RESEARCH ARTICLE

A Profile of Adverse Drug Reactions with Risk Factors among Geriatric Patients in a Tertiary Care Teaching Rural Hospital in India

Rima Shah¹, Bharat Gajjar², Sagun Desai¹

- ¹ SBKS Medical Institute and Research Center, Piparia, Vadodara
- ² Pramukhswami Medical College, Karamsad

Correspondence to:

Rima Shah (rima_1223@yahoo.co.in)

Received: 03.01.2012 Accepted: 28.03.2012

DOI: 10.5455/njppp.2012.2.113-122

ABSTRACT

Aims & Objective: To study the adverse drug reaction profile, its causality, severity, associated risk factors and preventability in geriatric patients in a tertiary care teaching rural hospital.

Materials and methods: Four hundred geriatric patients from various inpatient and outpatient departments were observed for occurrence of adverse drug events (ADEs) during August 2007 to October 2009. ADEs were either spontaneously reported or elucidated from personal interviews and analyzed.

Results: In forty seven (11.75%) patients, 57 events occurred of which 75.43% occurred in indoor and 24.56% in outdoor patients. Most patients (74.46%) were in the age range of 65 to 74 years. The male to female ratio was 1.47: 1. Majority of ADEs involved gastrointestinal system (43.85%), followed by cardiovascular system (14.03%), endocrine system (12.28%) and skin and mucous membranes (12.28%). 142 drugs were suspected to cause these ADEs. Chemotherapeutic agents were the most commonly suspected drugs followed by cardiovascular drugs, drugs acting on CNS and steroids. On assessing causality, majority of events were rated as 'possible' by both WHO-UMC (66.66%) and Naranjo's criteria (68.42%).

Severity assessment (Hartwig scale) showed that 19.29%, 68.42% and 12.28% ADEs were severe, moderately severe and mild respectively. Risk factors for ADR development found were socioeconomic status (p=0.000), number of diseases suffered (p=0.002), number of medicines taken per day (p=0.000), compliance (p=0.048) and inappropriate prescribing (p=0.004). 36.84% ADRs were definitely preventable and 17.54% were probably preventable by modified Schumock and Thornton scale.

Conclusion: ADRs is a major problem prevalent in geriatric patients and is significantly associated with socioeconomic status, number of diseases, number of medicines consumed per day, compliance to therapy and inappropriate prescribing.

KEY WORDS: Geriatric Patients; Adverse Drug Reactions (ADRs); Risk Factors for ADRs Severity of ADRs; Preventability of ADRs

INTRODUCTION

Geriatric population is defined as persons of equal to or more than 65 years of age.[1] Geriatric population is on rise due to increased longevity in India. Old persons are likely to suffer from more diseases, especially of chronic nature, requiring long term use of medication. Many physiological changes occur in the body as the age advances that influence pharmacokinetics and pharmacodynamics of a drug in the body.[2,3] Although medications used by older adults can lead to improvement in health related quality of life (HRQOL), negative outcomes due to drugrelated problems are considerable.[4-6] Major drug related problems include adverse drug events, inappropriate use of medicines and compliance issues. Different studies have reported rate of occurrence of ADRs in elderly as high as around 20% of which almost 50% are preventable.[7] A major threat to the healthrelated quality of life of frail elderly persons is adverse drug reactions (ADRs).[8] Specifically, ADRs in older adults can decrease functional status and increase in use of health services, and costs as well as mortality.[8] The fact that the consequences of ADRs are likely to be more pronounced in frail elderly persons is of major concern. Previously reported annual ADR rates ranged from 5% to 35% in community dwelling and outpatient older adults8. However, in India, the data regarding the incidence of ADRs are limited in elderly patients. Therefore, we undertook this study to find out the baseline data regarding the occurrence of ADRs and to further assess the causative drugs, severity, various causative factors responsible for development of ADRs and preventability in elderly.

AIMS OF THE STUDY

This study was carried out in geriatric patients with the aims of (i) to identify rate of occurrence of ADRs (ii) to generate a profile of ADRs with body system affected, its causal group of drugs (iii) causality analysis of reported ADRs with both WHO-UMC and Naranjo's method and comparison of both the methods in evaluating the causality (iv) severity and preventability

assessment of reported ADRs and (v) to identify the associated risk factors for development of ADRs in geriatric patients.

