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Original Research Article

Geriatric prescription analysis with respect to "STOPP" and "START" criteria: a descriptive study in the Indian scenario

Mangala B. Murthy*, Krishna Jagtap, Shreyas R. Burute, Sunita J. Ramanand, Shraddha M. Pore, Praveenkumar T. Patil

Department of Pharmacology, Government Medical College, Pandharpur road, Miraj, Maharashtra, India

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*Correspondence to: Dr. Mangala B Murthy, Email: mangala.bhaskar@ gmail.com

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ABSTRACT

Background: Patients; sixty-five years of age and above, are a special risk group as far as drug prescribing is concerned. Prescription irregularities in such patients may be hazardous. STOPP/START criteria are considered as the most up to-date set of explicit criteria for evaluating geriatric prescriptions. To analyse geriatric prescriptions in a tertiary care centre with respect to STOPP/START criteria and WHO core drug prescribing indicators so as to get an idea of pattern of drug prescription in geriatric patients as well as frequency of potentially inappropriate prescriptions. Descriptive cross-sectional study in a tertiary care hospital.

Methods: All inpatients aged 65 years and above who were prescribed at least one allopathic medication and consented to participate in the study were included and patients admitted for medical emergencies were excluded. Demographic data and details of drugs prescribed were collected from prescription chits and indoor case papers.

Results: There was a high frequency of polypharmacy, prescription of antimicrobials and injections. Proportion of patients receiving at least one potentially inappropriate medication (PIM) as per STOPP criteria was 21.01%. Proportion of patients subjected to at least one potential prescribing omission (PPO) as per START criteria was 33.33%. Proportion of patients exposed to potentially inappropriate drug prescriptions as a whole (PIPs=PIMs+PPOs) was 46.37%. Statistical analysis used as descriptive statistics like numbers and percentages were used for data analysis.

Conclusions: With regards to geriatric prescribing, adherence to WHO core prescribing indicators, prescription of drugs as per STOPP and START guidelines are indicative of scope for improvement.

Keywords: Polypharmacy, START criteria, STOPP criteria

INTRODUCTION

People above 65 years of age are commonly referred to as geriatric population and they would amount to 10.7% of total population of India by 2021. Challenges to the medical fraternity in treating geriatric patients arise from their frail and vulnerable body physique, physiological and pathological changes in their hepatic and renal function and multiple co-morbidities which makes them the highest consumers of prescribed drugs. These factors expose geriatric patients to potentially inappropriate prescriptions (PIP) defined as over use of drugs, irrational choice

leading to prescription of a potentially inappropriate medication (PIM) or under use of appropriate drugs leading to a potential prescribing omission(PPO). PIMs in turn predispose the elderly to a triad of adverse drug reactions, drug-drug and drug- disease interactions. while prescribing omissions (PPOs) fail to provide necessary protection against morbidity and mortality from certain diseases common in the elderly.

There are many criteria to evaluate rationality of drugs prescribed to geriatric patients. Beer's criteria, Phadke's criteria and Screening Tool of Older Person's potentially inappropriate Prescriptions (STOPP) and Screening Tool to Alert doctors to the Right Treatment (START) criteria are a few among the list. Beer's criteria, the most popular tool for studies on geriatric prescribing, has limitations like less importance being given to under use of drugs, drug interactions and therapeutic duplication.

On the other hand, STOPP comprises of 80 indicators pertaining primarily to important drug-drug and drug-disease interactions and therapeutic duplication. START incorporates 34 criterion based indicators of prescribing omissions. STOPP/START criteria are considered as the most up to-date set of explicit criteria for evaluating geriatric prescriptions based on drugs prescribed and disease present and require little clinical judgement, thus suitable for use by researchers, students and clinicians.

The present study was conducted to analyse geriatric prescriptions in a tertiary care centre with respect to STOPP/START criteria and WHO core drug prescribing indicators so as to get an idea of pattern of drug prescription in geriatric patients as well as frequency of potentially inappropriate prescriptions. The above information could be used as a baseline to take corrective measures if found necessary.

METHODS

Study design, place and duration of the study

This was a cross-sectional study of 3 months duration conducted in the inpatient departments of a tertiary care centre. All tenets of the Declaration of Helsinki were followed during the study. The study was approved by the institutional ethics committee and informed consent was sought from the patients before enrolment into the study.

Inclusion criteria

- Patients aged 65 years and above, of either sex, having a prescription for at least one drug prescribed by an allopathic doctor.
- Prescriptions given to inpatients of medicine, surgery, gynecology, ENT, ophthalmology and orthopedics were included in the study.

