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EVALUATION OF ADHERENCE TO HAART REGIMENS ON THE BASIS OF WHO CLINICAL STAGE AND INITIAL CD4 COUNT AT TERTIARY CARE CENTER

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ABSTRACT

Background: Adherence is generally defined as a patient's ability to follow a treatment plan, take medication at prescribed times and frequency and follow restrictions regarding food and other medications. Since the time of Hippocrates patients often tend to lie about taking their medicines. **Material & Methods:** The present cohort study was conducted at our tertiary care hospital. The study duration was of six months from September 2008 to April 2009. At the start of study around 260 HIV patients were registered for ART out of which 120 patients were enrolled for the study and were followed for six months. **Results:** The WHO clinical stages I and II were highly associated ($p < 0.001$) with adherence. There was highly significant ($p < 0.001$) association between initial III and IV WHO clinical stages and low adherence. In the present study the no relation was found between the initial CD4 count and adherence ($p>0.05$). Association of linkage with PLHA peer group and adherence was highly significant ($p < 0.001$), whereas absence of linkage with PLHA was associated with low adherence ($p < 0.001$). **Conclusion:** The most common reasons for missing of doses were observed as forgetting, being busy in other things and away from home. It can be stated from over study that good adherence is a valid region for the improvement in CD4 count. Also, it was observed that the highly adherent patients were found to have a significant improvement in WHO clinical stage ($p < 0.01$).

Key words: HAART, Adherence, WHO clinical stage, CD4 count.

INTRODUCTION

WHO states the adherence as "The extent to which a person's behavior-taking medication, following a diet and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" **(1)**. Thus, adherence ensures active participation from patients in their own care and that good communication exists between patient and the health professional. Adherence to medication was a big problem in ancient times and still is today. Indeed one of the most challenging problems facing physicians is their ability to improve patient compliance with prescribed regimens **(2)**. Adherence is generally defined as a patient's ability to follow a treatment plan, take medication at prescribed times and frequency and follow restrictions regarding food and other medications. Since the time of Hippocrates patients often tend to lie about taking their medicines**(3)**.

Health care providers and patients face significant challenges regarding adherence to ART **(4)**. In the

treatment of HIV/AIDS, it varies between 37% to 83% depending on the drug under study and the demographic characteristics of patient populations **(5)**. When adherence rate is between 50-85%, the resistance towards ART is likely. Factors that limit complete adherence to HAART are complex and incompletely defined and lead to missing of doses by patients. Too many pills, life-long use of medications with specific dietary and fluid restrictions and adverse drug reactions (ADRs), top the list **(6)**. However, most of the studies are conducted in developed western countries and there is scarcity of data from developing countries where the affected population burden with HIV/AIDS is much greater than the western world **(7)** and contrasting differences exist in socio-economic and educational parameters from that of the developed world **(8)**.

MATERIALS & METHODS

The present cohort study was conducted at our tertiary care hospital. The study duration was of six months from September 2008 to April 2009. This was a study on adherence of HAART regimen in HIV/AIDS patients registered with the newly established Anti-Retroviral Treatment Center (ART-C). At the start of study around 260 HIV patients were registered for ART out of which 120 patients were enrolled for the study and were followed for six months. Written informed consent from each and every participant was taken prior to study. Clearance from Institutional Ethics Committee was taken. Detailed socio-demographic data were taken and recorded along with general physical and clinical examination. As this ART center comes under the national program, dedicated adherence counseling by the professional counselor and support of the peer group, and use of NACO supplied (free of charge) antiretroviral drugs5 was employed in the study, which did not include any protease inhibitors. The treatment strategy for all patients was inclusion of two nucleoside reverse transcriptase inhibitors and one non-nucleoside reverse transcriptase inhibitor (2 NRTI + 1 NNRTI). Inclusion criteria for the patients includes adults i.e. > 18 years of age and patients who were on ART for at least 1 month. At a time the medications were given for a period of 30 days. The patients were told to bring their remaining pills at every visit. The patients who failed to bring their remaining pills (and thus making pill count impossible) were assigned 0% adherence. So, the adherence was calculated every month to have six reading for each patient. The data were analyzed by using software's MS Excel 2010, Epi Info v7 and SPSS v22.

