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Assessment of Adverse Drug Reactions in Geriatric Patients Admitted to a Tertiary Care Teaching Hospital in South India

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Abstract
Assessment of Adverse Drug Reactions (ADRs) in Geriatric patients was carried out in a south Indian tertiary care teaching hospital. Our study focused on the greater susceptibility of geriatric patients to ADRs, which are an important health issues and a leading cause of morbidity. A single-centre prospective observational study was conducted with a total of 227 patients to investigate the occurrence and characteristics of ADRs. Males (58.62%,) were affected more than females (41.38%,). Age, polypharmacy, and Co-morbid diseases were the primary risk factors, accounting for 100%, 100%, and 94.82% respectively. The most significant risk factors identified were hypertension (51.72%), and type II diabetes mellitus (44.82%). The prevalence of ADRs was determined as 25.5% (n=58) with an incidence rate of 6.82%, Odds ratio (0.34, p=0.059) and Relative risk (142.65, p=0.0005). Oral administration of drugs (72.41%) lead to the most ADRs. Antibiotics and Antiplatelets (20.69%) caused the most ADRs such as Constipation (20.68%) by Clopidogrel, Various Reactions from Antibiotics (>17%) followed by Oedema (13.8%) by Prednisolone. Skin and Appendages (32.76%) were implicated by the majority of reactions. Most of the reactions were possible (WHO-UMC Scale - 53.45%), Moderate (Hartwig and Siegel Scale – 31%) and possible (Liverpool Causality Assessment Tool – 60.34%). Clinical pharmacists reported the highest (82.76%) ADRs. Our study contributes to the pharmacovigilance programme of the nation. There is a pressing need of reporting the ADRs and to develop tools to empower healthcare professionals that would significantly decrease the time required for initial assessment of ADRs and related harm.

Keywords: Adverse Drug Reactions in Geriatrics; Drug Safety, Drug Related Problems, Post Marketing Surveillance, Pharmacovigilance.

1. Introduction

Assessment of Adverse Drug Reactions (ADRs) in Geriatric patients was carried out in a south Indian tertiary care teaching hospital. Adverse drug reactions (ADRs) are any response to a drug which is noxious and unintended and which occurs at doses normally used in the human for the prophylaxis, diagnosis or treatment of disease, or for the modification of physiological function.[1] ADRs are one of the major public health issues and found to be the cause of morbidity and mortality.[2] Fatal ADRs account for 3% of all deaths in the general population and 5% in hospitalized patients.[3] Geriatric population are highly susceptible to ADRs, WHO defines old age is a potential risk factor for ADRs, on average, 16% of hospitalized older patients experience significant ADRs, with commonly prescribed drug classes accounting for most ADRs.[4] Overall ADR-related mortality in hospitalized patients ranges from 0.14% to 4.7%, with the greatest risk being in those aged 75 years and older, It is due to the various physiological changes that precipitate pharmacokinetic, pharmacodynamic changes in the body, use of treatment for various comorbidities, decreased medication compliance, and adherence.[5] Some factors that may be responsible for the increase in adverse reactions in elderly patients are polypharmacy (prescription and over-the-counter (OTC)), increased pharmacokinetic and pharmacodynamic changes, drug-drug interaction, and compliance. Prescription errors, such as prescribing excessive doses of medications without considering the effect of age and frailty on drug disposition, particularly renal and hepatic clearance, is a major contributor to adverse drug reactions in the elderly. Another problem could be a failure to account for the elderly's increased pharmacodynamic sensitivity to a variety of regularly used medications, such as central nervous system and cardiovascular treatments.[6] There is an ambiguity between the geriatric hospital data and research findings such as the incidence of ADR-related hospital

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admissions was reported to be 5.9% in a hospital environment, while it was found to be 6.7 percent in a study conducted in India.[7] Improvements in the effective medical management of elderly patients can lead to improvements in their overall health, and safety.[8] Our study was carried out to assess and report the ADRs in hospitalized geriatric patients in the south India, Pharmacovigilance programme of India usually monitor the detection, assessment and reporting of ADRs.

