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A STUDY OF ADVERSE DRUG REACTION TO ANTIMICROBIAL AGENTS IN PATIENTS OF TERTIARY CARE HOSPITAL OF CENTRAL INDIA

Pharmacology

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KEYWORDS

Adverse drug reaction, Antimicrobial agents, Central India

Introduction

Drugs are the most common medical interventions, primarily used to relieve sufferings.[1] More than 50% of hospitalized patients and >70% of ICU patients receive Antimicrobial Agents (AMAs) for therapy or prophylaxis of infections.[2]

Adverse Drug Reactions (ADRs) are a major cause of morbidity and place a accountable burden on limited healthcare resources.[3] Adverse reaction can occur with any class of drugs. According to a study conducted by Novotny et al., the most troublesome classes of drugs contributing to Adverse Drug Reactions were antibiotics followed antitumor agents.[4] The prevalence of reported admissions resulting from ADRs accounts for approximately 5% (0.2 to 21.7%) in the developed countries, and at least one ADR has been reported to occur in 10-20% of hospitalized patients.[5,6]

Detecting ADRs and establishing preventive measures is essential for patient safety. Therefore, the importance of pharmacovigilance must be emphasized. Furthermore efficient spontaneous reporting system is necessary to uncover ADRs.[7] Adverse reaction monitoring and reporting are very important in identifying the adverse reaction trends in local population.[1]

Thus this study has been done to study the local pattern of ADRs to antimicrobial agents.

Material and Methods

After approval from institutional ethical committee this study was conducted at Gandhi medical college and Hamidia hospital, Bhopal for one year (2007) as thesis project. Patients aged more than 12 years with ADRs to antimicrobial from OPD/IPD of department of medicine, Dermatology, Orthopedics and ENT were included while below 12 years age excluded. Details about patients- Name, age and sex, Adverse Event- description, nature, localization, severity, start to course and outcome, about drug- name, dose, route, start/stop date and indication for use. Data for concurrent treatment was also recorded. After compilation data pattern of ADRs was studied and assessment of causality for drug ADR relation was done with help of WHO assessment scale.

Observation and Results

A total number of 222 patients were enrolled with ADRs due to antimicrobial. Out of all (N= 222) patients 53.2% (n=118) were males rest 46.8% (n=104) females. Most number of patients were young and young adults with highest percentage being between 31-40 years with 27%. Highest number of ADRs (332.4%) were reported with β-Lactams followed by Sluphonamide(15.8%), Macrolides (13.5%), Fluroquinolones (10%) and others. Outpatient department reported 83.8% (n=186) ADRs while indoor patients reported only 16.2% (n=36) patients. About 87% patients shown to have ADRs due to antimicrobial agents received drug orally, 10.4% had parentral and only 2.7% (Antifungal) had local administration. Most of the ADRs were manifested in first three days (76.1%) especially on second day (28.8%). On assessing causality 50.9% ADRs were certain, 40.5% Probable while only 8.6% were in Possible category of WHO causality assessment. Most common system affected were GIT (58.6%) followed by skin (33.3%), CNS, Renal etc. Cutaneous manifestation presented with rash and itching. Sulphonamides shown to have most (n=31) hypersensitivity reactions. Out of 222 patients, 58.5% (n=132) experienced moderate ADRs, mild in 36.9% and only 3.6% severe ADRs as far severity of ADRs is concerned.

Age Group (Years)	Number of patients with ADRs	Percentage
12-20	44	19.8%
21-30	53	23.9%
31-40	60	27.0%
41-50	18	8.1%
51-60	15	6.8%
≥ 60	32	14.4%
TOTAL	**222**	**100%**

Group of Antimicrobial Agent	Number of patients with ADRs	Percentage	ADRs
B-Lactam Antibiotics	72	32.4%	Loose motions (39), Gastritis (18), Rash (13), Bronchospasm (2)
Sulphonamides	35	15.8%	Rash and itching (24), FDE (5), Gastritis (4), Hyperpigmentation(1) SJS (1)
Macrolides	30	13.5%	Gastritis (14), Loose motions (10), Palpitation/sweating(1), Rash (2).
Fluroquinolones	22	10.0%	Gastritis (14), Rash (5), Ulcer mouth corner (1), Breathlessness (1).
Nitrofurans	2	0.9%	Rash (1), Gastritis (1).
Aminoglycosides	1	0.45%	Rash & itching (1)
Tetracycline	1	0.45%	FDE (1)
Antiprotozoal	8	3.6%	Rash (4), Gastritis (3), Breathlessness (1).
Antimalarial	15	6.8%	Gastritis (14), Rash (1).
Antifungal	6	2.7%	Pruritic rash (5), Nephrotoxicity (1).
Antitubercular	28	12.6%	Anorexia (9), Rash (8), Gastritis (4), Tingling/Weakening lower limb (3), Joint pain (1), Liver Tenderness (2), Hepatitis (1).
Antileprosy	2	0.9%	Hyperpigmentation of Face (1), Desquamation of skin(1)
TOTAL	**222**	**100%**	

