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The Role of Clinical Pharmacist in Pharmacovigilance at a Tertiary Care Hospital

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Abstract:
INTRODUCTION:*According to WHO, Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects of drugs, or any other drug-related problems.The World Health Organization (WHO) defines an adverse drug reaction (ADR) as "Any response to a drug which is noxious and unintended, and which occurs at normal doses.*
AIM:*This study aims to assess and report the possible adverse drug reactions in the patients and to appraise the role of clinical pharmacistin pharmacovigilance at a tertiary care hospital.*
STUDY DESIGN:A Prospective observational study.
RESULTS:*Adverse drug reactions are monitoredand are reported Based on age wise categorization, 40 – 50 age group patients had more ADRs. Our study results showed that the highest number of ADRs were observed in antibiotics based on the therapeutic class of drugs. Our study results showed that 87.5% of ADRs were due to oral administration. In our study highest number of ADRs affecting organ system were reported in GIT 15(37.5%),*
CONCLUSION:*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.The study was able to showcase the role of clinical pharmacist in monitoring the ongoing safety of medicines through continuous ADR monitoring and reporting to prevent occurring of possible ADRs and to create awareness among the healthcare professionals and patients about the therapy to attain beneficial effects.*

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I. Introduction

"Drug" a chemical substance that can causes the changes in organism's physiology and psychology to treat, cure, prevent or diagnose a diseases to get beneficial therapeutic effects. The World Health Organization (WHO) defined drug as "any substance or product that is used or intended to be used to modify or explore the physiological system, or pathological state in the benefit of the recipient". Drugs may be used for a limited duration, or on a regular basis for chronic disorders. Despite all the benefits of the drugs, the adverse reactions associated with them are also very common.

"ADR" The Adverse Drug Reaction is a response to the drug which is noxious and unintended occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, withdrawl of the drug or for the modification of physiological function.

"Adverse Event" (AE) is "any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does **not** necessarily have a **causal relationship** with this treatment". An adverse event (AE) can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not related to the medicinal product.

Pharmacovigilance: According to WHO, Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects of drugs, or any other drug-related problems.

The incidence of ADRs varies with studies ranging from as low as 0.15% to as high as 30%. The reporting of ADRs in India is less than 1% as compared to world average of 5%.

In 2010, Central Drugs Standard Control Organization (CDSCO) under the aegis of Govt., of India, Ministry of Health and Family welfare and Pharmacovigilance Programme of India (PvPI) has established adverse drug

monitoring Centre's in various tertiary care hospitals all over India with the objective to improve the reporting rate of ADR in India.

II. Materials And Methods

Aprospective observational study was conducted at a tertiary care hospital for a period of 6 months. A total of 40 patients were recruited under inclusion criteria.

Study design : Prospective observational study.
Study site: This was a tertiary care teaching hospital based study done in Department of General Medicine.
Study duration :6months.
Sample size :40
Patient enrollment: Patients are enrolled in the study based on inclusion and exclusion criteria.

Inclusion criteria:

1. Patients of age groups between 20-70 with both genders.
2. Subjects who are diagnosed with diseases and on treatment.
3. Patients who are coming to the general medicine, psychiatry, dermatology for regular check-up's/follow-ups.
4. Patients who had been hospitalized due to an ADR.
5. Patients who are willing to participate in the study.

Exclusion criteria:

1. Pregnant and lactating women.
2. Patients with hepatic impairment.
3. Drug addicted and unconscious patients.
4. Paediatric patients.
5. Patients who are not willing to participate.

III. Method of study

- Literature review on the study.
- Protocol was prepared and submitted to the institutional review board/ethical committee.
- After submission of protocol we got ethical approval from institutional ethics committee.
- On daily basis all study departments will be visited and discussed the health care professionals regularly about awareness and reporting habits.
- All patients and their case records will be reviewed and data will be collected in a data collection form. If any adverse drug reaction is identified further it will be analysed to confirm its causality, severity, preventability by using various scales and it is reported.
- 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 –UMC scale and Naranjo's scale.
- Severity of the ADRs was evaluated by Modified Hart wig and Siegel's scale.
- Preventability of ADRs was evaluated by Shamrock and Thornton preventability scale.
- The founded ADRs were reported in ADR reporting form to peripheral pharmacovigilance centres.
- Health care professionals will be encouraged in reporting suspected adverse drug reaction through explanation about importance of adverse reaction reporting and its reporting procedure through distribution of pamphlets and information leaflets, displaying charts about importance of pharmacovigilance.

Statistical analysis :
Chi square test was used to determine the p value and association between the adverse drug reactions and various factors .

