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ORIGINAL ARTICLE

A PHARMACOVIGILANCE STUDY TO ASSESS THE EFFECT OF ADVERSE DRUG REACTION ON PEDIATRIC HEALTH

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ABSTRACT

Background and Objective: This study investigated the incidence, demographic and clinical patterns, causative agents, causality, and severity of adverse drug reactions (ADRs) in children.

Methods: This study employed a retrospective observational design to investigate ADRs in pediatric patients in the pediatric, ear, nose, and throat, and dermatology departments. ADRs were identified through reports from doctors and nurses, which were based on patient complaints. According to the Institutional Review Board committee's statement, no ethical committee approval number was required for this study, as it involved only the assessment of symptoms in pediatric patients without any therapeutic interventions. The study was conducted at Chettinad Medical College and Research Institute from March 2011 to February 2012. During this period, 1788 inpatients were monitored for ADRs using a standardized reporting form. The likelihood of ADRs was evaluated using a probability scale, and reactions were classified according to World Health Organization criteria.

Results: The study found an ADR incidence rate of 0.73% among 1788 children. ADRs were more common in children aged 6–10 years (61.5%) and males (61.5%). Antimicrobial drugs were the leading cause of ADRs, responsible for 61.5% of cases. The causality assessment showed that 53.84% of ADRs were possible, 23.07% were probable, 7.69% were certain, and 15.38% were conditional. The majority of ADRs (85%) were mild, while 15% were moderate, and none were severe.

Conclusion: These findings highlight the importance of monitoring ADRs in children to ensure patient safety and promote safe medication use.

Keywords: Pharmacovigilance, The World Health Organization, Adverse drug reactions, Antimicrobial drugs, Causative agents.

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INTRODUCTION

Medications can have unintended consequences, and no drug is completely risk-free. An adverse drug reaction (ADR) is a harmful or unwanted response to a medication at normal doses. The World Health Organization (WHO) defines it as a response that's noxious, unintended, and occurs during standard use. Pharmacovigilance is the process of monitoring, evaluating, and preventing medication-related problems, including ADRs. Its primary goal is to ensure patient safety and enhance care by identifying and mitigating potential risks associated with medications [1]. These challenges ultimately burden public health, placing substantial economic strain on both society and healthcare systems that are already operating under significant pressure [2]. Raising awareness among patients and healthcare professionals about the importance of prompt detection, assessment, and reporting of ADRs is crucial. This proactive approach can mitigate risks, enhance patient safety, and ultimately improve public health outcomes [3]. Certain individuals are more susceptible to ADRs due to genetic factors, which can increase their risk [4]. Healthcare professionals prioritize safety and efficacy when prescribing medications, as all drugs can have unwanted effects, such as adverse reactions and side effects. In addition, interactions between multiple medications can further compromise safety and effectiveness. To minimize these risks, healthcare professionals should tailor their treatment choices to each patient's unique needs, opting for the safest and most effective options. ADRs significantly contribute to patient harm and mortality. Research suggests that ADRs occur in approximately 9.5–10.9% of hospitalized children. Hospital admissions attributed to ADRs range from 1.8% to 2.1%, with nearly 39.3% of these cases being life-threatening. In outpatient settings, ADRs affect around 1.0–1.5% of children [5,6]. Ensuring medicine safety in pediatrics is a worldwide concern. Enhancing pharmacovigilance knowledge and encouraging spontaneous reporting of ADRs are crucial steps toward promoting the safe use of medications in this population [7]. The primary objective of this study was to conduct a pharmacovigilance analysis to evaluate the impact of ADRs on pediatric health through a cross-sectional approach.

METHODS

Study design and setting

This study was a retrospective observational investigation conducted at Chettinad Medical College and Research Institute's pediatric, ear, nose, and throat (ENT), and dermatology departments. The study period spanned from March 2011 to February 2012, during which 1788 inpatients were monitored for ADRs using a standardized reporting system.

