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STUDY ON DRUG UTILIZATION PATTERNS AND ADVERSE DRUG REACTIONS (ADRS) SEVERITY ASSOCIATED WITH ANTIMICROBIAL AGENTS

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ABSTRACT

Background

In clinical practice, antimicrobial agents are among the most frequently used medications, especially in tertiary care hospitals where patients often arrive with complex or severe infectious conditions.This study evaluated the prescribing and utilization patterns of commonly used antimicrobial agents, along with their frequently employed routes of administration.

Aims and objectives :

1) To evaluate the prescription pattern of antimicrobial agents among patients in various departments of a tertiary care hospital.
2) To evaluate the drug utilization pattern and route of administration of antimicrobial agents, commonly used in tertiary care hospitals
3) To evaluate the most common symptoms and organ systems affected by different classes of antimicrobial agents.

Materials and Methods:

A total of 200 patients receiving antimicrobial therapy were enrolled to evaluate associated adverse effects. Each patient was monitored for medical history, medication history, and potential ADRs. The study further examined the distribution of cases, prescribing trends in management of different infections. The study also identified commonly used antimicrobial agents, the types of ADRs they cause, the routes of administration involved, and the organ systems affected across different departments of a tertiary care teaching hospital.

Results:

A total of 460 adverse drug reactions (ADRs) reports were generated from 200 patients, associated with 275 drug prescriptions. β-lactams were most prescribed (37.1%), followed by fluoroquinolones (24.7%), aminoglycosides (16.3%) and macrolides (11.6%). Doxycycline, metronidazole (2.5% each), albendazole (3.2%), vancomycin (1.0%) and antivirals (0.7%) were infrequently used. Antimicrobial drug utilization was most frequent in these clinical conditions. Among 275 prescriptions, respiratory infections accounted for the highest use (25.1%), followed by urinary tract infections (18.9%), skin/soft-tissue infections (17.1%), gastrointestinal infections (15.2%), bloodstream infections (11.2%), and other minor infections (12.3%). Oral antimicrobials were most prescribed (51.28%), while IV agents (35.63%) were mainly used for severe cases; topical formulations (13.09%) were preferred for minor eye, ear, and skin infections. Penicillins caused the highest ADRs (30%), followed by cephalosporins (20%), fluoroquinolones (15%), macrolides

(10%), and aminoglycosides (10%); other agents including sulfonamides, linezolid, antifungals, and antivirals together accounted for 15%.

Conclusion:

The study highlights that β-lactams were the most commonly prescribed antimicrobials, particularly for respiratory infections, with oral formulation being the primary route of administration. Penicillins and cephalosporins were the leading contributors to ADRs. These findings emphasize the need for rational antimicrobial use and strengthened pharmacovigilance to minimize adverse outcomes.

Keywords: Antimicrobial agents, Adverse drug reactions, Prescription pattern.

INTRODUCTION

In clinical practice, antimicrobial agents are among the most commonly used medications, especially in tertiary care hospitals where patients often present with complex or severe infections. High antibiotic use in such settings reflects the urgent need to treat a wide variety of infectious diseases from respiratory and urinary tract infections to skin, soft tissue, gastrointestinal and systemic infections. Evidence shows that irrational or excessive use of antimicrobials in hospitals contributes to adverse drug reactions (ADRs) and fosters antimicrobial resistance (AMR), posing a significant public-health challenge[1].

To promote safe and effective use of antimicrobials, a clear understanding of current prescribing practices and utilization patterns is essential. Previous studies in tertiary-care settings have documented frequent use of broad-spectrum antimicrobials especially β-lactams and cephalosporins often administered empirically, sometimes without adequate culture or sensitivity testing[2]. Additionally, misuse or overuse increases the risk of ADRs, which may affect multiple organ systems and compromise patient safety[1].

Evaluating both prescription patterns and the route of administration is crucial, as the choice between oral, intravenous or topical formulations directly influences therapeutic outcomes, safety, cost, and hospital stay[3,4]. Studies have shown that while oral antimicrobials are widely used for stable patients, intravenous therapy is often preferred in critical infections, sometimes leading to prolonged use even when step-down to oral therapy is feasible[3].

