DOI: 10.21276/sjams.2016.4.11.33

Scholars Journal of Applied Medical Sciences (SJAMS) **ISSN 2320-6691 (Online)**
Sch. J. App. Med. Sci., 2016; 4(11C):4023-4027 **ISSN 2347-954X (Print)**

(An International Publisher for Academic and Scientific Resources)
www.saspublisher.com

Original Research Article

A prospective study of adverse drug reactions monitoring in a tertiary care hospital, Rewa (MP)

Raj Bhupendra[1], Singh Prabhakar[2], More Pankaj[3], Indurkar Manoj[4], Pandey Vivek[5]
[1]Professor, Department of Pharmacology, S.S. Medical College, Rewa, (MP) – 486001
[2]Associate Professor, Department of Pharmacology, S.S. Medical College, Rewa, (MP) – 486001.
[3]Jr-3, Department of Medicine, S.S. Medical College, Rewa, (MP) – 486001.
[4]Professor, Department of Pharmacology, S.S. Medical College, Rewa, (MP) – 486001
[5]Jr-2, Department of Pharmacology, S.S. Medical College, Rewa, (MP) – 486001.

***Corresponding author**
Prabhakar Singh
Email: prabhakarsingh999@gmail.com

Abstract: The aim of study is to determine the pattern of suspected ADRs reported in ICU and ward admitted patients in a tertiary care hospital. Study was conducted in the department of Pharmacology and department of Medicine, SS Medical College and SGM Hospital, Rewa, MP during October 2014 to September 2015. Total 130 cases were enrolled in study that presented with suspected ADRs during study period, after taking written informed consent. Clinical evaluation and scrutiny of data was done to assess pattern, extent and duration of the suspected adverse drug reactions, affected organ system and involvement of therapeutic drugs classes as a part of the drug reaction. The result of this study showed that maximum (25%) patients belonged to the 18-25 years of age group, of these 55% was males and 45% were females. Mean (± SD) age of these patients was 34.84 ± 20.99 years. Among the reported suspected ADRs; maximum (26%) were skin rashes, followed by pruritus (15%), nausea, vomiting and rigor each occur 7%; Fever 6%, Apnea, oral ulcers and headache 3%. The most commonly affected organ system was skin and mucous membrane (44%), followed by central nervous system (11%), gastrointestinal system (10%), respiratory system (7%), and cardiovascular system (5%) in decreasing order. Of these; majority of suspected ADRs were associated with use of antimicrobials (68%), followed by NSAIDs (9%); Hematinics (5%); Antihypertensive, Antianginal, Antiepileptics, Hypoglycemic, Corticosteroids and Ionotrops (2%). The Hospital-based monitoring of suspected ADRs is convenient but it is under reported and the limitation of these studies is that they do not yield the exact incidence of suspected ADRs associated with particular drug use.
Keywords: suspected ADRs, Hypoglycemic, Corticosteroids and Ionotrops

INTRODUCTION:

Adverse drug reaction (ADR) contributes to the burden of drug related patient morbidity and mortality and also adding to the cost of patient health care. The detection and monitoring of ADRs is of vital importance for patient safety; as more than 50% of approved drugs are associated with some types of adverse effects that are not detected prior to their approval for clinical use [1]. The epidemiological importance of ADR is justified by its high prevalence rate – they causes 3% to 6% of hospital admissions at any age, and up to 24% in the elderly population; they have fifth rank among the all leading cause of death and moreover, they raised 5 to 10% of hospital costs [2]. An incidence of fatal ADRs is 0.23%-0.4% [3]. ADRs occur in both outpatients and inpatients. Out of total inpatients, 10.9% is estimated to experience an ADR during hospitalization. The preventability of ADRs among outpatients was 45%, however in inpatients it was 54% [4].

ADRs cause not only death and injury but they also affect the length of stay in hospitals which in turn leads to increased healthcare costs and decreased patient productivity [5]. The occurrence of reported ADRs is to be varies as it is influenced by various factors like age, gender, ethnicity, genetic factors, polypharmacy, drug interactions, multiple and inter-current diseases, increased length of hospital stay, dietary and environmental factors.