2. Methods

2.1 Study design, setting and participants

A Single Centre, Prospective Observational Study was designed and ethical considerations and acceptance was obtained from Institutional ethical committee and the voluntary written informed consent was obtained from the patients prior to their participation. This study was conducted for 10 months from October 2024 to July 2024 among 227 geriatric patients who were admitted in to the male and female in-patient departments of Government General Hospital at Hyderabad, Telangana, India.

2.2 Data collection methods

Data were collected according to the inclusion criteria from all the patients who were above 60 years and have given informed consent, with confirmed diagnosis from physician/doctor, having polypharmacy with suspected ADRs occurrence due to prescribed and over the counter (OTC) medications, patients who were willing to participate in our study, could read and write in English/ Telugu, who agree to comply with the study procedures were recruited in to the study. Patients who were below 60 years, using alternative medicines, drug addicted, unconscious, accidental or intentional alcohol and drug abuse patients were excluded from the study as they could interfere with the study procedures and compliance of patient towards the study..

2.3 Measures of variables

ADRs assessment included any unwanted reaction that appears immediately after the administration of a drug, any unintended reaction due to administration of a drug, any reaction that appears due to long-term use of a drug, any past history related to drug allergy or hypersensitivity. A specially designed Patient Data Collection Proforma was used to record the patient's demographic, medical, and medication histories. To assess the causality of ADRs, World Health Organisation-Uppsala Monitoring Centre (WHO-UMC) causality assessment questionnaire, Liverpool ADR Causality Assessment Tool (LCAT) were utilised which includes the categories certain, probable/likely, possible, unlikely, conditional/unclassified, un-assessable/unclassifiable. To assess the severity of ADRs Modified Hartwig and Siegel ADR Severity Scale was used.

2.4 Statistical analysis

We have used the Microsoft excel spread sheet to execute the descriptive statistics in percentages for the participants' demographics, age-groups, risk factors, route of administration of drug, ADRs occurrence time frame, ADRs associated with drugs and comorbid conditions, types of ADRs, ADRs department, organ system involvement and ADRs sequel, causality, severity to present the characteristics of our dataset, alongside Incidence, Prevalence of ADRs, Odds Ratio and Relative risks in the geriatric populations was estimated.

2.5 Ethical considerations

The study design, and the data collection, assessment procedures were approved by the Siddhartha institutional ethical committee [SIP/IECPD/Projects/2023-24/007]. In maintaining the participants' anonymity and confidentiality, no identifiable information were collected throughout the research. Participants were also informed in the informed consent form that their responses will never be disclosed; only the summary of the data would be presented in subsequent publications.

3. Results

3.1 Demographics

A total of 227 patients (Table 1) were recruited in to the study. Male patients (55.07%, 125/227) were more and Female patients (44.93%, 102/227) were less comparatively. Most of the patients were observed in the age groups of 60-<65 years (39.20%, 89/227), 65-<70 years (23.34%, 53/227) and 70-<75 years (16.74%, 38/227), only 2.64% of patients were observed in the age group of above 90 years (6/227). 64.75% of patients (147/227) had no formal education, In addition 98.67% of patients (224/227) reported that they were not speaking English at home it is considered it as a non-native or second or official language.

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Table 1. Patients' characteristics (n = 227)	
Variables	**Data [n(%)]**
Gender	
Male	**125** (55.07)
Female	**102** (44.93)
Age Group	[M=Mean, SD=Standard Deviation] (%)
60-<65 years	**89** [M = 63.05, SD = 1.58] (39.20)
65-<70 years	**53** [M = 67.81, SD = 1.67] (23.34)
70-<75 years	**38** [M = 72.63, SD = 1.44] (16.74)
75-<80 years	**21**[M = 77.38, SD = 1.49] (9.25)
80-<85 years	**11**[M = 82.45, SD = 1.43] (4.84)
85-<90 years	**9** [M = 87.22, SD = 1.31] (3.96)
≥90 years	**6** [M = 92.26, SD = 1.34] (2.64)
Educational qualification	
No formal education	147 (64.75)
Primary school	32 (14.09)
High school	15 (6.6)
Bachelors	4 (1.76)
Masters	3 (1.32)
Others (certificate, diploma, etc)	26 (11.45)
Language speaking at home	
Telugu	189 (83.25)
English	3 (1.32)
Hindi	35 (15.41)

