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Evaluation of potentially inappropriate medications among hospitalized geriatric patients in tertiary care referral hospital using STOPP/START criteria

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ABSTRACT

Objectives: To evaluate potentially inappropriate medications (PIM) and potential prescribing omission (PPO) among hospitalized geriatric patients using STOPP and START criteria respectively, to study morbidity and drug use pattern and to collect feedback from the physicians to improve rational drug therapy.
Method: OLOGY: A prospective observational study was carried out for a period of 12 months among patients aged ≥65 years. The study was conducted in three phases. During first phase, the patient's data were recorded in data collection form and analyzed using STOPP/START criteria. During second phase, the results of first phase were introduced to the physicians along with the criteria and feedback form. During third phase, the prescriptions were re-assessed to determine the acceptance of criteria.
Results: A total of 210 patients were included in the study during the entire study period with 108 patients in first phase and 102 patients in third phase. The prevalence of PIM detected using STOPP criteria during first and third phase were 43.5% and 40.2% respectively. Similarly the prevalence of PPO detected using START criteria during first and third phase were 52.8% and 53.9% respectively.
Conclusion: The study shows that there is high prevalence of PIM and PPO among hospitalized geriatric patients which are unacceptable and there should be consensus for considering such evidence based screening tools while prescribing drugs to elder peoples.

1. Introduction

Elder peoples are the part of healthcare society by which they are mostly exposed to several medications. Several characteristics of ageing and geriatric medicine affect prescribing for these people and render the selection of appropriate pharmacotherapy a challenging complex process.[1] Older people may have an increased risk of multiple co-morbidities and are more likely to be prescribed with several medications concomitantly, which increases the risk of adverse drug events (ADE).[2]

Use of multiple medications encompasses risk and benefits; for this reason appropriateness of drugs prescription and use are important indicators for assessing the quality of health for elderly.[4] Interpersonal variability in patient health, disability and disease usually increases considerably with ageing. It is a real challenge to administer proper therapy in elderly patients where there is significant potential for developing side-effects due to chronic use of drugs that can elicit strong systemic interactions.[3] Potentially inappropriate prescribing (PIP) is used to delineate variety of substandard prescribing practices that may lead to adverse drug events where much safer, cost effective alternative is available to treat the same condition. There is an increasing focus on potentially inappropriate medication use as a possible cause of adverse health outcomes in older populations and a number of screening tools are developed to measure and assist prescribers in detecting potentially inappropriate prescribing.[6] Use of multiple drugs holds the risk and benefit. So, measurement of appropriateness of prescribing and use of drugs are important indicators of assessing the quality of health in elderly.Inappropriate prescribing can cause substantial morbidity and represents a clinical and economic burden to patient and society.[1] Therefor inappropriate medication use in elderly thus becomes an important health issue globally. Changing prescribing behaviour such as PIP is a complex and challenging task. Several strategies have been used to alter prescribing practices with variable results, with no one interventional strategy proving to be consistently effective.[7] Efficient methodologies are developed for measuring the appropriateness of prescribing in elderly patients and several instrument based and

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criterion based tools have been developed for this reason. One of the most often used criterion based tool is STOPP/START criteria. The Screening Tool of Older People's potentially inappropriate Prescriptions (STOPP) and the Screening Tool to Alert doctors to Right Treatment (START) are two criterion based instruments. STOPP measures Potential prescribing commission while START measures potential prescribing omission.

The Screening Tool of Older Persons Prescriptions (STOPP) and the Screening Tool to Alert doctors to Right Treatment (START) criteria are evidence based set of criteria which were developed in Ireland using a modified Delphi process that involved 18 experts from geriatric pharmacotherapy from across the United Kingdom and Ireland.[8]

STOPP consist of 65 criteria that can be used systematically to identify potentially inappropriate medications (PIM) and START consist of 22 criteria, identify potential prescribing omissions (PPOs). The STOPP/START criteria offer advantages over beers criteria and other screening tools. The criteria are organized according to physiological systems to which each relates, thereby enhancing its usability.[8]

The aim of study is to evaluate potentially inappropriate medications (PIM) and Potential prescribing omission (PPO) among hospitalized geriatric patients using STOPP (The Screening Tool of Older Persons Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment) criteria respectively. The primary objective of this study is to evaluate the potentially inappropriate medications and to provide interventions for improving geriatric care and to highlight those drug classes which frequently contribute to most PIP.

