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Hospital Based Prospective Observational Study on Type, Severity, Prevention and Management of Adverse Drug Reactions

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A B S T R A C T

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." Adverse Drug Reactions (ADRs), ranking as the fifth leading cause of mortality, contribute significantly to hospitalizations worldwide. It pose a significant threat to patient safety and healthcare systems worldwide. Adverse Drug Reactions (ADRs) strain an already overwhelmed healthcare system, with a significant portion being preventable. Hence, Understanding ADR patterns is essential for improving patient care. This prospective observational study was aimed to evaluate ADRs, their severity, preventability and management for over a period of 6 months in a tertiary care hospital in Dakshina Kannada. Data collection included patient demographics, type of ADR, causative drugs, drug classifications, ADR descriptions and assessments of ADRs. Preventability and severity of ADRs were assessed using Modified Schumock and Thornton scale and Modified Hartwig and Siegel scale respectively. Among 250 collected ADRs, the majority (50.4%) occurred in the geriatric population and were more prevalent in females (52%). Most ADRs were type A (Augmented) reactions (73.2%). Antibiotics were the most common causative drugs (38%). The Modified Schumock and Thornton Criteria categorized a significant portion as probably preventable (45.2%). Severity assessment revealed a predominance of moderate ADRs (84.40%). This study sheds light on ADR severity, preventability and their management. The findings emphasize the need for tailored interventions, gender-specific considerations, and improved ADR reporting practices to enhance patient safety and reduce healthcare costs. Appropriate monitoring of adverse reactions is necessary to reduce the incidence and stop additional problems and occurrences.

Keywords: Adverse Drug Reactions (ADRs), Preventability, Severity Assessment, Management.

1. Introduction

"A reaction 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," is how the World Health Organization (WHO) defines an Adverse Drug Reaction (ADR).[1] Adverse drug reactions (ADRs), the world's fifth-leading cause of death, are a major factor in hospital admissions. [2] Pharmacovigilance (PV) is the science and activities concerned with the identification, evaluation, comprehension, and avoidance of side effects or any other drug-related issues.[7] Healthcare practitioners have a critical duty to manage adverse drug reactions (ADRs), especially with the ongoing introduction of novel medication regimens that may cause unanticipated ADRs. Regrettably, ADRs have a negative effect on patients' quality of life and undermine their trust in the medical establishment. Before pharmaceuticals are released into the market, safety profiles are evaluated to foresee possible side effects. Nevertheless, these evaluations frequently reveal negative consequences that materialize during a little research period. [3] It is estimated that major ADRs affect 5–8% of hospitalized patients, and that ADRs account for 10% of hospital expenses. The consequences associated with ADRs are primarily related to hospitalization and complications during hospitalization, such as extended hospital stays and increased healthcare costs.[4] Due to age-related physiological changes, pharmacokinetic and pharmacodynamic alterations, and other changes, the geriatric population—which makes up over 21% of the total population—consumes a remarkably large amount of drug treatments, which might lead to medication-related issues.[11] Finding and reporting adverse drug reactions (ADRs) is critical since it can help doctors prescribe more carefully and lower medical expenses. [5] Even with India's substantial contribution to the world's drug consumption, just 2% of all ADRs are reported worldwide. The incidence of ADRs in the Indian population varies from 1.7% to 25.1%, with 8% resulting in hospitalization. [6] Still, India comes in at number seven out of the top ten nations that contribute to the worldwide drug safety database. Many pharmaceuticals that were on the market were withdrawn because of safety concerns, which were brought up by the spontaneous reporting mechanism. India began a national pharmacovigilance program in 2010 to increase awareness of adverse events (AEs). The program is supported by Adverse Drug Reaction Monitoring Centers (AMCs), of which there were around 346 as of April 2021. [8] Improvements in healthcare can occur at many levels of the health system, but helping healthcare providers align their practices with evidence-based guidelines is a critical intervention.[10] Therefore, the purpose of this study was to investigate and evaluate the types, severity, preventability, and management of adverse drug reactions (ADRs) in a tertiary care hospital. The goal of the current study was to track adverse drug reactions (ADRs) in a tertiary care hospital with previously established clinical pharmacy services.

2. Materials and Methods

STUDY DESIGN: A Prospective observational study was carried out to assess preventibility, severity and management of ADRs.

SAMPLE SIZE: The sample taken for the study was 250.

STUDY DURATION: The study was conducted for a duration of 6 months from Jan 2024 – June 2024.

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. Any ADR reported to the ADR monitoring Centre of the institution

Exclusion Criteria: Incomplete ADR reports.