3.2 Adverse Drug Reaction Profile

Out of 227 participants (Table 2) 25.55% of (58/227) patients presented with the ADRs and nearly 75% patients were not presented with any kind of ADRs. Males were effected most (58.62%, 34/58) with the ADRs. The age group of 60-<65 years were observed with the highest percentage (41.37%, 24/58) while lowest percentage (1.72%, 1/58) were reported with in the age group of ≥90 years. Age, Polypharmacy and Co-morbid conditions were identified as the major risk factors (94-100%) while existing allergies (15.52%, 9/58) were being the least. The incidence rate was estimated to be 6.82% (58/850) which was calculated for average population of 850 during the study period and prevalence rate was calculated as 25.5% (58/277). The Odds ratio was estimated for all the ADRs to be 0.3451 (p=0.5958) and Relative risk at 142.65 (highly significant p=0.0005).

Table 2. Adverse Drug Reaction Profile (n = 58)	
Variables	**Data [n(%)]**
Population	
With ADRs	58 (25.55)
Without ADRs	169 (74.45)
Gender (with ADRs)	
Male	34 (58.62)
Female	24 (41.38)
Age Group (with ADRs)	
60-<65 years	24 (41.37)
65-<70 years	8 (13.79)
70-<75 years	10 (17.24)
75-<80 years	8 (13.79)
80-<85 years	5 (8.62)
85-<90 years	2 (3.44)
≥90 years	1 (1.72)
Risk Factors (for ADRs)	
Age	58 (100)
Polypharmacy	58 (100)
Comorbidities	55 (94.82)
allergies	9 (15.52)
Smoking	21 (36.21)
Alcohol	18 (31.03)
ADRs Prevalence	**25.55 %**
ADRs Incidence	**6.82%**
Odds Ratio	0.3451 (95 % CI; 0.0068 to 17.5917) ***P = 0.5958***
Relative risk	142.6579 (95% CI; 8.8665 to 2295.2898) ***P = 0.0005***

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3.3 ADRs Comorbidities

Out of the 58 identified ADRs (Table 3), most of the ADRs incidences were associated with the existing Hypertension (51.72%, 30/58), Diabetes mellitus (44.82%, 26/58) and Pulmonary tuberculosis (18.96%, 11/58). The least incidences associated with the comorbidities such as Coronary artery diseases, Rheumatoid arthritis, Bipolar disorders, and Post COVID complications etc., (1.72%, 1/58).

Table 3. ADRs with Comorbidities (n = 58)

Variables	Data [n(%)]
Comorbidities	
Hypertension	30 (51.72)
Diabetes mellitus	26 (44.82)
Pulmonary Tuberculosis	11 (18.96)
Human immune deficiency virus	8 (13.79)
Pulmonary diseases	8 (13.79)
Thyroid disorders	5 (8.62)
Kidney disorders	5 (8.62)
Coronary artery diseases	1 (1.72)
Anaemia	1 (1.72)
Rheumatoid arthritis	1 (1.72)
Leprosy	1 (1.72)
Spondylitis	1 (1.72)
Ascites	1 (1.72)
Bipolar disorder	1 (1.72)
Post covid	1 (1.72)

3.4 ADRs Eruption Time-frame

Most of the ADRs (72.41%, 42/58) were reported (Table 4) after the oral administration of the drugs, and the parenteral administration lead to the eruption of 16 ADRs (27.58%). Highest number of ADRs (15.51%, 9/58) were noticed and reported after seventy-two hours, ten days and thirty days of drugs administration both in the oral and parenteral form. Five percent of ADRs were seen in an hour and twenty-four hours after drugs were administered to the patient. ADRs were identified (1.72%, 1/58) even after 3 to 4 months of drugs administration.

