



# Treatment Adherence Pattern among HIV/AIDS Patients Receiving Treatment in the ART Centre of a Tertiary Hospital in Kolkata

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## ABSTRACT

**Background:** WHO recommended at least 95% adherence to antiretroviral drugs for better outcome in terms of improved CD4 count, body weight, general well-being and decreased chance of drug resistance. This study was conducted with the objectives of describing socio-demographic profile and adherence pattern to ongoing regimens in adults with HIV/AIDS in a tertiary hospital in Kolkata, India.

**Methods:** An observational, descriptive cross-sectional study was conducted on the adults receiving ART treatment. Patients above 15 years of age, who received at least one year of treatment before the day of the interview, comprise the study population. Sample size was 279. Information regarding socio-demographic profiles and the level of adherence to treatment in last one month and last one year were collected. The subjects were also asked about the reason behind the missed doses.

**Results:** Majority of the subjects were male and belonged to 25-44 years of age group. Most of the subjects were from low socioeconomic status and had poor level of education. Adherence level of treatment in last one year was adequate in 93.9% subjects, whereas 98.6% subjects had adequate adherence level in last one month. Fear of side effects from the drugs and forgetfulness were the major reasons behind the missed doses.

**Conclusion:** Emphasis should be given on awareness generation and proper counseling of the people with HIV/AIDS so as to maintain adequate adherence level of therapy improving their general well-being.

**Key words:** HIV/AIDS, adherence pattern, Antiretroviral therapy

## INTRODUCTION

AIDS or Acquired Immunodeficiency Syndrome is an advanced stage of Human Immunodeficiency Virus (HIV) infection, and is fatal in nature. HIV is a retro virus which breaks down the host's immune system, thus leading to different life threatening opportunistic infections, neurological disorders and/or unusual malignancies.<sup>1</sup> The host may be asymptomatic in earlier stage, but as the infection progresses, more severe symptoms appear.

HIV/AIDS is not only a viral disease which affects a person's physical, mental and social well-being, but also a social event that influences on how others behave towards People Living with HIV/AIDS (PLHIVs).<sup>1</sup>

In 2015 there were estimated 2.1 million new HIV infections worldwide, giving a total of 36.7 million people living with HIV.<sup>3</sup> The number of PLHIV on ART in 2015 was 17 million, which was 2 million more than the target of 15 million, set by United

Nations General Assembly in 2011.<sup>2</sup> In 2012, the estimated number of PLHIV in India was 20.89 lakh. The adult (15-49 years) prevalence of HIV has continued its steady decline from 0.41% in 2001 to 0.27% in 2011.<sup>3</sup> But still, India is the third highest contributor of PLHIV after South Africa and Nigeria.<sup>4</sup> It was estimated to have around 0.26% of National adult (15-49years) HIV prevalence in 2015.<sup>3</sup> The total number of PLHIV in 2015 in India was estimated to be 21.17 lakhs. India is estimated to have around 86 thousand new HIV infections in 2015, showing 66% decline in new infections from 2000 and 32% decline from 2007, the year set as baseline in the National AIDS Control Programme (NACP) phase IV.<sup>5</sup>

Adherence to therapy can be defined as the patient's ability to follow the treatment regimen, to take medications at prescribed frequency and time, and also to follow restrictions in food and other drug intake.<sup>6</sup> World Health Organization (WHO) has recommended at least 95% adherence to 1<sup>st</sup> line Anti Retroviral drugs (ARVs) for effective control of HIV infection.<sup>7</sup> According to existing global evidence, there is about 4-8% cases resistant to first line ARVs per year.<sup>8</sup> In this context, this study was conducted with the objective of describing the adherence pattern to ongoing ART regimens in adults with HIV/AIDS in a tertiary hospital setting, namely R. G. Kar Medical College and Hospital (RGKMCH), Kolkata, India.

## MATERIAL AND METHODS

An observational, descriptive cross-sectional study was conducted on the adults receiving treatment at the ART centre of R. G. Kar Medical College, Kolkata, from August 2013 to July 2014. Patients aged 15 years or above, who had given consent and received antiretroviral therapy for at least one year before the day of interview were considered as the study subjects. Sampling frame consists of the treatment cards of the patients aged 15 years or above, registered, alive and on ART till 31<sup>st</sup> July 2012 (i.e. one year before the first date of interview), as obtained from the register at ART Centre of R.G. Kar Medical College, Kolkata.

