Journal of Neonatal Surgery
ISSN(Online): 2226-0439
Vol. 13, (2024)
https://www.jneonatalsurg.com

OPEN ACCESS

A Study on the Patterns of Antibiotic-Associated Adverse Drug Reactions in a Multispecialty Hospital

Leena Sahu*[1], Dr. Gaurav Tiwari[1], Dr. Mrinal Das[2], Dr. Vaibhav Ottalwar[2], Dr. Naveen Gupta[1]

[1]Patel College of Pharmacy, Madhyanchal Professional University (MPU) Ratibad, Bhopal, MP, India.

[2]Apollo Hospitals Bilaspur, Chhattisgarh, India.

***Corresponding Author**:

Leena Sahu,

Patel College of Pharmacy, Madhyanchal Professional University, Ratibad, Bhopal, MP, India.

Email ID: sahuleena.sahu@gmail.com

Cite this paper as: Leena Sahu, Dr. Gaurav Tiwari, Dr. Mrinal Das, Dr. Vaibhav Ottalwar, Dr. Naveen Gupta, (2024) A Study on the Patterns of Antibiotic-Associated Adverse Drug Reactions in a Multispecialty Hospital. *Journal of Neonatal Surgery*, 13, 992-997.

ABSTRACT

Adverse drug reactions (ADRs) are a major concern in clinical practice, particularly among hospitalized patients receiving multiple medications. Antibiotics, one of the most widely prescribed drug classes, are frequently implicated and contribute substantially to morbidity and healthcare burden. This retrospective observational study was conducted over one year at a multispecialty hospital in Bilaspur, Chhattisgarh, to evaluate the incidence, causality, severity, and patterns of antibiotic-associated ADRs. Among 15,430 hospital admissions, 65 ADRs were identified, of which 38 (58.5%) were linked to antibiotics. The elderly population (≥45 years) was most affected, while males and females were equally represented. Cefoperazone + Sulbactam was the most frequently implicated antibiotic (31.6%), followed by Ceftriaxone and Piperacillin + Tazobactam. The predominant clinical manifestations were generalized itching and skin rashes. Causality assessment showed most reactions were "probable," and severity analysis revealed they were predominantly mild to moderate. These findings highlight the need for vigilant pharmacovigilance, rational antibiotic prescribing, and early recognition of hypersensitivity reactions. Strengthening antibiotic stewardship programs and continuous monitoring are crucial to minimize antibiotic-related ADRs and enhance patient safety in hospital settings.

1. INTRODUCTION

Adverse drug reactions (ADRs) are unintended and harmful effects of medications that increase morbidity, mortality, and healthcare costs, particularly in hospitalized patients receiving multiple drugs [1]. Antibiotics are among the most common causes of ADRs, with studies reporting 25–40% of ADRs linked to their use. In India, antibiotic consumption has risen sharply due to high infectious disease burden, availability of inexpensive generics, and over-the-counter access. This widespread use contributes not only to antimicrobial resistance but also to a higher risk of ADRs, many of which are preventable. Monitoring and reporting antibiotic-associated ADRs is therefore essential for improving patient safety. This study was conducted to evaluate the incidence, causality, severity, and patterns of antibiotic-related ADRs in a multispecialty hospital in Bilaspur, Chhattisgarh [2].

Adverse Drug Reactions (ADRS)

Adverse drug reactions (ADRs) are harmful or unintended effects of medications that can affect a patient's physical, mental, or functional health. They are especially concerning in hospitalized patients due to complex conditions and multiple medications, often leading to increased morbidity, mortality, longer hospital stays, and higher healthcare costs. The occurrence of ADRs varies globally, influenced by factors such as disease prevalence, economic status, culture, and ethnicity. Reported incidence ranges from 0.15% to 30%. Antibiotics are a common cause of ADRs; one Indian study attributed 40.9% of ADRs to antibiotics, while an Australian study reported 25%. These findings highlight the importance of pharmacovigilance and safe prescribing practices to reduce ADR risks [3]. Drugs are among the most commonly used medical interventions, primarily aimed at alleviating suffering and improving health outcomes. However, it has long been recognized that medications can also cause harm, reflecting the truth in the saying: "Drugs are double-edged weapons." While they offer therapeutic benefits, they may also lead to unintended and potentially harmful effects. Therefore, monitoring and reporting adverse drug reactions (ADRs) are essential for identifying patterns and trends within the local population, helping to enhance patient safety and improve overall healthcare practices [4].