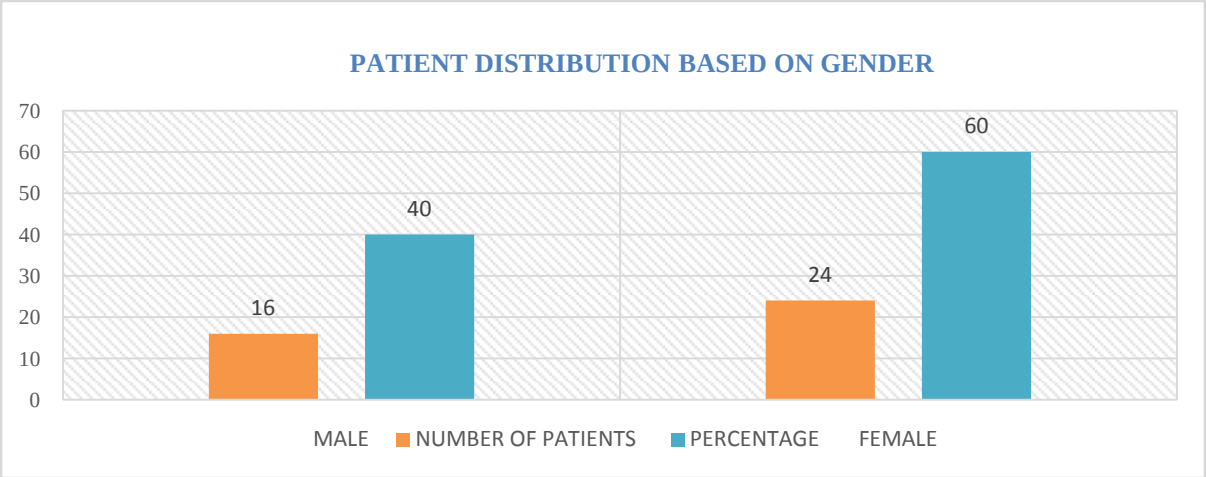
IV. Result

Aprospective observational study was conducted at a tertiary care hospital for a period of 6 months. A total of 40 patients were recruited under inclusion criteria.

PATIENT DISTRIBUTION BASED ON GENDER:
In our study we collected 40 cases. Out of 40 patients 16(40%) were male and 24(60%) were female, results were show in table 4 and figure 3.

GENDER	NUMBER OF PATIENTS	PERCENTAGE
MALE	16	40

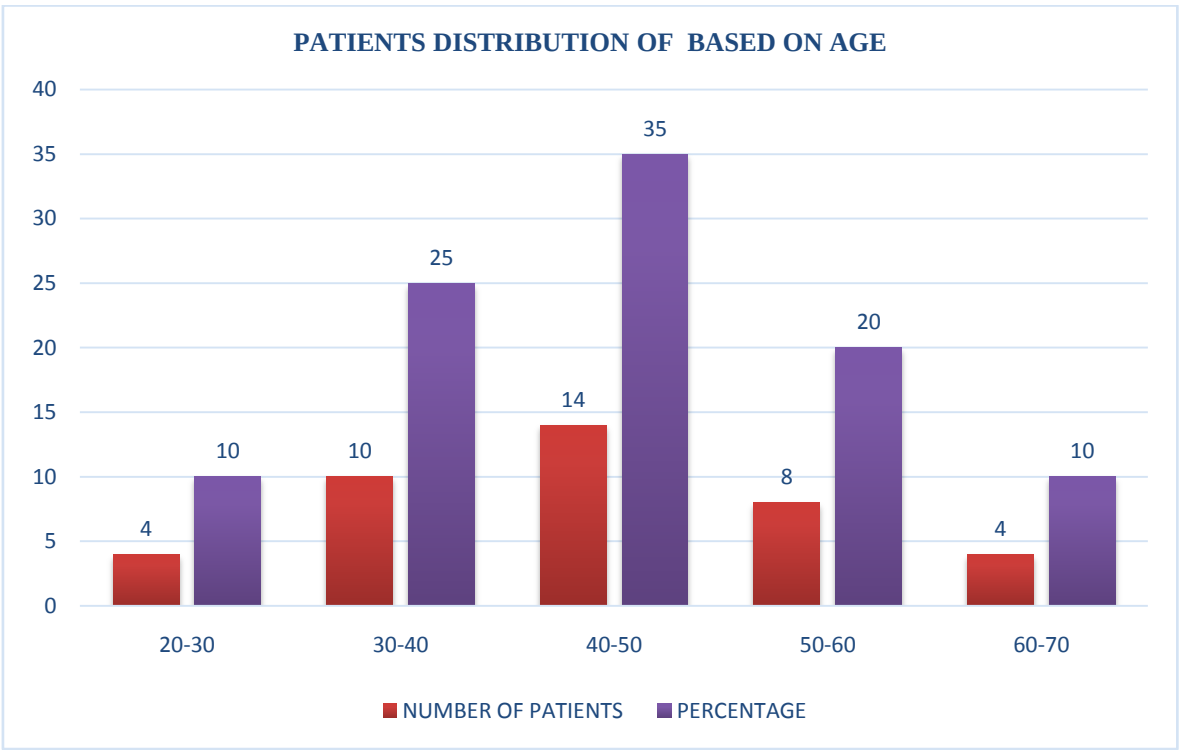
FEMALE	24	60
TOTAL	40	100



PATIENT CATEGORIZATION BASED ON AGE.