RESULTS

Total 120 patients were enrolled for the study. 62.5% were males and 37.5% were females. 59.66% of the patients were in age group of 30-45 yrs, 27.50% of patients in age group of 18-30 yrs and 13.33% patients were above 45 yrs of age. In present study 52.50% of the patients received AZT+3TC+NVP, 37.50% d4T+3TC+NVP and only 5.83% and 4.16% of patients were on AZT+3TC+EFV and d4T+3TC+EFV respectively. In the present study the WHO clinical stages I and II were highly associated ($p < 0.001$) with adherence. There was highly significant ($p < 0.001$) association between initial III and IV WHO clinical stages and low adherence. (Table 1)

Table 1: WHO clinical stage and Adherence

Clinical stage	High	Low	χ^2	P
I & II	79	16	6.25	≤ 0.001
III & IV	15	10	6.25	≤ 0.001

In the present study the no relation was found between the initial CD4 count and adherence ($p>0.05$). (Table 2) In the present study the association of linkage with PLHA peer group and adherence was highly significant ($p < 0.001$), whereas absence of linkage with PLHA was associated with low adherence ($p < 0.001$). (Table 3)

Table 2: Initial CD4 count and Adherence

CD4 count	High	Low	χ^2	P
>500	8	2	0.17	>0.05
200-499	47	9	1.93	>0.05
<200	39	15	2.16	>0.05

Table 3: Linkage with PLHA and Adherence

Linkage	High	Low	χ^2	P
Yes	72	5	29.14	≤ 0.001
No	19	21	33.60	≤ 0.001

DISCUSSION

Increase in the duration of HIV infection was highly significantly associated with adherence in our study. This finding was in concordance with the study of Paterson et al **(9)** whereas adherence study by Sarna et al **(10)** did not show any association with duration of HIV infection. In present study, initial WHO HIV clinical stages III and IV were associated with low adherence. Similarly, Senegalese study **(11)** also showed association of CDC HIV stage B and C with low adherence. However, in contrast Sough African study **(12)** did not find any association of WHO HIV staging and adherence. Our study found significant association of incidence of hospitalization with low adherence in concordance with other studies by Paterson et al **(9)** and Lazo et al **(13)**. No association was found between initial CD4 counts and adherence in present study. In contrast to this finding, Sarna et al **(10)** and Gordillo et al **(14)** separately concluded the association of CD4 count of less than 200/ μl at baseline with lower adherence. Present study in concordance with other study by Paterson et al (9) found no association of route of transmission of HIV with adherence.

The results of the present study showed high level of overall mean adherence i.e. 92.14%. High adherence was reported in our study in 78.33% patients. In contrast to this Paterson et al and Lucas et al observed low levels of adherence **(9)**. The findings were similar to the studies done by Orrell et al **(12)** and Etard et al **(11)** as regards the level of adherence and percentage of patients showing high adherence. Furthermore, our results fairly matched with two Indian studies, **(15)** which also reported the mean adherence more than 90% and above 80% patients reported higher adherence. Ours is an Indian study representing developing country showing high level of adherence which can be visualized by the meta-analysis done by Mills et al suggesting lower level of pooled adherence in North American studies and higher level of pooled adherence in African studies **(16)**.

The adherence to HAART in our study was found good. As the present study was done at the ART Center under the national HIV/AIDS programme, there was a permanent post of the Professional Adherence Counselor and also peer counseling by PLHA was advised. The peer counselors also made home visits of the low adherent patients and of those having risk of low adherence. As the previous studies suggested adherence as the most important issue in successfully managing HIV/AIDS, a multifaceted approach to improve adherence must be employed **(17)**. The present study showed good adherence levels for which dedicated adherence counseling could be credited. Furthermore, before initiating HAART, a lifelong treatment regimen, adequate patient preparation is must. Trial run of the regimen with vitamin pills or jelly beans may be employed. There should be active participation of the patients in their treatment decisions. The health care providers must help their patients in associating the medication doses with routine activities for example morning doses can be linked with the morning rituals like brushing teeth etc, so as to fit the regimen in the patients' routine. Use of weekly pill boxes, medication diaries, electronic devices (pagers, alarms, beepers), providing incentives are also quite successful in improving adherence.

CONCLUSION

We concluded from the present study that the adherence has shown dynamic behavior over time in our study. It was maximum at the first visit and then a dip was observed. Thereafter, it increased but not up to the initial level. The most common reasons for missing of doses were observed as forgetting (56.47%), being busy in other things (15.29%) and away from home (10%). As the highly adherent patients showed a significant ($p < 0.001$) rise in CD4 counts, it can be stated from over study that good adherence is a valid region for the improvement in CD4 count. Also, it was observed that the highly adherent patients were found to have a significant improvement in WHO clinical stage ($p < 0.01$) and slight weight gain ($p <$

0.05), whereas no relation was found between functional status and adherence.

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