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Incidence, Pattern, and Predictors of Adverse Drug Reactions among Hospitalized Patients: A prospective observational study in South India

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Abstract

Introduction

Adverse Drug Reaction (ADR) is one of the most common public health challenges that significantly affects morbidity, mortality, and healthcare costs. There was a scarcity of evidence on the incidence and risk factors associated with ADRs. The study aimed to assess the incidence, pattern, and predictors of ADRs among hospitalized patients.

Methods

A prospective, hospital-based, observational study was conducted among hospitalized patients in a tertiary care hospital located in Nellore, Andhra Pradesh, India. A semi-structured data collection form was used to collect data from the patient to assess ADRs. Binary logistic regression analysis was used to associate the demographics and clinical characteristics of patients with the development of ADRs.

Results

The cumulative incidence of ADRs among hospitalized patients was found to be 30.3% (95% CI 26.0-34.6). Antibiotics (29; 20.0%), Antihypertensives (15; 10.3%), and miscellaneous agents (17; 11.7%) are the most common class of drugs that involved in the development of ADRs. The gastro-intestinal tract (GIT), Central Nervous System (CNS), and skin are the most common organ system effected by ADRs.

Conclusion

One-fourth of the patients developed ADRs. The majority of ADRs were probable in causality, mild, probably preventable, and non-serious. Advanced age, polypharmacy,

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presence of comorbidity and complication, and long hospital stay were significantly associated develop ADRs among hospitalized patients. Healthcare professionals need to closely monitor the for the development of ADRs.

Key-words

Active surveillance, Adverse drug event, Adverse drug reaction, Inpatient, Pharmacovigilance,

Introduction

According to World Health Organization (WHO), Adverse Drug Reaction means (ADR) is "any noxious or unintended effect produced by the drug when it will be used in doses for prophylactic, therapeutic, diagnostic and prevention of disease or alteration of physiological function".[1]

Adverse Drug Reaction (ADR) is a global burden and significantly affects the morbidity, mortality, healthcare costs, and quality of life of the patients.[2] ADRs in hospital patients were divided into two broad categories, one is patients admitted into hospital due to ADR and another one is, after admission into hospital the patient may develop ADR.[3] ADR-oriented hospital admission rate is 5%, whereas ADRs developed after admission were 10-20%.[4]

ADRs are one of the major causes of morbidity and mortality. Early detection of ADRs is essential to save lives and improve quality of life. ADRs are also associated with a rise in the length of hospital stay, risk of infections, costs, and prevent the progression of the disease.[5]

Previous studies show that spontaneous reporting and active surveillance systems play a vital role in the detection of ADRs and in giving appropriate management strategies.[6] Most of the studies related to ADR reporting were conducted in well-developed countries. The reasons may be the availability of electronic health records, and patients are insured for their health care.[7]

In developing countries like India, reporting of ADRs is still infant stage. The major reasons are, healthcare professionals are unaware, stigma among the public, flexible regulatory system, and ADR reporting is not mandatory. The success of the ADR reporting system depends upon the collaborative work of all healthcare professionals and patients. ADR reporting is an important role of all healthcare providers (Physicians, Pharmacists, Nurses, and other Paramedical staff).[8]

In India, the Pharmacovigilance Program of India (PvPI) was started in July 2010, in collaboration with the Central Drug Standard Control Organization (CDSCO) and the Ministry of Health and Family Welfare (MoHFW), Government of India. Nearly one decade for PvPI, still most of the healthcare providers are unaware about ADR reporting and its importance.

Hospitals need a more effective way to identify events that do cause harm to patients, in order to select and test changes to reduce harm. The current study aimed to assess the incidence, pattern, and predictors of the ADRs among hospitalized patients.

Materials and methods

Study design

A prospective, hospital-based, observational study was conducted among hospitalized patients in a tertiary care hospital located in Nellore, Andhra Pradesh, India. The study was conducted for a period of two years from January 2017 to December 2018.