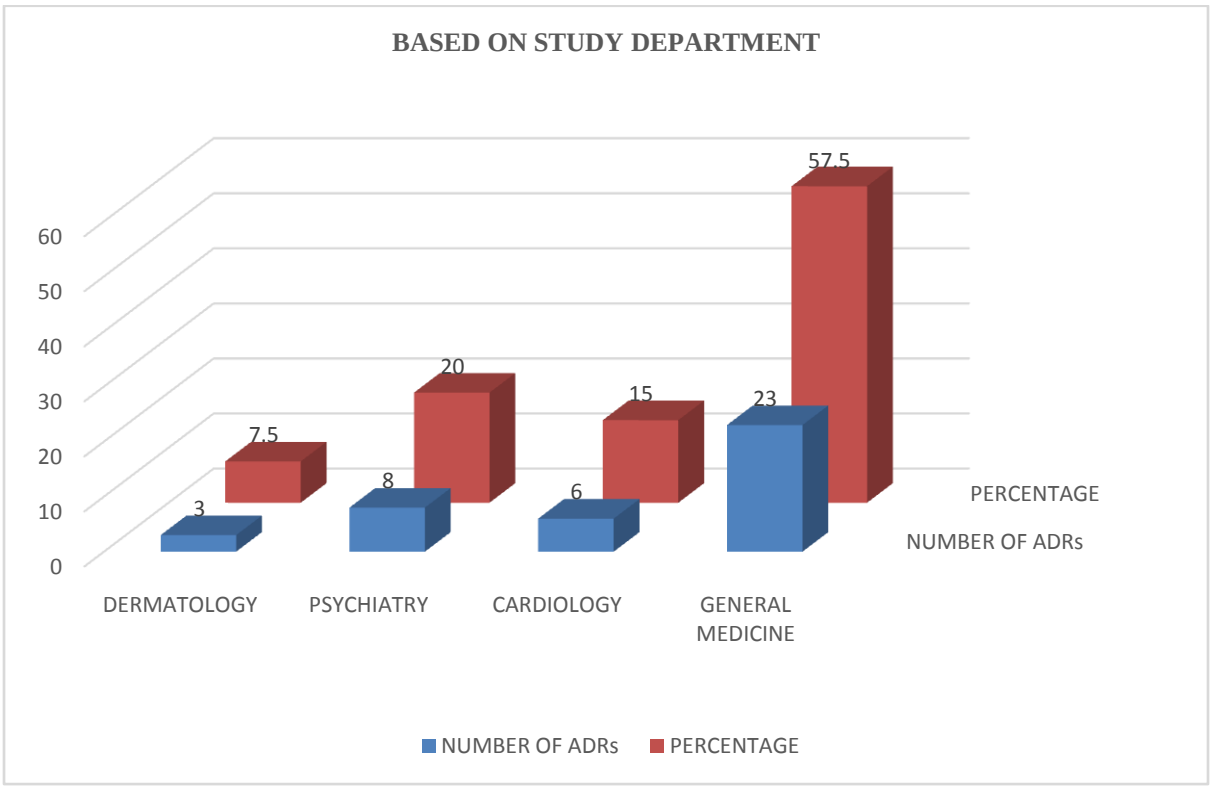
Out of 40 patients, based on the age group the majority of ADRs were found in between 40-50 with 14(35%) followed by 30-40 age group with 10(25%), 50-60 with 8(20%), 20-30 with 4(10%) and 60-70 with 4(10%).

AGE GROUP	NUMBER OF PATIENTS	PERCENTAGE (%)
20-30	4	10
30-40	10	25
40-50	14	35
50-60	8	20
60-70	4	10
Total	40	100



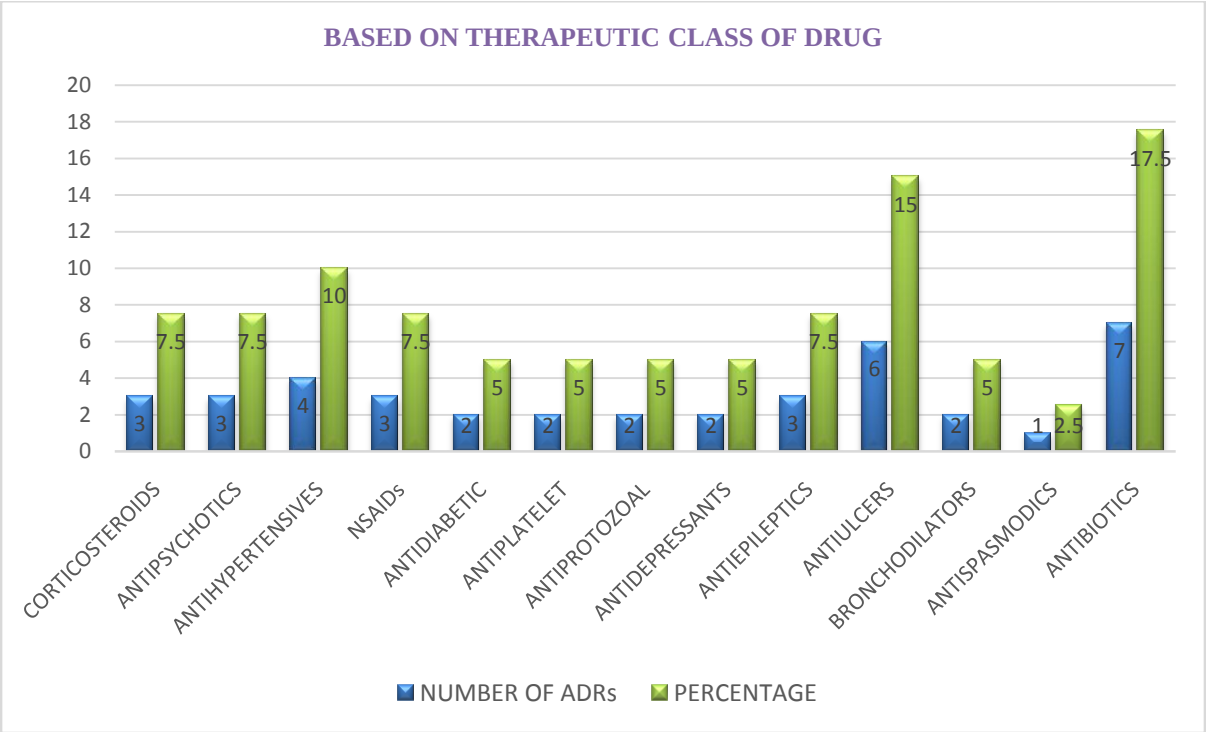
SUSPECTED ADVERSE DRUG REACTIONS REPORTED FROM STUDY WARDS:
Out of four departments included in the study, we observed more ADRs in general medicine with 23(57.5%) followed by psychiatry with 8(20%), cardiology with 6(15%) and Dermatology with 3(7.5%).