MATERIALS AND METHODS

A prospective observational study spread over two years and three months duration was undertaken from August 2007 to October 2009, in Shree Krishna Hospital and medical research centre, a 550 bedded tertiary care rural, teaching hospital attached to Pramukh Swami Medical College, Karamsad, India. The study protocol was approved by Human Research Ethics Committee of the institute prior to commencement of study.

Sample Size: Four hundred patients of geriatric age group (≥ 65 years), 200 each from various inpatient and outpatient departments of Shree Krishna Hospital (SKH) were recruited in the study

Criteria for Inclusion of Participants: Patients of either sex who had completed 65 years of age on 31st July, 2007 or earlier and attended to various outpatient or inpatient departments like Medicine, Surgery, Obstetrics and Gynecology, Orthopedics, Psychiatry, Skin, TB and Chest, Ophthalmology, ENT, Oncology and Dentistry were included in the study.

Criteria for Exclusion of Participants: Patients unable to communicate i.e. patients on ventilators, seriously ill patients requiring ICU admission or unwilling to participate were excluded from the study.

The study was conducted in both indoor and outdoor patients meeting inclusion criteria. A time period of 2 months each in a sequential manner was spent in departments of General medicine, Surgery, Obstetrics and Gynecology and Orthopedics and 15 days each in the departments of Psychiatry, Skin, TB and chest, Ophthalmology, ENT, Oncology and Dentistry. Patients were recruited in the study on prorata basis during the stipulated time period and all the patients participating in the study were explained clearly about the purpose and nature

of the study in the language they understood. Written informed consent was obtained before including them in the study. All indoor patients from respective departments were visited daily during their hospital stay and interviewed. All indoor patients were then followed up till they were discharged and their case record sheets reviewed for gathering necessary were information in a pre-structured case record form. All outdoor patients, new as well as old, meeting the inclusion criteria attending to various departments were interviewed for the first time on the day of enrollment and followed up after two weeks and their case sheets were reviewed to gather necessary information -as on that dayto fill up case record forms.

All the adverse drug events reported spontaneously as well as found out during interview by investigator were recorded in the case record form with all the necessary information. The primary researcher was trained in identification and reporting and analysis of the adverse drug events. In case of conflict in analysis of the reports, the opinion of the treating physician was also obtained. The researchers were not the part of a treating team of the patient and were not involved in any therapeutic decisions related to the patients involved in the study.

Data were analyzed to find out (i) frequency of patients developing ADE during therapy (ii) age and Sex distribution of reported ADEs (iii) system wise distribution of reported ADEs (iv) causality assessment by both WHO-UMC scale^[9] and Naranjo's probability score^[10] (v) severity of ADEs using scale of Hartwig and Siegle^[11] and (vi) preventability of ADEs using criteria of Schumock and Thornton modified by Lau et al, 2003^[12] (vii) different risk factors for ADEs in elderly.

For identifying the risk factors for development of ADEs in geriatric patients, association of ADEs with age of the patients, gender, literacy status, living status, socioeconomic status, [13] comorbidities, number of medicines consumed by the patient daily, compliance to therapy

(evaluated by patients' recall of taking drugs as prescribed), appropriateness of prescribing as assessed by Beer's criteria^[14] and duration of hospital stay was assessed using Chi square test.

Statistical Analysis: All data were analyzed with the help of SPSS version 14 software. Chi square test was used for analysis and p value less than 0.05 was considered as significant.

RESULTS

Out of total 400 patients, majority were in age group of 65 to 74 years (288, 72%), followed by age group of 75-84 years (85, 21.3%) and lowest number of patients (27, 6.8%) were in age group of more than 85 years. Of these, 241 (60.03%) were male and 159 (39.8%) were females. 200 patients were collected from different indoor departments and other 200 patients were collected from different outdoor departments of the hospital. Out of total 400 patients, 47 patients (11.75%) developed ADRs. Out of these, 33 (70.21%) patients were indoor and 14 (29.79%) patients were outdoor. Total number of events reported were 57, of which 43 (75.43%) events occurred in indoor patients and 14 (24.56%) developed in outdoor patients. Most of the patients fell within the age range of 65 to 74 years (35, 74.46%) followed by that of 75 to 84 years (11, 23.4%). Only one patient (2.12%) above the age of 85 had developed ADR. Of 47 patients who developed ADRs, 28 (59.57%) were men and 19 (40.42%) were women. On calculating incidence out of total 400 patients 11.61% were men and 11.94% were women yielding a ratio of 0.9 men to 1 woman patient.

