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Prevalence of Adverse Drug Reaction in patients receiving Beta Lactum antimicrobial agents at Medicine and surgery ICU of tertiary care Teaching Hospital in Central India

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ABSTRACT

The WHO defines an ADR as ''any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function." It do not include therapeutic failures, poisoning, accidental or intentional overdose. In many countries ADRs rank among the top 10 leading causes of mortality. So there is a need to study ADRs seriously to create awareness about ADRs among patients to motivate health care professionals in the hospital to report ADRs to minimize the risk. Early detection, evaluation and monitoring of ADR are essential to reduce harm to patients and thus improve public health. Main aim of the study was to monitor the safety (adverse drug reactions) of β- Lactum antibiotics commonly prescribed in medicine and surgery ICU of tertiary care teaching hospital in central India, for a period of Oct 2014 to Dec 2015 , establish most common Beta Lactum antibiotics that give maximum ADRs and assess the causality of ADR. To assesses the prevalence of Adverse Drug Reactions of β lactum antimicrobials in medicine and surgery ICU patients at one of the tertiary care teaching hospital in central India. To assess most commonly involved β-Lactum antibiotics associated ADR in medicine and surgery ICU 2. To analyse involvement of Age, Sex, and type of ADR occurring with respect to the use of particular Antimicrobials 3. To assess the causality of ADRs. The study will be carried out in medicine and surgery ICU of Tertiary care Teaching hospital in central India. During the study of use of β- lactum antimicrobials in Medicine and Surgery icu, from Oct 2014 to Dec 2015, along with demographic and clinical data, ADR developed with the concomitant use of Beta lactum antimicrobials were noted and tabulated in CDSCO form. And ADR data has been generated. A total of 54 ADRs were collected, tabulated in CDSCO forms, analyzed and assessed on WHO causality assessment scale. β Lactum comprises the major volume Antibiotics used in ICU patients so implementation of antibiotic guidelines for the hospital scenario and strict adherence should be ensured to promote their rational use. The health system should promote the spontaneous detection of the Adverse Drug Reactions and delivering the awareness classes for the healthcare professionals regarding the need for reporting the incidents, incorporating ADR information in patient charts.

Keywords : ADR –Adverse Drug Reaction, β-Beta

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INTRODUCTION

Adverse Drug reactions are the recognized hazards of drug therapy and they can occur with any class of drugs and many studies revealed that the incidence is more in case of antibiotics [1] Adverse Drug Reactions (ADRS) are important causes of mortality and morbidity in ICU patients. Early detection, evaluation, monitoring and reporting of ADR are essential to make drug treatment safe as well as effective.

Drugs are the most common medical interventions, primarily used to relieve sufferings. But it has been recognized long ago that drug themselves can prove fatal; as the saying rightly goes "Drugs are Double Edged Weapons". Adverse reaction monitoring and reporting are very important in identifying the adverse reaction trends [2]

The WHO defines an ADR as ''any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function." It do not include therapeutic failures, poisoning, accidental or intentional overdose [3]

In many countries ADRs rank among the top 10 leading causes of mortality. So there is a need to study ADRs seriously to create awareness about ADRs among patients to motivate health care professionals in the hospital to report ADRs to minimize the risk. Early detection, evaluation and monitoring of ADR are essential to reduce harm to patients and thus improve public health [4]

Antibiotics belong to different classes such as penicillins, cephalosporins, sulfonamides, and aminoglycosides, and they vary in respect of their chemical structure, mechanism of actions as well as adverse effects. Antibiotics are used commonly in routine practice for treatment and prophylaxis of various disease conditions [5]. More than 70% of ICU patients receive antibics for therapy or prophylaxis, with much of this use being empiric and over more than half of the recipients receiving multiple agents.