Exclusion criteria

- Patients admitted to ICU and patients on ventilators were excluded as in many of these patients, clinical judgment of an individual case may overrule guidelines.
- Patients not willing to participate in the study.

Sample size

Literature search revealed the frequency of potentially inappropriate prescriptions in geriatric age group to be 42%. Assuming this frequency and allowable error of 20%

of this frequency, a sample of 138 prescriptions were to be screened to achieve the study objectives.

Data collection

Data was collected from prescription chits, indoor case papers, and also by questioning the patient directly for clarifications wherever required. Pre-structured case record form was used to collect data. Data of demographic parameters like age, gender, was recorded along with disease parameters like diagnosis, concomitant diseases, drugs prescribed, dose of each drug, route of drug administration, frequency of administration of each drug and duration for which the drug was prescribed.

Analysis of prescriptions of enrolled patients was done as follows:

- Drugs prescribed were classified according to system to which the indication was related. (like H2 blockers under digestive system, antimicrobials were classified as chemotherapeutic agents in general).
- WHO drug prescribing indicators such as average number of drugs prescribed per prescription and percentage of prescriptions based on generic/brand names, proportion of prescriptions containing at least one antimicrobial, proportion of prescriptions containing injections and proportion of drugs prescribed from national list of essential medicines was calculated.
- STOPP criteria were applied for every drug of the prescription individually and marked as PIM whenever found. Proportion of patients receiving at least one PIM was calculated by dividing total number of prescriptions with at least one PIM by the total number of prescriptions analyzed, multiplied by 100.
- Similarly START criteria were applied to each prescription to look for omission errors. Proportion of patients subjected to PPOs was calculated by dividing the number of prescriptions with omission errors by total number of prescriptions analyzed, multiplied by 100.
- Proportion of patients exposed to potentially inappropriate prescription as a whole was calculated by adding the number of prescription with at least one PIPs due to either STOPP and/or START criteria and diving it by the total number of prescriptions analyzed multiplied by 100.
- To study the potential implications of the above potentially inappropriate prescriptions.

Statistical analysis as descriptive statistics like numbers and percentages were used for data analysis.

RESULTS

A total of 138 prescriptions were included in the study and the pre-calculated sample size was achieved. Geriatric patients whose prescriptions were studied ranged from 65 years to 95 years. The mean age of these patients was 71.72

years, 75 (54.34%) were males and 63 (45.65%) were females (Table 1).

Table 1: Demographic characteristics of patients to whom prescriptions under study were issued.

| Demographic parameter | Number of patients (%) N=138 |
|--------------------------|---------------------------------|
| Age in years | |
| Range | 65-95 years. |
| Mean age | 71.72 ± 6.80 years. |
| ≥ 65 years | 106 |
| ≥ 75 years | 22 |
| ≥ 85 years | 8 |
| ≥95 years | 2 |
| Total | 138 (100%) |
| Gender | |
| Males | 75 (54.34%) |
| Females | 63 (45.65%) |
| Total | 138 (100%) |

Total number of drugs prescribed to the patients in 138 prescriptions amounted to 958. Most commonly prescribed drugs were from cardiovascular system and chemotherapeutic agents (22% each). Others were drugs from gastrointestinal system, respiratory system, endocrine systemand multivitamins (Table 2).

Table 2: Distribution of drugs prescribed according to the organ system to which they belong.

| Organ system | Number (%) |
|-----------------------------------|--------------|
| Cardiovascular system | 217 (22.65%) |
| Antimicrobials | 213 (22.23) |
| Gastrointestinal system | 181 (18.89%) |
| Multivitamins | 93 (9.70%) |
| Respiratory system | 69 (7.20%) |
| Musculoskeletal system | 45 (4.69%) |
| Immunosuppressant | 41 (4.27%) |
| Endocrine and metabolic disorders | 25 (2.60%) |
| Iron preparations | 17 (1.77%) |
| Enzymes | 17 (1.77%) |
| Central nervous system | 16 (1.67%) |
| Genitourinary disorders | 8 (0.83%) |
| Others | 16 (1.67%) |
| Total | 958 |

Each prescription contained 6.94± 2.11 drugs on an average. Out of 958 drugs prescribed, very few drugs (ie. 261/958, 27.24%) were prescribed by generic name and as high as 72.75% were prescribed as brand name. 92.37% of the prescribed drugs belonged to NLEM. A high percentage of prescriptions contained at least one antimicrobial (82.60%) prescribed and 70.28% had at least one injection (Table 3).