Data collection methods

The study employed a systematic approach to identify and document ADRs in pediatric patients. Standardized reporting forms were used by healthcare professionals to collect data on ADRs, including patient demographics, ADR description, suspected medication, and relevant clinical information. ADRs were identified through reports from doctors and nurses based on patient complaints, highlighting the crucial role of healthcare professionals in detecting potential ADRs. The study's retrospective observational design involved reviewing existing data and records to identify ADRs that had occurred in the past. The data collection process involved identifying potential ADRs based on patient symptoms, reporting them using standardized forms, and then reviewing and

verifying the reports. The reported ADRs were subsequently entered into a database and analyzed to determine their frequency, causality, and classification. By using a standardized approach, the study ensured that the data were accurate, reliable, and comprehensive.

Ethical considerations

The Institutional Review Board committee reviewed the study protocol and assigned the ethical approval number 126/IHEC/02-11.

Inclusion and exclusion criteria

Inclusion criteria

- Pediatric patients admitted to the pediatric, ENT, and dermatology departments during the study period.
- Patients who experienced ADRs during their hospital stay.
- ADRs reported by healthcare professionals.

Exclusion criteria

- Patients with incomplete or missing ADR reports.
- Outpatients or patients not admitted to the hospital during the study period.
- ADRs not reported or documented by healthcare professionals.

Statistical analysis

Descriptive statistics, including frequency distributions and percentages, were used to summarize the data, and Chi-square tests were used to analyze associations between demographic and clinical factors and the occurrence of ADRs, where applicable.

RESULT

The study analyzed the frequency distribution of ADRs in children. Out of 1788 children, 13 (0.73%) experienced ADRs, while 1775 (99.27%) did not, suggesting a relatively low incidence of ADRs in the studied population (Table 1). The demographic and clinical patterns of ADRs in 13 children revealed that most ADRs occurred in children aged 6–10 years (61.5%), with males being more affected (61.5%) than females (Table 2). The skin was the most commonly affected body system (38.5%), followed by the gastrointestinal tract (30.8%) and nervous system (23.2%). ADRs were slightly more common with intravenous administration (54%) compared to oral administration (46%). Antimicrobial drugs were the most common causative agents, accounting for 8 out of 13 ADRs (61.5%) (Table 3). Specific reactions included loose stools, urticaria, rashes, itching, and reddish erythematous macules. Other causative agents included anti-malarial, anti-ulcerative, anti-emetic, and NSAID medications, with reactions, such as headache and loose stools. The categorization of ADRs by probability scale showed that the majority of ADRs (53.84%) were classified as "possible," followed by "probable" (23.07%), and "conditional" (15.38%) (Table 4). Only one ADR (7.69%) was deemed "certain." In terms of severity, the majority of ADRs (85%) were classified as "mild," while 15% were "moderate" (Table 5). Notably, no severe ADRs were reported.

The frequency distribution of ADRs in children reveals that out of 1788 children, 13 (0.73%) experienced ADRs, while 1775 (99.27%) did not. This suggests a relatively low incidence of ADRs in the studied population.

The demographic and clinical patterns of ADRs in 13 children reveal that most ADRs occurred in children aged 6–10 years (61.5%), with males being more affected (61.5%) than females. The skin was the most commonly affected body system (38.5%), followed by the gastrointestinal tract (30.8%) and nervous system (23.2%). ADRs were slightly more common with intravenous administration (54%) compared to oral administration (46%). These findings provide insight into the characteristics of ADRs in children.

The frequency distribution of ADRs in children by causative agent reveals that antimicrobial drugs were the most common culprits, accounting for 8 out of 13 ADRs (61.5%). Specific reactions included loose stools, urticaria, rashes, itching, and reddish erythematous macules. Other causative agents included anti-malarial, anti-ulcerative, anti-emetic, and NSAID medications, with reactions, such as headache and loose stools. This data highlights the importance of monitoring for potential ADRs when prescribing medications to children.

