

A PROSPECTIVE STUDY ON PRESCRIBING PATTERN OF BETA-LACTAM ANTIBIOTICS AND ADVERSE DRUG REACTION IN PAEDIATRIC PATIENTS AND THE ASSESSMENT OF PARENTAL KNOWLEDGE ATTITUDE AND PRACTICE IN A TERTIARY CARE HOSPITALSaid Ali^{1*}, Racheal Jacob² and Cibi Simon¹¹Pharm D Intern, Sreekrishna College of Pharmacy and Research Centre, Parassala, Kerala, India.²Senior Paediatric Consultant, (MD,DCH) Cosmopolitan Hospital, Pattom, Trivandrum, Kerala, India.***Corresponding Author: Dr. Md. Said Ali**

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ABSTRACT

The prescribing pattern of beta-lactam antibiotics which is a prospective study based on paediatric department. Paediatric patients prescribed with beta lactam antibiotics were included in the study and ADR if any were also noted. The aim of this study was to study the prescribing pattern of beta lactam antibiotics used in the paediatric inpatients and the assessment of adverse drug reaction and also assessing the parental knowledge attitude and practice and the impact of parental KAP before and after counselling. The data were collected and recorded in specially designed proforma. The knowledge attitude and practice of antibiotic usage in parents were assessed using a knowledge attitude and practice questionnaire. Informed consent was obtained and information was provided through patient information sheet. A total of 146 paediatric patients who were prescribed beta lactam antibiotics were selected for the study. From our study it was observed that among those paediatric patients prescribed with beta-lactam antibiotics the age group 2-5 years (54.1%) were more than the other age groups. During our study among 146 beta lactam antibiotics prescribed in paediatric patients. The highest number of prescriptions were found to be diagnosed with respiratory tract infection (61%) and the most frequently prescribed beta lactam antibiotic was ceftizoxime (33.6%). The parental knowledge attitude and practice regarding antibiotic usage in the children were assessed using a KAP questionnaire during their child's hospital stay and scored and their score were compared two weeks later. After re-administering them the same KAP questionnaire during their follow up visit. It was found out that the parental KAP improved after counselling.

INTRODUCTION

Antibiotics are the key drugs for treatment of bacterial infections and are the mostly prescribed drugs in paediatric group. Paediatric patients are among the most vulnerable group to contact illnesses. Evaluation of prescribing pattern will help in minimizing adverse drug reactions.

Beta lactam antibiotics, which are named for the beta-lactam ring in their chemical structure, include the penicillins, cephalosporins, and related compounds. Beta lactam antibiotics, which are named for the beta-lactam ring in their chemical structure, include the penicillins, cephalosporins, and related compounds. Bacteria often develop resistance to beta-lactam antibiotics by synthesizing a beta-lactamase, an enzyme that attacks the beta-lactam ring. To overcome this resistance, beta-lactam antibiotics are often given with beta-lactamase inhibitors such as clavulanic acid. beta-lactam antibiotics are indicated for the prevention and treatment of bacterial infections caused by susceptible organisms. At first, beta-lactam antibiotics were mainly active only

against Gram-positive bacteria, yet the recent development of broad-spectrum beta-lactam antibiotics active against various Gram-negative organisms has increased their usefulness.

METHODOLOGY**Study Period**

The study was carried out for a period of six months after getting clearance from Human Ethical Committee.

Study Design

A prospective observational study was conducted in patients from department of Pediatrics in Cosmopolitan Hospital (Trivandrum, Kerala, India) who were treated with beta-lactam antibiotics during the study period after obtaining permission for collection of data from the Human Ethical Committee.

Inclusion Criteria

- Patients of either gender with age below 12 years.
- Inpatients treated with beta lactam antibiotics in paediatric department.

- Patients admitted to PICU and treated with beta lactam antibiotics.
- Caretakers who are willing to participate in the study.

Exclusion Criteria

- Outpatients treated with Beta lactam antibiotics
- Immuno suppressed Paediatric inpatients.
- Caretakers of paediatric patients who are unwilling to participate.

Study Population

Sample size = $Z^2 * P(1-P) / e^2$

$$1 + [Z^2 * P(1-P) / e^2 N]$$

N= population size = 186

Z= z- score= 2.58

e= margin of error= 0.01

P= standard deviation= 0.5

Therefore sample size = 146

Study Procedure

The proposed study is a prospective observational study conducted for six months in the paediatric department of Cosmopolitan Hospital, Pattom, Trivandrum.

Written informed consents was obtained as per ICMR Biomedical Research Guideline Format from the parents of children satisfying the inclusion and exclusion criteria.

Data from parents were collected by using a suitably designed proforma from complete medical case record and direct interview from care takers. The parents were educated about the antibiotic use, disease, prevention of disease and management. ADR if any found during the study period were also noted in a ADR form and measured using suitable scales. To assessing the Knowledge, Attitudes and Practices (KAP) of the parents of children treated with beta-lactam antibiotics, suitably designed KAP questionnaires were administered on all the parents of enrolled patients before and after the introduction of an information leaflet. Finally the data collected is analysed using suitable statistical method with the assistance of a qualified statistician.

Data Analysis

The whole datas were analysed using SPSS Statistical Software. Using a Wilcoxon signed rank test, the knowledge, attitude and practice before and after counseling were assessed. The KAP was assessed at the time of patients hospital visit by using the KAP Questionnaire and scored. This instrument has 33 questions in 4 domains (Demographics, Knowledge, Attitude and Practice).

OBSERVATION AND RESULT

On the basis of the study conducted in the Pediatrics department of the tertiary care hospital for 6 months, the following results were obtained. There were a total of 146 patients who met the inclusion criteria and were included in our study. These patient records and Parental

interview were analyzed and that helped reach our conclusion.

1) GENDER WISE DISTRIBUTION

Among the 146 pediatric patients enrolled, male patients were 58.2 % followed by females 41.8%.

Table 4: Gender wise distribution.

