

Original Research Article

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Prevalence and factors associated with adherence to highly active anti-retroviral therapy among patients living with HIV and AIDS in a tertiary care unit in Kozhikode

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ABSTRACT

Background: Adherence to therapy is central to the success of anti-retroviral treatment (ART) and one of the most important factors influencing long term prognosis of HIV infection. In order to achieve this, patients are required to maintain more than 95% adherence to achieve lasting suppression of viral replication. The objective of the study was to assess the adherence to highly active antiretroviral therapy among people living with HIV (PLHIV) and the factors associated with adherence.

Methods: This was a cross-sectional study conducted among PLHIV patients attending ART clinic, government medical college, Kozhikode from June 2015 to 2016. Adherence was estimated using modified Morisky 8 items questionnaire. Pretested semi-structured questionnaire was used to study various associated factors by interview method.

Results: Of the 265 patients, the majority 246 (92.8%) were found to be treatment adherent and 19 (7.2%) were non-adherent. Most of the study population were in the age group 31-45 years and majority of the PLHIV were taking first line fixed dose regimens. Factors such as the early stage of the disease, using a method to remember, disclosure status, involvement in social activities, regular visit to ART clinic, financial and emotional support, involvement in social activities and HIV in the family were found to be positively associated with adherence.

Conclusions: Our study had found that a cordial environment in the ART centre will improve adherence and factors such as strong patient-provider relationship, including trust and engagement with the provider, which helps in improving ART adherence.

Keywords: Adherence, HAART, HIV, Factors, Morisky, Kerala

INTRODUCTION

HIV, one of the world's leading infectious diseases killers has claimed more than 25 million lives over the past three decades. Based on the UNAIDS report in 2015, there were 36.7 million 34.0-39.8 million people living with

HIV globally.¹ Highly active antiretroviral therapy (HAART) is the cornerstone in the management of patients with HIV infection. The initiation of widespread use of antiretroviral therapy markedly declines the incidence of most AIDS defining conditions and mortality both in the developed and developing world. Adequate

suppression requires strict adherence to antiretroviral therapy.^{2,3} In order to achieve the goal of antiretroviral therapy of undetectable levels of the virus in the blood (<50 copies/ml), patients are required to maintain more than 90-95% adherence. This means missing no more than one dose a month, if ARV medications are prescribed in once a day dose.^{4,5} WHO defines treatment adherence as the extent to which a person's behaviour taking medications, following a diet and/or executing lifestyle changes corresponds with agreed recommendations from a health care provider. There is not much published data relating to adherence issues from Kerala, especially from a public health facility under National AIDS Control Organization (NACO). The present study was conducted to assess the level of adherence and the factors associated with adherence to HAART among people living with HIV (PLHIV) attending ART clinic.

METHODS

This cross-sectional study was conducted in government medical college, Kozhikode in Kerala. The ART clinics at Kerala are named Ushus clinic and this clinic started functioning in 2004. It is under the direct control of National AIDS Control Organization (NACO) operating in liaison with Kerala State AIDS Control Society (KSACS). This clinic caters to population from the five districts of Kerala namely Malappuram, Kozhikode, Wayanad, Kannur and Kasaragod and provides free treatment. The study was conducted from July 2015 to 2016 for a period of one year. 3424 patients were started on ART from this centre from 2004 and during study period, 2492 patients were availing ART in the centre. According to a systematic review and meta-analysis by Mhaskar et al, the average adherence to ART is 70%.² Sample size was calculated by applying the formula $4pq/d^2$ p=prevalence 30% q=(100p) so 70%, taking the precision as 20% of p and estimated to be 233. Considering the drop out of 15% because of death or loss to follow up, the sample size is corrected to 268. After obtaining prior permission from NACO and KSACS, 280 PLHIV were recruited by simple random sampling. The patients were interviewed when they came for CD₄ count testing. Finally, 265 participants were enrolled into the study after getting an informed consent. The adherence to treatment was measured using Morisky medication adherence scale 8 items questionnaire which includes eight questions about drug taking behaviour over the past two weeks.⁶

It's a yes/no type of questionnaire. An answer of yes was assigned a score of 1 and an answer of "no" was assigned a score of 0 and the total score was calculated. A score of 3 to 8 means low adherence, 1 to 2 means medium adherence and a score of 0 means high adherence. Patient's satisfaction was assessed by a questionnaire with questions on patient's satisfaction about doctor's and worker's support, satisfaction regarding infrastructure. The responses were measured on a 4-points Likert scale

ranging from 4 indicates strongly agree and 1 indicates strongly disagree.

