

A prospective study on adverse drug reactions reported in a tertiary referral hospital

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ABSTRACT

Background: To determine the incidence of Adverse drug reactions in our hospital, to study the age wise distribution, the role of concurrent medication and the common drugs that are prone to cause adverse drug reactions and its seriousness.

Methods: After getting prior approval from Institutional ethical committee a prospective study was done where in cases attending OPD, ward, ICU were studied over a year. A complete history was taken regarding drug exposure (dosage, date started, duration and interruptions in use), initiation of drug use and onset of reaction, previous adverse drug reactions, improvement after decrease in dosage, disease states predisposing to eruptions, previous family and personal history of skin disease, environmental and occupational exposure to chemicals. Relevant laboratory test such as blood investigations, liver and renal function tests are carried out and results were analysed statistically by SPSS version 21 and interpretations done based on the results.

Results: Incidence of ADR among OPD =0.18, IPD=1.98, OPD+IPD=0.39 /1000cases. The highest incidence of Adverse drug reactions were found among the age group of 30-39 years (27.45%), 40-49 years (23.53%), with the highest among antibiotic group of drugs (35.29%) involving a maximum duration of 2-7 days. Drug reactions mostly occurred with the oral route (66.67%) and most of it requiring hospitalization (47.06%), 60.78% of reactions were manifested in skin, 58.82% of patients with ADR had concomitant medications and 19.61% had Diabetes mellitus, 90% of reactions abated after drug withdrawal with regard to its outcome 94.12% of reactions recovered.

Conclusions: The study suggest the adverse drug reactions commonly occur in middle age, mostly manifesting in skin with oral route of administration, associated with concomitant medications and it requires hospitalisation with a good recovery rate with diabetes being the common comorbid disorder.

Keywords: Adverse drug reaction, Diabetes, Hospitalisation, Incidence, Oral route, Withdrawal

INTRODUCTION

Adverse drug reactions has been defined as any noxious change which is suspected to be due to a drug, occurs at doses normally used in man, requires treatment or decrease in dose or indicates caution in the future use of the same drug.¹ Though ADR are of great concern to the general public, medical profession, pharmaceutical

industry and regulatory authorities, the concept of ADR reporting is still new in India and reporting of ADRs is scarce.

Drugs prescribed for disease are often themselves the cause of serious amount of adverse reactions ranging from mere inconvenience to permanent disability and death.²

In a study examining the incidence of skin eruptions, approximately 45% of all adverse drug reactions were manifested in the skin.³ Most drug eruptions are self-limiting and usually resolve after the offending agent has been discontinued. Severe and potentially life threatening reactions occur in 1 in 1000 hospitalized patients.⁴ The majority (75-80%) is non immunological and 20-25% is immune mediated. Mortality rate of Steven Johnson syndrome is below 5%, in case of erythema multi former it's significantly higher, while the rate of toxic Epidermonecrosis is 20-30% and most patients die from sepsis.

Adverse drug reactions are one of the leading causes of morbidity and mortality up to 35% of hospitalized patients experience an ADR, approximately 5% to 10% of all hospital admissions are due to ADRs. Over 2 Million serious ADRs yearly, 1,00,000 deaths yearly occur due to ADRs, ADRs are 4th leading cause of death ahead of pulmonary disease, diabetes mellitus and AIDS. With due concern over its importance we have undertaken this study to descriptively analyses the adverse drug reactions reported in our hospital premises.

Objectives

1. To determine the incidence of Adverse drug reactions in our hospital and the commonest type reported in our hospital.
2. To study the age wise distribution of Adverse drug reaction.
3. To study the role of concurrent medications in causing Adverse drug reactions.
4. To study about the common drugs those are prone to cause adverse drug reactions.
5. To study the seriousness of the adverse drug reaction and to stress the importance of reporting an adverse drug reaction.

METHODS

Prior approval from institutional ethical committee was obtained.

It was prospective observational study.

Site of the study was OPD, Ward and ICU.

Duration of the study was from March 2015 to February-2016.

Inclusion criteria

Patients of either sex male and female of age 5-70 yrs attending OPD, admitted in wards, intensive care unit of medicine, surgery, skin, psychiatry, paediatric, ophthalmology and ENT Department who have given consent.

Exclusion criteria

Patients who have not given consent, cases reported due to poisoning.

A set of following questions was put forth for the patients and relevant information is obtained

Questionnaire

- Age
- Sex
- Occupation
- Personal History
Family History
- Date of onset of Reaction
- Duration of Reaction
- Dosage of Drug, Route administered
- Date of Recovery
- Whether reaction abated after drug withdrawal
- Concomitant medications/Herbal Remedies with therapy dates
- Relevant tests/Laboratory Data with dates
- Preexisting medical illness
Previous reports of Adverse Drug Reactions
- Family History of Hypersensitivity Reactions
- Occupational Exposure
- Seriousness of Reaction: (Life threatening/ Hospitalization/ Disabling/ Requiring intervention)
- Outcome of the Reaction
(Fatal /continuing/recovery)

Routine blood investigations, liver and renal function tests are carried out.

