Original Article

Evaluation of Potentially Inappropriate Medication Use and Risk of Adverse Drug Reactions in Hospitalized Older Adults: An Observational Study in a Tertiary Care Hospital

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ABSTRACT

Background and Objectives: The older population are more vulnerable to inappropriate prescribing andrelated adverse events due altered physiology. The objectives of the present study were to determine the prevalence of potentially inappropriate medication use in hospitalized older adults and assess its relationship with adverse drug reactions.**Method:** This is a prospective, observational, study conducted in the medicine wards of Shri Mahant Indiresh Hospital, Dehradun, and Uttarakhand, India after obtaining approval of the Institutional Ethics Committee. A sample of 112 elderly patients (60 years and above) were included during the study period of 5 months. Inappropriate medications were identified by using 2015 updated Beers Criteria. Causality of the adverse events was assessed by Naranjo Adverse Drug Reaction Probability Scale. **Results:**It was found that at least one potentially inappropriate medication was received by 32.14% (36) patients. A total of 31 adverse drug reactions were observed in 30 patients. Of these, 13 (41.9%) were observed in 12 patients were due to inappropriate medications listed in 2015 updated Beers Criteria. No statistically significant association was found between adverse drug reactions and use of potentially inappropriate medications [$\chi^{2 = 1.16,}$ P = 0.281] [Odds ratio (OR): 1.61 {95% confidence interval (CI): 0.67:3.85} P = 0.283]. Clonidine, clonazepam and sliding scale use ofinsulin were found to be most common inappropriately prescribed medications. **Conclusion:**The study shows that there is high prevalence of potentially inappropriate prescribing and adverse drug reactions among the hospitalized older adults in medicine wards.

Key words: Elderly patients, Older adults, Beers criteria, Potentially inappropriate medications, Adverse drug reactions.

INTRODUCTION

Aging is a natural and complex phenomenon caused by accumulation of molecular damage over time. This damage leads to a gradual decrease in physiological reserves, an increased risk of many diseases and a general decline in the functional capacity of the individual.[1,2] The 1% rule estimates the rate of functional loss of organ system reserve capacity (i.e. ability to respond to physiologic challenges) at about 1% per year after age of 30 years.[3] These changes with age influence the decision making for the clinical management of elderly patients. Due to the anatomic and physiologic changes in older age, the pharmacokinetics and pharmacodynamics profile of drugs in the body are also affected. Thus, the human body require adjustment of drug selection and dosing for old age individuals.[4,5]

Although there are commonly used definitions of old age, there is no general agreement on the age at which a person becomes old. The United Nation has not adopted a standard criterion, but generally uses 60+ years to refer to the older population.[6] Most developed world countries have accepted the chronological age of 65 years as a definition of 'elderly' or older person.[3]

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Government of India adopted 'National Policy on Older Persons' in January 1999. The policy defines 'senior citizen' or 'elderly' as a person who is of age 60 years or above.[7]

India is an ageing nation and among the population over 60 years of age, 10% suffer from impaired physical mobility and 10% are hospitalized at any given time, both proportions rising with increasing age. In the population over 70 years of age, more than 50% suffer from one or more chronic conditions.[8]

Older people are likely to have multiple co-morbid conditions, so are more likely to be prescribed multiple medications simultaneously, which increase the risk of adverse drug events, drug-drug and drug-disease interactions.[9] Adverse drug reactions (ADRs) are common and often preventable in older individuals. Due to limited participation of older population in large randomized clinical trials, the age associated risks of drugs are difficult to ascertain.Therefore, the age associated safety data of drugs come from observational studies.[10,11]

Potentially inappropriate medications (PIM) are defined as medications in which risks outweigh benefits. Inappropriate prescribing in the elderly population is now considered as major public health issue, given its direct linkage to substantial morbidity, mortality and wastage of health resources that result from adverse drug reactions.[12] Studies using explicit drug-use review criteria have found that between 15% and 21% of community dwelling older adults take one or more medications that have a dose, duration, duplication, or drug-interaction problem.[13,14]

Various screening tools are available for the assessment of appropriateness of prescriptions of elderly patients; each of them is having its own advantages and disadvantages.[12] Studies show that since 2003, the most cited tool for assessment of PIM use in elderly is Beers Criteria.[15]The Beers criteria are based on expert consensus developed through an extensive literature review with a bibliography and questionnaire.[12] The Beers criteria firstly published in 1991, to determine potentially inappropriate prescribing in elderly nursing home residents. The criteria were updated and revised again validated by consensus technique in 1997 and 2003 and 2012.[16-19]