DEPARTMENT	NUMBER OF ADRs	PERCENTAGE (%)
DERMATOLOGY	3	7.5
PSYCHIATRY	8	20
CARDIOLOGY	6	15
GENERAL MEDICINE	23	57.5
TOTAL	**40**	**100**



ADVERSE DRUG REACTION BASED ON THE THERAPEUTIC CLASS OF THE DRUG:
Therapeutic group of the drugs associated with the adverse drug reactions. Out of 40 adverse reactions observed during study period, in that we found

THERAPEUTIC CLASS	NUMBER OF ADRs	PERCENTAGE (%)
CORTICOSTERIODS	3	7.5
ANTI PSYCHOTICS	3	7.5
ANTI HYPERTENSIVES	4	10
NSAIDs	3	7.5
ANTIDIABETIC DRUGS	2	5
ANTI PLATELETS	2	5
ANTI PROTOZOAL	2	5
ANTI DEPRESSANTS	2	5
ANTI EPILEPTICS	3	7.5
ANTI ULCERS	6	15
BRONCHO DILATORS	2	5
ANTISPASMODICS	1	2.5
ANTIBIOTICS	7	17.5
TOTAL	40	100.00

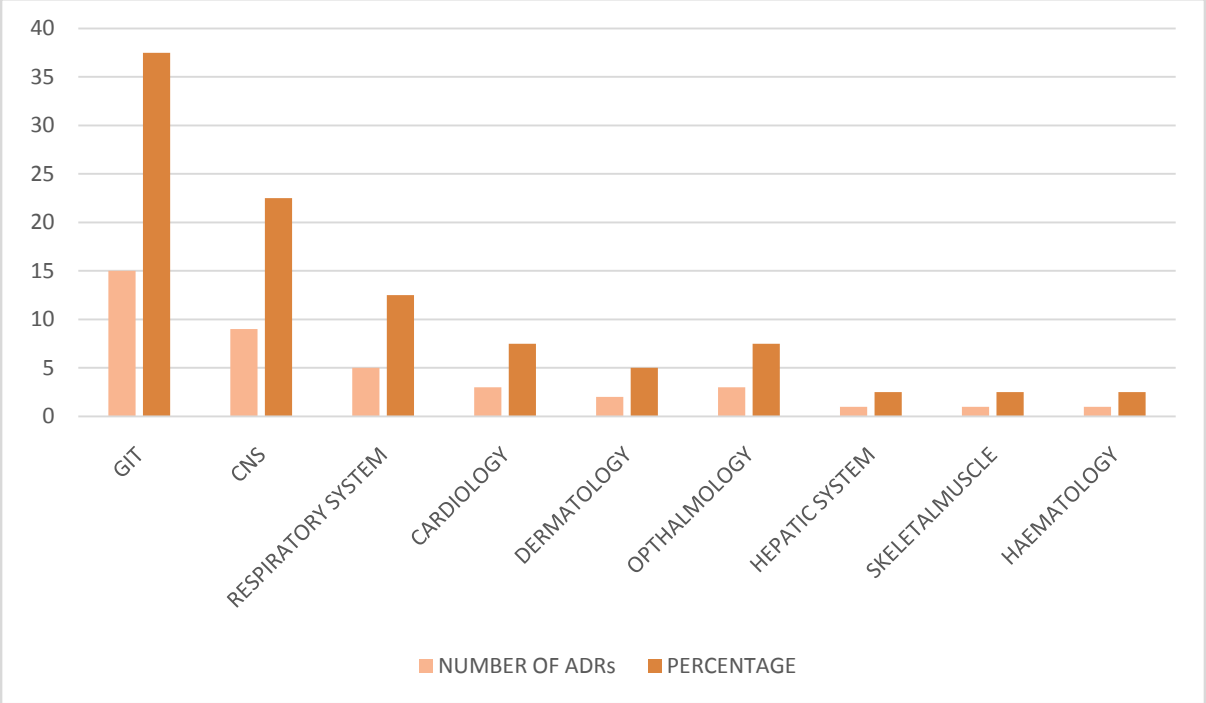


ORGAN SYSTEM AFFECTED DUE TO ADVERSE DRUG REACTION:

Among 40 adverse drug reactions observed during study period, 15(37.5%) were from Gastro intestinal tract, 9(22.5%) from CNS, 5(12.5%) were from respiratory system, 3(7.5%) were from cardiology, 3(7.5%) were from ophthalmology, 2(5%) were from dermatology, 1(2.5%) were from hepatic system, 1(2.5%) were from skeletal muscle, 1(2.5%) were from haematology.

