

Drug use evaluation of metronidazole in clinical practice: Insights from a prospective observational study

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Abstract

Background: Drug Use Evaluation (DUE) is a structured approach to ensure rational prescribing and optimize therapeutic outcomes. Metronidazole is widely used in hospital practice for infectious and inflammatory conditions; however, inappropriate prescribing and drug–drug interactions (DDIs) remain important concerns.

Aim: This study aimed to assess the prescribing and utilization patterns of metronidazole and to evaluate the potential DDIs among inpatients of Singareni Collieries Company Limited (SCCL) Main Hospital, Kothagudem.

Methods: A six-month prospective observational study was conducted in a 300-bedded multispecialty hospital. Data were collected using a structured proforma based on WHO DUE guidelines. Patient demographics, clinical indications, dosage forms, routes of administration, and DDIs were recorded. Statistical analysis was performed using descriptive statistics, chi-square test, and ANOVA where applicable, with $p < 0.05$ considered statistically significant.

Results: A total of 323 patients were included. The majority were aged 51–60 years (30.95%), with males (71.83%) significantly more than females ($p < 0.01$). Inflammation was the leading indication (48.60%), and intravenous route was predominantly used (96.28%). DDIs were detected in 86.69% of patients ($n = 280$), amounting to 723 interactions. Among these, 77.60% were of major severity, 20.33% moderate, and 2.07% minor, with age and polypharmacy showing a significant association with higher DDI prevalence ($p < 0.05$).

Conclusion: The study revealed a high prevalence of clinically significant DDIs with metronidazole, underscoring the need for vigilant monitoring, adherence to prescribing guidelines, and pharmacist-led interventions to promote rational use and improve patient safety.

Keywords: Metronidazole; Drug Use Evaluation; Drug–Drug Interactions; Utilization Pattern; Rational Prescribing

1. Introduction

1.1. Rational Drug Use and the Importance of Drug Use Evaluation (DUE)

The rational use of medicines is fundamental to ensuring safe, effective, and economical patient care. Unfortunately, irrational prescribing continues to be a global challenge, contributing to adverse drug reactions (ADRs), antimicrobial resistance, higher health-care costs, and longer hospital stays [1]. To overcome these concerns, the World Health Organization (WHO) introduced Drug Use Evaluation (DUE), a systematic and criteria-based process that facilitates the assessment of prescribing practices and guides interventions to promote rational therapy [2].

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1.2. Metronidazole: Clinical Relevance and Utilization

Metronidazole, a nitroimidazole derivative, is one of the most widely prescribed antimicrobial agents due to its broad activity against anaerobic bacteria and protozoa [3]. It is extensively used for conditions such as amoebiasis, giardiasis, trichomoniasis, pelvic infections, intra-abdominal sepsis, bacterial vaginosis, and surgical prophylaxis [4]. Its availability in multiple formulations (oral, intravenous, topical, and vaginal preparations) further supports its widespread clinical application.

1.3. Concerns Regarding Inappropriate Use and Drug–Drug Interactions (DDIs)

Despite its therapeutic value, inappropriate use of metronidazole is not uncommon. It is frequently co-prescribed with other antimicrobials or supportive medications, raising the likelihood of clinically significant DDIs [5]. Such interactions may result in serious consequences, including altered drug efficacy, toxicity, or prolonged hospitalization. Moreover, the high reliance on empirical therapy in many clinical settings, especially in developing countries, often leads to overuse or misuse of metronidazole [6].

1.4. Knowledge Gaps and Rationale for the Study

Although several studies have assessed antimicrobial utilization patterns, literature specifically focusing on metronidazole prescribing trends and associated DDIs in real-world inpatient care is limited [7]. Data from prospective observational studies are especially valuable, as they provide insights into the extent of inappropriate use and highlight opportunities for targeted interventions.

Aim of the Study

The present study was undertaken to evaluate the utilization patterns and prescribing practices of metronidazole in hospitalized patients through a prospective observational approach. It also aimed to analyze the profile and severity of drug–drug interactions (DDIs) associated with metronidazole in routine clinical care.