Table 4. Drug administration and time of ADRs eruption (n = 58)

Variables	Data [n(%)]
Route of administration	
Oral	42 (72.41)
Parenteral	16 (27.58)
ADRs appearance time	
In minutes	5 (8.62)
In hours	3 (5.17)
1 day	3 (5.17)
2 days	6 (10.34)
3 days	9 (15.51)
4 days	4 (6.9)
5 days	5 (8.62)
6 days	1 (1.72)
7 days	1 (1.72)
10 days	9 (15.51)
15 days	1 (1.72)
30 days	9 (15.51)
60 days	1 (1.72)
90 – 120 days	1 (1.72)

3.5 ADRs and Drugs association

Antibiotics and Antiplatelets (Table 5) precipitated the highest number of ADRs (20.69%, 12/58), followed by NSAIDs (15.51%, 9/58) and Corticosteroids (13.8%, 8/58).

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Table 5. Drug category and ADRs eruption (n = 58)	
Variables	**Data [n(%)]**
Drug category	
Antibiotics	12 (20.69)
Antiplatelets	12 (20.69)
NSAIDs	9 (15.51)
Corticosteroids	8 (13.8)
HMG CoA reductase inhibitors	4 (6.9)
Proton pump inhibitors	3 (5.17)
Antipsychotics	3 (5.17)
Electrolytes and supplements	2 (3.44)
Antihypertensives	1 (1.72)
Anticonvulsants	1 (1.72)
Antidepressants	1 (1.72)
Antidiarrheal	1 (1.72)
Mood stabilizers	1 (1.72)

3.6 Suspected Drug and ADRs

Constipation was the most reported ADRs (20.68%) which was associated with the Clopidogrel (Table 6), followed by the Oedema (13.8%) with the Prednisolone.

Table 6. Suspected Drug and ADRs (n = 58)		
Variables		**Data [n(%)]**
Suspected Drug	**Suspected ADR**	
CLOPIDOGREL	Constipation	12 (20.68)
PREDNISOLONE	Oedema	8 (13.8)
ASPIRIN	Bleeding from mouth	6 (10.34)
ATORVASTATIN	Pruritus	4 (6.9)
RISPERIDONE	Increased urinary incontinence	3 (5.17)
PANTOPRAZOLE	Increased Serum Creatinine	3 (5.17
ACECLOFENAC	Skin rashes	2 (3.44)
ANTI-TUBERCULAR TREATMENT	Reddish lesions	1 (1.72)
ANTI-TUBERCULAR TREATMENT	Skin reaction	1 (1.72)
ANTI-TUBERCULAR TREATMENT	Pangastritis	1 (1.72)
ANTI-TUBERCULAR TREATMENT	Liver injury	1 (1.72)
ANTI-TUBERCULAR TREATMENT	Systemic lupous erythematous	1 (1.72)
LITHIUM	Neuroleptic malignant syndrome	1 (1.72)
CEFOPERAZONE- SULBACTUM	Scaling of upper epidermal layer	1 (1.72)
CEFTRIAXONE	Cholelithiasis	1 (1.72)
AMOXICILLIN- CLAVULANATE	Loose stools	1 (1.72)
CILNIDIPINE	Drowsiness	1 (1.72)
NaHCO3	Severe hypoglycaemia	1 (1.72)
GABAPENTINE	Drowsiness	1 (1.72)
AMITRYPTYLLINE	Drowsiness & dizziness	1 (1.72)
CEFTRIAXONE	Macular rashes	1 (1.72)
RACECADOTRIL	Vomiting	1 (1.72)
IRON SUCROSE	Shortness of breathe	1 (1.72)
Anti-Retroviral	Multiple erythematous scaly plaques	1 (1.72)
DICLOFENAC	Circular hyper pigmenting plaque	1 (1.72)
OFLOXACIN	Scrotum ulcers	1 (1.72)
LINEZOLID	Skin reaction	1 (1.72)

3.7 ADRs and Organ systems

Highest ADRs (32.76%, 19/58) were observed in the Skin and appendages followed by the Gastrointestinal tract. The other organ systems were illustrated in the Fig 1.