The reporting of ADRs in hospitals is very important because innovative new drugs are usually used and severe ADRs are most likely to be seen in hospitals [6], the contribution of health care professionals towards reporting of ADRs is enormously significant and the spontaneous reporting of ADRs by healthcare workers is one of the most important methods of ADR detection. There is greater and urgent need to create and enhance the physician's and healthcare workers awareness about detection, management, prevention and reporting of ADR. Hence, this study was conducted to assess the clinical pattern, spectrum of suspected ADRs and causality in ICU and ward admitted patients.

MATERIAL & METHODS:

This study was conducted by Department of Pharmacology in ICU and ward admitted patients in department of Medicine of SGM Hospital, Rewa (M.P.) after getting approval from institutional ethical committee. The study was carried out between Oct.2014 to Sept 2015; total 130 cases were enrolled in study (that presented with suspected ADRs during study period), after taking written informed consent. For each patient with suspected ADR, a detailed history including drug history, personal history, family history, present and past medical history and history of previous drug allergy were documented. The any untoward event was labeled as adverse drug reaction after discussion with the treating physician.

Clinical evaluation and scrutiny of data were done to assess the pattern, extent and duration of the suspected adverse drug reactions, affected organ system and involvement of therapeutic drug classes as a part of the drug reaction. The causality of the suspected ADRs were assessed by WHO-UMC Causality Assessment Criteria as certain, probable/likely and possible. The data (pattern of reported suspected ADRs) were analyzed by using Microsoft Office Excel sheet 2007 and expressed in form of number and percentage.

RESULTS:

In this study maximum (25%) patients were belonged to the 18-25 years of age group, of these 55% were males and 45% were females. Among males maximum (26%) were belonged to 18-25 years and 41-60 years of age group. In females maximum 35% were belonged to 26-40 years of age. The mean (± SD) age of these patients was 34.84 ± 20.99 years. (Table1)

Among the reported suspected ADRs during study; maximum (26%) was skin rashes, followed by pruritus (15%). Nausea, vomiting and rigor each occur 7% in frequency. The frequency of others develop ADRs were as follow; fever 6%, apnea, oral ulcers and headache each occur in 3% of frequency. Tinnitus, altered sensorium, hepatitis, pedal edema, SJS, breathlessness and disorientation were occurring in 2% of frequency. The anxiety, hypotension, diarrhea, arrhythmia, gum hypertrophy, bullous eruption, constipation, vertigo, swelling lips, TEN, fatigue, visual disturbances, weight gain, oral candidiasis, red man syndrome, tachycardia slurring of speech, dryness of mouth psychosis, tremors, cough and hair changes each were noted only 1% infrequency. (Figure 1) In this study; the most common affected organ system is skin and mucous membrane (44%), followed by central nervous system (11%), gastrointestinal system (10%), respiratory system (7%), cardiovascular system (5%) and hepatobiliary system (2%) in decreasing order and 21% ADRs were appear in other groups which includes tinnitus, visual disturbances, fever, rigor, weight gain, dryness of mouth, hair changes accounting for 21% of total suspected ADRs. (Table 2)

The majority of suspected ADRs were associated with use of antimicrobials (68%), followed by NSAIDs (9%); Hematinics (5%); Antihypertensive, Antianginal, Antiepileptics, Hypoglycemis, Corticosteroids and Ionotrops, each groups were associated with2% of ADRs. Adrenergic, Antacids, Opioids, Bronchodialators, Antihistaminics and Anticholinergic drugs each groups were associated with 1% of ADRs. (Table 3) According to WHO-UMC Causality Assessment Criteria; majority of suspected ADRs (53%) were evaluated as being probable, followed by possible (44%) and only 3% ADRs was assessed as certain. (Figure 2)

Table 1: Age and gender wise distribution of subjects enrolled in study.

Age group (in years)	Male		Female		Total	
	n	%	n	%	n	%
0-17	8	12	10	17	18	14
18-25	19	26	15	26	34	26
26-40	13	18	20	35	33	25
41-60	19	26	8	14	27	21
61-80	13	18	3	5	16	12
80<	0	0	2	3	2	2
Total	72	100	58	100	130	100
Mean±SD	38.75±21.42		29.98±19.58		34.84±20.99	