Statistical analysis

Data analysis was carried out using SPSS software version 20. All the variables under consideration were categorical in nature. The distribution of variables according to different variables of adherence to ART was generated. The association of various parameters in relation to adherence levels for ART which was divided into binary (adherent versus non-adherent) was analysed using Fisher's exact test and chi-square test depending on the nature of frequency distribution. A probability value of less than 0.05 (<0.05) was considered significant.

RESULTS

Socio-demographic characteristics of respondents

Of 280 patients were selected through sampling, 265 gave consent to participate in the study. The response rate was 94.6%. 133 (50.2%) participants belonged to the 31-45 years age group. The proportion of males 155 (58.5%) was found to be higher than females 110 (41.5%). Majority of the participants were Hindus 143 (54%) followed by Muslims 110 (41.5%) and Christians 2 (4.5%). 196 (74%) of the patients were married and living with spouses. 196 (74%) participants belonged to the upper lower class and 63 (23.8%) belonged to lower middle class as per the modified Kuppuswamy scale. The use of addictive substances was reported among male participants only. 114 (73.5%) of the 155 male subjects reported smoking at some point in their life. 108 (69.7%) of the 155 male subjects had ever used alcohol. 3(1.1%) out of 155 male subjects gave a history of intravenous drug abuse. Currently, 12 (7.7%) were smokers and 8 (5.2%) were alcoholics. These are shown in (Table 1).

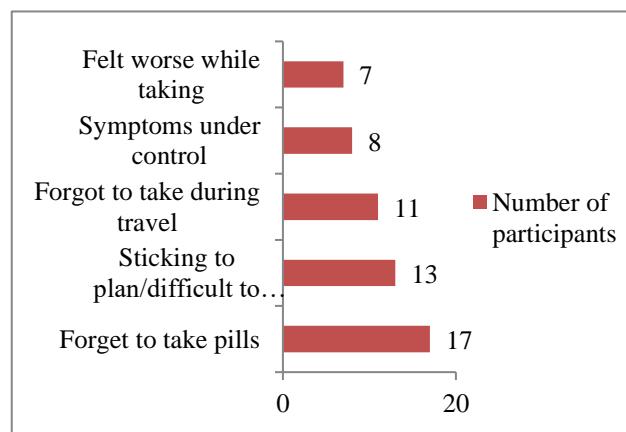


Figure 1: Reasons for non-adherence among PLHIV.

HAART adherence levels among PLHIV

In our study the adherence rate among the PLHIV was found to be 92.8% (95% C.I. 89.7-95.9%). 246 out of 265

participants were found to be adherent as per Morisky medication adherence scale. The median score among the adherent patients was 0 (IQR-0). The median score among the non-adherent patients was 4 (IQR-1.08).

Reasons for non-adherence as in Figure 1 were forgot during outside travels, difficult in sticking to treatment plan which further lead to difficulty in remembering to take drugs.

Table 1: Socio-demographic characteristics of the participants.

Characteristics	Frequency	Percentage
Age group (in years)		
≤30	16	6
31 to 45	133	50.2
46 to 60	104	39.2
>60	12	4.5
Gender		
Male	155	58.5
Female	110	41.5
Religion		
Hindu	143	54
Muslim	110	41.5
Christian	12	4.5
Locality		
Rural	234	88.3
Urban	31	11.7
Educational status		
Illiterate	37	14
Middle School	68	25.5
High School	135	51
Intermediate	10	3.8
Graduate	15	5.7
Marital status		
Married and living together	196	74
Single*	69	26
Type of family		
Nuclear	227	85.6
Joint	38	14.4
Employment status		
Working	150	56.6
Not working	115	43.4
Socio-economic status		
Lower	5	1.9
Upper lower	196	74
Lower middle	63	23.8
Upper middle	1	0.3

Table 2: Association between adherence and socio-demographic details.