In Darchy's report, antibiotics accounted for 11% of iatrogenic disease. Classen states that, although adverse events seem to occur in a small proportion of antibiotic courses, the frequency of antibiotic use makes them account for 23% of all adverse events recorded [6-7]

Main aim of the study was to monitor the safety (adverse drug reactions) of β- Lactum antibiotics commonly prescribed in medicine and surgery ICU of tertiary care teaching hospital in central India, for a period of Oct 2014 to Dec 2015, establish most common β- Lactum antibiotics that give maximum ADRs and assess the causality of ADRs.

AIM AND OBJECTIVES:

AIM:

To assess the prevalence of Adverse Drug Reactions of β- lactum antimicrobials in medicine and surgery ICU patients at one of the tertiary care teaching hospital in central India.

OBJECTIVES:

1. To assess most commonly involved β- Lactum antibiotics associated ADR in medicine and surgery ICU
2. To analyse involvement of Age, Sex, and type of ADR occurring with respect to the use of particular Antimicrobials
3. To assess the causality of ADRs.

STUDY SETTING:

The study will be carried out in medicine and surgery ICU of Tertiary care Teaching hospital in central India.

MATERIALS AND METHODS:

1. This Prospective, Observational study was carried out in the Department of Medicine and surgery ICU at Tertiary care teaching hospital in central India.
2. After Institutional Ethical committee permission study has been conducted.
3. During the study of use of β- lactum antimicrobials in Medicine and Surgery ICU, from Oct 2014 to Dec 2015, along with demographic and clinical data, ADR developed with the concomitant use of β-lactum antimicrobials were noted and tabulated in CDSCO form. And ADR data has been generated
4. ADRs developed with use of β- lactum antimicrobials, reported by nurses and staff working at Medicine and surgery ICU to the Pharmacovigilance unit from October 2014 to December 2015 has also been included and analyzed using Microsoft Excel.

STUDY CONDUCT –

ADR reports of patients admitted to Medicine and surgery ICU who **were** on β-lactum Antimicrobials therapy had been collected from Pharmacovigilance unit at the end of every 6 months from Oct 2014 till Dec2015.

STUDY PERIOD: October 2014 to December 2015

STUDY POPULLATION: Patients admitted in medicine and surgery ICU with occurrence of ADR while receiving β- lactum antibiotics at one of the tertiary care teaching hospital in central India.

STUDY DESIGN: OBSERVATIONAL STUDY

STATISTICAL ANALYSIS:

Data was tabulated and data analysis has been done in consultation with statistician using the suitable tests.

RESULTS AND OBSERVATIONS

A total of 54 ADRs were collected, tabulated in CDSCO forms, analyzed and assessed on WHO causality assessment scale. The data is collected during the period Oct 1014 to Dec 2015 was analyzed for the total number of ADRs reported and classification of drugs causing reactions.

1. Study revealed that male patients 37 (68.5%) predominated over females 17**(31.5 %)** in ADR occurrence
2. The age wise distribution of ADRs revealed adults patients accounted 38(**70.37%)** and Geriatrics 16(**29.63 %)**
3. Maximum ADR were reported with inj Piptaz 17(31.4%), followed by Inj C-Tri 14(25.9%), Inj Cefotaxim 11(**20.4%)** , Inj Ampiclox 4(**7.5%)** , Inj Meropenam 4(**7.5%),** Inj Ceftriaxone and Salbactum 2(3.7%) , Inj Ampicillin 1(1.8%), Inj Augmentin 1(1.8%)
4. Most common ADR was Diarrhoea 23(**42.6%)** followed by Itching 8(14.8%). Skin rash with Itching 6(11.1%), Nuasea and vomiting 6 (11.1%), Black stool 6(11.1%) Abdominal cramps 3(**5.6%),** Chest pain 2(3.7%), So Gastrointestinal system was most commonly affected system followed by skin.
5. Causality assessment is done by using WHO causality assessment Scale showed that out of 54 cases of ADR 31(57.4.%) were Probable , 17(31.4%)were Possible, and 6(**11.2%)**were certain.

