



## THE DEMOGRAPHICS OF ANTIBIOTIC ADVERSITY: UNRAVELING ADRS IN PEDIATRIC CARE

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### Abstract

**Background:** Adverse Drug Reactions (ADRs) are a significant concern in pediatric healthcare, potentially leading to increased morbidity and healthcare costs. This study aimed to characterize ADRs to antibiotics among pediatric patients, focusing on age and gender disparities.

**Methods:** A prospective observational study was conducted over 11 months at a tertiary care hospital involving 300 pediatric patients aged 28 days to 18 years. Antibiotics were prescribed according to standard treatment guidelines, and ADRs were assessed using the WHO causality assessment scale. Data were analyzed using IBM SPSS Statistics 25.

**Results:** A total of 34 ADRs were observed, with a higher prevalence in males (61.76%) compared to females (38.23%). The age group of 17-18 years exhibited the most ADRs (44.11%). Penicillins were the leading cause of ADRs (67.64%), followed by cephalosporins, macrolides, fluoroquinolones, and lincosamides. The most common ADRs were thrombophlebitis, eosinophilia, vomiting, and abdominal pain. Recovery from ADRs during the hospital stay was 100%.

**Conclusion:** The study highlights significant age and gender disparities in ADRs to antibiotics in pediatric patients, with adolescent males being the most affected group. These findings suggest the need for age and gender-specific considerations in antibiotic prescribing practices to enhance patient safety.

**Keywords:** Adverse Drug Reactions, Antibiotics, Pediatrics, Gender Disparities, Age Differences, Drug Safety.

### Introduction

Adverse Drug Reactions (ADRs) in pediatric populations represent a critical challenge in clinical pharmacology, with implications for patient safety and healthcare resource utilization. The susceptibility of children to ADRs, particularly in response to antibiotic therapy, necessitates a vigilant approach to medication management. This study is predicated on the need to elucidate the patterns of ADRs associated with antibiotic use in children, with a particular focus on the potential disparities across different ages and between genders.

The genesis of this research lies in recognizing that pediatric patients are not merely "small adults" but represent a dynamic cohort with distinct pharmacokinetic and pharmacodynamic profiles. The incidence of ADRs in this demographic has been reported to be as high as 9.5% in hospitalized

children, underscoring the need for targeted research [1]. Recent studies have indicated that ADRs are a significant cause of morbidity and hospital admissions in children, with antibiotics being one of the most common culprits [2].

The observation of potential age and gender-related differences in the incidence and nature of ADRs further strengthens the rationale for the current study. While some literature suggests that adolescents, particularly males, may exhibit a higher risk of ADRs [3], there is a paucity of research explicitly addressing these disparities within the context of antibiotic therapy in pediatric populations.

The objectives of this study are to characterize the ADRs associated with antibiotic use among pediatric patients and to discern any patterns related to age and gender. This study will contribute to the existing body of knowledge and inform safer prescribing practices. The justification for focusing on antibiotics stems from their widespread use and the consequent potential for ADRs, ranging from mild to severe, impacting the quality of life and increasing healthcare costs [4].

In alignment with the aims of this study, a prospective observational approach was deemed most suitable, allowing for the real-time capture of ADRs and associated demographic factors. The WHO causality assessment scale provides a standardized method for evaluating the relationship between the administered drug and the observed reaction, thereby ensuring the reliability of the findings [5].

This study aims to systematically characterize the ADRs to antibiotics in a pediatric population from a tertiary care setting and to identify any age and gender disparities. By doing so, the study aims to contribute to developing more nuanced and compelling antibiotic prescribing guidelines for children, ultimately enhancing patient safety and care outcomes.

## **Materials and Methods**

### **Study Design and Participants**

This prospective observational study was conducted over 11 months, encompassing a sample size of 300 pediatric patients.

### **Inclusion Criteria**

1. Patients aged between 28 days and under 18 years.
2. Both genders, admitted to or outpatients of the pediatric ward.
3. Informed consent obtained.

### **Exclusion Criteria**

1. Neonates (0-28 days) and individuals over 18 years.
2. Patients in NICU or PICU.
3. Referrals to higher centers or from other departments.

Antibiotics were prescribed as per the standard treatment guidelines of the hospital. The non-proprietary names of the antibiotics were used throughout the study. The antibiotics monitored were penicillins, cephalosporins, macrolides, fluoroquinolones, and lincosamides. Dosages were administered based on the patient's weight, expressed in mg/kg. For instance, amoxicillin was administered at 25 mg/kg (i.v.) every 8 hours. The dosage regimen was adjusted according to the patient's age, weight, and clinical condition.

