Cornous Biology
Research Article

A non-interventional data collection study on pharmacovigilance to improve drug safety in the pediatric population

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Volume: 2, Issue: 3, Pages: 23-29
DOI: https://doi.org/10.37446/corbio/rsa/2.3.2024.23-29
Received: 28 April 2024 / Accepted: 29 August 2024 / Published: 30 September 2024

Background: Due to developmental variations that affect medication metabolism and effects, drug safety in young populations is a major concern.

Methods: In order to assess adverse drug reactions (ADRs) and improve medication safety monitoring, this non-interventional study gathered data from 250 pediatric patients. The study was conducted over a period of 12 months from September 2021 to September 2022 at Anu Hospitals and Priya Children's Hospital, Vijayawada.

Results: With a focus on frequently prescribed drugs in pediatric care, the study examined the frequency, intensity, and type of adverse drug reactions (ADRs).

Conclusion: With a focus on frequently prescribed drugs in pediatric care, the study examined the frequency, intensity, and type of adverse drug reactions (ADRs).

Keywords: *Pharmacovigilance, Paediatrics, safety monitoring, Adverse drug reactions*

Introduction

The science of identifying, evaluating, and averting side effects or any other drug-related issue is known as Pharmacovigilance. It is essential to guaranteeing medication safety, particularly for susceptible groups like youngsters. Different pharmacokinetics and pharmacodynamics at different developmental stages present special issues for the pediatric population (Toma et al., 2021). There is a dearth of information on drug safety for children since pediatric groups are still underrepresented in clinical trials, despite advancements in pharmacovigilance. By monitoring and assessing adverse drug reactions (ADRs) in children through non-interventional data gathering, this study seeks to close that gap and advance drug safety procedures.

Materials and methods

Objectives:

- To collect real-world data on ADRs in pediatric patients.
- To assess the incidence, severity, and causality of ADRs.
- To improve pharmacovigilance practices for pediatric medications.

Study Design: This was a prospective, non-interventional study involving 250 pediatric patients. The study was conducted over a period of 12 months from September 2021 to September 2022 at Anu Hospitals and Priya Children's Hospital, Vijayawada (Leporini et al., 2022). Data on ADRs were collected from electronic medical records, interviews with caregivers and physician reports. ADRs were classified according to their severity (mild, moderate, severe) and causality (definite, probable, possible, unlikely) based on WHO-UMC causality assessment criteria (Keche et al., 2021).

Results and Discussion

Demographics

A total of 250 subjects were enrolled in the study, and the data were analyzed descriptively. Overall average age of enrolled subjects is 7.4286 Yrs, with a balanced distribution of genders. Out of the 250 subjects enrolled 182 (72.8 %) subjects were male and 68 (27.2 %) subjects were female; all are Asian race. The overall average height of enrolled subjects was 114.2536 cm, and the overall average weight was 20.8429 kg. There were no significant medical history and concurrent medical conditions for all enrolled subjects as per the data collected. The same was summarised in Table 1, Figure 1, Figure 2 & Figure 3.

Table 1. Summary statistics of demographics of all subjects

PARAMETER	Count (N= 250)
Age (Years)	
N	250
Mean	7.4286
Standard deviation	2.9483
Minimum	3
Maximum	17
Gender, n (%)	
N	250
Male	182 (72.8 %)
Female	68 (27.2 %)
Weight (Kg)	
N	250
Mean	20.8429
Standard deviation	8.7828
Minimum	6
Maximum	56
Height (cm)	
N	250
Mean	114.2536
Standard deviation	15.3977
Minimum	90
Maximum	162
Significant Medical History and Concurrent Medical Conditions	
Subject with NO Diabetes (Type 1/Type 2)	250 (100 %)
Subject with NO Thyroid	250 (100 %)
Subject with NO Cardiovascular Disease	250 (100 %)
Subject with NO Hypertension	250 (100 %)
Subject with NO Coronary Artery Disease	250 (100 %)
Subject with NO Asthma	250 (100 %)
Subject with NO Epilepsy	250 (100 %)