However, limited research integrates both the selection of antibiotics and their routes of administration in tertiary-care settings, leaving a gap in understanding whether current prescribing practices align with recommended standards. Addressing this gap can promote rational use of antimicrobials, strengthen stewardship strategies, and enhance patient safety as well as healthcare resource management.

2. MATERIALS AND METHODS

Study Site

This study was carried out in Index Medical College Hospital & Research Centre, Indore located in central India,

Study Design

This is a prospective observational study and adopted both spontaneous reporting and an active surveillance pharmacovigilance methodology. Data collection based on drugs, doses, and duration of disease. Institutional Ethics Committee approval was taken.

Study Population

Data were obtained from 200 outpatients receiving antimicrobial therapy for different infectious conditions across multiple clinical departments. Cases involving poisoning, anti-tubercular, anti-leprotic, or antimalarial treatments were excluded.

Prescriptions of enrolled patients were reviewed to assess antimicrobial prescribing patterns, including drug or drug combinations, dosage form, dose, frequency, generic or brand name, and accompanying medications.

All patients were monitored for adverse drug reactions (ADRs) through interviews, clinical examination, and review of medical records. Each ADR was documented with details on type, onset, and distribution, and its severity was evaluated using standard pharmacovigilance criteria. Management measures and recovery status were also recorded during follow-up.

Thus, the study assessed prescribing trends, drug-utilization patterns along with routes of administration, and identified common adverse drug reactions (ADRs) and the major organ systems affected during antimicrobial therapy.

3. RESULTS AND OBSERVATIONS

A prospective observational study was conducted on the prescriptions of 200 patients visiting the Index Medical College Associated Hospital, Indore.

Prescription Pattern of Antimicrobial Agents

Table 01: Prescription Pattern of Antimicrobial Agents

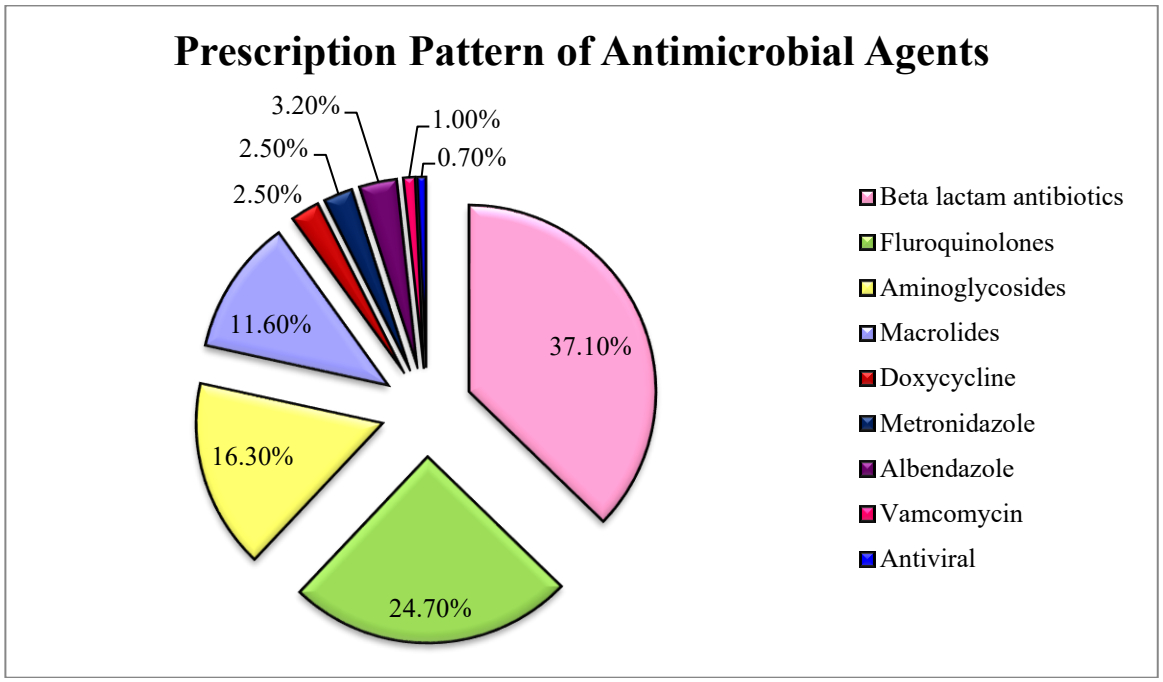
Antimicrobial class	Number of prescriptions(275)	Percentage (%)
Beta lactam antibiotics	102	37.1
Fluroquinolones	68	24.7
Aminoglycosides	45	16.3
Macrolides	32	11.6
Doxycycline	7	2.5
Metronidazole	7	2.5
Albendazole	9	3.2
Vancomycin	3	1.0
Antiviral	2	0.7
	275	