Majority of reported adverse drug events had affected gastrointestinal system (25, 43.85%) followed by cardiovascular system (8, 14.03%), endocrine system (7, 12.28%) and skin and mucous membranes (7, 12.28%). The least affected systems were ENT, musculoskeletal and blood (1 each, 1.75%). Frequencies of individual event in the respective systems are shown in table 1. A total number of 142 drugs were suspected to be the cause of the reported ADEs. Suspected drugs are shown in a group wise

manner in table 2. It is evident that chemotherapeutic agents were the most commonly suspected drugs followed by cardiovascular drugs, drugs acting on CNS and steroids.

Table-1: Affected Body System wise Distribution of ADRs

Sr. No.	Affected Systems and Events	No. of Events (%)
1	Gastrointestinal system	25 (43.86)
	Gastritis	15
	GI Bleed	4
	Diarrheoa	3
	Vomiting	2
	Constipation	1
	Cardiovascular System	8 (14.04)
	VPCs (ventricular premature contractions)	3
2	Atrial fibrillation	2
	Hypotension	2
	Myocardial Infraction	1
	Endocrine System	7 (12.28)
3	Hypoglycemia	4
	Glucose intolerance	3
	Skin and mucous membranes	7 (12.28)
	Oral candidiasis	3
4	SJ syndrome	2
	Maculopapular rash	1
	Fixed drug reaction	1
	Renal system	3 (5.27)
5	Facial puffiness	1
	Hyperkalemia	1
	Acute renal failure	1
	Respiratory system	2 (3.51)
6	Interstitial lung disease	1
	Pulmonary fibrosis	1
7	Central nervous system	2 (3.51)
	Drowsiness	2
8	ENT	1 (1.75)
	Tinnitus	1
9	Hematology	1 (1.75)
	Thrombocytopenia	1 (1.75)
10	Musculoskeletal system	1 (1.75)
	Prolonged muscle paralysis	1
Total		57(100)

The causality assessment of the ADRs was carried out using both the WHO – UMC criteria and Naranjo's scale. The analysis using WHO – UMC scale showed that in majority of the cases, a causality association was falling in the category

Table-2: Causal Drug Groups

Sr. No.	Causal Drug Groups for ADEs	Frequen cy (%)	No. of Events
	(no. of ADEs = 57)	-5 (75)	
1	Antimicrobials	46	17
		(32.39)	(29.82)
2	Cardiovascular drugs	21	8
		(14.79)	(14.03)
3	Antipsychotics,	13	7
	antidepressants and	(9.16)	(12.28)
	sedative- hypnotics		
4	Steroids	11	5
		(7.76)	(8.77)
5	Vitamins and minerals	10	3(5.26)
		(7.04)	
6	Aminophyllin	7 (4.93)	3
			(5.26)
7	Nonsteroidal anti-	7 (4.93)	3(5.26)
	inflammatory drugs		
	(NSAIDs)		
8	Oral hypoglycemic	7 (4.93)	2
	agents		(3.51)
9	Anaesthetic agents	6 (4.22)	2(3.51)
10	Antiarrhythmic drugs	5 (3.52)	2(3.51)
11	Opioid analgesics	4 (2.82)	2(3.51)
12	Anticancer drugs	3 (2.11)	1(1.75)
13	Laxatives	1 (0.70)	1(1.75)
14	Antiseptics	1 (0.70)	1(1.75)
	Total	142	57
		(100)	(100)

Table-3: Causality assessments of ADRs

Table-5: Causality assessments of ADRS				
Causality Category	WHO-UMC Scale Number of ADRs (%)	Naranjo Scale Number of ADRs (%)	Chi-square test (p value)	
Certain/ Definite	3 (5.26)	0 (0.00)	0.071	
Probable	16 (28.07)	18(31.57)	0.531	
Possible	38 (66.66)	39 (68.42)	0.841	
Unlikely/ Doubtful	0	0	-	
Conditional/ Unclassifiable	0	NA	-	
Total	57(100)	57(100)	-	

Chi square test, P value < 0.05 is considered significant

of 'possible' (38, 66.66%) and 'probable' (16, 28.07%) while in 3(5.26%) cases it was found to be 'certain'. No case fell in the category of unlikely/doubtful and conditional/unclassifiable (Table 3). Causality was also assessed using Naranjo's algorithm. This is an objective

questionnaire based method of evaluation. The common association was of possible (39, 68.42%) and probable (18, 31.57%) categories by this method. No statistically significant difference was found in causality analyses by both the methods (p>0.05).

