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Original Research Article

Pattern of adverse drug reactions reported at the adverse drug reaction monitoring centre at tertiary care teaching hospital in North India

Amita Jindal¹, Raj Kumar^{1*}, Sumir Kumar², Amandeep Kaur¹, Kiranjit³, Rakesh Tilak Raj⁴

¹Department of Pharmacology, ²Department of Skin and VD, ³Department of Chest and TB, GGS Medical College and Hospital, Faridkot, Punjab, India

⁴Department of Skin and VD, Govt. Medical College, Amritsar, Punjab, India

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*Correspondence:

Dr. Raj Kumar,

Email: anurajkumar76@gmail.com

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ABSTRACT

Background: The aim of the present study was to determine the pattern of adverse drug reactions (ADRs) reported at ADR monitoring centre (AMC) in Punjab.

Methods: This observational retrospective study was done in department of Pharmacology, GGS Medical College and Hospital, Faridkot from September 2020 to August 2021. A total of 148 ADRs were reported during the study period. Each ADR was analyzed for demographic data and characteristics of ADR. Assessment of causality, severity and preventability was done according to WHO UMC scale, modified Hartwig and Siegel scale and Modified Schumock and Thornton Preventability Scale respectively.

Results: A total of 148 ADRs were reported from both outpatients and in patients of various departments. Most of the ADRs were found in males (55%) and patients of age group 31-45 years (33%). Majority of ADRs were reported from dermatology department (40%). Overall, 38% of ADRs were due to antimicrobial drugs. Most of the ADRs were reported as possible (57%), followed by probable (41%) as per WHO causality assessment. Most of the ADRs were moderate severity (83%). 97% of the ADRs were found to be definitely preventable type.

Conclusions: We concluded that most of the ADRs were reported from antimicrobial drugs, so it is advisable to have close monitoring of the antimicrobial drug therapy to prevent ADRs in the patients. Although the majority of ADRs were moderate in nature but mostly were recovered. The study of ADRs in a particular institute using demographic patterns will contribute to patient safety by sensitizing the clinicians in that particular institute.

Keywords: Adverse events, ADRs causality, Preventability, Severity, Adverse drug monitoring centre, Pharmacovigilance, WHO causality scale

INTRODUCTION

Adverse reactions to the drugs are one of the main unavoidable risk factors in the use of drug therapy. It has been described by the world health organization (WHO) as a “noxious, unintended and undesired effect of a drug, which occur at doses normally used in humans for prophylaxis, diagnosis or cure of a disease”.¹ India is said to be the second highest market for the sale of prescription drugs in the world, yet only about 2% of the adverse drug

reactions are reported. The main cause for this low figure is the underreporting of the ADRs.² To get the real picture of the scenario, more of the ADR reporting is necessary. This study was conducted to ascertain the pattern of ADRs in tertiary care teaching institute. This study sensitized the health care professionals regarding pattern of ADRs that contributed to patient safety. Also, this study helped to identify and minimize, the preventable ADRs, thus ensuring a safe and effective use of the drug.

Aims and objectives

Aim and objectives of current investigation was to characterize the pattern of reported ADRs at AMC (Adverse Drug Monitoring Centre), Faridkot and to analyze the causality, severity and preventability of reported ADRs.

METHODS

This was an observational, retrospective, non-interventional study. This study was done in the department of pharmacology, GGS medical college and hospital, Faridkot. In this study, voluntary reported ADR forms received at ADR monitoring centre, GGS medical college and hospital, Faridkot over a period of one year from September 2020 to August 2021 were analyzed.

Inclusion criteria

Inclusion criteria for current study were; ADRs reported from outpatient (OPD) and in patient departments (wards, ICU, diagnostic and immunization departments) of GGS medical college and hospital, ADRs reported from either sex (male or female) and ADRs reported from all age groups.

Exclusion criteria

Exclusion criteria for current study were; ADRs due to poisoning of drugs (accidental or intentional), ADRs due to blood or blood products and ADRs due to alternate system of medicines like homeopathy, ayurvedic and Unani.

Evaluation of data for various parameters was done which include, patient demographics (age and gender), ADR characteristics (department wise distribution of ADRs, Outcome and management of ADRs, reporter professional status), drug characteristics (pharmacological class of drug), assessment of Causality was done according to WHO-UMC scale.³ Assessment of Severity was done according to Modified Hartwig and Siegel scale.⁴ Assessment of preventability was done using the classification system of modified Schumock and Thornton Preventability Scale.⁵ Data obtained was expressed in numbers and percentages wherever appropriate.