As shown in table no.1, the distribution of 275 antimicrobial prescriptions categorized according to different antimicrobial classes. Among all prescriptions, Beta-lactam antibiotics were the most frequently prescribed, accounting for 102 prescriptions (37.1%), indicating their primary role in treatment across the study population. Fluoroquinolones were the second-most utilized group, with 68 prescriptions (24.7%), followed by Aminoglycosides, prescribed in 45 cases (16.3%), reflecting their significance in moderate to severe infections.

Macrolides contributed to 32 prescriptions (11.6%), showing moderate usage. Drugs such as Doxycycline and Metronidazole were prescribed less commonly, each reported in **7** prescriptions (2.5%), indicating more selective clinical use. Albendazole, an antiparasitic agent, accounted for 9 prescriptions (3.2%), which may correspond to specific parasitic infections in the population.

More restricted use was observed for Vancomycin, with 3 prescriptions (1.0%), likely due to its role in resistant infections, and Antiviral agents, with only 2 prescriptions (0.7%), suggesting limited viral infection cases requiring such therapy.

Figure 01: Prescription Pattern of Antimicrobial Agents



As shown in figure no. 1, beta-lactam antibiotics are the most frequently prescribed antimicrobial agents (37.10%), followed by fluoroquinolones (24.70%), aminoglycosides (16.30%) and macrolides (11.60%). Other agents including doxycycline, metronidazole, albendazole, vancomycin and antivirals make up smaller proportions, indicating their more selective use in therapy.

Drug utilization pattern among commonly used antimicrobial agents

Common Indications for Antimicrobial Prescriptions

Table 02 : Common Indications for Antimicrobial Prescriptions

Indication	**Number of Prescriptions**	**Percentage (%)**
Respiratory Infections	69	25.1
Urinary Tract Infections (UTIs)	52	18.9
Skin & Soft Tissue Infections	47	17.1
Gastrointestinal Infections	42	15.2
Sepsis & Bloodstream Infections	31	11.2
Conjunctivitis, minor dental infections, post operative infections, pelvic inflammatory diseases, or gynecology infections	34	12.3
Total	**275**	

This table 2 highlights, the clinical indications for which antimicrobial agents were most commonly prescribed in the study. Respiratory infections accounted for the highest proportion of prescriptions (25.1%), indicating that conditions such as pneumonia, bronchitis, and upper respiratory tract infections are major drivers for antimicrobial use. Urinary tract infections (18%) and skin & soft tissue infections (17.1%) were also frequent, reflecting their common prevalence in outpatient and clinical settings. Gastrointestinal infections represented 15.2% of antimicrobial prescriptions, while sepsis and bloodstream infections contributed 11.2%, demonstrating the use of antimicrobials in both localized and systemic infections. A smaller yet notable share (12.3%) included prescriptions for conjunctivitis, minor dental infections, postoperative wound infections, pelvic inflammatory disease, and other gynecological infections, indicating targeted antimicrobial therapy for a range of less frequent but clinically important conditions.