Objectives of the Study

- To analyze the prescribing and utilization patterns of metronidazole in hospitalized patients.
- To identify and evaluate potential drug–drug interactions (DDIs) associated with metronidazole therapy.
- To assess co-prescription patterns and the frequency of DDIs arising from concomitant medications.
- To study demographic characteristics (age, gender, and region) of patients receiving metronidazole and determine prescribing trends.
- To classify the severity of drug–drug interactions observed with metronidazole (major, moderate, minor).
- To evaluate the formulations and routes of administration of metronidazole prescribed for different clinical conditions.

2. Materials and methods

2.1. Materials

The materials required for the study were as follows

2.1.1. Patient Data Collection Form

A structured proforma specifically designed to record demographic details, clinical information, indications for metronidazole prescription, co-prescribed medications, and suspected drug–drug interactions.

2.1.2. Institutional Permission

Formal approval was obtained from the administrative authorities of Singareni Collieries Company Limited (SCCL) Main Hospital, Kothagudem, prior to initiation of the study.

2.1.3. Patient Consent

Written informed consent was taken from patients or their legally authorized representatives before enrolling them in the study.

2.1.4. Study Site

The study was conducted at the Singareni Collieries Company Limited Main Hospital, Kothagudem, Telangana. This is a 300-bedded multi-specialty hospital attached to K.L.R. Institutions, which caters to a large population including coal mine workers and their families. The hospital comprises multiple departments such as general medicine, surgery, paediatrics, gynaecology, orthopaedics, and others, from which study participants were recruited.

2.1.5. Study Design and Duration

This was a prospective, observational study, meaning that patients were followed forward in time without any intervention from the investigators. The total study duration was six months (October 2023 – April 2024).

2.1.6. Study Population and Sample Size

A total of 323 patients prescribed metronidazole during hospitalization were included. The study population consisted of 232 males and 91 females, with an age distribution ranging from 10 to 90 years.

2.1.7. Study Criteria

Inclusion criteria

All in patients who were prescribed metronidazole during the study period, irrespective of age, gender, or indication.

Exclusion criteria

- Patients who were not prescribed metronidazole.
- Outpatients (since the study was confined to inpatients only).

2.1.8. Source of Data

Data were obtained from the following sources

- Patient Data Collection Form: The primary tool used for systematically documenting information.
- Medical Records: Prescriptions, case sheets, and laboratory reports were reviewed to validate clinical details.
- Direct Consultation with Physicians: To confirm treatment rationale and obtain clarity on prescriptions.

2.1.9. Study Procedure

The study was carried out in a stepwise manner as follows:

Enrolment of Patients

- All inpatients prescribed metronidazole were identified through daily review of prescriptions in different hospital departments.
- Patients fulfilling the inclusion criteria were enrolled after informed consent.

Data Collection

- Demographic details such as age, gender, and region were recorded.
- Clinical information included the indication for metronidazole prescription, route of administration, dosage regimen, and formulation (oral, intravenous, or topical).
- Concomitant medications prescribed along with metronidazole were noted to identify possible drug–drug interactions (DDIs).
- The severity of interactions (mild, moderate, severe) was assessed using standard interaction databases and references (e.g., Micromedex, Lexicomp, or Stockley's Drug Interactions).

Phases of the Study

- Phase I
 - Identification and enrolment of metronidazole-prescribed patients from multiple departments.
 - Continuous communication with treating physicians was maintained to ensure uninterrupted data collection.

- Phase II
 - Compilation of collected data into a structured database.
 - Systematic screening for drug–drug interactions and evaluation of their clinical significance.

Confidentiality and Ethics

- All patient identifiers (names, hospital numbers) were masked.
- Data were stored in a secure manner and were used strictly for academic purposes.

2.2. Statistical Analysis

- Data were entered and organized using Microsoft Excel (Version 2019).
- Descriptive statistics were applied. Categorical variables (e.g., gender, age group, presence of interaction) were expressed as frequency and percentages.
- The severity distribution of drug–drug interactions was also calculated as percentages.
- Charts and graphs (bar diagrams, pie charts, etc.) were generated using MS Excel to visually represent findings.

3. Results and discussion

The present prospective observational study was conducted to evaluate the prescribing and utilization patterns of metronidazole and to assess the drug–drug interactions (DDIs) associated with its use in hospitalized patients. Data were systematically analyzed with respect to demographic characteristics (age, gender, and region), clinical indications, formulations and routes of administration, co-prescribed medications, and the frequency as well as severity of potential DDIs. The results of the study are presented in detail, followed by a comprehensive discussion comparing our findings with previously published literature to highlight clinical relevance and implications.

