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A Prospective Study of Adverse Drug Reaction Monitoring in Tertiary Care Hospital

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ABSTRACT

The adverse drug reaction monitoring and reporting are very important in identify and preventing adverse drug reaction. The utmost important area during the therapy of patient is pharmacovigilance and it was not implemented in India by health care professionals. The observation of adverse drug reaction during the treatment helps to eliminate the drug induced diseases and death. Hence, this study aimed to estimate the incidence of adverse drug reactions causing hospital admission or occurring while in hospital. It is a prospective Cohort study of six months where the subjects have been followed-up and the outcomes are recorded. The maximum number of adverse drug reaction reported from the general medicine department was 26.66%. The geriatric patients had experienced more adverse drug reaction, accounting for about 44.90% followed by adults 34.90% and children 20.40%. The reason for geriatric falls in adverse drug reactions may be the alterations in Pharmacokinetic parameters, multiple drugs and polypharmacy.

Keywords: Adverse drug reaction, pharmacovigilance, polypharmacy, pharmacokinetic.

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INTRODUCTION

Drugs are always related to risk of adverse reactions. But, the safe use of drugs in patients is the responsibility of clinical pharmacist and healthcare professionals. The updated information on drugs can prevent the incidence of adverse drug reactions (ADR). Prolongation of hospital stay happens by serious ADRs. Hence, it is necessary to identify the drug, which causes ADR and generating the data on safe use of drugs. The literature review indicates that, sometimes severe and potentially life-threatening situations like Steven-Johnson Syndrome and toxic epidermal necrosis can occur. Although it is common and 1/3 to 1/2 of adverse drug reactions can be preventable. The World Health Organization (WHO) defines pharmacovigilance as the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem[1]. The epidemiological study shows that ADR prevalence rate is high and they cause from 3% to 6% of hospitalization and 24% of patients under elderly groups[2]. ADR monitoring and reporting activities are very low in India. It may be due to lack of awareness and lack of interest of healthcare professionals. Therefore, this study was aimed to identify ADRs, assess their causality, preventability and severity and also the risk factors in Indian ambulatory patients[3]. Majority of the ADRs were associated with oral administration of medicines followed by parenteral route. Most of the ADRs with injectable medications were severe. Gastrointestinal ADRs were most commonly observed with oral medications[4].

ADR Monitoring in India

Unfortunately, in spite of its immense need, the concept of ADR monitoring is still new in India. To overcome this shortcoming, the Drug Controller of India has, since 1990, started six ADR monitoring centers at Calcutta, Chandigarh, Lucknow, Mumbai, New Delhi, and Pondicherry. One of the main objectives of this project is to gather information on ADR and also to reciprocally provide data to physicians on the ADR profile of a specific drug[5]. The Science and Systems used for systematically identifying and correlating drug and side effects and taking corrective actions fall under the disciplines of Pharmacovigilance[6]. Potential drug interactions were identified by the solicitation of pharmaceutical histories and appropriate pharmacy records by the Pharmacist Investigator. This great effort to detect and correct potential Interactions of drugs may help successful treatment of the patients. The well trained and motivated clinical pharmacist plays important role in caring for patients. Hence, this study will increased the responsibility for health care of patients and also reduce the physician burden and can lead to

adequate care for millions of patients yet to be detected[7]. ADRs are a major universal problem and are one of the leading causes of mortality and morbidity in healthcare facilities globally. The incidence of ADR varies with studies. A published meta-analysis of the incidence of ADRs in hospitalized patients concluded that ADRs rank as the fourth to sixth leading cause of death in the United States and the overall incidence of serious ADR accounted for 6.7% of hospitalized patients. According to a study carried out at a private tertiary care hospital in South India, the incidence of ADRs was found to be 1.8%, out of which 12% of suspected ADRs were severe and 49% ADRs were moderate in severity. It is important to remember that most ADRs would subside once the offending agent is discontinued or dosage is reduced; however, many result in permanent damage. Therefore, it is important to motivate healthcare providers to understand their role and responsibility in the detection, management, documentation, and reporting of ADRs, and all essential activities for optimizing patient safety. The objective of this study was to monitor the ADRs caused by prescription drugs which are prescribed in tertiary care hospital.

MATERIALS AND METHOD

It is a prospective cohort study conducted with 60 patients where the subjects have been followed-up for the period of six months and the outcomes recorded. Patient data collection form and ADR monitoring form was designed to collect patient data and adverse drug reactions and other drug - related problems. Data were analyzed by using Instate excel sheet and Micromedex 2.0 is used for source of Information.

RESULTS AND DISCUSSION

A total number of 60 patients with adverse drug reactions were included in the present study. The data collection form was administered successfully in the study patients after explaining the study protocols. The patients were classified under gender distribution and were given in figure 1.

