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Original Research Article

Adverse drug reaction reporting in a tertiary care teaching hospital of Eastern Odisha: a five-year retrospective study

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ABSTRACT

Background: Adverse drug reactions (ADRs) related morbidity and mortality is a concern as it reduces quality of life, prolongs hospital stay and inflicts significant burden on the healthcare resources. This study was under taken to evaluate the patterns of spontaneously reported ADRs, at an ADR monitoring centre (AMC) in a tertiary care teaching hospital in Eastern India.

Methods: The present study was carried out for a period of five years from January 2020 to December 2024. Data were analysed for their demographic patterns, associated medications and reactions, system organ class affected, seriousness, outcomes and causality using the WHO causality scale. Mean, standard deviation, Chi-square ‘p’ and binomial ‘p’ were analysed.

Results: Total ADRs reported was 500. Highest ADRs was in the group of 30-60 years (48.6%), females reporting was 52.4%. Maximum cases reported in 2024 (42%). Department of psychiatry reported maximum ADRs (17.8%). 51.8% cases reported possible causality. Rash was the most common ADR in 25.6% and ceftriaxone sulbactam combination caused 16% ADRs. The most affected system organ class was skin and subcutaneous tissue disorder (61%).

Conclusions: The study depicted the pattern of reactions to various medications and helpful in augmenting the awareness of spontaneous reporting of ADRs amongst healthcare professionals, thereby enhancing patient safety and improving the quality of life.

Keywords: Adverse drug reactions, Causality assessment, Healthcare professionals, Patient safety

INTRODUCTION

World Health Organization (WHO) defines adverse drug reaction (ADR) as “a response to a medicinal product which is noxious, unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function”. ADRs are a constant healthcare issue in developing countries.¹ ADRs causes morbidity, mortality, and increases the expenses of the patients and health system of the country.² It is widely acknowledged that “no medication is completely free from side effects”. ADRs are common with polypharmacy thereby, directly increasing stay duration and burden on resources for the

patient.¹ ADRs risk factors includes demographic characteristics, duration of hospital stays, comorbidities, polypharmacy, hereditary factors, etc.² Reporting ADRs at the level of institution gives us crucial information on possible problems that might occur with the usage of the medication.

Pharmacovigilance, as defined by WHO, is the “science and activities relating to the detection, assessment, understanding, and prevention of adverse drug effects or any other medicine/vaccine related problem”.¹ ADR monitoring centres provide crucial insights on the adverse impact of medications on the population. Usage of these data would help us to know the various patterns and

characteristics of medication reactions, thereby providing an opportunity for improving the safety of medications. Voluntary reporting is commonly used and has added advantage of flexibility and low cost.³ Data which is collected through spontaneous reporting by the ADR monitoring centre (AMC) contributes to drug safety surveillance in clinical settings.

This study aimed to assess, the demographic patterns, severity, outcomes and causality assessment. In addition, it also identifies the categories of healthcare professionals and the departments involved in ADR reporting, the medications frequently causing reactions, the common reactions and the system organ class affected in a five-year period.

METHODS

This study was an analysis of reports at ADR monitoring centre, IMS and SUM Hospital, Bhubaneswar, retrospectively, between the period January 2020 to December 2024.

Patient of both gender reporting from OPD or IPD (wards, intensive care units, operation theatres) of IMS and SUM Hospital Bhubaneswar and SUM Ultimate Medicare, Bhubaneswar, were included in the study. Incomplete ADR form (lack of patient, medication, reaction and reporter details) was excluded from the study.

Demography of the patient, suspected medications, reactions, system organ class, severity, outcome, causality, action taken by reporter, routes of administration, department and reporter details were studied. The association of demographic variables, seriousness and outcomes with the number of ADRs for each year were also observed. The data on patient, medication, reaction and reporter were entered into Microsoft excel sheet. The ADR reporting form by Centre for Drug Standard and Control Organization is used for the study.⁴ Causality classification was based on WHO-Uppsala Monitoring Centre criteria.⁵ Outcome of events were categorised and action taken accordingly.

Data were expressed in number and percentage. Association of demographic variables with year wise ADR distribution were done by using Chi-square and binomial 'p' value.