Different studies have shown difference in prevalence of adequate ( $\geq 95\%$ ) adherence to antiretroviral therapy in India. A study conducted by Shah et al. showed 73% patients maintained adequate adherence considering 95% adherence as the cut off value for adequate adherence as mentioned by WHO.<sup>9</sup> So, prevalence of patients with adequate adherence was considered to be 73%. Using the formula, minimum sample size ( $n$ ) =  $z^2 * p (100-p) / d^2$  [where,  $n$  = minimum sample size;  $z$  = 1.96 for 95% confidence interval (CI);  $p$  = prevalence of patients with adequate ( $\geq 95\%$ ) adherence;  $d$  = abso-

lute precision, taken as 5%], the sample size ( $n$ ), as obtained, was 303. The sample size ( $n = 303$ ) was more than 10% of the total population ( $N = 2021$ ). So, using the finite population correction, the corrected minimum sample size ( $n_c$ ) was  $N*n/(N+n)$  i.e 264. Simple random sampling had been used on everyday visit to ART Centre for data collection. Sampling was done till the last week of the last month of the interview and a total of 279 patients were interviewed for the study. Each study subject was briefed about the purpose of the study. The subjects were assured of confidentiality and an informed consent was sought from each of them before initiating the interview. Permission was obtained from Ethical Committee of R.G. Kar medical College and hospital, and West Bengal State AIDS Prevention and Control Society (WBSAP&CS).

The ART adherence for a patient was measured at every monthly visit using the following formula.<sup>10</sup>

$$\text{Adherence} = \frac{\text{No. of tablets the patient had Consumed in a given duration}}{\text{No. of tablets the patient should have Consumed in the same duration}} \times 100\%$$

For effective treatment, adherence of 95% or more is required. While 100% adherence (i.e. missing no dose since the last visit) is desirable, adherence less than 95% is considered as inadequate or poor adherence. Hence, the adherence levels are classified as perfect (100%), adequate ( $\geq 95\%$  but  $< 100\%$ ) and inadequate or poor ( $< 95\%$ ).

Since adherence levels of the patients were noted for last 12 months, there were different adherence levels in different months. In this study, a patient's adherence was taken in last month, and last one year. For measuring the adherence level in last one year, the minimum level of adherence in last twelve months was considered, rather than taking the average value, as it would 'dilute' the result. For example, if a patient's adherence level in last three months were 100%, 99% and 92%, then the minimum value 92% was taken as the adherence level of the patient, which comes under inadequate ( $< 95\%$ ) adherence, but the average value of 97% will rather 'dilute' the situation as it will show an adequate level of adherence.

## RESULTS

The study conducted at ART centre of RGKMCH reveals that the age of the patients on treatment ranges from 20 to 62 years. The mean age is 37.09 years and standard deviation is 7.8 years. Most of the patients (41.6%) belong to age group of 35-44 years followed by 38% patients in 25-34 years age group, which corresponds to the period of maximum sexual activities, the most common route of HIV transmission.

**Table 1: Distribution of study subjects according to age and gender (N=279)**

Age Group (years)	Gender (%)		Total (n=279) (%)
	Male (n=198)	Female (n=81)	
15-24	7 (2.5)	4 (1.4)	11 (3.9)
25-34	63 (22.6)	43 (15.4)	106 (38.0)
35-44	85 (30.5)	31 (11.1)	116 (41.6)
45-54	37 (13.3)	3 (1.1)	40 (14.3)
55-64	6 (2.2)	0 (0.0)	6 (2.2)