RESULTS

A total of 148 Suspected ADR Reporting forms were collected from various departments of Guru Gobind Singh medical college and hospital, Faridkot during the study period (September 1, 2020 to August 31, 2021). Total number of ADRs reported was more in males (55%) than in females (45%) as shown in (Table 1). The percentage of ADRs was highest in the age group of 31-45 years (33%) as depicted in (Table 2).

Table 1: Gender Wise Distribution of ADRs.

Gender	N	%
Males	81	55
Females	67	45

Table 2: Age wise distribution of ADRs.

Age group (years)	N	%
Below 1 year (infants)	03	2
1-15	05	3
16-30	18	12
31-45	49	33
46-60	45	30
61-75	25	17
Above 75	03	2

Departmental status of ADRs reporting

Maximum number of ADRs were reported from dermatology department (40%), followed by radio-diagnosis (14%), immunization department (13%) and medicine department (12%), Chest and TB (8%) and other departments (13%) including ENT, pediatrics, radiotherapy, psychiatry, gynaecology and eye. ADRs among different classes of drugs were the highest for antimicrobials (38%), followed by vaccines and diagnostic agents, 14% each as shown in (Table 3).

Table 3: Characterization of drugs involved in ADRs.

Class of drug	N	%
Antimicrobials	57	38
NSAIDS	12	8
Opioids	1	0.68
Anti-cancer	14	9
Vaccines	20	14
Antiepileptic	3	2
Antipsychotics	4	3
Centrally acting muscle relaxants	4	3
Diagnostic agent (contrast media CECT)	20	14
Dietary supplements	5	3
Antihistaminis	3	2
Corticosteroids	3	2
Antipsoriatic (apremilast)	2	1

Among antimicrobial agents, antibiotics like Amoxicillin, Azithromycin, Vancomycin, and Ofloxacin were responsible for most of the skin reactions like maculopapular rashes, erythematous rashes etc, few anaphylactic reactions and abdominal pain, loose stools. Skin reactions were also caused by antifungal (fluconazole) and antiviral agents. Nausea, vomiting, hepatitis and pancytopenia were caused by antitubercular agents isoniazid, rifampicin, pyrazinamide and ethambutol. Kanamycin used for Tuberculosis also caused hearing loss.

Outcome of ADRs

Among 148 patients, 51% of patients recovered from the reactions, 29% were at recovering stage during the study period, 3% of ADRs were fatal while the outcome of 17% patients was unknown. Out of 148 ADRs, symptomatic treatment with dechallenge was done in 58% patients. Symptomatic treatment without dechallenge was done in 16% patients, only suspected drug was withdrawn in 9% and dose reduction of suspected drug was done in 8% patients.

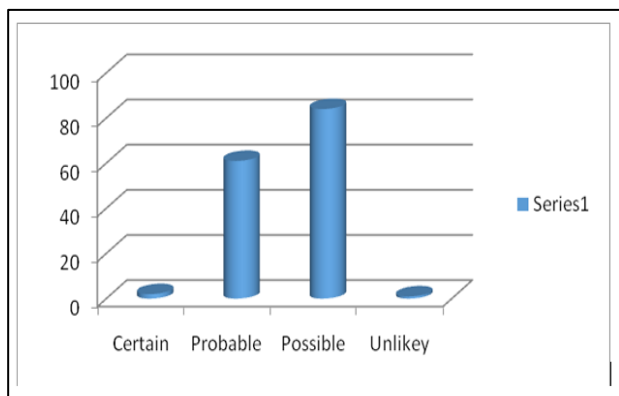


Figure 1: Causality assessment using WHO UMC scale.

Assessment of ADRs

According to WHO UMC, the causality assessment for ADRs was possible in 57% cases, probable in 41%, certain and Unlikely in 1% each as shown in (Figure 1). Out of 148 ADRs encountered, 15% were found to be mild, 83% were moderate and 2% were severe in nature as shown in (Figure 2).

