

ORIGINAL ARTICLE

Characterization of potentially inappropriate medications use in Indian elderly population and their impact on quality of life using Beers criteria

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None.

Abstract

Background: Polypharmacy is principal cause of potentially inappropriate medications (PIMs) in elderly patients, which include over prescribing, under prescribing, and misprescribing.

Methods: Elderly subjects (≥ 60 years), of either sex, receiving two or more medications for one or more chronic ailments, attending Geriatrics Outpatient Department (OPD), at All India Institute of Medical Sciences (AIIMS) New Delhi, were included. Their prescriptions were assessed for PIMs by using Beers criteria 2015 and were further followed up at least once in 6 months for adverse events, telephonically. The results were analyzed by using suitable regression models and correlation analysis.

Results: Three hundred eighty patients average age of 65.4 ± 4.7 years were enrolled. Eighty-eight percent of the people were having greater than or equal to two ailments. Each patient was prescribed 6.7 ± 2.1 medications with 65% of prescriptions having one or more PIMs. Out of the total prescribed drugs, 15% were satisfying Beers criteria for PIMs. There were 63 adverse drug reactions (ADRs) reported. A statistically significant correlation was observed among comorbidities, number of prescribed medications, PIMs, and ADRs. Quality of life (QOL) of the elderly patients was negatively correlated with polypharmacy and female sex.

Conclusion: A risk-benefit analysis of prescribed medications is part and parcel of prescribing, especially in elderly patients. In order to decrease further risks associated with inappropriate prescribing, there is need for indigenous guidelines and intensive training.

KEYWORDS

elderly, PIMs, polypharmacy

1 | INTRODUCTION

Worldwide, 8.5% of the population is 65 years and above,¹ whereas in India the population above 60 years is 8.6% (104 million).² Rampant age and lifestyle-related multimorbidities, altered

pharmacokinetics and pharmacodynamics requiring different prescription drugs.

The multiple comorbidities in elderly patients necessitate use of several drugs concurrently (polypharmacy) for a longer duration, which further enhances drug-related risks. Potentially inappropriate

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medications (PIMs) may be due to over prescribing, under prescribing, missed prescribing, or wrong prescribing of medicines. This vicious triad of multimorbidity, polypharmacy, and PIMs may enhance the incidence of adverse drug reactions (ADRs) together or independently.³⁻⁸

The occurrence of ADRs, in turn, necessitate use of other medications and thereby amplifying medication-associated risks.⁹ Management of ADRs is an additional economic burden on an already shrunken purse.¹⁰ ADRs also increase morbidity in the elderly population leading to a poor quality of life (QOL). Multimorbidity, polypharmacy, PIMs, and ADRs, have a huge impact on QOL in the elderly population.¹¹ Better QOL is the whole and sole aim of any treatment modality.

Numerous medication assessment tools can be used to identify PIM but their predictive validity needs to be validated in a particular region. One of the most widely used criteria in the world is the Beers criteria^{12,13} by the American Geriatric Society. In this study, the applicability of the Beers criteria was evaluated in Indian scenario by estimating the incidence of PIMs as per Beers criteria and by analyzing their impact from ADRs, QOL, and economic perspective of the elderly population.

2 | METHODS

2.1 | Study participants

A prospective observational study was conducted at the AIIMS New Delhi, India after obtaining ethical clearance from the institutional ethics committee. All participants of either sex who visited geriatric OPD at AIIMS, New Delhi, India from April 2016 to November 2017 were screened and those who satisfied the inclusion and exclusion criteria, agreed to respond to questionnaire and further follow-up, were enrolled in the study. The inclusion criteria were

the prescription of two or more medications and willingness to provide written informed consent. Participants not willing to provide informed consent, terminally ill participants or with HIV, mental disorders, and who had undergone organ transplantation were excluded. Monthly telephonic/OPD follow-ups were done for a period of 6 months. The study protocol is given in Figure 1.

