Analysis of ADR (Adverse Drug Reaction) in geriatric patients of a Tribal district, special reference to self-medication and traditional medicine

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Abstract

Introduction: Geriatric populations are vulnerable population for adverse drug reactions due to their pharmacokinetic limitations. ADR in older people are common cause of admission to hospital [1, 2] and important causes of morbidity and mortality. In more recent studies, the ADR rate in geriatric setting for the USA and Europe was greater (20%) than in studies carried out in general medicine settings [3]. In tribal distict, the availability of qualified doctors is an important issue, which may predispose to self- medication of modern medicines. There may also be use of various traditional medicines by quacks without prescription of authorized BAMS doctors). There is common concept that Traditional medicines are safer but reliable information (systematic toxicological evaluation) is not available [4]. Use of traditional medicine may associated with various adverse reaction that can affect oral health. Material and Methods: Study Design: This will be an open label, prospective, observational study.

Study site: It was conducted at PRM Medical College and Hospital, Baripada, situated in tribal district of Odisha. Data was also collected from a district headquarter hospital.

Collection of data: Data was collected from geriatric patients i.e. >60 years of age, (who/UN reference for elderly patient) attending the OPD of the PRM medical college hospital (especially in dermatology, pulmonary medicine and in general medicine OPD). Case of ADR in the geriatric patient when detected by the concerned treating doctors was evaluated in detail, the data was collected and entered into the suspected adverse drug reactions reporting form of PvPI (Pharmacovigilance programme, Govt of India (copy enclosed), as this is a routine procedure for collection and reporting of ADRs. During collection of data of ADR, detailed history of all the suspected medications for the ADRs was collected, special focus will be to obtain about use of prescribe or self-medication in each case and whether drugs used are prescribed or self-medications. Use of traditional medicine in each case was also be explored.

Results: In our Hospital the reported ADRs are found more in Modern medicine both in Geriatric as well as Adult age group. 100% of ADR cases in geriatric patients & 93.47% of

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ADR cases in adults were associated with modern medicines. Most common ADR in Geriatric patients in our series is ATT induced GI adverse effect & Hepatitis i.e. 6 out of total 14 cases (42.85%) of cases.

Conclusion: In our study self-medication induced ADRs were very common (45.65%) in adult population. In both Geriatric and adult Ofloxacin + Ornidazole combination was the most common offending drug for self-medication induced ADR (FDE).

Keywords: Geriatric, self-medication, traditional medicine, ADR

Introduction

Geriatric populations are vulnerable population for adverse drug reactions due to their pharmacokinetic limitations. ADR in older people are common cause of admission to hospital [1, 2] and important causes of morbidity and mortality. In more recent studies, the ADR rate in geriatric setting for the USA and Europe was greater (20%) than in studies carried out in general medicine settings [3]. In tribal district, the availability of qualified doctors is an important issue, which may predispose to self-medication of modern medicines. There may also be use of various traditional medicines by quacks without prescription of authorized BAMS doctors). There is common concept that Traditional medicines are safer but reliable information (systematic toxicological evaluation) is not available [4]. Use of traditional medicine may associated with various adverse reaction that can affect oral health [5].

There are no significant data on ADRs in Geriatric population with reference to self-medication, no data on ADRs with traditional medicine.

The burden of adverse drug reactions (ADRs) in the global scenario is high and accounts for considerable morbidity, mortality, and extra-cost to the patients ^[6]. Studies revealed that ADRs are leading to hospitalization and constitute a significant economic burden on patients in India ^[7]. Medicines safety monitoring is an essential element of healthcare and for high-quality medical care. Since safety monitoring of medicines as an integral part of clinical practice, the Ministry of Health and Family Welfare (MoHFW), Government of India launched the nationwide Pharmacovigilance Programme of India (PvPI) in the year 2010 to inspire confidence and trust among patients and healthcare professionals with respect to medicines safety ^[8]. Under-reporting of adverse drug reactions: a challenge for pharmacovigilance in India ^[9].