Ethical considerations:

The project was approved by the Institutional Ethics Committee (IEC) of the (IEC/2017/PP/032)Hospital.

- The names of the patients were not disclosed and maintained confidentiality
- Any type of serous or severe ADRs were brought to the notice of the concerned physician and IEC
- Confidentiality was maintained throughout the study (Initiation, process, data entry, and data analysis)

Study criteria

All the patients irrespective of gender, aged more than 18 years, and admitted in In-patient department during the study period are eligible for the study. Patients who are taking medical care on an out-patient or ambulatory basis, are not willing to participate, and are unconscious are excluded from the study

Sample size determination and sampling

The sample size was calculated by using Epi-Info 7 statistical software given centre for Disease Control. The estimated sample size was 384 by assuming 95% confidence interval, 80% power, 5% margin of error, and 50% of expected frequency from previous study. By assuming 20% dropout rate the final sample size was calculated as 460. A non-probable convenient sampling was used to select the patients who were willing to participate in the study

Data collection

A semi-structured data collection form was prepared using previous literature on variables associated with ADRs. Initially the data collection form was used among 20 patients to make necessary changes and improve the quality of extracted data. The form comprises three sections include; 1. Demographics, 2. Clinical profile, and 3. ADR characteristics

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1. Demographics: Participants demographic information like age, gender, location, educational status, marital status, household income, smoking status, alcohol use status, and physical activity are included.

2. Clinical profile: Clinical profile of the patient includes current diagnosis, medicines used, previous hospital admission, type of disease, co-morbidities, hospital stay, and complications of the disease are included in the form.

3. ADR characteristics: All the suspected ADRs are subjected to analyze type, causality, severity, predictability, preventability, organ specific classification.

All patient related data was collected by using a suitably designed data collection form. The major data sources used are patient case sheet, laboratory data, medication charts and nursing notes. Any untoward event after administration of the drug was labelled as adverse drug reaction after discussing with concerned physician. The study was not imposed any type of modifications in treatment, diagnosis, and laboratory advices. The patient will follow the medical care given by the hospital.

Data analysis

Descriptive statistics were used to represent socio-demographic, clinical, and ADR profile of the study participants. Binary logistic regression analysis was used to associate demographics and clinical characteristics of patients with the development of ADRs. Data analysis was performed using Epi-Info statistical software given by Centre for Disease Control (CDC), USA.

Results

A total of 442 hospitalized patients were enrolled in the study. Among 442 hospitalized patients, 134 patients experienced 145 ADRs. The cumulative incidence of ADRs among hospitalized patients was found to be 30.3% (95% CI 26.0-34.6). In the current study, most of the participants belonged to an age group of more than 60 years (169; 38.2%), males (248; 56.1%), non-smokers (319; 72.2%), non-alcoholics (278; 62.9%), performing moderate physical activity (208; 47.0%), suffering from infectious disease (306; 69.2%), absence of co-morbid condition (334; 75.5%), ordered 4 to 6 medications (178; 40.3%), absence of complications of the disease (364; 82.3%)), and stay in the hospital between 4 to 8 days (199; 45.0%). The distribution of the demographic and clinical profile of the study participants is represented in Table 1.

Antibiotics (29; 20.0%), Antihypertensives (15; 10.3%), and miscellaneous agents (17; 11.7%) are the most common class of drugs that involved in the development of ADRs among hospitalized patients. The distribution of potential offending drugs for the occurrence of ADRs among hospitalized patients were illustrated in Table 2.

The findings of the analysis of observed ADRs reveals that the majority of ADRs were probable in causality (78; 53.8%), mild in severity (86; 59.3%), probably preventable (79; 54.5%), and non-serious (63; 43.4%). The distribution of the causality, severity, preventability, and seriousness of the ADRs were depicted in Table 3. Skin (38; 26.2%), and Gastro-intestinal tract (GIT) (36; 24.8%) are the most common organ/system involved in the experience of ADRs among hospitalized patients. The distribution of ADRs according to organ/system involved were represented in Table 4.

