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A PROSPECTIVE STUDY ON CAUSALITY OF ADVERSE DRUG REACTIONS AT A TERTIARY CARE HOSPITAL

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ABSTRACT

The use of drugs is increasing day by day with the occurrence of new diseases, use of multiple drugs can lead to a variety of adverse drug reactions. Knowing the causality of ADRs caused by various classes of drugs helps to achieve better therapeutic regimen and deliver optimum patient care. This study aimed to assess causality (WHO-UMC scale and Naranjo scale) of ADRs. A prospective observational study was conducted over a period of 6 months at Srinivas Institute of Medical Science and Research Centre, Mukka, Dakshina Kannada. Data was collected in the reported ADR data collection form, which were then assessed for causality using WHO-UMC and Naranjo's algorithm scales. Out of the total 100 ADRs collected, it was found that incidence (60 ADRs) was higher in geriatric patients (above 60 years). Commonly reported ADR was constipation (35). The maximum number of ADRs were found in females (54%), while compared to males (46%)**.** 71% of the type A reactions (Augmented) and 29% type B (bizarre) reactions were reported. The class of drugs which commonly caused ADRs were antibiotics (58). General medicine department had highest number of reported ADRs (32). Assessment of ADR causality revealed majority of the ADRs were Probable (Naranjo- 72 ADRs. WHO – 72 ADRs). To minimize the incidence and prevent further complications and occurrence, proper monitoring of adverse reactions is required. Spontaneous reporting of ADR will help to improve the patient's safety and health and also it may help the physician to avoid those drugs which may cause fatal reactions. Hence, importance should be given in spontaneous reporting of ADR, to ensure the safety of the patient.

KEYWORDS: ADR, Causality, WHO, Naranjo.

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] ADRs, ranking as the fifth leading cause of mortality, contribute significantly to hospitalizations worldwide.[2] The risk factors associated with ADRs can be categorized into patient-related, drug-related, disease-related, and social-related factors. Predisposing elements encompass age, polypharmacy, gender, immune system factors, and pharmacogenetics. Managing ADRs stands as a crucial responsibility for healthcare providers, particularly in light of the continuous emergence of new drug therapies that may lead to unforeseen ADRs. Unfortunately, the occurrence of ADRs adversely impacts patients' quality of life, eroding their confidence in the healthcare system. To anticipate potential drug-related adverse effects, safety profiles are assessed before drugs are introduced to the market. However, such assessments often identify adverse effects that manifest within a limited study duration.[3] Research highlights that antimicrobials and analgesics are the primary culprits for ADRs, though variations in prescribing practices, utilization of novel drugs, and referral biases can influence this pattern and the responsible drugs.[4] Identifying and reporting ADRs hold paramount importance, potentially aiding physicians in prescribing vigilantly and subsequently reducing healthcare costs.[5] Despite India's significant share of global medicine consumption, the reporting of ADRs only accounts for a mere 2% of the global incidence. Within the Indian population, ADR incidence ranges between 1.7% and 25.1%, with 8% leading to hospitalization.[6]

METHODOLOGY

Study Site: Srinivas Institute of Medical Science and Research Centre, Mukka-574146.
Study Type: A prospective observational study.
Study Duration: 6 months
Sample Size: 100

INCLUSION CRITERIA

- ADR reports which are duly completed.
- Any ADR reported to the ADR monitoring Centre of the institution.

EXCLUSION CRITERIA

- Incomplete ADR reports.

DATA SOURCE

Data was collected 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 using WHO-UMC scale and Naranjo's algorithm scale. The required information of reported ADRs were collected from AMC of the institution.

