Prevalence of Potentially Inappropriate Medications among Geriatric Diabetes Mellitus Patients and Prescription Pattern at a Tertiary Care Hospital

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ABSTRACT

Introduction: Diabetes mellitus is a metabolic disease which is a major health care issue in geriatric population of Southeast Asian countries. Inappropriate prescriptions and polypharmacy are important prescribing issues with diabetic geriatric patients due to its associated co-morbid conditions. Beers criteria and WHO core indicators are developed for the rational use of drugs in this specific population. The incidences of potentially inappropriate medications (PIMs) are reduced by following the appropriate guidelines for the elderly patients. The aim and objectives of this study were to estimate the prevalence of potentially inappropriate medications using the Beers criteria and also to assess the prescribing pattern for geriatric outpatients diagnosed with diabetes mellitus. **Methodology:** The study is a prospective and cross-sectional in nature, consisting of geriatric patients (65 years and above) attending the medicine outpatients clinic of a tertiary care teaching hospital. The drug utilization aspects of the study were assessed by World Health Organization guidelines (WHO) and American Geriatric Society 2015 updated Beers criteria for drug-use indicators and incidence of potentially inappropriate medications, respectively. **Results and Discussion:** Medical records of 250 patients aged 65 years and above were assessed for this study. Nearly 52 patients were diagnosed with diabetes mellitus and its associated complication. A number of drugs prescribed to the patients were 436 with an average of 8.4 drugs per person. Cardiovascular drugs accounted for most (35.09%) followed by anti-diabetic drugs (31.88%) and multivitamins (11.92%). Potentially inappropriate medications were prescribed to 23 patients with a rate of 8.25% when reviewed with Beers Criteria 2015 by the American Geriatric Society. The common groups involved in PIMs were mostly benzodiazepines and anti-depressants. **Conclusion:** Potentially inappropriate medications and polypharmacy are major pharmacotherapeutic issues which go unnoticed especially in a country like India. This might be due to the shortage of doctors, lack of knowledge regarding PIMs, drug interaction and polypharmacy. There is a need for training of rational use of medicine among prescriber serving the geriatric population of the country.

Key words: Geriatric patients, polypharmacy; potentially inappropriate medications, rational use of medicines; beers criteria

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INTRODUCTION

Drug–drug and drug–disease interactions are the major pharmacological problem in the geriatric population because of the physiologic changes due to aging and degrading function of the organ system.[1] Non-rational prescribing of drugs in the geriatrics may lead to polypharmacy and use of potentially inappropriate medicines which in turn lead to adverse drug reactions, leading health concerns in the elderly.[2,3] These factors have contributed to increase the incidence of co-morbidities, increase hospital stay and prescription of more drugs which is responsible for increased healthcare costs.[4] Potentially inappropriate medications (PIMs) has been found to increases morbidity and mortality in geriatric population which necessitated the use of creation of Beers criteria for safe use of medicines among the elderly. It was first published by the American Society of Geriatrics in 1997 and updated in 2002 and 2012.[5,6] It provides guidelines to the healthcare professionals, consist of the list of medications to be avoided in the geriatrics (65 years or above) irrespective of diagnosis, drug-drug interaction or organ function like the kidney. Various studies showed rates of PIMs between 21.3%-37% among patients attending outpatient department, while patient admitted in the hospital have the prevalence of about 40%.[7,8] In India, the rate is 23.6% in patients admitted to the hospital.[9]

In the era of modern medicine, irrational use of drugs is a major health concern. The magnitude of polypharmacy in the prescription, the use of generic name and usage of antibiotics and injections are measured by prescribing indicators developed by World Health Organization.

The prescribers can practice rational use of medicine by following the country's essential drug list.[10] The present health care scenario is alarming due to the widespread practice of polypharmacy, use of PIMs in the geriatric and inappropriate use of antibiotics.[11]

Diabetes Mellitus (DM) is an important health issue for the aging population as it has a prevalence of approximately one-quarter (nearly 26%) of people over the age of 65 years and this proportion is expected to increase rapidly in the coming decades.[12] Older individuals with diabetes have increased co-morbidities such as hypertension, coronary heart disease, and stroke, functional disability and also have higher rates of premature death than those without diabetes. Older adults having diabetes mellitus and associated co-morbidities are also at greater risk for polypharmacy which may have more prevalence of adverse drug reactions and chances of prescription of PIMs also increase which may further deteriorate the health status and increase the financial and social burden.

