Study on Occurrence of Adverse Drug Reaction in Intensive Care Unit

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***Abstract*—Adverse Drug Reactions (ADRs) are undesirable effects of medications used in normal doses. The study observed a higher incidence of adverse drug reactions (ADRs) in ICU compared to other hospital areas, likely due to differences in surveillance systems and the higher risk profile of ICU patients with comorbidities and multiple drug therapy. Inclusion criteria targeted patients of any age and sex who developed an ADR during ICU admission, while excluding cases of drug abuse, overdose, unwilling participants, and those with insufficient data. Demographic and clinical data were collected, and Naranjo's Causality Assessment Scale assessed ADR risk. Out of 174 patients studied, 61.49% were men, with the majority (40.95%) being in late adulthood. Gastrointestinal issues were the most prevalent (33.33%), often linked to antibiotics (28.16%). Naranjo's scale classified most ADRs as probable (67.24%), and severity assessment (Hartwig's scale) indicated 53.44% were mild. Preventability analysis (Modified Schumock and Thornton scale) suggested 68.39% were likely preventable. Recovery occurred in 79.73% of cases, with ADR reduction in 20.38% and one fatality (0.57%) reported. Drug dechallenge occurred in 94.82% and rechallenge in 5.17% of cases. The study underscores a male predominance and the prevalence of late adulthood patients. Antibiotics were a significant contributor to ADRs, emphasizing the need for cautious antibiotic prescribing. Gastrointestinal issues were the most affected organ system. Most ADRs were probable, mild, and likely preventable. Identified risk factors included age, comorbidities, and polypharmacy. Standardized procedures implementation is advocated to mitigate ADR occurrences and ensure ICU patient safety.**

***Index Terms*—Adverse drug reaction, Intensive Care Unit, ADR Causality, Severity and preventability Assessment**

I. INTRODUCTION

Access to health is considered a fundamental human right, and the responsible use of medicines plays a crucial role in maintaining and improving population health. While medications are essential for preventing and treating a wide range of illnesses, they can also lead to unintended and harmful consequences known as Adverse Drug Reactions (ADRs). Unlike common "side effects," ADRs are typically defined as unwanted, harmful, and unintended effects that occur at normal therapeutic doses.

In clinical settings, particularly in Intensive Care Units (ICUs), the occurrence of ADRs is a significant concern due to the complexity of treatments, use of high-risk drugs, and vulnerability of critically ill patients. These individuals often receive multiple medications, have compromised organ functions, and require complex dosing strategies, increasing the likelihood of adverse outcomes. Studies suggest that ADRs account for approximately 3% to 6% of hospital admissions and may occur in 6% to 15% of hospitalized patients, with a substantial number resulting in severe outcomes or even death.

Globally, ADRs are one of the most common causes of iatrogenic harm, with an estimated 100,000 deaths annually in the United States attributed to serious drug reactions. In addition to health implications, ADRs impose a considerable economic burden. Each incident can increase hospitalization costs by thousands of dollars and extend the duration of hospital stays significantly.

In resource-limited settings like India, the impact of ADRs is magnified by limited healthcare infrastructure, budget constraints, and varying levels of health literacy. With a significant portion of healthcare spending allocated to medications, optimizing their safe and effective use becomes crucial for both patient safety and cost-efficiency.

ADR manifestations can range from mild symptoms such as skin rashes to severe and life-threatening conditions like anaphylaxis or organ failure. Immune-mediated reactions, including drug hypersensitivity syndromes, require careful clinical evaluation. Risk factors include gender, pre-existing conditions such as asthma or systemic lupus erythematosus, and the use of specific drug classes.

Given these challenges, the importance of pharmacovigilance and systematic monitoring of ADRs in ICU settings cannot be overstated. Identifying, reporting, and managing ADRs promptly can significantly reduce morbidity, mortality, and healthcare costs. This study aims to assess the incidence, patterns, and clinical relevance of ADRs in intensive care, with the goal of contributing to safer and more effective medication practices.

II. OBJECTIVES

Primary objective

- To determine the prevalence of ADR in intensive care unit.
- To examine the type and range of drug classes involved in ADR.
- To determine the causality, preventability, and severity of eachADR.