Gender	No of prescription	Percentage
Male	85	58.2
Female	61	41.8
Total	146	100

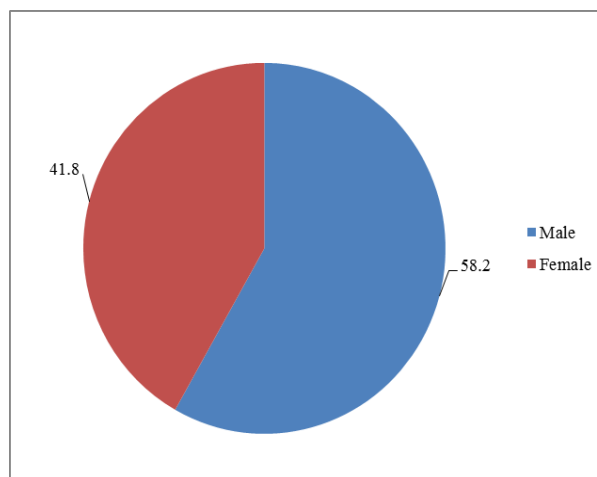


Figure 1: Percentage distribution of gender of paediatric patients prescribed with beta lactam antibiotics.

2) Age Distribution

Out of 146 patients included in the study, majority of the patients 54.1% belonged to the age group 2-5 years. The main reason may be because these age groups are more prone to infections.

Table 5: Age Wise distribution.

AGE	No of prescription	Percentage
<1	24	16.4
2-5	79	54.1
6-9	26	17.8
10-12	17	11.6
Total	146	100

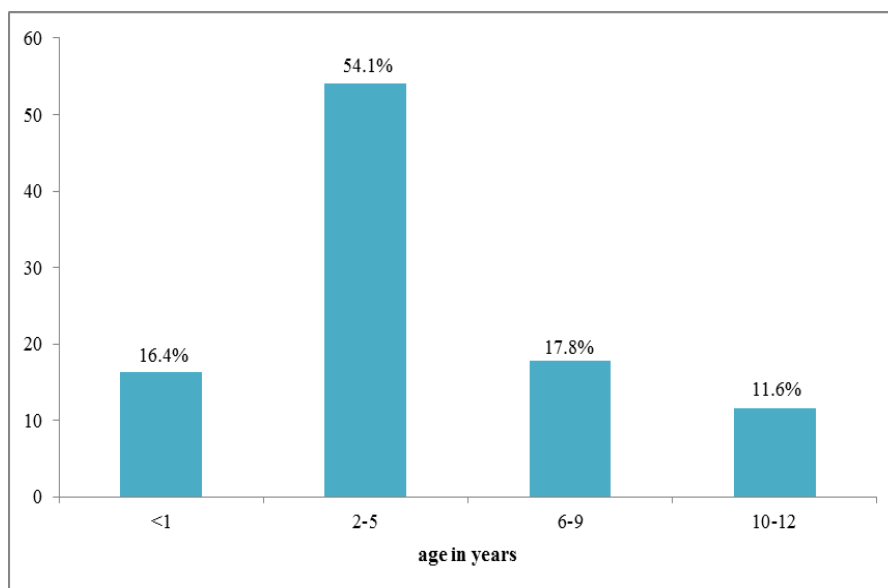


Figure 2: Percentage distribution of Age.

3) IMMUNISATION STATUS

Based on the immunization schedule, 87 % children were immunized to age and 13% of them were not immunized.

Table 6: Immunisation Status.

Immunised	No of prescription	Percentage
yes	127	87
no	19	13
Total	146	100

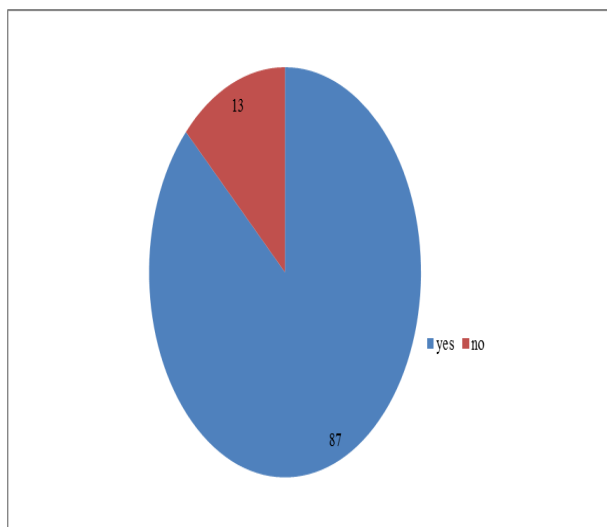


Figure 3: Percentage distribution of Immunisation Status.

4) DISEASES DIAGNOSED

Out of 146 cases collected, the highest number of pediatric patients were having Respiratory tract infections 61% followed by Gastrointestinal disorders 19.2 % as illustrated below.

Table 7: Disease diagnosed among the paediatrics.

Disease	No of prescription	Percentage
Rti	89	61
Gi	28	19.2
Uti	7	4.8
Cns	8	5.5
Others	14	9.6

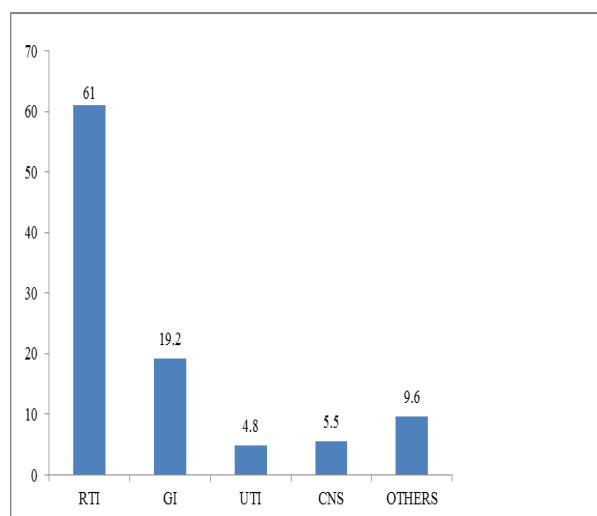


Figure 4: Percentage distribution based on disease.

5) BETA-LACTAM ANTIBIOTIC PRESCRIBED

Among 146 prescriptions of beta lactam antibiotics, the most frequently prescribed was Cephalosporin - Cefizoxime (Unizox) 33.6% followed by Cefotaxim 26.7%, both being third generation Cephalosporins.

Table 8: Beta Lactam antibiotics prescribed.

