ABSTRACT

Objective: The present study was aimed to assess the drug prescribing pattern and analyze the prescribing pattern using Beers criteria among elderly patients aged over 60 years.

Methods: The present study was a prospective observational study conducted in the outpatient Department of General Medicine in a tertiary care hospital for the duration of 3 months. Institutional Ethics Committee approval was taken prior to the initiation of the study. Written informed consent was taken from each study subject. A total of 287 subjects who were aged more than 60 years recruited into the study. The data were collected in a pre-structured case record form. Subjects’ demographic details, medical conditions, and drugs included in prescription were noted in the case record form.

Results: Among 287 subjects, 91.64% subjects belonged to 61-70 years age group, remaining 8.36% subjects were >71 year older, and 57.14% were males and 42.86% were females. Hypertension (HTN) was the most common cause of attending hospital followed by diabetes mellitus, central nervous system disorders, respiratory, cardiovascular disorders other than HTN, and infectious diseases. A total of 1574 formulations containing 1669 active ingredients and 90 fixed dose drug combinations were prescribed. And only 152 formulations were prescribed from the outside hospital formulary. The average number of drugs per prescription was 5.48±2.00. Among the individual drugs, vitamin B complex was the most commonly prescribed drug.

Conclusion: There is a need for more rational prescribing and to form guidelines for safe and effective use of medicines in elderly patients.

Keywords: Beers criteria, Elderly patients, Drug utilization pattern.

INTRODUCTION

In world, geriatric population occupies significant percentage with over 60% of the elderly population found in developing countries. The number of elderly persons aged 60 or over in developing countries expected to rise from 510 million in 2011 to 1.6 billion in 2050 [1]. In India, 7.4% of the population is more than 60 years old, and there is a sharp increase in elderly population in India [2]. It is estimated to rise to 12.4% by the year 2026 [2]. Elder people constitute a heterogeneous group due to age-related changes in pharmacokinetic and pharmacodynamic profiles of drugs [3]. Age-related changes in body weight, body composition, and decrease in body water and increase in body fat, decrease in renal and hepatic functions alter the pharmacokinetics of drugs. And up regulation and down regulation of the receptors alter pharmacodynamics of drugs and there is increased sensitivity to some of the drugs acting on central nervous system (CNS). Elderly persons use more medications than other age groups. They are associated with higher rates of chronic illness. Most of the elderly live with one or more chronic conditions. Hence, polypharmacy is the most common problem in elderly. Polypharmacy is the use of at least one potentially inappropriate drug or presence of five or more concurrent medications in one prescription [4,5].

Polypharmacy in elderly patients exposes them to increased drug interactions, increased adverse drug reactions (ADRs), and increased health care cost [6]. ADRs are more prevalent in elderly and most are type A reactions predictable from the known pharmacology of the drug and are mostly avoidable [7-9]. Elderly patients also suffer from depression and degenerative diseases such as Alzheimer’s disease affecting compliance.

Pattern of drug use, quality of drug use, determinants of drug use, and outcomes of drug use are important insights of drug utilization research. Drug utilization research is defined by the WHO as “study of marketing, distribution, prescription, and use of drugs in society, with special emphasis on the resulting medical, social, and economic consequences” [10]. Drug utilization ultimately assesses whether drug therapy is rational or not.

For the safe and appropriate use of medicines in an elderly, a criteria has been created by Beers [11]. Beers criteria were defined by Beers in 1991 and was updated in 1997, 2003 and 2012. The Beers criteria consist of medications to be avoided in the elderly irrespective of patient’s diagnosis, and those that should be avoided due to drug-disease drug-syndrome interactions and those drugs that should be used with caution in older [12]. The Beers criteria also have its deficiencies this led to the development of the newer tools such as the screening tools of older persons prescriptions and screening tool to alert doctors to right treatment [13,14].

The aim of present study was to assess the drug prescribing pattern and analyze the prescribing pattern using Beers criteria among elderly patients aged over 60 years in Osmania General Hospital, Hyderabad, a tertiary hospital.

METHODS

The present study was a prospective observational study conducted in the outpatient department of General Medicine, Osmania General Hospital, for the duration of 3 months. The study protocol was approved by the Institutional Ethics Committee prior to starting of the study. 287 subjects were included in the study. Written informed consent was taken from each subject before recruiting into the study.

Inclusion criteria

Subjects who aged more than 60 years and attending medicine outpatient department were included in the study.
Exclusion criteria
Subjects less than 60 years old and who were not willing to give informed consent were excluded from the study.