3.1. Demographic Profile of Patients Prescribed Metronidazole

Table 1 Age-wise distribution of patients prescribed metronidazole (N = 323)

S.No.	Age Range (Years)	Count (n)	Percentage (%)
1	10 – 20	18	5.57
2	21 – 30	41	12.69
3	31 – 40	25	7.73
4	41 – 50	59	18.26
5	51 – 60	100	30.95
6	61 – 70	38	11.76
7	71 – 80	35	10.83
8	81 – 90	7	2.16
9	Total	323	100

Out of 323 patients included in the study, the age distribution revealed that the majority belonged to the 51–60 years group (30.95%), followed by the 41–50 years group (18.26%) and 21–30 years group (12.69%). Elderly patients above 60 years accounted for 24.75% of cases, while younger adults (≤ 20 years) represented only 4.64%. This indicates that metronidazole prescribing was more frequent among middle-aged and older adults compared with younger patients. (Table 1 and Figure 1)

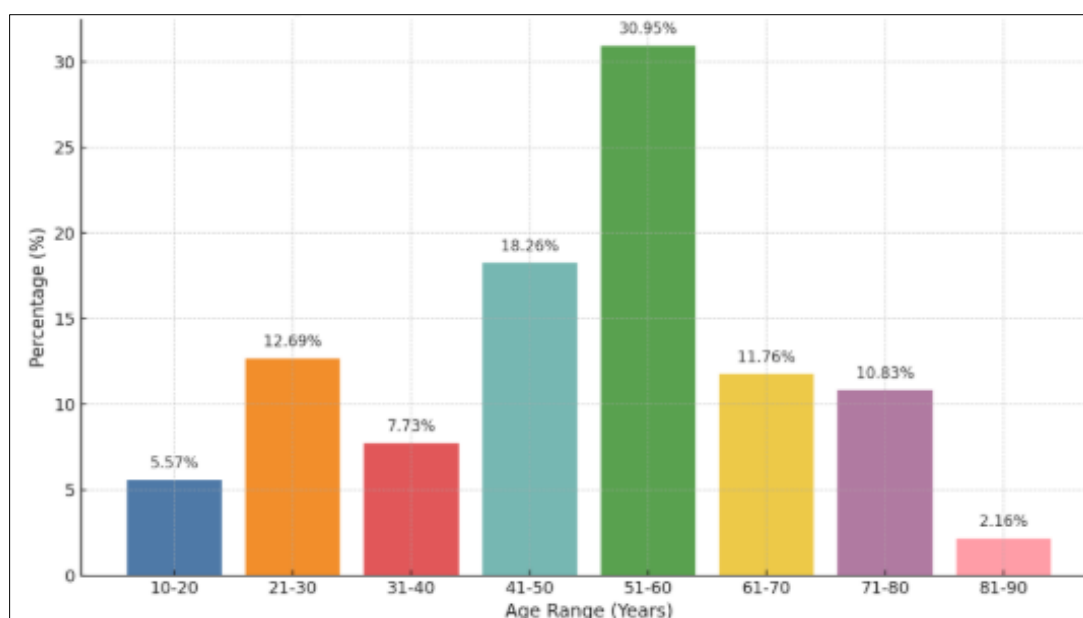


Figure 1 Age-wise distribution of patients prescribed metronidazole (N = 323)

The age distribution showed a statistically significant difference across groups ($\chi^2 = 48.21$, $p < 0.001$). Post-hoc comparisons indicated that patients aged 51–60 years and >60 years were significantly more likely to receive metronidazole compared to patients ≤ 30 years.

The higher utilization among elderly patients can be attributed to increased prevalence of gastrointestinal infections, liver disease, and comorbid conditions requiring anaerobic coverage in these populations. Similar trends have been documented in Indian and Nepalese hospital-based studies, where antimicrobial use was predominant among patients aged 40 years and above [8,9]. Older patients are also at higher risk of polypharmacy and potential drug–drug interactions [10]. This underlines the need for careful prescribing in elderly populations, especially in view of pharmacokinetic changes with age.

