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# Assessment of Adverse Drug Reactions and Drug-Drug Interactions in Polypharmacy among Geriatrics in a Tertiary Care Hospital

S.Praveena [1] ,G.Roopa sree[1] , B.Prashanthi [1] , Dr.T.Usha Nandini [1] , Dr.L.Reddenna [1] , Dr.V.Sreedhar [1]

[1]*Department of Pharmacy Practice ,Balaji College of Pharmacy, Ananthapuramu, Andhra Pradesh, India – 515001*

*Corresponding Author: S.Praveena*

***Abstract:*** *Polypharmacy is defined as the use of multiple medications by a single patient which is commonly observed among geriatric patients. The use of multiple medications has been shown to predispose patients to adverse drug reactions, drug-drug interactions and medication non compliance particularly in geriatric population. It is a Prospective Observational Study was conducted in a Tertiary care Hospital for a period of 6 months. The Patients who meet the inclusion criteria are recruited. The demographic details and baseline characteristics like age, gender, Social history, are taken. Data obtained from their case sheets and through direct patient interview. Assessment and evaluation of adverse drug reactions and drug-drug interactions is performed by using WHO causality assessment scale, stockley's drug interactions, Medscape and their frequencies are studied. In Our Study, Out of 287 Patients 72 ADRs and 22 drug interactions were observed. In those mostly Metformin and ceftriaxone causing ADRs in elderly patients .Out of 22 drug interactions the most prescribed Combinations Drugs Glimipride With Ranitidine, and Furosemide with metformin causes Hypoglycemia. In these Mild Drug interactions were 9 Moderate Drug interactions were 5 and Severe Drug interactions were 7.*

*Increasing age and polypharmacy were identified as the predictors of ADRs and Drug-drug interactions. The clinical pharmacist must remain attention in assessing, monitoring and preventing of Adverse Drug Reactions and Drug-drug interactions and making appropriate dosage or therapy adjustments.*

***Key words :*** *Adverse drug reaction, Drug interactions, Polypharmacy*

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## I. Introduction

Polypharmacy generally described as the existing of 5 or more medications by the similar patient[1,2].

Measures to avoid polypharmacy in geriatrics are Avoid unnecessary drug therapy, Treat the cause rather than symptom, Drug history, Choosing the drug, Dose titration, Choosing the right dosage form, Packaging and labelling, Good record keeping, Regular supervision and Review of treatment[3,4,5]. The World Health Organization (WHO) endorses an Adverse Drug Reaction is an "any response to a drug that is noxious and unintended, and that occurs at doses used in man for prevention, diagnosis, or therapy" And it may also acquire by the numerous health care practitioners or Physicians[6,7] . Many predisposing factors are involved for the occurrence of adverse drug reactions to the patient. There are mainly six predisposing factors are Polypharmacy, Multiple and intermittent diseases, Drug characteristics, Age, Gender ,Race and genetic factors[8]. In INDIA, utilize the "Suspected adverse drug reaction Reporting Form" to report any ADR. **Reporting of ADR** for health care professionals and consumers SUSAR now available on website of IPC to report ADR. Procedure includes A reporter can send filled ADR reporting form directly to **NCC (National Coordination Center)** or their nearest **AMC(ADR Monitoring Center).** These reports are confirmed by health care professionals and entered into "**vigiflow**" and Send to NCC for further assessment**.** Finally reports are reviewed at NCC and committed to WHO Uppsala Monitoring Center. The obtained information is entered in the Drug Safety Data Base and analyzed and assessed by experts to identify new signals[9,10,11,12] . Drug Interaction is defined as an interaction is said to happen when the outcome of one drug are changed by the existence of another drug, herbal medicine, food, drink or by some ecological chemical agent[13]. Mechanisms associated with Drug Interaction are Pharmaceutical interaction, Pharmacokinetic interaction, Pharmacodynamic interaction. The role of pharmacist includes Monitoring patients who are at greater risk of developing ADRs, who are prescribed with drugs highly likely to cause ADRs and minimize drug interactions by avoiding polypharmacy in Susceptible patients.

## II. Material and Methods

This prospective observational study was carried out on patients of Department of general Medicine at Governament General Hospital , Ananthapuramu, Andhra Pradesh from August 2018 to January 2019. A total 287 geriatric subjects(both male and female) of aged ≥ 60 years for in this study.