Disease characteristics	Adherent N (%)	Non-adherent N (%)	χ^2	P value	OR (95% C.I.)
Age					
<45 years	130 (93.5)	9 (6.5)	0.212	0.645	1.25 (0.48 to 1.37)
>45 years	116 (92.1)	10 (7.9)			
Gender					
Male	145 (93.5)	10 (6.5)	0.289	0.58	1.3 (0.51 to 3.2)
Female	101 (91.8)	9 (8.2)			
Marital status					
Married and living together	185 (94.4)	11 (5.6)	2.722	0.10	2.35 (0.9 to 5.73)
*Single	61 (88.4)	8 (11.6)			

Continued.

Disease characteristics	Adherent N (%)	Non-adherent N (%)	χ^2	P value	OR (95% C.I.)
Employment status					
Working	140 (93.3)	10 (6.7)	0.13	0.72	1.18 (0.46 to 3.02)
Not working	106 (92.2)	9 (7.8)			
Educational status					
Illiterates	36 (97.3)	1 (2.7)		0.48*	2.6 (0.33 to 20.1)
Primary, middle, high school and graduates	250 (92.1)	18 (7.9)			
Socio economic status					
Lower	186 (92.3)	15 (7.7)		0.74*	0.83 (0.26 to 2.61)
Upper	60 (93.7)	4 (6.3)			
Current alcohol usage					
Yes	5 (83.3)	1 (16.7)		0.37*	0.16 (0.02 to 1.60)
No	239 (83)	8 (17)			

*Fisher's exact test was used to calculate p value.

Table 3: Association between adherence and disease and therapy related factors.

Factors	Adherent n (%)	Non-adherent n (%)	Chi-square	P value	OR (95% C.I.)
Duration of HAART					
<1 year	22 (100)	0 (0)		3.02	0.202*
1 to 2 years	88 (94.6)	5 (5.4)			
>2 years	136 (90.7)	14 (9.3)			
Staging of disease					
Stage I and II	182 (95.8)	8 (4.2)		8.83	<0.001
Stage III and IV	64 (85.3)	11 (14.7)			3.9 (1.51 to 10.2)
Opportunistic infections					
Present	38 (79.2)	10 (20.8)		16.44	<0.001
Absent	208 (95.9)	9 (4.1)			0.16 (0.06 to 0.43)
Dosing					
Once daily	28 (84.8)	5 (15.2)		3.61	0.058
Twice daily	218 (94)	14 (6)			0.9 (0.78 to 1.05)
Method to remember					
Yes	208 (98.1)	4 (1.9)			<0.001*
No	38 (71.7)	15 (28.3)			20.5 (6.5 to 65.2)
Side effects					
Yes	63 (88.7)	8 (11.3)		2.45	0.118
No	183 (94.3)	11 (5.7)			0.47 (0.18 to 1.23)
Regular visit to ART clinic					
Yes	240 (94.5)	14 (5.5)		25.27	<0.001
No	6 (54.5)	5 (45.5)			14.3 (3.88 to 52.6)
Hospitalisation					
Yes	78 (86.7)	12 (13.3)		7.78	0.005
No	168 (96)	7 (4)			0.27 (0.10 to 0.71)
Overall health					
Improved	217 (93.5)	15 (6.5)			
Significantly improved	29 (96.7)	1 (3.3)	39.68	<0.001	
Not improved	0 (0)	3 (100)			

*Fisher's exact test was used to calculate p value.

Relationship between HAART adherence and PLHIV socio-demographics

Table 2 describes the association of adherence with socio demographic details. Adherence is marginally better among those below 45 years 130 (93.5%) compared to

those 45 years and above 116 (92.1%) and men were found to be more adherent but not statistically significant. Adherence was high 36 (97.3%) among the illiterates compared to the educated, but this association too statistically significant.

