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A STUDY ON COMMONLY REPORTED ADVERSE DRUG REACTIONS IN TERITIARY CARE TEACHING HOSPITALS

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Abstract:

Background: *Adverse drug reactions (ADRs) are a significant concern in healthcare, contributing to patient morbidity, extended hospital stays, and increased treatment costs. They are particularly prevalent in tertiary care settings due to polypharmacy, complex disease conditions, and the frequent use of high risk medications. Although pharmacovigilance systems are in place, ADRs are still underreported, highlighting the need for improved monitoring and reporting practices.*

Objective: *The present study was conducted to evaluate the incidence, pattern, causality, severity and preventability of ADRs in a tertiary care teaching hospital, along with their association with demographic and drug related factors.*

Methods: *A six-month prospective observational study was carried out in a multispecialty tertiary care hospital. ADR data were collected from both inpatient and outpatient departments using standardized reporting forms. The reported ADRs were assessed for causality using WHO-UMC and Naranjo scale. Data were analyzed using descriptive statistics and chi-square tests, considering $p<0.05$ as statistically significant.*

Results: *The incidence of ADRs was found to be 15.33%. A higher proportion of ADRs occurs in males (58.69%0 and in patients aged between 31 and 50 years. Most reactions were categorized as probable (98%0 according to both causality assessment scales. The majority of ADRs were mild in nature (93.47%), while a small percentage were moderate (6.52%). Most ADRs were deemed not preventable (98%). The gastrointestinal system was most affected (31.52%), and antibiotics were the leading drug class associated with ADRs. In most instances, discontinuation of the suspected drug resulted in patient improvement.*

Conclusion: *ADRs are commonly encounters in hospital settings but are generally mild and manageable strengthening pharmacovigilance systems and promoting active involvement of healthcare professionals, especially pharmacists, can enhance ADR detection, reporting, and overall patient safety.*

Keywords: *Adverse drug reactions, pharmacovigilance, drug safety, causality assessment, severity and preventability.*

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INTRODUCTION:

Adverse drug reactions (ADRs) are a major global health issue and a major cause of patient illness and healthcare costs. ADRs are unintended and harmful reactions to medications that happen at normal therapeutic doses. They occur frequently in clinical practice [1]. The risk of ADRs is much higher in tertiary care teaching hospitals, where patients often take many different medications for complicated conditions. These reactions not only put patients at risk, but they also make hospital stays longer, raise healthcare costs, and lower quality of life.

Pharmacovigilance is important for identifying, assessing, and stopping ADRs early. Hospital-based pharmacovigilance programs are very important for keeping an eye on ADRs and making sure that medicines are used safely. Numerous studies have underscored the significance of systematic ADR reporting to discern patterns associated with drug usage, patient demographics, and affected organ systems [2]. Such programs help find drugs and groups of people who are at high risk, which makes it possible to take targeted steps to lower the number of ADRs. When looking at ADRs, they are put into groups based on their cause, severity, and how easy they are to avoid.

Causality assessment helps figure out how likely it is that a drug will cause a certain reaction, and severity assessment looks at how the reaction affects the patient clinically. Preventability assessment finds ADRs that could have been avoided if the right steps had been taken, which improves clinical outcomes [3]. Research concentrating on cutaneous and systemic adverse drug reactions (ADRs) has underscored the significance of structured assessment instruments in elucidating ADR attributes and informing clinical decision-making [4].

Additionally, examining ADR patterns through the lens of demographic variables such as age and gender yields significant insights into vulnerability and risk distribution. Studies have demonstrated that the incidence and severity of adverse drug reactions (ADRs) can differ among various age groups and between genders, highlighting the necessity for personalized patient care [5]. Furthermore, the assessment of drug classes and impacted organ systems aids in identifying frequently involved medications and target organs, thereby enhancing prescribing practices and mitigating adverse outcomes [6].

Both prospective and retrospective studies in tertiary care hospitals have shown that continuous ADR monitoring increases reporting rates and makes patients safer. These studies underscore the necessity for healthcare professionals to engage actively in pharmacovigilance activities, encompassing the prompt reporting and documentation of adverse drug reactions (ADRs) [2]. Even though pharmacovigilance systems are available, underreporting is still a big problem because healthcare providers don't know enough about them, don't get enough training, or don't have enough time.

Pharmacists play a crucial and evolving role in adverse drug reaction (ADR) reporting, contributing significantly to pharmacovigilance and patient safety. Their responsibilities have expanded from traditional dispensing to active involvement in detecting, assessing, and reporting ADRs. Hospital pharmacists, in particular, are more actively engaged due to their clinical training, regular interaction with patients, and access to medical records, which enable better identification and evaluation of ADRs. Collaboration with prescribers further enhances their reporting efficiency. Community pharmacists also contribute by identifying ADRs, especially in settings with limited access to healthcare professionals. Studies highlight that pharmacists are well-positioned to improve ADR reporting rates and reduce drug-related risks, ultimately minimizing both clinical and economic burden[7].

