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Original Research Article

A Prospective Observational Study of Adverse drug reaction pattern to commonly used antibiotics in a Tertiary Care Hospital

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Abstract

Background: For the prevention, diagnosis, and treatment of all diseases, drugs are essential. In addition to being helpful to patients, they can cause undesirable side effects known as adverse drug reactions (ADRs). This study's objective was to assess and examine antibiotic-related adverse drug responses in patients in a tertiary care hospital in Bhagalpur, Bihar.

Methods: From February 2025 to June 2025, the Department of Pharmacology at Jawaharlal Nehru Medical College and Hospital in Bhagalpur, Bihar, conducted this prospective observational study. Patients were collected from the hospital ward and various OPD departments of JLNMCH in Bhagalpur, Bihar.

Results: A total of 69 adverse drug reactions were chosen for this investigation. There were 20 female and 49 male. The department of general medicine had the most patients, followed by general surgery and dermatology. The Naranjo scale was used to assess a drug's relationship to adverse drug reactions. The safety of drugs used in medicine must be evaluated and monitored, as well as public health, in order to prevent or lessen patient harm and hence enhance public health.

Conclusion: The most often prescribed drugs are antibiotics, therefore tracking adverse drug reactions (ADRs) may help clinicians identify and treat ADRs early on, protecting patients' quality of life as soon as possible.

Keywords: Antibiotics, ADR, Naranjo scale.

Introduction

"Any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function" is how the World Health Organization (WHO) defines adverse drug reaction (ADR). Adverse drug reactions (ADRs) account for 6.5% of hospital admissions in the National Health Service (NHS), making them the seventh most common cause of death.(1) The expenses associated with ADRs can occasionally surpass the cost of disease treatment.(2) Because infectious disorders are more widespread, particularly in India, antibiotics are thought to be the most often utilized drugs in hospital settings. These are thought to be the primary cause of ADRs.(3,4) Several studies in the Indian population have found that antibiotics are responsible for 3.2–40.9% of ADRs.(5-8) Self-drug, over-the-counter use, and illogical prescriptions could be the cause of this. Antibiotic resistance can also result from the overuse and irrational usage of antibiotics.(9) As a result, using antibiotics sensibly is essential for good health.

Since "drugs are double-edged weapons," as Phatak et al. correctly stated, ADR monitoring is an essential component of a patient's treatment.(10) The Uppsala Monitoring Center, Sweden, was first created in 1971 in cooperation with WHO and plays a significant role in the upkeep of the global database of ADRs. Pharmacovigilance centers are being set up in India's tertiary care facilities to prevent and track adverse drug reactions. ADRs can also be prevented by instituting an antibiotic policy in each institution and making sure that doctors administer the best antibiotic option.

Material and Methods

From February to June 2025, this prospective observational study was carried out in the pharmacology department of Jawaharlal Nehru Medical College and Hospital in Bhagalpur, Bihar. ADRs were collected from different departments like General medicine, Dermatology, Pediatrics,

Orthopaedics, Pulmonology and general surgery. The trial included all patients who experienced an adverse drug reaction (ADR) during the study period, regardless of their age or sex. Nursing mothers and pregnant women were not included. The case record form contained demographic information such as the patient's age, sex, marital status, medical and surgical history, allergies, and use of herbal remedies and cosmetics. On the case record form, the patient's prescription was recorded, along with the drug, dosage, frequency, and length of therapy.

The Rawlins and Thomson, Naranjo, and modified Hartwig scales were used to evaluate the severity, causation, and type of reactions, respectively.

Results

There were 69 ADRs reported during this study period. Twenty (36.3%) of individuals were female, and 49 (63.7%) were male (Table 1). ADRs were experienced by 57 (82.6%) adults and 12 (18.4%) children under the age of 12 (Table 2).

Table 1: Distribution of ADR's based on gender of the patient

Sex	No. of patients	Percentage
Male	49	63.7%
Female	20	36.3%
Total	69	100.0%

Table 2: Distribution of ADR's based on the age group of patients

Age group	No. of patients	Percentage
Adult	57	82.6%
Children	12	18.4%
Total	69	100.0%

As shown in Table 3, the maximum number of ADRs were received from General Medicine department-28, followed by Dermatology -14, Pediatrics -10, Orthopaedics -9, Pulmonology - 5 and General Surgery-3. The most commonly affected organ system was Gastrointestinal system -36(52.17%) followed by skin-28 (40.57%), Respiratory system-3 (4.34%) and urinary system-2 (2.89%). This is depicted in Table 4.

Table 3: Number of ADR's received from different – departments

Name of Departments	No. of patients
General Medicine	28
Dermatology	14
Pediatrics	10
Orthopaedics	9
Pulmonology	5
General Surgery	3

Table 4: Distribution of organ system affected due to ADR'S

Organ system	No. of patients	Percentage
Gastrointestinal system	36	52.17%
Skin	28	40.57%
Respiratory System	3	4.34%
Urinary System	2	2.89%

Table 5 shows that Piperacillin-16(23.18%) is causing the highest no. of ADRs i.e. followed by Ceftriaxone - 13(18.84%) and Cefotaxime-9(13.04%). Combination of Amoxicillin with Clavulanic acid showed 8(11.59%) of ADRs. Ofloxacin -7(10.14%) and Amikacin showed 5(7.24%) of ADRs.

