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# A HOSPITAL BASED PROSPECTIVE STUDY ON CLASSIFICATION, CAUSALITY, PREVENTABILITY, SEVERITY OF ADVERSE DRUG REACTIONS AND BARRIERS TO ADVERSE DRUG REACTION REPORTING

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## ABSTRACT

Adverse drug reactions (ADRs) pose a significant threat to patient safety and healthcare systems worldwide. Understanding ADR patterns and the barriers to reporting is essential for improving patient care. This prospective observational study was aimed to evaluate ADRs, their causality, severity, preventability and management, and barriers faced by healthcare professionals in reporting them, over a period of 6 months in a tertiary care hospital in Dakshina Kannada. Data collection included patient demographics, causative drugs, ADR descriptions, assessments of ADRs, and a questionnaire on reporting barriers. Causality, severity, and preventability of ADRs were assessed using established scales. Among 200 collected ADRs, the majority (50.5%) occurred in the geriatric population and were more prevalent in females (52%). Highest percentage of ADRs were reported from General Medicine department (47.5%). Most ADRs were type A (Augmented) reactions (73%). Antibiotics were the most common causative drugs (35%). Constipation was the most prevalent ADR (24%). The Naranjo and WHO-UMC scales indicated probable causality in most cases (73%). The Modified Schumock and Thornton Criteria categorized a significant portion as probably preventable (62%). Severity assessment revealed a predominance of moderate ADRs (68.5%). Barriers to ADR reporting were identified across 8 domains. While healthcare professionals exhibited strong knowledge (96%) and positive social influences in ADR reporting (100%), challenges included reporting skills deficits (10%), concerns about legal consequences (66%), lack of time (76%),

constraints (71%), and heavy workloads (80%). Encouragingly, healthcare professionals displayed high motivation (92%) and a commitment to reporting ADRs, indicating the potential for enhanced medication safety practices.

***KEYWORDS:*** *Adverse Drug Reactions (ADRs), Causality Assessment, Severity Assessment, Preventability.*

## INTRODUCTION

According to World Health Organization (WHO), an Adverse Drug Reaction (ADR) is defined as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function."[1]

Adverse drug reactions (ADRs), the fifth leading cause of mortality, significantly increase hospitalizations globally.[2] ADR risk factors include patient-related, drug-related, disease-related, and social-related elements such as age, polypharmacy, gender, immune system factors, and pharmacogenetics. Managing ADRs is vital for healthcare providers, especially as new drug therapies can lead to unforeseen ADRs. ADRs negatively affect patients' quality of life and their trust in healthcare. Although safety profiles are assessed before market release to predict potential ADRs, these assessments often detect adverse effects only within a limited study duration.[3]

Antimicrobials and analgesics are major causes of ADRs, though prescribing practices, new drugs, and referral biases can affect this pattern.[4] Identifying and reporting ADRs is crucial for reducing healthcare costs and helping physicians prescribe cautiously.[5] Despite India's significant medicine consumption, ADR reporting is only 2% of the global total. In India, ADR incidence ranges from 1.7% to 25.1%, with 8% resulting in hospitalization.[6] Although India is part of the WHO's global ADR monitoring program, poor reporting practices limit its contribution.[7] Nevertheless, India ranks seventh among the top contributors to the global drug safety database. Spontaneous reporting has led to the withdrawal of many unsafe drugs. To enhance AE monitoring, India launched a nationwide pharmacovigilance program in 2010, supported by 346 Adverse Drug Reaction Monitoring Centers (AMCs) as of April 2021.[8] These centers mainly use spontaneous reporting to document ADRs and AEs.[9]

Healthcare improvement can occur at various levels, but a key intervention is helping healthcare professionals adopt evidence-based practices.[10] This study focuses on improving Adverse Drug Reaction (ADR) reporting. Understanding the barriers to ADR reporting is crucial for developing effective strategies to overcome them, enhancing patient safety. Addressing these barriers requires a methodical, theory-based approach.[11] Theoretical insights into healthcare professionals' behaviors improve the chances of successful interventions by identifying factors and obstacles, suggesting techniques for behavior change, and explaining how these techniques work.[12]

The present study aimed to monitor ADRs in a well-established clinical pharmacy service at a tertiary care hospital, assessing type, causality, preventability, and severity and also to uncover barriers in ADR reporting among healthcare professionals, aiding tailored interventions to improve ADR reporting in Indian healthcare.

