RESEARCH ARTICLE

Journal of Case Studies and Case Reports
An International open access, peer-reviewed, referred journal Online ISSN: 2583-4428
Content Available at www.saap.org.in Published By: South Asian Academic Publications

A PROSPECTIVE OBSERVATIONAL STUDY ON CLINICAL SAFETY AND EFFICACY OF MEDICATIONS USED FOR THE TREATMENT OF GASTROINTESTINAL AND LIVER DISEASES

B. KRUPAKAR*, M. SWATHI, B. SHREYA, , CH. KOMAL DEEPU, K. ANIL KUMAR

Department of Pharmacy Practice, Avanthi Institute of Pharmaceutical Sciences, Gunthapally, Hyderabad, Telangana, India.

***Corresponding Author**
B. Krupakar

DOI: https://doi.org/10.37022/jcscr.v5i2.934

Article History: Received: 11 May 2026 Revised: 03 June 2026 Accepted 03 July 2026

Abstract
Gastrointestinal (GI) and liver diseases contribute significantly to global morbidity and remain a major challenge in clinical practice. The present study was conducted to evaluate the clinical safety and efficacy of medications used in the management of gastrointestinal and liver disorders in a tertiary care hospital setting. This prospective observational study included 60 patients admitted to Gleneagles Hospital, Hyderabad, over a period of six months. Patient demographics, disease characteristics, co-morbidities, social history, prescribed medications, adverse drug reactions, disease severity, and treatment outcomes were documented and analyzed. Among the study population, 44 (73.4%) were male and 16 (26.6%) were female, indicating male predominance. The majority of patients belonged to the age group of 21–30 years (23.3%), followed by 31–40 years (16.7%). Co-morbidities such as diabetes mellitus and hypertension were common, observed in 18 and 16 patients respectively. Social history revealed that 33 patients had habits such as smoking or alcohol consumption, which may have contributed to disease progression. Gastroesophageal reflux disease (GERD) was the most frequently reported GI disorder, while hepatitis was the most common liver-related disease. Polypharmacy was observed in 45 patients receiving more than six drugs. Hospital stay was less than six days in 32 patients, reflecting favorable recovery in most cases. However, severe outcomes including life-threatening conditions and fatalities were noted in a small proportion. The findings highlight the burden of GI and liver diseases and emphasize the importance of early diagnosis, rational drug therapy, and continuous monitoring of adverse drug reactions to improve clinical outcomes and patient safety.

Keywords: *Gastrointestinal diseases, Liver diseases, Clinical safety, Drug efficacy, Adverse drug reactions, Prospective observational study, Polypharmacy.*

INTRODUCTION

Gastrointestinal (GI) and liver diseases represent a major global health burden and are among the leading causes of morbidity and mortality worldwide. These disorders encompass a broad spectrum of acute and chronic conditions affecting the digestive system and hepatobiliary tract, significantly impacting patients' quality of life and healthcare resources [1]. The gastrointestinal tract plays an essential role in digestion, absorption, metabolism, and elimination, while the liver performs critical functions such as detoxification, bile production, protein synthesis, and regulation of metabolic processes [2]. Any dysfunction in these organs can result in severe clinical complications requiring prompt and effective management. The prevalence of gastrointestinal disorders such as gastroesophageal reflux disease (GERD), peptic ulcer disease (PUD), inflammatory bowel disease (IBD), and irritable bowel syndrome (IBS) has increased considerably over recent decades due to changes in dietary habits, sedentary lifestyle, stress, alcohol consumption, and smoking [3]. Similarly, liver diseases including hepatitis, non-alcoholic fatty liver disease (NAFLD), cirrhosis, and hepatocellular carcinoma remain major contributors to chronic illness globally [4]. According to the World Health Organization, liver diseases account for nearly 2 million deaths annually, with cirrhosis and viral hepatitis being major causes [5]. Pharmacotherapy remains the cornerstone in the management of both GI and liver disorders. Various drug classes such as proton pump inhibitors (PPIs), H2 receptor antagonists, antacids, antivirals, corticosteroids, immunosuppressants, and hepatoprotective agents are widely prescribed depending on disease condition and severity [6]. These medications are aimed at symptom relief, reducing disease progression, preventing complications, and

improving overall patient outcomes. However, long-term use of these therapies may also lead to adverse drug reactions (ADRs), drug interactions, and medication-related complications [7].