**Study Design:** Prospective observational study

**Study Location**: This was a tertiary care hospital based study done in Department of General Medicine, at Governament General Hospital,Ananthapuramu, Andhra Pradesh.

**Study Duration:** August 2018 to January 2019

**Sample size:** In order to asses the ADRs and Drug drug interactions, a sample size of 287 patientswas computed with 95% confidence interval, 5% marigin of error.

**Inclusion criteria:**

1. Patients age greater than 60 years.
2. Inpatients and out patients
3. Only patients prescribed with polypharmacy.

**Exclusion criteria:**

1. Pediatrics
2. Incomplete case sheets
3. Patients with psychiatric illness.
4. Patients with malignancy.

**Procedure and Methodology :** Patient who meets the inclusion criteria are provided with a consent form. Those who given their consent form are recruited for the present study. Patients demographic details like age, gender, social history and other baseline characteristics are taken. Principal diagnosis, concomitant disease states, medical history, concurrent medications and their dosage and medications which are taken prior to the admission are recorded. If available other data like biochemistry, Haematological, liver and renal function tests values are taken. Based on the data obtained from their case sheets and through direct patient interview the drug interactions , adverse drug reactions are identified in poly pharmacy patient. Assessment and evaluation of adverse drug reactions and drug interactions is performed by using WHO causality assessment scale, stock leys drug interactions , medscape.and their frequencies are studied . Educated and counselled the patients about the possible adverse drug reactions and drug interactions. Results were assessed by using suitable statistical tools.

**Stastistical Analysis:-** All the base line characters are described in descriptive statistics.

Adverse drug reactions and drug interactions in polypharmacy among geriatrics was assesed by Mean and standard deviation by using graph pad instat 3.1 version.

## III. Result

**Figure-1: Total number patients distribution according to their gender**

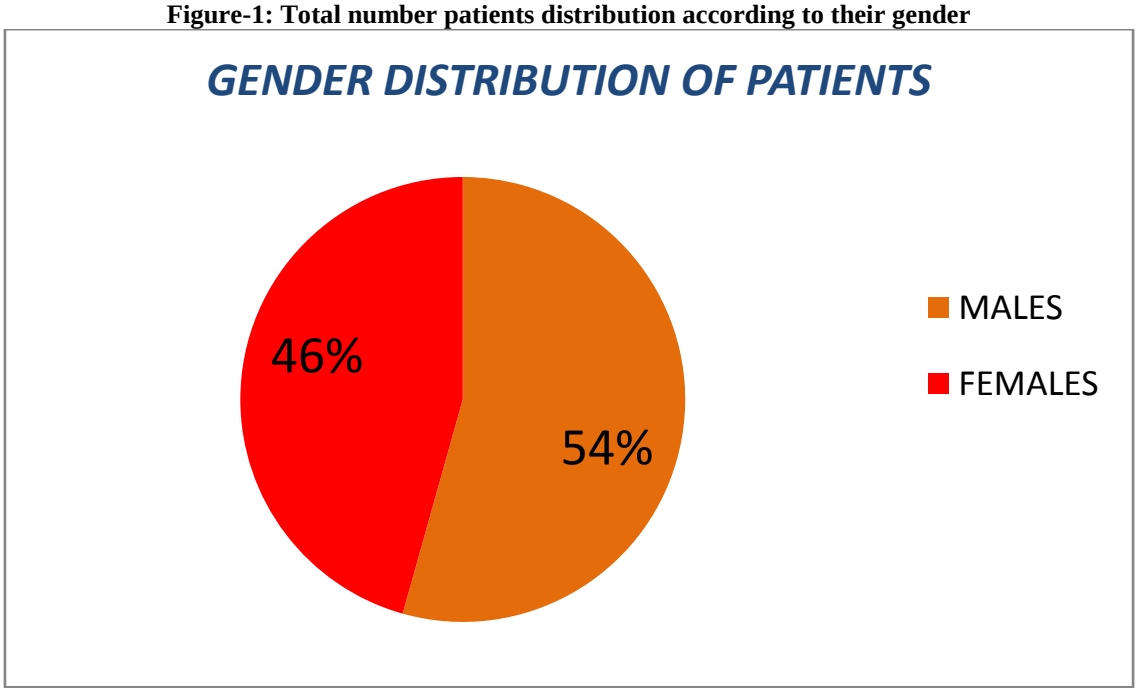


**Table- 1: Drugs suspected to cause ADRs (n=72) in elderly medical inpatients and outpatients at tertiary care teaching hospital**