2. Methodology

A Prospective observational study was conducted for a period of one year from September 2016 to August 2017 in three phases with an aim of evaluation of potentially inappropriate medications (PIM) and potential prescribing omissions (PPO) among hospitalized geriatric patients aged ≥65 years from various departments of tertiary care referral hospital situated at south India. All patients meeting the inclusion criteria were selected for the study. The total number of patients data collected during the entire study period was 210 cases. First phase was performed for a period of 4 months with 108 cases and third phase for a same period of 4 months with 102 cases. This study was approved by ethical committee of the institution and an official consent was also given for the purpose of performing the study.

The inclusion criteria's are all hospitalized geriatric inpatients ≥65 year age, both male and female patients, patients who were co-operative, inpatients admitted to various departments. The exclusion criteria's are patients in casualty and ventilator, prescriptions containing incomplete information, patients who were not co-operative, patients scheduled for short duration of hospitalisation (less than 24 h) or day care.

A specially designed data collection form was used to record and collect patient data. All relevant data for the study were collected from case file, prescription, interviewing patient for medical history, relevant laboratory reports, medication chart, vital parameters, medical diagnosis etc. are extracted to the specially designed data collection form.

The study subjects were selected on the strict basis of above mentioned inclusion exclusion criteria and the study was performed in 3 phases. During phase I, all relevant information collected from patient's case file, medication chart, interviewing patient care givers were collected and it was recorded in a predesigned data collection book. The collected data were analyzed and evaluated using STOPP/START criteria to detect potential inappropriate medications and potential prescribing omissions. The duration of this phase was 4 months. Duration phase II was 2 months. During the phase, inappropriate medications detected during first phase were reported to physicians of various departments in form of a newsletter along with STOPP/START criteria and their valuable feedback to improve geriatric prescribing practice were collected and documented. Potential measures to reduce inappropriate medication use among hospitalized geriatric patients were discussed with physicians. Phase III was the final phase where audit was re-performed using STOPP/START criteria for a period of 4 months to assess the reduction of PIM and acceptance of the criteria among physicians. The re-audit was done with different cases yet in compliance with the inclusion criteria and so is the total number of cases summed to 210.

Data was entered into Microsoft excel and the recorded data were statistically analyzed using statistical package for social sciences (SPSS) software version 21.0 for WINDOWS. Different tools were used to perform statistical analysis of data. Continues data were summarized using mean and standard deviation (SD), categorical variables were summarized using frequency with percentage and analyzed using Chi-square test. Mann Whitney *U* test were performed to compare potential inappropriateness between two phases.

3. ResultS

A total of 210 patients were randomly selected from the respective departments during the study period of 12 months and 108 patients were included in first phase and 102 patients in third phase. The baseline characteristics of study population were shown in Table 1. The patients are categorized to 3 groups based on age; 65–74, 75–84, ≥85. The mean age of patient population during Phase 1 was 72.59 ± 6.37 years and phase 3 was 71.99 ± 6.30 years. The patients belongs to age group 65–74 was more in number with 63.0% and 69.6% during phase 1 and Phase 3 respectively. The number of drugs prescribed per patient was categorized to three groups; < 5 drugs, 5 to 9 drugs, ≥10 drugs. It was found that average number of drugs prescribed for total study population was 9.43. The average number of drugs prescribed for first and third phase was 9.19 ± 2.89 and 8.94 ± 2.90respectively. Study population containing number of drugs between 5 and 9 (Polypharmacy) was more in number 56.5% (n = 61) and 63.7% (n = 65) during first and third phase respectively [Table 1].