Figure 02: Common Indications for Antimicrobial Prescriptions

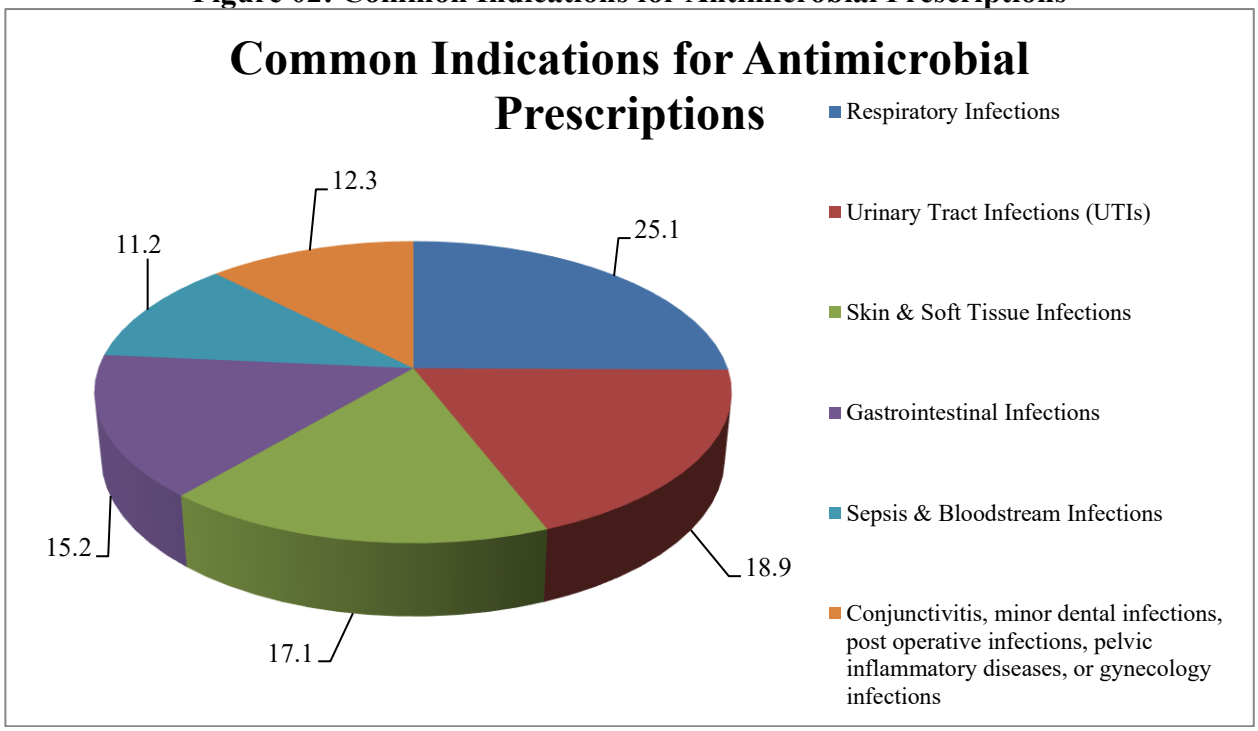


Figure no. 2 shows that most antimicrobials were prescribed for respiratory infections (25.1%), followed by urinary tract infections (18.9%) and skin & soft tissue infections (17.1%). Gastrointestinal infections (15.2%) and sepsis (11.2%) were also common reasons, while the remaining 12.3% were prescribed for various other infections such as conjunctivitis, dental, postoperative, and gynecological infections.

