

Nonadherence to Antiretroviral Therapy Among People Living with HIV/AIDS Attending Two Tertiary Care Hospitals in District of Northern India

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ABSTRACT

Introduction: Adherence to antiretroviral therapy is a principal predictor for the success of human immunodeficiency virus (HIV) treatment. It remains as a challenge to acquired immunodeficiency syndrome (AIDS) treatment and care with the widespread of the associated risks. Therefore, study aims to assess nonadherence level and factors associated with nonadherence to ART among people living with HIV/AIDS (PLHA). **Materials and Methods:** A hospital-based, cross-sectional study was conducted at two tertiary care hospital of Lucknow. A total of 322 adult HIV-positive patients registered in the ART center were included. Systematic random sampling was used to recruit patients. Nonadherence was assessed on the basis of pill count method. **Results:** A total of 10.9% of patients were found to be nonadherent to ART. Principal causes cited were being busy with other work (40.0%), felt sick or ill (28.5%), not having money (14.2%), and being away from home (11.4). Multivariate logistic regression analysis revealed that nonadherence was significantly associated with nonbeneficial perceptions towards ART (odds ratio (OR) 18.5; 95% confidence interval (CI) 3.2-106.6; $P = 0.001$), being counseled for adherence for more than 3 months (OR 13.9; 95% CI 1.6-118.9; $P = 0.01$), presence of depression (OR 2.6; 95% CI 1.0-6.7; $P = 0.04$), and those who were not satisfied with healthcare facilities (OR 5.63; 95% CI 1.88-16.84; $P = 0.00$). **Conclusion:** Although adherence to ART varies between individuals and over time, the factors that affect nonadherence can be addressed with proper periodic counseling and motivation of patients and their family members. Adherence to highly active antiretroviral therapy (HAART) could delay the progression of this lethal disease and minimize the risk of developing drug resistance.

Keywords: Antiretroviral therapy, nonadherence, pill count

Introduction

Antiretroviral therapy (ART) has improved the quality of life of human immunodeficiency virus (HIV) patients

worldwide. A reduction in HIV-related morbidity and mortality has been recognized in countries where ART has been made widely available. To achieve optimal results from ART, high levels of patient adherence to ART is essential. High levels of adherence to ART (at least 95%) are needed to ensure optimal benefits.⁽¹⁾

Globally over the past 2 years, there has been a rapid scale-up of access to treatment with ART. This in turn has averted an estimated 4.2 million deaths in low- and middle-income countries between 2002 and 2012. The number of people receiving HIV treatment reached 9.7

Access this article online	
Quick Response Code:	Website: www.ijcm.org.in
	DOI: 10.4103/0970-0218.170970

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Received: 23-12-14, **Accepted:** 12-02-15

million in low- and middle-income countries in 2012. As per the new World Health Organization (WHO) Report 2013 (Global update on HIV treatment), number of people eligible for ART in low- and middle-income countries globally is expected to rise from 16.7 to 25.9 million.⁽²⁾

Adherence is defined as a patient's ability to follow a treatment plan, take medications at prescribed times and frequencies, and follow restrictions regarding food and other medications.⁽³⁾ The national guidelines in India stipulates > 95% adherence to ART.

In Uttar Pradesh there are 20 ART centers. By January 2013, there were 25,578 currently on ART treatment including 24,163 adults and 1,415 children.⁽⁴⁾

Adherence to the highly active antiretroviral therapy (HAART) regimen appears to be the single most important variable that predicts a patient's ability to achieve and maintain suppression of HIV viremia to below the level of detection, and is thus critical for success of HAART. The national guidelines in India stipulates > 95% adherence to first-line regimen.

As per research studies in developing countries, there are multiple factors that influence adherence to ART and categorized as: Patient and family/care giver-related factors, medication-related factors, healthcare delivery system-related factors, and social/environmental factors.

Optimizing adherence and minimizing loss to follow-up are two major challenges for the ART rollout program in India. Despite of understanding the importance of ART adherence, no reliable data is available on level of nonadherence and factors associated with it, specifically in Uttar Pradesh. Till 2005 there are about 2,425 lost to follow-up cases in the state itself. Therefore, the present study aims to assess nonadherence level and factors associated with nonadherence to ART among people living with HIV/acquired immunodeficiency syndrome (AIDS; PLHA) in Uttar Pradesh, India.

