FREQUENCY OF COMMON COMPLICATIONS OF ANTIRETROVIRAL THERAPY IN PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME

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ABSTRACT

Objective: To determine the frequency of common complications of Anti-retroviralTherapy (ART) in Acquired Immunodeficiency Syndrome (AIDS) patients.

Material And Methods: This study was conducted in Department of Medicine, PGMI/LRH Peshawar. Duration of the study was one year (from 1st 2012 to 30th January 2013). Total 62 patients of either gender of all ages were enrolled in this descriptive cross-sectional study using Consecutive (non-probability) samplingtechnique fulfilling the inclusion criteria of All patients with Acquired Immunodeficiency Syndrome (AIDS) being diagnosed and confirmed on laboratory test of HIV-RNA PCR, Patients having stage III disease (according to WHO guidelines) and having CD4 count between < 350.

Results: In this study mean age was 36 years with standard deviation as ± 8.9 years. Seventy percent patients were male and 30% were female. Fifteen percent patients had skin rash, 23% patients had dyslipidaemia and 26% patients had drug inducehepatitis.

Conclusion: Complications are common with antiretroviral therapy used for treatment of AIDS. Complications are more common in male patients as compare to female. Drug induced hepatitis is the leading complication followed by dyslipidaemia and Skin rash

Key words: Antiretroviral therapy, Complications, AIDS.

INTRODUCTION

In the early 1980s, a number of homosexual men in New York, San Francisco and other areas of USA began to develop Pneumocystis pneumonia, Kaposi's sarcoma and other opportunistic infections. All of those people were immuno-deficient and that was the beginning of Acquired Immunodeficiency Syndrome (AIDS) epidemic. In 1983, Human Immunodeficiency Virus (HIV) was first detected in a patient with AIDS. Presently more than forty million people are HIV positive in the world. AIDS is still a major cause of death in parts of Africa, South East Asia and other developing countries as the treatment is very expensive and majority of people in these countries cannot afford it.[1]

Since the diagnosis of the first HIV/AIDS case in 1987, Pakistan has progressed to 3000+ cases nationwide. However, these numbers are likely to a vast underestimation of the actual picture. United Nations Acquired Immunodeficiency Syndrome (UNAIDS)/National Acquired Immunodeficiency Syndrome Control Programme (NACP) estimated 74000 HIV/AIDS cases in 2006 with a prevalence of 0.1%.[2]

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The treatment was revolutionized when Highly Active Anti-retroviral Therapy (HAART) was introduced in 1996.[1]HAART has dramatically reduced HIV-related morbidity and mortality. However, antiretroviral therapy is associated with some significant short and long-term toxicities, including skin rashes, insomnia, significant increases in serum liver enzymes, anaemia,hyperlipidaemia, insulin resistance, and fat redistribution syndromes, which may be associated with accelerated atherosclerotic cardiovascular disease; and other adverse events.[3,4,5,6]

Severe liver enzyme elevations (LEE) are frequently observed in patients.[3] Similar findings have been found in a study in which liver enzyme elevations (any ALT increase by > 3 times ULN or any increase of 100 U/L from baseline) developed in 284 (20.8%) patients during the follow up.[3]

In a study, out of 103 HIV+ patients, 26 (25.24%) developed sub-clinical hepatotoxicity. All of them having jaundice and necessitated discontinuation of their anti-tuberculosis therapy.[7] In another study the prevalence of hepatotoxicity (drug-induced hepatitis) was ranged from 20% to 77% in the HIV-positive group.[8]

Similarly, skin rashes are observed in 15-20% of the patients receiving ART, especially nevirapine & abecavir.[9]

The purpose of the study was to determine the frequency and severity of common complications of ART in patients with AIDS in tertiary care hospital of

Peshawar.

MATERIAL AND METHODS

This study was conducted in Department of Medicine, PGMI/LRH Peshawar. Duration of the study was one year (from 1st 2012 to 30th January 2013). Total 62 patients of either gender of all ages were enrolled in this descriptive cross-sectional study using Consecutive (non-probability) sampling technique fulfilling the inclusion criteria of All patients with Acquired Immunodeficiency Syndrome (AIDS) being diagnosed and confirmed on laboratory test of HIV-RNA PCR,having CD4 count between < 350.

After getting approval from the hospital ethical committee and informed written consent data was collected from patients with Acquired Immunodeficiency Syndrome (AIDS) presenting to out-patient department (OPD) of this institute, after being diagnosed and confirmed on laboratory test HIV-RNA PCR they were admitted in Department of Medicine and registered in HIV Family care centre of Postgraduate Medical Institute, Lady Reading Hospital, Peshawar for further evaluation. All included patients initiated on various ART were followed up at regular intervals for three months. At each follow-up visit, complete blood count, liver function tests (serum bilirubin, AST and ALT), and serum creatinine were performed in well-equipped laboratory of same institute. This routine was continued up to the end of the study period. The adverse clinical events and the abnormal laboratory findings were documented in prestructured Performa.