Antibiotic

Antibiotics are among the most widely prescribed medications globally, with their use continually rising. According to the World Health Organization (WHO), global antibiotic consumption between 2016 and 2018 ranged from 4.4 to 64.4 Defined Daily Doses (DDD) per 1000 inhabitants per day. India ranks among the top antibiotic consumers, with usage increasing from 3.2 billion DDDs in 2000 to 6.5 billion in 2015—an increase of 103%. Globally, antibiotic use rose from 8.2 to 13.6 DDD per 1000 inhabitants per day during the same period, representing a 65% increase. This surge in antibiotic use in India is largely attributed to a high burden of infectious diseases, widespread production of inexpensive generic antibiotics, rising income levels, and expanded government healthcare coverage. Additionally, the easy availability of antibiotics without a prescription has been a major concern. To address this, the Indian government has mandated red strip labeling on antibiotic packaging to discourage over-the-counter dispensing [5]. However, increased antibiotic use is closely linked to the growing problem of antimicrobial resistance and a higher incidence of adverse drug reactions (ADRs). The WHO defines an ADR 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 modification of physiological function". ADRs can result from any drug class, but antibiotics are particularly implicated. More than half of hospitalized patients receive at least one antibiotic during their stay, and studies suggest that 55.5% of antibiotic-related ADRs are preventable, contributing significantly up to 20–50% to total drug expenditure in hospitals [6].

2. METHODOLOGY

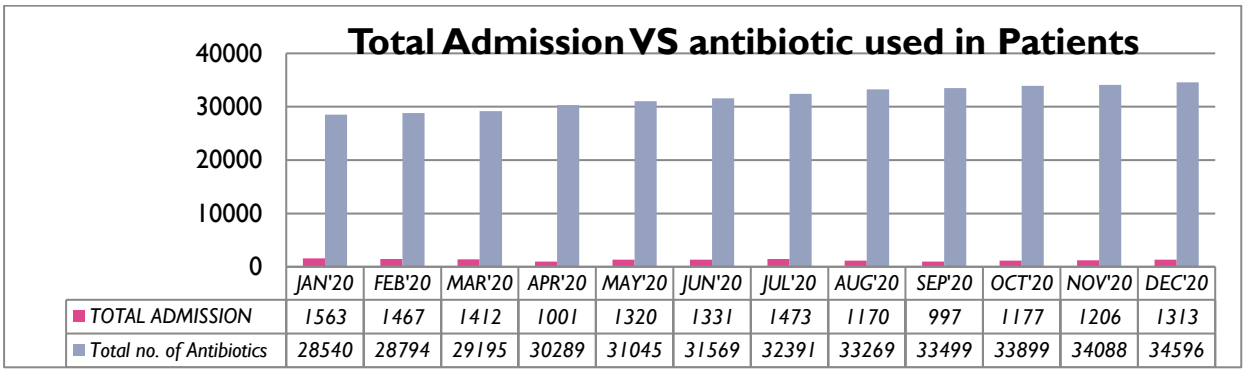
This study was designed as a retrospective, observational analysis conducted over a period of one year at a Multispecialty hospital. The study population included all in patients who received antibiotics during the study period [7]. Patients of all age groups and both genders were considered, while those with incomplete medical records or adverse drug reactions (ADRs) not associated with antibiotics were excluded. Reported ADRs were identified from hospital records, case sheets, pharmacovigilance forms, and other available clinical documentation [8, 9]. Data were collected from multiple sources, including patient case sheets, investigation reports, personal interviews with reporting clinicians or staff, as well as direct interviews with patients or their attendants. Additional information was gathered from the patients' past medication histories, previous prescriptions, medical and surgical intervention records, and referral letters [10]. Causality assessment of the reported ADRs was conducted using the Naranjo Causality Assessment Scale, which classifies reactions as definite, probable, or possible. To evaluate the preventability of ADRs, WHO probable Scale was used, categorizing them Certain, Probable, Possible, Unassessable, Unlikely, Conditional / Unclassified based on structured criteria. The modified Hartwig and Siegel severity scale was employed to determine the severity of the ADRs, classifying them as mild, moderate, or severe depending on factors such as the need for treatment modifications, extended hospital stay, or the level of disability caused by the reaction.