The categorization of ADRs by probability scale shows that the majority of ADRs (53.84%) were classified as "possible," followed by "probable" (23.07%), and "conditional" (15.38%). Only one ADR (7.69%) was

Table 1: Frequency distribution of adverse drug reactions in children

Variable distribution	Frequency	Percentage
Number of children with ADRs*	13	0.73
Number of children without ADRs*	1775	99.27
Total	1788	100

*ADRs: Adverse drug reactions, n=13

Table 2: Demographic and clinical patterns of adverse drug reactions in children

Demographic and clinical factors	Distribution of ADRs*	
	Frequency (n=13)	Percentage (n=100)
Age		
0–5 years	01	07.7
6–10 years	08	61.5
>10 years	04	30.8
Gender		
Male	08	61.5
Female	05	38.5
Body system affected		
GIT	04	30.8
Skin	05	38.5
Nervous system	03	23.2
Others	01	07.5
Route of administration		
Oral	06	46.0
I.V	07	54.0
Total	13	100

*ADRs: Adverse drug reactions, n=13; LV: Intravenous

Table 3: Frequency distribution of ADRs in children by causative agent

Causative agent	Symptoms	Distribution of ADRs*	
		Frequency (n=13)	Percentage (n=100)
Antimicrobial drugs (08)			
Amoxicillin	Loose stools	1	7.69
	Urticaria	1	7.69
Gentamycin	Reddish erythematous macules	1	7.69
Oflaxacin	Dark urine	1	7.69
Cefadroxil	Rashes all over the body	1	7.69
	Itching	1	7.69
Ceftriaxone+tazobactum	Loose stools	1	7.69
Amikacin	Itching all over the body	1	7.69
Antimalaria drugs (01)			
Chloroquine	Loose stools	1	7.69
Antiulcerative (02)			
Lansoprazole	Headache	2	15.38
Antiemetics (01)			
Ondansetron	Headache	1	7.69
NSAID (01)			
Paracetamol	Loose stool	1	7.69
Total		13	100

*ADRs: Adverse drug reactions, n=13

Table 4: Categorization of ADRs by probability scale

Probability scale	Number of ADRs*	Percentage of ADRs*
Certain	1	7.69
Probable	3	23.07
Possible	7	53.84
Unlikely	-	-
Conditional	2	15.38
Total	13	100

*ADRs: Adverse drug reactions, n=13

Table 5: Frequency distribution of severity of ADRs

Group	Number of ADRs*	Percentage of ADRs*
Mild	11	85
Moderate	2	15
Severe	-	-
Total	13	100

*ADRs: Adverse drug reactions, n=13

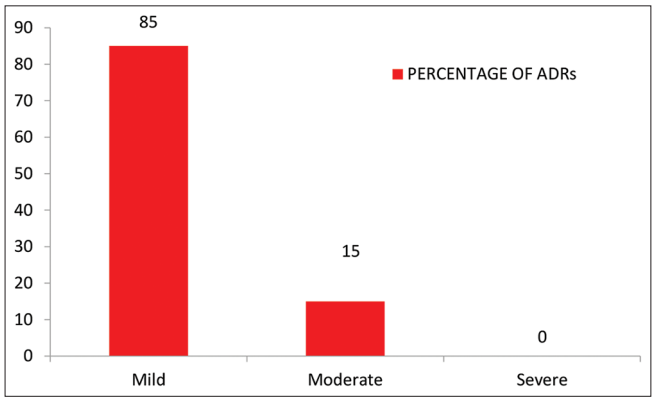

Figure 1: Frequency distribution of severity of ADRs. ADRs: Adverse drug reactions

deemed "certain." This distribution highlights the complexity of determining causality in ADRs and the need for careful evaluation to establish the likelihood of a drug-related reaction.

The frequency distribution of adverse drug reactions (ADRs) by severity reveals that the majority (85%) were classified as mild, while 15% were moderate. Notably, no severe ADRs were reported, as illustrated in Fig. 1. This suggests that most ADRs in the study were not serious and likely did not require significant medical intervention.