2.2 | Assessment of PIMs

For assessment of PIMs, the participants were interviewed and demographic features and medical history were recorded in the participant information sheet. All current prescriptions were scanned and all medications (from any other doctor also) including doses were noted. PIMs were identified according to updated Beers criteria 2015 and, accordingly, classified into five classes: drugs to be avoided, drug disease or drug syndrome interaction, drugs to be used with caution, drug-drug interaction, and drugs to be avoided depending on kidney function. Creatinine clearance where required was calculated by the Cockcroft-Gault Equation with the help of available data.

2.3 | Assessment of ADRs

Participants were interviewed and followed up telephonically for 6 months for any untoward events due to medicines. The assessment of ADRs were done by authors P.A., J.K., and Y.K.G. (all pharmacologists) using World Health Organization (WHO) causality scale (used for causality assessment) and severity was adjudged into five grades: 1, 2, 3, 4, and 5, according to the Common Terminal Criteria for Adverse Events (CTCAE) version 4.03.

Patients' ADRs were managed by author A.B.D. (geriatrician) and further management, if necessary, was done by respective speciality/

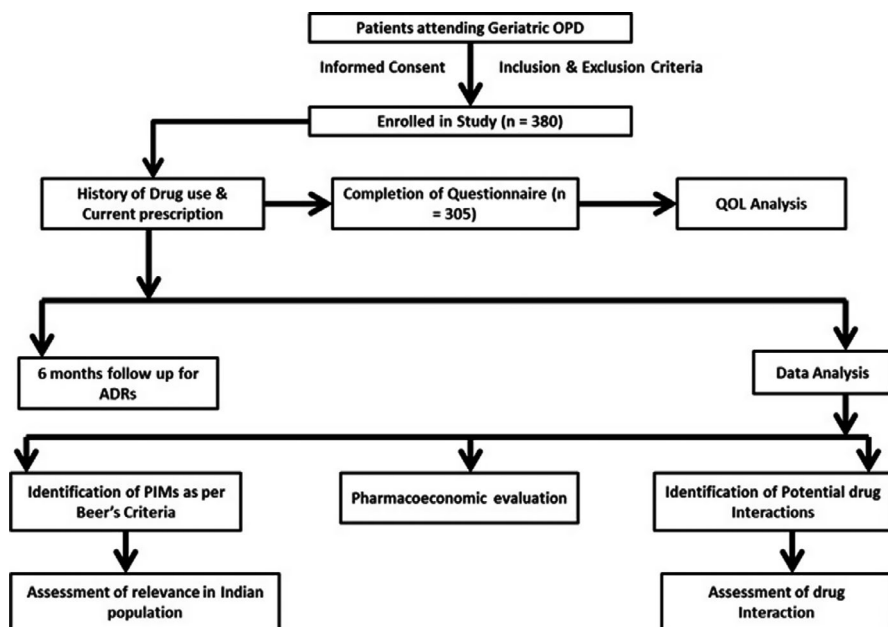


FIGURE 1 Study protocol. ADR, adverse drug reaction; OPD, Outpatient Department; PIM, potentially inappropriate medication; QOL, quality of life

super-speciality departments of the institution in which the study was conducted (i.e., All India Institute of Medical Sciences, New Delhi). The relationship between ADRs and PIMs as well as potential factors affecting ADRs in the study population was also evaluated.

2.4 | Assessment of quality of life

Functional assessment of non-life-threatening conditions – functional assessment of chronic illness therapy (FANLTC-FACIT), version 4, QOL questionnaire was given to each individual. It was filled either by the participant or interviewer within 20 minutes. In case of illiterate individuals, the questions and options were read out and marked as per verbal response of the patient. A relationship between QOL and PIMs along with factors affecting the QOL of the study population was determined. A logistic regression model was designed to establish a correlation among QOL and ADRs, PIMs, age, sex, number of drugs prescribed, and number of diseases. Permission was obtained from corresponding authority of FANLTC-FACIT for the use of the questionnaire in our study.

