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Original Article

Assessment of various adverse drug reactions of antiretroviral therapy (ART): A tertiary care centre study

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***ABSTRACT*:**
Background: ART has proved efficacious in reducing mortality and morbidity related to Human Immunodeficiency Virus (HIV) infection; however, is also associated with both short- and long-term drug-induced toxicities. Hence; we planned the present study to assess various adverse reactions of antiretroviral drug regimens. **Materials & methods:** We planned the present study to evaluate of various adverse reactions of antiretroviral drug regimens. A total of 50 patients who attended the tertiary care hospital branch of the hospital were included in the present study.Recording of the complete demographic, clinical and medical details of all the patients was done. Complete biochemical investigations of all the patients were carried out and the results were tabulated in the Microsoft excel sheet. All the results were analyzed by SPSS software. Chi-square test was used for assessment of level of significance. **Results:** Most common drug reactions observed in the present study were anaemia, thrombocytopenia, neutropenia, pruritus, vomiting, peripheral neuropathy and hepatitis. Among these adverse effects, anaemia, hepatitis and pruritus were the most common side effects encountered in the present study. **Conclusion:** Significant amount of adverse drug reactions are associated with ART, among which haematological associated ADR are the most common.
Key words: Adverse drug reaction, Antiretroviral drug therapy

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INTRODUCTION

RT has proved efficacious in reducing mortality and morbidity related to Human Immunodeficiency Virus (HIV) infection; however, is also associated with both short- and long-term drug-induced toxicities. These toxicities may reduce patient's quality of life and adversely affect treatment adherence; and consequently may lead to treatment failure.[1- 3] Nonetheless, they are severely under- reported. Spontaneous reporting of ADR is the foundation of national and international drug safety evaluation after licensing and approval for use in general population.[5]

The spectrum of adverse effects associated with ARVs may vary between developed and developing countries. Variance in psychological and socioeconomic support of HIV positive patients in the public health sector of developing countries coupled with co-morbidities make monitoring ADRs to antiretroviral a necessity. Studies on the incidence of ADR from developing and developed countries have reported incidence of ADR among patients on ARVs to range between 11%-35.9% with incidence as high as 54% in the presence of opportunistic infection.[5- 7] Hence; we planned the present study to assess various adverse reactions of antiretroviral drug regimens.

MATERIALS & METHODS

We planned the present study in the department of pharmacology of the medical institute and it included evaluation of various adverse reactions of antiretroviral drug regimens. We obtained written consent from all the patients after explaining in detail the entire research protocol. A total of 50 patients who attended the tertiary care hospital branch of the hospital were included in the present study. Inclusion criteria for the present study included:

- Patients within the age group of 18 years to 50 years,
- Patients with negative history of any known drug allergy,
- Patients with negative history of any other systemic illness,
- Patients who visited the tertiary care centre for initiation of antiviral therapy (ART)

Recording of the complete demographic, clinical and medical details of all the patients was done. Complete biochemical investigations of all the patients were carried out and the results were tabulated in the Microsoft excel sheet. Detailed recording of the suspected adverse drug reaction (ADRs) was done, based on criteria described

previously in the literature.[8]All the results were analyzed by SPSS software. Chi-square test was used for assessment of level of significance. P- value of less than 0.05 was taken as significant.

RESULTS

A total of 50 patients undergoing ART therapy were included in the present study. Mean age of the patients of the present study was 60.1 years. Among these 50 patients, 30 were males while the remaining 20 were females. Mean weight of the patients of the present study was 68.1 Kg. Most common drug reactions observed in the present study were anaemia, thrombocytopenia, neutropenia, pruritus, vomiting, peripheral neuropathy and hepatitis. Among these adverse effects, anaemia, hepatitis and pruritus were the most common side effects encountered in the present study.

Table 1: Demographic details of the patients

Parameter		Value
Number of patients		50
Mean age (years)		60.1
Mean weight (Kg)		68.1
Gender	Males	30
	Females	20

Graph 1: Demographic details of the patients

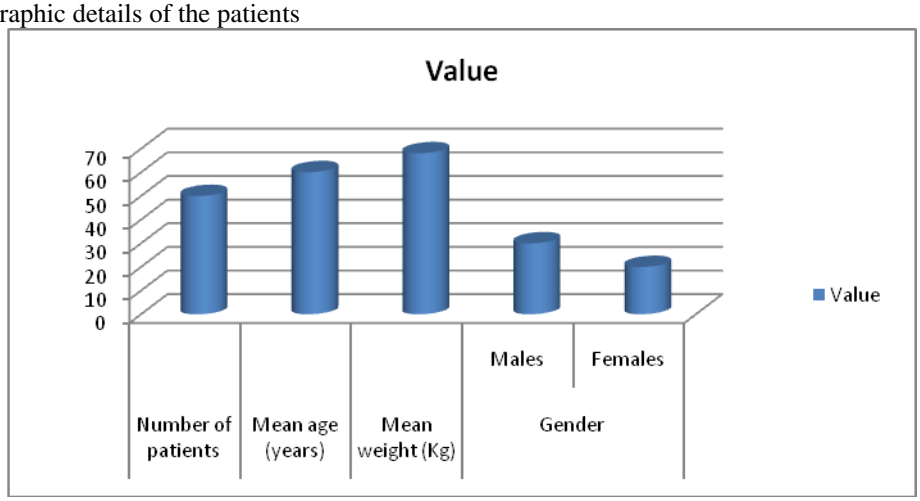
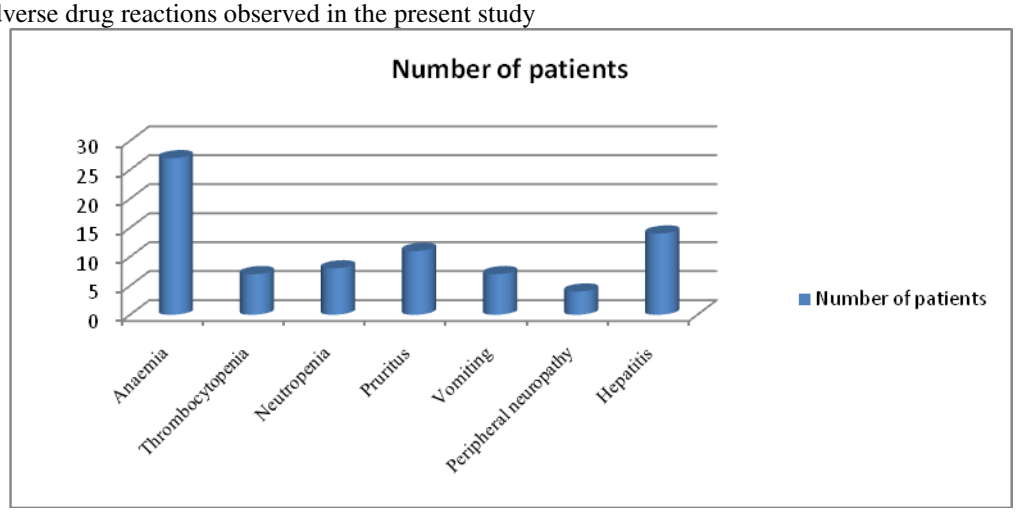