On evaluating severity assessment by Hartwig scale, out of 57 adverse drug reactions, 11 (19.29%) were severe, 39 (68.42%) were moderately severe, while 7(12.28%) were mild in nature. (Table 4)

Table-4: Severity of Adverse Drug Reactions (Hartwig Scale)

Severity	Severity Level	No. of events (%)	Total (%)	
Mild	1	1 (1.75)	7 (12.28)	
Milu	2	6 (10.53)		
	3	25 (43.86)	39	
Moderate	4a	5 (8.77)	(68.42)	
	4b	9 (15.79)	(00.42)	
	5	6 (10.53)		
Severe	6	4 (7.02)	11(19.30)	
	7	1 (1.75)		
Т	otal	57 (100)	57 (100)	

Different risk factors for ADR development were identified as socioeconomic status (p=0.000), number of medicines taken by patient per day (p=0.000), number of diseases patients were suffering from (p=0.002), compliance to the therapy by the patients (p=0.048) and inappropriate prescribing (p=0.004). (Table 5)

The preventability assessment of ADRs was carried out using modified Schumock and Thornton scale for all the reports including the serious cases. As shown in table 6, majority of ADRs were not preventable (26, 45.61%) followed by definitely preventable 21(36.84%) and 10 (17.54%) probably preventable.

DISCUSSION

ADRs were claimed to be the 4th leading cause of death in USA.^[7] In the recent past, observing, documenting and reporting of ADRs have gained a lot of importance all over the world.

Table-5: Association of ADRs with Different Parameters

Parameters	Total no.				
Parameter	of Patients	ADR Developed n(%)		P	
i ai ainetei	(n=400)	Yes	No	value*	
Age (years)					
65-74	288	35 (12.15)	253(87.85)		
75-84	75	11(14.67)	74(98.67)	0.397	
≥85	27	1 (3.70)	26 (96.30)		
		Sex			
Men	241	28(11.61)	213(88.39)	0.000	
Women	159	19 (11.95)	140 (88.05)	0.920	
	Li	teracy			
Illiterate	140	12(8.57)	128(91.43)		
10 th std	182	20 (10.99)	162(89.01)		
12 th std	30	6(20)	24(80)	0.061	
Graduate	36	5(13.89)	31(86.11)		
Postgraduate	12	4(33.33)	8(66.67)		
8		ily status	- ()		
Alone	47	4(8.51)	43(91.49)		
Family	353	43(12.18)	310(87.82)	0.463	
Tulliny		nomic statu			
Lower	172	16(9.30)	156(90.70)		
Middle	174	16(9.20)	158(90.80)	0.000	
			,	0.000	
Higher 54 15(27.78) 39(72.22) No. of Medicine currently taking					
Upto 5	99	3(3.03)	96(96.97)		
6-10	208	22(10.58)	186(89.42)	0.000	
6-10 ≥11	93	22(23.66)	71(76.34)	0.000	
	f concurrent	1 -			
1	85	3(3.53)	82(96.47)	I	
	137	14(10.22)	123(89.78)		
2					
3	92	10(10.87)	82(89.13)	0.000	
4	51	9(17.65)	42(82.35)	0.002	
5	24	7(29.17)	17(70.83)		
6	8	3(37.50)	5(62.50)		
7	3	1(33.34)	2(66.66)		
	Compliance (n=200 outdoor patients only)**				
Present	57	35(61.40)	22(38.60)	0.048	
Not present	143	12(8.39)	131(91.61)		
Appropriateness of prescribing##					
Appropriate	291	26(8.93)	265(91.07)	0.004	
Inappropriate	109	21(19.27)	88(80.73)		
	n of hospita			S	
1-7 Days	125	15(12)	110(88)		
8- 14 Days	48	11(22.92)	37(77.08)	0.063	
15-21 Days	17	3(17.65)	14(82.35)	0.003	
≥ 22 Days	10	4(40)	6(60)		
*Chi Cauaro toc	t n < 0.05 ic co		cianificant		

^{*}Chi Square test, p < 0.05 is considered as significant.

