

## Research Article

# Assessment of prescription pattern and monitoring adverse drug reaction of antibiotics in paediatric inpatients

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**Received:** 14 June 2016

**Accepted:** 08 July 2016

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### ABSTRACT

**Background:** Antibiotics constitute more than one third of prescriptions in paediatrics. Antibiotic prescribing pattern should be evaluated periodically in order to increase the rationality of use. The indiscriminate use of antibiotics results in increased occurrence of adverse drug reactions, suboptimal therapy, polypharmacy and antibiotic resistance. Hence, the present study is to assess the prescription pattern and the extent of adverse drug reactions due to antibiotic usage.

**Methods:** A prospective observational study was conducted in Basaveshwara Medical College Hospital and Research Centre, Chitradurga, Karnataka, India for a period of six months. This study included patients prescribed with antibiotics in paediatric ward. All data including patient's demographic details, symptoms and treatment pattern were collected and documented in data collection form. Adverse Drug Reactions (ADRs) were reported by using an ADR reporting form. ADR were assessed using Naranjo's scale.

**Results:** Among the 160 patients 54% patients were males, 45% patients were under the age group 1-5 years. 50% of the diagnosis was acute gastroenteritis and bronchopneumonia. 80% of total antibiotics prescribed were cephalosporins which include 99% of ceftriaxone. A total of 14 ADRs were observed in the study. The occurrence of probable ADR was 6% and possible ADR was 3%. 79% of ADR caused gastro intestinal disturbances while 14% caused dermatological disorders and 7% caused other disorders.

**Conclusions:** Although some ADR was present in the study, the antibiotic prescription in the patients who acutely needed was prescribed appropriately, where it proved to be beneficial.

**Keywords:** Antibiotics, Adverse drug reaction, Prescription pattern, Paediatric

### INTRODUCTION

Antibiotics are the key drugs for treatment of infections and are the mostly prescribed drugs in paediatric groups. Paediatric patients are among the most vulnerable group to contact illnesses and cause harmful effects of drugs due to differences in pharmacodynamic and pharmacokinetics. The use of antimicrobial agents, particularly antibiotics has become a routine practice for the treatment of paediatric illnesses.<sup>1</sup> Evaluation of prescribing pattern will help in minimizing adverse drug reactions, as pediatric groups are more liable to them and it shall also aid in providing cost effective medical care.<sup>2</sup>

Effective treatment is based on accurate diagnosis & rational treatment of the medical condition. The antibiotics are more effective and play an important role in management of infectious diseases if the diagnosis is accurate. However, they can lead to many serious consequences ranging from super infection and results in emergence of multidrug-resistant micro-organism which is expected to cause more serious infections.<sup>3</sup>

The increased incidence of antibiotic resistance is a major threat to the medical field.<sup>4</sup> Hence, studies are required to obtain baseline data about prescribing pattern and to communicate to the prescribers for improving prescription in terms of increased therapeutic value and

decreased adverse effects. The data collected will be helpful in planning longitudinal studies on prescribing and drug use patterns.<sup>5</sup>

Antibiotic guidelines are standard set of guidelines for the treatment of infectious diseases. These guidelines help the physician to prescribe the antibiotics rationally to paediatric patients when undeniably indicated (WHO model formulary for children, 2010). Children are at high risk for opportunistic infections due to intensive antibiotic therapy. The indiscriminate use of antibiotics results in increased incidence of adverse drug reactions, treatment failure, suboptimal therapy, polypharmacy and most importantly, the occurrence of antibiotic resistance. Drug utilization in paediatric pharmacotherapy is more essential since one-third of total prescriptions in preschool children are systemic antibiotics.<sup>2</sup> Judicious use of antibiotic is therefore an important way to reduce the antimicrobial resistance.

Hence, to bring out awareness in health care professionals on adverse drug reactions and prescription pattern the study was found to be beneficial.

**METHODS**

A prospective observational study was conducted at Basaveshwara Medical College Hospital & Research Centre (BMCH and RC), Chitradurga, Karnataka, India. The patients admitted in pediatric department of the hospital with infectious diseases were included in the study. In the study population, patients were categorized into four according to age group (<1years, 1-5years, 6-10ears and >10years). A data collection form that carries

demographic details of the patients like age, sex, diagnosis, prescription pattern and scores of ADR assessing scales were prepared.

The study was approved by the “Institutional Human Ethical Committee” of the S.J.M College of Pharmacy, Chitradurga (SJMCP/IEC/543D/2014-15; Date-13/10/2014). The data was entered in Microsoft Excel-2007 version and the results were analysed using Statistical Package for Social Services (SPSS 19.0). Descriptive Method was used for analysis.