Table 5 represents the management strategy advised for resolving ADRs and the outcome of the observed ADRs. Addition of another drug (59; 40.7%) and withdrawal of the drug (28; 19.3%) from the regimen are the most common management strategies that were applied to resolve ADRs among hospitalized patients.

The findings of the binary logistic regression analysis revealed that advanced age [(45-60 Y = OR 2.96; 95% CI 1.49-6.18), (≥ 61 Y = OR 8.83; 95% CI 4.62-17.89)] presence of comorbidity (OR 3.00; 95% CI 1.97-4.73), presence of complication (OR 3.01; 95% CI 1.82-5.00), use of more than four medications [(4-6 drugs = OR 2.21; 95% CI 1.33-3.72), (≥ 7 drugs = OR 5.10; 95% CI 2.90-9.09)] stayed in hospital for more than 3 days [(4-8 Days = OR 2.22; 95% CI 1.28-3.94), (9-12 Days = OR 4.77; 95% CI 2.56-9.10), (>12 Days = OR 5.64; 95% CI 2.24-14.38)] were significantly associated with the development of ADRs among hospitalized patients. The association of the patient demographics and clinical profile with the development of ADRs is represented in Table 6.

Discussion

ADRs are attributed to have a significant impact on the morbidity, mortality, cost, and quality of life of the patients. ADR monitoring is considered an essential component of the healthcare system to promote safe medication use among hospitalized patients. Majority of the healthcare professionals view ADR reporting as an optional activity, not as a mandatory professional obligation. Though PvPI captures ADR reports from various public and private hospitals and communicates the information to the respective regulatory authorities for further actions; still there was no active surveillance system to assess the true incidence of ADRs

among hospitalized patients. Also, the occurrence of ADRs is not distributed evenly among all individuals. Evidence shows that age, disease condition, number of drugs, complications, length of hospital stay, and genetic factors can influence the occurrence of ADRs. This is the prime study that was carried out to assess the cumulative incidence of ADRs and identify the predictors associated with ADRs among hospitalized patients. This study provides information on the occurrence of ADRs among hospitalized patients to all healthcare professionals and gives motivation to incorporate the ADR reporting system in their routine clinical practice.

The findings of the current study reveal that the incidence of ADRs among hospitalized patients was found to be 30.3% (95% CI: 26.0-34.6). A hospital-based study conducted in Japan showed ADR incidence rate 29.2% (95% CI: 27.7-30.7) which was nearly similar our study. [9] Another study conducted in Ugandan hospitalized patients showed an incidence rate of 25.0% (95% CI: 22-29).[10] However, low incidence rate was observed in studies conducted in Saudi Arabia 6.1 (95% CI: 5.4-6.9), and Ethiopia 3.6 (95% CI: 2.9-4.35). The variation in the incidence of ADRs among different studies is due to change in the population, clinical practice, design used to report ADRs.[11,12]On contrary to these studies, studies conducted in Japan 37.8% (95% CI: 60.6-69.5), and Uganda 48.9% (95% CI: 44.6-53.2) have shown high incidence of ADR compared to our study.[13,14]The discrepancy in the incidence of ADR might be due change in the population and data collection methods used to collect ADRs. However, the high rate of ADR frequency observed in the Ugandan study is linked with the use of geriatrics as study population.

The current study revealed that antibiotics (20.0%), antihypertensives (10.3%), and miscellaneous (11.7%) category of drugs are much contributed in the development of ADRs. Studies conducted in elsewhere also revealed that antimicrobials, and cardiovascular drugs are the major class of drugs that can cause ADRs among hospitalized patients which are nearly similar to our study.[15–17]Recommendation of combinations and long-term use is one of the reason for high rate of ADRs observed in antibiotic and antihypertensive therapy. In the current study, Gastro-intestinal tract (GIT), Central Nervous System (CNS), and skin are the most common organ system effected by ADRs. Few studies conducted in Pakistan, India, Ethiopia, and Uganda also reported that ADRs majorly targets the GIT organ system.[13,15,18,19] These findings helps healthcare professionals to lookup on possible drugs and ADRs among hospitalized patients for prevention and management.

