



A Study of Cutaneous Adverse Drug Reactions in Tertiary Care Hospital of Central India.

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ABSTRACT

Adverse drug reactions have been reported to be a major cause of morbidity, hospital admission and even death. They have also been blamed for prolonged hospitalization. This study was carried out to monitoring, categorization and assessment of cutaneous Adverse Drug Reaction in patients hospitalized / admitted at tertiary care hospital in Ujjain, M. P in the period of 1st November 2013 to 30th Sept 2014. All patients attending suspected CADR following drug intake as well as those admitted with CADR were evaluated during the study period. A total of 5678 cases were screened for CADR out of which total 124 patients experienced different types of CADR. The younger age group (21-40 years) was most affected by various types CADR. Male were found to be more susceptible to CADR in comparison to females. The commonest morphological type of CADR was maculopapular rash followed by urticaria, hyperpigmentation and fixed drug eruption. Antimicrobials, NSAIDs and antiviral drugs, which accounted for maximum number of CADR.

KEYWORDS : Adverse drug reaction, Pharmacovigilance, Cutaneous Adverse Drug Reaction.

INTRODUCTION –

Pharmacovigilance –an umbrella term used to describe the processes for monitoring and evaluating ADRs, is a key component of effective drug regulation systems, clinical practice and public health programmes. According to WHO, Pharmacovigilance is a science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any drug related problem.

Adverse drug reactions constitute a significant medical and national health problem. According to the reports, 5% to 35% all hospitalized patients experience an adverse drug reaction [1], 3% to 6% of all admissions to hospitals are primarily for a drug reaction and 24% to 30% of these patients develop a second reaction during their hospital stay [2].

Adverse drug reactions during hospitalization result in unnecessary taxation to the patient for treatment or diagnosis of his ailment. Knowledge of adverse reactions and their causality analysis may help the clinicians to recognize them and limit the ill effects [3].

Adverse drug reactions have been reported to be a major cause of morbidity, hospital admission [4] and even death. They have also been blamed for prolonged hospitalization [5].

Our hospital C. R. Gardi Medical College Ujjain is a tertiary care teaching hospital attached with R. D. Gardi Medical College Ujjain (M.P.), was chosen to be peripheral pharmacovigilance programme (NPP) till 2008. Presently our institute is an ADR monitoring centre and a part of pharmacovigilance programme of India.(PvPi).

AIMS & OBJECTIVES -

- Monitoring of cutaneous Adverse Drug Reaction in patients hospitalized / admitted at C. R. Gardi Hospital associated with R. D. Gardi Medical College.
- Categorization of cutaneous adverse drug reaction.
- Severity assessment of CADR's.

MATERIAL & METHODS –

It was a cross sectional surveillance study conducted at C. R. Gardi hospital attached with R.D. Gardi Medical College Ujjain (M.P) from 1st November 2013 to 30th Sept 2014. All patients attending suspected CADR following drug intake as well as those admitted with CADR were evaluated during the study period. After explaining the aim and objectives of the study, the written consent was obtained from the patients whose photographs were taken.

Inclusion Criteria :

1. Patients taking single medication or drugs of the same category.
2. Age : Between 2 and 80 yrs.
3. Sex : Male and Female.
4. The time interval between administration of a drug and the onset of a reaction should be within a specific period of time as described in the literature for a particular reaction.

Exclusion Criteria :

1. Patients' known to have an allergic reaction.
2. Patients taking drugs of different categories (more than 6 different categories).
3. Patient unaware of the drugs ingested/injected.
4. Repeat CADR with the same drug.

DATA COLLECTION AND ANALYSIS :

To identify the culprit drug for a particular type of CADR, attention was paid to the drug history, previous history of allergy, enlistment of all drugs taken preceding the onset of reaction, duration of reaction, type of cutaneous reaction, associated mucosal involvement and improvement of lesions on withdrawal of drug.

If more than one drug was thought to be responsible, the most likely offending agent was noted and the impression was confirmed by subsidence of the rash on withdrawing the drug.

All the ADR information from the study centres were collected on a standardized data collection form (CDSCO) Adverse Drug Event Reporting Form (6) and analysed. Cases were documented and further analyzed for incidence, types of CADR, drug classes and individual drug causing CADR, association of cutaneous reaction with drugs, and severity according to Hartwig et al (7).

The data was compiled on an excel sheet and subjected to further analysis.

OBSERVATIONS -

A total of 5678 cases were screened for CADR in a time frame of one year (1st Nov 2013 to 30th Sept 2014) out of which total 124 patients experienced different types of CADR. Male patients were more (59%) than female patients (41%) (figure -1). Younger patients in age group of 21-40 years were 47% out of total patients (Figure -2). The commonest morphological type of CADR is maculopapular rash followed by urticaria, hyperpigmentation, fixed drug eruption and bullous eruption.