Diabetes Mellitus and its co-morbid conditions shared a major bulk of revenue of global healthcare expenditures in 2010. This number is going to exceed by one-third of the present budget by 2030 on diabetes care.[13] India earned the title of "diabetes capital of the world" with around 40.9 million diabetic population which is expected to rise to 69.9 million by 2025.[14] Type 2 diabetes mellitus (T2DM) is one of the leading cause of death due to the associated co-morbid conditions of cardiovascular, cerebrovascular or peripheral arterial diseases.[15] It can be estimated that due to the negative prognosis and associated co-morbid conditions, there is a high surge of use of anti-diabetic drugs and other drugs thus affecting the financial prospective of the already dilapidating health care system. The objective of this study was to find the prevalence of PIMs and polypharmacy among this cohort. In addition, to also investigate the prescribing pattern of drugs in geriatric diabetes mellitus patients attending the outpatient department of medicine of a tertiary care hospital in Northwest India.

Methodology

Study settings

After confirming the diagnosis of diabetes mellitus of the patients from the consultant of outpatient department of medicine of a tertiary care teaching hospital, the geriatric patient's prescription was analyzed by BEERs criteria and WHO core indicator for the prescription.

Ethical considerations

Ethical clearance was taken from Institutional Ethics Committee before the commencement of the study. (AIIMS/IEC/2016/607)

Method

It was prospective and cross-sectional study consisting of geriatric patients aged above or equal to 65 years with the diagnosis of diabetes mellitus irrespective of its type. As this is a preliminary study formal sample size is not calculated. Keeping in mind the availability of patients it is decided to include patients on the basis of criteria laid below attending medicine out-patient department.

Inclusion criteria

1. Patients of above 65 years, either sex attending outpatient department of medicine during the study period over an 8 month period (May–December 2016).

2. Patients willing to participate.

Exclusion criteria

1. Admitted patient in medicine wards.

2. ICU patients and terminally ill.

After confirming the diagnosis and inclusion criteria of the geriatric patients, the patients were included in the study after they gave consent for the interview regarding their demographic data and also give permission to analyze their prescription for the prevalence of polypharmacy and PIMs. The information obtained from the prescriptions were transferred to a prepared excel sheet containing information regarding demography of the patient, medical conditions of the patient, and the pattern, dosage and number of prescribed drugs. WHO guidelines for prescription indicators were used for the drug utilization in the patients[10] this includes an average number of drugs, the percentage of generic drugs prescribed and percentage of antibiotics usage. Beers criteria 2015[16] was used as the reference for finding the drugs for their appropriateness and to determine which has the potential to cause adverse drug reactions, drug interaction and require dose adjustment due to disease or organ dysfunction. The criteria for polypharmacy is taken when the prescription has more than

4 drugs were determined. Medscape Drug Interaction Checker was used to check interaction between drugs.[17]

Analysis

SPSS version 20 (IBM Corporation, Armonk, NY, USA) was used to analyzed data of geriatric patients. Means, frequencies, and percentages were expressed as results in the study. ANOVA and Tukey's Post Hoc test were used to compare the means and standard deviation of different groups. Values of P<0.05 were considered as significant.

RESULTS

In the outpatient department of medicine, 250 geriatric patients were surveyed and out of which 52 patients were diagnosed with diabetes mellitus. In the study, 29 (55.76%) males and 32 (44.23%) females. 67.38 years was the mean age of the study population and most patients belong to younger elderly and they were 48 (92.3%) [Graph 1]. A total of 436 drugs were prescribed for the patients, giving an average of 8.34 drugs per person. Forty-seven (90.38%) patients had four drugs or more prescribed in the age group 65-74 which constitutes nearly 90.82% of the total prescribed drugs. In the age group 75-84, only three persons had more than 4 drugs which constitute 5.76%. The mean number of drugs prescribed was 8.31 ± 3.03 for patients within the age group of 65-74 years, 11.67 ± 4.04 for 75–84 years and 1.0 ± 0.0 for those of 85 years and above [Table 1]. The difference between the three groups was statistically significant (*P*<0.05).