Beta lactam Antibiotic	No of prescription	Percentage
Cefotaxim	39	26.7
Ceftizoxime (Unizox)	49	33.6
Cefpodoxime (Pecef, Monocef)	11	7.5
Cefuroxime (Supracef)	17	11.6
Amoxicillin+Clavulanic acid (Augmentin, Clamp)	23	15.8
Cefoperazone Tazobactam(KephazonTz)	2	1.4
Piperacillin Tazobactam (Tazact)	1	0.7
Cefotum	2	1.4
Cefixime	2	1.4
Total	146	100

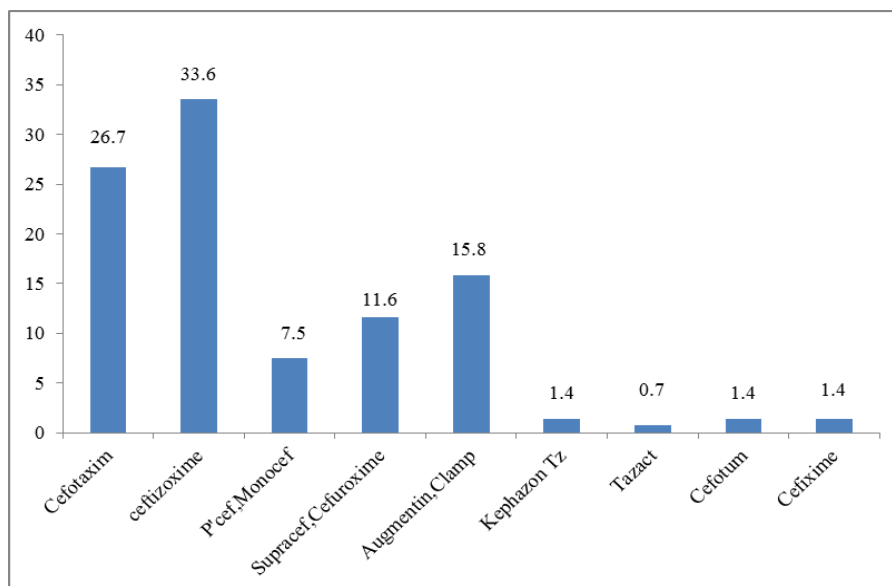


Figure 5: Percentage distribution of Beta Lactam antibiotics prescribed.

6) TYPE OF THERAPY

Table 9: Type of therapy of beta lactam antibiotic.

Type of Therapy	No of prescription	Percentage
Monotherapy	117	80.1
Combination therapy	29	19.9
Total	146	100

In our study it was evident that Single beta lactam antibiotic (monotherapy) was commonly observed in 117 (80.1 %) prescriptions when compared to Combination of beta lactam antibiotic which was seen in 29 (19.9%) prescriptions.

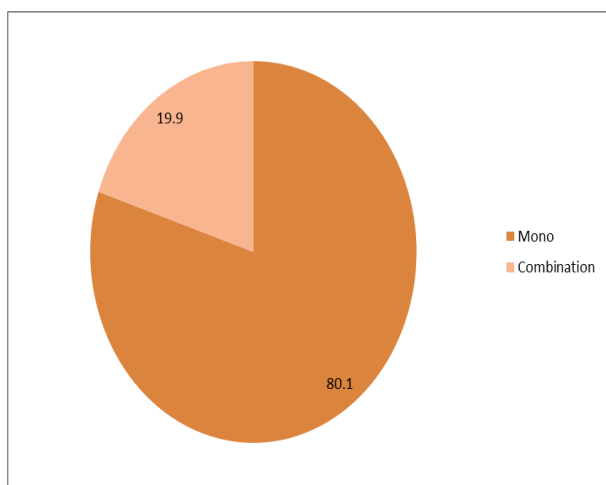


Figure 6: Percentage distribution of type of therapy of beta lactam antibiotic.

7) COMBINATION OF THERAPY

Table 10: Combination of Beta lactam antibiotics prescribed.

Combination of beta lactam antibiotic	No of prescription	Percentage
AMOXICILLIN+CLAVULANIC ACID	23	79.3
CEFOPERAZONE TAZOBACTAM	2	6.9
PIPERACILLIN+TAZOBACTAM	3	10.3
CEFOPERAZONE+SULBACTAM	1	3.4
Total	29	100

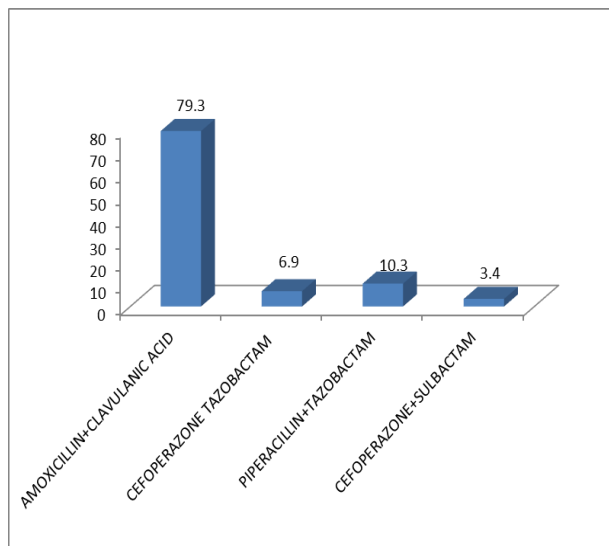


Figure 7: Percentage distribution of Combination of Beta lactam antibiotics prescribed.

8) FREQUENCY OF TREATMENT

Out of 146 inpatients, majority of the beta lactam antibiotics were given TDS ie in 61% followed by BD in 55 37.7%.

Table 11: Frequency of Treatment.

Frequency	No of prescription	Percentage
OD	2	1.4
BD	55	37.7
TDS	89	61
Total	146	100

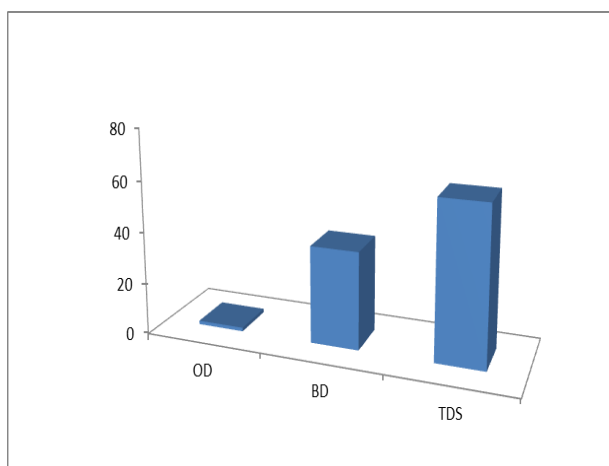


Figure 8: Percentage distribution of Frequency of Treatment.

