

# Pharmacovigilance in Geriatric Patient- A Prospective Observational Study done in a Tertiary Care Hospital of Odisha, India

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## ABSTRACT

**Introduction:** 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 and 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 (ADRs). There are few studies conducted in India regarding ADRs in Geriatric Patients and none in Odisha, India.

**Aim:** Pharmacovigilance study in Geriatric patients was taken up in a tertiary care hospital to assess the spectrum, cause, severity and preventability of ADRs.

**Materials and Methods:** This prospective, observational study was conducted in Department of Pharmacology in collaboration with Departments of Geriatric Medicine, Medicine and Skin and Venereal Disease (VD) of SCB Medical College and Hospital, Cuttack, Odisha, India. All geriatric patients (aged  $\geq 60$  years)

diagnosed with ADR, from September 2016 to September 2018, were included. The detailed information of type of ADR and its characteristics were filled up in Suspected ADR Reporting Form. The prevalence and profile of ADRs in geriatric patients were studied. Their causality, severity and preventability were assessed by World Health Organisation-Uppsala Monitoring Centre (WHO-UMC) System, Modified Hartwig's Severity Scale and Schumock and Thornton Preventability Scale, respectively.

**Results:** A total of 236 geriatric ADRs were reported in two years, out of which, the most common ADRs were cutaneous 100 (42.4%), followed by metabolic 68 (28.8%) and Gastrointestinal (GI) involvement 26 (11%). Out of the geriatric ADRs, 128 (54.2%) ADRs were possible, 65% were moderate in intensity and 70.3% ADRs were probably preventable.

**Conclusion:** Cutaneous and metabolic ADRs were most common in geriatric patients in present study. Majority of ADRs were possibly caused due to the drug used, were of moderate intensity and probably preventable.

**Keywords:** Adverse drug reactions, Cutaneous, Geriatric population

## INTRODUCTION

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem [1]. ADR is defined as a response to a drug which is noxious and 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].

ADRs rank as one of the top leading causes of death and illness in the developed world [3]. Recent data of US Food and Drug Administration (USFDA) shows that ADRs now ranks the 4<sup>th</sup> to 6<sup>th</sup> most common cause of death [4-6]. Detection and prevention of ADRs at the earliest is very important to reduce the morbidity and mortality keeping in view the high healthcare cost involved in the management of ADRs.

The Pharmacovigilance Program of India (PvPI) is a National programme of Government of India and was launched with a broad objective to safeguard the health of 1.27 billion people of India. ADRs are reported from all over the country to National Coordinating Centre-Pharmacovigilance Programme of India (NCC-PvPI), which also works in collaboration with the Global ADR Monitoring Centre at WHO-UMC in Sweden to contribute in the global ADRs database [1]. NCC-PvPI monitors the ADRs among Indian population and helps the regulatory authority of India i.e., Central Drugs Standard Control Organisation (CDSCO) in taking decision for safe use of medicines. The PvPI is a national programme and SCB Medical College Cuttack,

Department of Pharmacology is a designated ADR Monitoring Centre under this national programme and ADRs are collected from most of the departments of our college. After doing the causality assessment of the ADRs they are entered in vigiflow for onward transmission to National Coordinating Centre (NCC) at Ghaziabad. Statistical analysis is carried out and a signal is generated. Signal information is transmitted to CDSCO and UMC for ADR database.

In Geriatric population (adults over 60 years), physiological and pathological changes are observed which modulates the effects of drugs. In older people, there occur alterations in the number of receptors, changes in signal transduction, and differences in intracellular response. Renal and hepatic functions can also be altered and can affect both the pharmacokinetics and pharmacodynamics of administered drugs [7]. In the older patients, the multiplicity of disorders necessitates the use of numerous drugs. In addition, their modified pharmacokinetics and pharmacodynamics result in an increased sensitivity to many drugs. Studies from abroad as well as India have expressed that polypharmacy is common and is directly correlated with raised potential for ADRs, inappropriate prescription and drug interactions [8-11]. As the benefits of medications are always accompanied by harmful effects, it is not surprising that older people are at increased risk of developing ADRs [4]. This may explain why in older people there is sometimes a greater sensitivity to the effects of certain drugs and sometimes a diminished response to therapy. Several studies have been conducted on ADRs as a cause of admission to hospital in older population [12-15].