SOURCE OF DATA: Reported ADR data collection form was used to collect the data.The reported ADRs, which are already been confirmed by the physician-in-charge were collected from the AMC of the institution and were assessed for severity using Modified Hartwig and Siegel scale and preventability using Modified Schumock and Thornton scale.

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 severity and preventability of the reported ADRs, Modified Hartwig & Siegel scale and Modified Schumock & Thornton scale were used respectively.

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.

3. Results

DEMOGRAPHIC CHARACTERISTIC:

Age group:

The current study included 250 adverse drug reactions (ADRs) from different clinical departments of a tertiary care hospital in Dakshina Kannada between January 2024 and June 2024. The patients' ages ranged from 2 to 91 years, with 8 (3.2%) in the 2–20 years age group, 36 (14.4%) in the 21–40 years age group, 80 (32%) in the 41–60 years age category, and majority 126 (50.4%) were over the age of 61. The average age of the subjects was 57.49 years. It is clear from the statistics that older adults (those over 60) had a significantly higher frequency of adverse drug reactions (ADRs). The physiological alterations linked to aging and the widespread practice of polypharmacy in this population are the causes of this trend.

Gender

A higher count of ADRs was observed in females (52%), than males (48%), primarily due to the presence of sex-related differences.

TYPE OF REACTION

From the collected 250 ADRs, it was determined that 73.2% of these reactions were within the category of type A reactions (Augmented), while the remaining 26.8% were classified as type B reactions (Bizarre).

DRUG CLASSIFICATION

The group of drugs most frequently associated with ADR included antibiotics (95), anti hypertensives (40), anti-diabetic medications (28), analgesics (26), proton pump inhibitors (PPIs) (10) and corticosteroids (8).

Table 1: drug classification

Drug Class	**No. of ADRs**	**Percentage (%)**
Antibiotics	95	38
Anti-hypertensives	40	16
Analgesic	26	10.4
PPI	10	4
Anti-diabetic	28	11.2
Corticosteroids	8	3.2
Antipsychotics	5	2

Antiplatelets	4	1.6
Anticoagulants	3	1.2
Anticonvulsants	3	1.2
Laxatives	3	1.2
Others	25	10

SEVERITY ASSESSMENT

Using the Modified Hartwig and Siegel scale to measure ADR severity, it was found that most reported ADRs in the study fell into the moderate severity category, with mild and severe cases following. Table 2 offers a thorough analysis of the severity assessment.

Table 2: Severity of ADRs

Severity	**No. of ADRs**	**Percentage (%)**
Mild		
level 1	15	6
level 2	22	8.8
Moderate		
level 3	162	64.8
level 4 (a)	46	18.4
level 4 (b)	3	1.2
Severe		
Level 7	2	0.8

PREVENTABILITY ASSESSMENT

Modified schumock and thorton scale was used to assess preventibility of reported ADRs. Within this framework, it was observed that 112 reactions (45.2%) were categorized as probably preventable, while 98 reactions (39.2%) were deemed definitely preventable. Further insights into the assessment of ADR preventability can be found in Table 3.

Table 3: Preventability of ADRs

Preventability	**No. of ADRs**	**Percentage (%)**
Definitely preventable	98	39.2
Probably preventable	112	45.2
Not preventable	40	15.6

MANAGEMENT OF ADRS

For managing the 250 ADRs that were gathered, a variety of approaches were used. First, patients received active treatment in 129 cases to reduce the adverse drug reactions (ADRs). In 81 cases, the medicines that caused the ADRs were removed. To ensure complete care, 42 of these cases underwent further treatment to address the ADRs. In one case, a medication was later reintroduced indicating a cautious and patient-focused approach and a thorough monitoring and review procedure prior to considering its reinstatement. 19 of the instances had no therapy modifications, suggesting that the ADRs might be controlled without requiring substantial alterations to the treatment regimen. This emphasizes how crucial individualized patient care is. In two cases, dietary changes were also advised, demonstrating the study's comprehensive approach to ADR management by taking dietary aspects into account as possible causes of adverse reactions. Alternative medications were recommended in 12 cases to ensure patients received the essential care while lowering the chance of additional adverse drug reactions. Ultimately, the drug's dose was lowered in 7 cases, indicating a dedication to striking the ideal balance between efficient treatment and ADR prevention.