Therefore, a comprehensive evaluation of ADR reporting patterns in tertiary care teaching hospitals is essential for strengthening pharmacovigilance systems. By assessing the incidence of ADRs, classifying them based on causality, severity, and preventability, and analyzing their distribution across demographic and drug-related factors, this study aims to contribute to safer and more rational use of medications. Ultimately, such efforts will enhance patient safety, improve therapeutic outcomes, and support evidence-based clinical practice [3].

MATERIALS AND METHODS:

Study design

The study design was a prospective and observational study.

Study site

The study was conducted in a multispecialty tertiary care facility. Mamata Academy of Medical Sciences (MAMS) facility, Bachupally, Hyderabad, The hospital offers both inpatient and outpatient services in general medicine, general surgery, orthopaedics, obstetrics and gynaecology, paediatrics, ophthalmology, psychiatry, ENT, respiratory, neurology, cardiology, and urology.

Study period

The study was carried out between September 2025 and February 2026 at the ADR monitoring centre (Department of pharmacology).

Study criteria

Inclusion criteria

The study enrolled patients from both the inpatient and outpatient departments who had polypharmacy, co-morbidities, a history of allergy, and high-risk medications.

Exclusion criteria

Patients are not willing to participate in the study.

Method of data collection

Data was collected from inpatient and outpatient case records, medication charts, physicians, referrals, and structured interviews with patients.

Sample size calculation

Unlimited population:

$$n = \frac{Z^2 p(1-p)}{e^2}$$

Where

z is the z score

e is the margin of error

n is the population size

p is the population proportion

The sample size was calculated using the above formula

Data points to be noted

- Patient demographic details.
- Past medical history.
- Current medical condition.
- Allergy history.
- Description of reaction.
- Date and time of onset of reaction.
- Medication used, dose, route, frequency, date started, date stopped and indication for use.
- Suspected medication brand name, labelled strength, batch no, expiry date and manufacturer.
- De-challenge and re-challenge status.
- Reaction outcome.
- Causality assessment scores using the Naranjo scale and WHO UMC scale.
- Severity assessment by the Hartwig scale.
- Preventability assessment by the modified Schumock and Thornton scale.

Study procedure

- An Adverse Drug Reaction Monitoring Centre (AMC) is established in the Department of Pharmacology at Mamata Academy of Medical Sciences, Bachupally, to monitor and report adverse drug reactions according to the pharmacovigilance guidelines.
- With the aim of improving the reporting of adverse drug reactions, the current study was carried out in collaboration with the ADR Monitoring Centre. Postgraduate students and health professionals were made aware of the importance of ADR reporting and documentation. Awareness about pharmacovigilance activities and ADR reporting was created among physicians, nurses, and pharmacists.
- Patients under the care of different departments of the hospital were actively monitored for suspected adverse drug reactions.
- Whenever a suspected adverse drug reaction was identified, the relevant information of the patient, such as demographic information, diagnosis, drug name, dosage, route of administration, duration of drug administration, description of the adverse reaction, management, and outcome, was recorded by using a standard adverse drug reaction reporting form provided by the ADR Monitoring Centre.
- The adverse drug reactions identified were assessed for their causality by the WHO-UMC scale and the Naranjo Adverse Drug Reaction Probability Scale, their severity by the Hartwig Severity Assessment Scale, and their preventability by the Schumock and Thornton Preventability Scale.
- The identified adverse drug reactions were reviewed and validated by the ADR Monitoring Centre, Department of Pharmacology.
- The data were analysed to determine the commonly occurring adverse drug reactions in the tertiary care teaching hospital.

Data analysis

- Descriptive statistics were used to summarise the collected data.
- Data analysis was performed using software tools like SPSS and Microsoft Excel.