Results were analysed statistically by SPSS version 21 and interpretations done based on the results.⁵

RESULTS

The results were depicted as follows:

Incidence rates

Total OPD cases= 141272

Total IPD Cases= 19215

Total ADR reported Out Patient= 25

Total ADR reported Inpatient= 38

Incidence of ADR among OPD cases= $25/141272= 0.18/1000$ cases

Incidence of ADR among IPD cases= $38/19215= 1.98/1000$ cases

Incidence of ADR among OPD+IPD cases= 63/141272= 0.39/1000cases.

OPD= Outpatient,

IPD= Inpatient,

ADR =Adverse drug reaction.

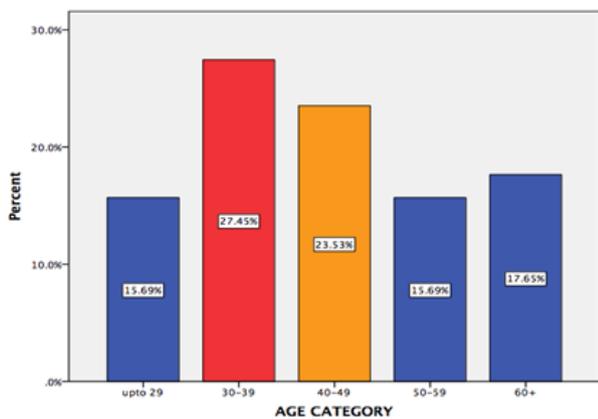


Figure 1: ADR with age-wise distribution of patients.

Figure 1 shows ADR with age-wise distribution of patients with highest incidence 27.45% (30-39) and 23.53% (40-49 yrs).

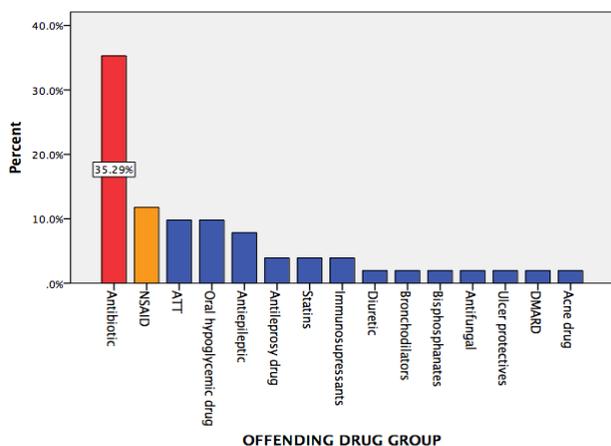


Figure 2: ADRs according to class of drug.

Figure 2 showing ADRs according to class of drug involved with highest incidence among antibiotic group of drugs (35.29%) and NSAID (12%).

Figure 3 showing duration of ADR involved. Most of the adverse drug reactions involved a maximum of 2-7 days (47.92%).

Figure 4 shows depicting ADR and the route of drug administration. The maximum no. of adverse reactions occurred with the oral route (66.7%) followed by parenteral (23.52%).

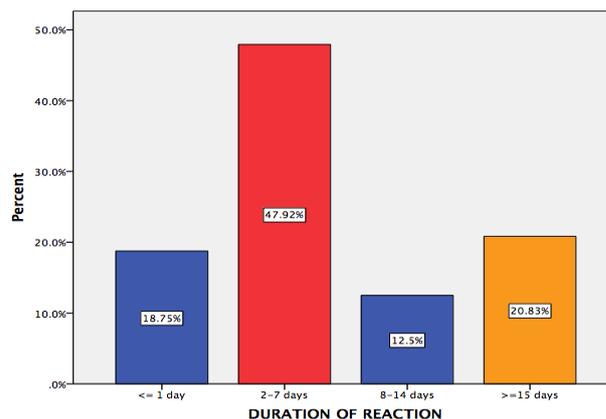


Figure 3: Duration of ADR involved.