Out of 138 prescriptions that were analyzed for prescribing errors in elderly as per both STOPP/START criteria,

46.37% of the prescriptions had at least one error either as per STOPP or START criteria. Considering STOP and START criteria separately, proportion of patients receiving prescriptions with at least one potentially inappropriate medication prescribed as per STOPP criteria was 21.01% while proportion of patients receiving a prescription with potential prescribing omission as per START criteria was 33.33% (Table 4).

Table 3: Analysis of prescriptions according to WHO core prescribing indicators.

| WHO core prescribing indicator | Number (%) | |
|--|--------------|--|
| Average number of drugs per prescription | 6.94 ± 2.11 | |
| Drugs prescribed by generic name | 261 (27.24%) | |
| Drugs prescribed by brand name | 697 (72.75%) | |
| Drugs prescribed from National list of essential medicines. (NLEM) | 885 (92.37%) | |
| Prescriptions with antimicrobials | 114 (82.60%) | |
| Prescriptions with injections | 97 (70.28%) | |

Table 4: Tally of potentially inappropriate prescriptions as per STOPP and START criteria.

| Prescription Characteristic | Number or percentage of prescriptions with the said characteristic n=138 |
|---|--|
| Number of prescriptions analyzed | 138 |
| Number of prescriptions with at least one PIM (potentially inappropriate medication) prescribed as per STOPP criteria | 29 |
| Proportion of patients receiving a prescription with at least one PIM | 21.01% |
| Total number of PIMs as per STOPP criteria | 29 |
| Number of prescriptions with at least one POP (potentially prescribing omission) as per START criteria | 46 |
| Proportion of patients receiving a prescription with at least one PPO | 33.33% |
| Total number of POPs as per START criteria | 61* |
| Total number of prescriptions with at least one PIP (either as per STOPP or START criteria) | 64 |
| Proportion of patients receiving a PIP as per either of the criteria | 46.37% |

^{*31} prescriptions had 1 PPO while 15 prescriptions had two PPOs.

There were 46 prescriptions with at least one prescribing omission out of which, 31 prescriptions had only one PPO while 15 prescriptions have 2 PPOs as per START criteria. Application of STOPP criteria to 138 prescriptions resulted in 29 PIMs. The most common potentially inappropriate medications prescribed were NSAIDs for long term pain relief in osteoarthritis, NSAIDs for patients of severe

hypertension, and loop diuretics prescribed as first line antihypertensive drugs. Others included concomitant use two drugs that increase anticholinergic drug burden and therapeutic duplications like prescription of the same drug by two routes in the same patient. One patient was prescribed long term aspirin at a dose higher than maximum recommended dose of 160mg/day (Table 5).

Table 5: Subgroup analysis of PIMs as per STOPP criteria.

| Drug category as per STOPP criteria | Type of STOPP criteria to which prescribing error was attributed | Number |
|---------------------------------------|---|--------|
| | Loop diuretics as first line treatment of hypertension | 4 |
| Cardiovascular system | Sildenafil prescribed concurrently for a patient of angina on treatment with nitrates. | 1 |
| Anti-platelet-anticoagulant drugs | Long term treatment with aspirin dose greater than 160mg/day. | 1 |
| Musculoskeletal system | NSAID prescribed long term for a patient of severe hypertension | 5 |
| | NSAID prescribed for a patient of severe heart failure | 2 |
| | Long term NASIDs for pain relief in osteoarthritis as first line therapy | 8 |
| Antimus carinic/ Anticholinergic drug | Concomitant use of two drugs with antimuscarinic property- Intestinal antispasmodic with first generation antihistaminic | 3 |
| Therapeutic duplication | 2 third generation cephalosporins prescribed together | 2 |
| | Two NSAIDs prescribed together | 2 |
| | H2 blocker in the same patient prescribed by both routes - iv and oral | 1 |
| Total number of PIMs | | 29 |

Table 6: Subgroup analysis of PIMs as per START criteria.