Materials and Methods

Study design

The present study is a hospital-based, cross-sectional, analytical study.

Study settings

The study was conducted at the ART center of King George's Medical University and Ram Manohar Lohia Institute of Medical Sciences, two tertiary care hospitals in Uttar Pradesh, India. Both these center provides ART free of charge and has the relevant resources for CD4 count estimation, counseling sessions, and regular check-ups.

Study participants

All PLHA patients from this center aged ≥ 18 years, and who have been receiving ART for at least 6 months were included in the study.

Sample size

Assuming nonadherence level as 30%⁽⁵⁾ and an absolute precision of 5%, the total sample size required was calculated to be 322 (formula used: $n = z^2pq/e^2$; where n = sample size, z = value of standard normal deviate = 1.96 at 95% confidence interval (CI), p = prevalence of non-adherence, $q = 1-p$, and e = absolute precision).⁽⁶⁾

Sample selection

During the study period, data was collected on three (alternate) days every week. Days of data collection were varied in consecutive weeks to reduce the bias for day-specific outpatient department attendance. Every sixth patient from the registration on that day was interviewed, if patient was not eligible for this study next consecutive patient was interviewed in private, until the target sample size was reached. A total of 322 patients were included in the study. Unwilling patients, patients who were unable to communicate, and seriously ill patients were excluded from the study.

Ethical clearance

This study was approved by Ethics Committee of King George's Medical University. Patients were first briefed about the purpose of the study and assured regarding the confidentiality of the data given. After written consent was obtained from the participants, they were interviewed.

Data collection tool

Patients were interviewed with the help of a predesigned and pretested schedule and data regarding sociodemographic characteristics and adherence to ART were collected. Becks Depression Inventory (Hindi) was used to assess depression in patients. The Beck Depression Inventory is a 21-item, self-report rating inventory that measures characteristic attitudes and symptoms of depression.⁽⁷⁾ Higher scores on scale indicated a greater number of depressive symptoms or a greater probability of major depressive disorder. The score ranged from 0 to 63. For the purpose of analysis the score was dichotomized, with ≥ 17 being indicative of depression.

Pill count method for assessment of nonadherence

Adherence percentage (A) was assessed using pill count method. $A = (\text{number of tablets or doses actually taken by a patient for a particular time period}) \div (\text{number of tablets or doses the patient should have taken during this time period})$. All patients with poor adherence percentage < 95% of treatment adherence were denoted as 'nonadherent'.⁽⁸⁾

Data management

Data was compiled and analyzed using the statistical software. The association between different sociodemographic and clinical variables in relation to nonadherence to HAART was determined using Pearson's chi-square test; Yates corrected chi-square, and Fisher's exact test was applied in appropriate cases. Independent variables that were found to be statistically significant in bivariate analysis were considered for application in the logistic regression model to determine the important predictors of nonadherence, with nonadherence as the dependent variable. For multivariate analysis, inter method was used. A *P*-value ≤ 0.05 was considered statistically significant.

Results

The mean age of the 322 patients enrolled in the present study was 38.3 ± 9.0 years. Most of the patients were male and Hindu (62.4 and 74.5%, respectively), 50% were each from rural and urban areas, and 28.6% were illiterate. The percentages of patients who were married, widowed, and separated were 63.4, 24.8, and 3.1%, respectively. In our study population, 34.8% of patients were unemployed. Majority (64.5%) of the patients belonged to middle socioeconomic class [Table 1]. In terms of treatment, majority (57.1%) of patients were on zidovudine (ZDV), lamivudine (3TC), and nevirapine (NVP) regimen. About one-fifth 20.2% had experienced side effects following ART in last 3 months.

Table 2 shows that 35 of the 322 (10.9%) patients were nonadherent to ART during current visit. Based on pillcounts, we found that 10.9% patients had $< 95\%$ adherence to ART, while 1.6% were even found to have adherence percentage < 50 . Same pattern of nonadherence was observed during their visit at ART center in last 2 months. Table 4 shows the major reasons cited for nonadherence;

- Busy with other things (40.0%);
- Felt sick or ill (28.5%);
- Don't have money to visit ART center (14.2%);
- Forgot to bring medicines when away from home (11.4%);
- Wanted to avoid side effects (2.8%); and
- Felt like the drug was toxic/harmful (2.8%).