2.5 | Assessment of economic burden due to PIMs

To determine economic burden due to PIM use, alternative medication PIM (only to be avoided category) was identified by literature search¹⁴ and then cost of the generic medicine of both PIM category and alternative were compared. Costs were obtained from janaushadhi.gov.in. Only medicines which were not available as generic, had their brand name costs considered.

2.6 | Statistical analysis

The data analysis was carried out using Stata version 14 and SPSS version 23. Data are presented in the form of frequency, percentage, median (range), and mean (standard deviation). The statistical tests applied were Chi Square test/ Fisher Exact test to compare between qualitative variables. The comparison for continuous data was done by applying Student t test/ Wilcoxon rank sum test. Univariate, bivariate, and multiple linear regressions were carried out for quantitative variables. Logistic regression model was used for qualitative variables. Any *p* value less than 0.05 was considered significant.

3 | RESULTS

3.1 | Characteristics of study participants

A total of 380 subjects, 215 men and 165 women, participated in the study. The mean age of study participants was 65.39 ± 4.74 years (Range = 60–88 years). There was no statistically significant difference in age among men and women. Out of 380 participants in the

study, 93% of the men and 97% of the women belonged to the less than 75 years age category.

3.2 | Multimorbidity in the study population

The maximum number of participants (i.e., 35%, 33%, 15%, 12%, 4%, and 1%) had two, three, four, five, and six concurrent illness, respectively. No difference was observed for multimorbidity between men and women with an average of three (1–6) diseases. Among the different concomitant illnesses, the majority 7% had hypertension and diabetes mellitus; 5% had hypertension and osteoarthritis; 4% had hypertension and chronic obstructive pulmonary disease (COPD); 2% had hypertension, diabetes mellitus, and osteoarthritis; and 1% had hypertension and coronary artery disease, or diabetes mellitus and coronary artery disease, or diabetes mellitus and neuropathy.

3.3 | Polypharmacy in the study population

The average number of drugs prescribed per prescription was 6.7 ± 2.1 , with no difference among men and women (6.31 ± 2.05 and 6.47 ± 2.09 , respectively). In all 67%, 17% and 16% participants were prescribed between five and eight drugs, less than five drugs, and more than eight drugs per prescription, respectively, with a maximum of 14 drugs prescribed to a single patient. A statistically significant positive correlation ($r[p]$ 0.368 [<0.001]) was observed between multimorbidity and polypharmacy.

3.4 | Potentially inappropriate medications in the study population

Out of 2452 prescribed medications in this study, 357 were PIMs and 66% of participants were prescribed one or more PIMs. Forty percent of the total participants were prescribed one PIM, 23% and 3% were prescribed two and three PIMs, respectively. The difference in prescription of PIMs between the two genders was not statistically significant. Table 1 gives the frequency of PIMs in participants based on patient characteristics. Six participants had creatinine clearance below 50 ml/min and seven participants had creatinine clearance below 60 ml/min. Disease wise, the frequency of PIMs increased with an increase in the number of diseases and a similar trend was observed for the number of drugs as well.

Out of 357 total PIMs, 250 belonged to the “to be avoided” category, 72 belonged to the “to be used with caution” category, 31 in the “drug-drug interaction” category, and four in the “should be avoided or have their dosage reduced with varying levels of kidney functions” category. No PIM in the category of “drug-disease interaction” was identified. For details of the drugs involved, please refer to Table 2. Proton pump inhibitors (pantoprazole, omeprazole, and rabeprazole) made up for the maximum number of PIMs prescribed

TABLE 1 Distribution of PIMs in the study population as per the characteristics of the study population

Variables	Age, y		Gender		Number of diseases			Number of drugs		
	60–74	≥75	Male	Female	1–2	3–4	≥5	<5	5–8	>8
Total number of participants N = 380	359	21	215	165	179	182	19	67	253	60
Participants with PIMs N = 249	236 (65.7)	13 (61.9)	134 (62.3)	115 (69.7)	106 (59.2)	126 (69.2)	17 (89.5)	23 (34.3)	176 (69.6)	50 (83.3)

Note: Figures in parenthesis are percentage values.

