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A comparison of adherence to antiretroviral medications in Human Immunodeficiency Virus depressed and non-depressed patients

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Abstract

A high level of adherence to Antiretroviral Treatment (ART) of at least 95% is needed for optimal suppression of Human Immunodeficiency Virus (HIV)'s RNA. Non-adherence's consequences have severe implications for managing People Living with HIV (PLHIV). Adherence predicts virologic outcomes in a dose-dependent manner. Depression is the most prevalent psychiatric disorder among PLHIV with a prevalence of 17% in Sub-Saharan Africa (SSA). To determine and compare the prevalence of non-adherence to Antiretroviral (ARV) drugs among depressed and non-depressed patients with HIV on ART. The study was conducted in Kano, Nigeria, at an HIV clinic located within a tertiary hospital. The study was a comparative cross-sectional study that enrolled 130 depressed and 130 non-depressed PLHIV. Statistically significant associations were found between depression and ART regimen type, Central Penetration Effectiveness (CPE), and pill burden. The prevalence of non-adherence among HIV depressed was 29.3%, while it was 23.6% amongst non-depressed using the adherence questionnaire. Depressed HIV patients have less adherenc e compared to non-depressed patients. It is recommended that consultation-liaison psychiatry is integrated into HIV treatment and car e.

Key words: HIV, adherence, depression, Nigeria.

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Introduction

Adherence to Antiretroviral Treatment (ART) is defined as the act of taking prescribed pills at the specified time and dose, and in the correct way and non-adherence is failure to take medication correctly or as prescribed.[1,2] Although these drugs do not cure Human Immunodeficiency Virus (HIV), they are highly effective in controlling viral replication, approximating the life expectancy of infected individuals to that of the general population; hence are often referred to as Highly Active Antiretroviral Therapy (HAART) or Combination Anti-Retroviral Therapy (cART).[1]

The long-term efficacy of cART in controlling HIV clinical state and progression relies on sustained and continuous adherence, the lack of which may result in the emergence of viral resistant strains, virologic failure, comorbidities, increased risk of sexual transmission and mortality.[2] The national guidelines for HIV treatment in Nigeria recommended first-line Antiretroviral (ARV) drugs for adults as Zidovudine (AZT) or Tenofovir (TDF) with Lamivudine (3TC) or Emtricitabine (FTC) and Nevirapine (NVP) or Efavirenz (EFV) for first-line treatment while there are various other regimens for HIV with other co-morbid issues.[3]

Several factors affect the distribution of antiretroviral agents in the Central Nervous System (CNS), notably the individual drugs' pharmacokinetic, pharmacodynamic and physiochemical characteristics.[4] Based on these factors, a hierarchical scoring of ARVs called Central Penetration Effectiveness (CPE) was devised to estimate the CNS potency of individual drugs. Each antiretroviral drug is assigned an integer from 0 to 1, with 0 indicating low or relatively poor estimated CNS penetration, 0.5 indicating medium or intermediate CNS penetration and 1 indicating high or relatively good estimated CNS penetration.[4] A total CPE score is the sum of all antiretroviral drugs in a regimen.

Estimated adherence of at least 95% is required for optimal suppression of HIV's Ribonucleic Acid (RNA) in the plasma of most patients.[1,5] Adherence rate of 95% has been reported to achieve viral suppression in 78% of patients and a drop in adherence rate to 80% reduces the viral suppression rate to as low as 20%.[5] Previous estimates of adherence in Sub-Saharan Africa range from 68% to 90%.[6-8] The consequence of non-adherence to cART has economic implications particularly in resource-limited settings, with increasing need for costly and often scarce higher generation cART, viral load assays and genetic testing for mutations, treatment of Acquired Immunodeficiency Syndrome (AIDS)-related complications, and loss of productive workforce.[7]

Major depression is the most prevalent mental illness among People Living with HIV (PLHIV) with an estimated prevalence of 17% in Sub-Saharan Africa (SSA). Despite the burden of depression among PLHIV, depression is often under diagnosed in clinical

practice in SSA.[9-11] Depression may be characterised by deficits in multiple domains of cognition including memory and psychomotor speed.[12,13] Deficits in these domains have been associated with a higher risk of mortality possibly through impaired medication adherence with consequent virologic failure and increased viral transmission.[14,15] Our aims were: i) to determine and compare the prevalence of non-adherence to antiretroviral medications among depressed and non-depressed patients with HIV on cART; ii) to identify the factors associated with nonadherence to antiretroviral medications among depressed and non-depressed patients with HIV on cART.

