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A Prospective Observational Study on Antimicrobial Prescribing Patterns and Associated Adverse Drug Reactions in Pediatric Lower Respiratory Tract Infections at a Tertiary Care Teaching Hospital in North India

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ABSTRACT

Background: Lower respiratory tract infections (LRTIs) remain one of the leading causes of morbidity and mortality among children worldwide, particularly in developing countries. Rational antimicrobial use is essential to ensure effective treatment while minimizing adverse drug reactions (ADRs) and antimicrobial resistance.
Aim: To evaluate antimicrobial prescribing patterns and associated adverse drug reactions in pediatric patients with LRTIs.
Methods: A prospective observational study was conducted over one year in the Department of Pharmacology and Pediatrics at a tertiary care hospital. A total of 150 pediatric patients (0–17 years) diagnosed with LRTIs and receiving at least one antimicrobial were included. Data regarding demographics, clinical presentation, antimicrobial use, culture sensitivity, and ADRs were collected. ADRs were assessed using Naranjo's algorithm and Hartwig severity scale. Statistical analysis was performed using SPSS and Jamovi software.
Results: The mean age was 8.45 ± 5.26 years with male predominance (58.7%). Bronchopneumonia (44.7%) was the most common diagnosis. Cephalosporins (38.7%) were the most frequently prescribed antimicrobials, followed by penicillin–β-lactamase inhibitors (22.7%). Intravenous administration was used in 61.3% cases. Culture positivity was high, with *Streptococcus pneumoniae* (30.2%) being the most common isolate. ADRs were observed in 18% of patients, most commonly gastrointestinal disturbances (7.3%). No statistically significant association was found between ADRs and antimicrobial class, number of drugs, route, or duration ($p > 0.05$).
Conclusion: Antimicrobial prescribing was largely rational and aligned with standard guidelines. ADRs were mild and infrequent. Strengthening antimicrobial stewardship and promoting culture-guided therapy are essential to improve patient outcomes and prevent resistance.

Keywords*: Antimicrobial, Prescribing, Drug, Pediatric, Tract Infections.*

INTRODUCTION

Lower respiratory tract infections (LRTIs) are among the most significant causes of morbidity and mortality in pediatric populations worldwide, particularly in low- and middle-income countries. According to global health estimates, LRTIs account for a substantial proportion of hospital admissions and deaths among children under five years of age, with pneumonia being the leading cause of infectious mortality in this age group [1,2]. Despite advances in vaccination, antimicrobial therapy, and healthcare infrastructure, the burden of pediatric LRTIs remains high, especially in developing nations like India [3].LRTIs encompass a broad spectrum of conditions including bronchopneumonia, pneumonia,

bronchiolitis, acute bronchitis, lung abscess, and empyema. These infections affect the bronchi, bronchioles, and alveoli, leading to impaired gas exchange and systemic inflammatory responses [4]. The etiology of LRTIs is diverse and includes bacterial, viral, and occasionally fungal pathogens. Among bacterial causes, *Streptococcus pneumoniae*, *Haemophilusinfluenzae*, and *Staphylococcus aureus* are the most frequently implicated organisms, whereas viral agents such as respiratory syncytial virus (RSV), influenza virus, and adenovirus are commonly associated with bronchiolitis and viral pneumonia [5,6].The clinical presentation of pediatric LRTIs varies widely depending on the causative organism, age of the child, and immune status. Common symptoms include cough, fever, breathlessness, and chest indrawing, while physical findings such as tachypnea, wheezing, and crepitations are frequently observed [7]. Early recognition and prompt treatment are critical to prevent complications such as respiratory failure, pleural effusion, and sepsis [8].Antimicrobial therapy plays a central role in the management of bacterial LRTIs. Empirical antibiotic therapy is often initiated based on clinical diagnosis, severity of illness, and local epidemiological patterns. However, inappropriate or irrational use of antimicrobials has become a major concern globally, contributing to the emergence of antimicrobial resistance (AMR) [9,10]. The overuse of broad-spectrum antibiotics, polypharmacy, and lack of adherence to standard treatment guidelines have been identified as key factors driving resistance [11].

In pediatric practice, antimicrobial prescribing is particularly challenging due to factors such as weight-based dosing, age-specific pharmacokinetics, limited clinical trial data, and the need to balance efficacy with safety [12]. In many settings, antibiotics are prescribed empirically without microbiological confirmation, which may lead to unnecessary exposure and increased risk of adverse drug reactions (ADRs) [13].

Adverse drug reactions are defined as any harmful or unintended response to a drug administered at normal doses for prophylaxis, diagnosis, or treatment [14]. Children are especially vulnerable to ADRs due to immature organ systems, differences in drug metabolism, and difficulties in communication of symptoms [15]. Common ADRs associated with antimicrobials include gastrointestinal disturbances, hypersensitivity reactions, nephrotoxicity, and hepatotoxicity [16]. Monitoring and reporting ADRs are essential components of pharmacovigilance and help in improving drug safety and therapeutic outcomes [17].

The World Health Organization (WHO) and Indian Council of Medical Research (ICMR) have emphasized the importance of rational antimicrobial use through antimicrobial stewardship programs. These programs aim to optimize antibiotic selection, dosing, duration, and route of administration to achieve the best clinical outcomes while minimizing toxicity and resistance [18,19]. In addition, culture and sensitivity testing plays a crucial role in guiding targeted therapy, although it is often underutilized due to cost, time constraints, or prior antibiotic use [20].Several studies conducted in India and other developing countries have highlighted variations in antimicrobial prescribing patterns in pediatric LRTIs. Cephalosporins and penicillin–β-lactamase inhibitor combinations are commonly used as first-line agents, while macrolides are employed for atypical infections [21,22]. However, there is growing concern regarding the increasing use of higher-end antibiotics such as carbapenems and glycopeptides, which should ideally be reserved for resistant infections [23].Understanding prescribing patterns and ADR profiles in pediatric LRTIs is essential for improving clinical practice, promoting rational drug use, and enhancing patient safety. Hospital-based studies provide valuable insights into real-world prescribing behaviors, microbial trends, and treatment outcomes [24].In the present study, we aimed to evaluate antimicrobial prescribing patterns and associated adverse drug reactions in pediatric patients with lower respiratory tract infections admitted to a tertiary care teaching hospital. By analyzing prescription trends, culture sensitivity patterns, and ADR incidence, this study seeks to contribute to evidence-based pediatric antimicrobial therapy and support antimicrobial stewardship efforts.

MATERIALS AND METHODS

The study was conducted in the **Department of Pharmacology in collaboration with the Department of Pediatrics** at**Rama Medical College, Hospital and Research Centre, Kanpur**, which is a tertiary care teaching hospital catering to both urban and rural populations of North India. The hospital has well-established pediatric inpatient services, including general pediatric wards, pediatric intensive care units (PICU), and emergency services, providing comprehensive care for children with infectious diseases. The present study was designed as a **prospective, observational, hospital-based study** aimed at evaluating antimicrobial prescribing patterns and associated adverse drug reactions (ADRs) in pediatric patients diagnosed with lower respiratory tract infections (LRTIs). A prospective approach was chosen to allow real-time data collection, continuous monitoring of antimicrobial therapy, and systematic documentation of ADRs during the course of hospitalization.

Study Population

The study population comprised **pediatric patients aged 0 to 17 years** who were admitted to the pediatric department with a clinical diagnosis of lower respiratory tract infection and received at least one antimicrobial agent during their hospital stay.

Sampling Technique
A **purposive sampling technique** was employed, wherein all eligible pediatric patients meeting the inclusion criteria during the study period were consecutively enrolled. This method ensured inclusion of a representative sample of LRTI cases encountered in routine clinical practice.

Sample Size Determination
The sample size was calculated using the standard formula for estimating proportions:
n=Z2×p×(1−p)d2n = \frac{Z^2 \times p \times (1-p)}{d^2}n=d2Z2×p×(1−p)

Where:
- **n** = required sample size
- **Z** = Z value for 95% confidence level (1.96)
- **p** = expected proportion of ADRs (assumed 10% based on previous studies)
- **d** = allowable error (5%)

Substituting values:
n=(1.96)2×0.10×0.90(0.05)2n = \frac{(1.96)^2 \times 0.10 \times 0.90}{(0.05)^2}n=(0.05)2(1.96)2×0.10×0.90n≈138n ≈ 138n≈138

To compensate for incomplete data or dropouts, the sample size was rounded up to **150 patients**, which constituted the final study population.

Inclusion Criteria
1. Pediatric patients aged **0–17 years**
2. Clinically diagnosed cases of **lower respiratory tract infections** (e.g., pneumonia, bronchopneumonia, bronchiolitis, bronchitis)
3. Patients receiving **at least one antimicrobial agent**
4. Patients admitted for **more than 24 hours**

Exclusion Criteria
1. Patients with **non-infectious respiratory conditions** (e.g., asthma without infection)
2. Patients discharged or referred within **24 hours of admission**
3. Cases with **incomplete medical records or missing essential data**
4. Patients not receiving antimicrobial therapy

Operational Definitions
- **Lower Respiratory Tract Infection (LRTI):** Infection involving bronchi, bronchioles, and lung parenchyma, diagnosed clinically and/or radiologically.
- **Antimicrobial Prescribing Pattern:** The selection, class, dosage, route, frequency, and duration of antimicrobial agents prescribed.
- **Adverse Drug Reaction (ADR):** Any unintended, harmful response to a drug administered at normal therapeutic doses.