Abbreviation: PIMs, potentially inappropriate medications.

in our study population followed by chlorpheniramine, clonazepam, and amitriptyline.

A statistically significant correlation was observed between multimorbidity and PIMs ($r[p] = 0.27 [0.00]$) as well as between polypharmacy and PIMs ($r[p] = 0.17 [0.00]$).

3.5 | Adverse drug reactions

During the 6 months of follow-up, 63 ADRs were observed and were assessed using CTCAE version 4.03 for grading severity (Table 3). Causality assessment was done according to the WHO causality assessment scale, and all ADRs fell into categories – possible and probable. No serious adverse event was reported.

A logistic regression model was designed to establish a correlation among ADRs and PIMs, age, sex, number of drugs prescribed, and number of diseases. A statistically significant, positive correlation was established among ADRs and age, total number of prescribed drugs, and PIM use (Table 4).

3.6 | Quality of life assessment

A comparison between QOL among the participants with and without PIMs showed no statistically significant relationship. A negative and statistically significant relationship was observed between the total number of drugs prescribed and the QOL of the patients. Female patients were associated with a statistically significant lower QOL as compared with male patients. The results of the model are shown in Table 5.

3.7 | Economic implications of PIMs

Of the 250 PIMs (in the to be avoided category) identified the total cost of the drug was Indian Rupee (INR) 2404 per day, which amounts to INR 8 per person per PIM per day. On the other hand, replacement of PIMs would have entailed a cost of INR 494 per person per day, which comes around to INR 2 per person per PIM per day. The difference in cost between the two groups was not statistically significant (Table 6).

4 | DISCUSSION

Worldwide, PIMs in the elderly are identified by various implicit and explicit criteria and Beers criteria are one of the explicit criteria. However, there may be situations in which use of medications included in the criteria can be appropriate.

The elderly population in this study was pretty young as compared with other reports. Bronskill et al reported that the average age of the elderly patients in nursing homes in America is around 85 years.¹⁵ The lower age may be on account of the lower life expectancy in India and the other reason could be difference in settings (i.e., OPD vs nursing home).

Multimorbidity (i.e., occurrence of more than one illness concomitantly) is a common finding in the elderly population. Marengoni et al reported that the number of comorbid conditions in the elderly varies from an average of 1.4 to 2.9, with dementia and heart failure being most frequent.¹⁶ Kersten et al also reported more than or equal to three concomitant diseases in the elderly population.¹⁷ Our study findings are in agreement with these findings as far as number of comorbidities is concerned, but the spectrum of comorbidities is different with hypertension and osteoarthritis and hypertension and COPD. The main challenge associated with comorbidities is that the focus is on index disorder and other disorders are relatively neglected, treatment when imparted because of polypharmacy can potentially predispose to drug-drug and drug-disease interactions and negative outcomes, including ADRs, increased length of hospital stay and mortality.^{8,18,19} Another challenge with multimorbidity is repetition of the same drugs due to treatment from different specialties, this could be avoided in our setup due to incorporation of all prescribed drugs in the final prescription of our geriatricians.

Of all the prescriptions, 66% were having one or more PIMs, which is much higher as compared with the 36% prevalence observed by Zang et al²⁰ and 43% by a systematic review.²¹ In our study, 14.4% of all prescribed medications were PIMs, similar to that of Blozik et al who reported it to be 14.3%.²² PIMs mostly belonged to “to be avoided category” (Beers criteria) and proton pump inhibitor (PPI) was the major culprit. The rampant use of PPIs is due to higher incidence of gastroesophageal reflux disease (GERD) in elderly patients and these are the drugs of choice due to their high