Table 1 : Gender distribution: (n =54)

Sr. No.	Gender	No. Of ADR	Percentage of ADR
1	Male	37	68.5 %
2	Female	17	**31.5 %**

Table 2 : Age group distribution

Sr. No	Age Group	No. Of ADR	Percentage of ADR
1	Adult	38	70.37 %
2	Geriatric	16	**29.63 %**

Table 3 : Antibiotics Implicated to Cause ADR (n = 54)

Sr. No	Drug	No. Of ADR	% of ADR
1	Inj Piptaz	17	31.4%
2	Inj C-Tri	14	25.9%
3	Inj Cefotaxim	11	**20.4%**
4	Inj Ampiclx	4	**7.5%**
5	Inj Meropenam	4	**7.5%**
6.	Inj Ceftriaxone and Salbactum	2	3.7%
7	Inj Ampicillin	1	1.8%
8	Inj Augmentin	1	1.8%

Table 4 : Type of ADR observed: (n=54)

Sr. No	Type Of ADR	ADR NO.	% of ADR
1	Dirrhoea	23	**42.6 %**
2	Nausea , vomiting	6	11.1 %
3	Skin rash and Itching	6	11.1 %
4	Black Stool	6	11.1%
5	Abdominal cramps	3	**5.6 %**
6	Chest pain	2	3.7%
7	**Itching over body**	8	14.8%

Table 5 : WHO Causality Assessment : (n=54)

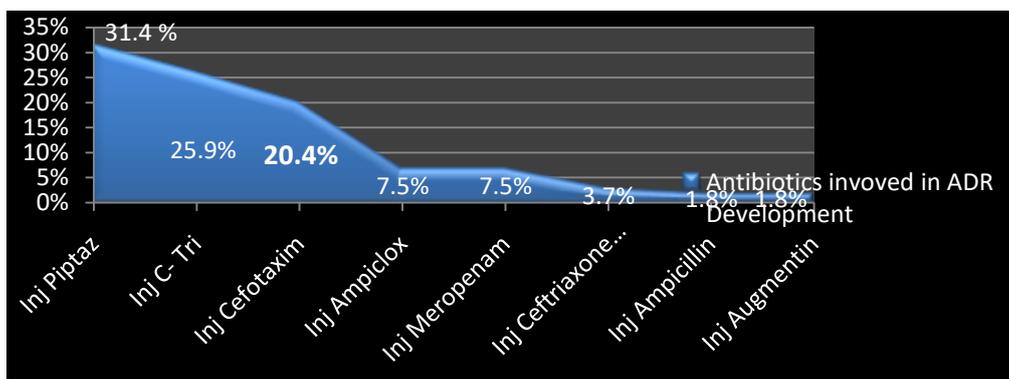| Sr. No	Probability	No. Of ADR	% of ADR
1	Certain	6	**11.2 %**
2	Probable	31	57.4 %
3	Possible	17	31.4 %
4	Unlikely	0	0
5	Conditional	0	0
6	Unclassifiable	0	0