Data Collection Tools
The following standardized tools and proformas were used:
1. **Patient Profile Form:**
   Included demographic details (age, sex, residence), clinical history, nutritional status, and socioeconomic status.
2. **Prescription Audit Form:**
   Used to record details of antimicrobial therapy including drug name, class, dose, route, frequency, duration, and combination therapy.
3. **ADR Reporting Form:**
   Based on **Indian Pharmacopoeia Commission (IPC) guidelines**, used for systematic documentation of adverse drug reactions.

Standard Assessment Scales
To ensure objectivity and reliability, validated scales were used:
- **Naranjo's Algorithm:**
  Used to assess causality of ADRs (definite, probable, possible, doubtful)
- **Hartwig and Siegel Severity Scale:**
  Used to classify ADR severity (mild, moderate, severe)

Data Collection Procedure

The data collection process was carried out in a systematic and stepwise manner:

1. **Patient Identification:**
   Pediatric patients diagnosed with LRTIs were identified daily from admission records in pediatric wards, PICU, and emergency units.
2. **Clinical Evaluation:**
   Detailed clinical information including presenting symptoms, physical findings, diagnosis, and comorbidities was recorded.
3. **Prescription Monitoring:**

All antimicrobial prescriptions were reviewed daily to assess:

   - Type and class of antimicrobial
   - Number of drugs prescribed
   - Route of administration (IV/oral/sequential)
   - Frequency and duration of therapy

4. **Laboratory and Radiological Data:**
   Relevant investigations including complete blood count, CRP, ESR, chest X-ray, and culture sensitivity reports were recorded.
5. **ADR Monitoring:**
   Patients were monitored throughout their hospital stay for any suspected adverse drug reactions.
   - Any new symptom after drug administration was evaluated
   - Suspected ADRs were documented using standard forms
   - Causality and severity were assessed using standardized scales
6. **Outcome Assessment:**
   Clinical outcomes were categorized as:
   - Complete recovery
   - Partial improvement
   - No improvement
   - Referral
   - Death

Ethical Considerations

- Approval was obtained from the **Institutional Ethics Committee of Rama Medical College, Kanpur** prior to commencement of the study.

RESULTS

A total of **150 pediatric patients** diagnosed with lower respiratory tract infections (LRTIs) were included in the present study. The results are described under demographic profile, clinical characteristics, microbiological findings, antimicrobial prescribing patterns, treatment outcomes, and adverse drug reactions. The present study included a total of 150 subjects with ages ranging from 0.5 to 17 years, indicating a wide pediatric age spectrum. The mean age of the study population was 8.45 ± 5.26 years, while the median age was 8.5 years, suggesting a relatively symmetric age distribution around the central value. The interquartile range (IQR) of 9 years reflects considerable variability in age among the participants.

Among the 150 pediatric subjects enrolled in this study on antimicrobial prescribing patterns and adverse drug reactions in lower respiratory tract infections (LRTIs), males constituted a higher proportion (58.7%) compared to females (41.3%). The male-to-female ratio was approximately 1.4 : 1, indicating a modest male predominance.

Table 1: Weight (kg) Distribution of patients

S. No.	Weight Range (kg)	Number of patients (n = 150)	Percentage(%)
1	< 10	18	12.0
2	10–20	45	30.0
3	21–30	39	26.0
4	31–40	28	18.7
5	> 40	20	13.3
6	Mean	26.8	
7	SD	12.4	
8	Median	25.5	
9	Min	5	
10	Max	54	

The weight of pediatric subjects in this study ranged from 5 kg to 54 kg, with a mean weight of 26.8 ± 12.4 kg and a median weight of 25.5 kg, indicating that most participants were of school-going age with moderate variation in body weight. The distribution reveals that the majority of children (30%) weighed between 10–20 kg, followed closely by those in the 21–30 kg range (26%). A smaller fraction of subjects weighed more than 40 kg (13.3%), corresponding to older adolescents, while 12% of participants weighed less than 10 kg, reflecting infants and toddlers.

As the majority of pediatric patients in this study were nutritionally normal (41.3%), while the remaining 58.7% exhibited varying degrees of malnutrition. Among the malnourished children, mild malnutrition was observed in 25.3%, moderate malnutrition in 20.7%, and severe malnutrition in 12.7% of the subjects.

Table 2: Distribution of Patients According to Duration of Illness (Days)

S. No.	Duration of Illness (Days)	Number of patients(n=150)	Percentage (%)
1	≤ 3 days	36	24.0
2	4–7 days	61	40.7
3	8–10 days	31	20.7
4	> 10 days	22	14.6
5	Mean ± SD (days)	6.9 ± 3.8	

As the duration of illness among pediatric patients ranged from 1 to 18 days, with a mean duration of 6.9 ± 3.8 days. The largest proportion of subjects (40.7%) reported symptoms lasting between 4 to 7 days, followed by 24% who presented within 3 days of onset, 20.7% who had illness lasting 8–10 days, and 14.6% who experienced symptoms for more than 10 days before seeking medical care.

Table 3: Distribution of Patients According to Diagnosis of LRTI

S. No.	Diagnosis	Number of patients(n = 150)	Percentage (%)
1	Bronchopneumonia	67	44.7
2	Pneumonia	39	26.0
3	Bronchiolitis	24	16.0
4	Acute Bronchitis	12	8.0
5	Empyema / Pleural Effusion	5	3.3
6	Lung Abscess	3	2.0

The predominance of bronchopneumonia reflects its high incidence among children due to the vulnerability of the developing respiratory system, immature immune defense, and frequent exposure to respiratory pathogens. It is commonly associated with bacterial infections such as *Streptococcus pneumoniae*, *Haemophilusinfluenzae*, and *Staphylococcus aureus*, particularly in undernourished or low-immunity children.

Pneumonia, the second most frequent diagnosis, remains a significant cause of morbidity and hospitalization in the pediatric age group. The substantial number of pneumonia and bronchopneumonia cases together (over 70%) indicates that bacterial LRTIs are the dominant clinical presentations in this study population.

Table 4: Distribution of Patients According to Clinical Symptoms

S. No.	Clinical Symptoms	Number of patients(n = 150)	Percentage (%)
1	Cough	132	88.0
2	Fever	126	84.0
3	Breathlessness / Dyspnea	92	61.3
4	Chest Indrawing	56	37.3
5	Nasal Discharge / Congestion	47	31.3
6	Wheezing	44	29.3
7	Sore Throat	38	25.3
8	Crepitations / Crackles	33	22.0
9	Cyanosis	11	7.3
10	Poor Feeding / Lethargy	18	12.0

The presence of systemic manifestations like poor feeding, irritability, or lethargy in younger children underscores the difficulty of recognizing respiratory distress in infants, where nonspecific symptoms often predominate.The overall symptom profile observed here closely mirrors previous pediatric studies, which consistently report cough and fever in over 80% of LRTI cases, and dyspnea in 60–70%. This confirms that early identification of these cardinal symptoms,

especially in the community setting, is vital for timely diagnosis, referral, and initiation of antimicrobial therapy to prevent complications. The predominance of tachypnea underscores its role as a sensitive and early clinical marker for LRTI diagnosis in children, as defined by WHO criteria. It reflects increased respiratory effort secondary to airway inflammation and alveolar involvement. Chest indrawing and retractions indicate a greater degree of respiratory compromise, commonly associated with pneumonia, bronchopneumonia, or bronchiolitis. These findings, when present, serve as reliable indicators for hospital admission and oxygen therapy.Hyperinflated lung fields were observed in 16% of cases, predominantly in patients diagnosed with bronchiolitis or those with viral etiologies, reflecting air trapping and over-distension of alveoli. Peribronchial thickening (9.3%) indicated chronic airway inflammation, often associated with recurrent respiratory infections or early obstructive airway disease.

Table 5: Distribution of Patients According to Laboratory Findings

S. No.	Laboratory Parameter / Finding	Abnormal Cases (n = 150)	Percentage (%)	Normal Range / Remarks
1	Elevated Total Leukocyte Count (TLC > 11,000/mm³)	79	52.7	Suggestive of bacterial infection
2	Neutrophilia (> 70%)	64	42.7	Seen in bacterial LRTI
3	Lymphocytosis (> 40%)	27	18.0	Associated with viral infection
4	Anemia (Hb< 11 g/dL)	56	37.3	Nutritional or infection-related
5	Raised ESR (> 20 mm/hr)	71	47.3	Indicates ongoing inflammation
6	Elevated CRP (> 6 mg/L)	66	44.0	Strong marker of bacterial infection
7	Hypoxemia (SpO_2 < 92%)	14	9.3	Indicates moderate–severe disease
8	Hyponatremia (Na^+ < 135 mmol/L)	22	14.7	May reflect dehydration / SIADH
9	Hyperglycemia (Stress related)	10	6.7	Transient response to infection
10	Normal Laboratory Profile	19	12.7	Mild or early-stage infection

Raised ESR (47.3%) and elevated C-reactive protein (CRP) levels (44%) were also frequently detected, supporting the presence of acute inflammatory processes and serving as reliable markers of infection severity. These inflammatory indicators are commonly used in clinical settings to guide antibiotic initiation and monitor treatment response.Interestingly, 12.7% of patients had a normal laboratory profile, indicating early-stage disease, partial prior antibiotic use, or predominantly viral etiology without marked systemic response.

