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POLYPHARMACY AND POTENTIAL DRUG – DRUG INTERACTIONS IN ELDERLY PATIENTS OF RURAL POPULATION ATTENDING GENERAL MEDICINE DEPARTMENT OF A TERTIARY CARE TEACHING HOSPITAL

Abhigna Ailla, Sirisha Goli* and Prasanna Vedula

Department of Pharmacology, RVM Institute of Medical Sciences and Research Centre, Siddipet - 502279, Telangana, India.

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Correspondence to Author:

Dr. Sirisha Goli

Associate Professor,
Department of Pharmacology,
RVM Institute of Medical Sciences
and Research Centre, Siddipet -
502279, Telangana, India.

E-mail: dr.sireesha.g@gmail.com

ABSTRACT: Aim and Objective: The present study was done to assess the prevalence of polypharmacy and to study its consequences in elderly people. **Methodology:** The study was prospective observational study, done in 500 elderly patients attending the Department of General Medicine in rural tertiary care teaching hospital in Telangana. The study was done for a period of 6 months from April 2019 to September 2019. Descriptive data was expressed in mean and percentages. Chi-square test was done to assess potential drug-drug interactions and number of medications received by the patients ($p < 0.05$ is considered significant). **Results:** Polypharmacy was present in 70.75% of elderly patients. The mean drugs prescribed for each patient was 5.7%. Severe potential drug-drug interactions were present in 16.82% patients. Potentially inappropriate medications were assessed using Beer's criteria and were present in 35.52% of patients. **Conclusion:** This study thus highlights the importance of reducing the practice of polypharmacy by the treating physician to reduce morbidity and to decrease economic burden on the elderly patients.

INTRODUCTION: The proportion of elderly population has been constantly increasing over the past few years. It has been increased from 20 million to 57 million^{1, 3} from 1951 – 1997 and has reached 104 million in 2011. Aging is a natural process and with increasing in age several social, physiological, pathological and behavioral changes occur. These changes may lead to various diseases in elderly people. Several medications are prescribed in order to treat these diseases. Polypharmacy is becoming unavoidable in elderly, as they often suffer from multiple comorbidities.

Polypharmacy is defined as, either the concomitant use of 5 or more drugs or administration of more medications in treating of multiple chronic diseases that are indicated clinically^{2, 4}. Polypharmacy is not necessarily ill-advised, but in many instances can lead to negative outcomes or poor treatment effectiveness, often being more harmful than helpful or presenting too much risk, for too little benefit. Hence it is required to monitor and review to validate whether all of the medications are still necessary.

Polypharmacy may lead to increased adverse drug reactions, drug-drug interactions, prescribing cascade and higher costs. It is often associated with decreased quality of life, including decreased mobility and cognition. There may also be duplication of drug prescription due to poor knowledge of patient and consulting more than one doctor.

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Drug-drug interaction (DDI) means that one drug alters the response of the other. Depending on the effect of DDI on patients, the DDI can be classified into beneficial, harmful or neutral. The mechanism of DDI includes inhibition or induction of drug-metabolizing enzyme, inhibition of drug transporters and competition on plasma albumin which can affect the pharmacokinetic parameters. Potential DDI can be minor, moderate or may even be major, having fatal consequences.

Prevalence of polypharmacy and its adverse consequences like increased incidence of adverse drug reactions and drug-drug interactions, with adequate sample population of elderly patients dwelling in rural areas, is less studied in developing countries like India.

This study is also important in the context of South Indian population, where there is increased incidence of chronic diseases like Diabetes Mellitus⁵ and hypertension, where tendency to take multiple medications is more. The study is being done in rural area, where people visit more than one physician and also take over the counter medications and Ayush medications.

The updated Beers Criteria for Potentially Inappropriate Medication Use in elderly (Beers List) developed in 2015, are guidelines to the physicians, which help them to improve the safety of prescribing medications for older adults. They emphasize on deprescribing medications that are unnecessary and this helps to reduce the problems of polypharmacy, drug interactions, and adverse drug reactions. Thereby the risk-benefit ratio of medications in at-risk people is improved.

Aim and Objectives: The aim of the study is to polypharmacy and potential drug – drug interactions in elderly patients of rural population attending General Medicine of Tertiary care hospital in Telangana.

Objectives:

1. To find out the prevalence of polypharmacy among the elderly patients.
2. To find out the prevalence and cause of potential drug – drug interactions among the elderly patients.

3. To find out potentially inappropriate medicines to be avoided in the elderly patients, according to Beer's criteria.

METHODOLOGY: The study was a prospective, observational study, done on patients attending Department of General Medicine in RVM Institute of Medical Sciences and Research Centre during June 2019 to September 2019. The study was started after taking permission from Institutional Ethics Committee. A total of around 500 elderly patients were taken as subjects, after taking written informed consent. The sample size for the given study has been calculated from the average number of elderly patients attending general medicine OP during last few months.

Elderly patients above 60 years age and of either gender, willing to give written informed consent were included in the study. Patients with malignancy and patients having incomplete prescriptions were excluded from the study. Data was collected and entered in Microsoft Office Excel 2016 and analysed using SPSS version 21.0.

