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Research Article

A PROSPECTIVE OBSERVATIONAL STUDY ON PATTERN OF ADVERSE DRUG REACTION TO ANTIBIOTICS COMMONLY PRESCRIBED IN THE HOSPITALIZED PEDIATRIC PATIENTS

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ABSTRACT

Objective: Antibiotics are the almost usually specified or authorized medication in hospitals, and antibiotics were found to be the almost bothersome classes of drugs providing or endowing to adverse drug reactions (ADRs). Therefore, the present study was conducted to check or regulate the precautions (ADRs) of antibiotics usually specified or authorized in the pediatrics unit.

Methods: A potential, experimental, non-interventionist study was conducted or executed in the Department of Pediatrics for a time of 6 months to analyze the ADRs reported spontaneously from the hospital using patient statistics, objective and medication information, data of ADRs, onset time, causal drug details, outcome, and severity.

Results: Among 72 ADRs observed, beta-lactams and quinolones were set up to be contributing the highest number of ADRs. The duct or abdominal system was the almost commonly affected organ, followed by respiratory system and the cardiovascular system. The assessment by the World Health Organization causation estimation scale demonstrated that 5.56% ADRs were certain, 55.56% were possible, 30.56% were probable, and 8.33% were unlikely.

Conclusion: Thus, the pattern of ADRs occurring in the pediatric population was observed and assessed. Early recognition and management of ADRs are essential to reduce the burden of ADRs.

Keywords: Adverse drug reactions, Antibiotics, World Health Organization causality assessment, Pediatrics.

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INTRODUCTION

Adverse drug reactions (ADRs) are a chief origin of anguish and place a strong burden on limited health-care resources. Drug safety is a major concern in the field of medicine. ADR reports can indicate the important safety issues on drug treatment. According to the World Health Organization (WHO), an ADR is described as "a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of a disease or for modifications of physiological function" [1].

Serious adverse events can cause admission to hospital, prolongation of hospitalization, increase in investigations or treatment costs, poor work adherence, birth defects, and danger to life leading to death. ADRs are crucial or essential origin of death and anguish. The primordial disclosure, assessment, checking, and recording of ADR are vital to cause drug treatment safe, constructive or capable, and cost efficient [2]. The occurrence and ferocity of ADRs can be controlled by patient-linked or connected elements such as age, sex, simultaneous illness, and genetic factors and drug-linked elements such as type of medication, course or way of administration, time or period of therapy, and dose. According to a study, the almost bothersome classes of medications providing to ADRs were antibiotics ensued by anticancer medications [3].

Antibiotics are the almost usually specified or authorized medication in hospitals, worldwide. However, extravagant and improper use of antibiotics gives its most important restriction or constraint, i.e., increased drug resistance [4]. The reasonable use of antibiotics is crucial in fitness care. Inhibition of ADRs is feasible or viable by actual or right checking, which reinforced the state mandate or regulation to institution alias a pharmacovigilance center in each medical college in the country [5,6].

Although India is the third largest medicine market in the world, it had documented only 2% of global ADRs until 2013. PvPI increased the ADR monitoring centers from 90 to 150 including the private hospitals, which led to increase in ADR reporting. India became the first country in reporting the individual case safety reports of more than one lakh to VigiFlow, Uppsala Monitoring Center. One of the most important ways to prevent adverse drug events is to share information since all medication errors are preventable which can be achieved by sensitizing awareness among the health-care professionals to report and follow-up the events [7].

Chief purpose of the study was to regulate the protection (ADR) of medication usually specified or authorized in the pediatric unit of tertiaries care teaching hospital, for 6 months, find maximum regular or usual antibiotics that provide most ADRs, regulate or ascertain the list of maximum usually pompous organ system, and estimate the causation of ADR.

METHODS

A potential, data-based, non-interventionist study was conducted or executed in the Department of Pediatrics from November 2016 to April 2017 to analyze the ADRs reported spontaneously from the hospital. Patient statistics, objective and medication information, data of ADRs, onset time, causal drug details, outcome, and severity were collected as per the Central Drug Standard Control Organization, Indian Pharmacopoeia Commission (CDSCO) adverse drug event reporting form. Descriptive statistics were used to analyze the data.

