Andhra Pradesh, India. DOI: <https://doi.org/10.5281/zenodo.23275427>**How to cite this Article:** Sahithi Yallamelli^{1*}, Koriche Umesh², Mounica Vattikuti Pilli³. (2026). Clinical Profile and Prescribing Patterns of Proton Pump Inhibitors In Patients With Liver Cirrhosis: A Cross-Sectional Observational Study. European Journal of Pharmaceutical and Medical Research, 13(10), 437-444.
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ABSTRACT

Cirrhosis, the end-stage outcome of chronic liver injury, is frequently accompanied by acid-related gastrointestinal complications, for which proton pump inhibitors (PPIs) are widely prescribed, although evidence supporting their routine use in this vulnerable population remains limited. Objective: This cross-sectional observational study assessed the clinical profile, prescribing pattern, and adverse effect burden of PPIs in cirrhotic patients attending the Gastroenterology Department, King George Hospital, Visakhapatnam. Methods: A total of 100 cirrhosis patients were enrolled over six months, and demographic, clinical, and therapeutic data were collected through patient and caregiver interviews and prescription review. Results: The study population was predominantly male (72%), with alcoholic liver disease the leading cause of cirrhosis (49%), followed by unspecified aetiologies (29%) and hepatitis B (11%). PPIs were used by 68% of patients, most often initiated for ulcer bleeding (42%) or abdominal pain (24%), with pantoprazole the most commonly prescribed agent (89%). Endoscopy was performed in 82% of patients, revealing ulcers in a substantial proportion of cases, and antibiotics (50%) and diuretics (36%) were the most common concomitant medications. Clinical improvement of 75% or greater was observed in more than half of PPI users. Insomnia (15%), headache, anorexia, and abdominal pain (9% each), and bloating and constipation (7% each) were the most frequently reported adverse effects, while 49% of patients experienced none. Conclusion: PPIs offer meaningful clinical benefit in managing gastrointestinal complications of cirrhosis, but their adverse effect profile warrants cautious, individualized prescribing supported by regular monitoring and larger, longer-term studies.

KEYWORDS: Cirrhosis; Proton pump inhibitors; Pantoprazole; Ulcer bleeding; Adverse effects; Clinical profile.**INTRODUCTION**

Alcohol usage, persistent hepatitis virus infection, primary biliary cholangitis, autoimmune diseases, and cryptogenic origins are some of the causes of liver cirrhosis. Ascites, hepatocellular carcinoma, upper gastrointestinal bleeding (UGIB), and other complications may result, and affected patients are at greater risk of mortality.^[1]

The pharmacokinetics of frequently administered drugs may be affected by the reduced synthetic and metabolic

activity that accompanies cirrhosis. Patients with cirrhosis show a prolonged half-life for proton pump inhibitors (PPIs), which are hepatically metabolized via the cytochrome P450 pathway.^[2] Moreover, stomach-acid suppression-related changes in the intestinal microbiota may permit bacterial translocation and overgrowth, which could lead to conditions such as spontaneous bacterial peritonitis (SBP).^[3] PPI consumption may therefore place cirrhosis patients at higher risk of toxicity and adverse outcomes; however, this remains debated. PPIs have been inconsistently

linked to infection, decompensation, and mortality in both retrospective and prospective studies. At present, no consensus guidelines exist regarding the overall safety of PPI use or the dose modifications required for patients with cirrhosis.^[3]

Research assessing how PPI use affects unfavourable outcomes in cirrhosis patients has often been constrained by small sample sizes, single-centre settings, limited ability to account for complex confounding, or a restricted focus on hospitalized cirrhosis patients. Crucially, while studies in hospitalized cirrhosis patients may help identify negative liver-related consequences linked to PPI exposure, possible protective associations between PPIs and non-liver-related outcomes can go unnoticed.^[4] Among the most commonly prescribed agents are pantoprazole, omeprazole, and rabeprazole, which serve as first-line drugs. Cirrhosis causes a 4- to 8-fold increase in systemic pantoprazole levels owing to the liver's reduced metabolic capacity, making it considerably more likely than other PPIs to result in toxic drug accumulation and consequent complications.^[5]

Rabeprazole carries a significantly reduced likelihood of cytochrome P450-mediated drug-drug interactions, as it is largely metabolized through a non-enzymatic route. Although conventional doses must still not be exceeded, this makes it comparatively safer for cirrhosis patients on complex multi-drug regimens.