The research question was "what is the prevalence of non-adherence to antiretroviral medications and factors associated with it among depressed and non-depressed patients with HIV on cART?".

Materials and Methods

Study area

The study was conducted in the city of Kano, Kano State, Nigeria. Kano is the most populous city in the country. Kano's 2023 population is now estimated to be at 4,348,481, with a growth rate of 3.06%.[16]

Study facility

Aminu Kano Teaching Hospital (AKTH) is a tertiary hospital in Kano. The Professor S.S Wali Virology Centre is an outpatient clinic in AKTH that provides HIV care and treatment services. The clinical has enrolled over 37,080 patients from inception in 2004.[17] Ethical approval was granted by the Aminu Kano Teaching Hospital Ethical Committee. The study was a comparative cross-sectional study. The study was conducted among adult HIV patients on cART at Aminu Kano Teaching Hospital. Inclusion criteria included adults, 18-65 years old, with positive antibodies to HIV1, HIV2 or both, who were diagnosed within the last 2 years and have been receiving cART for at least 6 months, at least 6 years of education completed, granted informed consent. Those excluded were those with a history of current substance abuse and/or dependence, Traumatic Brain Injury (TBI) with loss of consciousness of more than 30 minutes, and previous or current neurological or major psychiatric disorder unrelated to HIV. Others excluded were patients with sensory disabilities like blindness, hearing defect, history of positive hepatitis C virus infection from medical records, documented history of Central Nervous System (CNS) opportunistic infections, and those that do not understand Hausa or English language. The study was conducted over a period of 6 months. The sample size was determined using the standard formula for comparing two proportions.[18]

$$n = \frac{(Z\alpha + Z_1 - \beta)2\ [(P1q1) + (P2q2)]}{(P1-P2)2}$$

n= minimum sample size required in each group
=117.5

A non-response rate of 10% (11.75) was added to this sample size making it 129.25 (rounded up to 130 in each group). Participants in both groups were matched for age, gender, level of education and duration of diagnosis of HIV infection. Participants were selected using a two-stage systematic sampling technique. In the first stage, the Mini International Neuropsychiatric Interview (MINI) was administered to selected eligible participants to determine those with or without depression. The following instruments were used: i) a socio-demographic questionnaire; ii) an HIV-related clinical questionnaire; iii) the MINI International Neuropsychiatric Interview (MINI)-7; iv) a self-report medication use and adherence questionnaire; v) a Visual Analogue Scale (VAS). The MINI International Neuropsychiatric Interview (MINI)-7 version is a brief structured diagnostic interview developed for clinical and research purposes.[19] The sensitivity and specificity for a diagnosis of a depressive episode were 0.94 and 0.79 respectively.[20] It has high inter-rater reliability, with kappa coefficients ranging from 0.88 to 1.0.[20] The MINI has been translated into the Hausa language, using backward and forward translation in another study conducted in Kano, with inter-rater reliability found to be 84%.[21] The MINI has been used widely in Nigeria among HIV patients.[15]

A one-month recall period was used in administering the self-report questionnaire. The medication use and adherence questionnaire was developed by the AIDS clinical group trials study.[22] It has been validated and used previously among HIV adult patients in Nigeria.[23] Participants were required to indicate when they last missed a medication dose (<1 week, <1 month, 1-3 months, never) and how many times doses were missed (once, twice or more than two times). This resulted in a dichotomous variable of adherent (not more than one missed dose in the past month) or non-adherent (two or more doses missed).