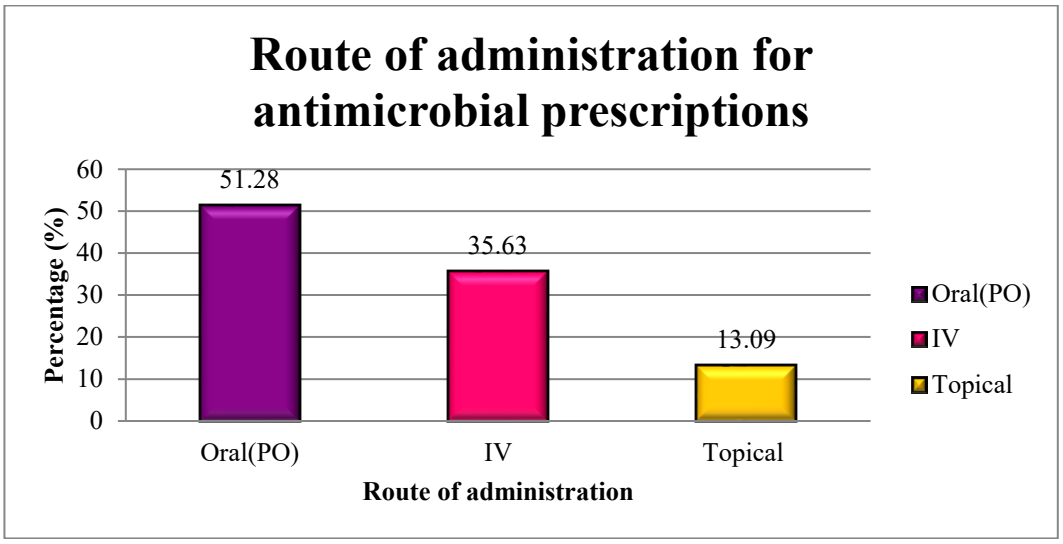
Route of Administration for Antimicrobial Prescriptions:

Table 03: Route of Administration for Antimicrobial Prescriptions

Route	Number of prescriptions	Percentage (%)
Oral (PO)	141	51.28
Intravenous (IV)	98	35.63
Topical	36	13.09
Total	275	

In this study, oral antimicrobial drugs accounted for the largest proportion of prescriptions (51.28%), reflecting their wide use in managing mild to moderate infections due to ease of administration, better patient compliance, and suitability for outpatient care. Intravenous (IV) antimicrobials represented 35.63% of prescriptions, commonly reserved for more severe or complicated infections requiring rapid and higher drug availability in the bloodstream, typically in hospital settings. Topical antimicrobials constituted 13.09% of the prescriptions and were primarily administered for localized infections of the skin, eyes, and ears, where direct application ensures targeted action with minimal systemic effects.

Figure 03 : Route of Administration for Antimicrobial Prescriptions



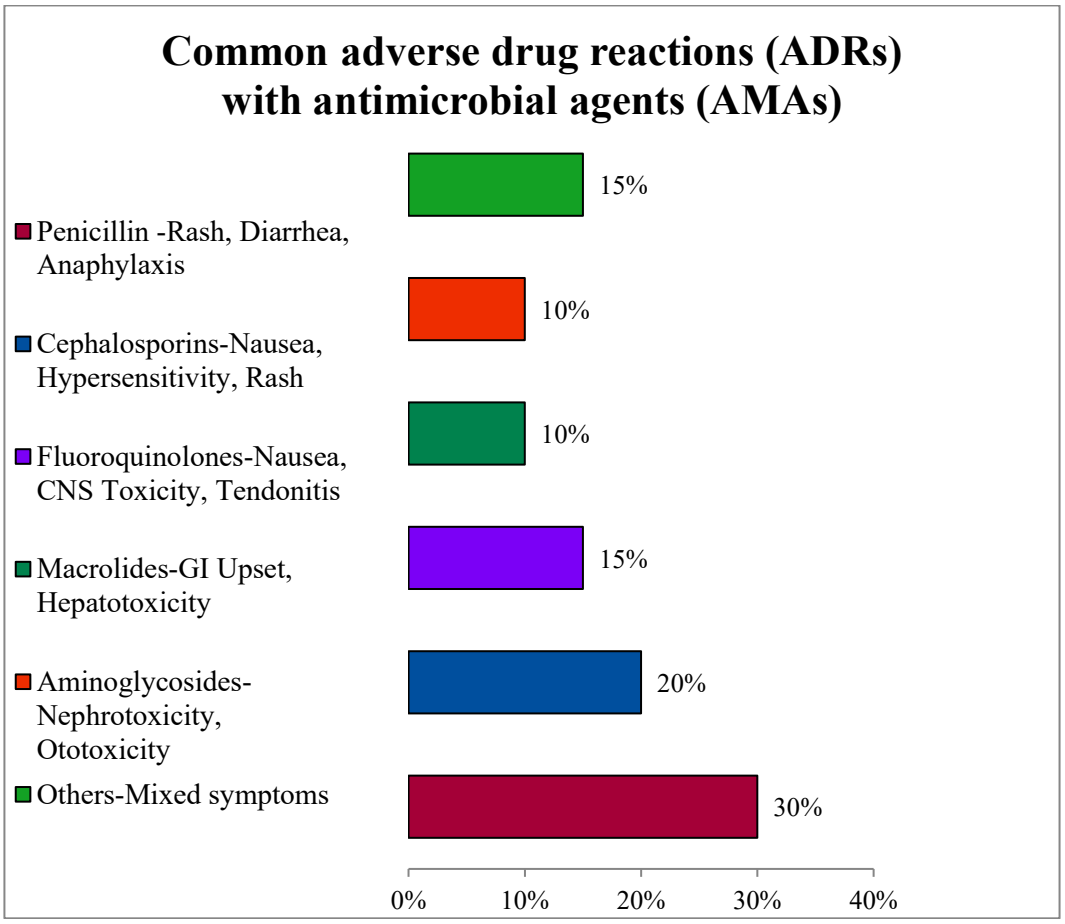
Oral antimicrobials (51.28%) were the most frequently prescribed, whereas intravenous (IV) antimicrobials (35.63%) were mainly used for severe infections. The topical route (13.09%). predominantly utilized for treating minor eye, ear, and skin infections.

