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Prescribing Patterns and Causality Assessment of Adverse Drug Reactions in Pediatric Inpatients with Respiratory Tract Infections: A Prospective Observational Study at A Tertiary Care Hospital

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Abstract

Objective: Respiratory tract infections (RTIs) are one of the leading causes of pediatric hospitalization globally and pose a significant risk of inappropriate prescribing and adverse drug reactions (ADRs). The purpose of this study was to evaluate the patterns of prescribing medications for pediatric patients with RTIs, measure the incidence and causation of ADRs, and determine clinical predictors of prolonged hospital stay in patients with RTIs who were hospitalized.

Methods: This was a prospective observational study that took place over six months at the Pediatrics Department at Tertiary care Hospital located in Rajajinagar, Bangalore, India. One hundred twenty-six pediatric patients between three months to 18 years of age, diagnosed with RTIs who were admitted to the hospital for inpatient treatment, were enrolled in the study. All data were collected on a pre-structured form. The severity of the patients' RTI was determined using the Pediatric Respiratory Severity Score (PRESS). To determine how frequently prescriptions were filled correctly per WHO's core prescribing indicators, the pattern of prescribing medications to these patients was also evaluated. ADRs were collected and evaluated using the Naranjo Criteria for Evaluation of ADRs. Participants were followed throughout their hospital admission until discharge; post-discharge follow-up was not performed. All statistical analyses were conducted using Chi-square, Mann-Whitney U, Kruskal-Wallis, Spearman's correlation coefficient, and logistic regression models.

Results: Upper respiratory tract infections (URTIs) were more frequent than lower respiratory tract infections (LRTIs) (65.08% vs 34.92%), with pharyngitis being the most frequently seen URTI (43.05%). In contrast, pneumonia was the most common LRTI (14.55%). The majority (53.71%) of respiratory tract infection (RTI) infections that occurred were mild in nature, while a severe infection had a statistically significant risk ($p = 0.005$) of 14.40 more odds of prolonged hospitalisation (11.11%).

A total of 691 medications were given per patient (6.85 ± 2.47 on average); antibiotics were given for 63.49% of the patient contacts, whereas injectable products were prescribed 88.09% of the time. Generic medicine was very common (86.22%). 10.32% of patients had an ADR associated with their treatment,

out of those, 30.77% of patients had a neurological type of ADR, 23.07% had a cutaneous type of ADR, and in each case, antibiotics were responsible for 46.15% of the ADR cases. Additionally, patients less than 6 years old had increased odds ($p = 0.025$) of receiving multiple antibiotics than those older than 6 years old. Disease severity and the type of RTI were the major predictive factors for corticosteroid & bronchodilator use.

Conclusion: RTI prescribing practices in the pediatric inpatient setting are primarily influenced by the severity of disease and type of RTI, as compared to the patient demographic characteristics. The findings of high levels of antibiotic and injectable medication usage; polypharmacy; and a high incidence of ADRs in this population suggest that there is an immediate need for evidence-based prescribing, antimicrobial stewardship, and formalized pharmacovigilance in pediatric inpatient settings.

Keywords: Respiratory tract infections; pediatric inpatients; prescribing patterns; adverse drug reactions; Naranjo scale; WHO prescribing indicators; antimicrobial stewardship; PRESS score.

1. Introduction

The respiratory infections are one of the leading causes of illness, hospitalization, and death among children, particularly among children less than 5 years of age (1). It has been estimated that there are approximately 120 million new cases of acute respiratory infections (ARI) among children [WHO, 1999] every year, leading to approximately 1.3 million deaths (2). The burden in India is worsened by malnutrition, crowded housing, low socioeconomic conditions, and pollutants, which increase the risk of developing ARI among children living in India (3).

Upper respiratory tract infections (URI) are generally divided into two groups: upper respiratory tract infections (URTIs) consisting of rhinitis, sinusitis, pharyngitis, tonsillitis, otitis media, laryngotracheitis; and lower respiratory tract infections (LRTIs) consisting of bronchitis, bronchiolitis, and pneumonia (4). In general, the majority of URTI's resolve without need for treatment and are viral infections, while the majority of LRTI's (especially pneumonia) can result in severe morbidity and generally require a long period of inpatient care. The clinical symptoms associated with viral and bacterial infections overlap to the extent that physicians often prescribe antibiotics based only on empirical evidence, which contributes to the development of resistant bacteria and exposes the patient to potentially unnecessary toxicities associated with drugs (5).

