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Research Article

# Prevalence of Polypharmacy and Potentially Inappropriate Medications in Elderly Patients: Cross Sectional Study Based on Updated Beer's Criteria 2019

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## Abstract

**Background:** Polypharmacy, contribute to increase risk of adverse drug reaction morbidity, mortality, increase length of hospital stay, hospital revisits and readmissions. We aimed to evaluate the prevalence and trends of polypharmacy and Potentially Inappropriate Medications (PIMs) in elderly patients using updates Beers Criteria 2019. We try to assess the severity of adverse drug events using modified Hartwig and Siegel scale in patients with PIMs.

**Methods:** This is prospective cross-sectional record-based study of over-the-counter, and potentially inappropriate medications in the prescriptions of patients (>60 years). PIMs has been identified and flagged and then further investigated to determine the presence or absence of any adverse effects. If harm occurred, severity of an adverse effect was rated using criterion developed by modified Hartwig and Siegel scale. Causality of the events was assessed by using Naranjo's Scale.

**Results:** Out of 583 patients polypharmacy was found in 36.0%, and excessive polypharmacy was found in 42.8% in pre admission medications. Most common Over-the-Counter (OTC) drugs out of which hydrocortisone (39.86%), ranitidine (21.62%), bisacodyl (14.86%), and diphenhydramine (12.84%) were the commonest. There was statistically significant positive correlation between with age and number of drugs prescribed (r2=0.16), while non-significant positive correlation was found between sex, Length of Stay (LOS), and number of drugs prescribed (r2=0.0002, r2=0.001). There was statically significant positive correlation between number of drugs prescribed to PIMs (r2=0.18). The most commonly PIMs related incidence reported include Insulin (regular) 31.25% (n=20), Trihexyphenidyl (THP) 18.75%, zolpidem 12.5%, acetylsalicylic acid 9.3%, pantoprazole 52 7.81%, furosemide 7.8%, hydrocortisone 6.25%, and glimepiride 6.25%. Total of 130 ADRs 50% were mild, 28.4% were moderate, and 21.5% were severe. Out of 130 incidence 64.6% were definitely preventable, 22.3% were probably preventable, and 13.0% were not preventable. Total 55 of 50.0% recovered completely from the ADRs, 33.0% had been recovering, 12.3% recovered with squeal, and 2.3% could not recovered and 2.3% had been fatal.

**Conclusion:** The study shows high uses of OTC and PIMs and PGx in elderly patients; which encourage intent need to develop awareness and action plans to encourage prescriber for use of possible alternatives to PIMs.

**Keywords: Beer's criteria; Potentially inappropriate medicines; Polypharmacy; Geriatrics medicines; Over the counter drugs**

## Bullet Points of the Study Highlights

### What is already known?

- Various different criteria have been developed to come across Potentially Inappropriate Medications (PIMs), and their huge variated uses in distinct community, and health services, with inconsistent health outcomes.
- PIMs and Pharmacogenomic drugs may be equally common, important risk factors for drugs adverse effects in elderly
- Without research studies and comparison, it is difficult to know which criteria detect more or fewer numbers of PIMs than other in the same cohort.

### What is new in this study to look at?

- Updated beers Criteria 2019 (modified version Beers Criteria 1991) used for detection of PIMs.
- Prevalence of utilization of over-the-counter (OTC) drugs in cohort also studied additionally with PIMs and Pharmacogenomic drugs.
- Severity of PIMs related adverse drug events

### What are the future clinical and research implications of the study findings to look at?

- Treatment quality indicators can be created and implement in populace based on these studies. Right intervention at proper time among elderly patients lessens morbidity, mortality, hospital stay, hospital revisits and readmissions.
- Ethnicity based pharmacogenomics studies should be implement, to study pharmacokinetic and pharmacodynamics of PGx drugs.