In the study, the most prevalent co-morbid conditions found in association with diabetes mellitus were hypertension (44%) patients, ischemic heart disease (18%), dyslipidemia (10%) of patients and the rest were divided in other system involved [Graph 2].

Drug utilization pattern

The total number of drugs under different classes prescribed for the management of diabetes mellitus can be used to find the prescription pattern of agents. 8.34 was the average number of drugs prescribed per patient in this study. Drugs prescribed by generic name were found to be 0.91%, antibiotic drugs 1.14% and injections 2.52%. 65.36% of the total drugs were prescribed from the Essential Drug List (EDL) [Table 2]. A total numbers of diabetes mellitus patients were treated with oral hypoglycemic (OHA) and injectable insulin were 45 (86.53%) and 2 (3.84%), respectively. On the other hand, the combinations of OHA and injectable insulin were prescribed to 3 patients (5.76%). Total number of oral hypoglycemic and injectable insulin given to the patients were 139 (31.88%) and 5 (1.14%), respectively. Biguanides (38.12%) was the highest prescribed OHA followed by sulfonylureas (34.53%), DPP-4 inhibitors (13.66%) and alpha-glycosidase inhibitors (13.66%). Only
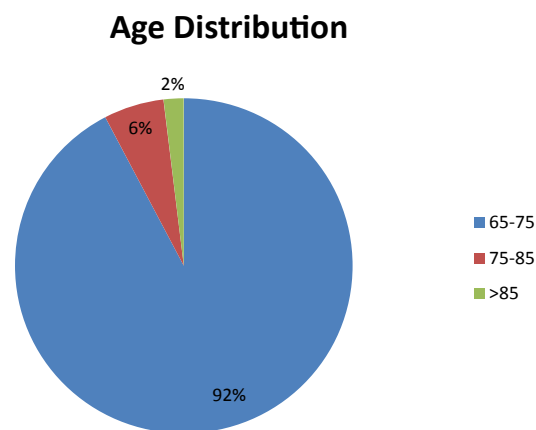
Age Distribution

Graph 1: Distribution of Age

Co-Morbidities
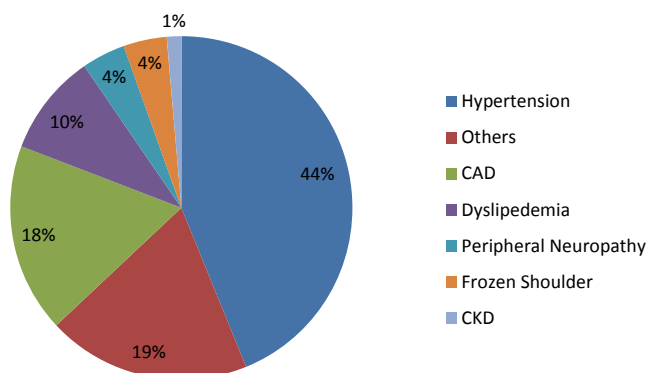
Graph 2: Diabetes Mellitus with its co-morbidities

1.14% of antidiabetic injectable were prescribed of the total drugs, intermediate-acting insulin- mustard 30/70 (40%) and short-acting insulin- regular insulin (40%) followed by long acting glargine (20%). The oral hypoglycemic and injectable insulin constitute 33.02% of the average drugs prescribed which in turn indicated that 67.97% constitute other drugs used for the management of complication or other co-morbidities of T2DM. Anti-hypertensive, anti-platelets, hypolipidemics, proton pump inhibitors and multi-vitamins were the other non-diabetic drugs prescribed were depending upon the co-morbid conditions of the patient.

Furthermore, it was found that for the management of diabetes mellitus and its complications, the drug utilization pattern in the study shows drug prescribed by brand names (99.08%) was more than the generic (0.91%).

Potentially inappropriate medication

According to Beer's criteria, it was found that 36 drugs (8.25%) were potentially inappropriate. Nearly 0.69 potentially inappropriate medicine (PIM) was recorded per prescription [Table 3]. Benzodiazepines and Anti-depressants were most frequently prescribed PIMs. PIM was most prevalent with an verage of 2 per prescription in 75-84 age group followed by 0.62 per prescription in 65-74 the age group [Table 1].