The data from all the study subjects were collected daily in OP timings, i.e., 9 am to 1 pm in a pre-structured case record form. Subjects demographic details include subject initials, age, gender, socioeconomic status were collected and medical conditions for which the subject was attending the hospital, all investigations, all drugs in the prescription, their dose, duration, frequency were noted in the structured case record form. The subjects were monitored for ADRs.

Data analysis
Age, gender wise distribution of subjects, frequency distribution of medical conditions, total number of drugs for prescription for each subject, average number of drugs per prescription expressed as mean and standard deviation, number of fixed dose drug combinations (FDCs), number of drugs prescribed from hospital formulary, system wise distribution of drugs, most commonly prescribed drugs in this study and their WHO Anatomical Therapeutic Classification (ATC), defined daily doses (DDDs) were analyzed. Based on the number of drugs in the prescription, they were divided into subjects prescribed with <5 drugs, 5-8 drugs and more than 8 drugs. Prescriptions with >5 drugs were considered as polypharmacy.

Frequency of prescriptions of potentially inappropriate medications (PIMs) was analyzed using 2012 updated Beers criteria [12].

Statistical analysis
Mostly descriptive statistics was used. Data were analyzed by the Chi-square test for comparing the proportions of polypharmacy between genders and to test the association between polypharmacy and frequency of prescriptions of PIMs. SPSS software version 24 was used to analyze the data.

RESULTS

Among 287 subjects who were aged >60 years and attending medicine outpatient department, 263 (91.64%) subjects belonged to 61-70 years age group, remaining 24 (8.36%) subjects were >71 years older. The minimum age was 61 years and maximum age 90 years. Out of 287 subjects, 164 (57.14%) were males and 123 (42.86%) were females. Maximum subjects were attended the department for hypertension (HTN) (63.07%) followed by diabetes mellitus (DM) (24.04%), central nervous system diseases (56 subjects), vitamins, minerals, and dietary supplements (98 subjects), and infectious diseases (181 subjects). Maximum subjects were attended the department for hypertension (HTN) (63.07%) followed by diabetes mellitus (DM) (24.04%), central nervous system diseases (56 subjects), vitamins, minerals, and dietary supplements (98 subjects), and infectious diseases (181 subjects).

A total of 1574 formulations were prescribed containing 1669 active ingredients. Of the 1574 formulations, 90 were FDCs and 1484 contained only one active ingredient. And only 152 formulations were prescribed from the outside hospital formulary. The average number of drugs per prescription was 5.48±2.00. Out of 287 subjects, 91 (3.171%) subjects had prescribed with less than 5 drugs, 178 subjects with 5-8 drugs and 18 subjects with more than 8 drugs. The minimum number of drugs per prescription was 1 and the maximum was 12 drugs (Fig. 1).

Polypharmacy is considered as more than 5 drugs per prescription. In this study, polypharmacy was present in 196 (68.29%) subjects; 84 female and 112 male subjects had polypharmacy (Fig. 2).

The difference in polypharmacy between male and female subjects was not statistically significant (p=1.000). The system wise distribution of drugs was shown in Table 2. Drugs acting on cardiovascular system (CVS) were the most frequently prescribed drugs (437 subjects), followed by vitamins, minerals, and dietary supplements (302 subjects), drugs acting on gastrointestinal tract (231 subjects), drugs acting on hematological system (126 subjects) together constitutes 69.63% and others contributes to the remaining 30.37%.

- Vitamin B complex (155 subjects) was the most frequently prescribed drug, followed by enalapril 5 mg (102 subjects), ranitidine 150 mg (101 subjects), pantoprazole 40 mg (94 subjects), amiodarone 5 mg (90 subjects), aspirin 150 mg (81 subjects), calcium lactate 300 mg (76 subjects), atorvastatin (71 subjects), diclofenac sodium 50 mg (61 subjects), and metformin 500 mg (58 subjects). These most commonly prescribed drugs and their ATC code, WHO DDD measure and number of DDDs was shown in Table 3.

Vitamin B complex (155 subjects) was the most frequently prescribed drug, followed by enalapril 5 mg (102 subjects), ranitidine 150 mg (101 subjects), pantoprazole 40 mg (94 subjects), amiodarone 5 mg (90 subjects), aspirin 150 mg (81 subjects), calcium lactate 300 mg (76 subjects), atorvastatin (71 subjects), diclofenac sodium 50 mg (61 subjects), and metformin 500 mg (58 subjects). These most commonly prescribed drugs and their ATC code, WHO DDD measure and number of DDDs was shown in Table 3.