DISCUSSION

ADRs can significantly impact both a patient's health and financial well-being. Therefore, effective monitoring of ADRs is crucial. Our study found a low incidence of ADRs in children with an incidence rate of 0.73%. This rate may vary across different hospitals, regions, or countries due to diverse factors. A comprehensive review of previous studies by Aagaard *et al.* [8] found that ADRs are a significant concern in pediatric care. The analysis revealed that hospitalized children experience ADRs at a rate of approximately 9.53% (95% confidence interval [CI]: 6.81–12.26), while outpatient settings report a lower incidence of around 1.46% (95% CI: 0.7–3.03). These findings highlight the need for vigilant monitoring and effective management of ADRs in children to ensure patient safety and optimize treatment outcomes.

Our study's demographic and clinical analysis of ADRs in children revealed several key findings. The majority of ADRs occurred in children aged 6–10 years, accounting for 61.5% of the cases, while 30.8% were in children over 10 years, and 7.7% in those under 5 years. Males were more affected than females, with 61.5% of ADRs occurring in boys.

Similar studies have reported varying demographics in ADR cases. A study by Gallo *et al*. found that 55.5% of ADR cases were in boys and 44.5% in girls [9]. Li *et al*. reported ADRs in 40.41% female patients and 59.59% male patients, highlighting differences in gender distribution across studies [10].

Digra *et al.* [11] found that 104 out of 28,864 patients (0.3%) developed ADRs. The majority of ADR cases were male (66.34%), while 33.65% were female and also found that ADRs primarily affected the dermatological system (67.30%), followed by the central nervous system (CNS) (11.53%), and the renal system (6.73%). Other affected systems included cardiovascular (4.80%), musculoskeletal (3.84%), and metabolic (2.88%) systems. The severity of ADRs was categorized as moderate (64.4%), severe (29.8%), and mild (5.76%) based on the Hartwig severity scale. An analysis of contributing factors revealed that 65.38% of patients had no identifiable risk factors, while 15.38% had inadequate monitoring, 5.7% had inappropriate use, and 13.46% had inappropriate prescriptions.

Kurma *et al*. [12] analysis of ADRs in the pediatric department found that 102 ADRs were reported, with males being more affected (60.8%) than females (39.2%). Notably, children aged 1–5 years were most susceptible to ADRs, accounting for 43.3% of cases. This highlights the need for close monitoring and caution when administering medications to young children.

According to Khan *et al*. [13], a study of pediatric patients revealed 16 ADRs among 8,912 admissions, yielding a rate of 1.7 ADRs/1,000 admissions. The study found that infants (31.2%) and children (56.2%) were more susceptible to ADRs, with females accounting for 81.2% of cases. Skin reactions were most prevalent, with maculopapular rash and erythema multiforme being common symptoms.

The present study showed that the skin was the most commonly affected body system, involved in 38.5% of cases, followed by the gastrointestinal tract (30.8%) and nervous system (23.2%). Intravenous administration was associated with slightly more ADRs (54%) compared to oral administration (46%). These findings provided insight into the characteristics of ADRs in the pediatric population studied.

Similarly, Priyadharsini *et al*. found that the skin was the most frequently affected organ system, accounting for 52% of ADRs, consistent with findings from previous studies [14]. Dash *et al*. study of 127 pediatric patients found 155 ADRs, with notable trends emerging. Females comprised 62.20% of patients, while males made up 37.79%. Children aged 2–11 years experienced the majority of ADRs (57.4%). The skin and mucous membranes were most frequently affected, and antiepileptic drugs (37.03%) and antimicrobial agents (25.92%) were the primary causes of ADRs, underscoring the need for vigilant monitoring in pediatric care [15]. Similarly, a study by Valder *et al*. also characterized the pattern of ADRs at a tertiary care teaching hospital, yielding comparable findings. Their research revealed that ADRs predominantly occurred in the General Medicine and Pediatric departments, with the skin and gastrointestinal tract being the most frequently affected systems. Cephalosporins were identified as the most common culprit antibiotic class, and fortunately, no fatalities were reported. This study further underscores the significance of ADR monitoring and reporting in promoting patient safety and rational medication use [16].

In contrast to our findings, Kharat *et al*. study revealed that CNS effects were the most common ADRs, followed by skin-related issues and gastrointestinal problems [17].