PARAMETER	Count (N= 250)
Subject with NO Drug Allergy	250 (100 %)
Subject with NO Others	250 (100 %)

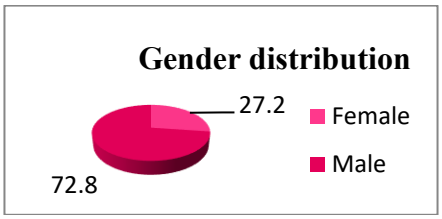

Figure 1. Gender distribution

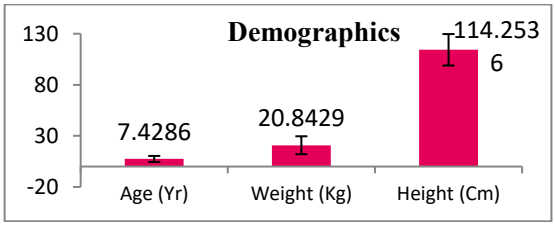

Figure 2. Demogrphics

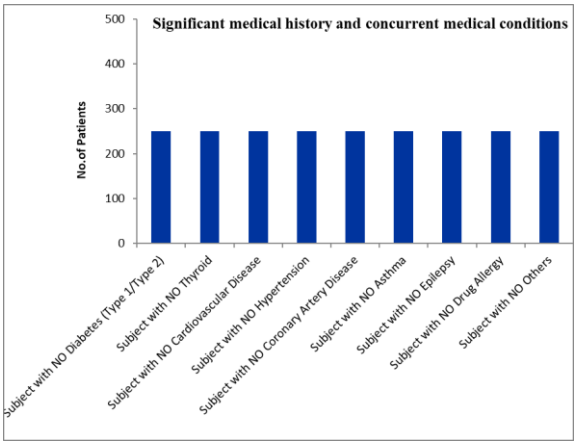

Figure 3. Significant medical history and concurrent medical conditions

As part of Data Collection, Adverse Drug Reaction Probability Scale was employed to identify ADRs of subjects. It was evident from Table 2 that, the Mean total score of adverse drug reaction probability scale was 0.435714 (SD 1.4603), indicating that the reaction was doubtful whether the ADR is likely related to factors other than a drug (Srinivasan et al., 2011; Bethesda, 2012).

Table 2. Summary statistics of adverse drug reaction probability scale

PARAMETER	Count (N= 250)
Total Score	
N	250
Mean	0.435714
Standard deviation	1.4603
Minimum	-3
Maximum	4

As part of data collection, Knowledge based questionnaires were employed to record the knowledge of subject's family members about the Adverse Events. It was evident from Table 3 that, out of 250, around 9 (3.6 %) members had excellent knowledge, 125 (50%) had good knowledge, 95 (38.00%) had moderate knowledge and 21 (8.4%) subjects had poor knowledge regarding the definition of ADR. Out of 250, about 89 (35.60 %) members had poor knowledge, 120 (48.00%) members had moderate knowledge, and 41 (16.40 %) members had good knowledge on differentiating whether the adverse drug reaction and ADR the Same. Out of 250, 107 (42.8 %) members had poor knowledge, 127