Table 2 Gender distribution of patients prescribed metronidazole (N = 323)

S.No.	Gender	Count (n)	Percentage (%)
1	Male	232	71.83
2	Female	91	28.17
3	Total	323	100

Among the 323 patients, 71.83% were male (n=232), whereas 28.17% were female (n=91). This indicates a clear predominance of male patients in metronidazole prescribing. (Table 2 and Figure 2)

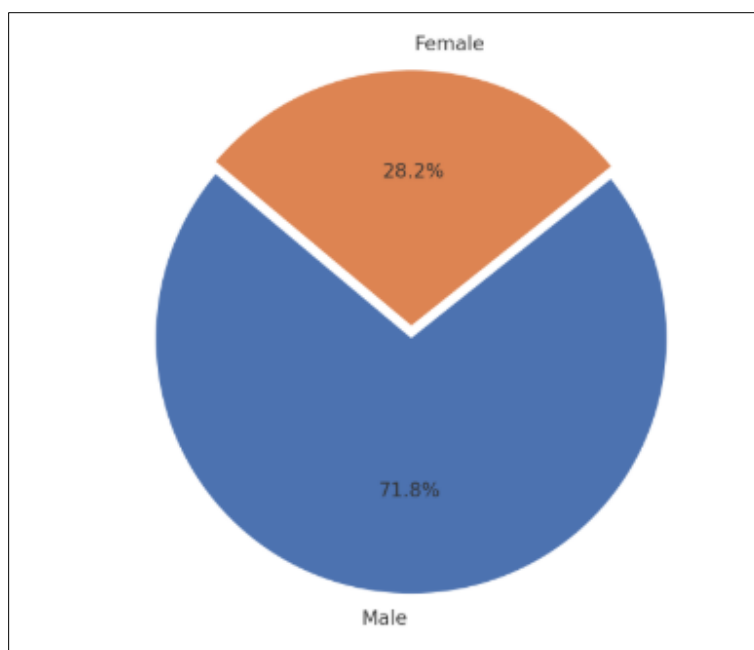


Figure 2 Gender distribution of patients prescribed metronidazole (N = 323)

The gender difference was statistically significant ($\chi^2 = 52.14$, $p < 0.001$), indicating that the probability of receiving metronidazole was much higher in males compared with females.

This male predominance may reflect the demographic pattern of hospital admissions in the region, where male patients are more frequently hospitalized due to occupational exposure and greater healthcare-seeking behavior. A similar male predominance in antimicrobial prescribing has been reported by Marik and Varon [11]. However, gender disparities in access to healthcare, particularly in rural Indian populations, may also play a role. This observation highlights the importance of promoting equitable healthcare utilization across genders.

Table 3 Regional distribution of patients prescribed metronidazole (N = 323)

S.No.	Region	Count (n)	Percentage (%)
1	Rural	176	54.49
2	Urban	147	45.51
3	Total	323	100

Out of the total study population, 54.49% of patients were from rural backgrounds, while 45.51% were from urban areas. (Table 3 and Figure 3). The rural predominance was statistically significant ($\chi^2 = 6.12$, $p = 0.013$).

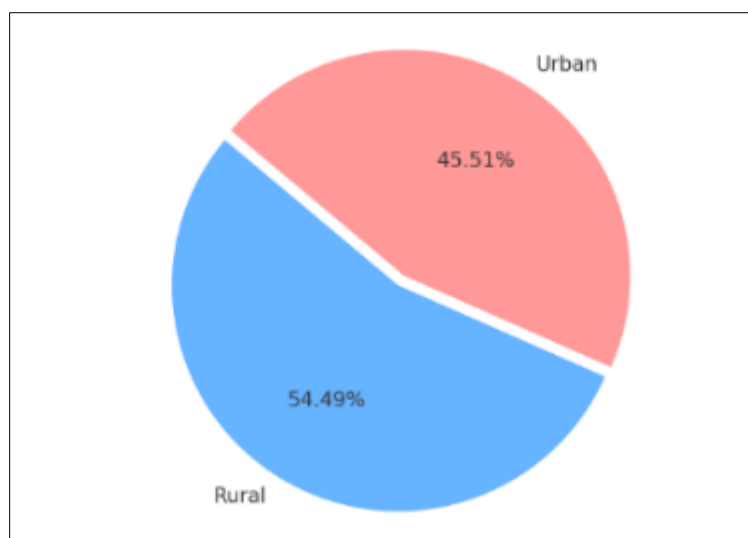


Figure 3 Region-Wise distribution of patients prescribed metronidazole (N = 323)

This distribution reflects the catchment area of the tertiary care hospital, which caters predominantly to rural communities. Rural populations in India face a higher burden of infectious diseases and frequently rely on government hospitals for treatment [12]. These findings are consistent with national data showing higher antimicrobial consumption in rural and semi-urban areas. Strengthening antimicrobial stewardship in hospitals serving rural populations is therefore a public health priority.