Table 6: Distribution of Patients According to Culture Testing

S. No.	Culture Test Status /Result	Number of Patients(n = 150)	Percentage (%)
1	Culture Done	96	64.0
2	Culture Not Done	54	36.0

As culture sensitivity testing was performed in 96 out of 150 pediatric subjects (64%), while 54 cases (36%) did not undergo culture testing primarily due to mild infections, early antibiotic initiation, or logistic limitations. Among those tested, positive bacterial growth was obtained in 91 cases (94.8%), confirming the bacterial nature of most LRTIs in this cohort.

Table 7: Distribution of Patients According to Culture/Organism Isolated

S. No.	Organism Isolated	Number of Isolates (n = 96)	Percentage (%)	Remarks
1	Streptococcus pneumoniae	29	30.2	Commonest cause of community-acquired pneumonia
2	Staphylococcus aureus	21	21.9	Frequently associated with bronchopneumonia; may show β-lactam resistance
3	Haemophilusinfluenzae	15	15.6	Common in children under 5 years; may follow viral infections
4	Klebsiellapneumoniae	11	11.5	Associated with severe pneumonia and hospital-acquired cases

5	Pseudomonas aeruginosa	9	9.4	Found in prolonged illness and resistant cases
6	Escherichia coli	6	6.3	May indicate secondary infection or aspiration pneumonia
7	Acinetobacterbaumannii	3	3.1	Opportunistic; seen in ICU or ventilated patients
8	No Growth / Sterile	2	2.1	Possibly due to prior antibiotic exposure or viral etiology
	Total	96	100.0	

The Gram-negative organisms (Klebsiellapneumoniae – 11.5%, Pseudomonas aeruginosa – 9.4%, and E. coli – 6.3%) represented 23% of total isolates. Their presence was predominantly observed in children with prolonged illness, prior antibiotic therapy, or hospital stay, suggesting possible nosocomial or multidrug-resistant infections. These isolates are of particular clinical concern due to their ability to produce extended-spectrum β-lactamases (ESBLs) or carbapenem resistance, complicating treatment decisions.

Table 8: Distribution of Common Antibiotic Sensitivity Patterns (n=81)

S. No.	Antibiotic Tested	Sensitive Isolates (n)	Percentage (%)	Remarks
1	Amoxicillin–Clavulanate	47	58.0	Moderate sensitivity in Gram-positive isolates
2	Ceftriaxone / Cefotaxime	61	75.3	High sensitivity for *S. pneumoniae* and *H. influenzae*
3	Azithromycin / Clarithromycin	43	53.1	Effective for atypical and mixed infections
4	Amikacin	55	67.9	Strong activity against Gram-negative organisms
5	Gentamicin	49	60.5	Moderate response in Gram-negative isolates
6	Ciprofloxacin / Levofloxacin	38	46.9	Reduced sensitivity; possible resistance trend
7	Piperacillin–Tazobactam	63	77.8	High sensitivity among resistant Gram-negative isolates
8	Meropenem / Imipenem	66	81.5	Broad-spectrum efficacy; reserved for severe infections
9	Vancomycin	24	100.0	100% sensitivity in *Staphylococcus aureus* isolates
10	Linezolid	21	100.0	Effective against Gram-positive cocci (MRSA)

Among the 81 isolates with available sensitivity reports (Table 15A), Ceftriaxone/Cefotaxime (75.3%) and Piperacillin–Tazobactam (77.8%) demonstrated high efficacy, followed by Meropenem/Imipenem (81.5%), which exhibited broad-spectrum sensitivity, particularly against Klebsiella, Pseudomonas, and E. coli isolates. Amikacin (67.9%) and Gentamicin (60.5%) also retained considerable activity against Gram-negative bacteria, though a moderate decline in sensitivity was noted compared to carbapenems.

Table 9: Distribution Patients of According to Co-morbidities

S. No.	Co-morbid Condition	Number of Patients (n = 150)	Percentage (%)
1	No Co-morbid Illness	102	68.0
2	Malnutrition	21	14.0
3	Anemia	14	9.3
4	Asthma / Recurrent Wheeze	6	4.0
5	Congenital Heart Disease (CHD)	3	2.0
6	Neurological Disorders (e.g., Cerebral Palsy, Seizures)	2	1.3
7	Chronic Kidney Disease (CKD)	1	0.7
8	Others (e.g., Thalassemia, Immunodeficiency)	1	0.7
	Total	**150**	**100.0**

Among co-morbid conditions, malnutrition (14%) was the most prevalent, followed by anemia (9.3%) and asthma or recurrent wheezing (4%). Smaller proportions of children had congenital heart disease (2%), neurological disorders (1.3%), chronic kidney disease (0.7%), and other immunocompromised states (0.7%).

The high frequency of malnutrition as a co-morbid factor reflects its well-established association with increased vulnerability to respiratory infections, impaired mucosal defenses, and prolonged recovery. Anemia, often overlapping with malnutrition, contributes to tissue hypoxia and poor immune response, thereby exacerbating infection severity. Asthma and recurrent wheezing were observed mainly in older children, where airway hyper-reactivity predisposes to recurrent bronchitis and secondary bacterial infections.

Congenital heart disease (CHD) and neurological disorders were relatively rare but clinically important co-morbidities, often associated with prolonged hospitalization and complications such as hypoxemia or aspiration pneumonia. Similarly, children with CKD or hematological disorders (e.g., thalassemia) represent a vulnerable subgroup requiring tailored antibiotic dosing and monitoring due to altered pharmacokinetics.Shorter stays (≤3 days) were observed mainly in mild infections, often managed with empirical antibiotics and supportive therapy before discharge with oral follow-up treatment. These cases may also represent patients who responded promptly to therapy or those who were shifted to outpatient monitoring.

Table 10: Distribution of Patients According to Class of Antimicrobials Prescribed

S. No.	Class of Antimicrobial	Number of Prescriptions (n=150)	Percentage (%)
1	Cephalosporins (e.g., Ceftriaxone, Cefotaxime)	58	38.7
2	Penicillins with β-lactamase inhibitors (e.g., Amoxicillin–Clavulanate, Piperacillin–Tazobactam)	34	22.7
3	Macrolides (e.g., Azithromycin, Clarithromycin)	21	14.0
4	Aminoglycosides (e.g., Amikacin, Gentamicin)	18	12.0
5	Carbapenems (e.g., Meropenem, Imipenem)	9	6.0
6	Fluoroquinolones (e.g., Levofloxacin, Ciprofloxacin)	6	4.0
7	Glycopeptides (e.g., Vancomycin)	4	2.6
	Total	**150**	**100.0**

As illustrated in Table 10, the most commonly prescribed class of antimicrobials for pediatric patients with lower respiratory tract infections (LRTIs) was cephalosporins (38.7%), followed by penicillins with β-lactamase inhibitors (22.7%), and macrolides (14%). These three classes together accounted for over 75% of all antimicrobial prescriptions, indicating that clinicians primarily relied on broad-spectrum antibiotics active against the common respiratory pathogens *Streptococcus pneumoniae*, *Staphylococcus aureus*, and *Haemophilusinfluenzae*.Cephalosporins, particularly third-generation agents like ceftriaxone and cefotaxime, were favored as empirical therapy owing to their proven efficacy, safety, and broad coverage for Gram-positive and Gram-negative bacteria. Their high utilization reflects adherence to standard pediatric LRTI management guidelines recommended by the Indian Academy of Pediatrics (IAP) and WHO.Macrolides (14%) were used in older children or cases suspected of atypical infections (e.g., *Mycoplasma pneumoniae* or *Chlamydia pneumoniae*). Their use as adjuncts to cephalosporins reflects rational prescribing practices based on mixed infection patterns.Aminoglycosides (12%), primarily amikacin or gentamicin, were used as combination therapy in severe or hospital-acquired infections to enhance Gram-negative coverage. Meanwhile, carbapenems (6%) and glycopeptides (2.6%) were reserved for critically ill patients or those with resistant pathogens, reflecting appropriate antibiotic stewardship.Fluoroquinolones (4%) were used sparingly, consistent with pediatric prescribing norms that restrict their use due to potential cartilage toxicity and emerging resistance patterns.

Table 11: Distribution of Patients According to Route of Antimicrobial Administration

S. No.	Route of Administration	Number of Patients (n = 150)	Percentage (%)
1	Intravenous (IV)	92	61.3
2	Oral (PO)	38	25.3
3	Combination (IV + Oral Sequential Therapy)	20	13.4
	Total	**150**	**100.0**

As the majority of pediatric LRTI cases (58%) were treated with single antimicrobial agents (monotherapy), while dual therapy was employed in 30.7% and polytherapy (≥3 drugs) in 11.3% of patients. This distribution pattern reflects a generally rational and judicious antimicrobial prescribing approach, emphasizing targeted rather than excessive antibiotic use.

Polytherapy was reserved for complicated or hospital-acquired infections, often in children with co-morbidities or poor initial response to empirical therapy. These regimens commonly included carbapenems or glycopeptides alongside other broad-spectrum antibiotics, indicating careful escalation guided by culture and sensitivity findings.