Table no. 4: Management of ADRs

Action Taken	**No. of ADRs**	**Percentage (%)**
Dietary intervention	2	0.8
Dose decreased	2	0.8
Dose decreased and treatment given	5	2
Drug changed / alternative drug	12	4.8
Drug withdrawn	38	15.2
Drug withdrawn and re introduced sometime later	1	0.4
Drug withdrawn and treatment given	42	16.8
No action taken	19	7.6
Treatment given for the reaction	129	51.6

OUTCOME OF MANAGEMENT

The study's recovery rates are quite promising, as 83% of the 250 ADRs that were gathered were determined to have been recovered. Furthermore, 15% of the cases were in the process of recovering, demonstrating effective management. A few 2% of instances were deemed to be unrecoverable, indicating that the majority of individuals undergoing ADRs saw a reduction or cessation of their symptoms. The aforementioned results demonstrate the efficacy of interventions and clinical management strategies implemented inside the hospital, which in turn lead to better patient outcomes and increased patient safety.

Table 5: Outcome of Management

Outcome of Management	**No. of ADRs**	**Percentage (%)**
Recovered	209	83
Recovering	37	15
Not Recovered	4	2

4. Discussion

The study's average patient age was in the late 50s, with a significant number of patients over 60, which is consistent with the findings of Sriram S et al. about increased risk of adverse drug reactions in the elderly population. This highlights the importance of age in ADRs, especially in elderly persons. Because of their altered physiology, concomitant diseases, and polypharmacy, which increases the risk of adverse effects, elderly individuals present special healthcare concerns. Given the aging of the world's population, it is imperative that researchers and healthcare professionals concentrate on elderly drug management. [9] Consistent with the preceding study by Sundaran S et al., this investigation also indicated that ADRs were more common among female patients. The persistently greater frequency of adverse drug reactions (ADRs) in women raises the possibility of gender-based variations in drug responses and reporting variables. Comprehending this phenomenon may facilitate customized medication administration and monitoring. It highlights that in order to improve patient safety and wellbeing, gender-sensitive pharmacovigilance approaches are essential. [4] Consistent with the findings of Gupta A et al.'s study, which also indicated that antibiotics were linked to the majority of ADRs, antibiotics were the primary class of medications associated with ADRs. This emphasizes how important it is to prescribe antibiotics carefully and to keep a close eye out for any adverse reactions. In particular, when there are alternatives or when antibiotics are not required, healthcare professionals must consider the potential risks and advantages of antibiotic therapy. In the end, improved medication safety and antibiotic stewardship initiatives can be informed by this knowledge, improving patient care. [1] Most reported ADRs were classified as Moderate level 3 when assessed for severity using the Modified Hartwig and Siegel scale. This pattern is in line with the results of a prior study by S Sundaran et al., in which a sizable proportion of ADRs also fell under Moderate level 3. The relevance of this particular category in clinical practice is highlighted by its regularity, since moderate level 3 ADRs frequently call for cautious management and observation in order to protect patient safety and enhance healthcare results. [4] Using the Modified Schmock and Thornton Preventability Scale, the evaluated ADRs were categorized; a significant proportion were classed as "Probably preventable." In contrast, the majority of ADRs were classified as "Not preventable" in Belhekar M N et al.'s study. [5] This variance emphasizes the necessity for context-specific preventative interventions to improve patient safety in clinical practice and emphasizes the intricacy of ADR preventability evaluation. The study's ADRs were treated in a number of ways, such as with particular drugs, drug withdrawal, and other tactics. In certain cases, the therapy was continued, while in others the causal medicine was reintroduced. This method is different from one used in a prior study by Hasan S et al., where the majority of cases involved no therapeutic modification, which was followed by the requirement for symptomatic treatment and specific treatment. These variations highlight how important it is to individualize ADR management to specific patients, taking into account each patient's unique characteristics and reaction. [3] As in a previous study by Shahjahan J et

al., a sizable majority of the gathered ADRs had recovered completely, with others still in the process. These results are consistent, which highlights the significance of early identification and suitable therapies for people with ADRs in order to achieve positive outcomes. [7]

5. Conclusion

The current study found that the incidence of adverse drug reactions (ADRs) was significant, especially in the geriatric population. This suggests that focused interventions and heightened awareness are necessary in this population. The need of taking gender-related issues into account when providing patient care is highlighted by gender variations in ADR reporting. The departmental differences in ADR reporting across specialties found in the study highlight how interdisciplinary ADR management is. Antibiotics were shown to be the primary cause of the majority of ADRs, with Type A (augmented) reactions being more common than other reactions. The study's identification of preventable ADRs and the severity of these reactions point to opportunities for intervention and improvement in patient safety.

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