STUDY OF ANTIBIOTIC UTILIZATION IN PEDIATRICS – A MULTICENTRIC OBSERVATIONAL STUDY

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ABSTRACT

Objective: To analyze the contents of the antibiotic prescribed in paediatrics in various health care facilities- an observational study. **Methods**: The observational study was carried out for a period of 4 months from February 2014 to April 2014 at four different hospitals of Navsari district during which prescriptions were reviewed. **Results**: Altogether 549 patients, 279 males (50.8%) and 270 females (49.2%) were enrolled. Most common diseases were upper respiratory tract infection (59.2%), lower respiratory tract infection (16.2%), gastroenteritis (13.1%), diarrhoea (2%), and malaria (2.7%). Most used antibiotics were Amoxicillin (27.9%), azithromycin (21.5%),

ceftriaxone (10.4%). In gastroenteritis most used drug was ofloxacin (3.5%), in diarrhoea was ofloxacin (0.5%), in URTI was amoxicillin (21.9%). When antibiotic prescribing was compared with standard guidelines adequate dose was found in 39.2% patients. Low dose was found in 32.8% patients, while high dose was found in 28.1% patients. **Conclusion:** The treatment regimen implemented in most of the cases was without doing any culture sensitivity test. It is mandatory to prepare guidelines for antibiotic prescription.

Key words: Pediatric antibiotic utilization, inpatient, outpatient, drug utilization evaluation.

Introduction

A drug use evaluation is performance improvement method that focuses on evaluating and improving medication use processes with the goal of improving patient outcomes [1]. For each individual patient, rational drug usage entails the prescription of a well-researched medication at the ideal dosage for the appropriate indication and at a reasonable cost [2]. Operations spanning Multiple disciplines that gather, organise, analyse, and report information on real drug usage are known as qualitative drug utilisation studies. The gathering, organising, and presentation of estimates or measurements of drug usage are all part of quantitative drug utilization research [3,4]. Epidemiological analysis of older patients' medication usage has recently gained a lot of attention, while research on drug use in children has been scarce [5]. About 28% of the world's population is made up of newborns and children, who are more prone to illness since their immune systems are still developing [6]. Among paediatric patients, antibiotics are one of the most often given therapeutic drugs. Several surveys, between 50 and 85 percent of children in both industrialized and developing nations receive antibiotics on a doctor's prescription [7,8]. Utilizing antibiotics ineffectively, this can result in antibiotic resistance, poor treatments, and higher healthcare costs

[9]. Epidemiological analysis of adults' medication usage is currently a hot topic, while research on drug use in children has been limited [10]. Due to pharmacodynamic and pharmacokinetic variations, paediatric populations are among the most susceptible to diseases and adverse medication effects [11,12]. Recurrent infections of the digestive and respiratory tract are common in the paediatric population [13]. Because of its close ties to fields like public health, pharmacovigilance, pharmacoeconomics, and pharmacogenetics, drug use studies in pharmacoepidemiology have grown in significance [14]. Setting priorities for research in this population can be made easier by increasing our understanding of how drugs are used in newborns [15].

Materials and Methods

Study site

This antibiotic utilization research investigation was carried out at four pediatric hospitals in Navsari district, Gujarat, India.

Study period

The study was an observational study conducted over a specific time frame of 4 months, from January 2014 to April 2014. Literature review, data entry format preparation, case collection, and data analysis was done.

Study design: An observational research project

Patient selection

Inclusion criteria:

- Willingness of parents/ legal representative to give written informed consent.
- Outpatients suffering from any infectious disease
- In patients suffering from any infectious disease

Exclusion criteria:

- Those receiving only topical antibiotics such as eye drops, ear drops, ointment etc.

Study material

Case report form

A specially designed case report form was used to enter all patients' details like patient's name, age, gender, weight, diagnosis, brand name of antibiotic, type, route of administration, dose, frequency, duration of administration, type of dosage form etc.

Enrollment of patients

Patient consent form

In this Title of study, purpose, procedure, Benefits, confidentiality, volunteer participation was briefly and clearly explained to patients'parents. It should obtain without undue inducement or element of force, fraud, duress or coercion.