Statistical analysis

- All the results were analysed by using SPSS version 31.0.2.0 (126). Descriptive statistics were applied to obtain frequencies for reported adverse drug reactions.
- Chi-square test for categorical variables: $P<0.05$ is considered significant

RESULTS:

TABLE 1: GENDER WISE DISTRIBUTION OF THE PATIENTS

GENDER	N(%)
Male	54 (58.69)
Female	38 (41.30)

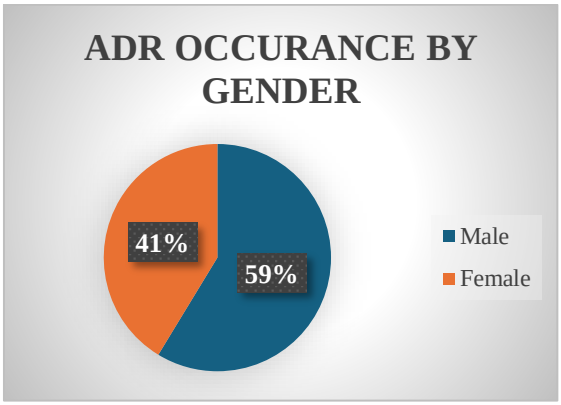


Fig 1: ADR OCCURANCE BY AGE

According to ADR occurrence by gender, the majority of the ADRs were seen in males 54(58.69%).

Table 2: Age-wise distribution of the patients

AGE	N(%)
10-20	2 (2.17)
21-30	8 (8.69)
31-40	23 (25)
41-50	23 (25)
51-60	22 (23.91)
61 & above	14 (15.21)

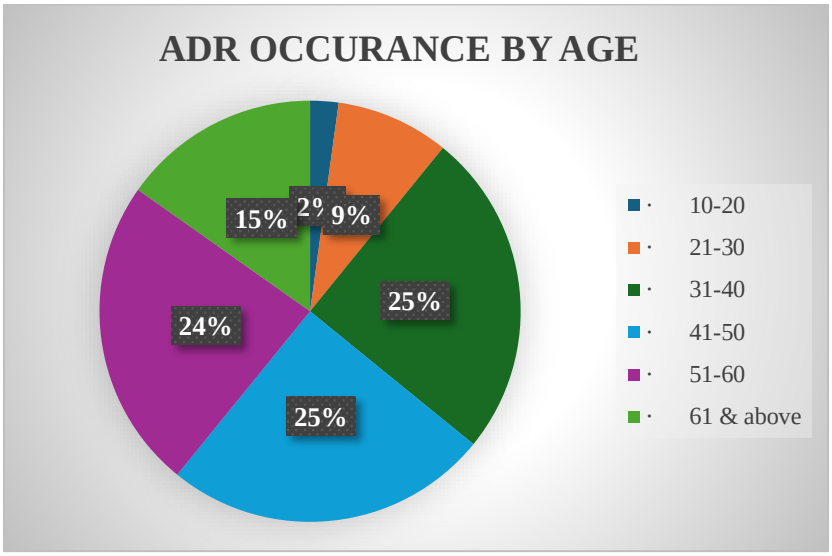


Fig 2: ADR OCCURANCE BY AGE

According to ADR occurrence, by age majority of the patients, where in the age group of 31 to 40 and 41 to 50 23(25%) respectively.

Table 3: EDUCATIONAL QUALIFICATION OF THE PATIENTS

EDUCATION	**N(%)**
Illiterate	33 (35.86)
Primary school	16 (17.39)
Secondary school	7 (7.6)
Intermediate	12 (13.04)
Graduate	7 (7.6)
Post Graduate	17 (18.47)

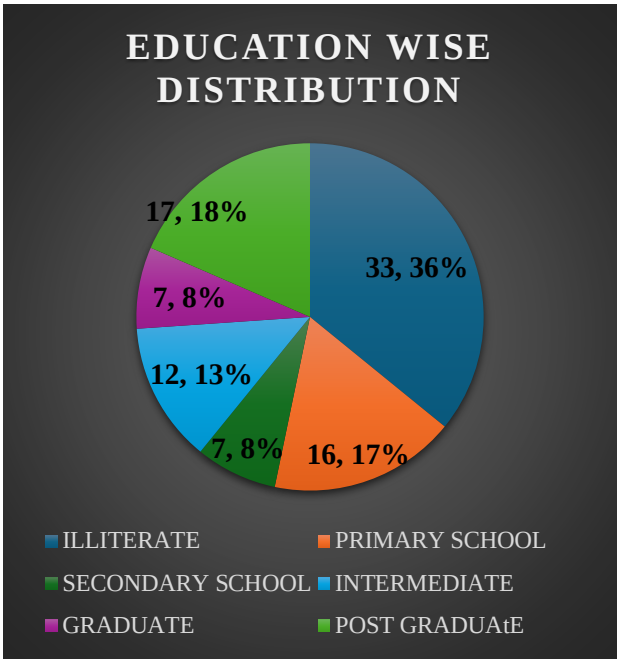


Fig 3: EDUCATION WISE DISTRIBUTION OF PATIENTS

According to education wise distribution, majority of the patients belonged to Illiterate i.e 33(36%).

