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An Analysis Of Adverse Drug Reactions In Special Age Groups - Geriatrics And Paediatrics At Tertiary Care Teaching Hospital.

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ABSTRACT

Geriatrics and paediatrics are two extremes age groups and elderly people commonly experiences adverse drug reaction since they exhibit numerous risk factors.. Most of the time ADRs occurring in elderly people goes unnoticed because it is difficult to recognise as they often present with unspecific symptoms. So more attention should be paid to identify ADRs in elderly people. Hence pharmacovigillance plays a crucial role in ADR monitoring. To assess and analyse the clinical spectrum of adverse drug reaction in geriatric and paediatric age group. 1. To assess the pattern of Adverse Drug Reactions in geriatric and paediatric age group. 2. To assess the drugs commonly involved in the development of ADRs in geriatric and paediatric age group. 3. To assess the relationship between ADR and causative drug by causality assessment. All ADRs reported in geriatric age group(≥ 65 years) and paediatric age group(≤ 12 years) indoor as well outdoor patients from January, 2017 to June, 2017 at ADR monitoring centre, Department of Pharmacology, AVBRH hospital , sawangi(meghe) , wardha were identified. ADRs reported by hospital staff including nurses, physicians and also spontaneously reported ADRs were collected and tabulated in CDSCO form. And ADR data has been generated. A retrospective analysis was done to find out the commonly involved drugs and clinical presentation of the geriatric and paediatric age group of patients. Causality assessment was done by using WHO causality assessment scale. A total of 56 ADRs were collected, tabulated in CDSCO forms, analyzed and assessed on WHO causality assessment scale. Out of 56 ADRs 37 were from geriatric patients (66.08%) while 19 from paediatric patients (33.93%). The most common causal drugs in geriatric patients was cardiovascular (14, 37.84%) followed by antimicrobials (7, 10.91%). While in paediatric patients, the most common causal drug group was antimicrobials (18, 94.74%) while only one ADR was reported with blood products (1, 5.26%). Causality assessment for majority of ADRs in geriatrics and paediatrics was probable (30, 53.58%) and possible (24, 42.85%) Extremes of age, associated co morbidity and polypharmacy increases the risk of ADRs in elderly. This calls for the need for active surveillance of drug safety monitoring in these ADR prone populations. Here pharmacovigillance plays crucial role in monitoring ADRs.
Keywords: ADR- Adverse drug reaction, WHO-UMC scale.

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INTRODUCTION

The possible reasons for higher prevalence of ADRs in geriatric patients are age related association of co- morbidities, polypharmacy, and altered pharmacokinetic and pharmacodynamics.[1] In addition, infants and very young children are at high risk of ADRs because their capacity to metabolize the drug is not fully evolved.

Geriatrics and paediatrics are two extremes of age groups. ADRs are commonly experienced by Elderly peoples. They usually present with many risk factors promoting the occurrence of adverse drug reactions (ADRs) [2] like e.g. multimorbidity which can lead to polypharmacy [3]. Further risk factors for ADRs in older adults include changes in renal and hepatic clearance, distribution and metabolism leading to prolonged half-lives or higher plasma concentrations if not taken into consideration [4].

The aging population with multiple chronic diseases has led to a rising prescription of medications. [5] The classes of drugs used commonly by the elderly include cardiovascular, antimicrobials, analgesics, hypoglycaemic agents, psychotropic drugs and anti- arthritics. Increased sensitivity to drug effects among the elderly results from changes in pharmacokinetics (how the body absorbs, transforms, and excretes medications) and pharmacodynamics (the effect of the drug on the body). For many drugs, both the half-life and active levels produced by a given dose increase with age, and for some drugs, a given active drug level will have a greater effect in older persons [6].

ADRs in older adults may be difficult to recognise as they often present with unspecific symptoms or are attributed to underlying diseases. Therefore, the causal association with drug treatment is difficult to assess [7, 8]. Pharmacovigillance (PV) plays crucial role in active surveillance. Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems [9].