### **Data Collection and Assessment Tools**

Data on antibiotic prescription, ADR incidence, and related demographic factors were meticulously recorded. ADRs were assessed using the WHO causality assessment scale, a standardized tool for determining the likelihood of a drug causing an adverse event. The severity of drug interactions was categorized into major, moderate, and minor, following the classification system proposed by Hartwig et al. (1992).

### Statistical Analysis

Data were analyzed using IBM SPSS Statistics 25 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used to summarize demographic characteristics and ADR occurrences. The variation of data was expressed as the standard deviation (SD) along with the number of observations (n).

### Ethical Considerations

The study adhered to the ethical guidelines of the Declaration of Helsinki. Ethical approval (IECVAMC- PHAR MAY04 020) was secured prior to the commencement of the study, and confidentiality of patient data was maintained throughout the research process. Informed consent was obtained from all participants' parents or legal guardians.

### Equipment and Materials

All medical equipment used in the administration of drugs and monitoring of patients was sourced from certified medical suppliers, with details of the manufacturers provided where applicable.

### Modifications and New Methods

Any modifications to standard procedures were documented in detail. For instance, if the standard dosing regimen was altered due to patient-specific factors, this was recorded, along with the rationale and outcome.

The methodology of this study was designed to ensure the accurate capture of ADRs associated with antibiotic use in pediatric patients, with a robust statistical approach to analyze the data. The detailed description of the methods allows for the reproducibility and reliability of the study, contributing valuable insights into the safe administration of antibiotics in children.

### Results

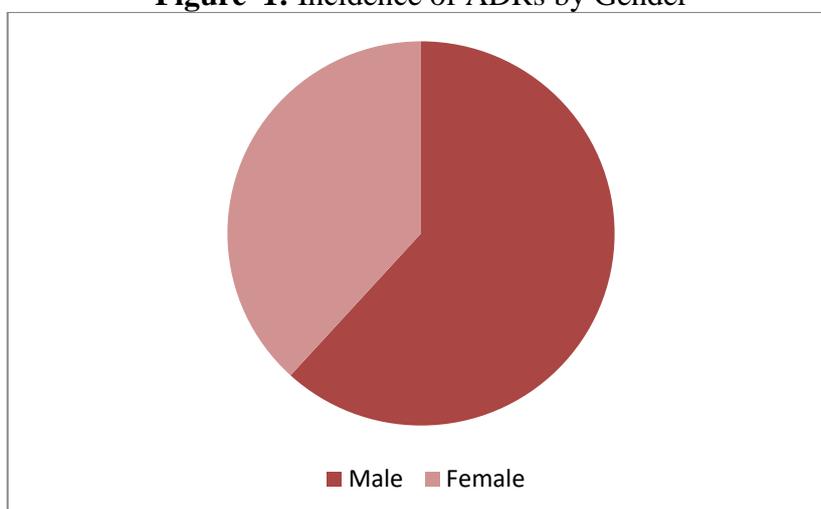
A total of 34 adverse drug reactions (ADRs) were recorded among pediatric patients who received antibiotic therapy. The distribution of these ADRs across gender and age groups and the association with specific antibiotic classes and types of ADRs observed are detailed in the following tables.

The incidence of ADRs by gender indicated a higher occurrence in male patients (Table 1).