Prescribing medications to children is often difficult due to the complexity of the pediatric population. There are differences in how children metabolize (drug pharmacokinetics) and respond to (drug pharmacodynamics) medications as a function of age, there are limited pediatric formulations that have been studied and proven safe in pediatric patients, and there is limited clinical trial data available for pediatric patients using most medications. As a result, physicians often use their own experience or the results of studies in adult patients to determine the dosage of the medicine. The use of these alternative methods increases the risk of polypharmacy, inappropriate dosing, and ADRs for children. Because ADRs in children may frequently go unnoticed or misdiagnosed as being caused by the underlying disease, adequate pharmacovigilance becomes critical.

The World Health Organization (WHO) has developed indicators that can be used to measure the rationality of prescribing practices at the facility level. Examples include the average number of medications prescribed per encounter, the percentage of medications prescribed by the generic name, the percentage of antibiotics prescribed, the percentage of injectable medications prescribed, and adherence

to the essential medicines list developed by the WHO. These indicators serve as an important benchmark for measuring the quality of prescribing practices. In addition, the use of formal tools to measure ADR causality, such as the Naranjo Probability Scale, provides a way to perform a complete safety assessment of the medication(s) being provided to children.

Although pediatric RTIs have a known global burden, little data analysing both prescribing rationality and ADR profiles from Indian tertiary care facilities is known as well as limited data regarding geographical variation. Therefore, the present study was designed to document the prescribing practices, estimate rates of ADRs, perform causality assessment related to ADRs, and identify clinical variables associated with increased length of stay for pediatric patients who have been admitted for RTI treatment at a tertiary care facility in Bengaluru, India.

2. Methods

2.1 Study Design and Setting

The study was carried out as a prospective observational study over a 6-month period from April to September 2020, following a 1-month planning phase. The research was an observational study and took place on the Pediatric Inpatient Ward of Tertiary care Hospital, Rajajinagar, Bangalore, Karnataka, India.

2.2 Ethics

In accordance with the Guidelines for the Protection of Human Subjects of Research of the Institutional Ethics Committee of Acharya & BM Reddy College of Pharmacy, the assessment of the current research was approved by Rajiv Gandhi University of Health Sciences (RGUHS). Informed consent was obtained from the family or legal guardian (ie, mother or father) of every child participants before they could participate in research. Participation in research was completely optional, while, as part of the research protocol, all information regarding the patient will be de-identified.

2.3 Study Population and Eligibility Criteria

Children (3 months to 18 years) admissions to the pediatric ward would be considered for inclusion. In addition to inclusion in the current research, other considerations will include: Children with previous chronic lung conditions (i.e. asthma, COPD, cystic fibrosis, chronic inflammatory lung disease, etc.); children immunocompromised through HIV/AIDS will have pre-existing issues and/or will have issues related to the ongoing use of immunosuppressive medications; Children having an allergic reaction to a specific medication will be excluded from the study.

2.4 Sample Size

The sample size was determined by using $N = Z^2 \times P(1 - P) / m$, which calculates the number of patients needed based on current data regarding the estimated prevalence of pediatric RTI found in many RTIs published previously. The minimum sample size needed was calculated to be 126; therefore, all eligible patients throughout the entire period of the study were included consecutively.

2.5 Data Collection

To collect data from each patient, a structured proforma designed by the authors was used to capture the following data: the patient's demographics (age, sex, weight), the patient's admission diagnosis, any pertinent medical history of the patient, the patient's vital signs at the time of admission, the patient's clinical examination findings, laboratory testing results, the prescribed medications to the patient (the name of the drug, dosage, route of administration, frequency and duration of use as stated in the discharge summary), and any ADR identified at some point during the patient's hospital admission and/or in the

doctor's discharge summary. The attending pediatrician's management or treatment of each patient was observed without the authors modifying the management/treatment plan.