Omeprazole considerably inhibits the CYP2C19 enzyme, carrying a high interaction risk, although it does not accumulate to the extent that pantoprazole does. Owing to the increased potential for drug interactions, daily maximum limits must be strictly reduced in mild-to-moderate cirrhosis.

Approximately 60.5% to 67% of all patients diagnosed with liver cirrhosis in India are currently on PPI therapy, and a notable proportion of this use is unsupervised: between 28% and 33.3% of cirrhotic PPI users take the drug over-the-counter without a prescription. Despite being the most pharmacokinetically hazardous agent for advanced liver disease, pantoprazole remains the most commonly prescribed PPI in India, accounting for 55.7% of prescriptions in cirrhotic cohorts.

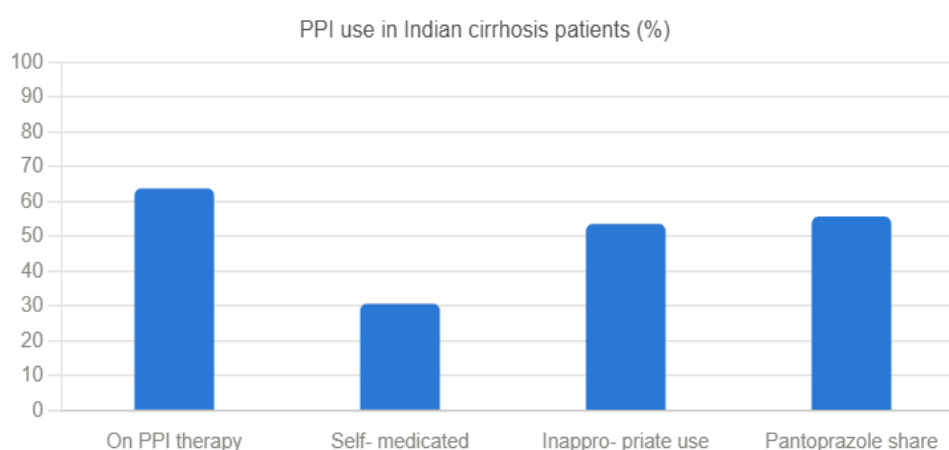


Figure 1: Inappropriate use of PPIs in cirrhosis patients.

MATERIALS AND METHODS

Study site

The study was conducted in the Gastroenterology Department at King George Hospital, Visakhapatnam.

Data source

Data were collected prospectively from a series of out-patients and in-patients diagnosed with liver cirrhosis at KGH. Patient demographic, clinical, and therapeutic data, along with other relevant information, were obtained from:

1. Personal interviews with patients to determine the chief complaint, history of the present illness, and past medical and medication history.
2. Patients' prescriptions.
3. Interviews with patient caregivers.

PATIENT SELECTION

Inclusion criteria

Subjects willing to give informed consent, and patients diagnosed with liver cirrhosis who were admitted to the study site during the study period, were included. Patients were categorized based on their PPI use.

Exclusion criteria

- Patients with altered mental status.
- Patients admitted to intensive care units.
- Patients not willing to give informed consent.

Method

This was a cross-sectional observational study.

Sample size

100 patients with liver cirrhosis using proton pump inhibitors.

Statistical parameters included in this study

Characteristics of the study population assessed included:

1. Age
2. Sex
3. Alcohol intake
4. Occupation
5. Socio-economic status
6. Type of liver cirrhosis
7. Smoking
8. Sleep patterns
9. Physical activities
10. Present and past medical history
11. Surgical history

12. Side effects experienced

RESULTS AND DISCUSSION

A total of 100 patients with liver cirrhosis were enrolled, comprising 72% (72/100) males and 28% (28/100) females.

Table 1: Percentage incidence of male and female patients in the selected population (n = 100).