## Introduction

With better medical facilities life expectancy increase from 66.24 to 69.16 since year 2010 to 2017 [1]. According to Population Census

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2011 there are nearly 104 million elderly persons (Aged 60 years or above) in India; 53 million females and 51 million males. A report released by the United Nations Population Fund and Help Age India suggests that the number of elderly persons is expected to grow to 173 million by 2026 [2]. Physiological and cognitive functions tend to change with an age-related change in pharmacokinetics and pharmacodynamics. Subsequently these patients are often excluded from randomized controlled clinical trials and the pharmacology 89 and recommended dosage regimen of most of the drugs in this population are not well established [3-5].

With advancing in age, there is an excessive occurrence of multiple chronic disease and comorbidity. Management of these comorbidities, potentially associated with an increase prevalence in the use of multiple drugs (polypharmacy and immoderate polypharmacy), which makes them at higher risk of probably beside the point use of PIMS [6]. PIMs are defined as "medications that should be averted because of their risk which outweighs their benefit especially when there equally or more effective but lower risk alternatives are available" [7]. PIMs use is normally evaluated using specific scales and Criteria which include the Beers Criteria, which are a set of explicit Criteria to identify PIMs. It was first developed in 1991 and consequently updated with the latest update in 2019 [8]. Several researches reported the superior use of PIMs in geriatric patients globally; in Canada and the United States, the prevalence was from 14% to 37%, whereas in Europe it was from 23%, 102 to 43% [9]. A retrospective study from Indonesia in 2014 reported a PIMs prevalence of 52.2% [10]. Moreover, researches with lower rates were reported in South Africa, Korea, and Nigeria, with prevalence's of 13.8%, 27.6%, and 32.1%, respectively [11,12]. Higher rates of 40.39%, 45.2%, and 53.5% were reported in New Zealand, Lebanon, and China, respectively [13-15]. Genetic variability of different populace can affect the exposure or safety of specific drugs, called as pharmacogenomics drugs (PGx) drugs. The Dutch Pharmacogenetics Working Group (DPWG) and the Clinical Pharmacogenetics Implementation Consortium (CPIC) have been developing guidelines for more than a decade [13-14], and have released public guidelines for implement PGx especially for gene-drugs pairs of *CYP2C9*, *CYP2C19*, *CYP2D6*, *SLCO1B*, and *VKORC1*. There are studies from United States, Netherland and Denmark reported use of at least one PGx drug in 20%-30% of older patients [15-17]. We are not aware of any study that has reported on frequency of OTC, PIMs and PGx drugs used in general Population of India. Therefore, we aimed to assess the co-occurrence of three risk factors (a) OTC (b) Polypharmacy (c) PIMs (d) PGx drugs and there potential ADRs amongst the Indian elderly patients.

## Methodology

This was a prospective cross-sectional, record-based study conducted involving elderly patients (>60 years) who were admitted at a tertiary care hospital during December 2018 to November 2019). A pharmacologist examined case notes of in-patients in indoor patient department and ICU over a period of 12 months using updated beers Criteria 2019 (modified version Beers Criteria 1991). Classification of diseases was done using International classification of Diseases- ICD-10th version, 2019 [8]. Data of patients with a Length of Stay (LOS) greater than 24 hours but less than 70 day was included. Incomplete pre-admission medication history, incomplete case records without discharge summary or discharge coding or stay of patient more than 70 days were excluded.

The patient's case sheet is reviewed using a two-stage process. In initial length patient record was reviewed for polypharmacy, which we defined as an individual's exposure to five or more than five but lesser than 10 drugs, while excessive polypharmacy in individual defined as exposure to 10 or more than 10 drugs. PIMs (updated Beer's criteria 2019) [10] and Pharmacogenomics drugs for which pharmacogenomic testing is recommended for the following genes: *CYP2C9*, *CYP2C19*, *CYP2D6*, *SLCO1B*, and *VKORC1* (based on CPIC and DPWG) [11] has been identified and flagged and then further investigated to determine the presence or absence of any adverse effects. Review of the patient notes done in following order: past medication history, list of over-the-counter drugs, PIMs before admission, PIMs prescribed during hospital stay, medical progress notes, and shift to ICU, and PIMs at the time of discharge. If harm occurred, severity of an adverse effect was rated using criterion developed by modified Hartwig and Siegel scale [13].