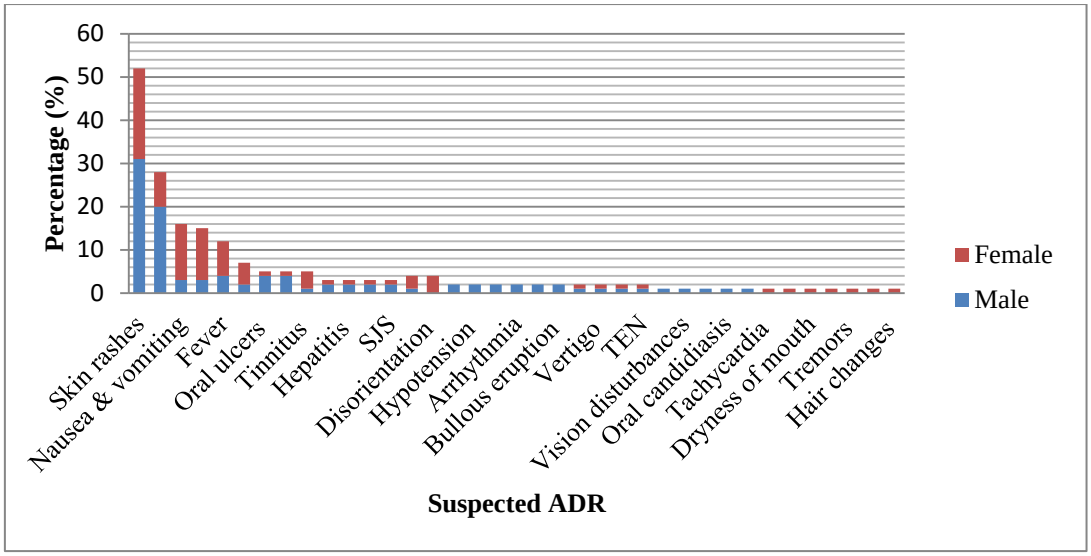

Fig 1: Frequency distribution of reported suspected ADRs during study period

Table 2: Frequency distribution of suspected ADRs according to the affected organ system

Organ system affected	Frequency of suspected ADRs					
	Male		Female		Total	
	n	%	n	%	n	%
Skin and mucous membrane	45	57	19	28	64	44
Central nervous system	8	10	8	12	16	11
Gastrointestinal system	5	6	10	15	15	10
Respiratory system	3	4	8	12	11	7
Cardiovascular system	6	8	2	3	8	5
Hepatobiliary system	2	3	1	1	3	2
Genitourinary system	0	0	0	0	0	0
Others	10	12	20	29	30	21
Total	79	100	68	100	147	100

Others include – tinnitus, visual disturbances, fever, rigor, weight gain, dryness of mouth, hair changes.

Table 3: Frequency distribution of suspected ADRs according to therapeutic classes of drugs

Class of drugs causing suspected ADRs	Frequency of suspected ADRs					
	Male		Female		Total	
	n	%	n	%	n	%
Anti-microbials	51	72	38	64	89	68
NSAIDS	6	9	6	10	12	9
Hematinics	0	0	6	10	6	5
Antihypertensive	1	1	2	4	3	2
Antianginal	2	3	1	1	3	2
Antiepileptics	3	4	0	0	3	2
hypoglycemic drugs	2	3	1	2	3	2
Corticosteroids	2	3	1	2	3	2
Inotrops(Digitalis)	2	3	0	0	2	1
Adrenergic	1	1	0	0	1	1
Antacids	1	1	0	0	1	1
Opioids	0	0	1	2	1	1
Bronchodilators	0	0	1	2	1	1
Antihistaminics	0	0	1	2	1	1
Anticholinergic	0	0	1	2	1	1
Total	**71**	**100**	**59**	**100**	**130**	**100**