2.6 Assessment Tools

Severity of RTI – All patients have had the Pediatric Respiratory Severity Score (PRSS) completed at the time of admission. The score evaluates five different clinical parameters: 1) the rate of respiration (tachypnoea) using age-specific threshold values, wheeze on auscultation; 3) utilization of accessory muscles during rest/breathing; 4) peripheral oxygen saturation level (at least ≤ 95% while breathing room air); and 5) feeding difficulties. Each parameter is scored either 0 or 1 (depending on whether or not the parameter exists). The total score can range from 0 – 5. A total score between 0 and 1 is classified as mild disease; between 2 and 3 is classified as moderate disease; and between 4 and 5 is classified as severe disease.8

Medication use, as reflected in prescribing indicators from the World Health Organization (WHO), was evaluated on an aggregate basis using 5 summarised prescribing indicators: 1) mean number of medications prescribed per patient, 2) proportion of medications prescribed by their generic names, 3) proportion of encounters in which antibiotics were prescribed, 4) proportion of encounters in which injectable medications were prescribed, and 5) proportion of medications prescribed from the list of essential medications maintained by WHO 7.

Suspected adverse drug reactions (ADRs) associated with any medications prescribed were assessed for causality using the Naranjo Adverse Drug Reaction Probability Scale, which is a 10-question form that is scored; scores are categorised as follows: ≥9 = definite; 5-8 = probable; 1-4 = possible; ≤0 = doubtful. Appropriate Naranjo scales were then scored individually per medication when suspected of causing adverse effects. 9

2.7 Statistical Analysis

Data were collected, recorded in Excel (Version 2016), and were evaluated using SPSS (Version 25.0). Categorical variables were described as frequencies and percentages whereas continuous variables were expressed as means ± standard deviation. Chi-square analysis was performed to test for associations between categorical variables. The Mann-Whitney U and Kruskal-Wallis tests were used to test for differences between continuous variables. Spearman's rank correlation was used to assess for associations between two continuous variables. Logistic regression was conducted to identify independent predictors of an extended length of hospital stay (defined as a length of stay equal to or greater than four days), use of corticosteroids, use of bronchodilators, use of fixed dose combination (FDC) medication, and number of antibiotics prescribed. Odds ratios (ORs) with 95% confidence intervals (CIs) were reported. Variables showing statistically significant associations in bivariate analyses were considered for inclusion in the multivariable model. Statistical significance was established as $p < 0.05$. There were no missing data for the variables included in the analysis. No formal interaction analyses or sensitivity analyses were performed.

3. Results

3.1 Demographic Profile

A combined total of 126 pediatric inpatients with RTI, resulted in an equal number of each sex; 71 (56.35%) being female and 55 (43.65%) being male. Ages among the included subjects (3 months - 18 years) were distributed as follows by age group: highest proportion was children ages 7 - 12 years (37

patients, 29.37%) followed by children ages 4 - 6 years (29.01%) and low numbers of children ages <12 months (14 patients, 11.11%) were included.

Table 1. Distribution of Study Population by Gender and Age Group

Category	Male n (%)	Female n (%)	Total n (%)
Infants (<12 months)	7 (5.56)	7 (5.56)	14 (11.11)
Toddlers (1–3 years)	12 (9.52)	6 (4.76)	18 (14.29)
Pre-school (4–6 years)	11 (8.73)	18 (14.29)	29 (23.01)
School-aged (7–12 years)	14 (11.11)	23 (18.25)	37 (29.37)
Adolescence (13–18 years)	11 (8.73)	17 (13.49)	28 (22.22)
Total	55 (43.65)	71 (56.35)	126 (100)

3.2 Type and Distribution of Respiratory Tract Infections

Upper respiratory tract infections (82 patients, 65.08%) were more common than lower respiratory tract infections (44 patients, 34.92%). Among the upper respiratory tract infections, the most often diagnosed disease was pharyngitis (27 patients, 21.4%), followed by viral fever (17 patients, 13.5%) and tonsillitis (13 patients, 10.3%). Among the lower respiratory tract infections, pneumonia (14 patients, 11.1%) was the most frequently diagnosed disease, while bronchitis and bronchiolitis each accounted for 13 patients (10.3%). School-age children had the highest incidence of URTIs (22.22%) and the highest burden of LRTIs were among infants (7.94%).

3.3 Severity Assessment Using PRESS Score

The majority of the children with respiratory tract infections (67 patients, 53.71%) presented with mild disease, while 45 patients (35.71%) presented with moderate disease, and 14 patients (11.11%) had severe disease. The highest proportion of children with severe disease was seen in the school aged group (3.18%). Signs that were present predominantly in children with bronchitis/bronchiolitis included tachypnoea (44.44%) and wheezing (46.30%), while accessory muscle use was the most commonly used sign identified in a child with pneumonia (56.00%). The presence of decreased SpO_2 levels was uncommon in children with an upper respiratory tract infection, but the presence of < 90% SpO_2 occurred in 46.15% of children with pneumonia. Difficulties with feeding were most often found in association with the diagnosis of pharyngitis (29.03%).