Clinical safety and efficacy evaluation of these medications in real-world settings is essential, as patient response may differ significantly from controlled clinical trials. Prospective observational studies provide valuable insights into prescribing patterns, disease progression, treatment outcomes, and ADR occurrence in routine clinical practice [8]. Such studies are especially important in tertiary care hospitals where complex cases with multiple co-morbidities are frequently managed [9].

Co-morbid conditions such as diabetes mellitus, hypertension, obesity, and alcohol-related disorders have been shown to worsen the prognosis of GI and liver diseases [10]. Furthermore, polypharmacy, which is common in these patients, increases the risk of medication errors and adverse events [11-13]. Therefore, monitoring therapeutic effectiveness and safety remains crucial for optimizing treatment regimens.

This study was undertaken to evaluate the clinical safety and efficacy of medications used in the treatment of gastrointestinal and liver diseases in a tertiary care hospital. The study aims to analyze patient demographics, disease distribution, co-morbidities, drug utilization patterns, adverse effects, and treatment outcomes to provide evidence for better clinical decision-making and improved patient care.

MATERIALS AND METHODS

Study Design

The present study was conducted as a prospective observational study to evaluate the clinical profile, treatment patterns, therapeutic outcomes, and safety of patients diagnosed with gastrointestinal and liver diseases in a tertiary care hospital setting. The study aimed to assess patient demographics, disease characteristics, associated risk factors, co-morbidities, and clinical outcomes during routine medical management.

Study Site

The study was carried out at Aware Gleneagles Global Hospital, a tertiary care multispecialty hospital equipped with advanced gastroenterology and hepatology care facilities.

Study Duration

The study was conducted over a period of six months.

Sample Size

A total of 60 patients diagnosed with liver and gastrointestinal diseases and fulfilling the eligibility criteria were included in the study.

Study Population

The study population consisted of adult male and female patients admitted to the gastroenterology and hepatology departments with confirmed diagnosis of liver and gastrointestinal disorders such as chronic liver disease, cirrhosis, hepatitis, gastrointestinal bleeding, gastritis, peptic ulcer disease, gastroesophageal reflux disease (GERD), and related complications [14].

Eligibility Criteria

Inclusion Criteria

Patients fulfilling the following criteria were included in the study:

- Male or female patients aged below 85 years
- Patients with confirmed diagnosis of liver and gastrointestinal diseases
- Patients who were conscious, cooperative, and able to provide informed consent
- Patients willing to participate in the study

Exclusion Criteria

The following patients were excluded from the study:

- Patients with terminal illness or severe unrelated co-morbid conditions
- Psychiatric patients or patients unable to provide informed consent
- Patients unwilling to participate in the study

Source of Data Collection

Data were collected from various clinical and hospital-based sources, including:

- Patient case records
- Inpatient and outpatient prescriptions
- Laboratory investigation reports
- Electronic medical records (EMR)
- Patient interviews and follow-up records

Data Collection Procedure

A structured patient data collection form was designed and validated according to the objectives of the study. Patients admitted to the gastroenterology and hepatology departments were screened based on inclusion and exclusion criteria. After obtaining informed consent, relevant clinical and demographic information was collected.

The following parameters were documented:

Patient Demographics and Clinical Characteristics

- Age and gender
- Duration of liver disease or gastrointestinal illness
- Etiology of liver disease (viral hepatitis, alcoholic liver disease, NAFLD, autoimmune liver disease)
- Presenting symptoms such as abdominal pain, hematemesis, melena, jaundice, ascites, vomiting, or shock

Laboratory Parameters

The following laboratory investigations were assessed:

- Hemoglobin (Hb)
- International Normalized Ratio (INR)
- Liver Function Tests (LFTs)
- Renal Function Tests (RFTs)
- Serum bilirubin
- Serum albumin
- Serum creatinine
- Electrolytes
- MELD (Model for End-Stage Liver Disease) score where applicable

Disease Classification and Severity Assessment

Patients were classified based on diagnosis and disease severity. Liver disease severity was assessed using standard clinical scoring systems such as MELD score and Child-Pugh classification where necessary [15].

Treatment Pattern Evaluation

Prescribed medications such as proton pump inhibitors, antibiotics, hepatoprotective agents, antivirals, diuretics, beta-blockers, lactulose, and supportive care medications were reviewed and documented.