Those who were married and living with spouses was found to be more adherent ($p=0.10$). Employed HIV-infected individuals, particularly those in low- and high-income countries, were more likely to adhere to ART than unemployed individuals. Those PLHIV who were employed were 27% more likely to adhere to ART than those who were unemployed. However, there was no

association between employment status and adherence rates. In the current study, participants belonging to middle class 93.7% are found to be better adherent than lower class 92.3% and adherence was high 239 (83%) among those who don't use alcohol currently compared to those who had current use but these associations were not significant.

Table 4: Adherence and recent CD4 count and cordial environment.

Factor	Level of adherence	Mean	SD	P value*
Recent CD4 count	Adherence (246)	516.09	239.2	<0.001
	Non adherent (19)	352.05	193.8	
Satisfaction score for infrastructure of ART clinic	Adherent (246)	42.66	3.97	0.023
	Non adherent (19)	40.47	7.91	
Rating of health facility	Adherent (246)	7.65	0.69	0.015
	Non adherent (19)	7.32	1.6	
Number of counselling sessions	Adherent (246)	4.17	0.71	0.001
	Non adherent (19)	3.53	1.12	

*P value was found out using t test.

Table 5: Association between adherence and health system related factors and social factors.

Factors	Adherent N (%)	Non adherent N (%)	Chi square	P value	OR (95% C.I.)
Part of HIV related network					
Yes	89 (98.9)	1(1.1)		0.006*	10.2 (1.33 to 77.7)
No	157(89.2)	18(10.8)			
Disclosure status					
Yes	239 (96.8)	8 (3.2)	84.42	<0.001	46.95 (14.1 to 152.9)
No	7(38.9)	11 (61.1)			
HIV in family					
Yes	133 (99.3)	1(0.7)		<0.001	1.15 (1.07 to 1.23)
No	113 (86.3)	18 (13.7)			
Financial/emotional support					
Yes	179(95.7)	8(4.3)	6.98	0.01	3.67 (1.42 to 9.53)
No	67(85.9)	11(14.1)			
Participation in social activities					
Yes	189 (98.4)	3(1.6)	17.7	<0.001	17.68 (4.97 to 62.85)
No	57 (78.1)	16 (21.9)			

*P value was found out using t test.

Table 6: Multivariate analysis.

Factors	Adjusted odds ratio	95% CI	P value
Method to remember to take drug daily	19.05	2.9 to 124.4	0.002
Number of tablets/days*	1.26	0.26 to 6.02	0.77
Hospitalisation for HIV related disease	0.12	0.02 to 0.69	0.02
Counselling sessions*	0.48	0.19 to 1.2	0.113
Disclosure	12.07	2.04 to 74.82	0.007
HIV in family	6.79	0.63 to 73.6	0.115
Part of social activities	14.81	2.27 to 96.4	0.005

*These were quantitative variables while all others were qualitative variables with yes or no responses.

Relationship between HAART adherence and PLHIV therapy related factors

In table 3 the association between adherence and therapy related factors are tabulated. Adherence found in the study was high 182 (95.8%) among those participants who were in the early stages (stage I and II). Adherence is also high among those who don't have opportunistic infections and the difference is statistically significant. Mean CD4 count was also significantly associated with adherence, the count being high in those who are adherent to the prescribed regime. 212 (80%) of patients are using a method to remember the time of drug intake. Using any method to remember is advised during the counselling on ART initiation. Out of 212 patients who had a method to remember, majority 153 (72.2%) were using alarms and 59 (27.8%) were being reminded by family members. Those who use a method to remind themselves are found to be good adherent compared to those who did not use a method. This association is found to be significant. Those who have not experienced side effects were found to be better adherent compared to those who experienced side effects, though the association is not statistically significant. The side effects reported are mainly GI symptoms and drug allergy. Those who come for regular follow up were found to be better adherent than those who miss their follow up. This association is found to be statistically significant. The participants who reported significant improvement with treatment had high adherence 29 (96.7%) and the association is statistically significant. Significant association was also found between hospitalisation and adherence. Those who were never hospitalised are found to be better adherent than those who were hospitalised.