But very limited studies on ADR in Geriatric population have been conducted in India [16] and no similar study was conducted in the state of Odisha, India. The present study was aimed to study geriatric ADRs in our tertiary care teaching hospital with following objectives- to determine socio-demographic profile of geriatric ADRs, to assess causality assessment by WHO-UMC scale and Naranjo ADR probability scale, to assess severity of ADR using Hartwig's severity scale and to assess preventability by Schumock and Thornton scale.

### MATERIALS AND METHODS

The present study was a prospective, observational study done in Department of Pharmacology, SCB Medical College, Cuttack in collaboration with Departments of Geriatric Medicine, Medicine and Skin and VD of SCB Medical College and Hospital, Cuttack, Odisha, India. Our Institution is a tertiary care teaching hospital and has an approved ADR Monitoring Centre (AMC) under the PvPI. The study was approved by the Institutional Ethics Committee (IEC), SCB Medical College and Hospital, Cuttack with IEC NO.-583/26.02.18 and was conducted for a period of two years from September 2016 to September 2018.

**Inclusion criteria:** Geriatric patients presenting in Geriatric Medicine Department, Medicine Department and Skin and VD Department with all types of suspected ADRs. Patients aged ≥60 years, of both gender and who gave consent were included in this study.

**Exclusion criteria:** Patients with drug abuse and with intentional or accidental poisoning were excluded.

### Study Procedure

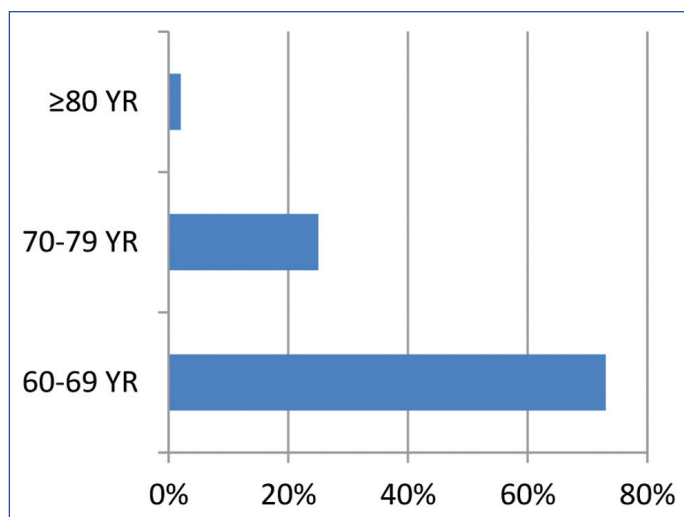
Geriatric patients of both sexes were evaluated in detail (both by clinical examinations and laboratory investigations). The following laboratory investigations like complete blood count, blood sugar, serum sodium, serum potassium, urine routine microscopy, liver function test, serum urea, serum creatinine and other investigations were done as per the requirement of the treating clinician. The detailed information was entered into the Suspected ADR Reporting Form of IPC and information regarding pre-existing diseases and other co-morbidities of the patients, details of all the medications including prescribed and self-medications were entered into the predesigned study format. The causality assessment was done by using WHO-UMC scale and Naranjo scale; the severity was assessed by Hartwig's scale. Preventability was assessed by Schumock and Thornton scale [1].

### STATISTICAL ANALYSIS

Details of ADRs obtained in present study for the geriatric patients were analysed statistically (using Microsoft Excel) with special reference to age groups (60-69 years, 70-79 years and ≥80 years) and gender. Ultimately the extents (severity) of ADRs in Geriatric populations attending to our hospital were assessed. Then analysed statistically by using excel and most data are expressed in percentages.