## MATERIALS AND METHODS

**Study design:** The present work was a prospective, observational study that was carried out to assess causality, severity, and preventability of ADRs and identify barriers to ADR reporting at a Tertiary Care Hospital in Dakshina Kannada for 6 months.

**Sample size:** A total of 200 ADRs were identified in the present study.

**Ethical clearance:** Ethical Clearance was obtained from the Institutional Ethics Committee (IEC) of Srinivas Institute of Medical Science and Research Centre (SIMS & RC), Mangalore.

**Inclusion criteria:** ADR reports which are duly completed and reported to the ADR monitoring Centre of the institution.

**Exclusion criteria:** ADR reports which are incomplete.

**Source of data:** Data was collected from AMC of the institution in the Reported ADR data collection form. The reported ADRs on the notification forms, after being confirmed by the physician-in-charge, were assessed for causality, severity and preventability. Concurrently, questionnaires on potential barriers for reporting ADRs were distributed among healthcare professionals. The filled questionnaires were collected and analyzed.

**Materials used:** Data collection form included the patient's demographic details and description of the causative drug, ADR encountered and assessment of ADR collected. For the assessment of Causality, severity and preventability of the reported ADRs, Naranjo's & WHO causality assessment scale,[13] Modified Hartwig & Siegel scale[14] and Modified Schumock & Thornton scale[15] were used respectively. A self-designed questionnaire was prepared and questions were divided based on 8 Domains (Knowledge, Skills, beliefs about consequences, Motivations and Goals, Lack of time, Heavy Workload, Social influences, Memory, attention and decision processes)

**Data analysis:** Statistical analysis involves collecting and scrutinizing every data sample in a set of items from which samples can be drawn and a suitable statistical test was applied to analyze the data. The collected data were analyzed using Microsoft Excel.

## RESULT

### Demographic characteristics

**Age group:** In the current study, 200 ADRs were documented across various clinical departments of a tertiary care hospital in Dakshina Kannada. The incidence of ADRs in various patients' ages ranged from 2 to 91 years: 6 in 2-20 age group, 29 were 21-40 age group, 64 were 41-60 age group, and 101 were over 61 age group. The data indicates that ADRs were notably higher among the geriatric population (over 60 years), likely due to age-related physiological changes and the common practice of polypharmacy in this age group.

**Gender:** ADRs were more frequently observed in females (52%) than in males (48%), likely due to sex-related differences.

### Department

Among the 200 collected ADRs, the General Medicine department reported the highest number with 95 ADRs. The Nephrology department accounted for 20 ADRs, followed by Cardiology with 19 ADRs, Respiratory Medicine with 15 ADRs, General Surgery with 13 ADRs, Oncology with 9 ADRs, Dermatology with 8 ADRs, Hepatology with 6 ADRs, Psychiatry with 6 ADRs, Gastroenterology with 5 ADRs, Orthopedics with 2 ADRs, Obstetrics and Gynecology with 1 ADR, and Pediatrics with 1 ADR.

**Table 1: Department wise distribution of ADR.**

| Department | No. of ADRs |
|---|---|
| Cardiology | 19 (9.5%) |
| Dermatology | 8 (4%) |
| Gastroenterology | 5 (2.5%) |
| General Medicine | 95 (47.5%) |
| General Surgery | 13 (6.5%) |
| Hepatology | 6 (3%) |
| Nephrology | 20 (10%) |
| Obstetrics and Gynecology | 1 (0.5%) |
| Oncology | 9 (4.5%) |
| Orthopedics | 2 (1%) |
| Pediatric | 1 (0.5%) |
| Psychiatry | 6 (3%) |
| Respiratory Medicine | 15 (7.5%) |

**Type of reaction**

73% of reported ADRs belonged to the category of type A reactions (Augmented), while the remaining 27% were classified as type B reactions (Bizarre).

**Drug classification**

The group of drugs most commonly associated with ADRs included antibiotics (70), analgesics (33), anti-hypertensives (27), anti-diabetic medications (23), proton pump inhibitors (PPIs) (15), and corticosteroids (10). Table 3 provides a comprehensive breakdown of ADRs caused by each drug classification.

