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## EVALUATION OF APPROPRIATENESS OF PRESCRIBING IN GERIATRIC PATIENTS: A COMPARISON OF 2012 BEERS CRITERIA AND STOPP/START CRITERIA

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## ABSTRACT

**Background**: Inappropriate prescriptions are particularly more prevalent in older patients and are often associated with adverse drug events, hospitalization, and wasteful utilization of resources. Different screening tools have been prepared for the assessment of appropriateness of prescription. **Objectives:** The main objectives of this study were to identify and compare PIMs using Beers and STOPP/START criteria. The START criteria were applied to detect potential prescribing omission in elderly patients and the STOPP and Beers criteria measures potentially inappropriate prescriptions. **Materials and methods:** A prospective observational study was carried out for a period of 6 months from February 2015 to July 2015 by assessing the case files of 260 patients whose age is greater than 65 years admitted to the various departments in the hospital. The prescription of patients were analyzed and evaluated using various criteria. **Results:** The prevalence of PIM among elderly patients in our study was comparable to other reports (22–41.8%). The grand total of PIPs according to STOPP-START criteria were 61.5%, 58.2% in first and second phase respectively. Beers criteria detected 38.5% and 41.8% of PIPs respectively in both phases. The STOPP-START criteria showed higher PIMs detection capability than Beers criteria. This study confirms the high prevalence of PIMs among older adults comparing prior studies.

KEYWORDS: Geriatric, Inappropriate prescription, Stopp/Start, Beers criteria.

## INTRODUCTION

The elderly are the segment of society, most exposed to medication. Inappropriate Medication Use by elderly people is a public health problem associated with adverse effects on health.<sup>[1]</sup> Inappropriate prescribing in older people can result in multiplied morbidity, adverse drug events, hospitalizations and mortality.<sup>[2]</sup> Optimization of drug prescribing in older populations is a priority due to the significant clinical and economic costs of drug related illness. Appropriateness of prescribing in older people can be assessed by process (i.e. what providers do) or outcome measures (i.e. patient outcomes) which are implicit or explicit.<sup>[3]</sup> The best known and most often used criterion-based instrument, the Beers criteria, has been well studied with respect to its capacity to predict mortality, use of health-care services, ADEs and quality of life. The Screening Tool of Older Persons' Prescriptions (STOPP) and the Screening Tool to Alert doctors to Right Treatment (START) criteria are two relatively new criterion-based instruments. STOPP

measures potentially inappropriate medicines (PIMs) and START potential prescribing omissions (PPOs).<sup>[4]</sup>

The Beers criterion was named after the late Dr. Mark Beers and was first published in 1991 and subsequently modified in 1997, 2003 and in 2012. [5] In 2012, the Society American Geriatrics (AGS) and an interdisciplinary panel of experts in geriatric care and pharmacotherapy reach consensus on the 2012 AGS Beers Criteria. Fifty-three medications or medication classes encompass the final updated criteria, which are divided into three categories: Potentially inappropriate medications or classes to avoid in older adults, potentially inappropriate medications or classes to avoid in older adults with certain diseases, and syndromes that the drugs listed can exacerbate, and medications to be used with caution in older adults.<sup>[6]</sup> The Beers list of criteria poses some serious problems and doubts have been raised about its use in geriatric pharmacotherapy; new criteria have been defined and validated for the identification of inappropriate drugs for elder people.<sup>[7]</sup>

STOPP consists of 65 commonly encountered instances of potentially inappropriate prescribing in older people, including drug-disease interactions, irrational prescribing and drugs that are known to increase risks (e.g. fall, cognitive decline) for the elderly. The criteria identify Potentially Inappropriate Medications (PIMs). START deals with the problem of under prescribing, i.e. failure to prescribe drugs that are indicated, and consists of a list of 22 specific, evidence-based prescribing indicators that each detects Potential Prescription Omissions (PPOs). Both STOPP and START are arranged according to relevant physiological systems for ease of use and each PIM and PPO generates one point; i.e. the scoring is not weighted.<sup>[4]</sup>

Most of the previous studies concluded that potentially inappropriate prescribing, as identified by the Beers and STOPP/START criteria, is highly prevalent among hospitalized older patients. Majority of study results concluded that STOPP/START criteria showed higher PIM detection capability than Beers criteria. At the same time study by Bradley C. Martin et al concluded that the 2012 Beers had the highest sensitivity and the lowest specificity while STOPP criteria had the lowest sensitivity but the highest specificity and with STOPP slightly outperforming Beers. A review article by MandaviKashyap et al stated that none of the tools in its original contour is applicable to any country. Ubeda A et al evaluated that the unnecessary drug duplication is one of the problems frequently detected in elderly patients with polypharmacy, together with incorrect dose and therapy duration.