Secondary objective

- To identify the risk factor that increase the occurrence of ADR

III. METHODOLOGY

The study was a prospective observational study conducted over a duration of 6 months within the ICU department of Sri Ramakrishna Multi-speciality Hospital in Coimbatore. The primary objective of this study is to assess the prevalence of adverse drug reactions (ADRs) in the intensive care unit, investigate the spectrum of drug classes implicated, and evaluate the causality, preventability, and severity of each ADR. The sample size was 174, determined with a confidence interval of 95% and a margin of error of 5%. Inclusion criteria encompassed patients of any age and sex who experienced an ADR during their ICU stay. Exclusion criteria included patients with drug abuse, intoxication, overdose-related ADRs, unwilling participants, and those with insufficient record data. Methodologically, the study utilized Naranjo's causality assessment scale, Modified Hartwig's criteria for severity, and Schumock-Thornton preventability scale. Data were collected using a specially designed format capturing patient details such as name, age, gender, admission and discharge dates, medical and medication history, social history, and suspected medications causing ADRs.

IV. RESULTS

A total number of 174 patients 107 (61.49%) were men and 67(38.51%) were female. The maximum number of patients were 73 (40.95%) in late adulthood. System most affected were Gastrointestinal in 58(33.33%) patients. The drug class mostly associated with ADR was Antibiotics in 49(28.16%) (Table. No - 4). According to causality assessment by Naranjo's scale majority of ADRs in patients 117(67.24%) were probable (Table. No - 1). Severity of suspected ADRs were assessed by Hartwig's severity assessment scale, revealed that 93(53.44%) were mild (Table. No - 2). Preventability of suspected ADRs were assessed by using Modified Schumock and Thornton scale, revealed that 119(68.39%) are probably preventable (Table. No - 3). About 137(79.73%) patients recovered, 36(20.38%) cases the ADR decreased and 1(0.57%) fatal case were reported. In 174 cases, drugs suspected for ADR is dechallenged in 165 (94.82%) patients and rechallenged in 9 (5.17%).

Table. No – 1 CAUSALITY ASSESSMENT OF SUSPECTED ADRS – BY NARANJO's SCALE(n=174)

CAUSALITY ASSESSMENT –NARANJO's SCALE	NUMBER OF PATIENTS	PERCENTAGE (%)
Definite	2	1.14
Probable	117	67.24
Possible	55	31.60

Table. No – 2 SEVERITY OF SUSPECTED ADRS – BY HARTWIG'S SCALE (n=174)

SEVERITY	NUMBER OF PATIENTS	PERCENTAGE (%)
Mild	93	53.44
Moderate	78	44.82
Severe	3	1.74

Table. No - 3PREVENTABILITY OF SUSPECTED ADRS – BY SCHUMOCK AND THORNTON SCALE (n=174)

PREVENTABILITY	NUMBER OF PATIENTS	PERCENTAGE (%)
Definite	19	10.91
Probable	119	68.39
Not Preventable	36	20.68

Table. No – 4 COMMON DRUG CATEGORY CAUSING ADR (n=174)

DRUG	NUMBER OF PATIENTS	PERCENTAGE (%)
Antibiotics	49	28.16
Anticoagulant	17	09.77
Anti-ulcer	17	09.77
Anti-convulsant	15	08.62
Anti-Hypertensive	13	07.47
Diuretics	13	07.47
Anti-fungal	11	06.32
Analgesics	11	06.32
Steroids	11	06.32
Insulin	6	03.44
Oral Anti diabetic	2	01.14
NSAIDS	2	01.14
Others	7	04.02

V. CONCLUSION

In this study, the maximum number of patients were males. Majority of the patients are late adulthood. Antibiotics contributed to the majority of the ADRs, highlighting the importance of antibiotics prescription. The most affected organ systems were the gastrointestinal system. The majority of ADRs were probable in causality assessment, mild in severity and probably preventable. The identified risk factors influencing ADR were age, comorbidities, and multiple drug therapy. It is important to note that better knowledge of preventable ADRs could help to design preventive strategies to protect patients from being affected by these reactions unnecessarily. ICU patients are at high risk for single and multiple organ failure as well as failure of organ systems. Impairment of renal and hepatic function predisposes patients to significant complications resulting from ADRs. Promoting the implementation of standardized procedures will reduce occurrence of ADR and to ensure the patient safety in the Intensive Care Unit.

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