The more recent update to the 2012 criteria is the 2015 American Geriatrics Society Beers Criteria. The 2015 AGS Beers Criteria are applicable to all older adults with the exclusion of those in palliative and hospice care. The intentions of the criteria are to: improve medication selection; educate clinicians and patients; reduce adverse drug events; and serve as a tool for evaluating quality of care, cost and patterns of drug use of older adults.[20]

The objectives of the present study were to determine the prevalence of potentially inappropriate medication use, ADRs in hospitalized older adults using American Geriatric Society updated Beers criteria 2015and assess the relationship between the use of PIMs and ADRs.

MATERIALS AND METHODS

Study Design and Ethical Considerations

This was a prospective, observational, cross sectional study conducted in the inpatient departments (General medicine, Pulmonary and Nephrology) of Shri Mahant Indiresh Hospital, Dehradun, and Uttarakhand, India after obtaining approval of the Institutional Ethics Committee (IEC).

Sample Size

For 95% confidence interval and with 8% precision, assuming a prevalence of PIM use of 25%, a sample size of 112 was calculated to assess the prevalence of PIM use in hospitalized older adults in the medicine wards of Shri Mahant Indiresh Hospital, Dehradun.

Study Duration

The data from the medicine wards of the hospital were collected and analyzed from February 2017 to June 2017.

Study Population

All the inpatients of age 60 years and above and patients willing to participate in the study and signed the informed consent, from inpatient wards of General medicine, Pulmonary and Nephrology, were included in the study. Patients in casualty and ventilator were excluded from the study.

Procedures

A daily visit to the medicine wards was made and patients as per inclusion criteria were selected randomly for the study. The consent of study subjects was taken in an Informed Consent Form after providing them the full information about the study.The details of the therapy of hospitalized elderly patients were noted in a case record form and regular follow up was taken on daily basis until discharge of the patient.

The medications in the prescriptions, their dosage regimen respective of their diagnosis were analyzed. Each medication was checked with 2015 updated Beers list tables and any medication if mentioned in the Beers list, was noted. Any adverse drug event (ADE) occurring to the patient was identified and causality of the events were assessed by Naranjo's Scale. The number of drug-drug interactions per prescription and the severity of

each interaction were also analyzed with Micromedex® dug interaction checker.

Data analysis

Continuous variables were expressed as mean with standard deviation (SD) and median with interquartile range (IQR). Categorical variables are presented as numbers with percentages (%). Association between PIM use and ADRs was assessed using Chi Square test of independence and a probability value of <0.05 was considered statistically significant.

RESULTS

A total of 112 hospitalized older adults were studied. Patient characteristics and prevalence of PIMs are depicted in **Table 1**. The mean age of the study population was 68.89 (SD = 6.1) years and median age was 68 years (range 60-85 years). The study population comprised of 67 (59.8%) male and 45 (40.2%) female patients. Of 112 studied subjects 36 (32.14%) received at least one PIM during their hospital stay, of which 21 (18.7%) patients received one PIM and the rest 15 (13.4%) patients received two PIMs. The prevalence of PIM use was higher in age group of 60-69 years with 25 (22.3%) patients followed by age group of 70-79 years with 9 (8.0%) patients and 80 years and above age group with 2 (1.8%) patients prescribed with PIMs.A total of 247 diseases were diagnosed in 112 studied subjects. In the patients receiving 0 to 9 medications at a time, PIM use was observed in 14 (12.5%) patients and in patients receiving 10 or more drugs, PIM use was observed in 22 (19.6%) patients.

A total of 1148 drugs were prescribed in 112 prescriptions. Average number of concurrent medications received by the patients at admission and during hospital stay was 10.25 with standard deviation of 3.6 (range 4 to 22) per patient. Polypharmacy was observed in 54.4% (61) patients, prescribed with more than 10 medications at a time.

Of 1148 prescribed drugs 51 (4.44%) were PIMs, according to the 2015 updated Beers Criteria as depicted in **Table 2**. Of the 51 prescribed PIMs the most common identified were clonidine with 10 (19.6%), sliding scale use ofinsulin and benzodiazepines with 8 (15.7%) prescriptions followed by prazosin with 5 (9.8%) prescriptions.