^{**} Compliance to treatment was evaluated only in outdoor patients, since indoor patients are administered medicines by staff nurse ensuring full compliance to therapy.

[#] Socioeconomic status classification by Kulshreshtha SP^[13] ## Appropriateness of prescribing as evaluated by Beer's criteria^[14]

Table-6: Preventability of ADRs

Sr. No.	Categories according to modified Schumock and Thornton scale	Type of ADRs	No. of events (%)
1	A	Definitely	21 (36.84)
	preventable		
2	В	Probably preventable	10 (17.54)
3	С	Not preventable	26 (45.62)
	Total	•	57 (100)

National Pharmacovigilance Programme of India has been in place since January 2005. Among various people, Geriatric population is the most vulnerable to development of ADRs for the obvious reasons. In the present study we found that 47 out of 400 geriatric patients (11.75%) developed ADRs. On one hand, it is higher than the reported incidence of ADRs of 3-6% in general population^[1] and on the other hand, it is lesser than that found in geriatric patients from UK (14.7)^[15] and from USA and Europe (20%).^[7] Several factors – genetic, ethnic, dietary, environmental, or simply less reporting of ADRs by patients may account for this relatively lower rate of ADRs among Indian geriatric patients.

Our finding that three fourths of the total adverse events occurred in indoor patients could be due to seriousness of illness, co morbidities, higher number of drugs prescribed and high percentage of inappropriate prescribing. One important reason could be that the indoor patients were under continuous observation of physicians and other paramedical staff resulting into more identification and recognition of adverse drug events as compared to that in outdoor patients, in whom adverse drug events may go unnoticed and therefore unreported.

As the age advances, the incidence of ADRs goes on increasing.^[15] Our findings are consistent with this, as far as the age groups of 65-74 years (12.35%) and 75-84 years (14.66%) are concern. Paradoxically in the age group of 85 years and above the incidence was lower (3.70%). However in an Indian study^[16] similar distribution pattern was found. We found apparently more incidences of ADRs in women (11.94%) than in men

(11.61%) giving ratio of 0.9 men to 1 woman patient. This is apparently consistant with other study wherein also more women had ADRs than the men.^[17]

The prevalence of gastrointestinal adverse effects was highest followed by that of cardiovascular events, endocrine system and skin & mucous membrane. The prevalence of ADRs pertaining to hematological, ENT and musculoskeletal system was the lowest. These findings are similar to those in another Indian study.[16] The most frequently implicated drug groups were cardiovascular antimicrobials, drugs, drugs acting **CNS** (like antipsychotics, on antidepressants and sedative-hypnotics) and steroids. Another study from India^[16] found that cardiovascular drugs and antimicrobials were the commonest drugs leading to ADR in elderly. A study from UK[15] showed that most frequently implicated drug groups causing ADRs in elderly were loop diuretics, opioids, steroids. anticoagulants and antimicrobials. Thus cardiovascular drugs and antimicrobials figured as two of the commonest drug groups causing ADRs in elderly.

Causality analysis of ADRs is done by using either WHO-UMC criteria or Naranjo's scale. However, there are very few studies wherein causality analysis of ADRs in geriatric patients has been carried out by both methods used concurrently. In our study, we carried out causality assessment using both the methods with the view to find whether there is any difference in assessment outcome by both methods. We found that there was no significant difference (p>0.05, table 3) in the assessment outcome by both methods and thus both methods measure the causality assessment similarly. In an earlier study by Sharma et al,[18] compared the causality assessment using both methods in spontaneously reported events showed that there was no difference between the two methods in grading ADRs but Naranjo's scale is more time consuming. Thus our study is in line with that of Sharma et al. Further, like Sharma et al,[18] we experienced that with the stringencies in both the methods, it becomes very difficult to ascribe the category of 'certain' or 'definite' to an observed ADR. Lack of information with regard to dechallenge or rechallenge, polypharmacy, use of fixed dose combinations and simultaneous stopping of more than one culprit drug at a time makes it a nearly impossible proposition to label the ADR as 'certain' or 'definite'. Some minor differences observed by us in the causality assessment using both the methods, though not statistically significant (P>0.05), could be because of peculiar nature of conditions imposed by the two methods. For example, in Naranjo's scale importance has also been given to the reappearance of the ADR subsequent to a placebo that we could hardly test.

