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THE ROLE OF CLINICAL PHARMACIST IN PHARMACOVIGILANCE AND DRUG SAFETY IN TERITIARY CARE TEACHING HOSPITAL.

Dr. M. Madan Mohan Rao[1*], C. Veera Vamsi[2], K. Sujan Kumar[2], J. Lavanya[2], E. Sam Jeeva Kumar[3]

1Associate Professor, Department of General Medicine, Rajiv Gandhi Institute of Medical Sciences, Kadapa.

2Pharm D internship students, P.Rami Reddy Memorial College of Pharmacy, Kadapa.

3Associate Professor, Department of Pharmacy Practice, P. Rami Reddy Memorial College of Pharmacy, Kadapa.

Abstract:

Pharmacovigilance is ''the science and activities concerned with the detection, assessment, understanding and prevention of adverse reactions or any other drug related problems to medicines''.‖Pharmacovigilance plays an important role in ensuring patients safety. The main aim of the study is the role of clinical pharmacist in pharmacovigilance and drug safety in Teritiary care teaching hospital. The patients were included based upon the inclusion and exclusion criteria. The Adverse reactions were assessed by using different scales and the assessed adverse reactions was reported to the pharmacovigilance centres. The study reveals that majority of the females(57%), younger age people (30%) and illiterates(57%) are affected with the drug related problems. Here by we conclude that clinical pharmacists could offer effective patient care by means of their intervention in pharmaceutical care and hence improved therapeutic outcome could be reached.

Key Words: *Pharmacovigilance, Adverse Drug Reactions (ADR), Clinical Pharmacist.*

Corresponding Author:

Dr. Madan Mohan Rao,

Associate Professor ,

Rajiv Gandhi Institute Of Medical Sciences, Kadapa.

Email.ID :- vamsiveera81@gmail.com

Phone:- 8019877715

QR code

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INTRODUCTION:

The **WHO** defines **pharmacovigilance** as —''the science and activities concerned with the detection, assessment, understanding and prevention of adverse reactions to medicines''[1]. The Pharmacovigilance Programme of India (PvPI) was initiated by the Government of India on 14th July 2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordination Centre for monitoring Adverse Drug Reactions (ADRs) in the country for safe-guarding Public Health. In the year 2010, 22 ADR monitoring centres including AIIMS, New Delhi was set up under this Programme. To ensure implementation of this programme in a more effective way, the National Coordination Centre was shifted from the All India Institute of Medical Sciences (AIIMS), New Delhi to the Indian Pharmacopoeia Commission, Ghaziabad, and Uttar Pradesh on 15th April 2011 [2].

National Scenario[3]:-

Several steps have been taken to increase the awareness amongst the health care professionals in India under this programme and therefore collect more data. Arriving at a meaningful conclusion on safety issue of medicines on the basis of the analysis of ADRs in the pharmacological database depends on the sample size of the database. The larger is the data for any drug, the higher will be the likelihood of saying with confidence that the conclusions or inferences being drawn from that data are meaningful and significant. Therefore, if an analysis is performed on a very small sample size the likelihood of any conclusion or inferences being drawn from that data decreases substantially. The Indian data includes adverse reactions from a large number of drugs and includes non serious adverse drug reactions data also besides the serious side effect data. The Medical Colleges (both Government & Private) are the corner stone of the Pharmacovigilance Programme of India. They act as peripheral Adverse Drug Reaction Monitoring Centres (AMCs) which are responsible for collecting the ADRs, performing the follow up with the patient to check completeness of the ADRs as per Standard Operating Procedures (SOPs) and to enter the Data in the prescribed software (VigiFlow) to report to NCC. ‖

Collection of ADRs reports[3]:-

- MCI approved medical colleges and hospitals
- Private hospital
- Public health programmes
- Autonomous Institutions (ICMR etc)

Mission[4] :- Safeguard the health of the Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with its use.

Vision[4]:

To improve patient safety and welfare in Indian population by monitoring the drug safety and thereby reducing the risk associated with use of medicines.

Objectives [4]:-

- To create a nation-wide system for patient safety reporting.
- To identify and analyse the new signal (ADR) from the reported cases.
- To analyse the benefit - risk ratio of marketed medications.
- To generate the evidence based information on safety of medicines.
- To support regulatory agencies in the decision-making process on use of medications.

