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Original Research Article

Cutaneous adverse drug reactions in geriatric patients in Odisha

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ABSTRACT

Background & Objective: Geriatrics is a speciality that focuses on healthcare of elderly people. Geriatric population is defined as people above 60 years of age. Geriatric population constitute 8.14% of total population in India. They have diverse physiological and pathological profiles which have an impact on the pharmacokinetic & pharmacodynamic properties of the administered drug. Very often they are under polypharmacy due to multisystem involvement and thereby subjected to numerous drug interactions and adverse drug reactions. There are few studies conducted in India regarding adverse drug reactions (ADRs) in Geriatric Patients and none in Odisha. Hence this study aims to evaluate the cutaneous ADRs encountered in geriatric patients.

Materials and Methods: This hospital based observational study was conducted in Dept of Pharmacology in collaboration with Medicine and Skin &VD of SCB Medical College & Hospital. All geriatric patients (aged ≥ 60 yrs) diagnosed with ADR, from August 2017 to July 2018, were included. The detailed information of type of ADR and its characteristics were filled up in Suspected Adverse Drug Reaction Reporting Form. The prevalence and profile of Cutaneous ADRs were studied. Their causality, severity and preventability were assessed by WHO-UMC System, Hartwig's Severity Scale and Schumock Thornton Preventability Scale respectively.

Result: A total of 102 geriatric ADRs were reported in 1 year, out of which 47% were Cutaneous ADRs. Out of the Cutaneous ADRs 73 % ADRs were probable, 62.5 % were Moderate in intensity and 58.3% of were definitely preventable. Rash (27%) was the most common cutaneous ADR detected.

Conclusion: Most of the ADRs were probably caused due to the drug, were moderate in intensity and definitely preventable.

1. Introduction

The medical prescription for patients over 60 years accounts for one-half of total prescriptions.[1]

Adverse drug reaction (ADR) is defined as a response to a drug which is noxious & unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.[2]

There was increased risk of adverse Drug Reactions (ADRs) in elderly because physiological & pathological changes in Geriatric population can alter pharmacokinetics & pharmacodynamics of administered drugs.[2]

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ADRs rank as one of the top leading causes of death & illness in the developed world.[3] Recent data of USFDA shows that ADRs now ranks the 4^{th} to 6^{th} most common cause of death.[3] Detection and prevention of ADRs at the earliest is very important to reduce the morbidity & mortality keeping in view the high healthcare cost involved in the management of ADRs.

Studies from out of the country as well as India have expressed that polypharmacy is common and correlated with raised potential for adverse drug reactions, inappropriate prescription and drug Interactions.[4–8]

The ADRs in elderly adults are four times more common than younger adults. One in six hospital admissions of elderly patients is due to ADRs.[9–11]

Literature Survey reveals that out of all Geriatric Adverse Drug Reactions in India, 5-7 % were cutaneous ADRs.[12–15]

Very few studies conducted regarding this in India & no such study in Odisha.

Hence this cutaneous ADRs study in Geriatric patients is taken up in our tertiary care hospital.

2. Aims & Objectives

This study was aimed to study cutaneous Adverse Drug Reactions with following objectives

1. Prevalence of cutaneous adverse drug reactions.
2. Profile of cutaneous adverse drug reactions.
3. Causality assessment by WHO-UMC Scale & Naranjo adverse drug reaction probability scale.
4. Severity assessment by HARTWIG'S scale.
5. Preventability by schumock & Thorton scale in our tertiary care teaching hospital.

3. Materials and Methods

3.1. Study design

1. Study type - A Hospital based observational study.
2. Study site – Dept of Pharmacology (ADR monitoring centre) in collaboration with Medicine Department and Skin &VD department of SCB medical college & Hospital, Cuttack.
3. Study period - August 2017 – July 2018.
4. Informed consent was taken from all patients.

3.2. Inclusion criteria

1. Geriatric Patients (≥ 60 yrs) of both sexes presenting in Medicine Department and Skin &VD department with all types of suspected ADRs were included in the study.
2. Details of the cutaneous ADRs were evaluated.

3.3. Exclusion criteria

1. Patients with drug abuse.
2. Patients with intentional or accidental poisoning.
3. The detailed information of Patients presented with ADRs were filled up in Suspected ADR Reporting form of Indian pharmacopoeia commission.
4. Prevalence of cutaneous Adverse Drug Reactions among all ADRs in Geriatric Patients.
5. Profile of cutaneous ADRs were evaluated.
6. The causality assessment done by WHO-UMC Scale & Naranjo ADR probability scale.
7. Severity assessed by Hartwig's Scale.
8. Preventability of ADRs assessed by Schumock & Thornton scale.

4. Results

Table 1: Number & % of ADRs in different body system

System involved	No. of ADR N-102	% of ADR
Cutaneous	48	47
Metabolic	33	32.3
GI	12	11.7
CNS	5	4.9
Respiratory	4	3.9
Total ADRs in geriatric patients-102		

The above table depicts the number of ADRs affecting different body systems. Most common body system involved was cutaneous i.e., 100 (42.3 %) ADRs, followed by Metabolic i.e., 68(28.8 %) ADRs. Followed by GI system i.e., 12(11.7%), CNS i.e.,5(4.9%), Respiratory i.e.,4(3.9%).Table 1

Table 2: Demographic profile of cutaneous ADRs in geriatric patients.

