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Original Research Article.

Analysis of Prevalence of Adverse Drug Reactions in Patients Admitted To a Tertiary Care Hospital

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ABSTRACT

Background: Adverse drug reaction (ADR) is an inevitable consequence of drug therapy, as no pharmacotherapeutic agent is completely safe and more than 50% of approved drugs are associated with some type of adverse effects that are not detected prior to their approval for clinical use. The present study was conducted to analyse the prevalence of Adverse Drug Reactions in Patients Admitted to a Tertiary Care Hospital.

Materials and Methods: This retrospective cross sectional study was conducted in the Department of Pharmacology, Government (RVRS) Medical College, Bhilwara, Rajasthan (India) over a period of 6 months. The sample size included was 540 retrospective inpatient treatment sheets. The treatment records of the diagnosed case of ADR in the register were initially identified and documented in ADR review form. The recorded data was compiled, and data analysis was done.

Results: In this retrospective cross-sectional study a sample of 540 retrospective inpatient treatment sheets were taken. The classes of drugs causing adverse reactions in order of their frequency were NSAIDS (32.43%), drugs acting on CNS (18.91%), Anti-TB drugs (13.51%). Minimum number of effects were due to anticancer drugs (2.70%). A large number of those ADRs were in the form of cutaneous reactions 64.86%. Gastrointestinal disturbances (16.21%) & Hepatobiliary (10.81%) were the second most common ADR. The large proportions of ADRs 62.16% to be mild type while 21.62% of the reactions are of moderate type and 10.81% severe type of reaction. The large fractions of ADRs fall on Type A (Augmented reactions) category of ADRs.

Conclusion: The present study concluded that drugs causing adverse reactions in order of their frequency were NSAIDS. Minimum number of effects were due to anticancer drugs. A large number of those ADRs were in the form of cutaneous reactions. The large proportions of ADRs to be mild type. The large fractions of ADRs fall on Type A (Augmented reactions) category of ADRs.

Keywords: Drugs, Adverse Drug Reactions, Records.

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INTRODUCTION

World Health Organization (WHO) defines an adverse drug reaction (ADR) as "one which is noxious and unintended, and which occurs in doses normally used in human for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological functions.[1] Drug-related problems (DRP), including adverse drug reactions (ADRs), constitute a significant health- and quality problem particularly affecting the elderly.[2] ADRs are as old as medicines. The criteria for serious adverse drug reactions (serious ADRs) have been specified by the WHO and include any untoward medical occurrence at any dose that results in death, life-threatening, requires or prolongs hospitalization, or results in persistent or significant disability or incapacity.[3] The overall incidence of serious and fatal ADR among hospitalized patients is 6.7% and 0.32%, respectively.[4] Sometimes, ADR-related costs, such as hospitalization, surgery and lost productivity, exceed the cost of the medications.[5]

The most commonly reported preventable ADEs were related to inappropriate dosing and choice of: 1) antiplatelet drugs, anticoagulants, diuretics, angiotensin-converting enzyme inhibitors resulting in undesired cardiovascular reactions; 2) combinations of psychoactive agents, antiepileptic drugs causing central nervous system (CNS)–side effects; 3) opioids associated with respiratory depression; 4) anti-infective agents despite history of allergy.[6] The present study was conducted to analyse the prevalence of Adverse Drug Reactions in Patients Admitted to a Tertiary Care Hospital.

MATERIALS AND METHODS

This retrospective cross-sectional study was conducted in the Department of Pharmacology, Government (RVRS) Medical College, Bhilwara, Rajasthan (India) over a period of 6 months. Before the commencement of the study ethical approval was taken from the Ethical Committee of the institute. The sample size included was 540 retrospective inpatient treatment sheets. Treatment records of individual cases containing clinical diagnosis were considered as sample and samples were collected by systemic random sampling method. From those records, necessary retrospective data was collected. The treatment records of the diagnosed case of ADR in the register were initially identified and documented in ADR review form. The recorded data was compiled, and data analysis was done.

