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

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ABSTRACT

INTRODUCTION Adverse drug reactions (ADR) are unintended, harmful effects at therapeutic doses, causing 0.2%-24% of hospital admissions and 3.7% fatalities, especially in the elderly (9%). ADRs increase hospital stays, treatment costs, and mortality risks. Pharmacovigilance in India, monitors ADRs through 250 centers, yet reporting remains low (<1% vs. 5% globally). It remains the responsibility of healthcare professionals to report the adverse drug reactions.

AIMS AND OBJECTIVES - 1. To assess the adverse drug reactions (ADRs) reported during a one year period (2024) based on severity, causality and its preventability. 2**.**To analyse which drugs have caused maximum ADR and the types of ADRs reported.

METHODS - A retrospective observational study was conducted after analysing all adverse drug reactions(ADR) forms received from hospital (one year). Drugs were classified according to the class. Causality assessment done using Naranjo scale and severity assessed using Hartwig scale. Reactions were analysed presented in bar, graphs and pie charts

RESULTS - A total of 440 ADRs were reported. Out of these Anti-TB drugs (22.5%) had the highest ADRs, followed by iron preparations (16.82%) and anti-microbials (14.55%). The occurrence of ADRs was almost equal among male(48.41%) and females(51.59), the maximum were in 31 to 40 age group. ADR reporting increased from 4-7% per month to 9-11% after an awareness session during Pharmacovigilance (PV) Week. The most common ADR caused by antitubercular therapy were hepatitis, numbness, chills and rigors, antimicrobials was rashes, tachycardia. Most of the reactions observed in the patients were mild(86.6%) and only 5.45% were severe.

CONCLUSION - This study highlights the positive impact of educational initiatives on ADR reporting and the need for continuous awareness programs to improve pharmacovigilance practices.

KEYWORDS – Adverse Drug Reactions, Manuscript writing, Retrospective Analysis, ADR monitoring center

INTRODUCTION

Adverse drug reactions (ADRs) is any serious, noxious and unpleasant effect occurring at a therapeutic dose which can either lead to withdrawal of treatment or use of any alternative methods. So, study of these unwanted effects by drugs can help in prevention of any future apocalyptic events.[1] ADRs account for 0.2%-24% of hospital admissions, and 3.7% of patients have fatal ADRs. Admissions due to ADRs in elderly patients have been reported to be higher (9%). ADRs lead to a number of medical and economic consequences, e.g. they prolong hospital stay, increase the cost of treatment and risk of death almost two-fold.' [2]

Majority of drugs routinely prescribed in medical practice for treating various diseases carry the risk of adverse effects, which in turn calls for "Pharmacovigilance". According to WHO, PV is “the science and the activities which relate to the detection, assessment, understanding and the prevention of adverse effects or any other drug-related problems”. The Uppsala Monitoring Centre (UMC, WHO), Sweden, maintains the international database of the ADR reports (WHO, 2002).[3]

(Pharmacovigilance)PV in India was initiated in 1986; in 2005, India launched the National Programme of Pharmacovigilance, renamed as the Pharmacovigilance Programme of India (PvPI) before becoming a WHO Collaborating Centre for Pharmacovigilance in 2010. PvPI safeguards the health of the community through monitoring and assessing the risks and benefits associated with drug use with the support of 250 ADR monitoring centres across India.[3]

But, it has been found that there is significant lack in monitoring and reporting of adverse drug reactions (ADRs) which is below 1% in India compared to the worldwide rate of 5%. Therefore, vigilant monitoring throughout the life cycle of drug is crucial and is the need of hour.The main objective of ADR monitoring is to identify the frequency of ADR and their risk factors. An analysis of ADR reporting helps us to understand the preventability.[4]
The purpose of this study was to assess the adverse drug reactions (ADRs) reported during a one year period (2024), evaluate the causality, severity and preventability of the reported ADRs. Awareness was created among the healthcare professionals during the Pharmacovigilance week which resulted in increased ADR reporting in the upcoming months.