| Name of drug | No of patients receiving the drug | No of patients developing ADRs (%) | ADRs according to system affected(Number of ADRs observed) |
|---|---|---|---|
| Enalapril | 42 | 8 (11.11%) | Respiratory system(8) |
| Pantoprazole | 117 | 4 (5.55%) | Gastrointestinal(4). |
| Ranitidine | 126 | 2 (2.77%) | Central nervous system(1),Gastro intestinal(1). |
| Metformin | 50 | 12 (16.66%) | Endocrine system(8),Central nervous system(4)<br>Central nervous system(4).<br>Gastrointestinal(10). |
| Ondansetron | 56 | 4 (5.55%) | Central nervous system(4) |
| Ceftriaxone | 156 | 10 (13.88%) | Central nervous system(2) |
| Amlodipine | 56 | 4 (5.55%) | Musculo-skeletal system(1),Gatrointestinal (1) |
| Telmisartan | 44 | 2 (2.77%) | Gastrointestinal(1) |
| Atorvastatin | 68 | 2 (2.77%) | Gatrointestinal(3)<br>Endocrine(7) |
| Cefixime | 40 | 1 (1.38%) | Gastro intestinal(7) |
| Ciprofloxacin | 22 | 3 (4.16%) | Gastrointestinal(1) |
| H.Mixtard | 46 | 7 (9.72%) | Gastrointestinal(5) |
| Calcium carbonate | 44 | 7 (9.72%) | |
| Azithromycin | 18 | 1 (1.38%) | |
| Theophylline | 92 | 5 (6.94%) | |

**Table-2: Number of patients suspected to ADRs due to medicines**

| Name of Drug | Adverse Drug Reaction | Number of patients |
|---|---|---|
| Enalapril | Cough | 8 |
| Pantoprazole | Abdominal pain | 4 |
| Ranitidine | Headache | 1 |
| | Abdominal pain | 1 |
| Metformin | Hypoglycemia | 8 |
| | Vertigo | 4 |
| Ondansetron | Headache | 4 |
| Ceftriaxone | Diarrhea | 10 |
| Amlodipine | Headache | 3 |
| | Dizziness | 1 |
| Telmisartan | Dizziness | 2 |
| Atorvastatin | Myalgia | 1 |
| | Dyspepsia | 1 |
| Cefixime | Diarrhea | 1 |
| Ciprofloxacin | Diarrhea | 3 |
| H.Mixtard | Hypoglycemia | 7 |
| Calcium carbonate | Constipation | 7 |
| Azithromycin | Vomiting | 1 |
| Theophylline | Vomiting | 5 |