**Table 2: Distribution of study subjects according to different socio-demographic variables (N=279).**

Variables	Frequency (%)
Religion :	
Hindu	245 (87.8)
Muslim	34 (12.2)
Language of communication :	
Bengali	234 (83.9)
Hindi	45 (16.1)
Education:	
Illiterate	86 (30.8)
Primary school	88 (31.5)
Middle school	49 (17.6)
Secondary school	15 (5.4)
Higher secondary	20 (7.1)
College or above	21 (7.5)
Marital status:	
Single	45 (16.1)
Married	204 (73.1)
Divorced/separated	12 (4.3)
Widowed	18 (6.5)
Socioeconomic status (Modified B G Prasad Scale, 2013):	
I	13 (4.7)
II	36 (12.9)
III	48 (17.2)
IV	118 (42.3)
V	64 (22.9)
Current employment status:	
Employed	195 (69.9)
Unemployed	84 (30.1)
District :	
Kolkata	126 (45.2)
24 Parganas (North)	103 (39.6)
24 Parganas (South)	6 (2.2)
Nadia	27 (9.7)
Howrah	4 (1.4)
Hooghly	13 (4.7)

**Table 3 : Distribution of study subjects according to their ART adherence patterns in last one month and last one year (N=279)**

Adherence level	Number of patients (%)
In last one month	
100%	271 (97.1)
95-100%	4 (1.4)
<95%	4 (1.4)
In last one year	
100%	206 (73.8)
95-100%	56 (20.1)
<95%	17 (6.1)

**Table 4: Distribution of study subjects according to level of adherence in last one year (N=279)**

Level of adherence	Patients (n=279) (%)
Adequate	262 (93.9)
Inadequate	17 (6.1)

**Table 5: Distribution of patients receiving ART depending on stated reason of missing dose(s) in last one year (N=73).**

Reason for missed dose in last one year	Patients (%)
Forgot to take	25 (34.2)
Forgot to carry	10 (13.7)
Side-effects	25 (34.2)
Late to collect medicine	2 (2.7)
Unaware of missed dose	11 (15.1)

**Table 6: Distribution of patients receiving ART according to the number of months with adequate adherence level in last one year (N=279).**

No. of months with adequate adherence in last one year	Patients (%)
12 months	262 (93.9)
11 months	15 (5.4)
9 months	1 (0.3)
8 months	1 (0.3)

Majority of the patients (71%) are male and 81(29%) patients were female [Table 1]. Hindus comprise the majority of the study subjects (87.8%). Almost 73% subjects were married at the time of the interview. Education level of majority of the subjects was of poor level, with 30.8% illiterates and 31.5% completing up to primary education. This study also reveals most of the study subjects were from poor socioeconomic status, having 42.3% in class IV and 22.9% in class V of B G Prasad scale (2013 modification). Among the study subjects, most of them were coming from Kolkata (45.2%) and North 24 Parganas (39.6%), followed by South 24 Parganas (2.2%), Nadia (9.7%), Howrah (1.4%) and Hooghly (4.7%). Almost 70% of the patients (69.9%) were employed at the time of interview. Among the 84 unemployed patients (30.1%), 66 patients were never employed. The rest 18 patients were employed at any point of their lives, but were unemployed during the time of interview. Among the 18 unemployed patients, 2 were unemployed before the diagnosis of HIV infection. Half of the patients, who were unemployed after their HIV diagnosis, were unemployed because of their HIV status and the rest half, due to illness.

In this study, the lowest adherence in last twelve months was considered as the level of adherence of the patient. Each patient's adherence is measured every month, on each visit. Most of the patients (73.8%) had perfect (100%) adherence in last one year, while 20.1% patients had adherence level in

between 95% and 100%. The rest 6.1% patients had less than 95% adherence, i.e. inadequate adherence. Hence majority of the patients (93.9%) had adequate adherence in last one year [Table 4]. When the adherence level in last one month before the interview was considered, only 1.4% patients had inadequate adherence [Table 3].

The most common reasons stated for missing of doses in last one year were because of perceived side effects from the medication (34.2%) and because they forgot to take the medicine (34.2%). About 13.7% of these patients forgot to carry their medication to their workplace and, thus, missed the dose. About 2.7% patients were late to attend ART Centre of RGKMCH to collect their medication. About 15.1% patients were not even aware that they missed one or more doses and couldn't state any reason [Table 5]. Of the 279 study subjects, 262 patients (93.9%) had adequate adherence in all the twelve months in last one year. Fifteen patients (5.4%) maintained adequate adherence in 11 months in last one year, one patient (0.4%) maintained adequate adherence in 9 months in last one year, while another patient (0.4%) maintained adequate adherence in 8 months in last one year [Table 6].

