



## Prescription Analysis And Prevalence Of Potentially Inappropriate Medication Use In Older Adults; An Observational Study

Dr. N. Senthil Kumar<sup>1</sup> Ms. Geena. K. Reji<sup>2</sup> Ms. Reema. K. A<sup>3</sup> Mr. Vijayarangan. S<sup>4</sup> Ms. Ramya. A<sup>5</sup>

JKKMRF'S Annai JKK Sampoorani Ammal College Of Pharmacy, Ethirnedu, B. Komarapalayam – 638183, Namakkal Dt, Tamilnadu<sup>1,2,3,4,5</sup>

### ABSTRACT

**Objectives:** The objectives of the present study were to determine prevalence of potentially inappropriate medications and Adverse Drug Reactions in older adults and to collect doctors' responses regarding the PIM list or any other criteria to treat older adults in India.

**Method:** This was an observational study conducted in different tertiary care hospitals of two districts, Erode and Salem after obtaining approval of the Institutional Ethics Committee. A sample of 250 older adults (60 years and above) and 97 doctors were included during the study period of 6 months from February 2019 to July 2019. Inappropriate medications were identified by using 2019 updated Beer's criteria. The causality of the adverse events was assessed by Naranjo Adverse Drug Reaction Probability Scale.

**Results:** Out of the 250 prescriptions, only 86(34.4%) of the prescriptions were appropriate and 164(65.6%) were inappropriate. The most commonly inappropriate prescribed medications were diuretics, ranitidine and tramadol. A total of 74 ADRs was observed in 74 patients. Of these, 57(22.8%) ADRs were due to inappropriate medications listed in Beers criteria. There was a significant association between the occurrence of ADRs and the use of PIMs listed in 2019 updated Beer's criteria [ $\chi^2 = 6.08, P = 0.013 (df = 1)$ ].

**Conclusion:** The study shows that there is a high prevalence of inappropriate medications and adverse drug reactions in the hospitalized older adults. Beer's criteria can be used as a guideline by the physicians while prescribing the drugs to the geriatric population.

**Keywords:** Elderly patients, Older adults, Potentially Inappropriate Medications, Adverse Drug Reactions, Beer's criteria.

#### \*Corresponding Author

**Geena. K. Reji**

The Tamilnadu Dr. M. G. R. Medical University,  
Chennai



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### INTRODUCTION

Most developed countries have accepted the chronological age of 65 years as a definition of 'elderly' or 'older person' [1]. In January, 1999 the Government of India adopted 'National Policy on Older Persons' and this policy defines 'senior citizen' or 'elderly' as a person who is of age 60 years or above. The population ageing, started in the last century with developing countries, is now encircling developing countries too due to various reasons including better healthcare systems. Nearly, there are 104 million aged persons (aged 60 years or above) in India; 53 million females and 51 million males, consistent with the population census 2011. From 5.6% in 1961, the proportion has increased to 8.6% in 2011 [2]. The medications in which risks outweigh benefits are defined as Potentially Inappropriate Medications (PIMs). Inappropriate prescribing in the elderly population is a major public health issue, given its direct linkage to substantial morbidity, mortality and wastage of health resources that result from adverse drug reactions [3]. Appropriateness in healthcare has been defined as "the outcomes of a process of decision making that maximizes net health gains within society's available resources". Appropriate prescribing also associated with a reduction of over-use, under-use and misuse of treatment [4].

Prescribing quality for elderly patients can be improved by reducing irrational and inappropriate prescribing, thereby resulting in the better health care. Therefore, assessment tools for appropriateness of elderly pharmacotherapy are the essential fundamentals in defining whether an improvement in prescribing is needed. Different screening tools prepared for the assessment of appropriateness of prescription and some of them are being used for assessment of appropriateness of prescription [3]. The Beer's criteria firstly published in 1991, to determine potentially inappropriate prescribing in elderly nursing home residents [5]. The 2019 American Geriatric Society (AGS) Beer's criteria update contributes to the

critically important evidence base and discussion of medications to avoid in older adults and the need to improve medication use in older adults. It includes 30 individual criteria of medications or medication classes to be avoided in older adults and 16 criteria specific to more than 40 medications or medication classes that should be used with caution or avoided in certain diseases or conditions. The 2019 AGS Beer's criteria is the third such update by the AGS and the fifth update of the AGS Beer's criteria since their original release [6].