The most commonly observed morbidity among the total study population was hypertension with 67.6% and 71.6% during first and third phase respectively. Diabetes mellitus is the second leading chronic disease with 47.2% (n = 51) and 48.0% (n = 49) during first and third phase respectively [Fig. 1].The prevalence of PIM identified using STOPP Criteria was (47, 43.5%) and (41, 40.2%) during first and third phase respectively. Similarly PPO identified using START Criteria was (57, 52.8%) and (55, 53.9%) during first and third phase respectively. Table 2 describes about potential inappropriate prescribing using STOPP Criteria in total study population (n = 210), Potential inappropriate prescribing identified was 43.5% (n = 47) and 40.2%

Table 1
Baseline characteristics of study population.

Category	Phase 1	Phase 3	Total
	F	F	F
Age			
65–74	68	71	139
75–84	35	28	63
≥85	5	3	8
Gender			
Male	73	66	139
Female	35	36	71
No.of drugs			
< 5 drugs	5	4	9
5–9 drugs	61	65	126
≥10 drugs	42	33	75
Duration of hospital stay			
< 3 days	3	1	4
3–5 days	42	36	78
6–8 days	39	37	76
≥9 days	24	28	52

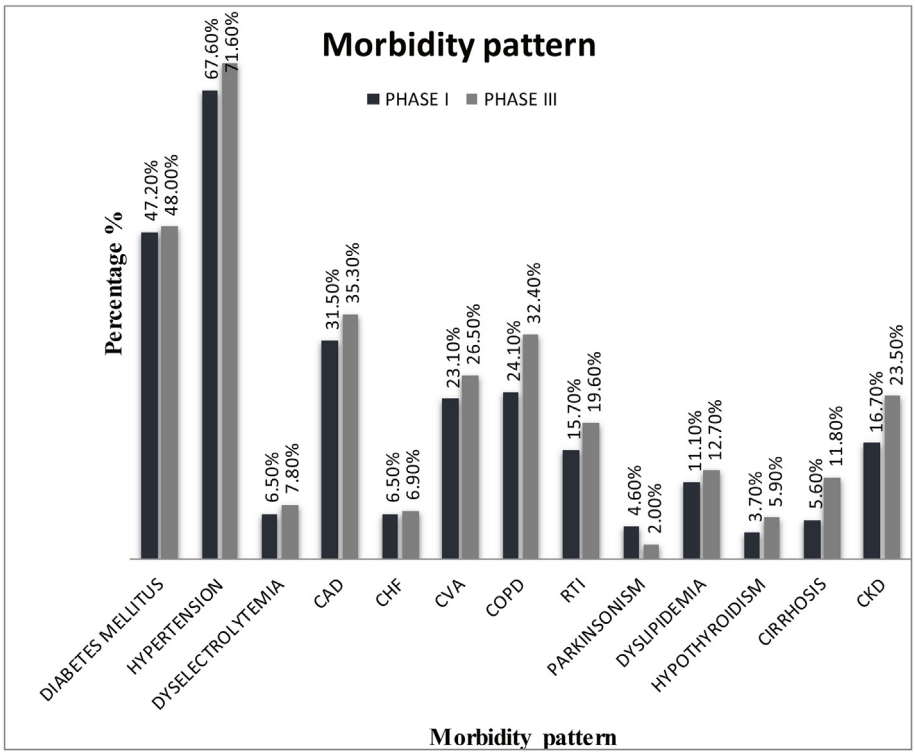

Fig. 1. Morbidity pattern of study population.

Table 2
Potentially inappropriate medications and Potential prescribing omission identified using STOPP and START criteria respectively.

Phases	STOPP Criteria			START Criteria		
	Yes	No	Total	Yes	No	Total
Phase 1						
F	47	61	108	57	51	108
PHASE 3						
F	41	61	102	55	47	102

Table 3
Comparison between two phases.