Table 2. Distribution of Study Population by RTI Severity and Age Group

Age Group	Mild n (%)	Moderate n (%)	Severe n (%)	Total n (%)
Infants	6 (4.76)	5 (3.97)	3 (2.38)	14 (11.11)
Toddlers	9 (7.14)	7 (5.56)	2 (1.59)	18 (14.29)
Pre-school	16 (12.70)	11 (8.73)	2 (1.59)	29 (23.02)
School-aged	21 (16.67)	12 (9.52)	4 (3.18)	37 (29.36)
Adolescence	15 (11.90)	10 (7.94)	3 (2.38)	28 (22.22)
Total	67 (53.17)	45 (35.71)	14 (11.11)	126 (100)

3.4 Prescribing Pattern

The physicians gave a total of 691 drugs to 126 patients. This means each patient got 6.85 drugs on average. Most of these drugs 416 to be exact were given to patients who had Upper Respiratory Tract Infections, which's about 60 % of all the drugs prescribed. The mostly prescribed drugs were antipyretics. They prescribed 116 of these drugs, which is about 16.79 % of all the drugs. The next prescribed drugs were antibiotics with 92 prescriptions, which is about 13.31 %. Then there were gastro-intestinal agents, with 76 prescriptions, which is about 11 %. The doctors also prescribed a lot of mucolytics and antihistamines with 65 and 61 prescriptions.

When we look at the antibiotics that were prescribed, we see that the combination of beta-lactam and beta-lactamase was the common making up about 63 % of all antibiotic prescriptions. The next most common was cephalosporins, which made up 14 % of all antibiotic prescriptions.For patients who had Lower Respiratory Tract Infections, the doctors prescribed bronchodilators. In fact 25 out of 30 prescriptions for bronchodilators were for these patients. The common bronchodilator prescribed was levosalbutamol also known as levolin, which made up about 73.33 %. They prescribed 16 corticosteroids to patients with Lower Respiratory Tract Infections. Only 7 to patients, with Upper Respiratory Tract Infections. The common corticosteroid prescribed was budesonide, which made up about 34.78 %.

Fixed dose combinations or FDCs were prescribed 151 times, which's about 21.85 % of all prescriptions. The common FDCs prescribed were ambroxol/guaiphenesin/terbutaline and amoxicillin/clavulanic acid both of which were prescribed 63 times making up about 41.72 % of all FDCs.

Table 3. WHO Core Prescribing Indicators

Indicator	Mean ± SD	Percentage (%)
No. of drugs per patient encounter	6.857 ± 2.475	–
Drugs prescribed by generic name	5.913 ± 2.216	86.23
Encounters with an antibiotic prescribed	0.778 ± 0.714	63.49
Encounters with an injectable prescribed	2.484 ± 1.506	88.10
Drugs from the Essential Drug List	3.619 ± 1.955	52.78

3.5 Adverse Drug Reactions

ADRs were recorded in 13 patients (10.32%). Male patients experienced a higher number of ADRs (9 patients, 69.23%). Neurological manifestations were the most frequent ADR type (4 patients, 30.77%), followed by cutaneous reactions (3 patients, 23.07%) and respiratory manifestations (3 patients, 23.07%), with gastrointestinal (2 patients, 15.38%) and cardiovascular events (1 patient, 7.69%) also noted. Antibiotics were the most commonly implicated drug class, responsible for 6 of 13 ADRs (46.15%).

Table 4. Profile of Adverse Drug Reactions

ADR Category	n	Percentage (%)
Neurological (drowsiness, irritability)	4	30.77
Cutaneous (rash, urticaria)	3	23.07
Respiratory (paradoxical bronchospasm)	3	23.07
Gastrointestinal (nausea, diarrhoea)	2	15.38
Cardiovascular	1	7.69
Total ADR cases	13	10.32% of study population

Using the Naranjo Scale, the majority of ADRs were classified as 'possible' (score 1–4), suggesting a plausible but not confirmed causal relationship with the suspect drug. No ADRs were classified as 'definite' (score ≥9).