Following factors had been taken into consideration during the review

- Any Complications end result of treatment was not considered as adverse events.
- Death was not considered an event unless PIMs clearly contributed to a death, rather than a part of a normal biologic process.
- Adverse events with intentional drug overdose were not considered. Adverse event rate per 1000 patient days was calculated using formula Total number of events divided by total length of stay multiplied by 1000).

## Statistical Analysis

Collected data had been entered in Microsoft office excel 2016. Categorical variables were presented as frequency, percentages, and mean SD. Pearson correlation were used for statistical analysis of categorical variables and correlation analysis respectively. 149 P value <0.05 were considered statistically significant.

### Ethical clearance

Ethical clearance to conduct study was obtained from Institutional Ethics Committee-Human Research (IEC-HR).

## Results

Out of 1245 case records, data of 583 patients meet the inclusion Criteria, out of which 61.3% (n=357) males, and 38.6% (n=226) females mainly aged between 65 years - 75 years (37.8%, n = 220) and (25.9% n = 151). Table 1 showing the demographic, clinical characteristics, comorbid conditions and distribution of patients across Indoor Patient Department (IPD) of the study population during the study period. Average Length of Stay (ALOS) was 8.6 (range 1 -48 days) while the average length of stay in patients with PIMs was 10.9 (range 1-59 days). Polypharmacy was found in 36.0%, and excessive polypharmacy was found in 42.8% in pre admission medications. There was statistically significant positive correlation between with age and number of drugs prescribed (r2=0.16). A positive non-significant correlation was found between sex, Length of Stay (LOS) with number of drugs prescribed (r2=0.0002, r2=0.001). There was statically significant positive correlation between number of drugs prescribed to PIMs (r2=0.18), (Figure 1 and 2). 116 patients were taking 148 Over the Counter (OTC) drugs, out of which 41.89% (n=52) were PGx drugs. Hydrocortisone (39.86%), ranitidine (21.62%), bisacodyl (14.86%), and diphenhydramine (12.84%) were the commonest. The total number of drugs prescribed to 583 patients

was 7089, out of which 6% (n=448) were identified to be PIMS (based on updated Beer's criteria 2019). Out of these 448 PIMs, 18.2% (n=82) were defined as PGx drugs. About 19.4% (n=87) PIMs and PGx drugs result in serious ADRs in which insulin (regular), PPIs and THP result in more than one ADRs in many patients. The most commonly PIMs related incidence reported includes, Insulin (regular) 31.25% (n=20), Trihexyphenidyl (THP) 18.75% (n=12), zolpidem 12.5% (n=8), acetylsalicylic acid 9.3% (n=6), pantoprazole 5 (7.81%), furosemide 5 (7.8%), hydrocortisone 6.25% (n=4), and glimepiride 6.25% (n=4), (Tables 2-4). Severity of ADRs was calculated in accordance Hartwig's severity assessment scale and three categories of ADRs had been assessed (mild, moderate and severe). Out of 130 ADRs 50% (n=65) were mild, 28.4% (n=37) were moderate, and 21.5% (n=28) were severe.

Out of 130 incidence 64.6% (n=84) were definitely preventable, 180 22.3% (n=29) were probably preventable, and 13.0% (n=17) were not preventable. Total of 50.0% (n=65) recovered completely from the ADRs, 33.0% (n=33) had been recovering), 12.3% (n=16) recovered with squeal, and 2.3% (n=3) could not recovered and 2.3% (n=3) had been fatal (Tables 5-7).