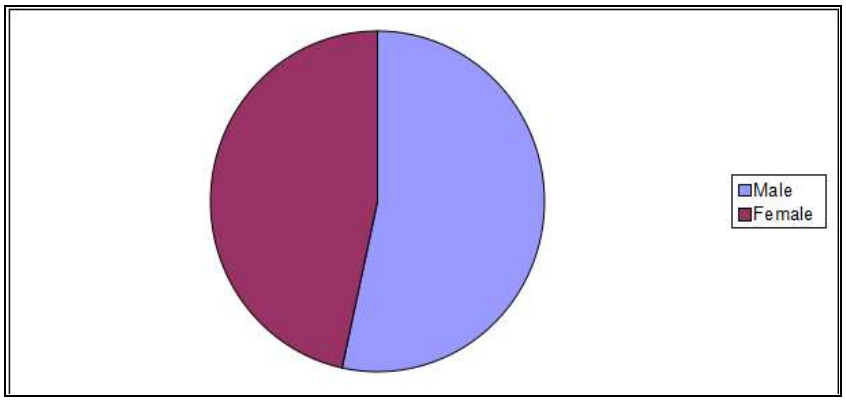

Figure 1: Gender Distribution

The maximum number of adverse drug reaction were reported from the general medicine 26.66% (n=16) followed by pediatrics 18.33% (n=11), pulmonology 11.66% (n=7), cardiology 10.20% (n=6), gastroenterology 3.30% (n=2), nephrology 8.33% (n=5) and dermatology 15.00% (n=9). Age wise distribution of the total population was analyzed that the geriatric patient were more accounted 44.90% followed by adults 34.90% and children 20.40%. The reason for geriatric falls in adverse drug reactions may be the multiple drugs and poly pharmacy. The age distribution was given in Figure 2.

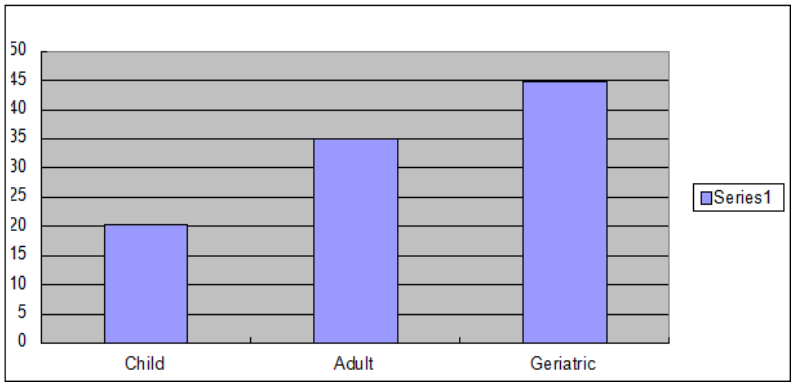

Figure 2: Age Wise Distribution of ADR

The numbers of adverse drug reactions received from different departments are assessed and was given in figure 3.

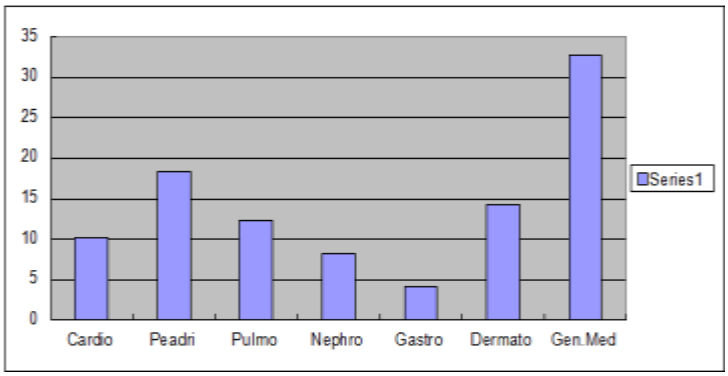

Figure 3: ADR Monitored In Various Departments

More number of adverse drug reactions were detected with antibiotics particularly in the General Medicine and Pediatrics Departments, which may be due to an increased use of antibiotics. Even though the Pediatric Department accounted opposite to the General Medicine Department, the adverse drug reaction occurrence was less. It may be due to less number admitted pediatrics patients when compared to adults and geriatric patients. In terms of use of antibiotics based on the culture and sensitivity patterns, in some cases, no change was made with the suspected drugs because of considering the risk-benefit ratio in specific patients. Drug re-challenge was not done

in any of the cases. The causality assessment of ADR had been done using the Naranjo scale, in which, no reactions were found to be unlikely and majority were probable with less number of possible and definite reactions. It was given in figure 4.