Table 04 : Most Common Symptoms by Antibiotic Class and Affected Organ System

Antibiotic Class	Common ADR Symptoms	Primary Organ System Affected	Number of Cases (%)
Penicillins	Rash, Diarrhea, Anaphylaxis	Skin, GI, Hypersensitivity	138 (30)
Cephalosporins	Nausea, Hypersensitivity, Rash	GI, Skin	92 (20)
Fluoroquinolones	Nausea, CNS Toxicity, Tendonitis	GI, Neurological	69 (15)
Macrolides	GI Upset, Hepatotoxicity	GI, Hepatic	46 (10)
Aminoglycosides	Nephrotoxicity, Ototoxicity	Renal, Neurological	46 (10)
Others	Mixed Symptoms	Multiple	69 (15)

As shown in table no. 04, each class of antimicrobials showed characteristic patterns of adverse drug reactions (ADRs) involving specific organ systems. Penicillins (138 cases; 30%) most commonly produced skin-related and gastrointestinal effects such as rashes, diarrhea, and occasional anaphylaxis. Cephalosporins (92 cases; 20%) frequently triggered nausea, hypersensitivity reactions, and rashes, mainly affecting the GIT and skin. Fluoroquinolones (69 cases; 15%) predominantly caused gastrointestinal discomfort along with neurological complications such as seizures and tendonitis. Macrolides (46 cases; 10%) primarily led to GI disturbances and liver toxicity. Aminoglycosides (46 cases; 10%) were associated with renal impairment and ototoxicity, impacting the kidneys and CNS. The remaining antimicrobial group, including agents like sulfonamides and linezolid (69 cases; 15%), showed mixed ADRs involving multiple organ systems.

Figure 04: Common adverse drug reactions (ADRs) with antimicrobial agents (AMAs)



As shown in figure 04, different antimicrobial classes exhibited characteristic ADR patterns. Penicillins (30%) mainly caused skin and gastrointestinal reactions, cephalosporins (20%) led to GIT and skin effects, and fluoroquinolones (15%) produced GIT and neurological symptoms. Macrolides (10%) affected the GIT and liver, aminoglycosides (10%) impacted the kidneys and CNS, while other agents like sulfonamides and linezolid (15%) caused diverse ADRs across multiple organ systems.

4. DISCUSSION

The present study analyzed 275 antimicrobial prescriptions to evaluate utilization patterns, clinical indications, routes of administration, and adverse drug reactions (ADRs). Among different antimicrobial classes, Beta-lactam antibiotics were the most frequently prescribed (102 prescriptions; 37.1%), highlighting their primary role in treating common bacterial infections. This finding aligns with previous studies that reported Beta-lactams as the most commonly prescribed class due to their broad-spectrum activity, safety profile, and affordability. Study report by Anand N et al. (2016), beta-lactam antibiotics and cephalosporins were found to be widely used in the intensive care units of a tertiary care hospital in South India[5].