## Discussion

The present study was conducted to identify the prevalence of OTC, polypharmacy, PIMs and PGx drugs using updated Beers Criteria 2019, CPIC and DPWG in geriatric patients in an inpatient setting. In our populace the most frequently used drug class with ADRs was PPIs (20%) used widely for acid suppression and gastric

**Table 1:** Demographics of studied group.

| Demographics | Total no. of male patient's n (%) | Total no. of female's n (%) | Total (583) |
|---|---|---|---|
| Age | | | |
| 65-75 years | 220(37.80%) | 151(25.95%) | 371(63.75%) |
| >75 years | 137(23.54%) | 74(12.71%) | 211(36.25%) |
| Mean age (years) | 73.47 ± 6.62 | 72.5 ± 6.35 | 73.11 ± 6.53 |
| Diagnosis | | | |
| Medicine | | | 475 (81.62%) |
| Cardiology | 121 (20.79%) | 65 (11.17%) | 186 (31.96%) |
| Neurology | 53 (9.11%) | 39 (6.70%) | 92 (15.81%) |
| Respiratory | 42 (7.22%) | 40 (6.87%) | 82 (14.09%) |
| Gastroenterology | 37 (15%) | 15 (2.58%) | 52 (8.93%) |
| Endocrinology | 18 (3.09%) | 7 (1.20%) | 25 (4.3%) |
| Endocrine | 14 (2.23%) | 10 (1.72% | 23 (3.95%) |
| Renal | 9 (1.55%) | 6(1.03%) | 15 (2.58%) |
| Surgery | | | 107(10.81%) |
| Surgery | 42 (7.22%) | 21 (3.61%) | 63 (3.43%) |
| Orthopedics' | 11 (1.89%) | 9 (1.55%) | 20 (3.43%) |
| Ophthalmology | 8 (1.37%) | 12 (2.06%) | 20(3.43%) |
| Oncology | 3 (0.52%) | 1(0.17%) | 4 (0.69%) |
| Average length of stay (Mean ± SD) | 8.6 ± 3.4 | Length of stay with PIMS Incidence (Mean ± SD) | 10.9 ± 4.8 |

**Table 2:** Comorbid conditions with reason for admission.

| Comorbid Conditions | Male n = 291 (61.39%) | Female n = 183 (38.61%) | Total n = 474 |
|---|---|---|---|
| Diabetes type - 2 with Dyslipidemia | 67 (14.14%) | 39 (8.23%) | 106 (22.36%) |
| Hypertension | 67 (14.14%) | 39 (8.23%) | 106 (22.36%) |
| Hypertension with Dyslipidemia | 65 (13.71%) | 28 (5.91%) | 93 (19.62%) |
| Hypertension with DM type-2 | 48 (10.13%) | 44 (9.28%) | 92 (19.41%) |
| Hypertension with CKD | 31 (6.54%) | 20 (4.22%) | 51 (10.76%) |
| Infection | 10 (2.11%) | 11 (2.32%) | 21 (4.43%) |
| Osteoarthritis | 3 (0.63%) | 2 (0.42%) | 5 (1.05%) |

**Table 3:** Total number of drugs prescribed pre, during and post hospitalization with potentially inappropriate medicines based on updates Beer's criteria 2019.

| | Pre admission n (%) | During Hospitalization n (%) | At Discharge n (%) |
|---|---|---|---|
| Total no. of Drugs Prescribed | | | |
| ≤ 5 drugs | 123 (21%) | 69 (11.8%) | 136 (25.8%) |
| 6-10 drugs | 210 (36%) | 199 (34.1%) | 183 (34.7%) |
| 11-16 drugs | 174 (29.8%) | 218 (37.3%) | 133 (25.2%) |
| >16 drugs | 76 (13%) | 97 (16.6%) | 75 (14.2%) |
| TOTAL | 583 | 583 | 527 |
| Medication prescribed per patient | | | |
| (Mean ± SD) | 9.4 ± 2.9 | 12.65 ± 3.56 | 10.1 ± 3.1 |
| Prevalence of Polypharmacy | | | |
| Polypharmacy | 36.00% | 34.10% | 34.70% |
| Excessive polypharmacy | 42.80% | 54.00% | 39.40% |
| Total no. of PIMs | | | |
| 1 | 1 (4%) | 10 (15.8%) | 5 (10.4%) |
| 2 | 7 (28%) | 31 (49.2%) | 24 (50%) |
| ≥3 | 17 (68%) | 22 (34.9%) | 19 (39.5%) |
| PIMS n (%) | 128 (28.5%) | 166 (37.0%) | 154 (34.3%) |
| Total PIMs | 448 | PIMs with incidence | 87 |