Drug-drug interaction

Medscape drug interaction checker was used to check interaction between drugs in the prescription of the patients. At least one potential drug-drug interaction (DDI) was found in 37 patients (69.23%). In the study, it was found that 2 drug interactions were serious and 153 need close monitoring [Table 3]. In the age group of 75-84, DDI was most prevalent with an average of 3.33 per prescription which is followed by 3.02 per prescription in the age group of 65-74 [Table 1]. The most common interactions found are between the classes of hypoglycemic, antihyperglycemic, antihypertensives and antiplatelets drugs through pharmacokinetics or pharmacodynamics interactions.

DISCUSSION

Diabetes mellitus (DM) is a metabolic disease characterized by chronic hyperglycemia due to decreased insulin secretion, insulin inaction or both.[18] In the study, 20.8% elderly patients diagnosed with diabetes mellitus in the cohort which is slightly lesser than the 26.9% as found in the data from IDF Diabetes Atlas, the International Diabetes Federation (2013) above the individual age of 65,[13] diabetes mellitus increases with age. The prevalence of diabetes mellitus in our study is more in men than women throughout most age ranges (56% and 44%,

respectively). Lifestyle disorders could be one of the reasons for more incidence of diabetes in males than in females. Our study correlates with other studies which show there is male predominance among the geriatric population.[19,20]

Polypharmacy is one of the leading cause of adverse drug reactions in the geriatric population.[21] Polypharmacy happens when more than or equal to four drugs are prescribed to the patients. Most probable reason for polypharmacy in diabetes mellitus patients could be comorbid conditions (obesity, hypertension, dyslipidemia, CVD) and also keep glycemic controls as it is a progressive disorder and ultimately requires multiple therapeutic agents.[22] In our study, drug per prescription was 8.34 which is comparatively on the higher side to the previous studies done geriatric patients in the USA (8.1), India (4.3) and Brazil (3.2).[23,25] In the study, the highest number of drugs prescribed was 17 drugs which are similar to one of the study.[26] It was found that the geriatric prescriptions constitute mostly antihypertensives and hypolipidemic (together 35.09%) followed by multivitamins and enzymes (11.92%). It is lesser than the cardiovascular drugs used in an Indian study.[27] In another study, which shows usage of multivitamins (10.8%) of total drugs in prescription is quite comparable to our study which was 11.92% of the total drugs in the prescriptions.[28] Physicians should evaluate and rationalize practice by incorporating necessary modifications cost-effective and rational medical care.

Generic drugs prescribed was evaluated and it was found only 0.91% which is far below than the standard derived or ideal indicators set by WHOs rule of prescription (100%).[29] In the present study, the lower percentage of prescriptions is shown with the generic name. The reason behind such lower use of generic drugs could be limited knowledge regarding the prescribing guidelines of WHO, lucrative promotions by the pharmaceutical companies, less confident in the quality of generic drugs and the shortage of generic drugs in the hospital. One of the solutions for easing the financial impact of diabetes mellitus is by prescribing generic drugs of high quality.

The number of patients prescribed antibiotics was 1.14% which was less than the standard (20.0%-26.8%) according to WHO's ideal value.[29] This optimum percentage of antibiotics usage shows that the doctors are judiciously and rationally using antibiotics. The percentage of patients where injectable drugs were prescribed was 2.52%. This result is less than the standard (13.4%-24.1%) which is derived for being ideal according to WHO.[29] Thus it reduces the cost of treatments as well as reduces the need of trained personnel for administration. It also reduces the risk of transmission of potentially serious communicable disease. It is also found that nearly 65.36% of drugs are prescribed from Essential Drug List (India) which is less than the ideal value set by WHO.[29] This could be due to decrease awareness regarding Essential Drug List (India).

In the present study, 72% of the cohort were found to have the cardiovascular disease which implies that management of hypertension form an integral part of the treatment of T2DM.[30] In our study, hypertension (44%) was the main cause of morbidity in the cohort. The prevalence of hypertension among diabetes patients is the highest among all the co-morbidities in the present study. This prevalence has been found to be quite comparable to other studies which also revealed that hypertension is the major cause of morbidity in the geriatric diabetic population.[31] This shows that non communicable diseases are the main cause of increasing morbidity in developing countries.

