A study on incidence of suspected adverse drug reactions in a tertiary care hospital

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Abstract

Background: An adverse drug reaction (ADR) is an injury caused by taking a medication during the course of the therapy and most of the times are not reported which is a matter of concern.

Objectives: The objective of this study was to find the incidence and prevalence of suspected adverse drug reactions in a tertiary care hospital.

Materials and Methods: Retrospective data collection from the dermatology department over a period of 1 year (2015-2016) and the relevant data was entered in a preformed format and percentage was analysed .we chose dermatology dept since most of the drug related side effects have cutaneous manifestations.

Results: Most common drug might have caused adverse drug reactions were 21.87% for Amoxicillin or its combinations followed by Phenytoin alone (9.35%) and in combination was 3.12%, followed as a monotherapy was Imatinib mesylate (9.37%), Phenytoin and Carbamazepine was 6.25 respectively and the least as a monotherapy was Allopurinol and Sorafenib constituting 3.12%. Various drugs in other different combinations also caused adverse drug reactions which was 3.12%.

Conclusion: As per Pharmacovigilance Programme of India (PVPI), it is mandatory to report all related and suspected adverse drug reaction and we opine that either government or private hospital should create awareness in patients as well as the health care professionals about the adverse drug reactions and its importance in reporting the same for taking necessary actions.

Keywords: Adverse Drug Reactions, Incidence, Retrospective

Introduction

Drugs are the most common used for 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" and adverse reaction monitoring and reporting are very important in identifying the adverse reaction trends in local population.(1)

ADR is defined as any undesirable effect of a drug beyond its anticipated therapeutics occurring during clinical use. The WHO defines an ADR as ''any response to a drug which is noxious and unintended, and which occurs at doses usually used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function." Thus this definition excludes overdose (either accidental or intentional), drug abuse, and treatment failure and drug administration errors.(2)

Cutaneous adverse drug reactions (CADRs) have been seen to be one of the most common adverse drug reactions (ADRs) in various studies. A wide variety of cutaneous manifestations ranging from maculopapular rashes to toxic epidermal necrolysis (TEN) can be caused by different classes of drugs. Many studies have showed that the overall incidence of CADRs in developed countries as 1-3%, while the incidence in developing countries is thought to be higher between 2% and 5%.(3,4)

We chose dermatology department, since most of the drug related adverse effects have a initial cutaneous manifestations. Hence the objective of this study was to find out the incidence of unreported adverse drug reactions in department of dermatology of a tertiary care hospital.

Materials and Methods

Ethics committee approval was obtained before conducting the study. Retrospective data collection from the dermatology department of Pariyaram Medical College Hospital over a period of 1 year (2015-2016) and the relevant data was entered in a preformed format and percentage was analysed.

Results

There were a total of 32 patient's information in the medical record related to adverse drug reactions which was entered out of which males were 17 (53.12%) and females were 15 (46.87%) **(Fig. 1).** Most commonly age of the patients who experience adverse drugs reactions are 51-60 and above 60 years, both of which constituted 25% and least was 10-20 years which constituted 9.35% **(Fig. 2).** Most common drug might have caused adverse drug reactions were 21.87% for Amoxicillin or its combinations followed by phenytoin alone (9.35%) and in combination was 3.12%, followed as a monotherapy was Carbamazepine and Imatinib mesylate was 6.25 respectively and the least as a monotherapy was Allopurinol and Sorafenib constituting 3.12%. Various drugs in other different combinations also caused adverse drug reactions **(Table 3 & 4).**