3.6 Statistical Associations and Predictors

Bivariate analysis demonstrated significant associations between RTI type and age group (p = 0.012), number of drugs prescribed (p = 0.005), duration of hospital stay (p = 0.001), number of antibiotics prescribed (p = 0.031), and RTI severity (p = 0.001). Gender showed no significant association with any outcome measure.

Table 5. Associations Between Contributing Factors and Duration of Hospital Stay

Variable	Test	p-value	Significance
Age group	Kruskal-Wallis	0.192	Not significant
Type of RTI	Kruskal-Wallis	0.001	Significant
Number of drugs prescribed	Spearman's correlation	0.001	Significant
Number of antibiotics	Mann-Whitney U	0.002	Significant
Gender	Mann-Whitney U	0.841	Not significant
Severity of illness	Kruskal-Wallis	0.001	Significant

According to a binomial logistic regression analysis, the independent variable that had the greatest effect on hospital length of stay was severity of disease. Moderate severity was associated with 3.72 times the odds (OR = 3.721; 95% CI: 1.35-10.25; p = 0.011) of being hospitalized for 4 or more days relative to mild severity, while severe cases had 14.40 times the odds (OR = 14.399; p = 0.005) of prolonged hospitalization compared to mild). Polypharmacy was also independently significant, as those receiving ≤6 medications were 58% less likely to have a hospital stay of 4 or more days than those receiving >6 medications (OR = 0.423; p = 0.042). Neither age group nor type of RTI were found to be independent predictors of hospital length of stay.

Table 6. Binomial logistic regression model on the duration of hospital stay

Predictor	Odds Ratio (OR)	95% Confidence interval	P-value
Age Group 3 months-1 year vs 1-3 years	1.85	0.35-9.72	0.466
3-6 years vs 1-3 years	0.62	0.16-2.40	0.492
6-12 years vs 1-3 years	0.81	0.23-2.90	0.751
12-18 years vs 1-3 years	0.84	0.22-3.14	0.791
Types of RTI URTI vs LRTI	1.44	0.47-4.40	0.528
Disease Severity Moderate vs Mild	3.72	1.35-10.29	0.011
Severe vs Mild	14.40	2.25-92.15	0.005

Total number of drugs prescribed ≤ 6 - > 6	0.42	0.18-0.97	0.042
Number of antibiotics prescribed 1 vs 0 antibiotics	1.30	0.53-3.20	0.572
≥ 2 vs 0 antibiotics	0.36	0.08-1.71	0.197

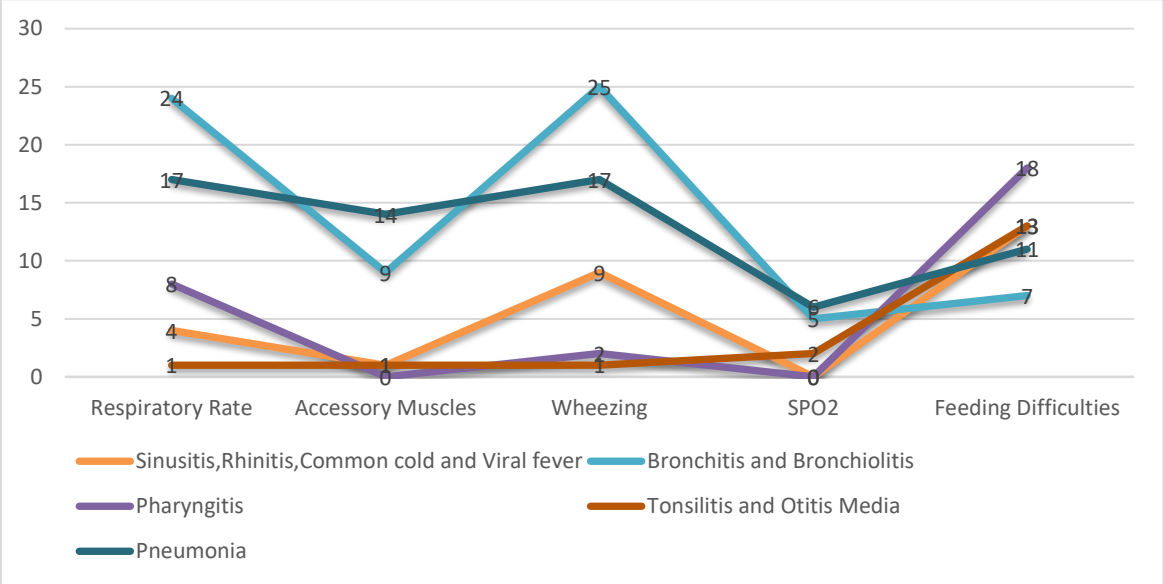

Figure 1: Pattern of changes in PRESS score among different respiratory tract infections

