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PRESCRIBING PATTERN AND SUSPECTED ADRs ASSOCIATED WITH ANTIBIOTICS PRESCRIBED FOR RTI IN PAEDIATRIC DEPARTMENT

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ABSTRACT

The study objective is to assess and analyze the prescribing pattern and suspected ADRs related with antibiotics prescribed for respiratory tract infections to the paediatric inpatients of a tertiary care hospital. A prospective observational study was carried out for a period of 6 months. One hundred and twenty case records of the inpatients were enrolled. Total of 120 inpatient prescriptions were collected. Males were predominant over females. Majority of the patients were between the age group 1- 5 years. The most common diagnosis was pneumonia (51.67%) among 110 lower respiratory tract infectious patients. The total number of antibiotic prescribed in our study was 178. Penicillins (48.32%) were the top most used class of antibiotics in this study followed by Cephalosporins (27.53%). Among Penicillins, Amoxicillin + Clavulanic acid (38.76%) were found to be mostly used. Monotherapy of antibiotics was high (52.81%). 85.4% of the antibiotics were given parenterally. Antibiotics were prescribed to paediatric patients based on empirical therapy. Among 84 Fixed Dose Combinations prescribed Amoxicillin + Clavulanic acid (82.1%) was the most commonly prescribed. In conclusion, we provide evidence justifying the need to modify the current approach to the management of RTI in the paediatrics. Minimizing inappropriate antibiotic use is thus the best way to control resistance.

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INTRODUCTION

Respiratory tract infections (RTI), one of the most common infections comprising of Upper Respiratory Tract Infection (URTI) and Lower Respiratory Tract Infection (LRTI) are associated with considerable expenditure of currency of the nation[1].

The most common URTIs include common cold, laryngitis, pharyngitis, tonsillitis, acute rhinitis, acute rhinosinusitis and acute otitis media. LRTIs include acute bronchitis, bronchiolitis, pneumonia and tracheitis. As primary care, antibiotics are preffered for RTI.[2].

It is estimated that at least 300 million episodes of Acute Respiratory Infections (ARI) occur every year in India.[3]. In many developing countries RTI is recognized as the leading cause of morbidity and mortality [4].

In India, Acute Respiratory Tract Infections (ARTI) is one of the main reason for millions of deaths. Out of these, 10-15% is due to Acute Lower Respiratory Tract Infections (ALRTIs)[5].The common LRTIs in children are pneumonia and bronchiolitis.

Paediatric population is susceptible to suffer from repeated respiratory tract infections. In developing countries 25% of all paediatric admissions are due to ARTI and which ultimately causes death of 3.5 million children each year[6].

ANTIBIOTICS

Antibiotics are substances produced by microorganisms, which suppress the growth of or kill other microorganisms at very low concentrations. Antibiotics are the commonly prescribed drugs for treatment of respiratory infections in paediatric department. Antibiotic treatment is beneficial to children only if symptoms persist for 10-14 days without improvement. Antibiotic use must be cautiously monitored, an improper or overuse of antibiotics could lead to resistance in any age group people. Paediatric patients are speciality group and inappropriate use of antibiotics may lead to further complications[7].

Proper antibiotic use is the best way to control resistance. The WHO Global Strategy defines the convenient use of antibiotics as the cost-effective which maximizes clinical therapeutic effect while minimizing both drug-related toxicity and evolution of antimicrobial resistance[8].

According to the NICE guidelines, retarded antibiotic prescribing and/or no prescribing as strategies are very effective compared with an instant antibiotic prescribing schedule. Among antibiotics, penicillins are considered all over the world as first line[2].

"The quality of medical care requires prescribing to be judicious, appropriate, safe, effective and economic. "Good" prescribing is a complex balance between various conflicting factors"[6].

WHO describes ADR as "any response to a drug which is noxious and unintended, and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function". To make drug treatment, safe, efficacious and cost effective, early detection, evaluation, monitoring and reporting of ADR is necessary [9].

The study of prescribing pattern is a part of the medical audit and seeks to examine, assess, and if demanded, suggest improvement in prescribing practices to make rational and cost-effective treatment[6].

The purpose of our study was to assess and figure out the pattern of antibiotic use, and to ensure that drugs are used appropriately, safely and effectively to improve patients health status. Moreover, continual improvement in appropriate and effective use of drugs like antibiotics has potential to reduce the overall cost of health care[9]. Hence the objective of our study was to identify, assess and examine the prescribing pattern and suspected ADRs related with antibiotics prescribed for RTI in paediatric department of tertiary care hospital .

