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Abstract

Utilization of potentially inappropriate medications in elderly patients in a tertiary care teaching hospital in India

Aim: To evaluate the use of potentially inappropriate medicines in elderly inpatients in a tertiary care teaching hospital. **Materials and Methods:** Retrospective analysis was performed for cases of elderly patients admitted between January 2010 and December 2010. Data on age, gender, diagnosis, duration of hospital stay, treatment, and outcome were collected. Prescriptions were assessed for the use of potentially inappropriate medications in geriatric patients by using American Geriatric Society Beer's criteria (2012) and PRISCUS list (2010). **Results:** A total of 676 geriatric patients (52.12% females) were admitted in the medicine ward. The average age of geriatric patients was 72.69 years. According to Beer's criteria, at least one inappropriate medicine was prescribed in 590 (87.3%) patients. Metoclopramide (54.3%), alprazolam (9%), diazepam (8%), digoxin > 0.125 mg/day (5%), and diclofenac (3.7%) were the commonly used inappropriate medications. Use of nonsteroidal anti-inflammatory drugs (NSAIDs) in heart and renal failure patients was the commonly identified drug–disease interaction. According to PRISCUS list, at least one inappropriate medication was prescribed in 210 (31.06%) patients. **Conclusion:** Use of inappropriate medicines is highly prevalent in elderly patients.

Key words: Beer's criteria, drug-disease interaction, geriatric patients, inappropriate medicines

INTRODUCTION

Inappropriate prescribing is a failure to provide quality medical care that should be achieved in standard clinical practice.^[1] It includes over- and under-prescribing that may result in increased morbidity, hospitalization, and even death. However, the selection of appropriate medication in the elderly people may be a challenging and complex process,

leading to increased risk of inappropriate prescribing.^[2] Medication is considered as potentially inappropriate in the elderly when the risk of adverse drug event exceeds its expected clinical benefit even when better-tolerated alternatives are available.^[3] Benzodiazepines, antihistamines, anticholinergics, and cardiac glycosides are the commonly prescribed inappropriate medicines among geriatric patients.^[4,5]

Several drug- or disease-oriented validated tools have been developed to identify potentially inappropriate prescribing in the elderly. They may be applied with minimal clinical evaluation and many of them are from North America [e.g. Beer's criteria, Improved Prescribing in the Elderly Tool (IPET)].^[6,7] The Beer's criteria were developed through an extensive literature review with a

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bibliography and questionnaire evaluated by nationally recognized experts in geriatric care, clinical pharmacology, and psychopharmacology using a modified Delphi technique to reach consensus. They have been widely utilized and most commonly cited for evaluation of use of potentially inappropriate medications in the elderly patients. In Beer's criteria, a total of 53 medications or medication classes are divided into three different categories as follows: potentially inappropriate medications and classes to be avoided, medications and classes to be avoided in the elderly with certain diseases and syndromes that can be exacerbated by the drugs, and medications to be used with caution.^[8] Another commonly used tool developed in Germany is known as PRISCUS list that contains a list of 83 potential inappropriate drugs for the elderly in a total of 18 drug classes.^[9] Application of these tools during prescription can help to prevent the use of potentially inappropriate drugs in geriatric patients.

There are no such criteria or drug list available for the evaluation of inappropriate medication in the elderly based on the availability of the drugs in Indian market. So, the present study was designed to assess the pattern of potentially inappropriate medications in a tertiary care teaching hospital of India by using such two tools - Beer's criteria and PRISCUS list - among the elderly in-patients.

MATERIALS AND METHODS

This retrospective study was carried out after obtaining the permission of Institutional Review Board, Government Medical College, Bhavnagar, Gujarat, India. All elderly patients (≥ 65 years), admitted in the medicine ward of Sir Takhtsinhji General Hospital, Bhavnagar between January 2010 and December 2010 were included in the study. Their medical records were collected from the record section of the institute. Patients admitted only for observation were excluded. Data were collected for age, gender, diagnosis, duration of hospital stay, treatment, and outcome. Drugs were coded with anatomical therapeutic classification (ATC). Prescriptions were assessed for the use of potentially inappropriate medications by using American Geriatric Society (AGS) Beer's criteria, 2012 and PRISCUS list by two observers independently.^[8,9] Drug-disease interactions and drugs to be used with caution in geriatric patients were also assessed using Beer's criteria.^[8]

Statistical analysis

Data were expressed as proportions and means [95% confidence interval (CI)]. All the statistical comparisons were done with the help of software GraphPadInstat 3.0 (Trial Version). $P < 0.05$ was considered as statistically significant.