9) Drug Allergy

During our study, among 146 pediatric patients 8.9 % of the parents stated that their children were allergic to few drugs like penicillins, sulfa drugs, clavulanate, clarithromycin etc whereas 91.1% of them were free off drug allergies.

Table 12: Drug allergies.

Drug Allergy	No of prescription	Percentage
Yes	13	8.9
No	133	91.1
Total	146	100

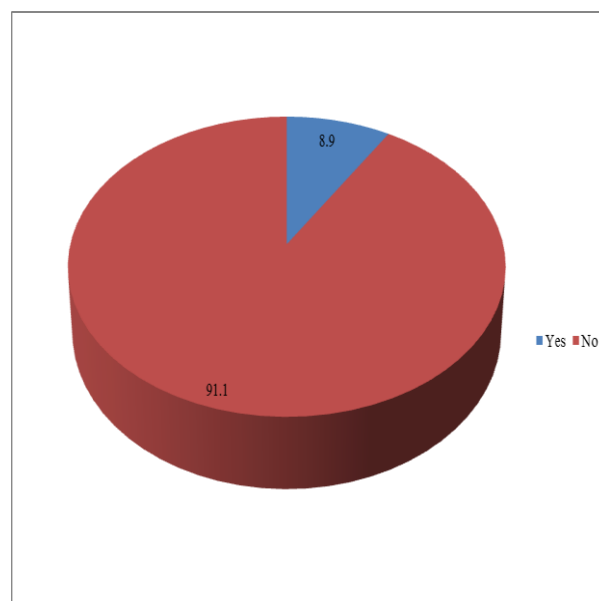


Figure 9: Percentage distribution of drug allergy.

10) Adverse Drug Reactions Reported

During the study period out of 146 patients 6.2% reported Adverse Drug reaction whereas the beta lactam antibiotics were safe to 93.8% patients

Table 13: ADR Reported.

ADR	No of prescription	Percentage
NO	137	93.8
YES	9	6.2
Total	146	100

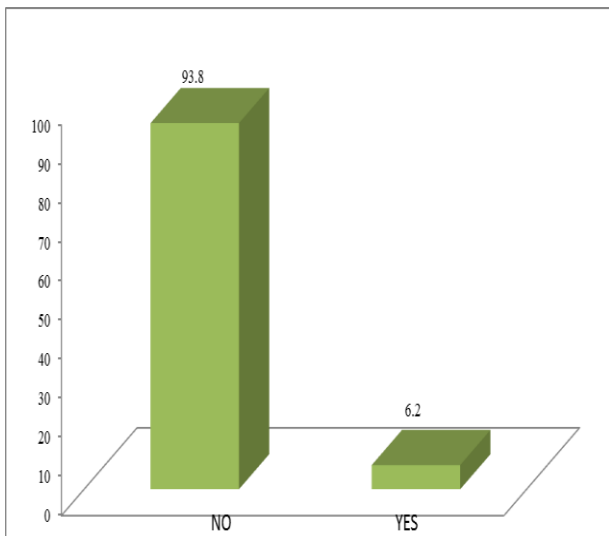


Figure 10: Percentage Distribution of ADR Reported.

11) Type of Adverse Drug Reaction

Out of the 9 patients who experienced adverse drug reaction, none of them experienced severe reactions like hypersensitivity and seizure. A Few of them reported to have experienced mild ADRs like diarrhea 2.7% followed by rashes in 2.1 % and vomiting in 0.7 % of them.

Table 14: Type of adverse drug reactions reported.

Type of Adr	No of prescription	Percentage
Vomiting	1	0.7
Diarrhoea	4	2.7
Vomiting + Diarrhoea	1	0.7
Rash	3	2.1
Nil	137	93.8
Total	146	100

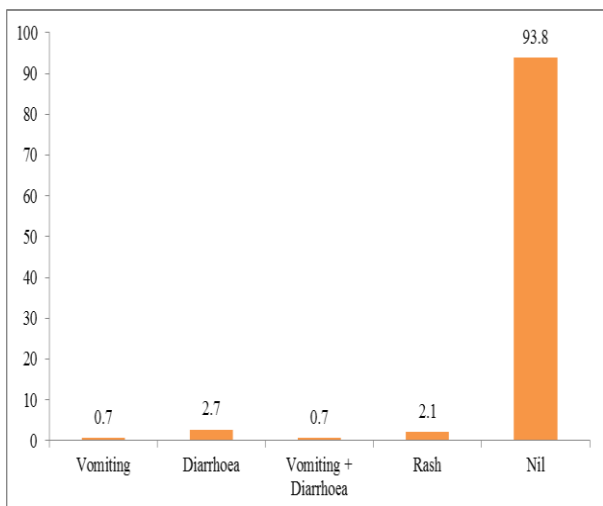


Figure 11: Percentage distribution of type of ADR.

12) System Affected By Adr

Among the 9 patients who reported to have faced ADR, the commonest was Gastrointestinal (diarrhoea) in 66.7% followed by Skin (rashes) in 33.3%.

Table 15: System affected by ADR.

Organs Affected	No of prescription	Percentage
Skin	3	33.3
Gastrointestinal	6	66.7
CNS	0	0.0
Total	9	100

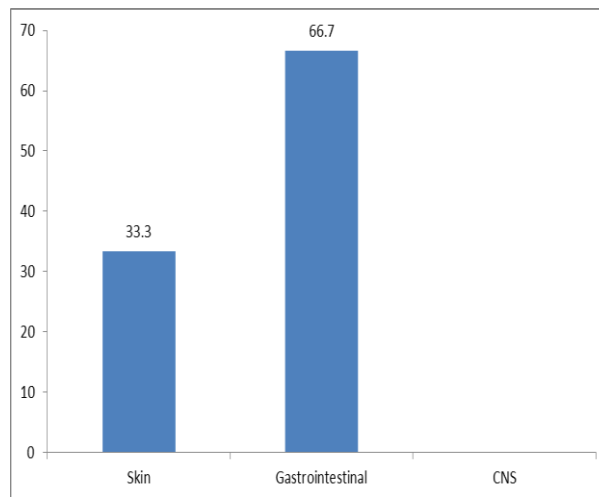


Figure 12: Percentage distribution of System affected by ADR.

13) Assessment of Adverse Drug Reaction

A) Naranjo Probability Scale

From the below table it is evident that among the 9 ADRs there were no ADRs with a definite causality. Most of the reactions had a Probable causality score in 55.6% followed by possible causality score in 33.3%.

Table 16: Naranjo Probability Scale.