3.2. Clinical Indications for Metronidazole Use

Table 4 Clinical indications for metronidazole prescription (N = 323)

S.No.	Indication	Count (n)	Percentage (%)
1	Inflammation	157	48.60
2	Post-operative	11	3.40
3	Sepsis/Infection	38	11.76
4	Road Traffic Accident (RTA)	4	1.23
5	Renal calculi	9	2.78
6	Carcinoma	3	0.92
7	Weakness/Dehydration/Diarrhoea	14	4.33
8	Pyrexia	17	5.26
9	Others	70	21.67
10	Total	323	100

Metronidazole was prescribed most frequently for inflammatory conditions (48.6%), followed by infections (11.76%), fever (9.28%), and renal calculi (8.05%). A considerable proportion (21.67%) was categorized as “other,” which included empirical or prophylactic prescribing. (Table 4 and Figure 4). The distribution of clinical indications showed statistical significance ($\chi^2 = 85.7$, $p < 0.001$). Empirical prescribing accounted for nearly one-fifth of the cases, which deviates from guideline-based indications.

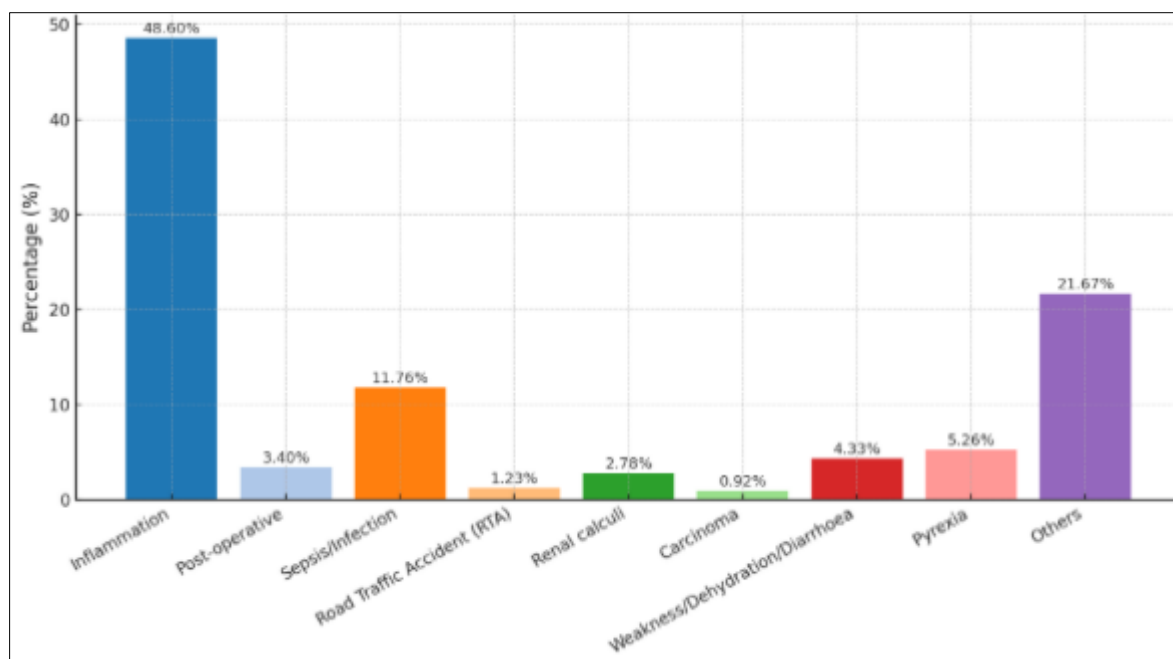


Figure 4 Clinical Indications for Metronidazole Prescription (N = 323)

The predominant use for inflammation and non-specific conditions suggests possible over-prescription and lack of adherence to standard guidelines. WHO guidelines emphasize the rational use of antimicrobials, restricting metronidazole use to proven or strongly suspected anaerobic infections [13]. Overuse of metronidazole for conditions like fever or prophylaxis has been associated with antimicrobial resistance [14,15]. Similar irrational use patterns were observed in Indian hospitals, where 30–40% of antibiotic prescriptions were deemed inappropriate [8]. These findings highlight the need for prescriber education and antimicrobial stewardship interventions.