Table 4: OCCUPATIONAL STATUS OF THE PATIENTS

OCCUPATION	N(%)
Student	10 (10.86)
Agriculture	49 (53.26)
Business	11 (11.95)
Employment	6 (6.52)
Housewife	16 (17.39)

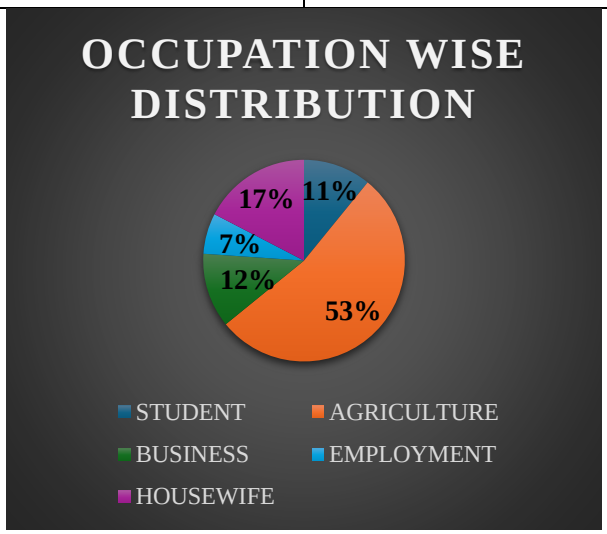


Fig 4: OCCUPATION WISE DISTRIBUTION OF PATIENTS

According to occupation wise distribution, majority of the patients belonged to agriculture i.e 49(53.26%).

SMOKING STATUS	N(%)
Yes	34 (36.95)
No	58 (63.04)

Table 5: SMOKING STATUS OF THE PATIENTS

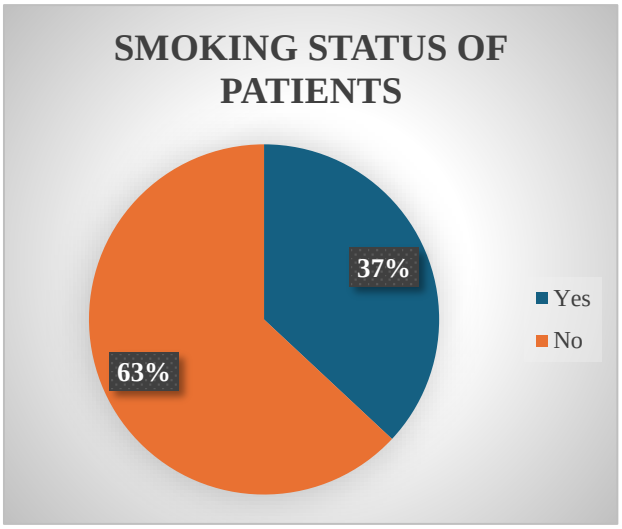


Fig 5: SMOKING STATUS OF PATIENTS

According to smoking status, the majority of the patients belonged to non-smokers i.e 58(63.04%).

Table 6: ALCOHOL STATUS OF THE PATIENTS

ALCOHOL STATUS	N(%)
Yes	59 (64.13)
No	33 (34.86)

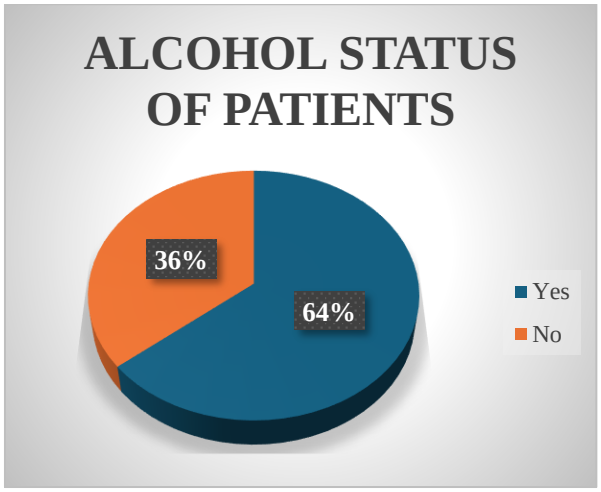


Fig 6: ALCOHOLIC STATUS OF PATIENTS

According to alcoholic status, majority of the patients belonged to alcoholics i.e 59(64.13%).

