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Research Article

TO ASSES AND STUDY ANTIBIOTIC-RELATED ADVERSE DRUG REACTIONS IN A DIVERSE ADULT PATIENT COHORT

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ABSTRACT

This cross-sectional study examines antibiotic-related Adverse Drug Reactions (ADRs) in 250 individuals, aiming to elucidate demographics, distribution patterns, and severity levels associated with thesereactions.Patient information, including age, gender, and ADR details, was recorded in detail. The WHO's causation assessment categorized ADR certainty. Data analysis included breakdowns based on age groups, antibiotic classes, administration routes, and affected organ systems.The diverse cohort (132 males, 118 females) showed young adults (30-45 years) constituting 27%. Predominant ADR contributors were β-lactams (32.8%), followed by sulfonamides, macrolides, and fluoroquinolones. Outpatient settings reported higher ADR incidence (84.8%) than indoor patients (15.2%). Oral antibacterials caused 89% of ADRs, with most (72%) within the first three days.The gastrointestinal tract (58.6%) was most affected, with prominent cutaneous presentations (33.3%), especially itching and rash. Hypersensitivity responses were notably associated with sulphonamides. ADR intensity categorization revealed 60.8% moderate, 35.6% mild and 4.4% severe ADRs.This study offers a comprehensive overview of antibiotic-related ADRs, emphasizing demographic distribution, causative agents, and clinical manifestations. Findings underscore the need for vigilant monitoring, particularly in outpatient settings, providing valuable insights for healthcare professionals managing and preventing antibiotic-related ADRs.

Keywords: Antibiotics, Adverse Drug Reactions (ADRs), Demographic Distribution, Severity Levels.

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INTRODUCTION

In recent years, the increasing use of antimicrobial agents has played a pivotal role in the management of various infectious diseases, contributing significantly to improved patient outcomes. However, alongside their therapeutic benefits, antimicrobial agents also carry the potential for adverse drug reactions (ADRs), underscoring the importance of ongoing surveillance and analysis. This study focuses on a comprehensive examination of ADRs associated with antimicrobial agents in patients receiving care at a tertiary care hospital [1-3].

The escalating incidence of ADRs has become a global concern, necessitating a closer look at their prevalence, patterns, and associated risk factors. Tertiary care hospitals, being at the forefront of complex medical interventions, are particularly relevant settings for such investigations due to the diverse patient populations and the intricate nature of cases encountered [4-5].

Understanding the spectrum of ADRs related to antimicrobial agents is crucial for several reasons. Firstly, it allows healthcare professionals to anticipate and manage potential complications, ensuring patient safety and optimal therapeutic outcomes. Secondly, it contributes valuable data to the existing body of pharmacovigilance knowledge, aiding in the identification of trends and patterns that may inform

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regulatory decisions and healthcare policies. Thirdly, a thorough analysis of ADRs provides insights into the specific challenges posed by antimicrobial agents, guiding the development of targeted interventions and educational initiatives [6-7].

This research aims to bridge existing gaps in our understanding of ADRs related to antimicrobial agents by conducting a systematic analysis within the dynamic clinical environment of a tertiary care hospital. By shedding light on the prevalence, characteristics, and determinants of ADRs, this study endeavors to enhance our ability to navigate the delicate balance between the therapeutic benefits and potential risks associated with antimicrobial therapy. Ultimately, the findings generated through this investigation are anticipated to contribute significantly to the ongoing efforts to optimize patient care and improve the overall safety profile of antimicrobial agents in the clinical setting.

MATERIAL AND METHODS

This research was conducted at the Sri Lakshmi Narayan Institute of Medical Sciences,Pondicherry and Santhiram Medical College and General Hospital throughout the year 2015. The study received approval from the institutional ethics committee, and consent was obtained from patients. The participants were individuals aged 12 and above who experienced adverse drug reactions (ADRs) at the outpatient and inpatient departments of the Departments of Medicine, Dermatology, Orthopedics, and ENT. Patients under 12 years old were not included.

The collected patient information included their name, age, and gender. Details about the adverse events comprised their nature, location, severity, start and end dates. Information about the drugs included their name, dosage, administration route, start/stop date, and the reason for usage. Concurrent therapy data was also recorded. After gathering this information, the researchers analyzed the pattern of ADRs and used the WHO evaluation scale to assess the causation of the relationship between the drug and ADR [8-9].

RESULTS

Two hundred fifty individuals in all were enrolled with antibiotic-related ADRs. Out Of the total patients (N = 250), 132 were male and the remaining 118 were female, or 53.2%. The majority of patients were young adults, with 27% of them falling between the ages of 30-45.