The Visual Analogue Scale (VAS) requested participants to "put a cross on the line below the point showing their best guess about how much medication they have taken in the last 4 weeks". Adherence levels assessed from the VAS were defined as follows: adherent as ≥95% and non-adherent as <95% of prescribed doses taken in the last month. The VAS tool has been shown to give estimates that parallel unannounced pill counts and predicted HIV viral load.[24,25]

Results

A total of 260 HIV patients were enrolled on the study (130 with depression and 130 without depression. Only 123 subjects in each group had complete data which was used for analysis.

Socio-demographic characteristics of the participants; The age range of the participants was 18 to 65 years, with mean age of 37.54 (Standard Deviation, SD±10.04) years. The mean age of HIV-depressed participants was 36.59 (SD±10.09) years and that of HIV-non-depressed participants was 38.50 (SD±9.4) years. This difference was not statistically significant (p=0.134). The mean years of education was 11.85 (SD±2.74) years in the HIV-depressed group and 12.09 (SD±2.79) years in the HIV-non-depressed group, with a little more than two-thirds (69.5%) of the study participants having 12 or more years of education. The study participants did not significantly differ in gender, level of education, employment status and average monthly income (p>0.05 respectively)

Clinical characteristics of the HIV-positive participants; Statistically significant associations were found between depression status and the following variables: ART regimen, CPE score and pill burden (p<0.05 respectively) (Table 1). There was no statistically significant difference between depressed and non-depressed groups with regard to adherence rates, VAS score, duration since diagnosis, and Nadir CD-4 count. (p>0.05 respectively) (Table 1).

Prevalence of non-adherence to ARVs among participants: 65 (26.4%) of the study population were not adherent to their ARVs. The prevalence of non-adherence was more among HIV-depressed patients (29.3%) compared to HIV-non-depressed patients (23.6%) (Figure 1). This difference, however, was not statistically significant (χ^2=0.732; p=0.386). The prevalence of medication non-adherence using the VAS was 40.7% among the entire study population. The prevalence among HIV-depressed and non-depressed patients was 46.3% and 35% respectively. This difference was not statistically significant (χ^2=2.848; p=0.092). Sociodemographic factors

associated with non-adherence to ARVs among depressed and non-depressed patients with HIV: there was no significant association between non-adherence and all sociodemographic factors in both groups of patients (p>0.05, respectively).

Clinical variables associated with non-adherence among depressed and non-depressed patients with HIV: only pill burden and VAS score were found to be significantly associated with non-adherence to ARVs among the depressed participants (p<0.05 respectively). There was no statistically significant difference between other clinical variables and non-adherence (p>0.05) (Table 2). Similarly, no significant association was found between non-adherence and all clinical variables among non-depressed patients (p>0.05) except for the VAS score (p<0.001) (Table 3).

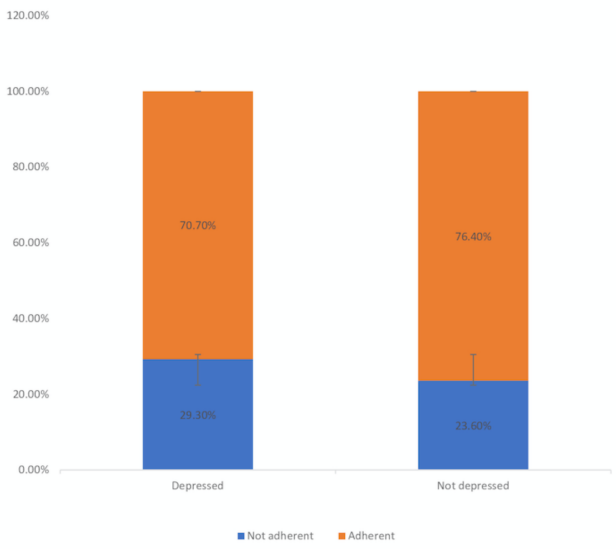

Figure 1. Prevalence of non-adherence to antiretrovirals among depressed and non-depressed patients with Human Immunodeficiency Syndrome (HIV).

Table 1. Clinical characteristics of Human Immunodeficiency Virus (HIV) depressed and HIV non-depressed patients.