Children in the younger age group (<6 years old) were more likely than older children to have received two or more antibiotics (OR = 0.214; p = 0.025). Severe cases had nearly 9 times the odds of receiving corticosteroids compared to mild cases (OR = 9.14; p = 0.017). Patients with URTI were significantly less likely than LRTI patients to receive bronchodilator therapy (OR =0.079; p < 0.001), while adolescents were less likely than toddlers to receive bronchodilator therapy (OR = 0.131; p = 0.027). Use of FDCs was significantly associated both with type of RTI (URTI vs LRTI: OR = 0.170; p = 0.022) and reduced hospital length of stay (OR = 0.397; p = 0.051), which is consistent with the short duration of treatment associated with FDCs.

4. Discussion

This prospective investigation offers one of the few structured evaluations of pediatric respiratory tract infection (RTI) prescribing and adverse drug reaction (ADR) causality conducted within an Employees' State Insurance (ESI) hospital in South India. By generating region-specific data applicable to a largely employed and peri-urban population, the study addresses a notable gap in the existing literature. Its central observations — namely, the preponderance of upper respiratory tract infections, widespread polypharmacy, antibiotic-associated ADRs, and illness severity as the principal determinant of clinical outcomes — echo patterns documented in prior research while simultaneously illuminating prescribing challenges particular to this institutional context.

The overrepresentation of female patients (56.35%) in the study cohort diverges from the male-skewed distributions reported by Khan et al.[8] and Tripathy et al.[15], a discrepancy that plausibly reflects

population-level differences in healthcare-seeking behaviour and the specific demographic composition of ESI-affiliated beneficiaries. The disproportionate RTI burden among school-age children (29.37%) corroborates the observations of Hotwani and Dave,[2] who attributed this vulnerability to heightened peer exposure and the transitional nature of adaptive immunity during this developmental window. Concurrently, the concentration of lower respiratory tract infections (LRTIs) among infants under one year of age — accounting for 71.4% of the LRTI subgroup — is consistent with data from Sitthikarnkha et al.[4] and reflects the well-established immunological insufficiency characteristic of early infancy.

Upper respiratory tract infections constituted the majority of diagnoses (65.08%), a distribution that mirrors the global epidemiological patterns described by Sharma et al.[16] and Hothan et al.[5] Within their respective categories, pharyngitis (21.4%) and pneumonia (11.1%) emerged as the most frequently encountered subtypes, replicating the findings of several prior Indian investigations. Notably, the combined prevalence of bronchitis and bronchiolitis (20.6%) highlights a considerable burden of lower airway obstructive disease in this clinical environment, warranting ongoing clinical attention.

The mean prescription drug count of 6.85 ± 2.47 per patient substantially exceeds the WHO-recommended threshold of fewer than two medicines per clinical encounter, signalling a clinically significant degree of polypharmacy. This finding is consistent with Mathew and Sayyed,[20] who reported an average of 6.12 drugs per encounter in a comparable tertiary setting, and stands in marked contrast to the considerably lower ratios of 2.37–2.38 documented in earlier outpatient-based studies.[2,16] While antibiotic prescribing was observed in 63.49% of encounters — somewhat below the 70–95% range reported in certain Indian tertiary care settings[7,18] — this frequency remains disproportionately high given the predominantly viral etiology of RTIs. The dominance of β-lactam/β-lactamase inhibitor combinations (63% of antibiotic prescriptions) and cephalosporins (14%) reflects a tendency toward empirical broad-spectrum therapy, a pattern also noted by Choudhury and Bezbaruah[21] and Hemamalini and Binu.[18]

The rate of injectable drug use (88.1%) far surpasses WHO benchmarks for acceptable parenteral prescribing (13.4–24.1%) and aligns with findings from Mathew and Sayyed,[20] who documented parenteral antibiotic use in 85.59% of cases at a similar center. Although intravenous administration is clinically warranted in select inpatient scenarios, a rate of this magnitude invites scrutiny and signals a need for institutional review. On a more favourable note, 86.23% of drugs were prescribed by generic name, exceeding the 68% rate reported by Hotwani and Dave[2] and approximating universal generic adoption. However, adherence to the national essential medicines list remained at 52.78%, indicating that evidence-based prescribing norms have yet to be fully integrated into routine clinical practice.