STATISTICAL 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

In the current study, a total of 100 ADRs were documented within the time period spanning from various clinical departments of a tertiary care hospital in Dakshina Kannada. The age distribution of the patients ranged from 21 to 91 years viz., 6 in 0-20 years age group, 14 in 21-40 years, 20 in 41–60 years age category and 60 were more than 61 years. A higher count of ADRs was observed in females (54%), than males (46%). A predominant number of 32 ADRs were reported from the General Medicine department. Subsequently, the General Surgery department accounted for 21 ADRs, Cardiology with 17 ADRs, followed by Respiratory Medicine with 12 ADRs, Nephrology with 9 ADRs, Gastroenterology with 6 ADRs, Psychiatry with 3 ADRs [Table 1]. From the collected 100 ADRs, it was determined that 71% of these reactions were type A reactions (Augmented), while the remaining 29% were classified as type B reactions (Bizarre). The group of drugs most frequently associated with ADR included antibiotics (58), anti-hypertensives (12), anti-diabetic medications (10), analgesics (6), proton pump inhibitors (5) corticosteroids (4), antipsychotics (3) and antiplatelets (2) [Figure 1]. Constipation (35) was the most prevalent reaction, succeeded by nausea and vomiting (28), allergic reactions (15), hypoglycemia (13) and hyperkalemia (5), drowsiness (3), bleeding (1) [Figure 2]. Individual cases underwent causality assessment utilizing the Naranjo's scale. The assessment revealed that 72 ADRs were categorized as probable, while 28 ADRs categorized as possible category [Table 2]. Causality of ADRs was also assessed using the WHO-UMC ADR probability scale. This analysis highlighted that a majority of the ADRs were rated as probable (72 ADRs), and possible (28 ADRs) [Table 3].

Table 1: Department Wise Distribution of ADR.

Department	No. of ADRs
Cardiology	17
Gastroenterology	6
General Medicine	32
General Surgery	21
Psychiatry	3
Nephrology	9
Respiratory Medicine	12

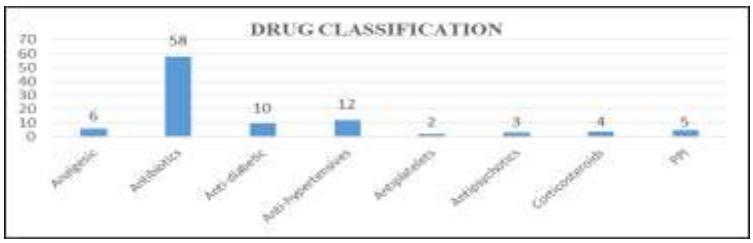

Figure 1: Drug Classification.

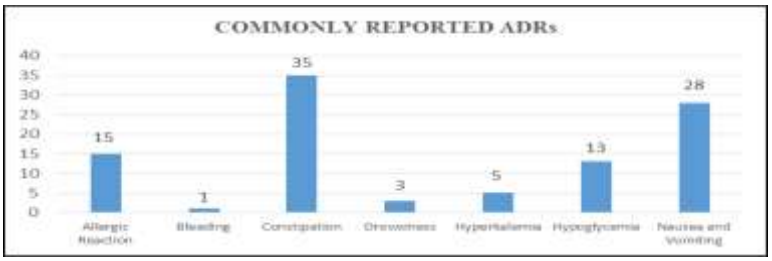

Figure 2: Commonly Reported Reactions.

Table 2: Causality Assessment of ADRs Using Naranjo's Scale.

Causality Assessment of ADR (Naranjo Scale)	No. of ADRs
Definite	0
Probable	72
Possible	28
Unlikely	0

Table 3: Causality Assessment of ADRs Using WHO-UMC Scale.

Causality Assessment of ADR (WHO-UMC Scale)	No. of ADRs
Certain	0
Probable/likely	72
Possible	28
Unlikely	0
Unassessable /unclassifiable	0

DISCUSSION

The study revealed most patients were in their late 50s or older[20], echoing Sriram S *et al*. 's findings on higher ADR risk in the elderly. Geriatric patients present unique healthcare challenges due to physiological changes, multiple conditions, and polypharmacy, increasing the likelihood of adverse reactions.[14]

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.[15]

In the study, all 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.[16]

The General Medicine department had the most ADR reports in the study similar to a study by Bhandare B *et al*., where 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.[17]

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.[1] Constipation was the most common ADR, mirroring Hasan S *et al.* 's study findings.[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.[18] 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*.[19] 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. This uniform categorization enhances the understanding of ADRs, enabling more precise diagnosis and management strategies for improved patient safety and healthcare quality.

CONCLUSION

The present study concluded that there was high incidence of ADRs, particularly among the geriatric population, highlighting the need for targeted interventions and increased vigilance in this demographic. Gender differences in ADR reporting emphasize the importance of considering gender-related factors in patient care. The study's departmental variations in ADR reporting across specialties underscore the multidisciplinary nature of ADR management. The types and causality assessments of ADRs emphasize the importance of systematic evaluation. Overall, this study provides a foundation for future initiatives aimed at enhancing patient safety and ADR reporting practices, ultimately contributing to the goal of safeguarding patients' well-being and reducing healthcare costs.

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