## METHODOLOGY

### Study design and Ethical considerations

This was an observational Study conducted in the inpatient departments of different tertiary care hospitals of two districts, Erode and Salem after obtaining approval of the Institutional Ethics Committee (REF NO: EC/PHARM D/ 2019 – 01).

### Sample size

In this study 250 patients were enrolled, also 97 doctor's responses regarding the PIM list.

### Study duration

This study was conducted for a period of 6 months from February 2019 to July 2019.

### Data collection

Patients who met the inclusion criteria were enrolled in the study. All information relevant to the study was collected from case records. The demographic characters, co-morbid conditions, drug dose, frequency, adverse drug reactions were documented in the pro forma. Responses from doctors are collected in a self-prepared questionnaire. Doctors of all departments were also included in the study.

### Inclusion Criteria:

Patients with 60 years or above and all inpatients were included irrespective of their disease conditions, doctors of all departments were included.

### Exclusion Criteria:

Patients below 60 years and outpatients, doctors who are not willing to participate in the study and gynecology, pediatrics department were excluded.

### Data analysis and interpretations

The study subjects were described in respect of their demographic profiles according to their age and gender. The continuous variables were described in terms of mean with standard deviation. The categorical variables were described in terms of percentages. In respect of categorical variables, the  $\chi^2$  (Chi-square) test was taken into account. The P-values less than or equal to 0.05 ( $P \leq 0.05$ ) were fixed as the level of significance.

## RESULTS

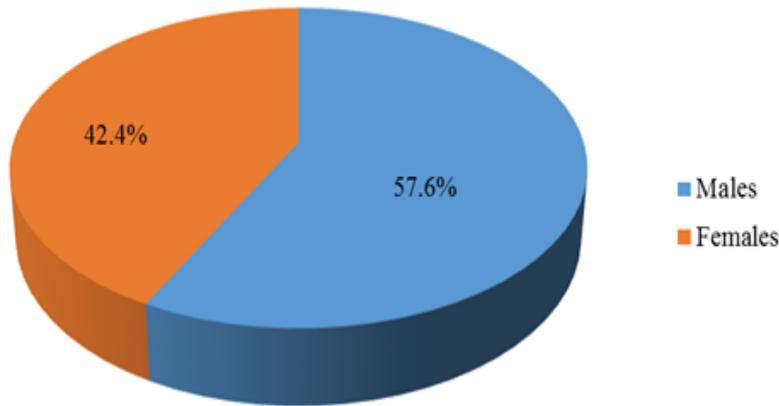
A total of 250 hospitalized older adults was studied. The mean age of the study population was  $71.6 \pm 7.0$  years (Table 1). The study population comprised of males 144 (57.6%) and females 106 (42.4%) (Fig. 1). A total of 690 diseases was diagnosed in 250 studied subjects, of which 73 (29.2%) patients was diagnosed with three diseases/co-morbidities followed by 63 (25.2%) with four or more, 58 (23.2%) patients with two and 56 (22.4%) with one disease/co-morbidities. The five most frequent diseases diagnosed were Hypertension 121(17.53%), followed by Diabetes Mellitus 120 (17.39%), Coronary Artery Disease 26 (3.76%), Chronic kidney disease 23 (3.33%) and COPD 18 (2.60%) (Table 2).

**Table 1: Age wise distribution**

S. NO	AGE GROUP (YEARS)	FREQUENCY (N=250)	PERCENTAGE (%)	MEAN $\pm$ SD
1	60-69	80	32.0	63.4 $\pm$ 2.5
2	70-79	141	56.4	73.4 $\pm$ 2.9
3	80-89	26	10.4	82.4 $\pm$ 2.2

4	≥90	3	1.2	93.3±2.9
	Total	250	100.0	71.6±7.0

**Fig. 1: Gender wise distribution**



**Table 2: Most common diagnosis**

S. NO	DIAGNOSIS	FREQUENCY	PERCENTAGE (%)
1.	Hypertension	121	17.53
2.	Diabetes Mellitus	120	17.39
3.	Coronary Artery Disease	26	3.76
4.	Chronic Kidney Disease	23	3.33
5.	COPD	18	2.60

A total of 2500 drugs was prescribed in 250 prescriptions with a maximum of 5-9 drugs 109 (43.6%), followed by 10-14 drugs 85 (34%), 15-20 drugs 38 (15.2%), 1-4 drugs 15 (6%) and 20 or more drugs 3 (1.2%). Out of the 2500 prescribed drugs, 297 (11.88%) PIM drugs were identified (Table 3). The most commonly identified PIM drug were Diuretics 48 (16.16%) and Ranitidine 42 (14.14%), followed by Tramadol 23 (7.74%), Spironolactone 21 (7.07%), Digoxin 17 (5.72%), Glimepiride 16 (5.38%), Diclofenac and Alprazolam 15 (5.05%), Enoxaparin and Levetiracetam 12 (4.04%), and the remaining drugs were occurred as single digits. Out of the 250 prescriptions, only 86 (34.4%) of the prescriptions were appropriate and 164 (65.6%) were inappropriate.