The literature related to the use of 2012 Beers criteria and STOPP/START criteria from India is scarce. Hence, this study was undertaken at a tertiary care hospital to identify PIMs using 2012 Beers and STOPP/START criteria. The primary objectives of the study were to Compare 2012 Beers criteria and STOPP/START criteria in terms of determining inappropriate prescriptions in elderly and providing interventions for improving geriatric care. Study of morbidity and drug use pattern in the elderly, Study the association of various patients attributes with PIPs, Determine the relationship between the number of prescribed drugs and PIPs; and to highlight those drugs that frequently contribute to most PIPs were the secondary objectives of the study.

## MATERIALS AND METHODS

A prospective observational study was conducted over a period of six months from February, 2015 to July, 2015 among geriatric inpatients admitted to various departments in a tertiary care hospital. The study was approved by the ethics committee of the hospital (IEC/ASH/2015/PD/18). The estimated sample size for phase 1 and phase 2 was found to be 81 using a significance level of 0.05 and 95% power. Based on the inclusion and exclusion criteria of the protocol approved by the IEC, 100 patients belonging to the age greater than 65 years of both sex were selected and enrolled for

the first phase and 160 patients were included in the second phase of this cross-sectional study. The participants of this study were a convenient sample of inpatient medical records admitted to various departments with an acute illness or an exacerbation of a chronic condition who signed the informed consent. Patients in casualty and ventilator, Patients receiving palliative and hospice care as suggested by various criteria and Prescriptions containing incomplete information are excluded from the study.

A specially designed data collection form was used for collecting the patient data. It contained the details of patient's demographics, presenting complaints, co morbidities, duration of diseases, past medical and medication history, family history, social status, occupation, results of all laboratory tests done, vital parameters, medication chart, discharge medications and all the relevant things which are necessary for the study. The study was conducted in the inpatient department of medicine, General nephrology, pulmonology, gastroenterology, neurology and cardiology departments of the hospital. All the relevant information were collected by interviewing the patients and patient care givers and also from case files and prescriptions.

Collected data from 100 patients during first phase were analyzed using 2012 Beers criteria and STOPP/START criteria. Drugs prescribed among the study population were compared with the drugs included in the 2012 Beers and STOPP/START criteria for a period of two months. Inappropriate medications were reported to the clinicians after phase one analysis by providing them with a newsletter along with the criteria and their feedback was collected verbally. A second phase of the study was carried out to assess the acceptance of criteria after obtaining the feedback from the physicians using 160 patients for a period of four months.

Data entry and statistical analysis were performed using IBM Statistical Package for Social Science version 20 and latest ARE software available. Data collected from 260 subjects were analyzed using appropriate statistical tools. The tests used were independent sample t-test and chi-square test. Results were presented in percentages.

#### RESULTS

#### **Demographic characteristics**

Prescription data were collected from 100 inpatients in phase one and 160 inpatients in phase two for analysis. As shown in table 1, gender -wise distribution showed that hospitalized male patients received more number of medications. The mean age of the participants was 72.05 (SD=6.333) years during first phase and 72.38 (SD=6.774) years during second phase. The patients belonging to the age group of 65-74 years were more in number. The average number of drugs prescribed per patient in the study population was 11.36 (SD=4.923) during first phase, an average of 11.05 (SD=4.572) during second phase. Most of the cases were collected

from general medicine department during both the phases (34.0% and 38.1%). The most commonly used drugs were cardiovascular system drugs and the prevalence of patients using proton pump inhibitors was found to be greater. The major systems affected most commonly during the first phase of study were cardiovascular (33.8%), endocrine (27.9%), and neurology (10%) and the systems affected during the second phase of the study included the Cardiovascular (33.3%), endocrine (26%) and respiratory (13.2%).