Geriatric populations are vulnerable population for adverse drug reactions due to their pharmacokinetic limitations. ADR in older people are common cause of admission to hospital [1, 2] and important causes of morbidity and mortality In an europian multicentric study Out of 644 elderly patients, 139 (21.6%; 95% confidence interval 18.5-25.0%) patients experienced an ADR. Serum electrolyte abnormalities were the most common ADR [10]. In an Indian study, 10 per cent ambulatory elderly patients were found to have ADRs. Of the total 4005 prescriptions, 406 were identified with ADRs, giving the occurrence of 10 per cent ADRs in elderly. Type A ADRs accounted for 46 per cent of the total ADRs. Majority of the ADRs (88.6%) were classified as 'probable'. The definitely preventable reactions were 22 per cent. The percentage of moderate reaction was 16 per cent. Only 1.6 per cent ADRs was severe in nature. The most common type of ADR was peripheral oedema. The most commonly offending class of drug was cardiovascular drugs (57.6%). This indicates that the elderly patients should be closely monitored for ADRs, to avoid clinically significant harmful consequences. The awareness of risk factors of ADR will help physicians to identify elderly patients with greater risk of ADRs and, therefore, might benefit from ADRs monitoring and reporting programme [11].

Traditional (Herbal/Ayurvedic medicines are frequently used by the patients either by prescription of doctors of Indian system of medicines or by Quacks or used by self-medications by the patients. Face-to-face interviews (using a structured questionnaire) with

515 users of herbal remedies were conducted in six pharmacy stores and six health food stores in the UK. Following a 'serious' suspected ADR, 156 respondents (30.3%) would consult their GP irrespective of whether the ADR was associated with the use of a herbal remedy or a conventional OTC medicine, whereas 221 respondents (42.9%) would not consult their GP for a serious ADR associated with either type of preparation Geriatric is the branch of medicine which aims to promote health by preventing and treating diseases and disability in older adults. Elderly people particularly are subjected to have multiple medical disorder; some have self-prescribed herbal medications and over-the-counter drugs; some adult physician prescribed medication to their patients without reviewing other mediation used by the elderly patient. This polypharmacy may result in many drug interaction and may cause some adverse drug reaction. So the main objective of our study was to assess the ADRs and inappropriate medication usage in geriatric patients.

Hence, the present study is planned with the following objectives.

Objectives

- Overall evaluation of ADRs in the geriatric patient of a tribal area and analysis of the suspected medication.
- Evaluation of extent of ADRs in tribal geriatric patients associated with self-medication.
- Evaluation of use of traditional medicines in these tribal geriatric populations and their contribution for ADRs.

Material and Methods

- **Study design:** This will be an open label, prospective, observational study.
- **Ethical issues:** The study protocol was submitted to our Institutional Ethics Committee and was approved by the IEC PRM Medical college Baripada vide IEC ref no-1.
- **Study site:** It was conducted at PRM Medical College and Hospital, Baripada, situated in tribal district of Odisha. Data was also collected from a district headquarter hospital.

Collection of data

- Data was collected from geriatric patients i.e. >60 years of age, (who/UN reference for elderly patient) attending the OPD of the PRM medical college hospital (especially in dermatology, pulmonary medicine and in general medicine OPD).
- Case of ADR in the geriatric patient when detected by the concerned treating doctors was evaluated in detail, the data was collected and entered into the suspected adverse drug reactions reporting form of PvPI (Pharmacovigilance programme, Govt of India(copy enclosed), as this is a routine procedure for collection and reporting of ADRs.
- During collection of data of ADR, detailed history of all the suspected medications for the ADRs was collected, special focus will be to obtain about use of prescribe or self-medication in each case and whether drugs used are prescribed or self-medications. Use of traditional medicine in each case was also be explored.
- Causality Assessment of ADR-The data was submitted to the causality Assessment Committee in Dept. of pharmacology for causality assessment by the WHO UMC Scale (Encloser-2) ultimately the causative drugs was identified.

Stastistical Analysis-After causative drugs were in each case of ADR, then the contribution of self-medication & Traditional Medicines for causing the particular ADR in Geriatric patients among all the cases of ÀDRs of our tribal area was found out by applying appropriate statistical methods. Categorical data was expressed in counts. Quantitative data was

summarized as mean and standard deviation. Chi square test was used to analyze the test of significance for categorical data an student's t test was used to analyze the test of significance for quantitative data.

Implications of the study

From the present study following information can be obtained:

- Overall ADRs in geriatric patients of a tribal were coming to different health care settings.
- Extent of ADRs in geriatric patients of tribal were due to self-medication and traditional medicines.

This may ultimately be a reference for health care authorities to decide for awareness programmes or regulatory steps for drug safety in tribal elderly vulnerable populations.