REPORTING OF ADVERSE DRUG REACTIONS[5] :-

Adverse Drug Reactiozs can be monitored through two ways:

1. Active surveillance system.
2. Passive surveillance system

Passive surveillance means no active measures are taken to look for adverse effects other than the encouragement of the health care professionals and others to report safety concerns. Reporting is entirely dependent on the initiative and motivation of the potential reporters. Spontaneous or voluntary reporting is a type of passive surveillance. Active surveillance, in contrast to passive surveillance requires a continuous pre organised process. An example of active surveillance is the follow up of patients treated with a particular medical products as in the cohort Event Monitoring (CEM).

Causality Assessment of Suspected ADRs[6]:-

Causality assessment of suspected ADRs can be made by using different scales, they are:-

1. WHO-UMC causality assessment saale.
2. Naranjo‘s scale.
3. Hartwig‘s Severity Assessment Scale
4. Schumock And Thronton Preventability Scale.

Reporting Serious ADRs to Pharmacovigilance Centres/ ADR Regulating Authorities[7]:-

According to FDA, a serious reaction is classified as one which is fatal, life threatening, prolonging hospitalisation, and causing a significant persistent disability, resulting in a congenital anomaly and requiring intervention to prevent permanent damage or resulting in death 35 Hartwig SC, Seigel J and Schneider PJ categorised ADRs into seven levels as per their severity. Level 1&2 fall under mild category whereas level 3& 4 under moderate and level 5, 6&7 fall under severe category. Karch and Lasanga classify severity into minor, moderate, severe and lethal. In minor severity, there is no need of antidote,

therapy or prolongation of hospitalisation. To classify as moderate severity, a change in drug therapy, specific treatment or an increase in hospitalization by at least one day is required. Severe class includes all potentially life threatening reactions causing permanent damage or requiring intensive medical care. Lethal reactions are the one which directly or indirectly contributes to death of the patient. Different ADR regulatory authorities are - Committee on safety of medicine (CSM), Adverse drug reaction advisory committee (ADRAC), MEDWATCH, Vaccine Adverse Event Reporting System, WHO-UMC international database maintains all the data of ADRs.

Role of the pharmacist practitioner in ADR management[8]:

1. Monitoring patients who are at high risk of developing adverse drug reactions.
2. Monitoring patients who are prescribed with drugs highly likely to cause adverse drug reactions.
3. Assessing and documenting the patient previous allergic status.
4. Assessing the patient_s drug therapy for appropriateness.
5. Assessing possible drug interactions in multiple therapies.
6. Encouraging healthcare professionals in reporting adverse drug reaction.
7. Documentation of suspected adverse drug reaction for future references.
8. Follow up of patients to assess the outcome of the reaction and management.
9. Obtaining feedback about reported reaction.
10. Educating healthcare professionals about the importance of reporting an adverse drug reaction.
11. Creating awareness about adverse drug reactions amongst health care professionals, patients and public.
12. Preparation and promotion of materials.
13. Communication with other healthcare professionals such as nurses and community pharmacies.
14. Conducting seminars on adverse drug reactions for healthcare professionals

The main aim of the study is the role of clinical pharmacist in pharmacovigilance and drug safety in Teritiary care teaching hospital.

MATERIALS AND METHODS:

A prospective observational study was conducted for 6 months in the General medicine, psychiatry and dermatology departments of Rajiv Gandhi Institute of Medical Sciences (RIMS), a 750 bedded tertiary care teaching hospital, Kadapa.

INCLUSION CRITERIA:

- Patients of all age groups with both genders.
- Subjects who are diagnosed with diseases and on treatment.
- Patients who are coming to the general medicine, psychiatry, dermatology for regular checkups/follow-ups.
- Patients who had been hospitalized due to an ADR.
- Patients who are willing to participate in the study .

EXCLUSION CRITERIA:

- Pregnant and lactating women.
- Patients with renal and hepatic impairment.
- Drug addicted and unconscious patients.
- Paediatric patients.

STUDY MATERIALS:

- Patient data collection Performa [Annexure- 1]
- ADR Reporting form. [Annexure - II]
- Adverse drug reaction confirmatory scales
- Naranjo's scale. [Annexure –III a]
- WHO scale. [Annexure–III b]
- Severity scale [Annexure – III c]
- Preventability scale**[**Annexure-III d]
- Informed consent form
- IPC suspected adverse reaction reporting form version 1.3.

