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A STUDY ON PHARMACOVIGILANCE IN GENERAL MEDICINE DEPARTMENT OF BANARAS HINDU UNIVERSITY HOSPITAL VARANASI

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ABSTRACT

Introduction: Research on Pharmacovigilance can increase our understanding about any response to a drug which is noxious and unintended which occur at normal doses of a drug used in human beings for therapy, diagnosis. Adverse drug reactions are considered as one among the leading causes of morbidity and mortality which can affect most organ system. Several contributing factors for adverse drug reactions are polypharmacy, age, dose and duration. It describe about drugs that are most frequently showing adverse drug reactions during the hospital stay and also explain about the organ systems mostly effected due to adverse drug reaction of drug. **Objective:** To study and evaluate patterns and profile of adverse n drug reactions at our general medicine department of Banaras Hindu University Hospital and assess the impact of passive surveillance of adverse drug reaction (ADRs) reporting. **Patients and Methods:** It was a prospective observational study done from June 2014 to December 2018 in 110 patients with ADRs in the general medicine department of university hospital, Banaras Hindu University. The clinical pattern, spectrum of ADRs reported and assessment of ADRs in terms of causality, severity and preventability .The causality, severity and preventability assessment was done on the basis of applying various scales for each of them. **Results and Discusions:** A total of 110 suspected ADRs were reported and evaluated in the department. Dermatological system (32%) was most commonly involved. Drug class most commonly associated was Antimicrobials (47%). 58% ADRs were classified as "Probable" in view of causality, while 48% were found to be "Moderate" in case of severity. In 71% of the cases the ADRs was "Probably Preventable". In majority of the cases the suspected drug was withdrawn and alternate therapy was instituted. Most patients recovered from the ADR.76% of these ADR was Type A. **Conclusion:** Awareness about ADR reporting is still poor amongst healthcare professionals in India. Conducting regular training programmes can improve the number of ADR reporting.

KEYWORDS: Pharmacovigilance, Adverse drug reactions, Banaras Hindu University, General Medicine, Causality.

INTRODUCTION

Pharmacovigilance is an important tool for monitoring of drug related problem after market authorization in "real world setting". Pharmacovigilance and all drug safety issues are relevant for everyone whose life is touched in any way by medical interventions. The evolution of Pharmacovigilance in recent years and its growing importance as a science critical to effective clinical practice and public health science are described.

Pharmacovigilance has been defined by the WHO[1] as „The science and activities relating to the "detection, assessment, understanding and prevention of adverse effects or any other drug-related problems".

The WHO defines an "Adverse drug reaction as "any response to a drug which is noxious and unintended and which occurs or doses normally used in man of prophylaxis diagnosis or therapy of disease or for the modification of physiologic function.[2]'' The mechanism of adverse reactions can be divided into direct toxicity studies and hypersensitivity reactions that occur due to the pharmacokinetic and pharmacodynamic alterations of the drug products.[3] Direct toxicity reactions may be attributed to the toxic effects of a compound or its metabolites which are apparent in various organ systems,

inducing noxious chemical reactions, physiological dysfunction, DNA damage or injury to cellular structures and tissues.[5,6] On the other hand, hypersensitivity reactions can be determined after the immune system of the individual shows an exaggerated response to a drug or its metabolites, which include allergy and anaphylactic reactions.[12] It has been suggested that the results of direct cytotoxicity and excessive immune reaction are noticeable in various organs like skin, liver, lungs, bone marrow and kidneys.[8][9] The types of adverse reaction can be studies in two main headings, i.e., more common ADRs including type A and B reactions; and less common ADRs which include type C, D and E reactions.[3][4]

To identify, assess and report suspected adverse drug reactions in the patients who are admitted in the hospital to prevent morbidity, mortality and cost of hospital stay.[13]

PATIENTS AND METHODS

This prospective observational study was conducted at general medicine department of Banaras hindu University, Varanasi in patients with suspected ADRs as Outpatients and inpatients in the Department. Study period was of 3.5 years from June 2014 to December 2017.

Before initiation of the study, a training programme on pharmacovigilance was conducted in medicine department for healthcare professionals. Data of spontaneously reported ADRs by healthcare professionals. were collected through the ADR reporting form, made available in medicine OPD and wards. All suspected adverse drug reactions that were due to the medications taken by the patients as outpatients and inpatients and age 13 years and more were included in the study. While the use of alternatives medicines like Homeopathy, Unani, Sidda, Ayurveda, over dosage, excess consumption, mentally retarded patients along with patients who were drug addicts and unconscious patients were all excluded from the study.

For each patient with suspected ADR, a detailed history was taken and any untoward event was labelled as adverse drug reaction after discussion with the treating physician.

A through scrutiny of data was done to assess pattern, extent, severity and duration of the reactions, to detect any predisposing or underlying disease/pathological factors, and to assess any other organ/ system involvement as a part of the drug reaction.

The causality of the reactions was assessed by WHO UMC scale, severity of ADR using Adapted Hartwig scale and preventability assessed by using Modified Schumock and Thornton scale. Follow up was done to assess the clinical progress of the cases.[10]

STATISTICAL ANALYSIS

The data was analysed by using descriptive statistics. For quantitative variables New Microsoft Excel Worksheet-2010 software was used to generate graphs and tables wherever necessary.

