

Review Article

Association between self-reported medication adherence and virologic outcome among human immuno-deficiency virus positive adults accessing care at a tertiary treatment centre in Rivers State, Nigeria

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ABSTRACT

Medication adherence reduces the risk of resistance to antiretroviral therapy. The frequently applied methods in measuring medication adherence are self-reported adherence and viral load monitoring. However, due to the backdrop of recall bias and overestimation of outcomes associated with self-reported adherence, viral load monitoring may be a better measure. This study assessed the association between medication adherence and virologic outcome among human immuno-deficiency virus (HIV) positive adults accessing care at a treatment centre in Rivers State, Nigeria. This cross-sectional study employed the systematic sampling technique to select eligible HIV-positive adults accessing care at the University of Port Harcourt Teaching Hospital between September 2022 to November 2022. Data were collected using a validated 3-item structured interviewer-administered questionnaire and analyzed with statistical package for social science (SPSS) version-26. Pearson's Chi-square was used to test for associations at a significance level of $p < 0.05$ and a 95% confidence interval. Confounding variables were controlled by stratifying into gender groups. 1600 participants were recruited; males (800), and females (800) with a mean age and standard deviation; males (44.53 ± 10.50), and females (40.58 ± 9.34). The mean self-reported optimal adherence levels were; male (98.7 ± 6.4), and female (97.3 ± 10.0) at $p < 0.001$. The virologic suppression levels were; male (89.5%), and female (89.6%). The association between self-reported adherence and virologic outcome; female (90.0%, $p = 0.268$) and male group (89.7%, $p = 0.485$). Self-reported adherence was not associated with virologic outcomes between gender groups. Hence, viral load monitoring is recommended as a standalone method of assessing medication adherence due to its additional advantage of measuring progress toward virologic suppression.

Keywords: Association, Self-reported, Medication adherence, Virologic outcome, HIV-positive

INTRODUCTION

Adherence to human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) treatment, care and support (HIV/AIDS management) is defined as the precise involvement of an HIV-positive patient in prescribed antiretroviral therapy, scheduled clinic appointments, nutritional plan, lifestyle modification, and laboratory investigations, family and social support.^{1,2}

Medication adherence also known as the adherence to HIV/AIDS treatment is one of the three components (treatment, care and support) of HIV/AIDS management among people living with HIV/AIDS (PLWHA). It is defined as the consistent intake of prescribed antiretroviral drugs by an informed HIV-infected person to reduce the risk of resistance to the drugs, and achieve and sustain virologic suppression.^{1,2}

Medication adherence involves four processes: initiation, implementation, medication persistence and discontinuation. The first phase of treatment known as initiation starts when an HIV-positive individual takes the first dose of the prescribed antiretroviral medication. The implementation phase begins with the dosing of the antiretroviral regimen. This is the extent to which a patient's actual dosing corresponds to the prescribed regimen from the initiation phase to the last dose of treatment. The third phase regarded as medication persistence is considered an important aspect of adherence and it is defined as "the length of time a client is on highly active antiretroviral therapy (HAART). The final phase which is the discontinuation phase is the moment a patient on ART stops taking the prescribed medication at the end of therapy when no more dose is required. Although, this may not apply in PLWHA since ART cannot be discontinued.^{1,2} However, it can be substituted or switched to another regimen. In non-adherent patients, ART is often discontinued due to medical, social, cultural or economic factors that affect treatment at one point or the other.¹