Figure 1: Gender Distribuion
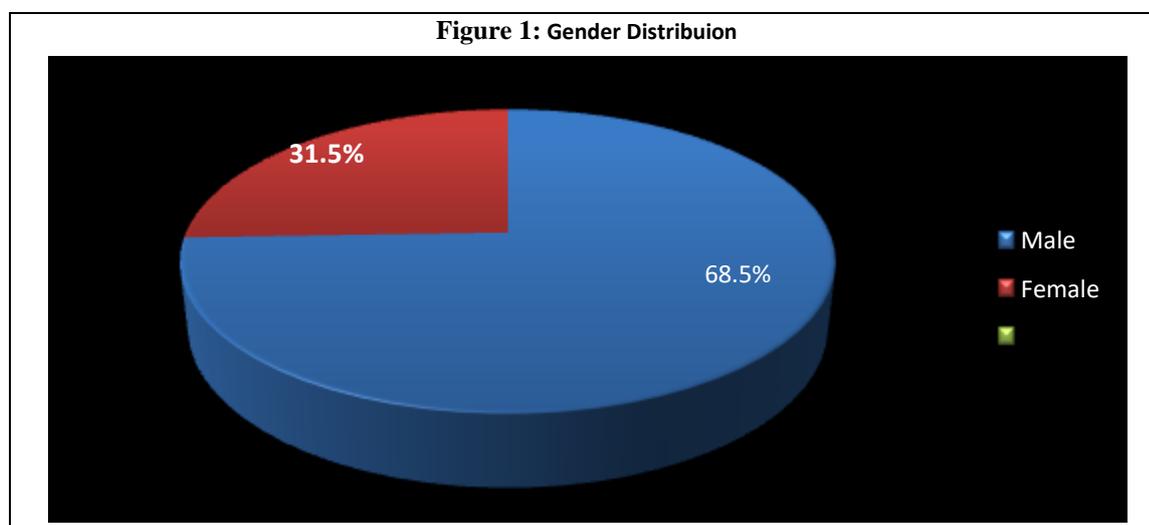
Figure 2: Age group distribution of ADR
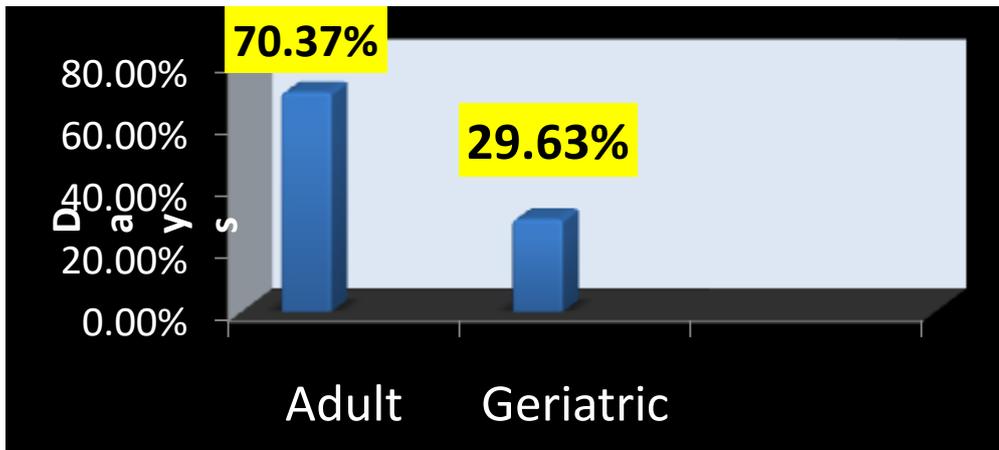
Figure 3: Antibiotics involved in ADR development