Relationship between HAART adherence and cordial environment in the ART clinic

Table 4 shows the association among adherence and recent CD4 count and cordial environment. This study found out higher adherence among those who attended a greater number of counselling sessions than who attend lesser number of counselling sessions and the association was statistically significant. Mean CD4 count was also significantly associated to adherence, the count being high in those who are adherent to regime. The satisfaction score among adherent people was high than who were non adherent and association was statistically significant. Adherent people rated health facility as good and the association between ART centre satisfaction and adherence was significant.

Relationship between HAART adherence and health system, social factors

Table 5 discusses about adherence and health system and social factors. In the present study, adherence is high among those who are part of a HIV related network and the association is statistically significant. In the present study, we found out that the satisfaction score among

adherent people is high among those who are non-adherent and it is statistically significant and adherent people rated health facility as good and association between ART centre satisfaction and adherence is significant. In the current study we found out that the adherence is significantly high among those who disclosed their HIV status to their family and friends. Adherence is also high among those who had others with HIV in the family and it is found to be statistically significant. Adherence was high 95.7% in those who had financial/emotional support and it is statistically significant. In this study, about 72.5% of the 265 participants reported getting involved in social activities. The adherence is high among those who participate in social activities 98.4% compared to those didn't participate in social activities 78.1%.

Multivariate analysis

All the variables which are found out as significant in univariate analysis and had enough number of observations were included in multivariate analysis which is shown in (Table 6). The multi variate analysis was done using enter method. Model was found to be statistically significant (Cox and Snell R^2 -0.290, Nagelkreke R^2 -0.720, p value <0.001). After doing multi variate analysis, method to remember to take drug daily, absence of hospitalisation due to HIV related illness, disclosure to family and friends and involving in social activities were found to be independently associated with adherence.

DISCUSSION

Overall, the patients living with HIV in present study had good adherence. The ART clinic where the study was conducted is a tertiary level teaching hospital. This fact along with counselling services offered in the centre may have contributed to the good adherence. The factors related to adherence can be classified as socio-demographic factors, disease and therapy related, cordial environment, health system related factors and social factors.

In socio-demographic factors, younger patients, male gender and educational status are not found to significantly influence on adherence. In 2007, Sarna et al had found similar results in New Delhi with the adherence being better among younger participants - a result with no statistical significance (p value - 0.113).⁷ A study by Gokran et al found that adherence is more among those aged less than 40 years - a statistically significant difference.⁸ In the growing literature on factors associated with antiretroviral adherence, a consistent relationship between gender and adherence has not been found. Arnsten et al, Turner et al, Altice et al, and Delgado et al also found that men are more adherent than women.⁹⁻¹² A study by Sarna et al, Cauldbeck et al in India revealed that adherence is higher among men, though it is not statistically significant.^{7,13} The study by

Anuradha et al too did not find educational status influencing adherence rates ($p=0.69$).

In our study, the majority of the participants were started on treatment after one year of diagnosis. The gap between diagnosis and treatment initiation ranged from 8 months to 25 years. The reason for delay in initiation is the criteria that treatment should be initiated only when CD₄ count is <350 count. In a trial conducted by Babiker et al, early antiretroviral treatment lowered the risk of serious AIDS related events by 72%. Early treatment also lessened the risk of serious non-AIDS events by 39%.