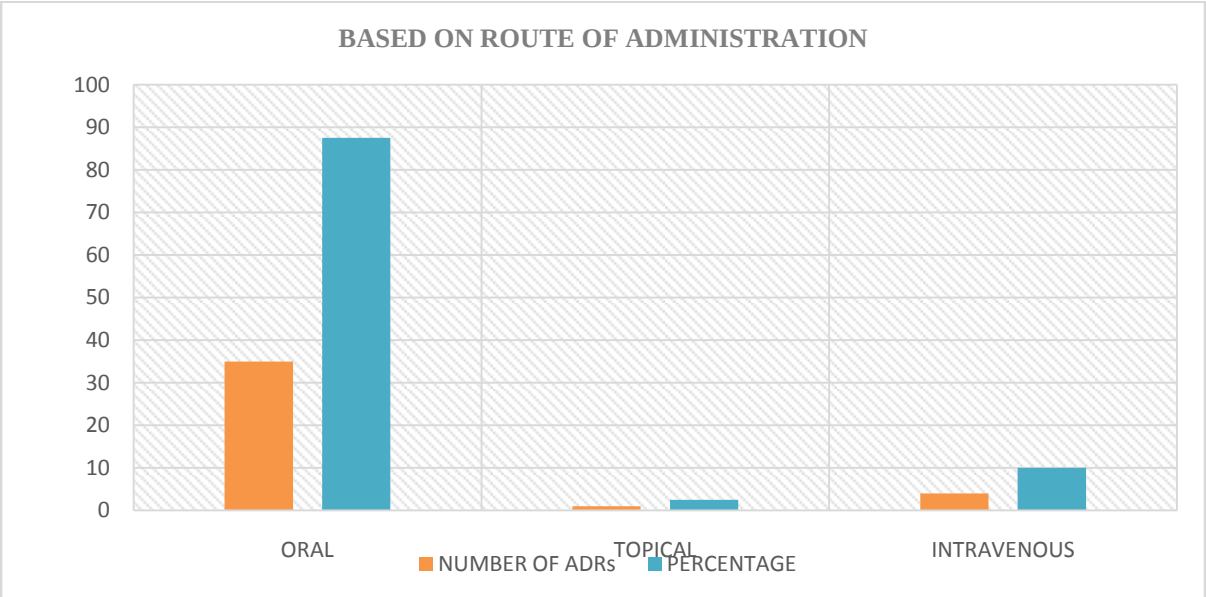
SYSTEM INVOLVED	NUMBER OF ADRs	PERCENTAGE (%)
GIT	15	37.5
CNS	9	22.5
RESPIRATORY SYSTEM	5	12.5
CARDIOLOGY	3	7.5
DERMATOLOGY	2	5
OPTHALMOLOGY	3	7.5
HEPATIC SYSTEM	1	2.5
SKELETAL MUSCLE	1	2.5
HAEMATOLOGY	1	2.5
TOTAL	40	100

Distribution of ADRs based on organ system involved.



ADVERSE DRUG REACTION BASED ON ROUTE OF ADMINISTRATION:

Among 40 adverse reactions observed during study period, in that 35(87.5%) were due to oral administration followed by 4(10%) due to Intravenous administration, 1(2.5%) due to Topical application.



DRUGS INVOLVED IN ADVERSE DRUG REACTIONS:

Among 40 adverse reactions that were observed during study period, the highest adverse reactions were due to Ranitidine (10%), followed by Clopidogrel (5%), Phenytoin (5%), Omeprazole (5%) and Betamethasone (2.5%), Dexamethasone, Prednisolone, Olanzapine, Aripiprazole, Clozapine, nifidipine, Amlodipine, Nitroglycerin, Furosemide, Indomethacin, Aspirin, Diclofenac, Metformin, Glimepiride, Metronidazole, Albendazole, Fluoxetine,

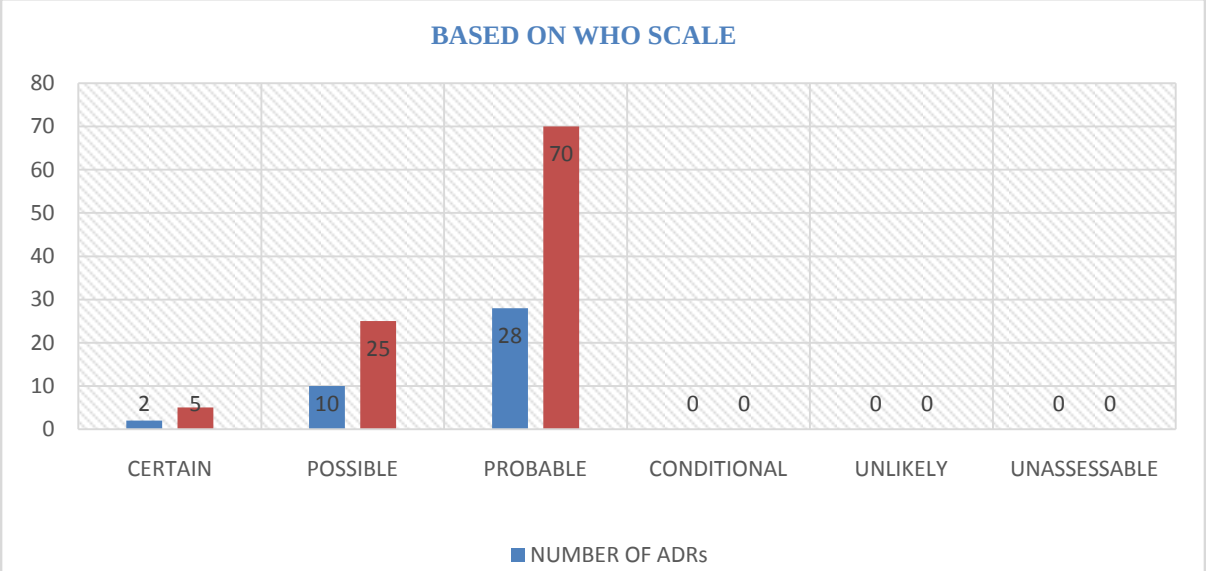
Sertraline, Levetiracetam, Salbutamol, Deriphyllin,Dicyclomine, Cefotaxime,Ceftriaxone,Amoxicillin, Cefoperazone,Erythromycin, Amikacin, Cefpodoxime, and results were shown in the following table.