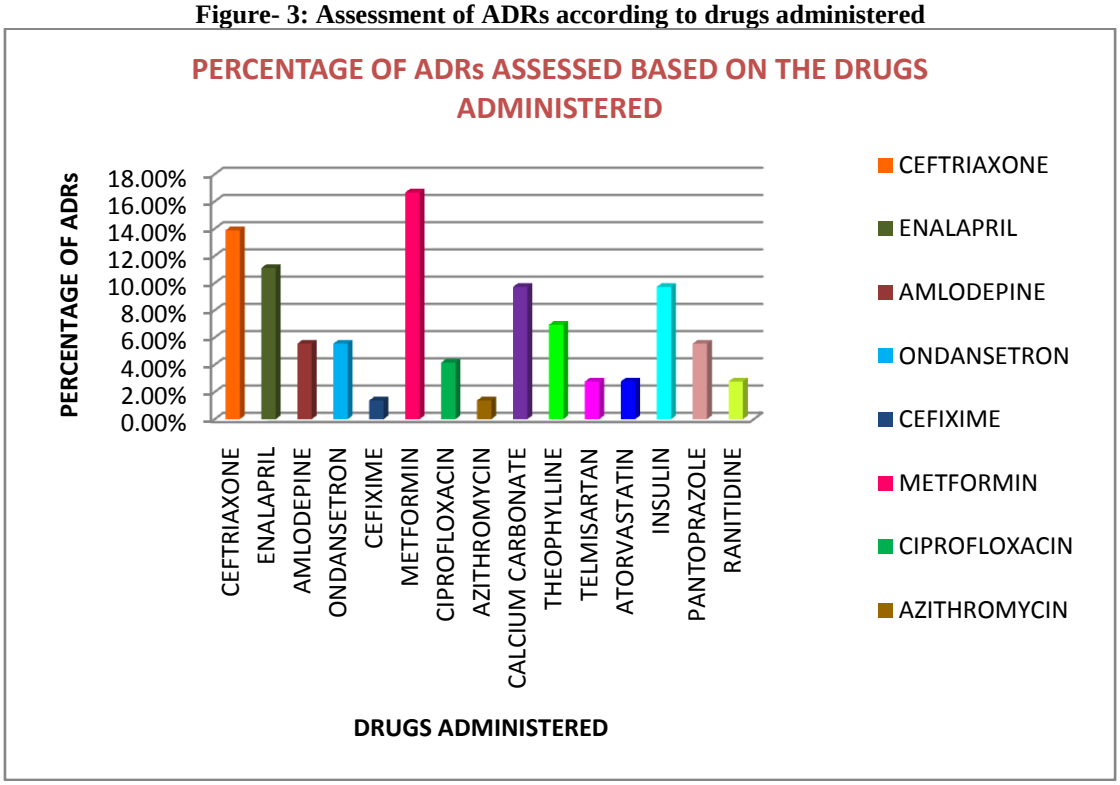
**Table- 3: Percentage of ADRs assessed based on the drugs administered to the patient**

| DRUGS | NUMBER OF ARDs | PERCENTAGE OF ADRs | SYSYTEM AFFECTED |
|---|---|---|---|
| MONOCEF | 10 | 13.88% | GI |
| ENAM | 8 | 11.11% | RESPIRATORY |
| AMLODEPINE | 4 | 5.55% | CNS |
| ONDANSETRON | 4 | 5.55% | CNS |
| CEFIXIME | 1 | 1.38% | GI |
| METFORMIN | 12 | 16.66% | ENDOCRINE SYSTEM |
| CIPROFLOXACIN | 3 | 4.16% | GI |
| AZITHROMYCIN | 1 | 1.38% | GI |
| CALCIUM CARBONATE | 7 | 9.72% | GI |
| THEOPHYLLINE | 5 | 6.94% | GI |
| TELMISARTAN | 2 | 2.77% | CNS |
| ATORVAS | 2 | 2.77% | MUSCULOSKELETAL SYSTEM, GI |
| INSULIN | 7 | 9.72% | ENDOCRINE SYSTEM |
| PANTOPRAZOLE | 4 | 5.55% | GI |
| RANITIDINE | 2 | 2.77% | GI , CNS |

