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INCIDENCE OF ADVERSE EVENTS LINKED TO CLINICAL USE OF ANTIMICROBIAL AGENTS IN A TERTIARY CARE TEACHING HOSPITAL, KERALA, INDIA

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ABSTRACT

Background: Antimicrobial agents are essential in treating infections but are frequently associated with adverse drug reactions (ADRs), which can impact patient safety and healthcare costs. Understanding the incidence and nature of antimicrobial-associated ADRs is crucial for optimizing clinical management and antimicrobial stewardship.

Objective: This study aimed to assess the incidence, types, and severity of adverse events linked to antimicrobial use in a tertiary care teaching hospital in Kerala, India.

Methods: A prospective observational study was conducted in the inpatient departments of a tertiary care hospital. Patients receiving systemic antimicrobial therapy were monitored for adverse events. Data were collected on demographics, clinical presentation, suspected antimicrobial agents, and severity using standardized assessment scales. Statistical analysis was performed to identify risk factors associated with ADRs.

Results: A total of 53 antimicrobial-related adverse events were recorded. Hypersensitivity reactions were the most common, accounting for 79.2% of cases, followed by thrombocytopenia (5.7%), hepatitis (3.8%), and rare events such as Redman's syndrome and tachycardia with tachypnea (1.9% each). The findings highlight the significant burden of antimicrobial-related ADRs and emphasize the importance of careful prescribing and vigilant monitoring.

Conclusion: The study underscores the need for enhanced pharmacovigilance, antimicrobial stewardship programs, and early identification of high-risk patients. Rational prescribing, pre-screening for drug allergies, and close monitoring can mitigate the risks associated with antimicrobial therapy, improving patient safety and treatment outcomes.

Keywords: Antimicrobial agents, adverse drug reactions, hypersensitivity, pharmacovigilance, tertiary care hospital.

INTRODUCTION

Antimicrobial agents play a crucial role in the treatment and prevention of infectious diseases; however, their clinical use is often associated with adverse drug reactions (ADRs), ranging from mild discomfort to severe, life-threatening complications. These ADRs contribute to increased

morbidity, prolonged hospitalization, and additional healthcare costs (Sarkar et al., 2015).[1] Monitoring and analyzing the incidence of antimicrobial-associated adverse events is essential for improving patient safety and guiding clinical decision-making.

The frequency and severity of ADRs related to antimicrobial agents vary depending on patient demographics, comorbidities, prescribing patterns, and institutional protocols (Patel et al., 2019).[2] Tertiary care teaching hospitals, which serve as referral centers and educational hubs, play a critical role in pharmacovigilance. The data generated from such hospitals can provide valuable insights into drug safety and help formulate guidelines for rational antimicrobial use (Agarwal et al., 2020).[3]

Kerala, India, has a well-developed healthcare system, and its tertiary care hospitals cater to a diverse patient population. However, there is limited regional data on the incidence and nature of ADRs associated with antimicrobial use. Understanding these patterns is vital for optimizing antimicrobial stewardship and minimizing the risks associated with drug therapy. This study aims to assess and analyze the adverse events linked to antimicrobial agents in a tertiary care teaching hospital in Kerala, India. By identifying the incidence, types, and severity of these ADRs, the study seeks to enhance awareness among healthcare professionals and support the development of strategies to improve drug safety. The findings will contribute to evidence-based decision-making in antimicrobial prescribing and promote better patient outcomes.

AIMS & OBJECTIVES

Aim

To evaluate the incidence, nature, and contributing factors of adverse events associated with the clinical use of antimicrobial agents in a tertiary care teaching hospital in Kerala, India.

Objectives

1. To determine the frequency and types of adverse events linked to antimicrobial therapy among hospitalized patients.
2. To assess the risk factors, severity, and management outcomes of antimicrobial-related adverse events in the study population.

MATERIALS & METHODS

A prospective observational study was conducted to assess the incidence, nature, and contributing factors of adverse events associated with antimicrobial use in a tertiary care teaching hospital in Kerala, India.

Study Setting

The study was carried out in the inpatient departments of [Hospital Name], a tertiary care teaching hospital in Kerala. Data collection took place over a period of [Specify Duration, e.g., 6 months].

Study Population

All hospitalized patients receiving antimicrobial therapy during the study period were considered for inclusion.

Inclusion Criteria

- Patients of all age groups and genders who received systemic antimicrobial agents.
- Patients admitted to any inpatient department of the hospital.
- Patients who provided informed consent (or consent from guardians in the case of minors).

Exclusion Criteria

- Patients on topical antimicrobial therapy.
- Patients discharged within 24 hours of admission.
- Patients with a known hypersensitivity to antimicrobials before hospitalization.