Probability of ADR	No of prescription	Percentage
Definite	0	0.0
Probable	5	55.6
Possible	3	33.3
Doubtful	1	11.1
Total	9	100.0

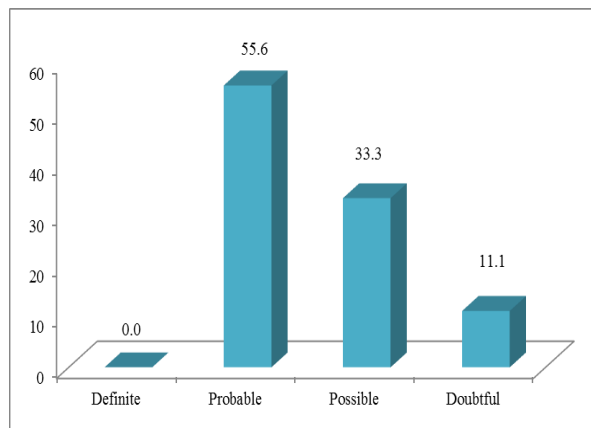


Figure 13: Percentage distribution of probability of ADR using Naranjo scale.

B) Hartwig Severity Scale

In our study were 9 pediatric patients reported to have faced ADR, most of them were of mild varieties 77.8 % followed by moderate in 22.2 %. There were no severe ADRs observed during the study period.

Table 17: Severity of ADR using Hartwig scale.

Severity of ADR	No of prescription	Percentage
Mild	7	77.8
Moderate	2	22.2
Severe	0	0.0
Total	9	100.0

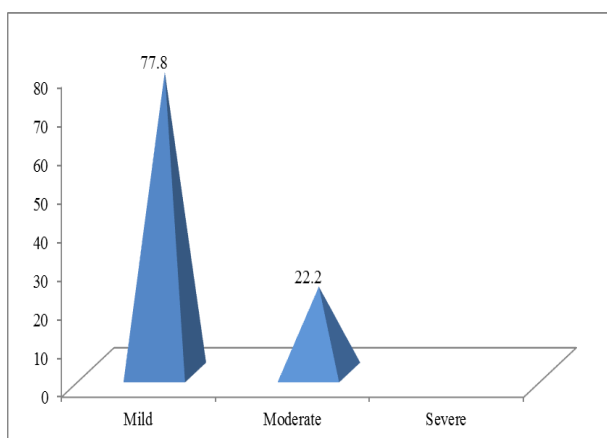


Figure 14: Percentage distribution of severity of ADR using Hartwig scale.

C) Schumock & Thornton Scale Of Preventability

Among the 9 ADRs observed during the study period, about 55.6 % of them were 'Not Preventable' and 33.3 % of them were 'Probably Preventable'

Table 18: Preventability of ADR using preventability scale.

Preventability	No of prescription	Percentage
Preventable	1	11.1
Probably	3	33.3
Not preventable	5	55.6
Total	9	100.0

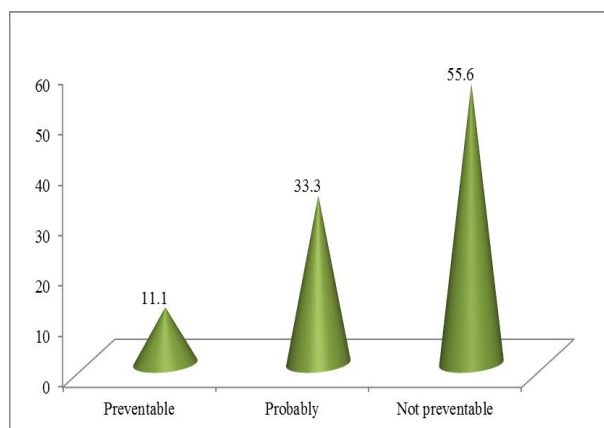


Figure 15: Percentage distribution of ADR using preventability scale.

D) Predictability

Predictability assessment was carried out in 9 of the patients who experienced an ADR and it was found out that almost 33.3% ADRs deemed 'Predictable' while 66.7% were 'Non Predictable'.

Table 19: Predictability of ADR.

Predictability	No of prescription	Percentage
Yes	3	33.3
No	6	66.7
Total	9	100.0

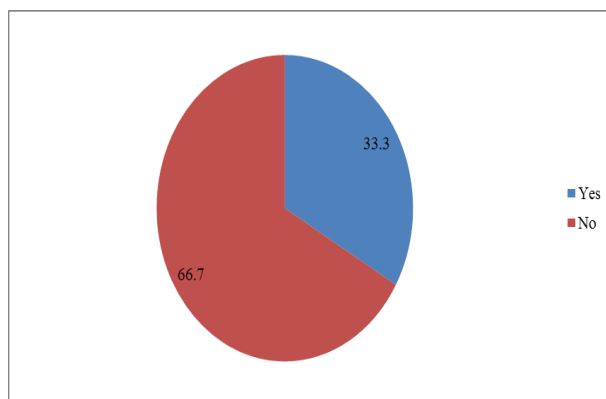


Figure 16: Percentage distribution of predictability of ADR.

14) Educational Status of Mothers

A parental KAP questionnaire was administered to 146 parents and it was analysed that majority of the mothers were Graduates 38.4% followed by 26.7% Professional Degree holders.

Table 20: Educational status of mothers.

Educational status	No of prescription	Percentage
Professional Degree	39	26.7
Graduate	56	38.4
Higher Secondary	31	21.2
Secondary	10	6.8
Primary	8	5.5
Illiterate	2	1.4
Total	146	100

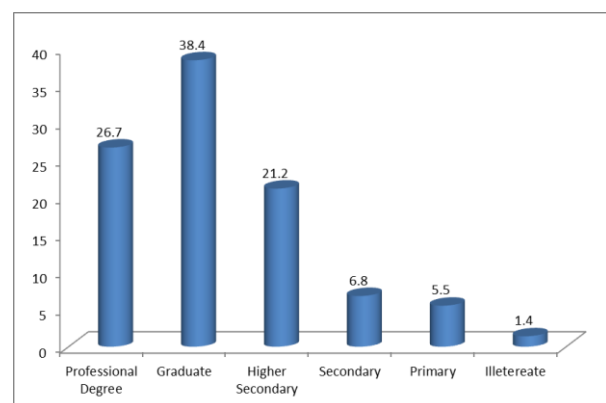


Figure 17: Percentage distribution of maternal educational status.