Sex	Number of patients	Percentage
Male	72	72%
Female	28	28%
Total	100	100%

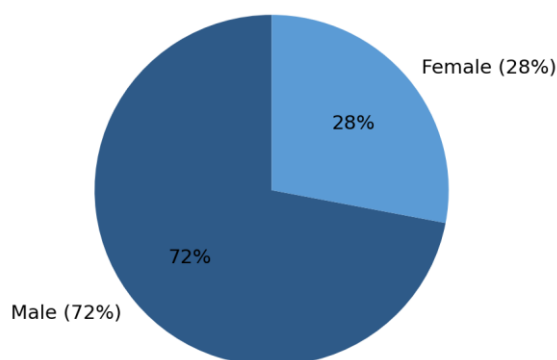


Figure 2: Gender distribution of the study population.

Table 2: Percentage incidence of males and females across types of liver cirrhosis.

Type of cirrhosis	Male	Female	Total
Alcohol	44	5	49
Hepatitis C	2	1	3
Hepatitis B	7	4	11
Biliary	2	6	8
Others	17	12	29
Total	72	28	100

Among the different types of liver cirrhosis, alcoholic liver cirrhosis was the most predominant, observed in 49% of patients (44 males and 5 females), followed by hepatitis B in 11% (7 males and 4 females), primary biliary cirrhosis in 8% (2 males and 6 females), and other aetiologies in 29% (17 males and 12 females).

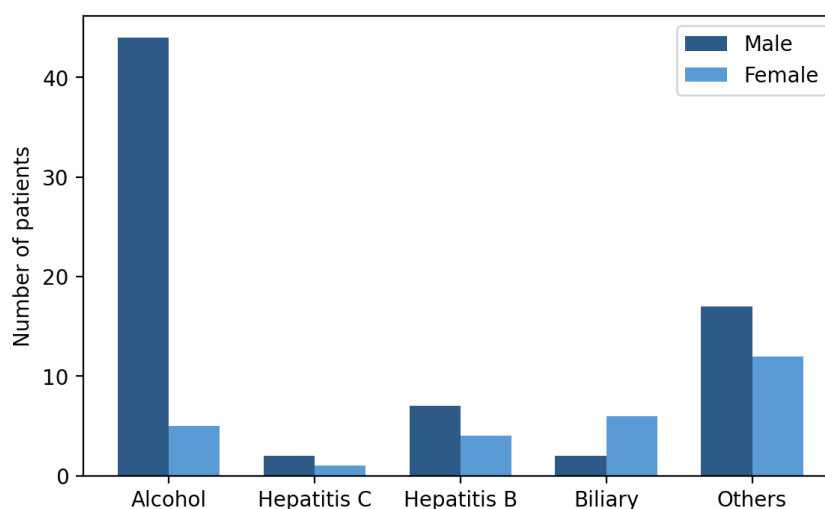


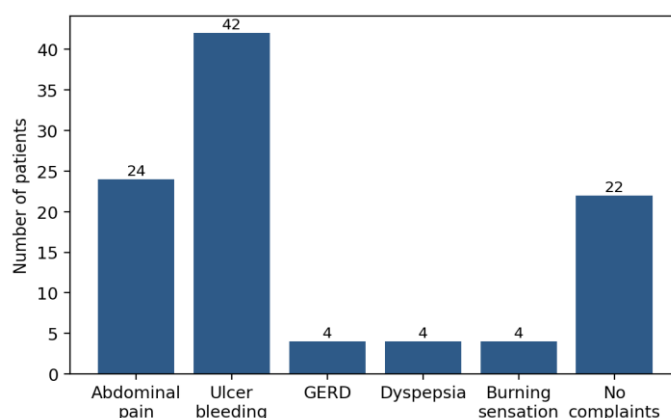
Figure 3: Distribution of male and female patients across types of liver cirrhosis.

Table 3: Symptoms for which PPI therapy was initiated.

S. No.	Symptom	Number of patients
1	Abdominal pain	24
2	Ulcer bleeding	42
3	GERD	4
4	Dyspepsia	4
5	Burning sensation	4
6	No complaints	22
7	Total	100

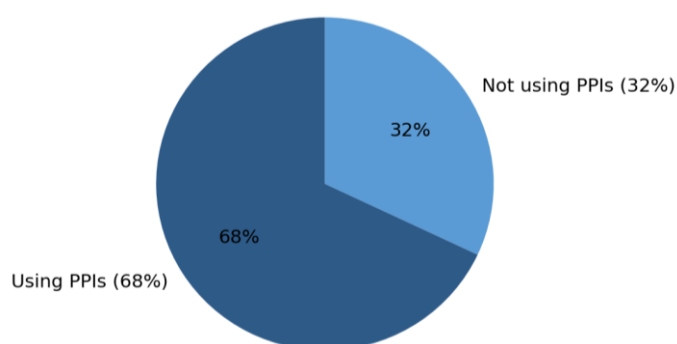
Among the 100 patients, 78% were started on PPIs for a defined indication: ulcer bleeding (42%), abdominal pain (24%), GERD (4%), dyspepsia (4%), and burning

sensation (4%); the remaining 22% were started on PPIs without any specific complaint.