**Table- 4: Percentage of ADRs observed based on the drugs administered to the patients**

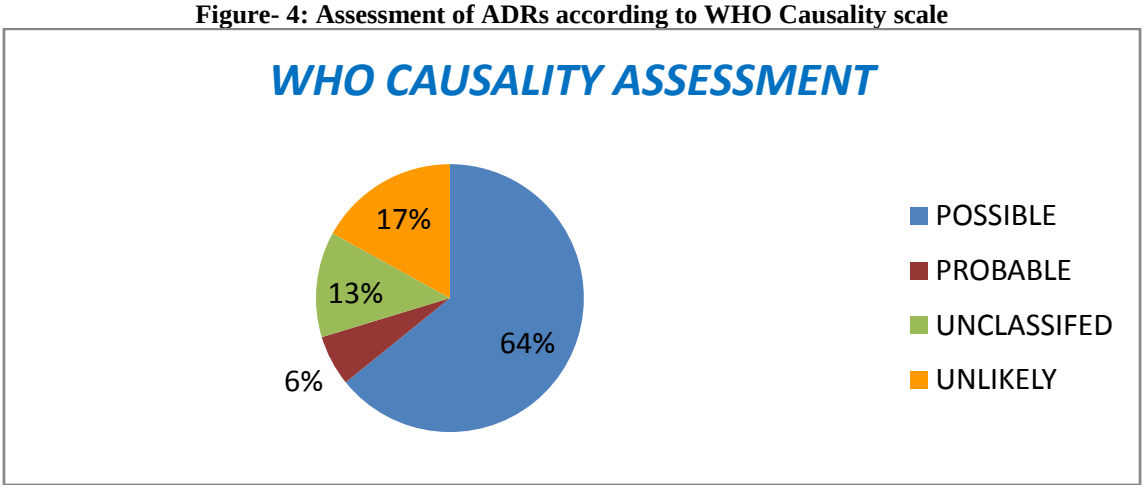
| DRUGS | PERCENTAGE OF ADRs | NUMBER OF ARDs | SYSYTEM AFFECTED | ADRs |
|---|---|---|---|---|
| CEFTRIAXONE | 13.88% | 10 | GI | DIARRHOEA |
| ENALAPRIL | 11.11% | 8 | RESPIRATORY | COUGH |
| AMLODEPINE | 5.55% | 4 | CNS | HEADACHE , DIZZINESS |
| ONDANSETRON | 5.55% | 4 | CNS | HEADAHE |
| CEFIXIME | 1.38% | 1 | GI | DIARRHOEA |
| METFORMIN | 16.66% | 12 | ENDOCRINE SYSTEM | HYPOGLYCEMIA , VERTIGO |
| CIPROFLOXACIN | 4.16% | 3 | GI | LOOSE MOTION |
| AZITHROMYCIN | 1.38% | 1 | GI | VOMITING |
| CALCIUM CARBONATE | 9.72% | 7 | GI | CONSTIPATION |
| THEOPHYLLINE | 6.94% | 5 | GI | VOMITING |
| TELMISARTAN | 2.77% | 2 | CNS | DIZZINESS |
| ATORVASTATIN | 2.77% | 2 | CNS , GI | MYALGIA, DYSPEPSIA |
| INSULIN | 9.72% | 7 | ENDOCRINE SYSTEM | HYPOGLYCEMIA |
| PANTOPRAZOLE | 5.55% | 4 | GI | ABDOMINAL PAIN |
| RANITIDINE | 2.77% | 2 | GI , CNS | HEADACHE , ABDOMINAL PAIN |

**Figure- 3: Assessment of ADRs according to drugs administered**




ADRs classified based on the medicine administered to the patients, out of 72 ADRs , mostly observed ADR were hypoglycemia on the administration of Metformin 12 (16.66%) and Insulin 7(9.72%) .