One of the outcomes of causality assessment is to rate the severity of a given ADR. For this purpose the most commonly and best used scale is Hartwig's scale. However the limitation of the scale is that, in a given case of ADR the level of severity can be assigned only at the final outcome. This reduces the use of scale to an academic exercise only. Still we used the scale to study the pattern of severity level of ADRs in elderly patients. We observed that nearly two thirds of the patients (68.42%) who developed ADR were at level 3 or 4 meaning that they required admission to the hospital for management of ADR, or prolongation of hospital stay by at least one day in case of already hospitalized patients and required either an antidote or interventional treatment. Another one fifth of the patients (19.29%) required direct admission to ICU or suffered permanent damage or death i.e level 5 or 6 or 7 of Hartwig's scale. If these findings are extrapolated, we can assume a similar scenario in other elderly patients who are on drug therapy. The carry home massage would be that we need to exercise caution and restrain in prescribing in elderly, identify occurrence of ADRs at the earliest or at least be ready to gear up for meeting the situation effectively.

In the present study, factors like higher socioeconomic status, number of medicines taken by patients, number of concurrent diseases patient suffered from, compliance to therapy by

patients and inappropriate prescribing were found to be significantly associated with occurrence of ADRs (p<0.05 in each case).

Socioeconomic Status: Significantly more number of ADRs occurred in patients of higher socioeconomic class. To best of our knowledge, no studies investigating relationship between ADR and socioeconomic status have been published from India. Very few studies, published from foreign countries have shown high association between lower socioeconomic class and occurrence of ADRs.[19] More such studies are required to be conducted in an Indian setting to find out the correlation between occurrence of ADR and socioeconomic status and discern the reason for discrepancy or inconsistency, if any.

Polypharmacy: We observed that as the number of medicines taken by patients increased, occurrence of ADRs also increased. This is consistent with the previously reported literature and studies. In a study done in UK,[15] only significant predictor of ADRs from multivariate analysis was the number of medicines taken by patients. Incidences of ADR have been consistently shown to increase in an exponential, rather than in a linear, manner with the number of drugs taken.[20] Similar findings were observed in an Indian study; where in 58% of ADRs were reported in patients receiving 4 or more medications concurrently.[16] As elderly patients are suffering from multiple and chronic diseases, clinicians are required to use more number of drugs in them. Therefore, before prescribing additional medication, it is important to determine whether the patient had developed ADR due to medication before the new addition. It may happen that additional medications prescribed to overcome the ADR caused by previous medication themselves may lead to problems of polypharmacy including direct ADR of newly added drug or its interactions with other drugs and additional costs. Several published reports have clearly shown direct relationship between number of ADR and cost of management thereof.^[20] In short, conscious efforts to avoid unnecessary polypharmacy will be beneficial to the patient in particular and health care system in general.

Concurrent Co-morbid Conditions: We found a direct relationship as number of diseases increased; there was increased occurrence of ADRs. Multiple diseases in a patient, increases need for use of more drugs and hence increases risk of ADRs. In addition, age related decline in physiological reserve, pathological derangements, pharmacokinetic and pharmacodynamic changes, functioning status of vital organs like liver, kidney etc. determine behavior of drugs in the body.[1] A carefully structured prescription by a physician, considering the above factors, can help minimize both the ADRs and drug interactions.

Patient Compliance to Therapy: It is a well documented fact that as the patient compliance to drug therapy increases, the number of ADRs decreases. Paradoxically we found the reverse; patients adhering well to the drug therapy developed significantly more ADRs in our study. We have no plausible explanation for this phenomenon, except a logical derivation that due to highly prevalent polypharmacy (75.25%), the compliant patients were exposed to more, and at times unnecessary, medicines leading to more ADRs and drug interactions, as against noncompliant patients, who inadvertently got spared from receiving unnecessary medicines and hence developing lesser number of ADR and drug interactions.