Comparison between two phases						
Criteria	Phases	No.	Mean rank	Mann whitney U	Z	P Value
STOPP	**I**	108	107.10	5335.0	0.444	0.657
	III	102	103.80			
START	**I**	108	104.24	5372.0	0.331	0.741
	III	102	106.83			

STOPP: p value > 0.05 (Not statistically significant).
START: p value > 0.05 (Not statistically significant).

(n = 41) during first and third phase respectively. A total of 41.9% (n = 88) potentially inappropriate prescribing was identified using STOPP Criteria during the entire study period. A total of 53.3% (n = 112) potential prescribing omissions were identified using START criteria during the entire study duration. Potential prescribing omission identified during first and third phase were 52.8% (n = 57) and 53.9% (n = 55) respectively. The comparative analysis of PIM detected using STOPP criteria during first and third phase of study was assessed using Mann Whitney *U* test (P-value: 0.657). A statistically significant reduction in PIM after intervention was not found (P > 0.05) between two phases. The comparative analysis of PPO detected using START criteria during first and third phase of study was assessed using Mann Whitney *U* test (P-value: 0.741). A statistically significant reduction in PPO after intervention was not found (P > 0.05) between two phases [Table 3].

Total instances of potentially inappropriate medications detected during the two phases of study are listed in Table 4. Total number of PIM instances detected using STOPP criteria during first and third phases were 69 and 62 respectively. Among them, the major PIM detected during first phase were NSAID's with moderate to severe hypertension (12, 17.4%), Neuroleptic drugs-prone to fall (8, 11.6%), Calcium channel blockers with chronic constipation (6, 8.7%), Aspirin at dose ≥ 150 mg (6, 8.7%), Duplication of drug class (5, 7.2%). The major potential inappropriateness detected during the third phase were NSAID's with moderate to severe hypertension (11, 17.8%), Neuroleptic drugs-prone to fall (10, 16.1%), Glibenclamide/Chlorpropamide in patients with type II diabetes mellitus (6, 9.7%), Duplication of drug

Table 4
Major Potentially inappropriate medications identified using STOPP criteria.

Stopp criteria		
Criteria	Phase I	Phase III
Cardiovascular system		
Calcium channel blockers with chronic constipation	6	3
Aspirin at dose > 150 mg/day	6	4
Musculoskeletal system		
NSAID with moderate-severe hypertension	12	
Urogenital system		
Antimuscarinic drugs with chronic constipation	1	0
Endocrine system		
Glibenclamide or chlorpropamide with type 2 DM	2	6
Drugs that adversely affect those prone to falls		
Benzodiazepines	3	2
Neuroleptic drugs	8	10
Duplicate drug class		
Any duplicate drug class prescription e.g. concurrent opiates, NSAID's SSRI's. loop diuretics, ACE inhibitors	5	4

Table 5
Major Potentially prescribing omission identified using STOPP criteria.

Start criteria		
Criteria	Phase I	Phase III
Cardiovascular system		
Antihypertensive therapy where systolic BP consistently > 160 mmHg	13	5
Statin therapy with a history of coronary, cerebral or peripheral vascular disease where functional status remains independent of activities of daily living and life expectancy is > 5 years	26	21
Endocrine system		
Metformin with type 2 diabetes ± metabolic syndrome (in the absence of renal impairment)	16	16
ACE inhibitor or ARB in diabetes with nephropathy i.e. proteinuria or micro albuminuria ± renal impairment	5	6
Antiplatelet therapy in diabetes mellitus with co-existing cardiovascular risk factors	10	6
Statin therapy in diabetes if co-existing major cardiovascular risk factors present	14	23

class (4, 6.5%).

Potential prescribing omissions identified using START criteria are listed in Table 5. The instance of PPO detected during phase one and three are 100 and 95 respectively. The major potential prescribing omissions identified during first phase were Statin therapy with history of coronary or cerebral or PVD (26, 26%), Metformin in patients with T2DM with or without metabolic syndrome (16, 16%), Statin therapy in DM if co-existing major cardiovascular risk present (14, 14%), lack of antihypertensive therapy were systolic blood pressure remains > 160 mmHg (13, 13.0%).