Table 5: Antibiotics causing ADR'S

Drugs	No. of ADR'S	Percentage
Piperacillin	16	23.18%
Ceftriaxone	13	18.84%
Cefotaxime	9	13.04%
Amoxicillin + Clavulanic acid	8	11.59%
Ofloxacin	7	10.14%
Amikacin	5	7.24%
Norfloxacin	3	4.34%
Gentamicin	3	4.34%
Azithromycin	2	2.89%
Erythromycin	2	2.89%
Doxycycline	1	1.44%

Majority of the reactions were Type A Augmented reactions as shown in Table 6.

Severity of reported ADRs were assessed using the Modified and Siegel scale (Table 7). Most of the ADRs were mild 51(73.91%), 14(20.28%), were moderate and only a few 4(5.79%) were severe. In this study, ADRs were assessed based on Naranjo's Causality assessment scale. Most of the reported ADRs were possible-60(86.96%) and some were probable-9(13.04%) (Table 8).

From this study it was found that there was a recovery from ADRs in total of 132 (95.6%) patients, although 0% had fatal ADRs. Unknown outcome was 0%. 6(4.3%) cases were recovering (Table 9).

Table 6: Type of reaction (Classification according to Rawlin & Thomson)

Category	No. of ADR'S	Percentage
Type A	54	78.2%
Type B	15	21.8%

Table 7: Level of Severity of reported ADR'S (Using the modified Hartwig & Siegel scale)

Level of Severity	No. of ADR'S	Percentage
Mild	51	73.91%
Moderate	14	20.28%
Severe	4	5.79%

Table 8: Causality assessment (According to Naranjo's Scale)

Causality parameters	No. of ADR'S	Percentage
Definite	0	0%
Probable	9	13.04%
Possible	60	86.96%
Unlikely	0	0%

Table 9: Outcome

Parameters	No. of ADR'S	Percentage
Fatal	0	0%
Recovering	3	4.3%
Recovered	66	95.6%
Unknown	0	0%

Discussion

Antibiotics are always used to treat infections. Since the prevalence of drug resistance is increasing, action to encourage the prudent use of antibiotics is desperately needed. The most often used and abused drugs by both patients and doctors are antibiotics.(11) This study looked at post-marketing surveillance studies to determine the pattern of adverse drug responses for the antibiotic drug class. When administered properly, antibiotics are thought to be safer drugs that are used to treat and prevent a variety of infectious diseases. Second only to drugs provided for cardiovascular conditions, antibiotics are thought to be the most prescribed drugs worldwide.(12) In our study, there were more males than females. According to our research, piperacillin has the highest number of adverse drug reactions.

Tazobactum and piperacillin are typically used together. Every side effect that has been recorded is one that may happen with piperacillin by itself.

Diarrhea, nausea, vomiting, abdominal pain, and dermatological responses are among the side effects of piperacillin. Despite being minor, these reactions are frequent. Many infections can be effectively treated with piperacilin. Since it is the most often used antibiotic, the study would have seen the most negative consequences. The third-generation cephalosporins, ceftriaxone and cefotaxime, were the second class of drugs that caused adverse drug reactions in this investigation. The gastrointestinal and skin systems were the most frequently linked to adverse drug reactions to cephalosprins. Numerous investigations that have documented a high percentage of dermatological symptoms are in agreement with the findings.(13) The most frequent cause of maculopapular rash was amoxicillin, which was consistent with Ghosh et al.'s findings. Similar to the findings by Salvo et al., one patient in our study developed Stevens Johnson syndrome as a result of the combination of amoxicillin and clavulanic acid.(14) ADRs to beta lactum antibiotics were highest in the epidermis and its appendages, followed by the gastrointestinal system, according to the studies above (15) Signs and symptoms and patterns of organ system involvement were quite comparable, with gastrointestinal effects (dizziness, headache, or insomnia) predominating, followed by effects on the central nervous system (nausea, vomiting, diarrhea, or stomach pain). In regard to the reported adverse effects of Flouroquinolones, body aches along with muscle and joint pains were also

observed in a few number of patients on Ciprofloxacin.

Patients who were prescribed Gentamycin with Amikacin reported experiencing vertigo, tinnitus, and hearing difficulties. After using Gentamycin, a woman experienced myoclonus, which is characterized by involuntary muscle jerks and spasms. Amikacin was used to treat a youngster who had abnormal kidney function testing. (16, 17).

Compared to other antibiotics, Macrolide drugs caused fewer adverse responses. Both erythromycin and azithromycin had moderate side effects, including gastrointestinal problems. Since serious adverse events are uncommon, macrolides are regarded as one of the safest classes of anti-infectives used in clinical settings. Some patients experienced adverse reactions and erythematous rash. According to one study, people taking Doxycycline for malaria prevention experienced an erythematous rash in areas of their bodies that were exposed to the sun. Additionally, it was discovered that, in comparison to other antimicrobials, doxycycline did not result in a noticeably higher percentage of all skin occurrences.

