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Assessment of Adverse Drug Reactions in the Diagnosed ADR Patients

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ABSTRACT:

Background: Drug-related problems (DRP), including adverse drug reactions (ADRs), constitute a significant health- and quality problem. The present study was conducted to assess adverse drug reactions in the diagnosed ADR patients.

Material and methods: This cross sectional study was conducted to assess adverse drug reactions in the diagnosed ADR patients over a period of 4 months. Before the commencement of the study ethical approval was taken from the Ethical Committee of the institute. The sample size included was 220 retrospective inpatient treatment sheets. Treatment records of individual cases containing clinical diagnosis were considered as sample. From those records, 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.

Results: In this cross-sectional study a sample of 220 patients were taken. The classes of drugs causing adverse reactions in order of their frequency were drugs acting on cardiovascular system (28.18%), anti-TB drugs (21.81%), NSAIDs(14.54%). A large number of those ADRs were in the form of cutaneous reactions 51.81%. Hepatobiliary (20%) were the second most common ADR. The large proportions of ADRs 55.90% to be mild type while 31.81% of the reactions are of moderate type and 12.27% severe type of reaction. The large fractions of ADRs fall on Type A (Augmented reactions) (81.36%) category of ADRs.

Conclusion: The present study concluded that maximum adverse reactions were caused by drugs acting on cardiovascular system. A large number of those ADRs were in the form of cutaneous reactions and to be mild type. The large fractions of ADRs fall on Type A (Augmented reactions) category of ADRs.

Keywords: cardiovascular system, anti-TB drugs, cutaneous reactions, ADRs.

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Introduction:

According to WHO, an adverse drug reaction was originally defined in 1972 as a response to a drug that is noxious and unintended and occur at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for modification of any physiological function.[1] An adverse drug reaction (ADR) can be defined as 'an appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product; adverse effects usually predict hazard from future administration and warrant prevention, or specific treatment, or alteration of the dosage regimen, or withdrawal of the product'.[2] Since 2012, the definition has included reactions occurring as a result of error, misuse or abuse, and to suspected reactions to medicines that are unlicensed or being used off-label in addition to the authorised use of a medicinal product in normal doses.[3] ADRs are of major concern in patients with complex therapeutic regimens. In European hospitals, up to 10% of patients experience an ADR during their stay.[4] There is an increase in the incidence of ADR with underlying systemic diseases, drug polymorphism, and long duration of therapy. The risk of ADR with cardiovascular drugs is about 2.4 times higher, compared to other drugs.[5] In the Indian population, the incidence of ADRs range between 1.7% and 25.1%, with 8% of them resulting in hospitalization, and the ADRs due to cardiovascular drugs are major contributors to morbidity in patients with cardiovascular diseases.[6] The present study was conducted to assess adverse drug reactions in the diagnosed ADR patients.

Material and methods:

This cross sectional study was conducted to assess adverse drug reactions in the diagnosed ADR patients over a period of 4 months. Before the commencement of the study ethical approval was taken from the Ethical Committee of the institute. The sample size included was 220 retrospective inpatient treatment sheets. Treatment records of individual cases containing clinical diagnosis were considered as sample. From those records, 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.

Results:

In this cross sectional study a sample of 220 patient were taken. The classes of drugs causing adverse reactions in order of their frequency were drugs acting on cardiovascular system (28.18%), anti-TB drugs (21.81%), NSAIDs(14.54%). A large number of those ADRs were in the form of cutaneous reactions 51.81%. Hepatobiliary(20%) were the second most common ADR. The large proportions of ADRs 55.90% to be mild type while 31.81% of the reactions are of moderate type and 12.27% severe type of reaction. The large fractions of ADRs fall on Type A (Augmented reactions) (81.36%) category of ADRs.

Table 1: Common adverse reactions with different drug group

Drug class	**N(%)**
Antibiotics	**28(12.72%)**
Anti TB drugs	**48(21.81%)**

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Anti-cancer drugs	**21(9.54%)**
Drugs acting on CNS	**17(7.72%)**
NSAIDs	**32(14.54%)**
Cardiovascular System	**62(28.18%)**
Others	**12(5.4%)**
Total	**220(100%)**

Table 2: Body Systems involved due to ADRs

Body Systems	**N(%)**
Skin & appendages	**114(51.81%)**
Hepatobiliary	**44(20%)**
GIT	**26(11.81%)**
CNS	**25(11.36%)**
Others	**11(5%)**
Total	**220(100%)**

Table 3: Analysis of Adverse Reactions based on the severity

ADR Severity	**N(%)**
Mild	**123(55.90%)**
Moderate	**70(31.81%)**
Severe	**27(12.27%)**
Total	**220(100%)**

Table 4: Analysis of Adverse Reactions based on Category

Category	**N(%)**
Type A (Augmented reactions)	**179(81.36%)**
Type B (Bizarre reactions)	**41(18.63%)**
Total	**220(100%)**

Discussion:

The development of drugs in the last decades has brought remarkable benefits for the patients, at the same time the incidence of Adverse Drug Reaction (ADR) has raised remarkably.[7,8] It is universally accepted that "No drug absolutely free from side effects". From the literature it is observed that 5% of all hospital admissions were related to drug-induced problems and 10–20% of hospitalized patients are developing ADRs, it is estimated that ADRs are the fourth to the sixth leading cause of death.[9]

In this cross sectional study a sample of 220 patient were taken. The classes of drugs causing adverse reactions in order of their frequency were drugs acting on cardiovascular system (28.18%), anti-TB drugs (21.81%), NSAIDs(14.54%). A large number of those ADRs were in the form of cutaneous reactions 51.81%. Hepatobiliary(20%) were the second most common ADR. The large proportions of ADRs 55.90% to be mild type while 31.81% of the reactions are of moderate type and 12.27% severe type of reaction. The large fractions of ADRs fall on Type A (Augmented reactions) (81.36%) category of ADRs.

Venkatesan *et al*. monitored the pattern of ADRs, their frequency, severity, and preventable of ADRs from a medicine ward at a tertiary care hospital for a period of 6 months. One thousand two hundred and twenty patients were monitored. The average number of drugs taken by patients was 10 ± 4.50. Using the Naranjo's algorithm, 60.93% of the ADRs were defined as "probable," whereas 38.12% were defined as "possible" and 0.93% were classified as "definite" in relation to the suspected drug.[10]

A study conducted by Suh et al, which revealed that the system most badly affected was the dermatological and gastrointestinal system.[11]

An Italian study surveying patients admitted through the emergency department to three hospitals found an initial diagnosis of an ADR in 21.2% of patients but 98% of those were deemed predictable and were not further analysed.[12]

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.[13]

A study done by Classen et al which indicated that NSAIDs have caused extensive damage to human health.[14]

Conclusion:

The present study concluded that maximum adverse reactions were caused by drugs acting on cardiovascular system. A large number of those ADRs were in the form of cutaneous reactions and to be mild type. The large fractions of ADRs fall on Type A (Augmented reactions) category of ADRs.

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