Among the antihypertensive drugs, enalapril was the most commonly prescribed drug followed by Amlodipine and among the hypoglycemic agents metformin was the most commonly prescribed drug followed...
by glibenclamide. Amoxicillin and potassium clavulanate combination was the most commonly prescribed antimicrobial drug. Deriphyllin (theophylline+etophylline) was the most commonly prescribed among respiratory drugs and phenytoin sodium was the commonly used antiepileptic drug. Total number of injections prescribed was 16, which were injection insulin, deriphyllin, and hydrocortisone.

Out of 1574 formulations, 67 formulations were PIMs identified in 58 subjects according to 2012 updated Beer’s criteria. Antihistamines were the most frequently prescribed PIMs (21 subjects), followed by non-steroidal anti-inflammatory drugs (NSAIDS), digoxin, spironolactone, chlordiazepoxide, amitryptilin, clonidine, alpznolam, amidarone, phenobarbital (Table 4).

About 50 subjects had only one PIM, 7 subjects had two PIMs and only one subject had three PIMs. There was statistically significant association between polypharmacy and PIMs use in elderly population (p<0.05).

During the study period, ADRs were recorded in four patients. Three subjects complained of dry cough due to enalapril and one patient complained of gynecomastia due to spironolactone. All were probable according to the WHO causality assessment [15].

**DISCUSSION**

Elderly population is growing rapidly in the world, especially in the developing countries. In developing countries persons aged more than 60 years were considered as elderly people. In India, due to low life expectancy compared to developed countries, normal retirement age and eligibility for senior citizenship and according to literature, 60 years is considered as cut off age for elderly [16]. Most of the elderly patients suffer from more than one chronic condition and it leads to polypharmacy. This study was undertaken to analyze the prescribing pattern in elderly and problems related to it.

In this study, 57.14% subjects belonged to male gender, higher than female subjects (42.86%). Almost all subjects were uneducated and belonged to low socioeconomic status. The most common condition for attending hospital was HTN; this is similar to other studies conducted in India [17]. Most commonly affected system was CVS followed by CNS and respiratory system. In CVS, most common condition was the HTN followed by coronary artery disease and left ventricular dysfunction. In CNS, cerebrovascular disease was most common, followed by epilepsy. And only 10.8% subjects had infectious diseases and remaining were non-communicable diseases. This shows an increasing trend of non-communicable diseases in India.

In the present study, FDCs were only 5.71%; this was very less compared to other studies [18]. Most common FDCs were deriphyllin (theophylline+etophylline) followed by amoxicillin and potassium clavulanate combination. And 90.34% drugs were prescribed from the local hospital formulary. This reflects more rational prescribing of drugs.

The average number of drugs per prescription was 5.48±2.00, this coincides with other studies [19]. Polypharmacy was present in 68.29% subjects. In a study by Shah et al., average number of drugs per prescription was 7.3±4.39 and polypharmacy was present in 75.25% patients [20]. Compared to this study, in our study, average number of drugs per prescription and polypharmacy was less. And polypharmacy increases PIMs. This polypharmacy leads to increased health care costs, adverse drug responses, drug interactions, non-adherence, and decline in functional status and cognitive impairment [21]. Hence, measures to control polypharmacy must be taken to avoid consequences.

Clinical trials are done in ideal conditions and mostly involve younger adults. Pharmacokinetics and pharmacodynamics of the drugs are different in elderly population. Hence, there is a need to enroll elderly patients in clinical trials to avoid unnecessary drug related events. Most of the elderly people suffer from hepatic and renal failures so the doses of the drugs that are eliminated by these routes must be adjusted.

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**Table 3: Most commonly prescribed drugs and their DDD**

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Drug</th>
<th>Number of prescriptions</th>
<th>ATC code</th>
<th>WHO DDD</th>
<th>Number of DDDs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>B complex</td>
<td>155</td>
<td>A11EA</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>Enalapril</td>
<td>102</td>
<td>C09AA02</td>
<td>10 mg</td>
<td>42.75</td>
</tr>
<tr>
<td>3</td>
<td>Rantididine</td>
<td>101</td>
<td>A02BA02</td>
<td>0.3 g</td>
<td>50.5</td>
</tr>
<tr>
<td>4</td>
<td>Pantoprazole</td>
<td>94</td>
<td>A02BC02</td>
<td>40 mg</td>
<td>94</td>
</tr>
<tr>
<td>5</td>
<td>Amlodipine</td>
<td>90</td>
<td>C08CA01</td>
<td>5 mg</td>
<td>90.5</td>
</tr>
<tr>
<td>6</td>
<td>Aspirin</td>
<td>81</td>
<td>B01AC06</td>
<td>1 tab=1 UD</td>
<td>81</td>
</tr>
<tr>
<td>7</td>
<td>Calcium lactate</td>
<td>76</td>
<td>A12AA05</td>
<td>2 g</td>
<td>11.4</td>
</tr>
<tr>
<td>8</td>
<td>Atorvastatin</td>
<td>71</td>
<td>C10AA05</td>
<td>20 mg</td>
<td>98.5</td>
</tr>
<tr>
<td>9</td>
<td>Diclofenac sodium</td>
<td>61</td>
<td>M01AB05</td>
<td>0.1 g</td>
<td>30.5</td>
</tr>
<tr>
<td>10</td>
<td>Metformin</td>
<td>58</td>
<td>A10BA02</td>
<td>2 g</td>
<td>14.5</td>
</tr>
</tbody>
</table>

