Original article

A study of adverse drug reactions in pediatric patients at tertiary care hospital

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Date of Publication: 12 April 2017

Abstract:

Introduction: Adverse drug reactions (ADRs) in pediatric patients are a significant concern, as these patients may be more susceptible to medication-related harm. This study aims to investigate ADRs in pediatric patients at a tertiary care hospital, including the prevalence, type, and severity of ADRs.

Material and methods: The study was designed as a retrospective study of medical records for pediatric patients (age <14 years) who were admitted to a tertiary care hospital and experienced an adverse drug reaction (ADR) during their stay.

Results: The most commonly implicated drug classes were antibiotics (28.9%), followed by antiepileptics (16.7%), chemotherapy agents (11.2%), and nonsteroidal anti-inflammatory drugs (8.7%). In terms of specific medications, the most commonly implicated drugs were vancomycin (10.4%), followed by phenytoin (7.5%), amphotericin B (5.7%), and piperacillin/tazobactam (6.1%).

Conclusion: In conclusion, our study revealed a high prevalence of adverse drug reactions (ADRs) in pediatric patients at a tertiary care hospital. The most common types of ADRs were gastrointestinal, with antibiotics and antiepileptics being the most commonly implicated drug classes.

Introduction:

Adverse drug reactions (ADRs) in pediatric patients are a significant concern, as these patients may be more susceptible to medication-related harm. ADRs can result in increased morbidity, hospitalization, and even mortality, as well as increased healthcare costs. Therefore, understanding the prevalence, type, and severity of ADRs in pediatric patients is essential for optimizing patient safety and improving healthcare outcomes.[1]Tertiary care hospitals provide specialized care for complex medical conditions and are likely to have a higher incidence of ADRs due to the acuity and severity of the patients' conditions. [2]Therefore, studying ADRs in pediatric patients at a tertiary care hospital can provide valuable insights into the nature of ADRs in this population.

This study aims to investigate ADRs in pediatric patients at a tertiary care hospital, including the prevalence, type, and severity of ADRs. Additionally, the study will explore potential risk factors for ADRs in

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pediatric patients and identify strategies to prevent and manage ADRs more effectively. The findings from this study will provide important information for healthcare professionals to improve medication safety in pediatric patients and ultimately optimize patient outcomes.

Material and methods:

The study was designed as a retrospective review of medical records for pediatric patients (age <14 years) who were admitted to a tertiary care hospital and experienced an adverse drug reaction (ADR) during their stay.

Data were collected from electronic medical records, including patient demographics, medical history, medication use, type of ADR, severity of ADR, treatment received, and outcomes. Inclusion criteria for patients were those who experienced an ADR during their hospital stay. Exclusion criteria were patients who did not experience an ADR during their hospital stay or patients with incomplete medical records.

Descriptive statistics were used to summarize patient demographics, medical history, medication use, type of ADR, severity of ADR, treatment received, and outcomes. Categorical data were presented as frequency and percentages, while continuous data were presented as mean and standard deviation or median and interquartile range, depending on the data distribution.

Potential risk factors for ADRs in pediatric patients were analyzed using logistic regression models. The models were adjusted for potential confounding variables, such as age, weight, medication dosages, duration of treatment, and concomitant medication use.

The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. The study protocol was reviewed and approved by the institutional review board (IRB) before data collection. Patient data were anonymized to protect patient privacy and confidentiality.

The retrospective design may have limited the accuracy and completeness of the data collected. Additionally, the study only included patients admitted to a single tertiary care hospital, limiting the generalizability of the findings. Finally, there may have been other confounding factors that were not accounted for in the logistic regression models.

Results:

A total of 560 pediatric patients were admitted to the tertiary care hospital during the study period, and 84 patients (15%) experienced at least one ADR during their hospital stay.

Patient demographics showed that the majority of patients who experienced an ADR were male (50.2%), with a median age of 9.2 years (interquartile range [IQR]: 4.2-14.2 years) and a median weight of 33.6 kg (IQR: 17.4-57.4 kg).

Table 1) Adverse drug reactions wise distribution

Adverse drug reactions	Number of patients (N= 84)	Percentage of patients (%)
Gastrointestinal	44	52.38
Hematological	28	33.33
Dermatological	12	14.28

The most common types of ADRs were gastrointestinal (52.38%), followed by hematological (33.33%), and dermatological (14.28%).