**RESULTS**

*Prescription pattern of antibiotics according to diseases*

A total of 191 antibiotics were prescribed among 160 patients. Among the total antibiotics prescribed, Cephalosporins were 152(80%), followed by aminoglycoside 18(9%), quinolones 13(7%), antibiotic combination 4(2%), B-lactamase inhibitors 2(1%), macrolide antibiotics 1(1%).

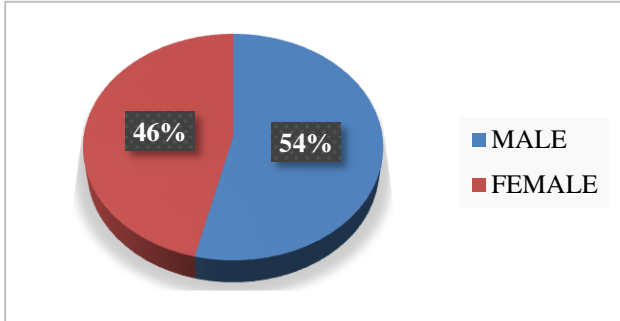
Among the total 191 antibiotics, 80% of antibiotics prescribed were cephalosporins which include 99% of ceftriaxone and 1% of cefixime. The mostly used aminoglycoside antibiotic was amikacin, and the widely used quinolone antibiotics were ofloxacin. Cephalosporins were prescribed for majority of diseases; those are mentioned in table no.1, while quinolones were mainly prescribed for typhoid fever.

**Table 1: Prescription of antibiotics according to diseases.**

Disease	Aminoglycoside	Cephalosporin	b-lactamase inhibitors	Quinolones	Macrolides	Combination therapy	Total
Acute Gastroenteritis	3	40					43
Broncho-Pneumonia	10	32	2			3	47
LRTI	1	22				1	24
Typhoid fever		19		13			32
URTI		16					16
Acute Bronchiolitis		8					8
UTI		7					7
Malaria		3					4
Meningitis	2	3					5
Pulmonary TB	2	2			1		5
Total	18	152	2	13	1	4	191
% of total antibiotics prescribed	9%	80%	1%	7%	1%	2%	100%

**Distribution of patient according to gender**

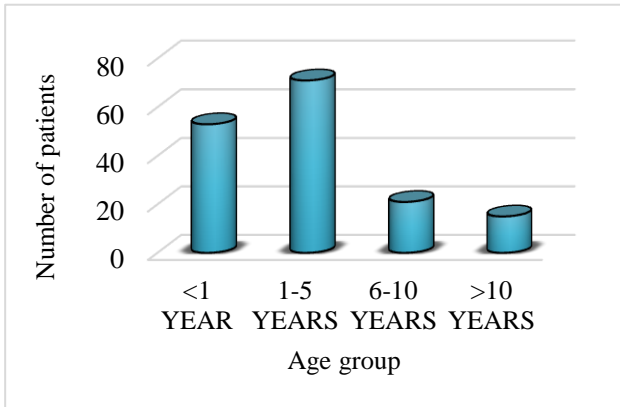
In the study population, 86 patients were males and 74 were females. The results are graphically represented in Figure 1.



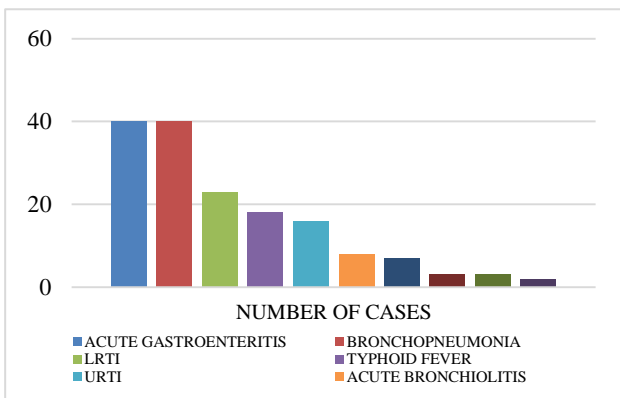
**Figure 1: Distribution of patients according to gender.**

**Distribution of patients according to age group**

In our study, patients were divided into four groups based on age. Out of 160 patients, 71 patients were from 1-5 years followed by 53, 21, 15 patients from <1 year, 6-10 years and > 10 years respectively. The results are graphically represented in Figure 2.