TABLE 2 Categorization of PIMs

Category of PIMs	Number of participants
To be avoided	250 (70)
Proton pump inhibitors	149 (59.6)
Benzodiazepine	45 (18)
Antihistaminic	41 (16.4)
Tricyclic antidepressant	8 (3.2)
NSAIDs	3 (1.2)
Central sympatholytic	2 (0.8)
Digoxin	1 (0.4)
Nitrofurantoin	1 (0.4)
To be used with caution	72 (20)
Diuretic	67 (93.1)
SSRI	3 (4.1)
Dabigatran	1 (1.4)
Carbamazepine	1 (1.4)
Drug disease interaction	0 (0)
Drug-drug interaction	31 (9)
Opioid analgesic, escitalopram, clonazepam	5 (41.7)
Torsemide, tamsulosin	2 (16.7)
Furosemide, tamsulosin	2 (16.7)
Opioid analgesic, clonazepam, amitriptyline	2 (16.7)
Oxybutynin, chlorpheniramine	1 (8.3)
To be avoided/ dose reduction with reduced kidney function	4 (1)
Pregabalin	4 (100)

Abbreviation: NSAIDs, nonsteroidal anti-inflammatory drugs; PIMs, potentially inappropriate medications; SSRI, selective serotonin reuptake inhibitor.

TABLE 3 Distribution of ADRs based on CTCAE grading and common events

Grade	Frequency (% age in parenthesis)	Common ADRs
1	31 (49.2)	Headache, dysgeusia, leg cramps, abdominal bloating
2	11 (17.5)	Ankle edema, vomiting, constipation, dry cough
3	13 (20.6)	Diarrhea, productive cough, vertigo, dizziness, melena
4	8 (12.7)	Hypoglycemic episodes, paroxysmal supraventricular tachycardia
5	0 (0)	None

Abbreviation: ADR, adverse drug reaction; CTCAE, Common Terminology Criteria for Adverse Events.

efficacy and lesser drug interactions.²³ Pantoprazole is associated with increased risk of *Clostridium difficile* infections, bone loss, and fracture, if used for more than 8 weeks consecutively and therefore it is recommended for long-term use only in selected conditions.^{24,25} Other PIMs were due to a side effect (e.g., strong anticholinergic effects²⁵ or increased chances of fall²⁶) with drugs like chlorpheniramine, hyoscine, amitriptyline, and oxybutynin; increases in the risk of gastrointestinal bleeding or peptic ulcer disease with nonsteroidal anti-inflammatory drugs (NSAIDs), like mefenamic acid, increased risk of orthostatic hypotension with prazosin, more chances of

toxicity with already compromised renal function in elderly patients, increased mortality with digoxin, and potential for pulmonary toxicity, hepatotoxicity, and peripheral neuropathy with anti-infectives, like nitrofurantoin. Notably, this spectrum of PIMs was different than Blozik et al who reported zolpidem, estradiol, trimipramine, and amitriptyline as PIMs.²² This may be attributed to differences in the populations studied.

As for drugs prescribed from the “drugs to be avoided category,” we identified diuretics (thiazide and chlorthalidone), selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs),

Independent variables	Odds ratio (95% CI) ^a	Odds ratio (95% CI) ^b	P value
Age, y	0.94 (0.89 to 1.01)	0.93 (0.87 to 1.00)	0.035
Sex	1.32 (0.77 to 2.27)	1.16 (0.66 to 2.03)	0.612
Total number of chronic illnesses	1.23 (0.96 to 1.59)	1.06 (0.80 to 1.41)	0.683
Total number of drugs	1.25 (1.10 to 1.43)	1.21 (1.05 to 1.41)	0.010
PIMs	1.62 (1.17 to 2.24)	1.46 (1.04 to 2.05)	0.030

Abbreviation: ADR, adverse drug reaction; CI, confidence interval; OR, odds ratio; PIMs, potentially inappropriate medications.

^aUnivariate.

^bBivariate.