**Table 4:** Commonly consumed Over the Counter drugs (OTC) pre-admission.

| OTC | ATC classification | PGx drugs | Total number (148) | (n%) |
|---|---|---|---|---|
| Hydrocortisone | A06 | - | 59 | 39.86% |
| Ranitidine | C05 | CYP3A4 | 32 | 21.62% |
| Bisacodyl | A03 | - | 22 | 14.86% |
| Diphenhydramine | R06 | CYP2D6 | 19 | 12.84% |
| NSAIDs | M01 | CYP2C9 | 11 | 7.43% |
| Tears Substitute | - | - | 4 | 2.70% |
| Antacids | C05 | - | 1 | 0.68% |

**Table 5:** Frequency distribution of Adverse Drug Events with type of Adverse Drug Effects, there evidence and recommendations.

| Class of Drugs | ATC classification | Drugs | | Total number of AEs 130 (%) | Type of AEs | Evidence | Recommendation |
|---|---|---|---|---|---|---|---|
| Proton pump inhibitors (PPIs) | C05 | Pantoprazole | CYP2C19 | 25 (19.2%) | Hypomagnesemia, bone fractures, deficient absorption of calcium, | Weak | CPIC: increase the starting dose and to monitor efficacy in normal metabolizers in treatment of H. Pylori infection and erosive esophagitis. |
| | | | | | vitamin B12 and iron deficiency anemia | | 50% reduction in daily dose poor metabolizers and chronic therapy |
| | | | | | | | DPWG: - |
| Insulin | A10 | Insulin (regular) | - | 22 (16.9%) | Hypoglycemia, Hypokalemia | Strong | - |
| Diuretics | | Furosemide | - | 21 (16.1%) | Hypokalemia, Hyponatremia | Strong | - |
| NSAIDs | M01 | Ibuprofen/ Diclofenac | CYP2C9 | 20 (15.3%) | Stroke, Cardiovascular disease, | | CPIC: Initiate therapy with 25-50% of the lowest recommended dose. |
| | | | | | Peptic ulcers | | DPWG: - |
| | | | | | Gastrointestinal bleeding | | |
| Anticholinergic | N06 | THP | CYP2D6 CYP2C19 | 17 (13.0%) | Tremors, Constipation, xerostomia | Strong | CPIC: 50% dose reduction in CYP2D6 poormetabolizers |
| | | | | | | | DPWG: decreasing dose for CYP2D6 intermediate and poor metabolizers, and increasing a dose or use an alternative in ultra- rapid metabolizers |
| Second generation sulfonylureas | A10 | Glimepiride* | CYP2C9 | 12 (9.2%) | Delayed recovery from Hypoglycemia | | - |
| Non-benzodiazepine's hypnotic | N05 | Zolpidem | - | 9 (6.9%) | | Strong | - |
| Corticosteroid's | A06 | Hydrocortisone | - | 4 (3.07%) | | Strong | - |

CPIC: Clinical Pharmacogenetics Implementation Consortium; DPWG: Dutch Pharmacogenetic Working Group

*Drug represents that no action is required for this gene-drug interaction; NA indicates not Pharmacogenomic drug Evidence obtained from one or well-designed and well executed Randomized Controlled Trials (RCTs).