Ethics

The study was evaluated and endorsed by the Institutional Ethics Committee of Vels University (Ref. No.: DOPV/2016/23). Confidentiality of data was maintained.

Table 1: Gender distribution of ADR in pediatrics

Gender	Overall=72 (%)
Male	40 (55.55)
Female	32 (44.44)

All values are mentioned as total (%). ADR: Adverse drug reaction

Table 2: Age group distribution of ADR

Age (years)	Overall=72 (%)
≤1	0 (0)
2–5	31 (43.05)
6–9	22 (30.99)
≥10	19 (26.76)

All values are mentioned as total (%). ADR: Adverse drug reaction

Table 3: Organ system affected due to ADR

S. No.	Organ system affected	Number of ADRs (%)
1	Urinary system	3 (4.17)
2	Gastrointestinal system	18 (25)
3	Respiratory system	13 (18.06)
4	Skin and appendages	10(13.89)
5	Central and peripheral system	8 (11.11)
6	CVS	11 (15.28)
7	Musculoskeletal system	8 (11.11)
8	Hematopoietic system	1 (1.39)
	Total	72 (100)

All values are mentioned as numbers and percentages. CVS: Cardiovascular system, ADR: Adverse drug reaction

RESULTS AND OBSERVATIONS

A sum of 72 ADRs was accumulated or gathered, filed or listed in CDSCO forms, studied or examined and appraised on the WHO causation computation scale. The information gathered amid the 6 months period was examined for the sum of ADRs recorded and the precipitating drug.

Study divulged or exposed that male patients, 40 (55.55%), were predominated over female patients, 32 (44.44%), in ADR occurrence (Table 1).

The age-wise transportation of ADRs divulged or exposed that young kids (2–5 years) were 43.05%, kids (6–9 years) were 30.99%, and children (>10 years) were 26.76% (Table 2).

This study reveals that gastrointestinal tract (25%) was the almost pompoused organ system by ADR due to medicines succeeded by the respiration system (18.06%), cardiovascular system (CVS) (15.28%), skin (13.89%), central nervous system (CNS) (11.11%), musculoskeletal system (11.11%), urinary system (4.17%), and hematopoietic disorders (1.39%) (Table 3).

Utmost ADR was declared with beta-lactams (ceftriaxone, cefotaxime, piperacillin/tazobactam, and amoxicillin/clavulanic acid) (52.78%), followed by quinolones (ciprofloxacin) (11.11%), aminoglycosides (amikacin and gentamycin) (22.22%), and metronidazole and others (13.89%) (Table 4).

The most common ADR was found to be abdominal pain (11.11%), vertigo (4.17%), dyspnea (1.39%), nausea and vomiting (11.11%), restlessness (1.39%), cough (13.89%), fatigue (8.33%), oral ulcers (1.39%), throat pain (11.11%), anxiety (1.39%), rashes (4.17%), diarrhea (5.56%), change in stool color (11.11%), body ache (1.39%), headache (5.56%), nasal blockage (1.39%), constipation (4.17%), and itching and inflammatory swelling (1.39%) (Table 5).

The estimation by the WHO Causation Estimation Scale demonstrated that, of 72 ADRs, 4 (5.56%) were certain, 40 (55.56%) were possible, 22 (30.56%) were probable, and 6 (8.33%) were unlikely (Table 6).

Table 4: Therapeutic class of antibiotics implicating ADR

S. No.	Class of drugs	Drug name	Number of ADRs (%)
1	Beta-lactams	Ceftriaxone	8 (25.00)
2		Cefotaxime	8 (11.11)
3		Piperacillin/tazobactam	4 (5.56)
4		Amoxicillin/clavulanic acid	8 (11.11)
5	Quinolones	Ciprofloxacin	8 (11.11)
6	Aminoglycosides	Amikacin	4 (19.44)
7		Gentamycin	2 (2.78)
8	Miscellaneous	Linezolid	1 (1.39)
9		Doxycycline	1 (1.39)
10		Clindamycin	2 (2.78)
11		Metronidazole	6 (8.33)
	Total		72 (100)