RESULTS

A total of 676 geriatric patients were admitted for treatment in the medicine ward during the study period, of whom 52.12% patients were females and 47.88% were males. The average age of geriatric patients was 72.69 years (95% CI: 72.12-73.27). A total 160 (23.76%) patients were more than 80 years of age. The common indications for the admission were ischemic heart disease (39.49%), hypertension (37.27%), cerebrovascular stroke (27.81%), diabetes mellitus (18.49%), and congestive heart failure (14.79%). The average number of total drugs prescribed per patient was 9.37 (95% CI: 9.09-9.64).

According to Beer's criteria, at least one potentially inappropriate medication was prescribed in 590 (87.3%) patients. There were a total of 340 (56.6%) female patients. The average potential inappropriate medication prescribed per patient was 2.62 (95 CI: 2.50-2.74). As shown in Table 1, metoclopramide (54.29%), alprazolam (9.02%), diazepam (7.99%), digoxin >0.125 mg/day (5.03%), and diclofenac (3.7%) were the commonly used inappropriate medications. A total of 14 medications that can exacerbate the disease due to drug-disease interaction were observed in the records of 128 (18.9%) patients. Use of nonsteroidal anti-inflammatory drugs (NSAIDs) in heart and renal failure patients was the commonly identified drug-disease interaction [Table 2]. Totally eight drugs, which are to be used with caution in geriatric patients, were used. Isosorbide dinitrate (47.48%) and aspirin (14.05%) prescribed in patients more than 80 years of age were the commonly prescribed drugs requiring cautious use in elderly patients as per the Beer's criteria [Table 3].

According to PRISCUS list, at least one inappropriate medication was prescribed in 210 (31.06%) cases. Totally 51% were female patients. A total of 26 and 9 medications were potentially inappropriate by Beer's criteria and PRISCUS list, respectively. All nine drugs (chlorpheniramine, prazosin, clonidine, digoxin, nifedipine immediate release, amitriptyline, fluoxetine, alprazolam, and diazepam) identified by PRISCUS were a part of Beer's criteria. PRISCUS list has identified inappropriate medications mainly from drugs acting on the central nervous system (CNS) and the cardiovascular system (CVS). Of the drugs acting on the CNS and CVS, it does not include antipsychotics (haloperidol and chlorpromazine), diuretics (spironolactone >25 mg/day), and amiodarone. Additional drugs screened by the Beer's criteria were drugs with anticholinergic property (promethazine, benzhexol, dicyclomine), pain medications (NSAIDs, pentazocine, methocarbamol), metoclopramide, and mineral oil.

DISCUSSION

The present study evaluated geriatric in-patients for the pattern of potential inappropriate medications. In our setup, a total of 26 potentially inappropriate medications mentioned in the Beer's criteria 2012 had been used. Use of at least one inappropriate medicine was quite higher (92.5% vs. 24%) in contrast to the reports of other studies from India.^[4,5] One possible reason could

Table 1: Potentially inappropriate medicines used in geriatric patients according to 2012 AGS Beer's criteria and PRISCUS list

Groups	Drugs	ATC code	Number (%) of patients prescribed
Anticholinergic			
First-generation antihistamines	Chlorpheniramine*	R06AB04	1 (0.14)
	Promethazine	R06AD02	14 (2.07)
Antiparkinsonism agents	Trihexyphenidyl (benzhexol)	N04AA01	3 (0.44)
Antispasmodic	Dicyclomine	A03AA07	12 (1.77)
Cardiovascular system			
α ₂ Blocker	Prazosin*	C02AC01	2 (0.29)
Central α ₂ agonist	Clonidine*	C02AC01	4 (0.59)
Antiarrhythmic	Amiodarone	C01BD01	14 (2.07)
Digitalis glycoside	Digoxin>0.125 mg/day*	C01AA05	34 (5.03)
Dihydropyridines	Nifedipine immediate release*	C08CA05	14 (2.07)
Potassium-sparing agent-diuretic	Spironolactone>25 mg/day	C03DA01	3 (0.44)
Central nervous system			
Tertiary TCA	Amitriptyline*	N06AA09	1 (0.14)
Antipsychotic	Haloperidol	N05AD01	14 (2.07)
	Chlorpromazine	N05AA01	4 (0.59)
Benzodiazepines short acting	Alprazolam*	N05BA12	61 (9.02)
	Lorazepam	N05BA06	20 (2.95)
Benzodiazepines long acting	Clonazepam	N03AE01	3 (0.44)
	Diazepam*	N05BA01	54 (7.99)
Gastrointestinal tract system			
Propulsive	Metoclopramide	A03FA01	367 (54.29)
	Mineral oil		15 (2.22)
Pain medication			
Non-COX selective NSAIDs	Aspirin>325mg/day	B01AC06	22 (3.25)
	Diclofenac	M01AB05	25 (3.70)
	Ibuprofen	M01AE01	10 (1.48)
	Mephenemic acid	M01AG01	1 (0.14)
Opioid analgesic	Pentazocine	N02AD01	13 (1.92)
Skeletal muscle relaxants	Methocarbamol	M03BA03	1 (0.14)