**Table 2: Drug classification.**

| Drug Class | No. of ADRs |
|---|---|
| Analgesic | 33 (16.5%) |
| Antibiotics | 70 (35%) |
| Anticoagulants | 2 (1%) |
| Anticonvulsants | 2 (1%) |
| Anti-diabetic | 23 (11.5%) |
| Anti-hypertensives | 27 (13.5%) |
| Antiplatelets | 3 (1.5%) |
| Antipsychotics | 4 (2%) |
| Corticosteroids | 10 (5%) |
| Laxatives | 2 (1%) |
| PPI | 15 (7.5%) |
| Others | 9 (4.5%) |

**Table 3: Drugs causing ADRs.**

| Drug class | Drug name | Frequency of ADRS (n=250) |
|---|---|---|
| Analgesic | Diclofenac | 1 |
| | Morphine | 1 |
| | Paracetamol | 7 |
| | Semi-ultracet | 1 |
| | Tramadol | 17 |
| | Ultracet | 6 |
| Antibiotic | Amoxicillin+ Clavulanate | 3 |
| | Azithromycin | 2 |
| | Cefoperazone | 1 |
| | Cefoperazone+Sulbactum | 4 |
| | Cefotaxime | 2 |
| | Ceftriaxone | 15 |
| | Ciprofloxacin | 1 |
| | Clindamycin | 1 |
| | Clotrimoxazole | 1 |
| | Levofloxacin | 2 |
| | Linezolid | 1 |
| | Meropenem | 17 |
| | Metronidazole | 5 |
| | Piperacillin+Tazobactum | 12 |
| | Rifagut | 1 |
| | Tigecycline | 1 |
| | Vancomycin | 1 |
| Anticoagulant | Enoxaparin | 1 |
| | Heparin | 1 |
| Anticonvulsant | Levetiracetam | 1 |
| | Phenytoin | 1 |
| Anti-Diabetic | Actrapid | 19 |
| | Glimepiride | 1 |
| | Metformin+Metoclopromide | 1 |
| | Sitagliptin | 1 |
| | Telmisartan | 1 |
| Anti-Hypertensive | Amiodarone | 1 |
| | Amlodipine | 1 |
| | Atenolol | 1 |
| | Cilnidipine | 2 |
| | Diltiazem | 1 |
| | Furosemide | 11 |
| | Lasilactone | 1 |
| | Losartan | 1 |
| | Mannitol | 1 |
| | Metoprolol Succinate | 1 |
| | Nifedipine | 1 |
| | Norepinephrine | 1 |
| | Spirinolactone | 1 |
| | Spirinolactone+ Furosemide | 1 |
| | Telmisartan | 1 |

| | | |
|---|---|---|
| | Torsemide | 1 |
| Anti-Platelet | Aspirin<br>Aspirin+Atorvastatin<br>Atorvastatin | 1<br>1<br>1 |
| Anti-Psychotic | Olanzapine<br>Risperidone | 2<br>2 |
| Corticosteroid | Dexamethasone<br>Hydrocort<br>Ipravent+Budecort<br>Ivabrad | 2<br>4<br>2<br>2 |
| Laxative | Cremaffin<br>Duphalac Syp | 1<br>1 |
| Others | Acetylcysteine<br>Atarax<br>Hydroxyzine HCL<br>$K^+$ Bind Powder<br>KCL With NS<br>Octreotide<br>Ondansetron<br>Pancreatin+Dimethicone<br>Streptokinase | 1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1 |
| PPI | Esomeprazole<br>Pantoprazole | 5<br>10 |

**Reported reactions**

Upon analyzing the collected adverse drug reactions (ADRs), it was found that nausea and vomiting (24%) was the most prevalent reaction, followed by constipation (18.5%), allergic reactions (11.5%), hypoglycemia (9.5%), hypokalemia (8.5%), and hyponatremia (4.5%).