INCIDENCE RATE OF ADRS:

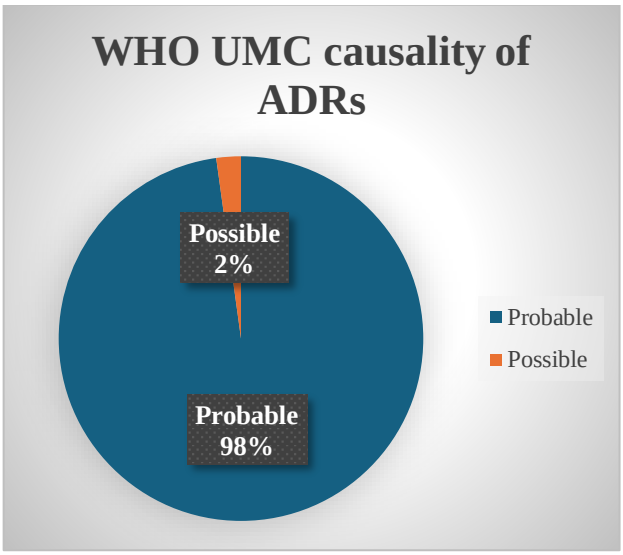
Adverse Drug reaction Incidence rate is calculated using the following formula.

$$\text{Incidence} = \frac{\text{No of ADR's}}{\text{Total number of cases}} * 100$$

92/600*100 =

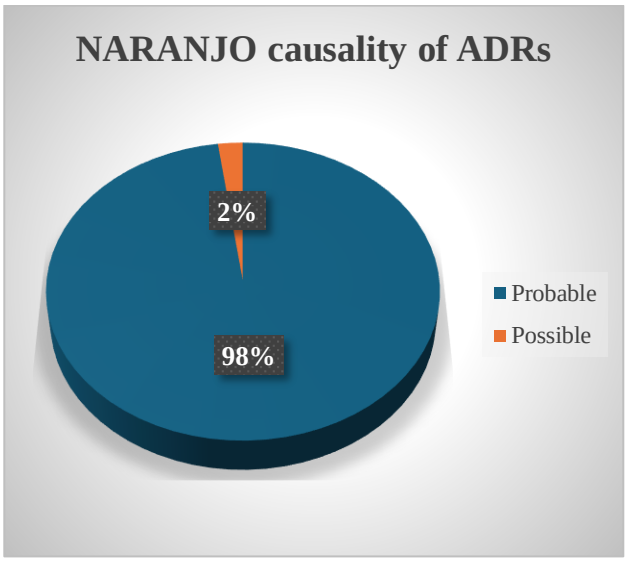
= 15.33% Incidence rate

WHO UMC CAUSALITY ASSESSMENT SCALE



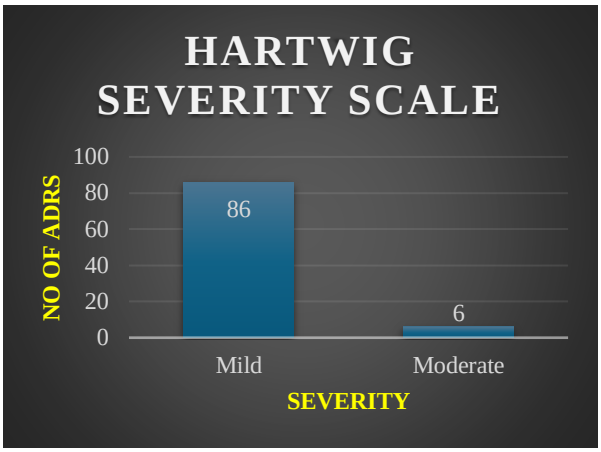
As per the WHO causality assessment scale, the majority of the patients' ADR was probable 90 (98%), followed by possible 2 (2%)

NARANJO CAUSALITY ASSESSMENT SCALE



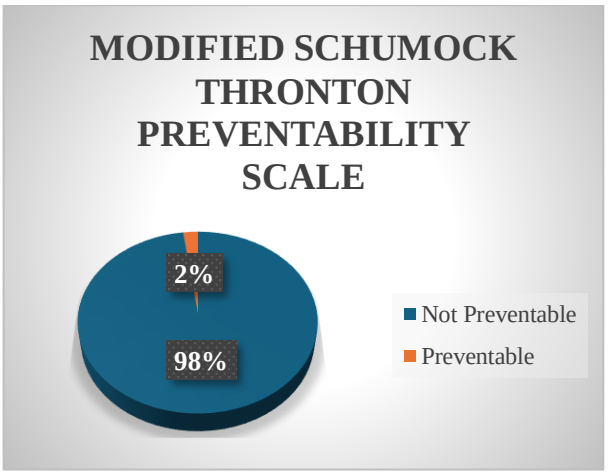
As per the Naranjo causality assessment scale majority of the patients ADR was probable 90(98%).