TABLE 4 Results of logistic regression model for ADRs (dependent variable)

TABLE 5 Results of linear regression model for Quality of Life Score (dependent variable)

Independent variables	Regression coefficient (95% CI)	P value
Age, y	0.24 (-0.81 to 0.55)	0.14
Sex	-3.72 (-6.75 to -0.70)	0.02
Total number of chronic illnesses	0.86 (-0.69 to 2.41)	0.28
Total number of drugs	-1.79 (-2.58 to -1.00)	0.00
PIMs	-0.33 (-2.22 to 1.57)	0.74
ADRs	-0.95 (-4.91 to 3.01)	0.64
Constant	70.74 (49.71 to 91.78)	0.00

Abbreviation: CI, confidence interval.

carbamazepine, dabigatran, and vasodilators. Zhang et al also reported diuretics to be the most commonly used drug from this category. They further identified dabigatran as accounting for a substantial number, but, in this study, we found that dabigatran, fluoxetine, and carbamazepine had a similar number of prescriptions.²⁰ As per Beers criteria in this category, all drugs, except for dabigatran and vasodilators, require a close monitoring of the sodium level, as these drugs are more likely to cause syndrome of inappropriate antidiuretic hormone or hyponatremia, especially in the elderly population. In our study, we found that out of six participants in whom sodium reports were available, sodium was normal in all cases except one who had asymptomatic hyponatremia. Dabigatran is associated with increased risk of bleeding and vasodilators are responsible for exacerbation of episodes of syncope.

Zhang et al reported the prescription of benzodiazepines in dementia and ibuprofen in gastric ulceration participants.²⁰ Another study reported about the use of PIMs in Parkinson's disease.²⁷ In our study, no one was prescribed any of the drugs that should be avoided in the disease condition he/she was suffering from. Secora et al showed an increased incidence of PIM use in chronic kidney disease cases and no significant difference in mortality.²⁸ In this study, we identified four participants who were being prescribed pregabalin despite their creatinine clearance below 60 ml/min. Zang et al identified spironolactone and famotidine in this category.²⁰

Regarding drug-drug interactions, a total of 12 cases were identified. Of those 12 cases, seven were prescribed opioid analgesics along with two other central nervous system (CNS) active drugs, either escitalopram and clonazepam or escitalopram and amitriptyline. Although other studies have identified use of flupentixol/melitracen, paroxetine with zolpidem, and olanzapine as a drug prescribed in this interaction study.²⁹ Apart from this, we also identified three prescriptions of peripheral α blockers along with diuretics and one prescription of two anticholinergic drugs simultaneously.

Besides identifying and characterizing PIMs in this study we have attempted to ascertain their impact by determining the incidence of ADRs, QOL, and economic burden to the patient. Heider et al reported an increased probability of adverse events in individuals exposed to PIMs.³⁰ In this study, 63 ADRs were observed (i.e., an incidence of 16.6%). O'Connor et al reported 11.4% to 14% ADRs in elderly patients attributable to hospitalization, which was significantly lesser as compared to younger people.³¹ A statistically significant relationship among PIMs, polypharmacy, and ADRs were observed in this study. Because 50% of ADRs are preventable in elderly individuals,³² hence a proper identification of the factors responsible is warranted. The study failed to identify interventions that can lead to reduction in adverse events,³³ although it considered different parameters as we did in our study. Although a statistically significant correlation between PIMs and ADRs was observed in this study, their direct attribution to a particular PIM is not possible due to polypharmacy, as these adverse events may be attributable to multiple drugs, thereby ascertaining the causality assessment to be certain was difficult. For example, there were four cases of diarrhea in participants who were on pantoprazole, but these participants were also on metformin which can also present with such symptoms. Of all the participants who were prescribed diuretics, the sodium levels were available only for six participants, and out of them one had asymptomatic hyponatremia, with sodium level of 132 meq/L.