Variable	HIV depressed N=123, frequency (%)	HIV non-depressed N=123, frequency (%)	χ^2	p
Adherence				
Adherent	87(70.7)	94 (76.4)	0.753	0.386
Not adherent	36(29.3)	29(23.6)		
VAS				
Poor (<95%)	57(46.3)	43(35.0)	2.848	0.092
Good (≥95%)	66(53.7)	80(65.0)		
EFV-based regimen				
Yes	16(13.0)	31(25.2)	5.155	0.023*
No	107(87.0)	92(74.8)		
Regimen with NRTI backbone				
Yes	18(14.6)	21(17.1)	0.122	0.727
No	105(85.4)	102(82.9)		
ARV line				
1st line	114(92.7)	114(92.7)	0.000	1.000
2nd line	9(7.3)	9(7.3)		
CPE score, n (%)				
Poor (<7)	18(14.6)	35(28.5)	6.157	0.013*
Good (≥7)	105(85.4)	88(71.5)		
Pill burden				
No	63(43.4)	82(56.6)	5.442	0.02*
Yes	60(59.4)	41(40.6)		
Duration of diagnosis in months				
<24 months	63(51.2)	65(52.8)	-	0.811
≥24 months	60(48.8)	58(47.2)		
Viral load				
Undetectable (<20 copies/ml)	68(54)	58(46)	-	0.069
≥20 copies/ml	35(41.7)	49(58.3)		
Nadir CD4 count				
<200 cells/ml	33(36.1)	45(44.6)	0.594	0.441
≥200 cells/ml	54(50.9)	56(55.4)		

*Sstatistical significance; VAS, Visual Analogue Scale; EFV, Efavirenz; Nucleoside Reverse Transcriptase Inhibitor (NRTI); ARV, Antiretroviral; CPE, Central Penetration Effectiveness.

Discussion

The overall prevalence of ARV non-adherence in this study was 26.4%. While among the HIV-depressed patients and non-depressed the prevalence was 29.3% and 23.6%, respectively. The average prevalence in this study (26.4%) is similar to a previous report documented in the neighbouring town of Zaria (27%)[7] and a multi-national study involving 5 African countries (28%).[26] It is however lower than estimates of South-South Nigeria (40.1%).[27] The discrepancies in reported estimates across Africa and in the different regions of Nigeria may be because of varied recall periods used in adherence measures.[27]

The current study used a one-month recall period because previous studies have shown this to be more objective than 1 or 2-

Table 2. Clinical factors associated with non-adherence to antiretroviral medications among depressed patients with Human Immunodeficiency Virus (HIV).

Variables	Adherent	Not adherent	χ^2	p
Duration of diagnosis				
<24 months	46(73.0)	17(27.0)	0.139	0.710
≥24 months	41(68.3)	19(31.7)		
Duration of treatment				
≤12 months	42(76.4)	13(23.6)	1.072	0.301
>12 months	45(66.2)	23(33.8)		
Viral load				
Undetectable (≤20copies/ml)	51(75.0)	17(25.0)	0.579	0.447
≥20 copies/ml	23(65.7)	12(34.3)		
Nadir CD4 count				
>200	24(72.7)	9(27.3)	0.006	0.937
≥200	41(75.9)	13(24.1)		
VAS				
Poor (<95%)	28(49.1)	29(50.9)	22.054	<0.001*
Good (>/=95%)	59(89.4)	7(10.6)		
CPE score				
Poor (<7)	13(72.2)	5(17.8)	0.000	1.000
Good (≥7)	74(70.5)	31(29.5)		
Pill burden				
No	39(61.9)	24(38.1)	4.026	0.045*
Yes	48(80)	12(20)		

*Statistical significance; df=1. VAS, Visual Analogue Scale; CPE, Central Penetration Effectiveness.

Table 3. Clinical factors associated with nonadherence to antiretroviral medications among non-depressed patients with Human Immunodeficiency Virus (HIV).