Observation

Table 1: Demographic Profile of ADR Case

Total Number of	Sex Distribution among ADR Cases Age Distribution among ADR Cases			
ADR Cases	Male	Female Adult		Geriatric
		Female	(15-59 Years) (>60)	(>60)
60	38(63.33%)	22(36.66%)	46(76.66%)	14(23.33%)

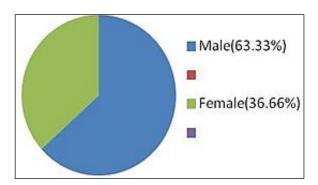


Fig 1: Sex distribution among ADR cases

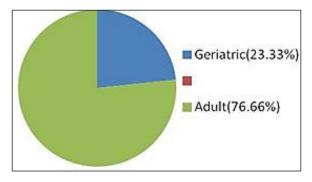


Fig 2: Age Distribution among ADR cases

- More numbers (63.33%) ADRS reported in male in comparison to 36.66% ADRS were reported in female.
- Less numbers (23.33%) ADRs reported in Geriatric age group in comparison to 76.66% ADRs reported in Adults.

Table 2: Comparative analysis of ADR in geriatric patients vs. Other Age Groups & Suspected Medication

of ADR Patients of Geriatric Patients	Traditional Modern Medicine Medicine
60 14(23.33%)	In geriatric (14)casesi.e.100% cases In geriatriccases with modern medicines. Doxophyline-FDE (1)-Nill ATT-Hepatitis (3) ATT - Gastritis & Vomitting (3) ATT - Pruritus & skin rashes (2) ATT - Seborrheic dermatitis(1) Cefadroxyl - maculopapular Rash & Diarrhoea(1) Insulin-hypoglycaemia (1) Ofloxacin/ornidazole-FDE(1) ASV - Pruritus & Vertigo(1) In adult age group (43)i.e 93.47% In other age group (3) i.e 6.52% cases with modern medicines. with traditional medicine Ofloxacin/ornidazole-FDE(12) Homeopathy medicine- Ofloxacin/ornidazole-FDE(1) Ofloxacin/ornidazole-FDE(1) Ofloxacin-FDE(1) Homeopathy medicine - Cefixime-FDE(1) Homeopathy medicine - Cefixime-FDE(1) Homeopathy medicine - Cefixime-FDE(1) Ayurvedic drug - Urticaria(1) NSAID-FDE(1) ATT - Hepatitis(2) ATT - Gastritis & vomiting(3) ATT - Fosychosis(1) ATT - Hypersensitive syndrome(Lichenoid type)(2) ATT - Pruritus(1) Amoxicillin & Clavulanic acid — Urticaria(1) Amoxicillin / Nimesulrde — pruritus(1) Ceftriaxone Maulopapular rashes(1) Pantoprazole - Rigour & Headache(1)

- Inj Iron Sucrose solution-Hypersensitive reaction (2).
- ASV-Skin Rash & Pruritus (1).
- Aspirin/clopdogrel-Dental Bleeding (1).
- Linezolid-Erythema multiformi (1).
- Etoricoxib-MPDR (1).
- Unknown drug-FDE (3).
- 14(23.33%) ADR cases in Geriatric patients were reported out of a total 60 ADR cases.
- 100% of ADR cases in geriatric patients & 93.47% of ADR cases in adults were associated with modern medicines.
- Most common ADR in Geriatric patients is ATT induced GI adverse effect & Hepatitis-

- total (3+3) = 6 out of 14 cases (42.85%).
- We have not got any ADR Case in Geriatric patients due to traditional medicine.
- Ofloxacin + ornidazole induced FDE was the most common ADR reported in adults i.e. 12 out of total 46 cases i.e. (26.08%) of total cases in adults.

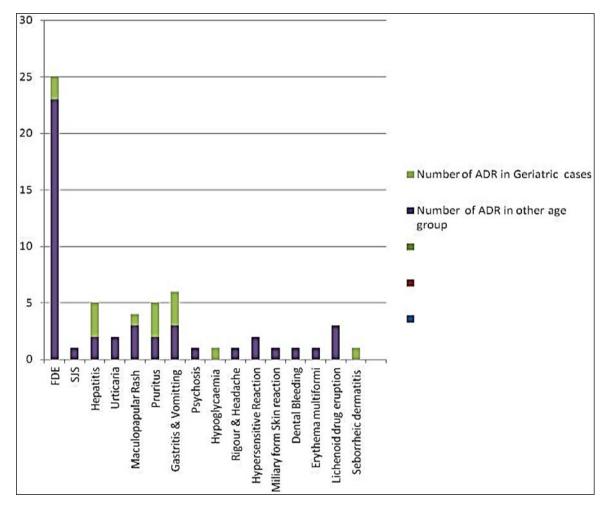


Fig 3: Comparative analysis of ADR in geriatric patients vs. other age groups & suspected medication