Table 12: Distribution of Patients According to Antimicrobial Combinations Used

S. No.	Antimicrobial Combination Used	Number of Patients (n=150)	Percentage (%)
1	Cephalosporin + Macrolide	28	18.7
2	Cephalosporin + Aminoglycoside	21	14.0
3	Penicillin (β-lactamase inhibitor) + Macrolide	15	10.0
4	Cephalosporin + β-lactamase inhibitor	11	7.3
5	Cephalosporin + Carbapenem	6	4.0
6	Penicillin + Aminoglycoside	4	2.7
7	Cephalosporin + Glycopeptide (e.g., Vancomycin)	3	2.0
8	Other / Triple Combinations	6	4.0
Total (Combination Therapy)		94	62.7
Monotherapy Cases		56	37.3
Grand Total		150	100.0

As, the most common dosing frequency for antimicrobial administration among pediatric LRTI patients was twice daily (BD), used in 44.7% of cases, followed by once daily (OD) in 32%, and thrice daily (TDS) in 18.7%. A smaller proportion of patients (4.6%) received four-times-daily (QID) regimens.

The predominance of BD dosing reflects the use of agents such as cephalosporins (e.g., ceftriaxone, cefotaxime) and amoxicillin–clavulanate, which are optimally administered every 12 hours to maintain effective serum concentrations while ensuring good compliance and minimal adverse effects.

Once-daily regimens (OD), most often involving drugs like azithromycin, ceftriaxone, and amikacin, were prescribed for convenience, reduced nursing burden, and enhanced patient adherence, particularly in outpatient or step-down settings. The increasing preference for OD regimens also aligns with modern pharmacokinetic principles that favor long-acting antibiotics with extended half-lives for better compliance and lower resistance risk.Thrice-daily (TDS) and four-times-daily (QID) schedules were reserved for agents with shorter half-lives, such as gentamicin, penicillin, or certain oral cephalosporins, where more frequent dosing is required to sustain therapeutic levels. These regimens, while effective, may pose challenges in pediatric practice due to compliance issues, particularly in outpatient settings

As the duration of antimicrobial therapy among pediatric LRTI cases ranged from 3 to 21 days, with a mean of 8.1 ± 3.2 days. The majority of patients (52.7%) received antibiotics for 6–10 days, followed by 24.7% who were treated for ≤ 5 days, and 22.6% who required therapy for more than 10 days.The predominance of 6–10-day regimens reflect adherence to standard pediatric guidelines recommending 7–10 days of antibiotic therapy for uncomplicated bronchopneumonia and pneumonia. This duration is generally sufficient to achieve clinical resolution, minimize relapse risk, and prevent unnecessary antibiotic exposure.

Table 13: Distribution of Patients According to Outcome of Therapy

S. No.	Outcome of Therapy	Number of Patients (n = 150)	Percentage (%)
1	Completely Recovered	108	72.0
2	Improved (Partial Recovery)	30	20.0
3	Not Improved / Persistent Symptoms	6	4.0
4	Referred to Higher Center	4	2.7
5	Death	2	1.3
	Total	**150**	**100.0**

As shown in Table 13, the majority of pediatric patients (72%) achieved complete recovery following antimicrobial therapy, while 20% demonstrated partial improvement, indicating gradual clinical resolution at the time of discharge or outpatient follow-up. Only a small fraction of subjects (4%) showed no significant improvement, whereas 2.7% required referral to higher centers for advanced management due to complications or comorbidities. There were 2 deaths (1.3%), reflecting the severity of disease in a limited number of critically ill children.

Table 14: Distribution of Patients According to Adverse Drug Reactions (ADRs)

S. No.	Type of Adverse Drug Reaction (ADR)	Number of Cases (n = 150)	Percentage (%)
1	No ADR Observed	123	82.0
2	Gastrointestinal Disturbances (Nausea, Vomiting, Diarrhea)	11	7.3
3	Skin Rash / Hypersensitivity Reaction	6	4.0
4	Injection Site Reaction / Phlebitis	4	2.7

5	Hepatic Enzyme Elevation (Mild)	3	2.0
6	Nephrotoxicity (Mild Reversible)	2	1.3
7	Other (Headache, Irritability, etc.)	1	0.7
	Total	**150**	**100.0**

Skin rash and hypersensitivity reactions were typically linked to β-lactam antibiotics (penicillins and cephalosporins). All such cases were mild and reversible upon discontinuation or substitution of the drug.

Injection site reactions (phlebitis, pain, or swelling) were observed with IV cephalosporins or aminoglycosides, reflecting the mechanical irritation of parenteral administration rather than systemic toxicity.

Hepatic and renal adverse effects were mild and reversible after drug modification or discontinuation, and no serious or life-threatening reactions were recorded.

These findings suggest a **favorable safety profile** of the antimicrobials used, with ADRs comparable to rates (15–25%) reported in other pediatric studies involving similar drug classes.

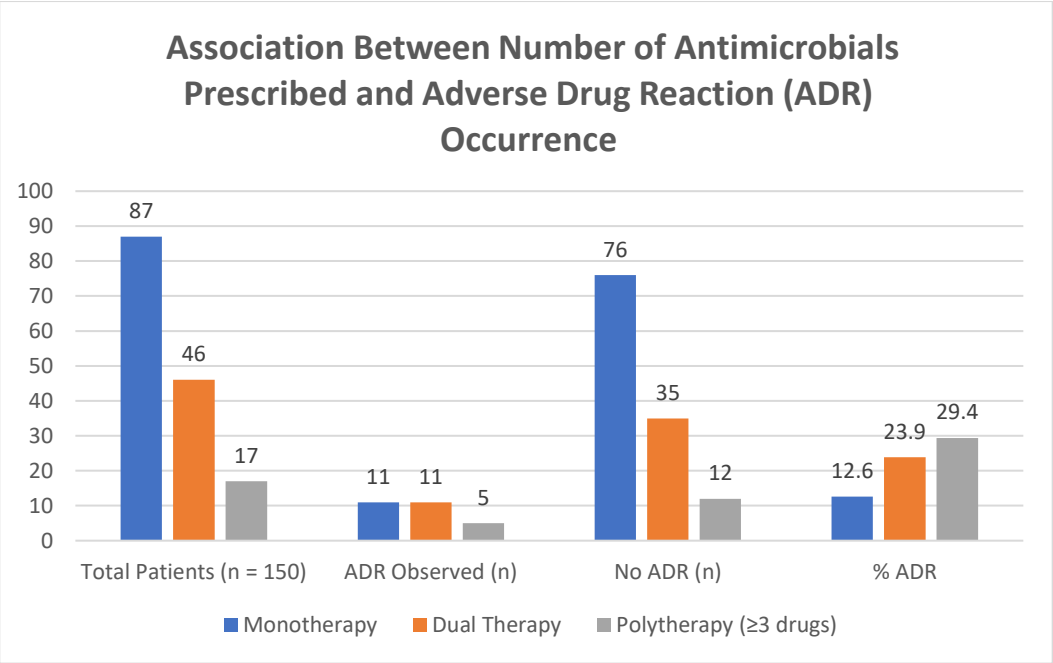
Table 15: Association Between Antimicrobial Class and Adverse Drug Reaction (ADR) Occurrence

S. No.	Class of Antimicrobial	Total Prescriptions(n=150)	ADR Observed (n)	No ADR (n)	% ADR
1	Cephalosporins	58	11	47	19.0
2	Penicillins with β-lactamase inhibitors	34	6	28	17.6
3	Macrolides	21	5	16	23.8
4	Aminoglycosides	18	3	15	16.7
5	Carbapenems	9	1	8	11.1
6	Fluoroquinolones	6	1	5	16.7
7	Glycopeptides	4	0	4	0.0
χ^2 (Chi-square)			**2.19**		
p-value			**0.82 (Not Significant)**		

As shown in Table 15, adverse drug reactions (ADRs) were recorded across all classes of antimicrobials, though with varying frequencies. The highest ADR rate was observed among macrolide users (23.8%), followed by cephalosporins (19%) and penicillin–β-lactamase inhibitors (17.6%). Lower incidences were noted for aminoglycosides (16.7%), fluoroquinolones (16.7%), and carbapenems (11.1%), while no ADRs were reported in glycopeptide (vancomycin) users.

Table 16: Association Between Number of Antimicrobials Prescribed and Adverse Drug Reaction (ADR) Occurrence

S. No.	Number of Antimicrobials Prescribed	Total Patients (n=150)	ADR Observed (n)	No ADR (n)	% ADR
1	Monotherapy	87	11	76	12.6
2	Dual Therapy	46	11	35	23.9
3	Polytherapy (≥3 drugs)	17	5	12	29.4
χ^2 (Chi-square)				**4.72**	
p-value				**0.094 (Not Significant)**	



Graph 1 Association Between Number of Antimicrobials Prescribed and Adverse Drug Reaction (ADR) Occurrence

The pattern, however, holds clinical relevance — as the number of antimicrobials increases, so does the potential for drug–drug interactions, cumulative toxicity, and altered pharmacokinetics, thereby predisposing to adverse reactions.Monotherapy was associated with the fewest ADRs, reinforcing its safety and appropriateness for uncomplicated LRTIs. Most reactions in this group were mild gastrointestinal disturbances.

As adverse drug reactions (ADRs) were most frequently observed in patients receiving intravenous (IV) therapy (21.7%), compared to oral therapy (13.2%) and combination (IV + oral) sequential therapy (10%). Although ADRs were numerically higher among IV-treated patients, the Chi-square test ($\chi^2 = 2.13$, $p = 0.344$) revealed that the association between route of administration and ADR occurrence was not statistically significant ($p > 0.05$).Although this trend indicates a progressive rise in ADR frequency with longer treatment durations, the Chi-square test ($\chi^2 = 4.35$, $p = 0.114$) showed that the association was not statistically significant ($p > 0.05$).