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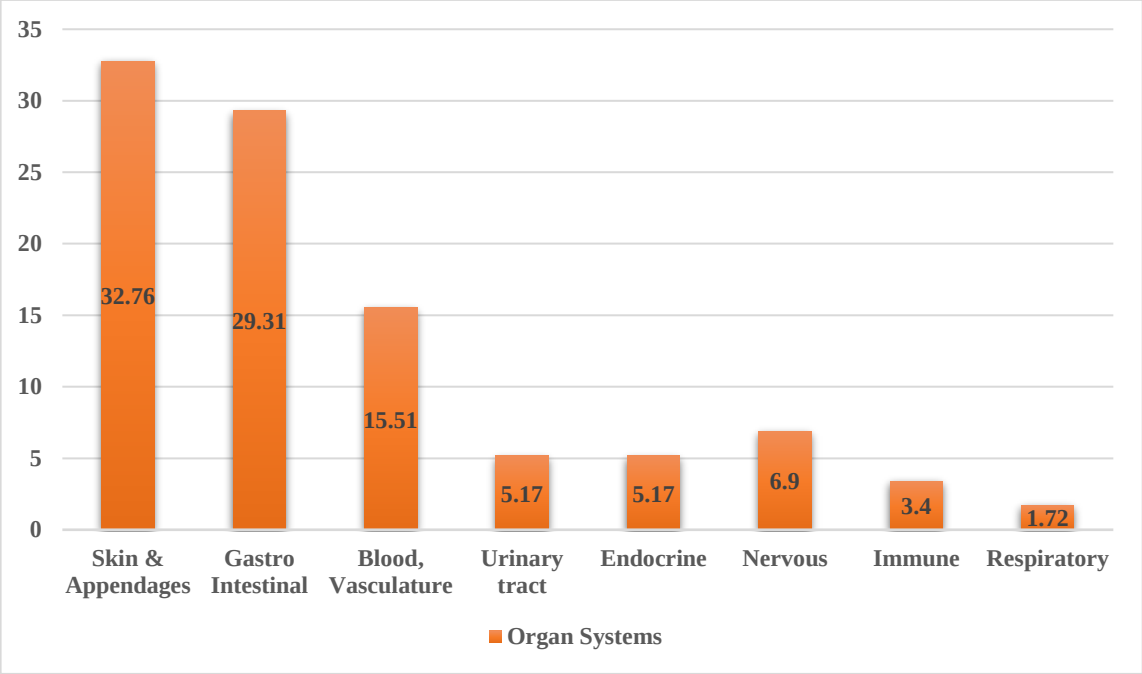

Fig 1. Organ Systems involved with ADRs

3.8 ADRs and Medical Departments

Dermatology witnessed the high accounts of ADRs reporting with thirty-two percentage (19/58) followed by the Gastroenterology (25.86%, 15/58) and General medicine (17.24%, 10/58). The other medical departments associated with ADRs were illustrated in the Fig 2.