Gender	Number & % ADRs
Male	33(68%)
Female	15(32%)
Total ADRs in geriatric patients -102, out of which cutaneous ADRs -48	

The above table depicts the demographic profile of cutaneous ADRs in geriatric patients. Maximum 68% cutaneous ADRs found in males.Table 2

Table 3: Number & % of cutaneous ADRs in different age group

Age Groups (Years)	Number & % of ADRs
Young Old(60-69 YR)	31(65%)
Old Old(70-79 YR)	17(35%)
Very Old(≥80 YR)	0
Total ADRs in geriatric patients -102, out of which cutaneous ADRs -48	

The above table depicts Number and percentage of cutaneous ADRs in different age group. Maximum 65% of cutaneous ADRs found in young-old age group (60-69yr).Table 3

Table 4: Type & % of cutaneous ADRS due to different drugs

Type of dermatological ADRs	Number of ADRs with %	Drugs causing ADRs
RASH	13(27%)	Ceftriaxone, Phenytoin, Ofloxacin, Cipro OZ, Paracetamol, Azithromycin
SJS	9(18.7%)	Cefuroxime, Linezolid, Ofloxacin, Nimesulide
Pruritus	7(14.5%)	Infusion Ofloxacin
Erythema	6(12.5%)	Levocetrizine, Phenytoin
Hypersensitivity	5(10.4%)	Dapsone
FDE	4(8.3%)	Ofloxacin, Nimesulide
TEN	3(6.2%)	Amoxyclav, Cefosulba
SJS-TEN	1(2%)	Piperacillin-Tazobactam

The above table depicts type and percentage of cutaneous ADRs due to different drugs. Maximum cutaneous ADRs is rash (27%) found in our study due to ceftriaxone, phenytoin, ofloxacin, ciprofloxacin-ornidazole, paracetamol, azithromycin followed by sjs (18.7%) due to cefuroxime, linezolid, ofloxacin, nimesulide.Table 4

Table 5: % of different cutaneous ADRs

Rash	13(27%)
SJS	9(18.7%)
Pruritus	7(14.5%)
Erythema	6(12.5)%
Hypersensitivity	5(10.4%)
FDE	4(8.3%)
TEN	3(6.2%)
SJS-TEN	1(2%)

The above table depicts rash (27%) most common cutaneous ADRs found in our study.

Table 6:

Causality category	WHO-UMC scaleNumber of ADRs (%)	Naranjo ADR probability scaleNumber of ADRs (%)
Certain/definite	0	39(81%)
Probable	35(73%)	9(19%)
Possible	13(27%)	0
Unlikely	0	0
Conditional/Unclassifiable	0	
Total	48(100%)	48(100%)

The above table shows the percentage of ADRs attributed to different categories of both WHO-UMC and Naranjo scales. WHO-UMC scale shows that 13(27%) ADRs in possible category, 35(73%) in probable category. Naranjo scale shows that 9(19%) ADRs in possible category and 39(81%) ADRs in probable category.Table 6

The above table shows Hartwig's severity scale, according to it 10 (20.8 %) ADRs were of mild intensity,

Table 7:

Severity	Level	Number of ADRs	Total (%)
Mild	1	0	20.8%
	2	10	
Moderate	3	0	62.5%
	4	30	
	5	8	
Severe	6	0	16.6%
	7	0	

30(62.5%) ADRs were of moderate intensity & 8(16.6%) ADRs were of severe intensity.Table 7

Table 8: Preventability of ADRs.

Definitely Preventable	28 Cutaneous ADRs
Probably Preventable	20 Cutaneous ADRs
Not Preventable	0
Total cutaneous ADRs in geriatric patient-48	

The above table shows preventability by schumock& Thornton scale, According to it 28 (58.3%) ADRs were definitely preventable, 20(41.7%) were probably preventable.Table 8

5. Discussion

1. In our study 48(47%) ADRs collected over 1 year in contrast to 7 (7.21%) ADRs by Maheshkumar pauldurai et al (Jan 2013- Jan 2014) out of Geriatric ADRs in respective studies.
2. In our study 35.4% ADRs in age group 70-79 years with no reports ≥ 80 years which may be due to less patients above 80yrs coming to Medicine and Skin &VD department.
3. Maximum 68% cutaneous ADRs was observed in the males in our study which nearly corroborate to the study by Devi SLS et al.
4. In our study cutaneous ADRs (47%) found to be most common out of total geriatric ADRs in contrast to commonest ADR in GI system (29.89%) by Maheshkumar pauldurai et al.
5. In our study Drugs induced rash (27%) was the maximum type of cutaneous ADRs in comparison to 5% rash by Devi SLS et al.[9]

6. Conclusion

1. Most of the ADRs were probably caused due to the drug, were moderate in intensity and definitely preventable.
2. Maximum Cutaneous ADRs found in males.

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8. Conflict of interest

The authors have no conflicts of interest regarding this investigation**.**

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