Multivariate logistic regression analysis [Table 3] revealed that nonadherence was significantly associated with nonbeneficial perceptions towards ART (odds ratio (OR) 18.5; 95% CI 3.2-106.6; *P* = 0.001), being counseled for adherence for more than 3 months (OR 13.9; 95% CI 1.6-118.9; *P* = 0.01), presence of depression (OR 2.6; 95% CI 1.0-6.7; *P* = 0.04), and those who were not satisfied with healthcare facilities (OR 5.63; 95% CI 1.88-16.84; *P* = 0.00). However, other factors like low socioeconomic

Table 1: Distribution of patients attending ART center according to their pattern of nonadherence to ART during preceding last 3 months (N = 322)

Adherence percentage	Last 3 months					
	1 st month		2 nd month		3 rd month	
	No.	%	No.	%	No.	%
Adherent						
≥95%	287	89.1	290	90.1	290	90.1
Nonadherent						
80-94%	28	8.7	24	7.5	22	6.8
51-79%	2	0.6	2	0.6	4	1.2
≤50%	5	1.6	6	1.9	6	1.9

ART: Antiretroviral therapy

status and who had any side effects which were significant during bivariate analysis were found to be insignificant during multivariate analysis.

Discussion

This study was conducted among 322 PLHA (≥ 18 years of age) to determine the pattern of nonadherence to ART and factors associated with nonadherence at two tertiary care hospitals of Uttar Pradesh. Our results revealed a nonadherence level of 10.9% amongst PLHA. Similar level of nonadherence was reported in other studies conducted at other centers; Wanchu *et al.* (10%) in northern India⁽⁹⁾ and Saha *et al.*, (11.6%) in West Bengal,⁽¹⁰⁾ using same study design and criteria to assess nonadherence in PLHA. Contrary to this, study conducted in Pune and Delhi by Sarna *et al.*,⁽¹¹⁾ used 4-day recall method to assess nonadherence reported a much higher (19%) nonadherence among patients receiving free ART. However, Gokarn *et al.*,⁽¹²⁾ reported a much lower (5%) nonadherence level using "self-report method" for calculating nonadherence to ART. This large variation in the level of nonadherence among different studies in the country could be explained due to variation in different methods that were used to assess the level of nonadherence.

Similar to other studies conducted at national and international level,⁽¹³⁻¹⁶⁾ socio-demographic characteristics like age, sex, religion, category, marital status, socioeconomic class, education level, and employment status of PLHA were not found to be affecting adherence to ART. However, in present study, 3.4% of PLHA "perceived ART to be nonbeneficial" for their illness and also higher level of non adherence (63.6%) was observed among these patients, a finding that is concurrent with a study by Pinheiro *et al.*,⁽¹⁶⁾ who also observed nonadherence higher among patients with negative perception towards ART. "Being busy" in other things was another principle reason for nonadherence followed by "illness" in present study, a finding that is similar to Saha *et al.*,⁽¹⁰⁾ and Byakika-Tusiime *et al.*,⁽¹⁷⁾ who also observed high level of nonadherence among PLHA who

Table 2: Distribution of patient attending ART center by their biosocial characteristics

Variable	Number	Percentage
Current age (years)		
18-30	69	21.4
31-35	75	23.2
35-40	78	24.2
41-50	66	20.5
>50	34	10.6
Gender		
Male	201	62.4
Female	121	37.6
Marital status		
Married	204	63.4
Widow/widower	80	24.8
Unmarried	28	8.7
Separated/divorced	10	3.1
Religion		
Hindu	245	76.1
Non-Hindu	77	23.9
Category		
General	126	39.1
OBC	158	49.1
SC/ST	38	11.8
Residence		
Urban	161	50
Rural	161	50
Type of family		
Nuclear	218	67.7
Joint	104	32.3
Family size		
≤5	211	65.5
6-10	82	25.5
≥16	29	9
Education		
Illiterate	92	28.6
Primary	34	10.6
Middle	63	19.6
High school	69	21.4
Intermediate	31	9.6
Graduate and above	33	10.2
Current employment status		
Employed	210	65.2
Unemployed	112	34.8
Socioeconomic class*		
I (upper)	39	12.1
II (middle)	37	11.5
III (lower middle)	38	11.8
IV (upper lower)	82	25.5
V (lower)	126	39.1

*Modified BG Prasad socioeconomic scale 2013, ART: Antiretroviral therapy, OBC: Other backward class, SC: Schedule caste, ST: Schedule tribe

were busy in other activities during the date given to them for follow-up.