The major PPO detected during third phase was lack of statin therapy in diabetes if co-existing major cardiovascular risk present (23, 24.2%), lack of Statin therapy with a history of coronary, cerebral or peripheral vascular disease (21, 22.1%), lack of metformin in patients with T2DM with or without metabolic syndrome (16, 16.8%).Fig. 2 describes about the feedback collected from the physicians during second phase of study.

4. Discussions

Potentially inappropriate medication use is an important healthcare issue among geriatric population which deserves attention.[28] The prevalence of PIM among geriatrics is high in general, but variable at different parts of the world. Several criteria are developed globally to evaluate potential inappropriateness, but a gold standard criterion is no longer available.

The socio-demographic details of study population were slightly different from the previous studies. The mean age of patients included in the study was 72.59 ± 6.37 years and 71.99 ± 6.30 years during first and third phase respectively which was lower than that of study conducted by M S A Wahab et al.[29] and C-L liu et al.[28] The mean age found by M S A Wahab et al.[29] was 82.34 ± 7.3 years and C-L liu*et al*[28] was 79.2 ± 6.7 years. This observation may be due to lower life expectancy of people in developing countries like India. The result of the study showed predominance of male 66.2% over female 33.8% population, which was similar to the study conducted by H N Vishwas

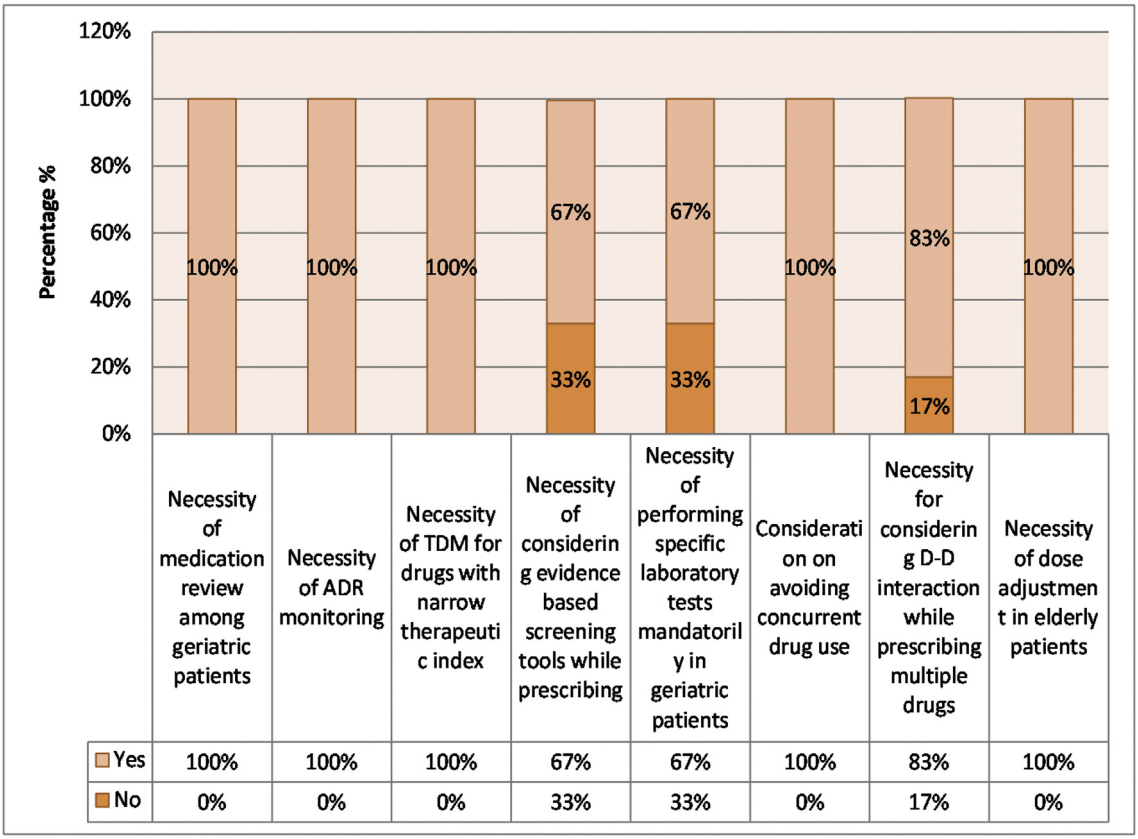

Fig. 2. Feedback from.

et al.[27] and Y S Karandikar et al..[23] H N Vishwas et al.[27] found (65%) male predominance over (35%) female and study conducted by Y S Karandikar et al.[23] found (61.7%) male dominance over (38.3%) female. The reason for male predominance over female among hospitalized elderly in India may be due to presence of more illness among male. The average number of drugs prescribed per patient was 9.19 ± 2.89 and 8.94 ± 2.90 during first and third phase respectively. Polypharmacy was detected in 96.1% of cases in the first phase and 95.7% of cases in the third phase. The percentage of polypharmacy is very when compared to that of Mukta N Chowta*et al*[33] and Y S Karandikar et al..[23] Mukta N Chowta et al.[33] detected (66.19%) patients and Y S Karandikar et al.[23] detected (56.0%) patients prescribed with polypharmacy. The implication of higher polypharmacy among geriatrics in our study setting may be due to more number of co-morbidities and multiple prescriber consulations. Most number of patients admitted for duration of hospital stay was within 3–5 days with 37.10% patients and 6–8 days was with 36.20% patients, whereas in the study conducted by NH Vishwas et al.