METHODOLOGY

STUDY SITE:

The study was conducted in RTI patients admitted in paediatric department of SSIMS & RC, Davangere, Karnataka.

STUDY DESIGN:

A prospective observational study.

STUDY DURATION:

The study was conducted for a period of six months.

SAMPLE SIZE:

The proposed sample size was 100 subjects.

SELECTION CRITERIA:

Inclusion criteria:

- All paediatric inpatients whose parents or legal guardians who are willing to give assent.
- All patients diagnosed with RTI.
- All prescriptions containing antibiotics in RTI patients.
- Patients with either sex.

Exclusion criteria

- Patients with tuberculosis.
- Patients in Intensive Care Unit (ICU).

ETHICAL APPROVAL:
Ethical approval was secured from The Institutional Ethical Committee of Bapuji Pharmacy College, Davangere, Karnataka.

DATA ANALYSIS:
A data collection form was prepared which contains details such as patient demographics details (age, sex, weight, DOA, etc), meticulous history, diagnosis, antibiotics prescribed, details of antibiotics causing suspected ADR. The data was collected from the case sheets of pediatric RTI inpatients to analyze prescribing pattern of antibiotics in management of RTI. The suspected ADR was identified by assessing the collected data. The final data was analyzed and represented graphically using MS Excel.

RESULTS
After proper examination, using the exclusion and inclusion criteria, 120 patients were enrolled in the study. Out of which 73 (60.8%) were males and 47 (39.2%) were female patients. Patients were divided into 4 age groups based on different age. In a total of 120 prescriptions, most of the patients were in the age group 1-5 years (N=57, 47.5%) followed by <1 year (N=37, 30.83%), 6-10 years (N=15, 12.5%) and 11-18 years (N=11, 9.17%).

- Among 120 paediatric patients, 62 (51.67%) were suffering from Pneumonia, followed by 18 (15%) suffering from Bronchiolitis

Table 1: DIAGNOSIS PATTERN IN PAEDIATRIC PATIENTS.

Diagnosis	No. of patients (n=120)	Percentage (%)
Pneumonia	62	51.67
Bronchiolitis	18	15
WALRI	11	9.17
Bronchitis	8	6.66
Bronchopneumonia	6	5
Pharyngitis	6	5
Asthma	5	4.17
Rhinitis	4	3.33
Total	120	100

Among 120 paediatric patients the distribution of illness according to diagnosis shows that majority (N=110, 91.67%) were suffering from LRTI, and (N=10, 8.33%) suffering from URTI. In our study 80 (66.7%) patients received single antibiotic.

Table 2: NUMBER OF ANTIBIOTICS IN EACH PRESCRIPTION.

No. of antibiotics per prescription	No. of patients (n=120)	Percentage (%)
Single Drug	80	66.7
Two Drug	27	22.5
Three Drug	9	7.5
Four Drug	3	2.5
Five Drug	1	0.8
Total	120	100

Among 178 antibiotics prescribed, the frequently prescribed antibiotic was Amoxicillin + Clavulanic acid (N=69).

Table 3: DISTRIBUTION OF ANTIBIOTICS ON THE BASIS OF DIAGNOSIS.

Diagnosis	A+C	P+T	AMX	AMK	AZM	CTM	CFP	CFT	CFZ	CP	DC	LZ	MP	MF	VM	TOTAL
Pneumonia	33	11	0	3	15	2	1	22	0	0	4	2	3	1	1	98
Bronchiolitis	14	1	0	4	2	1	0	3	2	0	0	0	0	0	0	27
WALRI	8	1	1	0	2	0	0	2	0	0	0	0	0	0	0	14
Bronchitis	4	0	0	0	1	1	1	3	0	0	0	0	0	0	0	10
Broncho-Pneumonia	3	1	0	0	0	0	0	4	0	1	0	0	0	0	0	9
Pharyngitis	4	1	0	0	1	0	1	2	0	0	0	0	0	0	0	9
Asthma	2	0	0	0	2	0	0	1	0	0	0	0	0	0	0	5
Rhinitis	1	0	0	0	0	2	1	1	0	0	1	0	0	0	0	6
TOTAL	69	15	1	7	23	6	4	38	2	1	5	2	3	1	1	178

A+C – Amoxicillin+ Clavulanic acid, P+T – Piperacillin + Tazobactam, AMX – Amoxicillin, AMK – Amikacin, AZM – Azithromycin, CTM – Cefotaxim, CFP – Cefpodoxim, CFT – Ceftriaxone, CFZ – Ceftazidime, CP – Chloramphenicol, DC- Doxycycline, LZ – Linezolid, MP – Meropenem, MF – Moxifloxacin, VM – Vancomycin.