Of the 247 diagnosed diseases, the four most frequent diseases diagnosed were hypertension in 27 (24.1%) patients, chronic kidney disease in 22 (19.6%) patients, Type 2 diabetes mellitus in 20 (17.8%) patients and chronic obstructive pulmonary disease in 11 (9.8%) patients [**Figure 1**].

A total of 31 ADRs were observed in 30 (26.8%) patients**[Figure 2]**. Causality of the events was assessed by Naranjo's Adverse Drug Reaction Probability Scale. Of these, 13 ADRs observed in 12 (10.7%) patients were due to PIMs listed in Beers Criteria and remaining 18 ADRs in 18 (16.1%) patients were due to other drugs. Of the 82 (73.2%) patients, not having any ADRs, 24 (21.4%) patients were receiving PIMs and 58 (51.8%) patients were not receiving any PIMs during their hospital stay [**Figure 3**].

All 13 ADRs due to medications listed in BC were due to PIM use regardless of the diseases/conditions during hospital stay. There was no significant association between the occurrence of ADRs and use of PIMs listed in the 2015 updated Beers Criteria [$\chi^{2 = 1.16,}$ P = 0.281 (df = 1)] [Odds ratio (OR): 1.61 {95% confidence interval (CI): 0.67:3.85} P = 0.283].

Drug interactions were checked with Micromedex® dug interaction checker and a total of 123 drug-drug interactions were found with an average of more than 1 drug interaction per prescription. Out of 123, moderate drug interactions were 65 (58.0%) followed by major 52 (42.3%) and minor drug interactions 6 (4.9%) as shown in **Table 3**.

DISCUSSION

The fastest growing population in the 21st century is the people over 85 years of age depicting aging of the population.[21]the aging population is accompanied by

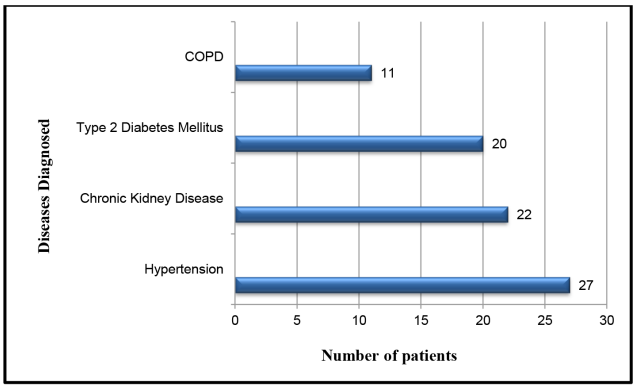
Table 1: Patient characteristics and prevalence of potentially inappropriate medication (PIM) use.

Characteristics	Total number of patients, N=112 (%)	Number of patients with PIM use, N=112 (%)
Gender		
Male	67 (59.8)	23 (20.5)
Female	45 (40.2)	13 (11.6)
Age in years		
60-64	26 (23.2)	10 (8.9)
65-69	36 (32.1)	15 (13.4)
70-74	25 (22.3)	3 (2.7)
75-79	17 (15.2)	6 (5.4)
≥80	8 (7.1)	2 (1.8)
Number of diseases		
1	31 (27.7)	7 (6.2)
2	33 (29.5)	13 (11.6)
3	42 (37.5)	14 (12.5)
≥4	6 (5.4)	2 (1.8)
Number of drugs prescribed		
0-4	2 (1.8)	0 (0)
5-9	49 (43.7)	14 (12.5)
10-14	52 (46.4)	16 (14.3)
≥15	9 (8.0)	6 (5.3)

Table 2: Potentially inappropriate medication (PIM) use among study subjects according to 2015 updated Beers criteria.

