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STUDY OF ADVERSE DRUG REACTION PROFILE IN A TERTIARY CARE HOSPITAL: A RETROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Introduction: ADR can increase the hospital stay, cost of treatment and also decreases the quality of life. Reporting of ADR ensures safe use of a drug. Present study was conducted to study the ADR profile in a tertiary care hospital. **Objectives:** 1. To study the Adverse Drug Reactions (ADRs) profile. 2. To assess the seriousness, causality, severity and outcome of ADRs. **Methods:** A retrospective observational study was conducted in a tertiary care hospital, BIMS, Belagavi among outpatients and inpatients with suspected ADR. After the approval by Institutional ethics committee, the recorded data of each patient in various departments was collected based on inclusion and exclusion criteria and then evaluated. The data regarding demographic details of patients, drugs and adverse drug reactions was entered in a specially designed proforma and later into MS excel sheet. **Results:** A total of 380 ADRs were analyzed out of which males and females showed an equal distribution of 50%. Majority of the patients were in the age group of 21-30(24%). Majority i.e., 192(28%) subjects had minor severity, followed by 78 (68%) subjects had moderate severity. Maximum ADRs were due to Anti TB drugs.(26%).Casualty assessment showed 187(66%) were probable, 93(33%) were possible and 2(1%) were certain. Cutaneous ADRs (51%) were the most common followed by CNS(22%) and musculoskeletal (12%)ADRs. Out of the 380 patients 155(55%) recovered, 86(30%) were recovering, 40(14%) had not recovered and one ADR had a fatal outcome. **Conclusion:** Most of the ADR's in the study were due to Anti-TB drugs which resulted in prolonged hospitalization and increased economic burden. To avoid the ADR's, it is important to identify and avoid the risk factors of ADR's and follow rational drug usage.

KEYWORDS: Adverse drug reactions, Casualty, Profile, Severity, Suspected drugs.

INTRODUCTION

Adverse drug reaction (ADR) is defined as 'any noxious change which is suspected to be due to drug, occurs at doses normally used in man, requires treatment or decrease in dose or indicates caution in the future use of the same drug'.[1]

ADRs are major cause for prolonged hospitalization, increase hospital expense, morbidity and mortality. Disease prevalence, economic status, culture and ethnicity contribute to different ADR patterns.[2] Pharmacovigilance aids in the active assessment, monitoring, and prevention of adverse drug reactions (ADR). It is critical to record and analyze ADRs in order to detect potential drug dangers and improve drug safety.[3]

ADRs are more likely with multiple drug therapy, and the risk of an ADR episode is multiplied by 1.14 for each extra medicine taken by the patient. Information about ADRs is mainly received through voluntary reporting systems. According to Pharmacovigilance Programme of India (PvPI) there is increasing trend of ADR's in the last five years.[4,5]

Though PvPI frequently recommends drug regulatory agencies and Healthcare professionals (HCPs) to improve medication safety, still there is a greater need to raise community and healthcare professional knowledge about the significance of closely monitoring drug outcomes, particularly newer ones. Awareness of ADR identification, management, prevention, and reporting is critical for improving patient care and lowering costs.

The current study aims to strengthen the ADR database through analysis and reporting of ADRs.[6]

OBJECTIVES

1. To study the Adverse Drug Reactions (ADRs) profile.
2. To assess the seriousness, causality, severity and outcome of ADRs.

MATERIAL AND METHODS

This retrospective observational study was conducted in a tertiary care hospital, BIMS, Belagavi. Our institution is an approved ADR monitoring center (AMC) under Pharmacovigilance Programme of India (PvPI).

After the approval by Institutional ethics committee, the recorded data of each patient in various departments was collected based on inclusion and exclusion criteriaand then evaluated. The data regarding demographic details of patients, drugs and adverse drug reactions was entered in a specially designed proforma and later into MS excel sheet.

Study design: Retrospective Observational study

Study subjects: Outpatients and Inpatients with suspected ADR.

Study area: Belagavi Institute of Medical Sciences, Belagavi, Karnataka. (Approved ADR center under PvPI)

Study period: 1 year

Inclusion criteria

All records of outpatients and inpatients with suspected adverse drug reaction.

Exclusion criteria

Patient records without proper documentation regarding information of ADR reporter, patient details, drug and ADR details were excluded.

Sample size: Complete enumeration was done. Total of ADRs reported in one year were 400. As per the inclusion criteria, 380 ADRs were included in the study.

Method of collection of data: Recorded data of ADR reports was collected and evaluated for seriousness, causality, severity and outcome using appropriate scales. Naranjo ADR probability scale[7] was used for causality assessment. Severity assessment was done using Hartwig severity assessment scale.[8]

Statistical analysis: Collected data was compiled and entered into Microsoft Excel sheet and analyzed using SPSS software version 26. Data analysis was carried out with simple descriptive statistics like frequency and percentage.