One of the main facilitators for adherence found in present study is in health system related factors which are early stage of infection, absence of opportunistic infections, usage of method to remember to take drugs and regular visit to ART clinic. As opportunistic infections are less in stage I and II, patients need to take only a smaller number of tablets. This could be the reason for the higher adherence in these stages. In a study conducted by Rai et al, the adherence is high among those who has less opportunistic infections though the association is not statistically significant.¹⁶ Reminders had been proven beneficial for improving adherence in patients of all ages.¹⁷ Elderly patients may be at risk of forgetting to take their medication because of memory problems. Adolescents, on the other hand, may be at risk for forgetting their dose because of their busy (social) lives. In a study done by Tran et al in Canada, 62.2 % of the participants had reported that they are using alarms.¹⁸ In a study by Roux et al it was found that use of mobile phones significantly improved adherence (p value <0.001).¹⁹ In a study by Kunutsoor et al, clinic attendance for reviews was significantly associated with medication adherence, with patients having regular follow up having four fold greater odds of achieving optimal ($\geq 95\%$) medication adherence odds ratio 3.89, 95% CI: 1.48 to 10.25, Fischer exact p value =0.000.²⁰ In a study by Cauldbeck et al, they found that regular follow up in ART centre was significantly associated with adherence.¹³ In the current study we found out that adherence is high among those who attended more number of counselling sessions than who attend less number of counselling sessions and the association between them is statistically significant. Every patient, before starting ART, undergoes three sessions of adherence counselling by adherence counsellor. If the patients miss medication or do not report on time to collect medications, adherence counselling is repeated. Group counselling is also conducted daily during OPD hours using audio visual aids, comprising of a television set playing educational information regarding HIV and drug adherence, in the patients waiting area. Patients who fail to come to OPD on scheduled day are contacted telephonically. Those who are lost to follow up are visited at their homes by outreach workers. Every time patient attends OPD to collect their monthly medication they have to first meet the counsellors.

Another factor that played a significant role in achieving adherence is being part of HIV network. Being a part of network will provide an environment to share the issues related with drug compliance. Assessment of cordial environment at the centre factored their experiences on maintaining confidentiality, experience of stigma both from doctors and counsellors and the infrastructure of the centre. A study by Joshi et al and Campero et al had found out that cordial environment is associated with good adherence.^{21,22}

The social factors which are found to be helpful in achieving good adherence are disclosing the disease status, financial/emotional support from family members, and participation in social activities. Anuradha et al, Pahari et al and Joshi et al also found that there was significant association between disclosure status and adherence.^{14,21,23} Anuradha et al report that the adherence is high among those who had financial/emotional support from family members.¹⁴ In studies by Lal et al and Ajith Kumar et al living with spouse was associated with good adherence and Johnson et al, also found that being in a marital relationship is associated with lower viral load.²⁴⁻²⁶

Limitations

The limitations of the study were CD₄ count was used as proxy indicator to assess adherence. Serum levels of the drugs would have been a better indicator, but could not be done considering the cost limitations. The data was collected only from patients attending government set up. Though this includes most patients who are receiving ART, a minor proportion of patients receiving treatment from private doctors and private hospitals might have been missed. Self-reporting that was used in this study is not the ideal method to assess substance abuse. It had to be used due to feasibility issues with the other methods.

CONCLUSION

The adherence to highly active anti-retroviral therapy in our study was found to be 92.8%. The majority of the study group were in the age group of 31 to 45 years. The factors that positively influence adherence was a method to remind drug intake, restricting hospitalisations, more counselling sessions, a regular visit to clinic, cordial environment at the ART clinic, part of HIV related network, disclosure status, financial/emotional support, involvement in social activities. A cordial environment in ART centre will improve adherence and support patient-provider relationship, increase trust and improve ART adherence.

Recommendations

It has been three decades since HIV was first diagnosed, yet we have not arrived anywhere near a permanent cure. Adherence to HAART will improve the quality of life. The following recommendations for intervention were

made based on our study results. The majority of the study population were in age group 31 to 45 years. This age group constitutes the economically productive population of the community. Health education regarding HIV and its prevention at the school and college level will aid in preventing the acquiring of infection among the younger adults. The gap between diagnosis and treatment initiation ranges from 8 months to 25 years. The reason for the delay in treatment initiation is due to the existing treatment guidelines on treatment initiation only when CD₄ count is <350. Considering the current evidence for early initiation of treatment irrespective of CD₄ count, the national treatment guidelines can be revised. The use of mobile phones/alarms as a reminder to take drug and sticking to treatment plan can be encouraged among those who are non-adherent. HIV related patient networks should be established in many places especially in areas of low adherence to improve adherence and tackle other issues. Anti-retroviral therapy should be continued free of cost.

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