All drugs are included in Beer's criteria, *Included in PRISCUS criteria, TCA = Tricyclic antidepressants, NSAIDs = Non-steroidal antiinflammatory drugs, AGS = American Geriatric Society, ATC = Anatomical therapeutic classification

be the use of updated Beer's criteria (2012) in the present study, wherein more number of potentially inappropriate medications have been classified than the previous list (2002). The commonly reported inappropriate medicine metoclopramide (54.3%) was not mentioned in the previous list of Beer's criteria (2002). It is mainly used for gastroparesis and as an antiemetic because of its low cost. It was not used for chemotherapy-induced vomiting in our setup. Though it is approved for the treatment of gastroparesis, its use is largely considered inappropriate because of the possibility of extrapyramidal adverse reactions. Prolonged treatment with metoclopramide can cause serious adverse reactions like persistent tardive dyskinesia.^[10] Its incidence is as high as 15%.^[10] US Food and Drug Administration (FDA) has placed a black box warning because of the risk of tardive dyskinesia.^[11] Other risk factors for tardive dyskinesia, intended benefit, and duration of use should be considered while prescribing metoclopramide.^[12] However, it is not considered an inappropriate medicine by PRISCUS criteria. Other prescribed inappropriate medicines were benzodiazepines (20.4%), NSAIDs (8.6%), and digoxin (5%). Benzodiazepines, antihistamines, anticholinergic drugs, and cardiac glycosides were the potentially inappropriate medicines reported by Indian studies.^[4,5] Benzodiazepines are used for the treatment of insomnia and anxiety in the elderly. They can affect the cognitive functions. Their sedative effect is a risk factor for fall and fracture.^[13-15] Digoxin is mainly used for heart failure and atrial fibrillation. Altered pharmacokinetics enhances digoxin toxicity in the geriatric patients.^[16,17] Use of inappropriate medications is associated with increased risk of adverse drug reaction (ADR), morbidity, mortality, and economic burden to the patient.^[18]

Potentially inappropriate medication due to drug-disease or drug-syndrome interaction that may exacerbate the diseases should also be kept in mind. Prescription of NSAIDs in the heart and renal failure patients was the commonly identified potential drug-disease interaction. Use of NSAIDs should be restricted in the patients susceptible for congestive heart failure. It worsens the heart failure by salt and water retention and by increasing peripheral vascular resistance.^[19] It can deteriorate the renal function by affecting the prostaglandin synthesis.^[20]

Higher number of potentially inappropriate medicines was identified with Beer's criteria than PRISCUS list (26 vs. 9). All nine drugs identified by PRISCUS list were included in the Beer's criteria. This suggests the importance of Beer's criteria for screening test to identify inappropriate medicines. However, many inappropriate medicines mentioned in the Beer's criteria are not used in India (e.g. guanabenz, guanfacine, trimethobenzamide, brompheniramine, carbinoxamine,

Table 2: Utilization potentially inappropriate medication used in geriatric patients due to drug-disease or drug-syndrome interaction that may exacerbate the disease or syndrome according 2012 AGS Beer's criteria

Disease	Groups	Drugs	ATC code	Total cases(%)
Cardiovascular system Heart failure	NSAIDs and COX2 inhibitor	Aspirin	B01AC06	84 (12.43)
		Diclofenac	M01AB05	2 (0.29)
	Non-dihydropyridine CCBs	Verapamil	C08DA01	3 (0.44)
Central nervous system Delirium	Anticholinergic	Dicyclomine	A03AA07	1 (0.14)
		Benzodiazepines	N05BA12	1 (0.14)
		Corticosteroid	H02AB09	1 (0.14)
	H2 receptor antagonist	Famotidine	A02BA03	1 (0.14)
		Ranitidine	A02BA02	4 (0.59)
		Diazepam	N05BA01	1 (0.14)
		Propulsive	Metoclopramide	A03FA01
Dementia and cognitive disorder				
Kidney/urinary tract system CRF/ARF	NSAIDs	Aspirin	B01AC06	34 (5.03)
		Diclofenac	M01AB05	1 (0.14)
Lower urinary tract symptoms, BPH	Anticholinergic	Atropine	A03A01	3 (0.44)