Criteria 1: PIMs according to organ system and therapeutic category		
Organ system, Therapeutic Category	**Drugs**	**Instances, N= 51 (%)**
Anticholinergics	Chlorpheniramine	1 (2)
	Dexchlorpheniramine	1 (2)
	Diphenhydramine	2 (4)
Antispasmodic	Atropine (excludes opthalmic)	2 (4)
Anti-infective	Nitrofurantoin	2 (4)
Cardiovascular		
Peripheral alpha-1 blockers	Prazosin	5 (9.8)
Central alpha blockers	Clonidine	10 (19.6)
Cardiovascular	Digoxin	2 (4)
	Nifedipine immediate release	1 (2)
Central Nervous System		
Benzodiazepines	Alprazolam	1 (2)
	Clonazepam	5 (9.8)
	Diazepam	2 (4)
Nonbenzodiazepine, benzodiazepine receptor agonist	Zolpidem	1 (2)
Endocrine	Insulin, sliding scale	8 (15.7)
Gastrointestinal	Metoclopramide	2 (4)
Pain Medications	Pentazocine	1 (2)
Criteria 2: PIMs due to drug-disease / drug-syndrome interaction		
Disease or Syndrome	Drugs	Instances, N= 51 (%)
History of falls or fracture	Anticonvulsants (Phenytoin)	1 (2)
History of falls or fracture	SSRIs (Sertraline)	1 (2)
CKD (creatinine clearance <30 ml/min)	NSAIDs (Aspirin)	2 (4)
Criteria 3: PIMs due to varying level of kidney function		
Creatinine clearance	**Drugs**	**Instances, N= 51 (%)**
Less than 30 ml/min	Spironolactone	1(2)

SSRIs= Selective Serotonin Reuptake Inhibitors. CKD= Chronic Kidney Disease



COPD= Chronic Obstructive Pulmonary Disease

Figure 1: Most common diseases among study subjects.

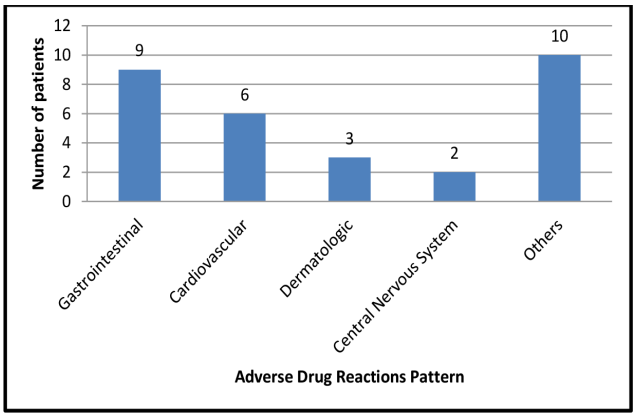
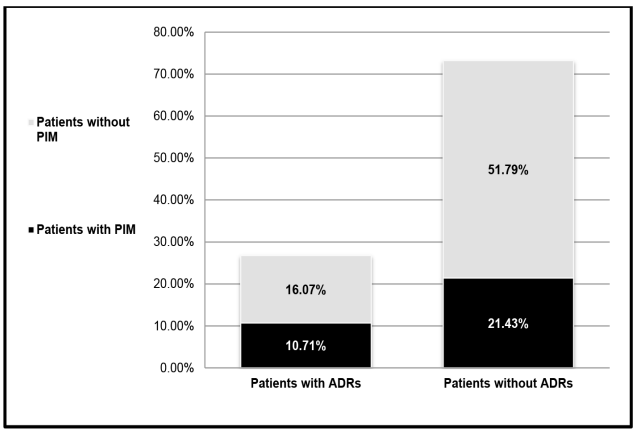


Figure 2: Adverse drug reaction patternsamong study subjects.



PIM= Potentially inappropriate medications. ADRs= Adverse drug reactions

Figure 3: Adverse drug reactions and use of potentially inappropriate medication use among study subjects.

Table 3: Drug-drug interactions in the prescriptions of study subjects.

Drug interaction	No of prescriptions	No of drug interactions
Major	38	52
Moderate	46	65
Minor	5	6

increasing presence of diseases and other comorbidities and so there is increased drug utilization by the older population. 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.[22]

The current study included a total of 112 elderly patients (aged 60 years and above), of which male patients were more prevalent (59.8%). Hypertension, chronic kidney disease, diabetes mellitus and chronic obstructive pulmonary disease were the most common diseases diagnosed among older adults in this study which is almost similar to other studies conducted in medicine outpatient department by Zaveri HG *et al*.[23] and in medicine wards by Harugeri A *et al*.[24]As the present study was carried out only in IPDs of general medicine, nephrology and pulmonary medicine, other diseases might prevail in different settings.Present study shows that 54.4% patients were prescribed with 10 or more drugs with an average of 10.25 ± 3.6 drugs per patient. Polypharmacy is one of the risk factor for PIM use and adverse drug events.[24,25]

Prevalence of PIM use among hospitalized older adults in the present study was found to be 32.14% which is higher than that reported in some prospective studies in India by Zaveri HG *et al*.[23] (23.5%), Harugeri A *et al*.[24] (23.5%), Kashyap M *et al*.[26] (21%), Shah KN *et al*.[27] (29.3%), Pradhan S *et al*.[28] (21.86%) and Vishwas HN *et al*.[29] (24.6%). While some prospective studies showed higher prevalence of PIM use [Danisha P *et al*.[30] (53%) and Momin TG *et al*.[31] (40%)].