HARTWIG SEVERITY ASSESSMENT SCALE



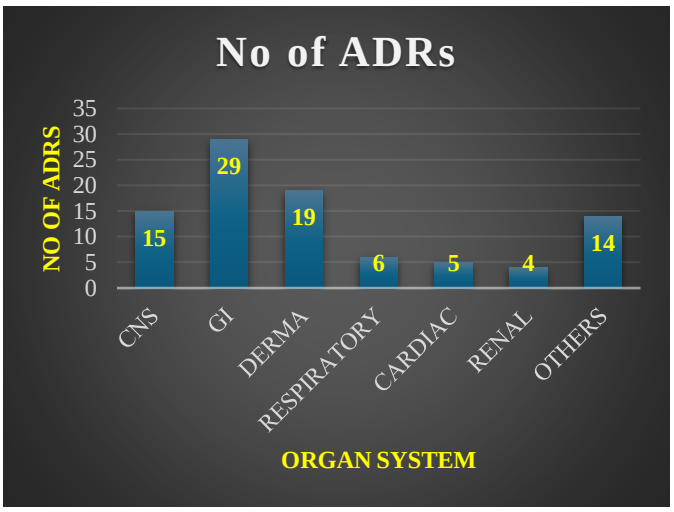
According to Hartwig severity assessment scale, majority of the adverse reactions were mild 86(93.47%) followed by moderate 6(6.52%).

MODIFIED SHUMOCK AND THRONTON PREVENTABILITY SCALE



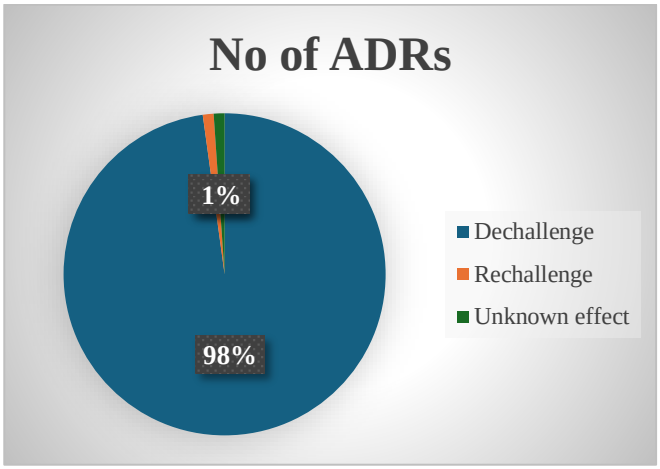
According to the Modified Schumock and Thornton, prevent ability scale, the majority of the adverse reaction were not preventable 90(98%).

ADR OCCURANCE AS PER ORGAN SYSTEM CLASSIFICATION



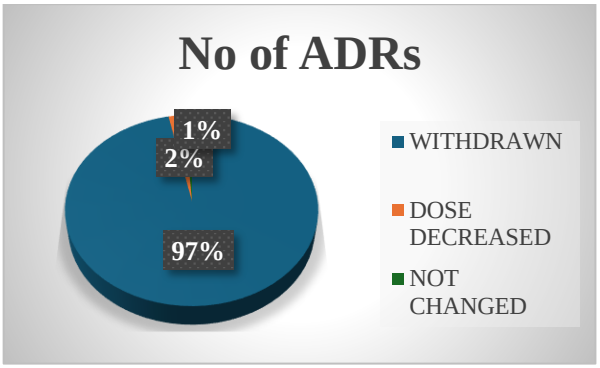
According to organ system classification, majority of the ADRs occurs in Gastrointestinal system 29(31.52%).

DECHALLENGE AND RECHALLENGE STATUS OF ADRs



According to the test for confirmation of ADRs, majority of the drugs were de-challenged 90(98%), while 1(1%) was rechallenged and unknown effect.

FATE OF THE DRUG AFTER REACTION



According to the fate of the drug after reaction, majority of the drugs were withdrawn 89(97%), followed by 2 (2%) dose altered and 1(1%) not changed.

GENDER VERSUS ADR SEVERITY DISTRIBUTION

Distribution of ADR severity according to gender

Gender	Mild (n%)	Moderate (n%)	Total
Male	52 (96.29%)	2 (3.70%)	54
Female	34 (89.47%)	4 (10.53%)	38
Total	86 (93.47%)	6 (6.52%)	92

CHI- SQUARE ASSOCIATION BETWEEN GENDER AND ADR SEVERITY

Variable	X^2 value	df	p-value	Significance
Gender Vs ADR severity	1.78	1	0.182	Not significant

According to the Chi-square test association between gender and ADR severity it has been found that there is no significance.