Evaluation parameters

Many evaluation criteria were taken into account, including demographic characteristics, Diagnosis, Antibiotic data etc.

Statistical analysis

The Mean & Standard Error of Mean were calculated. Data was coded and entered into SPSS for statistical analysis. Descriptive statistics calculated with all socio demographic and clinical data. Chi square test was performed. P <0.05 was considered to be significant.

Results and Discussion

Patient's descriptive

Total 549 patients, comprising 94 of Inpatient and 455 of Outpatient were reported. Most male patients were found in age group of 2-6 years 29.4% (82) followed by age group of less than 1 year 27.2% (76) patients. In female patients most numbers were found in age group of 2-6 years 35.2% (95), followed by a greater number of patients in age group of less than 1 year 26.3% (71) patients. Similar finding was there previously too [16].

Table 1-AGE GROUP DISTRIBUTION ACCORDING TO GENDER

Age group (year)	Male N (%)	Female N (%)
Less than 1	76(27.2)	71(26.3)
1-2	54(19.4)	43(15.9)
2-6	82(29.4)	95(35.2)
6-10	46(16.5)	33(12.2)
More than 10	21(7.5)	28(10.4)
Total	279(100)	270(100)

Types of diseases

In all age groups, URTI was the condition that required the most antibiotic prescriptions, followed by LRTI in terms of patient volume. Similar data found with R. Senthilselvi et al [17].

Table 2- DISTRIBUTION OF DIAGNOSIS IN DISEASES ACCORDING TO AGE GROUP

Age group (years)	Gastro-Enteritis N (%)	Diarrhoea N (%)	URTI N (%)	Malaria N (%)	LRTI N (%)	UTI N (%)	Combined diseases N (%)	Other N (%)
Less than 1	19(3.5)	7(1.3)	80(14.6)	1(0.2)	36(6.6)	0	4(0.7)	0
1-2	19(3.5)	0	53(9.7)	5(0.9)	14(2.6)	1(0.2)	2(0.4)	3(0.5)
2-6	16(2.9)	3(0.5)	113(20.6)	5(0.9)	25(4.6)	1(0.2)	8(1.5)	6(1.1)
6-10	8(1.5)	1(0.2)	53(9.7)	3(0.5)	9(1.6)	1(0.2)	3(0.5)	1(0.2)
More than 10	10(1.8)	0	26(4.7)	1(0.2)	5(0.9)	1(0.2)	0	6(1.1)
Total	72(13.1)	11(2)	325(59.2)	15(2.7)	89(16.2)	4(0.7)	17(3.1)	16(2.9)

Antibiotic descriptive

The most used antibiotics were of chemical class β-lactum 57.7% (317), followed by macrolides 22.2% (122). Flouroquinolones were used in 9.5% (52) patients, nitroimidazole and sulphonamides were used in 4.6% (25) patients. In overall patients, amoxicillin was used in 27.9% (153) patients followed by azithromycin in 21.5% (118) patients followed by ceftriaxone in 10.4% (57) patients.

Table 3(a) shows classwise distribution of antibiotics. Aminoglycosides were prescribed more in LRTI 0.9% (5). β-lactum drugs were prescribed more in URTI 35.3% (194) patients. Macrolides were most prescribed in URTI 19.9% (109). Fluoroquinolones were more prescribed in gestro enteritis 5.5% (30). Somewhat different data were obtained by *Sri and Mohiuddin* [16].