(50.80 %) had moderate knowledge, 13 (5.20 %) members had good knowledge and only 4 (1.60 %) members had excellent knowledge on who can report ADRs. Out of 250 subjects, 123 (49.20 %) members had poor knowledge, 112 (44.80 %) members had moderate knowledge, 13 (5.2 %) members had good knowledge and only 2 (0.80%) members had excellent knowledge on what is meant by Pharmacovigilance. Out of 250 members, all of them had poor knowledge on which method is commonly used for causality assessment of ADR and on what type of medication can cause ADRs (Nasso et al., 2020). Out of 250, 180 (72.00 %) subjects had poor knowledge, 66 (26.40 %) subjects had moderate knowledge, 2 (0.8%) subjects had good knowledge and 0.8 (0.71 %) subject had excellent knowledge on whether the collection of information on ADRs contribute to improving patient safety. Out of 250, 166 (66.40 %) subjects had poor knowledge, 77 (30.80 %) subjects had moderate knowledge, 5 (2.00 %) subjects had good knowledge and 2 (0.8 %) subjects had excellent knowledge on how important do you they it is for the public to report ADRs. Out of 250, 210 (84.00 %) subjects had poor knowledge, 38 (15.20 %) subjects had moderate knowledge, and 2 (0.8 %) subjects had good knowledge on considering reporting suspected ADRs in future. Out of 250, 235 (94.00 %) subjects had poor knowledge, 13 (5.20 %) subjects had moderate knowledge, and only 2 (0.8 %) subjects had good knowledge on where to find more information on ADR reporting. Out of 250, 212 (84.80 %) subjects had poor knowledge, and 38 (15.20 %) subjects had moderate knowledge, on where to find more information on to whom can they report ADRs. Out of 250 members, all of them had poor knowledge on how can ADRs be reported and on what type of ADRs should be reported (Aurich et al., 2022; Leitzen et al., 2023).

Table 3. Summary statistics of scale knowledge based questionnaires

PARAMETER	Count (N= 250)
Define ADR	
Excellent	9 (3.6 %)
Good	125 (50 %)
Moderate	95 (38.00 %)
Poor	21 (8.4%)
Are adverse drug reaction and ADR the Same?	
Excellent	0 (0 %)
Good	41 (16.40 %)
Moderate	120 (48.00 %)
Poor	89 (35.60 %)
Who can Report ADR?	
Excellent	4 (1.60 %)
Good	13 (5.20 %)
Moderate	127 (50.80 %)
Poor	107 (42.8 %)
What is meant by Pharmacovigilance	
Excellent	2 (0.80 %)
Good	13 (5.2 %)
Moderate	112 (44.80 %)
Poor	123 (49.20 %)
Which method is commonly used for causality assessment of ADR?	
Excellent	0 (0 %)
Good	0 (0 %)
Moderate	0 (0 %)
Poor	250 (100 %)
What type of medication can cause ADRs?	
Excellent	0 (0 %)
Good	0 (0 %)
Moderate	0 (0 %)
Poor	250 (100 %)
Does the collection of information on ADRs contribute to improving patient safety?	
Excellent	2 (0.8 %)
Good	2 (0.8 %)
Moderate	66 (26.40 %)
Poor	180 (72.00 %)
How important do you think it is for the public to report ADRs?	

PARAMETER	Count (N= 250)
Excellent	2 (0.80 %)
Good	5 (2.00 %)
Moderate	77 (30.80 %)
Poor	166 (66.40 %)
Would you consider reporting suspected ADRs in future?	
Excellent	0 (0 %)
Good	2 (0.80 %)
Moderate	38 (15.20 %)
Poor	210 (84.00 %)
Where can you find more information on ADR reporting?	
Excellent	0 (0 %)
Good	2 (0.80 %)
Moderate	13 (5.20 %)
Poor	235 (94.00 %)
To whom can ADRs be reported?	
Excellent	0 (0 %)
Good	0 (0 %)
Moderate	38 (15.20 %)
Poor	212 (84.80 %)
How can ADRs be reported?	
Excellent	0 (0 %)
Good	0 (0 %)
Moderate	0 (0 %)
Poor	250 (100 %)
What type of ADRs should be reported?	
Excellent	0 (0 %)
Good	0 (0 %)
Moderate	0 (0 %)
Poor	250 (100 %)

It was evident from Table 4 that, out of 250 subjects, only 5 (2.00 %) subjects were reported with Mild Abdominal pain, 6(2.40 %) subjects were reported with Mild Drowsiness, 22 (8.80 %) subjects were reported with Mild Gastritis, 41 (16.40 %) subjects were reported with Mild Nausea, 6 (2.40 %) subjects were reported with Mild Rashes, 2 (0.80 %) subject was reported with Mild Stomach pain, 2 (0.80 %) subject was reported with Mild Swollen eyes (Golder et al., 2016; Eldridge et al., 2022).