DATA ANALYSIS PROCEDURE

All the qualitative variables like sex, stage of disease, wereanalysed for percentages and frequencies. Mean $\pm$ standard deviation were calculated for quantitative variables like age and liver function tests (serum bilirubin, AST and ALT), and serum creatinine. For gender, male to female ratio was calculated. Results are presented in the form of tables and graphs. All the data wasanalysed by statistical program SPSS version 16 for windows.

RESULTS

A total of 62 HIV positive patients were studied so as to see the common complications of antiretroviral therapy in patients with AIDS. Mean age was 36 years with standard deviation as $\pm$ 1.26 .Age distribution among 62 patients was analysed as n=19(30%) patients were in age group 20-30 years, n=34(56%) patients were in age group 31-40 years, n=9(14%) patients were in age group 41-50 years. (Table No 1) Of 62 patients 43(70%) patients were male and female were 19(30%).(Table No 2) Dyslipidaemia was the leading complication noted in 16(26%) patients, followed by drug induced hepatitis observed in 14(23%) patients. Skin rash was seen in 9(15%) patients. (Table No 3)

Table No.1; Age Distribution

AGE DISTRIBUTION	FREQUENCY	PERCENTAGE
20-30 Years	19	30%
31-40 Years	34	56%
41-50 Years	9	14%
Total	62	100%

Table No.2; Gender Distribution

GENDER DISTRIBUTION	FREQUENCY	PERCENTAGE
MALE	**43**	**70%**
FEMALE	**19**	**30%**
Total	**62**	**100%**

Table No.3; Frequency of Common Complications

Common complications	FREQUENCY	PERCENTAGE
Skin Rash	9	15%
Dyslipidaemia	14	23%
Hepatitis (drug induced)	16	26%
Total	62	100%

Table No.4; Association of Common Complications with Age Group

Common complications	20-30 years	31-40 years	41-50 years	Total
Skin Rash	3	6		9
Dyslipidaemia	5	8	1	14
Hepatitis (drug induced)	6	9	1	16
Total	14	23	2	39

Table No.5; Association of Common Complications with Gender

Common complications	Male	Female	Total
Skin Rash	6	3	9
Dyslipidaemia	10	4	14
Hepatitis (drug induced)	11	5	16
Total	27	12	39

Association of common complications with age distribution was analysed in 9 cases of skin rash, 3 patients were in 20-30 years and 6 patients were in 31-40 years. In 14 cases of dyslipidaemia, 5 patients were in 20-30 years, 8 patients were in 31-40 years and one patient was in age range 41-50 years. In 16 cases of

hepatitis 6 patients were in 20-30 years, 9 patients were in 31-40 years and one patient was in age range 41-50 years.(Table No 4)

Association of common complications with gender distribution was analysed in 9 cases of skin rash, 6 patients were male and 3 patients were female. In 14 cases of dyslipidaemia, 10 patients were male and 4 patients were female. In 16 cases of hepatitis 11 patients were male and 5 patients were female. (Table No 5)

DISCUSSION

In our study 30% patients were in age group 20-30 years, 56% patients were in age group 31-40 years, 14% patients were in age group 41-50.Years. Whereas mean age was 36 years with standard deviation as ± 1.26. Similar results were found in study done by Wit FW et al in which 35% patients were in age group 20-30 years, 60% patients were in age group 31-40 years, 5% patients were in age group 41-50 years.

In our study 70% patients were male and 30% were female. Similar results were coated by Wit FW et al[10] in which 75% patients were males and 25% were females.

Our study shows that 15% patients had skin rash, 23% patients had dyslipidaemia and 26% patients had hepatitis. More over the complication were found more in age group 31-40 years and in male patients as compare to female patients. Similar findings were observed in study done by Clough et al[11] in which 12% patients had skin rash, 22% patients had dyslipidaemia and 25% patients had hepatitis. The ratio of complication were found more in age group 31-40 years and in male patients as compare to female patients.

At six months after starting treatment 64% of our patients had a viral load below 400 copies/ml. This compares well to a similar observational study in a hospital setting, where they achieved viral loads below 400 copies/ml in 65% of their patients after six months.[12]This differs from clinical trials of antiretroviral regimens, where upto 90% patients are reported to have viral loads below 400 copies/ml[13,14,15]

On the whole, CD4 cells increased following the use of first-line antiretroviral therapy as shown in this study as well as others.[16,17,18]However this response was not uniform. Age has an effect on CD4 response. Younger patients show a more robust response to treatment.[16]The age of our patients ranged from 17 to 60 years. Older patients have a lower T-cell response, due to the effect of age on thymic reconstitution of immune cells. Previous studies also suggest that lower CD4 cell count at baseline predicts a smaller increase in CD4 count after treatment.[10]

CONCLUSION

Complications are common with antiretroviral therapy used for treatment of AIDS. Complications are more common in male patients as compare to female. Drug induced hepatitis is the leading complication followed by dyslipidaemia and Skin rash.

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