DRUG NAME	NUMBER OF ADRs	PERCENTAGE (%)
BETAMETHASON	1	2.5
DEXAMETHASONE	1	2.5
PREDNISOLONE	1	2.5
OLANZAPINE	1	2.5
ARIPIPRAZOLE	1	2.5
CLOZAPINE	1	2.5
NIFIDIPINE	**1**	**2.5**
AMLODIPINE	1	2.5
NITROGLYCERIN	1	2.5
FUROSEMIDE	1	2.5
INDOMETHACIN	1	2.5
ASPIRIN	1	2.5
DICLOFENAC	1	2.5
METFORMIN	1	2.5
GLIMEPIRIDE	1	2.5
CLOPIDOGREL	2	5
METRONIDAZOLE	1	2.5
ALBENDAZOLE	1	2.5
FLUOXETINE	1	2.5
SERTRALINE	1	2.5
LEVETIRACETAM	1	2.5
PHENYTOIN	**2**	**5**
RANITIDINE	4	10
OMEPRAZOLE	2	5
SALBUTAMOL	1	2.5
DERIPHYLLIN	1	2.5
DICYCLOMINE	1	2.5
CEFOTAXIME	1	2.5
CEFTRIAXONE	1	2.5
AMOXICILLINE	1	2.5
CEFOPERAZONE	1	2.5
ERYTHROMYCIN	1	2.5
AMIKACIN	1	2.5
CEFPODOXIME	1	2.5
TOTAL	40	100

ASSESSMENT OF ADRs BASED ON WHO 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 as Probable/likely 28(70%) followed by Possible 10(25%), Certain 2(5%), 0% Conditional, 0% unlikely, Unassessable 0(0%).

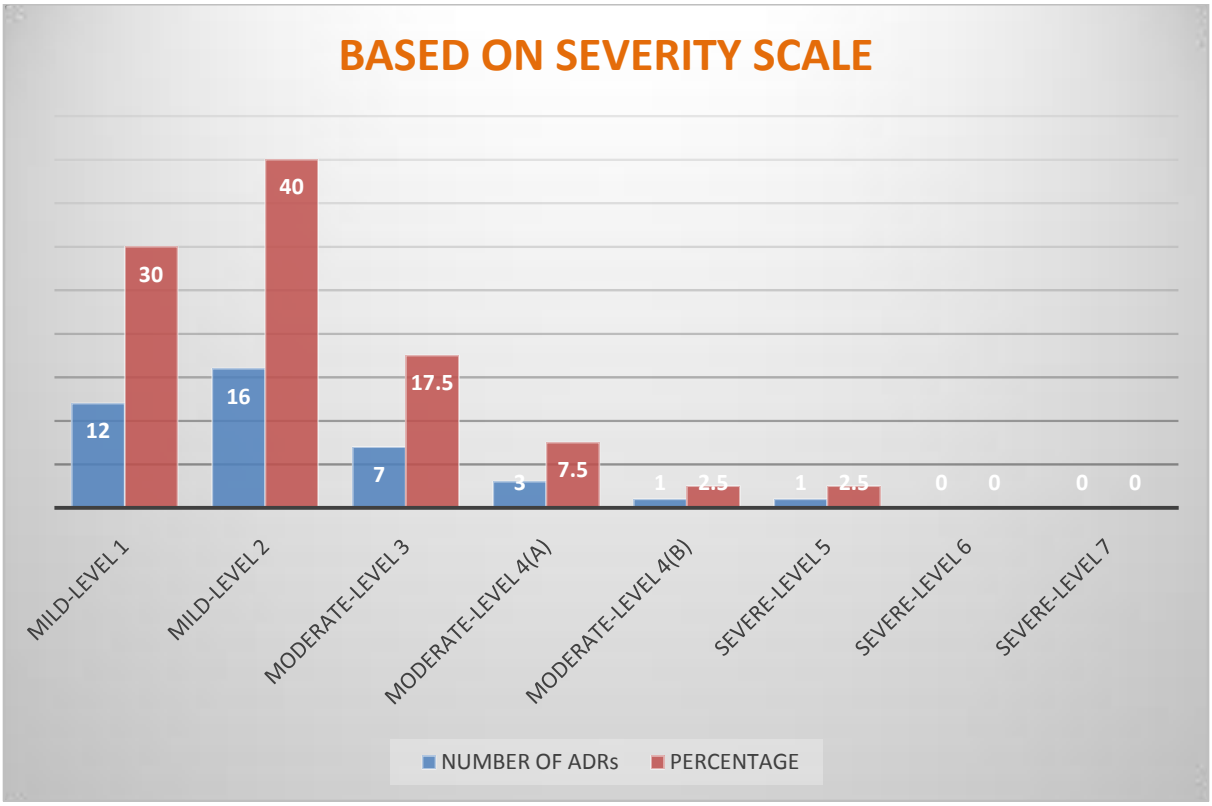
CAUSALITY	NUMBER OF ADRs	PERCENTAGE
CERTAIN	2	5
POSSIBLE	10	25
PROBABLE	28	70
CONDITIONAL	0	0
UNLIKELY	0	0
UNASSESSIBLE	0	0
TOTAL	**40**	**100**



ASSESSMENT OF ADRs BASED ON SEVERITY SCALE:

According to the Hart wig's severity assessment scale the majority of adverse drug reactions were rated as Mild-level II with 16(40%) followed by Mild–level 1 with 12(30%), Moderate-level III with 7(17.5%), Moderate-level IV(a) with 3(7.5%), Moderate-level IV(b) with 1(2.5%), Severe-level V with 1(2.5%).