Monitoring medication adherence among PLWHA differs depending on the methodology applied and this may involve the use of several methods. Studies have shown that there is no single gold standard in measuring medication adherence.^{3,4} The various methods of assessing adherence among HIV-positive patients are self-reported, pharmacy refill, pill counts, medication event monitoring system (MEMSCap), and viral load measurement. Self-reported adherence is the most frequently applied method involving the use of a complex questionnaire with outlined details on the type of ART regimen, the dose of the ART, dose intervals, route of administration and the number of days the medication was missed.^{5,6} The pharmacy refill method analyses drug intake based on the use of the patient's ART refill or prescription record as documented at the pharmacy without assessing the actual doses the patient took or missed subject and this may result in information bias.¹ The pill count method assesses the number of doses taken based on the remaining drugs in the drug packs when physically presented at the pharmacy. Here again, this may be subject to overestimation of adherence level because the absence of pills in the drug pack may not equate to the number of drugs taken.⁷ The medication event monitoring system (MEMSCap) is the use of an electronic device to monitor the dates and time the drug packs were opened which is assessed by the assumption that the medication is taken once a drug pack is opened.⁸ Finally, the viral load measurement, is seen as the only method that gives a true reflection of the adherence level of ART among PLWHA. It is equally accepted as the gold standard for monitoring the virologic outcome of patients and this is measured based on two consecutive viral load values 6-12 months apart, with associated adherence counselling after the first or baseline viral load test.^{9,10} For this study only self-reported adherence and viral load measurement will be applied as the methods for assessing medication adherence among participants.

Self-reported adherence focuses on a short assessment period i.e. ART history of each respondent 1-4 weeks before the study was conducted.¹¹ Even though this duration of assessment which involves a longer time frame may give a more representative result. However, to control for recall bias in 90-100% of respondents, a shorter duration of 1-week has been advocated.^{12,13} This method has proven to be effective when applied alongside viral load monitoring. According to the World Health Organization (WHO) self-reported adherence is classified into two levels: optimal adherence which is defined as the commitment and precise involvement of an informed HIV-infected patient to accurately and consistently take at least 95% of HAART at approximately the same time of the day as prescribed on the treatment plan. Suboptimal adherence occurs when an informed HIV-positive client takes <95% of the prescribed ART regimen.^{14,15} However, patients whose self-reported optimal adherence levels, are "perfect" (100%) or "near-perfect" ($\geq 95\%$) may not automatically have better virologic outcomes than those with "good enough" ($\geq 80-90\%$) adherence. Thus, categorizing patients according to various levels of adherence thresholds (80-90%, $\geq 95\%$, and $\geq 98-100\%$) may statistically vary from their virologic outcomes.^{16,17} But suboptimal adherence to ART in addition to clinical and immunologic failure may also result in virologic failure of the treatment regimen, as well as multi-drug resistant strains of the virus with a consequent increase in the burden of HIV/AIDS.¹⁷

Furthermore, the virologic outcome which is monitored using viral load measurement serves as a major indicator for virologic failure otherwise referred to as treatment failure among PLWHA on ART and this is grouped into two types, virologic non-suppression and virologic suppression. Virologic non-suppression is defined as the inability of an HIV-positive client/patient on ART to have or sustain the viral replication of ≥ 1000 copies/ml based on two consecutive viral load measurements 6-12 months apart, with adherence counselling after the first viral load assessment. This is associated with low self-reported adherence to ART and low recent CD4⁺ cell count.^{18,19} On the other hand, virologic suppression is achieved when a patient's plasma HIV RNA level is ≤ 1000 copies/ml or below the lower limits ($< 50- < 20$ copies/ml) of detection (LLOD) of currently used highly sensitive assays after two consecutive viral load measurements $\geq 6-12$ months apart.²⁰ Detection of viraemia is usually done using real-time polymerase chain reaction (RT-PCR) assays, known to be highly sensitive compared to the previously used PCR-based viral load platforms. Hence, depending on the methodology deployed, the level of medication adherence may differ, since using only one method has been shown to give biased results.^{4,21} Globally, PLWHA in developed nations have self-reported optimal adherence levels with associated better virologic outcomes than their counterparts in developing countries. This may be attributed to the increased resistance to ART with the corresponding unavailability of drug resistance testing before initiation of ART in resource-poor countries.²² It is

important to note that a great proportion of HIV-infected patients who self-reported optimal adherence levels and also experienced virologic failure were potentially confounded by recall bias with resultant overestimated actual adherence levels.^{23,24} Therefore, there may be a correlation between self-reported suboptimal adherence to ART and poor virologic outcome among PLWHA.