**Figure 4: Symptoms for which PPI therapy was started.****Table 4: Liver cirrhotic patients on PPIs versus not on PPIs.**

Category	Number of patients
Using PPIs	68
Not using PPIs	32
Total	100

Among the 100 patients with liver cirrhosis, 68% were using PPIs and 32% were not.

**Figure 5: Percentage incidence of patients using PPIs.****Table 5: Percentage incidence of patients using different types of proton pump inhibitors.**

S. No.	PPI	Number of patients
1	Pantoprazole	89
2	Rabeprazole	6
3	Omeprazole	5
4	Total	100

Among the 100 patients, pantoprazole was the most frequently used PPI (89%), followed by rabeprazole (6%) and omeprazole (5%).

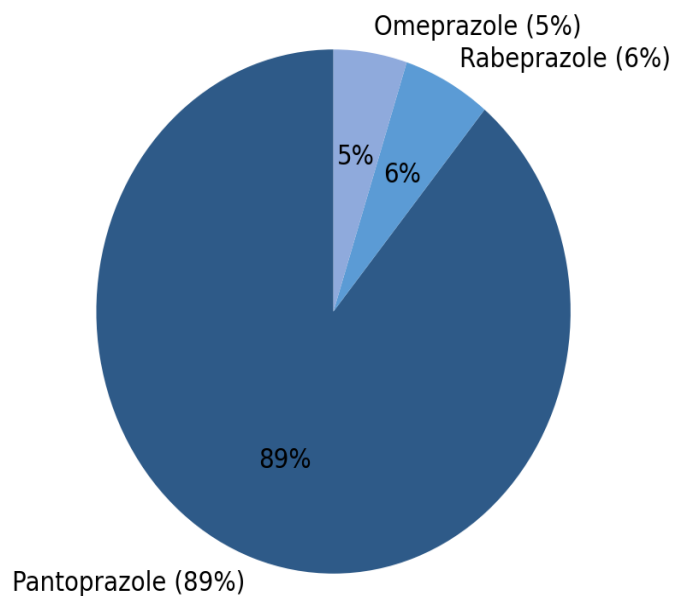


Figure 6: Percentage incidence of patients using different types of proton pump inhibitors.

Table 6: Improvement of condition after using PPIs.

S. No.	Improvement of condition	Number of patients
1	25%	17
2	50%	30
3	75%	44
4	100%	9

Among the 100 patients, condition improved by 25% in 17 patients, by 50% in 30 patients, by 75% in 44 patients, and by 100% in 9 patients.

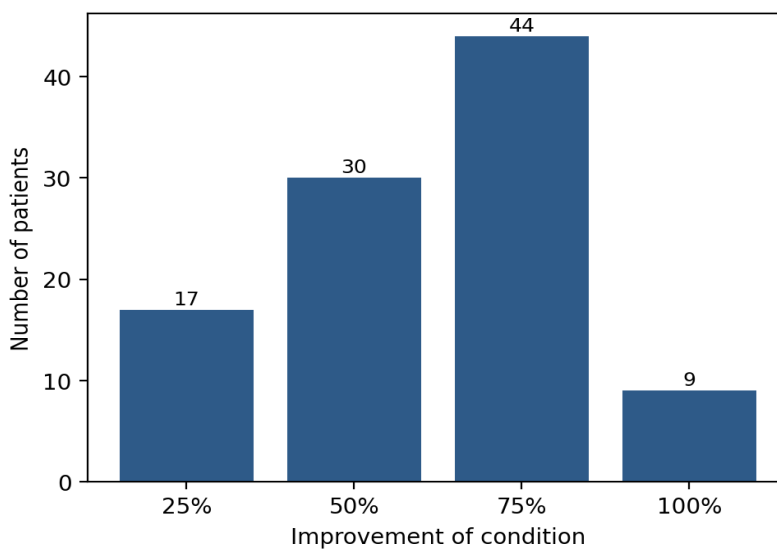


Figure 7: Percentage improvement of condition after PPI use.