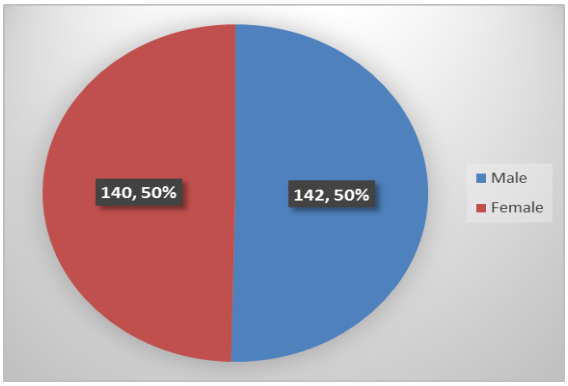
RESULTS

Total numbers of ADRs reported in one year were 400.As per the inclusion criteria, 380 ADRs were analyzed out of which males and females showed an equal distribution of 50%. (Graph 1). Majority in the study i.e., 68(24%) were in 21-30 years age group, followed by 65(23%) were in 31-40 years age group, 40 (14%) were in 41-50 years age group, 26(9%) were >60 years and 37 (13%) were <15 years (Table 1).

Among these maximum ADRs were due to Anti TB drugs(26%) (Table 2). Naranjo ADR probability scale[8] was used for causality assessment. Casualty assessment showed 187(66%) were probable, 93(33%) were possible and 2(1%) were certain. (Graph 2) Cutaneous ADRs (51%) were the most common followed by CNS(22%) and musculoskeletal (12%)ADRs. (Table 3).

Severity assessment was done using Hartwig severity assessment scale.[9] Majority i.e., 192(28%) subjects had minor severity, followed by 78 (68%) subjects had moderate severity and only 12 (4%) subjects had severe severity. (Graph 3).

Out of the 380 patients 155(55%) recovered, 86(30%) were recovering, 40(14%) had not recovered and one ADR had a fatal outcome. (Graph 4).



Graph 1: Gender distribution among study subjects.

Table 1: Age distribution among study subjects.

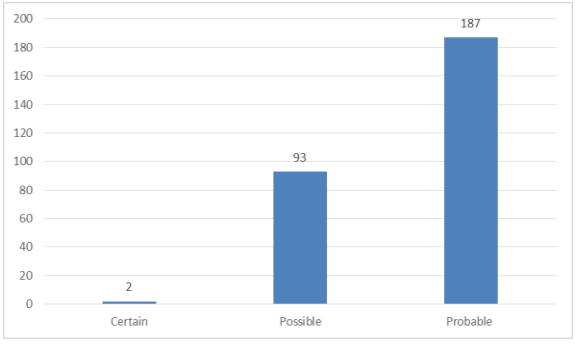
Age in years	Frequency	Percentage
0-10	11	4%
11-20	26	9%
21-30	68	24%
31-40	65	23%
41-50	40	14%
51-60	46	16%
61-70	16	6%
71-80	7	2%
81-90	3	1%
Total	282	100

Table 2: Distribution of suspected drug for ADR among study subjects.

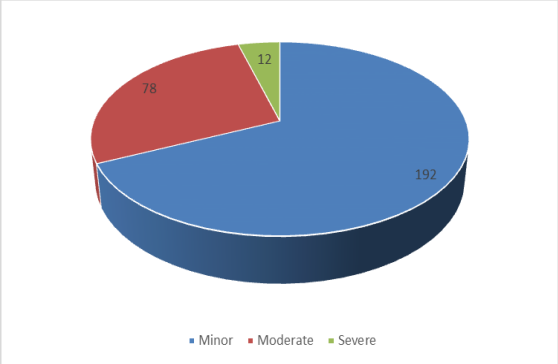
Suspected drug	Frequency	Percentage
Anti TB	72	25.53%
Antibiotic	64	22.70%
IV iron injection	30	10.64%
Anti snake venom	24	8.51%
IV fluid	21	7.45%
Antibiotic+IVF	20	7.09%
Rabies Antiserum	8	2.84%
ART	7	2.48%
NSAIDS	7	2.48%
Albumin	5	1.77%
Antiepileptic	4	1.42%
Diptheria toxin	4	1.42%
Antacids	3	1.06%
Antihypertensive	3	1.06%
Covishield	3	1.06%
Anti diuretic	3	1.06%
Antimalarial	2	0.71%
IV Calcium gluconate	1	0.35%
TT vaccine	1	0.35%

Table 3: Distribution of ADR'S according to the system affected.