**Table 1:** Incidence of ADRs by Gender

Gender	Number of ADRs	Incidence (%)
Male	21	61.76
Female	13	38.23

**Figure 1:** Incidence of ADRs by Gender

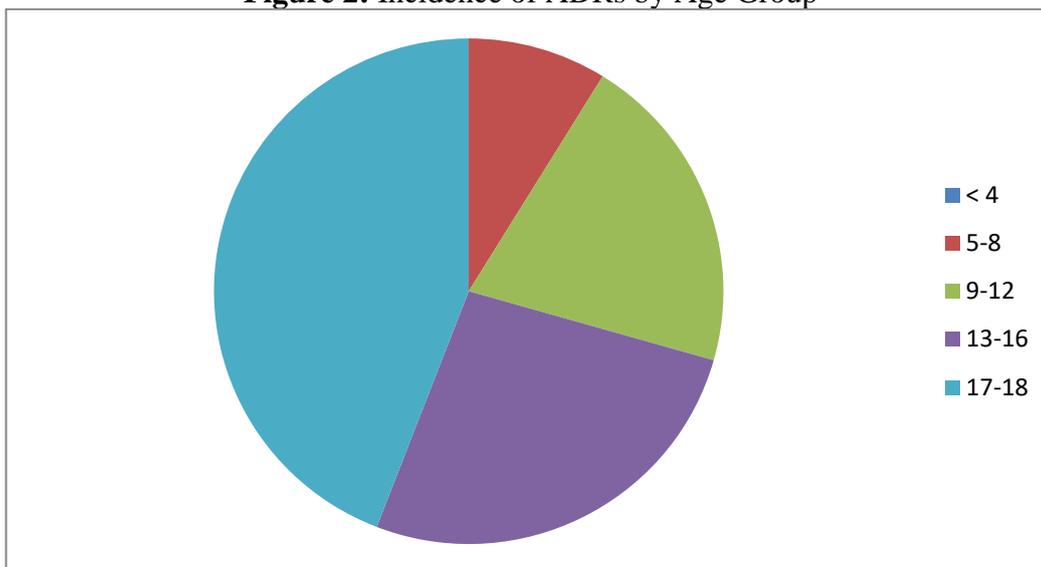


Age distribution of ADRs showed that patients aged 17-18 experienced the highest incidence, while no ADRs were reported in children under 4 years of age (Table 2).

**Table 2: Incidence of ADRs by Age Group**

Age Group (years)	Number of ADRs	Incidence (%)
< 4	0	0
5-8	3	8.82
9-12	7	20.58
13-16	9	26.47
17-18	15	44.11

**Figure 2: Incidence of ADRs by Age Group**

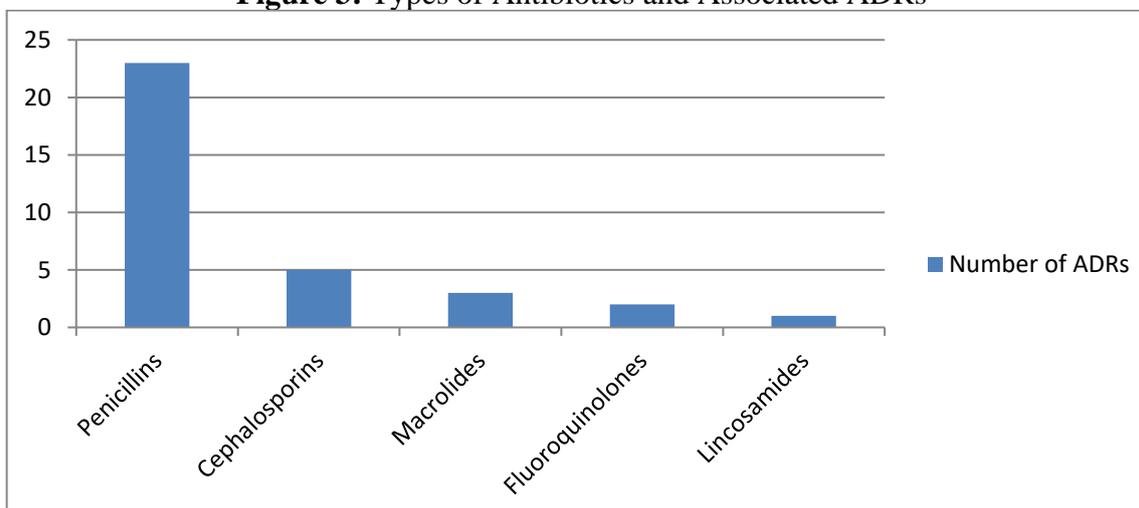


Penicillins were identified as the antibiotic class most commonly associated with ADRs (Table 3).

**Table 3: Types of Antibiotics and Associated ADRs**

Antibiotic Class	Number of ADRs	Incidence (%)
Penicillins	23	67.64
Cephalosporins	5	14.70
Macrolides	3	8.82
Fluoroquinolones	2	5.88
Lincosamides	1	2.94