**Figure- 4: Assessment of ADRs according to WHO Causality scale**



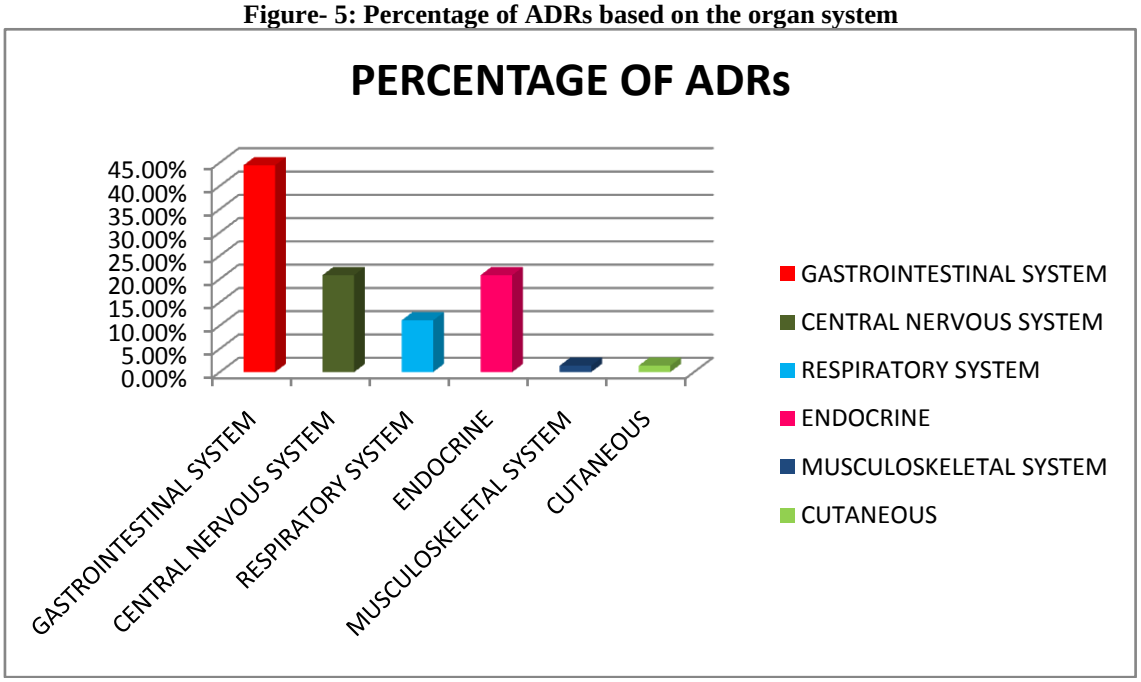

Causality assessment of ADRs was done by using WHO Causality Assessment scale out of 72 ADRs , 64% ADRs were classified as possible , 6% ADRs were classified as probable , 17% ADRs were classified as unlikely, 13% ADRs were classified as unclassified .

**Table- 5: Gender wise classification of ADRs**

| S.NO | GENDER | NO.OF ADRs | PERCENTAGE |
|---|---|---|---|
| 1. | FEMALES | 29 | 40.27 |
| 2. | MALES | 43 | 59.73 |

Percentage of ADRs are classified based on the gender of the patients out of 72 ADRs, 43 (59.73%) ADRs of males were more classified than females of ADRs 29 (40.27%).

**Figure- 5: Percentage of ADRs based on the organ system**




ADRs are classified on the basis of organ system out of 72 ADRs, the Gastrointestinal system ADRs were classified as 32 (44.44%), central nervous system ADRs were classified as 15(20.83%).

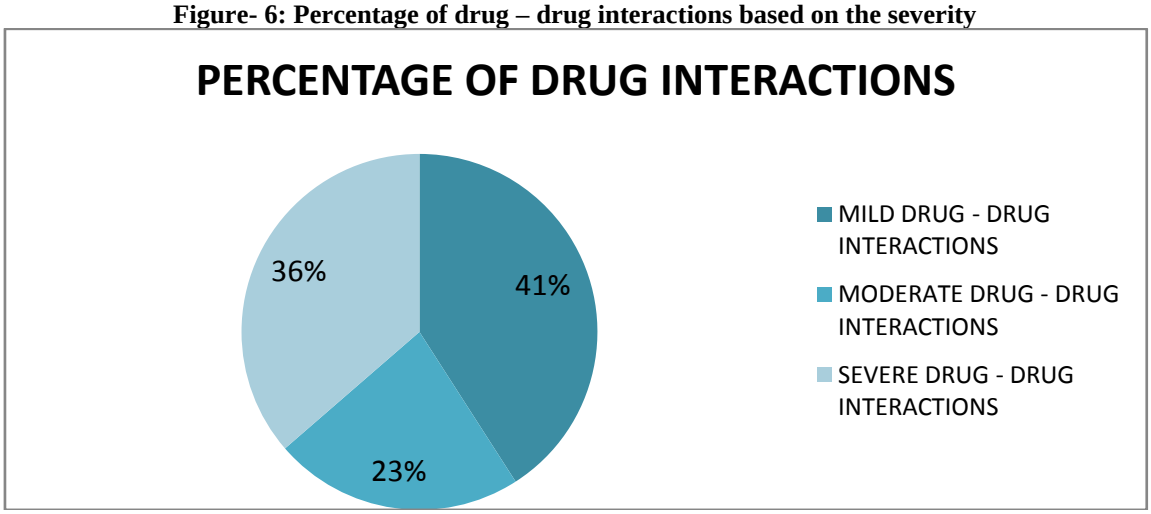
**Table- 6: Potential risk of drug-drug interactions in elderly patients prescribed with polypharmacy**