**Table 3: Percentage distribution of PIM drugs**

POTENTIALLY INAPPROPRIATE MEDICATION (PIM) USE ACCORDING TO 2019 UPDATED BEER'S CRITERIA		
ORGAN SYSTEM, THERAPEUTIC CATEGORY	DRUGS	INSTANCES, N =297
<b>PIMS ACCORDING TO ORGAN SYSTEM AND THERAPEUTIC CATEGORY</b>		

<b>Anticholinergics</b>	Chlorpheniramine	3(1.01)
	Promethazine	2(0.67)
	Hydroxyzine	1(0.33)
	Meclizine	3(1.01)
<b>Anti-parkinsonian agents</b>	Trihexyphenidyl	1(0.33)
<b>Antispasmodic</b>	Dicyclomine	1(0.33)
<b>Anti-infective</b>	Nitrofurantoin	1(0.33)
<b>Cardiovascular</b>	Prazosin	6(2.02)
<b>Central alpha angonists</b>	Digoxin	17(5.72)
	Nifedipine	4(1.34)
	Clonidine	2(0.67)
	Amiodarone	6(2.02)
<b>Central Nervous System</b>	Amitriptyline	3(1.01)
<b>Antipsychotics</b>	Phenobarbital	1(0.33)
<b>Benzodiazepines</b>	Lorazepam	6(2.02)
	Alprazolam	15(5.05)
	Clonazepam	6(2.02)
<b>Nonbenzodiazepine, benzodiazepine receptor agonist</b>	Zolpidem	1(0.33)
	Zaleplon	1(0.33)
<b>Endocrine</b>	Insulin, sliding scale	8(2.69)
	Glimepiride	16(5.38)
	Glibenclamide	5(1.68)
<b>Pain medications</b>	Diclofenac	15(5.05)
	Ibuprofen	1(0.33)
	Ketorolac	6(2.02)
<b>DRUGS TO BE USED WITH CAUTION IN OLDER ADULTS</b>		
	Tramadol	23(7.74)
	Carbamazepine	1(0.33)
	Dabigatran	2(0.67)
	Diuretics	48(16.16)
<b>PIMS DUE TO VARYING LEVEL OF KIDNEY FUNCTION</b>		
<b>Anti-infective</b>	Ciprofloxacin	1(0.33)
<b>Cardiovascular or hemostasis</b>	Enoxaparin	12(4.04)
	Spironolactone	21(7.07)
<b>Central nervous system and analgesics</b>	Pregabalin	4(1.34)
	Levetiracetam	12(4.04)
<b>Gastrointestinal</b>	Ranitidine	42(14.14)

Out of 2500 drugs prescribed, 77 drugs (3.08%) were causing ADR. The most common ADR drugs were observed under anti-diabetic drugs 18(23.37%), followed by Cardiovascular drugs 14 (18.18%), drugs acting on Central nervous system and analgesics 9 (11.68%), Gastrointestinal drugs 8 (10.38%), Antimicrobial drugs 5 (6.49%), Anti-cancer drugs and others 4 (5.19%), Respiratory drugs 3 (3.89%), Anti-hyperlipidemic drugs 2 (2.59%) and Anti-tubercular drugs 1