All the mentioned studies used Beers criteria (including Beers criteria 2003, 2012 and 2015) and other criteria as a screening tool for identification of PIMs. As reported by different studies, there is a varying prevalence of PIM use among older adults. This could be due to difference in patient characteristics, prescribing pattern and study designs.

The commonly used PIMs in this study were clonidine, benzodiazepines, insulin sliding scale and prazosin. Danisha P *et al*.[30] also reported similar commonly used PIMs except clonidine. Clonidine is central alpha-2 receptor blocker used as antihypertensive agent. Beers criteria states it as inappropriate drug in older adults as there is increased risk of CNS effects, bradycardia and orthostatic hypotension.[20]Benzodiazepines had been reported as most commonly used PIMs in several studies,[26,27,30,32] as Beers criteria states that benzodiazepines increase the risk of cognitive impairment, delirium, falls and fractures in older adults.[20]

A total of 31 ADRs in 30 (26.7%) patients were observed in present study which was higher than reported by Danisha P *et al*.[30] (5%), Onda M *et al*.[33] (8%) and Pasina L *et al*.[34] (9.7%). While Vishwas HN *et al*.[29] reported similar prevalence (27.7%) of ADRs and Harugeri *et al*.[24] reported higher prevalence (35.9%) of ADRs among the elderly patients.

Of the 31 ADRs in present study, the PIMs listed in Beers criteria accounted for 13 (41.9%) ADRs in 12 patients which is higher than that reported by Vishwas HN *et al*.[29] (7.3%). No statistically significant association was found between PIM use and ADRs in this study. Similarly, Vishwas HN *et al*.[29] Harugeri *et al*.[24] also found that the medications other than listed in Beers criteria were more likely to be associated with ADRs.

Polypharmacy is commonly observed in elderly patients which may increase the risk of drug-drug interactions. Present study found a total of 123 drug-drug interactions averaging more than 1 drug interaction per prescription although their clinical significance needs to be evaluated. Another study on elderly cancer patients reported 150 drug interactions in 445 patients.[35]

CONCLUSION

The study shows that the use of potentially inappropriate medications is common among the hospitalized

older adults in medicine wards. There is need to draw the attention of prescribers regarding the drug therapy of older adults. There was a high prevalence of ADRs among the study subjects. The use of PIM was not associated with increased risk of having adverse drug reaction among the hospitalized elderly patients. Preventable measures need to be adopted and close monitoring for detection and management of ADRs in the elderly patients should be done.

LIMITATIONS

The present study evaluated PIM use only in the hospitalized older adults in medicine wards so there is scope of further studies in other specialty wards as well as in the ambulatory elderly patients because all the older population is vulnerable to the potentially inappropriate medication use and adverse drug events.

The present study used 2015 Updated Beers Criteria as a selection tool for PIM use in elderly patients. Although it is most frequently used tool but is not comprehensive enough to detect all aspects of inappropriate prescribing in older adults and more studies are required to establish the pattern of appropriate drug use in elderly people.

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SUMMARY

This study reveals a high prevalence of PIM use and ADRs among the hospitalized geriatric patients in medicine wards. Although no statistically significant association was found between PIM use and ADRs, there is still need for careful prescribing and close monitoring for any adverse events in geriatric patients. There were high rate of drug interactions among the prescriptions although clinical significance of which need to be determined.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

ADR: Adverse Drug Reaction; **ADE:** Adverse drug event; **AGS:** American Geriatric Society; **COPD:** Chronic Obstructive Pulmonary Disease; **IEC:** Institutional Ethics Committee; **IPD:** Inpatient Department; **IQR:** Inter-quartile Range; **OR:** Odds Ratio; **SD:** Standard Deviation.

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