Table 4. Summary statistics of adverse events (AE) list

PARAMETER	Count (N= 250)
Abdominal Pain	**5 (2.00 %)**
Mild	5 (100 %)
Moderate	0 (0 %)
Severe	0 (0 %)
Drowsiness	**6 (2.40 %)**
Mild	6 (100 %)
Moderate	0 (0 %)
Severe	0 (0 %)
Gastritis	**22 (8.80 %)**
Mild	22 (100 %)
Moderate	0 (0 %)
Severe	0 (0 %)
Nausea	**41 (16.40 %)**
Mild	41 (100 %)
Moderate	0 (0 %)
Severe	0 (0 %)
Rashes	**6 (2.40 %)**

PARAMETER	Count (N= 250)
Mild	6 (100 %)
Moderate	0 (0 %)
Severe	0 (0 %)
Stomach Pain	**2 (0.80 %)**
Mild	2 (100 %)
Moderate	0 (0 %)
Severe	0 (0 %)
Swollen eyes	**2 (0.80 %)**
Mild	2 (100 %)
Moderate	0 (0 %)
Severe	0 (0 %)

Findings

The study found that pediatric patients had a considerable rate of adverse drug reactions (ADRs), most of which were minor and treatable. Given how frequently these drugs are used in pediatric care, antibiotics and analgesics were the most frequent offenders.

Implications for Pharmacovigilance

The study emphasizes how crucial effective pharmacovigilance systems are for identifying and averting adverse drug reactions in children. Drug safety could be improved with revised pediatric medication usage guidelines and better reporting and monitoring systems.

Limitations

The non-interventional nature of the study limits control over confounding factors.
Data were collected from a limited geographic region, which could not accurately reflect the larger pediatric population.

Conclusion

This study emphasizes the significance of pharmacovigilance in pediatric populations, stressing the necessity of ongoing ADR reporting and monitoring to enhance medication safety. The results open the door to safer therapeutic approaches for kids and advance knowledge of the risk profile of frequently administered pediatric drugs.
The systematic use of the Adverse Drug Reaction Probability Scale in the study demonstrated the causality of adverse drug reactions (ADRs) in a variety of clinical circumstances, according to the scale's summary statistics. The majority of the parents/guardians of the pediatric children who were enrolled had little understanding of what an adverse drug reaction (ADR) is, who to report it to, how to report it, and other pertinent information, according to the findings of knowledge-based surveys. Based on our findings we conclude that care takers of the pediatric population are to be educated more on the Adverse Drug Reactions incidence and ADR reporting practices.

Acknowledgement

The authors thank the management, principal, and staff of Sunrise University's Department of Pharmacy in Alwar, Rajasthan, India, for providing the facilities and for their steadfast support in seeing the current study project through to its conclusion.

Author contributions

Naga Satish Babu Doguparthy: Conceptualization and methodology; Priya Jain: Supervision; Manmeet Singh Saluja: Co-Supervision, Procurement of Raw materials and other sources; Raghavendra Kumar Gunda: Drafting and proof reading.

Conflict of interests

The authors declare no conflict of interest.

Funding

No funding has been made from anyone for this current work.

Ethics approval and informed consent

The study was approved by the Independent Ethics Committee- Fusion Clinical Research, Reference No. CSP/AR/01/2023 and informed consent was obtained from the parents or guardians of the pediatric participants. A high degree of confidentiality must be maintained regarding the patient's or individual's information. Patient information should not be disclosed in any way. Before sending the case report to your publication, we got the patient's signed informed consent.

AI Usage Declaration

The authors state that this manuscript's scientific substance, data interpretation, and reference citations were not produced using artificial intelligence (AI). However, AI-assisted technologies such as Grammarly, ChatGPT, and QuillBot were utilized exclusively for grammar correction, language refinement, and enhancing readability. The authors wrote all of the scientific content and thoroughly examined and confirmed the manuscript's accuracy, uniqueness, and completeness.

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