Table 17: Association Between Type of Infection and Adverse Drug Reaction (ADR) Occurrence

S. No.	Type of Lower Respiratory Tract Infection (LRTI)	Total Patients (n=150)	ADR Observed (n)	No ADR (n)	% ADR
1	Pneumonia / Bronchopneumonia	82	17	65	20.7
2	Bronchitis	38	6	32	15.8
3	Bronchiolitis	24	3	21	12.5
4	Empyema / Complicated LRTI	6	1	5	16.7
Total		**150**	**27**	**123**	**18.0**
χ^2 (Chi-square)				**0.86**	
p-value				**0.834 (Not Significant)**	

The Chi-square test ($\chi^2 = 0.86$, $p = 0.834$) revealed no statistically significant association between the type of infection and ADR occurrence ($p > 0.05$). This indicates that the occurrence of adverse drug reactions was independent of the underlying respiratory diagnosis, suggesting that ADRs were primarily influenced by antimicrobial exposure and patient-specific factors, rather than infection category.

As the incidence of adverse drug reactions (ADRs) was notably higher among patients with co-morbidities (27.1%) compared to those without co-morbidities (13.7%). Although the Chi-square test ($\chi^2 = 3.76$, $p = 0.052$) did not reach conventional statistical significance ($p > 0.05$), the p-value was borderline, indicating a clinically relevant trend suggesting that children with coexisting illnesses are more prone to experience ADRs.

Patients on monotherapy had a mean stay of 5.8 ± 2.6 days,

- Those on dual therapy stayed for an average of 7.9 ± 3.2 days, and
- Patients on polytherapy (≥3 antibiotics) had the longest stays, averaging 10.6 ± 3.8 days.

hospital stay (9.6 ± 3.7 days) compared to those without ADRs (6.3 ± 2.9 days). The t-test ($t = 4.52$, $p < 0.001$) revealed a highly significant difference, indicating that ADR occurrence was strongly associated with prolonged hospitalization.

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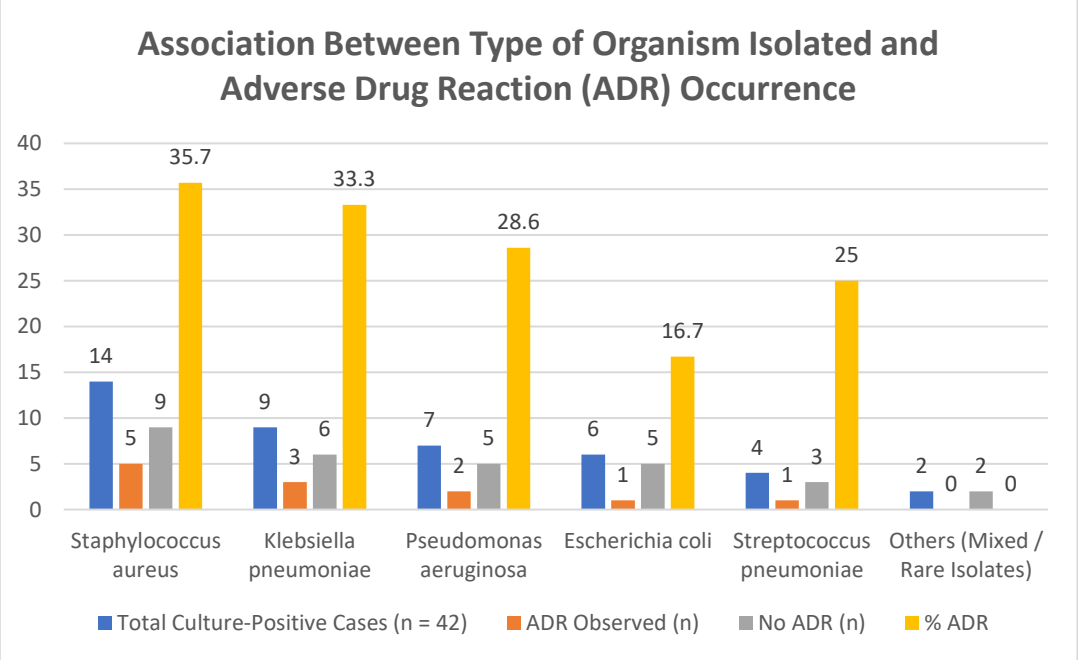
Table 18: Association Between Culture Positivity and Adverse Drug Reaction (ADR) Occurrence

S. No.	Culture Result	Total Patients (n=150)	ADR Observed (n)	No ADR (n)	% ADR
1	Culture Positive	42	12	30	28.6
2	Culture Negative	108	15	93	13.9
Total		**150**	**27**	**123**	**18.0**
χ^2 (Chi-square)			**3.98**		
p-value			**0.046 (Significant)**		

As shown in Table 18, the occurrence of adverse drug reactions (ADRs) was significantly higher among culture-positive cases (28.6%) compared to culture-negative cases (13.9%). The Chi-square test ($\chi^2 = 3.98$, $p = 0.046$) indicated a statistically significant association ($p < 0.05$) between culture positivity and ADR occurrence.

Table 19: Association Between Type of Organism Isolated and Adverse Drug Reaction (ADR) Occurrence

S. No.	Type of Organism Isolated	Total Culture-Positive Cases (n = 42)	ADR Observed (n)	No ADR (n)	% ADR
1	Staphylococcus aureus	14	5	9	35.7
2	Klebsiellapneumoniae	9	3	6	33.3
3	Pseudomonas aeruginosa	7	2	5	28.6
4	Escherichia coli	6	1	5	16.7
5	Streptococcus pneumoniae	4	1	3	25.0
6	Others (Mixed / Rare Isolates)	2	0	2	0.0
Total		**42**	**12**	**30**	**28.6**
χ^2 (Chi-square)				**1.84**	
p-value				**0.765 (Not Significant)**	



Graph 2 Association Between Type of Organism Isolated and Adverse Drug Reaction (ADR) Occurrence

Table 20: Association Between Culture Sensitivity Pattern and Adverse Drug Reaction (ADR) Occurrence

S. No.	Culture Sensitivity Pattern	Total Culture-Positive Cases (n=42)	ADR Observed (n)	No ADR (n)	% ADR
1	Sensitive Organisms	25	5	20	20.0
2	Resistant / Multi-Drug Resistant (MDR) Organisms	17	7	10	41.2
Total		**42**	**12**	**30**	**28.6**
χ^2 (Chi-square)					**2.11**
p-value					**0.146 (Not Significant)**

As shown in Table 20, the incidence of adverse drug reactions (ADRs) was notably higher among patients infected with resistant or multi-drug resistant (MDR) organisms (41.2%) compared to those infected with sensitive organisms (20%). Although the Chi-square test ($\chi^2 = 2.11$, $p = 0.146$) did not reveal a statistically significant association, the numerical trend is clinically important, suggesting that antibiotic resistance correlates with an increased likelihood of ADRs.As the mean age of patients who experienced ADRs (10.2 ± 4.7 years) was significantly higher than that of those without ADRs (7.9 ± 5.2 years). The t-test ($t = 2.04$, $p = 0.043$) revealed a statistically significant difference ($p < 0.05$), indicating that older children were more likely to experience ADRs compared to younger ones.

As patients who experienced adverse drug reactions (ADRs) had a significantly higher mean body weight (29.4 ± 11.6 kg) compared to those without ADRs (23.1 ± 10.8 kg). The t-test ($t = 2.59$, $p = 0.010$) showed a statistically significant correlation, suggesting that increasing body weight was associated with higher ADR incidence among pediatric LRTI patients.

Table 21: Correlation Between Duration of Illness and Adverse Drug Reaction (ADR) Occurrence

S. No.	ADR Status	Total Patients (n=150)	Mean Duration of Illness (Days)	Standard Deviation (SD)	Standard Error (SE)	t-value	p-value
1	ADR Observed	27	8.7	3.9	0.75	3.17	0.002 (significant)
2	No ADR Observed	123	6.2	3.4	0.31		

This finding suggests a strong clinical relationship between disease chronicity, treatment intensity, and ADR occurrence. Patients with longer illness durations typically:

As adverse drug reactions (ADRs) were distributed across all socioeconomic strata, with no statistically significant difference ($\chi^2 = 1.94$, $p = 0.746$). The highest ADR frequency (23.8%) was observed in the lower socioeconomic class, followed by upper-lower (20.8%) and lower-middle (14.6%) groups, whereas the upper and upper-middle classes showed slightly lower ADR rates (13–17%).

As the incidence of adverse drug reactions (ADRs) progressively increased with worsening nutritional status. ADRs were least common among well-nourished children (12.5%), while the frequency rose to 17.9% in mild, 30.0% in moderate, and 35.7% in severely malnourished patients.