15) Occupational Status Of Mothers

Considering the occupational status of the mothers, 44.5 % of them were working mothers whereas 55.5% of them were home makers.

Table 21: Occupational status of mother.

Maternal Occupational Status	No of prescription	Percentage
Working Mothers	65	44.5
Home Makers	81	55.5
Total	146	100

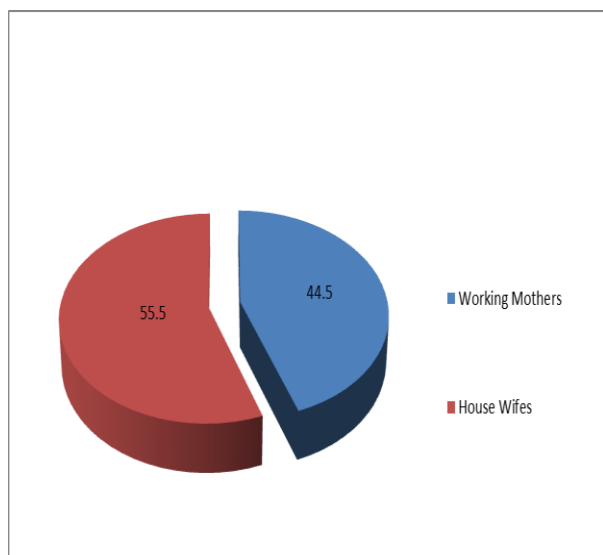


Figure 18: Percentage distribution of occupational status of mother.

16) Knowledge, Attitude and Practice of Mothers Regarding Antibiotic Usage For Their Child

The KAP on antibiotic usage was assessed using a structured KAP Questionnaire having 33 questions.

A) Level of Knowledge of Mothers

Table 1 clearly shows that before counseling the parental knowledge was ‘Poor’ in 86 (58.9%) parents and it was ‘Moderate’ in 60 (41.1) parents.

After counseling there was a remarkable hike in knowledge 71.2 % parents scored ‘Excellent’ and 28.8 % of their knowledge was ‘Good’.

Table 22: Distribution according to level of maternal knowledge on the antibiotic usage in their children.

Knowledge		Count	Percent
Pre	Poor	86	58.9
	Moderate	60	41.1
Post	Good	42	28.8
	Excellent	104	71.2

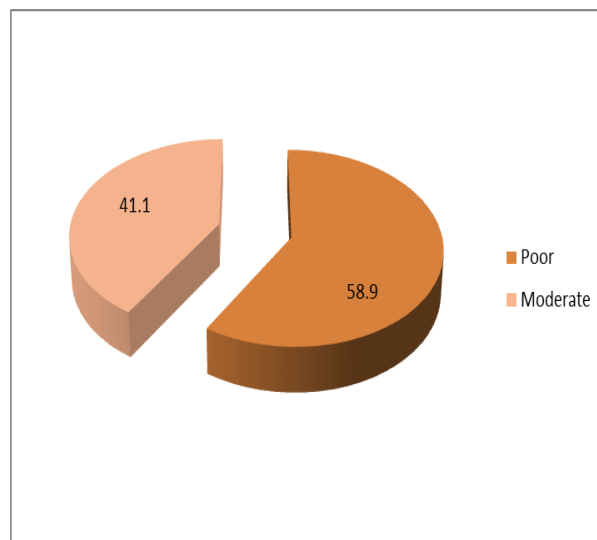


Figure 19: Percentage distribution of maternal knowledge on antibiotic usage for their children.

Figure 20 shows the improvement in parental knowledge from poor and moderate before counseling to good and excellent after counseling.

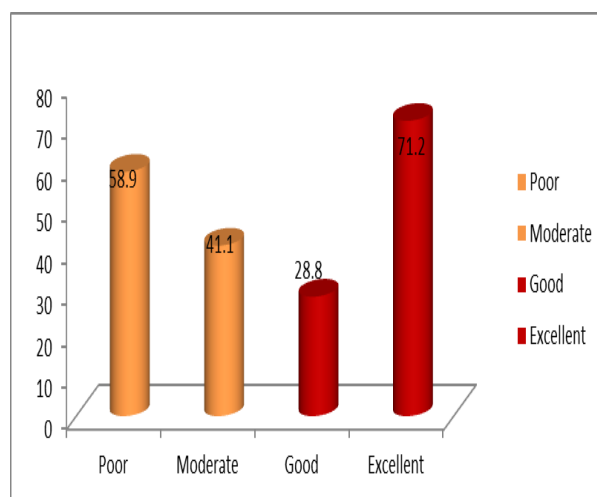


Figure 20: Percentage distribution showing in parental knowledge on antibiotic before and after counseling.

B) Level of Attitude of Mothers on Antibiotic Usage In Their Children

The attitude of mothers before counseling had changed from negative attitude 24% and moderately positive attitude 76% to moderately positive 61.6% and highly positive attitude in 38.4% parents after counseling.

Table 23: Distribution according to level of maternal attitude on the antibiotic usage for their children.

Attitude		Count	Percent
Pre	Negative Attitude	35	24
	Moderate Negative Attitude	111	76
Post	Moderate Positive Attitude	90	61.6
	Highly Positive Attitude	56	38.4

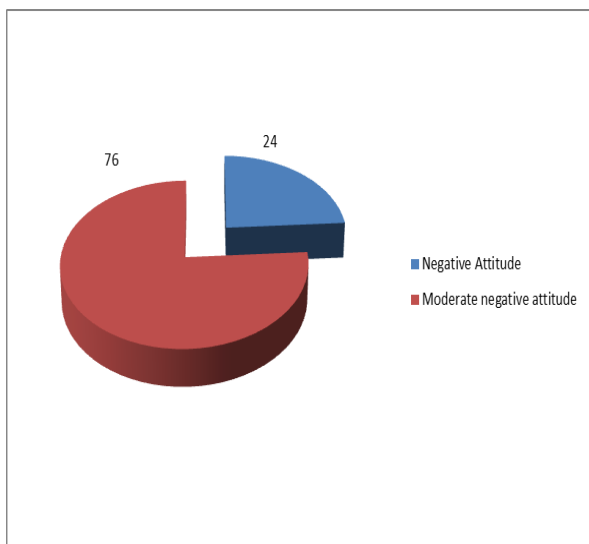


Figure 21: Percentage distribution of parental attitude on antibiotic usage before counselling.