Table 3: Comparative analysis of incidences of prescribed medication & self-medication in relation to types of ADR & suspected medication

Total Number of ADRs	Types of ADR	Suspected Medication	Prescribed Medication	Self- Medication
60	- FDE(25)	- Ofloxacin/ornidazole	1	12
		- Ofloxacin	1	0
		- Ornidazole	1	0
		- Fluconazole	3	0
		- Doxophyline	1	0
		- Cefixime	0	1
		- Amoxicillin & Nimesulrdes	0	1
		- NSAID	0	1
		- Unknown	0	3
	- Hepatitis (5)	- ATT	5	0
	- Gastritis & Vomitting (6)	- ATT	6	0
	- Hypersensitive syndrome	- ATT	2	0
	(Lichenoid type) (3)	- Homeopathy medicine	0	1
	- Pruritus & skin rashes (5)	- ATT	2	0

	- ASV	2	0
	- Amoxicillin & Nimesulrdes	0	1
- Maulopapular rashes (4)	- Ceftriaxone	1	0
	- Cefadroxyl	1	0
	- Pantoprazole	1	0
	- Etoricoxib	1	0
- Rigour & Headache (1)	- Pantoprazole	1	0
Hypersensitive			
- Reaction (2)	- Iron Sucrose solution	2	0
- Erethema Multiformis (1)	- Linezolid	1	0
- Dental Bleeding (1)	- Aspirin &Clopidogril	1	0
- Milliary form Skin reaction	- Homeopathy Medicine	0	1
- SJS	- Ofloxacin/ornidazole	1	0
- Seborrheic dermatitis	- ATT	1	0
- Pshychosis	- ATT	1	0
- Hypoglycemia	- Insulin	1	0
- Urticaria(2)	- Amoxicillin &Clavulanic acid	1	0
	- Ayurvedic medicine	0	1
	Total	38	22

- Most common ADR with Self-medication is Ofloxacin/ornidazole induced FDE (Adult age group).
- Most common ADR with Prescribed medication are ATT induced Hepatitis & GI Adverse effect (Geriatric age group).
- Most common ADR with Prescribed medication are ATT induced Hepatitis, GI Adverse effect & Hypersensitive syndrome (Lichenoid type).

Table 4: ADR with self & prescribed medication in geriatric vs. adult age group

Total ADR cases	Number of ADR	with Self-medication	Number of ADR with	prescribe medication
	Geriatric	Adult	Geriatric	Adult
60	1 (7.14%)	21 (45.65%)	13 (92.85%)	25 (54.34%)

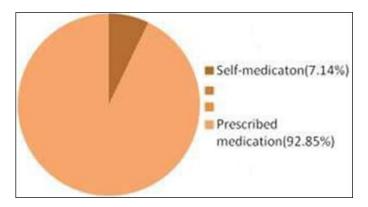


Fig 4: Comparative analysis of ADRs associated with self vs. Prescribed Medication in geriatric age group

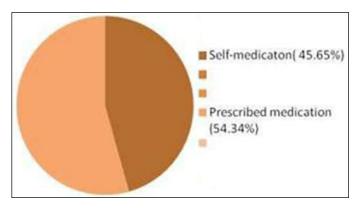


Fig 5: Medication in Adult age group

- Only 1 case (7.14%) of Geriatric ADR cases are found with self- medication in comparison to 45.65% of adult ADR cases.
- Where as 92.85% of ADR cases are found with prescribe medication in geriatric cases in comparision to 54.35% cases in adults. This indicate possibly less of self-medication in Geriatric Population, which is a good indication as they are prone for ADR.