ADRs were documented in 10.32% of patients, a figure that falls within the 5–17% range reported across comparable pediatric RTI populations.[12,13] Antibiotics accounted for 46.15% of all recorded ADRs, consistent with the antibiotic-attributable proportions described by Tripathy et al.[15] (66%) and Arora et al.[13] Neurological manifestations constituted the most commonly observed ADR category (30.77%), predominantly involving antihistamine-induced sedation, followed by cutaneous reactions (23.07%) and respiratory effects potentially attributable to bronchodilator use or paradoxical corticosteroid responses. This broader ADR profile contrasts with studies in which dermatological reactions predominate,[15] a difference likely attributable to the inclusion of antihistamines and bronchodilators as contributing agents in the present cohort. Reassuringly, no severe ADRs (Hartwig severity grades 5–7) were identified, suggesting that although the overall incidence was notable, the clinical impact of individual events remained within a mild-to-moderate range.

Illness severity was the strongest independent predictor of both extended hospital stay (severe RTI: OR 14.40; p = 0.005) and corticosteroid prescription (severe RTI: OR 9.14; p = 0.017), affirming the clinical applicability of the PRESS severity scoring instrument in this context. These findings extend the validation work of Kanwal et al.[1] and Miyaji et al.[17] to an Indian tertiary care pediatric population. The independent association between polypharmacy, defined as more than six concurrent medications, and prolonged admission (p= 0.042) suggests a self-reinforcing therapeutic cycle driven by clinical complexity. Younger age (under six years) as a predictor of multiple antibiotic use (p = 0.025) likely reflects heightened prescriber caution in physiologically vulnerable children, a tendency previously documented by Islahudin et al.[3] The robust association of bronchodilator prescription with LRTI diagnosis (p < 0.001) and younger age further affirms that drug selection in this cohort is guided predominantly by clinical presentation rather than patient demographics, indicating rational prescribing within this dimension.

Several limitations merit acknowledgement. As a single-center investigation, the generalisability of these findings to community or rural pediatric settings is uncertain. The three-month data collection period may not fully capture seasonal variation in RTI patterns. The absence of routine bacterial culture results constrained the ability to definitively distinguish viral from bacterial etiologies. The potential influence of parental pressure on prescribing decisions and observer effects from the Hawthorne phenomenon could not be quantified. Furthermore, underreporting of ADRs by clinical staff and the exclusion of over-the-counter medications may have led to incomplete capture of drug-related events. Future multi-center studies incorporating systematic microbiological confirmation and prospective antimicrobial stewardship interventions would substantially strengthen the evidence base in this domain.

5. Conclusion

This study demonstrates that pediatric RTI management in a tertiary care Indian hospital is characterized by high drug exposure, prevalent antibiotic and injectable prescribing, significant polypharmacy, and a notable ADR burden, all of which are primarily driven by disease severity and infection type rather than patient demographics. The findings reinforce the global evidence that irrational antibiotic prescribing in pediatric RTIs promotes ADRs and antimicrobial resistance. The study underscores an urgent need for sustained antimicrobial stewardship programs, evidence-based prescribing guidelines, and active pharmacovigilance systems tailored to the pediatric inpatient setting. Future work should include multicenter designs, extended follow-up to capture post-discharge ADRs, and the incorporation of rapid microbiological diagnostics to guide targeted therapy.

6. Declarations

6.1 Ethics Approval and Consent to Participate

Institutional Ethics Committee approval was obtained from Acharya & BM Reddy College of Pharmacy and the Rajiv Gandhi University of Health Sciences, Karnataka, prior to study initiation. Written informed consent was obtained from the parents or legal guardians of all enrolled participants. Assent was obtained from children who were able to provide it.

6.2 Conflict of Interest

The authors declare no conflict of interest. No funding was received from pharmaceutical companies or other commercial entities.

6.3 Funding
This study received no external funding. It was conducted as part of the Doctor of Pharmacy (Pharm.D) programme at Acharya & BM Reddy College of Pharmacy, Bengaluru.

6.4 Author Contributions
SR: study design, supervision, and manuscript revision. JA, AK, and ARG: data collection, analysis, and manuscript drafting. AS: clinical guidance, diagnosis verification, and review. All authors read and approved the final manuscript.

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