#### Table-1.

characteristics	Phase one (Percentage)	Phase two (Percentage)		
Gender				
male	61	63.75		
female	39	6.25		
Age				
distribution				
65-74	67	65.625		
75-84	30	28.75		
> 84	3	5.625		
Number of drugs per prescription				
<5	9	3.1		
5-9	34	41.9		
>9	57	55		

Departmentwise distribution		
General medicine	34.0	38.1
Nephrology	12.0	13.0
Pulmonology	2.0	12.5
Cardiology	18.0	11.9
Gastroenterology	17.0	7.5
Neurology	17.0	16.9
Duration of hospital stay		
Two	2	8
Three	17	15.6
Four	24	15
Five	21	16.9
Six	13	19.4
Seven	5	6.3
>seven	18	18.8
Morbidity pattern		
Cardiovascular disorders	33.8	33.3
Endocrinal disorders	27.9	26.0
Respiratory	6.5	13.2
Gastrointestinal	8.9	3
Neurological	10	10.4
Renal	7.93	11
Fall / fracture	0	0.3
Miscellaneous	4.97	2.8

### **Inappropriate prescriptions**

The percentage of inappropriate prescriptions during the first and the second phase was found to be 77% and 75% respectively. The grand total of PIPs according to STOPP-START criteria were 61.5%, 58.2% in first and second phase respectively. The percentage of PIPs obtained using Beers criteria were 38.5% and 41.8% for the first and the second phase respectively. The most commonly occurring IP using STOPP criteria was found to be the use of loop diuretic as first line monotherapy for hypertension during both first (14.6%) and second (11.4%) phase as shown in table 2. The most commonly occurring IP using START criteria was the omission of Metformin with type two diabetes in both phase one (28.0%) and in the phase two (21.2%) as shown in table 3. According to Beers, independent of diagnosis, the most frequently inappropriate drug use in both phase was sliding scale insulin use (28.5&29%).Considering diagnosis, the most widely prescribed contraindicated drug was olanzapine (antipsychotic) in patients with dementia (4.3%) in first phase and use of NSAID in CKD stage IV and V (3.2%) in second phase. Drugs to be used with caution were not prescribed in phase 1(0%)and 9.7% of Quetiapine use (atypical antipsychotics) was seen in second phase as shown in table 4.

Stopp Criteria	Phase 1 (number/percentage)	Phase 2 (number/percentage)
Loop diuretic for dependent ankle oedema only	3 (6.1%)	8(9.2%)
Loop diuretic as first-line monotherapy for hypertension	7 (14.6%)	10 (11.4%)
Aspirin at dose > 150 mg day	4 (8.2%)	8 (9.2%)
Long-term neuroleptics as long-term hypnotics (quetiapine)	2 (4.1%)	9 (10.3%)
NSAID with chronic renal failure	0(0%)	5 (5.7%)
NSAID (acetaminophen) with moderate-severe hypertension	5 (10.2%)	5 (5.7%)
NSAID with heart failure	3 (6.1%)	4 (4.6%)
Glibenclamide with type 2 DM	2 (4.1%)	6 (6.8%)
Beta-blockers in those with DM and frequent hypoglycaemic episodes	3 (6.1%)	3 (3.4%)
Duplicate Drug Classes	3 (6.1%)	0(0%)

## Table 2: Most Commonly Detected Inappropriate Prescriptions Using Stopp Criteria.

Table 3: Most Commonly Detected Inappropriate Prescriptions Using Start Criteria.

Start criteria	Phase 1 Number/Percentage	Phase 2 Number/Percentage
Aspirin or clopidogrel with a history of atherosclerotic coronary, cerebral or peripheral vascular disease in patients with sinus rhythm	3(4.9%)	7(8.2%)
Statin therapy with a history of coronary, cerebral or peripheral vascular disease, where functional status remains independent for activities of daily living and life expectancy is $> 5$ years	3(4.9%)	31 (36.2%)
ACE inhibitor with chronic heart failure	6(9.8%)	1(1.2%)
Metformin with type two diabetes	17 (28.0%)	18 (21.2%)
ACE inhibitor or ARB in diabetes with nephropathy	7(11.5%)	6 (7.1%)
Antiplatelet therapy in diabetes mellitus with co-existing major cardiovascular risk factor	7(11.5%)	4 (4.7%)
Statin therapy in diabetes mellitus if co-existing major cardiovascular risk factors present	10(16.4%)	10 (11.8%)

#### Table 4: Most Commonly Detected Inappropriate Prescriptions Using Beers Criteria.

Beers Criteria	Phase 1 (Number/Percentage)	Phase 2 (Number/Percentage)
Insulin, sliding scale	19 (28.5%)	36 (29%)
Alprazolam (short acting benzodiazepine)	3 (4.3%)	8 (6.5%)
Prazosin ( alpha 1 blocker)	3 (4.3%)	8 (6.5%)
Nifedipine immediate release	4 (5.8%)	4 (3.2%)
Clonidine ( alpha agonist)	4 (5.8%)	6 (4.8%)
Antipsychotics, first and second generation	6 (8.7%)	
Amiodarone (Antiarrhythmic)		8 (6.5%)

### **Predictors of PIPs**

A statistically significant positive correlation was found between the number of medicine prescribed, number of hospital days and the number of PIM calculated using STOPP/START criteria and Beers criteria. This relation was not found with age and gender.