The development of ADR is multifactorial. The findings of the binary logistic regression analysis revealed that advanced age, presence of comorbidity, complications of disease condition, use of more than four medications, and stay in hospital for more than 3 days were significantly associated with the development of ADRs among hospitalized patients. Advanced age is one of the major risk factors associated with the development of ADRs. The presence of comorbidities, multiple medications, nonadherence, and poor function of elimination organs are a few reasons for the high rate of ADRs among the geriatric population. Also, polypharmacy is one of the major risk factors that was associated develop ADRs among hospitalized patients. Increasing the number of drugs are greatly associated with pharmacokinetic or pharmacodynamic interactions that can cause the development of ADRs. Long hospital stay is one more risk factor that contributes to nosocomial infections, multiple drug therapy, and weakened immunity which may result in increased susceptibility towards ADRs. In line with the current study findings, various studies also reported similar predictors (advanced
age, polypharmacy, long hospital stay, comorbidities, and complications) for the development of ADRs.[13,15,17,19,20]

Strengths and limitations

The current is a prospective observational study that enables appropriate recording, causality assessment, and follow-up of ADRs. This study provides insights for healthcare professionals to understand the most common class of drugs involved, the severity level of ADRs, and predictors for the development of ADRs that help in a better management of the patient to achieve positive outcomes. The current study findings act as a baseline for future research in Pharmacovigilance. Though the study was well designed and prospectively observed for the development of ADRs among hospitalized patients, the duration of follow-up was restricted to the hospital alone and the sample size was limited. Future research considering a large sample size and long follow-up are recommended.

Conclusion

The study concludes that the cumulative incidence of ADRs among hospitalized patients was found to be 30.3%. Majority of ADRs were probable in causality, mild, probably preventable, and non-serious. Advanced age, polypharmacy, presence of comorbidity and complication, and long hospital stay were significantly associated develop ADRs among hospitalized patients. Continuous communication of ADR findings to the healthcare professional is essential to promote safe use of drugs in the hospital settings.

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Conflict of interest

The authors declare that they have **no** conflicts of interest and **NO** affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

Ethical considerations

The study was protocol, data collection tool, and informed consent procedures were approved by the hospital research ethics committee (IEC/2017/PP/032). The study was conducted according to ICH-GCP guidelines. All the study subjects were explained about the study and its objectives, and informed consent was obtained.

Author's contribution

All authors contributed to drafting and revising the manuscript. KKC and HHM were involved in the design of the study, data collection, and data analysis. All authors have read and approved the final manuscript.

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Table 1: Socio-demographic and clinical profile of the hospitalized patients (n=442)

Variable	Frequency (%)
Age in years (Mean ± SD)	
18-44	120 (27.1)
45-60	153 (34.6)
≥ 61	169 (38.2)
Gender	
Male	248 (56.1)
Female	194 (43.9)
Smoking status	
Smoker	123 (27.8)
Non-smoker	319 (72.2)
Alcohol use status	
Alcoholic	164 (37.1)
Non-alcoholic	278 (62.9)
Physical activity	
Sedentary	127 (28.7)
Moderate	208 (47.0)
Vigorous	107 (24.2)
Type of illness	
Infectious	306 (69.2)
Non-infectious	136 (30.8)
Co-morbidity	
Present	108 (24.4)
Absent	334 (75.5)
Number of medications	
≤ 3	169 (38.2)
4-6	178 (40.3)
≥ 7	95 (21.5)
Presence of complications	
Yes	78 (17.6)
No	364 (82.3)
Length of hospital stay (Days)	
≤ 3	132 (29.9)
4-8	199 (45.0)

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8-12	86 (19.4)
> 12	25 (5.6)

Table 2: Potential offending drugs for the experienced ADRs among hospitalized patients (n=145)