Strong -Harms, adverse events and risks clearly outweigh benefits Weak -Harms, adverse events and risks may not outweigh benefits.

**Table 6:** Severity of Adverse Drug Reactions (ADRs).

| Category | Number of ADRs (n=130) | Percentage (N %) |
|---|---|---|
| Mild (level 1,2) | 65 | 50.00% |
| Moderate (level 3,4) | 37 | 28.46% |
| Severe (level 5, 6, 7) | 28 | 21.54% |

**Table 7:** Preventability of Adverse drug reactions.

| Category | Number of ADRs (130)) | Percentage (%) |
|---|---|---|
| Definitely preventable | 84 | 64.60% |
| Probably preventable | 29 | 22.30% |
| Not preventable | 17 | 13.00% |

acid reflux suppression. Most PPIs are actively metabolized into active metabolites by hepatic enzyme CYP2C19, genotypes linked to PPIs exposure. Lower exposure result in therapy failure and higher exposure associated with improved efficacy and adverse effects as on long term use [15]. In present study infection with Clostridium difficile, Hypomagnesemia, bone fractures, deficient absorption of calcium and vitamin B12 and iron deficiency anemia were the most serious adverse effect related to it. Similar result was found in study conducted in Japan [16,17]. Beers Criteria recommended avoiding schedule use for more than 8 weeks. These recommendations apply to both oral and intravenous PPIs. Histamine-2 receptor antagonists can be another safe alternative, but not recommended in older patients with or at high risk of delirium as it can potentially induce or worse delirium. The second most common PIMs with incidence were Insulin (regular) 16.9%. hypoglycaemia, hypokalaemia, delirium and loss of consciousness were the most common adverse effect related to it. Beers Criteria has revised insulin, to minimize the confusion about inappropriate insulin regimens. The Criteria advice to avoid using insulin sliding scale with short or rapid acting insulin without concurrent use of basal or long or long-acting insulin to minimize the risk of hypoglycaemia [18-23]. The third most common PIMs with incidence were Furosemide with rate of 18.3%. Hypokalaemia, hyponatremia, syndrome of inappropriate antidiuretic hormone secretion, fatigue and muscle weakness are the most common ADRs seen related to it. This result in increase monitoring of serum electrolytes. Beers Criteria recommended its use with cautions. The fourth most commonly prescribed PIMs and PGx with incidence was NSAIDs with rate of 16.20%. NSAIDs are widely use and their adverse effects need to be addressed. Stroke cardiovascular events, gastrointestinal hemorrhage, and peptic ulcer disease were most commonly observed ADRs especially in high risk patients taking