Clinical Outcome Assessment

Treatment outcomes were evaluated based on:

- Symptomatic improvement
- Reduction in gastrointestinal bleeding episodes
- Stabilization of liver function parameters
- Length of hospital stay
- Mortality or discharge status

Safety Assessment

Safety was evaluated by documenting adverse drug reactions (ADRs), treatment-related complications, and progression of disease during hospitalization.

Statistical Analysis

The collected data were compiled, organised, and analysed using appropriate statistical tools.

- Descriptive statistics were used for baseline demographic and clinical characteristics.
- Continuous variables were expressed as mean ± standard deviation (SD).
- Categorical variables were expressed as frequencies and percentages.
- Comparative analysis of interventions and outcomes was performed using the Chi-square test or Fisher's exact test wherever applicable.
- Multivariate analysis was performed to identify independent predictors of poor clinical outcomes, such as high MELD score, delayed intervention, prolonged hospitalisation, and mortality.
- Statistical significance was considered at $p < 0.05$ [16-19].

Ethical Considerations

Before initiation of the study, ethical approval was obtained from the Institutional Ethics Committee of Aware Gleneagles Global Hospital. Written informed consent was obtained from all participants, and confidentiality of patient information was maintained throughout the study in accordance with ethical guidelines.

RESULTS AND DISCUSSION

Gender-wise Distribution

A total of 60 patients were included in the study. Among them, 44 patients (73.4%) were males and 16 patients (26.6%) were females, as shown in Table 01. The predominance of male patients may be attributed to higher exposure to lifestyle-related risk factors such as alcohol consumption, smoking, and unhealthy dietary habits, which are known contributors to liver and gastrointestinal disorders.

Table 01: Gender-wise distribution of patients

Gender	Number of Patients	Percentage (%)
Male	44	73.4
Female	16	26.6

Age-wise Distribution

The age-wise analysis showed that the highest number of patients belonged to the 21–30 years age group (14 patients), followed by 31–40 years and 41–50 years (10 patients each), as presented in Table 02 and Figure 01. This indicates that liver and gastrointestinal diseases are increasingly common among younger and middle-aged adults.

Table 02: Age-wise distribution of patients

Age Group (Years)	Number of Patients
0–10	1
11–20	5
21–30	14
31–40	10
41–50	10
51–60	8
61–70	5
71–80	4
81–90	3

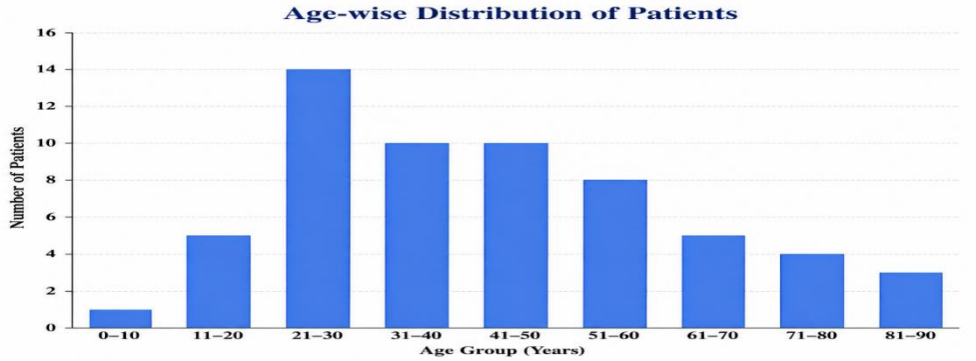

Figure 01: Age-wise distribution of patients diagnosed with liver and gastrointestinal diseases.

Co-morbidity-based Distribution

Co-morbidity analysis revealed that Diabetes Mellitus (18 patients) and Hypertension (16 patients) were the most common associated conditions, followed by Type 2 DM + HTN (9 patients), as shown in Table 03 and Figure 02. These findings highlight the strong association between metabolic disorders and liver/GI diseases.