Among 178 antibiotics, there were 85 (47.7%) Penicillins, 50 (28.1%) Cephalosporins, 23(12.9%) Macrolides, 7 (3.9%) Aminoglycosides, 5 (2.8%) Tetracyclines, 3 (1.7%) Carbapenems, 2 (1.1%) Oxazolidinones, 1 (0.6%) Fluoroquinolones , 1 (0.6%) Glycopeptides and 1 (0.6%) Chloramphenicol.

Table 4 :CATEGORIZATION OF CLASS OF ANTIBIOTICS.

Antibiotic class	No. of antibiotics (n=178)	Percentage (%)
Penicillins	85	47.7
Cephalosporins	50	28.1
Macrolides	23	12.9
Aminoglycosides	7	3.9
Tetracyclines	5	2.8
Carbapenems	3	1.7
Oxazolidinones	2	1.1
Fluoroquinolones	1	0.6
Glycopeptides	1	0.6
Chloramphenicol	1	0.6
TOTAL	178	100

Out of 178 antibiotics prescribed, Amoxicillin+ Clavulanic acid (N= 69, 38.76%) was mostly prescribed followed by Ceftriaxone (N= 38, 21.35%).

Table 5 :DISTRIBUTION OF INDIVIDUAL ANTIBIOTICS.

Name of drug	No. of antibiotics (n=178)	Percentage (%)
Amoxicillin	1	0.56
Chloramphenicol	1	0.56
Moxifloxacin	1	0.56
Vancomycin	1	0.56
Ceftazidime	2	1.12
Linezolid	2	1.12
Meropenem	3	1.7
Cefpodoxime	4	2.25
Doxycycline	5	2.81
Cefotaxime	6	3.37
Amikacin	7	3.93
Piperacillin+Tazobactam	15	8.43
Azithromycin	23	12.92
Ceftriaxone	38	21.35
Amoxicillin+clavulanic acid	69	38.76
Total	178	100.00

Most of the antibiotics were prescribed by IV route (N= 152, 85.4%), followed by Oral route (N= 26, 14.6%). Out of 120 patients, maximum number of patients were hospitalized for 5 days (N= 40, 33.3%) of treatment, followed by 7 days (N= 22, 18.3 %). In spectrum wise distribution of antibiotics, it was seen that broad spectrum antibiotics were mostly prescribed (N= 154, 86.5%) followed by narrow spectrum antibiotics (N= 24, 13.5%).

Among 178 antibiotics prescribed, 94 (52.81%) were treated with monotherapy and 84 (47.19%) were treated with combination therapy.

Table 6 :TYPE OF ANTIBIOTIC THERAPY.

Mode of therapy	No. of antibiotics (n=178)	Percentage (%)
Combination Therapy	84	47.19
Mono-Therapy	94	52.81
Total	178	100

Most commonly prescribed fixed dose combination (FDC) was Amoxicillin+Clavulanic acid (82.1%) followed by Piperacillin+Tazobactam (17.9%).

Among the total 11 suspected ADRs observed, 3 (27.2%) occurred in Penicillins, 2 (18.2%) occurred in Macrolides, Cephalosporins, Aminoglycosides and 1 (9.1%) occured in Glycopeptide and Tetracycline.

Table 7 :DISTRIBUTION OF SUSPECTED ADRs BASED OF ANTIBIOTICS PRESCRIBED.

Drug class	Drug	Description of ADR	No. of patients
Penicillin	Piperacillin+ Tazobactam	Rash	2
		Swelling of face and rash	1
Macrolide	Azithromycin	Diarrhoea	2
Cephalosporin	Ceftriaxone	Urticaria	1
	Ceftazidime	Diarrhoea	1
Aminoglycoside	Amikacin	Angioedema	1
		Black tarry stools	1
Glycopeptide	Vancomycin	Rash	1
Tetracycline	Doxycycline	Diarrhoea	1

DISCUSSION

The overall data of 120 patients with RTI were collected from the paediatric department of a tertiary care teaching hospital. Out of 120 prescriptions, 73 (60.8%) patients were males and 47 (39.2%) were females. This study also reveals a male pred.ominance over female and was similar to the study conducted by Puskar Kunwor et al[3] which showed males were 70 (70%) and Akhil J Issac et al[10] where males 86 (54%).