MATERIALS AND METHODS

A retrospective observational study was conducted after analysing all adverse drug reactions(ADR) forms received from hospital (in patient and out patient departments) of BIMS Belagavi after obtaining clearance from Institutional Ethical Committee. The study includes one year data (Jan 01, 2024 to dec 31, 2024). Reports were analysed according to the following parameters,

- Demographic data of the patient – age, sex
- ADRs will be analysed into type, number and percentage
- Drugs causing ADRs are classified and described as number and percentage.
- Causality were assessed by using Naranjo scale
- Severity by using modified Hartwig’s and Seigel scale
- Awareness speech on Pharmacovigilance during the Pharmacovigilance week

All records of outpatient and inpatient with suspected adverse drug reaction that were reported to the ADR monitoring center (AMC) were included in the study. ADR forms that were incomplete, without proper documentation regarding information of drug details and ADR details were excluded. The collected data were entered in MS Excel sheet and presented in percentage / proportion and graphs.

RESULTS

Total numbers of ADRs reported in the year 2024 were 456.
As per the inclusion and exclusion criteria, totally 440 ADRs were analyzed and following were the results obtained

Figure 1: GENDER DISTRIBUTION AMONG STUDY SUBJECTS

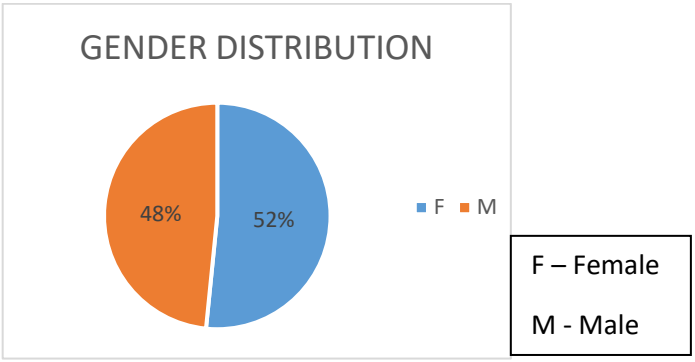


Table 1: AGE DISTRIBUTION AMONG STUDY SUBJECTS

AGE	FREQUENCY
1 to 10	23
11 to 20	52
21 to 30	57
31 to 40	140
41 to 50	74
51 to 60	49
61 to 70	30
71 to 80	15
Grand Total	**440**

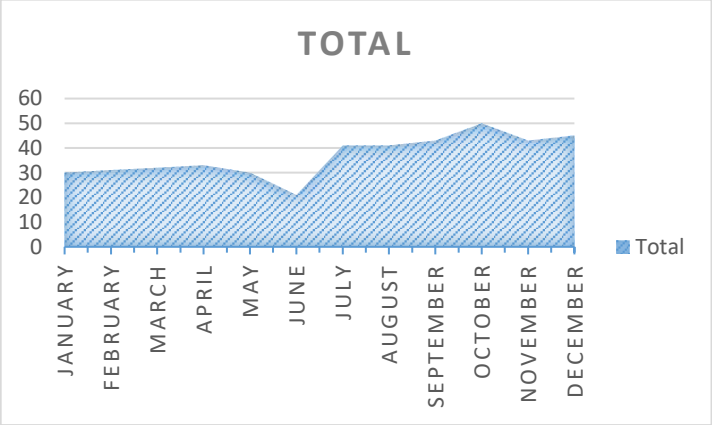
Figure 1 and Table 1 shows the demographic characteristics of the subjects in the study. Total of 440 subjects analyzed out of which males and females showed almost an equal distribution of 50%, Male 213 and female 227 and the maximum were in 31 to 40 age group (140) followed by 41 to 50 age group (74) least were in 71 to 80 age group probably because of old age negligence.