**Figure 3: Types of Antibiotics and Associated ADRs**

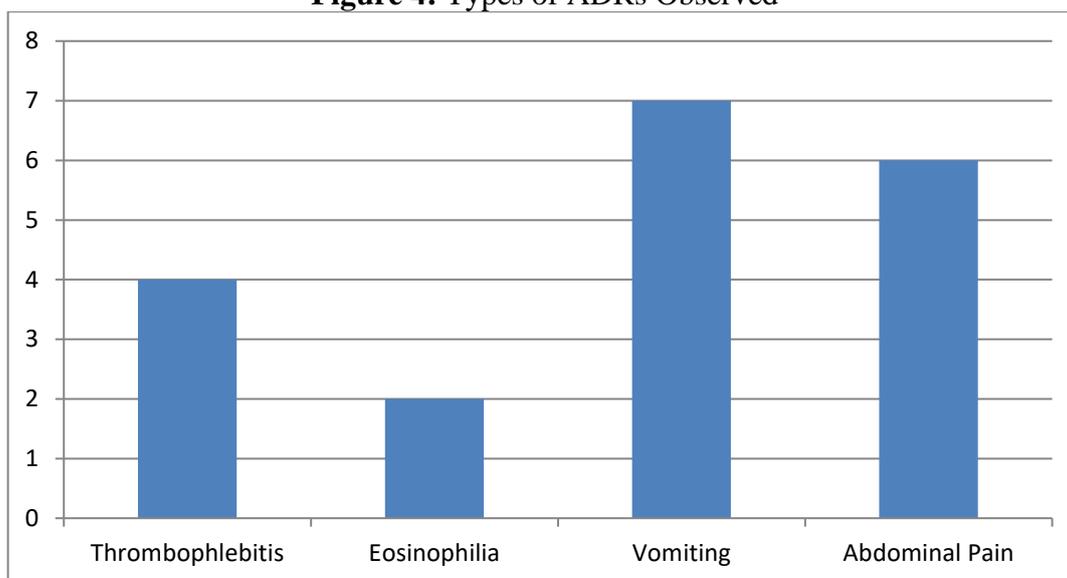


The specific ADRs observed were thrombophlebitis, eosinophilia, vomiting, and abdominal pain, with vomiting being the most frequently reported ADR (Table 4).

**Table 4:** Types of ADRs Observed

ADR Type	Number of Cases
<b>Thrombophlebitis</b>	4
<b>Eosinophilia</b>	2
<b>Vomiting</b>	7
<b>Abdominal Pain</b>	6

**Figure 4:** Types of ADRs Observed



## Discussion

The analysis of ADRs to antibiotics in a pediatric population within this study has revealed noteworthy patterns, particularly concerning age and gender. The predominance of ADRs in males (61.76%) compared to females (38.23%) is consistent with existing literature that suggests gender may play a role in the incidence and severity of ADRs [6]. The mechanisms behind these differences remain fully elucidated, but they may be related to pharmacokinetic and pharmacodynamic variations, hormonal influences, and differences in drug metabolism between genders [7].

Age-wise, the highest incidence of ADRs was observed in the oldest age group (17-18 years), which accounted for 44.11% of the ADRs. This finding is in line with studies that indicate that as children grow older, the pharmacokinetics of drugs change, potentially leading to an increased risk of ADRs [8]. Adolescents, in particular, may be undergoing physiological changes that affect drug metabolism, such as increased enzyme activity and changes in body composition [9].

The predominance of ADRs associated with penicillins (67.64%) reflects their widespread use in pediatric care and underscores the necessity for vigilant monitoring when these antibiotics are prescribed. This is supported by previous research that identifies beta-lactam antibiotics as a common cause of ADRs in children [10].

The types of ADRs observed, such as thrombophlebitis, vomiting, and abdominal pain, are well-documented in pediatric patients receiving antibiotic therapy [1]. The complete recovery of patients from ADRs during their hospital stay is encouraging and suggests that with prompt recognition and management, the prognosis for ADRs in pediatric patients is favourable.

However, this study is not without limitations. Although adequate for preliminary observations, the sample size may not capture the full spectrum of ADRs in the pediatric population. Additionally, the study was conducted in a single tertiary care centre, which may limit the generalizability of the

findings. Future studies with larger, more diverse populations and multicenter designs must validate these results.

The study's strengths include its prospective design and the use of standardized tools for ADR assessment, which enhance the reliability of the findings. Moreover, the detailed age and gender stratification provides valuable insights into the risk factors associated with ADRs in pediatric patients.

### **Conclusion**

The study has identified significant age and gender disparities in ADRs to antibiotics among pediatric patients, with a notable predominance in adolescent males and a high incidence associated with penicillins. These findings underscore the importance of considering age and gender when prescribing antibiotics to children. They also highlight the need for further research into the underlying mechanisms of ADRs in pediatric populations to optimize antibiotic therapy and enhance patient safety, aligning with the study's objectives to characterize ADRs and inform safer prescribing practices.

### **Conflicts of Interest**

The authors declare that they have no conflicts of interest.

### **Sources of Funding**

The authors received no specific funding for this work.

### **Abbreviations:**

ADR: Adverse Drug Reaction

IBM SPSS: International Business Machines Corporation Statistical Package for the Social Sciences

WHO: World Health Organization

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