The findings from our study were found to be consistent with the observations reported by Kumar A et al (2020)[6].

Fluoroquinolones were the second-most prescribed group (68 prescriptions; 24.7%), consistent with reports that emphasize their effectiveness in urinary tract infections and respiratory infections similar to findings by Chandy et al(2013)[7].

Aminoglycosides accounted for 45 prescriptions (16.3%), reflecting their use in moderate to severe infections, particularly in hospital settings. However, when compared with the findings of Pamarthi Sanjana et al. (2024), it appears that aminoglycosides were prescribed less frequently in our study than reported in their research[8].

Macrolides (32 prescriptions; 11.6%) showed moderate utilization, while Doxycycline and Metronidazole (7 prescriptions each; 2.5%) and Albendazole (9 prescriptions; 3.2%) were less commonly used, indicating selective therapy for specific bacterial and parasitic infections

Restricted use of Vancomycin (3 prescriptions; 1.0%) and antiviral agents (2 prescriptions; 0.7%) reflects their reserved use in resistant infections and viral cases, respectively, consistent with antimicrobial stewardship principles[9].

The clinical indications for antimicrobial prescriptions revealed that respiratory infections were the most frequent (25.1%), corroborating studies showing pneumonia, bronchitis, and upper respiratory tract infections as primary drivers for outpatient antimicrobial use[10,].

Urinary tract infections (18%) and skin and soft tissue infections (17.1%) were also prevalent, reflecting similar patterns observed in regional and global prescription audits[11,12].

Gastrointestinal infections (15.2%) and sepsis/bloodstream infections (11.2%) demonstrate that antimicrobials were utilized across both localized and systemic infections, whereas a smaller proportion (12.3%) addressed conditions such as conjunctivitis, dental infections, postoperative wound infections, and gynecological infections, which aligns with reports on targeted therapy for less common infections[13].

Regarding the route of administration, oral antimicrobials comprised the largest share (51.28%), reflecting convenience, outpatient suitability, and better patient adherence, in agreement with previous studies reporting oral therapy as the preferred choice for mild to moderate infections[14].

Intravenous antimicrobials accounted for 35.63% of prescriptions, typically reserved for severe or complicated infections requiring rapid systemic levels, a finding consistent with hospital-based antimicrobial utilization data[15].

Topical antimicrobials (13.09%) were primarily used for localized skin, eye, or ear infections, supporting the principle of targeted therapy with minimal systemic exposure[16].

Analysis of adverse drug reactions (ADRs) demonstrated class-specific patterns. Penicillins (138 cases; 30%) mainly produced dermatological and gastrointestinal effects, consistent with their known hypersensitivity potential[17].

Cephalosporins (92 cases; 20%) were associated with nausea, hypersensitivity, and skin reactions, aligning with prior pharmacovigilance reports[18]. Fluoroquinolones (69 cases; 15%) caused gastrointestinal discomfort, neurological symptoms, and tendonitis, echoing documented safety concerns[19]. Macrolides (46 cases; 10%) primarily induced gastrointestinal and hepatic disturbances.

Aminoglycosides (46 cases; 10%) were linked to nephrotoxicity and ototoxicity, a recognized ADR profile reported in multiple studies[20]. Remaining agents, including sulfonamides and linezolid (69 cases; 15%), exhibited mixed ADRs affecting multiple organ systems, reflecting the broad adverse effect potential of less frequently used antimicrobials.

In comparison to other studies, the distribution and ADR patterns observed in this study are largely consistent with global and regional antimicrobial utilization trends. However, the lower use of restricted agents like Vancomycin and antiviral suggests adherence to stewardship guidelines aimed at minimizing resistance and ADRs, reinforcing the need for continuous monitoring and rational prescribing practices.

5. LIMITATIONS

This study is limited by its single-center design, small sample size, and short study duration, which may restrict generalizability. ADRs may be under-reported due to dependence on documented records. Additionally, antimicrobial resistance patterns are also not assessed.

6. CONFLICT OF INTEREST: Nil

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