NSAIDs=Non-steroidal antiinflammatory drugs, CCBs=Calcium channel blockers, CRF=Chronic renal failure, ARF=Acute renal failure, BPH=Benign prostatic hyperplasia, AGS=American geriatric society

Table 3: Utilization of potentially inappropriate medication to be used with caution in geriatric patients according to 2012 AGS Beer's criteria

Group	Drugs	ATC code	Total cases(%)
Vasodilators	Nitroglycerine	C01DA02	43 (6.36)
	Isosorbide dinitrate	C01DA08	321 (47.48)
	Nifedipine (SR)	C08CA05	16 (2.36)
	Verapamil	C08DA01	6 (0.88)
	Nicorandil	C01DX16	8 (1.18)
	Prazosin	C02AC01	2 (0.29)
Aspirin	Aspirin in patients>80 years of age	B01AC06	95 (14.05)
Antiepileptics	Carbamazepine	N03AF01	6 (0.88)
SSRIs	Fluoxetine	N06AB03	3 (0.59)

SR=Sustained released, SSRIs=Selective serotonin reuptake inhibitors, ATC=Anatomical therapeutic classification, AGS=American geriatric society

meprobamate, etc.) and are reported in this study. The designation of certain drugs as inappropriate medicine is debatable. Use of amiodarone in the absence of other antiarrhythmic drugs and low-dose amitriptyline for neuropathic pain may be appropriate in a particular case.^[21] No consensus was reached for amitriptyline as an inappropriate medicine in PRISCUS list. There is a need to create a separate list of potentially inappropriate medicines for India as for USA, Canada, France, Ireland, and Norway,^[7,21-25] considering the prescribing pattern, approved drug list for Indian population, local availability, need for laboratory monitoring, and cost-benefit ratio of alternative drugs. Beer's criteria also need to be compared with other tools to identify inappropriate medications, such as START (Screening Tool to Alert doctors to the Right Treatment) and STOPP (Screening Tool of Older Persons' potentially inappropriate Prescriptions) criteria, in an Indian setup.

Our data suggest that prescription of inappropriate medications is highly prevalent. Using tools for inappropriate medications should be routinely practiced to avoid potential inappropriate medications in geriatric patients. In one Italian study, use of inappropriate medications was significantly reduced by disseminating the list of drugs always to be avoided along with alternative drugs, reviewing the prescriptions, and through educating sessions.^[26] Clinicians should always remember the possibility of adverse reactions while treating an elderly patient. Any new symptom should be considered drug related until proven otherwise.^[27-29] The GerontoNet ADR risk score study reports that the risk of adverse reactions increases by fourfold with the number of medications ≥ 8 . Other risk factors include history of adverse reactions, heart failure, liver disease, presence of four or more conditions, and renal failure.^[30] In our study, approximately nine drugs were found to be prescribed per patient. For avoiding polypharmacy, the drug regimen should clearly be focused and prioritized on a particular goal to be achieved - prolonging longevity; reducing symptoms; minimizing medication burden, adverse effects, and costs.^[27] "The Medication Appropriateness Index" is available to evaluate the inappropriate medications based on the following: indications for the drug; effectiveness of drug for the condition; correct dosage and duration; correct and practical directions; possibility of clinically significant drug-drug interactions, drug-disease or drug-condition interactions; unnecessary duplication with other drugs; and being the least expensive alternative compared with others of equal usefulness.^[31,32] Clinicians should be made aware of potential inappropriate medications used in geriatric patients by periodic evaluation. Prescribing guidelines can be made for the particular hospital for geriatric patients,

where separate geriatric clinics do not exist. Expert recommendations through computer-based feedback may help to reduce the number of medications.^[27]

There are several limitations of the study. Pattern of inappropriate medicine use only represents the usage in tertiary care teaching hospitals of India. Use of it can be different in primary, secondary, and specialized care institutions. Due to the retrospective nature of the study, rationality for the indications of potentially inappropriate medications could not be checked. There is a possibility of bias because of the lack of electronic prescription record system in our setup. There is no individualized evaluation of risk and benefit for each patient. Inappropriate medicines could have been prescribed because of poor tolerance of alternative drugs or possibility of drug interaction with them. Because of the lack of documentation of adverse events in indoor case papers, we could not estimate direct risk of adverse events due to potentially inappropriate medications in the elderly. The study has identified the potentially inappropriate medicines according to Beer's criteria and PRISCUS list based on American and German populations, respectively. The possibility of adverse drug events may be differing in Indian population because of prescribing, environmental, and genetic differences.

CONCLUSION

It is an important screening tool to identify potentially inappropriate medications. The use of inappropriate medicines in the elderly patients is problematic. Clinicians should evaluate the medications they prescribe to geriatric patients using drug formularies.

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