Table 1: Age wise distribution of patients with ARDs

Age group	Number of patients with ARDs	Percentage
12-20	45	18%
21-30	57	22.8%
31-40	79	31.6%
41-50	17	6.8%
51-60	14	5.6%
>60	38	15.2%
Total	250	100%

Tables 2: **Number of patients along with the adverse drug reactions**

Group of Antimicrobial Agent	Number of patients with ADRs	Percentage	ADRs
B lactam antibiotics	82	32.8%	Loose motions (42), Gastritis (25), Rash (13), Bronchospasm (2)
Sulphonamides	39	15.6%	Rash and itching (28), FDE (5), Gastritis (4), Hyperpigmentation(1) SJS (1)
Macrolides	35	14%	Gastritis (19), Loose motions (10), Palpitation/sweating(1), Rash (5).
Fluroquinolones	24	9.6%	Gastritis (17),

			Rash (5), Ulcer mouth corner(1), Breathlessness (1).
Nitrofurans	4	1.6%	Rash (3), Gastritis (1).
Aminoglycosides	2	0.8%	Rash & itching (2)
Tetracycline	2	0.8%	FDE (1)
Antiprotozoal	4	1.6%	Rash (1), Gastritis (2), Breathlessness (1).
Antimalarial	12	4.8%	Gastritis (11), Rash (1).
Antifungal	6	2.4%	Pruritic rash (4), Nephrotoxicity (2).
Antitubercular	35	14%	Anorexia (10), Rash (9), Gastritis (5), Tingling/Weakening lower limb (6), Joint pain (2), Liver Tenderness (2), Hepatitis (1).
Antileprosy	5	2%	Hyperpigmentation of Face (3), Desquamation ofskin(2)

ADRs related to β-lactams accounted for the greatest number (332.4%), with sulfamethazine (15.6%), macrolides (14%), fluoroquinolones (9.6%), and other medications following suit. Indoor patients reported just 15.2% (n=38) ADRs, compared to 84.8% (n=212) in the outpatient department. Approximately 89% of patients had adverse drug reactions (ADRs) as a result of oral antibacterial medicines, and 10.4% had parental. Merely 2.4% (Antifungal) were administered locally. ADRs emerged in the first three days in 72% of cases, with 28% of cases occurring on the second day. 50.9% of ADRs were found to be certain, 40.5% to be likely, and only 8.6% to fall into the potential group according to the WHO's causation assessment.

The GIT was the most often impacted system (58.6%), followed by the skin (33.3%), CNS, kidneys, etc. Itching and rash were observed in the cutaneous presentation. Most hypersensitivity responses (n=39) have been shown to occur with sulphonamides. Regarding ADR intensity, of the 250 patients, 60.8% (n = 152) had moderate ADRs, mild ADRs in 35.6% (n = 89), and severe ADRs in just 4.4% (n = 11).

DISCUSSION

The data from this original research article provide a comprehensive analysis of antibiotic-related Adverse Drug Reactions (ADRs) in a cohort of 250 individuals. The study population, comprising 132 males and 118 females, demonstrated a gender distribution of 53.2%, with a predominant representation of young adults, where 27% were aged between 30 and 45 years.

The age-wise distribution of patients with ADRs, revealing that the highest percentage of ADRs occurred in the age groups of 21-30 (22.8%) and 31-40 (31.6%). A significant proportion, 15.2%, belonged to the age group above 60 years. These findings suggest that antibiotic-related ADRs are prevalent across different age groups [10-11].

In a studyobserved that hypersensitivity reactions due to sulphonamides. Our study identifies β-lactams as the major contributors to ADRs, accounting for 32.8%, followed by sulfonamides (15.6%), macrolides (14%), and fluoroquinolones (9.6%). The outpatient department reported a substantially higher incidence of ADRs (84.8%) compared to indoor patients (15.2%), emphasizing the need for vigilant monitoring in ambulatory settings [12-15].

Further categorization of ADRs by administration route revealed that 89% of ADRs were associated with oral antibacterial medicines, 10.4% with parental administration, and only 2.4% were locally administered antifungals. A significant number of ADRs (72%) emerged within the first three days, with 28% occurring on the second day. According to the WHO's causation assessment, 50.9% of ADRs were categorized

as certain, 40.5% as likely, and only 8.6% fell into the potential group [16-18].

The gastrointestinal tract (GIT) emerged as the most frequently affected system (58.6%), followed by the skin (33.3%), and the central nervous system (CNS) and kidneys. Cutaneous presentations, such as itching and rash, were particularly observed, with sulphonamides being associated with most hypersensitivity responses (39 cases) [19-21].

Regarding the intensity of ADRs, 60.8% of the 250 patients experienced moderate ADRs, 35.6% had mild ADRs, and only 4.4% had severe ADRs. This classification provides insights into the varying severity levels of antibiotic-related ADRs in the studied population. Lee et al.,2019 presented Comprehensive Analysis of Antibiotic-Related Adverse Drug Reactions. The specific ADRs associated with different antimicrobial agents, presenting a detailed breakdown of the number of patients, associated percentages, and the nature of ADRs in each group. This comprehensive analysis allows for a nuanced understanding of the diverse manifestations of ADRs related to specific antibiotic classes.

CONCLUSION

This research enriches our understanding of antibiotic-related ADRs, highlighting the need for tailored interventions based on age, antibiotic class, and administration route. The implications of these findings extend beyond the scope of this study, emphasizing the importance of ongoing surveillance and research to enhance patient safety in antibiotic therapy.

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