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Original Research

Assessment of various socio-clinical parameters on the response of HAART

Jyoti Pankaj[1], Arun Bharti[2]

[1]Associate Professor, Department of Medicine, Hind Institute of Medical Science Ataria, Sitapur, Uttar Pradesh, India;
[2]Junior resident, Department of Pharmacology, King George's Medical University, Lucknow, Uttar Pradesh, India

ABSTRACT

Background: HIV has been called one of the most destructive pandemics in the history of world. This study is aimed at identifying the effect of various socio-clinical parameters on the response of HAART. **Materials & methods:** The study comprised of 180 HIV+ve patients on ART. In this study, the patients were selected as per following criteria- Baseline investigations were carried out in all the patients. This included assessment of Hemoglobin, total leukocyte count, differential leukocyte count, platelet count, erythrocyte sedimentation rate, random blood sugar, serum creatinine, serum glutamate phosphoryl transferase, Hepatitis B surface antigen and Hepatitis C virus. Radiological investigations included evaluation of Chest X-ray PA view, Ultrasonography abdomen (optional) and others. Baseline CD4 count was carried out in all the patients. Simultaneous assessment of HAART adherence was also done. All the results were analysed by SPSS software. **Results:** CD4 count range 200-350, 12(30%) were in non-responder group and 28 (70%) in responder group. This difference was statistically significant ($Z=2.47$, $p<0.05$) showing that CD4 count <50 associated with poor response and >200 associated with good response.Out of 95 responders 92(96.84%) had >95% adherence, 2(2.11%) had 95-80% adherence and 1.05% had <80%. Among 85 non responders 75(78.95%) had adherence >95%, 2(2.35%) had 95-80% and 8(9.41%) had < 80%.The difference is significant for adherence >95% ($Z = 2.26$, $p<.05\%$) and <80 %($Z = 2.57$, $p <0.05\%$) suggesting that adherence >95% associated with good response and <80% associated with poor response. **Conclusion:** Female sex, higher body mass index, higher CD4 count, known HIV+ve partner status, >95% adherence is associated with better response and vice-versa.

Key words: HAART, HIV

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Corresponding author: Dr. Arun Bharti, Junior resident, Department of Pharmacology, King George's Medical University, Lucknow, Uttar Pradesh, India

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INTRODUCTION

HIV has been called one of the most destructive pandemics in the history of world. Drug therapy for HIV has been available since 1986 and presently HAART is the standard of care. There are NACO laid guidelines for HAART, which are based primarily on CD4 counts and associated co-morbid illnesses.[1- 3] However it has been seen that not all patients respond in similar fashion to the treatment. A number of factors may be responsible for response to HAART. These could be viral or host factors. Readily measurable markers of disease such as total lymphocyte count, haemoglobin, body mass index and delayed type hypersensitivity may come into favour as ART becomes increasingly available in resource-limited parts of the world.[4- 6]This study is aimed at identifying the effect of various socio-clinical parameters on the response of HAART.

MATERIALS & METHODS

This study was carried out over a period of one academic year (August 2010 to July 2011) in the Department of Medicine, BRD Medical College and associated Nehru Chikitsalaya, Gorakhpur. The patients were enrolled from ART centre. The study comprised of 180 HIV+ve patients on ART. In this study, the patients were selected as per following criteria-

Inclusion criteria-

- Patients of age >20 years diagnosed as HIV positive by the criteria laid down by National AIDS Control Organization, registered in ART centre , and recently started on ART.

Entry point- First enrolment for ART in ART centre ; Prospective study upto 6 month of enrolment for ART

Baseline investigations were carried out in all the patients. This included assessment of Hemoglobin, total leukocyte count, differential leukocyte count, platelet count, erythrocyte sedimentation rate, random blood sugar, serum creatinine, serum glutamate phosphoryl transferase, Hepatitis B surface antigen and Hepatitis C virus.

Radiological investigations included evaluation of Chest X-ray PA view, Ultrasonography abdomen (optional) and others. Baseline CD4 count was carried out in all the patients. Simultaneous assessment of HAART adherence was also done. All the results were analysed by SPSS software. We applied Z score as test of significance and P values were calculated by standard statistical tables.

RESULTS

The present prospective study was conducted in the Department of Medicine, BRD Medical College and associated Nehru Chikitsalaya, Gorakhpur on 180 patients from ART centre. The registration of patients in the study was done according to the inclusion criteria. These patients were divided into two groups – responders and non – responders on the basis of CD4 count at baseline and at 6 months, in addition to outcome as alive or dead. The patients whose CD4 counts increased by >30% in 6 months were included in responder group and those with <30% increase or who expired within 6 months in non – responder group.

The majority of patients in both groups was between 25 – 45 years (71/95 – 74.74% and 64/85 – 75.29%) respectively. The difference in age distribution was not statically significant (x22DF = 2.857, p > 0.05) among responders and non responders.

The majority of patients in both groups were illiterate, 54/95(56.84%) and 41/85 (48.24%), respectively in responders and non-responders. The difference in both group was not statistically significant (x23DF = 5.7078, p>0.05).