METHODS

The study was conducted at the University of Port Harcourt Teaching Hospital located in Alakahia, Obio-Akpor LGA, along the East-West Road, and shares a boundary with the University of Port Harcourt main campus. The hospital is a 950-bed tertiary health facility with sixteen clinical departments. This tertiary health facility with multi-disciplinary specialists provides care for in-patient, out-patient and emergency services to HIV-positive patients as it also serves as a major referral point for primary and secondary health facilities within the state. The out-patient HIV/AIDS services are rendered within the ARV therapy centre which reviews a large number of PLWHA on weekdays apart from public holidays.²⁵ This study is a hospital-based comparative cross-sectional study to assess the association between self-reported medication adherence and virologic outcome among HIV-positive adults accessing care at a tertiary centre in Rivers State, Nigeria.

The systematic random sampling technique was employed to select eligible participants for this study using the daily clinic register from the adult ART therapy clinic at the University of Port Harcourt Teaching Hospital between September 2020 and November 2020 until the sample size was reached. Data was collected using a validated 8-item interviewer-administered structured questionnaire subdivided into different sections and was adapted from the brief medication questionnaire.²⁶ During the study, a blood sample for viral load monitoring was collected for each eligible respondent, after administration of the questionnaire, using Roche COBAS TaqMan96 (version 2.0) for real-time PCR HIV-1 RNA assay.²⁷ The virologic outcome of each eligible participant was determined by comparing the results of the viral load test (VLT) measured during the study and the VLT 6-12 months before it was conducted (recorded on the patient's folder/care card). Each participant's VLT was classified into 2; virologic suppression (<1000 copies/ml), and virologic non-suppression (\geq 1000 copies/ml).¹⁷ The overall result was categorized and compared between the gender group. Data were entered into Microsoft excel, checked for completeness, coded, cleaned and analyzed on statistical package for the social sciences (SPSS) version-25 software. Categorical variables were presented as frequencies and proportions, while the continuous variables were summarized as mean and standard deviation. To assess the association between dependent and independent variables, Pearson's Chi-square and

Fisher's exact tests were used for categorical variables. The statistical significance level was set at $p < 0.05$ and a 95% confidence interval. Multiple logistic regression was used to control for confounding variables.

Ethical approval was sought from the research ethics committee in the study area and written informed consent was obtained from each participant before commencing the study. All eligible respondents were made to understand the aim of the study, given the option to participate or not and refrain from answering any uncomfortable questions. The clinic care card numbers were used to guarantee anonymity and absolute confidentiality.

RESULT

A total of 1700 questionnaires were administered to eligible participants of which 100 of them were excluded from the data analysis; 67 omitted key questions and the other 33 declined from the viral load test. Thus, a total of 1600 questionnaires (800 HIV-positive males, 800 HIV-positive females) were analyzed with a response rate of 94%.

The socio-demographic characteristics of the study reported a mean age of respondents among the males (44.53 ± 10.50) and females (40.58 ± 9.34) groups at $p < 0.001$. However, the male group was observed to have a higher proportion of respondents compared to their female counterparts in the following categories of variables; married (75.8% versus 58.6%, $p < 0.001$); secondary level of education (64.5% versus 57.3%, $p = 0.001$); residing in urban areas (81.1% versus 62.5%, $p < 0.001$); being a Christians (97.4% versus 96.5%, $p = 0.171$). On the other hand, the female group revealed a higher proportion of participants among; the Igbo ethnic group (38.4% versus 34%, $p = 0.003$) and business as an occupational group (29.5% versus 27.9%, $p < 0.001$) (Table 1).

The male group (98.7 ± 6.4) revealed a higher self-reported mean adherence score compared with the female group (97.3 ± 10.0) with a statistically significant gender difference ($p = 0.001$) (Table 2). A greater proportion of the male group (94.5%) also self-reported optimal adherence levels as opposed to the female group (89.1%) with a statistically significant gender difference ($p < 0.001$) (Table 3). The female group had a higher proportion of respondents who achieved virologic suppression compared with the male group (89.6% versus 89.5%). There was no statistically significant gender difference. The proportion of respondents who self-reported optimal level of adherence and also achieved virologic suppression was higher among the male group than the female group, though there was no observed significant statistical association between self-reported level of adherence and virologic outcome between the gender groups; male (0.485) versus female (0.268) (Table 4).