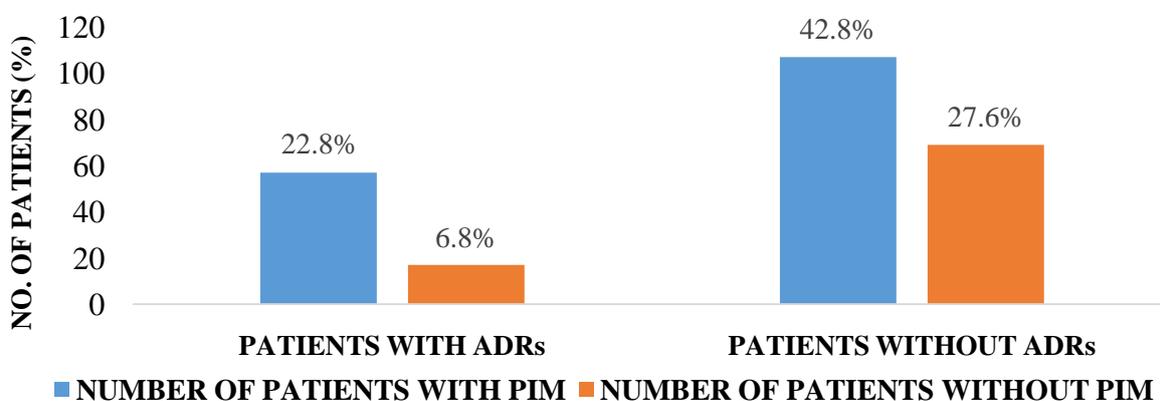
(1.29%). The most common organ system involved was Gastrointestinal 29 (39.18%), followed by endocrine 14 (18.91%), others 10 (13.51%), cardiovascular 9 (12.16), Central nervous system 8 (10.81%) and dermatology 4 (5.40%) (Table 4).

**Table 4: Percentage distribution of ADR pattern among study subjects**

S. NO	ORGAN SYSTEM INVOLVED	FREQUENCY	PERCENTAGE (%)
1	Gastrointestinal	29	39.18
2	Endocrine	14	18.91
3	Cardiovascular	9	12.16
4	Central nervous system	8	10.81
5	Dermatologic	4	5.40
6	Others	10	13.51

A total of 74 ADRs was observed in 74 patients (29.6%). Of these, 57 (22.8%) ADRs were due to PIMs listed in Beers criteria and 17 (6.8%) ADRs were due to other drugs. Of the 176 (70.4%) patients not having any ADRs, 107 (42.8%) patients were receiving PIMs and 69 (27.6%) patients were not receiving any PIMs during their hospital stay (Fig. 2). There was a significant association between the occurrence of ADRs and the use of PIMs listed in 2019 updated Beer’s criteria [ $\chi^2 = 6.08$ ,  $P = 0.013$  ( $df = 1$ )]. The severity assessment of ADR was assessed using the Naranjo scale. Out of the 74 observed ADRs, 48.6% (36) were probable ADR and 54.1% (38) was possible ADR.

**Fig. 2: ADRs and use of PIMs among study subjects**



A total of 97 doctors’ responses regarding PIM criteria or any other guidelines available in India to treat older adults were collected. Only 8.2% (8) doctor’s responded that they are aware of criteria’s to treat older adult in India and 91.8% (89) of the doctors were not aware of any such criteria. Only 6.2 % (6) of the doctors informed that the PIM list or other guidelines were available and 93.8% (91) replied as not available. 95.9% (93) of doctor’s replied that there is a need of PIM criteria in India and 4.1% (4) replied that there is no need of such criteria. Among the doctors 98.9% (96) replied, the PIM will improve the clinical practice and only 1.1% (1) were replied negatively. Among the doctors 98.9%(96) had opined that the PIM list will reduce the chance of ADR and only 1.1%(1) opined negatively. The results were statistically very highly significant ( $P < 0.001$ ) (Table 5).

**Table 5: PIM list can reduce the chance of ADR and improve the treatment option**

RESPONSE	FREQUENCY	PERCENTAGE (%)	X <sup>2</sup>	SIGNIFICANCE
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<b>YES</b>	96	98.9		
<b>NO</b>	1	1.1	93.041 df=1	P<0.001
<b>TOTAL</b>	97	100.0		

## DISCUSSION

The fastest growing population in the 21st century is the people over 85 years of age depicting aging of the population[7].The aging population is accompanied by the increasing presence of diseases and so there is increased drug utilization by the older population. The elderly population is also vulnerable to the adverse drug events which often can be prevented by detecting risk factors.

Many primary care physicians possess a poor knowledge of potentially inappropriate medications and are unaware of prescribing guidelines and screening tools for PIM use such as Beers Criteria [8].