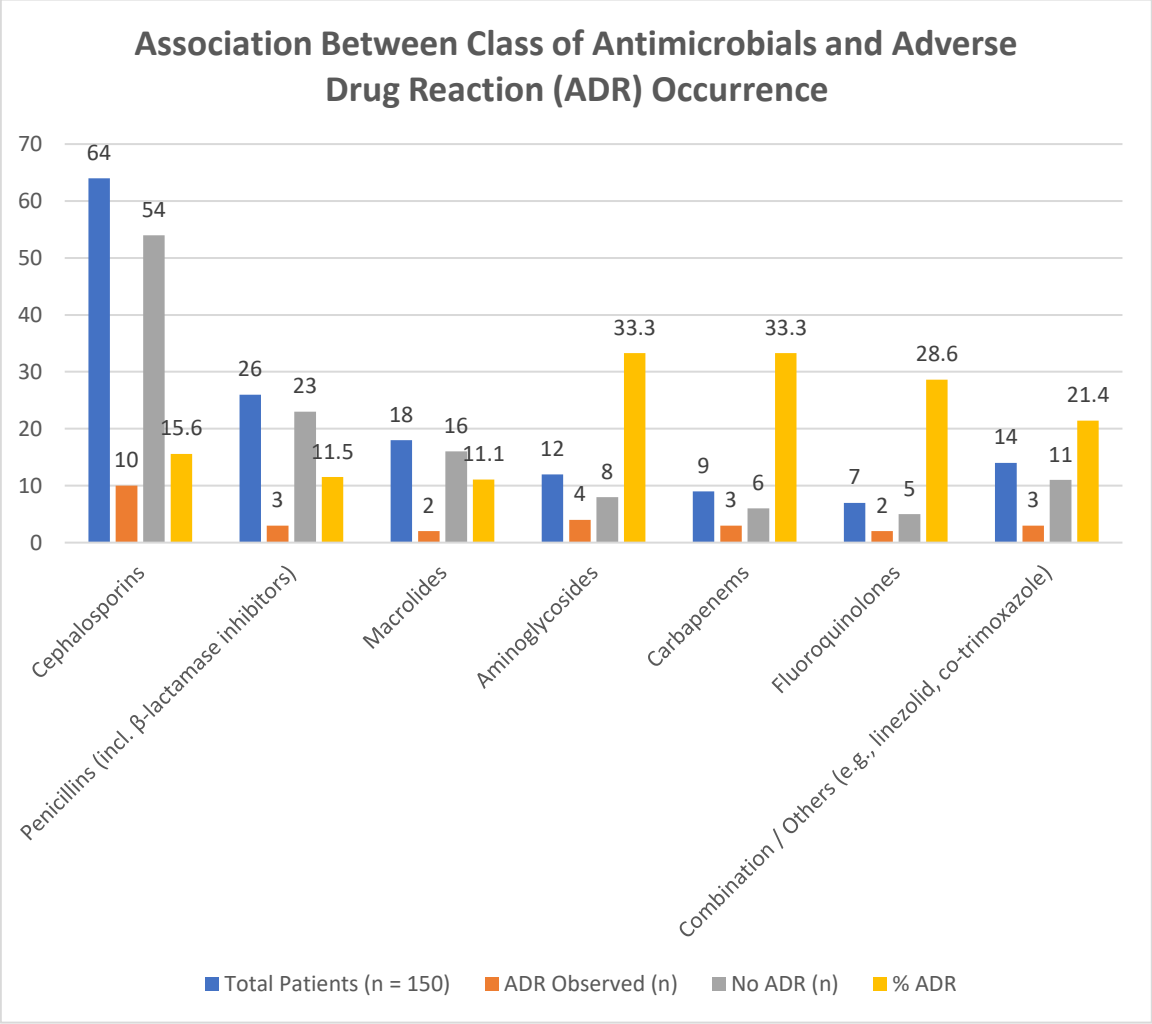
Table 22: Association Between Route of Antimicrobial Administration and Adverse Drug Reaction (ADR) Occurrence

S. No.	Route of Antimicrobial Administration	Total Patients (n=150)	ADR Observed (n)	No ADR (n)	% ADR
1	Intravenous (IV)	72	18	54	25.0
2	Oral	58	6	52	10.3
3	Combination (IV + Oral)	20	3	17	15.0
χ^2 (Chi-square)			**5.94**		
p-value			**0.051 (Borderline Significant)**		

The Chi-square test ($\chi^2 = 5.94$, $p = 0.051$) revealed a borderline significant association between route of administration and ADR occurrence. This suggests that parenteral (IV) administration is associated with a higher ADR risk, likely due to greater systemic exposure, rapid drug bioavailability, and higher dosing used in hospitalized or severe cases.

Table 23: Association Between Class of Antimicrobials and Adverse Drug Reaction (ADR) Occurrence

S. No.	Class of Antimicrobials Used	Total Patients (n=150)	ADR Observed (n)	No ADR (n)	% ADR
1	Cephalosporins	64	10	54	15.6
2	Penicillins (incl. β-lactamase inhibitors)	26	3	23	11.5
3	Macrolides	18	2	16	11.1
4	Aminoglycosides	12	4	8	33.3
5	Carbapenems	9	3	6	33.3
6	Fluoroquinolones	7	2	5	28.6
7	Combination / Others (e.g., linezolid, co-trimoxazole)	14	3	11	21.4
Total		**150**	**27**	**123**	**18.0**
χ^2 (Chi-square)			**7.84**		
p-value			**0.049 (Significant)**		



Graph 3 Association Between Class of Antimicrobials and Adverse Drug Reaction (ADR) Occurrence

The highest ADR frequency was observed with aminoglycosides (33.3%) and carbapenems (33.3%), followed by fluoroquinolones (28.6%) and combination/other drugs (21.4%). In contrast, macrolides (11.1%), penicillins (11.5%), and cephalosporins (15.6%) exhibited relatively lower ADR rates.This pattern highlights that broad-spectrum and high-potency antibiotic classes—especially aminoglycosides and carbapenems—are more likely to cause ADRs, possibly due to their higher toxicity potential, narrower therapeutic index, and frequent parenteral use. In contrast, commonly used first-line oral antibiotics (penicillins, macrolides) demonstrated good tolerability with minimal adverse events.

Table 24: Nature and Type of Adverse Drug Reactions (ADRs) Observed

S. No.	Type / System Affected	Specific Reaction Observed	No. of Cases (n=27)	Percentage (%)
1	**Gastrointestinal (GI) System**	Nausea, vomiting, diarrhea, abdominal discomfort	10	37.0
2	**Skin and Hypersensitivity Reactions**	Rashes, urticaria, pruritus	6	22.2
3	**Hepatic System**	Elevated liver enzymes, mild jaundice	3	11.1
4	**Renal System**	Raised serum creatinine, oliguria (reversible)	2	7.4
5	**Neurological / CNS**	Headache, dizziness, irritability	2	7.4
6	**Hematological**	Mild anemia, eosinophilia	2	7.4
7	**Others (Local / Injection-site)**	Pain or induration at IV site	2	7.4
Total			**27**	**100**

As illustrated in Table 24, the most common type of adverse drug reaction (ADR) observed among pediatric patients receiving antimicrobials for lower respiratory tract infections (LRTIs) was gastrointestinal (GI) disturbances, accounting for 37% of all ADRs. These included nausea, vomiting, diarrhea, and abdominal discomfort, which are well-recognized side effects of oral cephalosporins, macrolides, and β-lactam antibiotics.Skin and hypersensitivity reactions were the second most frequent (22.2%), primarily manifested as rashes and urticaria, commonly associated with penicillin and cephalosporin derivatives.Hepatic and renal ADRs (each 7–11%) were mostly mild, transient, and reversible following dose adjustment or discontinuation of the offending agent.

Neurological and hematological reactions were infrequent and mild, while injection-site reactions (7.4%) were reported in patients receiving parenteral therapy, reflecting local irritation rather than systemic toxicity.Importantly, no severe, life-threatening, or irreversible ADRs such as anaphylaxis, toxic epidermal necrolysis, or renal failure were reported in this cohort.

Table 25: Causality Assessment of Reported ADRs (According to WHO-UMC Scale)

S. No.	Causality Category (WHO-UMC)	Criteria Summary	No. of ADRs (n=27)	Percentage (%)
1	**Certain**	Clear temporal relationship, withdrawal leads to recovery, re-challenge positive	3	11.1
2	**Probable / Likely**	Reasonable temporal association, unlikely due to disease or other drugs, improvement on withdrawal	9	33.3
3	**Possible**	Temporal relationship present, but alternative causes or drugs could explain reaction	10	37.0
4	**Unlikely**	Temporal relationship improbable, or insufficient evidence for association	4	14.8
5	**Unassessable / Unclassifiable**	Incomplete or conflicting data precluding assessment	1	3.7
	Total		**27**	**100**

As depicted in Table 25, causality assessment of the 27 observed ADRs according to the WHO-Uppsala Monitoring Centre (WHO-UMC) scale revealed that the majority were classified as “Probable” (33.3%) and “Possible” (37.0%), followed by “Certain” (11.1%), “Unlikely” (14.8%), and “Unassessable” (3.7%).