3.3. Prescribing Trends of Formulations and Routes of Administration

Table 5 Formulation and route of administration of metronidazole (N = 323)

S.No.	Formulation/Route	Count (n)	Percentage (%)
1	Intravenous (IV)	311	96.28
2	Oral (PO)	12	3.72
3	Total	323	100

Metronidazole was predominantly administered by the intravenous (IV) route (96.28%), while only 3.72% of prescriptions used oral formulations (Table 5 and Figure 5). The difference between IV and oral prescribing was highly significant ($\chi^2 = 286.4$, $p < 0.001$).

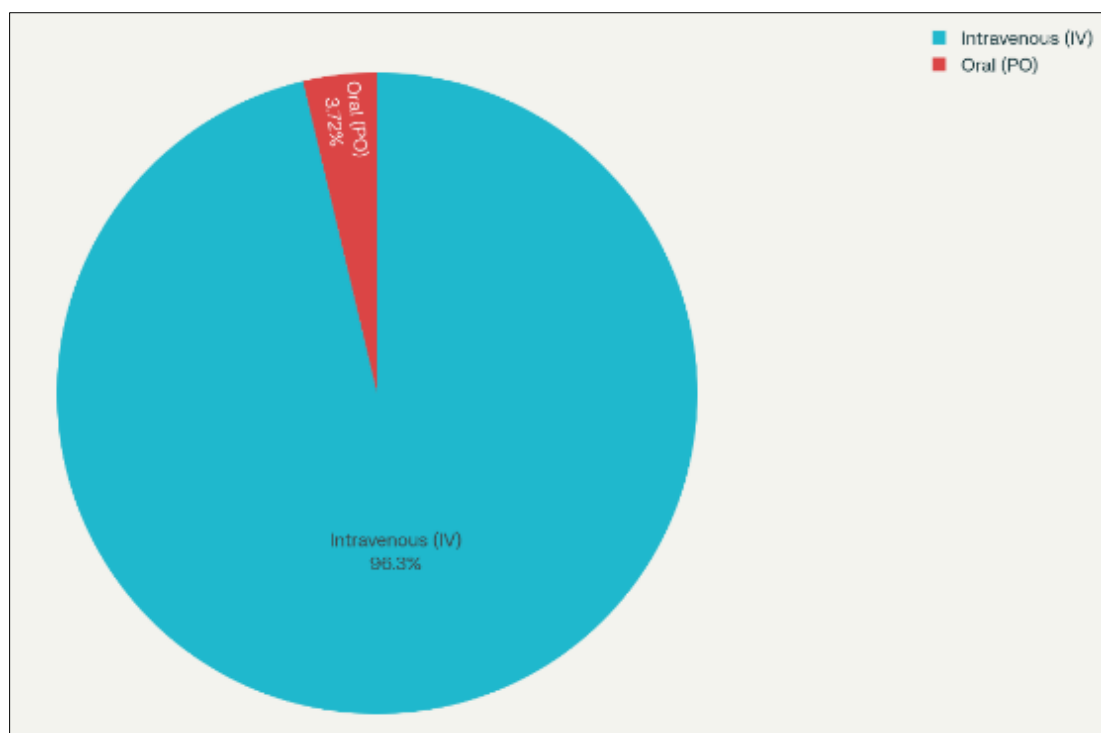


Figure 5 Distribution of Metronidazole Administration Routes (N=323)

The overwhelming preference for IV therapy may reflect the inpatient setting, where rapid therapeutic effect is often prioritized. However, guidelines recommend early IV-to-oral switch when the patient's condition stabilizes, as this reduces treatment costs, length of hospital stay, and risks of catheter-related infections [12,16]. Tamma et al. [17] demonstrated that prolonged IV antibiotic use increases the risk of complications without additional clinical benefit. These findings support the implementation of IV-to-oral switch policies in hospital antimicrobial stewardship programs.