Collected Data and Reporting Source

Apollo Hospital Bilaspur Chhattisgarh is a 300-bed Multispecialty hospital and is one of the largest health care centres in Bilaspur Chhattisgarh. Severance was registered as a Regional Pharmacovigilance Center in 2020 and is using a computer-based pharmacovigilance monitoring system. ADR reporting is voluntary and can be reported by a physician, pharmacist, nurse, or patient who recognizes the ADR event. These voluntary reports are reviewed by the ADR-monitoring team, which includes a physician and Clinical pharmacist. Then the clinical and demographic information of the reported ADR is stored in a pharmacovigilance system database and noted in the patient's electronic medical record (EMR). The computerized system improves medication safety by alerting medical practitionersto drug allergies and any drug-drug interactions the patient experienced.

Discussion

ADR in 2020



	JAN'20	FEB'20	MAR'20	APR'20	MAY'20	JUN'20	JUL'20	AUG'20	SEP'20	OCT'20	NOV'20	DEC'20
TOTAL ADMISSION	1563	1467	1412	1001	1320	1331	1473	1170	997	1177	1206	1313
Total no. of Antibiotics	28540	28794	29195	30289	31045	31569	32391	33269	33499	33899	34088	34596

Figure 1. Monthly Trends of Hospital Admissions and Antibiotic Usage in 2020.