Table 03: Distribution based on co-morbidities

Co-morbidities	Number of Patients
Normal	11
Diabetes Mellitus	18
Type 2 DM + HTN	9
Hypertension	16
Hypotension	1
Others	2
Asthma and TB	2
Hypothyroidism	1

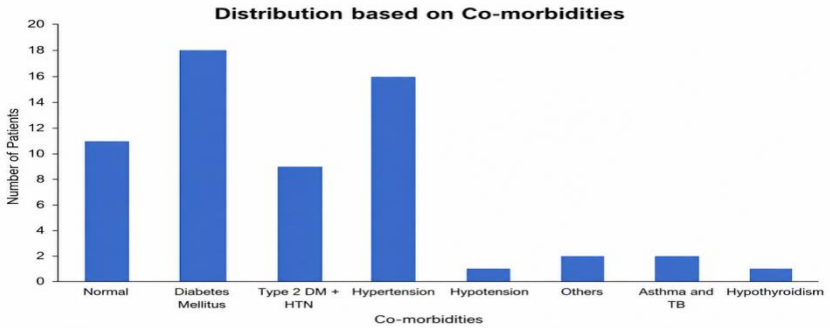

Figure 02: Distribution of patients based on associated co-morbidities.

Social History Distribution

Social history analysis showed that 33 patients had social habits such as smoking or alcohol consumption, while 27 patients had no such habits,

Disease Severity Distribution

Disease severity assessment revealed that 32 patients required hospitalisation, 18 patients were serious, 8 were life-threatening, and 2 cases were fatal, as shown in Table 04 and Figure 03. This indicates the significant clinical burden of liver and gastrointestinal diseases.

Table 04: Distribution based on disease severity

Severity	Number of Patients
Fatal	2
Life-threatening	8
Serious	18
Significant	10
Hospitalized	32

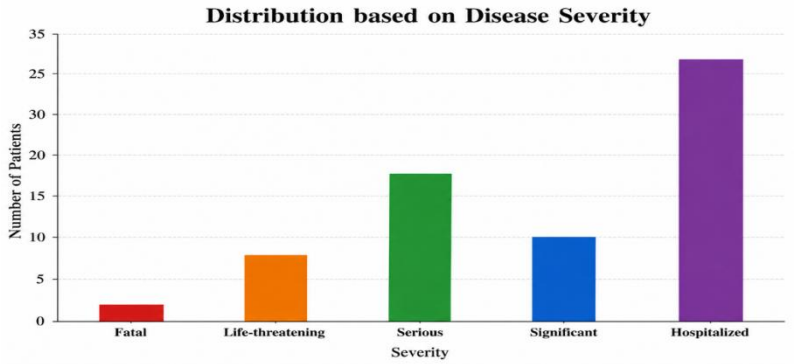

Figure 03: Distribution of patients according to disease severity.

Distribution Based on Number of Drugs Prescribed

Drug utilisation analysis showed that 45 patients received more than six drugs, while 15 patients received 4–6 drugs, as shown in Table 5 and Figure 4. This reflects the prevalence of polypharmacy in managing complex liver and GI disorders.

Table 06: Distribution based on the number of drugs prescribed

Number of Drugs	Number of Patients
0–1 drug	0
2–3 drugs	0
4–6 drugs	15
More than 6 drugs	45

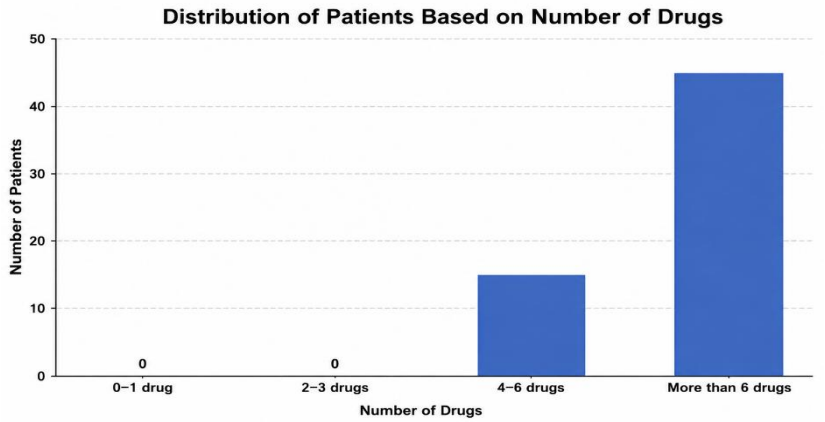

Figure 04: Distribution of patients based on the number of drugs prescribed during treatment.

Length of Hospital Stay

The majority of patients (32 patients) had hospital stays of less than 5 days, while 18 patients stayed for 6–15 days and 10 patients stayed for more than 15 days, as shown in Table 07. This suggests effective early management in most cases.