**Table 4: Reported reactions.**

| Commonly reported reactions | No. of ADRs |
|---|---|
| Allergic Reaction | 23 (11.5%) |
| Anemia | 2 (1%) |
| Arrhythmia | 1 (0.5%) |
| Bleeding | 2 (1%) |
| Burning Micturition | 2 (1%) |
| Constipation | 48 (24%) |
| Diarrhea | 8 (4%) |
| Drowsiness | 5 (2.5%) |
| Fever | 3 (1.5%) |
| Headache | 4 (2%) |
| Hyperkalemia | 5 (2.5%) |
| Hypoglycemia | 19 (9.5%) |
| Hypokalemia | 17 (8.5%) |
| Hyponatremia | 9 (4.5%) |
| Hypotension | 4 (2%) |
| Leukocytosis | 1 (0.5%) |

| | |
|---|---|
| Nausea and Vomiting | 37 (18.5%) |
| Thrombocytopenia | 4 (2%) |
| Others | 6 (3%) |

**Assessment of Reported ADRs**

**1. Causality assessment**

Individual cases underwent causality assessment utilizing the Naranjo's scale. The assessment revealed that 146 ADRs (73%) were categorized as probable, while 35 ADRs (17.5%) categorized as possible category. A comprehensive breakdown of the causality assessment can be found in Figure 1.

Causality of ADRs was also assessed using the WHO-UMC ADR probability scale which is presented in Figure 2. This analysis highlighted that a majority of the ADRs were rated as probable (73%), followed by possible (17.5%), and a smaller proportion were considered certain (5%).

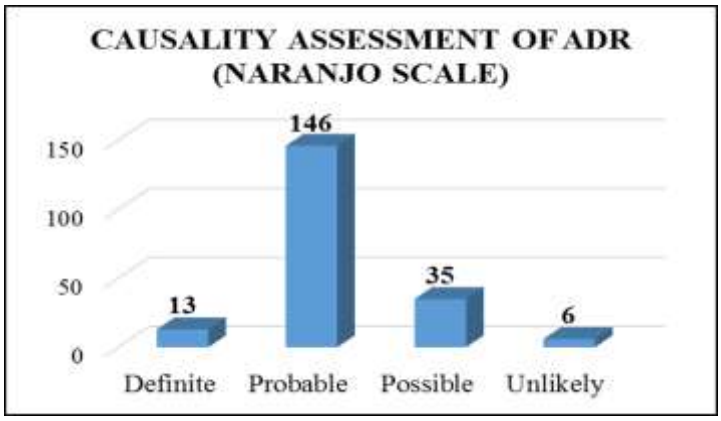


**Figure 1: Causality assessment of ADRs using Naranjo's scale.**

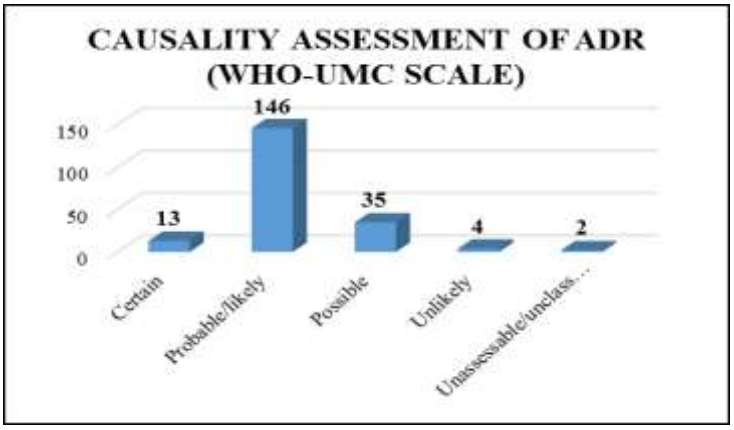


**Figure 2: Causality assessment of ADRs using WHO-UMC scale.**

## 2. Severity assessment

The Severity of ADRs was assessed using the Modified Hartwig and Siegel scale, it became apparent that the majority of the reported ADRs in the study were classified as moderate in severity, followed by mild and severe cases. A comprehensive breakdown of the severity assessment can be found in Figure 3.

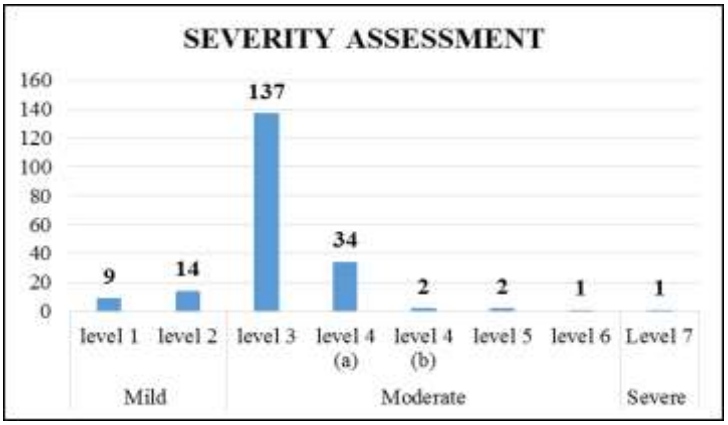


**Figure 3: Severity assessment of ADRs.**

## 3. Preventability assessment

Preventability of suspected ADRs was assessed using the Modified Schumock and Thornton Criteria. Within this framework, it was observed that 124 reactions (62%) were categorized as probably preventable, while 57 reactions (28.5%) were not preventable. Further insights into the assessment of ADR preventability can be found in Figure 4.