| Drug – Drug interactions | Number of patients in which DI occured | Number of patients receiving drugs | Potential risk |
|---|---|---|---|
| Ceftriaxone+calcium carbonate | 3 | 22 | Precepitation in kidneys |
| Aspirin+Furosemide | 9 | 31 | Risk of Hypokalemia |
| Chloroquine+Primaquine | 4 | 11 | Risk of haemolysis in G6pd deficient patients |
| Enalapril+Furosemide | 7 | 43 | Risk of hypotension |
| Hydrocartisone+Enoxaparin | 1 | 7 | Risk of haemmorage |
| Telmisartan+insulin aspart | 1 | 15 | Risk of hypoglycemia |
| Enoxaparin+Clopidogrel | 4 | 13 | Risk of haemorrhage |
| Ceftriaxone+Enoxaparin | 2 | 9 | Decrease prothrombin time |
| Glimepride+Ranitidine | 11 | 33 | Risk of hypoglycemia |
| Phenytoin+ paracetmol | 3 | 99 | Risk of hepatotoxicity |
| Apirin+atenolol | 3 | 26 | Increase blood pressure |
| Diclofenac sodium+Metaprolol | 5 | 20 | May increase Blood pressure |
| Insulin regular+Metformin | | | |
| Ceftriaxone+Furosemide | 15 | 41 | Risk of hypoglycemia |
| Dexamethasone+Furosemide | 9 | 25 | Increased risk of Nephrotoxicity |
| Cefixime+Furosemide | 1 | 19 | Risk of hypokalemia |
| Aetaminophen+Enoxaparin | 7 | 27 | Risk of nephrotoxicity |
| Hydrocartisone+Furosemide | 2 | 13 | Risk of haemmorage |
| Aspirin+diclofenac | 4 | 11 | Risk of hypokalemia |
| Ranitidine+Theophylline | 6 | 25 | Increase anticoagulation<br>Monitor Nausea,Vomtings,Seizures |
| Metaprolol+Furosemide | 10 | 54 | Risk of hypokalemia |
| Furosemide+Metformin | 4 | 23 | Risk of Hypoglycemia |
| | 11 | 27 | |

**Table- 7: Proportion of severity of potential drug –drug interactions out of total drugs prescribed in elderly patients among polypharmacy admitted in department of medicine**

| | Number of interactions | Percentage |
|---|---|---|
| Total number of Drug-drug interactions | 22 | |
| Mild Drug-drug interactions | 9 | 40.90% |
| Moderate Drug-drug interactions | 5 | 22.72% |
| Severe Drug-drug interactions | 8 | 36.36% |

**Figure- 6: Percentage of drug – drug interactions based on the severity**




Based on severity of DIs 122 DIs are assessed, but the total number of DIs observed in the patients were 22. Out of 22 drug interactions, 9 (40.90%) DIs were assessed as mild drug interaction, 5 (22.72%) DIs were assessed as moderate drug interaction, 7 (36.36%) DIs were assessed as severe drug interactions as shown in figure.

**Table- 4.8: Mean and standard deviation according to age**

| Age | Number of subjects | Mean ±SD | P Value |
|---|---|---|---|
| 60-70years | 88 | 56.21 ± 2.059 | <0.0001 |
| 70-80years | 104 | 64.44 ± 2.565 | 0.0001 |
| 80-90years | 63 | 74.01 ± 2.915 | 0.0001 |
| >90years | 32 | 82.75 ± 3.253 | <0.0001 |

**Table 4.9: Mean and Standard deviation of developing ADRs**

| | Number of patients developing ADRs | Mean± Standard deviation | P Value |
|---|---|---|---|
| Adverse Drug Reaction | 72 | 0.2508±1.048 | <0.0001 |

**Table 4.10: Mean and Standard deviation of Drug-Drug Interactions**

| | Number of drug interactions | Mean ± Standard deviation | P Value |
|---|---|---|---|
| Total number of Drug-drug interactions | 22 | | |
| Mild drug-drug interactions | 09 | 0.4090±0.8541 | <0.0001 |
| Moderate drug-drug interactions | 05 | 0.22±0.7561 | <0.0001 |
| Severe drug-drug interactions | 08 | 0.36±1.177 | <0.0001 |

Mean and standard deviation of mild drug –drug interactions were 0.4090 ± 0.8541,Moderate Drug –drug interactions were 0.22 ± 0.7561, Severe Drug-drug interactions were 0.36±1.177.

## IV. Discussion

Several studies showed that Assessment of Adverse drug reactions and Drug - drug interactions in polypharmacy among Geriatrics. Most of them are cross sectional and observational studies which are conducted among polypharmacy geriatric patients. There are few studies that educate about Adverse drug reactions and drug interactions which shows significant improvement in minimizing the ADRs and drug interactions[14].

In the present study baseline characteristics shows that males are more affected than females to develop ADRs and drug interactions. In this study population most of the subjects are belongs to 60-70 years, which indicates aging is a major risk factor for the development of ADRs and drug interactions[15].