Offending drug	Frequency (%)
Antibiotics	**29 (20.0)**
Azithromycin	2 (1.4)
Doxycycline	3 (2.1)
Ceftriaxone	3 (2.1)
Metronidazole	2 (1.4)
Cefixime	3 (2.1)
Cefazolin	2 (1.4)
Ciprofloxacin	2 (1.4)
Amoxycillin + Clavulanic acid	2 (1.4)
Nitrofurantoin	2 (1.4)
Piperacillin and Tazobactam	2 (1.4)
Fluconazole	1 (0.7)
Clindamycin	2 (1.4)
Cotrimoxazole (Sulfamethoxazole and Trimethoprim)	3 (2.1)
Anti-malarial	**9 (6.2)**
Artemether and Lumefantrine	3 (2.1)
Primaquine	2 (1.4)
Artesunate	2 (1.4)
Hydroxy Chloroquine	2 (1.4)
Anti-ulcer and antacids	**5 (3.4)**
Pantoprazole	3 (2.1)
Ranitidine hydrochloride	2 (1.4)
Antidiabetics	**9 (6.2)**
Insulin	3 (2.1)
Metformin	2 (1.4)
Glibenclamide	1 (0.7)
Glipizide	1 (0.7)
Pioglitazone	2 (1.4)
Anti-platelet	**4 (2.7)**
Aspirin	2 (1.4)
Clopidogrel	2 (1.4)
Anti-asthmatics	**11 (7.6)**
Salbutamol	3 (2.1)
Budesonide	1 (0.7)
Ipratropium bromide	3 (2.1)
Montelukast	1 (0.7)
Aminophylline	3 (2.1)
Antipyretics and analgesics	**7 (4.8)**
Ibuprofen	2 (1.4)
Diclofenac	5 (3.4)
Corticosteroids	**8 (5.5)**

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Prednisolone	4 (2.7)
Dexamethasone	2 (1.4)
Hydrocortisone	2 (1.4)
Anti-hypertensive	**15 (10.3)**
Enalapril	2 (1.4)
Nifedipine	2 (1.4)
Amlodipine	1 (0.7)
Labetalol	2 (1.4)
Clonidine	1 (0.7)
Metoprolol	1 (0.7)
Losartan	3 (2.1)
Frusemide	3 (2.1)
Antitubercular	**4 (2.7)**
Forecox (Isoniazid, Rifampicin, Ethambutol, and Pyrazinamide)	4 (2.7)
Anticonvulsant	**9 (6.2)**
Lorazepam	3 (2.1)
Phenytoin	2 (1.4)
Carbamazepine	2 (1.4)
Clobazam	2 (1.4)
Haematinics	**8 (5.5)**
Ferrous fumarate	2 (1.4)
Iron Folic Acid (IFA)	4 (2.7)
Multivitamin	2 (1.4)
Anti-histamine	**10 (6.9)**
Chlorpheniramine Malleate	4 (2.7)
Cetirizine hydrochloride	4 (2.7)
Cinnarizine	2 (1.4)
Miscellaneous	**17 (11.7)**
Magnesium sulphate	2 (1.4)
Cabergoline	2 (1.4)
Misoprostol	1 (0.7)
Atorvastatin	1 (0.7)
Disodium hydrogen citrate	1 (0.7)
Levothyroxine	1 (0.7)
Ondansetron	1 (0.7)
Domperidone	2 (1.4)
Lactulose	2 (1.4)
Amitriptyline	2 (1.4)
Enoxaparin	2 (1.4)

Table 3: Causality, severity, preventability, and seriousness of ADR (n=145)

Parameter	Frequency (%)

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Causality*	
Definite	19 (13.1)
Probable	78 (53.8)
Possible	42 (28.9)
Doubtful	6 (4.1)
Severity[@]	
Mild	86 (59.3)
Moderate	52 (35.9)
Severe	7 (4.8)
Preventability[#]	
Not preventable	2 (1.4)
Probably preventable	79 (54.5)
Definitely preventable	64 (44.1)
Seriousness[$]	
Not serious	63 (43.4)
Hospitalization (initial/prolonged)	25 (17.2)
Required intervention to prevent damage/impairment	49 (33.8)
Life threatening	2 (1.4)
Disability	0 (0.0)
Death	0 (0.0)
Others	6 (4.1)