METHOD OF STUDY:

Literature review on the study was done.Protocol was prepared and submitted to the institutional review board/ethical committee of RIMS, Kadapa for approval. After submission of protocol we got ethical approval from institutional ethics committee. On daily basis all study departments were visited and discussed with the health care professional regularly about awareness and reporting habits. All patients and their case records were reviewed and data was collected in data collection form. The identified adverse drug reaction were analysed to confirm its causality, severity preventability by using various adverse drug reaction confirmatory scales. Health care professionals were encouraged in reporting suspected adverse drug reaction and they had been explained n about importance of adverse drug reaction reporting and its reporting procedures. Obtained inform consent form and patients were enrolled according to eligibility criteria. Patient demographic data, complaints and relevant laboratory data were collected. Analysis of ADRs was done by using various scales. Causality of ADRs was evaluated by WHO –UMS scale and Naranjo's scale. Severity of the ADRs was evaluated by Modified Hartwig and Siegel's scale. Preventability of ADRs

was evaluated by Schumock scale. The founded ADRs were reported in ADR reporting form to peripheral pharmacovigilance centres.

RESULTS AND DISCUSSION:

A prospective observational study was conduct in south Indian tertiary care hospital RIMS (Rajiv Gandhi institute of medical science), Kadapa for a period of 6 months .A total of 60 patients were recruited under inclusion criteria.

PATIENT DISTRIBUTION BASED ON GENDER:

In our study we screened 60 cases. Out of 60 patients 26 (43%) were male, 34(57%) were female.

Table 01: Patient Distribution Based on Gender

Gender	No. of patients	Percentage (%)
Male	26	43
Female	34	57
Total	60	100

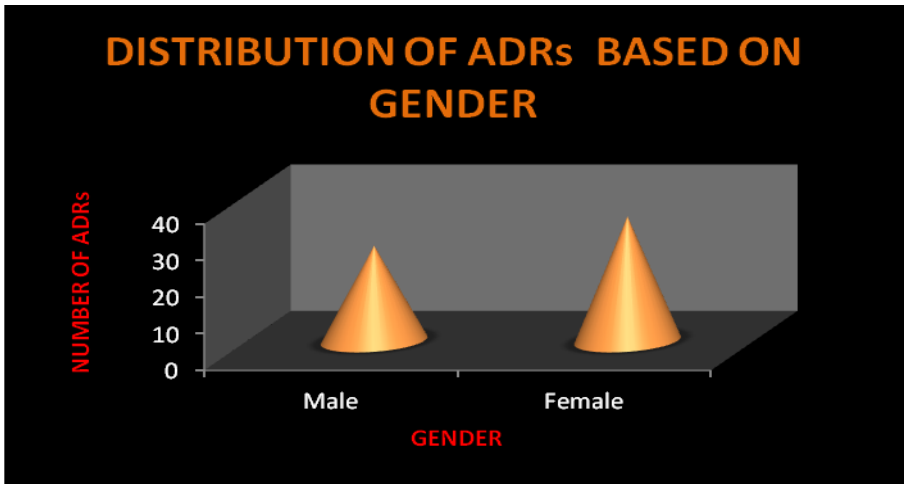


Fig.01: Patient Distribution Based on Gender

PATIENT CATEGORIZATION BASED ON AGE

Out of 60 patients, 4 (7%) patients were found in the age group of 11-20, 15(25%) patients were in between 21-30, 10(17%)were in between 31-40, 9(15%) were in between 41-50, 8(13%) were in between 51-60, 12(20%) were in between 61-70, 12(20%) were in between 61-70, 2(3%) were in between 70-80, 1(2%) were between 81-90.

Table 02: Patient Categorization Based on Age

Age group	Total No. of patients (N=60)	Percentage (%)
11-20	4	7
21-30	15	25
31-40	10	17
41-50	9	15
51-60	8	13
61-70	12	20
71-80	2	3
81-90	1	2
Total	60	100