All values are mentioned as numbers and percentages. ADR: Adverse drug reaction

Table 5: Types of reactions observed

S. No.	Type of reaction	Number of ADRs (%)
1	Abdominal pain	8 (11.11)
2	Vertigo	3 (4.17)
3	Dyspnea	8 (11.11)
4	Restlessness	1 (1.39)
5	Cough	0 (13.89)
6	Fatigue	6 (8.33)
7	Oral ulcers	1 (1.39)
8	Throat pain	1 (1.39)
9	Nausea and vomiting	8 (11.11)
10	Anxiety	1 (1.39)
11	Rashes	3 (4.17)
12	Diarrhea	4 (5.56)
13	Change in stool color	2 (11.11)
14	Body ache	1 (1.39)
15	Headache	4 (5.56)
16	Nasal blockage	1 (11.11)
17	Constipation	3 (4.17)
18	Itching and inflammatory swelling	1 (1.39)
	Total	72 (100)

ADRs: Adverse drug reactions

DISCUSSION

Antibiotics are reasoned or studied as the second most specified or authorized medication in the universe, only after to the drugs suggested for cardiac diseases [8]. Antibiotics are utilized for remedy and prevention or protrusion of different compatible state and are continued or reasoned as secured drugs when utilized reasonably. However, as with further medications, they also exhibit ADRs. This study attempted to determine the sign or paradigm of ADRs of antibiotic medication class. In the studies carried out in Nigerian children, antibiotics were the maximum or almost reported medication class in ADR incident or matter and they were the next almost considered in a further study [9]. In this study it was observed male patients were more than female patients. Further study, moreover, demonstrated the male supremacy and the age group almost considered were grown-ups in during examination. [10]. High antibiotic ADRs were noticed in pediatrics departments and perhaps due to periodic or regular direction of medication in these units. The alimentary tract was the most affected system by ADR due to antibiotics followed by the respiratory system, CVS, skin, CNS, musculoskeletal system, urinary system, and hematopoietic disorders. Further studies, moreover, established the preponderance or prevalence of the alimentary canal system succeeded by the dermis in ADR occurrence [11,12]. Among the ADRs, major proportions of adverse reactions were seen with beta-lactam antibiotics which were similar to the observation by Tunger *et al*. [13]. This can be explained by the more common prescribing of beta-lactam antibiotics among the study population [14]. When we analyze the presentation of reactions, almost 75% showed abdominal pain followed by throat pain, cough,

Table 6: Classification of ADR Based on WHO Causality Assesment Scale

S. No.	Type of reaction	Number of ADRs (%)
1	Certain	4 (5.56)
2	Possible	40 (55.56)
3	Probable/likely	22 (30.56)
4	Unlikely	6 (8.33)
5	Unclassified	0 (0.00)
6	Conditional	0 (0.00)
	Total	72 (100)

All values are mentioned as numbers and percentages. WHO: World Health Organization

rashes, nausea, and vomiting. Causality assessment of ADRs by the WHO Probability Scale revealed that 40% of ADRs were probable and 60% of ADRs were possible in accordance with a study done which had recorded 88.6% as probable [15]. The drug suspected to have caused the ADR was dechallenged in several patients, its dose was modified in some patients and was substituted with another drug in few patients [16]. A great majority of the cases or ills cured from ADR since neither one of the recorded reactions were deadly or harmful [17]. ADR result in diminished quality of life which leads to hospitalizaton and sometimes to death [18]. Most of the ADRs are observed by medical supervision from reports and patient complaints [19].

CONCLUSION

Monitoring of ADRs is a continuous process as the number of newer drugs entering the pharmaceutical market is increasing. Health-care experts possess an essential role or duty in checking the progressive protection of medication. The occurrence of adverse drug events is not equivalent or constant of proportionality to the several or various medication being taken but enlarges extraordinarily as several or various medication advances. Pharmacovigilance demands or wants to be imposed in our state for superior or finer and safe utilize of drugs. Early recognition and management of ADRs are essential to reduce the burden of ADRs.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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