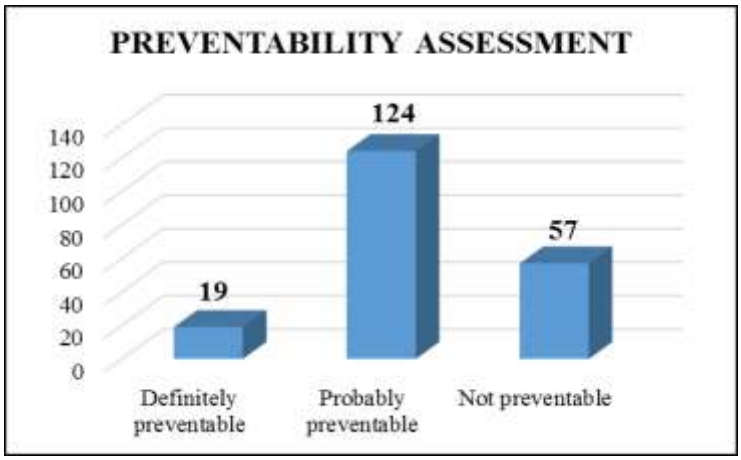


**Figure 4: Preventability assessment of ADRs.**

## Management of ADRs

Among the 200 collected ADRs, a range of strategies was employed to address these adverse events. Firstly, in 102 cases, patients were actively treated to relieve the ADRs, Additionally,

in 74 cases, the responsible drugs were withdrawn. Of these, 48 cases received additional treatment to address the ADRs, ensuring comprehensive care. In one instance, a drug was reintroduced at a later time, suggesting a careful monitoring and evaluation process before considering its reintroduction, reflecting a cautious and patient-focused approach. In 9 cases, no changes were made to the therapy, indicating that the ADRs were manageable without the need for significant adjustments to the treatment plan. This highlights the importance of individualized patient care. Furthermore, dietary interventions were recommended for two cases, revealing the study's holistic approach to ADR management by considering dietary factors as potential contributors to adverse reactions. In 7 cases, alternative drugs were prescribed, ensuring that patients continued to receive necessary treatment while minimizing the risk of further ADRs. Finally, in 3 cases, the dose of the drug was reduced, demonstrating a commitment to finding the right balance between effective treatment and ADR prevention.

**Table 5: Management of ADRs.**

| Action taken | No. of ADRs | Percentage (%) |
|---|---|---|
| Dietary intervention | 2 | 1 |
| Dose decreased | 3 | 1.5 |
| Dose decreased and treatment given | 3 | 1.5 |
| Drug changed / alternative drug | 7 | 3.5 |
| Drug withdrawn | 25 | 12.5 |
| Drug withdrawn and re introduced sometime later | 1 | 0.5 |
| Drug withdrawn and treatment given | 48 | 24 |
| No action taken | 9 | 4.5 |
| Treatment given for the reaction | 102 | 51.5 |

**Outcome of management**

The recovery rates observed in this study are highly encouraging, with 166 (83%) of the 200 collected ADRs found to be recovered. Additionally, 30 cases (15%) were in the process of recovery, indicating positive progress in their management. Only 4 (2%) cases were classified as not recovered, suggesting that the majority of patients experiencing ADRs experienced improvement or resolution of their symptoms.


**Figure 5: Outcome of management.**

**Barriers to ADR reporting**

With the assistance of a self-designed questionnaire, interviews were carried out with a total of 50 healthcare professionals, comprising 8 physicians, 10 nurses, 18 Pharm D interns, and 14 MBBS interns.