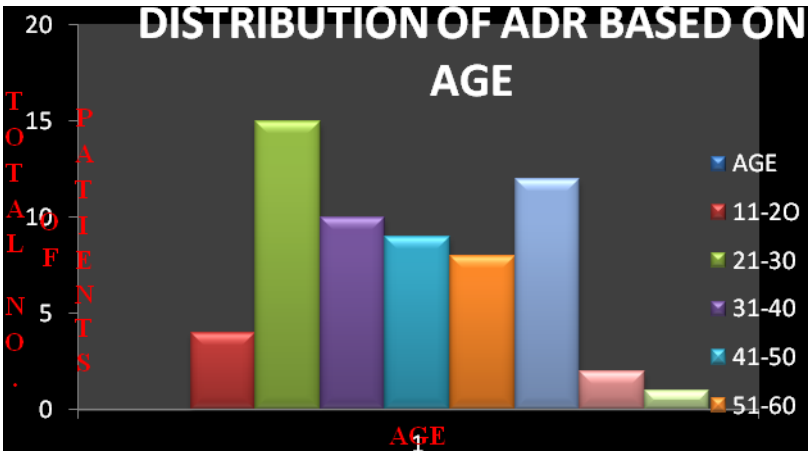


Fig. 02: Patient Categorization Based on Age

LITERACY DISTRIBUTION

Among 60 study population 26 (43%) were literates, 34 (57%) were illiterates and result were shown in table 6.3 and figure 8

Table 03: Literacy Distribution

Education	Number of ADRs	Percentage (%)
Literates	**26**	**43**
Illiterates	**34**	**57**
Total	**60**	**100**

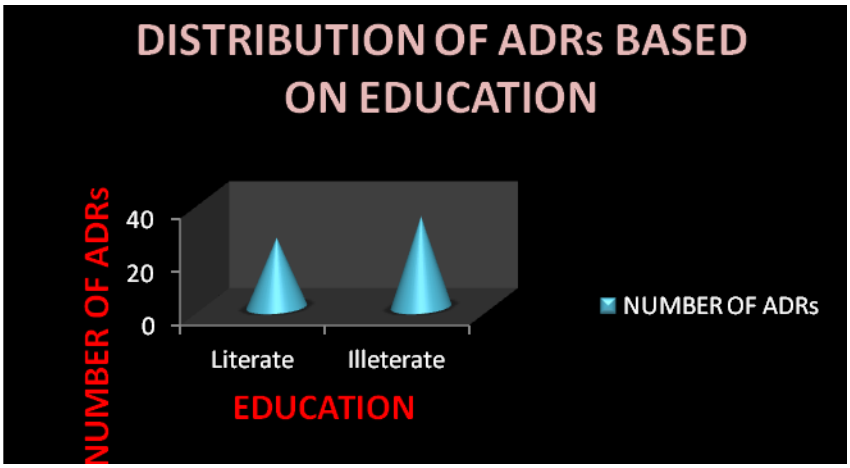


Fig. 03: Literacy Distribution

SUSPECTEDADVERSE DRUG REACTIONS REPORTED FROM STUDY WARDS:

Out of three departments included in the study 16(26%) were observed in Dermatology,7(12%) were in Psychiatry,37(62%) were in Medicine.

Table 04: Distribution Based On Study Departments

DEPARTMENT	NUMBER OF ADRs	PERCENTAGE (%)
DERMATOLOGY	**16**	**26**
PSYCHIATRY	**7**	**12**
GENERAL MEDICINE	**37**	**62**

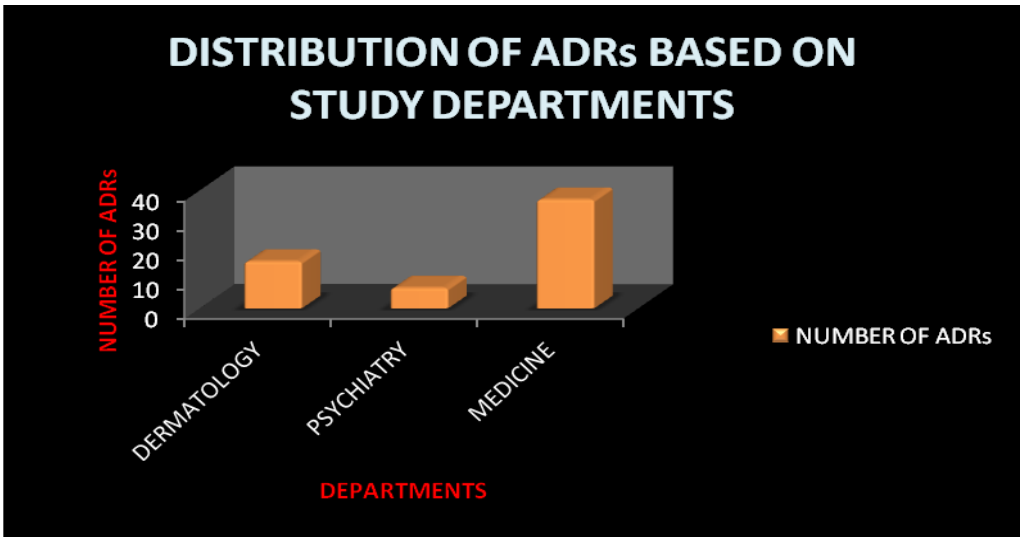


Fig.04: Distribution Based On Study Departments

ADVERSE DRUG REACTION BASED ON THE THERAPEUTIC CLASS OF THE DRUG:

Therapeutic group of the drugs associated with the adverse drug reactions. Out of 60 adverse reactions observed during study period, 8(13.33%) were corticosteroids and anti psychotics, anti hypertensive,1(1.67%) were anti inflammatory, anti diabetic, diuretic, DMARD, Hematinic, Anti platelet,Anti protozoal, Anti acne ,Anti depression, Immuno suppressants, 2(3.33%) were anti histamines ,GABA inhibitor,Anti viral;3(5%) were anti epileptic, Cardiac glycoside, Anti ulcer, Bronchodilator; 6(10%) antibiotic.

Table 05: Based On Therapeutic Class of The Drug

THERAPEUTIC CLASS	**NUMBER OF ADRs**	**PERCENTAGE(%)**
CORTICOSTERIOD	8	13.33
ANTI PSYCHOTICS	8	13.33
ANTI HYPERTENSIVES	8	13.33
ANTI INFLAMATORY	1	1.67
ANTIDIABETIC	1	1.67
DIURETIC	1	1.67
DMARD	1	1.67
HEMATINIC	1	1.67
ANTI PLATELET	1	1.67
ANTI PROTOZOAL	1	1.67
ANTI ACNE	1	1.67
ANTI DEPRESSION	1	1.67
IMMUNOSUPRESSANT	1	1.67
ANTI HISTAMINES	2	3.33
GABA INHIBITOR	2	3.33
ANTI VIRAL	2	3.33
ANTI EPILEPTIC	3	5.00
CARDIAC GLYCOSIDE	3	5.00
ANTI ULCER	3	5.00
BRONCHO DILATOR	3	5.00
ANTIBIOTICS	6	10.00
TOTAL	**60**	**100.00**