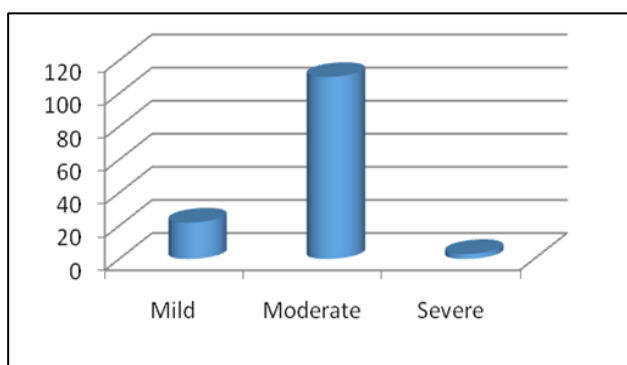


Figure 2: Severity assessment using modified Hartwig and Seigel scale.

Out of 148 ADRs, most (97%) were found to be definitely preventable, 3% were found to be probably preventable and none was found to be not preventable as shown in (Figure 3). Reporter's professional status: ADRs were reported by healthcare professionals like Physicians, nurses and radiographers. During the study period we

observe that the majority of ADRs were reported by physicians (63%), followed by nurses (24 %) and radiographers (13%).

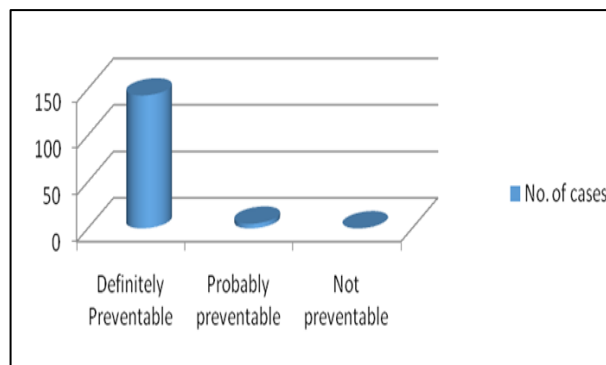


Figure 3: Preventability assessment using modified Schumock and Thornton scale.

DISCUSSION

The present study was conducted for detection and analysis of ADRs reported from various departments of a tertiary care hospital in Faridkot, Punjab. The total number of ADRs reported was 148 in one year. The reason of underreporting of ADRs may be due to covid pandemic lockdown, in this study period as lesser number of OPDs was under functional. Secondly, maximum number of Health care professionals had COVID duties. The demographic details of present study showed that ADRs reported were more in males as comparison to females. More ADRs were reported from males (55.86%) in the study conducted by Badar et al which was similar to our study.⁶ A higher percentage of ADRs occur in adult age group (31-45 years) in our study. Maximum numbers of ADRs were reported in the age group of 31-40 years by Badar et al.⁶ The department reporting maximum ADRs (63.01%) was from dermatology department in the study conducted by Lilute et al.⁷ In the present study also, maximum number of ADRs were reported from skin department. The most common drug class causing the ADRs in our study is antimicrobials (38%). This result is consistent with the study carried out by Badar et al. in which maximum number of ADRs occurred with antimicrobials.⁶ In outcomes of the reactions, most of the patients have shown recovery after the withdrawal of offending drug with the treatment of ADRs. Four fatal reactions were also noted in the study. In our study, causality assessment by WHO-UMC scale showed that 57% ADRs were possible and 41% were probable. The present study was consistent with the study conducted by Venkatsubaiiah et al in which 48.82% ADRs were possible and 27.17% were probable.⁸ Similar results were also shown by Sharma et al. in which possible ADRs were 48% and probable ADRs were 43%. Assessment of severity by Modified Hartwig and Siegel scale indicated 83% as moderate and 15% as mild. Only three severe ADRs have been encountered in our centre during the study period. Similar results were shown by study

conducted by Zaman et al. in which 83.95% ADRs were moderate and 14.97% were mild.⁹ Assessment of preventability by modified Schumock and Thornton scale showed that 97% of ADRs were definitely preventable, 3.38% were probably preventable and none was under not preventable category. In the study conducted by Palaian et al two third of ADRs (64.7%) were definitely preventable.

Implications

This study will be useful to increase awareness among healthcare professionals regarding ADR reporting. ADR reporting can further be improved by conducting awareness and sensitization training programs on ADR reporting among health care professionals.

CONCLUSION

This study provides valuable insight as regards to the pattern of ADRs in a tertiary care teaching hospital. Majority of ADRs were reported from adult age group especially from males. Although the majority of ADRs were moderate in nature but mostly were recovered. ADR reporting was maximum from Dermatology department and the antimicrobials contributed to maximum of ADRs.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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