Orrell *et al.*,⁽¹⁸⁾ and Sinha *et al.*,⁽¹⁹⁾ reported that people cope better with ART adherence, if they share their HIV

status with others (family/relatives), a finding which was not found consistent with the present study. In the present study, 14.2% of the nonadherent patients reported “financial burden” as one of the reason for nonadherence, a finding consistent with the study by Achappa conducted in south India.⁽²⁰⁾

Nonsatisfaction with the healthcare facilities among patients who perceived that visits were too frequent to take medications was also found to be an independent predictor for poor adherence, a finding consistent with study done by Orrell *et al.*⁽¹⁸⁾ The study revealed the importance of counseling at each visit after every month, as those who were last counseled within 3 months were about 14 times less prone to become nonadherent. This may be due to continued counseling by which patients were able to express concerns about their health and is concurrent with other study findings.^(19,21) Depression was found as independent predictor of nonadherence in our study indicating the severity of the disease, likely to cause nonadherence; which was found to be consistent with other studies.^(11,19)

Limitations

However, the study was subject to several limitations. It is possible that selection bias occurred, as only those PLHA who were on ART at the time of data collection were included, whereas those who were lost to follow-up or could not attend the ART center to collect drugs could not be enrolled in the study. Secondly, the study was conducted in hospital settings, therefore its generalizability is limited.

Conclusions

Achieving 100% adherence for all the patients on ART is a great challenge. Long counseling gaps, wrong perception towards ART, presence of depression, and nonsatisfaction with health services were found to be barriers to adherence.

Timely detection of nonadherence behavior and appropriate monitoring of patients, difficulties with ART could potentially help patients to maintain adherence, and therefore improve the treatment outcomes. Adherence is a process, not a single event, and adherence support must, therefore, be integrated into regular clinical follow-up. Investigation of factors associated with long-term adherence would require longer follow-up than the present study. In order to maximize the benefits of ART, patients should be educated on the need of adhering to the right dose at the right time as an intervention against barriers to adherence. Utilization of multiple measures of

Table 3: Factors associated with nonadherence to ART (N = 322)

Variables	Adherence to ART		Unadjusted OR (95% CI)	Adjusted OR (95% CI)
	Adherent (n = 287)	Nonadherent (n = 35)		
Age				
>35	158 (88.8)	20 (11.2)	1.08 (0.53-2.21)	NA
≤35	129 (89.6)	15 (10.4)	Reference	
Gender				
Female	104 (86.0)	17 (14.0)	1.66 (0.82-3.36)	NA
Male	183 (91.0)	18 (9.0)	Reference	
Marital status*				
Married	179 (87.7)	25 (12.3)	1.50 (0.69-3.26)	NA
Single	108 (91.5)	10 (8.5)	Reference	
Type of family				
Nuclear	194 (89.0)	24 (11.0)	1.04 (0.49-2.22)	NA
Joint	93 (89.4)	11 (10.6)	Reference	
Residence				
Urban	143 (88.8)	18 (11.2)	1.06 (0.52-2.15)	NA
Rural	144 (89.4)	17 (10.6)	Reference	
Current employment status				
Unemployed	95 (84.8)	17 (15.2)	1.90 (0.94-3.87)	NA
Employed	192 (91.4)	18 (8.6)	Reference	
Religion				
Non-Hindu	68 (88.3)	9 (11.7)	1.11 (0.49-2.49)	NA
Hindu	219 (89.4)	26 (10.6)	Reference	
Category				
OBC	138 (87.3)	20 (12.7)	1.68 (0.75-3.73)	NA
SC/ST	33 (86.8)	5 (13.2)	1.75 (0.56-5.50)	
General	116 (92.1)	10 (7.9)	Reference	
Education				
Up to high school	229 (88.8)	29 (11.2)	1.22 (0.48-3.08)	NA
More than high school	58 (90.6)	6 (9.4)	Reference	
Socioeconomic** status				
Upper lower and below	179 (86.1)	29 (13.9)	2.91 (1.17-7.25)	2.04 (0.67-6.14)
Lower middle and above	108 (94.7)	6 (5.3)	Reference	
Perception towards ART				
Nonbeneficial	4 (36.4)	7 (63.6)	17.68 (4.8-64.15)	18.50 (3.2-106.6)
Beneficial	283 (91.0)	28 (9.0)	Reference	
Perceived sideeffects				
Yes	52 (80.0)	13 (20.0)	2.67 (1.26-5.64)	1.90 (0.73-4.97)
No	235 (91.4)	22 (8.6)	Reference	
Time elapsed since last counseling				
1-3 months	223 (94.1)	14 (5.9)	1.94 (0.24-15.31)	2.17 (0.25-18.53)
> 3months	33 (62.3)	20 (37.7)	18.78 (2.3-148.4)	13.93 (1.6-118.9)
<1 months	31 (91.9)	1 (3.1)	Reference	
Disclosure of HIV status				
No	213 (88.0)	29 (12.0)	1.67 (0.67-4.20)	NA
Yes	74 (92.5)	6 (7.5)	Reference	
Social support				
Absent	238 (87.8)	33 (12.2)	3.39 (0.78-14.62)	NA
Present	49 (96.1)	2 (3.9)	Reference	
Distance travelled to reach ART center (km)				
<50	107 (88.4)	14 (11.6)	1.13 (0.53-2.45)	NA
50-100	50 (89.3)	6 (10.7)	1.04 (0.38-2.83)	NA
>100	130 (89.7)	15 (10.3)	Reference	
Number of pills taken per day				
Two	166 (88.8)	21 (11.2)	1.09 (5.35-2.23)	NA
Three	121 (89.6)	14 (10.4)	Reference	