Table 1: Socio-demographic characteristics of HIV-positive male and female respondents.

Variables	Males (n=800)	Females (n=800)	Test statistic (p value)
Age group (years)			
Less than 20	5 (0.6)	1 (0.1)	106.161 (<0.001) ^b
20-29	65 (8.1)	94 (11.8)	
30-39	194 (24.3)	367 (45.9)	
40 and more	536 (67.0)	338 (42.3)	
Mean age±SD	44.53±10.50	40.58±9.34	
Marital status			
Single	144 (18.0)	160 (20.0)	93.782 (<0.001) ^b
Cohabiting	6 (0.8)	9 (1.1)	
Married	606 (75.8)	469 (58.6)	
Separated	2 (0.3)	25 (3.1)	
Divorced	3 (0.4)	7 (0.9)	
Widowed	39 (4.9)	130 (16.3)	
Tribe			
Igbo	272 (34.0)	307 (38.4)	17.888 (0.003) ^b
Hausa	10 (1.3)	0 (0.0)	
Yoruba	23 (2.9)	13 (1.6)	
Ikwerre	150 (18.8)	134 (16.8)	
Kalabari	22 (2.8)	16 (2.0)	
Others	323 (40.4)	330 (41.3)	
Education			
No formal education	4 (0.5)	18 (2.3)	20.660 (0.001) ^b
Primary	76 (9.5)	96 (12.0)	
Secondary	516 (64.5)	458 (57.3)	
Undergraduate	11 (1.4)	25 (3.1)	
Tertiary	177 (22.1)	189 (23.6)	
Post graduate	16 (2.0)	14 (1.8)	
Occupation			
Trading	71 (8.9)	141 (17.6)	317.133 (<0.001) ^b
Business	221 (27.9)	236 (29.5)	
Civil/Public servant	133 (16.6)	86 (10.8)	
Engineering	16 (2.0)	0 (0.0)	
Retired	34 (4.3)	19 (2.4)	
Students	33 (4.1)	22 (2.8)	
Artisan	164 (20.5)	82 (10.3)	
Housewife	0 (0.0)	152 (19.0)	
Others	97 (12.1)	8 (1.0)	
Unemployed	31 (3.9)	54 (6.8)	
Residence			
Rural	72 (9.0)	147 (18.4)	68.610 (<0.001) [*]
Semi-urban	79 (9.9)	153 (19.1)	
Urban	649 (81.1)	500 (62.5)	
Religion			
Christianity	779 (97.4)	772 (96.5)	3.532 (0.171) ^b
Islam	15 (1.9)	25 (3.1)	
African tradition	6 (0.8)	3 (0.4)	

*Significant ^bFisher's exact**Table 2: Self-reported mean adherence scores of HIV-positive male and female respondent.**

Variable	Males (n=800)	Females (n=800)	Test statistic (p value)
Self-reported adherence score	98.7±6.4	97.3±10.0	3.354 (0.001) [*]

Table 3: Self-reported level of adherence in HIV-positive male and female respondents.

Variables	Optimal	Sub-optimal	Test statistic (p value)
Males (n=800)	756 (94.5)	44 (5.5)	15.373 (<0.001) *
Females (n=800)	713 (89.1)	87 (10.9)	

*Significant

Table 4: Association between self-reported adherence and virologic outcome of HIV-positive male and female respondents.

Variables	Males (n=800)			Females (n=800)		
	Suppressed	Unsuppressed	Test statistic (p value)	Suppressed	Unsuppressed	Test statistic (p value)
Adherence						
Optimal	678 (89.7)	78 (10.3)	0.487 (0.485)	642 (90.0)	71 (10.1)	1.227 (0.268)
Suboptimal	38 (86.4)	6 (13.6)		75 (86.2)	12 (13.8)	

DISCUSSION

The socio-demographic characteristics of the present study reported that a greater proportion of the male respondents among those ≥ 40 years of age, married, Christian, living in urban areas, and attained a tertiary level of education than their female counterparts. On the other hand, respondents who were of the Igbo tribe and those who reported business as their occupation were more among the female group than their male counterparts. These findings are in agreement with previous studies conducted in Nigeria, South Africa, Canada, and the United States of America which reported significant gender differences in the socio-demographic characteristics of respondents in favour of the male group compared to their female counterparts.^{14,28-32} This suggests that sociodemographic variables like; age, marital status, tribe, religion, place of residence, level of education, and occupation may influence adherence to ART and the virologic outcome of PLWHA.