RESULTS

The study included a total of 500 cases. Maximum proportions of cases belong to 30-60 years age group i.e. 243 (48.6%) followed by <30 years (179, 35.8%) and ≥60 years (78, 15.6%). The mean±SD of age was 39.3±17.9 years, median age of 38 years, wide interquartile range (IQR) of 25-53 years, indicating a broad age distribution spanning from 1 to 83 years. The sample shows a near-equal distribution between genders, with females

constituting a slight majority (52.4%, n=262) compared to males (47.6%, n=238).

Table 1: Distributions of age, gender and years.

Characteristics	N	%
Age (years)		
<30	179	35.8
30-60	243	48.6
≥60	78	15.6
Mean±SD	39.3±17.9	
Median (IQR)	38(25-53)	
Range (Min.-Max.)	(1-83)	
Gender		
Male	238	47.6
Female	262	52.4
Year		
2020	35	7
2021	50	10
2022	43	8.6
2023	162	32.4
2024	210	42
Total	500	100

There was a clear increase in case frequency in the later years of study. Most cases were recorded in 2023 (n=162, 32.4%) and 2024 (n=210, 42%), collectively accounting for 74.4% of the total sample (Table 1).

Table 2: Distributions of drugs causing ADRs.

Drug name	N	%
Amoxicillin + clavulanic acid	13	2.6
INH + rifampicin + ethambutol + pyrazinamide	14	2.8
Ferric carboxy maltose	15	3
Ofloxacin + ornidazole	29	5.8
Ceftriaxone + sulbactam	80	16
Diclofenac	16	3.2
Metronidazole	5	1
Olanzapine	24	4.8
Ondansetron	6	1.2
Paracetamol	10	2
Piperacillin + tazobactam	34	6.8
Risperidone	11	2.2
Rituximab	8	1.6
Sodium valproate	10	2
Tramadol	11	2.2
Vancomycin	9	1.8
Others	205	41
Total	500	100

The cases were broadly distributed across various medical departments, with the highest concentration observed in psychiatry department, which accounted for the single largest proportion of cases, with (n=89) cases, representing 17.8% of the total sample. The next most frequent

departments were general medicine (n=69, 13.8%), general surgery (n=67, 13.4%), O and G (obstetrics and gynecology) (n=56, 11.2%), skin and VD (n=55, 11%). Together, these five departments accounted for 67.2% of total cases. Departments with the lowest frequency of cases included medical oncology (n=13, 2.6%), neurology (n=13, 2.6%), emergency medicine (n=14, 2.8%), and ENT (n=14, 2.8%). The majority of health care personnel were doctors (n=414), comprising 82.8% followed by pharmacists (n=80, 16.0%) and nursing personnel represented the smallest fraction of cases (n=6), accounting for only 1.2%. Non-serious cases make up the vast majority, at 475 (95%), the most common outcome is recovered, reported in 340 cases (68%). The most common route of administration was i.v. in 275 cases (55%) followed by oral in 212 cases (42.4%). Possible causality was the most frequently assigned category, at 259 cases (51.8%). Drug withdrawn, was the major action taken in 445 cases (89%).

The most common drugs responsible for causing ADRs were ceftriaxone + sulbactam, piperacillin + tazobactam and ofloxacin + ornidazole (Table 2).

Table 3: Distributions of ADRs (>5).

ADRs	N	%
Diarrhoea	8	1.6
Dizziness	17	3.4
Dyspnoea	11	2.2
EPS	8	1.6
FDE	34	6.8
Gastritis	6	1.2
Hepatitis	6	1.2
Itching	105	21
Pedal oedema	10	2
Rash	128	25.6
Redness	6	1.2
Rigor	21	4.2
Tremor	5	1
Urticaria	5	1
Vomiting	29	5.8
Weight Gain	13	2.6
Others	88	17.6
Total	500	100

Rash was the most common ADR, reported in 128 cases (25.6%) followed by itching in 105 cases (21%) and FDE (fixed drug eruption) in 34 cases (6.8%). Collectively, cutaneous reactions (rash, itching, FDE) account for 267 cases, which was 53.4% of the total 500 cases. This suggested that dermatological ADRs are the primary concern in this study population. The distribution of ADRs is summarized in Table 3.