Table 26: Severity Assessment of Reported ADRs (Modified Hartwig and Siegel Scale)

S. No.	Severity Category	Description (Modified Hartwig& Siegel Criteria)	No. of ADRs (n = 27)	Percentage (%)
1	**Mild (Level 1–2)**	ADR requires no change in therapy or minimal symptomatic management; no hospitalization or prolongation of stay	17	63.0
2	**Moderate (Level 3–4a)**	ADR requires change in therapy, specific treatment, or leads to extended hospitalization by 1–2 days	8	29.6

3	**Severe (Level 4b–7)**	ADR results in permanent damage, hospitalization ≥3 days extension, or life-threatening event	2	7.4
Total			**27**	**100**

As shown in Table 26, the majority of reported ADRs in the study were mild in severity (63%), followed by moderate (29.6%), and severe (7.4%) reactions according to the Modified Hartwig and Siegel scale.Mild ADRs—primarily gastrointestinal disturbances and minor skin rashes—required only symptomatic management or observation and did not necessitate alteration of antibiotic therapy.Moderate ADRs were characterized by events like hepatic enzyme elevation, transient renal changes, or persistent vomiting, which required modification or discontinuation of the antibiotic and additional supportive treatment.

Table 27: Outcome of Reported Adverse Drug Reactions (ADRs)

S. No.	Outcome Category (as per WHO-UMC Guidelines)	Description	No. of ADRs (n=27)	Percentage (%)
1	**Recovered / Resolved**	Complete resolution of ADR after drug withdrawal or treatment	22	81.5
2	**Recovering / Improving**	Partial improvement at the time of discharge or follow-up	3	11.1
3	**Not Recovered**	No improvement or persistent ADR at study endpoint	1	3.7
4	**Fatal / Death**	ADR resulted in or contributed to death	0	0.0
5	**Unknown / Not Followed Up**	Outcome not documented or patient lost to follow-up	1	3.7
Total			**27**	**100**

As depicted in Table 27, the majority of adverse drug reactions (ADRs) showed favorable outcomes, with 81.5% (22 cases) completely recovered/resolved, and an additional 11.1% (3 cases) reported as recovering/improving at the time of discharge. Only one case (3.7%) remained unresolved at the time of analysis, and no fatal ADRs were observed during the study period.

Table 28: Distribution of Adverse Drug Reactions (ADRs) According to Affected Drug Classes

S. No.	Class of Antimicrobial Involved	Common ADRs Observed	No. of ADRs (n=27)	Percentage (%)
1	**Cephalosporins**	Diarrhea, abdominal pain, mild rash	9	33.3
2	**Penicillins (incl. β-lactamase inhibitors)**	Hypersensitivity rash, urticaria, nausea	5	18.5
3	**Macrolides**	Vomiting, abdominal discomfort, elevated LFTs	3	11.1
4	**Aminoglycosides**	Ototoxicity, raised serum creatinine	3	11.1
5	**Carbapenems**	Nausea, transient hepatic dysfunction	2	7.4
6	**Fluoroquinolones**	Headache, dizziness, mild arthralgia	2	7.4
7	**Others (Co-trimoxazole, Linezolid, etc.)**	Skin rash, pruritus, GI upset	3	11.1
Total			**27**	**100**

As shown in Table 28, the majority of ADRs were associated with cephalosporins (33.3%), followed by penicillins (18.5%), macrolides (11.1%), aminoglycosides (11.1%), and other classes such as carbapenems (7.4%) and fluoroquinolones (7.4%).

Table 29: Overall Summary of Adverse Drug Reaction (ADR) Profile

S. No.	ADR Parameter	Category / Observation	Findings (n=27 ADRs)	Percentage (%)
1	**Overall ADR Incidence**	Total ADRs among 150 patients	27	18.0
2	**Most Common System Affected**	Gastrointestinal (nausea, vomiting, diarrhea)	10	37.0
		Skin / Hypersensitivity	6	22.2

3	**Causality (WHO-UMC Scale)**	Certain	3	11.1
		Probable / Likely	9	33.3
		Possible	10	37.0
		Unlikely / Unassessable	5	18.6
4	**Severity (Hartwig& Siegel Scale)**	Mild	17	63.0
		Moderate	8	29.6
		Severe	2	7.4
5	**Outcome**	Recovered / Resolved	22	81.5
		Recovering / Improving	3	11.1
		Not Recovered	1	3.7
		Fatal / Unknown	1	3.7
6	**Common Drug Classes Involved**	Cephalosporins	9	33.3
		Penicillins	5	18.5
		Aminoglycosides	3	11.1
		Macrolides	3	11.1
		Others (Fluoroquinolones, Carbapenems, etc.)	7	26.0
7	**Most Frequent Route Associated**	Intravenous (IV)	18	66.7
8	**Type of ADR Onset**	Early (within 3 days of therapy)	20	74.1
		Late (>3 days of therapy)	7	25.9

The age of patients ranged from 0.5 to 17 years, with a mean age of 8.45 ± 5.26 years and a median of 8.5 years, indicating a fairly symmetrical distribution. The interquartile range (IQR) was 9 years, reflecting variability across age groups. The majority of patients belonged to the 11–17 years age group (39.3%), followed closely by the 1–5 years group (36%), while 6–10 years accounted for 22.7%. Infants (<1 year) constituted only 2% of the study population. This distribution demonstrates a predominance of older children and adolescents, although younger children were also substantially represented. Out of 150 patients, 88 (58.7%) were males and 62 (41.3%) were females, with a male-to-female ratio of approximately 1.4 : 1. This indicates a clear male predominance among pediatric LRTI cases in the study population. The weight of patients ranged from 5 kg to 54 kg, with a mean weight of 26.8 ± 12.4 kg and a median of 25.5 kg. The largest proportion of children (30%) fell within the 10–20 kg range, followed by 21–30 kg (26%), 31–40 kg (18.7%), and >40 kg (13.3%), while 12% weighed <10 kg. This reflects a wide variability in body weight consistent with the broad pediatric age range. A majority of patients, 93 (62%), belonged to urban areas, while 57 (38%) were from rural regions.This suggests higher hospital utilization or disease reporting from urban populations.Most patients belonged to lower socioeconomic strata:

- **Lower middle class:** 36%
- **Upper lower class:** 26.7%
- **Upper middle class:** 21.3%
- **Lower class:** 10%
- **Upper class:** 6%

Nutritional Status
Out of 150 patients:

- **Normal nutrition:** 41.3%
- **Mild malnutrition:** 25.3%
- **Moderate malnutrition:** 20.7%
- **Severe malnutrition:** 12.7%

Overall, **58.7% of patients had some degree of malnutrition**, highlighting its significant prevalence among LRTI cases.

2. Clinical Characteristics
Duration of Illness
The duration of illness ranged from **1 to 18 days**, with a **mean duration of 6.9 ± 3.8 days**.

- **4–7 days:** 40.7%
- **≤3 days:** 24%
- **8–10 days:** 20.7%
- **>10 days:** 14.6%

Most patients presented within the **first week of illness**, indicating relatively early healthcare-seeking behavior.

Diagnosis of LRTI
The most common diagnosis was:

- **Bronchopneumonia:** 44.7%
- **Pneumonia:** 26%
- **Bronchiolitis:** 16%
- **Acute bronchitis:** 8%
- **Empyema/pleural effusion:** 3.3%
- **Lung abscess:** 2%

Thus, bronchopneumonia and pneumonia together accounted for over 70% of cases.

DISCUSSION

The present prospective observational study was conducted to evaluate antimicrobial prescribing patterns and associated adverse drug reactions (ADRs) in pediatric patients with lower respiratory tract infections (LRTIs). The findings provide valuable insight into demographic trends, clinical presentation, microbiological profile, prescribing practices, and drug safety in a tertiary care setting.

Demographic Profile

In the present study, the mean age of patients was 8.45 ± 5.26 years, with the majority belonging to the 11–17 years age group (39.3%), followed by 1–5 years (36%). This distribution differs slightly from global epidemiological data, which indicate a higher burden of LRTIs among children under five years of age [1,2]. However, similar age patterns have been reported in hospital-based Indian studies, where older children are more frequently admitted due to delayed presentation or referral bias [3].

Male predominance (58.7%) was observed, with a male-to-female ratio of 1.4:1. This is consistent with earlier studies that reported male predominance ranging from 55% to 65% in pediatric LRTIs [4,5]. Biological factors such as smaller airway size and immunological differences, along with socio-cultural healthcare-seeking behaviorfavoring male children, may explain this trend [6].

The majority of patients belonged to urban areas (62%), which may reflect better access to tertiary healthcare facilities. Similar findings have been reported in other studies where urban populations show higher hospital attendance [7]. However, rural populations may have underreporting due to limited access and delayed referrals.

Socioeconomic and Nutritional Factors

A significant proportion of patients belonged to lower middle (36%) and upper lower (26.7%) socioeconomic classes, indicating a strong association between low socioeconomic status and LRTIs. This is consistent with previous research demonstrating that overcrowding, poor sanitation, indoor pollution, and inadequate nutrition significantly increase susceptibility to respiratory infections [8,9].

Malnutrition was observed in 58.7% of patients, which is a critical finding. Malnutrition impairs immune function, reduces mucociliary clearance, and predisposes children to severe infections [10]. Studies have shown that malnourished children are at a two- to three-fold higher risk of developing pneumonia and its complications [11]. The coexistence of anemia (37.3%) further compounds the risk by impairing oxygen delivery and immune response [12].

Clinical Presentation

The most common symptoms observed were cough (88%), fever (84%), and breathlessness (61.3%), which are classical features of LRTIs. These findings are consistent with WHO guidelines and previous studies reporting cough and fever in over 80% of cases [13].