Aim

To assess and analyse the clinical spectrum of adverse drug reaction in geriatric and paediatric age group.

Objectives:

- To assess the most commonly occurring ARD in geriatric and paediatric age group
- To assess the drugs commonly involved in the development of ADRs in geriatric and paediatric age group.
- To assess the causal relationship between ADR and the drug.

MATERIALS AND METHODS

Department of Pharmacology, AVBRH hospital, sawangi(meghe) , wardha is a recognized Adverse Reaction Monitoring Centre (Pharmacovigilance centre).The suspected ADRs from indoor as well as outdoor patients were diagnosed by treating consultants, and relevant details of each ADR were filled by nursing staff in spontaneous ADR reporting form and all ADRs were reported to Department of pharmacology which is Pharmacovigilance centre. Each report was sent to the National coordinating centre through Vigiflow and simultaneously entered in the Microsoft Excel sheet. All ADRs reported in geriatric (≥65 years) and paediatric (≤12 years) patients from January 2017 to June 2017 6 months duration were identified. Data were analyzed and the causality assessment was done to find out the relationship between the initiation of Drug and occurrence of ADR, Type of ADR, number of adverse events, causal drug groups and body system involved in both groups. Causality assessment was done using WHO-UMC scale.

Study conduct: ADR reports of indoor as well as outdoor patients had been collected from Pharmacovigilance unit from Jan 2017 till July2017.

Study period: Jan 2017 till July2017.

Study population: Indoor as well as outdoor patients at one of the tertiary care teaching hospital in central India.

Study design: Observational Study

Statistical analysis

Data was tabulated and data analysis has been done in consultation with statistician using the suitable tests.

RESULTS AND OBSERVATIONS

A total 56 ADRs were collected, tabulated in CDSCO forms, analyzed and assessed on WHO causality assessment scale. Out of 56 ADRs, 37 were from geriatrics and 19 ADRs from Paediatrics during study period. In Geriatrics out of 37, 26 were male and 11 were females while in Paediatrics out of 19, 13 were boys and 6 were girls. In Geriatrics the most commonly affected system was Gastrointestinal (54.05%), followed by Skin and appendages (27.03%),and CNS system is minimally affected (18.92%) while in Paediatrics out of 19 ADRs , skin and appendages were maximally affected (47.37%)followed by GIT(26.32%) and others (21.06%) as shown in (Table 1)

Table 1: Commonly affected body system in geriatrics and paediatrics

Sr. No.	Geriatrics	(n=37)	Paediatrics	(n= 19)
1	Gastrointestinal	(54.05%)	Skin and appendages	(47.37%)
2	Skin and appendages	(27.03%)	Gastrointestinal	(26.32 %)
3	CNS	(18.92%)	CNS	(5.27%)
4			Others	(21.06%)

The most common ADR in Geriatrics was Nausea and vomiting (9, 24.33%) followed by Dizziness (7, 18.91%), diarrhoea (6, 16.21%) and skin rash (6, 16.21%) while the most common ADR in Paediatrics was urticarial rashes (5, 26.32%) followed by, itching all over the body (3, 15.79%) and Vomiting (3, 15.79%) (Table 2)

Table 2: ADR pattern in Geriatrics and paediatrics

Adverse drug Reactions In Geriatrics	Total No. Of cases n = 37		Adverse drug Reactions In Paediatrics	Total No. Of cases 19	
vomiting	9	(24.33%)	Urticarial rashes	5	(26.32 %)
diarrhoea	6	(16.21%)	Itching all over the body	3	(15.79%)
Metallic test	5	(13.51%)	Burning sensation	1	(5.27%)
dizziness	7	(18.91%)	vomiting	3	(15.79%)
Skin rash	6	(16.21%)	diarrhoea	2	(10.53%)
Itching over the body	4	(10.81%)	Fever	2	(10.53%)
			Chills and rigors	2	(10.53%)
			seizures	1	(5.27%)

In Geriatrics maximum ADRs were reported with antimicrobials (7, 18.91%), followed by Diuretics (6, 16.21), antihypertensives (6, 16.21), Anti diabetics (5, 13.51%), NSAIDS (5, 13.51%).But collectively Cardiovascular class of drugs had caused maximum ADRs (14, 37.84%).