Skin and subcutaneous tissue disorders, which accounts for 305 cases (61%) of the total ADR cases was the most frequently affected system organ class. The high

percentage confirmed that skin, subcutaneous system involvement are the overwhelmingly dominant system involvement in the ADR. This was followed by gastrointestinal with 62 cases (12.4%), nervous system with 52 cases (10.4%). These three systems (skin, gastrointestinal, and nervous) collectively account for 419 cases (83.8%) of all reported adverse events. The remaining system organ classes account for a small percentage (Table 4).

Table 4: System organ class and adverse drug events.

System organ class	N	%
Vascular disorders	10	2.0
Reproductive system and breast disorders	1	0.2
Hepatobiliary disorders	6	1.2
Renal and urinary disorders	1	0.2
CVS	2	0.4
Immune systems disorders	3	0.6
GIT	62	12.4
Nervous system disorders	52	10.4
Skin and subcutaneous tissue disorders	305	61
Musculoskeletal and connective tissue disorders	26	5.2
Respiratory system	14	2.8
Endocrine disorders	15	3
Infections and infestations	1	0.2
General disorders and administration site conditions	2	0.4
Total	500	100

The 30-60 years age group, consistently accounts for the largest proportion of cases in most years i.e. 51.4% in 2020, 53.5% in 2022, 52.5% in 2023, and 46.2% in 2024. Overall, 30-60 years age group had the maximum cases of ADR in all the years except 2021, with $p < 0.05$. The distribution of cases across age groups varied significantly by year with 30-60 years as the significant age group. The p values for individual years (0.074 for 2020, 0.013 for 2021, 0.018 for 2022, < 0.001 for each 2023 and 2024) indicate that the age distribution was significantly different from an expected distribution in several of the individual years.

The binomial p values of gender for all the years except 2020 was non-significant with $p > 0.05$ (Table 5).

The majority of cases across all years were classified as not seriousness, 475 (95%) out of 500 total cases. Only 25 (5%) were classified as serious. The percentage of serious cases were in the range of 0-9.9% over the years. Majority of the cases 68% recovered and 30.6% of cases were recovering. Thus, about 98.6% were either recovered or recovering. Only 1.4% of cases belonged to others category that comprised of Unknown, not recovered and recovered with sequelae. The year wise scenario revealed similar pattern (Table 6).

Table 5: Association of age and gender with year wise ADRs.

Demographic variables	Years					Total
	2020	2021	2022	2023	2024	
Age group (in years)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
<30	8 (22.9)	23 (46)	11 (25.6)	50 (30.9)	87 (41.5)	179 (35.8)
30-60	18 (51.4)	20 (40)	23 (53.5)	85 (52.5)	97 (46.2)	243 (48.6)
≥60	9 (25.7)	7 (14)	9 (20.9)	27 (16.6)	26 (12.3)	78 (15.6)
Non-parametric Chi-square 'p'	0.074	0.013	0.018	<0.001	<0.001	<0.001
Gender						
Male	24 (68.6)	20 (40)	23 (53.5)	78 (48.1)	93 (44.3)	238 (47.6)
Female	11 (31.4)	30 (60)	20 (46.5)	84 (51.9)	117 (55.7)	262 (52.4)
Total	35 (100)	50 (100)	43 (100)	162 (100)	210 (100)	500 (100)
Binomial 'p'	0.02	0.20	0.64	0.69	0.11	0.09

Table 6: Association of seriousness and outcomes with year wise ADRs.

Seriousness	Years					Total
	2020	2021	2022	2023	2024	
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
No	32 (91.4)	49 (98)	43 (100)	146 (90.1)	205 (97.6)	475 (95)
Yes	3 (8.6)	1 (2)	0 (0)	16 (9.9)	5 (2.4)	25 (5)
Outcomes						
Recovered	27 (77.1)	13 (26)	36 (83.7)	91 (56.2)	173 (82.4)	340 (68)
Recovering	7 (20)	36 (72)	7 (16.3)	66 (40.7)	37 (17.6)	153 (30.6)
Others*	1 (2.9)	1 (2)	0 (0)	5 (3.1)	0 (0)	7 (1.4)
Total	35 (100)	50 (100)	43 (100)	162 (100)	210 (100)	500 (100)

*Unknown, not recovered, recovered with sequelae.

DISCUSSION

In the current study, 48.6% and 35.8% of ADRs are in 30-60 and <30 years respectively. This shows that a high majority of ADRs in our study are occurring within the age of 60 years. Similar findings were reported in various other studies.⁶⁻¹³ Geriatric population are usually more susceptible to ADRs due to comorbidities, inappropriate use of medications, multiple prescriptions, inadequate monitoring.¹⁴ However, in our study only 15.6% were geriatric age group ADRs. Future investigations on the non-geriatric age group can be carried out in order to decipher a possible explanation of the high incidence of ADRs.