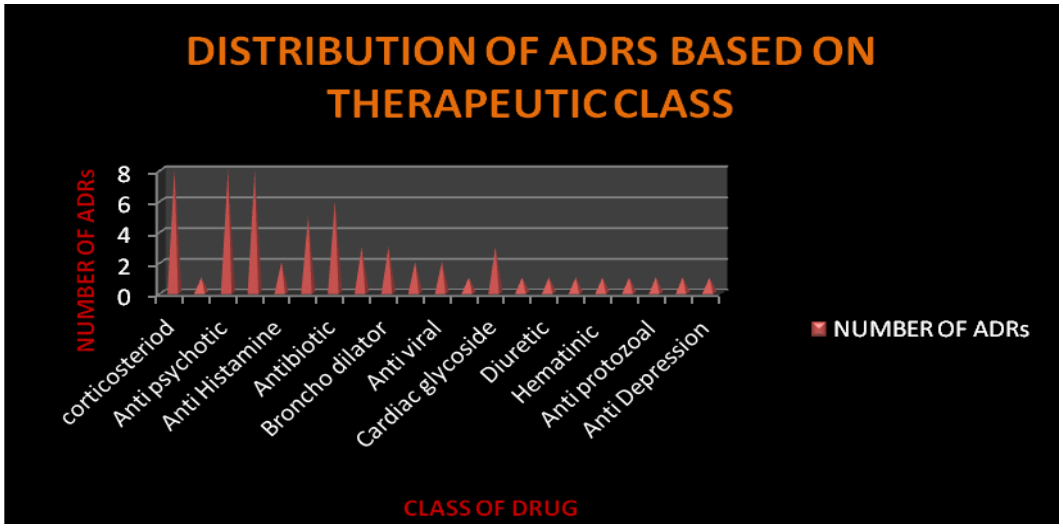


Fig.05: Distribution based on Therapeutic class

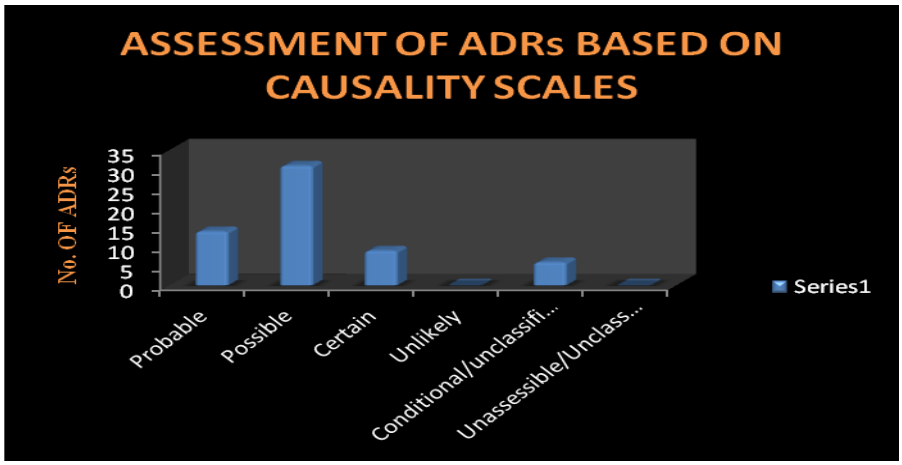
ASSESSMENT OF ADRs BASED ON CAUSALITY SCALE:

The suspected adverse drug reactions were assessed by using WHO scale of assessment for causality assessment scale. According to the WHO causality scale Majority of adverse drug reactions were rated certain 9(15%), probable/likely 14(23%), possible 31(52%), unlikely 0(0%), Conditional 6 (10%), Unassessible 0(0%).

Table 6: Based On Causality Scale

CAUSALITY	NUMBER OF ADRs	PERCENTAGE
CERTAIN	9	15
POSSIBLE	31	52
PROBABLE	14	23
CONDITIONAL	6	10
UNLIKELY	0	0
UNASSESSIBLE	0	0
TOTAL	**60**	**100**

Fig 06: Based On Causality Scale



ASSESSMENT OF ADRs BASED ON SEVERITY SCALE

According to the severity scale the adverse drug reactions were identified, among mild–level 11(12%), mild-level II 2(8%), moderate-level III 20(33%), moderate-level IV (a) 19(32%), moderate-level IV (b) 1(2%) Severe level V 1(2%).

Table 07: Based on Severity Scale

Severity of ADR	No. of ADRs	Percentage (%)
Mild-Level1	11	18%
Mild-Level 2	8	13%
Moderate-Level 3	20	33%
Moderate-Level 4(a)	19	32%
Moderate-Level 4(b)	1	2%
Severe-Level5	1	2%
Severe-Level6	0	0%
Severe-Level7	0	0
Total	**60**	**100**