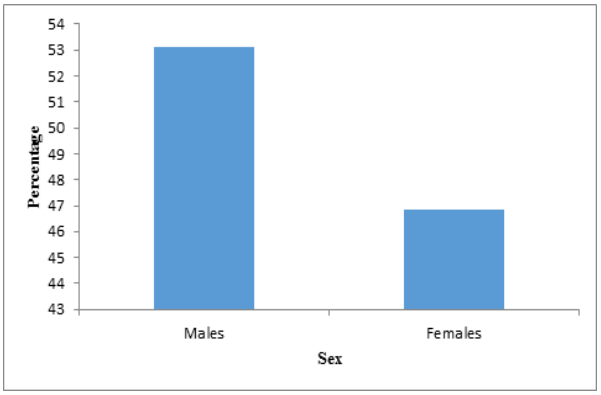

Fig. 1: Sex Distribution

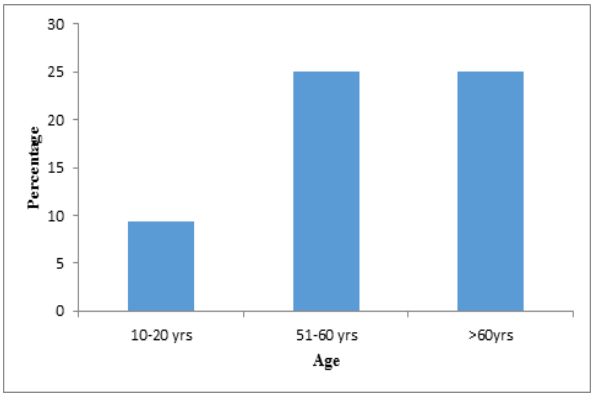

Fig. 2: Age Distribution

Table 3: Adverse drug reaction related to drug combinations

Drug Combinations	Percentage (%)
Atorvastatin + Clopidogrel	3.12%
Hydroxychloroquine, Etodolac, Rabeprazole & Deflazacort	3.12%
Allopurinol & Losartan	3.12%
Phenytoin. Ecospirin, & Digoxin	3.12%
Acebrophyllin, Esomeprazole, Domeperidone & Moxifloxacin,	3.12%
Hydroxychloroquine & Methyl Presnisolone	3.12%
Diclofenac, Cefixime, Paracetamol & Mefenamic Acid	3.12%
Amoxicillin+Clavunilic Acid & Tamsulosin	3.12%
Amixycillin+ Clavulinin Acid	3.12%
Aspirin+ Clopidogrel, Aspirin, Pantoprazole	3.12%
Sorafenib	3.12%
Gabapentin, Moxifloxacin, Cefpodoxime	3.12%
Temisartan, Metaprolol, Clopidogrel, Atorvastatin	3.12%
Isoniazid, Rifampicin, Pyrazinamaide, Ethambutol	3.12%
Amoxycillin+Clavunilicacid, Mefenamic Acid	3.12%
Azithromycin, Mefenamic Acid	3.12%
Amoxycillin+ Clavunilic Acid	3.12%
Amoxycillin+Clavuniliac Acid, Paracetamol, Cetrizine	3.12%
Cefixime, Cetrizine, Paracetamol	3.12%
Clobazam, Oxcarbazepin	3.12%
Aspirin+ Clopidogrel, Aspirin, Losartan	3.12%

Monotherapy

Monotherapy	Percentage (%)
Imatinib mesylate	9.37
Phenytoin	6.25
Carbamazepine	6.25
Amoxicillin	3.12%
Allopurinol	3.12%
Sorafenib	3.12%
Gefitinib	3.12%

Discussion

Predictability of the reactions is based on the incidence of the adverse drug reactions and literature reports as many of these drugs are known to cause these reactions, hence they fall under the categories of Type A adverse drug reactions.

In many countries, drug utilization studies have been performed by means of prescription databases, such as the Tayside database in Scotland, the VAMP database in England,the Saskatchewan database in Canada,[the Compass and the Kaiser Permanente databases in USA, and the Pharma database in the Netherlands.[5-9]

In this study, the more number of males for Adverse Drug Reactions was found and it may be due to the fact that majority of the admitted patients were male during that year compared to females. Adverse drug reactions seen in our study is seen more in elders than younger's which may be sue to due age related pharmacokinetic and pharmacodynamic changes and also may be due to co-morbid illnesses like coronary artery disease, diabetes, hypertension and etc and more relevantly with polypharmacy. It is easy to predict and expect the adverse drug reactions in a monotherapy, but very difficult to attribute the same when given in combinations and especially in elders as they usually have co-morbid conditions.

The limitations of this study relates to its retrospective aspect, however a prospective study over long period may give substantial data regarding the same.

Conclusion

As per Pharmacovigilance Programme of India (PVPI), it is mandatory to report all related and suspected adverse drug reaction and we opine that

either government or private hospital should create awareness in patients as well as the health care professionals about the adverse drug reactions and its importance in reporting the same for taking necessary actions.

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