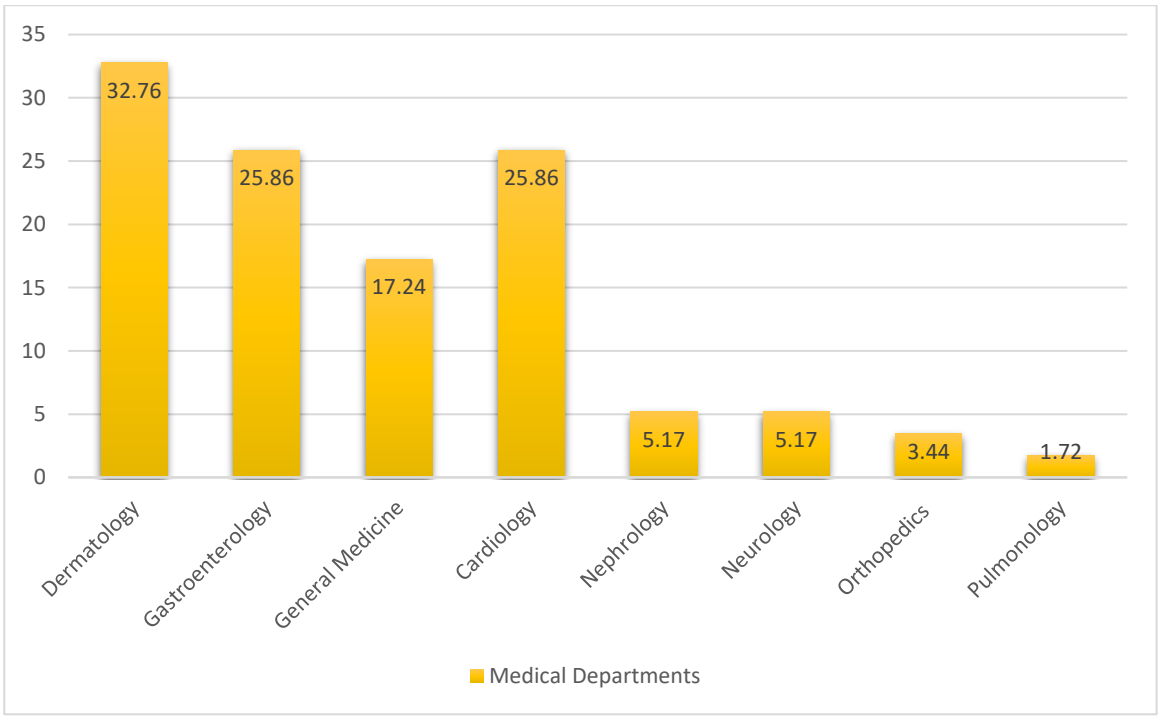

Fig 2. Medical Departments reported with ADRs

3.9 ADRs Assessment Scales/Tools

ADRs assessment was done using different assessment scales (Table 7). Most of the ADRs identified were Possible, Moderate and Probable. When ADRs were assessed with WHO-UMC ADRs scale, 53.45% of ADRs (31/58) were identified as Possible, with Liverpool Causality Assessment Tool 60.34% of ADRs (35/58)were Possible, with Hartwig and Siegel Severity Assessment Scale 31% of ADRs (18/58) were Moderate-3 category.

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Table 7. ADRs Assessment scales/tools (n = 58)	
Variables	**Data [n(%)]**
WHO-UMC Scale	
Certain	3 (5.17)
Probable/Likely	24 (41.38)
Possible	31 (53.45)
Unlikely	0 (0)
Liverpool Causality Assessment Tool	
Unlikely	0 (0)
Possible	35 (60.34)
Probable	19 (32.76)
Definite	4 (6.9)
Hartwig and Siegel Severity Assessment Scale	
Mild (1)	9 (15.51)
Mild (2)	10 (17.24)
Moderate (3)	18 (31.03)
Moderate (4a)	7 (12.06)
Moderate (4b)	4 (6.9)
Severe (5)	8 (13.8)
Severe (6)	1 (1.72)
Severe (7)	1 (1.72)

3.10 ADRs Sequela

Out of the 58 ADRs, 93% (54/58) of the cases, drugs were withdrawn (Table 8), in addition to this 70% (41/58) of drugs were substituted with the other drugs, 22% (13/58) cases were not substituted. 93% of the cases were supplied with the supportive treatments. Dechallenge of the drugs were done in 54 cases (93%), ADRs symptoms were completely resolved in the 45 cases (77.59%).