Variables	Adherent	Not adherent	χ^2	p
Duration of diagnosis				
<24 months	52(80.0)	13(20.0)	0.603	0.437
≥24 months	42(72.4)	16(27.6)		
Duration of treatment				
≤12 months	39(84.8)	7(15.2)	2.157	0.142
>12 months	55(71.4)	22(28.6)		
Viral load				
Undetectable (≤20 copies/ml)	44(75.9)	14(24.1)	0.052	0.819
>20 copies/ml	39(79.6)	10(20.4)		
Nadir CD4 count				
<200	34(75.6)	11(24.4)	0.015	0.904
≥200	44(78.6)	12(21.4)		
VAS				
Poor (<95%)	25(58.1)	18(41.9)	10.755	<0.001*
Good (≥95%)	69(86.3)	11(13.7)		
CPE score				
Poor (<7)	29(82.9)	6(17.1)	0.680	0.409
Good (≥7)	65(73.9)	23(26.1)		
Pill burden				
No	60(73.2)	22(16.8)	0.953	0.329
Yes	34(82.9)	7(17.1)		

*Statistical significance; df=1. VAS, Visual Analogue Scale; CPE, Central Penetration Effectiveness.

week periods.[28] The result suggests at least 1 in 4 patients receiving treatment for HIV in this study have missed at least 5% of their prescribed ART doses (<75% adherence) in the preceding month. This is particularly concerning because the efficacy of HAART depends solely on maintaining high rates of treatment adherence, considered as adherence equal to or greater than 95% of the prescribed dosages.[29] A possible reason for this level of non-adherence amongst others may include a progressive decline in funding by international partners in the last few years. This situation has warranted clinicians to occasionally prescribe previously free drugs when stocks run out.

Another important finding of this study is the higher prevalence of non-adherence found among depressed patients (29.3% *vs* 23.6%) when compared to non-depressed patients. While the margin of difference is not significant in this study, it might become statistically significant with a larger sample. Other studies have reported a similar pattern but with statistically significant differences. These include studies in the USA (45.1% *vs* 25.9%),[30] and Zaria, Nigeria (63.6% *vs* 21.1%).[7] The insignificant difference between the two groups in this study suggests that other factors in isolation or combination with depression affect adherence. Nevertheless, a few reasons may have accounted for the contrasting findings in the literature.

Firstly, the current study had an equal number of patients that were demographically matched in the depressed and non-depressed group while the previous study populations were more diverse and had significantly more patients without depression. For instance, the study in Zaria may have found a significantly higher prevalence of non-adherence among depressed patients because the study population was predominantly female (68.4%).[7]

Secondly, while most studies use self-report of patients to assess adherence, an American study reported a nonadherence level of 45.1% among depressed patients using a composite measure.[30] This measure combined the patient self-report and appointment adherence to calculate the global composite adherence as against the patient self-report used in the current study. This could have resulted in a higher estimate. The significance of the method used in varying estimates is seen in the findings of the current study. While the non-adherence rate with the self-report questionnaire was 29.3% and 26.9% among depressed and non-depressed patients respectively; it was 46.3% and 35% respectively using the visual analogue scale. This trend is in keeping with studies in Ethiopia.[31] Kalichman *et al.* concluded that self-reported recall of missed medications may overestimate adherence while VAS correlates better with objective adherence measures (unannounced pill counts).

The study in the USA examined the relationship between depression and adherence longitudinally over time while the others including the current study examined cross-sectionally.[30] The high prevalence of non-adherence among depressed participants in this study though not statistically significant may be a result of any or a combination of factors. Clinical depression often presents with hopelessness for the future and low energy that can affect willingness to follow through with health-sustaining behaviours like adherence. Patients with depression may also have somatic symptoms and be more concerned about the adverse effects of ARVs making them less likely to be fully adherent. In addition, self-report measures of adherence used in these studies may be vulnerable to recall bias. This may be more remarkable in patients with depression who sometimes present with memory problems and could give incorrect self-report of adherence.

Adherence is a complex behaviour that may require more than a single-item measure to assess. On the other hand, it is uncertain whether depression preceded or followed non-adherence. However, the cross-sectional design of this study makes inference about the causal direction of the relationship between depression and non-adherence impossible.

