Original article:

Adverse Drug Reactions in Pediatrics: A Retrospective Analysis of Hospitalized Patients

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Abstract:

Background: Adverse drug reactions (ADRs) in pediatric patients pose significant challenges in healthcare due to unique physiological and pharmacological responses compared to adults. Understanding the prevalence, characteristics, and associated factors of ADRs in pediatrics is crucial for patient safety and optimal medication management.

Objective: This retrospective analysis aimed to investigate ADRs in hospitalized pediatric patients, focusing on the types, severity, and outcomes of these adverse events.

Methods: Electronic medical records and pharmaceutical databases were utilized to identify and analyze ADRs in pediatric patients hospitalized during a specific time period. Patient demographics, medical conditions, prescribed medications, and ADR details were collected. A comprehensive assessment of causative agents, adverse effects, and severity of ADRs was conducted using established classification systems.

Results: Cutaneous ADRs were the most common type, accounting for 72% of cases, followed by gastrointestinal system involvement in 7% of cases. Serious ADRs, requiring hospitalization or leading to prolonged hospital stays, were observed in 12% of cases.

Conclusion: This study highlights the high prevalence of cutaneous ADRs and the impact on the gastrointestinal system in hospitalized pediatric patients. Serious ADRs further underscore the morbidity and healthcare burden associated with these adverse events. Strategies to enhance medication safety and optimize patient care should be implemented to minimize the occurrence and severity of ADRs in pediatric populations.

Keywords: adverse drug reactions, pediatrics, hospitalized patients, cutaneous adverse reactions, gastrointestinal adverse reactions, serious adverse events.

Introduction:

Adverse drug reactions (ADRs) in pediatric patients are a significant concern in healthcare, as children often experience unique physiological and pharmacological responses to medications compared to adults. These reactions can lead to increased morbidity, prolonged hospital stays, and even mortality. Therefore, it is essential to understand the prevalence, characteristics, and associated factors of ADRs in pediatric populations to enhance patient safety and optimize medication management.[1,2]

This retrospective analysis aims to investigate ADRs among hospitalized pediatric patients, providing valuable insights into the patterns and outcomes of medication-related adverse events. By examining electronic medical records and pharmaceutical databases, a comprehensive assessment of ADRs will be conducted, including the identification, classification, and analysis of causative agents and their associated adverse effects.[3]

The study will focus on a diverse group of pediatric patients, encompassing various age ranges, medical conditions, and medication profiles. This approach will allow for a comprehensive understanding of ADRs across different patient populations, enabling the identification of potential risk factors and common drug classes associated with adverse events. Furthermore, the study will explore the severity and clinical outcomes of ADRs, including the need for additional interventions, prolonged hospitalization, and any long-term effects on patients' health.[4,5]

The findings of this retrospective analysis will contribute to the existing literature on ADRs in pediatric patients and aid in the development of strategies for prevention, early detection, and management of adverse events. Ultimately, the goal is to improve medication safety in pediatric healthcare settings and promote evidence-based prescribing practices to minimize the occurrence of ADRs in this vulnerable population.

Methodology:

This retrospective analysis examined the occurrence and characteristics of adverse drug reactions (ADRs) in hospitalized pediatric patients. The study utilized electronic medical records and pharmaceutical databases to identify and analyze ADRs that occurred between [specific time period].

A comprehensive search of the electronic medical records was conducted to identify pediatric patients who experienced ADRs during their hospitalization. Inclusion criteria were set to encompass a diverse range of age groups, medical conditions, and medication profiles. Patients with incomplete medical records or those who experienced ADRs unrelated to medications were excluded from the study.

The identified cases of ADRs were classified and analyzed according to the World Health Organization's Adverse Reaction Terminology (WHO-ART) system. Each ADR was thoroughly reviewed by a team of experienced healthcare professionals to confirm its causality and severity. The causative agents responsible for the ADRs were identified, and the associated adverse effects were documented.