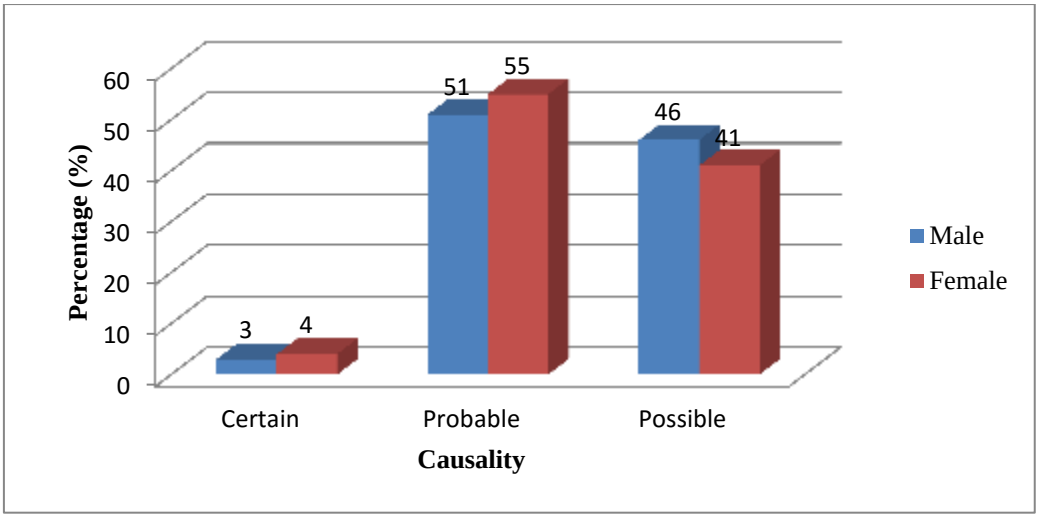

Fig-2: Causality assessment (WHO-UMC Causality Assessment) Criteria.

DISCUSSION:

Imparting knowledge and awareness of suspected ADRs reporting among health care professionals would introduce the reporting culture among medical practitioners and increase the reporting rates of ADRs. In the present study, the mean age of subjects was 34.84 ± 20.99 years for males and 29.98±19.58 years for females; the mean age difference between the gender was not statistically significant ($p>0.05$), the eldest being 85 years and the youngest subject being 1 year of age. Majority of the study subjects were males (55%) indicating higher incidence of suspected ADRs in males which is similar to other studies e.g. Gupta *et al.;* [7] in 2003, and Chawla *et al.;* [8] in 2011.

In our study the commonest suspected ADR was skin rashes (26%), which is in concordance with previous studies Arulmani *et al.;* [9] 2007, followed by pruritus (15%),nausea, vomiting and rigor (7%); fever (6%); apnea, oral ulcer and headache 3% each; tinnitus, altered sensorium, hepatitis, pedal oedema, SJS, breathlessness and disorientation 2% each. Anxiety, hypotension, diarrhea, arrhythmia, gum hypertrophy, bullous eruption, constipation, vertigo, swelling lips, TEN, fatigue, visual disturbances, weight gain, oral candidiasis, red man syndrome, tachycardia slurring of speech, dryness of mouth psychosis, tremors, cough and hair changes were seen only in 1% of ADRs. More than one suspected ADR were frequently observed in the same subject. The gender wise differences in suspected ADRs were not statistically significant.

According to affected organ system of suspected ADRs, the skin is the commonest organ that involved in 44% of total suspected ADR, which is similar with previous studies in which dermatological manifestations were most common ADR Arulmani *et al.;* [9] 2007; Murphy *et al.;* [10] in 1993; Jose *et al.;* [11] in 2006; Glassen *et al.;* [12] in 1991; Prosser *et al.;* [13] in 1990. This was followed by involvement of Central nervous system (11%), gastrointestinal system (10 %), respiratory system (7%), cardiovascular system (5%) and hepatobiliary system (2%). Remaining 30% of ADR were classified as miscellaneous which includes tinnitus, visual disturbances, fever, rigour, and weight gain, dryness of mouth and hair changes**.** In our study, majority of suspected ADRs were associated with use of antimicrobials (68%) which is similar to various previous studies Wester *et al.;* [14] in 2007; Gor *et al.;* [15] in 2008; Vora *et al.;* [16] in 2011; Leape *et al.;* [17] in 1991, probably this may due to AMAs are most commonly prescribed drugs in our hospital setting, followed by NSAIDs (9%), Hematinics (5%), Antihypertensive, Antianginal, Antiepileptics, Hypoglycemis and Corticosteroids each were associated with 2% of suspected ADRs. use of Ionotrops were associated with 2% of suspected ADRs. use of Adrenergic, Antacids, Opioids, Bronchodialators, Antihistaminics and Anticholinergic each were associated with 1% of suspected ADRs in of study subjects. The gender related difference in different therapeutic drug class of drugs associated with suspected ADRs were statistically not significant**.**

CONCLUSION:

Adverse drug reactions monitoring, particularly of serious nature, is mandatory. Adequate awareness of suspected ADRs reporting and precautions of prescribing drugs are essential. Careful planning and monitoring of drug therapy can prevent majority of ADRs. The Hospital-based monitoring of suspected ADRs is convenient but the limitation of these studies is that they do not yield the exact incidence of suspected ADRs associated with a particular drug use. In our study, males have higher incidence of suspected ADRs, which have a ranged from common mild reactions like skin rashes, pruritus, and nausea and vomiting to severe

reactions like SJS and TEN. The most common suspected ADRs were generalized skin rashes and pruritus and commonest drugs presented with suspected ADRs were antimicrobials and NSAIDs. Frequent conduction of sensitization workshops regarding suspected ADR reporting involving undergraduates, postgraduates, practitioners and paramedical staff is very important for creating awareness for ADR reporting.

REFERENCE:

1. Rabbur RS, Emmerton L. An introduction to adverse drug reaction reporting systems in different countries. International Journal of Pharmacy Practice. 2005 Mar 1; 13(1):91-100.
2. Onder G, Pedone C, Landi F, Cesari M, Della Vedova C, Bernabei R, Gambassi G. Adverse drug reactions as cause of hospital admissions: results from the Italian Group of Pharmacoepidemiology in the Elderly (GIFA). Journal of the American Geriatrics Society. 2002 Dec 1; 50(12):1962-8.
3. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. Jama. 1998 Apr 15; 279(15):1200-5.
4. Hakkarainen KM, Hedna K, Petzold M, Hägg S. Percentage of patients with preventable adverse drug reactions and preventability of adverse drug reactions–a meta-analysis. PloS one. 2012 Mar 15; 7(3):e33236.
5. Alomar MJ. Factors affecting the development of adverse drug reactions (Review article). Saudi Pharmaceutical Journal. 2014 Apr 30; 22(2):83-94.
6. Vallano A, Cereza G, Pedròs C, Agustí A, Danés I, Aguilera C, Arnau JM. Obstacles and solutions for spontaneous reporting of adverse drug reactions in the hospital. British journal of clinical pharmacology. 2005 Dec 1; 60(6):653-8.
7. Gupta R, Sheikh A, Strachan D, Anderson HR. Increasing hospital admissions for systemic allergic disorders in England: analysis of national admissions data. Bmj. 2003 Nov 13; 327(7424):1142-3.
8. Arulmani R, Rajendran SD, Suresh B. Adverse drug reaction monitoring in a secondary care hospital in South India. British journal of clinical pharmacology. 2008 Feb 1; 65(2):210-6.
9. Murphy BM, Frigo LC. Development, implementation, and results of a successful multidisciplinary adverse drug reaction reporting program in a university teaching hospital. Hospital pharmacy. 1993 Dec; 28(12):1199-204.
10. Jose J, Rao PG. Pattern of adverse drug reactions notified by spontaneous reporting in an Indian tertiary care teaching hospital. Pharmacological research. 2006 Sep 30; 54(3):226-33.
11. Classen DC, Pestotnik SL, Evans RS, Burke JP. Computerized surveillance of adverse drug events in hospital patients. Jama. 1991 Nov 27; 266(20):2847-51.
12. Prosser TR, Kamysz PL. Multidisciplinary adverse drug reaction surveillance program. American Journal of Health-System Pharmacy. 1990 Jun 1; 47(6):1334-9.
13. Wester K, Jönsson AK, Spigset O, Druid H, Hägg S. Incidence of fatal adverse drug reactions: a population based study. British journal of clinical pharmacology. 2008 Apr 1; 65(4):573-9.
14. Gor AP, Desai SV. Adverse drug reactions (ADR) in the inpatients of medicine department of a rural tertiary care teaching hospital and influence of pharmacovigilance in reporting ADR. Indian journal of pharmacology. 2008 Jan 1; 40(1):37.
15. Vora MB, Trivedi HR, Shah BK, Tripathi CB. Adverse drug reactions in inpatients of internal medicine wards at a tertiary care hospital: A prospective cohort study. Journal of Pharmacology and Pharmacotherapeutics. 2011 Jan 1; 2(1):21.
16. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, Newhouse JP, Weiler PC, Hiatt HH. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. New England journal of medicine. 1991 Feb 7; 324(6):370-6.