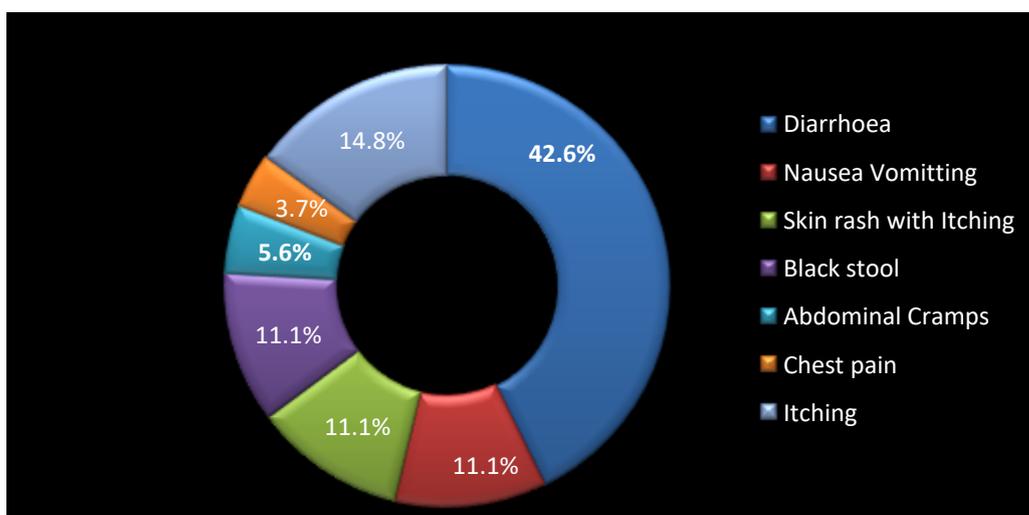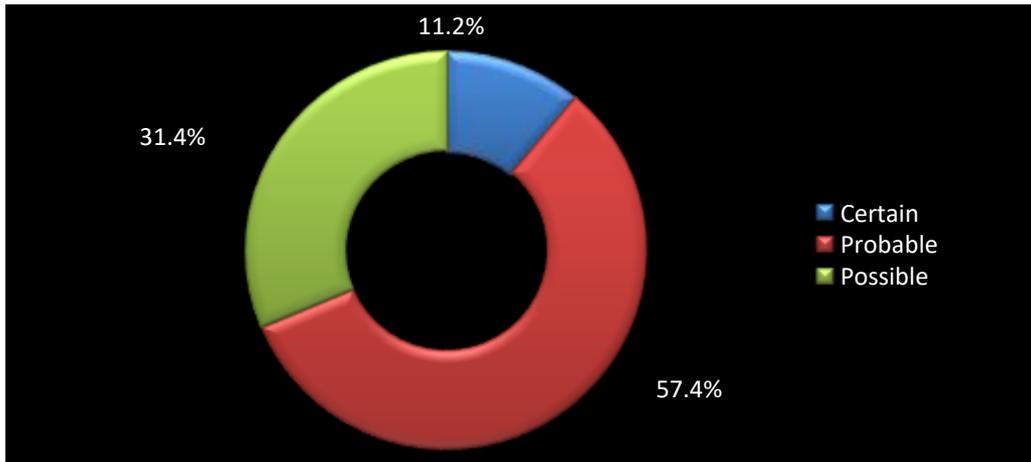**Figure 4:** ADR developed with use of antibiotics

Figure 5: Probability Assessment

11.2%

31.4%

57.4%

■ Certain
■ Probable
■ Possible

DISCUSSION

Among Beta Lactum Class of antimicrobials, Broad spectrum antibiotics cephalosporins were the most used antibiotic class, as shown by another study [6] and therefore in this study maximum ADR is reported with broad spectrum antibiotics like Inj Piptaz and Inj Ceftriaxone as these antibiotics were used maximally during the study period to treat serious infections in ICU patients. The predominance of male sex for ADRs with antibiotics may be due to majority of the admitted patients in ICU was male with more antibiotic use during the study period.

Analysis of the age wise distribution showed the predominance of adult patients. The study conducted by Jimmy Jose et al. and Suthar and Desai also showed the male predominance and the age group most accounted were adults in both the studies [8-9].

CONCLUSION

β- Lactum comprises the major volume Antibiotics used in ICU patients so implementation of antibiotic guidelines for the hospital scenario and strict adherence should be ensured to promote their rational use. The health system should promote the spontaneous detection of the Adverse Drug Reactions and delivering the awareness classes for the healthcare professionals regarding the need for reporting the incidents, incorporating ADR information in patient charts to improve the scenario in under-reported hospitals.

Reporting of Adverse Drug Reactions to antibiotics and other drugs, proper documentation and periodic reporting to regional pharmacovigilance centres will ensure Antibiotics safety . A periodic survey is needed for implementation of antibiotic policies.

This should be followed by analytical studies to link the drug utilization data to figures on morbidity, outcome of treatment, quality of care, and ultimately assess the rationality of drug therapy.

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