DDD: Defined daily dose, ATC: Anatomical therapeutic classification

**Table 4: Frequency of the prescription of PIMs**

<table>
<thead>
<tr>
<th>S. No.</th>
<th>PIMs</th>
<th>Number of drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Antihistamines</td>
<td>21</td>
</tr>
<tr>
<td>2</td>
<td>NSAIDS</td>
<td>12</td>
</tr>
<tr>
<td>3</td>
<td>Digoxin</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>Spironolactone</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>Chlordiazepoxide</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>Amitriptylin</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>Clonidine</td>
<td>2</td>
</tr>
<tr>
<td>8</td>
<td>Alprazolam</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>Amiodarone</td>
<td>1</td>
</tr>
<tr>
<td>10</td>
<td>Phenobarbital</td>
<td>1</td>
</tr>
</tbody>
</table>

PIM: Potentially inappropriate medications, NSAIDS: Non-steroidal anti-inflammatory drugs

**Fig. 2: Polypharmacy in male and female**

The average number of drugs per prescription was 5.48±2.00, this coincides with other studies [19]. Polypharmacy was present in 68.29% subjects. In a study by Shah et al., average number of drugs per prescription was 7.3±4.39 and polypharmacy was present in 75.25% patients [20]. Compared to this study, in our study, average number of drugs per prescription and polypharmacy was less. And polypharmacy increases PIMs. This polypharmacy leads to increased health care costs, adverse drug responses, drug interactions, non-adherence, and decline in functional status and cognitive impairment [21]. Hence, measures to control polypharmacy must be taken to avoid consequences.

Clinical trials are done in ideal conditions and mostly involve younger adults. Pharmacokinetics and pharmacodynamics of the drugs are different in elderly population. Hence, there is a need to enroll elderly patients in clinical trials to avoid unnecessary drug related events. Most of the elderly people suffer from hepatic and renal failures so the doses of the drugs that are eliminated by these routes must be adjusted.

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accordingly to avoid adverse consequences. In an observational study, for admission into intensive care unit due to unpreventable adverse drug events, compared to controls study group took more number of drugs [22].

Among the drugs, B complex vitamin was the most commonly prescribed drug. According to category wise distribution vitamins, minerals, and dietary supplements were the second most commonly prescribed drugs. Hence, this suggests elderly also suffer from nutritional deficiencies and in our study most complained of generalized body pains. There was increase in the use of drugs that decrease gastric acidity such as ranitidine and pantoprazole. This suggests more number of drugs per prescription led to increased prescription of these gastrointestinal drugs to avoid gastric irritation. Most commonly prescribed cardiovascular drug was enalapril followed by amiodipine. In a study on prescribing patterns of antihypertensive drugs in geriatric patients, most commonly prescribed drug was amlopidine, which was second most common in our study [23]. In the present study, most commonly prescribed drug for type 2 DM was metformin, similar to other study in diabetes patients attending tertiary care hospital in Navi Mumbai [24]. Among antiepileptic drugs, phenytoin was the most commonly prescribed drug despite its various drug-drug interactions. Similarly, phenytoin was the most commonly prescribed drug in a study by Pathak et al. [25].

Beers criteria were used to monitor PIMs in the present study. Antihistamines were the most common PIMs among them. Chlorpheniramine maleate was the most commonly prescribed PIM in our study. First generation of antihistamines are included in Beers criteria so other alternative drugs such as second and third generation antihistamines can be used in elderly patients. Second most commonly prescribed PIMs were NSAIDS. Beers criteria suggest that non COX selective NSAIDS can be used in elderly patients. Second most commonly prescribed drug in a study by Pathak et al. [25].

CONCLUSION
The present study analyzed the commonly encountered problems in elderly. number of drugs per prescription, most commonly prescribed drugs and use of inappropriate medication in geriatric patients. So far and safe effective use of medicines in an elderly, we need guidelines to avoid PIMs and drug related problems. There is a need for a awareness among physicians regarding medication use in elderly.

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REFERENCES