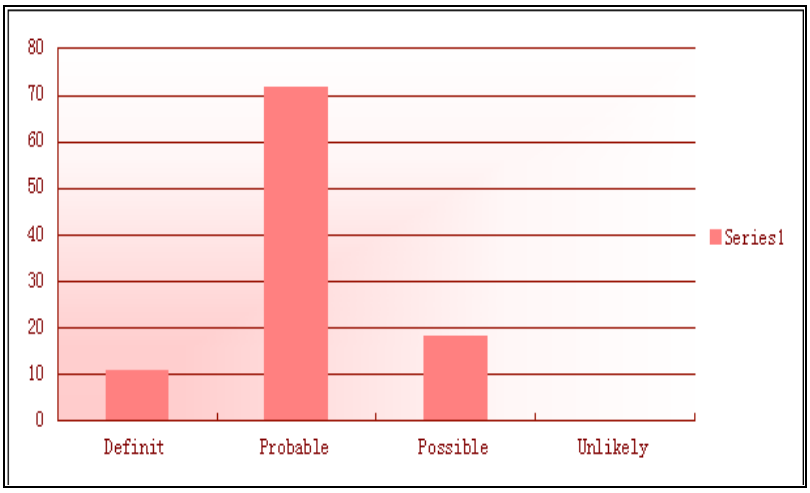

Figure 4: Classification of ADR

All the cases were treated satisfactorily and no deaths were reported. The generic names of the drugs used in various departments are collected and classified as per the pharmacological effects and it was given in Table 1.

Table 1 Group of drugs involved in adverse drug reactions

S.no	Drugs	No. of cases	Total	Percentage
1.	NSAIDS		17	37.8%
	1.Ibuprofen	4		
	2.Nimusulide	4		
	3.Diclofenac sodium	4		
	4.Aspirin	3		
	5.Acetaminophen	2		
2.	ANTIBIOTICS		11	26.0%
	1.Cefatoxime	1		
	2.Ciprofloxacin	1		
	3.Amoxicillin	1		
	4.Ampicillin	1		
	5.Erythromycin	2		
	6.Co-Trimoxazole	2		
	7.Cefoxacine	1		
	8.Sparfloxacin	2		
3.	CVS DRUGS		4	12.0%
	1.Atenolol	1		
	2.Atrovastatin	1		
	3.Ramipril	1		
	4.Losartan	1		
4.	ASTHMATIC DRUGS		1	2.0%

	1.Salbutamol	1		
5.	ANTI CONVULSANTS		2	2.0%
	1.Phenytoin	1		
	2.Phenobarbitoin	1		
6	GIT DRUGS		2	2.0%
	1.Omeprazole	1		
	2.Pantaprazol	1		
7.	ANTI VIRAL DRUGS		1	2.0%
	1.Lamivudin	1		
8	HERBAL DRUGS	10	10	16.0%

The level of severity of the reported ADR was assessed by using the modified Hartwig and Slegel scale and was shown in figure 5.

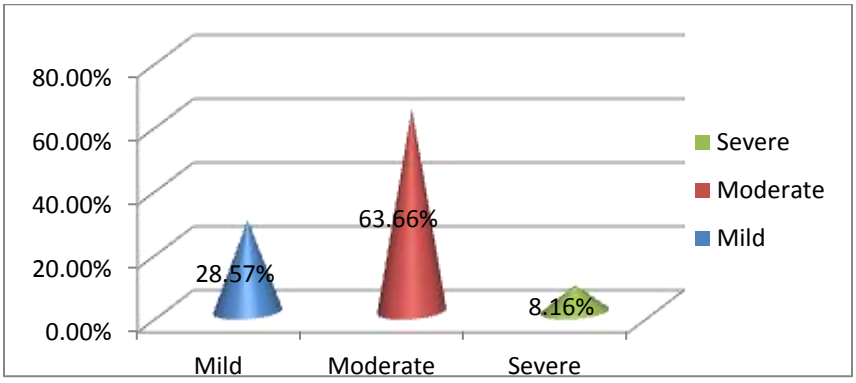

Figure 5: Severity of ADR by using Hartwig and Slegel scale

In this study, the suspected ADR were identified, but the possible risk factors related to the occurrence of ADRs were not determined. The risk factors were more in advanced age (> 80 years), multiple diseases, prescription with multiple drugs and longer duration of treatment. Advanced age was the significant risk factor for ADR. The study also found that increased number of medications and co-morbidity increases the risk of occurrence of ADR. It was co-incited with previous study results. One report has suggested that pharmacological, immunological and hormonal difference has predisposed the women to take more medications than men. Some previous studies reported that some ADR were more common in females as compared to males.

CONCLUSION

The spread of ADR in our society is increased persistently. The reasons are improper patient counseling, irrational use of medications, and lack of patient-prescriber's communication. It is also concluded that the co-ordination between HCPs and patients is very important to improve the quality of therapy and to prevent the future happenings of adverse drug reaction. For that purpose, more attention should be focused on the pharmacovigilance of the drug. It may be

possible to report more such adverse drug reactions, which might be beneficial for treatment of diseases and better patient care.

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