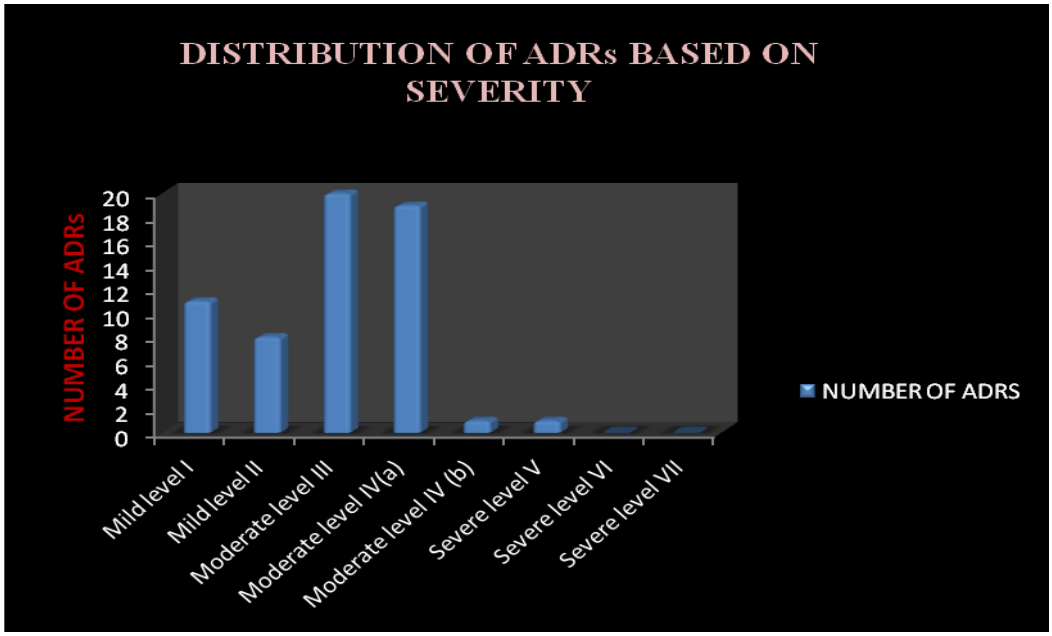


Fig.07: Based on Severity Scale

ASSESSMENT OF ADRs BASED ON NARANOJ'S SCALE:

The suspected Adverse drug reactions were assessed by using Naranjo's probability assessment scale according to the Naranjo's algorithm majority of the reported adverse drug reactions were rated as possible28 (47%) ,probable 27(45%) and followed by definite 5(8%).

Table 08: Based on Naranoj's Scale

Probability	No. of ADRs	Percentage (%)
Probable	27	45
Possible	28	47
Definite	5	8
Unlikely	0	0
Total	**60**	**100**

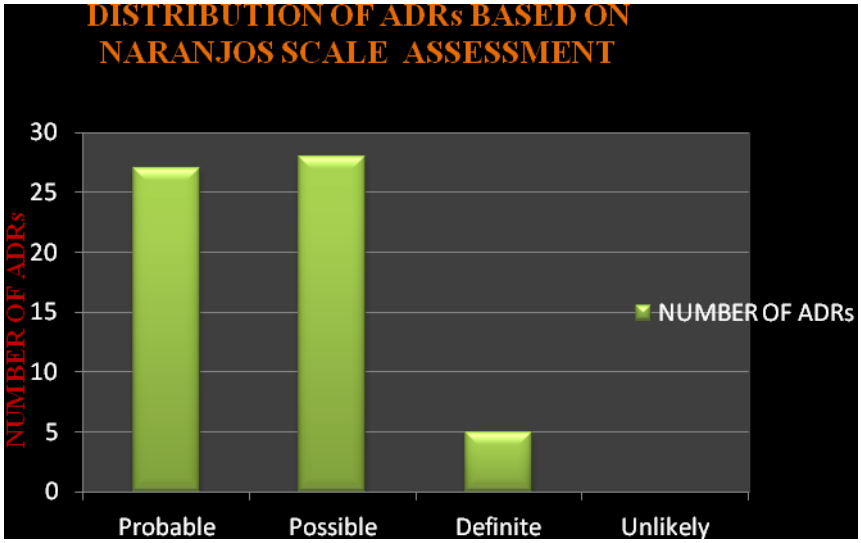


Fig.08: Based on Naranoj's Scale

ASSESSMENT OF ADRs BASED ON PREDICTABILITY SCALE:

The suspected Adverse drug reactions were assessed by using Predictability assessment scale according to this scale majority of the reported adverse drug reactions were rated as predictable56 (93%) ,Unpredictable4(7%) .