Table 5: Comparative assessment of ADRs in geriatric & adult population in relation to modern and traditional medicine

Incidnce of ADR in	Modern Medicine	Traditional Medicine
Geriatric	14	Nill
Adult	43	3

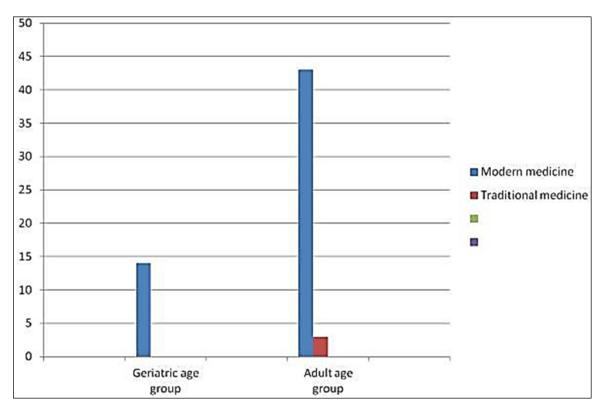


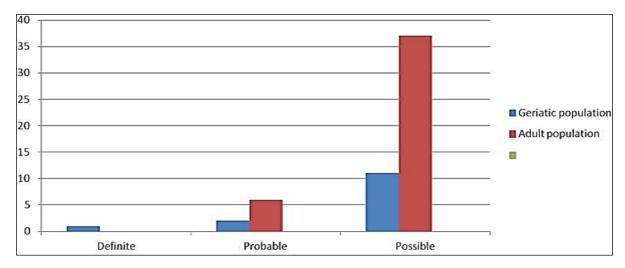
Fig 6: Comparative assessment of ADRs in geriatric & adult population in relation to modern and traditional medicine

• In our Hospital the reported ADRs were found more in Modern medicine both in Geriatric as well as Adult age group.

Causality assessment scale	Geriatric population	Adult population
Definite	1	0
Probable	2	6
Possible	11	37

Causality assessment scale as per UMC

Total



14

Fig 7: Causality Assessment Scale AS per UMC

Results

Total number of ADRs collected in our study over a period of 3 months is 60.

- Out of the total number of ADR cases more numbers (63.33%) are reported in male in comparison to 36.66% ADRS were reported in females.
- Out of the ADR cases 23.33% were reported in Geriatric age group which is less in comparison to 76.66% ADRs reported in Adults.
- In our Hospital the reported ADRs are found more in Modern medicine both in Geriatric as well as Adult age group. 100% of ADR cases in geriatric patients & 93.47% of ADR cases in adults were associated with modern medicines.
- Most common ADR in Geriatric patients in our series is ATT induced GI adverse effect & Hepatitis i.e. 6 out of total 14 cases (42.85%) of cases. In our series most common ADR with prescribed medication in geriatric age groups is also ATT induced Hepatitis & GI Adverse effect.
- We have not got any ADR Case in Geriatric patients due to traditional medicine.
- Most common ADR with Self-medication is Ofloxacin/ornidazole induced FDE (Adult age group).
- Only 1 case (7.14%) of Geriatric ADR cases are found with self-medication in comparison to 45.65% of ADR due to self-medication in adult cases.
- 92.85% of ADR cases are found with prescribe medication in geriatric cases in comparison to 54.35% cases in adults. This indicate possibly less of self-medication in Geriatric Population than adult cases, which is a good indication as geriatric patients are more prone for ADR.

Discussion

The present ICMR STS study project entitled Analysis of ADR (Adverse Drug Reaction) in Geriatric patients of a Tribal district, special reference to self-medication and

- traditional medicines.
- Our medical college & district head quarter hospital is situated in a tribal district. Most of the patients coming to the hospital are from tribal area. So most of our study population are from tribal area.
- In our study we have collected data only of ADR cases. In this study we found that out of total ADR cases collected, 23.33% ADRs were in Geriatric patients & rest 76.66 % of ADRs were in Adult patients. We have not followed all the OPD geriatric cases & the adult cases and found the incidence of ADRs among these patients, we have collected data only of ADR cases. In comparison in an European multicentric study Out of 644 elderly patients, 139 (21.6%; 95% confidence interval 18.5-25.0%) patients experienced an ADR. Serum electrolyte abnormalities were the most common ADR [10]. In an Indian study, 10 per cent ambulatory elderly patients were found to have ADRs. Of the total 4005 prescriptions, 406 were identified with ADRs, giving the occurrence of 10 per cent ADRs in elderly. The most common type of ADR was peripheral oedema. The most commonly offending class of drug was cardiovascular drugs (57.6%) [11]. In contrast in our study in elderly patients the most common ADR was drug induced hepatitis & Gastritis, most common offending drug was anti tubercular drugs ATT. This difference may possibly be due to more concentration in our study in pulmonary medicine in comparison to general medicine department. Though incidence of TB in India is more in adults in comparison to geriatric cases [17] but increase increasing finding in our study regarding ATT induced Hepatitis & GI ADRs possibly due to poor tolerance of Geriatric patients to ATT (Anti Tubercular Treatment).
- In our Hospital out of the reported ADRs more cases were with Modern medicine both in Geriatric as well as Adult age group. 100% of ADR cases in geriatric patients & 93.47% of ADR cases in adults were associated with modern medicines.