Table 7: Percentage incidence of patients for whom endoscopy was performed.

Endoscopy	Number of patients
Done	82
Not done	18
Total	100

Endoscopy was performed in 82 of the 100 patients and was not performed in the remaining 18.

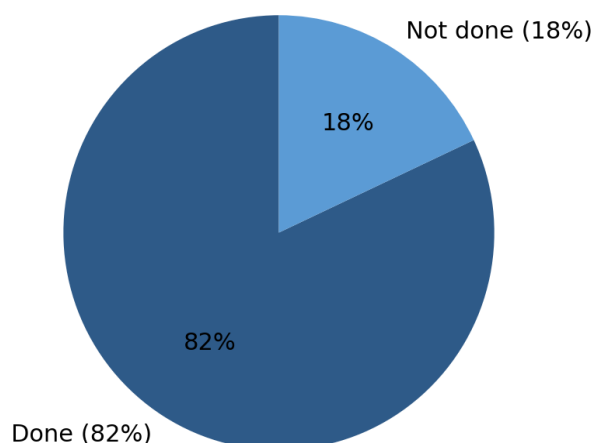


Figure 8: Percentage incidence of patients for whom endoscopy was performed.

Table 8: Patients in whom ulcer was detected during endoscopy.

S. No.	Endoscopy finding	Number of patients
1	Ulcer detected	39
2	Ulcer not detected	43

Of the patients who underwent endoscopy, ulcers were detected in 39 patients and not detected in 43 patients.

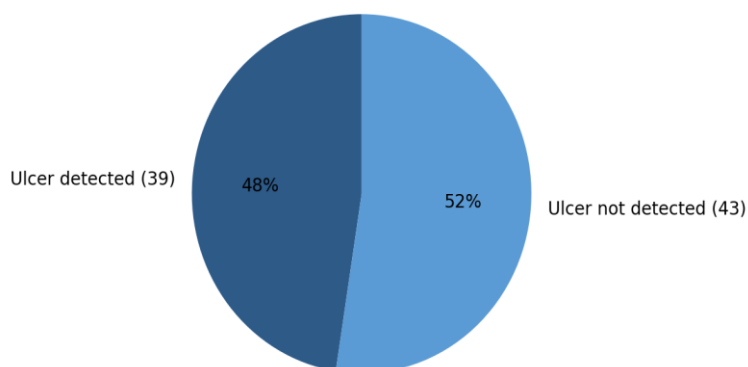


Figure 9: Patients in whom ulcer was detected during endoscopy.

Table 9: Concomitant drugs used by patients along with PPIs.

S. No.	Concomitant drug	Number of patients
1	Antibiotics	50
2	NSAIDs	29
3	Diuretics	36
4	Antihypertensives	18
5	Hypoglycaemic agents	29
6	Anti-thyroid drugs	12
7	Antibiotics + diuretics	28

Among the 100 patients, 50% were on antibiotics concomitantly with PPIs, followed by diuretics (36%), hypoglycaemic agents (29%), NSAIDs (29%), a

combination of antibiotics and diuretics (28%), antihypertensives (18%), and anti-thyroid drugs (12%).