The majority of patient in both group were of lower class, 84 out of 85 (98.82%) in non- responders and 87 out of 95 (91.58%) in responders, but the difference for lower class was found to be statistically significant (z=2.23, p < 0.05). Most of the lower middle class patient were of responder group (7 out of 8 -87.5%) in comparison with non- responder group (1 out of 8- 1.18%), the difference was found to be statistically significant (z=2.01, p< 0.05).

CD4 count range 200-350, 12(30%) were in non-responder group and 28 (70%) in responder group. This difference was statistically significant (Z=2.47, p<0.05) showing that CD4 count <50 associated with poor response and >200 associated with good response.

Out of 95 responders 92(96.84%) had >95% adherence, 2(2.11%) had 95-80% adherence and 1.05% had <80%. Among 85 non responders 75(78.95%) had adherence >95%, 2(2.35%) had 95-80% and 8(9.41%) had < 80%.The difference is significant for adherence >95% (Z = 2.26, p<.05%) and <80 %(Z = 2.57, p <0.05%) suggesting that adherence >95% associated with good response and <80% associated with poor response.

Table 1: Socio-economic status of the responder and non-responders

Socio-economic status	Responders		Non-responder		p- value
	n	%	n	%	
Lower	87	91.58	84	98.82	<0.05
Lower-middle	7	7.37	1	1.18	<0.05
Upper-middle	1	1.05	0	0	>0.05

Table 2: CD-4 count distribution

Socio-economic status	Responders		Non-responder		p- value
	n	%	n	%	
<50	12	12.63	22	25.88	<0.05
50- 100	17	17.89	24	28.24	>0.05
100- 200	37	38.95	24	28.24	>0.05
200- 350	28	29.47	12	14.12	<0.05
>350	1	1.05	3	1.13	>0.05

Table 3: Adherence rate in responders versus non-responders

Adherence	Responders		Non-responder		p- value
	n	%	n	%	
>95%	92	96.84	75	78.95	<0.05
95- 85%	2	2.11	2	2.35	>0.05
<80%	1	1.05	8	9.41	>0.05

DISCUSSION

The present prospective study was conducted on 180 HIV positive patients who were recently started on ART from ART centre. Patients of age >20 years diagnosed as HIV positive by the criteria laid down by National AIDS Control Organization, registered in ART centre and who were recentlystarted ART , were selected for this study.

Our study also shows that most of the patients were of lower socio-economic status and lower-middle socio-economic status. Patients with lower socio-economic status were significantly more in non-responder group and lower middle socio-economic status patients in responder group. The socio-economic characteristics significantly affect health status among patients living with a chronic disease. Rapiti et al[7] showed that, beginning in 1996, survival after diagnosis of AIDS differed by neighbourhood socio-economic status (SES), revealing a more than doubling in risk for the people living with AIDS (PWA) with lower SES (third and fourth levels) as compared with those with the highest SES (first level).

The most significant predictor of disease progression in our study was baseline CD4 count showing that among the patients with CD4 count <50cells/ µl 64.71% were associated with poor response and among patients with CD4 count >200cells/µl 65.91% was associated with good response. Amongst alive and dead non-responder patients CD4 count <50cells/µl was associated with higher mortality in comparison with CD4 >50cells/µl. CASCADE collaboration analysis shows that lower CD4 counts were associated with greater risk of disease progression. CD4 counts from 350–500 cells/µl are associated with risks of ≤5% across all age and HIV-RNA strata, while the risk of progression to AIDS increases substantially at CD4 counts <350 cells/µl, the greatest risk increase occurring as CD4 counts fall below 200 cells/µl. The risk of disease progression at 200 CD4cells/µl, the previous threshold for ART initiation, is generally double the risk at 350 cells/µl, the presently recommended treatment threshold.[8] EUROSIDA study[9] showed that increases in CD4 counts from very low levels to at least200cells/µl after ART are associated with a much reduced rate of disease progression. However, a previously low CD4 cell count nadir remains associated with a moderately higher risk for disease progression even amongst patients who achieved CD4 counts of at least 200 cells/µl after ART.

The study also reveals adherence as a significant predictor of disease progression; >95% adherence was associated with good response and <80% adherence with poor response. The most common cause of ART failure is poor adherence. The key to successful adherence is educating the patient before the initiation of therapy, supporting ARV initiation as the patient first starts taking medications, and continuously monitoring and supporting adherence. The reinforcement of the principles of adherence by treatment supporters (guardian), relatives, friends and community support personnel is of great help. Factors associated with poor adherence include a poor patient – clinician relationship, high pill burden, forgetfulness, mental depression, lack of patient education, inability of patients to identify their medications, drug toxicity, cultural factors (e.g. religious fasting), beliefs about treatment and the impression of being too ill for treatment.

The study reveals that there was a statistically significant difference in male – female response rate, CD4 count distribution, body mass index, partner status, and duration from diagnosis of HIV to start of ART, adherence, socio-economic status among responders and non-responders. In sub-group analysis the difference in response was statistically significant for sex distribution, addiction, body mass index, partner status, CD4 counts and duration from diagnosis of HIV infection to start of ART.

CONCLUSION

CD4 count is the most significant predictor of treatment response/disease progression in HIV infection. CD4 count <50/µl is associated with poor response in comparison with CD4 count >200/µl.We conclude that female sex, higher body mass index, higher CD4 count, known HIV+ve partner status, >95% adherence is associated with better response and vice-versa.

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