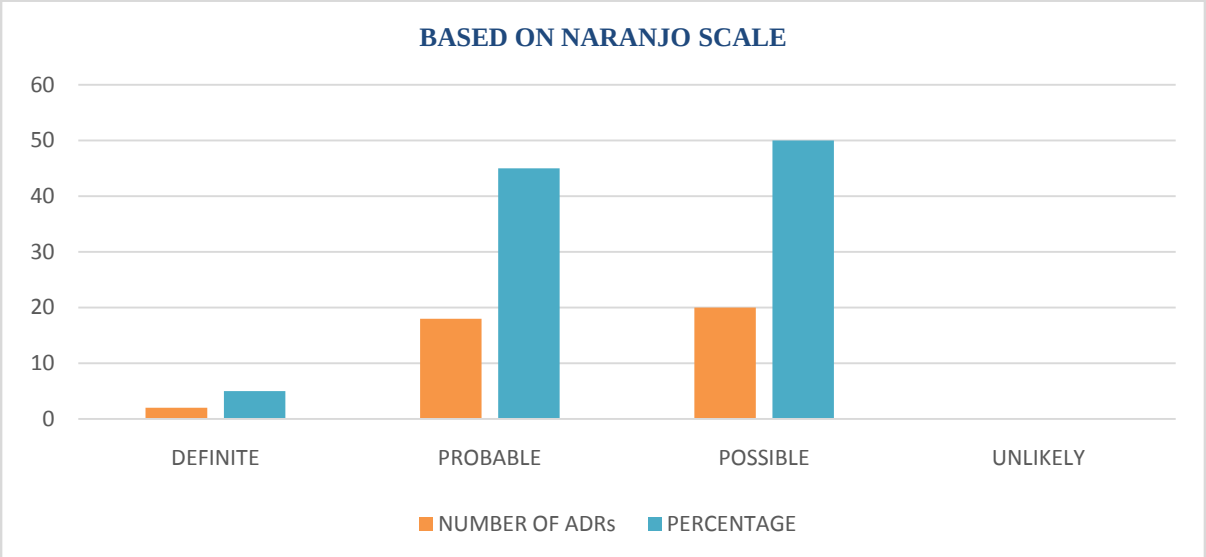
SEVERITY OF ADR	NUMBER OF ADRs	PERCENTAGE (%)
Mild-Level1	12	30
Mild-Level 2	16	40
Moderate-Level 3	7	17.5
Moderate-Level 4(a)	3	7.5
Moderate-Level 4(b)	1	2.5
Severe-Level5	1	2.5
Severe-Level6	0	0
Severe-Level7	0	0
Total	**40**	**100**



ASSESSMENT OF ADRs BASED ON NARANJO 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 Possible 20 (50%) followed by Probable 18(45%) and Definite 2(5%).

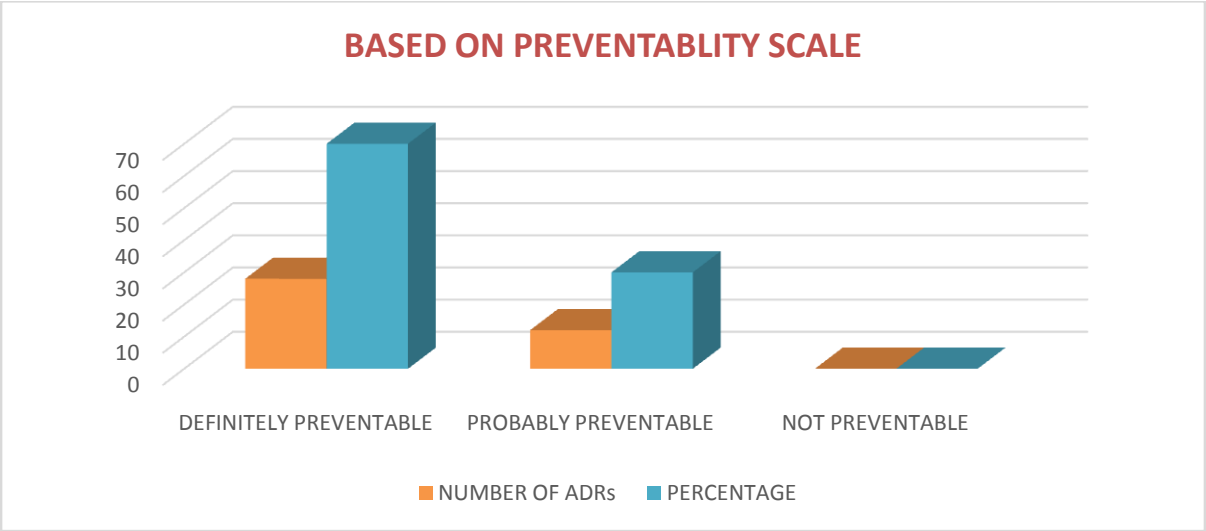
PROBABILITY	NO. OF ADRS	PERCENTAGE (%)
DEFINITE	2	5
PROBABLE	18	45
POSSIBLE	20	50
UNLIKELY	0	0
TOTAL	40	100



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 28(70%), probably preventable 12(30%), not preventable 0%.

PREVENTABILITY	NUMBER OF ADRs	PERCENTAGE (%)
DEFINITELY PREVENTABLE	28	70
PROBABLY PREVENTABLE	12	30
NOT PREVENTABLE	0	0
TOTAL	40	100



V. Discussion

In our study 40 patients with 40 suspected Adverse Drug Reactions were screened and enrolled for the study based on previously discussed inclusion and exclusion criteria. From these it was observed that females are majorly affecting than males. It was similar to the observation done by "BASIL ELIYAS, BABU GANESAN" study.

Based on age wise categorization, 40 – 50 age group patients had more ADRs. As per statistical analysis this was considered to be not quite statistically significant($p > 0.05$, by using Chi-square test). Our study was supported by"M. MANASA REKHA" study.Our study results showed that the highest number of ADRs were observed in antibiotics based on the therapeutic class of drugs. As per statistical analysis this was considered to be not quite statistically significant ($p>0.05$, by using chi-square test). it is supported by "MEDA VENKATASUBBAIAH, P. DWARAKANADHA REDDY" study.Our study results showed that 87.5% of ADRs were due to oral administration and this has been supported by "SINGH H, DULHANI N, KUMAR BN, SINGH P" where they reported with 135(87.66%) of ADRs were oral route of administration.