FDE = Fixed drug eruption
SJS = Steven Johanson Syndrom

Discussion

Adverse reaction s to medicines are common, yet often preventable, cause of illness, disability and even death. Increase number of ADRs was seen in males as compared to females. Study done by Pirmohammed *et al*[8] in UK observed that reported reversed which may be due to under reporting by females. Number of patients was more for OPD as more number of patients exposed to antimicrobial treatment was OPD patients. Majority of ADRs occurred at third day of exposure and majority of ADRS were GI and hypersensitivity reactions. Maximum number of hypersensitivity reactions occurred due to sulphonamides. In a study Neuman *et al*[9] (2002) observed that hypersensitivity reactions due to sulphonamides occurred within 72 hours of drug administration due to IgE mediated hypersensitivity. The results were comparable to our study. The cutaneous ADRs were maximum to sulphonamides, followed by β-Lactam antibiotics, antitubercular, and fluroquininolones. Naldi *et al*[10] (1999) observed similar findings and reported hypersensitivity from sulphonamides followed by cephalosporines. The most frequent cutaneous reaction were maculopapular rash followed by urticarial rashes. Jha *et al*[11] (1999) showed similar results. Maximum number of ADRs were attributed to β-lactum antibiotics which is frequently mentioned in pharmacology textbooks. As most of the ADRs followed a reasonable sequence time sequence and the ADRs couldn't be attributed to disease or other drugs, most ADRs on causality analysis falls in certain category.

The ultimate aim of our study to add information for safety of drug use and about ADRs.

REFERENCES

1. Phatak Abimanyu, Nagari B.G. Safety of medicines. Pharma Times. 2003;35:19–21.
2. Dhar K., Sinha A., Gaur P., Goel R., Chopra V. S., Bajaj U. Pattern of adverse drug reactions to antibiotics commonly prescribed in department of medicine and paediatrics in a tertiary care teaching hospital, Ghaziabad. J App Pharm Sci, 2015;5(04):078-082.
3. Patinen J L, Neuvoren PJ: Drug-related deaths in a university central hospital. Eur J Clin Pharmacol. 2002, 58:415.
4. Novotny J., Novotny M. Adverse drug reactions to antibiotics and major antibiotic drug interactions. Gen. Physiol. Biophys. 1999;18:126–139.
5. Einarson TR: Drug-related hospital admissions. Ann Pharmacother. 1993,27:832-840.
6. Brennan TA, Leape LL, Laird NM, Herbert L, Localio RA, Lawthers AG, et al. Incidence of adverse drug events and negligence in hospitalized patients: Results of Harvard Medical Practice study. N Eng J Med.1991;324:370-6.
7. WHO. A guide to detecting and reporting adverse drug reactions. WHO, Geneva, 2002. Available at: http://apps.who.int/medicinedocs/en/d/Jh2992e/. Accessed on 24 April 2017.
8. PIrmahamed M, James S, Meakin S, Green C,Scott A, Wally T et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients. BMJ 2004;329:15-9.
9. Neuman MG, Malkiewicz IM, Phillips EJ, Rachlis AR, Ong D, Yeung E, Shear NH. Monitoring adverse drug reactions to sulfonamide antibiotics in human immunodeficiency virus-infected individuals. Ther Drug Monit. 2002 Dec;24(6):728-36.
10. Naldi L, Conforti A, Venegoni M, Troncon MG, Caputi A, Ghiotto E, Cocci A, Moretti U, Velo G, Leone R. Cutaneous reactions to drugs. An analysis of spontaneous reports in four Italian regions. Br J Clin Pharmacol. 1999 Dec;48(6):839-46.ppal R, Malhotra S, Bhargava VK. Cutaneous adverse reactions in in-patients in a tertiary care hospital. IJDYL 1999;65(1):14-7.