[27] only 16.1% patients were admitted for a duration of 1–4 days and 66.1% patients were admitted for a duration of 5–9 days. The variation in the duration of hospital stay may be due to the difference in the study setting and disease conditions. The morbidity pattern shows that hypertension (67.5%-first phase, 71.6%-third phase) and diabetes mellitus (47.2%-first phase, 48%-third phase) were the major chronic diseases prevailing among geriatric population included in the study. These data complies with the study conducted by Mubrak N. Al ameri et al.,[34] were they also observed hypertension and diabetes as the major chronic diseases among the geriatrics. Co-existence of hypertension with diabetes mellitus were more likely to be associated with complications resulting in hospitalisation among our study subjects. The study conducted by Sandra V K et al.[2] describes about the association of comorbidities and PIM. It reflects that the leading chronic diseases among geriatric population are hypertension and diabetes mellitus.

The results of the study indicate a substantial rate of PIM and PPO detected using STOPP and START criteria respectively. Higher overall prevalence of PIM use was observed in the present study with 43.5% and 40.2% during first and third phase respectively compared with a study carried out by Y S Karandikar et al.[23] (19.8%) could be due to difference in study setting. On the contrary, the study conducted by krystina parker et al.[17] detected (63%) overall prevalence of PIM according to STOPP criteria, which was higher than PIM observed in the present study. The observed difference may be due to changes in disease characteristics and treatment guidelines.

The total number of PIM instances detected using STOPP criteria during first and third phases were 69 and 62 respectively. Among them the major potentially inappropriate medications identified were NSAID's in patients with moderate to severe hypertension (17.4%-first phase, 17.8%- third phase), Neuroleptic drugs – prone to fall (11.6%-first phase, 16.1%- third phase), Calcium channel blockers with chronic constipation (8.7%-first phase, 4.8%- third phase), Aspirin at dose ≥ 150 mg (8.7%-first phase, 6.5%- third phase), and duplication of drug class such as concurrent use of proton pump inhibitors (Pantoprazole and Rabeprazole together), two prokinetic drugs together (Itopride and Metoclopramide) etc. with (7.2%-first phase, 6.5%- third phase). The results of C. Ryan et al.[26] were similar to some extent and reported a high occurrence of NSAID's in patients with moderate to severe hypertension (11.3%) and duplication of therapy (8.4%), whereas Krystina parker*et al*[17] reported Calcium channel blockers with chronic constipation (14%) and Aspirin at dose ≥ 150 mg (8%) to be most frequent. The overall prevalence of PPO detected in the present study as per START criteria was 52.8% and 53.9% during first and third phase respectively was very high when compared with study carried out by C-L liu*et al*[28] (41.9%).