Table 2: DISTRIBUTION OF SUSPECTED DRUG FOR ADR

DRUGS	FREQUENCY	PERCENTAGE
Analgesic	34	7.73%
Anti - TB drug	99	22.50%
Anti Diabetic	6	1.36%
Anti Thyroid drugs	2	0.45%
Anti-microbials	64	14.55%
Antiepileptic	17	3.86%
Antihypertensive	14	3.18%
Antispasmodic	6	1.36%
Antitussives	2	0.45%
Diphtheria Anti toxin	3	0.68%
Inj. Anti snake venom	33	7.50%
Inj. Factor 8	4	0.91%
Normal Saline	5	1.14%
Inj. Rabies vaccination	26	5.91%
IV Iron preparations	74	16.82%
Monoclonal Antibody	2	0.45%
NSAIDs	14	3.18%
RL Saline	32	7.27%
Sedative	13	2.95%
Grand Total	**440**	**100%**

The table 2 shows the distribution of the drugs causing adverse drug reactions (ADRs) in a tertiary care hospital. Anti-TB drugs (22.5%) had the highest ADRs, followed by IV Iron preparations (16.82%) and anti-microbials (14.55%). NSAIDs, analgesics, and antihypertensives had moderate ADRs.

Figure 2 : MONTHWISE DISTRIBUTION OF ADRs REPORTED



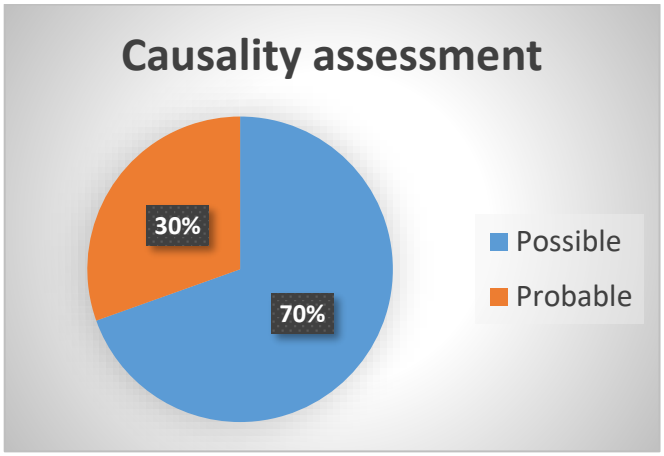
The Figure 2 represents the monthly distribution of adverse drug reactions (ADRs) in a tertiary care hospital. October (11.36%) had the highest ADRs, followed by December (10.23%) and September/November (9.77% each). July and August (9.32% each) also showed increased cases. The lowest ADRs were in June (4.77%). ADR reporting increased from 4-7% per month to 9-11% after an awareness session during Pharmacovigilance (PV) Week.

Table 3 shows the distribution of ADRs according to system wise in which most frequently were reported in skin and subcutaneous tissue (28.4%) (which includes symptoms like rashes, hypersensitivity reactions, redness, itching, blisters, dermatitis and all skin manifestations) followed by General disorders (18.4%) which includes symptoms like chills, fever, malaise, oedema and gastrointestinal (12.9%) like (abdominal discomfort, abdominal distention, abdominal pain, constipation, diarrhoea, dry mouth, vomiting, nausea)

Table 3 :DISTRIBUTION OF ADRs ACCORDING TO THE SYSTEM AFFECTED

SUSPECTED SYSTEM	FREQUENCY
Administration site conditions	1
Cardiac disorder	17
Gastrointestinal	57
General disorders	81
Injection site infection	9
Injury or poisoning	18
MDR	8
Musculoskeletal disorder	21
Nervous system disorder	41
Ocular effects	11
Oral lesion	9
Pedal Edema	10
Respiratory system	32
Skin and subcutaneous tissue disorders	125
Grand Total	440