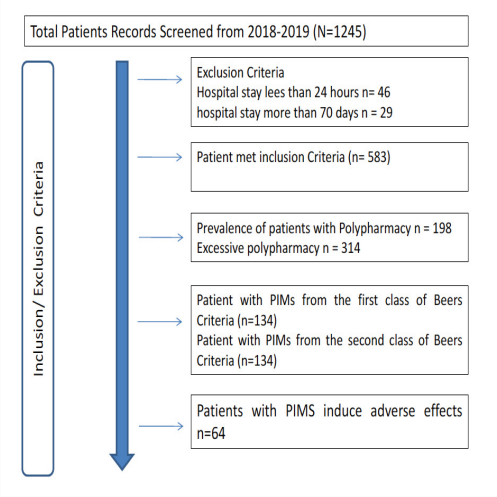


**Figure 1**: Flow of Patient s throughout the study.

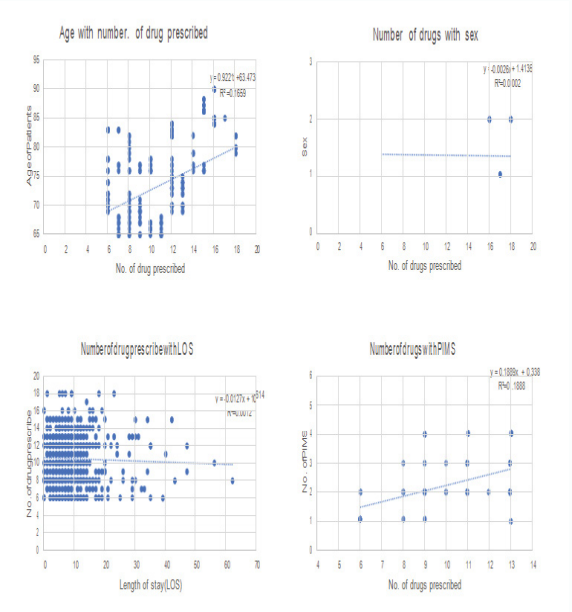


**Figure 2**: Correlation between Age, sex, length of stay with number of drugs prescribed and numbers of drugs prescribed with PIMs.

oral or parenteral corticosteroids (3.07%). Topical NSAIDs, lidocaine patch, topical capsaicin cream, and acetaminophen are potential alternatives to NSAIDs therapy for chronic pain [24-25]. The fifth most commonly found PIMs and PGx with incidence was first generation anticholinergics Trihexyphenidyl (THP) 13.8%. Increased tremors, dryness of mouth and constipation were the most commonly observed side effects. Beers Criteria does not recommend it use for prevention of extrapyramidal symptoms with antipsychotics. For Parkinson disease levodopa with carbidopa can be used as alternative [26]. Sixth most commonly used PIMs and PGx with incidence was glimepiride 10.7%. Prolonged hypoglycaemia was the most commonly observed side effect with it. Repaglinide, dipeptidyl peptidase 4 (DPP-4) inhibitors, or insulin may be used as initial therapy include [27]. It's worth recommending, exercise and diet modifications are important for properly managing diabetes in older patients. Seventh most commonly prescribed PIMS with incidence was non-benzodiazepines (zolpidem) 7.60%. According to American Geriatric society, hypnotics are known to increase the risk of cognitive impairment, delirium and fractures. Serotonin-norepinephrine reuptake inhibitors and buspirone can be used as an alternative, for patient with anxiety, except with high risk of fall [28]. Lastly acetylsalicylic acid was the eight most commonly prescribed PIMs. Bleeding and peptic ulcers were the most commonly observed ADRs. Beers Criteria recommended using it with caution. Alternatively, nutritional interventions such as the use of fish oils rich in eicosatetraenoic acid should be considered, which has been shown to benefit patients with high risk of cardiovascular events in a long-term study [28] In our study, the use of PGx drugs was high (18.2%). which was mainly due to frequent use of PPIs, NSAIDs and anticholinergics in our studied populace. Similar results reported by Netherland, Denmark, United States, and Rhineland where 20%-30% of the total drug used was PGx [15-18]. There will be a potential benefit of pre-emptive pharmacogenetic genotyping especially of *CYP2C19* and *CYP2D6* as this polymorphism mainly influences the metabolism of over-the-counter painkillers and PPIs used widely without physician consultation. This will reduce potential ADRs and increase beneficial drug outcomes.

## Strengths and Limitations

To the best of our knowledge there are no published researches that evaluate the prevalence of PIMs and PGx in Indian population. The strength of our study is that we used interview-based medication data (including OTC drugs) which likely reflects actual medicines used. Our is single center study so result cannot be generalized to entire population. This study exclusively included only the first & second-class drugs of Beers Criteria.

## Conclusion

The results of this study identify high uses of OTC and prevalence of polypharmacy in elderly patients which make them more prone for exposure to PIMs and PGx drugs. The study identified the most common PIMs and PGx drugs among the elderly patients admitted to the largest tertiary care hospital with intent to encourage prescriber to use the 2019 Beers criteria and possible alternatives to PIMs and PGx drugs. The findings highlight the need for more efforts to develop awareness and action plans to concordance to Beers Criteria among healthcare providers.

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