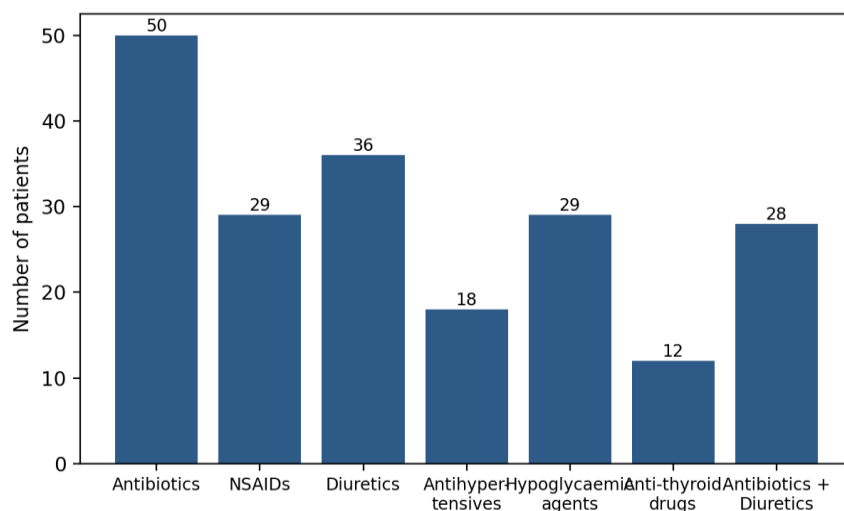


Figure 10: Concomitant drugs used by patients along with PPIs.

Table 10: Percentage incidence of side effects observed with proton pump inhibitors.

Side effect	Number of patients
Insomnia	15
Diarrhoea	4
Headache	9
Bloating	7
Constipation	7
Flatulence	6
Anorexia	9
Abdominal pain	9
Dry skin	3
Belching	5
Muscle pain	2
No side effects	49

The most frequently observed side effect was insomnia (15%), followed by headache, anorexia, and abdominal pain (9% each), bloating and constipation (7% each),

flatulence (6%), belching (5%), diarrhoea (4%), dry skin (3%), and muscle pain (2%); no side effects were reported in 49% of patients.

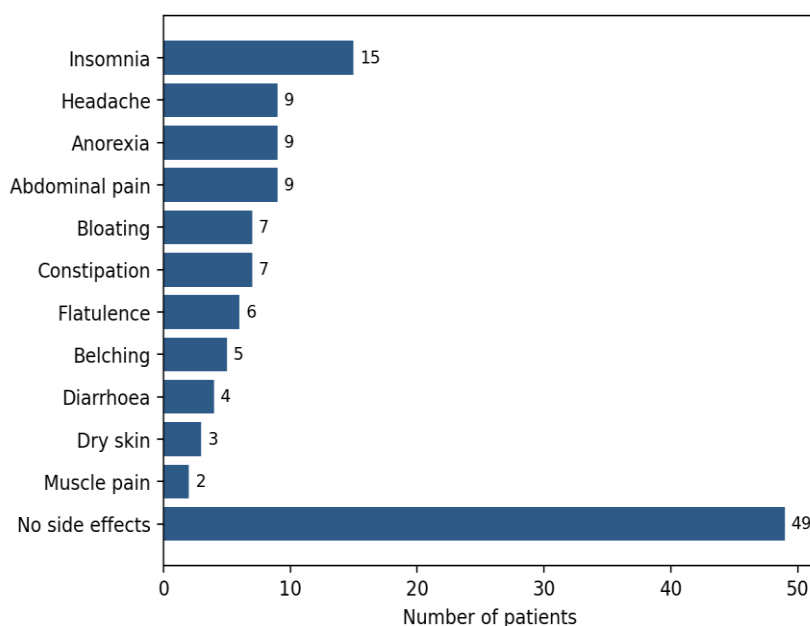


Figure 11: Percentage incidence of side effects observed with proton pump inhibitors.

CONCLUSION

This study suggests that proton pump inhibitor (PPI) use was associated with clinical improvement among patients with liver cirrhosis, particularly in the management of post-endoscopic and ulcer-related complications. Adverse effects were also reported, including insomnia (15%), headache, anorexia, and abdominal pain (9% each), bloating and constipation (7% each), flatulence (6%), belching (5%), diarrhoea (4%), dry skin (3%), and muscle pain (2%). These findings highlight the importance of careful, individualized use of PPIs in patients with cirrhosis, with regular assessment of the potential benefits and risks of therapy.

The findings should be interpreted in light of the study's limitations. The study was conducted over a relatively short period of six months and included 100 patients, which may limit the generalizability of the findings. Further prospective studies involving larger patient populations and longer follow-up periods are warranted to better evaluate the clinical effectiveness and safety of PPI therapy in patients with liver cirrhosis. Overall, judicious prescribing, individualized treatment decisions, and appropriate monitoring may help promote safer and more evidence-based use of PPIs in this patient population.

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Conflict of interest

The authors declare no conflict of interest.

Statement of ethical approval

This study involved human subjects; appropriate institutional ethical approval and informed consent procedures were followed as described in the Materials and Methods section.

Statement of informed consent

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

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