### RESULTS

Demographic characteristics revealed most of the patients 172 (72.9%) were in the age group 60-69 years followed by age group 70-79 years in 58 (24.5%) [Table/Fig-1]. The median (IQR) for age was found to be 67 year (63-70) years. Males constituted the majority i.e., 158 of all ADRs (67%) while females comprised 78 cases (33%) of ADRs. In this present study, most common ADR was cutaneous ADRs (42.4%), followed by metabolic i.e., 68 (28.8%) ADRs [Table/Fig-2].



[Table/Fig-1]: Age wise distribution of Adverse Drug Reactions (ADR). X-axis showing ADRs in percentage, Y-axis showing age

System involved	No. of ADR (n-236)	% of ADR
Cutaneous	100	42.4
Metabolic	68	28.8
Gastrointestinal (GI)	26	11
Central Nervous System (CNS)	12	5
Respiratory	10	4.3
Haematological	10	4.3
Musculoskeletal	6	2.5
Nephrology	4	1.7

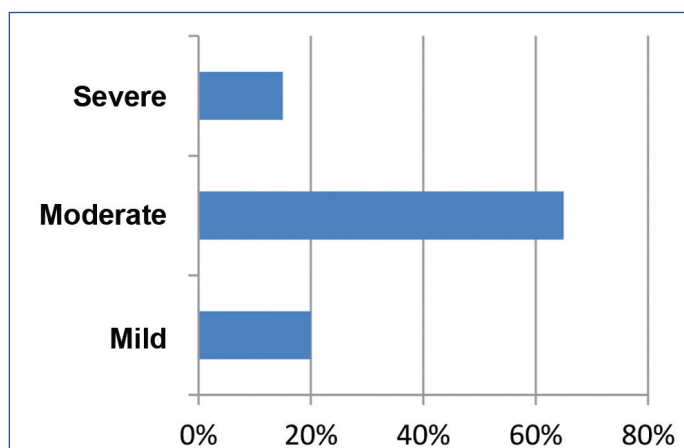
[Table/Fig-2]: Adverse Drug Reactions (ADR) in different body system.

[Table/Fig-3] shows the percentage of ADRs attributed to different categories of both WHO-UMC and Naranjo scales. In WHO-UMC scale, no definite, unclassifiable, certain and other categories of ADRs were found. Naranjo scale shows 120 (50.8%) ADRs in possible category and 116 (49.2%) ADRs in probable category. No definite, doubtful etc., categories of ADRs were found according to Naranjo Scale in the present study.

[Table/Fig-4] shows Hartwig's severity scale, according to it 46 (20%) ADRs were of mild intensity, 154 (65%) ADRs were of moderate intensity and 36 (15%) ADRs were of severe intensity.

Causality categories	WHO-UMC scale	Naranjo scale
Probable	108 (45.8%)	116 (49.2%)
Possible	128 (54.2%)	120 (50.8%)
Total	236	236

[Table/Fig-3]: Causality Assessment of ADRs by WHO-UMC and Naranjo Scales.



[Table/Fig-4]: ADRs According to Hartwig's Severity Scale. X-axis showing ADRs in percentages, Y-axis showing severity

[Table/Fig-5] shows preventability by Schumock GT and Thornton AP scale.