Inappropriate Prescribing: There is a direct relationship between inappropriate prescribing and the rate of ADR. A positive association was found between potentially inappropriate drug prescribing, as defined by the Beers criteria, and ADRs during first-visit of elderly outpatients in a Taiwan study. [21] Consistant to this, we also found a significantly higher rate of ADRs, 19.27% in case of inappropriate prescriptions versus 8.93% in case of appropriate prescriptions (p=0.004). This once again emphasizes on rational use of medicines, especially in the elderly.

Other Factors: Age, sex, level of literacy, family status and length of hospital stay had no impact on occurrence of ADRs in elderly patients in this study. (p>0.05 in each case)

"Prevention is better than cure" is the basic tenet of medical practice. This also applies to ADRs. It may be difficult to prevent all the ADRs. However it is possible to forecast some ADRs, especially the dose related augmented (type A) ones. Establishing the preventability status of the ADRs with regard to drugs can help partially to this effect. Moreover, it may also help in adopting appropriate preventive strategies. Preventability analysis of ADRs in our study showed that just over half of the ADRs (31, 54.38%) were 'definitely' or 'probably' preventable, which is consistent with the broad range of figures (30-70%) suggested in literature.[22,23] Considering the burden of ADRs and related morbidity or/and mortality along with the cost burden involved in the treatment of ADRs, it is desirable to put these strategies in practice despite its complex nature. These strategies include, computerized prescribing and monitoring systems,[24-26] presence of pharmacists on ward rounds,[27,28] need for better monitoring,[29] and enhanced education of prescribing, leading to error reduction.[30]

CONCLUSION

At last, it will be prudent to say that timely diagnosis of ADR in the elderly will remain a challenge for the diagnostic skills of even the most experienced clinician. The basic rule in the process of identifying an ADR is simply to ask oneself 'Could this patient's condition be due to one or more of the drugs he/she is taking?' Additional monitoring and attention towards patients who are at high risk could reduce the impact of ADR both in terms of cost and quality of care.

ACKNOWLEDGEMENT

We would like to thank Dr. Amit Shah and Dr. Jatin Dhanani for their help in statistical analysis.

REFERENCES

- Starner CI, Gray SL, Guay DRP, Hajjar ER, Handler SM. Geriatrics. In: Dipiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM, editors. Pharmacotherapy A Pathophysiologic Approch. 7th ed. New York: McGraw Hill; 2008. p. 57-66. (24)
- Kane RL, Ouslander JG, Abrass IB. Clinical implications of the aging process. In: Essentials of Clinical Geriatrics, 5th ed. New York: McGraw-Hill; 2004. p3-15.
- 3. Masoro EJ. Physiology of aging. In: Tallis R, Fillit H, editors. Brockle- hurst's Textbook of Geriatric Medicine, 6th ed. London: Churchill- Livingstone; 2003. p.291-99.
- Hanlon JT, Schmader K, Gray SL. Adverse drug reactions. In: Delafuente JC, Stewart RB, editors. Therapeutics in the Elderly, 3rd ed. Cincinnati(OH): Harvey Whitney, 2000: p289– 314.
- 5. Handler SM, Wright RM, Ruby CM, Hanlon JT. Epidemiology of medication-related adverse events in nursing homes. Am J Geriatr Pharmacother 2006;4:264-72.
- Institute of Medicine. Committee on Identifying and Preventing Medication Errors: Preventing Medication Errors: Quality Chasm Series. Washington, DC: National Academy Press; 2006.
- 7. Wiffen P, Gill M, Edwards J, Moore A. Adverse drug reactions in hospital patients. Bandolier Extra 2002; 1–15 [cited 2009 Nov 5] available from: URL: http://www.bandolier.com
- 8. Hanlon JT, Pieper CF, Hajjar ER, Sloane RJ, Lindblad CI, Ruby CM et al. Incidence and predictors of all and preventable adverse drug reactions in frail elderly post hospital stay. J Gerontol Med Sci 2006;61A:511-5.
- World Health Organization (WHO). The Importance on Pharmacovigilance. Safety Monitoring on Medicinal Products. Geneva (Switzerland): Office of Publications, World Health Organization; 2002.
- 10. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981; 30(2):239-45.
- 11. Hartwing SC, Siegel J, Schnelder PJ. Preventability and severity assessment in reporting adverse drug reactions. Am J Hosp Pharm 1992;49:2229-32.
- 12. Lau PM, Stewart K, Dooley MJ. Comment: hospital admissions resulting from preventable adverse