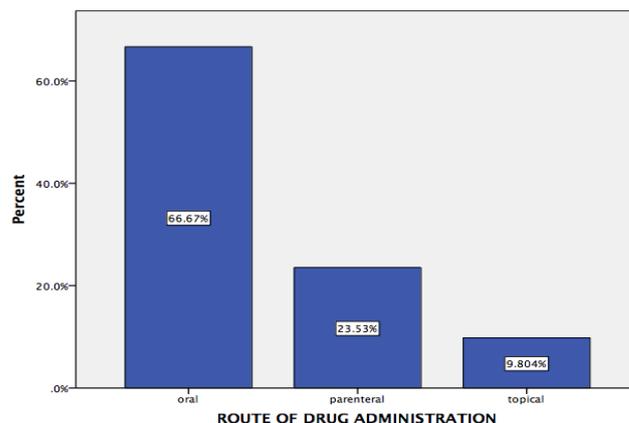


Figure 4: Depicting ADR and the route of drug administration.

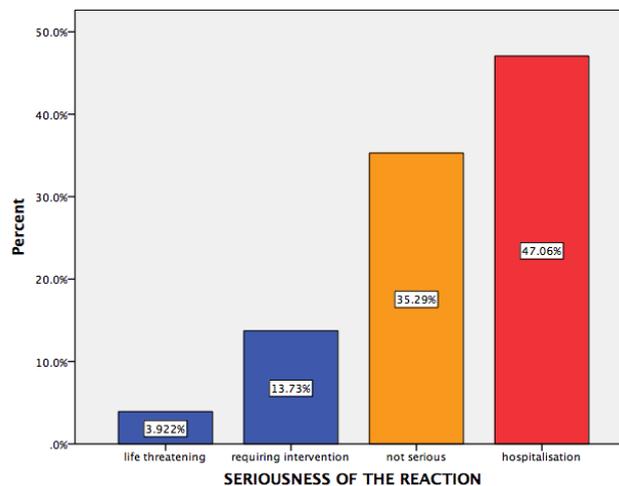


Figure 5: Seriousness of the reaction according to the ADR.

Figure 5 showing seriousness of the reaction according to the ADR involved with most of the reactions required hospitalization (47.06%).

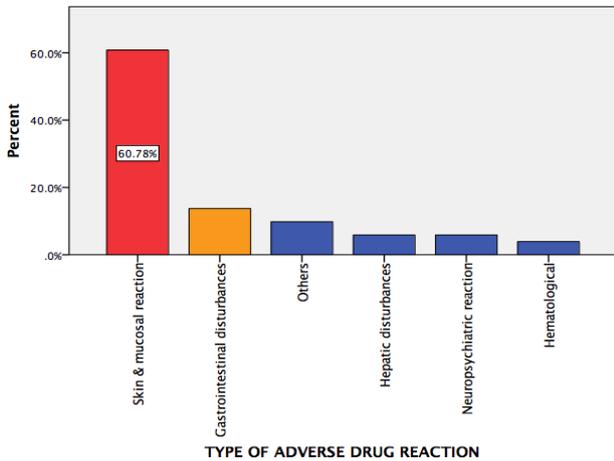


Figure 6: distribution of patients according to the system involved.

Figure 6 showing distribution of patients according to the system involved. 60.78% of reactions were manifested in skin and 18% in GIT.

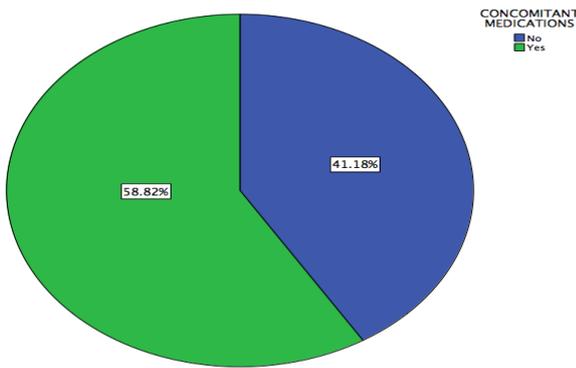


Figure 7: depicting patients who experienced ADRs and had concomitant medications.

Figure 7 shows depicting patients who experienced ADRs and had concomitant medications about 58.82% of patients with ADR had concomitant medications.

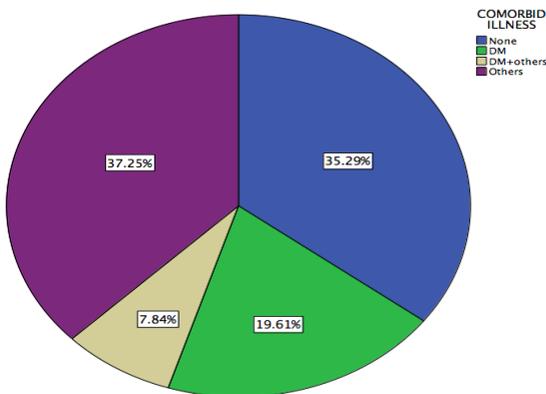


Figure 8: Distribution of patients who had comorbid illness.

Figure 8 showing distribution of patients who had comorbid illness (37.25%).