Metformin was found to be the most commonly used antidiabetic drug as analyzed by the prescription pattern of antidiabetic drugs in India and also at global level followed by sulfonylureas or Insulin.[32] Among the oral hypoglycemic prescribed, biguanides were the highest (38.12%) followed by sulfonylureas (34.53%), DPP-4 inhibitors (13.66%) and

Table 1: Prescription Pattern of Drugs with Potentially Inappropriate Medicine (PIM) and Drug-Drug Interaction (DDI) per prescription in geriatric population

Age Group	No. of Drugs prescribed			Mean ± SD	PIM	DDI
<4	4-8	9-12	≥ 13			
65-74	3	123	227	46	8.31 ± 3.03*	30	145
75-84	0	8	11	16	11.67 ± 4.04*	6	10
≥ 85	2	0	0	0	1.0 ± 0.0	0	0

Note: Inter-group comparisons were made by using one way ANOVA followed by Tukey's post hoc test. Results are expressed in Mean±SD:* $p<0.05$- significant as compared to ≥85 age group. Comparison of 65-74 age groups to 75-84 age groups is non-significant.

Table 2: Summary of results from WHO's manual for prescribing indicators assessment

Prescription Indicators derived	Total Drugs	Average or percent per prescription	WHO's Standard or ideal
Drugs prescribed	436	8.34	1.6-1.8
Drugs prescribed by generic name	4	0.91%	100%
Drug encounter with antibiotics	5	1.14%	20%-26.8%
Drug encounter with injections	11	2.52%	13.4%-24.1%
Drugs prescribed from Essential Drug List	285	65.36%	100%

Table 3: Demographic data of prescription and PIM in geriatric population (BEERs Criteria 2015)

Total Prescription	52
Total Drugs	436
Average Prescription of Drugs	8.34
Potential Inappropriate Medicine (PIM)	36
PIM per prescription	0.69
Drug Interaction per prescription	2.98
(Serious: 2 and Need Close Monitoring: 153)	
Adverse Drug Interaction	0

alpha-glycosidase inhibitors (13.66%). Only 1.14% of antidiabetic injectable were prescribed of the total drugs, intermediate-acting insulin- mixtard 30/70 (40%) and short-acting insulin- regular insulin (40%) followed by long acting glargine (20%). Among the antibiotics, only 1.14% is used which shows that comorbid conditions of urinary tract infection and skin infections are less in the present study. The most common antibiotics used in this study are from cephalosporins. The average of drugs from classes of oral hypoglycemic and injectable insulin prescribed was 33.02% which in turn indicated that 67.97% constitute other drugs used for the treatment of co-morbidities of diabetes mellitus of the total prescribed drugs.

In our cohort, PIMs was found in 44.23% of the patients. This is higher as compared to results from USA (27.5%) and Ireland (25%). [33-35] Insulin, antidepressants like amitriptyline and nortriptyline, anti-epileptics, diuretics, and benzodiazepines were the common PIMs encountered in the study. The use of some of this drugs need cautions to be used in elderly, need to reduce dose on kidney function, avoided due to drug-drug interactions and drug with strong anticholinergic properties according to American Geriatrics Society Beers Criteria 2015. Information technology and computerized systems in medication management cab be utilized to decrease the incidence of PIMs in the geriatric population.

CONCLUSION

Diabetes mellitus is a major cause of mortality but several studies indicate that diabetes is likely underreported as a cause of death. In India, the burden of diabetes mellitus is increasing rapidly. The impact of morbidity and mortality due to the metabolic disease pose an enormous and significant healthcare burdens. The goal of glycemic control for diabetes mellitus must also include attention to the treatment of complication associated with it. Thus polypharmacy and prescribing PIMs occur more in such type of patients due to associated comorbid conditions. Thus, the prevalence of polypharmacy and PIMs constitute major health hazards in the geriatric population. Healthcare professionals should be trained in the care of geriatric patients. The prescribers should be acquainted with the knowledge of the generic name and EDL for rational use of drugs and thus reduce the economic burden on the society. In order to avoid adverse drug reactions in the geriatric population, it is essential to develop the national list of PIMs on the basis of race and ethnicity in the country. Metformin was the most common individual OHDs to be prescribed followed by Glimepiride in this study. Polypharmacy, high use of fixed drug combination and prescription by brand names were some of the irrationalities seen in the study.

Acknowledgments

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