(Continued)

Table 3: (Continued)

Variables	Adherence to ART		Unadjusted OR (95% CI)	Adjusted OR (95% CI)
	Adherent (n = 287)	Nonadherent (n = 35)		
Sexual intercourse during last three months				
Yes	174 (86.9)	26 (13.1)	1.90 (0.86-4.21)	NA
No	113 (92.7)	9 (7.3)	Reference	
Treatment apart from ART				
Yes	21 (80.8)	5 (19.2)	2.11 (0.74-6.00)	NA
No	266 (89.9)	30 (10.1)	Reference	
Satisfaction with health care facilities				
Not satisfied	21 (61.8)	13 (38.2)	7.48 (3.30-16.94)	5.63 (1.88-16.84)
Satisfied	266 (92.4)	22 (7.6)	Reference	
Alcohol intake				
Yes	106 (87.7)	15 (12.3)	1.28 (0.62-2.60)	NA
No	181 (91.1)	20 (9.9)	Reference	
Depression***				
Present	44 (73.3)	16 (26.7)	4.65 (2.22-9.73)	2.62 (1.01-6.76)
Absent	243 (92.7)	19 (7.3)	Reference	

*Single includes unmarried, widow, divorced, and separated, **Modified BG Prasad socioeconomic scale 2013, ***Becks Depression Inventory. ART: Antiretroviral therapy, OBC: Other backward class, SC: Schedule caste, ST: Schedule tribe, HIV: Human immunodeficiency virus, OR: Odds ratio, CI: Confidence interval, NA: Not available

Table 4: Reasons for nonadherence to antiretroviral therapy (N = 35)

Reasons for nonadherence	No.	Percentage
Personal		
Were busy with other things	14	40
Don't have money	5	14.2
Were away from home	4	11.4
Medications		
Felt sick or ill	10	28.5
Wanted to avoid side effects	1	2.8
Felt like the drug was toxic/harmful	1	2.8

adherence to be incorporated in the care plans and multiple target interventions focus to resolve the barriers to adherence should be implemented based on barriers present.

Acknowledgement

I am thankful to Dr Neetu Gupta, Dr. Suman Shukla, Medical Officer ART centre, Mrs Rajnigandha, Counsellor, ART Centre, King George's Medical University Lucknow, Dr. Abhishek Gupta, Dr. Pallavi Shukla, Dr. Ravikantand my dear juniors for their constant encouragement and motivation.

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How to cite this article: Shukla M, Agarwal M, Singh JV, Tripathi AK, Srivastava AK, Singh VK. Nonadherence to antiretroviral therapy among people living with HIV/AIDS attending two tertiary care hospitals in district of northern India. *Indian J Community Med* 2016;41:55-61.

Source of Support: Nil, **Conflicts of Interest:** None declared.