#### Comparison between stopp/start and beers criteria

The start criteria were formulated to be used in tandem with STOPP to provide a more complete assessment of PIPs. The grand total of PIPs according to STOPPSTART criteria were 61.5%, 58.2% in first and second phase respectively. Beers criteria detected 38.5% and 41.8% of PIPs respectively in both phases. The

STOPP-START criteria detected a larger number of patients with any PIM than the Beers criteria; (p=0.000). The rate of PIP detected varied significantly between the two criteria with STOPP/START criteria being able to detect more PIPs than Beers criteria (p < 0.05).

#### Comparison between two phases

There was no statistically significant difference between two phases. The result shows that there was no significant reduction in PIM after intervention.

#### Sensitivity and specificity

Beers criteria show comparatively higher sensitivity than other two criteria. 2012 Beers had the highest sensitivity (0.49218) compared to others. There was no significant difference between specificity of the three criteria.

## DISCUSSION

Inappropriate medication use is an issue of health care quality in geriatric population. Prevalence of inappropriate medication use is high in general, but is variable in different parts of the world. The results of the study indicate a substantial rate of PIM and PPO using BEERS and STOPP/START criteria. The prevalence of PIM among elderly patients in our study was comparable to other reports (22–41.8%).<sup>[8,9,10]</sup>

Grand total of PIPs according to STOPP-START criteria were 61.5%, 58.2% in first and second phase respectively. Loop diuretic as first-line monotherapy for hypertension accounts for 14.6% of the PIMs detected by STOPP criteria in first phase and 11.4% in second phase. The remaining PIMs associated with STOPP criteria includes Loop diuretic use only for dependent ankle edema (phase 1 - 6.1% and phase 2 - 9.2%), Aspirin at dose > 150 mg/day (phase 1 - 8.2% and phase 2- 9.2%), Long-term neuroleptic as long-term hypnotics (phase 1 -4.1% and phase 2-10.3%). NSAID with moderate-severe hypertension (phase 1- 20.4% and phase 2- 9.1%), NSAID with heart failure(phase 1-6.1% and phase 2-4.6%), Beta-blockers in those with DM and frequent hypoglycemic episodes(phase 1- 6.1% and phase 2-3.4%) and duplication of therapy(phase 1-6.1%). Ubeda A et al evaluated that the unnecessary drug duplication is one of the problems frequently detected in elderly patients with polypharmacy, together with incorrect dose and therapy duration.<sup>[8]</sup>

The majority of omissions with START criteria includes Statin therapy with a history of coronary, cerebral or peripheral vascular disease, where functional status remains independent for activities of daily living and life expectancy is > 5 years (phase 1- 4.9% and phase 2-36.2%), Metformin with type two diabetes (phase 1-28.0% and phase 2- 21.2%), Statin therapy in diabetes mellitus if co-existing major cardiovascular risk factors present (phase 1-16.4% and phase 2- 11.8%), ACE inhibitor or ARB in diabetes with nephropathy (phase 1-11.5% and phase 2- 7.1%), similar to other underutilization studies.<sup>[5]</sup> Regarding cardiovascular omissions, doubts about the efficacy of statins in very elderly patients can be a reason for the non-prescription of these drugs. However, low dose aspirin in secondary prevention morbidity and mortality has evidenced benefits.<sup>[8]</sup> Several studies have reported a link between an underuse of cardiovascular medicines and adverse health outcomes.<sup>[8,11]</sup> In this study, we found a positive relationship between the number of medicines and occurrence of potential omissions.

The Start Tools, used together with STOPP criteria, enabled a more complete assessment of potential inappropriate prescribing in older people.<sup>[10]</sup> These findings support our contention that STOPP and START

criteria should be used in tandem on the basis that inclusion of inappropriate medicines and omission of essential medicines are closely and inextricably linked problems in geriatric pharmacotherapy.<sup>[9]</sup>