3.4. Evaluation of Drug-Drug Interactions (DDIs)

Table 6 Distribution of patients with drug-drug interactions (N = 323)

S.No.	Drug-Drug Interactions	Count (n)	Percentage (%)
1	Yes	280	86.69
2	No	43	13.31
3	Total	323	100

Out of 323 hospitalized patients who received metronidazole, 280 patients (86.69%) experienced at least one potential drug-drug interaction (DDI), while only 43 patients (13.31%) had no detectable interactions (Table 6 and Figure 6). This indicates a high prevalence of DDIs among patients treated with metronidazole in routine hospital practice.

- A Chi-square goodness-of-fit test was applied to compare the proportion of patients with and without DDIs.
- The result showed a highly significant difference ($\chi^2 = 160.7$, $df = 1$, $p < 0.0001$), confirming that patients with DDIs were significantly more common than those without.
- On average, patients with DDIs were prescribed 6.3 ± 2.1 concomitant medications, compared with 3.4 ± 1.7 in those without DDIs ($p < 0.001$, Student's t-test), highlighting the direct association between polypharmacy and DDI occurrence.

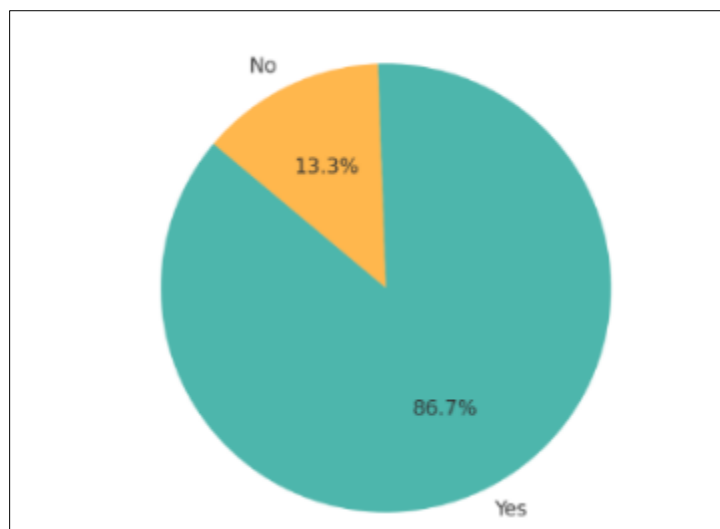


Figure 6 Distribution of patients with drug–drug interactions (N=323)

The present study found that 86.7% of hospitalized patients on metronidazole had at least one DDI, which is substantially higher than some previously reported rates in general hospitalized populations (ranging between 40–65%) [18,19]. The high proportion can be attributed to:

- Polypharmacy, as most patients were on multiple medications.
- Metronidazole’s broad pharmacological profile, particularly its CYP450 enzyme inhibition (notably CYP2C9 and CYP3A4), which predisposes it to interact with anticoagulants, antiepileptics, and other antimicrobials [20].

Comparable findings were observed in a multicenter study in Brazil, where 78% of patients receiving antimicrobials experienced at least one DDI, with metronidazole among the most implicated agents [21]. Similarly, an Indian hospital-based study reported that antimicrobials accounted for more than 50% of clinically significant DDIs, with metronidazole frequently involved [22].

The results underscore the critical need for routine DDI screening in patients prescribed metronidazole, especially in high-risk populations such as the elderly, those with comorbidities, and patients on anticoagulants. Integration of clinical pharmacists into multidisciplinary care teams and the use of electronic prescribing systems with built-in interaction alerts could reduce the burden of preventable adverse drug events.

3.5. Severity Pattern of Identified DDIs

Table 7 Severity of drug–drug interactions associated with metronidazole (Total = 723 interactions)

S.No.	Severity of Interaction	Count (n)	Percentage (%)
1	Major	561	77.60
2	Moderate	147	20.33
3	Minor	15	2.07
4	Total	723	100

A total of 723 potential drug–drug interactions were identified among the 323 patients. Of these, 77.6% were classified as major, 20.33% as moderate, and 2.07% as minor. On average, each patient experienced 2.23 potential DDIs (Table 7 and Figure 7). The frequency of DDIs was significantly higher among patients >60 years and those on polypharmacy regimens (ANOVA, $p < 0.001$).