The incidence of ADRs in females was higher than male counterparts in our analysis, similar to other reported studies.^{6,7,10,11} Females experience more reactions in comparison to males.^{15,16} This could be due to difference in pharmacokinetic and pharmacodynamic profile, hormonal changes during the various phases of life and the genomic constitutional differences, are some of the factors which might cause reactions in females.¹⁷ In addition, females take more medications than males which could result in higher incidence of drug-drug interactions.¹⁵ More incidence of ADRs were reported in the later part of the study period, 2023 and 2024, which might be due to the effect of sensitization programme conducted for the

health care professionals. This pattern was also reported by Thakare et al.¹¹

Amongst all departments, psychiatry, general medicine and general surgery reported most ADRs. This could be due to patients' overall condition and multiple medications. Various studies have reported maximum ADRs from the medicine department.^{6-8,10}

Our study revealed that a very high percentage of physicians reported ADRs followed by pharmacists. The nursing community reporting ADRs was very low in our set up. This finding was inconsistent with the study done by James et al where pharmacists were the major reporters followed by nurses.⁸ 95% of ADR cases were reported as non-serious in our study, which was similar to other studies in the literature.⁸⁻¹⁰ Majority of the patients recovered in our study after the causative drug has been withdrawn, findings consistent with other studies.⁹⁻¹⁰ The most common routes of administration of drugs responsible for ADRs was intravenous in our analysis, which was alike other analysis.^{8,9} Sharma et al, reported more reaction in oral route.¹² As per WHO causality scale, in our study, majority of ADR reported were categorised as possible, similar to other reports.^{8,10,12}

The most common group of medication responsible for causing ADRs were antimicrobials in our study, this

finding was consistent across various studies.^{6,7,9-13,18,19} Ceftriaxone and sulbactam combination was responsible for most ADRs amongst antimicrobials in the present study, followed by piperacillin tazobactam and ofloxacin ornidazole combination. This could be due to the fact that antimicrobials are one of the most prescribed class of medications in our hospital set up. It is also reported that antimicrobials are also prescribed for clinical conditions where it is not warranted for, thereby nurturing an opportunity not only for drug-drug interactions but also antimicrobial resistance.²⁰⁻²² Others represent 41% of cases. This large percentage suggests a wide variety of less common drugs were involved, or that many drugs were used in smaller frequencies that were grouped together for brevity.

Rash, itching and fixed drug eruptions were most common (53.4%). Similar analysis was also reported by other research projects.^{6,7,9,10,12,18} Cutaneous related reactions are reported early as these manifest quickly and observed by the healthcare professional during the initial treatment process.^{20,23} Skin and subcutaneous tissue disorders was most commonly affected system in our study. Similar results were also corroborated by various studies.^{6,7,9,10,12,19} Gastrointestinal disorders were the second common system organ class reported in this study. Few studies have mentioned the same in their analysis.^{7,8}

CONCLUSION

In this study, adverse reactions are more in females and 30-60 age group had the maximum number of reported cases. Psychiatry department reported maximum number of ADRs. Physicians reported most ADRs amongst all other healthcare professionals. Majority of the cases were reported in 2024, the last year of the study period. Maximum number of cases were non serious and recovered after the drug is withdrawn. In WHO causality scale, most of the medication belong to possible category. Antimicrobials (beta lactam group) caused the maximum number of ADRs. Rash, was the most frequently reported ADR, cutaneous disorders was the most common system involved.

The findings from our study could provide useful insights into the pattern of reactions to various medications used in our set up and would be helpful in augmenting the awareness of spontaneous reporting of ADRs amongst healthcare providers, thereby enhancing patient safety measures, and increasing the quality of life. Sensitization programme on recognizing and reporting ADRs should be undertaken on a continuous basis to reduce the burden of underreporting in the healthcare system.

However, there are certain limitations in our study. It is retrospective in nature; hence incomplete ADR forms could not be included in the study. Potential underreporting of cases by the healthcare professionals as report has to be spontaneous and voluntary. Non-inclusion of preventability data which may had an impact on the study.

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