Figure 3: DISTRIBUTION OF CAUSALITY ASSESSMENT AMONG STUDY SUBJECTS



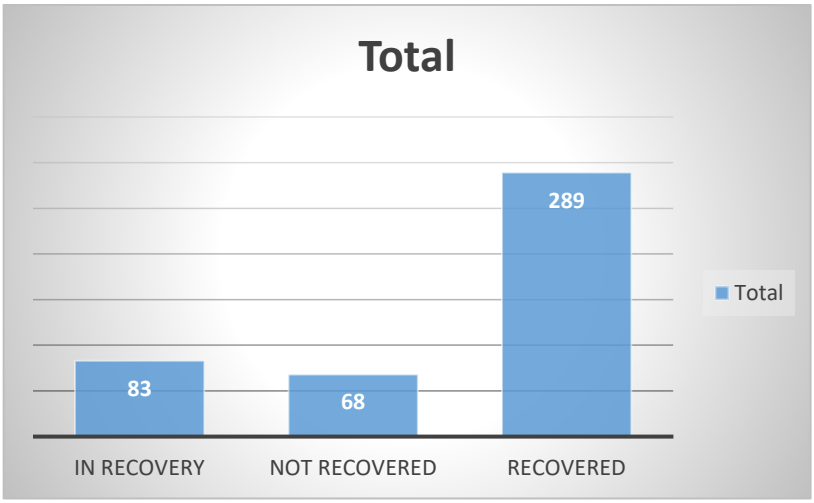
The causality assessment of ADRs Figure 3 shows that most cases were classified as Possible (69.55%), indicating uncertainty about a direct drug reaction due to multiple contributing factors. Probable cases (30.45%) suggest a stronger likelihood of a drug-related reaction based on clinical evaluation

Table 4: DISTRIBUTION OF SEVERITY AMONG STUDY SUBJECTS

Severity	Frequency	Percentage (%)
Mild	380	86.36%
Moderate	36	8.18%
Severe	24	5.45%
Total	**440**	**100%**

Table 4 shows the assessment of severity based on Hartwig scale of which almost all reported ADRs of about 380 (86%) were mild and 36 (8%) were moderate and very less 24 (5%) were severe who were in recovering phase (Figure 4). It shows the outcome among the study subjects were 289 (65.5%) were recovered, 83 subjects (18.8%) were in recovering phase and about 68 people (15.5%) were not recovered

Figure 4: DISTRIBUTION OF OUTCOME AMONG STUDY SUBJECTS



DISCUSSION

In this one-year retrospective analysis, 440 confirmed ADRs were reported to our AMC (Jan–Dec 2024), while Vemurii et al[4] study observed only 95 ADRs in a period of 6 years, which was very less compared to our observation, and Nirojini et al[5] observed 295 ADRs over a period of 9 months which was similar to our study.

Our study showed nearly equal distribution of ADRs among males and females (Graph 1), consistent with mixed departmental reporting. In comparison, Dutta et al[6] study showed male predominance (male:female 1.5:1) and Prajapati et al. [8] reported a male predominance (1.38:1) among serious ADRs, while Lihite et al. [9] and Vemuri et al. [4] found slight female preponderance. Dutta et al. [6] observed male predominance (1.5:1). Thus, our balanced ratio reflects reporting from both inpatient and outpatient settings, including dermatology, TB, and infusion clinics.

The majority of ADRs in our study occurred in 31–40 years (31.8%)(Table 1), similar to adult-predominant distributions in Indian pharmacovigilance centers. Lihite et al. [9] found peak incidence in 21–30 years, and Prajapati et al. [8] reported a higher mean age (36.9 years), while Dutta et al. [6] and Shah et al. [10] reported more cases in the 16–30-year group. Our slightly older modal age could relate to ATT and iron infusion–related ADRs typical in working-age adults. One study showed that the younger population is more likely to report ADRs [11]

Using Hartwig scale[13] most ADRs in our study were mild (86.4%),(Table 4) followed by moderate (8.2%) and severe (5.4%) based on Hartwig's scale. This pattern closely matches Lihite et al., [9] who reported 87% mild ADRs, also with Singh et al[1] who reported 87% of non serious ADRs, whereas Prajapati et al [8] showed serious ADR that included higher severity levels and fatalities also Dutta et al[6] showed (91%) serious ADRs. Vemuri et al [4] reported mostly moderate(52%) reactions. Our study showed recovery rates of about 65%(Graph 4) whereas John et al[13] showed very good recovery rates of about 89%.