* Naranjo ADR probability scale; [@] Hartwig and Siegel ADR severity assessment scale; [#]Modified Schumock and Thornton preventability scale

Table 4: Distribution of ADRs according to Organ/System (n=145)

Organ/System	Frequency (%)
Skin	18 (12.4)
GI tract	39 (26.9)
Hepato-biliary (Liver and Gallbladder)	5(3.4)

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Cardiac	11 (7.6)
Haematology	9 (6.2)
CNS	28 (19.3)
Renal (Kidney)	8(5.5)
Respiratory system	5(3.4)
Endocrine	6 (4.1)
Eye	2 (1.4)
Others	14(9.6)

Table 5: Management and outcome of observed ADRs (n=145)

Parameter	Frequency (%)
Outcome of ADR	
Not recovered	15 (10.3)

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Recovered	60 (41.4)
Continuing	1 (0.7)
Recovering	37 (25.5)
Unknown	32 (22.1)
Fatal	0 (0.0)
Management of ADR	
Addition of another drug	59 (40.7)
Withdrawal of drug	28 (19.3)
Substituted with another drug	3 (2.1)
Dose reduction	24 (16.5)
No change	15 (10.3)
No information	16 (11.0)

Table 6: Binary logistic regression analysis of patient characteristics associated with the ADR development (n=442)

Variable	Frequency (%)	Occurrence of ADR	COR (95% CI)	*P-value*
Age in years				

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18-44	120 (27.1)	12 (10.0)	Ref	Ref
45-60	153 (34.6)	38 (24.8)	2.96 (1.49-6.18)	0.001
≥ 61	169 (38.2)	84 (49.7)	8.83 (4.62-17.89)	<0.001
Gender				
Male	248 (56.1)	76 (30.6)	Ref	Ref
Female	194 (43.9)	58 (29.9)	0.96 (0.64-1.45)	0.865
Smoking status				
Smoker	123 (27.8)	39 (31.7)	Ref	Ref
Non-smoker	319 (72.2)	95 (29.8)	0.91 (0.58-1.44)	0.693
Alcohol use status				
Alcoholic	164 (37.1)	54 (32.9)	Ref	Ref
Non-alcoholic	278 (62.9)	80 (28.8)	0.82 (0.54-1.25)	0.359
Physical activity				
Sedentary	127 (28.7)	39 (30.7)	Ref	Ref
Moderate	208 (47.0)	63 (30.3)	0.98 (0.61-1.59)	0.935
Vigorous	107 (24.2)	32 (29.9)	0.96 (0.55-1.68)	0.894
Type of illness				
Infectious	306 (69.2)	90 (29.4)	Ref	Ref
Non-infectious	136 (30.8)	44 (32.3)	1.15 (0.74-1.77)	0.535
Co-morbidity				
Absent	334 (75.5)	81 (24.2)	Ref	Ref
Present	108 (24.4)	53 (49.1)	3.00 (1.91-4.73)	<0.001
Number of medications				
≤ 3	169 (38.2)	29 (17.1)	Ref	Ref
4-6	178 (40.3)	56 (31.5)	2.21 (1.33-3.72)	0.002
≥ 7	95 (21.5)	49 (51.6)	5.10 (2.90-9.09)	<0.001
Presence of complications				
No	364 (82.3)	94 (25.8)	Ref	Ref
Yes	78 (17.6)	40 (51.3)	3.01 (1.82-5.00)	<0.001
Length of hospital stay (Days)				
≤ 3	132 (29.9)	21 (15.9)	Ref	Ref
4-8	199 (45.0)	59 (29.6)	2.22 (1.28-3.94)	0.004
8-12	86 (19.4)	41 (47.7)	4.77 (2.56-9.10)	<0.001
> 12	25 (5.6)	13 (52.0)	5.64 (2.24-14.38)	<0.001