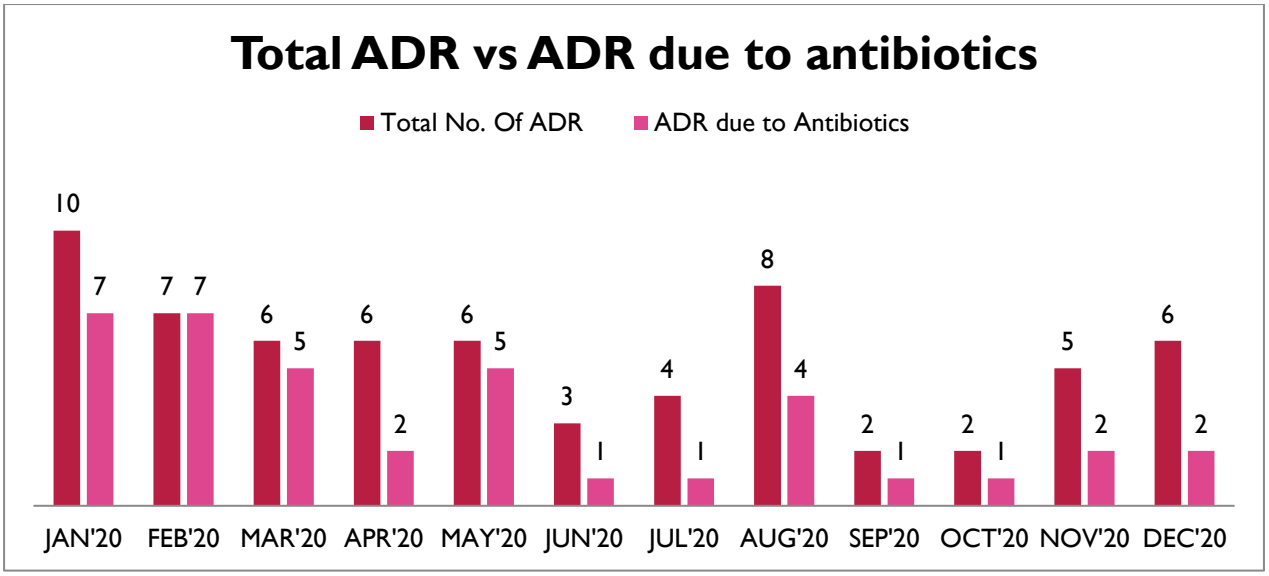


Figure 2. Monthly Distribution of Total Reported ADRs vs Antibiotic-Associated ADRs in 2020.

In 2020, a total of 15,430 hospital admissions were recorded, during which 381,174 antibiotics were administered. The monthly trend of hospital admissions remained relatively stable, while the overall number of antibiotics used steadily increased throughout the year, peaking in December. This relationship is illustrated in Figure 1, which shows the comparison between total admissions and antibiotic usage across months. Despite stable admission numbers, the occurrence of adverse drug reactions (ADRs) fluctuated. Out of 65 ADRs reported in 2020, 38 (58.46%) were attributed to antibiotics. The monthly distribution of ADRs demonstrated that January and February recorded the highest numbers, whereas September and October reported the fewest. Figure 2 highlights this pattern, contrasting the total ADRs with those specifically associated with antibiotics. Demographic analysis revealed that ADRs were equally distributed between males and females (19 each). Age-wise, the elderly population (≥45 years) was the most affected group, accounting for 50% of antibiotic-associated ADR cases, followed by adults (39%) and children (11%), as summarized in Table 1. Drug-wise analysis showed that Cefoperazone + Sulbactam was the most frequently implicated antibiotic (12 cases), followed by Ceftriaxone and Piperacillin + Tazobactam (5 cases each). Other antibiotics contributed fewer cases, as detailed in Table 2. With regard to clinical presentation, generalized itching was the most commonly reported ADR (16 cases, 42.1%), followed by itching with rashes (6 cases, 15.7%) and facial rashes (2 cases, 5.2%). Other symptoms such as swelling, hypersensitivity, and systemic allergic reactions were less frequent, but still clinically significant. These findings are summarized in Table 3.

Table 1. Age and Gender Distribution of Patients with Antibiotic-Associated ADRs

S. No.	Population(age)	Male	Female	Total
1	Children (0-18yrs) -4	1	3	4
2	Adults (19-45yrs) -15	6	9	15
3	Elderly (45yrs and above) -19	12	7	19
Total		19	19	38

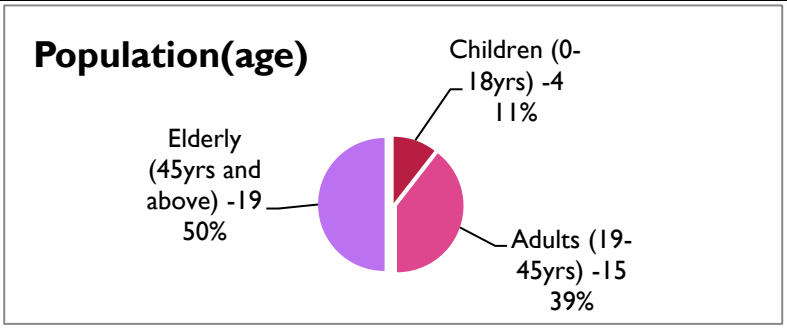


Figure 3. Age-Wise Distribution of Antibiotic-Associated ADR Cases

Among the 38 reported antibiotic-related ADR cases, males and females were equally affected (19 each). The elderly group (45+ years) had the highest number of cases (19), followed by adults (15), and children (4). Adult females (9) and elderly males (12) were the most affected within their respective age groups.