Table 8. ADRs Sequela (n = 58)	
Variables	**Data [n(%)]**
Drug withdrawal	
Yes	54 (93.1)
Unknown	4 (6.9)
Drug substitution	
Yes	41 (70.69)
No	13 (22.41)
Unknown	4 (6.9)
Supportive treatment	
Yes	54 (93.1)
Unknown	4 (6.9)
Dechallenge	
Yes	54 (93.1)
Unknown	4 (6.9)
Rechallenge	
Yes	0
No	54 (93.1)
Unknown	4 (6.9)
ADRs symptoms resolved	
Yes	45 (77.59)
No	9 (15.51)
Unknown	4 (6.9)

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3.11 ADRs Reporting

Clinical pharmacists were the prime healthcare personals who identified and reported more than 82% (48/58) of ADRs, only 8% of the ADRs (5/58) were identified and reported by the Doctors/Physicians, followed by the patients, patient representatives and Nursing staff. Fig 3 illustrates the ADRs reporting by different healthcare professionals.

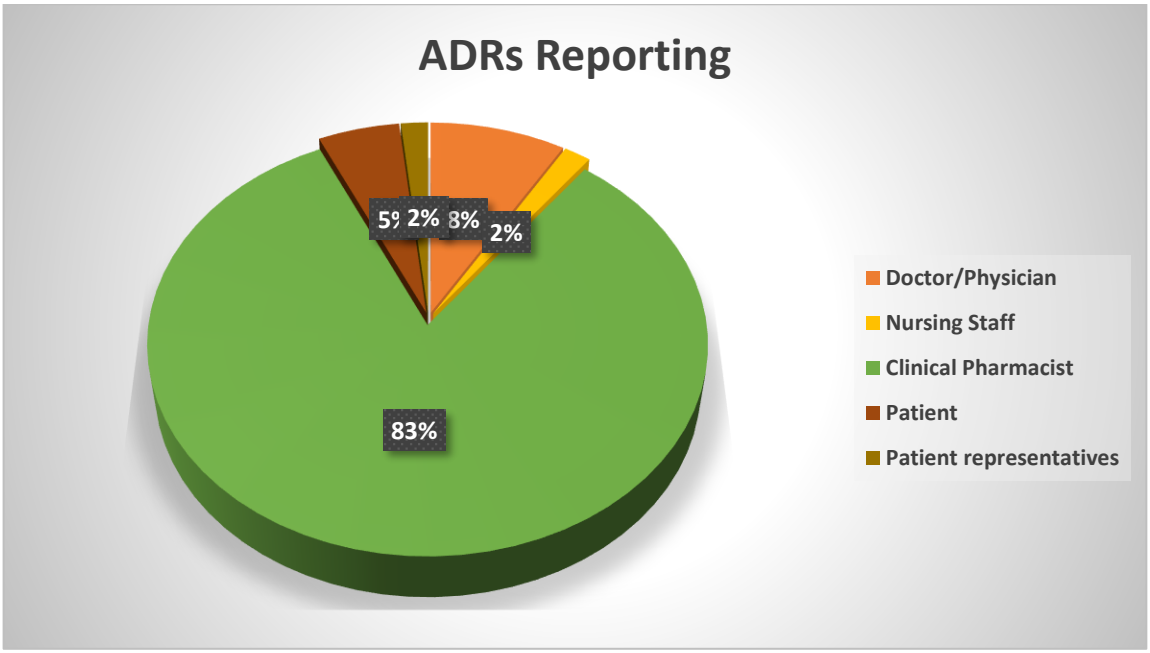

Fig 3. ADRs Reporting

4. Discussion and Implications

Regardless of the vigilant pre and post-marketing surveillances, ADRs remain as the serious public health issue across the globe leading to mortality, morbidity, and financial disruption. It was estimated that more than 2 million ADRs occur each year in the patients who were hospitalized, eventually results in the deaths of more than one hundred thousand patients.[9] Although serious efforts were made for the prediction of an ADRs, they remain to be challenging to detect clinically due to lack of comprehensive data, and small sample ADR studies.[10,11]

Our single centred prospective observational study focused on identifying and assessing the ADRs in the geriatric population, and to understand the ADRs reporting behaviour by the medical and paramedical professionals among the patients who were admitted in to the government general hospital which is also a tertiary care teaching centre in the south India. The results from this study uncovered that the significant amount of the ADRs were identified and reported in south Indian hospital, however the amount of reports would not meet the complete clinical requirements needed by the country. The professionals involved in identifying the ADRs were prominently clinical pharmacists which would be a uplifting scenario of the healthcare system in promoting the better and rational patient care.