No significant association was found between any of the sociodemographic factors with medication non-adherence in the current study. This observation was made in both depressed and non-depressed groups. The demographic matching of participants in depressed and non-depressed groups in terms of age, gender and level of education may have created an overmatching bias that obscured any sociodemographic-adherence relationship. The absence of gender association with medication nonadherence is in keeping with previous studies.[8,32] Different assessment tools might have varying usefulness in specific patient groups. No association was found between the level of education and self-report medication non-adherence in both depressed and non-depressed patients. This is in keeping with the findings of Oku *et al*.[27]

In this study, there was no significant association between the duration of diagnosis of HIV and medication non-adherence among both depressed and non-depressed patients. This may be a result of continuous counselling offered to patients on ART. Similarly, duration of treatment was not associated with non-adherence in both groups. This should be interpreted with caution since most of the participants in this study had a short duration of treatment. Excluding participants on treatment for more than two years might have limited generalisation of our study.

HIV viral load and Nadir CD4 count are two clinical variables that have been used as proxy markers of self-reported medication non-adherence in the past.[23] In contrast, this study did not find any association between these variables and self-reported adherence in both depressed and non-depressed patients. This is not surprising since self-reported adherence was obtained for the preceding month while the corresponding Nadir CD4 counts were obtained at enrolment and viral load was taken twice yearly. The long interval between the clinical measures and adherence assessment may have negated any possible association. Also, about 25% of CD4 count results and 15% of recent viral load assay results were unavailable on the electronic medical records and could have affected the analysis. Nevertheless, the lack of association is supported by a study in another part of the country.[23]

A multinational African study found patients on stavudine and zidovudine-containing regimens were less likely to adhere compared to Truvada-based regimens.[33] In contrast, this study found no such association with these drugs or any other drug/regimen among depressed and non-depressed patients. This may be due to the diverse regimen in the current study that may have reduced the power to identify any association. Participants in this study were likely on drugs with fewer adverse effects. Also, some patients have been switched across regimens in the last year.

Self-reported medication adherence was found to be significantly associated with pill burden among depressed patients but not among non-depressed patients. Pill burden was defined as taking more than one ARV pill daily or an additional pill apart from the ARVs. While most patients in the current study were taking a daily fixed dose (single) tablet regimen, about 89% of those with a pill burden were taking daily cotrimoxazole tablets. More patients in the depressed group (48.8%) had a pill burden compared to the non-depressed (33.3%). Some patients may have a pill burden due to treatment of an ARV-associated adverse effect. The high pill burden and cotrimoxazole prophylaxis in the depressed group might imply they had a severe illness at treatment initiation that

warranted treatment and or prophylaxis against opportunistic infections. Studies in South-south Nigeria found similar associations with pill burden in the general HIV population.[34,35] The Nigerian study however considered 3 or more pills as a pill burden.

The VAS was significantly associated with self-reported adherence among both depressed and non-depressed patients. This association suggests that VAS has utility in the clinical monitoring of adherence. The VAS is simple, brief, non-invasive and can be printed on the table to take repeated measures of many patients, eliminating the cost of printing questionnaires. It may also be useful in monitoring other aspects of behaviour e.g., exercise, sleep hygiene, adherence to other medications, *etc*. The VAS also reflects patients' insight into their adherence behaviour compared to other measures. Considering the relatively good sensitivity and specificity of VAS against the adherence questionnaire found in this study, any report of non-adherence using the VAS at any time along the HIV care continuum should stimulate adherence counselling. Additional research examining the use of VAS against objective measures like eMEMS, pill count or pharmacy refill in our setting will be important.

Limitations

The reasons for non-adherence were not explored in this study.

Conclusions

The prevalence of self-reported medication non-adherence among depressed HIV patients and among non-depressed patients in this study are concerning because the long-term clinical efficacy of cART solely depends on optimal adherence that ensures healthy longevity and prevents the emergence of viral resistance and treatment failure. The VAS may be an inexpensive and easy-to-use alternative to an adherence questionnaire. It is recommended that investigation into more evidenced-based interventions that improve adherence be undertaken.

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