Table 2. Frequency of Antibiotic-Associated ADRs by Drug

GENERIC NAME	COUNT
Cefoperazone+Sulbactum	12
Ceftriaxone	5
Piperacillin+Tazobactam	5
Meropenem	3
Ceftriaxon+Tazobactam	2
Cefuroxime	2
Amoxicillin+ Clavulanic Acid	1
Amoxicillin+Pota.Clavonic Acid /Metronidazole	1
Cefepime	1
Cefepime+Tazobactum	1
Ciprofloxacin	1
Colistimethate Sodium	1
Meropenem & Vancomycin	1
Metronidazole	1
Teicoplatin	1

A total of 38 antibiotic-related ADR cases involved various drugs. Cefoperazone + Sulbactam was the most frequently associated antibiotic (12 cases), followed by Ceftriaxone and Piperacillin + Tazobactam (5 each). Other antibiotics like Meropenem, Ceftriaxon + Tazobactam, and Cefuroxime had lower counts (2–3), while several others were linked to only one ADR case each.

Table 3. Clinical Manifestations of Antibiotic-Associated ADRs

ADR TYPE	Count
Itching All Over Body	16
Itching And Rashes All Over Body	6
Rashes Over Face	2
Allergic Reaction	1
Chest Pain , Headache And Rashes On Face	1
HYPERSENSIVITY REACTION (Shivering)	1
Itching & Rashes In The Abdominal And Both Limb	1
Itching ,Multiple Rashes Over Trunk ,	1

Itching All Over Chest	1
Itching And Swelling Under Both Eye And Breathing Difficulty	1
Itching On Forehead And Back	1
Itching On Leg	1
Rashes All Over Body	1
Rashes And Redness In All Over Body	1
Redness And Rashes On Upper Lip	1
Swelling Of Lips Itching All Over Body	1
Swelling Of Whole Body ,Rashes All Over Body Upper And Lower Limb	1

The most common adverse drug reaction was itching all over the body (16 cases), followed by itching and rashes all over the body (6 cases) and rashes over the face (2 cases). Other types of ADRs, including allergic reactions, swelling, localized rashes, and hypersensitivity, were each reported only once, indicating a wide variety of less frequent individual symptoms.

3. RESULT

Out of 15,430 hospital admissions in 2020, a total of 65 Adverse Drug Reactions (ADRs) were reported, with 38 (58.46%) attributed to antibiotic use. The most frequently implicated antibiotic was Cefoperazone + Sulbactam (12 cases). ADRs were equally distributed between males and females; with the elderly population (45+ years) being the most affected age group. The most common ADR manifestation was generalized itching reported in over 57% of cases.

4. CONCLUSION

This study demonstrates that antibiotics remain a leading cause of adverse drug reactions (ADRs) in hospitalized patients, with more than half of all reported ADRs in 2020 linked to antibiotic use. The burden was greatest among the elderly population (≥45 years), reflecting their heightened vulnerability due to comorbidities, polypharmacy, and altered pharmacodynamics. Among the drugs implicated, β-lactam combinations such as Cefoperazone + Sulbactam, Ceftriaxone, and Piperacillin + Tazobactam were most frequently associated with ADRs. The predominant clinical manifestations were generalized itching and cutaneous rashes, which, while often mild to moderate, carry the potential for escalation into more severe hypersensitivity reactions if not promptly recognized. These findings underscore the importance of strengthening antibiotic stewardship programs, enhancing pharmacovigilance practices, and promoting rational prescribing habits to reduce preventable drug-related harm. Early recognition of hypersensitivity symptoms and systematic ADR reporting should be integrated into routine clinical practice to improve patient outcomes. Finally, increasing awareness among healthcare professionals and patients, alongside continuous monitoring, will be essential strategies to ensure safer and more effective use of antibiotics in hospital settings.

Acknowledgement

Correspondence authors sincerely acknowledge Guide, Dean sir for continuous support and guidance.

Conflict of Interest

No conflict of interest.

Funding

NIL

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