The current study included a total of 250 older patients (aged 60 years and above), of which the age group distribution between 70-79 years is constituted with 141 (56.4%), which is the highest percentage, whereas the study conducted by Senthilvel R *et al*.[9] reports that 84 (42%) of the patients belong to the age group of 65-69 years. The male patients (57.6%) were more prevalent than female patients. Similar gender prevalence was found in studies carried out in older inpatients by Rohit SR *et al* [10] (59.8%), Harugeri A *et al*[11](60.6%). While some studies by Jhaveri *et al*[12] (52.12%), Shah *et al*[13] (59.32%) showed a higher prevalence of female patients.

In this study, most of the patients were diagnosed to have three diseases/co-morbidities 73 (29.2%), while a prospective study by Vishwas HN *et al*[14] reported that most patients diagnosed to have two diseases (3.7%).In this study, Hypertension (17.53%), Diabetes Mellitus (17.39%), Coronary Artery Disease (3.76%), Chronic Kidney Disease (3.33%) and COPD (2.60%) were the most common diseases diagnosis. Studies conducted in medicine wards by Harugeri *et al* [11] also reported Hypertension (41.5%), Diabetes (34%) and COPD (18.5%) as the most frequent diagnoses in the study population. Polypharmacy is one of the risk factor for PIM use and adverse drug events. The present study shows that 43.6% patients were prescribed with 5 to 9 drugs. While a study conducted by Rohit SR *et al*[10] reported 54.4% patients were prescribed with 10 or more drugs.

The prevalence of PIM use among hospitalized older adults in the present study was found to be 65.6%, which is higher than that reported by Rohit SR *et al*[10] (32.14%), Harugeri *et al*[11] (23.5%) and Shah *et al*[13] (29.3%). The commonly used PIMs were diuretics (16.16%) and ranitidine (14.14%). While studies conducted by Rohit SR *et al*[10] reported the most commonly used PIMs as clonidine (19.6%), benzodiazepines (15.8%), insulin sliding scale (15.7%) and prazosin (9.8%). In our study, only 34.4% of the prescriptions were appropriate and 65.6% were inappropriate, whereas in a study conducted by Senthilvel *et al*[9], 64.5% prescriptions were appropriate and 35.5% were inappropriate.

In this study, the majority of the ADRs were caused by anti-diabetic drugs(23.37%) whereas in study conducted by Jayanthi *et al*[15] reports that the majority of ADRs were caused by Antimicrobials(22.5%). A total of 74 ADRs in 74(29.6%) patients were observed in the present study, which was higher than reported by Rohit SR *et al*[10] (26.7%). While a higher prevalence of ADRs was reported by Harugeri *et al*[11] (35.9%) among the elderly patients. The most common organ system involved was gastrointestinal 29(39.18%), whereas in a study conducted by Jayanthi *et al*[15] reported dermatological side effects 34.83% as the most common organ system affected.

The 57(22.8%) ADRs were due to medications listed in Beer's criteria due to PIM use. There was a significant association between the occurrence of ADRs and the use of PIMs listed in 2019 updated Beer's criteria [ $\chi^2 = 6.08$ , P = 0.013 (df = 1)]. While in study conducted by Rohit SR *et al*[10] and Harugeri *et al* [11] reported that the medications other than listed in Beer's criteria were more likely to be associated with ADRs.

Among 97 doctors, most of them responded that there are no specific criteria in India to treat older adults and there is a need of PIM criteria in India in order to improve the quality of life in older adults.

## CONCLUSION

The current study could assess the prescribing patterns of medicines in the geriatrics according to Beer's criteria 2019. The study report shows that the prevalence of PIM is increasing and PIM drugs are causing ADRs. The inappropriate medication use can be avoided by using the Beer's criteria 2019. Most of the doctors said that there are no PIM list or any other guidelines available to treat older adults in India and opined that introducing PIM list can improve the quality of life of older adults. Beer's criteria can be used as a guideline by the physicians while prescribing the drugs to the geriatric population.

## LIMITATIONS

- We planned to check the self-medication practices among the older adults, but the patients was uncorporate for that and didn't get any responses.
- We planned to take responses from 120 doctors, but it gets limited to 97; the major problem with the doctors was they were so busy with their works and some of them wereincorporative.

## ACKNOWLEDGEMENT

We heartily thank Dr. N. Senthil Kumar (Principal) and Ms. Ramya. A (Assistant Professor, Department of Pharmacy Practice), Annai JKK Sampoorani Ammal College of Pharmacy, Komarapalayam for providing their immense support throughout our study.

## AUTHORS CONTRIBUTIONS

All authors have contributed equally in this piece of work.

## CONFLICT OF INTEREST

The authors have no conflict of interest to disclose.

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