The barriers to ADR reporting were categorized into 8 distinct domains. In the "Knowledge" domain, it was found that 48 out of 50 healthcare professionals were well-informed about ADRs and had knowledge about the ADR reporting system in India. However, 5 healthcare professionals were identified as lacking the necessary skills for reporting ADRs. Notably, interns and physicians exhibited a good understanding of ADR reporting and found it manageable. Conversely, some nurses faced challenges in reporting ADRs due to skill deficiencies.

Within the "Beliefs about consequences" domain, a majority of healthcare professionals (33) expressed concerns about potential litigation issues. In the "lack of time" and "heavy workload" domains, most healthcare professionals (38) cited a lack of time, and 40 mentioned heavy workloads as significant obstacles to ADR reporting.

In the "Social influences" domain, all healthcare professionals participating in the study confirmed active ADR reporting within the hospital and highlighted the absence of teamwork-related issues among colleagues. Hospital managers and colleagues did not discourage ADR reporting.

Conversely, in the "Motivation and goals" domain, 46 out of 50 healthcare professionals displayed high motivation to report ADRs and consistently reported suspected ADRs in the

hospital. Finally, in the "Memory, attention, and decision process" domain, 42 healthcare professionals reported that they never forgot to report suspected ADRs.

**Table 6: Barriers identified in ADR Reporting.**

| Sl no | Barriers domain | Response by the healthcare professional | |
|---|---|---|---|
| | | Yes | No |
| 1 | Knowledge | 48 (96%) | 2 (4%) |
| 2 | Skills | 45 (90%) | 5 (10%) |
| 3 | Beliefs about consequences | 33 (66%) | 17 (34%) |
| 4 | Heavy workload | 40 (80%) | 10 (20%) |
| 5 | Lack of time | 38 (76%) | 12 (24%) |
| 6 | Social influences | 50 (100%) | 0 |
| 7 | Motivation and goals | 46 (92%) | 4 (8%) |
| 8 | Memory, attention, and decision process | 42 (84%) | 8 (16%) |

## DISCUSSION

In the study, significant proportion of ADRs occurred in over 60 years age, aligning with Sriram S *et al*.'s findings on higher risk in the geriatric population for ADRs. This emphasizes age as a key factor in ADRs, particularly among older adults. Geriatric patients pose unique healthcare challenges due to altered physiology, coexisting conditions, and polypharmacy, increasing the risk of adverse reactions. With the global population aging, it's crucial for healthcare providers and researchers to focus on medication management for the elderly.[16]

This study found that ADRs were more common among female patients, aligning with Sundaran S *et al*.'s earlier study. The consistent higher prevalence of ADRs in females suggests potential gender-based differences in drug responses and reporting factors.[17]

In the present study, ADRs were classified as either type A or type B reactions. This categorization aligns with the findings of a study conducted by Shahjahan J *et al*., in which all ADRs were either type A or type B reactions. This alignment highlights the importance of recognizing and understanding these common types of ADRs to improve patient safety.[18]

The General Medicine department had the most ADR reports in the study. Similar to a study by Bhandare B *et al*., General Medicine consistently sees a high number of ADR cases in healthcare settings. This is due to the department's diverse medical conditions, often requiring multiple medications, initial treatments, and medication adjustments, leading to a higher ADR risk. Additionally, the department's larger patient volume and management of chronic diseases result in increased ADR opportunities.[19]

Antibiotics were the primary class of drugs associated with ADRs, in line with Gupta A *et al*.'s study that also found a majority of ADRs linked to antibiotics. This highlights the significance of cautious antibiotic prescribing and vigilant monitoring for adverse events. Healthcare providers must weigh the potential risks and benefits of antibiotic therapy, especially when alternatives exist or when antibiotics are unnecessary. Such awareness can inform antibiotic stewardship programs and enhance medication safety.[1]

Constipation was the most common ADR, mirroring Hasan S *et al.*'s study findings. This high incidence highlights the importance of healthcare providers monitoring and managing constipation as a side effect. It also highlights the need for patient education about the possibility of constipation with specific medications and the importance of preventive measures.[3]

The assessment of ADRs using both Naranjo's and the WHO causality assessment scales showed consistent patterns in the study. The majority of ADRs were categorized as "Probable" according to Naranjo's scale, which aligns with Padmavati S *et al.'s* study, confirming the reliability of our findings.[20] Similarly, the WHO causality assessment scale indicated a significant proportion of ADRs as "Probable," closely matching the results reported by Grace R J *et al.*[21] These consistent outcomes with previous research underscore the robustness and reproducibility of both causality assessment scales. Standardized tools like these support accurate ADR evaluation, ensuring a systematic and reliable approach.