Table 07: Distribution based on length of hospital stay

Length of Stay	Number of Patients
Below 5 days	32
6–15 days	18
Above 15 days	10

Distribution of Liver and Gastrointestinal Diseases

Among the disease conditions, GERD was the most prevalent condition, especially among male patients (14 males and 1 female), followed by Hepatitis (12 cases), IBD (10 cases), and PUD (10 cases), as shown in Table 08. This indicates the growing burden of acid-related disorders and chronic liver diseases.

Table 08: Distribution of liver and gastrointestinal diseases

Diseases	Male	Female
Hepatitis	8	4
NAFLD	3	3
Cirrhosis and Fibrosis	5	2
IBD	7	3
PUD	7	3
GERD	14	1

Antibiotics Used for GI Diseases

Among antibiotics, Piperacillin-Tazobactam was the most commonly prescribed drug (30 patients, 50%), followed by Ceftriaxone (9 patients, 15%), as shown in Table 09. This reflects the need for broad-spectrum antibiotics in managing infections associated with GI disorders.

Table 09: Distribution of antibiotics used for GI diseases

Drugs	Number of Patients	Percentage (%)
Tazobactam	30	50
Ceftriaxone	9	15
Cefoperazone Sodium	6	10
Meropenem	5	8
Doxycycline	3	5
Polymyxin E	3	5

Azoles, Antifungals, and Proton Pump Inhibitors Used in GI Diseases

The utilization of azoles in gastrointestinal diseases was minimal, with only Ketoconazole prescribed in 2 patients (3%), indicating a lower incidence of fungal infections requiring azole therapy in the study population. This suggests that fungal complications were relatively uncommon among the admitted GI patients.

Similarly, antifungal use was limited, where Amphotericin-B was administered to 2 patients (3.3%) and Fluconazole to 1 patient (1.6%). The lower prescription frequency of antifungal agents reflects selective use in patients with confirmed or suspected fungal infections.

Among acid-suppressive therapies, Proton Pump Inhibitors (PPIs) were widely prescribed, highlighting their major role in the management of gastrointestinal disorders. Pantoprazole was the most frequently used PPI, prescribed in 36 patients (60%), followed by Esomeprazole in 17 patients (28.3%) and Rabeprazole in 5 patients (8.3%). The high utilisation of PPIs demonstrates their importance in reducing gastric acid secretion, promoting ulcer healing, and providing gastroprotection in patients with acid-related disorders such as GERD and peptic ulcer disease.

Antibiotics Used in Liver Diseases

The antibiotic utilisation pattern in liver diseases was similar to that in GI diseases, with Piperacillin-Tazobactam being the most prescribed (50%), as shown in Table 10.

Table 10: Distribution of antibiotics used in liver diseases

Drug	Number of Patients	Percentage (%)
Tazobactam	30	50
Ceftriaxone	9	15
Cefoperazone Sodium	6	10
Meropenem	5	8
Doxycycline	3	5
Polymyxin Z	3	5

Distribution of Hepatoprotective Agents

Among hepatoprotective agents, Ursodeoxycholic acid was the most commonly used (10 patients, 16.6%) followed by Hepamerz (5 patients, 8.3%). These agents play an important role in improving liver function and reducing hepatic complications.

CONCLUSION

The present study demonstrated that gastrointestinal and liver diseases are commonly associated with significant co-morbidities and lifestyle-related risk factors, particularly among male patients. GERD, hepatitis, and diabetes mellitus were among the most prevalent conditions observed. The study also highlighted the extensive use of multiple medications, indicating the complexity of disease management in these patients.Although the majority of patients showed favorable recovery with shorter hospital stays, some experienced serious complications, emphasizing the need for careful monitoring and individualized therapy. The occurrence of adverse drug reactions underlines the importance of pharmacovigilance in routine clinical practice. Overall, this study supports the role of timely diagnosis, effective treatment strategies, and patient counseling in improving therapeutic outcomes and reducing disease burden in gastrointestinal and liver disorders.

FUNDING

Nil

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this paper.

ACKNOWLEDGMENT

We also thank the patients who consented to participate in this research.

AUTHOR CONTRIBUTIONS

M. Swathi conceived and designed the study. B. Shreya, B. Krupakar, Ch. Komal Deepu, and K. Anil Kumar contributed to data collection, data analysis, literature review, manuscript preparation, and critical revision. All authors read and approved the final version of the manuscript.

ETHICAL STATEMENT

The ethical committee clearance was obtained from Gleneagles Global Hospital before initiating the study. Reference number: AIPS/ 04/ IEC/05

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