Table 3(a) Chemical class wise distribution of anti-infective drugs in different diagnosis

Chemical class of antibiotics	Diagnosis							
	Gastro-Enteritis N (%)	Diarrhoea N (%)	URTI N (%)	Malaria N (%)	LRTI N (%)	UTI N (%)	Combined diseases N (%)	Other N (%)
Aminiglycosides	0	1(0.2)	1(0.2)	0	5(0.9)	0	0	0
β-lactum	18(3.3)	3(0.5)	194(35.3)	11(2)	77(14)	1(0.2)	7(1.3)	6(1.1)

Macrolides	1(0.2)	0	109(19.9)	1(0.2)	7(1.3)	0	3(0.5)	1(0.2)
Tetracyclines	0	0	0	0	0	0	0	1(0.2)
Fluoroquinolones	30(5.5)	5(0.9)	9(1.6)	2(0.4)	0	1(0.2)	2(0.4)	3(0.5)
Nitroimidazole	17(3.1)	2(0.4)	2(0.4)	1(0.2)	0	0	3(0.5)	0
Sulphonamides	6(1.1)	0	10(1.8)	0	0	2(0.4)	2(0.4)	5(0.9)
Total	72(13.1)	11(2)	325(59.2)	15(2.7)	89(16.2)	4(0.7)	17(3.1)	16(2.9)

Table 3(b) shows distribution of antibiotics in various diagnoses. In gastroenteritis most use drug was ofloxacin 3.5% (19). In diarrhoea more used drug was ofloxacin 0.5% (3). In URTI most used drug was amoxicillin 21.9% (120). In LRTI most used drug was amoxicillin 4.9% (27). While in study done by Maqbool et al ceftriaxone and amikacin were used more [18].

Table 3(b) Distribution of antibiotic drugs according to diagnosis in pediatric patients

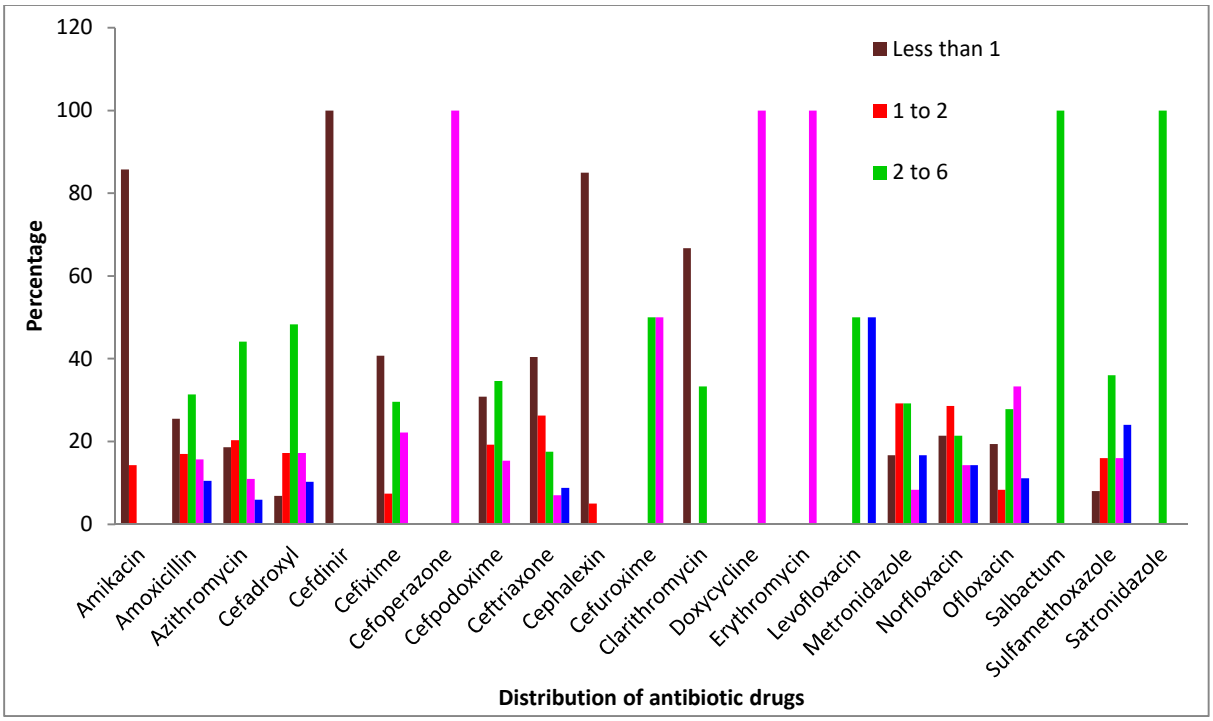
Name of antibiotics	**Diagnosis**							
	Gastro-Enteritis N (%)	**Diarrhoea N (%)**	**URTI N (%)**	**Malaria N (%)**	**LRTI N (%)**	**UTI N (%)**	**Combined diseases N (%)**	**Other N (%)**
Amikacin	0	1(0.2)	1(0.2)	0	5(0.9)	0	0	0
Amoxicillin	0	0	120(21.9)	0	27(4.9)	0	1(0.2)	5(0.9)
Azithromycin	1(0.2)	0	105(19.1)	1(0.2)	7(1.3)	0	3(0.5)	1(0.2)
Cefadroxyl	0	0	29(5.3)	0	0	0	0	0
Cefdinir	0	0	0	0	1(0.2)	0	0	0
Cefixime	2(0.4)	2(0.4)	11(2)	0	9(1.6)	1(0.2)	2(0.4)	0
Cefoperazone	0	0	0	0	1(0.2)	0	0	0
Cefpodoxime	2(0.4)	0	7(1.3)	0	17(3.1)	0	0	0
Ceftriaxone	13(2.4)	1(0.2)	4(0.7)	11(2)	23(4.2)	0	4(0.7)	1(0.2)
Cephalexin	0	0	20(3.6)	0	0	0	0	0
Cefuroxime	0	0	2(0.4)	0	0	0	0	0
Clarithromycin	0	0	3(0.5)	0	0	0	0	0
Doxycycline	0	0	0	0	0	0	0	1(0.2)
Erythromycin	0	0	1(0.2)	0	0	0	0	0
Levofloxacin	1(0.2)	0	1(0.2)	0	0	0	0	0