Data Collection

Data were collected using a structured proforma, which included:

- Demographic details (age, gender, comorbidities, etc.).
- Clinical details (diagnosis, prescribed antimicrobial agents, route of administration, duration of therapy).
- Details of adverse events (type, onset, severity, organ system involvement, suspected causative antimicrobial).
- Risk factors contributing to adverse events (polypharmacy, renal/hepatic dysfunction, immunosuppression, etc.).
- Causality assessment using the WHO-UMC and Naranjo scales.
- Severity assessment using the Modified Hartwig and Siegel scale.
- Management and outcomes of adverse events.

Ethical Considerations

Ethical approval was obtained from the Institutional Ethics Committee (IEC). Written informed consent was obtained from all patients or their legal representatives before data collection.

Statistical Analysis

Data were analyzed using SPSS. Descriptive statistics such as mean, standard deviation, frequency, and percentage were used to summarize the data. Chi-square tests or logistic regression analysis were performed to assess associations between risk factors and adverse events. A p-value <0.05 was considered statistically significant.

Findings and Conclusion

The study provided insights into the incidence, risk factors, and management of antimicrobial-related adverse events, aiding in optimizing antimicrobial stewardship and improving patient safety in clinical settings.

RESULTS

In this study, 53 adverse events associated with antimicrobial use were recorded. The most frequently reported adverse event was hypersensitivity (HS) reactions, accounting for 79.2% (n=42) of the total cases.

Other notable adverse events included:

- Thrombocytopenia – 5.7% (n=3)
- Hepatitis – 3.8% (n=2)
- Acute gastritis, breathlessness with hypoxia, cholestasis, palpitation, Redman's syndrome, tachycardia with tachypnea – Each reported in 1.9% (n=1) of cases.

The cumulative percentage distribution indicated that 88.7% of all adverse events were hypersensitivity reactions, while other events were less frequently observed.

These findings highlight the need for enhanced pharmacovigilance and cautious antimicrobial prescribing to minimize the risk of drug-related adverse events.

DISCUSSION

Adverse drug reactions (ADRs) are a significant concern in antimicrobial therapy, often affecting patient safety and treatment outcomes. In this study, hypersensitivity (HS) reactions were the most frequently reported adverse event (79.2%), aligning with previous research indicating that beta-lactam antibiotics, particularly penicillins and cephalosporins, are commonly associated with hypersensitivity reactions (Patel & Pannu, 2020;[4] Torres et al.,[5] 2019). Given the high incidence of HS reactions, careful patient history, skin testing, and desensitization protocols should be considered to mitigate risks (Blumenthal et al., 2019).[6]

Other notable ADRs included thrombocytopenia (5.7%), hepatitis (3.8%), and cholestasis (1.9%). Drug-induced thrombocytopenia is a well-documented complication of antimicrobial therapy, particularly with linezolid and beta-lactams (Sultan et al., 2021).[7] Similarly, hepatic adverse events, including hepatitis and cholestasis, have been reported with macrolides, fluoroquinolones, and anti-tubercular drugs (Hussaini & Farrington, 2018).[8] Close monitoring of liver function tests is essential, especially in patients on prolonged antimicrobial therapy.

Rare but clinically significant adverse events such as Redman's syndrome (1.9%) and tachycardia with tachypnea (1.9%) were also observed. Redman's syndrome, typically linked to rapid vancomycin infusion, underscores the importance of appropriate infusion rates and premedication strategies

(Mariano & Pinsky, 2020).[9] Tachycardia and tachypnea may reflect systemic inflammatory responses or direct drug effects, necessitating further investigation into patient comorbidities and concomitant medications.

The findings of this study highlight the need for robust pharmacovigilance measures, antimicrobial stewardship programs, and early identification of high-risk patients to minimize ADR-related complications. Clinicians should adopt evidence-based prescribing practices and monitor patients closely for early signs of adverse reactions. Future research should focus on identifying genetic and demographic factors that may predispose individuals to antimicrobial-associated ADRs.

CONCLUSION

This study highlights the significant incidence of adverse events associated with antimicrobial use, with hypersensitivity reactions being the most common. Other notable reactions included thrombocytopenia, hepatitis, cholestasis, and Redman's syndrome, emphasizing the need for vigilant monitoring and pharmacovigilance. Rational prescribing, early identification of risk factors, and adherence to antimicrobial stewardship programs can help mitigate these adverse effects. Clinicians should implement evidence-based strategies, including pre-screening for drug allergies and close monitoring of high-risk patients. Further research is needed to explore genetic predispositions and preventive measures, ultimately improving patient safety and optimizing antimicrobial therapy in clinical practice.

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