FANLTC estimates QOL for individuals with chronic illnesses which are non-life-threatening. In this study, the average QOL for participants was found to be 75. Women had lower QOL as compared with men but the difference was not statistically significant. Lower QOL was associated with polypharmacy and female sex only

TABLE 6 Details of economic analysis

PIM	Cost of one tablet (PIM) in INR	Units consumed (PIM)	Cost of PIMs (INR)	AD	Cost of one tablet (AD) in INR	Units consumed (AD)	Cost of AD (INR)
Pantoprazole	10.4	144	1497.6	Ranitidine	1	144	144
Chlorpheniramine	6	123	738	Escitalopram	2.52	41	103.32
Clonazepam	1.63	39	63.57	Cetirizine	3.85	39	150.15
Amitriptyline	2.4	8	19.2	Duloxetine	4.15	8	33.2
Alprazolam	2.3	4	9.2	Escitalopram	3.85	4	15.4
Omeprazole	8.16	3	24.48	Ranitidine	0.66	3	1.98
Prazosin	12.5	2	25	Losartan	8.1	2	16.2
Rabeprazole	3	2	6	Ranitidine	0.66	2	1.32
Hyoscine	2.75	2	5.5	Tramadol	4.59	2	9.18
Hydroxyzine	1.75	2	3.5	Cetirizine	2.52	2	5.04
Digoxin	2.1	1	2.1	Metoprolol	8.98	1	8.98
Nitrofurantoin	7.1	1	7.1	Ciprofloxacin	3.7	1	3.7
Mefenamic acid	2.3	1	2.3	Paracetamol	1.47	1	1.47
Total			2403.55				493.94

Abbreviation: AD, alternative drug; INR, Indian Rupee; PIMs, potentially inappropriate medications.

and not with PIMs, although Harrison et al found a negative association between the increasing number of PIM prescriptions and QOL.¹¹

The American Geriatric Society (AGS) has in some cases proposed an alternative to drugs deemed to be PIMs in Beers criteria,¹⁴ although many drugs lack an alternative. By using alternatives from literature and also those provided by the AGS, we tried to calculate the difference in the economic burden of the study population due to PIMs. We observed a marked difference in the basic cost of drugs under PIMs and alternative category, although this difference was not statistically significant in the two groups when we considered per person per day cost of PIMs. Moriarty et al reported that PIMs impose economic burden and hence interventions to improve proper prescribing of these medications is required.³⁴ In this study, a reason for no difference could be the heterogeneity in the number of units per PIM and the cost of unit doses. However, from a patient's perspective, the economic burden due to the difference in cost in some cases, particularly for pantoprazole and chlorpheniramine, could be sizable.

The aim of this study was to identify the incidence of PIMs in geriatric subjects based on the 2015 update of Beers criteria but the findings of the study were also in accordance with updated Beers criteria released in 2019. The study is unique in being the first of its kind from India and which also focusses on the clinical significance of PIMs and therefore has evaluated the correlation of PIMs with ADRs, QOL, and their economic burden. The study was carried out at a tertiary care center, where state-of-the art care for the elderly is imparted and because it caters to a broad spectrum of patients from all over the country, so it can be generalized to the population. This study includes drug intake data obtained directly from the

individuals concerned, thereby preventing any bias due to use or non-use of medications and due to medication duplication. Besides, the participants were followed up for any adverse events due to drug use, therefore, results can be more promising and correlatable. However, the period of follow-up for ADRs (6 months) may not reflect long-term complications like bone loss/fracture. In addition, the economic part of the study only included drug cost, proper evaluation of direct, indirect, intangible costs consideration, and data regarding conversion of QOL to the utility factor is necessary for proper pharmaco-economic analysis.

5 | CONCLUSION

Many medications are considered potentially inappropriate only in certain circumstances, or in most circumstances but with some key exceptions. However, it is not only important to know that a medication is included on the Beers criteria list, but to know why it is included in the list. In the absence of country-specific adaptations of the Beers criteria, in most cases, it is reasonable to use broad based categories included in the criteria to identify potentially inappropriate medications and whether the rationale or recommendation is applicable after weighing against clinical judgment, risk vs benefit and economic standpoint.

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CONFLICT OF INTEREST

None.

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