Metronidazole	16(2.9)	2(0.4)	2(0.4)	1(0.2)	0	0	3(0.5)	0
Norfloxacin	10(1.8)	2(0.4)	0	0	0	1(0.2)	0	1(0.2)
Ofloxacin	19(3.5)	3(0.5)	8(1.5)	2(0.4)	0	0	2(0.4)	2(0.4)
Salbactum	1(0.2)	0	0	0	0	0	0	0
Sulfamethoxazole	6(1.1)	0	10(1.8)	0	0	2(0.4)	2(0.4)	5(0.9)
Satronidazole	1(0.2)	0	0	0	0	0	0	0
Total	72(13.1)	11(2)	325(59.2)	15(2.7)	89(16.2)	4(0.7)	17(3.1)	16(2.9)

While emphasizing on the administration of antibiotics to both inpatients and outpatients, In outpatient most frequently used antibiotics were amoxicillin, azithromycin, sulphamethoxazole, cefpodoxime. While in inpatients mostly used antibiotics were ceftriaxone, ofloxacin, amikacin. When we consider distribution of antibiotics according to gender, Amoxicillin, azithromycin, cefixime, cefadroxyl, ceftriaxone, cephalexine, metronidazole, and ofloxacin were the most commonly used antibiotics in male patients, accounting for 52.3% (80), 52.5% (62), 51.9% (14), 37.9% (11), 49.1% (28), and 55% (11), respectively. The most common antibiotics used in female patients were amoxicillin 47.7% (73), azithromycin 47.5% (56), cefadroxyl 62.1% (18), cefpodoxime 57.7% (15), ceftriaxone 50.9% (29), ofloxacin 50% (18), sulfamethoxazole 56% (14) etc. In other study more prescribed drugs were amikacin, fluoroquinolones and ampicillin [19].

Figure 1 shows distribution of antibiotics in age group. In different age group antibiotic selection was different. Amoxicillin was used in 2-6year patients 31.4% (48), azithromycin was used in 2-6year patients 44.1% (52), ceftriaxone was used in less than 1year patients 40.4% (23), sulfamethoxazole was used in 2-6year patients 36% (9).