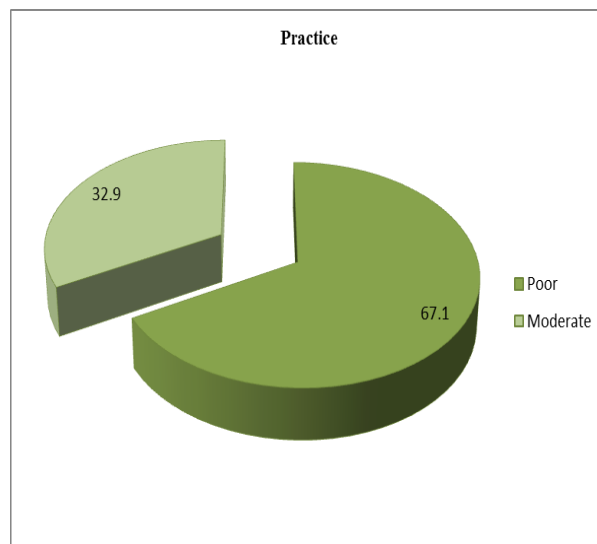


Figure 23: Percentage distribution of pre counselling parental practice of antibiotic usage in their children.

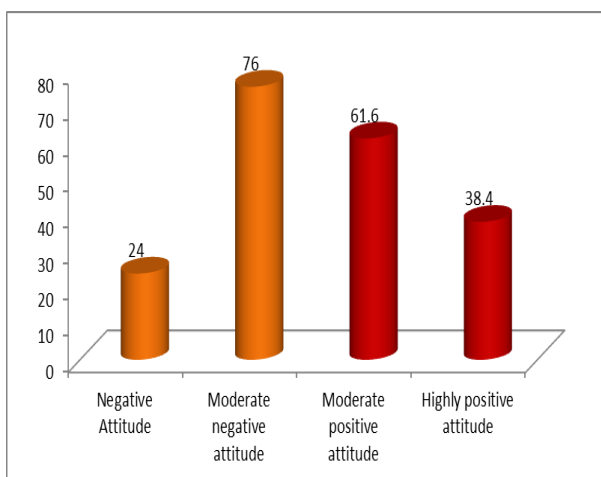


Figure 22: Percentage distribution showing the comparison of parental attitude on antibiotic usage in their children before and after counselling.

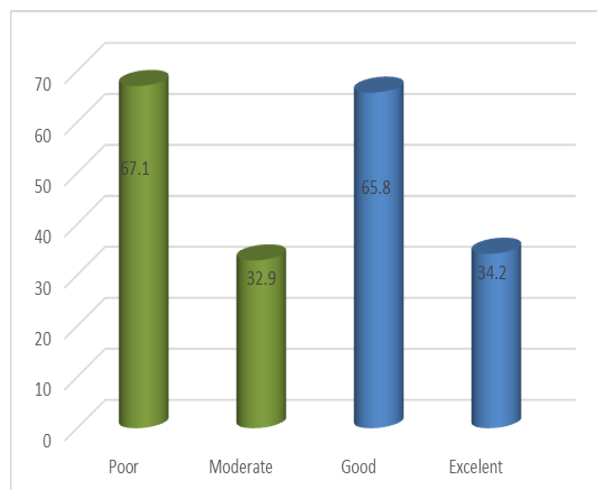


Figure 24: Percentage Distribution Showing The Comparison of Parental Practice of Antibiotic Usage In Their Children Before and After Counselling.

C) Level of Practice of Parental Antibiotic Usage

Out of 146 parents 67.1% had poor and 32.9% moderate practices on antibiotics usage in their children pre counselling. It had changed to good in 65.8 parents and Excellent in 34.2% parents after the counseling session.

Table 24: Distribution according to level of maternal practice on antibiotic usage in their children.

Practice		Count	Percent
Pre	Poor	98	67.1
	Moderate	48	32.9
Post	Good	96	65.8
	Excellent	50	34.2

Table 25: Effectiveness of counseling on parental knowledge of antibiotic use.

Knowledge	Mean	SD	N	Mean Difference	Wilcoxon signed rank test	P
Pre	6.2	2.6	146	14.6	-10.5	.000
Post	20.8	3.2	146			

17) Impact of Patient Counselling on Parental Knowledge, Attitude And Practice Using A Structured Kap Questionnaire

A) Knowledge

Effective counseling was given and after the counseling session we had obtained a p value less than 0.01 which is significant and the mean value had increased from 6.2 to 20.8 with a mean difference of 14.6.

This clearly shows that counseling was effective improving parental knowledge regarding the use of antibiotics in their children.

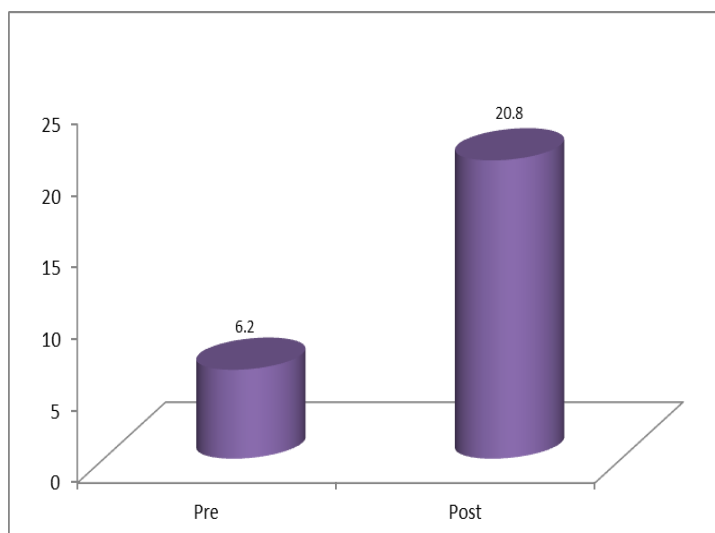


Figure 25: Percentage distribution showing the effectiveness of patient counselling on knowledge.

B) Attitude

From the below statistical analysis it can be concluded that the attitude of mothers had been positively changed

after counseling. The p value obtained is less than 0.01 which is significant and the mean value had increased from 11.3 to 24.2 with a mean difference of 12.9.

Table 26: Effectiveness of counseling on attitude on antibiotic use.