According to Rawlin and Thompson, Type A majority was found in the analysis of reported ADR types. This outcome is consistent with research by Oshikoyo et al. and Starveva et al.(18) Type A responses can be avoided and are dose-related. About 21% of reactions are type B, which includes hypersensitivity reactions.(19)

Conclusion

The task of tracking adverse drug reactions is continuous, unrelenting, and continual. Pharmacovigilance is becoming more and more necessary as additional drugs are introduced to the market. It is essential to keep an eye on the negative effects of both newer and possibly dangerous drugs. According to the study's findings, our hospital environment has a decent rate of spontaneous reporting of antibiotic adverse drug reactions.

To guarantee drug safety, the health system should encourage the unprompted reporting of adverse drug reactions to antibiotics and other drugs, as well as appropriate documentation and routine reporting to pharmacovigilance centers.

All hospitals could benefit from the active participation of a skilled clinical pharmacist in identifying adverse drug reactions and providing education to medical workers about the importance of reporting incidents.

References

1. Hettihewa LM, Sirisena B. Causality assessment and the severity of the adverse drug reactions (ADR) actively detected in hospital-in patients in tertiary care hospital Sri Lanka: prospective observational survey. Asian J. Res Biol Pharm Sci. 2014;2(1):1-10.
2. World Health Organization. Pharmacovigilance. Available at:http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/index.html. Accessed 10 January 2015.
3. Patil SB, Raikar SR, Janardhan M, Rao YV, Bhaskar HN, VahilaN. A profile of adverse drug reactions in a rural tertiary care hospital. Nat J Physiol Pharm Pharmacol. 2016; 6(6):559-62.
4. Sriram S, Ghasemi A, Ramasamy R, Devi M, Balasubramanian R, Ravi TK. Prevalence of adverse drug reactions at a private tertiary care hospital in south India. J Res Med Sci. 2011; 16(1):16-25.
5. Vijaishri R, Andhuvan G. A prospective study on antibiotics-associated spontaneous adverse drug reaction monitoring and reporting in a tertiary care hospital. Asian J Pharm. 2017; 11(4):834-40.
6. Jindal M, Sharma RK. Antimicrobial-related adverse drug reaction in a tertiary care hospital. Asian J Pharm Clin Res. 2017; 10(8): 229-31.
7. Sharma S, Khajuria V, Mahajan V, Gillani Z, Richa, Tandon V. Adverse drug reactions profile of antimicrobials: A 3-year experience, from a tertiary care teaching hospital of India. Indian J Med Microbiol. 2015; m33(3): 393-400.
8. Geer M, Koul P, Tanki S, Shah M. Frequency, types, severity, preventability and costs of adverse drug reactions at a tertiary care hospital. J Pharmacol Toxicol Method. 2016; 81:323-34.
9. Park SH. Is antibiotic resistance microorganism becoming a significant problem in acute cholangitis in Korea. Clin Endosc. 2012; 45:111-2.
10. Phatak A, Nagari BG. Safety of medicines. Pharma Times. 2003; 35:19-21.
11. Fonacier L, Hirschberg R., Gerson. Adverse drug reactions to Cephalosporins in hospitalized patients with a history of penicillin allergy. Allergy Asthma Proc. 2005:26:135-41.
12. Tunger O, Dinc. G. Ozbakkaloglu B, Atman UC, Algun U. Evaluation of rational antibiotic use. Int. J. Antimicrbial agents 2000; 15:131-5.
13. Cross ref. Jose J. and P.G. Rao. Pattern of adverse drug reactions notified by spontaneous reporting in an Indian tertiary care teaching hospital. Pharmacol. Res, 54: 226-233.
14. Salvo F., Polimneni G. Maretti, U, Conforti A, Leone R, Leone O, et.al. Adversed drug reactions related to amoxicillin alone and in

association with clavulanic acid. Data fro spontaneous reporting in Italy. J. Antimicrobial Chemotherapy 2007: 60.121-6.
15. Marie RL, Sanders CV, Faro S, Janney A. Williams ww, Derks F, Aldridge KE, Piperacillin vs Carbenicillin in the therapy of serious infections. Arch. Intern. Med 1982, oct 25; 142(1).2000-2005.
16. Sarva, H and panichpisal, K. (2012). gentamicin induced myoclonus. A case report and literature review of antibiotics-induced myoclonus. Neurologist. 2012;18(6); 385-388.
17. Mudd, P.A, Edmunds, Al, Glatz, F. Campbell, K, C.M. & Rybak L.P. (2014). Ototoxicity. Medscape. (May7, 2012).
18. Oshikoyo, K.A. Najokamma O. F chukwara Ha, ojo 10, 2007.Adverse drug reactions in Nigerian children. Paediatric Perinat drug Ther 8,81-88.
19. Games, Rabeto E. Pascal D,2005, Epidemiology of hypersensitivity drug reactions curr. opin. allergy clin. Immunol 5, 309-316.