Schumock GT and Thornton AP	ADRs n (%)
Definitely preventable	46 (19.5%)
Probably preventable	166 (70.3%)
Not preventable	24 (10.2%)
Total	236 (100%)

**[Table/Fig-5]:** Preventability of Geriatric ADRs by Schumock and Thornton Scale

## DISCUSSION

The present study was aimed to determine socio-demographic profile of geriatric ADRs, to assess causality assessment by WHO-UMC scale and Naranjo ADR probability scale, to assess severity of ADR using Hartwig's scale, to assess preventability by Schumock and Thornton scale. A 72.9% of collected ADRs belong to age group 60-69 years [Table/Fig-1]. A study conducted by Pauldurai M et al., revealed a result of 69% of ADRs in the above mentioned age group [2]. Age wise occurrence of ADRs was 25% within the age group 70-79 years and 2% above 80 years of age group. Such findings may be due to less number of patients aged more than 70 years visit geriatric, medicine and skin and VD department. Gender distribution of ADRs revealed a male preponderance (i.e., 67% in males). This finding was consistent with findings obtained by Pauldurai M et al., ADRs in male was 73.19% and in female was 26.81%. Another study by Shree Lakshmi Devi S et al., revealed ADRs in male 55.31% and female 44.69% [17]. Another study by Jayanthi CR et al., revealed ADRs in male was 62.9% and females were 37.1% in elderly [18].

The ADRs were categorised according to system involved as cutaneous, metabolic, GI, Central Nervous System (CNS), respiratory, haematological, renal and musculoskeletal type obtained in this present study [19]. Cutaneous ADRs contributes to 42.4% of total ADRs [Table/Fig-3]. Next to cutaneous was metabolic which comprised to 28.8%. Least was of renal type (1.7%) ADRs, in contrast to most common ADRs in GI system (29.89%) by Pauldurai M et al., [2]. In this present study, 45.8% geriatric ADRs were in probable category and 54.2% were in possible category according to WHO-UMC scale in contrast to 70.10% geriatric ADRs in probable category, 27.83% ADRs in possible category and 2.06% in certain category by Pauldurai M et al., [2]. In this present study, depicted 50.8% geriatric ADRs were possible category and 49.2% of ADRs probable according to Naranjo ADR probability scale in contrast to 29.89% ADRs in possible category and 70.10% ADRs in probable category by Pauldurai M et al., [2].

Severity assessment of ADRs according to Hartwig's scale, 65% geriatric ADRs were moderate in intensity and nearly corroborate to the findings of 74/97 study done by Pauldurai M et al., [2]. According to Schumock and Thornton preventability scale 70.3% ADRs were probably preventable, 19.5% ADRs were definitely preventable and 10.2% were not preventable [Table/Fig-6]. Due to unavailability of data the finding could not be compared. Another study by Nagaraju K et al., [19] revealed 83 (68%) of moderate ADRs, 30 (25%) mild and 9 (7%) severe ADRs. This present study revealed 154 cases (65%) were of moderate in intensity and 46 cases (20%) were of mild in intensity and 36 cases (15%) were of severe in intensity that is corroborated with Jayanthi CR et al., study in which 46 (51.68%) were found to be mild, 35 (39.32%) moderate and 8 (8.98%) severe [18]. In this present study, 70.3% ADRs were probably preventable which is corroborated with Jayanthi CR et al., that revealed 92.1% ADRs

as probably preventable [18]. Another study Rukmangathen R and Brahmanapalli VD shows 48.3% probable and 51.7% possible ADRs according to WHO-UMC scale which was not corroborated with the present study [20].

## Limitation(s)

Only three clinical departments involved in this present study. There are limited studies on pharmacovigilance in geriatric patients.

## CONCLUSION(S)

This extensive pharmacovigilance study conducted in a tertiary care hospital showed varied ADRs with higher reports in males compared to females and more reports were obtained in young-old age group of geriatric patients. Dermatological ADRs had highest incidence among all geriatric ADRs. Most of the ADRs were probably caused due to the drug, were moderate in intensity and probably preventable. Hence, this study further emphasises need of pharmacovigilance to reduce incidence of geriatric ADRs and increasing awareness among healthcare professionals, patients and public.

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- Manual Googling: Dec 07, 2021
- iThenticate Software: Dec 13, 2021 (16%)

#### ETYMOLOGY: Author Origin

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