| Drug category as per START criteria | Type of START criteria to which prescribing error was attributed | Number |
|--|---|--------|
| CVS | Antiplatelet therapy with a documented history of coronary, cerebral or peripheral vascular disease. | 5 |
| | Statin therapy with a documented history of coronary, cerebral or peripheral vascular disease, unless the patient's status is end-of-life or age is > 85 years. | 11 |
| | ACE inhibitor in systolic heart failure. | 10 |
| | Appropriate beta-blocker with stable systolic heart failure. | 2 |
| | Beta-blocker with ischaemic heart disease | 6 |
| | Antihypertensive therapy where systolic blood pressure consistently > 160 mmHg and/or diastolic blood pressure consistently > 90 mmHg; 0r > 140/90 if diabetic. | 8 |
| | Atrial fibrillation not prescribed warfarin/aspirin. | 2 |
| Respiratory system | Regular inhaled beta-2 agonist or antimus carinic bronchodilator (e.g. ipratropium, tiotropium) for mild to moderate asthma or COPD. | 3 |
| | Regular inhaled corticosteroid for moderate-severe asthma or COPD | 9 |
| Musculoskeletal | Vitamin D and calcium supplement in patients with known osteoporosis and/or previous fragility fracture | 2 |
| system | Bisphosphonates and vitamin D and calcium in patients taking long-term systemic corticosteroid therapy. | 3 |
| Total | (| 51 |

Similarly, application of START criteria to the prescriptions under study, showed 61 incidences of prescribing omissions. A high frequency of POPs was related to the cardiovascular system. Omission of ACE inhibitors/ARBs from therapeutic regime of patients with

heart failure, betablockers from patients with ischemic heart disease, statins from patients with established coronary, cerebrovascular disease were common. Prescribing omissions in the respiratory diseases were due to lack of long term corticosteroid use in patients of severe bronchial asthma. PPO of vitamin D, calcium supplements and bisphosphonates from therapy offered to patients of osteoporosis was also seen (Table 6).

DISCUSSION

Geriatric age group is a special risk group with respect to drug prescribing. Rationalizing drug prescriptions in geriatric patients is a complicated task requiring a multistep approach like - prior assessment of drug prescribing pattern in the existing setup, identifying problem areas and suggesting interventions to improve prescribing pattern. This has to be followed by repeated mop up rounds to maintain rational prescribing in elderly. As a first step to this approach, analyzing the prescriptions for existing pattern of prescribing in the elderly and adherence to WHO core prescribing indicators was done.

Existing prescription pattern in the elderly shows a high utilization of drugs related to the cardiovascular system and antimicrobials in our set up. This is in concordance with studies conducted in India where 3 most commonly used drug classes belong to cardiovascular system, gastrointestinal system and antimicrobials. 12,13 Studies conducted in other developing countries like Nigeria also show an increased tendency towards prescription of drugs related to cardiovascular system. WHO core prescribing indicators include elements like average number of drugs per prescription, proportion of prescriptions containing antibiotics, injections, proportion of drugs prescribed by generic name and from national list of essential medicines (NLEM). This is a set of basic minimum standard to which prescriptions in a setup should adhere to. In the present study, all the WHO drug prescribing indicators were found to be discordant with the standards recommended by WHO. Although, these prescribing indicators are basically meant to gauge rational prescribing in an OPD setup, it has been used by many tertiary care centres to evaluate rational prescribing practices in their hospital inpatient department. WHO core prescribing indicators in the present study fall within the range of WHO prescribing indicators as assessed in inpatient departments in various studies. Average number of drugs prescribed per patient in the present study was 6 and this is similar to study conducted by Mushira Taskeen at Hyderabad. 14 Other studies have averages between 5.5 to 9.6 drugs prescribed to geriatric patients. This confirms to the findings that polypharmacy is rampant in geriatric patients. There was also an increased tendency towards prescription of antimicrobials, injections and prescribing brand names. These findings were also similar to other studies conducted on geriatric patients in India. 12,13,15

Polypharmacy in the elderly is a result of multiple comorbidities like hypertension, diabetes, heart failure and their complications. However, polypharmacy can also have adverse consequences in the elderly leading to prescribing cascade. Prescribing cascade is misrepresentation of the adverse effects, drug-drug interactions or drug disease interactions as a disease

symptom leading to prescription of another drug to treat it. This further complicates the picture of polypharmacy. Continuous medication reviews to reduce number and frequency of medications in elderly could serve as a remedial step in reducing polypharmacy.