Figure 1 Representation of distribution of antibiotic drugs according to age group



When we talk about dosage form distribution in pediatrics, most antibiotics were prescribed in syrup form 45.7% (251). Antibiotics prescribed in tablet form were 39% (214), while in injection form were 15.3% (84). Similar findings were obtained with another study too [20].

When discussing antibiotic prescription with diff. Dosage forms, ceftriaxone 57% (10.4), ofloxacin 2.9% (16), amikacin 1.3% were mostly prescribed in injection form. While azithromycin 41% (103), amoxicillin 21.5% (54), metronidazole 7.6% (19), sulfamethoxazole 6.4% (16) were prescribed in syrup form. Amoxicillin 45.8% (98), cefadroxyl 13.6% (29), cefixime 7.5% (16), were prescribed in tablet forms.

When we emphasize on distribution of dosage form in diff. Age groups, different dosage forms were prescribed in various age groups. In most age group syrup form was preferred except more than 10 years age; it had more prescription of tablet form. Overall injection form was prescribed in 15.3% (84); syrup form was prescribed in 45.7% (251), while tablet form was prescribed in 39% (214) patients.

Comparison with standard guidelines

When antibiotic prescribing was compared with standard guidelines, Figure 2 shows that adequate dose was found in 39.2% (215) patients. Low dose was found in 32.8% (180) patients, while high dose was found in 28.1% (154) patients.

Figure 2 Representation of dose according to standard guidelines

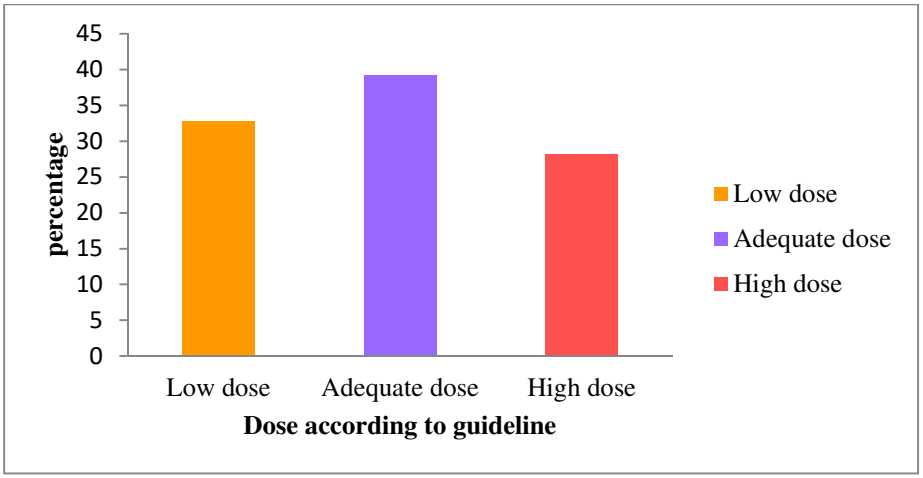


Table 4 shows dose according to guidelines in diff. Type of patients. In inpatients adequate doses were prescribed in 60.6% (57) patients, low doses were in 8.5% (8) patients and high doses were in 30.9% (29) patients. In outpatients, adequate doses were prescribed in 34.7% (158) patients,

low dose were in 37.8% (172) patients and high doses were in 28.1% (154) patients. Significant difference was found between the dose prescribed and type of patients. (X^2=34.062, p= 0.000)

Table 4 Dose according to guideline in different type of patient

Type of patient	Dose according to guidelines		
	Low dose	Adequate dose	High dose
Inpatient	8(8.5)	57(60.6)	29(30.9)
outpatient	172(37.8)	158(34.7)	125(27.5)
Total	180(32.8)	215(39.2)	154(28.1)
X^2=34.062, p=0.000*			

Chi-Square test was applied.