Descriptive statistics was expressed using proportion and percentages and mean±SD. Chi-square (χ^2) test was used between different categorical variables including polypharmacy and drug interactions. Statistical significance was considered at p-value <0.05.

RESULTS: The present study was taken up to study polypharmacy in the elderly population in a tertiary care teaching hospital. A total of 335 cases were included, which satisfied the eligibility criteria. Though required sample size was 500 cases, only 335 cases because of short duration and less patient inflow during this period. Polypharmacy was noted in 237 cases. Prevalence of polypharmacy was 70.75%. Majority of cases were of the age group 60-65 years **Table 1**.

TABLE 1: TABLE SHOWS AGE WISE DISTRIBUTION OF CASES

Age group	Number of cases
60-65	207
66-70	71
71-75	23
>75	24

In the present study, polypharmacy was more prevalent **Table 2** among male cases (61.79%) as

compared to female cases (38.2%). 62.69% of cases (total number= 210 cases) had 5-9 drugs per prescription **Table 3**. In this study, number of drugs per prescription ranged from 2-13.

TABLE 2: TABLE SHOWS GENDER WISE DISTRIBUTION OF TOTAL CASES

No of cases	Outpatient (93 cases)	In patient (242 cases)	Total number (%)
Males	75	132	61.79%
Females	18	110	38.2%

TABLE 3: TABLE SHOWS NUMBER OF CASES ACCORDING TO THE TOTAL NUMBER OF DRUGS PER PRESCRIPTION

	Outpatient cases	In patient cases	Total cases
≤ 4 drugs	23	75	98
5-9 drugs	67	143	210
> 9 drugs	3	24	27

TABLE 4: TABLE SHOWS PERCENTAGE OF CASES WITH POLYPHARMACY

No of drugs	Percentage (%)
5-9 drugs (polypharmacy)	62.69%
≥ 10 drugs (hyperpolypharmacy)	8%

TABLE 5: TABLE SHOWS MEAN NUMBER OF DRUGS PER PRESCRIPTION

Mean no of drugs	Males	Females	Total mean±SD
In patient cases	5.76 ±2.16	5.75±1.78	5.75±2.15
Outpatient cases	5.64±2.15	5.66±1.80	5.65±1.80

Chi square test was applied to study the number of drugs in polypharmacy and incidence of potential drug interactions. The level of significance (p value) was ≤ 0.05. p value obtained after applying chi square statistics was highly significant (0.001).

It implies that there was proportionate increase in drug drug interactions with increase in the number of drugs. Moderate drug drug interactions were more common, as compared to minor and severe

drug interactions **Table 6**. A total of 32 drug duplications (13.5%) were observed in this study.

TABLE 6: TABLE SHOWS NO OF DRUGS AND NO OF CASES WITH POTENTIAL DDI

	DDI	No DDI	Total
≤4 drugs	10	88	98
≥ 5 drugs	177	60	237
Total	187	148	Grand total- 335

TABLE 7: TABLE SHOWS NUMBER OF POTENTIAL DRUG INTERACTIONS ACCORDING TO THEIR SEVERITY

Severity of drug interactions	Number of such interactions
Mild	36
Moderate	236
Severe	55

Pharmacodynamic drug interactions were more common compared to pharmacokinetic interactions. The interaction between ondansetron and tramadol, which could result in risk of serotonin syndrome was the most common drug interaction **Table 8**.

TABLE 8: TABLE SHOWS SOME OF THE MAJOR CLASSES OF DRUGS WITH THERAPEUTIC DUPLICATION

S. no.	Classes of drugs with therapeutic duplication	Drugs with therapeutic duplication
1	Analgesics	Aceclofenac- Tramadol+ Paracetamol
2	Penicillins	Piperacillin- Amoxicillin
4	CVS agents causing additional hypotension	Ramipril+ Nicorandil+ Furosemide

In the present study, potentially inappropriate medications (PIM) prescribed to the elderly patients were studied according to the modified Beer's criteria and were listed **Table 9**. These are the list of medications which are to be avoided in

the elderly or used only if benefits outweigh the risks that are involved. Potentially inappropriate medications were present in 35.52% of cases.

TABLE 9: TABLE SHOWS A FEW MAJOR DDIS AND THEIR ANTICIPATED CONSEQUENCES

Major drug drug interactions	Anticipated consequences
Ondansetron- Tramadol- Linezolid	Risk of serotonin syndrome
Clarithromycin- Atorvastatin	Risk of rhabdomyolysis due to increased levels of Atorvastatin
Ofloxacin- Tramadol	Increased risk of seizures

Enoxaparin- Clopidogrel	Increased risk of bleeding
Alprazolam- Tramadol	Additional CNS depression leading to respiratory distress, coma and death
Ciprofloxacin- Insulin	Severe hypoglycemia
Methotrexate- Pantoprazole	Increased blood levels of Methotrexate

TABLE 10: TABLE SHOWS SOME OF THE POTENTIALLY INAPPROPRIATE MEDICATIONS (PIM) IN ELDERLY ACCORDING TO BEER'S CRITERIA

S. no.	Potentially inappropriate medications	No of cases
1	Ketorolac	1
2	Buscopan	4
3	Diclofenac	14
4	Insulin	15
5	Ibuprofen	5
6	Clonazepam	4
7	Alprazolam	3
8	Nitrofurantoin	1
9	Metoclopramide	1
10	Pantoprazole	18
11	Chlorpheniramine	3

Drugs acting on gastrointestinal system were the most commonly prescribed drugs, with ranitidine seen in most of the prescriptions. Antibiotics and NSAIDs were also commonly prescribed.