Table09: Based On Predictability Scale

PREDICTABILITY	**NUMBER OF ADRs**	**PERCENTAGE (%)**
PREDICTABLE	56	93
UNPREDICTABLE	4	7
TOTAL	**60**	**100**

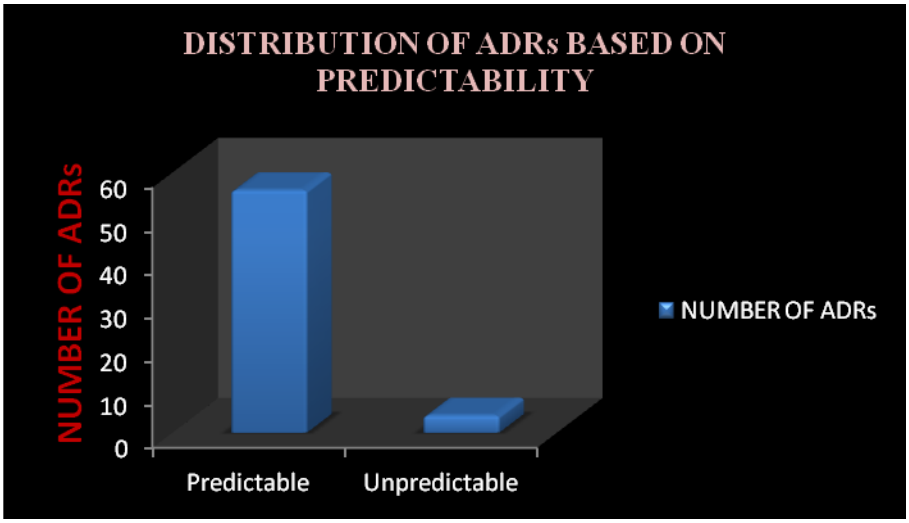


Fig.09: Based On Predictability Scale

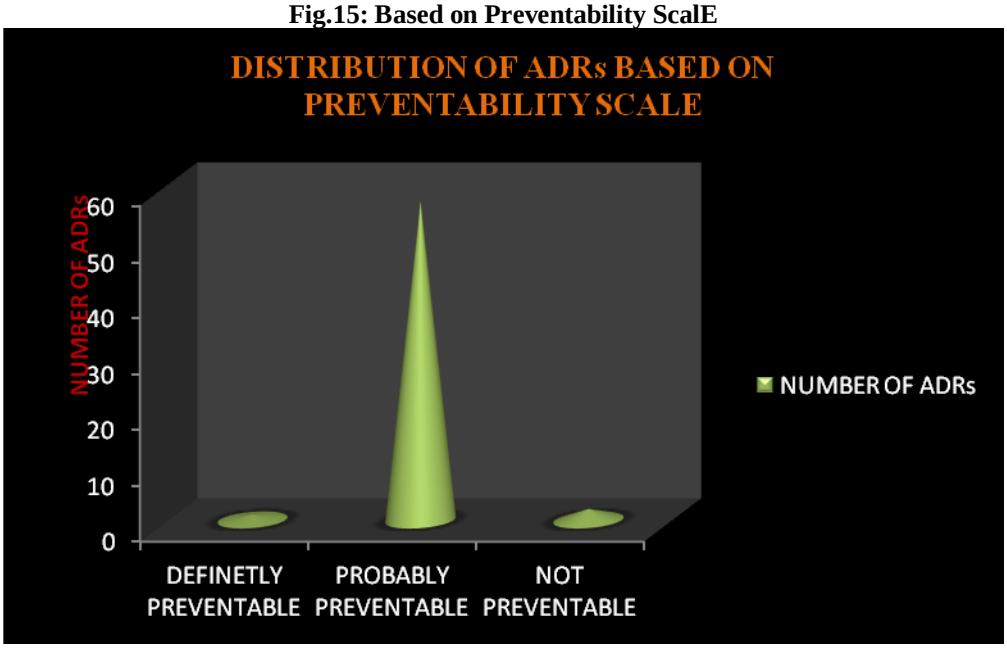
ASSESSMENT OF ADRs BASED ON PREVENTABILITY SCALE:

The suspected adverse drug reactions were assessed by using Preventability assessment scale. According to this scale, majority of the reported adverse drug reactions were rated as definitely preventable 1 (2%) ,probably preventable 57(95%) not preventable 2(3%) .

Table 10: Based on Preventability Scale

PREVENTABILITY	NUMBER OF ADRs	PERCENTAGE (%)
DEFINITELY PREVENTABLE	1	2
PROBABLY PREVENTABLE	57	95
NOT PREVENTABLE	2	3
TOTAL	**60**	**100**

Fig.15: Based on Preventability ScalE



CONCLUSION:

The most of the observed results were comparable to the literature reviews. .

All most all ADRs were reported to peripheral pharmacovigilance centers. Causality of the ADRs was probable for most cases according to Naranjo's scale and possible according to WHO-UMC criteria. Severity of the ADRs was mild according to Hartwig and Siegel severity assessment scale. Majority of ADRs were probably preventable according to Schumock and Thornton scale. The number of ADRs reported during study period were good but still it requires continuous education on pharmacovigilance programme of India and to increase awareness and knowledge of the health care professionals.

Clinical pharmacists are the upcoming breed of pharmacists in our country. Clinical pharmacists can contribute improved patients outcomes by monitoring the drug therapy and can also promote rational use of drugs. Contribution of clinical pharmacists in identifying , monitoring, reporting of suspected adverse drug reactions and by effective utilizing the knowledge of clinical pharmacist by clinicians will increases the patient care and not only reduces the incidences of adverse drug reaction and also decreases the economic burden on health care system.

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CONFLICTS OF INTEREST: We do not have any conflict of interest.

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