## DISCUSSION

The study conducted at the ART centre, RGKMCH reveals among the 279 patients, 41.6% belonged to 35-44 years of age group, followed by 38% in 25-34 years of age group. The mean age of the patients is  $37.09 \pm 7.8$  years. The findings in this study are in accordance with those of Wanchu et al.<sup>11</sup> (mean age of  $37.04 \pm 7.6$  years), SK Sharma et al.<sup>12</sup> (mean age  $34 \pm 10$  years). Majority of the patients were male (71%). This finding is in accordance with the fact that most of the sexually active population belongs to these year group. The M:F ratio is about 2.4:1, which is in accordance with the M:F ratio of 2.6:1 by Lal V et al.<sup>8</sup> Most of the patients in our study were Hindu (87.8%) while the rest were Muslim. Similar finding was observed in the study of Khan MA et al., where 86.58% subjects were Hindu.<sup>13</sup> As per modified B G Prasad's scale (2013), 42.3% patients belonged to class IV socioeconomic scale, followed by 22.9% patients in class V scale. So majority of the patients were of poor socioeconomic status, which is a similar finding as in the study by Lekha Tull et al., which showed majority patients belonging to poor socioeconomic status.<sup>14</sup> Our study reveals that majority of the subjects (69.9%) were employed at the time of interview. A study by Sarna et al. showed 82% patients were employed.<sup>15</sup>

Different studies have adopted different method for adherence measurement. Shah et al. considered 95% adherence level as cut off for adequate level and adherence was measured for last 4 days; 73% patients were found to be adequately adherent to ART.<sup>9</sup> Sharma et al. considered 100% as the cut off value for adequate adherence and adherence levels were measured for last one month, six months and life time. In his study 59% patients were found to have adequate adherence level. This difference of proportion of patients with adequate adherence level may be explained but the strict cut off value (of 100%) for adequate adherence.<sup>12</sup> Wanchu et al., in their study, measured adherence level in last 3 days, 7 days and 28 days and the cut off value considered for adequate adherence was 100% (not more than one missed dose in preceding 3 days/7 days/28 days) and 74% patients were found to have adequate adherence level.<sup>11</sup> Sanjay Sinha et al. considered 95% as the cut off level and adherence was measured for last 4 days which revealed 63% patients were adequately adherent.<sup>16</sup> Because of adopting different cut off values, methods and duration, the adherence levels in the above mentioned studies may not be comparable with this study.

There were different reasons, as stated by the study subjects, for which they missed their doses once or more. Table 5 shows most common reasons for missed doses were either the patients forgot to take the medicine (34.2%) or they didn't take it due to fear from side-effects (34.2%). About 13.7% study subjects forgot to carry their medicine with them and hence missed the dose, while 2.7% study subjects were late to collect their medicine on time. The meta-analysis by Mhaskar et al. revealed in 50% studies, cost of medication was the most common obstacle to adherence.<sup>17</sup> Studies by Safren et al.<sup>18</sup>, Shah et al.<sup>9</sup>, Sharma et al.<sup>12</sup>, Wanchu et al.<sup>11</sup>, Sarna et al.<sup>15</sup> revealed different reasons for non-adherence, like cost of medication, adverse events, patients ran out of tablet, patients were away from home, couldn't return to clinic/social stigma, busy with other things, forgot to take medicine etc.

## CONCLUSION

The study conducted at the ART centre of RGKMCH shows that majority of the study subjects were male and most of the subjects belong to 25-44 years of age group. This is the most productive age group and also most vulnerable age group for HIV infection because of higher sexual activities. Also, globally, males are mostly affected by HIV/AIDS. Majority of the subjects belonged to poor socioeconomic status and had lower level of education.

Our study reveals majority of the subjects (93.9%) maintained adequate adherence in last one year before interview. Forgetfulness and fear of side effects were found to be the most common reasons behind missing of doses among the study subjects.

It is of utmost importance that the PLHIVs have adequate knowledge about the disease and also the do's and don'ts regarding the therapy so that they can comply themselves to the advised recommendations and realize its importance for a successful therapy, that has been proven to raise the quality of life of the patients.

Ethical approval: Obtained from R. G. Kar medical College and Hospital Ethical Committee, West Bengal State AIDS Prevention & Control Society.

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