Using Naranjo's scale[14] 69.6% of our ADRs were classified as possible (Graph 3) and 30.4% as probable. Lihite et al. [9] similarly reported a high percentage of possible ADRs (94%), whereas Nirojini et al[5] and Dutta et al. [6] found most ADRs as probable (80%) and (74%) respectively. A study by Maqbool et al[15] showed 50% definite, confiming by means of rechallenge tests. The predominance of "possible" causality in our data reflects limited rechallenge or laboratory confirmation which was the same limitation in a study conducted by Pathak et al[16]. The skin and subcutaneous tissue was the most frequently affected system (28.4%),(Table 3) consistent with findings of Prajapati et al [8] (18.9%) and Lihite et al. [9] (63.5%). This shows dermatologic ADRs are the most visible and easily recognized category across centers. Other affected systems were general disorders (18.4%) and gastrointestinal (12.9%), similar to the pattern reported by Vemuri et al[4]. and Dutta et al[6] Whereas a study conducted by Nirojini et al[5] showed CNS to be most affected system, symptoms constituting of headache, giddiness, sedation etc.

Our study identified anti-tuberculosis agents (22.5%) (Table 2) as the most common group associated with ADRs, followed by iron preparations (16.8%) and anti-microbials (14.6%). This aligns with Maqbool et al[15] with Anti-TB drugs (35%) and also with Prajapati et al[8] where anti-tuberculosis drugs (34.4%) followed by antiretrovirals and anti-microbials were the leading cause of ADRs. Vemuri et al[4] reported antimicrobials (19.4%) and anti-tubercular drugs (17.6%) as the most frequent offenders. In contrast, Lihite et al[9] and Shah et al[10] which were dermatology-based studies, found topical corticosteroids and antimicrobials/antiepileptics as the main culprits. Dutta et al[6] reported NSAIDs (28.5%) and fluoroquinolones (24.4%) as leading causes, typical of general medical wards. A study conducted by Singh et al[1] among the reported 270 suspected ADRs, antimicrobials have recorded maximum no of ADRs which account for almost half of the overall. The inclusion of

intravenous iron among the top three groups in our study is a unique finding, highlighting the importance of pharmacovigilance in infusion and maternal health units.

Our results represent a broad multi-departmental ADR pattern. The mixed case distribution explains our moderate age range, balanced sex ratio, and high proportion of mild ADRs. The prominence of anti-tuberculosis and IV iron–related ADRs underscores the need for targeted preventive protocols in ATT and care during infusions. Strengthening follow-up documentation and active surveillance during initiation of ATT and also other antimicrobials and IV therapies will help improve causality assessment and minimize preventable ADRs.

CONCLUSION

Beyond clinical pattern comparison, the results emphasize the importance of awareness and reporting behavior among healthcare professionals, as highlighted by Upadhyaya et al[17] Similarly, Bowalekar et al[18] and Bagle et al[19] noted that despite satisfactory theoretical knowledge of pharmacovigilance, active reporting remains suboptimal due to barriers such as lack of feedback, training, and perceived complexity of reporting systems. A study by Costa et al[20] showed lack of awareness about pharmacovigilance and its importance was a major reason for underreporting of ADRs and also Shamim et al[21] further reinforced that underreporting is a global concern, with attitude and practice gaps among clinicians being major limitations in pharmacovigilance efficiency

Being an institution with an Adverse Drug Reaction Monitoring Center (AMC), years of effort have been dedicated to raising awareness among doctors, patients, and nurses. In our study, ADR reporting increased from 4-7% per month to 9-11% after an awareness session during Pharmacovigilance (PV)(Graph 2). Regular awareness initiatives play a vital role in enhancing ADR reporting. Most ADRs stem from polypharmacy, and a patient's history of drug allergies is vital in preventing allergic reactions.

Integrating these perspectives, it becomes evident that establishing a robust culture of pharmacovigilance requires not only an effective reporting infrastructure but also sustained educational interventions. Continuous sensitization through workshops, inclusion of ADR reporting modules in medical curricula, and active feedback mechanisms from AMCs can enhance both the quantity and quality of ADR submissions.

Ultimately the ADR reporting supports the health authorities like the FDA, EMA or WHO in deciding whether to recall, restrict or reclassify drugs.

CONFLICT OF INTEREST AND FUNDING – NIL

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