In our study highest number of ADRs affecting organ system were reported in GIT 15(37.5%), it is supported **by "MEDA VENKATASUBBAIAH, P. DWARAKANADHA REDDY"** where their results showed that most common organ system involved in the development of ADRs were GIT 67(26.38%).

Based on the Naranjo's probability assessment of the adverse reaction reported, 20(50%) ADRs were coming in the category of possible. But it is not similar to the observation done by **"Dr. G. RAMYA BALA PRABHA"** where they had reported that 41(78.84%) were probable ADRs.Causality assessment of adverse reaction were done by using WHO-UMC causality assessment scale, 28(70%) ADRs were under the category of probable. It was not similar to the observation done **by"Dr. MADHAN MOHAN RAO"** where they had reported that majority of ADRs under the category of possible 31(52%).Severity assessment of the adverse reaction reported were done, 16(40%) ADRs were mild level-2. It is similar to the observation done **by "Dr. JIHANA SHAJAHAN"** where they had reported that 166(55.3%) ADRs were mild.Based on preventability assessment scale the major ADRs were in the category of definitely preventable 28(70%). But it is not similar to the observation done **by "Dr. JIHANA SHAJAHAN"** where they had reported that 54(18%) probably preventable.

VI. Conclusion

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.The Clinical Pharmacists are an asset for health care team and patients. The lively participation of clinical pharmacists can play a significant role in the identification and documentation of ADRs by virtue of their role in patient drug monitoring.Causality of the ADRs was possible for most cases according to Naranjo's scale and probable according to WHO-UMC criteria. Severity of the ADRs was mild according to Hart wig and Siegel severity assessment scale and majority of ADRs were definitely preventable according to Schumock and Thornton scale. The study was able to showcase the role of clinical pharmacist in monitoring the ongoing safety of medicines through continuous ADR monitoring and reporting to prevent occurring of possible ADRs and to create awareness among the healthcare professionals and patients about the therapy to attain beneficial effects. The findings will encourage the healthcare team to be aware of more ADR-prone medications and their preventability by enhancing the aptitude of prescribers to manage ADRs more effectively.

References:

[1]. M. ManasaRekha*, M. Manasa , Department of Pharmacy Practice, Annamacharya college of Pharmacy, A Study On Role Of Doctor Of Pharmacy In Identification And Reporting of Adverse Drug Reactions In An Antiretroviral Therapy Ward Of A Tertiary Care Teaching Hospital. PRINT ISSN: 2394-6679 | E-ISSN: 2347.

[2]. Dr. M. Madan Mohan Rao1*, et. al., On The Role Of Clinical Pharmacist In Pharmacovigilance And Drug Safety In Tertiary Care Teaching Hospital.

[3]. Kiran roy1*, Divya s1, PratibhaNadigi, Bhanuprakash2. Monitoring and Analysis of Adverse Drug Reactions in a Private Tertiary Care Teaching Hospital.Received 14 January 2015, Revised and Accepted: 03 February 2015.

[4]. VikasDhikav*, Sindhu Singh**, KS Anand*** Adverse Drug Reaction Monitoring In India. JIACM 2004;5(1).

[5]. Indian Journal of Pharmacy Practice, Vol 10, Issue 1, Jan-Mar, 2017. Fatima Tahniyath on Clinical Pharmacist-A Need for the Study.

[6]. M. Shamna, C. Dilip, M. Ajmal, P. Linu Mohan, C. Shinu, C.P. Jafer, Yahiya Mohammed. On A Prospective Study on Adverse Drug Reactions of Antibiotics In A Tertiary Care Hospital.

[7]. KhawajaTahir Mahmood1, Fatima Amin2 Minaa Tahir3 and Ikram U1 Haq4. Pharmacovigilance -A Need for Best Patient Care in Pakistan.A Review.KhawajaTahirMahmood et al /J. Pharm. Sci. & Res. Vol.3(11), 2011,1566-1584

[8]. Singh H, Dulhani N1, Kumar BN, Singh P3, Tewari P2, Nayak K on A Pharmacovigilance Study In Medicine Department Of Tertiary Care Hospital In Chhattisgarh, India. Singh, et al. J Young Pharm. 2010; 2 (1): 95-100.

[9]. Prasanna R. Deshpande1,2, Raghuram Vantipalli1, C. H. Chaitanya Lakshmi1, E. Jagadeswara Rao3, Bishnu Regmi4, Abdul Ahad5, P. Sharmila Nirojini1. On Clinical Pharmacist: The Major Support To Indian Healthcare System In Near Future. Journal of Pharmacy and Bioallied Sciences July-September 2015 Vol 7 Issue 3.

[10]. AnjanAdhikari, NiladriBhattacharjee, Sangitha Bhattacharya, Rania indu, moumitha Ray.On Evaluation of Adverse Drug Reaction in Tertiary Care Hospital. Journal of Young Pharm, 2017; 9(3):311-314.

[11]. Mishra and Kumar, J Pharmacovigilance 2013, 1:2 DOI:10.4172/23296887.1000108. On Pharmacovigilance: Current Scenario in a Tertiary Care Teaching Medical College in North India.

S.Kashif Zia, et.al. "The Role of Clinical Pharmacist in Pharmacovigilance at a Tertiary Care Hospital." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 19(1), 2020, pp. 58-68.