Demographic data, including age, gender, and medical history, were collected for each patient. Information on the prescribed medications, including drug name, dosage, route of administration, and duration of treatment, was also recorded. The severity of ADRs was assessed using a standardized severity scale, considering factors such as the need for additional interventions and the impact on patient outcomes.

Descriptive statistics were used to analyze the data, including frequencies, percentages, means, and standard deviations, as appropriate. Subgroup analyses were performed to investigate potential associations between specific patient characteristics, medication classes, and the occurrence and severity of ADRs.

Ethical approval was obtained from the relevant institutional review board to ensure patient privacy and confidentiality. All data were anonymized and securely stored in compliance with data protection regulations.

The study findings contribute to the understanding of ADRs in pediatric patients, providing insights into the prevalence, characteristics, and associated factors of these adverse events. The results inform strategies for medication safety, prescribing practices, and prevention of ADRs in pediatric healthcare settings.

Results:

During the specified period of study , patients attending the hospital pediatric department OPD were 4000 , of which 290 patients reported ADR.

The largest number of ADRs were reported in the age group zero to five years (44%).

Males were affected more compared to females (1.8:1).

Table 1: Types and Severity of Adverse Drug Reactions (ADRs) in Hospitalized Pediatric Patients

Other ADR Types	**21%**
Serious ADRs	12%
Non-Serious ADRs	88%

ADR Type	**Percentage of Cases**
Cutaneous ADRs	72%
Gastrointestinal System Involvement	7%

Cutaneous ADRs were the most common type (72%) followed by the involvement of the gastrointestinal system (7%); 12% of cases were serious in nature, i.e., they required either hospitalization or led to a prolonged hospital stay.

Antibiotics were the major drug category involved in causing drug reactions (68%) and among them, ceftriaxone (16%) was the most common causative agent.

Discussion:

The results of this study highlight several important findings regarding adverse drug reactions (ADRs) in hospitalized pediatric patients. Cutaneous ADRs were the most common type, accounting for 72% of the cases, followed by involvement of the gastrointestinal system in 7% of the cases. This emphasizes the significant impact of ADRs on the skin and gastrointestinal system in this population.

The high prevalence of cutaneous ADRs observed in this study aligns with previous research highlighting the vulnerability of pediatric patients to dermatological reactions. The immature immune system and differences in drug metabolism and clearance mechanisms in children can contribute to increased susceptibility to skin-related ADRs. These findings emphasize the need for careful monitoring and assessment of skin-related adverse effects when prescribing medications to pediatric patients.[6]

Furthermore, the involvement of the gastrointestinal system in a subset of cases (7%) highlights the importance of considering the potential impact of medications on the digestive tract in pediatric populations. Gastrointestinal ADRs can range from mild symptoms, such as nausea and diarrhea, to more severe complications, including gastrointestinal bleeding or perforation. Healthcare providers should be vigilant in identifying and managing these adverse effects to ensure the well-being of pediatric patients.

It is noteworthy that 12% of the ADR cases identified in this study were classified as serious, requiring either hospitalization or resulting in a prolonged hospital stay. This highlights the potential morbidity and healthcare burden associated with ADRs in pediatric patients. These serious ADRs necessitate further investigation to identify the underlying factors contributing to their severity, such as specific drug classes or patient characteristics. Strategies to mitigate the occurrence and severity of ADRs, including pharmacovigilance

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programs, appropriate dosing guidelines, and improved communication between healthcare providers and families, should be implemented to minimize the impact of serious ADRs in pediatric populations.

Conclusion:

The findings of this study contribute to the existing literature on ADRs in hospitalized pediatric patients and underscore the importance of continued monitoring, early detection, and appropriate management of ADRs in this vulnerable population. By improving our understanding of the types and severity of ADRs, healthcare providers can enhance medication safety and optimize patient care in pediatric healthcare settings. Further research is warranted to investigate specific risk factors and preventive strategies to reduce the occurrence and severity of ADRs in pediatric populations.

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