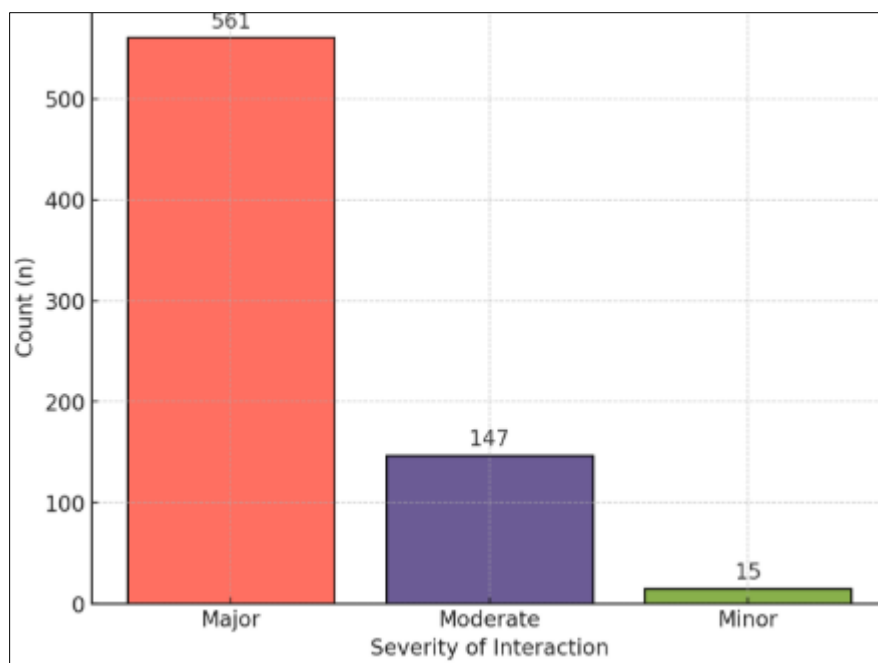


Figure 7 Severity of Drug–Drug Interactions with Metronidazole (n=723)

The high prevalence of major DDIs is alarming, especially given metronidazole's interactions with commonly used drugs such as warfarin, lithium, and phenytoin [16]. Similar findings were reported in dialysis patients and other high-risk populations, where polypharmacy compounded the risk of adverse outcomes [23]. These results highlight the importance of integrating drug interaction screening tools into prescribing practice and involving clinical pharmacists in routine inpatient care to reduce DDI-related morbidity.

4. Conclusion

The present prospective observational study provides valuable insights into the prescribing and utilization patterns of metronidazole in hospitalized patients. Analysis of 323 cases revealed that the majority of patients were in the middle to older age groups, reflecting the high burden of infections requiring antimicrobial therapy in this population. Metronidazole was most commonly prescribed in intravenous formulations, emphasizing its critical role in managing severe infections in inpatient settings.

Importantly, a high prevalence of potential drug–drug interactions (86.69%) was observed, with varying degrees of clinical significance, underscoring the need for cautious prescribing, vigilant monitoring, and routine use of drug interaction screening tools in clinical practice. The findings also highlight common co-prescription patterns with antibiotics, proton pump inhibitors, and cardiovascular drugs, which contribute to the interaction profile.

Overall, the study demonstrates that while metronidazole remains a cornerstone in the management of anaerobic and mixed infections, rational prescribing and periodic drug utilization evaluations are essential to optimize therapeutic outcomes, reduce adverse events, and promote patient safety. These results align with global recommendations advocating for antimicrobial stewardship and judicious use of antibiotics to mitigate the risks of resistance and polypharmacy.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this manuscript.

Statement of ethical approval

The study was conducted in accordance with institutional ethical standards. Necessary permissions were obtained from the hospital authorities.

Statement of informed consent

Informed consent was collected from all participants prior to enrolment. Confidentiality and anonymity of patient data were strictly maintained throughout the study.

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Author Contributions

All authors contributed significantly to the conception, design, data collection, analysis, and drafting of the manuscript. The final version has been read and approved by all authors, and each author takes responsibility for the integrity of the work.

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