- drug reactions. Ann Pharmacother 2003 Feb;37(2):303-5.
- 13. Kulshreshtha SP. Manual for socio-economic status scale, National Psychological Corporation, 1975; Agra-2.
- 14. Beers MH, Ouslander JG, Fingold SF, Morgenstern H, Reuben DB, Rogers W et al. Updating Beers criteria for potentially inappropriate medication use in older adults. Arch. Internal Med. 2003 Dec 8;163(22):2716-24.
- 15. Davies EC, Green CF, Taylor S, Williamson PR, Mottram DR, et al. Adverse Drug Reactions in Hospital In-Patients: A Prospective Analysis of 3695 Patient-Episodes. PLoS ONE 2009;4(2): e4439.
- 16. Sharma H, Aqil M, Imam F, Alam MS, Kapur P, Pillai KK. A pharmacovigilance study in the department of medicine of a university teaching hospital. Pharmacy practice 2007;5(1):46-9.
- 17. http://www.rediff.com/money/2009/feb/09indi as-per-capita-income-doubles-to-rs-38084.htm [cited on 9th Nov 2009].
- 18. Sharma M, Gupta SK, Gupta VB, Chatterjee. A comparative study of Causality Assessment Scales used in the analysis of spontaneously reported events: WHO-UMC criteria vs Narenjo probability scale. Journal of pharmacovigilance and drug safety 2009 jan-march;6(1):5-9.
- 19. Odubanjo E, Bennett K, Feely J. Influence of socioeconomic status on the quality of prescribing in the elderly a population based study. Br J Clin Pharmacol 2004 Sep;58(5):496-502.
- Koh Y, Kutty FBM, Li SC. Drug related problems in hospiatalised patients on polypharmacy: the influence of age and gender. Ther Clin Risk Manag. 2005 March; 1(1): 39–48.
- 21. Chia-Ming Chang, Pheng-Ying Yeh Liu, Yea-Huei Kao Yang, Yi-Chingang, Chun-Feng Wu, Feng-Hwa Lu. Use the Beers criteria for prediction of adverse drug reactions among elderly. Pharmacotherapy, 2005 Jun;25(6):831-38.
- 22. Bates DW, Cullen DJ, Laird N, Peterson LA, Small AD, Servi D, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE prevention study group. JAMA 1995 jul;274(1):29-34.
- 23. Ducharme MM, Boothby LA. Analysis of adverse drug reactions for preventability. Int J Clin Pract 2007; 61(1): 157–61.
- 24. Evans RS, Pestotnik SL, Classen DC, Horn SD, Bass SB, Burke JP. Preventing adverse drug events in hospitalized patients. Ann Pharmacother 1994;28: 523-7.

Rima Shah et al. A Profile of Adverse Drug Reactions among Geriatric Patients

- 25. Raschke RA, Gollihare B, Wunderlich TA, Guidry JR, Leibowitz AI. A computer alert system to prevent injury from adverse events. JAMA 1998;280(15):1317-20.
- 26. Dormann H, Criegee-Rieck M, Neubert A, Egger T, Levy M et al. Implementation of a computer-assisted monitoring system for the detection of adverse drug reactions in gastrenteroloy. Ailment Pharmacol Ther 2004;19: 3039.
- 27. Kucukarslan SN, Peters M, Mlynarek M, Nafziger DA. Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medicine units. Arch Intern Med 2003;163:2014-8.
- 28. Leape LL, Cullen DJ, Dempsey Clapp M, Burdick E, Demonaco HJ, Erickson JI et al. Pharmacist participation on physician rounds and adverse

- drug events in the intensive care unit. JAMA 1999;282:267-70.
- 29. Pirmohamed M, Ferner RE. Monitoring drug treatment. Br Med J 2003;327:1179-81.
- 30. Dean B, Schachter M, Vincent C, Barber N. Causes of prescribing errors in hospital inpatients: a prospective study. Lancet 2002;359:1373-8.

Cite this article as: Shah RB, Gajjar BM, Desai S. A profile of adverse drug reactions with risk factors among geriatric patients in a tertiary care teaching rural hospital in India. Natl J Physiol Pharm Pharmacol 2012; 2:113-122.

Source of Support: Nil

Conflict of interest: None declared