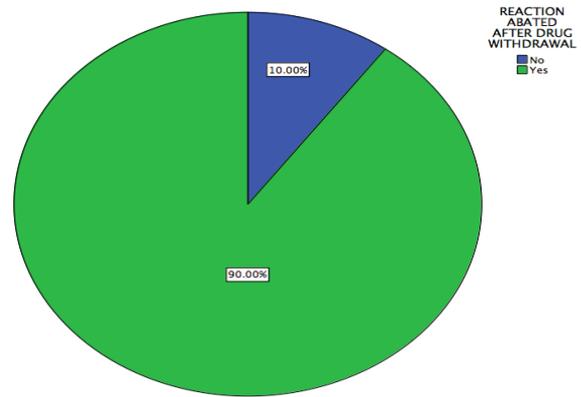


Figure 9: Depicting distribution of patients whose reactions abated.

Pie chart depicting distribution of patients whose reactions abated after drug withdrawal 90% of reactions abated after drug withdrawal.

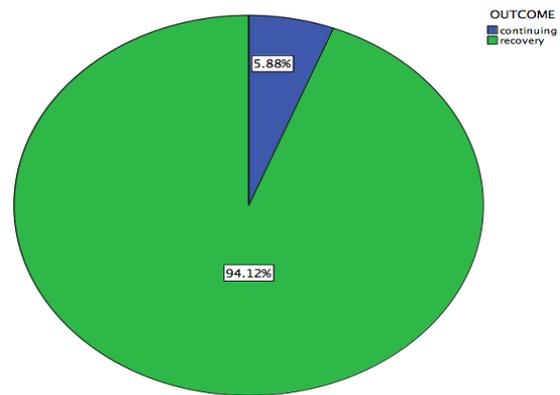


Figure 10: Distribution of patients and their outcomes.

In Figure 10, 94.12% of reactions were recovering, 5.88% of reactions were continuing.

DISCUSSION

Comparing the age group of occurrence of adverse drug reactions, the highest incidence were found among the age group of 30-39 years (27.45%), 40-49 years (23.53%), above 60 years (17.65%), 50-59 years and <30 (15.69%) suggesting that its more common in middle age but can occur at any age.

With regard to the occurrence among the drugs the highest incidence were among antibiotic group of drugs (35.29%) rest being NSAID (12%), ATT (10%), OHA (10%), antiepileptic (8%). About 5% of reactions were of antileptotic drug, statins, immunosuppressants. About 2% of reactions were among diuretic, bronchodilators,

bisphosphonates, antifungals, ulcer protectives, DMARD'S, suggesting that antimicrobial drugs are the commonest cause of adverse drug reactions.

These results are in accordance with the study that showed incidences of adverse drug reactions are more common with Amoxicillin group of antibiotics.⁶

Most of the adverse drug reactions 47.92% involve a maximum of 2-7 days indicating that good recovery within 2-7 days for most of the drug reactions.

Comparing the route of administration of drugs, the maximum no. of adverse reactions occurred with the oral route (66.7%) followed by parenteral (23.52%) and topical (9.804%), while considering the seriousness of the reaction most of the reactions required hospitalization (47.06%), 3.29% of reactions were not serious, 13.73% of reactions required intervention and 3.922% were life threatening suggesting that most of the reactions are serious requiring hospitalisation.

These results are in accordance with the study that concluded that adverse drug reactions are serious requiring hospitalisation.⁷

Considering the systemic involvement of adverse drug reactions 60.78% of reactions were manifested in skin, 15% of patients had GI disturbances, 5% of patients had hepatic and neuropsychiatric disturbances, 2% of reactions were hematological and 10% of reactions were due to other system involvement.

With regard to concurrent medications 58.82% of patients with ADR had concomitant medications and 41.18% had not taken any other medications.

About 35.29% had no comorbid illness, 19.61% had DM, and about 37.25% had other illness suggesting that Diabetes mellitus is an important co-morbid illness.

About 90% of reactions abated after drug withdrawal and 10% reactions did not abate even after drug withdrawal. With regard to its outcome 94.12% of reactions were recovering, 5.88% of reactions were continuing and they have good recovery following withdrawal of the drug.

CONCLUSION

After Drug Reactions are diagnosed and treated, clear information was provided to the patient regarding the type of reaction experienced. The patient was advised to carry a card or any form of emergency identification in their wallet that lists drug allergies and intolerance.

The names of the medication potentially cross reacting

drugs and drugs that can be safely taken are important part of this evaluation.

Genetic and family counselling as part of the patient care were planned especially in SJS, TEN and drug hypersensitivity syndromes.

The importance of reporting Drug reactions to the regulatory agency and physicians was stressed; other doctors were made aware of the reporting system and importance of reporting an adverse drug reaction.

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Conflict of interest: None declared

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

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