In Paediatrics maximum ADRs were reported with Beta lactam antimicrobials (8, 42.11%) followed by Aminoglycosides (4, 21.06%), macrolids (3, 15.79%) and Fluoroquinolones (2, 10.53%). (Table 3).

Table 3: Causative Agents responsible for development of ADR in Paediatrics and Geriatrics

	Paediatrics	n=19	Geriatrics	n =37
Antimicrobial agents	Beta lactums	8 (42.11%)	Antimicrobials	7 (18.91%)
	Aminoglycosides	4 (21.06%)	NSAIDS	5 (13.51%)
	macrolides	3 (15.79%)	Diuretics	6 (16.21%)
	fluoroquinolones	2 (10.53%)	Ant diabetic drugs	5 (13.51%)
	Antimalarials	1 (5.27%)	antihypertensive	6 (16.21%)
Blood products		1 (5.27%)	Antiarrhythmics	2 (5.50%)
			benzodiazepines	4 (10.81)
			laxatives	2 (5.50%)

The assessment by WHO-UMC causality assessment scale had shown that out of 56 ADRs 24 ADRs possible, 30 ADRs probable, and 2 ADRs as certain. (Table 4).

Table 4: WHO causality Assessment n = 56

| Type of reaction	No. Of ADR	percentage
probable	30	53.58 %
possible	24	42.85 %
certain	02	3.58 %
unlikely	0	0

DISCUSSION

In this study of Adverse Drug reaction, the predominance of males over females is found in geriatrics which is similar with the findings of study done by Dhar et al [10]. It was observed that the most common age group of Geriatrics is between 60 to 65 years in which ADRs had occurred. The finding was similar with the study done by Pauldurai et al [11]. In paediatrics most commonly affected age group was 5 to 10 years while Priyadarshini et al. reported more number of ADRs in 1-6 years [12].

The most commonly affected system in Geriatrics was gastrointestinal system followed by skin and appendages and CNS which was similar with Pauldurai et al. This might be due to maximum oral intake of medications like antimicrobial agents, antidiabetics, antihypertensive during study period. In paediatrics skin reactions were common which was similar to the study done by Priyadarshini et al. This might be due to skin reaction could be easily recognised.