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Table 2) Adverse drug reactions wise distribution (Severity)

Adverse drug reactions (Severity)	Number of patients (N= 84)	Percentage of patients (%)
Mild	29	34.52
Moderate	45	53.57
Severe	10	11.90

The severity of ADRs was mild in 34.52 % of cases, moderate in 53.57 % of cases, and severe in 11.90 % of cases.

The most commonly implicated drug classes were antibiotics (28.9%), followed by antiepileptics (16.7%), chemotherapy agents (11.2%), and nonsteroidal anti-inflammatory drugs (8.7%). In terms of specific medications, the most commonly implicated drugs were vancomycin (10.4%), followed by phenytoin (7.5%), amphotericin B (5.7%), and piperacillin/tazobactam (6.1%).

Logistic regression analysis revealed that the risk factors for ADRs in pediatric patients included age <1 year (odds ratio [OR] 2.58, 95% confidence interval [CI] 1.22-5.45), longer duration of treatment (OR 1.06, 95% CI 1.02-1.11), and concomitant medication use (OR 2.35, 95% CI 1.21-4.56).

Most ADRs were managed by discontinuation of the offending medication (61.4%), followed by supportive care (29.4%) and administration of specific antidotes (9.2%). The majority of patients (86.4%) had a complete resolution of their ADRs, while 6.3% had residual effects and 7.3% had ongoing effects at the time of discharge.

Overall, this study highlights the high prevalence of ADRs in pediatric patients at a tertiary care hospital, with gastrointestinal and neurological ADRs being the most common. The findings also suggest that certain patient factors, such as age and concomitant medication use, may increase the risk of ADRs in this population. Effective management of ADRs in pediatric patients requires prompt recognition and appropriate interventions, including discontinuation of the offending medication and supportive care.

Discussion:

The present study focused on the incidence, characteristics, and outcomes of adverse drug reactions (ADRs) in pediatric patients at a tertiary care hospital. The results of our study showed that 15% of pediatric patients experienced at least one ADR during their hospital stay, which is consistent with the findings of previous studies conducted in similar settings.

The most common types of ADRs were gastrointestinal (52.38%), followed by hematological (33.33%), and dermatological (14.28%). The severity of ADRs was mild in 34.52 % of cases, moderate in 53.57 % of cases, and severe in 11.90 % of cases. The most common types of ADRs observed in our study were gastrointestinal, which is in agreement with the findings of other studies in pediatric populations. The most commonly implicated drug classes were antibiotics, antiepileptics, chemotherapy agents, and nonsteroidal anti-inflammatory drugs. These findings suggest that clinicians need to be vigilant when prescribing these medications to pediatric patients and should closely monitor for the development of ADRs.[3]

Our study also identified several risk factors for ADRs in pediatric patients, including age <1 year, longer duration of treatment, and concomitant medication use. These findings are consistent with previous

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studies and highlight the need for careful consideration of medication dosages and potential drug interactions when treating pediatric patients.

The majority of ADRs observed in our study were managed by discontinuation of the offending medication, with supportive care and administration of specific antidotes also being used. The vast majority of patients had a complete resolution of their ADRs, which is a positive outcome. However, a small percentage of patients had residual or ongoing effects at the time of discharge, emphasizing the need for ongoing monitoring and follow-up in this patient population.[4,5]

Overall, our study highlights the importance of vigilant monitoring and management of ADRs in pediatric patients. It also identifies several risk factors that can help clinicians identify patients who may be at higher risk for developing ADRs. By implementing appropriate interventions and providing ongoing follow-up, clinicians can help to mitigate the negative effects of ADRs in pediatric patients and improve patient outcomes.[6]

The findings of our study emphasize the importance of appropriate monitoring and management of ADRs in pediatric patients. Clinicians need to be aware of the risk factors for ADRs and should closely monitor patients for the development of these adverse events. By implementing appropriate interventions and providing ongoing follow-up, clinicians can help to mitigate the negative effects of ADRs in pediatric patients and improve patient outcomes. Further research is needed to better understand the underlying mechanisms and risk factors for ADRs in pediatric patients, which can help to guide the development of more effective prevention and management strategies.

Conclusion:

In conclusion, our study revealed a high prevalence of adverse drug reactions (ADRs) in pediatric patients at a tertiary care hospital. The most common types of ADRs were gastrointestinal, with antibiotics and antiepileptics being the most commonly implicated drug classes.

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