AGE GROUP VERSUS ADR SEVERITY DISTRIBUTION

Distribution of ADR severity according to age

Age group	Mild (n%)	Moderate (n%)	Total
10-20	2 (2.17%)	0	2
21-30	6 (6.52%)	2 (2.17%)	8
31-40	21 (22.83%)	2 (2.17%)	23
41-50	23 (25%)	0	23
51-60	22 (23.91%)	0	22
61 & above	12 (13.04%)	2 (2.17%)	14
Total	86 (93.48%)	6 (6.52%)	92

CHI- SQUARE ASSOCIATION BETWEEN GENDER AND ADR SEVERITY

Variable	X^2 value	df	p-value	Significance
Drug Class Vs ADR severity	7.48	5	0.188	Not significant

According to the Chi-square test association between age and ADR severity, it has been found that there is no significance.

DRUG CLASS VERSUS ORGAN SYSTEM DISTRIBUTION

Drug Class	**CNS n (%)**	**GI n (%)**	**Derma n (%)**	**Respiratory n (%)**	**Cardiac n (%)**	**Renal n (%)**	**Others n (%)**	**Total**
Antibiotics	2 (2.17)	12 (13.04)	10 (10.87)	2 (2.17)	0	1 (1.09)	7 (7.61)	34
Anti-histamines	2 (2.17)	0	0	1 (1.09)	0	0	0	3
Vitamins	0	2 (2.17)	0	0	0	0	3 (3.26)	5
NSAIDs & Opioids	1 (1.09)	6 (6.52)	2 (2.17)	0	0	2 (2.17)	0	11
Antipsychotics	1 (1.09)	0	0	0	1 (1.09)	0	0	2
Antacids	0	3 (3.26)	0	0	0	0	1 (1.09)	4
OHA	1 (1.09)	2 (2.17)	0	0	1 (1.09)	0	1 (1.09)	5

Anticonvulsants	2 (2.17)	0	0	0	0	0	1 (1.09)	3
ATT	0	1 (1.09)	0	0	0	0	1 (1.09)	2
Cardiac agents	1 (1.09)	1 (1.09)	0	0	4 (4.35)	0	2 (2.17)	8
Steroids	0	1 (1.09)	1 (1.09)	0	0	0	1 (1.09)	3
Haematinics	1 (1.09)	0	0	0	0	0	2 (2.17)	3
Anticholinergics	1 (1.09)	0	0	1 (1.09)	0	0	1 (1.09)	3
PPI	0	1 (1.09)	0	0	0	0	4 (4.35)	5
Hemostatic agents	0	0	0	0	0	1 (1.09)	1 (1.09)	2
Total	**15 (16.30)**	**29 (31.52)**	**19 (20.65)**	**6 (6.52)**	**5 (5.43)**	**4 (4.35)**	**14 (15.22)**	**92**

CHI- SQUARE ASSOCIATION BETWEEN DRUG CLASS AND ORGAN SYSTEM

Variable	X^2 value	df	p-value	Significance
Drug Class Vs ADR severity	72.54	84	0.81	Not significant

According to the Chi-square test association between drug class and organ system, it has been found that there is no significance.

DISCUSSION:

Adverse Drug Reaction (ADR) monitoring is a crucial component of the pharmacovigilance system, as it helps detect various adverse effects that may not be identified during clinical trials. Post-marketing surveillance plays a significant role in identifying rare, delayed, or previously unrecognized adverse reactions associated with commonly used medications. Spontaneous reporting of suspected or serious ADRs remains one of the most important methods for identifying drug-related safety concerns in real-world clinical settings.

Clinical pharmacists play a vital role in strengthening pharmacovigilance activities within hospitals. Their active participation in ward rounds and patient monitoring helps in early identification, documentation, and reporting of adverse drug reactions. At MAMS Hospital, the Department of Clinical Pharmacy has been involved in encouraging Pharm.D interns to report ADRs; however, ADR reporting has sometimes been limited due to the restricted availability of interns. As part of the present study, awareness programs were conducted in coordination with the Adverse Monitoring Centre (AMC) to encourage healthcare professionals in the hospital to actively participate in ADR reporting.

During the study period, the overall incidence rate of ADRs observed in this study was 15.33%. Previous studies have reported ADR incidence rates ranging from 11.2% to 50.9%, while a systematic review conducted in Indian hospitals reported an incidence rate ranging from 1.45% to 28.26%. The findings of the present study therefore fall within the range reported in earlier literature.

The current study further evaluated ADRs using established pharmacovigilance assessment tools including causality, severity, and preventability scales. According to the WHO–UMC causality assessment scale, the majority of ADRs were categorized as probable (90 cases, 98%), while 2 cases (2%) were classified as possible. Similarly, the

Naranjo causality assessment scale also indicated that 98% of ADRs were probable, confirming a strong association between the suspected drug and the adverse reaction.

Severity assessment was performed using the Hartwig Severity Assessment Scale, which revealed that most of the ADRs were mild (86 cases, 93.47%), while 6 cases (6.52%) were categorized as moderate in severity. No severe reactions were identified during the study period. These findings suggest that although ADRs were relatively frequent, most of them were manageable and did not result in severe clinical consequences.