Commonly ADR causing drug in geriatrics were cardiovascular drugs, antimicrobials and followed by NSAIDs and Antidiabetic drugs. Similar findings were given by Amin et al [13]. Findings of the Study done by Parmar et al [14] showed that antimicrobials are mainly responsible for ADR development followed by NSAIDs and ACE inhibitors and antidaibetics. Probably most frequently implicated drugs groups were cardiovascular drugs ,antimicrobials, Anti diabetic drugs because commonly associated co- morbid conditions are frequently encountered in older age for which these drugs are routinely prescribed. In paediatrics Beta lactam antimicrobials were most commonly found drugs responsible for ADRs, as Antimicrobials agents are frequently prescribed drugs in paediatric age group. Another study with similar finding was done by Mandha et al [15]] Many ADR related study has been done and many of these studies used WHO- UMC scale for causality assessment. Findings of Causality assessment in this study were similar with certain studies [11, 12].
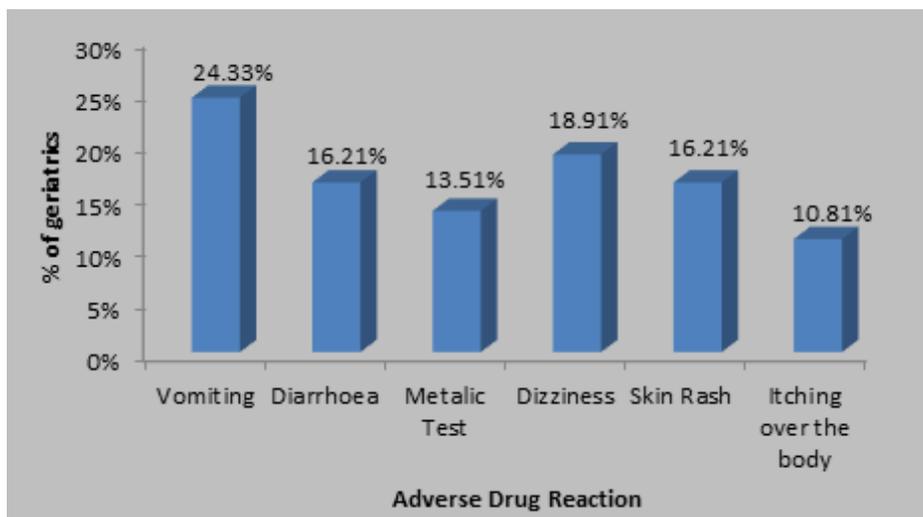
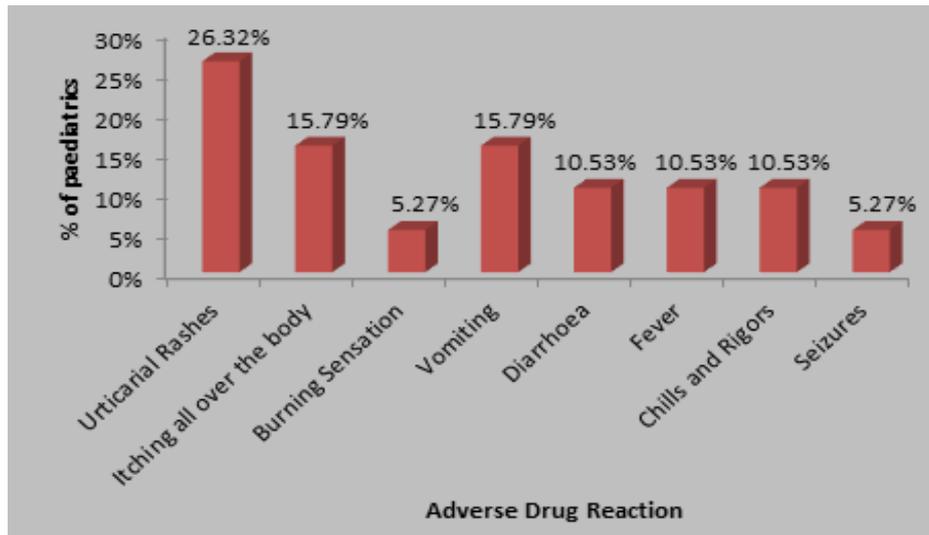**Graph 1: Commonly affected body system for geriatrics**
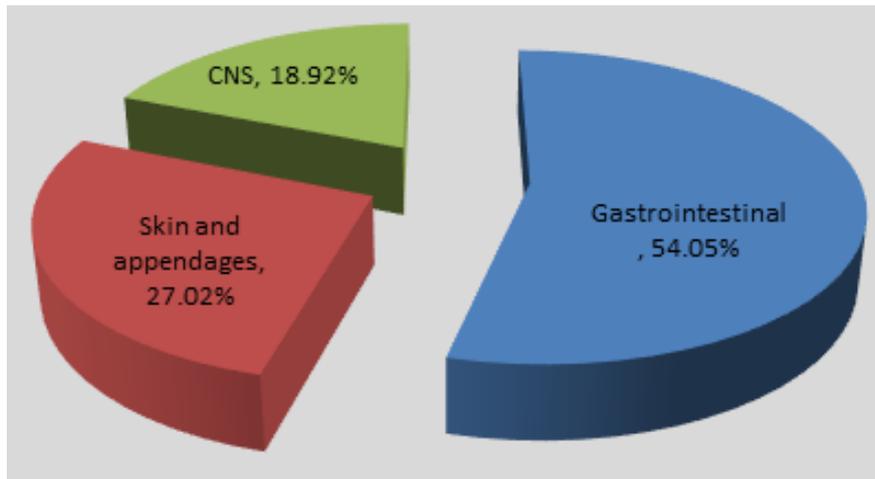
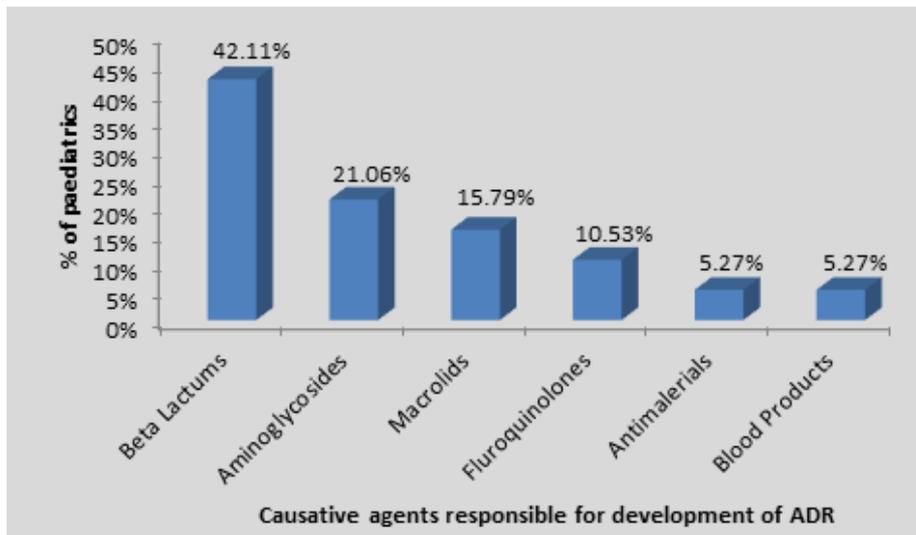**Graph 2: Commonly affected body system for paediatrics**
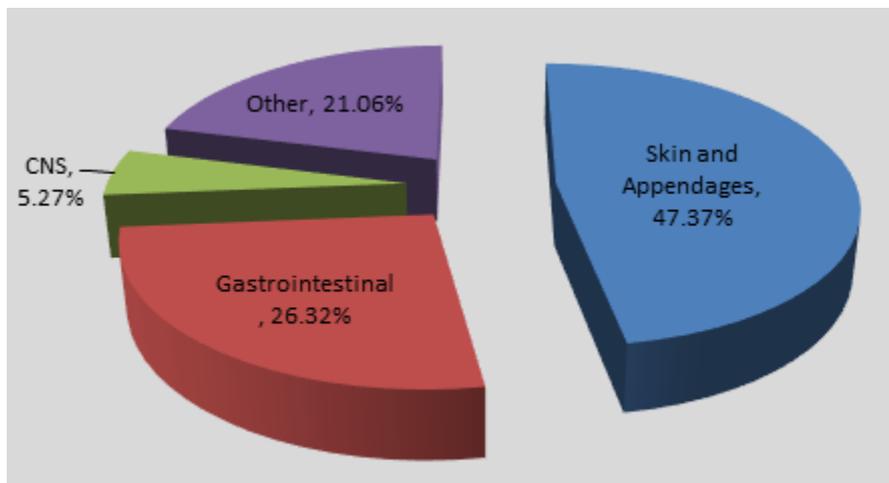
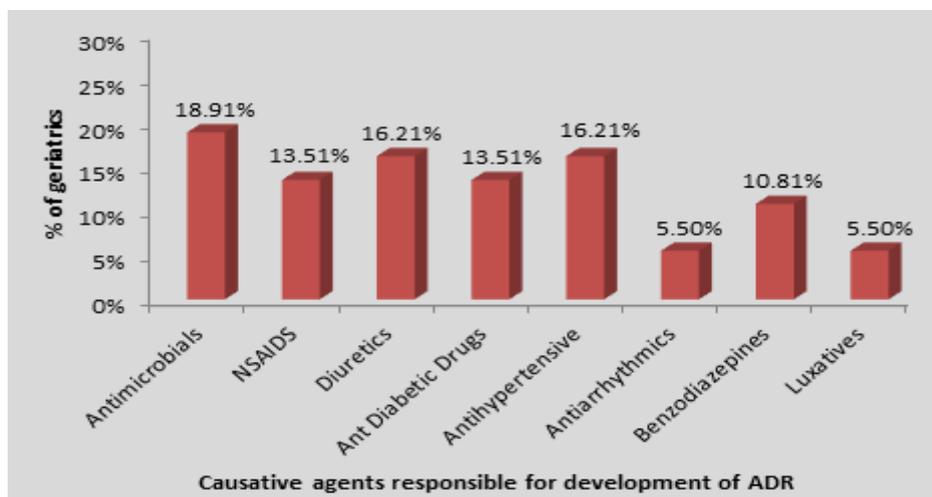**Graph 3: Adverse drug reaction in geriatrics**
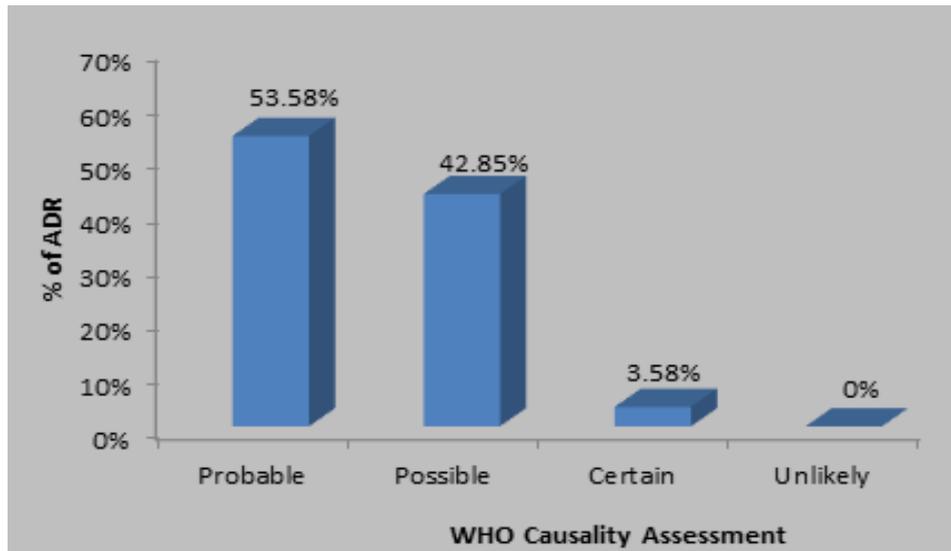
Graph 4:Adverse drug reaction in paediatrics

Graph 5: Causative agents in paediatrics

Graph 6: Causative agents in geriatrics

Graph 7: WHO Causality Assessment

CONCLUSION

As Geriatrics and Paediatrics are two vulnerable groups and ADR prone groups pharmacovigilance plays important role to find out unnoticed ADRs which are frequently encountered with geriatrics. This call for an active surveillance, Physician role is crucial in identifying such unnoticed ADRs and treating them efficiently. As pharmacokinetics and pharmacodynamics are changed in elderly, which is mainly responsible for increased sensitivity and development of ADRs in geriatrics which should have been considered while prescribing drugs.

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