Polypharmacy is a unbiquitos problem plaguing nearly health care system. Here we investigated not only ADRs, but also DRPs during hospitalization among patients receiving polypharmacy. Elderly patients are the largest consumers of medication. As the Older People are more likely to receive numerous medications[16] .

The present study was conducted to asses and evaluate the ADRs and DIs at a tertiary care hospital in Anantapur, India. The study was conducted and randomly selected in medical units. Most of the patients in the study belong to the age group of 60-70 years (36.23%). The major occurrence of ADRs according to system was Gastrointestinal system (44.4%),Centralnervoussystem(22.2%),Respiratorysystem(11.11%),Endocrine(23.83%) and cutaneous system(1.38%). In this gastro intestinal system are more affected. Incidence CNS Symptoms was found to be (22.2%). Musculo-skeletal ADRs (2.77%) ie., myalagia was associated with Atorvastatin. This values are similar in the study Dinesh Zaver bhai Kamejaliya etal[15].

In our study out of 287 patients, 72 patients developed ADRs .Gender wise distribution of ADRs in males were 43 (59.72%) and Females are 29 (40.27%). Incidence of ADRs were more males when compare to females.

Causality assessment was done by using WHO Scale which revealed that 64% of the reactions were categorized as "possible", 17% has" probable",13% as unclassified and 6% of the reactions were unlikely.

- In the present study Metformin and ceftriaxone causing ADRs in elderly patients with a percentage 16.66% and 13.8% respectively which was prescribed in 50 and 156 number of patients. These drugs affects the Gastrointestinal system and Endocrine system.

In our study Anti-ulcerative agents such as Pantaprazole and Ranitidine and Antibiotics Ceftriaxone and Cefixime are majorly prescribed. We found commonest group of drugs prescribed to admitted patients for Anti-ulcer drugs, Anti-Hypertensives,Anti-Diabetic and Cardiovascular drugs[17] . Polypharmacy is unavoidable as elderly patients usually suffer from many chronic diseases. As a general rule, Health care providers should minimize the number of medications prescribed for older adults.

Hypertension and diabetes were the most common co morbidities. Among the comorbidities diabetes are more common in elderly patients. There is a correlation between frequency of drug interaction and age, the number of medications and number of comorbidities. Patients with age 70 years had the high risk of having drug interactions. The insulin - metformin combination was the most commonly used to be avoided drug combinations results in risk of hypoglycemia. The contraindicated drug combination was ceftriaxone and calcium carbonate drugs and it was observed in three patients (2.45%). This drug interaction may result in precipitation in kidney[18].

The drugs most implicated were Non steroidal anti-inflammatory agents(NSAIDS including Aspirin, Diclofenac), ACE Inhibitor like Enalapril, Biguanides (Metformin), Sulphonylureas (Glimepride) which was similar to Yvonne Koh et al[16].

Enoxaparin with clopidogrel combination was the most frequently used to the elderly patients. It was observed in four patients (3.27%).A number of studies have identified these interactions responsible for the greatest number severe bleeding. However these combinations are sometimes unavoidable and might be indicated. Thus, carefull monitoring and evaluation of the risk of drug interactions and benefits of continuing both medication is important[18].

Out of 287 patients, In our study 22 Drug-drug interactions were identified. In these Mild Drug-drug interactions were 9(40.90%), Moderate Drug-drug interactions were 5(22.72%) and Severe Drug-drug interactions were 7(31.81%)[18].

## V. Conclusion

The use of medicines in a disease condition is necessary, but unnecessary load of drugs to patient will increase the safety problems. Increasing age and polypharmacy were identified as the predictors of ADRs and Drug-drug interactions. Adverse drug reactions are commonly seen in elderly patients, usually within first week of Hospitalization. Among them Geriatrics males were more affected. Anti-diabetic drugs and Antibiotics is the major cause for Adverse drug reactions in geriatrics. The drugs most implicated in Drug interaction were Non steroidal anti-inflammatory agents(NSAIDS including Aspirin, Diclofenac), ACE Inhibitor like Enalapril, Biguanides (Metformin), Sulphonylureas (Glimepride).The clinical pharmacist must remain attention in identifying, monitoring and prevention of ADRs and Drug-drug interactions and making appropriate dosage or therapy adjustments.

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