Attitude	Mean	SD	N	Mean Difference	Wilcoxon signed rank test	P
Pre	11.3	3.6	146	12.9	-10.6	0.000
Post	24.2	4.0	146			

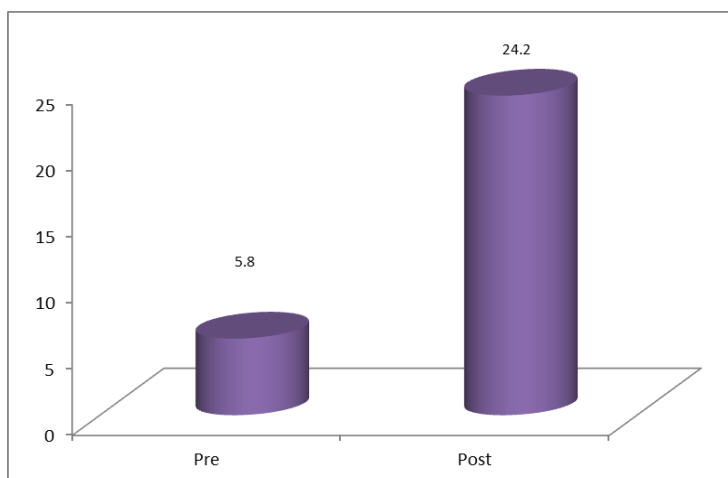


Figure 26: Percentage distribution showing the effectiveness on counselling on parental attitude on antibiotic usage.

C) Practice

The practice of mothers on antibiotics usage had improved as its evident from the table shown below. It is statistically proven as the p value being less than 0.01 and hence significant and the change in mean value from 5.8 to 24.7 and the mean difference being 18.4.

Table 27: Effectiveness of counseling on parental practice on antibiotic use.

Practice	Mean	SD	N	Mean Difference	Wilcoxon signed rank test	P
Pre	5.8	2.6	146	18.4	-10.5	0.000
Post	24.2	4.0	146			

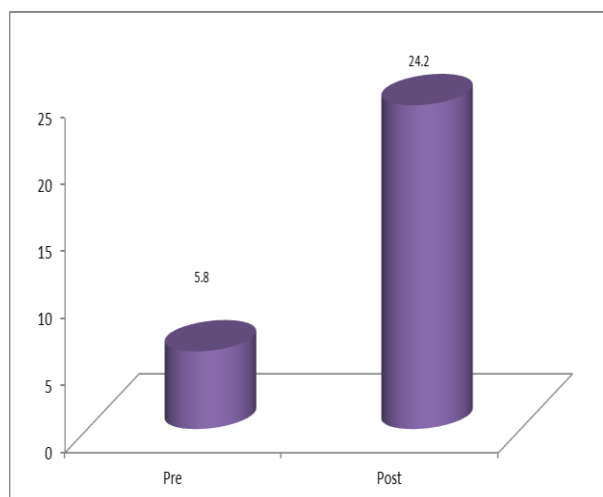


Figure 27: Percentage distribution showing the comparison of effectiveness of patient counselling on the maternal practice of antibiotic use.

DISCUSSION

In this study we conducted 6 month surveillance on paediatric patients prescribed with beta lactam antibiotics. During this study period 146 paediatric patients were enrolled in our study. we collected the results from medical records and interviewer administered KAP questionnaire to assess the knowledge attitude and practice regarding the antibiotic use in their children.

In our study we found out that out of 146 paediatric patients who were prescribed with beta lactam antibiotics in the paediatric department in cosmopolitan hospital in Trivandrum. Male patients (58.2%) were found to be more than female patients (41.8%) which was found to be different from the study by sattanatham et al as the number of female patients were more in this study.^[1]

In our study we conducted that majority of paediatric patients admitted and given beta lactam antibiotics were of the age group 2–5 years (54.1%) which was inconsistent with the study conducted by laya vahdati et al which means that the age group is more prone to infections.^[2]

Among 146 prescriptions of beta lactam antibiotics, the most frequently prescribed was Cephalosporin - Ceftizoxime 33.6 % followed by Cefotaxim 26.7%, both being third generation Cephalosporins this data is also different from the study by sattanathan k etal in which the most prescribed beta lactam antibiotic was Ceftriaxone followed by ampicillin.^[1] The frequency of administration of beta lactam were mostly thrice 61% where as the frequency of administration found out in a study conducted by laya vahdati rad was twice daily.^[2]

During our study, among 146 pediatric patients 8.9 % of the parents stated that their children were allergic to drugs whereas 91.1% of them were free off drug allergies and these parents statements were taken into

consideration and they are treated safely with the non allergic drugs. Similar results were found in other studies as well.^[3,4]

During the study period out of 146 patients 6.2% reported adverse drug reaction whereas the beta lactam antibiotics were safe to 93.8% patients. The ADRs experienced were mild and not life threatening. These all were mild and unthreatening and cured by changing the dose and by giving it after a test dose and in rare cases the very drug was withdrawn and substitute was given. None of them experienced severe reactions like hypersensitivity and seizure. A Few of them reported to have experienced mild ADRs like diarrhea in 2.7% followed by rashes in 2.1% and vomiting in 0.7% which is different from the study of Deepak Bhatt and Kailash as they found the most occurring adverse drug reaction was hypersensitivity.^[5,6] The KAP on antibiotic usage was assessed using a structured KAP Questionnaire having 33 questions. It clearly shows that before counseling the parental knowledge was 'Poor' in 58.9% parents and it was 'Moderate' in 41.1% parents while after. This result was consistent with the study done by Noraida et al.^[7] After counseling there was a remarkable hike in knowledge, that is, 71.2% parents scored 'Excellent' and 28.8% of their knowledge was 'Good'. The attitude of mothers before counseling had changed from negative attitude 24% to highly positive attitude in 38.4% parents after counselling. This is consistent with other studies.^[8,9] Before counseling out of 146 parents 67.1% had poor and 32.9% moderate practices on antibiotics usage in their children precounseling. It had changed to good in 65.8 parents and excellent in 34.2% parents after the counseling session. All the pre counselling section which is consistent with the study of Miao yu et al.^[10] In that particular study, the pre knowledge attitude and practice of the parents were poor and the after the counselling section the knowledge attitude and the practice were improved, similar to our study.

CONCLUSION

Antibiotic prescription in the pediatrics were prescribed appropriately. Beta lactam antibiotics were the highly prescribed antibiotic due to its safety and efficacy.

This study mainly focused to enhance the parental awareness about the antibiotics to prevent its misuse and hence avoid its resistance. Physicians play a key role in health and hence physician-patient communication is very important to increase medication adherence and to reduce self medication. Various pharmacovigilance awareness programs should be conducted to increase the spontaneous reporting of ADRs.

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