This study obtained a prevalence of 38.5% PIMs in patients with the Beers criteria in phase 1 and 41.8% in phase 2. Most commonly prescribed PIMs in the study site were found to be insulin sliding scale, 28.5% in phase 1 and 29% in phase 2. It was followed by benzodiazepines and Prazosin at a rate of 4.3% in phase 1 and 6.5% in phase 2.Concerns over the suitability of using BEERS criteria outside United States are reenforced by the present study. BEERS criteria proved more sensitive (0.49218) for the detection of PIMs than STOPP/START criteria, and there is no significant difference in specificity (0.9) on detecting errors for the three screening tools. The STOPP-START criteria detected a larger number of patients with any PIM (61.5% &58.2%) than the Beers criteria (38.5% & 41.8%); (p=0.000). The rate of PIP detected varied significantly between the two criteria, STOPP/START criteria being able to detect more PIPs than Beers criteria (p < 0.05). Nineteen instances of PIP and 21 cases of PPO listed in STOPP/START criteria are not mentioned in Beers' criteria which include omission of drugs (PPO), excessive duration and dose of proton pump inhibitors, beta-blockers with DM and episode of hypoglycemia, loperamide for unknown cause of diarrhoea, systemic corticosteroids instead of inhaled corticosteroids in chronic obstructive pulmonary disease, use of opioids, benzodiazepines. first generation antihistamines. vasodilators in patients with history of falling, and duplicate drug class prescriptions. All of these add unnecessarily to the cost and complexity of drug regimens for older people without providing additional therapeutic benefit.<sup>[9]</sup> 67 instances of these (PIP +PPO) were identified in the present study. Although STOPP criteria are fundamentally different from Beers' criteria and therefore not directly comparable, each of the prevalence studies documented prevalence rates of PIMs using both sets of criteria.

The study revealed a typical morbidity pattern in our hospital of which the most common cardiovascular and endocrine disorder was hypertension and diabetes mellitus respectively. Comorbid hypertension and DM were more likely to be associated with complications resulting in hospitalizations among our study population. The association with multimorbidity has also been described in other studies.<sup>[9,10]</sup> In many studies it was shown that polypharmacy and increasing age were important risk factors for IP. This study obtained similar results using STOPP/START and BEERS criteria where the most common inappropriate prescriptions were found in the age group 65-74 years and in patients receiving multiple (>9) drug prescriptions. Karandikar Yet al found that polypharmacy was the most significant predictor of PIM use. There was no statistically significant association when prevalence of PIM was

correlated with variables like age, gender, duration of hospital stay, and associated comorbidities in a study conducted by Taufik G. Momin et al.<sup>[11]</sup> In contrast, reports from our study sample showed an association between polypharmacy and duration of hospital stay using the three instruments. There was no statistically significant difference between two phases (STOPP-P value; 0.6008, BEERS-P value; 0.4684 and START-P value; 0.4826).

The study results were reported to the clinicians and junior practitioners of various departments in our hospital. Most of them were unaware of such screening tools and they accepted that many of the inappropriate prescriptions were clinically significant and measures should be adopted to minimize them. Their valuable suggestions and feedback on the current prescribing practice were collected and documented. The results of this study reflect the need to update clinicians on the screening tools guiding appropriate prescribing in elderly.

This study has certain limitations like insufficient follow up of the patients studied which caused difficulty in finding out the adverse drug events. The screening tools being used here were developed in Europe and America, prevalence of IPs defined by these criteria may differ from that in India because of differences in clinical practices and patient characteristics. No screening tool is universally accepted. This suggests the need for the development of such validated screening tools in India considering the clinical guidelines and population characteristics of India. The criteria need regular updating in line with emerging evidence.

Using these tools, pharmacists can alert physicians to consider whether medication is a possible cause of adverse health outcomes in older people. The three instruments used in this study all focus on different aspects of appropriate prescribing including both underand over- prescribing.

#### CONCLUSION

Prevalence of Polypharmacy is high, that is considered the most important predictive factor of PIM which is usually unavoidable in the elderly. Thus, there is an evident need to implement strategies for improving geriatric prescription and clinical documentation. Pharmacists assume the role of being co-responsible for geriatric drug therapy, as well as propagators of global knowledge in this area. The study obtained a significant amount of inappropriate prescriptions with each tools used. Further updates to each criterion will be required to develop a better predictive tool. With different screening tools available, several fundamental issues still remain unobserved with respect to different clinical setting of each nation. There is no single, universally-accepted tool for defining inappropriate prescribing patterns among elderly and hence it is not wise to conclude that any criterion is perfectly suitable in its original contour. Therefore, there is a need for modification of existing

screening tools that matches with real time practice for proper assessment of the level of inappropriate prescribing in elderly.

#### Abbreviations

PIMs-potentially inappropriate medicines, STOPP-START-, IPs-inappropriate prescriptions, ADEsAGR-

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