Respondents who self-reported optimal level of adherence were greater in proportion among the male group than the female group. This was attributed to the fact that a greater proportion of the female group had missed at least a dose of their ART due to side effects in the last 7-days before each participant partook in the study. These findings are consistent with previous studies conducted in Nigeria and Brazil.^{33,34} On the contrary, a greater proportion of the female group self-reported optimal adherence levels than the male group with a statistically significant association between the gender groups. These findings are in line with a systematic review conducted in sub-Saharan Africa and other cross-sectional studies done in South Africa, Tanzania, the Gambia and the United States of America.^{32,35-38} Although, two other studies carried out in Nigeria and Cameroun showed no statistically significant association between the variables of interest in between male and female gender.^{39,40} This implies that gender may play a vital role in self-reporting of medication adherence.

The virologic outcome of participants in this present study reported a better viral load suppression among the female

group compared to their male counterparts. These proportions were shown to be way beyond the 2018 Nigerian AIDS indicator and impact survey (NAIIS) national and Rivers State. These values were almost approaching the “third 90” of the 2015 UNAIDS treatment target, yet below the “third 95” of the current 2020 UNAIDS fast-track treatment target.⁴¹ However, the improvements observed in the virologic outcome of respondents in the study area may have been because of the personal efforts patients make to adhere to their treatment plan. These findings are in concordance with the global data recorded in countries like Chile, Mexico, Singapore, Kenya, Lesotho and other previous studies conducted in South Africa and Haiti.^{9,42,43} Though, there was no observed significant gender difference, the proportion of respondents with virologic suppression was slightly higher among the female group than their male contemporary, yet below the “third 90” of the previous 2015 UNAIDS treatment target. On the other hand, a greater proportion of respondent who were virally suppressed were seen among the male group compared to the female group in studies done in Zambia, Nepal, and the United States of America; even though there was no observed statistically significant gender difference in the study.^{31,44,45} The virologic outcome reported in this present study may still have been a result of the personal efforts of participants despite the barriers they face in the course of adhering to their treatment plan.

Concerning the association between self-reported adherence and virologic outcome, respondents who self-reported optimal medication adherence and achieved virologic suppression were slightly higher among the female group than the male group. The findings are in agreement with a meta-analysis and another study carried out in Cameroun which also reported no significant gender disparity in the association between both variables.^{17,40} On the contrary, two meta-analyses and some cross-sectional studies conducted in Nigeria, Kenya, and South Africa observed that an association existed between both variables.^{6,46-49} Though self-reported adherence is a common method of assessing medication adherence, viral

load measurement is considerably superior given the UNAIDS treatment target for the control of the epidemic. The aim of HIV treatment is mainly the achievement of viral load suppression. Therefore, viral load measurement can be a more reliable indicator of assessing medication adherence.

Limitations

The study is descriptive in design. Also, the study was not multi-centred, rather was conducted at just one tertiary treatment centre.

Strengths

A detailed protocol was adopted to minimize anticipated interviewer bias at the point of data collection, measurement, and interpretation of findings. Potential biases and confounders were controlled using a standardized questionnaire, adequate training of interviewers, stratifying participants into two gender groups, and maintaining the privacy and confidentiality of all participants. The systematic sampling technique employed on daily basis by the use of the clinic register to select respondents minimized sampling bias.

CONCLUSION

Though there was no significant association between gender groups, a greater proportion of the females self-reported optimal adherence levels and also achieved virologic suppression than their male counterparts. However, there was no association between self-reported adherence and virologic outcome of respondents.

Recommendations

Viral load monitoring is vital in assessing medication adherence as well as measuring progress towards virologic suppression and is not a substitute for self-reported adherence. It is equally important to strengthen all strategies to ensure that patients are fully adherent to their medications to improve virologic outcomes.

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