Table 1: Common adverse reactions with different drug group

Drug class	N(%)
Antibiotics	8(21.62%)
Anti TB drugs	5(13.51%)
Anti-cancer drugs	1(2.70%)
Drugs acting on CNS	7(18.91%)
NSAIDs	12(32.43%)
Cardiovascular System	2(5.4%)
Others	2(5.4%)
Total	37(100%)

Table 2: Body Systems involved due to ADRs

Body Systems	N(%)
Skin & appendages	24(64.86%)
Hepatobilliary	4(10.81%)
GIT	6(16.21%)
CNS	2(5.4%)
Others	1(2.7%)
Total	37(100%)

Table 3: Analysis of Adverse Reactions based on the severity

ADR Severity	N(%)
Mild	23(62.16%)
Moderate	10(27.02%)
Severe	4(10.81%)
Total	37(100%)

Table 4: Analysis of Adverse Reactions based on Category

Category	N(%)
Type A (Augmented reactions)	29(78.37%)
Type B (Bizarre reactions)	8(21.62%)
Total	37(100%)

RESULTS

In this retrospective cross-sectional study a sample of 540 retrospective inpatient treatment sheets were taken. The classes of drugs causing adverse reactions in order of their frequency were NSAIDS (32.43%), drugs acting on CNS (18.91%), Anti-TB drugs (13.51%). Minimum number of effects were due to anticancer drugs (2.70%). A large number of those ADRs were in the form of cutaneous reactions 64.86%. Gastrointestinal disturbances (16.21%) & Hepatobiliary (10.81%) were the second most common ADR. The large proportions of ADRs 62.16% to be mild type while 21.62% of the reactions are of moderate type and 10.81% severe type of reaction. The large fractions of ADRs fall on Type A (Augmented reactions) category of ADRs.

DISCUSSION

In this retrospective cross-sectional study, a sample of 540 retrospective inpatient treatment sheets were taken. The classes of drugs causing adverse reactions in order of their frequency were NSAIDS (32.43%), drugs acting on CNS (18.91%), Anti-TB drugs (13.51%). Minimum number of effects were due to anticancer drugs (2.70%). A large number of those ADRs were in the form of cutaneous reactions 64.86%. Gastrointestinal disturbances (16.21%) & Hepatobiliary (10.81%) were the second most common ADR. The large proportions of ADRs 62.16% to be mild type while 21.62% of the reactions are of moderate type and 10.81% severe type of reaction. The large fractions of ADRs fall on Type A (Augmented reactions) category of ADRs.

Pirmohamed et al concluded from a prospective analysis of about 18,820 patients in UK in which about 1225 admissions were related to ADRs giving a prevalence of 6.5%.[7]

In a review they reported that more than 80% of ADRS causing admission or occurring in the hospital are Type A in nature and thus predictable from the known pharmacology of the drug and therefore potentially avoidable. Among serious ADRs majority of the patients lead to hospitalization.[8]

A study conducted by Suh et al, which revealed that the system most badly affected was the dermatological and gastrointestinal system.[9] The most common ADR involved the skin and appendages in inpatient (63.33%) departments which is similar to the study done by Lei in 2007.[10] Murphy and Frigo developed and implemented an ADR reporting program in Loyola University Medical Center, a 563-bed tertiary care teaching hospital located in the western suburbs of Chicago. This study revealed that the most common adverse reactions were rash; and antibiotics were the most commonly implicated drug class.[11]

The majority of ADRs observed in admitted patients, and antibiotics were involved in the majority of ADRs, this is due to the reason, that almost all inpatients have received antibiotic therapy either for prophylactic or curative therapy. The results were consistent with previous studies.[12-14]

CONCLUSION

The present study concluded that drugs causing adverse reactions in order of their frequency were NSAIDS. Minimum number of effects were due to anticancer drugs. A large number of those ADRs were in the form of cutaneous reactions. The large proportions of ADRs to be mild type. The large fractions of ADRs fall on Type A (Augmented reactions) category of ADRs.

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