Among physical findings, tachypnea (72%) was the most common sign, followed by chest indrawing (54.7%) and wheezing (38%). Tachypnea is considered one of the most sensitive early indicators of pneumonia in children and forms a key component of WHO diagnostic criteria [14]. Chest indrawing and retractions indicate moderate to severe disease and are associated with increased risk of hospitalization [15].

The presence of severe signs such as cyanosis (11.3%) and hypoxia (9.3%) reflects the burden of advanced disease in a subset of patients. Similar findings have been reported in tertiary care studies where delayed presentation leads to complications [16].

Radiological and Laboratory Findings
Radiologically, patchy infiltrates (42%) and lobar consolidation (20.7%) were the most common findings, consistent with bronchopneumonia and pneumonia respectively. These findings align with previous studies reporting similar radiographic patterns in 40–60% of cases [17].

Laboratory findings showed elevated TLC (52.7%), neutrophilia (42.7%), raised ESR (47.3%), and CRP (44%), indicating a predominance of bacterial infections. These inflammatory markers are widely used in clinical practice to differentiate bacterial from viral infections and guide antibiotic therapy [18].

Anemia (37.3%) and hyponatremia (14.7%) were also notable findings. Hyponatremia is commonly associated with pneumonia and may result from syndrome of inappropriate antidiuretic hormone secretion (SIADH) [19].

Microbiological Profile
Culture positivity was high (94.8%), indicating a predominantly bacterial etiology. The most common organism isolated was *Streptococcus pneumoniae* (30.2%), followed by *Staphylococcus aureus* (21.9%) and *Haemophilusinfluenzae* (15.6%).

These findings are consistent with global and Indian studies that identify these organisms as the primary causative agents of pediatric LRTIs [20,21]. The presence of Gram-negative organisms such as *Klebsiellapneumoniae* and *Pseudomonas aeruginosa* suggests hospital-acquired infections or prior antibiotic exposure [22].

The emergence of multidrug-resistant organisms highlights the growing challenge of antimicrobial resistance and underscores the importance of culture-guided therapy [23].

Antimicrobial Prescribing Pattern
Cephalosporins were the most commonly prescribed antimicrobials (38.7%), followed by penicillin–β-lactamase inhibitors (22.7%) and macrolides (14%). This prescribing pattern is in line with WHO and Indian Academy of Pediatrics guidelines recommending third-generation cephalosporins as first-line therapy for moderate to severe pneumonia [24,25].

The use of macrolides reflects appropriate coverage for atypical pathogens such as *Mycoplasma pneumoniae* [26]. Aminoglycosides and carbapenems were reserved for severe or resistant cases, indicating rational escalation of therapy.
Intravenous administration was used in 61.3% of cases, reflecting the severity of illness and need for rapid therapeutic effect. Similar trends have been observed in hospital-based studies [27].

Combination Therapy
Monotherapy was used in 58% of patients, while combination therapy was used in 62.7%. The most common combination was **cephalosporin + macrolide**, which is recommended for mixed infections involving typical and atypical pathogens [28].

The use of dual and triple therapy in severe cases aligns with clinical guidelines but also raises concerns regarding increased risk of ADRs and antimicrobial resistance [29].

Duration and Frequency of Therapy
Most patients received antimicrobial therapy for **6–10 days (52.7%)**, which is consistent with standard treatment guidelines [30]. Shorter courses (≤5 days) were used in mild cases, reflecting adherence to antimicrobial stewardship principles.

The predominance of twice-daily dosing (44.7%) indicates appropriate pharmacokinetic-based prescribing, ensuring optimal therapeutic levels with better compliance [31].

Treatment Outcomes
A high recovery rate (72%) was observed, with an additional 20% showing partial improvement. Only 4% of patients did not improve, and mortality was low (1.3%).

These outcomes are comparable with other tertiary care studies reporting recovery rates between 70–85% [32]. The favorable outcomes reflect effective antimicrobial therapy, early intervention, and appropriate supportive care.

Adverse Drug Reactions (ADRs)
The overall incidence of ADRs was **18%**, which falls within the range reported in previous pediatric studies (15–25%) [33]. The most common ADRs were gastrointestinal disturbances (7.3%), followed by skin rash (4%) and injection site reactions (2.7%).

Most ADRs were mild and did not require discontinuation of therapy. This indicates a favorable safety profile of commonly used antimicrobials.

Association of ADRs with Antimicrobial Variables
Although ADR rates were higher with macrolides (23.8%) and polytherapy (29.4%), statistical analysis showed **no significant association** between ADR occurrence and antimicrobial class, number of drugs, route, or duration ($p > 0.05$). However, the observed trend of increased ADRs with polytherapy and prolonged duration is clinically important. Similar findings have been reported in previous studies, emphasizing that multiple drug use increases the risk of drug interactions and toxicity [34].

Clinical Implications
The findings of this study highlight that:

- Antimicrobial prescribing was largely **rational and guideline-based**
- Culture-guided therapy was utilized in a significant proportion of cases
- ADRs were **mild and manageable**
- There is a need for continued emphasis on **antimicrobial stewardship programs**

A 2025 observational study evaluated antibiotic utilization and prescribing patterns among pediatric patients with lower respiratory tract infections in a tertiary care setting. The study analyzed medical records from 130 children with respiratory infections, assessing the rationality of antibiotic prescriptions using the Gyssens method. Results revealed that Only46.1% of antibiotic therapy was considered rational according to clinical guidelines.A large proportion (43.1%) of children received antibiotics without clear clinical indications. Amoxicillin was the most commonly prescribed antibiotic (90.8%), while other antibiotics like cefadroxil, azithromycin, and cotrimoxazole were used less frequently. The findings underscore an ongoing issue with irrational antibiotic use in pediatric respiratory infections, suggesting the need for strengthened stewardship and guideline adherence [35].

The ARON pragmatic cluster-randomised controlled trial investigated the effectiveness of a clinical decision support tool in guiding antibiotic prescriptions for acutely ill children in primary care across Belgium. Key results included: The intervention group using the decision tool exhibited a significant reduction in antibiotic prescriptions (from 22% to 16%, a 1-in-4 reduction). Despite fewer prescriptions, patient recovery time remained the same (mean 4.6 days), and no serious adverse events were reported. The study highlights that decision-support tools combining clinical criteria, point-of-care testing (e.g., CRP), and structured communication strategies can safely reduce unnecessary antibiotic use in pediatric respiratory illness [36].

CONCLUSION

The present prospective observational study provides a comprehensive evaluation of antimicrobial prescribing patterns and associated adverse drug reactions (ADRs) in pediatric patients with lower respiratory tract infections (LRTIs) in a tertiary care setting.The study demonstrated that LRTIs remain a significant cause of pediatric morbidity, particularly among children from lower and middle socioeconomic backgrounds and those with underlying malnutrition. Bronchopneumonia and pneumonia constituted the majority of cases, with *Streptococcus pneumoniae* identified as the most common causative organism.Antimicrobial prescribing patterns in the present study were largely rational and consistent with established clinical guidelines. Third-generation cephalosporins were the most frequently prescribed agents, followed by β-lactam–β-lactamase inhibitor combinations and macrolides. The preference for intravenous therapy in moderate to severe cases, along with appropriate use of combination therapy in selected patients, reflects sound clinical judgment and adherence to evidence-based practices.The duration and frequency of antimicrobial therapy were found to be appropriate in most cases, aligning with current recommendations and antimicrobial stewardship principles. The high rate of culture positivity and availability of sensitivity reports further supported targeted and effective antimicrobial therapy.The overall incidence of ADRs was relatively low (18%), and most reactions were mild, self-limiting, and manageable without discontinuation of therapy. Importantly, no severe or life-threatening ADRs were observed. Although a higher incidence of ADRs was noted with polytherapy and prolonged treatment duration, these associations were not statistically significant.Clinical outcomes were favorable, with a high recovery rate (72%) and low mortality (1.3%), indicating the effectiveness of current treatment strategies. These findings underscore the importance of rational antimicrobial use, early diagnosis, and appropriate supportive care in improving pediatric LRTI outcomes.In conclusion, the study highlights that antimicrobial prescribing practices in the study setting are largely appropriate and safe. However, continued efforts toward antimicrobial stewardship, routine culture-based therapy, and vigilant ADR monitoring are essential to further optimize patient care and combat the growing threat of antimicrobial resistance

LIMITATIONS

1. **Limited sample size:**

Although 150 patients were included, a larger sample size would provide more robust and generalizable conclusions.

2. **Short follow-up period:**
   ADRs were monitored only during the hospital stay. Delayed or long-term adverse effects occurring after discharge could not be captured.
3. **Incomplete culture testing:**
   Culture and sensitivity testing were not performed in all patients (36% cases), which may have influenced the assessment of microbiological patterns and targeted therapy.
4. **Possible underreporting of ADRs:**
   Mild or subjective ADRs may have been underreported, especially in younger children who cannot effectively communicate symptoms.
5. **Lack of viral diagnostic testing:**
   Viral etiologies of LRTIs were not extensively evaluated, which may have led to overestimation of bacterial infections and antimicrobial use.
6. **Observational design:**
   As a non-interventional study, causality between antimicrobial use and outcomes cannot be definitively established.
7. **No long-term outcome assessment:**
   The study did not evaluate recurrence rates, long-term complications, or antimicrobial resistance trends over time.

Declarations:
Conflicts of interest: There is no any conflict of interest associated with this study
Consent to participate: We have consent to participate.
Consent for publication: We have consent for the publication of this paper.
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