The total instances of PPO found during the study period were 100 and 95 during first and third phase respectively. The major PPO identified are lack of statin therapy with history of coronary or cerebral or PVD (26%-first phase, 22.1%-third phase), lack of metformin in patients with T2DM with or without metabolic syndrome (16%-first phase, 16.8%-third phase), Lack of statin therapy in DM if co-existing major cardiovascular risk present (14%-first phase, 24.2%-third phase), lack of antihypertensive therapy were systolic blood pressure remains > 160 mmHg (13%-first phase, 5.3%-third phase). Whereas the major PPO detected by C-L liu*et al*[28] was patients were having omission of statin in DM with CV risk (19.4%). Whether this may be associated due to inadequate awareness of prescribing statins or old age remains uncertain. In India, prescription of dyslipidaemic agents might be based on target lipid profile levels. Therefore, more investigations are needed to clarify the reason for omission of statin for diabetic patients with multiple cardiovascular risks.

During second phase, the results of PIM and PPO detected during first phase were compiled and reported in form of a newsletter to the physicians of concerned departments in which the study was conducted. Most of them were unaware about the screening tools to determine potential inappropriateness and most of the physicians accepted that many of the identified PIM and PPO are clinically significant. Their valuable suggestions to improve rational geriatric prescribing were collected and documented in a feedback form.A statistically significant reduction in PIM and PPO was not found between the two phases of study after intervention. There was no statistical significant difference found between the two phases of study with STOPP (p = 0.657), START (P = 0.74). The reason for absence of statistically significant reduction in PIM and PPO between two phases was due to fewer acceptances of the criteria among physicians. The overall study results indicate the urgent need of physicians to be updated on evidence based screening tools and necessity of medication review to provide rational prescribing of drugs in elderly. There are some limitations in the study like limited sample size selected, limited number of departments selected, insufficient follow-up on patients studied which made difficulty in finding adverse drug events, single centred nature of study, lack of patient related outcome. As the screening tool is developed in Europe, the prevalence of PIM detected may differ from India due to difference in patient characteristics and treatment guidelines.None of the screening tools are universally accepted. This study suggests the need for development and implementation of validated screening tools in India by considering population characteristics and treatment guidelines.

5. Conclusion

Elder people have substantial inter-individual variability in health, morbidity, disability and age related changes which make physicians difficult to generalize the prescriptions. The study shows that there is high prevalence of PIM and PPO detected using STOPP/START criteria among hospitalized geriatric patients aged above 65 years. This study also highlights about the most prevalent morbidity found among elderly were hypertension and diabetes mellitus. The most commonly used drug class among elderly were found to be anti-hypertensives and antibiotics.

This study suggests about the drugs which should be used with caution or drugs which need alternative to use. The class of drugs which usually contribute to most of PIM were NSAID's in patients with moderate to severe hypertension and PPO were lack of statin therapy with a history of coronary, cerebral or peripheral vascular disease. The valuable suggestions from physicians to improve rational geriatric prescribing were collected and documented in a feedback form. The prevalence of PIM and PPO detected among patients included in the third phase showed that a positive impact of pharmacist intervention in reduction of inappropriate prescribing was not found between the two phases.

As a healthcare professional; clinical pharmacist also has the key role to improve geriatric care, thereby providing rational drug therapy. Thus it can be concluded that the high prevalence of potential

inappropriate prescribing among elderly is not acceptable and there should be consensus for referring evidence based screening tools while prescribing drugs to elderly peoples to improve rational drug therapy.

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