Figure -1.

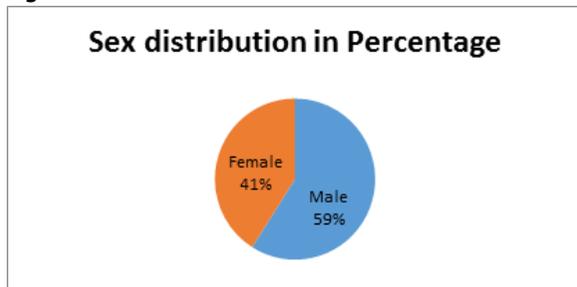


Figure -2.

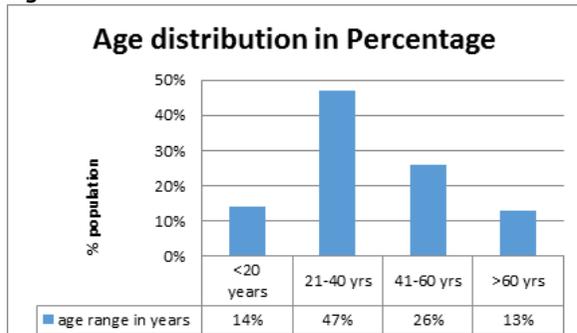


Table -1. Clinical spectrum of CADR

Sno	type of cutaneous reaction	number of cases	% of total cases
1	Maculopapular rash	42	33.87
2	urticaria	30	24.19
3	hyperpigmentation	15	12.09
4	fixed drug eruption	10	8.06
5	bullous eruption	6	4.83
6	erythema multiforme	4	3.22
7	acneform eruptions	4	3.22
8	angioedema	2	1.61
9	photoallergy	2	1.61
10	sjs/ten	2	1.61
11	contact dermatitis	2	1.61
12	miscellaneous	5	4.03

(miscellaneous- purple striae skin erosion, lips erosion, skin irritation)

Causative Drug groups -

The three main causative drug groups from which maximum percentage of patients had experienced CADR were antimicrobials (41.93%), antiviral (20.96%), NSAIDs (31.43%). The remaining drug groups i.e. Antimalarial, Antiulcer, Steroids, Depigmentation & Acne drugs accounted for rest of CADR (5.66%) (Table -2).

Table -2.

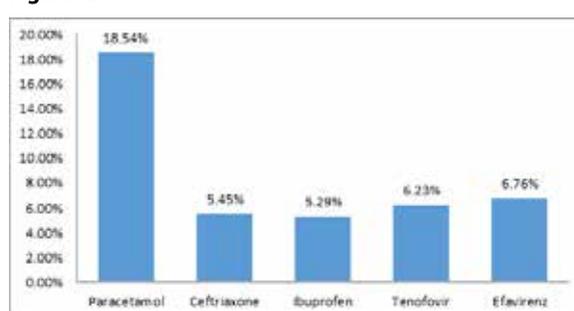
Causative Drug Group	Percentage of occurrence
Antimicrobials	41.93
NSAIDs	31.45
Antivirals	20.96
Antimalarials, Antiulcer, Steroids, Depigmentation & Acne Drugs	5.66

Causative Drugs -

Forty one offending agents were found responsible to cause various forms of CADR

The five leading and frequently encountered drugs which affected ≥ 5% of total cases of CADR were paracetamol (18.54%) Ceftriaxone (5.45%), Ibuprofen (5.29%) Tenofovir (6.23%) Efavirenz (6.76%) (Figure -3).

Figure -3.



Severity Assessment -

Severity Assessment of CADR was done by Moified Hartwig and Siegel Scale (7). According to this scale total 93.54% cases were mild, 4.83% were moderate and 1.61% were severe ADRs (Table -3).

Table-3.

Severity Category	No. of ADRs	Percentage of Cases
Mild	116	93.54%
Moderate	06	4.83%
Severe	02	1.61%
Total	124	100%

RESULTS & CONCLUSION -

The present study was undertaken to get better knowledge of spectrum of CADR in rural teaching hospital of Ujjain district. The study was conducted between 1st November 2013 to 31st May 2015. Evaluation of the data was done for various parameters comprising patient demographics, drug and reaction characteristics.

The incidence of CADR was 2.61% and the younger age group (21-40 years) was most affected by various types CADR. Male were found to be more susceptible to CADR in comparison to females. The commonest morphological type of CADR was maculopapular rash followed by urticaria, hyperpigmentation and fixed drug eruption.

Antimicrobials were found to be profoundly used drug group as the major number of reactions were seen with this drug group only. Other leading drug groups were NSAIDs and antivirals drugs, which accounted for maximum number of CADR. Paracetamol, Efavirenz & Tenofovir are the commonly incriminated agents for causing various CADR. Mild ADR cases were more (93.54%) and only few cases (1.61%) were severe.

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