When evaluating the severity of ADRs using the Modified Hartwig and Siegel scale, the majority of reported ADRs were categorized as Moderate level 3. This pattern closely matches the findings of a previous study conducted by S Sundaran *et al*., where a significant proportion of ADRs were similarly classified as Moderate level 3. This consistency emphasizes the importance of this specific category in clinical practice, as Moderate level 3 ADRs often demand careful management and monitoring to ensure patient safety and improve healthcare outcomes.[17]

The assessed ADRs were classified using the Modified Schmock and Thornton Preventability Scale, with a significant portion categorized as "Probably preventable." This contrasts with Belhekar M N *et al.'s* study, where most ADRs were labeled "Not preventable".[5]

ADRs in the study were managed with various methods, including specific medications, drug withdrawal, and other strategies. Some cases involved re-introducing the causative drug, while in others, therapy remained unchanged. This approach differs from a previous study by Hasan S *et al.,* where the highest percentage of cases involved no change in therapy, followed by the need for specific treatment and symptomatic treatment. These variations emphasize the importance of tailoring ADR management to individual cases, considering each reaction and patient's unique characteristics.[3] A significant majority of the collected ADRs had fully recovered, with others in the process of recovery, mirroring a prior study by Shahjahan J *et al.* The consistency in these findings emphasizes the importance of prompt recognition and appropriate interventions for individuals experiencing ADRs, leading to favourable outcomes.[18]

In the "Knowledge" domain, the study's results indicated that nurses, interns, and physicians in the hospital were knowledgeable about what ADRs are and understood the ADR reporting system in India. Within the "Skills" domain, it was found that interns and physicians were proficient in reporting ADRs and found it to be a straightforward process. However, a few nurses faced difficulties in reporting ADRs due to skill deficiencies. These findings align with a study conducted by Cheema E *et al.*[22]

In "Beliefs about consequences", “Lack of time" and “Heavy workload” domains, the study identified fear of punishment and litigation, as well as a lack of time and increased workloads, as major barriers to reporting ADRs in the hospital. These observations are consistent with a study conducted by Mirbaha F *et al.*[12]

In the "Social influences" domain, it was observed that healthcare professionals in the hospital actively reported ADRs, and there was no evidence of a lack of teamwork or disapproval from hospital managers or colleagues regarding ADR reporting. In contrast, in the "Motivation and Goals" domain and the "Memory, Attention, and Decision Process" domain, the study found that healthcare professionals were highly motivated to report suspected ADRs, and most of them consistently remembered to report such cases in the hospital. These findings differ from those of the study conducted by Mirbaha F *et al.*[12]

## CONCLUSION

The present study concluded that there is a high incidence of ADRs, particularly among the geriatric population, underscoring the need for targeted interventions and increased vigilance

for this demographic. Gender differences in ADR reporting highlight the importance of considering gender-related factors in patient care. The study's findings on departmental variations in ADR reporting across specialties emphasize the multidisciplinary nature of ADR management. The classification and causality assessments of ADRs demonstrate the importance of systematic evaluation. Additionally, the identification of preventable ADRs and the severity of these reactions highlight opportunities for improving patient safety. The analysis of barriers to reporting ADRs points to specific areas for improvement, such as addressing concerns about litigation, time constraints, heavy workloads, and skill deficiencies. Overall, this study provides a foundation for future initiatives to enhance patient safety and ADR reporting practices, ultimately contributing to safeguarding patient well-being and reducing healthcare costs.