**Figure 2: Distribution of patients according to age group.**



**Figure 3: Distribution of patients according to disease.**

**Table 2: Distribution of patient based on number of antibiotics per prescription.**

Total number of prescriptions	160	100%
Prescriptions with one antibiotic	132	83%
Prescriptions with two antibiotics	26	16%
Prescriptions with more than two antibiotics	2	1%

**Table 3: Distribution of ADR base on antibiotics prescribed.**

Drug class	Drug	Description of ADR	Number of patients
Cephalosporins	Ceftriaxone	Vomiting	5
		Rashes	1
		Diarrhoea	3
		Vomiting and diarrhoea	3
		Arthralgia	1
Quinolones	Ofloxacin	Arthralgia	1
b-lactamase inhibitors	Tazobactam	Rashes	1

**Table 4: Causality assessment of ADR Using Naranjo scale.**

Severity	Number of patients	% of occurrence
Doubtful (0)	0	0%
Possible (1-4)	5	3%
Probable (5-8)	9	6%
Definite (>9)	0	0%

**Distribution of patients according to disease**

In the study population, 25% patients had acute gastro enteritis and bronchopneumonia, followed by 14% LRTI patients, 11% typhoid patients, 10% URTI patients, 5% acute bronchiolitis patients, 4% UTI patients, 2% malaria patients, 2% meningitis patients and 1% pulmonary TB patients which is depicted in Figure 3.

**Distribution of patient based on number of antibiotics per prescription**

Among the total 160 patients, one antibiotic was prescribed to 132 (83%) patients, two antibiotics for 26 (16%) patients and three antibiotics for 2 (1%) patients. Table 2 explains the distribution of patient based on number of antibiotics per prescription.

**Distribution of ADRs based on antibiotics prescribed**

Among the total 14 ADR observed, 12 (86%) ADR occurred in cephalosporins, 1 (7%) ADR was occurred in quinolones and B-lactamase inhibitor which is shown in Table 3.

### **Causality assessment of ADR using Naranjo scale**

A total of 14 ADRs were observed in 160 prescriptions. The percentage of occurrence of probable (5-8) ADR is 6% and possible (1-4) ADR is 3% among the total prescriptions collected which is explained in Table 4.

### **DISCUSSION**

The safety of drugs used in patients of an adult age group cannot be extrapolated to a paediatric age group.<sup>6</sup> The pharmacokinetics and pharmacodynamics of many commonly used drugs vary significantly between these two age groups of patients.<sup>7</sup> Further, adverse drug reactions (ADRs) in children can have a relatively more severe effect when compared to adults. The ADRs can lead to significant morbidity among children.<sup>8</sup> It has been observed that ADR in pediatric not only result in hospital admissions or prolonged hospitalization but also may lead to permanent disability or even death.<sup>9</sup>

Kanish R conducted a study on prescribing pattern of antibiotics in the department of paediatrics in a tertiary care medical college hospital. Cephalosporins were maximally prescribed followed by aminoglycosides which is also the trend seen in another study done by Pandey AA on prescription analysis of paediatric outpatient practice in Nagpur city.<sup>2,10</sup> In the present study, the total antibiotics prescribed contains cephalosporin 152 (80%), aminoglycoside 18 (9%), quinolones 13 (7%), antibiotic combination 4 (2%), B-lactamase inhibitors 2 (1%), macrolide antibiotics 1 (1%) each. 80% of antibiotics prescribed was cephalosporin which include 99% of ceftriaxone and 1% of cefixime. The mostly used aminoglycoside antibiotic was amikacin, and the widely used quinolone antibiotics were ofloxacin.

Shamshy K conducted a study on Drug utilization of antimicrobial drug in paediatrics population in a tertiary care hospital in Erode.<sup>11</sup> In the present study a total of 14 ADRs were observed in 160 prescriptions. The percentage of occurrence of probable (5-8) ADR is 6% and possible (1-4) ADR is 3% among the total prescriptions collected. Among the total of 14 ADR observed, 12 (86%) ADRs were occurred with cephalosporins, 1(7%) ADR was occurred with quinolones and B-lactamase inhibitors. 79% of ADR caused gastro intestinal disturbances while 14% caused dermatological disorders and 7% caused other disorders. Gastro intestinal disorders mainly include diarrhoea and vomiting. Rashes are the main dermatological disorder. Arthralgia is also observed, but compared to other ADR its occurrence is very less.

### **CONCLUSION**

Antibiotic prescriptions showed some risks such as presence of some ADR and prescription other than monotherapy of antibiotics.

Antibiotic prescription in the patients who acutely needed was prescribed appropriately, where it proved to be beneficial.

### **ACKNOWLEDGEMENTS**

Authors are thankful to the management SJM Vidyapeetha, and Principal of SJM College of pharmacy and Basaveshwara Medical College Hospital and Research Centre, Chitradurga, Karnataka, India for providing suitable facilities for the successful completion of our study.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Issac AJ, Yogananda R, Mohamed Shehin T. Assessment of prescription pattern and monitoring adverse drug reaction of antibiotics in paediatric inpatients. *Int J Contemp Pediatr* 2016;3:1071-5.