Preventability analysis was conducted using the Modified Schumock and Thornton Preventability Scale, which showed that 90 ADRs (98%) were classified as not preventable. This indicates that the reactions occurred despite appropriate drug use and standard treatment practices.

Organ system classification of ADRs revealed that the gastrointestinal system was the most commonly affected system, accounting for 29 cases (31.52%). Gastrointestinal adverse reactions are frequently reported in many pharmacovigilance studies due to the widespread use of medications that can cause gastric irritation, nausea, vomiting, or diarrhea.

Assessment of dechallenge and rechallenge status indicated that the suspected drug was withdrawn in 90 cases (98%), resulting in improvement of symptoms. Only 1 case (1%) involved rechallenge, while the outcome remained unknown in another case. This further supports the causal relationship between the drug and the adverse event.

Regarding the fate of the drug after the reaction, the majority of medications were withdrawn (89 cases, 97%), while 2 cases (2%) required dose alteration and 1 case (1%) continued without change. These findings demonstrate that timely identification and management of ADRs can help prevent further complications and ensure patient safety.

Overall, the results of this study are consistent with findings reported in several other Indian pharmacovigilance studies, highlighting the importance of systematic ADR monitoring in hospital settings. The study also emphasizes the critical role of clinical pharmacists in strengthening ADR detection, documentation, and reporting practices.

CONCLUSION:

The present study highlights the importance of active Adverse Drug Reaction (ADR) monitoring in improving patient safety and strengthening pharmacovigilance practices in hospital settings. During the study period, the incidence rate of ADRs observed was 15.33%, which falls within the range reported in several previous studies conducted in Indian hospitals.

Causality assessment using both the WHO–UMC and Naranjo scales showed that the majority of ADRs were categorized as probable (98%), indicating a strong relationship between the suspected drugs and the observed adverse reactions. Severity assessment using the Hartwig scale revealed that most ADRs were mild (93.47%), while a small proportion were moderate (6.52%), suggesting that most reactions were manageable with appropriate clinical intervention.

Preventability analysis using the Modified Schumock and Thornton scale indicated that most ADRs (98%) were not preventable. Organ system classification showed that the gastrointestinal system was the most commonly affected, accounting for 31.52% of ADRs. In most cases, the suspected drug was withdrawn following the occurrence of the reaction, which resulted in improvement of patient symptoms.

The study also highlights the crucial role of clinical pharmacists in identifying, documenting, and reporting ADRs. Active participation of healthcare professionals and increased awareness about pharmacovigilance can significantly improve ADR reporting rates and enhance medication safety.

Overall, the findings emphasize the importance of strengthening pharmacovigilance systems in hospitals and promoting active ADR monitoring to ensure safe and effective use of medications.

REFERENCES:

1. Kumar DP. Patterns of adverse drug reactions: a study in a tertiary care. International Journal of Basic & Clinical Pharmacology. 2019 Jun 4;8(7):1497–7.
2. Lhamo Y, Purohit K, Singh S, Chopra D, Bharti M. Pattern, severity, and preventability of adverse drug reactions from a Northern Indian tertiary care facility: A retrospective analysis. International Journal of Risk & Safety in Medicine. 2024 Dec 5;36(1):5–13.
3. Yadav P, Rao GK, Rataboli PV, Gurav SS. Adverse Drug Reaction Monitoring and Reporting in a Tertiary Care Teaching Hospital in Goa. Medical Journal of Dr DY Patil Vidyapeeth. 2025 May;18(3):463–72
4. S Padmavathi et al. “Causality, severity and preventability assessment of adverse cutaneous drug reaction: a prospective observational study in a tertiary care hospital.” *Journal of clinical and diagnostic research: JCDR* vol. 7,12

(2013): 2765-7. doi:10.7860/JCDR/2013/7430.3753
5. Singh A, Jain A, Soni M, Shukla P, Joonmoni Lahon, Verma AK. Pattern of adverse drug reactions reported at a tertiary care teaching hospital in northern India. International Journal of Basic & Clinical Pharmacology. 2020 Mar 24;9(4):625–5.
6. Venkatasubbaiah M, Dwarakanadha Reddy P, Satyanarayana SV. Analysis and reporting of adverse drug reactions at a tertiary care teaching hospital. Alexandria Journal of Medicine [Internet]. 2018 Dec;54(4):597–603.
7. 1*Dr. Tripuramallu Rajithasree, 2Vitrouth Akshitha, 3Thudi Deekshitha Reddy, 4Aiyesha Ahsan, 5Dr. Chandrasekhara Rao Baru. (2026). Ensuring Drug Safety: A