The reason behind such finding may be-

- 1) More number of patients using Modern medicine may have come to our Medical College as it is a college of modern medicine.
- 2) More use of modern medicine by patients.
- 3) The patients taking traditional medicine and had ADRs may have gone to traditional medicine practitioners.

The literature search in this regard for comparative analysis of ADR with modern medicine versus traditional medicine could not reveal sufficient data.

Self-medication is an important challenging issue. In the present study Only 1 case (7.14%) of Geriatric ADR cases are found with self-medication in comparison to 45.65% of adult ADR cases were found with self-medication. Whereas 92.85% of ADR cases are found with prescribe medication in geriatric cases in comparison to 54.35% cases in adults.

This indicates possibly less of self-medication in Geriatric Population than adult cases, which is a good indication as geriatric patients are more prone for ADR. Less self-medication induced ADR in Geriatric patients even in this

Tribal district with limitation of availability of doctors is really inspiring. But in a study on self-medication Practices amongst elderly Population in an Urban Health Center of Maharashtra, India, A.K. Jawarkar, V.R. Wasnik *et al.* have shown that "the overall prevalence of self-medication among elderly population was 48%. Allopathic drugs were the commonest mode of self-medication (95%). The commonest reason for self-medication was easy availability of medicines in medical stores and other shops, time saving factor (69%). Local pharmacist (89%) was the main source of information. Joint and muscle pain was the

commonest indication identified for self-medication (89%) [13].

■ In Kermanshah-Iran study out of 272 elderly, the prevalence of self-medication was 83%. The most common reasons for self-medication were certainty of its safety (93%), prior consumption of the drug (87.6%), busy offices of physicians (82%), non-seriousness of the illness (77.8%) and prior experience of the disease (73%). The most common drugs used for self-medication were analgesics (92%), cold drugs (74%), vitamins (61%), digestive drugs (54%) and antibiotics (43%) [13].

But in our study we have not analyzed the prevalence of self-medication rather we have analyzed incidence of self-medication among ADR cases in elderly patients & our study revealed just 7.14% of ADR cases were with self-medication and the offending drug was Ofloxacin + ornidazole FDC taken for diarrhoea.

Summary

Total number of ADRs collected in our study over a period of 3 months is 60. Out of the ADR cases 23.33% were reported in Geriatric age group which is less in comparison to 76.66% ADRs reported in Adults. In our Hospital most of the reported ADRs are found with Modern medicine both in Geriatric as well as Adult age group. 100% of ADR cases in geriatric patients & 93.47% of ADR cases in adults were associated with modern medicines. We had not got any ADR Case in Geriatric patients due to traditional medicine. This may possibly be due to less number of patients taking traditional medicines are coming to our hospital. Most common ADR in Geriatric patients in our series is ATT induced GI adverse effect & Hepatitis i.e. 6 out of total 14 cases (42.85%) of cases. All these cases were with prescribed medication. Only 1 case (7.14%) of Geriatric ADR cases were found with self-medication in comparison to 45.65% of ADR due to self-medication in adult cases. Most common ADR with Self-medication was Ofloxacin/ornidazole induced FDE (Adult age group).

92.85% of ADR cases were found with prescribe medication in geriatric cases in comparison to 54.35% cases in adults. This indicate possibly less of self-medication in Geriatric Population than adult cases, which is a good indication as geriatric patients are more prone for ADR.

Conclusion

From our study we conclude that (only one case) even in our tribal area less number of Geriatric ADRs were found with self-medication. But self-medication induced ADRs were very common (45.65%) in adult population. In both Geriatric and adult Ofloxacin+Ornidazole combination was the most common offending drug for self-medication induced ADR (FDE). Most common ADR in Geriatric population were ATT induced Hepatitis and GI ADR. Among the ADR cases we did not found any significant number of cases with traditional medicine. But a combined study with AYUSH and Institute of Modern medicine can explore the comparative data of ADR among modern and traditional medicine.

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