The present study reveals that the most prevailing age group among paediatrics who received antibiotics was 1-5 years (47.5%). This indicates that more chances of infections are in 1-5 age group. Same findings were seen in study conducted by Resmi T.M. et al[11] where 80 patients (52.28%) belongs to 1-5 age group and Akhil J Issac et al[10] where 71 patients in 1-5 age groups.

Most prevalent disease among the study was Pneumonia [62, (51.67%) and is treated commonly by Amoxicillin+ Clavulanic acid [69, (38.76%) and this result was comparable with study conducted by Tupakula Karthik Babu et al[12] where Pneumonia was the common diagnosis with 52% and Choudhary DK. et al[13] where Amoxicillin + Clavulanic acid [65, (35%)]was prescribed commonly.

Out of 120 paediatric inpatients, majority were given with single antibiotic (66.7%) followed by two antibiotics (22.5%) which was comparable with study conducted by Dr. Shruthi K V et al[6] which showed that majority of the patients were given single antibiotic (45.3%).The WHO recommends that the average number of drugs in each prescription should be less than two.

It is observed that the use of Penicillin class [85(47. 7%)] of antibiotic was higher than other class of antibiotics. This result was comparable with the study conducted by Vijay R Kokani et al[14] where Penicillins are the most prescribed antibiotics with 63% and is contradictory with the study conducted by Divya Kancherla et al[4] and Hemamalini MB et al[8] where Cephalosporins was the most commonly used antibiotic class.

In our study broad spectrum antibiotics contributed to 85.4% of the total antibiotics, and this result is comparable with the study conducted by Puskar Kunwor et al[3] where broad spectrum antibiotics were prescribed more [66,(65.34%)].

From178 antibiotics prescribed, 113 (63.5%) were given twice daily, followed by 33 (18.5%) given thrice daily, 30 (16.9%) given as once daily and 2 (1.1%) given as four times daily. This result is comparable with the study conducted by Laya Vahdati Rad et al[15] where 106 (68.34%) antibiotics were given twice daily. Majority of the patients were given mono therapy [94 (52.81%)] followed by combination therapy [84 (47.19%)].

In fixed dose combination therapy, Amoxicillin + Clavulanic acid (82.1%) was the commonly prescribed drug followed by Piperacillin +Tazobactam (17.9%). This result is comparable with the study conducted by Vijay R Kokani et al[14] where Amoxicillin + Clavulanic acid was most commonly prescribed.

In the present study a total of 11 suspected ADRs were observed in 120 prescriptions. Among these, 3 (27.2%) with Penicillins, 2 (18.2%) with Macrolides, Cephalosporins, Aminoglycosides, and 1 (9.1%) with Glycopeptide and Tetracycline. 54.5 % of ADR caused dermatological disorders and 45.5 % caused gastrointestinal disturbances. Rashes are the main dermatological disorder and gastro intestinal disorder mainly include diarrhoea. In a study conducted by Akhil J Issac et al[10] a total of 14 ADRs were noticed, in which 12 appeared due to cephalosporins, 1 by both Quinolones and beta lactamase inhibitors. 79% of ADR caused GI disturbances which mainly include diarrhoea and vomiting.

CONCLUSION

Respiratory infections produce diseases with global impact in children. For treating paediatric illness the use of antibiotics has become a routine practice. Examining and managing the antibiotic use is of growing concern. The present study was carried out to estimate the prescribing pattern and identify suspected ADRs associated with antibiotics. In order to minimise the threat by antibiotic resistance of microbes, an antibiotic policy should be carefully instituted and implemented. The doses prescribed to the paediatrics should be calculated according to the body surface area inorder to minimise adverse drug events.

Antibiotic prescriptions showed risks such as occurence of ADR and prescriptions other than monotherapy of antibiotics. Early signals of irrational use of drugs can be detected by frequent prescription overlook.

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CONFLICT OF INTEREST

There is no conflict of interest between the authors.

ABBREVATIONS

RTI – Respiratory Tract Infection
ADR – Adverse Drug Reaction
URTI – Upper Respiratory Tract Infection
LRTI – Lower Respiratory Tract Infection
ARTI -- Acute Respiratory Tract Infections
ALRTI – Acute Lower Respiratory Tract Infections
WALRI – Wheezing Associated Lower Respiratory Infection
FDC – Fixed Dose Combination
NICE – National Institute for Health and Care Excellence

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