## REFERENCES

1. Gupta A, Kaur A, Shukla P, Chhabra H. Adverse drug reactions pattern in a tertiary level teaching hospital: A retrospective study. Indian Journal of Pharmacy Practice, 2017; 10(1): 27–31.
2. Iftikhar S, Sarwar MR, Saqib A, Sarfraz M. Causality and preventability assessment of adverse drug reactions and adverse drug events of antibiotics among Hospitalized patients: A multicenter, cross-sectional study in Lahore, Pakistan. Public Library of Science ONE, 2018; 13(6).
3. Hassan S, Kumar UU, Mascarenhas V, Suresh G, Raj KC, Nayak P. A prospective study on adverse drug reactions in inpatients of General Medicine Department in a tertiary care hospital- a clinical pharmacist-led study. Journal of Pharmaceutical Research International, 2021; 111–22.
4. Ding WY, Lee CK, Choon SE. Cutaneous adverse drug reactions seen in a tertiary hospital in Johor, Malaysia. International Journal Dermatology, 2010; 49(7): 834-41.
5. Belhekar MN, Tondare SB, Pandit PR, Bhave KA, Patel TC. A prospective study on causality, severity and preventability assessment of adverse drug reactions in a tertiary care hospital in India. International Journal of Basic & Clinical Pharmacology, 2019; 8(1): 104-10.
6. Shanmugam H, Panneerselvam N, Lawrence A. Adverse drug reactions of cardiovascular drugs in intensive cardiac care unit in a tertiary care hospital: A prospective study. Biomedical and Pharmacology Journal, 2019; 12: 1079-83.

7. Sushma M, Kavitha R, Divyasree S, Deepashri B, Jayanthi CR. Questionnaire study to assess the knowledge, attitude and practice of pharmacovigilance in a paediatric tertiary care centre. Journal of Chemical and Pharmaceutical Research, 2011; 3: 416-22.
8. Kochhar DrAM. Pharmacovigilance Programme of India (PvPI) and Advantages of Enrolment as Adverse Drug Reaction Monitoring Centre (AMC) under PvPI, 2021.
9. Thakare V, Dongerkery K, Langade D. Prospective observational study to evaluate adverse drug reactions pattern in a tertiary level teaching hospital. National Journal of Physiology, Pharmacy and Pharmacology, 2019; 9(5): 434–7.
10. Ferlie EB, Shortell SM. Improving the quality of health care in the United Kingdom and the United States: a framework for change. Milbank Quarterly, 2001; 79(2): 281–315.
11. Eccles M, Grimshaw J, Walker A, Johnston M, Pitts N. Changing the behavior of healthcare professionals: the use of theory in promoting the uptake of research findings. Journal of Clinical Epidemiology, 2005; 58(2): 107–12.
12. Mirbaha F, Shalviri G, Yazdizadeh B, Gholami K, Majdzadeh R. Perceived barriers to reporting adverse drug events in hospitals: A qualitative study using theoretical domains framework approach. Implementation Science, 2015; 10(1): 1–10.
13. Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. Clinical Pharmacology and Therapeutics, 1981; 30(2): 239-245.
14. Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. American journal of hospital pharmacy, 1992; 1, 49(9): 2229-32.
15. Schumock GT, Thornton JP. Focusing on the preventability of adverse drug reactions. Hospital pharmacy, 1992; 1, 27(6): 538.
16. Sriram S, Ghasemi A, Ramasamy R, Devi M, Balasubramanian R, Ravi TK, Sabzghabaee AM. Prevalence of adverse drug reactions at a private tertiary care hospital in south India. Journal of research in medical sciences: the official journal of Isfahan University of Medical Sciences, 2011; 16(1): 16.
17. Sundaran S, Udayan A, Hareendranath K, Eliyas B, Ganesan B, Hassan A, et al. Study on the classification, causality, preventability and severity of adverse drug reaction using spontaneous reporting system in hospitalized patients. Pharmacy, 2018; 6(4): 108.
18. Shajahan J, Parathoduvil AA, Purushothaman S. An analysis of seriousness, predictability and preventability of adverse drug reactions reported at a tertiary care teaching hospital in Kerala, India: A retrospective observational record based study. International Journal of Basic & Clinical Pharmacology, 2018; 7(12): 2433.

19. Bhandare B. A study on adverse drug reactions in a tertiary care hospital in Bangalore. Indian Journal of Pharmacy and Pharmacology, 2017; 4(1): 49–54.
20. S. P. 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, 2013; 7(12): 2765–7.
21. Grace JR, Saina AK, E M, R S, Subeesh V. Assessment of adverse drug reactions occurring at Department of Neurology of a Tertiary Care Hospital in India. Asian Journal of Pharmaceutical and Clinical Research, 2018; 11(10): 457–64.
22. Cheema E, Haseeb A, Khan TM, Sutcliffe P, Singer DR. Barriers to reporting of Adverse Drugs Reactions: A cross sectional study among community pharmacists in United Kingdom. Pharmacy Practice, 2017; 15(3): 931.