TABLE 11: TABLE SHOWS NUMBER OF DRUGS OF EACH MAJOR DRUG CLASS WITH POLYPHARMACY

S. no.	Therapeutic class	No of drugs
1	Antibiotics	289
2	Non steroidal anti inflammatory drugs	142
3	Hypoglycaemic drugs	59
4	Drugs acting on gastrointestinal system	349
5	Drugs acting on respiratory system	111
6	Drugs acting on Central nervous system	27
7	Drugs acting on Cardiovascular system	121
8	Analgesics	78
9	Drugs acting on blood	79
10	Multivitamins/ miscellaneous drugs	245

DISCUSSION: The present study was done to study polypharmacy and its consequences in elderly population attending the Department of General Medicine in rural tertiary care hospital in Telangana. In this study, majority of patients admitted were of age group 61-65 years of age. Polypharmacy in this study was more common in male patients (61.79%) compared to female patients (38.2%). Similar findings were seen in the study done by Tamilselvan *et al*, in which 59% males and 41% females showed polypharmacy⁶. The prevalence of polypharmacy was found to be

70.75%. This prevalence rate is similar to the study done by Salwe *et al*⁷, according to which 80% of the admitted cases and 60% of the discharged cases had polypharmacy. The mean number of drugs prescribed to the patients was 5.7 (range from 2 to 13 drugs). Hyperpolypharmacy with intake of ≥ 10 medications was seen in 8% of the patients. A number of co. morbidities in this age group and self-medication for relieving symptoms are the patient related factors responsible for polypharmacy in this age group. Drug-drug interactions and drug duplications are important consequences of polypharmacy. In this study, it was seen that there is proportionate increase in number of drug drug interactions with increase in the number of drugs prescribed to the patients. This finding is similar to the study done by Akshay Khandeparkar⁸ in hospitalized patients in Goa Medical College. A total of 32 drug duplications (13.5%) were observed in this study, with majority of the drugs belonging to the classes of analgesics, penicillins with β lactamase inhibitors and drugs which modify coagulation.

The potential drug-drug interactions (DDIs) were divided according to their severity. Majority of cases (72.17%) had moderate DDIs. 16.82% of cases had severe DDIs and 11% of cases had minor DDIs. These findings were similar to the study done by Varsha Shetty *et al*⁹, in which major DDIs were seen in 21.42% of cases. The interaction between Ondansetron and Tramadol which can result in serotonin syndrome, is the most common major potential drug- drug interaction seen. Potentially inappropriate medications according to Beer's criteria were present in 35.52% of cases. Proton pump inhibitors like Pantoprazole which was commonly prescribed in many cases, needs to be avoided in the elderly, because it increases incidence of *Clostridial difficile* infection. It also increases bone loss causing greater risk of fractures in elderly¹⁰. Anticholinergics, first generation antihistamines and Benzodiazepines have to be avoided in the elderly, as there is risk of cognitive decline and can cause fall in elderly patients. Insulin is to be avoided as there is increased risk of

hypoglycemia. This does not apply to titration of basal insulin or use of additional short- or rapid-acting insulin in conjunction with scheduled-insulin. Interventions to reduce polypharmacy must address several issues such as appropriate medication usage in elderly, which include using the drug for the appropriate indication, avoiding drug-drug duplication in the same class of therapeutics, inappropriate and complex dosing, drug-drug interaction, drug disease interaction and drug food interaction. There should be proper coordination between primary care provider and specialists. Use of drug holidays, and education of patients regarding the adverse drug effects and other issues related to compliance should be addressed. The pharmacist should also not give refills of drugs without any prescription.

This study helps to create awareness among clinicians and medical students regarding the various drug interactions due to polypharmacy among elderly patients. The study also helps to create awareness among doctors, that elderly patients visit more than one doctor and take OTC drugs and drugs of alternative medicines like AYUSH apart from their prescribed drugs. So, healthcare providers should take proper drug history, keep the dosing schedule as simple as possible, and limit the frequent number of medication changes. Regular medication review and timely interventions in prescriptions are essential in clinical practice to address the increasing challenges involving prescriptions to older patients^{11, 12}.

Educational interventions can be conducted in different ways, including educational sessions for health professionals aiming to reduce drug use; distribution of educational materials; training to expand the knowledge and skills of patients, caregivers, and health professionals; educational programs for prescribers or consumers; and patient education to optimize polypharmacy. This study

will not only reduce the economic burden on patients but also to improvise health care to elderly patients.

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