Next step was to identify problem areas in geriatric prescribing. This was done by analyzing the prescriptions to identify prescription of any inappropriate medication (PIM) as per STOPP criteria and prescribing omission(PPO) as per START criteria. Proportion of patients subjected to at least one inappropriate medication, prescribing omission or either of them (PIP) as a whole was assessed. In the present study it was observed that 21% patients were subjected to a potentially harmful medication (PIM). Study conducted in Ireland showed proportion of patients receiving PIM to be 14%, while a study from Australia showed a prevalence of 37.5%. 15,16 It was as high as 51% in a study conducted by Delleur. 17 A study conducted by Gallenger reports the proportion on PIMs to be between 12-40% and the results of the present study falls between the same range. 18 Thus, studies conducted all over the world on geriatric patients have shown wide variations with respect to this parameter. Reason for variation may be due to conduct of study in different settings like outpatient departments, primary care settings or hospital based settings and it is well known that prescription of PIMs tends to be higher in hospital based settings as compared to PIMs reported in community studies. Considering the type of drug prescribed inappropriately in geriatric patients as per STOPP criteria, prescription of long term NSAIDs as first line treatment of osteoarthritis, long term NSAIDs to patients of hypertension and heart failure, prescription of loop diuretics as first line antihypertensive and therapeutic duplications were some of the commonly encountered PIMs in the present study. Study published in European Journal of pharmacology shows prescription of NSAIDs in patients of hypertension as a common PIM while studies analyzing prescriptions as per Beers criteria show common PIMs related to prescription of antihistaminic, muscle relaxants and long acting benzodiazepines. 16-19 Thus, criteria adopted for identification of PIMs play a very important role in explaining the discrepancies between studies in this regard. Other explanations for differences in the type of PIPs reported from studies conducted in different geographical areas may be related to the epidemiology of diseases treated in a particular area, local availability of drugs, cost and treatments guidelines followed in a particular setup. Potential implications of PIMs prescribed in our study could be worsening of hypertension and heart failure when NSAIDs are prescribed to patients with these diseases, prescription of aspirin beyond 150mg/day could lead to higher incidences of gastric bleeding in the elderly, concomitant prescription of drugs with anticholinergic action leads to atropinic side effects like glaucoma, dryness of mouth, retention of urine in patients with benign prostatic hypertrophy and constipation. First line use of NSAIDs instead of paracetamol for long term treatment of osteoarthritis is not

advisable in the elderly as it can lead to occult blood loss and analgesic nephropathy. Loop diuretics are not to be chosen as first line treatment of hypertension as better drugs in terms of efficacy and tolerability for hypertension are available. Concomitant prescription of sildenafil and nitrates in the elderly may cause dangerous hypotension.

Considering the START criteria for potential prescribing omissions (PPOs), it was found that proportion of patients exposed to PPOs in the present study was 33.33%. Most common instances of underutilization included ACE inhibitors in patients of heart failure, statins in patients with evidence of cerebral, coronary or peripheral vascular disease, Antihypertensive therapy where systolic blood pressure consistently >160 mmHg and/or diastolic blood pressure consistently >90 mmHg; 0r >140/90 if diabetic, vitamin D and calcium supplement in patients with known osteoporosis and/or previous fragility fracture, antiplatelet therapy in the presence of coronary cerebral vascular disease betablockers for stable angina, regular inhaled corticosteroid for moderate-severe asthma or COPD. These results were similar to a study conducted by Pyszka LL.²⁰ The potential implications of underutilization of antihypertensives, ACE inhibitors and statins and betablockers for the above said indications reduce the survival benefit offered by these drugs and increase mortality and morbidity form cardiovascular disorders. Underutilization of regular inhaled corticosteroids increase the exacerbation of acute asthma further leading to hospitalizations and underutilization of drugs that increase bone mineral density in patients of osteoporosis increase the incidence of fractures in the elderly. Considering proportion of patients exposed to errors of prescribing as a whole (either a PIM or PPO), it was found that 46% of the elderly were exposed to one of these errors of prescribing. In fact, errors due to omission were 1.6 times more as errors due to commission. A study conducted by Galvin in Europe also showed that errors due to omission were more than errors due to commission although the actual proportion of errors were less in this European study as compared to our study (14% PIM and 30% PPO vs 21% PIM and 33.33% PPO in our study).

CONCLUSION

To summarize, with regards to geriatric prescribing, adherence to WHO core prescribing indicators, prescription of drugs as per STOPP and START guidelines are indicative of a scope for improvement in the present setup. Sensitization of prescribers with respect to the above aspects of geriatric prescribing, encouraging consideration of elderly as a special risk group and emphasis on these aspects of prescribing in teaching curriculum may bring down the discrepancies in geriatric prescribing to an acceptable level. Actual assessment of the extent to which observed deficiencies in prescribing practices led to clinically observable adverse events was not done in the present study. Further studies to actually assess the clinical implications of inappropriate prescribing have to be conducted to evaluate the health as well as economic

consequences of inappropriate prescribing in the geriatric population.

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Institutional Ethics Committee

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