Overall our study identified that older adult males were affected more with the ADRs, which deviated from several studies done across the globe.[11,12,13,14,15] The deviations in ADRs occurrence in men and women is believed to the variations in the contributing factors such as amount of fat mass, glomerular filtration, intra and extracellular water levels, genetics, hormone, and immune system etc.,[16,17,18,19,20] The age group 60-<65 years, observed with the highest ADRs, a significant ADRs were observed with in the age groups of 65-70, 70-75 and 75-80 years, this strong association between ages and ADRs from our study correlates with other studies.[21,22,23] Education also showed an impact on how the patients were understanding the drug regimens, medication adherence system, ADRs detection and reporting patterns, similar observations were reported in various studies.[24,25]

The prevalence of ADRs in our study was recorded at 25.5 % for the geriatric population under observation and the incidence rate was found to be 6.82%, these observations corelated with the other studies.[26,27,28,29,30,31] Odds ratio (p=0.59) and Relative risk (p=0.0005) was observed with high chances of correlations with the drugs and associated ADRs, similar such kind of corelations were found from various studies.[32,33,34,35] Majority of the ADRs were non serious, severe ADRs were seldomly observed and restricted to single digits, and no deaths related to ADRs were observed in the period of our study, this would be the usual scenario in many studies.[36,37,38] As our study was designed and propagated by the clinical pharmacist, there was a collection and reporting bias, most of the ADRs identified by the clinical pharmacists (>82%), Doctors reported only 5 ADRs which might reflect the work load of doctors and deficiency in the patient-doctor ratio in the south India, Nursing staff in other hand were involving themselves mostly in their activities and does little support in

addressing the drug related problems. Patients and their representatives were completely devoid of ADRs, however the reported percentages from them were higher than the nurses and almost equal to the doctors, this could be a positive sign of patient involvement in the collective clinical care and this would impact the health system in south India.

5. Limitations

In our study, there were limitations such as, we did this for a period of 10 months, which limited our scope to explore other ADRs and also limited our exposure to other groups of patients with different comorbid conditions. The study sample and duration was small which didn't allow us to assess the full potential of drugs causing ADRs and this sample was not the entire representative of south India. Re-challenging an ADR was not possible, since; it was highly discouraged, to avoid harm and discomfort to the patient. Causality assessment was only limited to the use of three scales. The severity of the ADR was based on the patient's description of the ADR and the medical perspective of the doctors on duty. We could not able to identify the medical department specific ADRs severity as we had to collect the data from all the departments. Analysis could be made only on the basis of the patient description and a few laboratory parameters. Laboratory analysis was inefficiently performed in few samples, not allowing us to completely study the patient conditions. Inspite of these limitations, our study revealed some clinically important findings related to the geriatric ADRs.

6. Conclusion

Our study contributes to the pharmacovigilance programme of the nation which makes continues efforts in establishing the drug safety across the nation and also in providing the signals necessary to monitor the drug related problems specifically ADRs. However considering the limitations of our study, as the larger group of geriatric populations are at significant risk of ADRs and related hospital admissions, there is a greater need for understanding the ADRs patterns and how these would affect the quality of life and these are largely preventable by the improved pharmacological methods and applications. Future studies with larger population and longer follow-up are required to understand the risk of ADRs, research needs to work on developing tools and skills to empower healthcare professionals to identify ADRs, this would significantly decrease the time required for initial assessment of ADRs related harm and which ultimately brings out better patient care.

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