Antimicrobial drugs were the leading cause of ADRs in our pediatric study population, responsible for 61.5% of cases. Various antibiotics, including amoxicillin, gentamycin, ofloxacin, cefadroxil, ceftriaxone + tazobactum, and amikacin, were associated with different reactions, such as loose stools, urticaria, rashes, itching, and reddish erythematous macules. Other causative agents included antimalarial, anti-ulcerative, anti-emetic, and NSAID medications, which caused symptoms, such as

headache and loose stools. These findings highlight the importance of monitoring for potential ADRs when prescribing medications to children.

Our analysis of ADR causality showed that most cases were classified as possible, indicating a potential relationship between the medication and the adverse event. A notable proportion was categorized as probable, suggesting a stronger association. A smaller number were deemed certain or conditional, while none were considered unlikely. This breakdown underscores the challenges in establishing causality and the importance of thorough assessment.

According to Chandrabhan *et al*. [18], a study reported 111 ADRs, with a higher incidence in males (54.96%) and individuals aged 18–60 years (79.28%). The gastrointestinal system was most frequently affected (36.36%), and Ceftriaxone was the most commonly implicated drug (11.71%). The majority of reactions was type A (86.49%) and classified as possible according to the WHO-UMC scale (74.77%). Most ADRs were mild (82.88%) based on the modified Hartwig's and Siegel scale.

According to Jiang *et al*. [19], a retrospective study of 1,803 ADRs reported between 2011 and 2020 found that 36.77% were mild, 43.26% moderate, and 19.97% severe. Causality assessment revealed 0.33% definite, 58.68% probable, and 40.99% possible ADRs. Over half (53.97%) were deemed preventable. ADR severity correlated with age, number of suspected drugs, and preventability. Antimicrobial agents were the primary cause, and the gastrointestinal system was most frequently affected.

The severity assessment of ADRs in our study showed that the majority (85%) was mild; indicating that most reactions were not serious and likely did not require significant medical intervention. A smaller proportion (15%) was classified as moderate, suggesting that these reactions may have required some medical attention or changes to treatment. Notably, no severe ADRs were reported, which is reassuring. However, continued monitoring is essential to ensure patient safety.

According to Deepthi Rani *et al*. [20], younger children were more susceptible to ADRs, with those under 2 years experiencing the highest incidence (40%). Allergic reactions were most common (40%), followed by gastrointestinal issues (25%), CNS effects (15%), respiratory problems (10%), and metabolic imbalances (10%). Most ADRs were mild (60%), with 30% moderate and 10% severe. Antibiotics were the primary cause (40%), followed by antipyretics/analgesics (30%) and vaccines (15%).

James and Rani found that antibiotics were the leading cause of ADRs, likely attributed to their widespread use. The skin was the most frequently affected organ system, involved in 75% of cases. Furthermore, according to modified Hartwig's criteria, the majority of the reactions (75%) were classified as mild [21].

Limitations

This study on ADRs in children has some limitations. The small sample size may limit generalizability, and variability in ADR reporting and assessment methods may affect comparability with other studies. In addition, limited demographic and clinical data may not capture all relevant factors, and inconsistent causality, severity, and avoidability assessments across studies make comparisons challenging. These limitations underscore the need for further research to better understand ADRs in pediatric populations.

CONCLUSION

Our study highlights the significance of monitoring ADRs in children to ensure their safety and well-being. With an incidence rate of 0.73%, ADRs were found to be more common in children aged 6–10 years and in males. The skin, gastrointestinal tract, and nervous system were the most frequently affected body systems, and antimicrobial drugs were the leading cause of ADRs. While most reactions were mild, thorough assessment and continued monitoring are crucial to prevent potential harm. These findings can inform strategies to promote safe medication use in pediatric patients and underscore the importance of tailored approaches to minimize ADRs in this vulnerable population.

AUTHOR CONTRIBUTIONS

The first author collected data from Chettinad Medical College and Research Institute. The second and third authors performed the statistical analysis and prepared the manuscript. All three authors previously worked at the same institution but have since moved to new institutions. The authors contributed equally to this work**.**

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Nil.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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