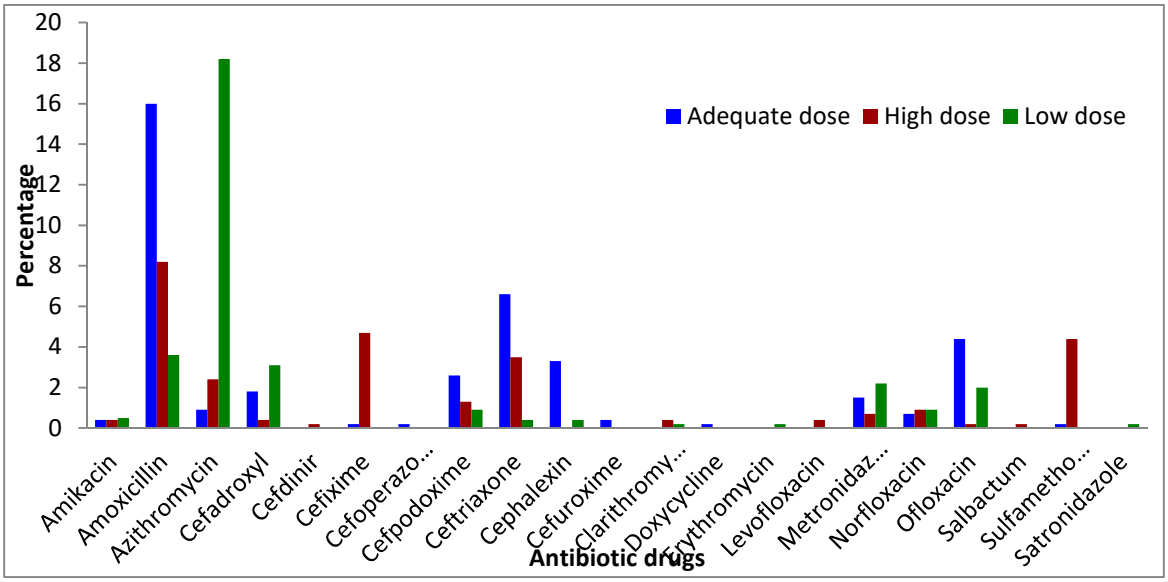
*----significant (P < 0.05)

According to guideline in diff. Gender, in male patients, low doses were prescribed in 32.3% (90) patients, adequate doses were prescribed in 40.9% (114) patients while high doses were prescribed in 26.9% (75) patients. In female patients, low doses were prescribed in 33.3% (90), adequate doses were prescribed in 37.4% (101) patients and high doses were prescribed in 28.1% (154) patients. Significant difference was not found between dose prescribed and male and female patients. (X^2=0.743, p=0.690)

According to guidelines of chemical class of antibiotics, most adequate doses were prescribed of β-lactum antibiotics 31% (170), followed by fluoroquinolones 5.1% (28). High doses were prescribed of sulphonamides 4.4% (24), macrolides 2.7% (15). low doses were prescribed of macrolides 18.6% (102) and β-lactum 8.4% (46).

Figure 3 shows dose according to guidelines of prescribed antibiotic drugs. Most adequate doses were prescribed of amoxicillin 16% (88) and ceftriaxone 6.6% (36). High doses were prescribed of 8.2% (45) and cefixime 4.7% (26). Low doses were prescribed of azithromycin 18.2% (100) and amoxicillin 3.6% (20).

Figure 3 Representation of dose according to guidelines of prescribed antibiotic drugs.



Conclusion

According to the study, the majority of the time, treatment plans were followed without doing any type of culture sensitivity test, which could result in the widespread use of irrational prescriptions. There is the need for microbiological support for clinicians to increase the rate of appropriate prescription. From this study, feedback information can be provided to the prescribers and to improve the prescription patterns so as to avoid antibiotic prescription for viral cases and enable the patients to get the prescription for the required period. According to this study, the majority of prescriptions contained broad spectrum antibiotics, which contributed to the development of drug resistance. From this study it can be concluded that it is mandatory to prepare guidelines for antibiotic prescription and use appropriate drugs for the disease rather than prescribing broad spectrum antibiotics. The findings of this study show that continuing medical education (CME) programmes for doctors on the usage of antibiotics are necessary.

Acknowledgments: None.

Conflict of interest: None.

Financial support: None.

Ethics statement: Study has been approved by Human Research Ethics Committee with proposal number MPC/HREC/01/2013-14.

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