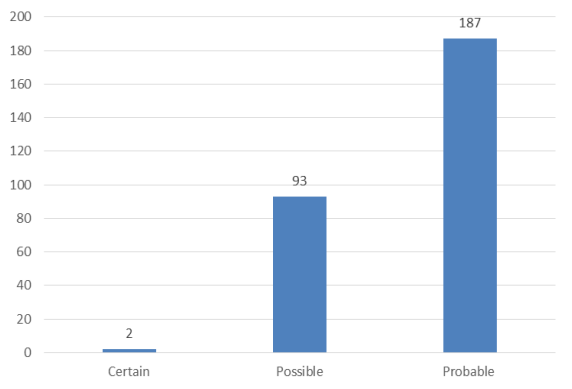
Suspected drug	Frequency	Percentage
Cutaneous	145	51.42%
CNS	62	21.99%
Musculoskeletal	34	12.06%
Respiratory	16	5.67%
Gastrointestinal	14	4.96%
CVS	10	3.55%
Haematological	1	0.35%



Graph 2: Distribution of casualty among study subjects.



Graph 3: Distribution of severity among study subjects.



Graph 4: Distribution of outcome among study subjects.

DISCUSSION

In this study a total of 382 ADR'S were included. It was found in this study that frequency of ADR'S was almost equal in both males and females(53%). Similar finding is seen in the other studies.[1,9] Whereas in a study by Lihite et al.[10] majority of ADRs were observed in female patients (54%) than in male patients (47%). Also, one of the studies reported that women were more susceptible to ADR's than men due to association of factors like greater concentration of adipose tissue and hormonal determinants that can affect metabolism may lead to development of ADR which was consistent with this study.[11]

In this study, highest number of ADR's was observed in 21-40 years age group patients (47%). Similar finding was seen in study by Jha N et al.[12] In a study by Lihite et al.[10] patients belonging to age group of 21–40 years reportedto experience maximum number of ADRs (47.9%) which was similar to this study.

In this study, AntiTB drugs 26(36%) were the most common group of drugs responsible for ADR's followed by Antibiotics (23%). Study by Jha et al.[12] showed antibiotics were the most common suspected drugs whereas Padukadan et al.[13] found NSAIDs to be the most common offending drug in their study. Venkatasubbaiah et al.[14] reported antibiotics as the most common offending drug. This variation is because of different patterns of drug used in different populations.

In this study, Cutaneous ADRs (51%) were the most common followed by CNS (22%) and musculoskeletal (12%)ADRs. This observation was consistent with other studies who also reported similar reactions as the most frequent ones.[15,16] Lihite et al.[10] reported 63.52% of cutaneous ADR's followed by 15.29% of CNS ADR's which was in accordance to this study. Whereas in a study by Venkatasubbaiah et al.[14] most common organ system involved in ADR's was GI (26.38%) followed by skin (24.08%).

Evaluation for seriousness showed 192(68%) as minor and 78(28%) as moderate severity and 12(4%) were severe. The most common reason for such severity was prolongation of hospitalization. In a study by Venkatasubbaiah et al.[14] 55% were mild and 39% were moderate ADR's which were consistent with this study. Similar findings were seen in other studies.[17] ADR in few study participants was life threatening in the current study which needed an intervention to prevent hepatitis and decreased vision due to Anti-TB drugs. In this study major contribution of ADRs constituted chills, itching and rashes which were of minor severity. A very small number belonged to severe grade similar to the study conducted by Geer et al.[17] and Venkatasubbaiah et al.[14]

Many studies have shown that patients taking more medications suffer from ADR's.[18,19] Similarly our study also showed that polypharmacy is a risk factor for ADR's.

Causality assessment in our study identified 187(66%) as probable, 93(33%) as possible and 2 (1%) as certain due to rechallenge test or due to patient's ADR history to the same drug. In contrary to this study, study by Lihite et al.[10] reported most of the ADRs (93.7%) as possible, and only 10 ADR reports as probable; Venkatasubbaiah et al.[14] reported 48% as possible and 28% as probable.

23Assessment of outcome showed that 155(55%) patients recovered from the reaction and 86(30%) were recovering at the time of reporting of ADR. Shajahan J et al.[20] showed similar pattern of recovery in his study (64% recovered and 30% were recovering). Lihite et al.[10] too observed most of the ADR reports were mild in nature and recovered during study period. In a study by Venkatasubbaiah et al.[14] majority (36.2%) patients have recovered fromthe reactions and 30.7% were at recovering stage during the study period which was consistent with this study.

CONCLUSION

Most of the ADR's in the study were due to Anti-TB drugs which resulted in prolonged hospitalization and increased economic burden. Majority had minor severity. Causality assessment showed most of the ADR'S as probable Cutaneous ADRs were the most commonin the study constituting to half of the population. More than half of the study population recovered during and others were recovering during the study period. One patient had fatal outcome. To avoid the ADR's, it is important to identify and avoid the risk factors of ADR's like polypharmacy found in this study. Rational drug usage has to be followed.

It's also critical to thoroughly record prior responses to any given medication and rule out any potential drug interactions. It's essential to cautiously use drugs in special groups.

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