Table 2: Adverse drug reactions observed in the present study

Adverse reaction	Number of patients	Frequency
Anaemia	27	54
Thrombocytopenia	7	14
Neutropenia	8	16
Pruritus	11	22
Vomiting	7	14
Peripheral neuropathy	4	8
Hepatitis	14	28
Others	3	6

Graph 2: Adverse drug reactions observed in the present study



DISCUSSION

In the present study, we observed that most common drug reactions observed in the present study were anaemia, thrombocytopenia, neutropenia, pruritus, vomiting, peripheral neuropathy and hepatitis. Khan K et al explored the occurrence of adverse drug reactions (ADRs) to antiretroviral therapy among human immune-deficiency virus (HIV)/AIDS patients. Patient socio-demographic details along with clinical features and susceptible ADRs were observed during the study period. Out of 743 patients, 571 (76.9%) were men, and 172 (23.1%) were women. Overall 314 (42.2%) patients experienced ADRs. A total of 425 ADRs were reported, with 311 (73.1%) occurring in men and 114 (26.8%) in women, with a significant statistical relationship (P value (P) = 0.02, OR = 1.21). Overall 239 (56.2%) ADRs were recorded among Chinese, 94 (22.1%) in Malay, and 71 (16.7%) in Indian patients, which had a statistically significant association with ADRs (P = 0.05, OR = 1.50). Out of a total 425 among ADRs, lipodystrophy was recorded in 151 (35.5%) followed by skin rashes in 80 (18.8%), anemia in 74 (17.4%), and peripheral neuropathy in 27 (6.3%) patients. These findings suggested a need of intensive monitoring of ADRs in HIV treatment centres across Malaysia.[9]

Forna F et al evaluated clinical toxicity in HIV-infected persons receiving antiretroviral therapy (ART) in Uganda. They calculated probabilities for time to toxicity and single-drug substitution as well as multivariate-adjusted hazard ratios for development of toxicity. ART (stavudine plus lamivudine with nevirapine [96%] or efavirenz [4%]) was prescribed for 1029 adults, contributing 11,268 person-months of observation. Toxicities developed in 543 instances in 411 (40%) patients (incidence rate = 4.47/100 person-months): 36% peripheral neuropathy (9% severe); 6% rash (2% severe); 2% hypersensitivity reaction; < or =0.5% acute hepatitis, anemia, acute pancreatitis, or lactic acidosis; and 13% other. Probabilities of remaining free from any toxicity at 6, 12, and 18 months were 0.76, 0.59, and 0.47 and from any severe toxicity at 6, 12, and 18 months were 0.92, 0.86, and 0.85, respectively. For 217 patients (21%), 222 single-drug substitutions were made, mostly because of peripheral neuropathy or rash. Clinical toxicities were common, but no patients discontinued ART because of toxicity. The most common toxicities, peripheral neuropathy and rash, were managed with single-drug substitutions.[10] Lartey M et al explored the types and risk factors for ADRs in a cohort starting ART in a teaching hospital in Accra, Ghana where the main regimens used were a combination of nucleotide and non nucleotide reverse transcriptase inhibitors. Stepwise logistic regression procedures were used to model the effect of gender on the development of ADRs controlling for other variables like age, marital status, weight at baseline and CD4 at baseline. The period prevalence of ADRs was 9.4%. The two most common adverse reactions were anaemia and diarrhoea. Female sex was a statistically significant independent predictor of an adverse drug reaction. CD4 counts 250 cells/mm3 or more was significantly associated with the occurrence of an ADR. The occurrence of anaemia in females was statistically significant compared to males. Adverse drug reactions were less common than expected, anaemia was the commonest ADR.[11]Since adverse drug reactions are one of the common causes for poor adherence to treatment, evaluation of ADRs may help clinicians to optimize the drug regimens. Observational studies conducted in the developed world have documented possible virological, immunological, and clinical differences between men and women receiving ART, which may account for differences in ADRs among male and female patients.[11, 12]

CONCLUSION

From the above results, the authors concluded that significant amount of adverse drug reactions are associated with ART, among which haematological associated ADR are the most common. However; future studies are recommended.

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