RESULTS

A total of 110 suspected ADRs were reported and evaluated from the department. Dermatological system (32%) was most commonly involved. Drug class most commonly associated was Antibiotics (41%). 54% ADRs were classified as "Possible" in view of causality, while 48% were found to be "Moderate" in case of severity. In 71% of the cases the ADRs was "Probably Preventable". In majority of the cases the suspected drug was withdrawn and alternate therapy was instituted. Most patients recovered from the ADR.76% of these ADR was Type A.

DISCUSSION

During study a total of 110 patients ADRs cases were collected, analysed and evaluated.

1. Distribution of ADRs by Healthcare professionals.

ADR reported by Health care professionals	NO. of ADR (n=110)	Percentage (%)
DOCTORS REPORT	63	57.5%
PHARMACIST REPORT	28	25%
NURSES REPORT	6	5%
PATIENT	13	12.5

Out of 110 reported ADRs only 6 were reported by nurses and highest 63 by doctors, 28 by pharmacist and 13 by patient.

2. Distribution of ADRs by Patients Age

AGE	NO.OF ADR's
<18	12
19-30	19
31-60	65
61 above	14

The data explain that, the maximum patients who had encountered ADRs were in age group between 31-60 and minimum number in age group lower than 18 year.

3. Distribution of ADRs by gender of patients.

Gender	No of ADR's (n=110)	Percentage %
Male	58	52.7%
Female	52	47.3%

Table shows the gender distribution of patients who had encountered ADR"s during the study period at the study site. Study reveals male were more affected by ADR as compared to female patients.

4. Distribution of ADRs by the classification of ADRs

AGE	NO.OF ADR's	AGE
<18	12	<18
19-30	19	19-30

It shows the classification of ADR‟s encountered into Type A and Type B based Thompson‟s and Rawlins classification. It was observed that most of reported ADRs were Type A.

5. Distribution of ADRs by Probability.

Probability	No. of ADR (N=110)	Percentage %
Definite	2	0.9%
Probable	50	42.8%
possible	56	54.37%
doubtful	2	1.83%

Table shows the probability assessment of ADR based on Nariño's probability assessment scale. The result showed that most of the encountered ADR were possible

6. Distribution of ADRs by Severity of.

SEVERITY	NO OF ADR N= 110	PERCENTAGE %
MILD	24	20%
MODERATE	72	69%
SEVERE	14	11%

Severity of ADRs encountered during the study period was determined by using the Hartwig‟s Severity Assessment Scale. The results of the assessment of the severity as shown in table 6 and explain that most of ADR were moderate in severity followed mild and severe cases.

7. Distribution of ADRs by Preventability.

Preventability scale	No. of ADR's (N=110)	Percentage %
Definitely preventable	5	5%
Probably preventable	78	70%
Not preventable	27	25%

Table 8 and Figure 8 shows the preventability of the ADR‟s was assessed by using Modified Shumock and Thornton Criteria. The results were revealed that 5% are definitely preventable, 70% probably preventable and 25% were not preventable.

8. Distribution of ADRs by Organ and system affected.

SYSTEN OR ORGAN	NO.OF ADR'S (N=110)	PERCENTAGE (%)
1. Dermatological	32	27%
2.Gastro-Intestinal Tract	8	7%
3.Hematological	24	22%
4.CNS	13	11%
5.Respiratory system	2	1.8%
6.Hepatology	2	1.8%
7.Cardiology	3	2.4%
8.Endocrinology	1	1%
9.ENT	7	6%
10.Immunology	18	18%
11.Nephrology	3	2%
Total	110	100%

This clearly explain about the organs and system affected by adverse drug reaction during research study. It explains about which organ and system affected in one hundred and ten patients who reported adverse drug reaction. It provides mean percentage of organ or system affected.

Table shows the various organs and systems affected by ADR‟s encountered during the study period. The most organ systems affected by ADR‟s were Dermatological, Gastro-Intestinal Tract, Hematological, CNS, Renal, Cardiology, Pulmonology, Immunology, ENT, Hepatology and Endocrinology.

09. Distribution of ADRs by Therapeutic Drug Classes implicated

DRUGS	NO.OF ADR's (N=110)9)	PERCENTAGE %
Antibiotics	41	35%
Antiepileptic	10	10%
Antihypertensive	7	7%
Steroids.	2	2%
NSAIDs	4	4%
Diuretics	3	3%
Anticancer	6	6%
Anti histamines	1	1%
Anti viral	8	8%
Anti tuberculosis	7	7%
Electrolytes	1	1%
Bronchodilator	8	8%
Anti fungal	3	3%
Anti anaemic	3	3%
Anti gout	1	1%
Anti coagulants	5	5%
Total	109	100%

In this table data revealed that maximum number of ADRs encountered by the antibiotic class of drug after

that antiepileptic.

10. Distribution of ADRs by Outcome of management of ADR's

Outcome of ADR	Percentage ADR's
Recovered	43.31%
Recovering	36.54%
Continuing	21%

This clearly explains the outcome of reported ADR‟s suggested that 43.31% cases were recovered from the reported ADR‟s, 36.54% were recovering and 21% were continuing.

CONCLUSION

Hospital based ADR monitoring and reporting programmes aim to identify and quantify the risks associated with the use of the drugs. This information may be useful in identifying and minimizing the preventable ADRs while enhancing the knowledge of the prescribers to deal with ADRs more efficiently. Pharmacovigilance programmes have been introduced in India but it still appears to be in its primitive stage. Regular training programmes by the way of workshop and seminars must be carried out for health care professionals to increase the awareness about ADR reporting.

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